Complete Summary

GUIDELINE TITLE

Structural neuroimaging in first-episode psychosis.

BIBLIOGRAPHIC SOURCE(S)

National Institute for Health and Clinical Excellence (NICE). Structural neuroimaging in first-episode psychosis. London (UK): National Institute for Health and Clinical Excellence (NICE); 2008 Feb. 24 p. (Technology appraisal guidance; no. 136).

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Psychosis

GUIDELINE CATEGORY

Diagnosis
Technology Assessment

CLINICAL SPECIALTY

Neurology
Psychiatry
Radiology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To determine whether it is clinically and cost effective to scan routinely all those with first-episode psychosis by either structural magnetic resonance imaging (MRI) or computed axial tomography (CT) techniques compared with the standard practice of carrying out selective radiological examinations contingent on clinical findings suggestive of an underlying structural cause

TARGET POPULATION

Patients in the United Kingdom with a first episode of psychosis

INTERVENTIONS AND PRACTICES CONSIDERED

1. Magnetic resonance imaging (MRI)
2. Computed axial tomography (CT) scan

Note: Neither of these imaging options is recommended as a routine part of the initial investigations for first-episode psychosis.

MAJOR OUTCOMES CONSIDERED

- Clinical effectiveness
    - Number (or percentage) of patients with scans identifying abnormalities
    - Number with pathology that would influence patient care and was not suspected based on history and/or physical examination and the pathology found
    - Incidental pathology found
    - Number (or percentage) of patients with a scan affecting their clinical treatment
    - Number (or percentage) of patients with a change in diagnosis due to the scan, time to diagnosis, confidence in diagnosis
- Cost effectiveness

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary 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Searches of Unpublished Data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 West Midlands Health Technology Assessment Collaboration, University of Birmingham (see the "Availability of Companion Documents" field).

Clinical Effectiveness

Identification of Studies

A scoping search based on the Aggressive Research Intelligence Facility (ARIF) search protocol was undertaken to identify systematic reviews and background material (see Appendix 1 of the Assessment Report [see the "Availability of Companion Documents" field]).

For the main clinical effectiveness review the following sources were searched:

- Bibliographic databases: Cochrane Library (Wiley) 2006 Issue 4 (CENTRAL); MEDLINE (Ovid) 1966 to November Week 3 2006; MEDLINE (Ovid) In-Process and Other Non-Indexed Citations 4 December 2006; EMBASE (Ovid) 1980 to 2006 Week 48; CINAHL (Ovid) 1982 to November Week 4 2006; PsycINFO (Ovid) 1967 to November Week 4 2006.
- Citations of relevant studies.
- Research registries of ongoing trials included the National Research Register, Current Controlled Trials, and Clinical Trials.gov.
- Relevant internet resources.
- Hand search of appropriate journals-(Magnetic Resonance in Medicine (1985 to 2007), NMR in Biomedicine (1985 to 2007)), American Journal of Psychiatry (1985-2007).
- Further information from contact with relevant experts.

Details of all search strategies may be found in Appendix 2 of the Assessment Report (see the "Availability of Companion Documents" field). No language or date restrictions were applied. All citations were exported, or entered by hand, into Reference Manager version 11 (ISI, Carlsband, CA, USA).

Additional searches were carried out on the comparative sensitivity of computed tomography (CT) and magnetic resonance imaging (MRI) scanning, which were used to inform part of the economic evaluation (see section 6.2.1.3 of the Assessment Report [see the "Availability of Companion Documents" field]).

Inclusion and Exclusion Criteria and Process

Three reviewers independently scanned all titles and abstracts identified by the searches for inclusion. The full text was obtained for potentially relevant articles. Publications in foreign languages were assessed using the English abstract where available or a translator was used. Studies were included in the review of effectiveness if they met the following criteria:

Population: adults or children presenting with psychosis, particularly a first episode of psychosis (FEP). Psychosis was considered to be a first episode if the study described psychosis as new, first or of recent onset, a new or first hospital admission for psychosis, first contact with any medical services for psychosis, or antipsychotic treatment naïve. In cases where it was unclear whether the population were presenting with a first episode, the study was included and clearly marked as such.

