Complete Summary

GUIDELINE TITLE

Chronic heart failure. National clinical guideline for diagnosis and management in primary and secondary care.

BIBLIOGRAPHIC SOURCE(S)

National Collaborating Centre for Chronic Conditions. Chronic heart failure. National clinical guideline for diagnosis and management in primary and secondary care. London: National Institute for Clinical Excellence (NICE); 2003. 163 p. [347 references]

GUIDELINE STATUS

This is the current release of the guideline.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- May 2, 2007, Antidepressant drugs: Update to the existing black box warning on the prescribing information on all antidepressant medications to include warnings about the increased risks of suicidal thinking and behavior in young adults ages 18 to 24 years old during the first one to two months of treatment.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Chronic heart failure

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Risk Assessment
Treatment

CLINICAL SPECIALTY

Cardiology
Family Practice
Geriatrics
Internal Medicine

INTENDED USERS

Health Care Providers
Hospitals
Nurses
Patients
Physicians
Public Health Departments

GUIDELINE OBJECTIVE(S)

- 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
- To define the most effective combination of symptoms, signs, and investigations required to establish a diagnosis of heart failure and those which will influence therapy or provide important prognostic information
- To give guidance on the treatment, monitoring, and support of patients with heart failure

TARGET POPULATION

Adult patients (aged 18 years or older) who have symptoms or a diagnosis of chronic heart failure.

Note: The guideline does not cover "acute" heart failure but does include comment on exacerbation of the syndrome and the causes and treatment of this, recognising that chronic heart failure often has an undulating course. The guideline does not address the screening or diagnosis of people who are

asymptomatic, nor does it address the management of patients with right heart failure as a consequence of respiratory disease.

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis/Monitoring

1. Evaluation of history, symptoms, and signs
2. 12-lead electrocardiography (ECG)
3. Chest x-ray
4. Biochemical markers, including natriuretic peptides (B-type natriuretic peptide or N-terminal pro-B-type natriuretic peptide)
5. Blood tests, including electrolytes, urea, and creatinine, full blood count, liver function tests, thyroid function tests, glucose, and lipids
6. Imaging techniques, including transthoracic or transoesophageal Doppler 2D echocardiography, radionuclide imaging, or cardiac magnetic resonance imaging
7. Urinalysis
8. Peak flow or spirometry
9. Assessment of functional capacity
10. Assessment of fluid status
11. Assessment of cardiac rhythm
12. Therapeutic drug monitoring of serum digoxin concentrations

Pharmacological Treatments

1. Angiotensin-converting enzyme (ACE) inhibitors
2. Angiotensin-II receptor antagonists
3. Beta-blockers
4. Digoxin
5. Diuretics, including loop diuretics, thiazides, potassium-sparing diuretics
6. Nitrates and other vasodilators
7. Spironolactone
8. Amiodarone
9. Anticoagulants
10. Aspirin
11. Statins
12. Isosorbide/hydralazine combinations
13. Inotropic agents
14. Calcium channel blockers

Non-pharmacological Treatments

1. Exercise programmes 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 revascularisation

2. Cardiac transplant
3. Cardiac resynchronisation therapy
4. Implantable cardioverter-defibrillators (ICDs)

General Management Principles

1. Providing referral for more specialist advice
2. Discharge planning
3. Providing a multidisciplinary team approach to heart failure management
4. Providing support to patients and carers through effective communication, prognosis discussion, and referral to local support groups
5. Diagnosing and treating anxiety and depression
6. Providing information on end of life issues

MAJOR OUTCOMES CONSIDERED

- Quality of life
- Life expectancy
- Mortality
- Exercise capacity
- Signs and symptoms
- Hospitalisation rates
- Predictive value of tests
- Sensitivity and specificity of diagnostic tests
- Renal function
- Cost-effectiveness

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Searching for the Evidence

There are three stages to evidence identification and retrieval:

1. The technical team set out a series of specific clinical questions (see Appendix A of the full guideline document) that covered the issues identified in the project scope. The consensus/reference group (CRG) met to discuss, refine, and approve these questions as suitable for identifying appropriate evidence within the published literature.
2. The information scientist developed a search strategy for each question to identify the available evidence. Identified titles and abstracts were reviewed for relevance to the agreed clinical questions and full papers obtained as appropriate. Full papers were assessed for inclusion according to predefined criteria (see Appendix B of the full guideline document).
3. The full papers were critically appraised and the pertinent data entered into evidence tables that were then reviewed and analysed by the guideline

development group (GDG) as the basis upon which to formulate recommendations.

Limited details of the searches with regard to databases and constraints applied can be found in Appendix B of the full guideline document. Grey literature was searched for using the System for Information on Grey Literature in Europe (SIGLE). No formal contact was made with authors of identified studies. Additional contemporary articles were identified by the GDG on an ad hoc basis. Stakeholder evidence identified via a process established by the National Institute for Clinical Excellence (NICE) was incorporated where appropriate and was assessed for inclusion by the same criteria as evidence provided by the electronic searches.

Searches were re-run at the end of the guideline development process, thus including evidence published up to the end of September 2002. Studies recommended by stakeholders or GDG members that were published after this date were not considered for inclusion. This time-point should be the starting point for searching for new evidence for future updates to this guideline.

