

**Prophylaxis for patients
who have experienced a
myocardial infarction**

*drug treatment,
cardiac rehabilitation and
dietary manipulation*

Clinical Guideline A

Prophylaxis for patients who have experienced a myocardial infarction

Issue date: April 2001

Review date: April 2003

Ordering Information

Copies of this Guideline can be obtained from the NHS Response Line by telephoning 0870 1555 455 and quoting ref.23652. A patient version of this document, Treatments Following a Heart Attack, can also be obtained by quoting ref: 23653.

Distribution of Guidelines

This document has been circulated to the following:

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This Guidance is written in the following context:

This guidance represents the view of the Institute which was arrived at after careful consideration of the available evidence. Health professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of health professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

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INHERITED Clinical Guideline A: Summary Table



National Institute for
Clinical Excellence

Prophylaxis for patients who have experienced a myocardial infarction drug treatment, cardiac rehabilitation and dietary manipulation

Issue date: April 2001 Review date: April 2003

Drug treatment		Monitoring	Notes	Non drug treatment
PRIOR MI NO HEART FAILURE	Early initiation (in hospital) of beta-blocker + anti-platelet drug (aspirin) + ACE-inhibitor. If not initiated in hospital, Primary Care should initiate ASAP.	ACE-inhibitors: check renal function prior to initiation & at each significant dose increase.	Continue treatment long term. Beta-blockers & ACE- inhibitors also considered for management of symptoms (e.g. in stable angina) or risk factors (e.g. hypertension).	Rehabilitation Patients should be offered enrolment in a rehabilitation programme that has a prominent exercise component within it. Be guided by functional ability and patient preference.
	Patients not taking a statin should be assessed & have treatment initiated 12 weeks after index MI.	Statins: measure initial serum cholesterol to exclude familial lipid disorders & identify levels <4mmol/l (do not need to treat). Additional measurements assess response & inform compliance.	Calcium channel blockers, nitrates, and potassium channel activators should only be used in patients intolerant of beta-blockers & ACE inhibitors. Verapamil or diltiazem should be considered initially. Subsequent treatment with other calcium channel blockers, nitrates or potassium channel activators is then appropriate.	
PRIOR MI WITH HEART FAILURE	Early initiation (in hospital) of an anti-platelet drug (aspirin) plus an ACE-inhibitor. If not initiated in hospital, Primary Care should initiate ASAP.	ACE-inhibitors: check renal function prior to initiation & at each significant dose increase.	Particular care is required when initiating drug treatments in this group of patients Continue treatment long term. Patients are likely to continue to need symptomatic treatment with a loop diuretics. In patients with mild symptoms of heart failure (NYHA grade 1 or 2) it is unclear whether spironolactone decreases premature mortality. It may represent a reasonable choice of adjuvant symptomatic therapy.	Diet Not possible to recommend specific dietary manipulation due to nature of available evidence.
	Initiate spironolactone at any point in patients with moderate or severe heart failure (NYHA 3 or 4).	Spironolactone: monitor serum potassium.		
PRIOR MI WITH DIABETES	Initiate beta-blockers at any point. Start with low dose & slowly increase, e.g. at fortnightly intervals, over a period of up to 12 weeks.	Beta Blockers: BNF recommends hospital supervision for initiation. There may be a group of patients with heart failure for whom GPs (based on their knowledge of the patient's clinical condition) feel able to initiate. Discussion at a local level may inform appropriate methods.	There is no evidence on which to recommend the use of statins. Statin use will be influenced by clinical and practical considerations, such as whether patients were treated with them prior to developing heart failure.	
	There is evidence that intensive insulin therapy initiated soon after admission for acute myocardial infarction reduces mortality. To achieve the benefits demonstrated in the single trial in this area involves 4 daily insulin injections continuing for at least 3 months.			

INHERITED Clinical Guideline A

Prophylaxis for patients who have experienced a myocardial infarction *drug treatment, cardiac rehabilitation and dietary manipulation*

Issue date: April 2001 Review date: April 2003

The summary table overleaf has been derived from the guideline referenced above.

