



Complete Summary

GUIDELINE TITLE

Clinical guidelines for type 2 diabetes. Prevention and management of foot problems.

BIBLIOGRAPHIC SOURCE(S)

National Collaborating Centre for Primary Care. Clinical guidelines for type 2 diabetes. Prevention and management of foot problems. London (UK): National Institute for Clinical Excellence (NICE); 2004 Jun. 104 p. [194 references]

GUIDELINE STATUS

This is the current release of the guideline.

This release updates a previously published guideline: Royal College of General Practitioners. Clinical guidelines for type 2 diabetes: prevention and management of foot problems. London: Royal College of General Practitioners; 2000 Apr. 96 p.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Foot problems in patients with type 2 diabetes

Note: This guideline does not address the issue of neuropathic pain in people with diabetes.

GUIDELINE CATEGORY

Counseling
Diagnosis
Evaluation
Management
Prevention
Risk Assessment
Treatment

CLINICAL SPECIALTY

Endocrinology
Family Practice
Internal Medicine
Podiatry

INTENDED USERS

Health Care Providers
Hospitals
Nurses
Patients
Physicians
Podiatrists
Public Health Departments

GUIDELINE OBJECTIVE(S)

To provide a standard set of recommendations for the prevention and management of foot problems in patients with type 2 diabetes mellitus

TARGET POPULATION

Adults and children with type 2 diabetes cared for by primary and secondary healthcare professionals

Note: The guideline does not cover people who have not been diagnosed as having type 2 diabetes, for example, those in a pre-diabetic state or people with impaired glucose tolerance.

INTERVENTIONS AND PRACTICES CONSIDERED

1. Organisation of care, including arrangement of recall and frequent review as part of ongoing care, and management by multidisciplinary foot care and foot protection teams
2. Foot care education interventions
3. Screening for the foot at raised risk of ulceration (testing of foot sensation using a 10-g monofilament or vibration, palpation of foot pulse, inspection of foot deformity, inspection of footwear)
4. Encouragement of self-monitoring and self-care
5. Footwear in patients at raised risk
6. Management of foot care emergencies

7. Investigation and treatment of vascular insufficiency
8. Systemic antibiotic therapy for foot ulcers
9. Dressings and topical agents for foot ulcers

Currently, there is not sufficient trial evidence to recommend the use of growth factors, topical ketanserin, hyperbaric oxygen therapy, or cultured human dermis (or equivalent).

MAJOR OUTCOMES CONSIDERED

- Cost effectiveness
- Sensitivity and specificity of diagnostic tests
- Morbidity
- Mortality
- Haemoglobin A_{1c}
- Ulcer rate
- Amputation rate
- Compliance
- Skin condition
- Wound healing
- Time to wound healing
- Infection response
- Ulcer size
- Hospitalization

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

This guideline is an update of the guideline entitled *Clinical Guidelines and Evidence Review for Type 2 Diabetes: Prevention and Management of Foot Problems* originally published by the Royal College of General Practitioners. The update incorporated newly identified and accepted research evidence into the existing evidence review, undertaken for the development of the original guideline. The Guideline Development Group therefore considered the entire body of evidence--that previously identified and that newly identified--in its discussions.

Sifting and Reviewing the Evidence

Studies were considered for inclusion if they addressed some aspect of screening, management, care, prevention or education relating to the foot care of people with diabetes. In each area considered, the best evidence available was used. For interventions, the guideline developers only considered systematic reviews or meta-analyses of randomised controlled trials, or randomised controlled trials.

Studies which addressed Type 1 as well as Type 2 diabetes were included since, although their aetiology is different, their management is almost identical. Most of

the evidence is presented as a qualitative overview (narrative) as it was not possible (on the whole) to undertake and present a meta-analysis of studies.

Review of Existing Economic Studies

Both the original guideline and this revision searched for existing papers that were economic studies. Additionally any cost or cost-effectiveness information included in any paper was considered. The original guideline included a systematic appraisal of available evidence of effectiveness, compliance, safety, and health service resource use and costs of medical care for foot complications in Type 2 diabetes. Following the review, economic analyses attempted a robust presentation showing the possible bounds of cost-effectiveness that may result. The range of values used to generate low and high cost-effectiveness estimates reflected available evidence and the concerns of the original development group. In this revision any additional economic studies were identified and included.

