Appendix 1

NHS
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Chest pain of recent onset

Assessment and diagnosis of recent onset chest pain or discomfort of suspected cardiac origin

This guidance partially updates NICE technology appraisal guidance 73 (published November 2003)

NICE clinical guideline 95
Developed by the National Clinical Guideline Centre for Acute and Chronic Conditions

NICE clinical guideline 95
Chest pain of recent onset: assessment and diagnosis of recent onset chest pain or discomfort of suspected cardiac origin

Ordering information
You can download the following documents from www.nice.org.uk/guidance/CG95

- The NICE guideline (this document) – all the recommendations.
- A quick reference guide – a summary of the recommendations for healthcare professionals.
- 'Understanding NICE guidance' – a summary for patients and carers.
- The full guideline – all the recommendations, details of how they were developed, and reviews of the evidence they were based on.

For printed copies of the quick reference guide or 'Understanding NICE guidance', phone NICE publications on 0845 003 7783 or email publications@nice.org.uk and quote:

- N2113 (quick reference guide)
- N2114 ('Understanding NICE guidance').

NICE clinical guidelines are recommendations about the treatment and care of people with specific diseases and conditions in the NHS in England and Wales.

This guidance represents the view of NICE, which was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer, and informed by the summary of product characteristics of any drugs they are considering.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

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Contents

This guidance partially updates NICE technology appraisal guidance 73 (published November 2003).

Recommendation 1.3.6.1 in this guideline replaces recommendation 1.1 of NICE technology appraisal guidance 73. The NICE technology appraisal guidance and supporting documents are available from www.nice.org.uk/guidance/TA73

Introduction

Conditions causing chest pain or discomfort, such as an acute coronary syndrome or angina, have a potentially poor prognosis, emphasising the importance of prompt and accurate diagnosis. Treatments are available to improve symptoms and prolong life, hence the need for this guideline.

This guideline covers the assessment and diagnosis of people with recent onset chest pain or discomfort of suspected cardiac origin. In deciding whether chest pain may be cardiac and therefore whether this guideline is relevant, a number of factors should be taken into account. These include the person's history of chest pain, their cardiovascular risk factors, history of ischaemic heart disease and any previous treatment, and previous investigations for chest pain.

For pain that is suspected to be cardiac, there are two separate diagnostic pathways presented in the guideline. The first is for people with acute chest pain and a suspected acute coronary syndrome, and the second is for people with intermittent stable chest pain in whom stable angina is suspected. The guideline includes how to determine whether myocardial ischaemia is the cause of the chest pain and how to manage the chest pain while people are being assessed and investigated.

As far as possible, the recommendations in this guideline have been listed in the order in which they will be carried out and follow the diagnostic pathways. But, as there are many permutations at each decision point, it has been

necessary to include frequent cross-referencing to avoid repeating recommendations several times.

The algorithms presented in appendix C show the two diagnostic pathways.

This guideline does not cover the diagnosis and management of chest pain that is unrelated to the heart (for example, traumatic chest wall injury, herpes zoster infection) when myocardial ischaemia has been excluded. The guideline also recognises that in people with a prior diagnosis of coronary artery disease, chest pain or discomfort is not necessarily cardiac.

The term 'chest pain' is used throughout the guideline to mean chest pain or discomfort.

The guideline will assume that prescribers will use a drug's summary of product characteristics to inform decisions made with individual patients.

Person-centred care

This guideline offers best practice advice on the care of people who present with recent chest pain or discomfort of suspected cardiac origin.

Treatment and care should take into account people's needs and preferences. People with recent chest pain or discomfort of suspected cardiac origin should have the opportunity to make informed decisions about their care and treatment, in partnership with their healthcare professionals. If people do not have the capacity to make decisions, healthcare professionals should follow the Department of Health's advice on consent (available from www.dh.gov.uk/consent) and the code of practice that accompanies the Mental Capacity Act (summary available from www.publicguardian.gov.uk). In Wales, healthcare professionals should follow advice on consent from the Welsh Assembly Government (available from www.wales.nhs.uk/consent).

Good communication between healthcare professionals and the person with chest pain is essential. It should be supported by evidence-based written information tailored to the person's needs. It should be recognised that the person may be anxious, particularly when the cause of the chest pain is unknown. The options and consequences at every stage of the investigative process should be clearly explained. Investigations, treatment and care, and the information people are given about them, should be culturally appropriate. It should also be accessible to people with additional needs such as physical, sensory or learning disabilities, and to people who do not speak or read English.

If the person agrees, families and carers should have the opportunity to be involved in decisions about treatment and care.

Families and carers should also be given the information and support they need.

Key priorities for implementation

Presentation with acute chest pain

- Take a resting 12-lead electrocardiogram (ECG) as soon as possible. When people are referred, send the results to hospital before they arrive if possible. Recording and sending the ECG should not delay transfer to hospital. **[1.2.2.1]**
- Do not exclude an acute coronary syndrome (ACS) when people have a normal resting 12-lead ECG. **[1.2.2.5]**
- Do not routinely administer oxygen, but monitor oxygen saturation using pulse oximetry as soon as possible, ideally before hospital admission. Only offer supplemental oxygen to:
    - people with oxygen saturation (SpO_2) of less than 94% who are not at risk of hypercapnic respiratory failure, aiming for SpO_2 of 94–98%
    - people with chronic obstructive pulmonary disease who are at risk of hypercapnic respiratory failure, to achieve a target SpO_2 of 88–92% until blood gas analysis is available. **[1.2.3.3]**
- Do not assess symptoms of an ACS differently in ethnic groups. There are no major differences in symptoms of an ACS among different ethnic groups. **[1.2.1.6]**

Presentation with stable chest pain

- Diagnose stable angina based on one of the following:
    - clinical assessment alone **or**
    - clinical assessment plus diagnostic testing (that is, anatomical testing for obstructive coronary artery disease [CAD] and/or functional testing for myocardial ischaemia). **[1.3.1.1]**
- If people have features of typical angina based on clinical assessment and their estimated likelihood of CAD is greater than 90% (see table 1), further diagnostic investigation is unnecessary. Manage as angina. **[1.3.3.5]**

Table 1 Percentage of people estimated to have coronary artery disease according to typicality of symptoms, age, sex and risk factors

	Non-anginal chest pain				Atypical angina				Typical angina			
	Men		Women		Men		Women		Men		Women	
Age (years)	Lo	Hi	Lo	Hi	Lo	Hi	Lo	Hi	Lo	Hi	Lo	Hi
35	3	35	1	19	8	59	2	39	30	88	10	78
45	9	47	2	22	21	70	5	43	51	92	20	79
55	23	59	4	25	45	79	10	47	80	95	38	82
65	49	69	9	29	71	86	20	51	93	97	56	84

For men older than 70 with atypical or typical symptoms, assume an estimate > 90%.

For women older than 70, assume an estimate of 61–90% EXCEPT women at high risk AND with typical symptoms where a risk of > 90% should be assumed.

Values are per cent of people at each mid-decade age with significant coronary artery disease (CAD)[1].

Hi = High risk = diabetes, smoking and hyperlipidaemia (total cholesterol > 6.47 mmol/litre).

Lo = Low risk = none of these three.

The shaded area represents people with symptoms of non-anginal chest pain, who would not be investigated for stable angina routinely.

Note:

These results are likely to overestimate CAD in primary care populations.

If there are resting ECG ST-T changes or Q waves, the likelihood of CAD is higher in each cell of the table.

- Unless clinical suspicion is raised based on other aspects of the history and risk factors, exclude a diagnosis of stable angina if the pain is non-anginal (see recommendation 1.3.3.1). Other features which make a diagnosis of stable angina unlikely are when the chest pain is:
    - continuous or very prolonged **and/or**
    - unrelated to activity **and/or**
    - brought on by breathing in **and/or**
    - associated with symptoms such as dizziness, palpitations, tingling or difficulty swallowing.

  Consider causes of chest pain other than angina (such as gastrointestinal or musculoskeletal pain). **[1.3.3.6]**

[1] Adapted from Pryor DB, Shaw L, McCants CB et al. (1993) Value of the history and physical in identifying patients at increased risk for coronary artery disease. Annals of Internal Medicine 118(2): 81–90.

- In people without confirmed CAD, in whom stable angina cannot be diagnosed or excluded based on clinical assessment alone, estimate the likelihood of CAD (see table 1). Take the clinical assessment and the resting 12-lead ECG into account when making the estimate. Arrange further diagnostic testing as follows:
    - If the estimated likelihood of CAD is 61–90%, offer invasive coronary angiography as the first-line diagnostic investigation if appropriate (see recommendations 1.3.4.4 and 1.3.4.5).
    - If the estimated likelihood of CAD is 30–60%, offer functional imaging as the first-line diagnostic investigation (see recommendation 1.3.4.6).
    - If the estimated likelihood of CAD is 10–29%, offer CT calcium scoring as the first-line diagnostic investigation (see recommendation 1.3.4.7). **[1.3.3.16]**
- Do not use exercise ECG to diagnose or exclude stable angina for people without known CAD. **[1.3.6.5]**

1 Guidance

The following guidance is based on the best available evidence. The full guideline (www.nice.org.uk/guidance/CG95) gives details of the methods and the evidence used to develop the guidance.

1.1 Providing information for people with chest pain

1.1.1.1 Discuss any concerns people (and where appropriate their family or carer/advocate) may have, including anxiety when the cause of the chest pain is unknown. Correct any misinformation.

1.1.1.2 Offer people a clear explanation of the possible causes of their symptoms and the uncertainties.

1.1.1.3 Clearly explain the options to people at every stage of investigation. Make joint decisions with them and take account of their preferences:

- Encourage people to ask questions.
- Provide repeated opportunities for discussion.
- Explain test results and the need for any further investigations.

1.1.1.4 Provide information about any proposed investigations using everyday, jargon-free language. Include:

- their purpose, benefits and any limitations of their diagnostic accuracy
- duration
- level of discomfort and invasiveness
- risk of adverse events.

1.1.1.5 Offer information about the risks of diagnostic testing, including any radiation exposure.

1.1.1.6 Address any physical or learning difficulties, sight or hearing problems and difficulties with speaking or reading English, which may affect people's understanding of the information offered.

1.1.1.7 Offer information after diagnosis as recommended in the relevant disease management guidelines[2].

1.1.1.8 Explain if the chest pain is non-cardiac and refer people for further investigation if appropriate.

1.1.1.9 Provide individual advice to people about seeking medical help if they have further chest pain.

1.2 People presenting with acute chest pain

This section of the guideline covers the assessment and diagnosis of people with recent acute chest pain or discomfort, suspected to be caused by an acute coronary syndrome (ACS). The term ACS covers a range of conditions including unstable angina, ST-segment-elevation myocardial infarction (STEMI) and non-ST-segment-elevation myocardial infarction (NSTEMI).

The guideline addresses assessment and diagnosis irrespective of setting, because people present in different ways. Please note that 'Unstable angina and NSTEMI' (NICE clinical guideline 94) covers the early management of these conditions once a firm diagnosis has been made and before discharge from hospital.

1.2.1 Initial assessment and referral to hospital

1.2.1.1 Check immediately whether people currently have chest pain. If they are pain free, check when their last episode of pain was, particularly if they have had pain in the last 12 hours.

1.2.1.2 Determine whether the chest pain may be cardiac and therefore whether this guideline is relevant, by considering:

- the history of the chest pain
- the presence of cardiovascular risk factors
- history of ischaemic heart disease and any previous treatment
- previous investigations for chest pain.

[2] For example, 'Unstable angina and NSTEMI' (NICE clinical guideline 94), 'Anxiety' (NICE clinical guideline 22) and 'Dyspepsia' (NICE clinical guideline 17).

1.2.1.3 Initially assess people for any of the following symptoms, which may indicate an ACS:

- pain in the chest and/or other areas (for example, the arms, back or jaw) lasting longer than 15 minutes
- chest pain associated with nausea and vomiting, marked sweating, breathlessness, or particularly a combination of these
- chest pain associated with haemodynamic instability
- new onset chest pain, or abrupt deterioration in previously stable angina, with recurrent chest pain occurring frequently and with little or no exertion, and with episodes often lasting longer than 15 minutes.

1.2.1.4 Do not use people's response to glyceryl trinitrate (GTN) to make a diagnosis.

1.2.1.5 Do not assess symptoms of an ACS differently in men and women. Not all people with an ACS present with central chest pain as the predominant feature.

1.2.1.6 Do not assess symptoms of an ACS differently in ethnic groups. There are no major differences in symptoms of an ACS among different ethnic groups.

1.2.1.7 Refer people to hospital as an emergency if an ACS is suspected (see recommendation 1.2.1.3) and:

- they currently have chest pain **or**
- they are currently pain free, but had chest pain in the last 12 hours, and a resting 12-lead ECG is abnormal or not available.

1.2.1.8 If an ACS is suspected (see recommendation 1.2.1.3) and there are no reasons for emergency referral, refer people for urgent same-day assessment if:

- they had chest pain in the last 12 hours, but are now pain free with a normal resting 12-lead ECG **or**
- the last episode of pain was 12–72 hours ago.

1.2.1.9 Refer people for assessment in hospital if an ACS is suspected (see recommendation 1.2.1.3) and:

- the pain has resolved **and**
- there are signs of complications such as pulmonary oedema.

Use clinical judgement to decide whether referral should be as an emergency or urgent same-day assessment.

1.2.1.10 If a recent ACS is suspected in people whose last episode of chest pain was more than 72 hours ago and who have no complications such as pulmonary oedema:

- carry out a detailed clinical assessment (see recommendations 1.2.4.2 and 1.2.4.3)
- confirm the diagnosis by resting 12-lead ECG and blood troponin level
- take into account the length of time since the suspected ACS when interpreting the troponin level.

Use clinical judgement to decide whether referral is necessary and how urgent this should be.

1.2.1.11 Refer people to hospital as an emergency if they have a recent (confirmed or suspected) ACS and develop further chest pain.

1.2.1.12 When an ACS is suspected, start management immediately in the order appropriate to the circumstances (see section 1.2.3) and take a resting 12-lead ECG (see section 1.2.2). Take the ECG as soon as possible, but do not delay transfer to hospital.

1.2.1.13 If an ACS is not suspected, consider other causes of the chest pain, some of which may be life-threatening (see recommendations 1.2.6.5, 1.2.6.6 and 1.2.6.7).

1.2.2 Resting 12-lead ECG

1.2.2.1 Take a resting 12-lead ECG as soon as possible. When people are referred, send the results to hospital before they arrive if possible. Recording and sending the ECG should not delay transfer to hospital.

1.2.2.2 Follow local protocols for people with a resting 12-lead ECG showing regional ST-segment elevation or presumed new left bundle branch block (LBBB) consistent with an acute STEMI until a firm diagnosis is made. Continue to monitor (see recommendation 1.2.3.4).

1.2.2.3 Follow 'Unstable angina and NSTEMI' (NICE clinical guideline 94) for people with a resting 12-lead ECG showing regional ST-segment depression or deep T wave inversion suggestive of a NSTEMI or unstable angina until a firm diagnosis is made. Continue to monitor (see recommendation 1.2.3.4).

1.2.2.4 Even in the absence of ST-segment changes, have an increased suspicion of an ACS if there are other changes in the resting 12-lead ECG, specifically Q waves and T wave changes. Consider following 'Unstable angina and NSTEMI' (NICE clinical guideline 94) if these conditions are likely. Continue to monitor (see recommendation 1.2.3.4).

1.2.2.5 Do not exclude an ACS when people have a normal resting 12-lead ECG.

1.2.2.6 If a diagnosis of ACS is in doubt, consider:

- taking serial resting 12-lead ECGs
- reviewing previous resting 12-lead ECGs

- recording additional ECG leads.

Use clinical judgement to decide how often this should be done. Note that the results may not be conclusive.

1.2.2.7 Obtain a review of resting 12-lead ECGs by a healthcare professional qualified to interpret them as well as taking into account automated interpretation.

1.2.2.8 If clinical assessment (as described in recommendation 1.2.1.10) and a resting 12-lead ECG make a diagnosis of ACS less likely, consider other acute conditions. First consider those that are life-threatening such as pulmonary embolism, aortic dissection or pneumonia. Continue to monitor (see recommendation 1.2.3.4).

1.2.3 Immediate management of a suspected acute coronary syndrome

Management of ACS should start as soon as it is suspected, but should not delay transfer to hospital. The recommendations in this section should be carried out in the order appropriate to the circumstances.

1.2.3.1 Offer pain relief as soon as possible. This may be achieved with GTN (sublingual or buccal), but offer intravenous opioids such as morphine, particularly if an acute myocardial infarction (MI) is suspected.

1.2.3.2 Offer people a single loading dose of 300 mg aspirin as soon as possible unless there is clear evidence that they are allergic to it.

If aspirin is given before arrival at hospital, send a written record that it has been given with the person.

Only offer other antiplatelet agents in hospital. Follow appropriate guidance ('Unstable angina and NSTEMI' [NICE clinical guideline 94] or local protocols for STEMI).

1.2.3.3 Do not routinely administer oxygen, but monitor oxygen saturation using pulse oximetry as soon as possible, ideally before hospital admission. Only offer supplemental oxygen to:

- people with oxygen saturation (SpO_2) of less than 94% who are not at risk of hypercapnic respiratory failure, aiming for SpO_2 of 94–98%
- people with chronic obstructive pulmonary disease who are at risk of hypercapnic respiratory failure, to achieve a target SpO_2 of 88–92% until blood gas analysis is available.

1.2.3.4 Monitor people with acute chest pain, using clinical judgement to decide how often this should be done, until a firm diagnosis is made. This should include:

- exacerbations of pain and/or other symptoms
- pulse and blood pressure
- heart rhythm
- oxygen saturation by pulse oximetry
- repeated resting 12-lead ECGs **and**
- checking pain relief is effective.

1.2.3.5 Manage other therapeutic interventions using appropriate guidance ('Unstable angina and NSTEMI' [NICE clinical guideline 94] or local protocols for STEMI).

1.2.4 Assessment in hospital for people with a suspected acute coronary syndrome

1.2.4.1 Take a resting 12-lead ECG and a blood sample for troponin I or T measurement (see section 1.2.5) on arrival in hospital.

1.2.4.2 Carry out a physical examination to determine:

- haemodynamic status
- signs of complications, for example pulmonary oedema, cardiogenic shock **and**

- signs of non-coronary causes of acute chest pain, such as aortic dissection.

1.2.4.3 Take a detailed clinical history unless a STEMI is confirmed from the resting 12-lead ECG (that is, regional ST-segment elevation or presumed new LBBB). Record:

- the characteristics of the pain
- other associated symptoms
- any history of cardiovascular disease
- any cardiovascular risk factors **and**
- details of previous investigations or treatments for similar symptoms of chest pain.

