To offer best practice advice on the care of adult patients (aged 18 years or older) who have symptoms or a diagnosis of chronic heart failure, Spironolactone is licensed to treat patients with heart failure. ACE inhibitor therapy should not be initiated in a patient with a clinical suspicion of hemodynamically significant valve disease (including coronary heart disease) or aortic stenosis, aortic arch aneurysm, aortic dissection, aortic regurgitation, ischemic heart disease, or atrial fibrillation.

The guideline was validated through two consultations. Editorial responsibility for the full guideline rests with the GDG. For more information, see the sources of funding, major outcomes considered, and target population below.

**Target Population**
Adult patients (aged 18 years or older) who have symptoms or a diagnosis of chronic heart failure
**To offer best practice advice on the care of adult patients (aged 18 years or older) who have symptoms or a diagnosis of heart failure.**

**Interventions and Practices Considered**

**Assessment/Diagnosis**

1. Evaluation of history, symptoms, and perform clinical examination
2. 12-lead electrocardiography (ECG)
3. Transthoracic Doppler 2D echocardiography
4. Alternative methods of heart imaging (radionuclide angiography, cardiac magnetic resonance imaging or transoesophageal Doppler 2D echocardiography)
5. Chest x-ray
6. Biochemical markers, including natriuretic peptides (B-type natriuretic peptide or N-terminal pro-B-type natriuretic peptide)
7. Blood tests, including electrolytes, urea, and creatinine, estimated glomerular filtration rate (eGFR), full blood count, liver function tests, thyroid function tests, glucose, and lipids
8. Urinalysis
9. Peak flow or spirometry

**Pharmacological Treatments**

1. Angiotensin-converting enzyme (ACE) inhibitors
2. Angiotensin-II receptor antagonists
3. Aldosterone antagonists
4. Hydralazine in combination with a nitrate
5. Beta-blockers
6. Digoxin
7. Diuretics, including loop diuretics, thiazides, potassium-sparing diuretics
8. Nitrates and other vasodilators
9. Spironolactone
10. Calcium channel blocker (amlodipine)
11. Amiodarone
12. Anticoagulants
13. Aspirin
14. Inotropic agents (dobutamine, milrinone, enoximone)

**Non-pharmacological Treatments**

1. Exercise programs and rehabilitation
2. Provision of lifestyle advice on diet, physical activity, weight reduction, sexual activity, alcohol use and smoking cessation, air travel, and driving regulations
3. Vaccination (influenza, pneumococcal)

**Invasive Procedures**

1. Coronary revascularization
2. Cardiac transplant
3. Cardiac resynchronization therapy
4. Implantable cardioverter-defibrillators (ICDs)

**General Management Principles**

1. Referral to specialist
2. Discharge planning
3. Rehabilitation programme
4. Ongoing monitoring (functional, fluid status, cardiac rhythm, serum digoxin concentrations)
5. Providing a multidisciplinary team approach to heart failure management
6. Providing support to patients and carers through effective communication, prognosis discussion, and referral to local support groups
7. Diagnosing and treating anxiety and depression
8. Providing information on end of life issues
Major Outcomes Considered
- Quality of life
- Life expectancy
- Mortality
- Exercise capacity
- Signs and symptoms
- Adverse effects
- Hospitalization rates
- Predictive value of tests
- Sensitivity and specificity of diagnostic tests
- Renal function
- Cost-effectiveness

Methodology

Methods Used to Collect/Select the Evidence
Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Note from the National Guideline Clearinghouse (NGC): This guideline was developed by the National Collaborating Centre for Acute and Chronic Conditions (NCC-ACC) on behalf of the National Institute for Health and Clinical Excellence (NICE). See the "Availability of Companion Documents" field for the full version of this guidance.

Searching for the Evidence
The Information Scientist developed a search strategy for each question. Key words for the search were identified by the Guideline Development Group (GDG). A separate health economic search strategy was developed looking for economic studies in chronic heart failure. Papers that were published in peer-reviewed journals (including e-publications ahead of print versions where identified) were considered as evidence by the GDG. Conference paper abstracts and non-English language papers were excluded from the searches. The dates to be searched for each question were agreed with the GDG before the review was undertaken. See Appendix D in the full version of the current guideline for the search strategies.

Types of Study
Each clinical question dictated the appropriate study design that was prioritized in the search strategy; however, the strategy was not limited solely to these study types. For intervention studies, randomized controlled trials (RCTs) were the preferred sources of evidence. Cohort studies and lower levels of evidence were only considered if RCTs data was not available.

The evidence was restricted to meta-analysis or systematic reviews for the following question:
- What is the diagnostic accuracy of a collection of symptoms and signs, or a scoring system vs gold standard in the diagnosis of heart failure?

For the remaining diagnostic reviews, cross-sectional studies were preferred or case control data if these were not available.

From a health economic perspective, full economic evaluations (cost-effectiveness, cost-utility and cost-benefit analyses), cost-consequence analyses and comparative costing studies that addressed the clinical question were included. Studies were prioritized for inclusion if they were from a UK perspective and based intervention effectiveness on data from one or more RCT. A judgement was made on a question by question basis regarding whether to include studies from a non-UK perspective or that used observational evidence, depending on the availability and quality of the other evidence.

The research fellow or health economist identified relevant titles and abstracts for each clinical question from the search results and full papers were obtained. Exclusion lists were generated for each question together with the rationale for the exclusion. The exclusion lists were presented to the GDG. See Appendices C and D in the full version of the current guideline document for review protocols and literature search details.

Re-run Evidence
Literature searches were repeated for all of the evidence-based questions at the end of the GDG development process allowing any relevant papers published up until 9 October 2009 to be considered. Future guideline updates will consider new evidence published after this date.

Health Economics Evidence
The economist critically appraised the full papers and undertook the data extraction. For economic studies, an assessment of applicability (directly applicable, partially applicable or not applicable) and methodological quality (minor limitations, potentially serious limitations, very serious limitations) was performed and tabulated with footnotes indicating the reasons for the assessment. Results, uncertainty and limitations of included economic analyses were also summarized and discussed. The costs presented have not been inflated. Studies judged to have an applicability rating of ‘not applicable’ were excluded. A judgment was made on a question by question basis regarding whether to include studies with a quality rating of ‘very serious limitations’, depending on the availability and quality of the other evidence.
To offer best practice advice on the care of adult patients (aged 18 years or older) who have symptoms or a diagnosis of chronic heart failure.