Health Economics Evidence

While evidence on cost effectiveness was extracted from the main searches wherever it existed, this was rare; hence it was necessary to undertake a separate search for information on the potential costs and benefits of the interventions and management strategies considered in this guideline. The information scientist carried out these searches with guidance on search terms from the health economist. The GDG realised that few formal cost effectiveness analyses would be identified, therefore the search for economic evidence was very broad and designed to identify information about the resources used in providing a service or intervention and/or the benefits that can be attributed to it. No study design criteria were imposed a priori (i.e., the searches were not limited to randomized controlled trials or formal economic evaluations). Further details of the searches for economic evidence are given in Appendix C of the full guideline document.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Evidence Categories

Ia: Evidence obtained from systematic review of meta-analysis of randomised controlled trials

Ib: Evidence obtained from at least one randomised controlled trial

IIa: Evidence obtained from at least one well-designed controlled study without randomisation

IIb: Evidence obtained from at least one other type of well-designed quasi-experimental study

III: Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies, and case studies

IV: Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities.

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Synthesising the Evidence

Abstracts of articles identified from the searches were screened for irrelevant items, and hard copies were ordered of papers that appeared to provide useful evidence relevant to each clinical question. Each paper was assessed for its methodological quality against pre-defined criteria using a validated evaluation tool. Papers that met the inclusion criteria were then assigned a level according to the evidence hierarchy as detailed in Section 3 of the full guideline document and in the section of this summary titled "Rating Scheme for the Strength of the Evidence." Owing to practical limitations, selection, critical appraisal, and data extraction were undertaken by one reviewer only. However evidence was considered carefully by the guideline development group (GDG) for accuracy and completeness.

Each clinical question dictated the appropriate study design that should be prioritised in the search strategy. In addition certain topics within any one clinical question at times required different evidence types to be considered. Randomised control trials (RCTs) were the most appropriate study design for a number of clinical questions as they lend themselves particularly well to research into medicines. They were not, however, the most appropriate study design for all clinical questions. For example, the evaluation of diagnostic tests is more suited to alternative research designs. Furthermore, RCTs are more difficult to perform in areas such as rehabilitation and lifestyle, where interventions may be tailored to the needs of the individual. As such, pharmaceutical interventions tend to be placed higher in the evidence hierarchy than other equally important interventions. This should not be interpreted as a preference for a particular type of intervention or as a reflection of the quality of the evidence, particularly for those clinical areas where non-RCT evidence is valid and most appropriate.

Where available, evidence from well-conducted systematic reviews was appraised and presented. Trials included within these reviews are listed in the evidence table but were not critically appraised. Studies identified in addition to those included in the systematic review were included in the appraisal process.

The study populations considered varied between clinical questions. At times evidence was not available from studies that included a heart failure population; therefore it was necessary to consider studies in other chronic conditions. Where this occurred it is indicated in the relevant evidence statement.

Study quality, although formally assessed, was not used as a basis for informing the evidence level assigned to evidence statements. Descriptive limitations of studies are, however, included in the statements as appropriate. On occasion the GDG identified a clinical question that could not be appropriately answered through undertaking a systematic review (where the evidence was scarce, or where the question could not usefully be answered with the largely dichotomous output of a review). These questions were addressed via an expert-drafted discussion paper, subject to consideration by the GDG. In these instances there was no formal search strategy used by the clinical expert or assessment of the studies cited. These review papers were developed and used as a basis for discussion by the GDG as a whole.

Finally, national and international evidence based guidelines were referred to during the development process. These were not formally appraised owing to the inherent difficulties of such a process, in that the consistency of process and of evidence base can be difficult to ascertain across such documents.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Nominal Group Technique)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The Developers

Two multiprofessional groups, supported by a technical team from the National Collaborating Centre for Chronic Conditions (NCC-CC), were involved in the development of the guideline:

- A small **guideline development group** (GDG) that met monthly for twelve months and undertook the detailed evidence assessment and recommendation drafting
- An extension of the GDG, the larger **consensus/reference group** (CRG), which met twice throughout the process: once early in the development to ensure the clinical questions and aims were appropriate, and again at the end of the process to review the recommendations drafted by the GDG. The group employed formal consensus techniques in their consideration of clinically important areas where there was insufficient evidence.

Nominations for group members were invited from various stakeholder organisations, which were selected to ensure an appropriate mix of clinical professions and patient groups. Group membership details can be found on pp iii–iv of the full guideline document.

Involvement of Patients with Heart Failure

As part of the development process, the NCC-CC was keen to ensure that the guideline development process was informed by the views of patients with heart failure and their carers. This was achieved in two ways:

- By securing patient organisation representation on the guideline development group
- By carrying out a focus group to ensure that the views of people directly affected by heart failure informed the development of the guideline.

Patient representatives from the Cardiomyopathy Association and the British Heart Foundation were members of the GDG. They were therefore involved at every stage of the guideline development process and were able to consult with their wider constituencies throughout the process.

Drafting the Recommendations

Evidence for each topic was extracted into tables and summarised in evidence statements. The GDG reviewed the evidence tables and statements at each meeting and reached a group opinion. Recommendations were explicitly linked to the evidence supporting them and graded according to the level of the evidence upon which they were based, using the grading system detailed in Section 3 of the full guideline document and in the section of this summary titled "Rating Scheme for the Strength of the Recommendations." It should be noted that the level of evidence determines the grade assigned to each recommendation and as such does not necessarily reflect the importance attached to the recommendation.