1.2.5 Use of biochemical markers for diagnosis of an acute coronary syndrome

1.2.5.1 Take a blood sample for troponin I or T measurement on initial assessment in hospital. These are the preferred biochemical markers to diagnose acute MI.

1.2.5.2 Take a second blood sample for troponin I or T measurement 10–12 hours after the onset of symptoms.

1.2.5.3 Do not use biochemical markers such as natriuretic peptides and high sensitivity C-reactive protein to diagnose an ACS.

1.2.5.4 Do not use biochemical markers of myocardial ischaemia (such as ischaemia-modified albumin) as opposed to markers of necrosis when assessing people with acute chest pain.

1.2.5.5 Take into account the clinical presentation, the time from onset of symptoms and the resting 12-lead ECG findings when interpreting troponin measurements.

1.2.6 Making a diagnosis

1.2.6.1 When diagnosing MI, use the universal definition of myocardial infarction[3]. This is the detection of rise and/or fall of cardiac biomarkers (preferably troponin) with at least one value above the 99th percentile of the upper reference limit, together with evidence of myocardial ischaemia with at least one of the following:

- symptoms of ischaemia
- ECG changes indicative of new ischaemia (new ST-T changes or new LBBB)
- development of pathological Q wave changes in the ECG
- imaging evidence of new loss of viable myocardium or new regional wall motion abnormality[4].

The clinical classification of MI includes:

- Type 1: spontaneous MI related to ischaemia due to a primary coronary event such as plaque erosion and/or rupture, fissuring or dissection.
- Type 2: MI secondary to ischaemia due to either increased oxygen demand or decreased supply, such as coronary spasm, coronary embolism, anaemia, arrhythmias, hypertension, or hypotension.

1.2.6.2 When a raised troponin level is detected in people with a suspected ACS, reassess to exclude other causes for raised troponin (for example, myocarditis, aortic dissection or pulmonary embolism) before confirming the diagnosis of ACS.

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[3] Thygesen K, Alpert JS, White HD et al. on behalf of the joint ESC/ACCF/AHA/WHF Task Force for the redefinition of myocardial infarction (2007). Universal definition of myocardial infarction. Journal of the American College of Cardiology 50: 2173–95.

[4] The Guideline Development Group did not review the evidence for the use of imaging evidence of new loss of viable myocardium or new regional wall motion abnormality in the diagnosis of MI, but recognised that it was included as a criterion in the universal definition of MI. The Guideline Development Group recognised that it could be used, but would not be done routinely when there were symptoms of ischaemia and ECG changes.

1.2.6.3 When a raised troponin level is detected in people with a suspected ACS, follow the appropriate guidance ('Unstable angina and NSTEMI' [NICE clinical guideline 94] or local protocols for STEMI) until a firm diagnosis is made. Continue to monitor (see recommendation 1.2.3.4).

1.2.6.4 When a diagnosis of ACS is confirmed, follow the appropriate guidance ('Unstable angina and NSTEMI' [NICE clinical guideline 94] or local protocols for STEMI).

1.2.6.5 Reassess people with chest pain without raised troponin levels (determined from appropriately timed samples) and no acute resting 12-lead ECG changes to determine whether their chest pain is likely to be cardiac.

If myocardial ischaemia is suspected, follow the recommendations on stable chest pain in this guideline (see section 1.3). Use clinical judgement to decide on the timing of any further diagnostic investigations.

1.2.6.6 Consider a chest X-ray to help exclude complications of ACS such as pulmonary oedema, or other diagnoses such as pneumothorax or pneumonia.

1.2.6.7 Only consider early chest computed tomography (CT) to rule out other diagnoses such as pulmonary embolism or aortic dissection, not to diagnose ACS.

1.2.6.8 If an ACS has been excluded at any point in the care pathway, but people have risk factors for cardiovascular disease, follow the appropriate guidance, for example 'Lipid modification' (NICE clinical guideline 67), 'Hypertension' (NICE clinical guideline 34).

1.3 People presenting with stable chest pain

This section of the guideline addresses the assessment and diagnosis of intermittent stable chest pain in people with suspected stable angina.

Angina is usually caused by coronary artery disease (CAD). Making a diagnosis of stable angina caused by CAD in people with chest pain is not always straightforward, and the recommendations aim to guide and support clinical judgement. Clinical assessment alone may be sufficient to confirm or exclude a diagnosis of stable angina, but when there is uncertainty, additional diagnostic testing (functional or anatomical testing) guided by the estimates of likelihood of coronary artery disease in table 1 is required.

1.3.1.1 Diagnose stable angina based on one of the following:

- clinical assessment alone **or**
- clinical assessment plus diagnostic testing (that is, anatomical testing for obstructive CAD and/or functional testing for myocardial ischaemia).

1.3.2 Clinical assessment

1.3.2.1 Take a detailed clinical history documenting:

- the age and sex of the person
- the characteristics of the pain, including its location, radiation, severity, duration and frequency, and factors that provoke and relieve the pain
- any associated symptoms, such as breathlessness
- any history of angina, MI, coronary revascularisation, or other cardiovascular disease **and**
- any cardiovascular risk factors.

1.3.2.2 Carry out a physical examination to:

- identify risk factors for cardiovascular disease
- identify signs of other cardiovascular disease

- identify non-coronary causes of angina (for example, severe aortic stenosis, cardiomyopathy) **and**
- exclude other causes of chest pain.

1.3.3 Making a diagnosis based on clinical assessment

1.3.3.1 Anginal pain is:

- constricting discomfort in the front of the chest, or in the neck, shoulders, jaw, or arms
- precipitated by physical exertion
- relieved by rest or GTN within about 5 minutes.

Use clinical assessment and the typicality of anginal pain features listed below to estimate the likelihood of CAD (see table 1):

- Three of the features above are defined as typical angina.
- Two of the three features above are defined as atypical angina.
- One or none of the features above are defined as non-anginal chest pain.

Table 1 Percentage of people estimated to have coronary artery disease according to typicality of symptoms, age, sex and risk factors

	Non-anginal chest pain				Atypical angina				Typical angina			
	Men		Women		Men		Women		Men		Women	
Age (years)	Lo	Hi	Lo	Hi	Lo	Hi	Lo	Hi	Lo	Hi	Lo	Hi
35	3	35	1	19	8	59	2	39	30	88	10	78
45	9	47	2	22	21	70	5	43	51	92	20	79
55	23	59	4	25	45	79	10	47	80	95	38	82
65	49	69	9	29	71	86	20	51	93	97	56	84

For men older than 70 with atypical or typical symptoms, assume an estimate > 90%.

For women older than 70, assume an estimate of 61–90% EXCEPT women at high risk AND with typical symptoms where a risk of > 90% should be assumed.

Values are per cent of people at each mid-decade age with significant coronary artery disease (CAD)[5].

Hi = High risk = diabetes, smoking and hyperlipidaemia (total cholesterol > 6.47 mmol/litre).

Lo = Low risk = none of these three.

The shaded area represents people with symptoms of non-anginal chest pain, who would not be investigated for stable angina routinely.

Note:

These results are likely to overestimate CAD in primary care populations.

If there are resting ECG ST-T changes or Q waves, the likelihood of CAD is higher in each cell of the table.

1.3.3.2 Do not define typical and atypical features of anginal chest pain and non-anginal chest pain differently in men and women.

1.3.3.3 Do not define typical and atypical features of anginal chest pain and non-anginal chest pain differently in ethnic groups.

1.3.3.4 Take the following factors, which make a diagnosis of stable angina more likely, into account when estimating people's likelihood of angina:

- increasing age
- whether the person is male
- cardiovascular risk factors including:
  - a history of smoking

[5] Adapted from Pryor DB, Shaw L, McCants CB et al. (1993) Value of the history and physical in identifying patients at increased risk for coronary artery disease. Annals of Internal Medicine 118(2): 81–90.

- diabetes
- hypertension
- dyslipidaemia
- family history of premature CAD
- other cardiovascular disease

- history of established CAD, for example previous MI, coronary revascularisation.

1.3.3.5 If people have features of typical angina based on clinical assessment and their estimated likelihood of CAD is greater than 90% (see table 1), further diagnostic investigation is unnecessary. Manage as angina.

1.3.3.6 Unless clinical suspicion is raised based on other aspects of the history and risk factors, exclude a diagnosis of stable angina if the pain is non-anginal (see recommendation 1.3.3.1). Other features which make a diagnosis of stable angina unlikely are when the chest pain is:

- continuous or very prolonged **and/or**
- unrelated to activity **and/or**
- brought on by breathing in **and/or**
- associated with symptoms such as dizziness, palpitations, tingling or difficulty swallowing.

Consider causes of chest pain other than angina (such as gastrointestinal or musculoskeletal pain).

1.3.3.7 If the estimated likelihood of CAD is less than 10% (see table 1), first consider causes of chest pain other than angina caused by CAD.

1.3.3.8 Consider investigating other causes of angina, such as hypertrophic cardiomyopathy, in people with typical angina-like chest pain and a low likelihood of CAD (estimated at less than 10%).

1.3.3.9 Arrange blood tests to identify conditions which exacerbate angina, such as anaemia, for all people being investigated for stable angina.

1.3.3.10 Only consider chest X-ray if other diagnoses, such as a lung tumour, are suspected.

1.3.3.11 If a diagnosis of stable angina has been excluded at any point in the care pathway, but people have risk factors for cardiovascular disease, follow the appropriate guidance, for example 'Lipid modification' (NICE clinical guideline 67), 'Hypertension' (NICE clinical guideline 34).

1.3.3.12 For people in whom stable angina cannot be diagnosed or excluded on the basis of the clinical assessment alone, take a resting 12-lead ECG as soon as possible after presentation.

1.3.3.13 Do not rule out a diagnosis of stable angina on the basis of a normal resting 12-lead ECG.

1.3.3.14 A number of changes on a resting 12-lead ECG are consistent with CAD and may indicate ischaemia or previous infarction. These include:

- pathological Q waves in particular
- LBBB
- ST-segment and T wave abnormalities (for example, flattening or inversion).

Note that the results may not be conclusive.

Consider any resting 12-lead ECG changes together with people's clinical history and risk factors.

1.3.3.15 For people with confirmed CAD (for example, previous MI, revascularisation, previous angiography) in whom stable angina

cannot be diagnosed or excluded based on clinical assessment alone, see recommendation 1.3.4.8 about functional testing.

1.3.3.16 In people without confirmed CAD, in whom stable angina cannot be diagnosed or excluded based on clinical assessment alone, estimate the likelihood of CAD (see table 1). Take the clinical assessment and the resting 12-lead ECG into account when making the estimate. Arrange further diagnostic testing as follows:

- If the estimated likelihood of CAD is 61–90%, offer invasive coronary angiography as the first-line diagnostic investigation if appropriate (see recommendations 1.3.4.4 and 1.3.4.5).
- If the estimated likelihood of CAD is 30–60%, offer functional imaging as the first-line diagnostic investigation (see recommendation 1.3.4.6).
- If the estimated likelihood of CAD is 10–29%, offer CT calcium scoring as the first-line diagnostic investigation (see recommendation 1.3.4.7).

1.3.3.17 Consider aspirin only if the person's chest pain is likely to be stable angina, until a diagnosis is made. Do not offer additional aspirin if there is clear evidence that people are already taking aspirin regularly or are allergic to it.

1.3.3.18 Follow local protocols for stable angina[6] while waiting for the results of investigations if symptoms are typical of stable angina.

[6] NICE is developing the clinical guideline 'The management of stable angina' (publication expected July 2011).

1.3.4 Diagnostic testing for people in whom stable angina cannot be diagnosed or excluded by clinical assessment alone

This guideline addresses only the diagnostic value of tests for stable angina. The prognostic value of these tests was not considered.

The Guideline Development Group carefully considered the risk of radiation exposure from diagnostic tests. It discussed that the risk needs to be considered in the context of radiation exposure from everyday life, the substantial intrinsic risk that a person will develop cancer during their lifetime and the potential risk of failing to make an important diagnosis if a particular test is not performed. The commonly accepted estimate of the additional lifetime risk of dying from cancer with 10 millisieverts of radiation is 1 in 2000[7]. The Guideline Development Group emphasised that the recommendations in this guideline are to make a diagnosis of chest pain, not to screen for CAD. Most people diagnosed with non-anginal chest pain after clinical assessment need no further diagnostic testing. However in a very small number of people, there are remaining concerns that the pain could be ischaemic, in which case the risk of undiagnosed angina outweighs the risk of any potential radiation exposure.

1.3.4.1 Include the typicality of anginal pain features and the estimate of CAD likelihood (see recommendation 1.3.3.16) in all requests for diagnostic investigations and in the person's notes.

1.3.4.2 Use clinical judgement and take into account people's preferences and comorbidities when considering diagnostic testing.

1.3.4.3 Take into account people's risk from radiation exposure when considering which diagnostic test to use.

[7] Gerber TC et al. (2009) Ionizing radiation in cardiac imaging: a science advisory from the American Heart Association Committee on Cardiac Imaging of the Council on Clinical Cardiology and Committee on Cardiovascular Imaging and Intervention of the Council on Cardiovascular Radiology and Intervention. Circulation 119(7): 1056–65.

1.3.4.4 For people with chest pain in whom stable angina cannot be diagnosed or excluded by clinical assessment alone and who have an estimated likelihood of CAD of 61–90% (see recommendation 1.3.3.16), offer invasive coronary angiography after clinical assessment and a resting 12-lead ECG if:

- coronary revascularisation is being considered **and**
- invasive coronary angiography is clinically appropriate and acceptable to the person.

1.3.4.5 For people with chest pain in whom stable angina cannot be diagnosed or excluded by clinical assessment alone and who have an estimated likelihood of CAD of 61–90% (see recommendation 1.3.3.16), offer non-invasive functional imaging after clinical assessment and a resting 12-lead ECG if:

- coronary revascularisation is not being considered **or**
- invasive coronary angiography is not clinically appropriate or acceptable to the person.

1.3.4.6 For people with chest pain in whom stable angina cannot be diagnosed or excluded by clinical assessment alone and who have an estimated likelihood of CAD of 30–60% (see recommendation 1.3.3.16), offer non-invasive functional imaging for myocardial ischaemia. See section 1.3.6 for further guidance on non-invasive functional testing.

1.3.4.7 For people with chest pain in whom stable angina cannot be diagnosed or excluded by clinical assessment alone and who have an estimated likelihood of CAD of 10–29% (see recommendation 1.3.3.16) offer CT calcium scoring. If the calcium score is:

- zero, consider other causes of chest pain
- 1–400, offer 64-slice (or above) CT coronary angiography
- greater than 400, offer invasive coronary angiography. If this is not clinically appropriate or acceptable to the person and

revascularisation is not being considered, offer non-invasive functional imaging. See section 1.3.6 for further guidance on non-invasive functional testing.

1.3.4.8 For people with confirmed CAD (for example, previous MI, revascularisation, previous angiography), offer non-invasive functional testing when there is uncertainty about whether chest pain is caused by myocardial ischaemia. See section 1.3.6 for further guidance on non-invasive functional testing. An exercise ECG may be used instead of functional imaging.

1.3.5 Additional diagnostic investigations

1.3.5.1 Offer non-invasive functional imaging (see section 1.3.6) for myocardial ischaemia if invasive coronary angiography or 64-slice (or above) CT coronary angiography has shown CAD of uncertain functional significance.

1.3.5.2 Offer invasive coronary angiography as a second-line investigation when the results of non-invasive functional imaging are inconclusive.

1.3.6 Use of non-invasive functional testing for myocardial ischaemia

1.3.6.1 When offering non-invasive functional imaging for myocardial ischaemia use:

- myocardial perfusion scintigraphy with single photon emission computed tomography (MPS with SPECT) **or**
- stress echocardiography **or**
- first-pass contrast-enhanced magnetic resonance (MR) perfusion **or**
- MR imaging for stress-induced wall motion abnormalities.

Take account of locally available technology and expertise, the person and their preferences, and any contraindications when

deciding on the imaging method. [This recommendation updates and replaces recommendation 1.1 of 'Myocardial perfusion scintigraphy for the diagnosis and management of angina and myocardial infarction' (NICE technology appraisal guidance 73)].

1.3.6.2 Use adenosine, dipyridamole or dobutamine as stress agents for MPS with SPECT and adenosine or dipyridamole for first-pass contrast-enhanced MR perfusion.

1.3.6.3 Use exercise or dobutamine for stress echocardiography or MR imaging for stress-induced wall motion abnormalities.

1.3.6.4 Do not use MR coronary angiography for diagnosing stable angina.

1.3.6.5 Do not use exercise ECG to diagnose or exclude stable angina for people without known CAD.

1.3.7 Making a diagnosis following investigations

1.3.7.1 Confirm a diagnosis of stable angina and follow local guidelines for angina[8] when:

- significant CAD (see box 1) is found during invasive or 64-slice (or above) CT coronary angiography **and/or**
- reversible myocardial ischaemia is found during non-invasive functional imaging.

[8] NICE is developing the clinical guideline 'The management of stable angina' (publication expected July 2011).

Box 1 Definition of significant coronary artery disease

Significant coronary artery disease (CAD) found during invasive coronary angiography is ≥ 70% diameter stenosis of at least one major epicardial artery segment or ≥ 50% diameter stenosis in the left main coronary artery:

- Factors intensifying ischaemia.
  Such factors allow less severe lesions (for example ≥ 50%) to produce angina:
  - Reduced oxygen delivery: anaemia, coronary spasm.
  - Increased oxygen demand: tachycardia, left ventricular hypertrophy.
  - Large mass of ischaemic myocardium: proximally located lesions.
  - Longer lesion length.
- Factors reducing ischaemia.
  Such factors may render severe lesions (≥ 70%) asymptomatic:
  - Well developed collateral supply.
  - Small mass of ischaemic myocardium: distally located lesions, old infarction in the territory of coronary supply.

1.3.7.2 Investigate other causes of chest pain when:

- significant CAD (see box 1) is not found during invasive coronary angiography or 64-slice (or above) CT coronary angiography **and/or**
- reversible myocardial ischaemia is not found during non-invasive functional imaging **or**
- the calcium score is zero.

1.3.7.3 Consider investigating other causes of angina, such as hypertrophic cardiomyopathy or syndrome X, in people with typical angina-like chest pain if investigation excludes flow-limiting disease in the epicardial coronary arteries.

2 Notes on the scope of the guidance

NICE guidelines are developed in accordance with a scope that defines what the guideline will and will not cover. The scope of this guideline is available from www.nice.org.uk/guidance/CG95 – click on 'How this guidance was produced'.

The guideline covers adults who have recent onset chest pain or discomfort of suspected cardiac origin, with or without a prior history and/or diagnosis of cardiovascular disease. It includes those presenting with either acute or stable chest pain.