Copies of the full guideline can be obtained free of charge from the Institute's website (www.nice.org.uk), and the NHS Response Line by telephoning 0870 1555 455 and quoting ref. 23652. A patient version of this document, *Treatments Following a Heart Attack*, can also be obtained by quoting ref. 23653 for an English only version or ref. 23654 for an English/Welsh version.

This guideline is a part of the Inherited Clinical Guidelines work programme. It was commissioned by the Department of Health before the Institute was formed in April 1999. It has followed closely the development brief that was agreed at the time of commissioning. The developers have worked with the Institute to ensure, in the time available, that the guideline has been subjected to validation and to consultation with stakeholders. However it has not been possible to subject it to the full guideline development process that the Institute has now adopted.

The Institute's full guideline is derived from the detailed guideline entitled "Prophylaxis for patients who have experienced a myocardial infarction: drug treatment, cardiac rehabilitation and dietary manipulation." The detailed guideline was commissioned by the Department of Health from the Centre for Health Services Research, University of Newcastle upon Tyne and the Medicines Evaluation Group, Centre for Health Economics, University of York. The detailed guideline is also available on the Institute's website (www.nice.org.uk) and the National Electronic Library for Health's website (www.nelh.nhs.uk) The Guideline developers are listed in Appendix A of the full NICE guideline document.

This Guidance is written in the following context:

This Guidance represents the view of the Institute which was arrived at after careful consideration of the available evidence. Health professionals are expected to take it fully into account when exercising their clinical judgement. This Guidance does not, however, override the individual responsibility of health professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

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This guideline is a part of the 'inherited' clinical guidelines work programme. It was commissioned by the Department of Health before the Institute was formed in April 1999. It has followed closely the development brief that was agreed at the time of commissioning. The developers have worked with the Institute to ensure, in the time available, that the guideline has been subjected to validation and to consultation with stakeholders. However it has not been possible to subject it to the full guideline development process that the Institute has now adopted.

1. Evidence

- 1.1 The recommendations in this guideline are graded according to the system set out below.

The recommendations were graded as follows:

- A** directly based on category I evidence (meta-analysis of randomised controlled trials or at least one randomised controlled trial)
- B** directly based on category II evidence (at least one controlled study without randomisation or one other type of quasi-experimental study) or extrapolated recommendation from category I evidence
- C** directly based on category III evidence (non-experimental descriptive studies) or extrapolated recommendation from category I or II evidence
- D** directly based on category IV evidence (expert committee reports or opinions and/or clinical experience of respected authorities) or extrapolated recommendation from category I, II or III evidence

- 1.2 This guideline makes recommendations for patients who have survived a myocardial infarction and has the aim of decreasing subsequent premature mortality.

Recommendations for drug treatment are made assuming that clinicians will take account of both patient tolerability and compliance, and the indications, contraindications and cautions as listed in the British National Formulary (BNF) or Summary of Product Characteristics.

Within three of the drug groups discussed in this guideline (beta-blockers, ACE inhibitors, statins) not all medicines have a license for the indications discussed in the guideline.

In reaching treatment decisions, clinicians will want to share the information in this guideline with patients so that they are informed about and involved in decision making about their care.

2. Guidance

2.1 Drug treatment

2.1.1 Patients with prior myocardial infarction who do not have heart failure

Which drugs?

- 2.1.1.1 All patients should be offered long term treatment firstly with a beta-blocker and an antiplatelet drug (aspirin), and then with a statin and an ACE inhibitor. This sequencing of initiation reflects the evidence from trials and estimates of cost-effectiveness. **A** Not all ACE inhibitors or statins have a license for this indication.
- 2.1.1.2 The precise lower limit of the level of cholesterol that should be treated is unclear. Across the statin trials considered, the lower limit of the range of cholesterol values defining entry into the trials varied; one large trial enrolled patients with serum cholesterols down to 4 mmol/l. License indications currently suggest a lower limit of 4.8 mmol/l or 5.5 mmol/l depending on the drug used. **D**
- 2.1.1.3 Beta-blockers and ACE inhibitors can also be considered for the management of symptoms (e.g. in stable angina) or risk factors (e.g. hypertension). **D**