Undertaking of Own Economic Studies

Additional economic analyses (including modelling) were not undertaken due to the lack of available, robust information about the areas of potential interest.

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

- I. Evidence from:
 - meta-analysis of randomised controlled trials, or
 - at least one randomised controlled trial
- II. Evidence from:
 - at least one controlled study without randomization, or
 - at least one other type of quasi-experimental study
- III. Evidence from non-experimental descriptive studies, such as comparative studies, correlation studies, and case-control studies
- IV. Evidence from expert committee reports or opinions and/or clinical experience of respected authorities

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The guideline recommendations were developed by a multidisciplinary and lay Guideline Development Group (GDG) which was convened by the National Collaborating Centre for Primary Care. The GDG comprised both members from the original development group and new members. Two service users were identified via Diabetes UK. The guideline development group consisted of relevant health care professionals, patient representatives and guideline developers, including a systematic reviewer.

The derivation of recommendations usually involves assessment of evidence, processes of interpretation and consensus to arrive at recommendations. The mix of evidence, interpretation and consensus will vary between topic areas. The grading of recommendations takes account of this and therefore variation may occur between different groups presented with the same evidence. Whilst evidence statements can be formulated without reference to the context in which clinicians practice, this is not always the case with recommendations.

Areas without Consensus

There may be areas where the group was unable to reach consensus on an area, no matter whether evidence is available or not. Where this has happened there is scope to report that a consensual recommendation could not be reached, to present the opposing views, and leaving the final view to the user of the guidelines.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Recommendation Grades

- A. Directly based on category I evidence
- B. Directly based on:
 - Category II evidence, or
 - Extrapolated recommendation from category I evidence
- C. Directly based on:
 - Category III evidence, or
 - Extrapolated recommendation from category I or II evidence
- D. Directly based on:
 - Category IV evidence, or
 - Extrapolated recommendation from category I, II or III evidence

COST ANALYSIS

This guideline provides a systematic appraisal of available evidence of effectiveness, compliance, safety and health service resource use and costs of medical care for foot complications in Type 2 diabetes. Following the review, economic analyses attempt a robust presentation showing the possible bounds of cost-effectiveness that may result. The range of values used to generate low and high cost-effectiveness estimates reflect available evidence and the concerns of the original development group. In this revision any additional economic studies were identified and included.

METHOD OF GUIDELINE VALIDATION

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, and these comments were considered by the Guideline Development Group.

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

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

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

In addition to these evidence-based recommendations, the guideline development group also identifies recommendations drawn from the National Institute for Clinical Excellence (NICE) 2003 technology appraisal of patient education models for diabetes.

Foot Care in Diabetes

Foot Care: General Management Approach

D - Effective care involves a partnership between patients and professionals, and all decision making should be shared.

D - The role that any informal carers of the person with diabetes have in providing care and receiving information to allow them to fulfill this role should be discussed

with the person with diabetes, and any decisions about this should be that of the person with diabetes.

A - Arrange recall and annual review as part of ongoing care.

D - Healthcare professionals and other personnel involved in the assessment of diabetic feet should receive adequate training.

A - As part of annual review, trained personnel should examine patients' feet to detect risk factors for ulceration.

B - To improve knowledge, encourage beneficial self-care, and minimise inadvertent self-harm, healthcare professionals should discuss and agree with patients a management plan that includes appropriate foot care education. (Refer to Appendix 26 of the original guideline document about issues and topics that might be covered in patient education.)

C - Extra vigilance should be used for people who are older (over 70 years of age), have had diabetes for a long time, have poor vision, have poor footwear, smoke, are socially deprived, or live alone.

D - Healthcare professionals may need to discuss, agree, and make special arrangements for people who are housebound or living in care or nursing homes to ensure equality of access to foot care assessments and treatments.

NICE 2003 - Structured patient education should be made available to all people with diabetes at the time of initial diagnosis, and then as required on an ongoing basis, based on a formal, regular assessment of need.

A - Offer patient education on an ongoing basis. (Refer to Appendix 26 of the original guideline document for issues and topics that might be covered in patient education.)

B - Use different patient education approaches until optimal methods appear to be identified in terms of desired outcomes.

Foot Examination and Monitoring

A - Regular (at least annual) visual inspection of patients' feet, assessment of foot sensation, and palpation of foot pulses by trained personnel is important for the detection of risk factors for ulceration.