The guideline addresses assessment and investigation irrespective of setting including:

- assessment at initial presentation
- early, initial pharmacological interventions such as oxygen, antiplatelet therapy and pain relief before a cause is known
- choice and timing of investigations
- education and information provision, in particular involving patients in decisions
- where relevant and where associated with chest pain or discomfort, the special needs of people from different groups are considered.

The guideline does not cover the management, including prognostic investigations, and symptom control once the cause of chest pain or discomfort is known. It does not address non-ischaemic chest pain (for example, traumatic chest injury) or pain which is known to be related to another condition, or when there are no cardiac symptoms.

How this guideline was developed

NICE commissioned the National Collaborating Centre for Acute Conditions (now the National Clinical Guideline Centre for Acute and Chronic Conditions) to develop this guideline. The Centre established a Guideline Development Group (see appendix A), which reviewed the evidence and developed the recommendations. An independent Guideline Review Panel oversaw the development of the guideline (see appendix B).

There is more information about how NICE clinical guidelines are developed on the NICE website (www.nice.org.uk/HowWeWork). A booklet, 'How NICE clinical guidelines are developed: an overview for stakeholders, the public and the NHS' (fourth edition, published 2009), is available from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N1739).

3 Implementation

NICE has developed tools to help organisations implement this guidance (see www.nice.org.uk/guidance/CG95).

4 Research recommendations

The Guideline Development Group has made the following recommendations for research, based on its review of evidence, to improve NICE guidance and patient care in the future. The Guideline Development Group's full set of research recommendations is detailed in the full guideline (see section 5).

4.1 *Cost-effectiveness of multislice CT coronary angiography for ruling out obstructive CAD in people with troponin-negative acute coronary syndromes*

Research question

Is multislice CT coronary angiography a cost-effective first-line test for ruling out obstructive CAD in people with suspected troponin-negative acute coronary syndromes?

Research recommendation

Investigation of the cost-effectiveness of multislice CT coronary angiography as a first-line test for ruling out obstructive CAD in people with suspected troponin-negative acute coronary syndromes.

Why this is important

Current European Society of Cardiology guidelines state that in troponin-negative ACS, with no ST-segment change on the ECG, 'a stress test is recommended ... in patients with significant ischaemia during the stress test, coronary angiography and subsequent revascularisation should be considered'. Yet stress testing has relatively low sensitivity and specificity for diagnosing CAD in this group of people. Therefore a significant proportion of at-risk people are missed while others with normal coronary arteries are subjected to an unnecessary invasive coronary angiogram. Multislice CT coronary angiography is highly sensitive and provides a potentially useful means for early rule-out of CAD in troponin-negative acute coronary disease. We need to know whether it is cost effective compared with exercise ECG as a first test in the diagnostic work up of this group.

4.2 Novel cardiac biomarkers in people with acute chest pain

What is the effectiveness and cost effectiveness of new, high-sensitivity troponin assay methods and other new cardiac biomarkers in low, medium, and high risk people with acute chest pain?

Research recommendation

Evaluation of new, high-sensitivity troponin assay methods in low, medium and high risk groups with acute chest pain.

Evaluation of other putative biomarkers compared with the diagnostic and prognostic performance of the most clinically effective and cost-effective troponin assays.

Why this is important

Newer more sensitive troponin assays may offer advantages over previous assays in terms of diagnostic accuracy. They may allow exclusion of myocardial infarction earlier than the 12 hour time frame currently required. Other proposed biomarkers need to be compared to the best available troponin assays.

4.3 Refining the use of telephone advice in people with chest pain

Research question

In what circumstances should telephone advice be given to people calling with chest pain? Is the appropriateness influenced by age, sex or symptoms?

Research recommendation

To develop a robust system for giving appropriate telephone advice to people with chest pain.

Why this is important

The telephone is a common method of first contact with healthcare services, and produces a near uniform emergency response to chest pain symptoms. Such a response has considerable economic, social and human costs. Research should be conducted to clarify if an emergency response in all circumstances is appropriate, or if there are identifiable factors such as age, sex, or associated symptoms that would allow a modified response and a more appropriate use of resources.

Stable chest pain

4.4 Establishing a national registry for people who are undergoing initial assessment for stable angina

Research question and recommendations

Can a national registry of people presenting with suspected angina be established to allow cohort analysis of treatments, investigations and outcomes in this group? Such a registry would provide a vital resource for a range of important research projects, including:

- development and validation of a new score for assessing the estimated likelihood of disease, addressing outstanding uncertainties in the estimation of the likelihood of CAD based on simple measures made at initial assessment (history, examination, routine bloods, resting 12-lead ECG)
- assessment of the extent to which new circulating biomarkers add additional information to measures made at initial assessment
- provision of a framework for trial recruitment without significant work-up bias allowing evaluation of the diagnostic and prognostic test performance of CT-based, MR, echocardiography, and radionuclide technologies.

Why this is important

A national prospective registry of consecutive people with suspected stable angina before initial diagnostic testing does not currently exist in the UK or in any other country. Establishing such a registry would offer the following methodological strengths: statistical size, representative patients without

work-up bias, contemporary data. This would overcome key problems in much of the existing evidence base.

Accurate assessment of the likelihood of coronary disease is needed to inform the cost-effective choice of investigative technologies such as CT coronary calcium scoring for people with chest pain that may be caused by myocardial ischaemia. The data on which the estimated likelihood of CAD is based date from 1979 in a US population and may not be applicable to contemporary UK populations. There remain continuing uncertainties about the initial assessment of people with suspected stable angina. For example, the possible contributions of simple clinical measures such as body mass index, routine blood markers (for example, haemoglobin) or novel circulating biomarkers to estimates of the likelihood of CAD are not known and require further assessment in the whole population and in predefined subgroups including ethnic minorities.

4.5 *Cost-effectiveness of multislice CT coronary angiography compared with functional testing in the diagnosis of angina*

Research question

What is the clinical and cost effectiveness of multislice CT coronary angiography compared with functional testing in the diagnosis of angina in a population of people with stable chest pain who have a moderate (30–60%) likelihood of CAD?

Research recommendation

Further research should be undertaken to evaluate the clinical and cost effectiveness of multislice CT coronary angiography compared with functional testing in the diagnosis of angina in a population of people with stable chest pain who have a moderate (30–60%) likelihood of CAD.

Why this is important

Multislice CT coronary angiography has developed rapidly in recent years. Published reviews have shown it to be highly effective in the diagnosis of anatomically significant CAD, and costing data indicate that tests can be run at a relatively low cost. However, questions remain about the ability of multislice CT coronary angiography to accurately identify stenoses of functional significance (that is, those that are sufficient to cause angina) in people with stable chest pain. This is especially true for people with a moderate likelihood of significant CAD.

Cost-effectiveness modelling to date has used the diagnosis of CAD as a short-term outcome, and as such inexpensive anatomical tests like multislice CT coronary angiography fare better than functional testing strategies such as MPS with SPECT, stress perfusion MR imaging and stress echocardiography. Because the diagnosis of angina is the true outcome of interest, health economic modelling is needed to evaluate diagnostic technologies on their ability to diagnose stable angina.

4.6 Information about presenting and explaining tests

Research question

All people presenting with chest pain will need to decide whether to accept the diagnostic and care pathways offered. How should information about the diagnostic pathway and the likely outcomes, risks and benefits, with and without treatment, be most effectively presented to particular groups of people, defined by age, ethnicity and sex?

Research recommendation

To establish the best ways of presenting information about the diagnostic pathway to people with chest pain.

Why this is important

Methods of communication (both the content and delivery) will be guided by current evidence-based best practice. Controlled trials should be conducted based on well-constructed randomised controlled clinical trials comparing the

effects of different methods of communication on the understanding of the person with chest pain. Such studies might consider a number of delivery mechanisms, including advice and discussion with a clinician or a specialist nurse as well as specific information leaflets or visual data.

Any trials should also investigate the feasibility of introducing a suggested guideline protocol to be used with all people presenting with chest pain when faced with options concerning their clinical pathway.

Only by clearly explaining and then discussing the proposed diagnostic and care pathways can the healthcare professional be reasonably certain that informed consent has been obtained and that a patient's moral, ethical and spiritual beliefs, expectations, and any misconceptions about their condition, have been taken into account. Consideration should be given to any communication problems the person may have.

5 Other versions of this guideline

5.1 Full guideline

The full guideline, 'Chest pain of recent onset: assessment and diagnosis of recent onset chest pain or discomfort of suspected cardiac origin' contains details of the methods and evidence used to develop the guideline. It is published by the National Clinical Guideline Centre for Acute and Chronic Conditions, and is available from www.rcplondon.ac.uk and our website (http://guidance.nice.org.uk/CG95/Guidance).

5.2 Quick reference guide

A quick reference guide for healthcare professionals is available from http://guidance.nice.org.uk/CG95/QuickRefGuide/pdf/English

For printed copies, phone NICE publications on 0845 003 7783 or email publications@nice.org.uk (quote reference number N2113).

5.3 *'Understanding NICE guidance'*

A summary for patients and carers ('Understanding NICE.guidance') is available from http://guidance.nice.org.uk/CG95/PublicInfo/pdf/English

For printed copies, phone NICE publications on 0845 003 7783 or email publications@nice.org.uk (quote reference number N2114).

We encourage NHS and voluntary sector organisations to use text from this booklet in their own information about chest pain or discomfort of recent onset.

6 Related NICE guidance

Published

- Unstable angina and NSTEMI. NICE clinical guideline 94 (2010). Available from www.nice.org.uk/guidance/CG94
- Lipid modification. NICE clinical guideline 67 (2008). Available from www.nice.org.uk/guidance/CG67
- MI: secondary prevention. NICE clinical guideline 48 (2007). Available from www.nice.org.uk/guidance/CG48
- Hypertension. NICE clinical guideline 34 (2006). Available from www.nice.org.uk/guidance/CG34
- Statins for the prevention of cardiovascular events. NICE technology appraisal guidance 94 (2006). Available from www.nice.org.uk/guidance/TA94
- Anxiety (amended). NICE clinical guideline 22 (2007). Available from www.nice.org.uk/guidance/CG22
- Dyspepsia (amended). NICE clinical guideline 17 (2005). Available from www.nice.org.uk/guidance/CG17
- Myocardial perfusion scintigraphy for the diagnosis and management of angina and myocardial infarction. NICE technology appraisal guidance 73 (2003). Available from www.nice.org.uk/guidance/TA73

Under development

NICE is developing the following guidance (details available from www.nice.org.uk):

- Stable angina. NICE clinical guideline. Publication expected July 2011.
- Prevention of cardiovascular disease. NICE public health guidance. Publication date to be confirmed.

7 Updating the guideline

NICE clinical guidelines are updated so that recommendations take into account important new information. New evidence is checked 3 years after publication, and healthcare professionals and patients are asked for their views; we use this information to decide whether all or part of a guideline needs updating. If important new evidence is published at other times, we may decide to do a more rapid update of some recommendations.

Appendix A: The Guideline Development Group and NICE project team

Guideline Development Group

Professor Adam Timmis (Chair)
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Dr Philip Adams
Cardiologist Consultant, Royal Victoria Infirmary, Newcastle Upon Tyne

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Ms Liz Clark
Patient representative

Dr Richard Coulden
Consultant Cardiothoracic Radiologist, Glenfield Hospital, Leicester

Professor Harry Hemingway
Public Health Physician Epidemiologist, University College London Medical School, London

Mrs Cathryn James
Clinical Pathways Adviser/Emergency Care Practitioner, Yorkshire Ambulance Service Headquarters, Wakefield

Ms Heather Jarman
Consultant Nurse in Emergency Care, St George's Healthcare NHS Trust, London

Dr Jason Kendall
Consultant in Emergency Medicine, Frenchay Hospital, Bristol

Mr Peter Lewis
Chief Clinical Physiologist, Prince Charles Hospital, Merthyr Tydfil, Wales

Dr Kiran Patel
Consultant Cardiologist and Honorary Senior Lecturer in Cardiovascular Medicine, Sandwell and West Birmingham NHS Trust and University of Birmingham, West Bromwich, West Midlands

Professor Liam Smeeth
Professor of Clinical Epidemiology, London School of Hygiene and Tropical Medicine, London

Mr John Taylor
Patient representative

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Head of Health Economics, National Clinical Guideline Centre for Acute and Chronic Conditions

Laura Sawyer
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David Hill

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Marian Cotterell

Information Scientist (until January 2009), National Clinical Guideline Centre for Acute and Chronic Conditions

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Clinical Health Psychologist, Department of Clinical Psychology, University of Hull, Hull

Professor Steve Goodacre

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Dr Marcus Hardbord

Consultant Physician and Gastroenterologist, Chelsea and Westminster Hospital, London

Ms Helen Williams

Consultant Pharmacist for Cardiovascular Disease, Southwark Health and Social Care, London

NICE project team

Philip Alderson

Associate Director

Sarah Willett

Guideline Commissioning Manager

Andrew Gyton

Guidelines Coordinator

Nichole Taske
Technical Lead

Appendix B: The Guideline Review Panel

The Guideline Review Panel is an independent panel that oversees the development of the guideline and takes responsibility for monitoring adherence to NICE guideline development processes. In particular, the panel ensures that stakeholder comments have been adequately considered and responded to. The panel includes members from the following perspectives: primary care, secondary care, lay, public health and industry.

Dr Rob Walker (Chair)
General Practitioner, Workington

Dr Mark Hill
Head of Medical Affairs, Novartis Pharmaceuticals Ltd

Mrs Ailsa Donnelly
Lay member

Dr John Harley
Clinical Governance and Prescribing Lead and General Practitioner, North Tees PCT

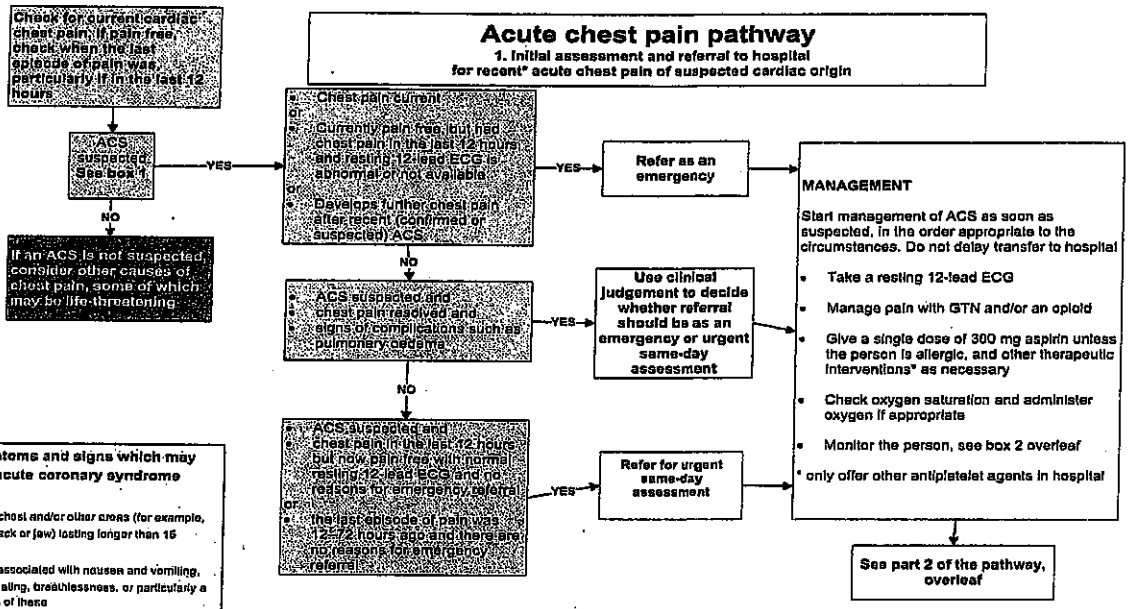
Mr Robin Beal
Consultant in Accident and Emergency Medicine, Isle of Wight

Mrs Sarah Fishburn
Lay member

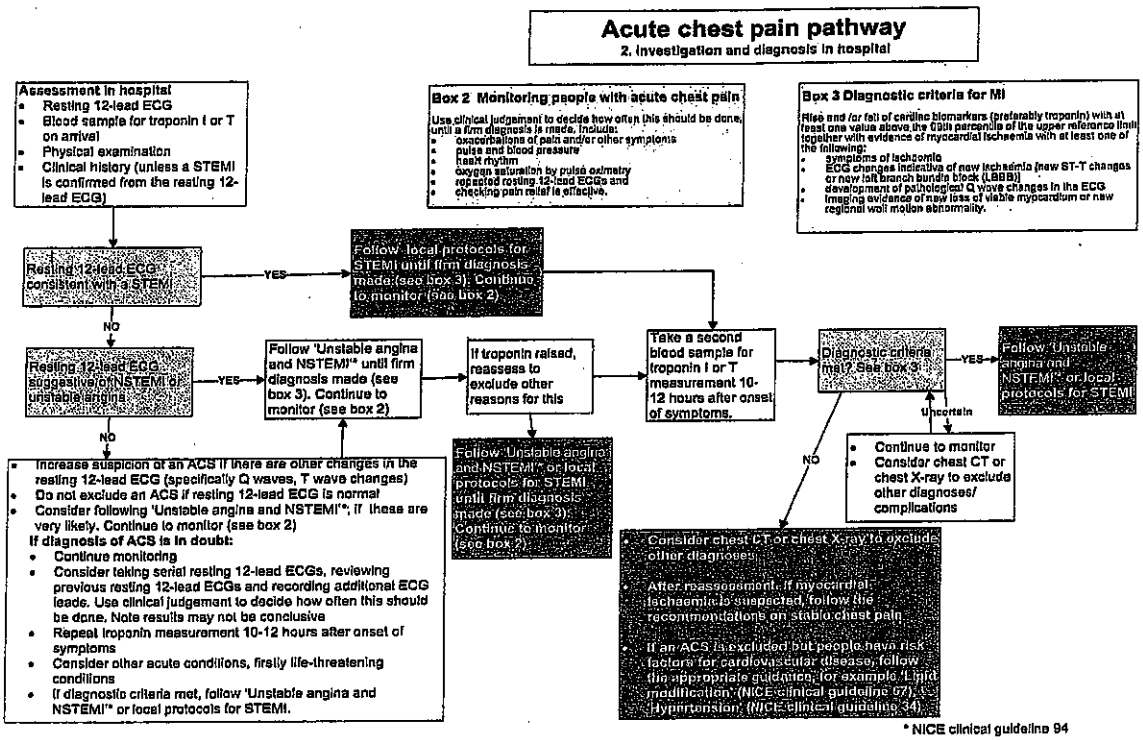
Appendix C: The algorithms

Acute chest pain pathway parts 1 and 2: see pages 47 and 48.

The pathway should be read with the recommendations in this document.



