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What makes a good clinical guideline?

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- Clinical guidelines are systematically developed statements designed to help practitioners and patients decide on appropriate healthcare for specific clinical conditions and/or circumstances.[1]
- Good guidelines can change clinical practice and influence patient outcome.
- The way in which guidelines are developed, implemented and monitored, influences the likelihood that they will be followed.
- Guidelines should provide extensive, critical and well-balanced information on the benefits and limitations of various diagnostic and therapeutic interventions so that the physician can carefully judge individual cases.[2]
- Applying guidelines to individual care is always likely to require judgement, even when recommendations are properly linked to evidence.[3]

Abbreviated prescribing information is on page 7

What makes a good clinical guideline?

Guidelines can be used in a wide range of settings to promote effective and efficient healthcare – for example, to guide the introduction of new procedures or services, promote effective healthcare in primary or secondary care settings, encourage the adoption of cost-effective interventions and improve the timing and processes of the discharge of patients.[4]

If guidelines are to achieve their potential, they should have adequate resources and be introduced through partnerships that may include clinicians, providers, purchasers and the public.

The role of purchasers in this process may involve identifying the best evidence of effectiveness and cost-effectiveness or valid national guidelines and then prioritising areas for the introduction of local guidelines. Guidelines that have cost-reduction as their main rationale may not always be an appropriate basis on which to make a clinical decision; neither will guidelines that take no heed of the required level of resources. Together with their associated criteria and standards, guidelines may be detailed within a service specification and referred to in the contract. However, by itself, contracting is unlikely to be sufficient to implement clinical guidelines.[4]

Box 1. National Institute for Clinical Excellence (NICE) guidelines for the management of motor neurone disease (MND)[5]

The NICE guidance on the use of riluzole (rilutek) for the treatment of Motor Neurone Disease (MND) was published in January 2001.

NICE has recommended to the NHS that riluzole should be available for the treatment of individuals with MND in accordance with its licensed indications. A neurological specialist who is experienced in the management of MND should start treatment with riluzole.

Routine supervision of therapy may be managed by GPs but this should be under an agreement known as a shared care arrangement with the specialist

Andrew Dillon, NICE Chief Executive, stated, 'The additional months of life which this medicine offers to people with the ALS [amyotrophic lateral aclerosis] form of MND makes it an important and worthwhile treatment. It is both a clinically and cost effective intervention when used in accordance with its licensed indications and the Institute is very pleased to be able to recommend its use.'

Defining terms

Guidelines

Guidelines reduce unacceptable or undesirable variations in practice and provide a focus for discussion among health professionals and patients. They enable professionals from different disciplines to come to an agreement about treatment and devise a quality framework, against which practice can be measured. Guidelines can help commissioners and purchasers to make informed decisions and provide managers with a useful framework for assessing treatment costs.

Protocols

Protocols are rigid statements allowing little or no flexibility or variation. A protocol sets out a precise sequence of activities to be adhered to in the management of a specific clinical condition. There is a logical sequence and precision of listed activities.[6]

Care pathways

Care pathways determine locally agreed, multidisciplinary practice, based on guidelines and evidence where available, for a specific patient/client group. Care pathways form all or part of the clinical record, document the care given and help to evaluate outcomes for continuous quality monitoring.[7]

Legal implications

Clinicians' concerns about the legal status of guidelines and potential litigation resulting from non-compliance may be a barrier to their implementation.[4] In the UK, mere

Box 2. Good clinical guidelines should be:[8]

- **Valid** – leading to the results expected of them.
- **Reproducible** – if using the same evidence, other guideline groups would come to the same results.
- **Cost-effective** – reducing the inappropriate use of resources.
- **Representative/multidisciplinary** – by involving key groups and their interests.
- **Clinically applicable** – patient populations affected should be unambiguously defined.
- **Flexible** – by identifying the expectations relating to recommendations as well as patient preferences.
- **Clear** – unambiguous language, which is readily understood by clinicians and patients, should be used.
- **Reviewable** – the date and process of review should be stated.
- **Amenable to clinical audit** – the guidelines should be capable of translation into explicit audit criteria.

Box 3. Guidelines on the web

http://www.nice.org.uk
National Institute for Clinical Excellence.

http://www.sign.ac.uk
The Scottish Intercollegiate Guidelines Network (SIGN) develops and publishes evidence-based clinical practice guidelines for use by the health service in Scotland. This website also includes SIGN's criteria for the appraisal of guidelines.

http://www.healthcentre.org.uk/hc/library/guidelines.htm
UK and worldwide guidelines available on the Internet (not necessarily formally appraised or reviewed).

http://www.suffolk-maag.ac.uk/guidelines
A general practice development group has been established in Suffolk to, among other tasks, examine all proposed guidelines to see whether they are sensible and relevant to Suffolk before they are introduced.

http://text.nlm.nih.gov/ftrs/pick?collect=ahcpr&t=924522691
Clinical guidelines published by the US Health Agency, but not fully available on the web.