Agreeing the Recommendations

Once the evidence review had been completed and an early draft of the guideline produced, a one-day meeting of the CRG was held to finalise the recommendations. This included a premeeting vote on the recommendations and a further vote at the CRG meeting, where the groups were asked to consider the draft guideline in two stages.

1. Are the evidence-based statements acceptable and is the evidence cited sufficient to justify the grading attached?
2. Are the recommendations derived from the evidence justified and are they sufficiently practical so that those at the clinical front line can implement them prospectively? There were three types of recommendation to be considered:
    - A recommendation from the GDG based on strong evidence – usually non-controversial unless there was important evidence that had been missed or misinterpreted
    - A recommendation that was based on good evidence but where it was necessary to extrapolate the findings to make it useful in the National Health Society (NHS) – the extrapolation approved by consensus
    - Recommendations for which no evidence exists but which address important aspects of heart failure care or management – and for which a consensus on best practice could be reached

This formal consensus method has been established within the NCC-CC, drawing on the knowledge set out in the health technology appraisal, and practical

experience. It approximates to a modification of the RAND Nominal Group Process and will be fully described in future publications.

Writing the Guideline

The guideline was drawn up by the technical team in accordance with the decisions of the guideline groups.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Typical Grading of Recommendations

A: At least one randomised controlled trial as part of a body of literature of overall good quality and consistency addressing the specific recommendation **(evidence levels Ia and Ib)**

B: Well-conducted clinical studies but no randomised clinical trials on the topic of recommendation **(evidence levels IIa, IIb, and III)**

C: Expert committee reports or opinions and/or clinical experience of respected authorities. This grading indicates that directly applicable clinical studies or good quality are absent **(evidence level IV)**.

GPP: Recommended good practice based on the clinical experience of the Guideline Development Group

DS: Diagnostic studies

NICE: Evidence from the National Institute for Clinical Excellence (NICE) guidelines or health technology appraisal programme.

COST ANALYSIS

Identified titles and abstracts from the economics searches were reviewed by the health economist and full papers obtained as appropriate. The full papers were critically appraised by the health economist and the relevant data was conveyed to the Guideline Development Group alongside the clinical evidence for each question. Given that the economics searches were so broad and that no standard measure of assessing the quality of economic evidence is available, careful consideration was given to each study design and the applicability of the results to the guideline context. An important issue in this respect is that much of the evidence on costs and benefits comes from the healthcare system in the United States and is therefore of limited applicability to a United Kingdom guideline.

As well as presenting existing evidence on the costs and benefits of a broad range of interventions to the Guideline Development Group, the issue of echocardiography in the diagnosis of heart failure was identified as an important area for further economic analysis. This choice was made on the grounds that the diagnostic procedure may be associated with:

- Potentially large health benefits

- A potentially large effect on National Health Service resources
- Uncertainty surrounding the benefits and resources
- A potentially large service impact

While health economic analysis can provide a framework for collating information from a variety of sources in order to estimate and systematically compare costs and benefits, this is a complex and labour-intensive process, and it does require a level of clinical evidence that is not always readily available. As a result the cost effectiveness of echocardiography in the diagnosis of heart failure was the only issue prioritised for further analysis. The results of this analysis are discussed briefly in section 6.1 of the full guideline document, with further detail in Appendix G of the full guideline document.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The draft guideline was circulated to stakeholders according to the formal National Institute for Clinical Excellence (NICE) stakeholder consultation and validation phase prior to publication, and modifications, agreed by the Guideline Development Group, were made as a result.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Evidence categories (Ia-IV) and recommendation grades (A-C) are defined at the end of the Major Recommendations field.

In addition to evidence-based recommendations, the guideline development group (GDG) also identifies good practice points (GPP) as well as evidence from diagnostic studies (DS) and from the National Institute for Clinical Excellence (NICE) guidelines or health technology appraisal programme (NICE).

Diagnosing Heart Failure

The full evaluation of heart failure is more than stating whether the syndrome is present or not; it requires consideration of the underlying abnormality of the heart, the severity of the syndrome, the aetiology, precipitating and exacerbating factors, identification of concomitant disease relevant to the management, and an estimation of prognosis. It is important to exclude other conditions that may masquerade as heart failure (see below and Table 2 in the full version of the original guideline document).

Other Conditions That May Present with Similar Symptoms

- Obesity

- Chest disease – including lung, diaphragm, or chest wall
- Venous insufficiency in lower limbs
- Drug-induced ankle swelling (e.g., dihydropyridine calcium channel blockers)
- Drug-induced fluid retention (e.g., nonsteroidal anti-inflammatory drugs [NSAIDs])
- Hypoalbuminaemia
- Intrinsic renal or hepatic disease
- Pulmonary embolic disease
- Depression and/or anxiety disorders
- Severe anaemia or thyroid disease
- Bilateral renal artery stenosis

*Elderly patients are likely to have a number of concomitant medical problems.

Cardiac Assessment

GPP - Take a careful and detailed history and perform a clinical examination. These should be combined with tests to confirm the presence of heart failure and make a complete diagnosis.

B - Health care professionals should seek to exclude a diagnosis of heart failure through the following investigations:

- 12-lead electrocardiography (ECG)
- and/or natriuretic peptides (B-type natriuretic peptide [BNP] or N-terminal pro-B-type natriuretic peptide [NTproBNP]) – where available

If one or both are abnormal, a diagnosis of heart failure cannot be excluded and transthoracic Doppler 2-dimensional (2D) echocardiography should be performed because it consolidates the diagnosis and provides information on the underlying functional abnormality of the heart.