Erectile dysfunction and other sexual health issues may also be an issue for some men. Further research is needed to determine the best way to counsel patients with chronic heart failure about their sexual health.

Reach consensus recommendations where the evidence was inadequate.


Serum urea, electrolytes, creatinine and estimated glomerular filtration rate (eGFR) (NICE technical advice [TA] [new 2010 – 2011]).

Offer beta blockers licensed for heart failure to all patients with heart failure who are not taking beta blockers and for whom the diagnosis of heart failure is confirmed.

Healthcare providers need to use clinical judgement, knowledge and expertise when deciding whether it is appropriate to offer beta blockers to patients with heart failure. The need to balance the benefits and risks of treatment should be considered.


All patients with chronic heart failure require monitoring. This monitoring should include:

- Cardiac function
- Drug levels
- Laboratory tests
- Auscultation
- Body weight
- Urine output
- Blood pressure
- Heart rate
- Signs of infection
- Symptoms
- Details of medication

Clear instructions should be given as to how the patient/carer can access advice, particularly in the high level of care and support that can be provided in the community.

For patients who have had an acute MI and who have symptoms and/or signs of heart failure and left ventricular systolic dysfunction.

Switch stable patients who are already taking a beta blocker from a non-optimally tolerated or target dose to the optimal tolerated or target dose.

Depression in adults with a chronic physical health problem. Treatment and management [2003].

The palliative needs of patients and carers should be identified, assessed and managed at the earliest opportunity.

Issues of sudden death and living with uncertainty are pertinent to all patients with heart failure. The opportunity to have open and honest discussions with patients and carers about the potential for sudden death is important.

The guideline was validated through two consultations.

The Guideline Development Group (GDG) comprised a multidisciplinary team of health professionals and two people affected by heart failure. The GDG included an expert statistician and an information scientist, who were responsible for developing the guideline’s evidence base, or any economics modelling.

Including studies with a quality rating of ‘very serious limitations’, depending on the availability and quality of the other evidence included. The GDG used the grading of evidence from the Cochrane Collaboration (www.cochrane.org) and the Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology.

The first draft of the guideline (the Full guideline, National Institute for Clinical Excellence [NICE] guideline and NICE technical advice) was validated through informal feedback from members of the guideline development group and consultation with key stakeholders.

The Information Scientist developed a search strategy for each question. Key words for the search were identified by GDG members based on initial scoping searches, guidelines, and other key sources. Searches were conducted by the Information Scientist using the following electronic databases:

- MEDLINE
- EMBASE
- Cochrane Library
- CINAHL
- PsycINFO
- ACP Journal Club
- Clinical Evidence
- Health Technology Assessment

The evidence was restricted to meta-analyses, systematic reviews, or RCTs published in English. The bibliographic databases were searched from their inception up to 30 April 2009. Manual searches and reference checking were undertaken to identify any additional studies.

The evidence was synthesized by the GDG and presented in clinical sets, which included all the relevant evidence. The GDG combined the findings from the evidence synthesis with clinical experience and local knowledge to develop the guideline recommendations.

Guideline Summary NGC-8071

GUIDELINE TITLE


The guideline was developed by the National Collaborating Centre for Acute and Chronic Conditions (NCC-ACC) on behalf of the National Institute for Health and Clinical Excellence (NICE). See the "Availability of Companion Documents" field for the full version of this guidance.

Appraising the Evidence

The research fellow or health economist, as appropriate, critically appraised the full papers and undertook data extraction. Critical appraisal checklists were compiled for each full paper. The evidence was considered carefully by the Guideline Development Group (GDG) for accuracy and completeness.


Clinical Evidence

The research fellow critically appraised the full papers and undertook the data extraction. For non-observational studies, where possible, this included meta-analysis of data and synthesis of data into a Grades of Recommendation Assessment, Development and Evaluation (GRADE) ‘evidence profile’. The evidence profile shows for each outcome an overall assessment of both the quality of the evidence as a whole (low, moderate or high), as well as an estimate of the size of effect.

Evidence Synthesis for Intervention Studies

If possible, a meta-analysis was performed on the data using Review Manager. Dichotomous outcomes were analysed as relative risks (RR) and with the 95% CI. Continuous data were analysed as weighted mean difference (WMD). Where possible, data from the intention-to-treat analyses were used. Fixed effects (Mantel-Haenszel) techniques were used to calculate risk ratios (relative risk) for the binary outcomes. The continuous outcomes were analysed using an inverse variance method for pooling weighted mean differences and, where the studies had different scales, standardised mean differences were used. If heterogeneity was present, a random effect model was used and the two outputs compared. If the two models gave comparable results, those yielded by the fixed effect model are reported. If the two models yielded different results, heterogeneity was investigated.

Statistical heterogeneity was assessed by considering the chi-squared test for significance at p<0.05 or an I-squared inconsistency statistic of >50% to indicate significant heterogeneity. When there were a high number of studies, a p-value of 0.1 was taken as a threshold for heterogeneity. Where significant heterogeneity was present, we presented the results study by study.

Hazard ratios are reported in addition to relative risk for the mortality outcomes. Relative risks are referred to in the main text of the document unless there was a difference in the likely interpretation of the results (for example, if one estimate of effect implied a significant benefit and the other estimate of effect no benefit or harm). The methods outlined in the paper by Tierney were used to estimate the 'O – E' and 'V' statistics. The data were analysed using the generic inverse variance method.

GRADE was not used for studies reporting on diagnostic accuracy. Here the sensitivity, specificity, positive predictive value, negative predictive value, likelihood ratio and diagnostic odds ratio were reported if available.