http://www.sghms.ac.uk/phs/hceu/nhsguide.htm
The Health Care Evaluation Unit's Critical Appraisal instrument is available on the Internet. Its aim is to encourage the systematic development of clinical guidelines in the UK and to provide a structured and transparent approach to their appraisal. It can be used by independent appraisers to assess existing guidelines or by guideline developers as an *aide memoire*.

deviation from a guideline is unlikely to be accepted as evidence of negligence by a court, unless the deviation itself were of a type that no doctor acting under ordinary skill and care would make. Doctors cannot be found negligent simply because they follow a practice that is rejected by another school of medical thought.[9]

The NHS Executive has stated that: 'Clinical guidelines can still only assist the practitioner; they cannot be used to mandate, authorise or outlaw treatment options. Regardless of the strength of the evidence, it will remain the responsibility of the practising clinicians to interpret their application.'[3]

Potential barriers to developing good clinical guidelines[10]

- The guideline has not been developed by a fully multidisciplinary group that is representative of those who will be using it, with the result that there is a 'lack of ownership'.
- Recommendations that do not take due account of the evidence can result in sub-optimal, ineffective or harmful practice.
- There is often insufficient, misleading or misinterpreted scientific evidence about what to recommend.
- Guideline development groups often lack the time, resources and skills to gather and scrutinise evidence in detail.
- Value judgements made by a guideline group may be the wrong choice for individual patients.
- Recommendations are influenced by the opinions, clinical experience and composition of the guideline group (ie, if it is not truly multidisciplinary or representative).
- Patients' needs may not be the only priority in making recommendations; those of doctors, risk managers or politicians may also be involved.
- Conflicting guidelines from different professional bodies can confuse and frustrate practitioners.
- Guidelines that are inflexible can cause harm by leaving insufficient room for clinicians to tailor care to patients' individual needs and personal circumstances.

Table 1. Guideline evaluation checklist – assessing the validity of clinical guidelines*

	Yes	No	Cannot tell	N/A
Responsibility for guideline development				
● Is the agency responsible for guideline development clearly identified?				
● Was external funding and/or support received for developing the guidelines?				
● If they were received, is there evidence that potential biases were taken into account?				
Objectives				
● Are the reasons for developing the guidelines clearly stated?				
● Are the objectives of the guidelines clearly defined?				
Guideline development group				
● Is there a description of the individuals – for example, professionals and interest groups, including patients – who were involved in developing the guidelines?				
● If so, did the group represent all the key groups/stake holders/disciplines?				
● Is there a statement of how potential biases or conflicts of interest of the panel members are taken into account?				
● Were these dealt with adequately?				
● Is there a description of the methods used to seek views of interested parties not on the panel?				
Identification and interpretation of evidence				
● Is there a description of the sources of information used to collect (that is, identify and select) the evidence on which the guidelines are based?				
● Where databases are used, is there a description of the search strategy used?				
● If so, are the sources and search strategies adequate and referenced?				
● Is there a description of the methods used to interpret and assess the strength of the evidence?				
● Are these methods satisfactory, in terms of weighting or rating the evidence?				
● If a synthesis method was used to summarise the evidence (for example, meta-analysis or decision analysis) is the method explicitly described?				
● Is this method satisfactory?				
● Is there an explicit link between the major recommendations and the level of supporting evidence?				
Formulation of recommendations				
● Is there a description of the methods used to formulate recommendations?				
● If so, are these methods satisfactory?				
● If formal expert or group judgement techniques were used to reach consensus, are the techniques explicitly described?				
● Does the document give explicit information about the strength of the consensus?				
● If the guideline was developed locally, has it been adapted from national guidelines?				
● Does the guideline have accompanying patient information leaflets?				
Likely costs and benefits				
● Is there an adequate description of the health benefits that are likely to be gained from the recommended management?				
● Is there an adequate description of the potential harms and risks that may occur as a result of the recommended management?				
● Is there an adequate description of the costs and resources likely to be incurred or released by the recommended management?				