- 2.1.1.4 Calcium channel blockers, nitrates, and potassium channel activators have no effect on premature mortality making their role the management of symptoms and risk factors (principally hypertension). **A** They should therefore only be used in those patients who are intolerant of beta-blockers and ACE inhibitors. **D** Given their effect on non-fatal myocardial infarction, verapamil or diltiazem should then be considered initially. **B** Subsequent necessary treatment with other calcium channel blockers, nitrates or potassium channel activators is then appropriate. **D**

When to start drug treatment

- 2.1.1.5 The recommended starting points for drug treatments are based on the initiation points in the clinical trials.
- 2.1.1.6 Beta-blockers, antiplatelet drugs (aspirin) and ACE inhibitors should be initiated whilst patients are in hospital as there is evidence to support benefit following early initiation. If this does not happen then primary care clinicians should initiate them as soon after discharge as possible. **A**
- 2.1.1.7 Although there is no evidence of long-term benefit from the use of statins initiated prior to 12 weeks post-infarct, many patients will have been taking statins prior to admission or will have them initiated in hospital. All patients discharged from hospital who are not already taking a statin should be assessed and have treatment initiated 12 weeks after a myocardial infarction. **A**

Monitoring treatment

- 2.1.1.8 Patients being considered for treatment with a statin should have an initial serum cholesterol measurement both to exclude familial lipid disorders and to identify those patients with a serum cholesterol level that does not need treating. Once these have been excluded, further measurement allows an assessment of response to treatment and informs the assessment of compliance with treatment. The frequency of such monitoring is unclear, however the National Service Framework for Coronary Heart Disease suggests annually. **D**
- 2.1.1.9 Patients being considered for treatment with ACE inhibitors should have their renal function checked prior to initiation and after each significant dose increase. **D**

Continuation of treatment

- 2.1.1.10 Based on the evidence from the trials, treatment should continue long term. **D**
- 2.1.1.11 The treatment durations, for which there is at least one trial that provides direct support, are three and a half years for antiplatelet drugs (aspirin), four years for beta-blockers and ACE inhibitors and six years for statins. In the absence of a clear reason to stop treatment it seems reasonable to continue treatment indefinitely. **D**

2.1.2 Patients with prior myocardial infarction who have diabetes

- 2.1.2.1 There is evidence that intensive insulin therapy initiated soon after admission for acute myocardial infarction reduces mortality. **B** To achieve the benefits demonstrated in the single trial in this area involves 4 daily insulin injections continuing for at least three months. **B**

2.1.3 Patients with prior myocardial infarction and heart failure

- 2.1.3.1 Patients with prior myocardial infarction and heart failure are a relatively ill group of patients and care is required when initiating drug treatments. **D**
- 2.1.3.2 All patients should be offered long term treatment with an ACE inhibitor and then a beta-blocker (not all beta-blockers have a license for this indication). In addition they should be treated with an antiplatelet drug (aspirin). Patients who have moderate or severe heart failure (New York Heart Association (NYHA) grade 3 or 4) should be treated with spironolactone. All of these treatments are cost effective. **A**
- 2.1.3.3 Patients are likely to continue to need symptomatic treatment with a loop diuretic. **D** In patients with mild symptoms of heart failure (NYHA grade 1 or 2) it is unclear whether spironolactone decreases premature mortality. It may represent a reasonable choice of adjuvant symptomatic therapy. **D**
- 2.1.3.4 As patients with heart failure were almost always excluded from trials there is no evidence on which to recommend the use of statins in such patients. Statin use will be influenced by clinical and practical considerations, such as whether patients were treated with them prior to developing heart failure. **D**