Health Economist Evidence

The economist critically appraised the full papers and undertook the data extraction. For economic studies, an assessment of applicability (directly applicable, partially applicable or not applicable) and methodological quality (minor limitations, potentially serious limitations, very serious limitations) was performed and tabulated with footnotes indicating the reasons for the assessment. Results, uncertainty and limitations of included economic analyses were also summarized and discussed. The costs presented have not been inflated. Studies judged to have an applicability rating of ‘not applicable’ were excluded. A judgment was made on a question by question basis regarding whether to include studies with a quality rating of ‘very serious limitations’, depending on the availability and quality of the other evidence included.
Distilling and Synthesising the Evidence and Developing Recommendations

The evidence from each full paper was distilled into an evidence table and synthesized into an evidence profile and evidence statements before being presented to the GDG. The results of health economic modelling undertaken for the guideline were also presented to the GDG. This evidence was then reviewed by the GDG and used as a basis upon which to formulate recommendations.

The clinical evidence tables are located in Appendix E, and the health economics evidence tables are located in Appendix G of the full version of the current guideline.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Note from the National Guideline Clearinghouse (NGC): This guideline was developed by the National Collaborating Centre for Acute and Chronic Conditions (NCC-ACC) on behalf of the National Institute for Health and Clinical Excellence (NICE). See the "Availability of Companion Documents" field for the full version of this guidance.

Guideline Development Group

The Guideline Development Group (GDG) comprised a multidisciplinary team of health professionals and two people with heart failure. The GDG was recruited following an application process as specified in the NICE Guideline Manual. Membership details of the GDG are included at the front of this guideline. Members of the GDG declared any potential conflicts of interest in accordance with NICE policy. These are listed in Appendix L in the full version of the current guideline. The GDG met approximately monthly from January 2009 – June 2010. The GDG was supported by the technical team.

The Technical Team

The technical team met approximately two weeks before each GDG meeting and comprised the following members: GDG chair, GDG clinical advisor, Information Scientist, Research Fellow, Health Economist, Project Manager and Operations Director.

Involvement of People with Chronic Heart Failure (CHF)

The National Clinical Guideline Centre for Acute and Chronic Conditions (NCGC) was keen to ensure the views and preferences of people with CHF and their carers informed all stages of the guideline. This was achieved by:

- Having two people with CHF as patient representatives on the guideline development group (GDG)
- Consulting with the Patient and Public Involvement Programme (PPIP) housed within NICE during the pre-development (scoping) and final validation stages of the guideline
- Inclusion of patient groups as registered stakeholders for the guideline

The Process of Guideline Development

The basic steps in the process of producing a guideline update are:

- Identifying areas of existing guidance that need updating
- Developing clinical questions
- Developing the review protocol
- Systematically searching for the evidence
- Critically appraising the evidence
- Undertaking new health economic analysis
- Distilling and synthesizing the evidence and writing recommendations
- Agreeing the recommendations
- Structuring and writing the guideline
- Updating the guideline

Identifying Areas of Existing Guidance That Need Updating

The NCGC conducted a preliminary search for new evidence using the search strategies from the original guideline. The views of healthcare professionals and patients were also sought to identify any change in practice or additional relevant published evidence. Key areas that would directly result in changes to recommendations were highlighted for updating.

Developing Evidence-based Questions

The technical team drafted a series of clinical questions that covered the guideline scope. The GDG refined and approved these questions, which are shown in Appendix B in the full version of the current guideline.

Agreeing the Recommendations

The GDG employed formal consensus techniques to:

- Ensure that the recommendations reflected the evidence-base
- Approve recommendations based on lesser evidence or extrapolations from other situations
- Reach consensus recommendations where the evidence was inadequate
To offer best practice advice on the care of adult patients (aged 18 years or older) who have symptoms or a diagnosis of heart failure, a clinical guideline has been developed by the National Institute for Health and Clinical Excellence (NICE). The guideline usually makes recommendations within medication licence indications. Exceptionally, where there is a firm evidence base for a treatment, the GDG may make recommendations outside this licence and these are identified in the guideline.

Ensure the patient is stable and does not have a condition or device that would preclude an exercise programme. Referral to cardiac rehabilitation should be considered in patients with heart failure in sinus rhythm if lifetime risk (of death or another event) is at least 10%.

An angiotensin II receptor antagonist (ARB) licensed for heart failure* (especially if the patient has mild to moderate heart failure) should be considered for all patients who require pharmacological treatment of heart failure. It should be titrated to the recommended dose or maximum tolerated dose, whichever is lower. Adjustments should be made to reduce the risk of side effects as far as possible.

Chronic heart failure. Educational resource. Clinical case scenarios for primary care. London (UK): National Institute for Health and Clinical Excellence (NICE) permission to include summaries of their clinical guidelines with the intention of disseminating and facilitating implementation. The registered stakeholders for this guideline are detailed on the NICE Web site www.nice.org.uk.

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

Undertaking New Health Economic Analysis

The Guideline Development Group (GDG) agreed a priority area for original health economic modelling for the guideline. The analysis undertaken assessed the cost-effectiveness of serial measurement of circulating natriuretic peptide concentration for optimising medical therapy, compared to clinical assessment and to usual care. The full report is presented in Appendix H in the full version of the current guideline document.

The following general principles were adhered to:

- The GDG was consulted during the construction and interpretation of the model.
- The GDG informed the structure and the validity of model inputs.
- The model was based on clinical evidence identified from the systematic review of clinical evidence.
- Model inputs and assumptions were reported fully and transparently.
- Sensitivity analysis was used to explore uncertainties in model inputs and methods.
- Costs were estimated from a National Health Service (NHS) and personal social services (PSS) perspective.

A health economics section presented in each relevant chapter of the full version of the guideline document gives, where appropriate, an overview of the cost-effectiveness evidence-base, or any economics modelling.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

The guideline was validated through two consultations.

1. The first draft of the guideline (the Full guideline, National Institute for Clinical Excellence [NICE] guideline and Quick Reference Guide) were consulted with Stakeholders and comments were considered by the Guideline Development Group (GDG).

2. The final consultation draft of the Full guideline, the NICE guideline and the Information for the Public were submitted to stakeholders for final comments.