	Yes	No	Cannot tell	N/A
Peer review				
● Were the guidelines subjected to independent review by experts or outside panels (for example, a peer review journal) prior to their publication or release?				
● If so, is explicit information given about methods and how comments were addressed?				
● Were the guidelines piloted or pre-tested?				
● Is information given about the pilot or pre-test process and findings?				
Updating				
● Is there a mention of a date for reviewing or updating the guidelines?				
● Is there an adequate description of how this will take place?				
● Is the body responsible for reviewing and updating the guidelines clearly identified?				
Other guidelines				
● Is there a mention of other sets of guidelines that deal with the same topic?				
● If so, is there a discussion of possible conflicts among existing guidelines and the reasons for them?				
Overall assessment of the development process				
● Is there an accurate summary in the document that reflects the methods, contents and recommendations?				
● Overall, have the potential biases of guideline development been adequately addressed?				
Applicability				
● Are the health professionals for whom the guidelines are intended, identified?				
● Is there a satisfactory description of the patients to whom the guidelines are meant to apply?				
● Is there a description of the circumstances (clinical or non-clinical) in which exceptions might be made in using the guidelines?				
● Is there an explicit statement of how the patient's preferences should be taken into account in applying the guideline?				
Clarity				
● Do the guidelines describe the condition to be detected, treated or prevented in unambiguous terms?				
● Are the different possible options for management of the condition clearly stated in the guidelines?				
● Can each major recommendation be found easily and are they clearly presented?				
Guideline dissemination and implementation				
● Does the guideline document suggest possible methods for dissemination and implementation?				
● Are the proposals realistic and/or practical?				
National guidelines only				
● Is provision made for the adaptation of the guideline into a local guideline?				
● If so, does the guideline suggest/specify the methods for local development?				
Monitoring of guidelines/clinical audit				
● Does the guideline document specify criteria for monitoring compliance?				
● Does the guideline identify clear standards or targets?				
● Does the guideline document define measurable outcomes that can be monitored?				

*Adapted from the St George's Health Care Evaluation Unit *Appraisal Instrument for Clinical Guidelines*; the Leicestershire *Evidence Based Guidelines Checklist* and the *Agency for Health Care Policy and Research Guidelines*. N/A = not applicable

Implementation

The development of good guidelines does not ensure their use in practice. Systematic reviews of strategies for changing professional behaviour show that relatively passive methods of disseminating and implementing guidelines – by publication in professional journals or mailing to targeted healthcare professionals – rarely lead to changes in professional behaviour.[11]

There is no single effective way to ensure the use of guidelines in practice, so organisations should use multifaceted interventions to disseminate and implement them. Strategies should be chosen by assessing available resources and perceived barriers to care, as well as research evidence on the effectiveness and efficiency of different strategies.

Evaluation

Evaluation ensures that the process of care reflects guideline recommendations. The data required for this exercise should be specified at the outset and should be linked to areas of strong evidence within the guideline.[11]

Identifying a good clinical guideline (Table 1)

In the UK, The Health Care Evaluation Unit assesses national guidelines that are funded by the NHS Executive or the Department of Health.[12] There are other guideline development programmes that include formal appraisal – for example, the Scottish Intercollegiate Guidelines Network. If appraised guidelines are not available from these sources, organisations should undertake their own appraisals.

In conclusion, the development of good clinical guidelines should consider all relevant disciplines and stakeholders as well as local circumstances.

Guidelines should be firmly based on reliable evidence relating to clinical effectiveness and cost-effectiveness, and any recommendations should be linked to the evidence, with references and a grading of the supporting evidence.

Active educational intervention should be adopted for the effective dissemination of the results.

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Abbreviated prescribing information: Rilutek®

Presentation: Rilutek Tablets contain riluzole 50mg. **Indications:** Riluzole is indicated to extend life or the time to mechanical ventilation for patients with amyotrophic lateral sclerosis (ALS). Clinical trials have demonstrated that Rilutek extends survival for patients with ALS. There is no evidence that riluzole exerts a therapeutic effect on motor function, lung function, fasciculations, muscle strength or motor symptoms. Riluzole has not been shown to be effective in the late stages of ALS. The safety and efficacy of riluzole has only been studied in ALS. **Dosage and administration:** Adults and Elderly: One 50mg tablet bd; Children: Not recommended; Renal impairment: Not recommended; Hepatic impairment: See warnings and precautions. **Contra-indications:** Severe hypersensitivity to riluzole. Patients with hepatic disease where baseline transaminases are greater than 3 times ULN. Pregnancy, breast feeding. **Warnings and Precautions:** Prescribe with care in patients with history of abnormal liver function or patients with increased transaminase, bilirubin and/or GGT levels. Measure serum transaminases regularly during initiation of treatment with riluzole and frequently in patients who develop elevated ALT levels during treatment. Treatment should be discontinued if ALT level increases to 5 times ULN. Discontinue riluzole in the presence of neutropenia. Any febrile illness must be reported to the physician. Do not drive or use machines if vertigo or dizziness are experienced. **Interactions:** *In vitro* data suggests CYP 1A2 as the primary isozyme in the oxidative metabolism of riluzole; inhibitors or inducers of CYP 1A2 may affect the elimination of riluzole. **Pregnancy and lactation:** Contra-indicated. **Side effects:** Asthenia, nausea and elevations in LFT's are the most frequent events seen. Less frequent events include pain, vomiting, dizziness, tachycardia, somnolence and circumoral paraesthesia. **Legal Category:** POM. **Package Quantities and Basic NHS Price:** Each box of Rilutek Tablets contains 4 blisters of 14 tablets; £286.00.
Marketing Authorisation Number: Rilutek tablets 50mg EU/1/96/010/001.
Full Prescribing Information and further information is available on request from Aventis Pharma Limited, 50 Kings Hill Avenue, Kings Hill, West Malling, Kent. ME19 4AH. **Date of preparation:** November 2000.

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