GPP - Efforts should be made to exclude other disorders that may present in a similar manner.

GPP – To evaluate possible aggravating factors and/or alternative diagnoses the following tests are recommended.

- Chest x-ray
- Blood tests:
    - Biochemical profile including electrolytes, urea, and creatinine
    - Full blood count
    - Thyroid function tests
    - Liver function tests
    - Fasting lipids
    - Fasting glucose
- Urinalysis
- Peak flow or spirometry

GPP – Transthoracic Doppler 2D echocardiographic examination should be performed to exclude important valve disease, assess the systolic (and diastolic) function of the (left) ventricle, and detect intracardiac shunts.

GPP – Transthoracic Doppler 2D echocardiographic studies 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.

GPP – The reporting of Doppler 2D echocardiography should be by those experienced in doing so.

B – Alternative methods of imaging the heart should be considered when a poor image is produced by echocardiography. Such methods may include radionuclide angiography, cardiac magnetic resonance imaging, or transoesophageal Doppler 2D echocardiography.

Diastolic Heart Failure

GPP - Where the diagnosis is unclear, or if a diagnosis of diastolic heart failure is being considered, the patient should be referred for more specialist assessment.

Review of Existing Diagnoses

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

GPP - 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.

Treating Heart Failure

Treatments are available that can improve the life expectancy and quality of life of a person with heart failure. Treatment recommendations are given below and include aspects of lifestyle, pharmacological therapy, and invasive procedures. It is also helpful to consider the need to keep patients fully informed about their condition and the treatment options, and this is reflected in the recommendations.

Lifestyle

Exercise Training and Rehabilitation

B - Patients with heart failure should be encouraged to adopt regular aerobic and/or resistive exercise. This may be more effective when part of an exercise programme or a programme of rehabilitation.

Smoking

GPP - Patients must be strongly advised not to smoke. Referral to smoking cessation services should be considered.

Alcohol

C - Patients with alcohol-related heart failure should abstain from drinking alcohol.

GPP - Health care professionals should discuss alcohol consumption with the patient and tailor their advice appropriately to the clinical circumstances.

Sexual Activity

GPP - Health care professionals should be prepared to broach sensitive issues with patients, such as sexual activity, as these are unlikely to be raised by the patient.

Vaccination

GPP - Patients with heart failure should be offered an annual vaccination against influenza.

GPP - Patients with heart failure should be offered vaccination against pneumococcal disease (only required once).

Air Travel

GPP - Air travel will be possible for the majority of patients with heart failure, depending on their clinical condition at the time of travel.

Driving Regulations

GPP - Heavy Goods Vehicle and Public Service Vehicle license: physicians should be up to date with the latest Driver and Vehicle Licensing Authority guidelines. Check the Web site for regular updates: www.dvla.gov.uk/

Pharmacological Therapy for Patients with Heart Failure due to Left Ventricular (LV) Systolic Dysfunction

Drug therapy is required for the vast majority of patients with heart failure. It is the responsibility of the individual prescriber to check the dosage of medication. This document should be read as a guide to treatment rather than being considered a protocol that must be followed prescriptively in all patients. Treatment should be tailored to the individual patient, with referral for more specialist advice being considered where appropriate.

Note that at the time of issue of this guideline, the following drugs in this guideline are unlicensed in the United Kingdom for the treatment of heart failure or its common signs or symptoms.

- Angiotensin II receptor antagonists

- The positive inotropic agents (Dobutamine and Dopamine)
- Calcium channel blockers (Amiodipine)

Recommendations on Specific Drugs

Recommendations for pharmacological therapy for patients with heart failure due to left ventricular systolic dysfunction are summarised in the algorithm on page 22 in the full version of the original guideline document.

Diuretics

C - Diuretics should be routinely used for the relief of congestive symptoms and fluid retention in patients with heart failure and should be titrated (up and down) according to need following the initiation of subsequent heart failure therapies. Please refer to Table 4 in the full version of the original guideline document for information on specific dosages and side effects of diuretics.

Angiotensin-converting Enzyme (ACE) Inhibitors

A - All patients with heart failure due to left ventricular systolic dysfunction should be considered for treatment with an ACE inhibitor. Please refer to Table 5 in the full version of the original guideline document for information on practical recommendations on the use of ACE inhibitors.

A - ACE inhibitor therapy should be instituted in patients with heart failure due to left ventricular systolic dysfunction before beta-blockade is introduced.

GPP - ACE inhibitor therapy should be initiated at the appropriate dose and titrated upwards at short intervals (for example, every 2 weeks) until the optimal tolerated or target dose is achieved. (Refer to Table 5 in the full version of the original guideline document for information on practical recommendations on the use of ACE inhibitors.)

GPP – Blood biochemistry (urea, creatinine, and electrolytes) should be measured after initiation and at each dose increment.

Beta-blockers

A - Beta-blockers licensed for use in heart failure should be initiated in patients with heart failure due to left ventricular systolic dysfunction after diuretic and ACE inhibitor therapy (regardless of whether or not symptoms persist). (Refer to Table 6 in the full version of the original guideline for information on practical recommendations on the use of beta-blockers.)