The final draft was submitted to the Guideline Review Panel for review prior to publication.

Recommendations

Major Recommendations

Note from the National Guideline Clearinghouse (NGC): This guideline was developed by the National Collaborating Centre for Acute and Chronic Conditions (NCC-ACC) on behalf of the National Institute for Health and Clinical Excellence (NICE). See the "Availability of Companion Documents" field for the full version of this guidance.

Diagnosing Heart Failure

Symptoms, Signs and Investigations
To offer best practice advice on the care of adult patients (aged 18 years or older) who have symptoms or a suspicion of heart failure, and to ensure the patient is stable and does not have a condition or device that would preclude an exercise test, it is advisable to refer patients with suspected heart failure and previous myocardial infarction (MI) urgently, to have transthoracic Doppler 2D echocardiography and specialist assessment within 2 weeks. [new 2010]

Measure serum natriuretic peptides (B-type natriuretic peptide [BNP] or N-terminal pro-B-type natriuretic peptide [NTproBNP]) in patients with suspected heart failure without previous MI. [new 2010]

Because very high levels of serum natriuretic peptides carry a poor prognosis, refer patients with suspected heart failure and a BNP level above 400 pg/ml (116 pmol/litre) or an NTproBNP level above 2000 pg/ml (236 pmol/litre) urgently, to have transthoracic Doppler 2D echocardiography and specialist assessment within 2 weeks. [new 2010]

Refer patients with suspected heart failure and a BNP level between 100 and 400 pg/ml (29–116 pmol/litre) or an NTproBNP level between 400 and 2000 pg/ml (47–236 pmol/litre) to have transthoracic Doppler 2D echocardiography and specialist assessment within 6 weeks. [new 2010]

Be aware that:

- Obesity or treatment with diuretics, angiotensin-converting enzyme (ACE) inhibitors, beta-blockers, angiotensin II receptor antagonists (ARBs) and aldosterone antagonists can reduce levels of serum natriuretic peptides
- High levels of serum natriuretic peptides can have causes other than heart failure (for example, left ventricular hypertrophy, ischemia, tachycardia, right ventricular overload, hypoxemia [including pulmonary embolism], renal dysfunction [GFR <60 ml/minute], sepsis, chronic obstructive pulmonary disease [COPD], diabetes, age >70 years and cirrhosis of the liver). [new 2010]

Perform transthoracic Doppler 2D echocardiography to exclude important valve disease, assess the systolic (and diastolic) function of the (left) ventricle, and detect intracardiac shunts. [2003]

Transthoracic Doppler 2D echocardiography should be performed on high-resolution equipment, by experienced operators trained to the relevant professional standards. Need and demand for these studies should not compromise quality. [2003]

Ensure that those reporting echocardiography are experienced in doing so. [2003]

Consider alternative methods of imaging the heart (for example, radionuclide angiography, cardiac magnetic resonance imaging or transoesophageal Doppler 2D echocardiography) when a poor image is produced by transthoracic Doppler 2D echocardiography. [2003]

Consider a serum natriuretic peptide test (if not already performed) when heart failure is still suspected after transthoracic Doppler 2D echocardiography has shown a preserved left ventricular ejection fraction. [new 2010]

Be aware that:

- A serum BNP level less than 100 pg/ml (29 pmol/litre) or an NTproBNP level less than 400 pg/ml (47 pmol/litre) in an untreated patient makes a diagnosis of heart failure unlikely
- The level of serum natriuretic peptide does not differentiate between heart failure due to left ventricular systolic dysfunction and heart failure with preserved left ventricular ejection fraction. [new 2010]

Perform an electrocardiogram (ECG) and consider the following tests to evaluate possible aggravating factors and/or alternative diagnoses:

- Chest X-ray
- Blood tests:
  - Electrolytes, urea and creatinine
  - eGFR (estimated glomerular filtration rate)
  - Thyroid function tests
  - Liver function tests
  - Fasting lipids
  - Fasting glucose
  - Full blood count
  - Urinalysis
- Peak flow or spirometry [2003, amended 2010]

Try to exclude other disorders that may present in a similar manner. [2003]

When a diagnosis of heart failure has been made, assess severity, aetiology, precipitating factors, type of cardiac dysfunction and correctable causes. [new 2010]

Review of Existing Diagnoses

The basis for historical diagnosis of heart failure should be reviewed, and only patients whose diagnosis is confirmed should be managed in accordance with this guideline. [2003]

If the diagnosis of heart failure is still suspected, but confirmation of the underlying cardiac abnormality has not occurred, then the patient should have appropriate further investigation. [2003]

Treating Heart Failure

Lifestyle

Smoking
Patients should be strongly advised not to smoke. Referral to smoking cessation services should be considered. [2003]

Alcohol
Patients with alcohol-related heart failure should abstain from drinking alcohol. [2003]

Healthcare professionals should discuss alcohol consumption with the patient and tailor their advice appropriately to the clinical circumstances. [2003]

Sexual Activity
Healthcare professionals should be prepared to broach sensitive issues with patients, such as sexual activity, as these are unlikely to be raised by the patient. [2003]

Vaccination
Patients with heart failure should be offered an annual vaccination against influenza. [2003]

Patients with heart failure should be offered vaccination against pneumococcal disease (only required once). [2003]

Air Travel
Air travel will be possible for the majority of patients with heart failure, depending on their clinical condition at the time of travel. [2003]

Driving Regulations
Large Goods Vehicle and Passenger Carrying Vehicle licence: physicians should be up to date with the latest Driver and Vehicle Licensing Agency guidelines. Check the Department for Transport Web site for regular updates. [2003]

Pharmacological Treatment of Heart Failure

Medicines Adherence
For more information refer to the National Guideline Clearinghouse (NGC) summary of the NICE guideline, Medicines adherence. Involving patients in decisions about prescribed medicines and supporting adherence (NICE clinical guideline 76).