* If a recent ACS is suspected in people whose last episode of chest pain was more than 72 hours ago and who have no complications such as pulmonary oedema: carry out a detailed clinical assessment, confirm the diagnosis by resting 12-lead ECG and blood troponin level (take into account the length of time since the suspected ACS when interpreting the troponin level). Use clinical judgement to decide whether referral is necessary and how urgent this should be

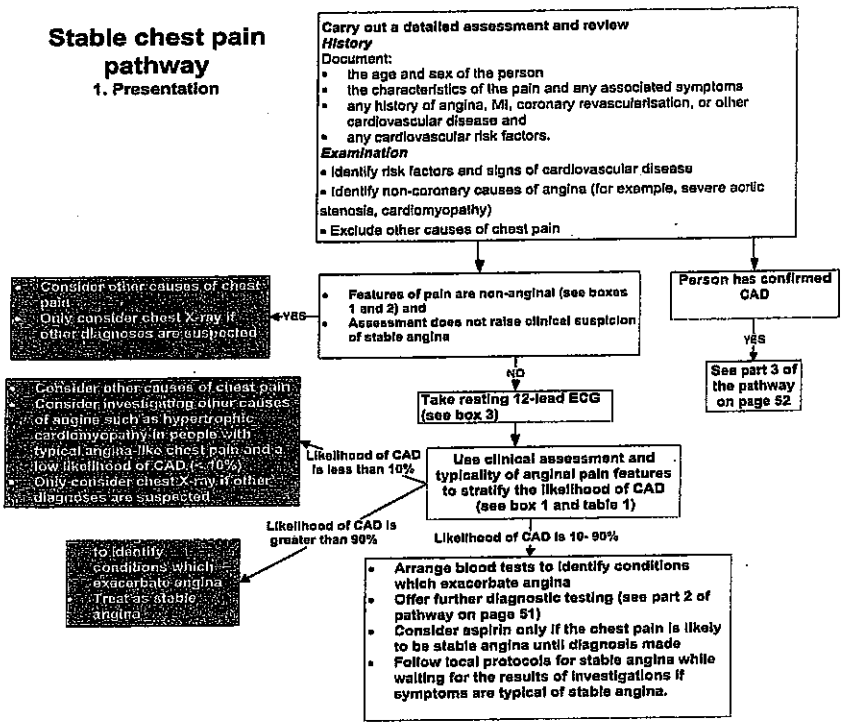

Acute chest pain pathway
2. Investigation and diagnosis in hospital
Assessment in hospital
Resting 12-lead ECG
Blood sample for troponin I or T on arrival
Physical examination
Clinical history (unless a STEMI is confirmed from the resting 12-lead ECG)
Box 2 Monitoring people with acute chest pain
Use clinical judgement to decide how often this should be done, until a firm diagnosis is made. Include:
exacerbations of pain and/or other symptoms
pulse and blood pressure
heart rhythm
oxygen saturation by pulse oximetry
repeated resting 12-lead ECGs and
checking pain relief is effective.
Box 3 Diagnostic criteria for MI
Rise and /or fall of cardiac biomarkers (preferably troponin) with at least one value above the 99th percentile of the upper reference limit together with evidence of myocardial ischaemia with at least one of the following:
symptoms of ischaemia
ECG changes indicative of new ischaemia (new ST-T changes or new left branch bundle block (LBBB))
development of pathological Q wave changes in the ECG
imaging evidence of new loss of viable myocardium or new regional wall motion abnormality.
Resting 12-lead ECG consistent with a STEMI
YES
Follow local protocols for STEMI until firm diagnosis made (see box 3). Continue to monitor (see box 2)
NO
Resting 12-lead ECG suggestive of NSTEMI or unstable angina
YES
Follow 'Unstable angina and NSTEMI'* until firm diagnosis made (see box 3). Continue to monitor (see box 2)
If troponin raised, reassess to exclude other reasons for this
Follow 'Unstable angina and NSTEMI'* or local protocols for STEMI until firm diagnosis made (see box 3). Continue to monitor (see box 2)
Take a second blood sample for troponin I or T measurement 10-12 hours after onset of symptoms.
Diagnostic criteria met? See box 3
YES
Follow 'Unstable angina and NSTEMI'* or local protocols for STEMI
Uncertain
NO
Continue to monitor
Consider chest CT or chest X-ray to exclude other diagnoses/ complications
NO
Increase suspicion of an ACS if there are other changes in the resting 12-lead ECG (specifically Q waves, T wave changes)
Do not exclude an ACS if resting 12-lead ECG is normal
Consider following 'Unstable angina and NSTEMI'*, if these are very likely. Continue to monitor (see box 2)
If diagnosis of ACS is in doubt:
Continue monitoring
Consider taking serial resting 12-lead ECGs, reviewing previous resting 12-lead ECGs and recording additional ECG leads. Use clinical judgement to decide how often this should be done. Note results may not be conclusive
Repeat troponin measurement 10-12 hours after onset of symptoms
Consider other acute conditions, firstly life-threatening conditions
If diagnostic criteria met, follow 'Unstable angina and NSTEMI'* or local protocols for STEMI.
Consider chest CT or chest X-ray to exclude other diagnoses
After reassessment, if myocardial ischaemia is suspected, follow the recommendations on stable chest pain
If an ACS is excluded but people have risk factors for cardiovascular disease, follow the appropriate guidance, for example 'Lipid modification' (NICE clinical guideline 67) or 'Hypertension' (NICE clinical guideline 34)
* NICE clinical guideline 94

Stable chest pain pathway parts 1–3: see pages 50–52.

The pathway should be read with the recommendations in this document.

Stable chest pain pathway

1. Presentation



Box 1 Typical stable angina symptoms

- Constricting discomfort in the front of the chest, in the neck, shoulders, jaw, or arms
- Precipitated by physical exertion
- Relieved by rest or GTN within about 5 minutes

Typical angina: all of the above
Atypical angina: two of the above
Non-anginal chest pain: one or none of the above

See recommendation 1.3.3.4 for risk factors which make angina more likely.

Box 2
Stable angina is unlikely if chest pain is:

- continuous or very prolonged and/or
- unrelated to activity and/or
- brought on by breathing in and/or
- associated with symptoms such as dizziness, palpitations, tingling or difficulty swallowing

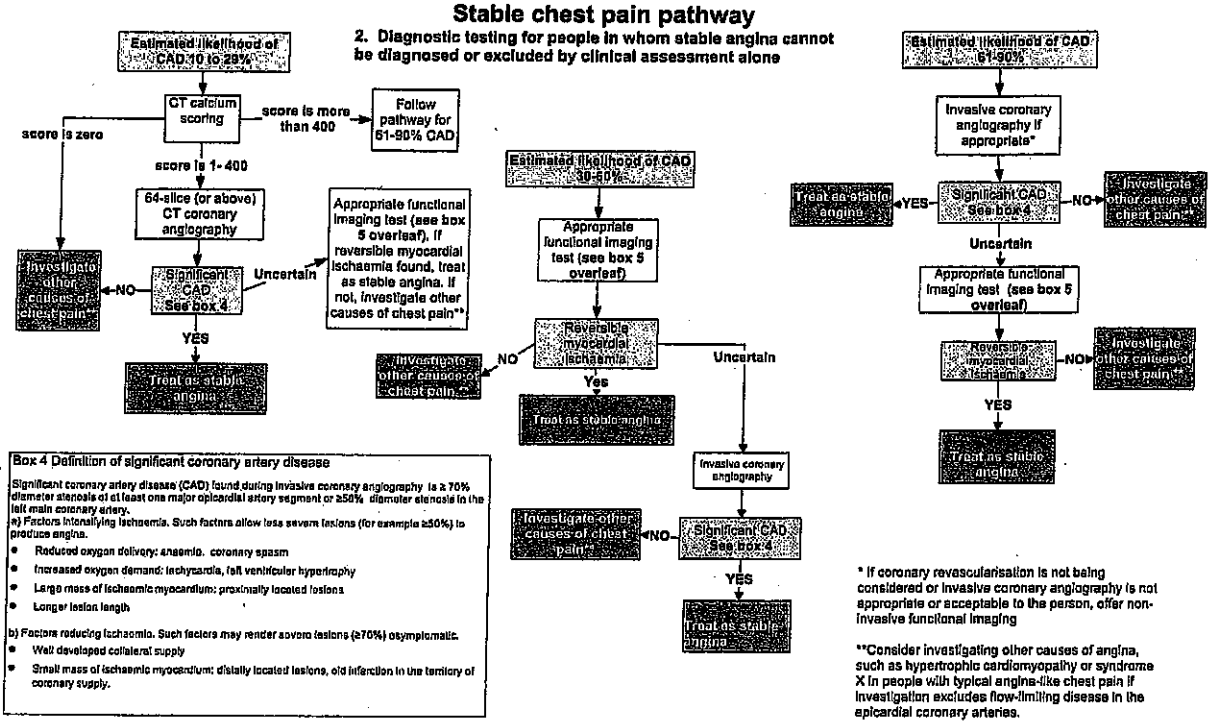
Box 3 Changes on a resting 12-lead ECG consistent with CAD which may indicate ischaemia or previous infarction

- pathological Q waves in particular
- LBBB
- ST-segment and T wave abnormalities (for example, flattening or inversion).

Results may not be conclusive. Consider resting 12-lead ECG changes together with people's clinical history and risk factors. Note that a normal resting 12-lead ECG does not rule out stable angina.

Stable chest pain pathway

2. Diagnostic testing for people in whom stable angina cannot be diagnosed or excluded by clinical assessment alone



Box 4 Definition of significant coronary artery disease

Significant coronary artery disease (CAD) found during invasive coronary angiography is ≥ 70% diameter stenosis of at least one major epicardial artery segment or ≥50% diameter stenosis in the left main coronary artery.

a) Factors intensifying ischaemia. Such factors allow less severe lesions (for example ≥50%) to produce angina.

- Reduced oxygen delivery: anaemia, coronary spasm
- Increased oxygen demand: tachycardia, left ventricular hypertrophy
- Large mass of ischaemic myocardium: proximally located lesions
- Longer lesion length

b) Factors reducing ischaemia. Such factors may render severe lesions (≥70%) asymptomatic.

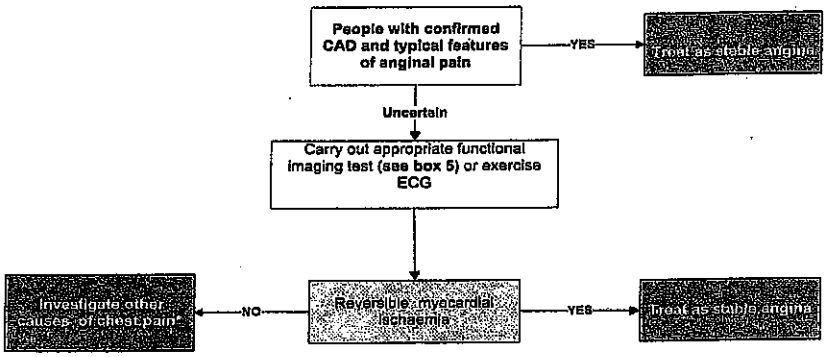
- Well developed collateral supply
- Small mass of ischaemic myocardium: distally located lesions, old infarction in the territory of coronary supply.

* If coronary revascularisation is not being considered or invasive coronary angiography is not appropriate or acceptable to the person, offer non-invasive functional imaging

**Consider investigating other causes of angina, such as hypertrophic cardiomyopathy or syndrome X in people with typical angina-like chest pain if investigation excludes flow-limiting disease in the epicardial coronary arteries.

Stable chest pain pathway

3. Established prior diagnosis of coronary artery disease



Box 5

When offering non-invasive functional imaging for myocardial ischaemia use:

- myocardial perfusion scintigraphy with single photon emission computed tomography (MPS with SPECT) or
- stress echocardiography or
- first-pass contrast-enhanced magnetic resonance (MR) perfusion or
- MR imaging for stress-induced wall motion abnormalities.

Take account of locally available technology and expertise, the person and their preferences, and any contraindications, when deciding on the imaging method.

Note: This recommendation updates and replaces recommendation 1.1 of NICE technology appraisal guidance 73.

* Consider investigating other causes of angina, such as hypertrophic cardiomyopathy or syndrome X in people with typical angina-like chest pain if investigation excludes flow-limiting disease in the epicardial coronary arteries.

Appendix 2

Good Medical Practice: Providing good clinical care

2. Good clinical care must include:

    a. adequately assessing the patient's conditions, taking account of the history (including the symptoms, and psychological and social factors), the patient's views, and where necessary examining the patient

    b. providing or arranging advice, investigations or treatment where necessary

    c. referring a patient to another practitioner, when this is in the patient's best interests

3. In providing care you must:

    a. recognise and work within the limits of your competence

    b. prescribe drugs or treatment, including repeat prescriptions, only when you have adequate knowledge of the patient's health, and are satisfied that the drugs or treatment serve the patient's needs

    c. provide effective treatments based on the best available evidence

    d. take steps to alleviate pain and distress whether or not a cure may be possible

    e. respect the patient's right to seek a second opinion;

    f. keep clear, accurate and legible records, reporting the relevant clinical findings, the decisions made, the information given to patients, and any drugs prescribed or other investigation or treatment

    g. make records at the same time as the events you are recording or as soon as possible afterwards

    h. be readily accessible when you are on duty;

    i. consult and take advice from colleagues, where appropriate;

    j. make good use of the resources available to you.

Good clinical care

Supporting self care

Good Medical Practice: Good communication

22. To communicate effectively you must:

a. listen to patients, ask for and respect their views about their health, and respond to their concerns and preferences

b. share with patients, in a way they can understand, the information they want or need to know about their condition, its likely progression, and the treatment options available to them, including associated risks and uncertainties

c. respond to patients' questions and keep them informed about the progress of their care

d. make sure that patients are informed about how information is shared within teams and among those who will be providing their care.

23. You must make sure, wherever practical, that arrangements are made to meet patients' language and communication needs.

The doctor-patient partnership

Children and young people

Good Medical Practice: Relatives, carers and partners

29. You must be considerate to relatives, carers, partners and others close to the patient, and be sensitive and responsive in providing information and support, including after a patient has died. In doing this you must follow the guidance in *Confidentiality*.

Children and young people

Being open and honest with patients if things go wrong

Appendix 3

Abertawe Bro Morgannwg University Health Board

Interim Complaints Policy and Procedures

This document can be made available in alternative formats, or other languages, on request, as is reasonably practicable to do so

Originator:	Director of Nursing
Date Approved:	20th January 2010
Approved by:	Executive Board
Date for Review:	As needed to conform to revised management structures and new WAG guidance. No later than August 2010
Policy ID:	

Contents

Abertawe Bro Morgannwg Health Board

Interim Complaints Policy and Procedure

1 INTRODUCTION

1.1 The establishment of the Abertawe Bro Morgannwg University Health Board (ABMUHB) through merger of the former Abertawe Bro Morgannwg NHS Trust and the Bridgend, Neath Port Talbot and Swansea Local Health Boards requires that policies and procedures are reviewed to ensure that they meet the needs of the new integrated organisation.

1.2 A review has been undertaken of the policies and procedures for dealing with the concerns of patients and those speaking on their behalf across the former organisations, and the opportunity taken to consider practice elsewhere in the NHS in Wales, to develop an integrated policy and associated procedures which are fit for purpose across the ABMU Health Board.

1.3 The revised Interim Complaints Policy and Procedure is designed to comply with guidance issued by the Welsh Assembly Government (WAG) in 'A Guide to Handling Complaints in Wales' (April 2003) as amended and updated by 'Interim Guidance on the Handling of Concerns in the New NHS Structure' (October 2009); 'Apologies and Explanations – Guidance from the Welsh Risk Pool' (November 2009); 'Being Open' – National Patient Safety Agency (2005, relaunched November 2009).

1.4 This Interim Policy and Procedures is designed around the management structures existing at December 2009 and will need to be reviewed when revised management structures are implemented within the Health Board.

1.5 Information and communication in relation to this Interim Policy and Procedures will be provided in the appropriate format or language of choice on request, as far as is reasonably practicable to do so.

2 SCOPE

2.1 Complaints about services provided by the Health Board may be made by users of the Health Board's services or anyone authorised to act on their behalf. This may include solicitors, where formal notification of a claim has not been given. (Where legal proceedings are started after the complaint investigation has begun, the investigation should be completed and a response provided in accordance with this policy).

2.2 This policy and associated procedures will apply to all staff of the Health Board receiving and / or involved in the investigation of and response to such complaints.

2.3 The Health Board has a contractual relationship with primary care contractors - general medical practitioners, NHS dentists, pharmacists, optometrists, and with prison healthcare services. At present, it is not responsible for investigating complaints concerning the provision of services by these organisations, which are required to establish appropriate policies and procedures to respond directly to complainants. Such complaints are often, however, received initially by Health Board staff. The contractual relationship does include a responsibility for oversight of clinical governance, and for administration of the further stages where these complaints are not resolved locally. The procedures for dealing with complaints received and further stages are included as separate sections within this document.

2.4 This policy and procedures do not apply to clinical services provided privately, even when provided within Health Board premises, but will apply to complaints about Health Board services or facilities used.

3 POLICY STATEMENT

3.1 The Health Board and its staff will at all times try to provide the highest possible quality of care to users of its services. On occasions, we may not always get it right, or service users' expectations may not be met. When this happens, we will try to put it right as quickly and effectively as possible.

3.2 Through this policy and associated procedures, the Health Board will ensure that any service user who is not satisfied with the services provided will have a clear route to express that dissatisfaction. The Health Board will listen to all such complaints in an open and positive manner, will ensure that they are

investigated fairly and objectively, and that an open and honest response will be provided.

3.3 Where service users find difficulty in expressing a complaint, the Health Board will either provide support directly or will advise on where support is available to ensure that no service user is left in a position where they feel their complaints cannot be expressed or resolved.

3.4 Staff of the Health Board will work with complainants to try to ensure that all complaints are resolved through this process. Should a complainant remain dissatisfied, they will be provided with clear information on other ways in which they can seek resolution.

3.5 The Health Board will see all complaints as an opportunity to review the way in which it works, to identify opportunities for improvement and to learn lessons and share good practice in order to continually improve the quality of the services it provides.

4 RESPONSIBILITIES

4.1 The **Health Board** is accountable for the performance of the organisation. The Board will need to be assured that the investigation into and responses to complaints are appropriate, effective, and completed within relevant time limits, and that lessons learned lead to continual improvement in clinical and management practice. This will be exercised through the **Quality and Safety Committee** or equivalent committee of the Board.

4.2 A nominated **Non Officer Member** will have designated responsibility for maintaining an overview of complaints and will be a member of the Quality and Safety Committee.