C - Beta-blockade therapy for heart failure should be introduced in a "start low, go slow" manner, with assessment of heart rate, blood pressure, and clinical status after each titration.

GPP - Patients who develop heart failure due to left ventricular systolic dysfunction and who are already on treatment with a beta-blocker for a concomitant condition (for example, angina, hypertension) should continue with a

beta-blocker – either their current beta-blocker or an alternative licensed for heart failure treatment.

Aldosterone Antagonists

A - Patients with heart failure due to left ventricular systolic dysfunction who remain moderately to severely symptomatic despite optimal therapy (as outlined in the algorithm in the original guideline document) should be prescribed spironolactone at a dose of 12.5 to 50 mg once per day, and specialist advice should be sought. (Refer to Table 7 in the full version of the original guideline document for specific information on practical recommendations for the use of spironolactone.)

GPP - Patients with heart failure taking spironolactone should have blood potassium and creatinine levels monitored for signs of hyperkalaemia and/or deteriorating renal function. If hyperkalaemia is a problem, then the dose of spironolactone should be halved and biochemistry rechecked.

Digoxin

Digoxin is recommended for:

- **A** - Worsening or severe heart failure due to left ventricular systolic dysfunction despite ACE inhibitor, beta-blocker, and diuretic therapy
- **C** - Patients with atrial fibrillation and any degree of heart failure

Angiotensin II Receptor Antagonists

A - At the time of issue of this guideline, angiotensin II receptor antagonists are not licensed in the United Kingdom for heart failure and studies are ongoing. However, angiotensin II receptor antagonists may provide an alternative to ACE inhibitors for patients intolerant of ACE inhibitors (for example, because of cough). (Refer to Table 8 of the full version in of the original guideline document for specific information on currently available angiotensin II receptor antagonists.)

GPP - The triple combination of ACE inhibitor, beta-blocker, and angiotensin II receptor antagonist should be avoided, pending the results of further trials.

Amiodarone

GPP - The decision to prescribe amiodarone should be made in consultation with a specialist.

GPP - The need to continue the prescription should be reviewed regularly.

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

Anticoagulants

A - Anticoagulation is indicated for patients with the combination of heart failure and atrial fibrillation (also refer to the recommendations below concerning patients with heart failure and atrial fibrillation).

GPP - 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.

Aspirin

B - 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).

Statins (Hydroxymethylglutaryl-coenzyme A Reductase Inhibitors)

GPP - Patients with the combination of heart failure and known atherosclerotic vascular disease should receive statins only in accordance with current indications. Specific trials in this area are ongoing.

Isosorbide/hydralazine Combination (Specialist Initiation Only)

A - An isosorbide/hydralazine combination may be used in patients with heart failure who are intolerant of ACE inhibitors or angiotensin II receptor antagonists.

Inotropic Agents (specialist use only)

A - 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.

Calcium Channel Blockers

A - Amlodipine 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.

Major Comorbidities that Impact on the Pharmacological Management of Heart Failure

The presence of certain comorbidities may affect the drugs that can be used for the treatment of heart failure or increase the likelihood of side effects. The major comorbidities that impact on the management of heart failure are summarised in Table 9 in the full version of the original guideline document.

Side Effects of Drugs Commonly Used in the Treatment of Heart Failure

All drugs have side effects. See the Summary of Product Characteristics for individual drugs for details.

Improving Adherence to Pharmacological Therapy

B - Dosing regimens should be kept as simple as possible, and the health care professional should ensure that the patient and carer are fully informed about their medication.

Invasive Procedures

Although drug therapy is the mainstay of treatment of heart failure, some patients will also benefit from diagnostic or interventional invasive procedures. These procedures are normally organised by a specialist. This guideline can only give general advice, and specialist advice is strongly recommended where such procedures might be considered.

Coronary Revascularisation

C - Coronary revascularisation should not be **routinely** considered in patients with heart failure due to systolic left ventricular impairment, unless they have refractory angina.

Cardiac Transplantation

C - Specialist referral for transplantation should be considered in patients with severe refractory symptoms or refractory cardiogenic shock.

Cardiac Resynchronisation Therapy

A - Resynchronisation therapy should be considered in selected patients with left ventricular systolic dysfunction (left ventricular ejection fraction $\leq$35%), drug refractory symptoms, and a QRS duration >120 ms. The results of ongoing trials will help guide appropriate patient selection.

Implantable Cardioverter-Defibrillators (ICDs)

NICE 2000 – Recommendation from *NICE Technology Appraisal Guidance No. 11*, "Guidance on the use of implantable cardioverter defibrillators for arrhythmias" (Available from: www.nice.org.uk/Docref.asp?d=10239).

The use of ICDs should be routinely considered for patients in the following categories:

1. Secondary prevention, that is for patients who present, in the absence of a treatable cause, with:
    - Cardiac arrest due to either ventricular tachycardia (VT) or ventricular fibrillation
    - Spontaneous sustained VT causing syncope or significant haemodynamic compromise
    - Sustained VT without syncope/cardiac arrest, and who have an associated reduction in ejection fraction (less than 35%) but are no worse than Class III* of the New York Heart Association functional classification of heart failure

2. "Primary prevention" for patients with:
    - A history of previous myocardial infarction and all of the following:
        - Non-sustained VT on Holter (24-hour ECG) monitoring
        - inducible VT on electrophysiological testing
        - Left ventricular dysfunction with an ejection fraction less than 35% and no worse than Class III* of the New York Heart Association functional classification of heart failure
    - A familial cardiac condition with a high risk of sudden death, including long QT syndrome, hypertrophic cardiomyopathy, Brugada syndrome, arrhythmogenic right ventricular dysplasia, and following repair of tetralogy of Fallot.