Judgement on whether a condition was considered to be psychotic was made according to Appendix 3 of the Assessment Report (see "Availability of Companion Documents" field) following clinical input.

Studies investigating populations of mixed psychiatric patients that had a subgroup of psychotic patients were included if other criteria were met.

In order to capture the subgroup of psychotic patients with a possible psychiatric misdiagnosis, or those who were experiencing a change in their pre-existing psychotic disorder, the reviewers also looked for studies evaluating:

- Patients who had a prior diagnosis of a psychotic disorder but were failing to respond to treatment
- Patients who had a prior diagnosis of a psychotic disorder, had previously responded to antipsychotic treatment but had a recent deterioration in their condition.

Intervention (diagnostic investigation): MRI or CT with or without contrast media.

Comparator: current standard National Health Service (NHS) practice without MRI or CT neuroimaging, or before MRI or CT neuroimaging.

Outcomes: See the "Major Outcomes Considered" field.

Study design: Any design that gave diagnostic yield, including prospective or retrospective before and after studies, were included.

Exclusion criteria: Studies employing functional imaging techniques such as magnetic resonance spectroscopy, diffusion weighted MRI, diffusion tensor imaging, perfusion MRI, or positron emission tomography (PET) were excluded.

Studies were excluded where the primary aim of the study was to investigate the cerebral morphometry (such as shape, size or volume measurements) associated with psychosis or a specific psychotic illness.

Individual case reports were excluded.

Cost Effectiveness

Search Strategy and Numbers of Papers Found

A comprehensive search for literature on the cost and cost-effectiveness of structural neuroimaging in first episode psychosis was carried out. The strategies

in full may be found in Appendix 2 of the Assessment Report (see the "Availability of Companion Documents" field).

Studies on costs, quality of life, cost effectiveness and modelling were identified from the following sources:

- Bibliographic databases: MEDLINE (Ovid) 1966 to November Week 3 2006; EMBASE (Ovid) 1980 to 2006 Week 47, Cochrane Library (Wiley) 2006 Issue 4; (CENTRAL) DARE and NHS EED and the Office of Health Economics HEED database November 2006 issue.
- Industry submissions
- Internet sites of national economic units

Searches were not be limited by date and there were no language restrictions.

A total of 967 abstracts were identified. Of these, 46 were regarded as potentially relevant and full papers were requested. It was found that no papers reported directly on the cost-effectiveness of neuroimaging in patients with first-episode psychosis. As a consequence, the inclusion criteria were broadened to encompass papers that reported use of neuroimaging within the mental health clinical area more generally as it was felt that this would still provide useful information to inform the overall economic evaluation. For the quality of life (QoL) papers, all papers reporting utility-based QoL values within the mental health clinical field were also included.

Refer to the Assessment Report (see the "Availability of Companion Documents" field) for more details.

NUMBER OF SOURCE DOCUMENTS

Clinical Effectiveness

25 studies were included in this systematic review:

- 24 studies of a diagnostic before-after type design evaluating the clinical benefit of computed axial tomography (CT), structural magnetic resonance imaging (MRI) or combinations in treatment naïve, first episode or unspecified psychotic patients
- A review of published case reports of misidentification syndromes

Cost Effectiveness

Seven papers were classified as economic evaluations. There were also two cost papers and eleven quality of life papers.

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

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 West Midlands Health Technology Assessment Collaboration, University of Birmingham (see the "Availability of Companion Documents" field).

Data Extraction Strategy

Data extraction from included studies was carried out independently by two reviewers. Study characteristics, outcome results and aspects of study quality were collected using a standardised form. Any discrepancies were resolved by discussion, and where necessary, by involvement of a third reviewer.