4.3 The **Chief Executive** is responsible to the Board for the effective handling of complaints and will sign, or establish delegated responsibility to named Executive Directors for signature of, all formal complaint responses. Delegated responsibility has been given to the Director of Acute Care and the Director of Primary Care, Community and Mental Health.

4.4 The **Director of Nursing** is responsible for establishing and implementing appropriate processes for the management of complaints on behalf of the Chief Executive, and for ensuring, with the Medical Director and Director of Therapies and Health Sciences, that lessons learned are identified and implemented within the

Health Board. This executive function will be discharged through the Quality and Safety Team.

4.5 The **Complaints Manager** will be accountable to the Director of Nursing for ensuring that complaints are managed efficiently and effectively within the organisation, including:

- the development, implementation and review of the Board's Complaints Policy and Procedure
- the management of the corporate complaints handling function, currently within the Governance Support Unit (GSU)
- ensuring effective liaison and joint working between the corporate complaints handling team and the Complaints Leads in the directorates and localities
- developing and maintaining links to the Community Health Councils (CHC), Patient Experience department and / or others who can provide support to complainants who may have difficulty in expressing their concerns, and ensure these are known to complainants where appropriate
- identifying indicators to demonstrate that the standards for the handling of complaints are being met.

It is important that the essential links between the management of incidents, complaints and claims are recognised. The Complaints Manager will therefore work within an overall Clinical Governance framework that will include the management of incidents and claims, the final structure of which is yet to be determined.

4.6 **Clinical / Locality Directors** and **Hospital Managers** will:

- identify a **Complaints Lead** to lead processes within the directorate / locality and liaise with colleagues in the corporate complaints department and in other directorates / localities
- within the terms of this policy, ensure that robust and thorough investigations are carried out to an appropriate level and that open and comprehensive responses are provided to all complaints
- promote a culture of openness and responsiveness to complaints investigations and maintain pressure for these to be dealt with within agreed timescales
- ensure that action plans are identified as a result of complaints investigations and that these are implemented
- ensure that lessons learned are identified and implemented, and brought to the attention of the wider Health Board organisation where relevant
- ensure that the causes of, outcomes, action plans and lessons learned from complaints are regularly reported to, and considered by, the directorate / locality management team

- take a personal role in investigations, meetings with complainants and / or conflict resolution as necessary and appropriate
- ensure, in cooperation with Human Resources colleagues or others as appropriate, support for staff who are the subject of complaint or otherwise involved in investigation where this is requested or identified as necessary.

4.7 **Complaints Handlers** within the corporate complaints function will:

- ensure that complaints are clarified and acknowledged within appropriate timescales
- seek to resolve, through personal contact in the first instance, where appropriate (e.g. where no investigation is needed)
- ensure that appropriate investigation and response plans are agreed with directorate / locality Complaints Leads
- ensure that complaints are recorded in the Datix system
- ensure that communication is maintained with complainants
- ensure that draft responses are quality assured to confirm that they answer all questions raised, and are consistent with the agreed style before putting them forward for signature
- draft responses in relation to investigations involving more than one directorate / locality

4.8 **All staff** will work to the best of their ability to avoid complaints arising through good practice and through being responsive to the needs and expectations of patients at the point of contact. When complaints arise, staff will cooperate openly and honestly with investigations in accordance with this policy and procedures.

4.9 The **Patient Experience Manager and Facilitator** have no formal role within the complaints policy and procedures but can provide support in a number of ways which can both help to prevent a concern becoming a complaint and to assist in resolution when a complaint has been made. Reference will be made within the procedures to areas where this assistance may be valuable.

5 Education and Training

5.1 It is essential that all staff are trained to deal with complaints to a level commensurate with their roles.

5.2 All 'front line' staff (i.e. those who have contact with patients) should be trained to appropriate levels in customer relations. A large proportion of formal complaints demonstrate unhelpful attitudes and / or a breakdown in communication. Many of these

can be avoided at source if the staff involved are able to respond positively to concerns as they arise.

5.3 Directorates, localities and the Governance Support Unit will need to undertake an initial training needs analysis against the roles identified within this Interim Policy and Procedures, and ensure that continuing development needs are identified through individual performance appraisals and personal development plans.

6 PROCEDURES – SERVICES PROVIDED BY ABMU HB

NOTES:

These procedures do not apply to complaints made about services provided by primary care contractors, i.e. general medical practices, NHS dental practices, optometrists, pharmacists et al, or to Prison healthcare services. For these complaints, please see Sections 10 or 11.

Where a complaint spans the pathway of care (i.e. covers both primary and secondary care), the Interim Guidance on the Handling of Concerns in the New NHS Structure states that the Health Board would investigate all matters in question in an integrated fashion, without having to have a separate practice-based investigation first. The procedures below will apply, adapted appropriately in relation to the links with the primary care practice(s) involved and should be discussed with locality Complaints Lead.

6.1 Verbal Complaints

6.1.1 The majority of complaints are expressed verbally to staff at the point of care or contact. Staff should respond immediately and sympathetically to try to resolve those concerns that are within their competence, or to refer the concern to their immediate manager, senior member of staff or appropriate clinician for resolution.

6.1.2 In some areas of the Health Board, a Lead Nurse, Patient Support, will be available to support staff in the handling of verbal complaints and to assist patients / complainants by helping them to express and to resolve questions and concerns.

6.1.3 Where a complaint has been resolved in this way, a 'Record of Complaint' form (Appendix 2) should be completed by the member of staff / manager and returned to the directorate / locality

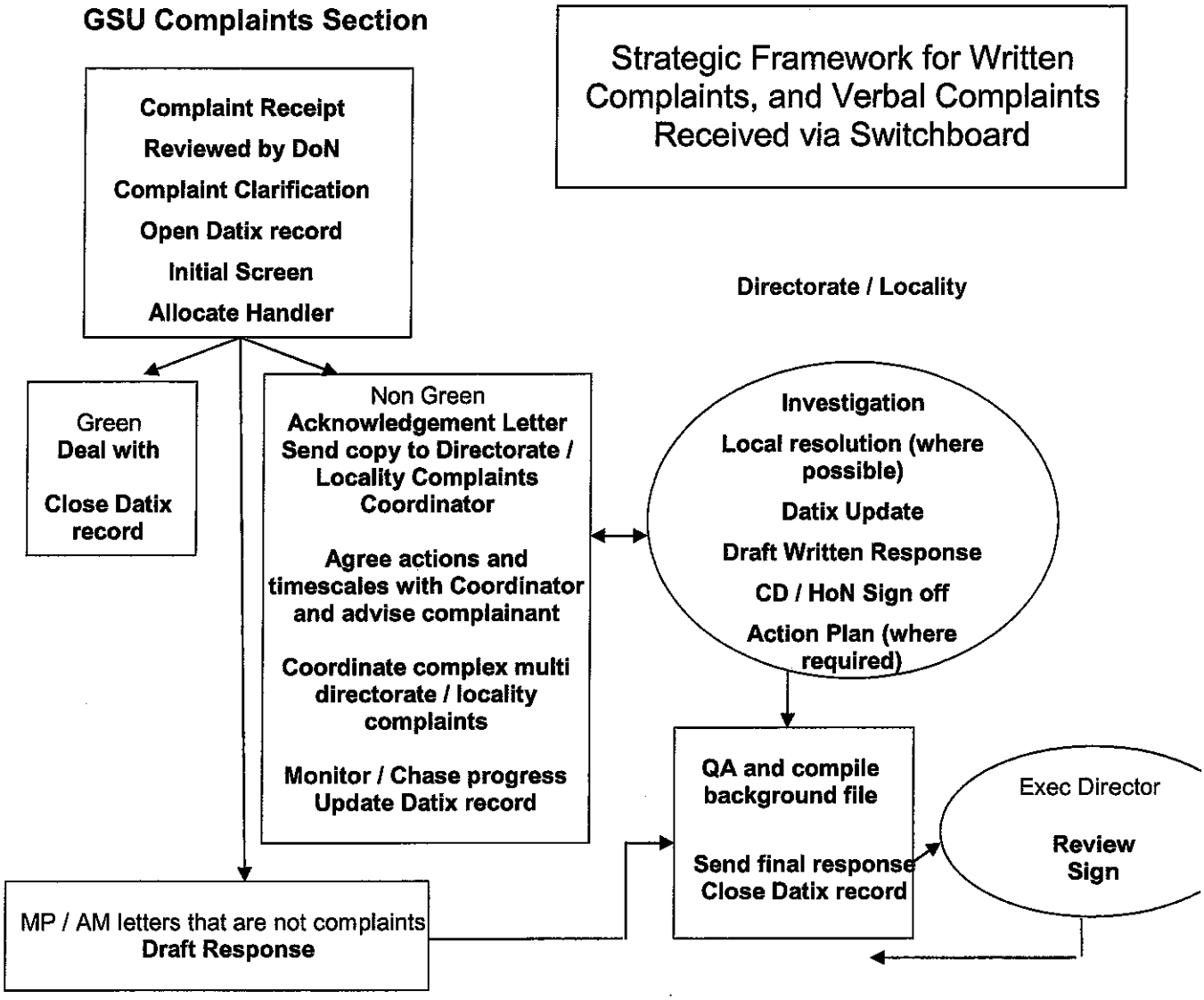
Complaints Lead. Details will be entered onto the Datix system, to enable trends to be identified.

6.1.4 Every effort should be made by staff to resolve issues raised at this level, within 2 working days of the complaint being made. Only where this is not possible should the patient / complainant be advised, and supported, to raise this as a formal complaint.

6.1.5 Where verbal complaints are received via the switchboard, they will be referred to the Governance Support Unit (GSU). The Complaints Handler in GSU will contact the directorate or service area to obtain the information to resolve the complaint, or to arrange for the complainant to speak to someone within the directorate / service area directly. The emphasis, as above, will be to ensure that the complaint is resolved quickly and sympathetically without the need for the complainant to enter into the more formal complaints procedures unless absolutely necessary.

6.1.6 Where the complaint cannot be resolved through this process, the complainant will be advised and supported to make a formal complaint.

6.2 Formal Complaints



6.2.1 Formal complaints are:

- verbal complaints received either at the point of contact or within the GSU which cannot be resolved through the informal process outlined above because the issues raised are too complex or too serious
- all written complaints – which may be from patients, relatives, carers, either directly or through the Community Health Council (CHC), Welsh Assembly Members (AM's), Members of Parliament (MP's), Local Councillors or solicitors acting on behalf of a patient although not in a formal legal capacity

6.2.2 Where verbal complaints cannot be resolved informally, as above, the complainant should be encouraged, and supported where necessary, to put the complaint in writing in order to provide a clear basis for the subsequent investigation and response.

6.2.3 Where complainants would benefit from support in expressing a complaint, they should be referred to the Community Health Council who will provide support and assistance.

6.2.4 Any written complaints received by staff corporately or within directorates / localities should be forwarded immediately to the GSU.

Acknowledgement of complaints

6.2.5 On receipt, all formal complaints will be reviewed by the Director of Nursing and will be triaged by the Complaints Manager, with advice and comment from the Director of Nursing as appropriate, into GREEN or NOT GREEN (See Appendix 5).

Green Complaints

6.2.6 Complaints categorised as GREEN will be managed within the GSU. Each will be allocated to a Complaints Handler, who will:

- register the complaint on Datix
- contact the complainant to clarify the issues, where necessary
- obtain the necessary information directly from colleagues in directorates / departments as quickly as possible (e.g. by telephone / email / meeting) to provide a response
- contact the complainant directly (by telephone or by meeting where possible) and explain the response
- draft a brief written response / confirmation of the conversation (where necessary) for signature
- provide a copy of the response to the directorate / department.

6.2.7 The response to a GREEN complaint will normally be provided within 2 working days. Under these circumstances, an acknowledgement is not necessary.

6.2.8 If it becomes clear that it will not be possible to provide a response within 2 working days, the Complaints Officer should write to acknowledge receipt of the complaint and explain the actions being taken to ensure a rapid response.

'Not Green' Complaints

6.2.9 Complaints categorised as NOT GREEN will be allocated to the Complaints Handler for the relevant directorate / locality, who will:

- enter the complaint on Datix

- contact the complainant where necessary to clarify the points raised within the complaint, establish the issues and what outcomes the complainant is seeking
- send a written acknowledgement within 2 working days of receipt of the complaint into the Health Board.

6.2.10 The acknowledgement letter will:

- confirm receipt of the complaint
- where the complainant is the patient, indicate that consent to access case notes and clinical records is assumed unless the complainant notifies otherwise **or**
- include a request for the consent of the patient to access to case notes and clinical records, if the person making the complaint is not the patient or if the complainant is the patient but has indicated that consent is not to be assumed [**NB** – if the patient has given any indication that consent is not to be assumed, the complaint letter should be considered very carefully to identify any factors which may require an individual response, outside the mainstream complaints process outlined here]
- state the name of the person within the GSU who will be the point of contact for communication relating to the complaint
- indicate that further contact may be made with the complainant, preferably by telephone or meeting, to clarify any issues necessary to enable a full and proper investigation
- indicate that a response will normally be provided within 20 working days, and that if this not going to be possible due to the complexity of the investigation needed and / or other factors (e.g. unavailability of key staff), the complainant will be contacted as quickly as possible to explain what is involved and the proposed timescale for investigation and response
- See Template letters, Appendix 3

Investigation

6.2.11 The Complaints Handler in GSU will notify the Complaints Lead in the relevant directorate / locality of receipt of the complaint and notify the Datix reference or forward the complaint itself by email within 2 working days of receipt.

6.2.12 The directorate / locality Complaints Lead will assess the complaint, with colleagues as appropriate, and will determine the nature and timescale of the investigation to be undertaken. This will be notified to, and agreed with, the Complaints Handler in GSU – see paragraph 6.2.16 below.

6.2.13 At this stage, the complaint should be further categorised to Yellow, Amber or Red, depending on the severity of the issues

raised and / or outcome for the patient. Criteria for categorisation are detailed in Appendix 5, together with the likely level of investigation needed.

6.2.14 Where more than one directorate / locality is involved, the GSU Complaints Handler will notify each of the directorates / localities and agree with them the issues to which they are required to respond. Each of the directorate / locality Complaints Leads will confirm the investigation process and anticipated timescale.

6.2.15 Where more than one agency or organisation is involved – e.g. Welsh Ambulance Services Trust, Local Authority – the GSU Complaints Manager will:

- contact their counterpart in the other organisation and maintain the communication links
- pass on the relevant parts of the complaint
- agree the process for investigation and response, whether combined – which is preferred where possible - or separate, and the process for sharing of information
- agree the arrangements for any meetings to be held and whether these will be joint or separate
- advise the complainant of the way in which the complaint is to be managed and keep them informed of progress.

6.2.16 The target will be for all investigations to be completed and responses to be signed and sent within 20 working days of receipt of the complaint. Where, exceptionally, it is identified at the start or during the investigation that this will not be achieved, the complainant will be notified by the Complaints Handler in GSU at the earliest opportunity, together with an explanation for the extended timescale and a realistic indication of when the investigation will be completed, and subsequent steps (e.g. offer of a meeting, written response). In setting the timescale, the principle should be 'Investigate once, investigate well'. The 20 day deadline should not be a reason for an inadequate investigation, which may well lead to a dissatisfied complainant and further investigation. Timescales should not however be unreasonably extended and all staff involved should maintain a sense of urgency in working towards a resolution. The Complaint Handler will make sure that the complainant is kept aware of progress.

6.2.17 The directorate / locality Complaints Lead will ensure that an open and full investigation is carried out at the appropriate level. Positive consideration should be given to arranging a meeting between the complainant and relevant clinical or other staff involved. This can offer:

- the opportunity for the complainant to fully express and explain their concerns and to feel that they have been properly listened to
- the opportunity to discuss the issues interactively rather than engaging in prolonged correspondence
- a reduction in internal correspondence and bureaucracy
- potential agreement on the explanations and actions, leading to the complainant being satisfied with the process and outcome.

6.2.18 Where relationships between the clinical staff and complainant have broken down, or where it is felt that it would be helpful to the outcome of a meeting, the directorate / locality Complaints Lead should consider seeking the advice of the Independent Complaints Facilitation service (see Appendix 1) or the Health Board's Patient Experience department, who can offer independent mediation and facilitation.

6.2.19 All staff asked to participate in an investigation into a complaint will do so honestly and openly. It is recognised that some staff may find this uncomfortable, particularly where they may feel they are being challenged at a professional or personal level or may be concerned about potential disciplinary action. Nevertheless, it is essential that all staff recognise that a failure of a treatment or care process, or in some cases a failure to meet a patient's expectations, must be examined openly and objectively to ensure that lessons are learned and future practice improved. Managers / Complaints Leads should ensure that support is provided for staff who request it.

6.2.20 Within the 20 day / otherwise agreed timescale, the directorate / locality Complaints Lead will ensure that a draft response is provided which:

- responds to all the issues raised in the complaint, and any further issues raised in subsequent discussion / correspondence with the complainant
- offers full and clear explanations of issues investigated in language which the complainant will be able to understand, and with explanations of any technical terms used
- offers full apologies for shortcomings identified
- indicates the action that will be taken to ensure that similar issues will not arise again, or that the risk will be minimised where unavoidable
- is set out in a style which is agreed within the Health Board (Template letter– See Appendix 4)
- Is approved by the Clinical / Locality Director / Head of Nursing / General Manager, as appropriate within the directorate / locality.

6.2.21 Where more than one directorate / locality is involved, the Complaints Leads will provide information on the findings of their investigations to the Complaints Handler in GSU who will draft a comprehensive response, which will be agreed with the relevant Clinical / Locality Directors / representatives before being submitted for signature.

6.2.22 Where a meeting has been held (see 6.2.17 above) and a satisfactory outcome achieved, the letter may refer to the notes of the meeting – to be attached to the letter – without repeating or going into further detail. Full apologies should still be offered for any shortcomings identified.

6.2.23 Where, at the conclusion of investigations, it is found that any or all of the issues raised are not substantiated, this should be clearly stated. It is to be anticipated that in many cases the complainant will not be happy with this response. The likelihood of this can be minimised by:

- explaining the findings face to face, in order to provide discussion of the points raised and findings of the investigation
- offering a full explanation in the letter
- continuing to be sympathetic to the fact that the complainant felt that this was an issue (which may indicate a different failure – e.g. communication).

Quality Assurance / Sign Off

6.2.24 The directorate / locality Complaints Lead will send the draft response to the GSU Complaints Handler (via Datix where possible, or via email) in sufficient time to allow the response to be quality assured and signed off within the 20 day target or otherwise agreed timescale.

6.2.25 The GSU Complaints Handler will review the draft response from the perspective of the complainant to ensure that it answers all the questions raised and is presented in a way which is responsive and sympathetic to the complainant's concerns.