When to start drug treatment

- 2.1.3.5 The recommended starting points for drug treatments are based on the initiation points in the trials.
- 2.1.3.6 ACE inhibitors and antiplatelet drugs (aspirin) should be initiated whilst patients are in hospital as there is evidence to support benefit following early initiation. If this does not happen then primary care clinicians should initiate them as soon after discharge as possible. **A**
- 2.1.3.7 Beta-blockers can be initiated at any point. Treatment should start with low doses and should be slowly increased, for example at fortnightly intervals, over a period of up to 12 weeks. **A**
- 2.1.3.8 Given the limited experience initiating beta-blockers it is currently unclear whether this can be done safely in primary care. Whilst the BNF recommends hospital supervision it seems possible that there are a group of patients with heart failure for whom general practitioners (based on their knowledge of the patient's clinical condition) may feel able to initiate treatment in primary care. Unfortunately the characteristics of this patient group are not currently clear. Discussion at a local level may inform appropriate methods of treatment initiation. **D**
- 2.1.3.9 Spironolactone can be initiated at any point. In patients with moderate to severe symptoms of heart failure (NYHA grade 3 or 4), given the time involved in achieving full dosages of beta-blockers, it seems reasonable to consider initiating spironolactone before beta-blockers. **D**

Monitoring treatment

- 2.1.3.10 Patients being considered for treatment with ACE inhibitors should have their renal function checked prior to initiation and after each significant dose increase. **D**

2.1.3.11 Patients being treated with spironolactone should have their serum potassium monitored. **D**

Continuation of treatment

2.1.3.12 Based on the evidence from the trials, treatment should continue long term. **D** The treatment durations, for which there is at least one trial that provides direct support, are three and a half years for ACE inhibitors, two and a half years for beta-blockers and two years for spironolactone. In the absence of a clear reason to stop treatment it seems reasonable to continue treatment indefinitely. **D**

2.2 Non-drug treatment

2.2.1 Rehabilitation

2.2.1.1 Patients should be offered enrolment in a rehabilitation programme that has a prominent exercise component within it. **A** Although many of the trials imposed upper age limits for recruitment, the guideline development group felt that in a service setting it was more appropriate to be guided by functional ability and patient preference. **D**

2.2.2 Diet

2.2.2.1 Given the nature of the available evidence of the effectiveness of dietary manipulation as a strategy for secondary prophylaxis it is not possible to recommend specific dietary manipulation. **B**

3. Detailed Guideline

3.1 These recommendations are derived from the guideline entitled “Prophylaxis for patients who have experienced a myocardial infarction: drug treatment, cardiac rehabilitation and dietary manipulation.” The guideline was commissioned by the Department of Health from the Centre for Health Services Research, University of Newcastle upon Tyne and the Medicines Evaluation Group, Centre for Health Economics, University of York. It is available on the the Institute’s website (www.nice.org.uk) and the National Electronic Library for Health’s website (www.nelh.nhs.uk). The Guideline developers are listed in Appendix A.

3.2 This guideline was commissioned by the Department of Health before the Institute was formed in April 1999. It has followed closely the development brief which was agreed at the time of commissioning. The developers have worked with the Institute to ensure, in the time available, that the guideline has been the subject of validation and consultation with stakeholders. It has not been possible to subject it to the full guideline development process which the Institute has now adopted.

4. Scope

4.1 The guideline addresses a number of related questions:

4.1.1 What are the benefits in mortality and major morbidity, from treatment with statins, beta-blockers, ACE inhibitors, antiplatelet agents, calcium channel blockers, potassium channel activators, cardiac rehabilitation, and Mediterranean diet or polyunsaturated fatty acids in patients who have experienced an MI.

4.1.2 What benefits exist for identifiable major subgroups of patients who have experienced an MI? (The main clinical area examined here is the subgroup of patients who develop heart failure following an MI).

4.3 Interventions falling outside scope of this guideline:

4.3.1 It is acknowledged that the choice of primary care drug treatments to prevent subsequent mortality and major morbidity is only one of the uncertainties faced by clinicians and patients. Relevant areas that were identified during the guideline development process but are not covered by this guideline are:

- Smoking cessation programmes
- Symptomatic management of angina
- Exercise programmes in heart failure
- Dietary regimes other than those identified above
- Identification and referral to secondary care for worsening symptoms of cardiovascular disease

5. Implementation

5.1 This guideline is published as part of a range of clinical resources to support the Coronary Heart Disease National Service Framework. Its implementation should take place as part of the health improvement plans for each local health economy.

