



Complete Summary

GUIDELINE TITLE

Guidance on the use of continuous subcutaneous insulin infusion for diabetes.

BIBLIOGRAPHIC SOURCE(S)

National Institute for Clinical Excellence (NICE). Guidance on the use of continuous subcutaneous insulin infusion for diabetes. London (UK): National Institute for Clinical Excellence (NICE); 2003 Feb. 23 p. (Technology appraisal guidance; no. 57).

GUIDELINE STATUS

This is the current release of the guideline.

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SCOPE

DISEASE/CONDITION(S)

Type I diabetes

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Management
Treatment

CLINICAL SPECIALTY

Endocrinology
Family Practice

Internal Medicine
Pediatrics

INTENDED USERS

Advanced Practice Nurses
Nurses
Patients
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To examine the clinical and cost-effectiveness of continuous subcutaneous insulin infusion (CSII) using insulin pumps compared with multiple daily injections (MDI) for diabetes

TARGET POPULATION

Adults with type I diabetes

INTERVENTIONS AND PRACTICES CONSIDERED

Continuous subcutaneous insulin infusion (CSII)

MAJOR OUTCOMES CONSIDERED

- Clinical effectiveness
 - Glycated haemoglobin
 - Insulin dose
 - Weight change
 - Cholesterol levels
 - Patient preference
 - Quality of life
 - Adverse effects
- Cost-effectiveness

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases
Searches of Unpublished Data

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Clinical Excellence (NICE) commissioned an independent

academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an assessment report. The assessment report for this technology appraisal was prepared by the Southampton Health Technology Assessments Centre. (See the "Availability of Companion Documents" field.)

A systematic review of the literature and an economic evaluation were undertaken.

Data Sources

Electronic databases were searched, including the Cochrane Library, Medline, Embase, PubMed, Science Citation Index, Web of Science Proceedings, DARE and Health Technology Assessment (HTA) databases, PsychINFO, National Health Service (NHS) Economic Evaluation Database, EconLIT, and Health Management Information Consortium database. References of all retrieved articles were checked for relevant studies, and experts were contacted for advice and peer review, and to identify additional published and unpublished references. Manufacturer submissions to the National Institute of Clinical Excellence (NICE) were reviewed.

Study Selection

Studies were included if they fulfilled the following criteria:

- Interventions: continuous subcutaneous insulin infusion (CSII) using insulin pumps compared with optimised multiple daily injections (MDI) (at least 3 injections per day)
- Participants: people with insulin-treated diabetes (Type 1 or Type 2). Newly diagnosed patients were excluded.
- Outcomes: glycated haemoglobin, insulin dose, weight change, cholesterol levels, patient preference, quality of life, adverse effects
- Design: Parallel randomised controlled trials (RCTs) and randomised and nonrandomized crossover studies with a minimum duration of 10 weeks on each treatment

Studies in non-English language or available only as abstracts were excluded from the main analysis.

Titles and summaries of studies being assessed for inclusion were checked by two reviewers. Full texts of selected studies were assessed for inclusion by one reviewer and checked by a second. Differences in opinion were resolved through discussion.

Sources of information, search terms, and a flow chart outlining the identification of studies are described in Appendix 2 of the Assessment Report (see the "Availability of Companion Documents" field).

NUMBER OF SOURCE DOCUMENTS

Searching identified 20 studies comparing continuous subcutaneous insulin infusion (CSII) with multiple daily injections (MDI). These included eight parallel randomised controlled trials (RCTs), nine randomised crossover studies, and three non-random crossover studies. Fourteen studies included adults with Type 1 diabetes, four studies included pregnant women, and two studies included adolescents. The quality of reporting and methodology of the studies, many of which dated from many years ago, was often poor by today's standards, with just two studies having adequate randomisation and none reporting adequate allocation concealment.

Six further studies (one parallel RCT and five random crossover studies) were identified comparing analogue with soluble insulin in CSII. Randomisation and allocation concealment were adequate in the parallel RCT but not reported in the crossover studies.

No economic evaluations comparing CSII with optimised MDI were found.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Clinical Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an assessment report. The assessment report for this technology appraisal was prepared by the Southampton Health Technology Assessments Centre. (See the "Availability of Companion Documents" field.)

Data Extraction and Quality Assessment

Data extraction and quality assessment were undertaken by one reviewer and checked by a second reviewer, with any disagreement resolved through discussion. The quality of included studies was assessed in accordance with Cochrane Reviews Database (CRD) Report 4.

Data Synthesis

Data on the clinical effectiveness of continuous subcutaneous insulin infusion (CSII) for diabetes were synthesised through a narrative review with full tabulation of results of all included studies, with meta-analysis performed where appropriate. Cost effectiveness analysis examined the marginal costs of CSII compared to multiple daily injections (MDI), and considered evidence on the marginal benefits such as improved control, adverse events, and quality of life.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Considerations

Technology appraisal recommendations are based on a review of clinical and economic evidence.