*Note: Marked limitation of physical activity. Although patients are comfortable at rest, less than ordinary physical activity will lead to symptoms (symptomatically "moderate" heart failure)

Oxygen Therapy and Continuous Airway Pressure

The evidence for oxygen therapy and continuous positive airway pressure was considered during development of this guideline, but it was not possible to make specific recommendations because of the small evidence base. For further details, see the full version of the original guideline document.

Recommendations for Treatment of Heart Failure Not Due to Left Ventricular Systolic Dysfunction

Valve Disease

C - Patients with heart failure due to valve disease should be referred for specialist assessment and advice regarding follow-up.

C - ACE inhibitor therapy should not be initiated in a patient with a clinical suspicion of haemodynamically significant valve disease, until the valve disease has been assessed by a specialist.

Patients with valve disease (but no heart failure) should also be assessed by a specialist, as the onset of heart failure increases the risk of surgery and reduces the likelihood of full recovery.

Diastolic Dysfunction

GPP - The diagnosis and treatment of diastolic dysfunction 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.

Other Causes

The management of other causes of heart failure requires specialist input. This would include congenital heart disease, cardiomyopathies, and specific heart muscle disease such as amyloid.

Recommendations for Patients with Heart Failure and Atrial Fibrillation

C - For patients with heart failure and atrial fibrillation, specialist advice should be sought as to whether the aim is improvement of heart rate control or cardioversion (return to sinus rhythm).

A - Anticoagulation is indicated for patients with heart failure and atrial fibrillation (see also recommendations above concerning anticoagulation).

Recommendations for Different Subgroups of Patients with Heart Failure

Age

A - The management of heart failure should be determined by clinical criteria, irrespective of the age of the patient.

GPP - Tolerance of drugs may be lower and side effects require closer and more frequent monitoring in older patients.

Gender

GPP - The principles of pharmacological management of heart failure should be the same for men and women.

GPP - The potential teratogenic effects of drugs should be considered.

Pregnancy

GPP - 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.

Ethnicity

GPP - The principles of pharmacological management should be the same for all patients with heart failure, regardless of ethnicity.

Monitoring

The clinical condition of a person with heart failure may fluctuate, and repeated admission to hospital is common, particularly for patients with more severe heart failure. Monitoring of clinical status is necessary and will involve health care professionals in both primary and secondary care. Patients and their carers are playing an increasing role in monitoring, but this requires appropriate education and support.

Clinical Review

GPP - All patients with chronic heart failure require monitoring. This monitoring should include (Refer to the information below and to section 8.1 in the full version of the original guideline document for specific information on assessments to be made at clinical review):

- 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, and creatinine*

*Note: This is a minimum. Patients with comorbidities or coprescribed medications will require further monitoring. Monitoring serum potassium is particularly important if a patient is taking digoxin or spironolactone.

Assessments to be Made at Clinical Review

Assessment of Functional Capacity

Chiefly from history, but more objectively by use of New York Heart Association class, specific quality-of-life questionnaires, 6-minute walk test, or maximal exercise test. Note: Not all of these tests are likely to be necessary or appropriate at each assessment.

Assessment of Fluid Status

Chiefly by physical examination – changes in body weight, extent of jugular venous distension, lung crackles and hepatomegaly, extent of peripheral oedema, and lying and standing blood pressure (postural drop in blood pressure may indicate hypovolaemia)

Assessment of Cardiac Rhythm

Chiefly by clinical examination, but may require 12-lead electrocardiogram (ECG) or 24-hour electrocardiographic ("Holter") monitoring if suspicion of arrhythmia

Laboratory Assessment

Checking of serum biochemistry (urea, electrolytes, creatinine) is essential, but other tests (such as thyroid function, haematology, liver function, level of anticoagulation) may also be required depending on the medication prescribed and comorbidity.

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

GPP – 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.

GPP- Patients who wish to be involved in monitoring of their condition should be provided with sufficient education and support from their health care professional to do this, with clear guidelines as to what to do in the event of deterioration.

Therapeutic Drug Monitoring of Serum Digoxin Concentrations

GPP – 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-compliance.

GPP – The serum digoxin concentration should be interpreted in the clinical context, as toxicity may occur even when the concentration is within the "therapeutic range."

Referral and Approach to Care

The management of heart failure is likely to be shared between health care professionals in both primary and secondary care. Patients and their carers are increasingly involved in management decisions. Work with patient focus groups suggests that the major failings of management relate to poor communication between health care professionals, and between health care professionals and the patients they care for.

Referral for More Specialist Advice

GPP - Patients with heart failure require specialist advice in the following situations:

- Heart failure due to valve disease, diastolic dysfunction or any other cause except left ventricular systolic dysfunction
- One or more of the comorbidities outlined in Table 9 in the full version of the original guideline document
- Angina, atrial fibrillation, or other symptomatic arrhythmia
- Women who are planning a pregnancy or who are pregnant

GPP - The following situations also require referral:

- Severe heart failure
- Heart failure that does not respond to treatment as discussed in this guideline and outlined in the algorithm on page 54 in the full version of the original guideline document
- Heart failure that can no longer be managed effectively in the home setting

Discharge Planning

GPP - 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.