Dosing regimens should be kept as simple as possible, and the healthcare professional should ensure that the patient and carer are fully informed about their medication. [2003]

Heart Failure Due to Left Ventricular Systolic Dysfunction

First-line Treatment
Offer both angiotensin-converting enzyme (ACE) inhibitors and beta-blockers licensed for heart failure to all patients with heart failure due to left ventricular systolic dysfunction. Use clinical judgement when deciding which drug to start first. [new 2010]

Second-line Treatment
Seek specialist advice before offering second-line treatment to patients with heart failure due to left ventricular systolic dysfunction. [new 2010]

Seek specialist advice and consider adding one of the following if a patient remains symptomatic despite optimal therapy with an ACE inhibitor and a beta-blocker:

- An aldosterone antagonist licensed for heart failure (especially if the patient has moderate to severe heart failure [New York Heart Association (NYHA) class III-IV] or has a myocardial infarction (MI) within the past month or
- An angiotensin II receptor antagonist (ARB) licensed for heart failure* (especially if the patient has mild to moderate heart failure [NYHA class II-III]) or
- Hydralazine in combination with nitrate (especially if the patient is of African or Caribbean origin [this does not include mixed race. For more information, refer to the full version of the guideline document]) and has moderate to severe heart failure [NYHA class III-IV]). [new 2010]

*Not all ARBs are licensed for use in heart failure in combination with ACE inhibitors.

ACE Inhibitors (First-line Treatment)
Start ACE inhibitor therapy at a low dose and titrate upwards at short intervals (for example, every 2 weeks) until the optimal tolerated or target dose is achieved. [2010]

Measure serum urea, creatinine, electrolytes and eGFR at initiation of an ACE inhibitor and after each dose increment (for practical recommendations on treatment with ACE inhibitors see the NGC summary of the NICE guideline, Chronic kidney disease. Early identification and management of chronic kidney disease in adults in primary and secondary care (NICE clinical guideline 73). [2010]

For more information, see Appendix D in the full version of the guideline document.

Beta-blockers (First-line Treatment)
Offer beta-blockers licensed for heart failure to all patients with heart failure due to left ventricular systolic dysfunction, including:

- Older adults and
- Patients with:
  - Peripheral vascular disease
  - Erectile dysfunction
- Diabetes mellitus
- Interstitial pulmonary disease
- Chronic obstructive pulmonary disease (COPD) without reversibility [new 2010]

Introduce beta-blockers in a ‘start low, go slow’ manner, and assess heart rate, blood pressure, and clinical status after each titration. [2010]

Switch stable patients who are already taking a beta-blocker for a comorbidity (for example, angina or hypertension), and who develop heart failure due to left ventricular systolic dysfunction, to a beta-blocker licensed for heart failure. [new 2010]

Aldosterone Antagonists (Second-line Treatment)

In patients with heart failure due to left ventricular systolic dysfunction who are taking aldosterone antagonists, closely monitor potassium and creatinine levels, and eGFR. Seek specialist advice if the patient develops hyperkalaemia or renal function deteriorates (for more information see Appendix D in the full version of the guideline document). [new 2010]

For patients who have had an acute MI and who have symptoms and/or signs of heart failure and left ventricular systolic dysfunction, treatment with an aldosterone antagonist licensed for post-MI treatment should be initiated within 3–14 days of the MI, preferably after ACE inhibitor therapy. (This recommendation is from Post myocardial infarction: secondary prevention in primary and secondary care for patients following a myocardial infarction [see the NGC summary of NICE clinical guideline 48]). [2007]

Patients who have recently had an acute MI and have clinical heart failure and left ventricular systolic dysfunction, but who are already being treated with an aldosterone antagonist for a concomitant condition (for example, chronic heart failure), should continue with the aldosterone antagonist or an alternative, licensed for early post-MI treatment. (This recommendation is from Post myocardial infarction: secondary prevention in primary and secondary care for patients following a myocardial infarction [see the NGC summary of NICE clinical guideline 48]). [2007]

Hydralazine in Combination with Nitrate (Alternative First-line Treatment)

Seek specialist advice and consider hydralazine in combination with nitrate for patients with heart failure due to left ventricular systolic dysfunction who are intolerant of ACE inhibitors and ARBs. [new 2010]

Angiotensin II Receptor Antagonists (Second-line or Alternative First-line Treatment)

Consider an ARB licensed for heart failure as an alternative to an ACE inhibitor for patients with heart failure due to left ventricular systolic dysfunction who have intolerable side effects with ACE inhibitors. [new 2010]

Monitor serum urea, electrolytes, creatinine and eGFR for signs of renal impairment or hyperkalaemia in patients with heart failure who are taking an ARB (for more information see Appendix D in the full version of the guideline document. For practical recommendations on treatment with ARBs see the NGC summary of the NICE guideline, Chronic kidney disease. Early identification and management of chronic kidney disease in adults in primary and secondary care (NICE clinical guideline 73). [new 2010]

Digoxin

Digoxin is recommended for:


All Types of Heart Failure

Diuretics

Diuretics should be routinely used for the relief of congestive symptoms and fluid retention in patients with heart failure, and titrated (up and down) according to need following the initiation of subsequent heart failure therapies. [2003]

The diagnosis and treatment of heart failure with preserved ejection fraction should be made by a specialist, and other conditions that present in a similar way may need to be considered. Patients in whom this diagnosis has been made should usually be treated with a low to medium dose of loop diuretics (for example, less than 80 mg furosemide per day). Patients who do not respond to this treatment will require further specialist advice. [2003]

Calcium Channel Blockers

Amiodipine should be considered for the treatment of comorbid hypertension and/or angina in patients with heart failure, but verapamil, diltiazem or short-acting dihydropyridine agents should be avoided. [2003]

Amiodarone

The decision to prescribe amiodarone should be made in consultation with a specialist. [2003]

The need to continue the amiodarone prescription should be reviewed regularly. [2003]

Patients taking amiodarone should have a routine 6-monthly clinical review, including liver and thyroid function test, and including a review of side effects. [2003]

Anticoagulants

See also the NGC summary of the NICE guideline, Atrial fibrillation. National clinical guideline for management in primary and secondary care (NICE clinical guideline 36) for recommendations on the use of anticoagulants in patients with atrial fibrillation.