A - Examination of patients' feet should include:

- Testing of foot sensation using a 10 gram monofilament or vibration (using biothesiometer or calibrated tuning fork)
- Palpation of foot pulses
- Inspection for any foot deformity
- Inspection of footwear

C - Monofilaments should not be used to test more than ten patients in one session and should be left for at least 24 hours to "recover" (buckling strength) between sessions.

C - Classify foot risk as:

- Low current risk (normal sensation, palpable pulses)
- At increased risk (neuropathy or absent pulses or other risk factor)
- At high risk (neuropathy or absent pulses plus deformity or skin changes or previous ulcer)
- Ulcerated foot

D - Self-monitoring and inspection of feet by people with diabetes should be encouraged.

Care of People at Low Current Risk of Foot Ulcers (Normal Sensation, Palpable Pulses)

B - To improve knowledge, encourage beneficial self-care, and minimise inadvertent self-harm, healthcare professionals should discuss and agree with patients a management plan that includes appropriate foot care education (Refer to Appendix 26 of the original guideline document for issues and topics that might be covered in patient education.)

Care of People at Increased Risk of Foot Ulcer (Neuropathy or Absent Pulses or Other Risk Factor)

D - Patients with risk factors for ulceration should be referred to a foot protection team (a team with expertise in protecting the foot; typically, members of the team include podiatrists, orthotists, and foot care specialists).

D - Arrange regular review, 3 to 6 monthly, by a foot protection team.

D - At each review:

- Inspect patient's feet.
- Review need for vascular assessment.
- Evaluate footwear.
- Enhance foot care education. (Refer to appendix 26 for information about issues and topics that might be covered in patient education.)

Care of People at High Risk of Foot Ulcers (Neuropathy or Absent Pulses Plus Deformity or Skin Changes or Previous Ulcer)

A - Patients at high risk for ulceration should be referred to a foot protection team.

D - Arrange frequent review, 1 to 3 monthly, by a foot protection team.

At each review:

- **A** - Inspect patient's feet.
- **D** - Review need for vascular assessment.
- **D** - Evaluate provision and provide appropriate:
 - Intensified foot care education
 - Specialist footwear and insoles
 - Skin and nail care

D - Ensure special arrangements for access to the foot protection team for those people with disabilities or immobility.

Care of People with Foot Ulcers

D - For a new foot ulcer, urgent (within 24 hours) assessment by an appropriately trained health professional should be arranged.

D - Ongoing care of an individual with an ulcerated foot should be undertaken without delay by a multidisciplinary foot care team.

D - The multidisciplinary foot care team should comprise highly trained specialist podiatrists and orthotists, nurses with training in dressing of diabetic foot wounds, and diabetologists with expertise in lower limb complications. They should have unhindered access to suites for managing major wounds, urgent inpatient facilities, antibiotic administration, community nursing, microbiology diagnostic and advisory services, orthopaedic/podiatric surgery, vascular surgery, radiology, and orthotics.

D - Patients who may benefit from revascularisation should be referred promptly.

C - Patients with non-healing or progressive ulcers with clinical signs of active infection (redness, pain, swelling, or discharge) should receive intensive, systemic antibiotic therapy.

D - In the absence of strong evidence of clinical or cost effectiveness, healthcare professionals should use wound dressings that best match clinical experience, patient preference, and the site of the wound, and consider the cost of the dressings.

D - Wounds should be closely monitored and dressings changed regularly.

B - Dead tissue should be carefully removed from foot ulcers to facilitate healing, unless revascularisation is required.

B - Total contact casting may be considered for people with foot ulcers unless there is severe ischaemia.

D - Currently, there is a lack of trial evidence on the use of the following interventions in the treatment of foot ulcers and they are not recommended: cultured human dermis (or equivalent), hyperbaric oxygen therapy, topical ketanserin, or growth factors.

B - For patients with foot ulcers or previous amputation, healthcare professionals could consider offering graphic visualisations of the sequelae of disease and providing clear, repeated reminders about foot care.

Care of People with Charcot Osteoarthropathy

D - People with suspected or diagnosed Charcot osteoarthropathy should be referred immediately to a multidisciplinary foot care team for immobilisation of the affected joint(s) and for long-term management of offloading to prevent ulceration.