5.2 Local health communities will need to review existing service provision against this guidance. This review should result in an implementation strategy which will identify the resources required to implement fully the recommendations set out in Section 2 of the guidance, the people and processes involved and the timeline over which full implementation is envisaged.

5.3 Relevant local clinical guidelines and protocols should be reviewed in light of this guidance and revised accordingly.

5.4 To enable clinicians to audit their own compliance with this guideline it is recommended that, if not already in place, management plans are recorded for each patient who has suffered a myocardial infarction.

5.5 The following audit criteria can be used to support the evaluation of clinical practice and continuous improvement in the management of patients following a myocardial infarction. These six criteria are suitable for use in primary care and are concordant with those within the National Service Framework for Coronary Heart Disease.

5.6 The baseline population is those patients discharged from hospital having survived a myocardial infarction. The audit criteria require the identification of a sub-set of patients with heart failure.

- Number (and %) of all patients with and without heart failure appropriately taking beta-blockers
- Number (and %) of all patients with and without heart failure appropriately taking aspirin
- Number (and %) of all patients with and without heart failure appropriately taking a statin (taking account of serum cholesterol level)
- Number (and %) of patients with and without* heart failure appropriately taking an ACE inhibitor

* This criterion is not directly concordant with the NSF due to evidence that has emerged since the NSF was written.

- Number (and %) of patients with heart failure appropriately taking spironolactone
- Number (and %) of all patients (i) offered and (ii) enrolled into a rehabilitation programme

5.7 This information should be incorporated into local clinical audit data recording systems and consideration given (if not already in place) to the establishment of appropriate categories in electronic record systems.

5.8 Prospective clinical audit programmes should record the proportion of treatments adhering to the guidance. Such programmes are likely to be more effective in improving patient care when they form part of the organisation's formal clinical governance arrangements and where they are linked to specific post-graduate activities.

6. Review Date

6.1 The Institute will review the evidence for prophylaxis for patients who have experienced a myocardial infarction in April 2003.

Appendix A

Guideline Development Group

Guideline developers

The Guideline Development Group is a multiprofessional team brought together on a project basis, to consider the evidence of clinical and cost effectiveness and develop the guideline.

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Jane Skinner

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Appendix B

Guideline Advisory Committee

The Guidelines Advisory Committee (GAC) is a standing committee of the Institute. It has responsibility for agreeing the scope and commissioning brief for clinical guidelines and for monitoring progress and methodological soundness. The GAC considers responses from stakeholders and advises the Institute on the acceptability of the guidelines it has commissioned. The members of the GAC are:

Stephanie A Amiel, BSc, MD, FRCP

RD Lawrence Professor of Diabetic Medicine,
Kings College

Mr. Charles Collins

Consultant General Surgeon,
Taunton

Joyce Cormie

Consumer Representative

Professor Mike Drummond

Director, Centre for Health Economics (CHE)
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Chairman: Professor Martin Eccles

Professor of Clinical Effectiveness,
Centre for Health Services Research,
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Appendix C

Treatments following a heart attack

The patient information in this appendix has been designed to support the production of your own information leaflets. You can download it from our website at www.nice.org.uk where it is available in English and Welsh. If you would like printed copies of the leaflets please ring the NHS Response Line on 0870 1555 455 and quote reference number 23653 for the English patient leaflet and 23654 for the bi-lingual patient leaflet.

About clinical guidelines

The National Institute for Clinical Excellence (NICE) is a part of the NHS. It produces guidance for both the NHS and patients on medicines, medical equipment and clinical procedures and where they should be used. This guidance exists to help patients and their healthcare team make the right decisions about health care. They are developed by teams of healthcare professionals, patients and scientists who look at the best evidence about care for a particular condition. The advice in this booklet is based on the results of scientific studies and expert knowledge on the best ways to provide treatment following a heart attack.

Clinical guidelines are recommendations for good practice. They are not regarded as a substitute for a health professional's clinical judgement. Therefore there may be good reasons for the treatment you are offered to differ from the recommendations in this booklet. If the care you receive is very different, then you (and/or your carer) should discuss the reasons with your doctor or nurse.