In patients with heart failure in sinus rhythm, anticoagulation should be considered for those with a history of
thromboembolism, left ventricular aneurysm, or intracardiac thrombus. [2003]

Aspirin
Aspirin (75–150 mg once daily) should be prescribed for patients with the combination of heart failure and atherosclerotic arterial disease (including coronary heart disease). [2003]

Inotropic Agents
Intravenous inotropic agents (such as dobutamine, milrinone or enoximone) should only be considered for the short-term treatment of acute decompensation of chronic heart failure. This will require specialist advice. [2003]

Heart Failure Due to Valve Disease
Patients with heart failure due to valve disease should be referred for specialist assessment and advice regarding follow-up. [2003]

ACE inhibitor therapy should not be initiated in a patient with a clinical suspicion of hemodynamically significant valve disease, until the valve disease has been assessed by a specialist. [2003]

General

Age
The management of heart failure should be determined by clinical criteria, irrespective of the age of the patient. [2003]

Tolerance of drugs may be lower and side effects require closer and more frequent monitoring in older patients. [2003]

Gender
The principles of pharmacological management of heart failure should be the same for men and women. [2003]

In women of reproductive age who have heart failure, contraception and pregnancy should be discussed. If pregnancy is being considered or occurs, specialist advice should be sought. Subsequently, specialist care should be shared between the cardiologist and obstetrician. [2003]

The potential teratogenic effects of drugs should be considered. [2003]

Comorbidities
Manage comorbidities according to:

- Hypertension: management of hypertension in adults in primary care (NICE clinical guideline 34)
- Post myocardial infarction: secondary prevention in primary and secondary care for patients following a myocardial infarction (see the NGC summary of NICE clinical guideline 48)
- Type 2 diabetes. The management of type 2 diabetes (see the NGC summary of NICE clinical guideline 87) and other relevant NICE guidance. This is particularly important in heart failure with preserved ejection fraction. [new 2010]

Invasive Procedures
Coronary Revascularisation
Coronary revascularisation should not be routinely considered in patients with heart failure due to systolic left ventricular impairment, unless they have refractory angina. [2003]

Cardiac Transplantation
Specialist referral for transplantation should be considered in patients with severe refractory symptoms or refractory cardiogenic shock. [2003]

Cardiac Resynchronisation Therapy
Refer to the NGC summary of the NICE technology appraisal (TA) guidance, Cardiac resynchronisation therapy for the treatment of heart failure (NICE TA guidance 120) [2007]. Please refer to the NICE Web site for updates on the review status of this appraisal.

Implantable Cardioverter Defibrillators
Refer to the NGC summary of the NICE TA guidance, Implantable cardioverter defibrillators for arrhythmias (NICE TA guidance 95) [2006]. Please refer to the NICE Web site for updates on the review status of this appraisal.

Rehabilitation
Offer a supervised group exercise-based rehabilitation program designed for patients with heart failure.

- Ensure the patient is stable and does not have a condition or device that would preclude an exercise-based rehabilitation program (the conditions and devices that may preclude an exercise-based rehabilitation program include: uncontrolled ventricular response to atrial fibrillation, uncontrolled hypertension, and high-energy pacing devices set to be activated at rates likely to be achieved during exercise)
- Include a psychological and educational component in the program.
- The program may be incorporated within an existing cardiac rehabilitation program. [new 2010]

Monitoring
Clinical Review
All patients with chronic heart failure require monitoring. This monitoring should include:


- A clinical assessment of functional capacity, fluid status, cardiac rhythm (minimum of examining the pulse), cognitive status and nutritional status
- A review of medication, including need for changes and possible side effects
- Serum urea, electrolytes, creatinine and eGFR (this is a minimum. Patients with comorbidities or co-prescribed medications will require further monitoring. Monitoring serum potassium is particularly important if a patient is taking digoxin or an aldosterone antagonist). [2003, amended 2010]

More detailed monitoring will be required if the patient has significant comorbidity or if their condition has deteriorated since the previous review. [2003]

The frequency of monitoring should depend on the clinical status and stability of the patient. The monitoring interval should be short (days to 2 weeks) if the clinical condition or medication has changed, but is required at least 6-monthly for stable patients with proven heart failure. [2003]

Patients who wish to be involved in monitoring of their condition should be provided with sufficient education and support from their healthcare professional to do this, with clear guidelines as to what to do in the event of deterioration. [2003]

When a patient is admitted to hospital because of heart failure, seek advice on their management plan from a specialist in heart failure. [new 2010]

**Serum Digoxin**

Routine monitoring of serum digoxin concentrations is not recommended. A digoxin concentration measured within 8 to 12 hours of the last dose may be useful to confirm a clinical impression of toxicity or non-adherence. [2003]

The serum digoxin concentration should be interpreted in the clinical context as toxicity may occur even when the concentration is within the ‘therapeutic range’. [2003]

**Serum Natriuretic Peptides**

Consider specialist monitoring of serum natriuretic peptides in some patients (for example, those in whom uptitration is problematic or those who have been admitted to hospital). [new 2010]

**Referral and Approach to Care**

**Referral for More Specialist Advice**

Refer patients to the specialist multidisciplinary heart failure team for:

- The initial diagnosis of heart failure and
- The management of:
  - Severe heart failure (NYHA class IV)
  - Heart failure that does not respond to treatment
- Heart failure that can no longer be managed effectively in the home setting. [new 2010]

**Discharge Planning**

Patients with heart failure should generally be discharged from hospital only when their clinical condition is stable and the management plan is optimised. Timing of discharge should take into account patient and carer wishes, and the level of care and support that can be provided in the community. [2003]

The primary care team, patient and carer must be aware of the management plan. [2003]

Clear instructions should be given as to how the patient/carer can access advice, particularly in the high-risk period immediately following discharge. [2003]

**Multidisciplinary Team Approach to Heart Failure Management**

Heart failure care should be delivered by a multidisciplinary team with an integrated approach across the healthcare community. [2003]

**Non-NHS Agencies**

Standard one of the 'National service framework for older people' states: "Social care services will not use age in their eligibility criteria or policies to restrict access to available services." This applies to patients with heart failure. (See www.dh.gov.uk [2003]