Emergency Referral

D - Refer patients to a multidisciplinary foot care team within 24 hours if any of the following occur:

- New ulceration (wound)
- New swelling
- New discolouration (redder, bluer, paler, blacker, over part or all of foot).

Definitions

Evidence Categories

- I. Evidence from:
 - meta-analysis of randomised controlled trials, or
 - at least one randomised controlled trial
- II. Evidence from:
 - at least one controlled study without randomization, or
 - at least one other type of quasiexperimental study
- III. Evidence from non-experimental descriptive studies, such as comparative studies, correlation studies, and case-control studies
- IV. Evidence from expert committee reports or opinions and/or clinical experience of respected authorities

Recommendation Grades

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 - Extrapolated recommendation from category I evidence
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 - Category III evidence, or
 - Extrapolated recommendation from category I or II evidence
- D. Directly based on:
 - Category IV evidence, or
 - Extrapolated recommendation from category I, II or III evidence

CLINICAL ALGORITHM(S)

An algorithm is provided in the original guideline document for the pathway of care for the prevention and management of foot problems in patients with type 2 diabetes.

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

Appropriate and careful management of patients with type 2 diabetes can delay or prevent foot complications. Preventive measures and rapid and intensive treatment of foot complications may help to minimize serious sequelae, such as the need for amputation.

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- This guidance represents the view of the Institute, which was arrived at after careful consideration of the evidence available. Health professionals are expected to take it fully into account when exercising their clinical judgement. 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.
- The guideline does not include identification of undiagnosed diabetes, the general management of diabetes (other than aspects that relate to the prevention of foot complications), or the management of foot problems in people who do not have type 2 diabetes. The guideline does not cover surgical procedures, amputation, or post-amputation rehabilitation. The guideline does not cover neuropathic pain.
- Guidelines are only one type of information that healthcare professionals may use when making decisions about patient care. It is assumed that this guideline, like all guidelines, will be used by healthcare professionals who will also bring to bear their clinical knowledge and judgement in making decisions about caring for individual patients. It may not always be appropriate to apply either specific recommendations or the general messages in this document to each individual or in every circumstance.

DESCRIPTION OF IMPLEMENTATION STRATEGY

Implementation in the National Health Service (NHS)

Local health communities should review their existing service provision for people with diabetes against this guideline. The review should consider the resources required to implement the recommendations set out in the original guideline document (and in the "Major Recommendations" field of this summary), the people and processes involved, and the timeline over which full implementation is envisaged. It is in the interests of people with diabetes that the implementation timeline is as rapid as possible.

Relevant local clinical guidelines, care pathways, and protocols should be reviewed in the light of this guidance and revised accordingly. The implementation of this guideline will build on the National Service Frameworks for Diabetes and the Diabetes Information Strategy in England and Wales and should form part of the service development plans for each local health community in England and Wales.

Key Priorities for Implementation

General Management Approach

- Effective care involves a partnership between patients and professionals, and all decision making should be shared.
- Arrange recall and annual review as part of ongoing care.
- As part of annual review, trained personnel should examine patients' feet to detect risk factors for ulceration.
- Examination of patients' feet should include:
 - Testing of foot sensation using a 10 g monofilament or vibration
 - Palpation of foot pulses
 - Inspection of any foot deformity and footwear
- Classify foot risk as: at low current risk; at increased risk; at high risk; ulcerated foot.

Care of People at Low Current Risk of Foot Ulcers (Normal Sensation, Palpable Pulses)

- Agree a management plan including foot care education with each person.

Care of People at Increased Risk of Foot Ulcers (Neuropathy or Absent Pulses or Other Risk Factor)

- Arrange regular review (3 to 6 monthly) by foot protection team.
- At each review:
 - Inspect patient's feet.
 - Consider need for vascular assessment.
 - Evaluate footwear.
 - Enhance foot care education.

Note: If patient has had previous foot ulcer or deformity or skin changes manage as high risk.

Care of People at High Risk of Foot Ulcers (Neuropathy or Absent Pulses Plus Deformity or Skin Changes or Previous Ulcer)

- Arrange frequent review (1 to 3 monthly) by foot protection team.
- At each review:
 - Inspect patient's feet.
 - Consider need for vascular assessment.
 - Evaluate and ensure the appropriate provision of:
 - Intensified foot care education
 - Specialist footwear and insoles
 - Skin and nail care
- Ensure special arrangements for those people with disabilities or immobility.