What is a heart attack?

A heart attack (also known as myocardial infarction or MI) happens when one of the blood vessels supplying the heart gets blocked. This starves the heart of oxygen and causes a part of the heart muscle to stop working (known as an infarct). This means that the rest of the heart stops working properly. The effects can be very sudden.

What is heart failure?

Heart failure means the heart can no longer efficiently pump blood around the body. Although not everyone gets this, it is usually an effect of having a heart attack. Heart failure can develop quite quickly but more often it is a slow process, taking a number of years.

Drug treatments following a heart attack

There are a number of medicines that might be given after a heart attack. They include:

- | | |
|-----------------------|---|
| Aspirin | This thins the blood which helps to stop the blood from clotting and blocking up blood vessels. Blocked blood vessels can lead to a heart attack. |
| Beta-blockers | These help to reduce the workload of the heart. |
| ACE-inhibitors | When a heart attack has caused damage to heart tissue, ACE-inhibitors can help to lessen the effects of the damage by reducing the work-load of the heart (ACE stands for angiotensin converting enzyme). |
| Statins | High levels of cholesterol in the blood can gradually build up on the inside walls of some blood vessels (the arteries) and cause a narrowing of the vessel or a blockage. Statins can help to reduce the cholesterol build-up. |
| Diuretics | Diuretics help reduce the amount of fluid in the body by acting on the kidneys to increase the amount of urine passed. This reduces the workload of the heart. Spironolactone is a mild diuretic which is particularly good for people with heart failure. A loop diuretic is a more powerful form of diuretic. |

As with all medication, you may experience side effects from these drugs. If you feel unwell or experience a change in your general well-being please discuss this with your doctor or nurse.

Following a heart attack it is particularly important that you take your medication as prescribed. Any changes to prescribed medicines (including the dose or times when the drug is taken) should be discussed and agreed between you and your doctor or nurse.

What drugs will be prescribed, and when?

If you have had a heart attack, but do not have heart failure

- If you have had a heart attack but you do not have heart failure you should be prescribed aspirin, a beta-blocker and an ACE-inhibitor. Treatment with these drugs should start whilst you are still in hospital, or soon after you go home.
- If you are not already on a statin, about twelve weeks after a heart attack your doctor should consider prescribing a statin for you.
- Treatment with these medicines will usually continue for the long term.

If you have had a heart attack and do have heart failure

- If you have had a heart attack and you do have heart failure you should be prescribed an ACE- inhibitor, a beta-blocker and aspirin. A Statin may also be prescribed.
- Treatment with an ACE-inhibitor should start whilst you are still in hospital, or soon after you go home.
- Your doctor will take particular care in starting your treatment with a beta-blocker and will usually start with low doses that will be slowly increased.
- You may also need a loop diuretic to help your symptoms. However if you have more severe heart failure you should be prescribed spironolactone.
- Treatment with these medicines will usually continue for the long term.

If you have had a heart attack and have diabetes

- As well as the other drug treatments for your heart, you may also be offered insulin injections four times a day for at least three months.

Tests related to drug treatment

There are a number of tests that the healthcare team will need to carry out if you have had a heart attack. Some of these will take place straight away and will help decide which treatment is best. Some will be carried out on an ongoing basis to make sure that the treatment is working.

The table below shows some of the tests.

Test	For people taking
Blood tests for cholesterol level and liver function	Statins
Tests for renal (kidney) function	ACE-inhibitors
Blood tests for potassium levels	Spironolactone

Other treatment

If you have had a heart attack you should be offered the chance to go on a rehabilitation programme. This should include exercise, and may also involve advice on diet and lifestyle changes.

What should I do?

If you or someone you care for has had a heart attack, you can discuss this guideline with your GP, specialist or nurse. If you have access to the internet and would like to find out more about heart disease, visit the NHS Direct website (www.nhsdirect.nhs.uk).

Further information

For further information about NICE, the Clinical Guidelines Programme or other versions of this guideline (including the sources of evidence) you can visit the NICE website at www.nice.org.uk. Full copies of the guideline can be requested from 0870 1555 455, quoting the reference number 23652.

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