Technology Appraisal Process

The National Institute for Health and Clinical Excellence (NICE) invites 'consultee' and 'commentator' organisations to take part in the appraisal process. Consultee organisations include national groups representing patients and carers, the bodies representing health professionals, and the manufacturers of the technology under review. Consultees are invited to submit evidence during the appraisal and to comment on the appraisal documents.

Commentator organisations include manufacturers of the products with which the technology is being compared, the National Health Service (NHS) Quality Improvement Scotland and research groups working in the area. They can comment on the evidence and other documents but are not asked to submit evidence themselves.

NICE then commissions an independent academic centre to review published evidence on the technology and prepare an 'assessment report'. Consultees and commentators are invited to comment on the report. The assessment report and the comments on it are then drawn together in a document called the evaluation report.

An independent Appraisal Committee then considers the evaluation report. It holds a meeting where it hears direct, spoken evidence from nominated clinical experts, patients and carers. The Committee uses all the evidence to make its first recommendations, in a document called the 'appraisal consultation document' (ACD). NICE sends all the consultees and commentators a copy of this document and posts it on the NICE website. Further comments are invited from everyone taking part.

When the Committee meets again it considers any comments submitted on the ACD; then it prepares its final recommendations in a document called the 'final appraisal determination' (FAD). This is submitted to NICE for approval.

Consultees have a chance to appeal against the final recommendations in the FAD. If there are no appeals, the final recommendations become the basis of the guidance that NICE issues.

Who is on the Appraisal Committee?

NICE technology appraisal recommendations are prepared by an independent committee. This includes health professionals working in the NHS and people who are familiar with the issues affecting patients and carers. Although the Appraisal Committee seeks the views of organisations representing health professionals, patients, carers, manufacturers and government, its advice is independent of any vested interests.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

No economic evaluation of insulin pumps was found in the literature.

The Assessment Group considered that too many assumptions were required for cost effectiveness to be measured in terms of cost per quality-adjusted life year gained (CQG). The approach taken was to look at the costs and consequences associated with multiple daily injections (MDI) therapy compared with continuous subcutaneous insulin infusion (CSII) therapy. The additional cost of CSII therapy compared with MDI therapy is estimated to be between 1100 and 1400 pounds sterling per year, depending on the type of pump and whether it lasts 4 or 8 years. These estimates were made allowing for cost offsets (comprising reduced insulin costs and lower medical costs for adverse events), estimated to be about £130 per year.

The two manufacturers also produced economic analyses. One manufacturer estimated a cost per quality-adjusted life year (QALY) of 8400 pounds sterling for CSII therapy against MDI therapy. Because of the absence of utility data comparing CSII and MDI therapies, the other manufacturer suggested how great a patient's utility gain would have to be to make CSII therapy cost effective compared with MDI therapy. It was estimated that utility gains of 8 to 25% and 3 to 8% would be needed to attain a cost per QALY of 10,000 and 30,000 pounds sterling, respectively.

METHOD OF GUIDELINE VALIDATION

External Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Consultee organizations from the following groups were invited to comment on the draft scope, Assessment Report and the Appraisal Consultation Document (ACD) and were provided with the opportunity to appeal against the Final Appraisal Determination.

- Manufacturer/sponsors
- Professional/specialist and patient/carer groups
- Commentator organisations (without the right of appeal)

In addition, individuals selected from clinical expert and patient advocate nominations from the professional/specialist and patient/carer groups were also invited to comment on the ACD.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

- Continuous subcutaneous insulin infusion (CSII or "insulin pump therapy") is recommended as an option for people with type 1 diabetes provided that:
 - Multiple-dose insulin (MDI) therapy (including, where appropriate, the use of insulin glargine) has failed; and
 - Those receiving the treatment have the commitment and competence to use the therapy effectively.
- People for whom MDI therapy has failed are considered to be those for whom it has been impossible to maintain a haemoglobin A_{1c} level no greater than 7.5% (or 6.5% in the presence of microalbuminuria or adverse features of the metabolic syndrome) without disabling hypoglycaemia occurring, despite a high level of self care of their diabetes. "Disabling hypoglycaemia," for the purposes of this guidance, means the repeated and unpredictable occurrence of hypoglycaemia requiring third-party assistance that results in continuing anxiety about recurrence and is associated with significant adverse effect on quality of life.
- CSII therapy should be initiated only by a trained specialist team, which should normally comprise a physician with a specialist interest in insulin pump therapy, a diabetes specialist nurse, and a dietitian.
- All individuals beginning CSII therapy should be provided with specific training in its use. Ongoing support from a specialist team should be available, particularly in the period immediately following the initiation of CSII. It is recommended that specialist teams should agree a common core of advice appropriate for CSII users.
- The recommendations in this guidance are also applicable to children, adolescents, pre-pregnant and pregnant women for whom MDI therapy is deemed to have failed. Because of the risks of ketoacidosis to the fetus, pregnant or pre-pregnant women who switch to CSII therapy should do so only on the advice and under the care of a specialist team (defined above).
- CSII therapy is not recommended for people with type 2 diabetes who require insulin therapy.
- Established users of CSII therapy should have their insulin management reviewed by their specialist team so that a decision can be made about whether a trial of a switch to MDI incorporating insulin glargine would be appropriate.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is not specifically stated.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Appropriate use of continuous subcutaneous insulin infusion (CSII) therapy for diabetes
- CSII therapy may enable people with diabetes to have greater control over their condition, as well as lower anxiety about episodes of hypoglycaemia.