GPP - The primary care team, patient and carer must be aware of the management plan.

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

Multidisciplinary Team Approach to Heart Failure Management

A - Heart failure care should be delivered by a multidisciplinary team with an integrated approach across the health care community.

Non-National Health Service (NHS) Agencies

GPP - Standard one of The Older People National Service Framework (NSF) 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.doh.gov.uk/nsf/olderpeople.htm)

GPP - 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.

GPP - 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.

GPP - The education needs of non-NHS agency carers should be considered.

Supporting Patients and Carers

Understanding the information needs of patients and carers is vital. Key issues identified by patient focus groups include the importance of honesty and accurate information, and the potential value of support groups. The recommendations below are based on earlier consensus guidelines produced by a Royal College of Physicians´ working party.

Communication

GPP - Good communication between health care professionals and patients and carers is essential for the best management of heart failure.

C - 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.
- Provide the most important information first.

- Explain how each item will affect patients personally.
- Present information in separate categories.
- Make advice specific, detailed, and concrete.
- Use words the patients will understand; confirm understanding by questions; define unfamiliar words; write down key words; draw diagrams, and keep a copy in the medical notes.
- Repeat the information using the same words each time.
- Prepare material, written or taped, to back up handwritten notes.
- 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.

C - The content, style and timing of information provision should be tailored to the needs of the individual patient.

GPP - Health care professionals should assess cognitive ability when sharing information.

GPP - Carers and relatives of patients who are cognitively impaired should be made aware of treatment regimens for the patients they care for and be encouraged to identify any need for clinical support.

GPP - Management of heart failure should be seen as a shared responsibility between patient and health care professional.

GPP - 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.

Prognosis

GPP – Prognosis should be discussed with patients and carers in a sensitive, open, and honest manner.

Support Groups

GPP – Health care professionals should be aware of local cardiac support networks and provide this information to patients and carers.

Anxiety and Depression

Depression tends to be more common in patients with heart failure than in the general population. Drug therapy with antidepressants may lead to complications such as fluid retention, hypotension, and arrhythmias.

C - The diagnosis of depression should be considered in all patients with heart failure.

C - 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.

C - Where it is apparent that depression is co-existing with heart failure, then the patient should be treated for depression following the NICE guideline ("Depression: the management of depression in primary and secondary care"), scheduled for publication in February 2004.

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

GPP - Patients with heart failure should consult a health care professional before using over-the-counter therapies for depression such as St John´s wort (*Hypericum perforatum*). Health care professionals should be aware of the potential interaction with prescribed medication and should always ask about self-medication, including the use of herbal products.

End of Life Issues

There is substantial evidence for considerable unmet palliative needs of patients with heart failure and their informal carers. The main areas of need include symptom control, psychological and social support, planning for the future, and end of life care.

GPP - 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.

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

GPP - Patients with heart failure and their carers should have access to professionals with palliative care skills within the heart failure team.

Definitions:

Evidence Categories

Ia: Evidence obtained from systematic review of meta-analysis of randomised controlled trials

Ib: Evidence obtained from at least one randomised controlled trial

IIa: Evidence obtained from at least one well-designed controlled study without randomisation

IIb: Evidence obtained from at least one other type of well-designed quasi-experimental study

III: Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies and case studies

IV: Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities.

Grading of Recommendations

A: At least one randomised controlled trial as part of a body of literature of overall good quality and consistency addressing the specific recommendation **(evidence levels Ia and Ib)**

B: Well-conducted clinical studies but no randomised clinical trials on the topic of recommendation **(evidence levels IIa, IIb, and III)**

C: Expert committee reports or opinions and/or clinical experience of respected authorities. This grading indicates that directly applicable clinical studies or good quality are absent **(evidence level IV)**.

GPP: Recommended good practice based on the clinical experience of the Guideline Development Group

DS: Diagnostic studies

NICE: Evidence from the National Institute for Clinical Excellence (NICE) guidelines or health technology appraisal programme

CLINICAL ALGORITHM(S)

Algorithms are provided in the original guideline document for the summarisation of recommendations for the diagnosis of heart failure and for the pharmacological treatment of symptomatic heart failure due to left ventricular (LV) systolic dysfunction.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

A more equitable and evidence-based approach to the diagnosis and treatment of heart failure in adults in England and Wales

POTENTIAL HARMS

Refer to the full version of the original guideline document for information on possible side effects of medications.

CONTRAINDICATIONS

CONTRAINDICATIONS

- Beta-blockers are contraindicated in patients with reversible airways disease.
- Absolute contraindications to the use of angiotensin-converting enzyme (ACE) inhibitors include a history of anuria or angioedema with past exposure to the drug, bilateral renal artery stenosis, pregnancy, and cardiogenic shock. Hypotension is not necessarily a contraindication, but consultation with a specialist is advised before use in a patient with a systolic blood pressure less than 80 mmHg.
- ACE inhibitors and angiotensin-II receptor antagonists may be contraindicated in patients with renal dysfunction (e.g., serum creatinine >200 micromoles/litre). Patient requires specialist assessment.
- Peripheral vascular disease may be an absolute contraindication to beta-blocker ACE inhibitor therapy where there is a high index of suspicion for renal artery stenosis.
- Verapamil, diltiazem, or short-acting dihydropyridine agents should be avoided for treatment of comorbid hypertension and/or angina in patients with heart failure.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

This guidance is written in the following context: This guidance represents the view of the Guideline Development Group and the National Institute for Clinical Excellence, which was arrived at after careful consideration of the evidence available. Health professionals in the National Health Service in England and Wales are expected to take it fully into account when exercising their clinical judgment. The guidance does not, however, override the individual responsibility of health professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

It should be noted that the level of evidence determines the grade assigned to each recommendation and as such does not necessarily reflect the importance attached to the recommendation.