Management plans for patients with heart failure should be discussed with non-NHS agencies where they are involved in or responsible for the care of a person with heart failure. [2003]

The principles of pharmacological management for a patient cared for in a non-NHS institution should be similar to those for any other patient with heart failure. [2003]

The education needs of non-NHS agency carers should be considered. [2003]

**Communication**

Good communication between healthcare professionals and patients and carers is essential for the best management of heart failure. [2003]

Guidelines for good communication:

- Listen to patients and respect their views and beliefs.
- Give patients the information they ask for or need about their condition, its treatment and prognosis, in a way they can understand including information about any serious side effects of drugs to be prescribed.
To offer best practice advice on the care of adult patients (aged 18 years or older) who have symptoms or a suspected diagnosis of heart failure, it is essential to provide specific, detailed, and concrete advice. Make sure to share information with patients’ partners, close relatives, or carers if they ask you to do so. When patients cannot indicate their consent for such sharing of information, it is advisable to share the information that those close to the patient need or want to know, except where you have reason to believe that the patient would object if able to do so. [2003]

The content, style, and timing of information provision should be tailored to the needs of the individual patient. [2003] Healthcare professionals should assess cognitive ability when sharing information. [2003]

Carers and relatives of patients who are cognitively impaired should be made aware of treatment regimes for the patients they care for and be encouraged to identify any need for clinical support. [2003]

Management of heart failure should be seen as a shared responsibility between patient and healthcare professional. [2003]

Unless specifically excluded by the patient, carers and relatives should be involved in the management of the patient, particularly where the patient cannot look after him- or herself. [2003]

Prognosis
Prognosis should be discussed with patients and carers in a sensitive, open and honest manner. [2003]

Support Groups
Healthcare professionals should be aware of local cardiac support networks and provide this information to patients and carers. [2003]

Anxiety and Depression
The diagnosis of depression should be considered in all patients with heart failure. [2003]

Where depression is likely to have been precipitated by heart failure symptoms then reassessment of psychological status should be undertaken once the physical condition has stabilised following treatment for heart failure. If the symptoms have improved no further specific treatment for depression is required. [2003]

Where it is apparent that depression is co-existing with heart failure, then the patient should be treated for depression in line with Depression. The treatment and management of depression in adults (NICE clinical guideline 90) and Depression in adults with a chronic physical health problem. Treatment and management (NICE clinical guideline 91). [2003]

For patients with heart failure, the potential risks and benefits of drug therapies for depression should be considered carefully. [2003]

Patients with heart failure should consult a healthcare professional before using over-the-counter therapies for depression such as St John’s wort (Hypericum perforatum). Healthcare professionals should be aware of the potential interaction with prescribed medication, and always ask about self-medication, including the use of herbal products. [2003]

End of Life
Issues of sudden death and living with uncertainty are pertinent to all patients with heart failure. The opportunity to discuss these issues should be available at all stages of care. [2003]

The palliative needs of patients and carers should be identified, assessed and managed at the earliest opportunity. [2003]

Patients with heart failure and their carers should have access to professionals with palliative care skills within the heart failure team. [2003]

Clinical Algorithm(s)
Clinical algorithms are provided in the full version of the guideline document for:

- Diagnosing heart failure
- Treating heart failure

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is not specifically stated for each recommendation.
Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits
Appropriate management and treatment of patients with chronic heart failure to prevent or delay the progression of congestive heart failure and reduce or prevent the development of complications

Potential Harms
Side effects of medications

Qualifying Statements

Qualifying Statements

- This guidance represents the view of National Institute for Health and Clinical Excellence (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.
- Healthcare providers need to use clinical judgement, knowledge and expertise when deciding whether it is appropriate to apply guidelines. The recommendations cited here are a guide, and may not be appropriate for use in all situations. The decision to adopt any of the recommendations cited here must be made by the practitioner in light of individual patient circumstances, the wishes of the patient, clinical expertise and resources.

Guideline Limitations

- NICE clinical guidelines usually do not cover issues of service delivery, organisation or provision (unless specified in the remit from the Department of Health).
- NICE is primarily concerned with Health Services and so recommendations are not provided for Social Services and the voluntary sector. However, the guideline may address important issues related to the interface of National Health Service (NHS) clinicians with these sectors.
- Generally, the guideline does not cover rare, complex, complicated or unusual conditions.
- It is not possible in the development of a clinical guideline to complete extensive systematic literature reviews of all pharmacological toxicity. NICE expect the guidelines to be read alongside the Summaries of Product Characteristics.
- The guideline usually makes recommendations within medication licence indications. Exceptionally, where there was clear supporting evidence, recommendations outside the licensed indications have been included. As far as possible where this is the case, it is indicated.

Implementation of the Guideline

Description of Implementation Strategy
The Healthcare Commission assesses how well National Health Service (NHS) organisations meet core and developmental standards set by the Department of Health in 'Standards for better health' (available from www.dh.gov.uk). Implementation of clinical guidelines forms part of the developmental standard D2. Core standard C5 states that NHS organisations should take into account national agreed guidance when planning and delivering care. The National Institute for Health and Clinical Excellence (NICE) has developed tools to help organisations implement this guidance. These are available on the NICE Web site http://guidance.nice.org.uk/CG108; see also the "Availability of Companion Documents" field.

Key Priorities for Implementation
The following recommendations have been identified as priorities for implementation.