Quality Assessment Strategy

There is no validated quality assessment tool for diagnostic before and after studies. Therefore, an evaluation was made of test accuracy quality assessment tools to determine whether any could be tailored to meet the needs of this review. The QUADAS tool was chosen but was modified to more appropriately capture the quality and validity issues apparent in the included studies. The full tool was piloted on a selection of studies prior to full data extraction and subsequently modified. However, the modified QUADAS tool did not fully capture all of the quality criteria that needed to be considered. Therefore the quality assessment strategy included four additional questions:

- What was the explanation given for patients who did not receive a scan?
- Were the patients recruited consecutively?
- Was the study and/or collection of clinical variables conducted prospectively?
- Who performed the clinical evaluation and image analysis?

Following tabulation of quality criteria, possible threats to study validity were discussed.

Refer to the Assessment Report for further details of the QUADAS tool and its modification (see the "Availability of Companion Documents" field).

Data Synthesis

Study characteristics and results were tabulated. Analysis was qualitative, conclusions being based on patterns revealed in the tables of included studies. It was not possible to pool results for quantitative analysis due to the scarcity of

data, the poor quality of included studies and the heterogeneity of study characteristics.

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 stated

COST ANALYSIS

A systematic review of studies on the cost effectiveness of structural neuroimaging in first-episode psychosis found no relevant economic evaluations. Nor was any evidence found on differential treatment responses to antipsychotic drugs in organic and functional psychoses or on quality-of-life benefits following early diagnosis (from routine screening). Because of the lack of data to populate a comprehensive decision-analytical model, the Assessment Group used a threshold analysis to estimate the cost effectiveness of routine scanning as compared with the standard diagnostic strategy of selective scanning contingent on clinical findings suggestive of an underlying structural cause of first-episode psychosis. A threshold analysis predicts the quality-adjusted life year (QALY) gain required for a technology to be regarded as cost effective. By combining the incremental cost of routine scanning with cost-effectiveness thresholds of 20,000 pounds sterling and 30,000 pounds sterling per QALY, the QALY gains needed to make routine scanning cost effective (or the QALY losses that could be tolerated if the strategy is cost saving) are estimated. A 12-month time horizon was assumed in the Assessment Group's threshold analysis. It was assumed that people considered to have functional psychoses will receive a predefined sequence of atypical antipsychotic medications.

In conclusion, the threshold analysis showed that, if the prevalence of organic psychosis due to a brain tumour or cyst lies in the region of 5%, then, under the Assessment Group's assumptions, routine structural neuroimaging is cost saving. If the prevalence of organic psychoses is close to 0.5%, then, under the Assessment Group's assumptions, magnetic resonance imaging (MRI) is no longer cost saving, and computed axial tomography (CT) is only cost saving if 50% of people receive hospital care. However, evidence for determining the true prevalence of treatable lesions in the population under test is extremely limited.

See Section 4.2 of the original guideline document for more detailed discussion of the cost-effectiveness analysis.

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

Structural neuroimaging techniques (either magnetic resonance imaging [MRI] or computed axial tomography [CT] scanning) are not recommended as a routine part of the initial investigations for the management of first-episode psychosis.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for the recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate use of neuroimaging (magnetic resonance imaging [MRI] or computed axial tomography [CT]) in cases of first-episode psychosis

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. 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

- The Healthcare Commission assesses the performance of National Health Service (NHS) organisations in meeting core and developmental standards set by the Department of Health in 'Standards for better health' issued in July 2004. The Secretary of State has directed that the NHS provides funding and resources for medicines and treatments that have been recommended by National Institute for Health and Clinical Excellence (NICE) technology appraisals normally within 3 months from the date that NICE publishes the guidance. Core standard C5 states that healthcare organisations should ensure they conform to NICE technology appraisals.
- 'Healthcare Standards for Wales' was issued by the Welsh Assembly Government in May 2005 and provides a framework both for self-assessment by healthcare organisations and for external review and investigation by Healthcare Inspectorate Wales. Standard 12a requires healthcare organisations to ensure that patients and service users are provided with effective treatment and care that conforms to NICE technology appraisal guidance. The Assembly Minister for Health and Social Services issued a Direction in October 2003 which requires Local Health Boards and NHS Trusts to make funding available to enable the implementation of NICE technology appraisal guidance, normally within 3 months.
- NICE has developed tools to help organisations implement this guidance (listed below). These are available from the NICE Web site (www.nice.org.uk/TA136) (see also the "Availability of Companion Documents" field).
    - Audit support for monitoring local practice
    - A costing statement explaining the resource impact of this guidance

IMPLEMENTATION TOOLS

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

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

Getting Better

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

National Institute for Health and Clinical Excellence (NICE). Structural neuroimaging in first-episode psychosis. London (UK): National Institute for Health and Clinical Excellence (NICE); 2008 Feb. 24 p. (Technology appraisal guidance; no. 136).