6.2.26 The GSU Complaints Handler will ensure that the format of the response is consistent with the Health Board's standards.

6.2.27 In all cases, the response letter will include a contact point for further discussion if requested, and emphasise that it is the Health Board's wish to resolve the complainant's concerns through local resolution.

6.2.28 The final response will include information on how the complainant can access the Independent Review or Ombudsman processes if they are not satisfied with the response and if the matter cannot be resolved through further effort at local level.

6.2.29 The finalised response letter will be signed by the Chief Executive or Executive Director nominated to act on his behalf.

7 FURTHER LOCAL RESOLUTION

7.1 Where the complainant is dissatisfied with the response and has continuing, or additional, concerns, they should be offered the opportunity of meeting with the person who led the investigation or a more senior manager / clinician as appropriate to the circumstances for a further attempt at local resolution.

7.2 Consideration should be given at this stage to seeking the advice / involvement of the Independent Complaints Facilitation service (see Appendix 1) or the Health Board's Patient Experience department, who can offer facilitation and mediation services to help achieve resolution.

7.3 Where such a meeting still does not lead to resolution of the complainant's concerns, they must be advised of the alternative options available for pursuing their complaint through the Independent Review process or via the Public Services Ombudsman for Wales.

8 FORMAL COMPLAINTS – STAGE 2 – INDEPENDENT REVIEW

8.1 Where, exceptionally, a complainant is not satisfied with the response provided by the Health Board, they can request an Independent Review. This process is independent of the Health Board. Such a request must be made within 28 calendar days following completion of the Trust's formal response.

8.2 The Complaints Manager must ensure that the complainant is aware of how to contact the Independent Review Secretariat. If the request for Independent Review is received in writing within the Health Board, the Complaints Manager will ensure that this is immediately sent on to the Independent Review Secretariat . If the request is made orally, the Complaints Manager will produce a written summary of the issues raised, give a copy to the

complainant and send a copy to the Independent Review Secretariat.

8.3 The Independent Review Secretariat will arrange for a Lay Reviewer to consider requests for an Independent Review together with a Lay Advisor nominated by the Welsh Assembly Government. The Independent Review Secretariat will undertake the administration of this process.

8.4 The Complaints Manager will inform the Complaints Leads in the relevant directorates / localities that a request for independent review has been received. The Complaints Leads will ensure that all involved in the complaint are informed accordingly.

8.5 The Complaints Manager will act as liaison with the Independent Review Secretariat. All managers and staff of the Health Board will co-operate with the Secretariat and make every effort to respond as soon as possible to requests for information.

8.6 The Lay Reviewer may determine that an Independent Review Panel is not appropriate and refer the complaint back for further local resolution. The Lay Reviewer may also recommend the use of the Independent Complaints Facilitation service (see Appendix 1), in which case he/she will explain the reason for the recommendation.

8.7 If the Lay Reviewer decides that an Independent Review Panel is to be held, key staff involved in the complaint will be called to the Panel hearing. The Complaints Manager will ensure that such staff are fully briefed, and receive whatever help and support they require to assist their preparation for the hearing

Independent Review Panel Final Report

8.8 Following an Independent Review Panel, a report will be issued to the Health Board and the complainant. Staff involved will receive a copy of the Panel's report directly from the Independent Review Secretariat.

8.9 The Chief Executive must respond to the complainant on each of the report's recommendations within 20 working days. The Complaints Manager, in liaison with directorate / locality Complaints Leads and other clinical and management staff as appropriate will ensure that a response is prepared which addresses all the points raised.

8.10 The letter will include:

- A formal apology
- Any action the Health Board is taking as a result of the Panel's deliberation, and the timescale in which the Board has agreed to consider other policy issues
- Information about the right of the complainant to refer their complaint to the Public Services Ombudsman for Wales.

8.11 This letter will be copied to the Independent Review Secretariat and the NHS Performance Quality and Regulation Division of the Welsh Assembly Government. The Independent Review Secretariat will inform the Chair and Panel Members of the results as a way of providing feedback and learning for Panels.

8.12 If, following consideration of the proposed responses and actions, further decisions are made relating to the outcome of the case that are relevant to the complainant, these will be notified to the complainant and the Welsh Assembly Government directly by the Chief Executive.

8.13 The final letter from the Chief Executive will be the completion of the NHS Complaints Procedure.

8.14 The outcomes and resulting action plans of all independent review panels will be reported to the Quality and Safety Committee, and further evidence will be provided against an agreed timescale to confirm that the action plan has been implemented.

9 THE PUBLIC SERVICES OMBUDSMAN FOR WALES (OMBUDSMAN)

9.1 Complainants may ask the Ombudsman to investigate their complaint where they:

- are not happy that their request for Independent Review has been refused
- are not happy with the results of an Independent Review Panel
- are not happy with the response from the Health Board and choose to go direct to the Ombudsman without going through Independent Review.

9.2 The Health Board will co-operate with the Ombudsman and make every effort to respond as soon as possible to requests for information. The Complaints Manager will act as Liaison Officer with the Ombudsman's office.

9.3 If the Ombudsman decides to interview key staff involved in the complaint the Complaints Manager will ensure that such staff are

fully briefed, and receive whatever help and support they require to assist their preparation for the interview.

9.4 Following the Ombudsman's investigation a draft report will be sent to the staff interviewed for comment.

9.5 When the final report is received by the Health Board, the Complaints Manager, in liaison with directorate / locality Complaints Leads and other clinical and management staff as appropriate will ensure that a response is prepared which addresses all the points raised. The Chief Executive will send the response to the complainant.

9.6 If, following consideration of the proposed responses and actions, further decisions are made relating to the outcome of the case that are relevant to the complainant, these will be notified to the complainant and the Welsh Assembly Government by the Chief Executive.

9.7 The outcomes and resulting action plans of all Ombudsman's enquiries will be reported to the Quality and Safety Committee and further evidence will be provided against an agreed timescale to confirm that the action plan has been implemented.

10 PROCEDURES – SERVICES PROVIDED BY PRIMARY CARE CONTRACTORS

10.1 The Health Board has a contractual relationship with independent contractors in primary care i.e. general medical practices, NHS dental practices, optometrists, pharmacists. This includes contractual arrangements for the provision of out of hours general medical services and with NHS Direct. These will be collectively referred to as 'primary care contractors' within this section.

10.2 Under the terms of these contracts, the Health Board is not empowered to undertake investigations into complaints against the services provided, but the practices / organisations concerned are required to have their own complaints procedures in place.

10.3 In addition, general medical, general dental practices and the out of hours service providers are required to provide information to the Health Board in relation to the number of complaints received, grouped into defined categories, and their performance against defined standards – e.g. response within 20 working days.

10.4 Complaints about services provided by independent contractors may be received by staff of the Health Board. This procedure sets out how these should be managed.

10.5 The Health Board has an obligation to monitor clinical governance standards within primary care. Information received through complaints and their resolution can assist in this.

10.6 This procedure will retain the successful relationships and working arrangements developed by the former Local Health Boards with their independent contractors and with their local populations. The responsibility for managing these complaints will remain with the Localities.

10.7 This will therefore be an Interim procedure, pending consideration of standardising the approach and documentation across the localities.

Receipt of Complaint

10.8 Some service users will still have information relating to the complaints procedures and contact arrangements for the former Local Health Boards. A number of complaints may still, therefore, be received in the locality offices until the new contact arrangements in this policy are fully established

10.9 Many complaints about primary care issues are made verbally, usually by telephone. If these are received in the appropriate locality office, they should be referred to the locality Complaints Lead who will, as far as possible, resolve the complaint by telephone within the NHS guidelines. Experience has shown that some of these callers will be seeking clarification, understanding and empathy rather than to express a complaint, but the call may include underlying concerns which should not be overlooked.

10.10 Locality offices will have arrangements to ensure that if the Complaints Lead is not available, there are suitable alternative arrangements.

10.11 Telephone complaints received via the Switchboards or elsewhere within the Health Board should be transferred to the Complaints Department in the Governance Support Unit (GSU) (Tel no>...)

10.12 The Complaints Handler in GSU should take the caller's details and establish what the call is about. When it is identified that the call is about services provided by a primary care contractor, the

Complaints Handler should advise the caller that they will make arrangements for someone who can advise them further to contact them straightaway. The Complaints Handler should then contact the appropriate locality Complaints Lead and arrange for an immediate call back to the complainant. The locality Complaints Lead will assume responsibility for the Health Board's management of the complaint from this point.

10.13 Where the complaint is about services provided by a primary care contractor, the complainant will be advised to either make the complaint direct to the practice concerned or to put it in writing to the Health Board, who will arrange for it to be passed to the practice for investigation. Written information on the complaints procedure will be provided where appropriate.

10.14 Complainants who need support in putting forward a complaint should be directed to the Community Health Council for assistance.

10.15 Written complaints received in locality offices should be notified immediately to the GSU Complaints Department for registration, where Datix is not currently available in the locality. Written complaints about primary care contractors received at any other point within the Health Board should be sent immediately to the GSU Complaints Department, who will register them on Datix and pass them immediately to the locality Complaints Lead.

10.16 All complaints received should be registered on the Datix system, by the GSU Complaints Handler or, for complaints received directly, by the Complaints Lead in the locality when Datix is available to them.

Acknowledgement

10.17 The locality office will acknowledge all complaints in relation to primary care services within 2 working days of receipt, ensuring that they are entered onto Datix (when available) and / or notified to the GSU Complaints Department.

10.18 The acknowledgement letter must ensure that the complainant is advised:

- that the complaint will be passed to the primary care practice, who will respond directly to the complainant
- that written consent to do this must be provided by the complainant, or by the patient where the complainant is not the patient

- that support is available from the Community Health Council if needed
- of the timescale for response and what will happen if that needs to be extended
- of the right to Independent Review and Ombudsman services if the complainant is not satisfied with the response.

10.19 The three different localities currently have different styles of acknowledgement letter and different working arrangements with the primary care contractors in their area. In this Interim procedure, it is not proposed to alter those arrangements. Discussion will need to be held within the Primary Care and Mental Health Services Division to agree a uniform approach and processes.

Responses

10.20 Primary care contractors are responsible for investigating and responding directly to complainants. [NB - In the Swansea locality, where a complaint involves both NHS Direct and the Out of Hours service provider, the locality Complaints Lead may coordinate the separate responses to provide a single combined response to the complainant.]

10.21 The three different localities have different levels of involvement with their primary care practices in relation to discussion of / sight of responses to complaints passed to them from the locality office. Under this Interim Procedure, these arrangements will continue pending discussions on standardisation.

Independent Review / Ombudsman

10.22 Where a complainant is not satisfied with the response received from the primary care practice, he / she has the right to refer to the Independent Review (IR) Secretariat and / or the Public Services Ombudsman.

10.23 Where a request is made to the Health Board for such a review, this will be passed by the GSU Complaints Manager to the locality Complaints Lead, who will advise the complainant of the procedures to follow and / or arrange for the request to be passed on to the appropriate body.

10.24 The locality Complaints Lead will act as liaison with the IR Secretariat / Ombudsman's office and will arrange the provision of necessary documentation etc.

10.25 The locality Complaints Lead will arrange support for staff, including those of the primary care contractors, involved in the reviews where this is appropriate.

10.26 On receipt of the IR Panel's report, the Chief Executive of the Health Board will be responsible for sending a response to the complainant within 20 working days apologising for any shortcomings identified and confirming any actions to be taken. The locality Complaints Lead, with the primary care practice concerned, will ensure that action plans are identified and agreed and will draft a response for approval and final signature by the Chief Executive.

Clinical Governance

10.27 All three localities currently have arrangements in place for consideration of clinical governance issues arising out of complaints about primary care contractor services. These will continue pending discussions on standardisation or changes to management arrangements

10.28 The localities will continue to collate information on the number and types of complaints received and responded to by primary care contractors on a quarterly and annual basis and will present coordinated reports to the Health Board's Risk Management Group (to be replaced by the Quality and Safety Steering Group?) and Quality and Safety Committee. The format and presentation arrangements of these reports will need to be agreed.

10.29 The reports will include information on lessons learned and actions taken to improve services and patient safety.

Primary Care Support

10.30 Where appropriate, the localities will remind primary care contractors of the Primary Care Support provision, which can provide confidential counselling and support for general practitioners, dentists and community pharmacists involved in a complaint, whether it is in the early informal stages or has progressed to a more formal level.

Review

10.31 This Interim Procedure will be subject to review in relation to:

- the continuing development of organisational management arrangements
- standardisation of policies, procedures and working practices across the new integrated Health Board
- further information on the Welsh Assembly Government's intention, as signalled in the 'Interim Guidance on the Handling of Concerns in the New NHS Structure' that the remit of the Health Board will be extended to enable it to undertake an investigation into concerns raised about primary care.

11 PROCEDURES – PRISON HEALTHCARE SERVICES

11.1 Healthcare services to Swansea Prison are commissioned by the Health Board. The prison is required to have its own procedures and to respond to complainants directly. Complaints received within the Health Board relating to the primary care of prisoner inmates should be treated in the same way as complaints relating to primary care contractors – see Section 10 above. Complaints relating to secondary care services to prison inmates should be treated in the same way as for other members of the public. A Protocol for the Management of Complaints within HMP Swansea is attached as Appendix 6. Please note that this has not yet been updated to reflect the new Health Board arrangements.

11.2 Healthcare services to Parc Prison, Bridgend are provided by private contract between the prison and a health care provider. Complaints received within the Health Board should be returned to the complainant with advice to contact the prison service direct.

12 ACTION PLANS / LESSONS LEARNED

12.1 In concluding a complaint investigation which identifies any failure in service or opportunity for improvement, the directorate / locality Complaints Lead will ensure that an Action Plan is prepared and documented to address the issues identified. This should include the timescales for implementation and the means by which completion of the action will be confirmed.

12.2 The Action Plan should be sent by the directorate / locality Complaints Lead to the GSU Complaints Handler, or entered on Datix, at the same time as the draft response. Where this is not possible, a date should be given by which this will be available.

12.3 Progress against completion of actions contained within the Action Plans should be part of the clinical governance reports to each directorate / locality management team meeting and should be reported to the Health Board level committee responsible for overseeing clinical governance. Overall progress and / or the progress on specific actions may also be included in the performance review of directorates / localities by the Executive Team.

12.4 Reports should be produced in relation to the number of complaints received and key indicators of progress and resolution at intervals to be agreed, but no less than quarterly, to the Risk Management Group / Quality and Safety Steering Group and Quality and Safety Committee. These should also include information on issues arising, trends, action plans and lessons learned, and should be summarised in an annual report to these committees and the Health Board.

Appendix 1: General Guidance on Aspects of Complaints

a) Confidentiality and Consent

All care must be taken to ensure that the duty of confidentiality owed to the patient is not breached.

The Interim Guidance on the Handling of Concerns in the New NHS Structure states that 'for concerns raised by a person who is the patient in question' it is legitimate to assume that the patient expects the matter to be investigated. The patient's consent to the use of their medical records may therefore be implied and the investigation may commence immediately. It is, however, good practice to inform the patient that this may happen and a statement to this effect will be included in the Acknowledgement letter.

Complaint letters received from patients must be examined carefully to ensure that there is no statement or suggestion that implied consent is not given.

In all other cases, e.g. where the complaint is made by a friend, relative or advocate (including solicitors), it will be necessary to consider what consent may be appropriate, as the situation dictates. The guidance refers to the Confidentiality Code of Practice for Health and Social Care Wales, to be found at: http://www.wales.nhs.uk/sites3page.cfm?orgid=783&pid=31174

The default position in relation to anyone acting on behalf of a patient, and/or if there is any doubt about the patient's own implied consent, is that the patient's express consent for access to and use of personal information to investigate a complaint must be obtained. NB - if the patient has given any indication that consent is not to be assumed, the complaint letter should be considered very carefully to identify any factors which may require an individual response, outside the mainstream complaints process outlined here]

It is essential that at all times during the complaints procedure, any information accessed about the patient is only that relevant to the complaint being investigated and must be processed fairly and lawfully (Data Protection Act , first principle).

Any member of staff who has concerns about confidentiality should seek advice from the Information Governance Manager in the first instance, or from the GSU Complaints Manager.

b) Filing of Complaints Correspondence

Correspondence relating to complaints should be filed separately from, and must not be included within, patients' clinical care records.

c) Access to Health Records

If a complaint letter includes an appropriate formal request for access to the patient's health records, this will be forwarded to the Heath Records Manager for action under the Data Protection and Access to Health Records Acts.

d) Freedom of Information Act 2000

Complaints that contain requests for information made under the FOIA will be passed to the Health Board's Freedom of Information Officer for consideration and co-ordination of appropriate action.

e) Support for complainants

Where a complainant is unable to express their complaint effectively, or lacks confidence to complain, they should be advised to seek support from the Community Health Council, who provide advocacy services. Assistance can also be provided in some circumstances by the Health Board's Patient Experience department, whose staff are trained in mediation techniques.

Where the problem relates to language difficulties, the GSU Complaints Manager or locality / directorate Complaints Lead, or any other member of staff authorise to do so, should contact the Language Line to arrange interpretation services.

f) Independent Complaints Facilitation

The Welsh Assembly Government has established the Independent Complaints Facilitation Service to assist in resolution of complaints at Local Resolution level. The Complaints Manager will advise whether the circumstances of any particular case meet the broad criteria for using this service. Should this proceed, all staff involved will be fully informed and supported through the process.

g) Patients lacking capacity

All complaints will be treated seriously and extreme care will be taken not to overlook a real and serious underlying complaint, which may be masked by a patient's disability or incapacity.

The Mental Capacity Act 2005 provides a statutory framework to empower and protect vulnerable people who may not be able to make their own decisions. It makes it clear who can take decisions in which situations and how they should go about this. It enables people to plan ahead when they may loose capacity.

There are five key principles:

- A presumption of capacity – every adult has the right to make his or her own decisions and must be assumed to have capacity to do so unless it is proved otherwise
- The right for individuals to be supported to make their own decisions – people must be given all appropriate help before anyone concludes that they cannot make their own decisions
- That individuals must retain the right to make what might be seen as eccentric or unwise decisions
- Best interests – anything done for on behalf of people without capacity must be in their best interests
- Least restrictive intervention – anything done for or on behalf of people without capacity should be the least restrictive of their basic rights and freedoms.

The Act set out a single clear test for assessing whether a person lacks capacity, which can be undertaken by any doctor or nominated person.

h) Complaints involving vulnerable adults

Guidance should be sought from the Protection of Vulnerable Adults (POVA) Team for any complaint that is made to staff where there is a suspicion of any form of abuse or neglect.