Diagnosis

- Refer patients with suspected heart failure and previous myocardial infarction (MI) urgently, to have transthoracic Doppler 2D echocardiography and specialist assessment within 2 weeks. [new 2010]
- Measure serum natriuretic peptides (B-type natriuretic peptide [BNP] or N-terminal pro-B-type natriuretic peptide [NTproBNP]) in patients with suspected heart failure without previous MI. [new 2010]
- Because very high levels of serum natriuretic peptides carry a poor prognosis, refer patients with suspected heart failure and a BNP level above 400 pg/ml (116 pmol/litre) or an NTproBNP level above 2000 pg/ml (236 pmol/litre) urgently, to have transthoracic Doppler 2D echocardiography and specialist assessment within 2 weeks. [new 2010]

Treatment

- Offer both angiotensin-converting enzyme (ACE) inhibitors and beta-blockers licensed for heart failure to all patients with heart failure due to left ventricular systolic dysfunction. Use clinical judgment when deciding which drug to start first. [new 2010]
Offer beta-blockers licensed for heart failure to all patients with heart failure due to left ventricular systolic dysfunction, including:
- Older adults and
- Patients with:
  - Peripheral vascular disease
  - Erectile dysfunction
  - Diabetes mellitus
  - Interstitial pulmonary disease
  - Chronic obstructive pulmonary disease (COPD) without reversibility [new 2010]
- Seek specialist advice and consider adding one of the following if a patient remains symptomatic despite optimal therapy with an ACE inhibitor and a beta-blocker:
  - An aldosterone antagonist licensed for heart failure (especially if the patient has moderate to severe heart failure [New York Heart Association (NYHA)] class III–IV] or has had an MI within the past month) or
  - An angiotensin II receptor antagonist (ARB) licensed for heart failure (especially if the patient has mild to moderate heart failure [NYHA class II–III]) or
  - Hydralazine in combination with nitrate (especially if the patient is of African or Caribbean origin and has moderate to severe heart failure [NYHA class III–IV]) [new 2010]

Rehabilitation
- Offer a supervised group exercise-based rehabilitation program designed for patients with heart failure.
- Ensure the patient is stable and does not have a condition or device that would preclude an exercise-based rehabilitation program
- Include a psychological and educational component in the program
- The program may be incorporated within an existing cardiac rehabilitation program [new 2010]

Monitoring
- All patients with chronic heart failure require monitoring. This monitoring should include:
  - A clinical assessment of functional capacity, fluid status, cardiac rhythm (minimum of examining the pulse), cognitive status and nutritional status
  - A review of medication, including need for changes and possible side effects
  - Serum urea, electrolytes, creatinine and estimated glomerular filtration rate (eGFR) [2003, amended 2010]
- When a patient is admitted to hospital because of heart failure, seek advice on their management plan from a specialist in heart failure. [new 2010]

Discharge Planning
- Patients with heart failure should generally be discharged from hospital only when their clinical condition is stable and the management plan is optimized. Timing of discharge should take into account patient and carer wishes, and the level of care and support that can be provided in the community. [2003]

Implementation Tools
Audit Criteria/Indicators
Clinical Algorithm
Foreign Language Translations
Patient Resources
Quick Reference Guides/Physician Guides
Resources
Slide Presentation
Staff Training/Competency Material
For information about availability, see the Availability of Companion Documents and Patient Resources fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories
IOM Care Need
- End of Life Care
- Living with Illness
IOM Domain
- Effectiveness
- Patient-centeredness
Identification of Information and Availability

**Bibliographic Source(s)**

**Adaptation**
Not applicable: The guideline was not adapted from another source.

**Date Released**
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**Guideline Developer(s)**
National Clinical Guideline Centre for Acute and Chronic Conditions - National Government Agency [Non-U.S.]

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**Guideline Committee**
Guideline Development Group

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**Financial Disclosures/Conflicts of Interest**
In accordance with guidance from National Institute for Health and Clinical Excellence (NICE), all Guideline Development Group (GDG) members' interests were recorded on a standard declaration form that covered consultancies, fee-paid work, share-holdings, fellowships, and support from the healthcare industry. These are listed in Appendix L of the full version of the guideline document (see "Availability of Companion Documents" field).

**Guideline Status**
This is the current release of the guideline.


**Guideline Availability**

**Availability of Companion Documents**
The following is available:
- Print copies: Available from the National Health Service (NHS) Response Line 0870 1555 455, ref: N2268. The following are also available:
To offer best practice advice on the care of adult patients (aged 18 years or older) who have symptoms or a diagnosis of heart failure, the following is available:


**Patient Resources**

The following is available:


Print copies: Phone NICE publications on 0845 033 7783 or e-mail publications@nice.org.uk. ref: N2269.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline’s content.

**NGC Status**

This NGC summary was completed by ECRI on July 14, 2004. The information was verified by the guideline developer on November 29, 2004. This summary was updated by ECRI Institute on November 6, 2007, following the U.S. Food and Drug Administration advisory on Antidepressant drugs. This NGC summary was updated by ECRI Institute on January 27, 2011.

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To offer best practice advice on the care of adult patients (aged 18 years or older) who have symptoms or a -
An aldosterone antagonist licensed for heart failure (especially if the patient has moderate to severe heart failure -
Having two people with CHF as patient representatives on the guideline development group (GDG)
- Make advice specific, detailed and concrete.
Older adults
A clinical assessment of functional capacity, fluid status, cardiac rhythm (minimum of examining the pulse),

Explanation
Cost
- Serum urea, electrolytes, creatinine and eGFR (this is a minimum. Patients with comorbidities or co.
- Allowing the patient to reach critical points in the care pathway more quickly

Diabetes mellitus

For patients with heart failure, the potential risks and benefits of drug therapies for depression should be considered -

\[2003\]
The content, style and timing of information provision should be tailored to the needs of the individual patient.

Referral and Approach to Care
Serum Natriuretic Peptides

should be short (days to 2 weeks) if the clinical condition or medication has changed, but is required at least 6
In prioritizing key priorities for implementation, the GDG took into account the following criteria:
relevant published evidence. Key areas that would directly result in changes to recommendations were highlighted for
views of healthcare professionals and patients were also sought to identify any change in practice or additional
preferences of people with CHF and their carers informed all stages of the guideline. This was achieved by:

Involvement of People with Chronic Heart Failure (CHF)

with heart failure. The GDG was recruited following an application process as specified in the NICE Guideline Manual.
The clinical evidence tables are located in Appendix E, and the health economics evidence tables are located in

\[2003\]

Each clinical question dictated the appropriate study design that was prioritized in the search strategy; however, the

\[2003\]

The research fellow critically appraised the full papers and undertook the data extraction. For non

\[2003\]

Very low
Quality

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