ADAPTATION

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

DATE RELEASED

2008 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

Committee Members: Professor Keith Abrams, Professor of Medical Statistics, University of Leicester; Dr Jeff Aronson, Reader in Clinical Pharmacology, Radcliffe Infirmary; Professor David Barnett (*Chair*) Professor of Clinical Pharmacology, University of Leicester; Professor Stirling Bryan, Director of the Health Economics Facility, University of Birmingham; Professor John Cairns, Public Health and Policy, London School of Hygiene and Tropical Medicine; Dr Mark Charkravarty, Head of Government Affairs and NHS Policy, Procter and Gamble Pharmaceuticals (UK) Ltd; Ms Lynn Field, Nurse Director, Pan Birmingham Cancer Network; Professor Christopher Fowler, Professor of Surgical Education, University of London; Dr Fergus Gleeson, Consultant Radiologist, Churchill Hospital; Ms Sally Gooch, Former Director of Nursing and Workforce Development, Mid Essex Hospitals Services NHS Trust; Mrs Barbara Greggains, Lay Member; Mr Sanjay Gupta, Former Service Manager in Stroke, Gastroenterology, Diabetes and Endocrinology,

Basildon and Thurrock University Hospitals Foundation NHS Trust; Mr Terence Lewis, Mental Health Consultant, National Institute for Mental Health in England; Professor Gary McVeigh, Professor of Cardiovascular Medicine, Queens University, Belfast; Dr Ruairidh Milne, Senior Lecturer in Health Technology Assessment, National Coordinating Centre for Health Technology; Dr Neil Milner, General Medical Practitioner, Tramways Medical Centre, Sheffield; Dr Rubin Minhas, General Practitioner, CHD Clinical Lead, Medway PCT; Dr Stephen Saltissi, Consultant Cardiologist, Royal Liverpool University Hospital; Dr Lindsay Smith, General Practitioner, East Somerset Research Consortium; Mr Cliff Snelling, Lay Member; Dr Ken Stein, Senior Lecturer, Peninsula Technology Assessment Group (PenTAG), University of Exeter; Dr Rod Taylor, Associate Professor in Health Services Research, Peninsula Medical School, Universities of Exeter and Plymouth

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:

- Structural neuroimaging in first-episode psychosis. Quick reference guide. London (UK): National Institute for Health and Clinical Excellence (NICE); 2008 Feb. 2 p. (Technology appraisal 136). Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.
- Costing statement: structural neuroimaging in first-episode psychosis. London (UK): National Institute for Health and Clinical Excellence (NICE); 2008 Feb. 1 p. (Technology appraisal 136). Available in Portable Document Format (PDF) from the NICE Web site.
- Structural neuroimaging in first-episode psychosis. Audit support. London (UK): National Institute for Health and Clinical Excellence (NICE); 2008 Feb. 6 p. (Technology appraisal 136). Available in Portable Document Format (PDF) from the NICE Web site.
- Structural neuroimaging in psychosis. Systematic review and economic evaluation. Assessment Report. NHS R&D Programme. West Midlands Health Technology Assessment Collaboration. 2007 Jun. 199 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: N1473. 11 Strand, London, WC2N 5HR.

PATIENT RESOURCES

The following is available:

- Structural neuroimaging for examining people who have had a first episode of psychosis. Understanding NICE guidance - Information for people who use NHS services. London (UK): National Institute for Health and Clinical Excellence (NICE); 2008 Feb. 4 p. (Technology appraisal 136).

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

Print copies: Available from the NHS Response Line 0870 1555 455. ref: N1474. 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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