Guideline Limitations

The document and recommendations are subject to various limitations. The sponsoring authority, the National Institute for Clinical Excellence (NICE), is concerned primarily with health services, and so these recommendations only indirectly refer to social services, the voluntary sector, and post-transplant care. Nonetheless, the importance of other agencies cannot be overstated and in each locality the aim should be to integrate heart failure care across all relevant sectors.

A systematic approach was used to locate and appraise the evidence and explicit inclusion criteria were applied. Due to the magnitude of the literature potentially relevant to heart failure, the inclusion criteria aimed to limit the included studies to those of a higher quality conducted primarily in patients with heart failure. Where these were not available, well-conducted studies outside heart failure, or lower level studies in patients with heart failure, were included.

Unpublished Trials

The developers have referred in the text to all key ongoing trials which the developers were aware were going to publish within months of the cut-off date for literature searches, and which, in the opinion of the guideline development group, could conceivably impact on the guideline. This is intended to help the reader in using the guideline in the near future. The findings of such trials did not influence the formulation of recommendations in any way.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Implementation in the National Health Service

Local health communities should review their existing service provision for the management of heart failure against this guideline as they develop their Local Delivery Plans. The review should consider the resources required to implement fully the recommendations detailed below and in Section 1 of the original guideline document, the people and processes involved, and the timeline over which full implementation is envisaged. It is in the interests of patients that the implementation timeline is as rapid as possible.

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

Suggested audit criteria are listed in Appendix E of the original guideline document.

The following recommendations have been identified as priorities for implementation.

Diagnosis

- The basis for historical diagnoses of heart failure should be reviewed, and only patients whose diagnosis is confirmed should be managed in accordance with this guideline.
- Doppler 2D echocardiographic examination should be performed to exclude important valve disease, assess the systolic (and diastolic) function of the (left) ventricle, and detect intracardiac shunts.

Treatment

- All patients with heart failure due to left ventricular systolic dysfunction should be considered for treatment with an angiotensin-converting enzyme (ACE) inhibitor.
- Beta-blockers licensed for use in heart failure should be initiated in patients with heart failure due to left ventricular systolic dysfunction after diuretic and ACE inhibitor therapy (regardless of whether or not symptoms persist).

Monitoring

- All patients with chronic heart failure require monitoring. This monitoring should include:
    - A clinical assessment of functional capacity, fluid status, cardiac rhythm, and cognitive and nutritional status
    - A review of medication, including need for changes and possible side effects
    - Serum urea, electrolytes, and creatinine

Discharge

- Patients with heart failure should generally be discharged from hospital only when their clinical condition is stable and the management plan is optimised.
- The primary care team, patient, and carer must be aware of the management plan.

Supporting Patients and Carers

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

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

End of Life Care
Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

National Collaborating Centre for Chronic Conditions. Chronic heart failure. National clinical guideline for diagnosis and management in primary and secondary care. London: National Institute for Clinical Excellence (NICE); 2003. 163 p. [347 references]

ADAPTATION

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

DATE RELEASED

2003 Jul

GUIDELINE DEVELOPER(S)

National Collaborating Centre for Chronic Conditions - National Government Agency [Non-U.S.]

SOURCE(S) OF FUNDING

National Institute for Clinical Excellence (NICE)

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Guideline Development Group (GDG)
Consensus Reference Group (CRG)

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* Attended and contributed to at least one GDG meeting

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

All group members made a formal 'declaration of interests' at the start of the guideline development and provided updates throughout the process. The National Collaborating Centre for Chronic Conditions (NCC-CC) and the group leaders monitored these, and no conflicts were identified.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format [PDF] format from the National Institute for Clinical Excellence (NICE) Web site.

Print copies: Available from the Royal College of Physicians of London, 11 St. Andrews Place, London NW1 4LE, UK. Telephone +44 (0)20 7935 1174

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- National Collaborating Centre for Chronic Conditions. Chronic heart failure. Management of chronic heart failure in adults in primary and secondary care. London (UK): National Institute for Clinical Excellence (NICE); 2003 Jul. 40 p. (Clinical Guideline; no. 5).

Electronic copies: Available in Portable Document Format [PDF] format from the National Institute for Clinical Excellence (NICE) Web site.

Print copies: Available from the National Health Service (NHS) Response Line 0870 1555 455, ref: N0247.

PATIENT RESOURCES

The following is available:

- Management of heart failure: Understanding NICE guidance – information for people with heart failure, their carers, and the public. National Institute for Clinical Excellence (NICE), 2003 Jul. 21 p.

Electronic copies: Available in Portable Document Format (PDF) from the National Institute for Clinical Excellence (NICE) Web site.

Print copies: Available from the National Health Service (NHS) Response Line 0870 1555 455, ref N0248. 11 Strand, London, WC2N 5HR.

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 to 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.

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