Where there is an allegation of or implication of abuse or inappropriate behaviour by a member of staff, the person receiving that information must immediately refer to and follow the requirements of the Health Board's Professional Abuse Policy.

i) Complaints made by or involving children and young persons

Children and Young People have the right to influence and have a say in the care provided within the Health Board. Children and Young People are active citizens in the world and have rights to their own opinions, to express

them, and have their opinion taken fully into account. (*The United Nations Convention of the Rights of a Child (1991).*

A child under the age of sixteen may bring a complaint on his or her own behalf if they are judged to be "competent". In such cases the "Frazer Ruling" (what used to be known as the Gillick Competence) is used and it is usual that the Clinician assesses competence. To be adjudged competent, the child has to have sufficient intelligence and maturity to fully understand what is involved in bringing a complaint, what the procedure entails, the involvement that will be expected of him or her and the likely consequences of complaining. Where a child has given information in confidence to the professional, which they do not want shared with their parents, their privacy must be respected.

Where staff are aware that parents are separated or divorced, the GSU Complaint Handler or directorate / locality Complaints Lead (by mutual agreement) will attempt to find out who has parental responsibility for the child.

The Complaints Procedure will apply equally to complaints made by children and young people on their own behalf.

Guidance should be sought from the Child Protection Team for any complaint that is made to staff where there is a suspicion of any form of abuse or neglect.

Where there is an allegation of or implication of abuse or inappropriate behaviour by a member of staff, the person receiving that information must immediately refer to and follow the requirements of the Health Board's Professional Abuse Policy.

Advocacy services specifically designed to meet the needs of children and young people are available. Further information can be provided by the Complaints Manager.

j) Community Health Councils

Community Health Councils have an important role in assisting complainants at each stage of the process, and will often communicate with the Health Board on the complainant's behalf. The local Community Health Councils have Complaints Advocates who fulfil this role, and who also participate in monitoring the Health Board's management of complaints.

Advice on how to contact the local Community Health Council for assistance in making a complaint will be well publicised within all local health service premises.

k) Complaints involving bereavement

Some of the most difficult complaints arise following the death of a patient.

Sympathetic arrangements, including the offer of a meeting, will be made to give grieving relatives the opportunity to ask questions and understand what happened.

The services of the Health Board's Bereavement Officers will be offered and the bereaved family will also be offered information on Community Health Council, advocacy, chaplaincy services, patient representatives or patient representative groups and independent voluntary support groups.

l) Complaints from solicitors; intention to take legal action; requests for compensation

At all times it is important to remember that a complaint has the potential to develop into a legal claim but a legal claim may be avoided by open and sympathetic handling and management of a complaint.

Complainants can make their complaint through a solicitor if they wish and this should not be seen as evidence that the complainant has decided to take formal legal action. The stages and aspects of the Complaints procedure will be applied.

Whilst a case may switch between formal processes, the actions to fully investigate any concerns are common to all events where something is alleged to or appears to have gone wrong, whether they be adverse incidents, complaints or claims. An important aim of the Health Board's investigation into any complaint will, therefore, be to place the Health Board in a position to form an early view on the appropriate handling and management of the case overall. The Governance Support Unit will advise on and support the local investigation of complaints accordingly.

If a complainant states that they intend to take legal action, the complaints procedure will continue until formal notification of a claim is received and it is appropriate to register the matter as a legal claim. Any investigation underway at this stage will be completed.

Whilst financial payments of any nature are outside the formal remit of the NHS Complaints procedure, all requests for compensation will be acknowledged and considered by the Governance Support Unit once the investigation is complete. Such consideration will accord with the principles of the Claims Policy and Procedure.

The Governance Support Unit will also identify any cases where it may be appropriate to proactively consider offering a payment for any reason. Such cases will be discussed fully with the Risk Management Group / Quality and Safety Steering Group.

m) Mixed sector complaints

Some complaints may contain issues that relate to more than one service provider. In such cases the Health Board will co-operate fully with the other body, seeking to resolve the complaint through each local complaints procedure e.g. Social Services.

n) Allegations against staff (excluding complaints made by children and young persons - see section h)

Where complaints contain allegations against a member of staff, the Investigating Officer will provide a copy of the complaint letter to the member of staff at the beginning of the investigation. The member of staff will be given full opportunity to comment upon the complaint made and provided with, or advised how to access, support and advice. Staff have a right to seek the assistance of their professional organisation, trade union or defence organisation, or to the support of a friend or relative if they so wish.

Directorate Managers and/or directorate / locality Complaints Leads will ensure that the staff involved receive a copy of the response to the complaint.

o) Complaints following an Adverse Incident

Where a complaint is received relating to an Adverse Incident that is under investigation, the investigation already in progress will continue, absorbing any additional issues highlighted by the complaint, and form the basis of the response/meeting with the complainant.

p) Inquest cases

The investigation into a complaint will continue in parallel with the inquiries of the Coroner, whose role is limited to determining the cause of death. Relatives concerned at the cause of death may be advised to contact the Coroner.

It should be possible for the Health Board to issue a formal response to the complaint independently of the inquest. This is especially important, as there may be a delay of several months before the coroner's inquest takes place.

The Governance Support Unit will advise and support the directorate / locality Complaints Lead on the appropriate actions to be taken.

q) The Mental Health Act Commission

The Mental Health Act Commission can investigate any complaint made by a patient or ex-patient detained under the provisions of the Mental Health Act, although the Commission will normally expect complainants to use the Health Board's procedures in the first instance.

Where patients or their representatives wish to raise issues directly with the Commission they will be given any help, information or advice they require to write to the Commission. Support is also available via the Advocacy Service of the Community Health Councils.

r) Complainants acting beyond reasonable limits

Staff must be courteous at all times but support and advice will be available for staff when a complainant's behaviour or actions go beyond acceptable limits.

This includes:

- personal abuse or aggression towards staff
- a continuing unwillingness to accept documentary evidence of treatment as factual
- an unreasonable or repetitive focus on matters already determined or matters for which nothing further can reasonably be done to assist them
- repeated or numerous different complaints.

Staff should contact their manager in the first instance, who should seek advice from the Directorate Management Team with subsequent referral to the Governance Support Unit or Executive Team, if necessary or appropriate.

Where necessary, a letter will be sent to the complainant on behalf of the Health Board setting parameters for a code of behaviour and lines of communication. If these terms are contravened consideration will be given to implementing other action which, in the most extreme cases, may involve legal action.

A zero tolerance approach will be adopted towards abusive, aggressive, or threatening complainants.

Such behaviour may mask a genuine problem with service provision. The issues raised must, therefore, still be considered and investigated as appropriate, ensuring that the complaints procedure has been correctly implemented as far as possible and that no material element of a complaint

is overlooked or inadequately addressed. This will also apply to new complaints raised by previously recognised 'habitual' complainers.

A response should be provided to the complainant in accordance with this policy.

s) Enquiries from political representatives

When a local councillor, MP, AM or MEP writes on behalf of a constituent, the issue is often about non-clinical matters and/or a request for information. In such instances, the matter is considered an enquiry and dealt with outside the Complaints Policy and Procedure.

A response will be provided within 5 working days. If confidential information contained in the patient's health records needs to be accessed to answer the enquiry, the patient's consent is required.

If the matter raised is a clinical complaint, it will be managed as a complaint made on behalf of a patient in accordance with this Interim Policy and Procedure.

t) Private medical care

The Complaints Policy and Procedure will not apply to any complaint made about clinical care provided on a Private basis. It will, however, apply to complaints made about private treatment facilities run by the Health Board.

u) Cases involving criminal proceedings

If allegations are received that a criminal offence has occurred, then the matter must be reported immediately to the relevant Executive Director, who will advise on contact with the police. Any member of staff against whom such allegations are made or who is involved in enquiries, must be advised of his/her right to seek the assistance of his/her professional organisation, trade union or defence organisation. Consideration should be given to devolving this responsibility to Clinical / Locality Directors.

v) Complaints and disciplinary procedures

The outcome of a complaint investigation is only likely to lead to instigation of actions under the Health Board's Disciplinary Policy when the investigation reveals that the actions/conduct of an individual or individuals:

- involved a deliberate intent to harm
- was a flagrant disregard for the safety of patients or others (e.g. treating patients whilst under the influence of alcohol)
- forseeably placed the safety of patients, staff or others at risk
- was a deliberately repeated breach of policy or procedures

- was a criminal act (e.g. assault)
- was a malicious act
- evidences repeated non-reporting of errors or violations
- evidences repeated failure to engage in learning lessons

The Health Board will utilise the 'Incident Decision Tree' tool, developed by the National Patient Safety Agency, to ensure appropriate and consistent decisions are made in this respect. Further information on the Incident Decision Tree will be incorporated into relevant policies and procedures. The individual's line manager and relevant professional head of service will be involved in the decision-making process.

If a complainant requests information of any disciplinary action taken, they are entitled to be informed in general terms of the disciplinary sanctions imposed on any staff member.

w) Referral to Professional Regulatory Bodies and the National Clinical Assessment Authority (NCAA)

Once Local Resolution is completed, the Health Board may refer a complaint to a statutory professional regulatory body if the investigation reveals that such action is appropriate. A complainant is entitled to be informed if such action is taken but it must be made clear to the complainant that any information obtained during the complaint investigation may need to be passed on to the regulatory body.

An individual can complain directly to a professional regulatory body as the same time as making a complaint under the NHS Complaints Procedure. The fact that a complainant has also made contact with a professional regulatory body is not grounds for the complaints procedure to stop at any stage. Advice on individual cases can be sought from the regulatory body.

The Health Board can enlist advice from the NCAA in appropriate cases.

x) Anonymous complaints

All such complaints should be referred to the GSU Complaints Manager. Every effort will be made to verify the substance of anonymous complaints and an investigation will take place if appropriate.

y) Other relevant Policies and Legislation

This procedure is to be interpreted and applied consistently with the following:

- Code of Openness (1995)
- Access to Health Records Act 1990

- Data Protection Act 1998
- The Caldicott Report, WHC(98)80
- Human Rights Act 1998
- Freedom of Information Act 2000,
- Race Relations Amendment Act 2000
- Carlile Report (2002)
- Mental Capacity Act 2005
- Being Open (NPSA 2005, relaunched 2009)
- NHS Wales directions on handling Complaints

Appendix 2: Record of Verbal Complaint

Abertawe Bro Morgannwg University Health Board
Record of a Verbal Complaint Form

To be completed by front line staff

Complainant's Details:

Name:.....
Address:.....
.....
.....
.....
.....

Patient's details (If not complainant):

Name:.....
Address:.....
.....
.....
Hospital No /DOB: .....

Details of Complaint:

Date:

.....
.....
.....
.....
.....
.....

Action Taken

.....
.....
.....
.....
.....

Was complainant satisfied with explanation/apology provided? **Yes** **No** **Not Sure?**
Has complainant been advised of the Complaints Procedure? **Yes** **No**
Has complainant been provided with a Complaints Leaflet? **Yes** **No**

Name of person completing the form

Designation & Directorate

Hospital/Site

Ward/Department

Section B: to be completed by Senior Manager
Does the complaint constitute an adverse event? **Yes** **No**
Has an Incident Form been completed? **Yes** **No**

Senior Manager

Designation

Copy to be sent to the Governance Support Unit, ABMUHB Headquarters, 1 Talbot Gateway, Baglan Energy Park, Baglan, Port Talbot SA12 7BR

Appendix 3: Acknowledgement Letters - Templates

To be finalised

Appendix 4 – Response Letter - Template

To be finalised

Appendix 5: Guidelines for Grading of Complaints Investigations

The grading system adopted for complaints is based upon, but does not precisely mirror, the process and matrices used within the Health Board for grading adverse incidents and prioritising risks within the Risk Register (see Risk Management Policy and Strategy).

This is an interim system and will be subject to further discussion and development.

Complaints will be graded for the purposes of investigation according to the actual outcome/consequences of the care/treatment, as follows:

	Non-clinical or process issues that can be easily and speedily addressed, with no harm having arisen (e.g. Outpatient appointment was delayed but no consequences in terms of health).
YELLOW	Clinical issues that have resulted in no harm, or Clinical or process issues that have resulted in avoidable: • minor harm (e.g. injury requiring first-aid treatment) or • short-term, non-permanent harm or impairment of health, with full recovery in up to 1 month (e.g. Minor healthcare associated infection, temporary increase in pain)
AMBER	Clinical or process issues that have resulted in avoidable: • semi-permanent injury or impairment of health or damage, with recovery in up to 1 year; • additional interventions required or treatment needed to be cancelled; • extra stay in hospital, readmission or return to surgery; • necessity for transfer to another centre for treatment/care.
	Clinical or process issues that have resulted in avoidable: • loss of life or unnecessary shortening of life expectancy; • irrecoverable injury or impairment of health, having a lifelong adverse effect on lifestyle, quality of life, physical and mental well-being (e.g. patient not been sent a further appointment due to a breakdown in communication, delaying vital treatment and resulting in the loss of a limb)

Initial grading into Green / Not Green will be made by the Complaints Manager in the Governance Support Unit immediately on receipt of the complaint.

For complaints initially identified as 'Not Green', the directorate / locality Complaints Lead will make the immediate assessment of the grade, with colleagues as appropriate, and will agree the grade with the Complaint Handler in the Governance Support Unit. At this time, it is recognised that all the facts will not be available. The complaint investigation may therefore be re-graded as the facts and issues emerge e.g. once the investigation has begun it may become clear that the patient's death/injury was not related to their treatment.

The potential for reoccurrence should be considered, and may require the grading to be advanced.

The nature of the investigation will be influenced by the grading decision:

GREEN	No formal investigation required, but will need sufficient enquiry to establish the facts to inform the response. The Complaints Handler will liaise with the directorate / locality Complaints Lead and / or directly with other service managers as necessary.
YELLOW	Sufficient investigation to establish all the relevant facts. Staff directly connected with the complaint must be involved and their recollection of events recorded. All reasonable efforts must be made to contact key staff who are no longer working for the Health Board. It is suggested that a multidisciplinary meeting is the most effective means by which to conduct a review of the health records, ensure appropriate discussion of the issues raised in the complaint and develop a draft response. The clinicians involved must agree the draft response in relation to clinical accuracy. The investigation should be completed within 15 days to enable a response within the 20 day deadline, unless agreed otherwise
AMBER	Due to the more serious nature of the issues identified, it is suggested that a Clinical Review will be appropriate in most cases. This is a peer review conducted by people who were not involved in the clinical care of the patient, examining whether the care of the patient should have been handled differently in part or in total. If this is likely to extend the investigation timescale beyond 15 days, the complainant should be notified at the earliest opportunity of the reason and the anticipated timescale, which will not be unreasonably extended
RED	Due to the very serious nature of the issues identified, it is suggested that the nature of the investigation is agreed with the Complaints Manager in the Governance Support Unit, who may need to seek advice as appropriate from Executive Directors. It should be anticipated that a Clinical Review or full Root Cause Analysis may be required. Where necessary, appropriate and suitably trained personnel from across the Health Board may be nominated to form an investigative team. As this is likely to extend the investigation timescale beyond 15 days, the complainant should be notified at the earliest opportunity of the reason and the anticipated timescale, which will not be unreasonably extended

Appendix 6: Protocol for HMP Swansea

Bwrdd Iechyd Lleol
Local Health Board
Abertawe
Swansea

Protocol for the Management of Complaints within HMP Swansea

Purpose

This protocol has been developed to set out the roles and responsibilities of both Swansea LHB and HMP Swansea in providing access to the NHS Complaints Process within HMP Swansea.

Background

From April 2006 the LHB will assume responsibility for the commissioning of healthcare services for the population of HMP Swansea. Specifications for the service to be provided have been developed. Services will be commissioned in two distinct ways. The majority of primary care services will be commissioned from the HMP Swansea [called "prison provided services"], with the exception of General Medical Services and General Dental Services which will be commissioned by the LHB directly. All secondary care services will be commissioned directly by the Local Health Board.

Access to NHS Complaints Process

From 1st April 2006, prisoners will be able to access the NHS Complaints Procedure (2003) for complaints related to primary care services commissioned by the LHB. It should be noted that, under the existing arrangements, prisoners should be able to access this procedure for complaints relating to secondary or tertiary care (ie services provided by NHS Trusts).

Procedure for Handling complaints

First Stage: Local Resolution

A flowchart outlining the process for handling complaints is at Appendix 1.

Complaints will be dealt with in line with the NHS Complaints Guidance (April 2003). The NHS Complaints Procedure is not a legal or disciplinary process but aims to resolve complaints with a view to improving patient services. The first stage of the NHS Complaints Procedure aims to resolve issues at a local level. In this respect, the Healthcare Manager will need to be able to direct complaints to the appropriate service provider.

Complainants have the right to expect:

- Their concerns to be thoroughly investigated and dealt with promptly
- Written complaints should be acknowledged within 2 days
- A full response including an explanation and an apology for any distress or misunderstanding caused, made within 20 days

The recruitment of a Head of Healthcare/Clinical Nurse Manager is underway. Until this appointment is made, however, the lead role for the management of this protocol will be Mrs Helen Davey, Head of Healthcare [Governor].

There are two ways in which a complaint can be made – in person or in writing.

Complaints made in person

Many complaints or expressions of concern can be dealt with to the patient's satisfaction, either at the time of the complaint, or within 2 working days. Such complaints should still be logged within a designated complaints book, which will include a description of the nature of the complaint and the action taken to resolve it.

Any member of staff likely to receive a complaint or concern should be able to take appropriate action, dealing with the issues rapidly and in a sensitive manner. This includes:

- Checking that the patients immediate health needs are being met
- Giving the complainant the opportunity to discuss their concerns in private – and encourage them to speak openly and freely
- Where the complaint concerns a clinical matter, ensuring that it is discussed with the clinician concerned and, if the clinician is not available, making an appointment to discuss it
- Know when to refer the complaint to the Healthcare Manager either for advice or direct handling.

If the complainant is dissatisfied with the initial response and wishes to pursue the matter further, the complaint should be put in writing and signed by the complainant (see procedure for written complaints below).

Written Complaints

Colour coded forms and envelopes (to protect confidentiality) will be freely available on each wing (sample at Appendix 2). There are sealed boxes available on each wing currently used for complaints. These are to be emptied daily by a designated officer – the complaints envelopes will be coded to enable the appropriate officer to transfer code on to the complaint – which they will then be able to acknowledge and log appropriately – the colour coded complaints should then be directed to the Head of Healthcare (Governor) until the substantive Head of Healthcare/Clinical Nurse Manager is in post.

The log should be maintained detailing the nature of the complaint; date received, date acknowledged; numerical reference code; date of full response/explanation and whether the matter has been resolved. The reference number should be included within all subsequent correspondence. Correspondence relating to complaints should not be kept within the medical records, but held in confidence within a dedicated filing system.

As part of the process Prisoners making complaints will have access to the trained advocates in the Community Health Council.