Care of People with Foot Care Emergencies and Foot Ulcers

- Foot care emergency (new ulceration, swelling, discolouration)
 - Refer to multidisciplinary foot care team within 24 hours.
- Expect that team, as a minimum, to:
 - Investigate and treat vascular insufficiency.
 - Initiate and supervise wound management.
 - Use dressings and debridement as indicated.
 - Use systemic antibiotic therapy for cellulitis or bone infection as indicated.
 - Ensure an effective means of distributing foot pressures, including specialist footwear, orthotics, and casts.
 - Try to achieve optimal glucose levels and control of risk factors for cardiovascular disease.

Suggested audit criteria are listed in Section 10 of the original guideline document. These can be used as the basis for local clinical audit, at the discretion of those in practice.

IMPLEMENTATION TOOLS

Audit Criteria/Indicators
Clinical Algorithm
Patient Resources
Quick Reference Guides/Physician Guides

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

Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

National Collaborating Centre for Primary Care. Clinical guidelines for type 2 diabetes. Prevention and management of foot problems. London (UK): National Institute for Clinical Excellence (NICE); 2004 Jun. 104 p. [194 references]

ADAPTATION

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

DATE RELEASED

2004 Jun 17

GUIDELINE DEVELOPER(S)

National Collaborating Centre for Primary Care - National Government Agency
[Non-U.S.]

SOURCE(S) OF FUNDING

National Institute for Clinical Excellence (NICE)

GUIDELINE COMMITTEE

Guideline Development Group

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Committee Members: Dr Robert Young (Chair)* Consultant Diabetologist, Salford Royal Hospital Trust, Hope Hospital, Manchester; Mrs Rose Chiverton, Patient Representative; Mrs Sheila Clarkson*, Diabetes Specialist Nurse, Blackburn Royal Infirmary; Mrs Alethea Foster*, Chief Podiatrist, Diabetic Foot Clinic, King's College Hospital, London; Dr Roger Gadsby, General Practitioner, Nuneaton and Senior Lecturer in Primary Care, University of Warwick; Aileen McIntosh*, Deputy Director, Sheffield Evidence Based Guidelines Programme, Public Health, SchARR, University of Sheffield; Mr Michael O'Connor, Patient Representative; Dr Jean Peters, Senior Lecturer in Public Health, SchARR, University of Sheffield; Dr Gerry Rayman, Consultant Diabetologist, Diabetes Centre, Ipswich Hospital

(* member of original guideline development group)

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

This release updates a previously published guideline: Royal College of General Practitioners. Clinical guidelines for type 2 diabetes: prevention and management of foot problems. London: Royal College of General Practitioners; 2000 Apr. 96 p.

GUIDELINE AVAILABILITY

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

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- National Collaborating Centre for Primary Care. Type 2 diabetes. Prevention and management of foot problems. London (UK): National Institute for Clinical Excellence (NICE); 2004 Jan. 27 p. (Clinical guideline; no. 10). Electronic copies: Available in Portable Document Format (PDF) format from the [National Institute for Clinical Excellence \(NICE\) Web site](#).
- Type 2 diabetes. Prevention and management of foot problems. Quick reference guide. National Collaborating Centre for Primary Care, 2004 Jan. 2 p. Electronic copies: Available from the [NICE Web site](#).
- Type 2 diabetes. NICE footcare guideline (revision). Algorithm. National Collaborating Centre for Primary Care, 2004 Jun. 2 p. Electronic copies: Available from the [NICE Web site](#).

Print copies: Available from the National Health Service (NHS) Response Line 0870 1555 455, ref: N0409. 11 Strand, London, WC2N 5HR.

Additionally, Audit Criteria can be found in Section 10 of the [original guideline document](#).

PATIENT RESOURCES

The following is available:

- Prevention and management of foot problems in people with type 2 diabetes: Understanding NICE guidance - information for people with type 2 diabetes, their families and carers, and the public. National Institute for Clinical Excellence (NICE), 2004 Jan. 23 p.

Electronic copies: Available from the [National Institute for Clinical Excellence \(NICE\) Web site](#).

Print copies: Available from the National Health Service (NHS), 11 Strand, London, WC2N 5HR. Response Line 0870 1555 455, ref N0479.

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 12, 2004. The information was verified by the guideline developer on November 26, 2004.

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