POTENTIAL HARMS

Adverse events that may be associated with continuous subcutaneous insulin infusion (CSII) treatment include catheter site infection (which can be prevented by regular change of the infusion cannula and a high order of personal hygiene), blocked cannula tubing, and ketoacidosis due to lack of insulin in cases of pump malfunction.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

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

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Implementation and Audit

- National Health Service (NHS) Trusts and consultants treating people with diabetes should review policies and practices regarding the treatment of people with diabetes to take account of the guidance (see the "Major Recommendations" field).
- The cost of ongoing consumables and, in due course, replacement pumps, should be funded by the NHS for established continuous subcutaneous insulin infusion (CSII) users for whom multiple daily injections (MDI) with insulin glargine is considered inappropriate or proves to be inadequate to maintain adequate glycaemic control (see the "Major Recommendations" field).

- Local guidelines or care pathways on the care of people with diabetes should incorporate the guidance (see the "Major Recommendations" field).
- Specialist teams who assume responsibility for initiating CSII should agree a common core of advice appropriate for CSII users in England and Wales.
- To measure compliance locally with the guidance, the following criteria can be used. Further details on suggestions for audit are presented in Appendix C of the original guideline document.
 - Insulin pump therapy (CSII) is considered as a treatment option for a person with type 1 diabetes for whom MDI therapy has failed, and who has the commitment and competence to use the CSII therapy effectively.
 - CSII is initiated only by a trained specialist team that comprises a physician with a specialist interest in insulin pump therapy, a diabetes specialist nurse and a dietitian.
 - A person beginning CSII therapy is provided with specific training in its use and has ongoing support from a specialist team, particularly in the period immediately following the initiation of CSII.
 - A person on CSII therapy is reviewed by his or her specialist team, who make a decision on whether it is appropriate for the person to undergo a trial of switching to MDI incorporating insulin glargine.
- Local clinical audits on the care of patients with diabetes also could include criteria for the management of diabetes based on the standards in the National Service Framework for Diabetes.

IMPLEMENTATION TOOLS

Audit Criteria/Indicators
 Foreign Language Translations
 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

IOM DOMAIN

Effectiveness
 Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

National Institute for Clinical Excellence (NICE). Guidance on the use of continuous subcutaneous insulin infusion for diabetes. London (UK): National Institute for Clinical Excellence (NICE); 2003 Feb. 23 p. (Technology appraisal guidance; no. 57).

ADAPTATION

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

DATE RELEASED

2003 Feb

GUIDELINE DEVELOPER(S)

National Institute for Health and Clinical Excellence (NICE) - National Government Agency [Non-U.S.]

SOURCE(S) OF FUNDING

National Institute for Health and Clinical Excellence (NICE)

GUIDELINE COMMITTEE

Appraisal Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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Practitioner, Hattersley Health Centre, Hyde, Cheshire; Professor Philip Routledge, Professor of Clinical Pharmacology, University of Wales; Ms Anne Smith, Lay Representative; Trustee, Long Term Medical Conditions Alliance; Professor Andrew Stevens (*Vice-Chair*) Professor of Public Health, University of Birmingham; Dr Cathryn Thomas, General Practitioner & Senior Lecturer, Department of Primary Care and General Practice, University of Birmingham; Dr Norman Vetter, Reader, Department of Epidemiology, Statistics and Public Health, University of Wales College of Medicine; Dr David Winfield, Consultant Haematologist, Royal Hallamshire Hospital, University of Wales College of Medicine

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

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 Health and Clinical Excellence \(NICE\) Web site](#).

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Guidance on the use of continuous subcutaneous insulin infusion for diabetes. Quick reference guide. London (UK): National Institute for Health and Clinical Excellence (NICE); 2003 Feb. 2 p. (Technology appraisal 57). Available in Portable Document Format (PDF) from the [National Institute for Health and Clinical Excellence \(NICE\) Web site](#).
- Clinical and cost effectiveness of continuous subcutaneous insulin infusion for diabetes. Assessment report. NHS HTA Programme. 2002 Aug. 180 p. Available in Portable Document Format (PDF) from the [NICE Web site](#).

Print copies: Available from the National Health Service (NHS) Response Line 0870 1555 455. ref: N0195. 11 Strand, London, WC2N 5HR.

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

PATIENT RESOURCES

The following is available:

- Guidance on the use of continuous subcutaneous insulin infusion for diabetes. Information for the public. London (UK): National Institute for Health and Clinical Excellence (NICE); 2003 Feb. 2 p. (Technology appraisal 57).

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

Print copies: Available from the Department of Health Publications Order Line 0870 1555 455. ref: N0196. 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

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