Swansea Community Health Council has a trained advocate who may also be contacted at Britannia House, Llandarcy, Swansea – 01792 324201. This number will, in future be included on the phone cards issued to all prisoners to enable them to access the service. It is proposed that a schedule of dates and times be agreed with the CHC to ensure that there is an appropriate mechanism by which anyone wishing to access this service can be assured of an appointment in a confidential environment.

If the complainant then expresses continuing dissatisfaction and wishes to proceed to Independent Review, this should also be logged.

The Head of Healthcare will need to identify the source of individual complaints to ensure that they are dealt with in an appropriate and timely fashion. (refer to flow chart Appendix 1).

- **Complaints in respect of Prison Healthcare staff, and/or in respect of services commissioned by the LHB but provided by HMP Swansea** i.e. General Medical Services (GMS) from 1st April 2006 until 31st may 2006; Pharmacy and Optometry:

  - Designated officer will code and log complaint, and ensure that standard acknowledgement slip is given to complainant. Officer will then log complaint and hand immediately to Head of Healthcare.
  - Head of Healthcare should ensure that complainant has been made aware of the process
  - Investigate and discuss with the relevant staff or Healthcare professional
  - Prepare full written response, in line with Guidance, within 20 days
  - Inform the LHB of the complaint and provide copies of all correspondence.
  - Ensure that response to complainant is delivered in confidential manner in sealed envelope.

- **Complaints in respect of services commissioned directly by the LHB** i.e. Dental Services and GMS (after 31st May 2006)

- Designated Officer to code and log complaint, and ensure that standard acknowledgement slip is given to complainant, and hand complaint to Head of Healthcare.
- Head of Healthcare and inform LHB immediately
- Head of Healthcare to liaise with Healthcare professionals to provide response to LHB to enable the LHB to satisfy themselves with the explanation, and forward same to the complainant with a covering letter signed by the LHB Chief Executive in line with the Guidance. (Response addressed to complainant in a sealed enveloped marked "confidential", which is forwarded to Head of Healthcare for handing directly to complainant to protect confidentiality)

- **Complaints in respect of Secondary Care Services commissioned by the LHB which include:**

Mental Health	Swansea NHS Trust
Forensic Psychiatry	Bro Morgannwg NHS Trust
Sexual Health	Swansea NHS Trust
Substance Misuse Liaison	Swansea NHS Trust

Together with any necessary inpatient services:

- Designated Officer to code and log complaint, and ensure that standard acknowledgement slip is handed to complainant.
- Head of Healthcare to ensure that complainant has been made aware of process and possible delays in response times
- obtain consent to forward to relevant Trust (included within complaints form) to enable investigation through their Complaints Procedure – in line with NHS Guidance.
- Trust will respond directly to complainant with copies to LHB. As above, these responses should be addressed to the complainant, and marked "confidential" and should be handed, unopened by Head of Healthcare to the complainant to protect confidentiality.

In line with the above, wherever and whenever possible, complaints should be dealt with within the guidelines, i.e. acknowledged within 2 days (by standard acknowledgement slip), with full response within 20 working days. Should this prove impossible due to the nature of the investigation, or availability of key personnel, the complainant, and the LHB should be kept informed of the reasons for delay. The full response should include an apology and explanation as appropriate; refer to any remedial action that has been taken as a result of the complaint, and offer a meeting to discuss the complaint, if appropriate. There should also be an explanation of the next stage should the complainant remain dissatisfied. The Head of Healthcare should have a procedure in place to ensure that complainants who are moved elsewhere, or released, are still provided with an appropriate and timely response to a complaint made whilst at HMP Swnsea.

An information leaflet (Appendix 3) will be made available so that the prison population are aware of their right to complain, and to ensure that they are aware of the procedure. This leaflet will contain information on the procedure, time limits, local resolution, contacts for CHC and LHB, and the next stage of the process should local resolution fail.

Second Stage: Independent Review

The second stage of the procedure, should the complainant remain dissatisfied, is to request Independent Review. These requests should be made within one month of the end of local resolution. An independent lay reviewer and lay advisor will review the complaint taking clinical advice if there is a clinical component to the complaint. The complainant will be informed, in writing, of the decision whether to take no further action; refer back for further local resolution; or convene a panel.

Within a community setting, other than when the CHC Advocacy service has been utilised and they act on behalf of a complainant, a complainant would be expected to put this request for Independent Review in writing and include copies of all relevant correspondence. In view of the difficulties this would present in a prison setting, it would be part of the role of the Healthcare Manager to support the complainant through this process.

Arrangements for panel hearings, and the appropriate level of security clearance will need clarification with the Independent Review Secretariat.

If a complainant remains dissatisfied beyond the second stage of the NHS Complaints procedure they can request that the Public Services Ombudsman for Wales review their complaint.

Complaints Involving more than one service

Where complaints arise that involve both prison service and healthcare issues, the complainant should receive a seamless response. However, individual issues within each complaint must be dealt with either via the prison service process, or the NHS complaints process, and referral from one process to another can only be undertaken with the complainants consent. It is essential, therefore, that the Head of Healthcare within the Prison service takes into account all aspects of the complaint to ensure that it is dealt with appropriately.

Reporting Mechanisms

Complaints in respect of the healthcare provision at HM Prison Swansea, will be regarded as complaints against or about services provided/commissioned by the Local Health Board.

In this respect, we will request monthly reports from HM Prison Swansea which can be completed from the information held within the Complaints Log. It is proposed that the Complaints Manager of Swansea LHB visit the office of the Head of Healthcare on a monthly basis to generate this report from the information held on the complaint log, and copies of the relevant correspondence Such report will detail:

- Number of complaints within period
- Whether formal written complaints or verbal complaints
- Confirmation that all have been appropriately acknowledged and responded to within guidelines above.
- The type of complaint, ie whether in respect of clinical management; accessing healthcare; respect of an individual etc.
- Number that have been resolved locally, or have requested IRP
- Outline of actions taken/ systems changed as a result of complaints

An annual review should be held to ensure that lessons are learnt by the service providers.

Formal reports will be made on a quarterly basis to the Board of the LHB. Copies of these reports will also be presented to the Independent Monitoring Board to ensure that they are kept informed of issues affecting HM Prison Swansea.

The above will be subject to monitoring visits to ensure compliance with the NHS Complaints Guidance.

Role of Independent Monitoring Board

The NHS complaints procedure does not in any way affect the prisoner's right to complain at any stage to the Independent Monitoring Board [IMB]. The IMB continues to have a statutory duty to hear any complaint or request which a prisoner wishes to make. On receipt of a complaint with a clinical element, the IMB should advise the prisoner how to progress the complaint through the NHS complaints procedure. The LHB will ensure that the IMB are included within the reporting and monitoring mechanisms, as stated above, and will work closely with the IMB in the interest of improving services, and ensuring safety of prisoners within the Healthcare provision.

The Complaints manager from the LHB will present a copy of the quarterly complaints report to the next available meeting of the IMB.

A Memorandum of Understanding will be drawn up between CHC and IMB to ensure that there is a full understanding of the roles and responsibilities of each organisation, together with a mechanism for alerting each other to potential problems/difficulties particularly in respect of prisoners who may self-harm or be suicide risks, to ensure the safety of prisoners.

Appendix 4

Appendix 4

Background and Chronology:

Mrs A was visiting her ex husband on 27 June 2011, when she suddenly developed chest pain, which radiated into her back and abdomen. Mrs A took two puffs of GTN spray with no relief (standard medication for angina). She was taken by Mr A to Singleton hospital as he thought that she was having a heart attack. Mrs A was taken to the SAU, where Mr A explained that she had heart and kidney disease. Mr A said that her assessment was slow and there seemed to be no urgency from the medical staff. He was not made aware of the possible differential diagnosis and left to go home at 12 midnight. He was contacted at 3.30am and informed that Mrs A had suffered a cardiac arrest. She was certified dead at 4.20am, by which time Mr A had been able to return to the hospital.

Time line:

7.45pm – 8.00pm	- arrive at Singleton hospital and taken to SAU (surgical and medical assessment unit)
8.35pm	- first ECG taken
9.00pm	- first set of observations recorded and triage note recorded by nurse
9.00pm	- first assessment by a doctor
9.03pm	- patient front sheet generated
9.10pm	- IV paracetamol given for pain
10.00pm	- first seen by medical registrar
11.30pm	- CXR completed
11.30pm	- 5mg of morphine given IV
12.00am	- Mr A leaves hospital
1.00am	- medical registrar discussed case with on call medical consultant who requests a CT chest
2.00am	- seen by on call medical consultant, advised starting labetolol (an agent to lower blood pressure)

3.15am	- CT chest completed and aortic dissection confirmed
3.25am	- cardiac arrest on HDU
3.30am	- Mr A phoned at home and returns to hospital
4.20am	- certified dead and Mr A informed

Questions and Responses:

1. Was Mrs A's care within the A&E department reasonable?

Please note that Mrs A's care was delivered on the SAU (surgical and medical assessment unit) rather than in the ED. However the standard of initial care should be the same as directed by the Manchester triage guidelines and NICE guidelines for 'chest pain of recent onset'. The trust did confirm in their response that the patients care was on the SAU. That said the trusts response was not reasonable - see below.

If Mrs A had presented to the ED it would have been expected that she would have had an ECG and definitive care plan 20 minutes after presentation. This would require an ECG, correctly interpreted by an experienced clinician within 10 minutes of arrival.

Mrs A arrived at 8.00pm (best case scenario, may have been as early as 7.45pm) and was transferred to SAU, having an ECG by 8.35pm. This was not a reasonable standard of care. Mrs A's ECG did not show a STMI (acute MI) but was grossly abnormal, with her in extreme discomfort (the medical notes describe her 'writhing on the bed in agony'). Her physiology was also abnormal with a BP of 256/124 (normal is 120/80), all of which would have given her an orange triage category (Manchester triage group) to be seen within 10 rminutes of arrival. She was seen by a doctor at 9.00pm, 60 minutes after arrival.

The examining doctor (a medical SHO) recorded a good clinical history and examination. It was clearly documented that there was chest pain through to the back with a known history of hypertension and secondary renal failure. The doctor actively looked for physical signs associated

with aortic dissection, such as differential BP in both arms and delays in the peripheral pulses. There was marked difference in the BP in both arms, with the right = 256/124 and the left 159/129 (100 mm of mercury difference). The SHO noted that the probable differential was that of ?biliary colic, pancreatitis or aortic dissection.

Presented with these findings an aortic dissection should have been ruled out as soon as practically possible and until this had happened the elevated blood pressure should have been treated. Failure to do so was an unacceptable standard of care.
It would be beyond the expertise of a SHO in medicine to deliver this standard of care and there is evidence within the notes that the SHO contacted the medical registrar as soon as possible.

The medical registrar did not see the patient until 1.00pm (a further 60 minutes), which introduced a significant delay. He did take a good history and performed good examination, even noting that there was an early diastolic murmur which is common in proximal aortic dissection. At this stage an ECHO (an ultrasound examination of the heart) should have been requested to rule out a dissection.

There are cardiology services at Singleton (ref hospital web site) that would have been able to perform an ECHO. The gold standard in this setting would be trans-oesophageal ECHO, but this requires specialist equipment and sometime sedation. A trans-thoracic ECHO would have been a good substitute and can be performed by most junior cardiology registrars. It has a sensitivity of 98% for a proximal dissection, the type that Mrs A had.

If an ECHO had been performed, given the clinical presentation, it would have been abnormal and the patient would have been considered for transfer to Morrison for investigation and treatment with possibly a different outcome.

2. Please confirm whether there was a delay in diagnosing Mrs A's condition and what effect, if any, it had on outcome

Yes there was an unacceptable delay in diagnosis, the best possible time line should have been:

8.00pm	- arrive at hospital
8.10pm	- ECG completed and reviewed by doctor, who confirms no MI but abnormal ECG
8.20pm	- patient seen and examined (completed by 8.30pm as triage category orange
8.30pm	- patient reviewed by a senior doctor, who confirms aortic dissection needs to be ruled out
8.30pm – 9.00pm	- trans-thoracic ECHO performed by cardiology, aortic dissection ruled in (certainty not ruled out)
9.00pm	- transfer to Moriston hospital for cardiac surgeons to arrange definitive investigation and decide on treatment.

It is likely that if Mrs A had been seen in a cardio thoracic centre before her arrest at 3.30am she might have survived. However the opinion of a cardiothoracic surgeon should help clarify this.

3. Please confirm whether there was a delay in treating .Mrs A's condition and if so whether the delay was reasonable and what additional action if any should have been taken.

There was a delay in treating Mrs A's condition. What should have happened was that aortic dissection should have been ruled out as soon as the possibility was raised. It was not acceptable to wait for a blood test to 'rule in' biliary colic or pancreatitis when the possibility of a life threatening condition, such as aortic dissection had been raised. The test in a DGH setting to rule out aortic dissection is a bedside ECHO, whilst Mrs A was waiting for an ECHO her elevated BP should have been treated. There no evidence to support that this was done.

4. Please provide your opinion of the clinician's communication with Mr and Mrs A during her admission.

The clinical notes only indicate that Mr A was spoken to after Mrs A had died at 4.30am. There is no documentation prior to this to indicate that aortic dissection, which is known to have a high mortality (up to 80%) even when diagnosed early was discussed with Mr or Mrs A. There is always the possibility that the condition was discussed with Mrs A (after 12.00am) and not shared with Mr A as he had left. It would have been good medical practice to share any concern with the patient relating to the possibility of a life threatening diagnosis, unless it was felt that it would be too distressing for the patient. It has been recognised by the trust that this was a failing for which they have apologised.

5. With respect to the x-ray, given Mrs A's symptoms, was it reasonable for the hospital to prioritise another patient over her?

It was not reasonable to wait for a chest X-ray (CXR) to confirm or rule out the diagnosis of aortic dissection. In 50% of patients with proven aortic dissection the CXR is normal; it is therefore not a very useful investigation.

An ECHO should have been considered first. Having said this, in most EDs, where it is very easy to get a CXR in the resuscitation room, all patients with a ? aortic dissection will get a CXR, as it is so convenient to arrange. In a SAU the patient would have to go to the main X-ray department adding to risk and delay.

Given Mrs A's clinical condition there was no indication to send her to X-ray, she should have had an urgent bedside ECHO to rule out aortic dissection. It is difficult to comment on the prioritisation of other patients as I'm not aware of their clinical conditions.

6. Should an X-ray have been conducted sooner and if so what effect if any would that delay have had on the diagnosis, treatment and eventual outcome?

Please see response above, in an ED a CXR would have been done as routine, but a CXR was not the best investigation to rule out an aortic dissection on a SAU. The appropriate test for this would have been a bedside ECHO. If this had been done it would have been abnormal (98% sensitivity).

Mrs A's CXR was abnormal and its appearance is highly suggestive of an aortic dissection, so even though it is not the most sensitive test to rule out aortic dissection in the particular case it was abnormal and if done earlier would have lead to earlier diagnosis and a possible change in outcome.

7. Did the UHB's response to Mr A's initial complaint address all of the necessary clinical issues?

No. The consultant physician (CP) has not acknowledged that there was a delay in assessing Mrs A, who presented with typical features of aortic dissection. There should be recognition of this failing in the complaint response.

The trust has accepted that there was a failure to communicate the differential diagnosis and apologised for this.

The CP has not recognised that the process to rule out aortic dissection was incorrect and should have been done much more urgently. I am not reassured that there is a pathway in place for patients who present to Singleton hospital with ? aortic dissection. If this pathway exists then the response should say if it was adhered to. If there is no pathway then the trust should acknowledge this and look to develop the appropriate pathway of care.

The CP has said that lowering the BP can be dangerous and should be done in an HDU environment. This is agreed and antihypertensives should have been given in a critical care setting. Mrs A did not have any medications to reduce her BP during her admission but labetolol was written up on her drug chart, but not given, presumably because by this time she has arrested on HDU.

The time lines for the diagnostic tests were far too slow and this should have been referred to in the trusts response.

It is unreasonable for the trust to say that aortic dissection is a rare event that must be evaluated in a systemic manner. It is rare; about 1 in 10,000 patients who present to the ED will have this condition, but if the diagnosis is made earlier the chance of survival is greatly increased. The trust has made no attempt to say how they will minimise this poor outcome from happening again in the future.

8. Please provide me with any additional comments or observations you have in relation to these matters.

It is very unlikely that the trust has a clinical pathway for patients presenting to the SAU with ? aortic dissection. This is a significant risk for the trust as such presentations are common, even though the diagnosis of aortic dissection is rare. The trust should remedy this to prevent this occurrence happening again.

References

1. CG95 Chest pain of recent onset: full guideline 24 March 2010

2. Aortic Dissection (Diagnosis and Management of) ESC Clinical Practice Guidelines 2001

3. Manchester Triage Group. *Emergency triage,* 2d edition. Oxford, Blackwell. Publishing Ltd, 2006

Recommendations:

See below

Conclusions:

1. The timeline for Mrs A's assessment and investigations was too slow; she should have been seen and assessed within 10 minutes of arrival.

2. The clinical assessment, when it did happen, was reasonable and the differential diagnosis included aortic dissection. As soon as the possibility of aortic dissection was raised Mrs A should have had an urgent test to rule this out, the most appropriate test in a DGH setting would have been an ECHO, either trans-thoracic or trans-oesophageal (preferred) .

3. Mrs A's blood pressure should have been treated until the possibility of aortic dissection had been ruled out. This might have required an earlier transfer to HDU.

4. There does not seen to be an agreed guideline in place within the trust for patients who present to the SAU with ? aortic dissection. This is a significant clinical risk that needs to be addressed.

5. It is admitted by the trust that communication between Mr and Mrs A and the medical team were not good.

Appendix 5

Appendix 5

Questions and Responses:

Thank you for asking my advice regarding this investigation. This relates to an unfortunate lady who sadly died of acute aortic dissection. I have read my colleague's advice at HI 10 and note that you require clarification as to whether Mrs A might have survived if she had been seen in a cardiothoracic centre before she arrested.

I will limit my advice to this particular question, aside from adding that I concur with my colleague's advice and opinions as they appear in HI 10.

In my opinion if Mrs A had been seen in a cardiothoracic centre before she arrested her chances of survival would have been far greater than if not. Aortic dissection is a common and lethal emergency condition. It is the commonest aortic emergency, twice as common as a ruptured abdominal aneurysm. Survival depends on early diagnosis and surgical intervention. Survival after early emergency surgery is 80%. Survival without surgical intervention is less than 1%. All patients with acute aortic dissection involving the ascending aorta (as here) should have surgical treatment as soon as possible.

References:

"Acute dissection" Lancet (1997) 349: 1461-64 and Oxford Textbook of Surgery 2nd edition 2000, 2392-97.

Conclusions:

This lady may have survived if she had been seen in a cardiothoracic centre before she arrested