Effective HEALTH CARE

Implementing Clinical Practice Guidelines:

Can guidelines be used to improve clinical practice?

- Practice guidelines are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.
- The introduction of guidelines can change clinical practice and affect patient outcome. The ways in which guidelines are developed, implemented and monitored influence the likelihood of adherence.
- Guidelines are more likely to be effective if they take into account local circumstances, are disseminated by an active educational intervention, and implemented by patient specific reminders relating directly to professional activity.
- Guidelines should be firmly based on reliable evidence of clinical and cost effectiveness. Recommendations should be explicitly linked to the evidence. Few national or local guidelines are sufficiently based upon the evidence.
- National initiatives are needed to help provide the evidence base which can be incorporated into national and local guidelines.
- Priority should be given to the development and introduction of local guidelines where nationally produced rigorous guidelines exist or where the evidence base is readily available. Priority should be given to areas where current practice diverges from best practice providing the potential for significant gains in health.
- A coherent programme of research is needed to ensure that guidelines are used to their full potential.

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A BULLETIN ON THE EFFECTIVENESS OF HEALTH SERVICE INTERVENTIONS FOR DECISION-MAKERS

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A. Guidelines and Effective Health Care

A1. There is increasing interest in the potential of clinical practice guidelines to promote the effectiveness and efficiency of health care. The NHS Executive has recommended that guidelines should be used to 'inform contracts'.[1,2] Previous Effective Health Care bulletins recommended the development of guidelines to rationalise the use of investigations and treatments.[3,4] It has been argued that health care commissioners should purchase guidelines/protocols rather than simple procedures.[5]

Practice guidelines are 'systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances'.[6] Guidelines should identify recommendations for appropriate and cost effective management of clinical conditions or the appropriate use of clinical procedures with the principal aim of promoting good performance.

A2. This bulletin examines the evidence on whether practice guidelines can change the behaviour of health professionals and, if so, how best to introduce them into clinical practice. The bulletin also considers the characteristics of high quality guidelines and how purchasers might use guidelines in commissioning.

B. Evaluating Guideline Implementation:

B1. The literature evaluating clinical guidelines is scattered across many generalist and specialist journals. Grimshaw and Russell undertook a systematic review of rigorous evaluations of clinical guidelines published between 1976 and 1992.[7] For this bulletin the review has been updated to include previously unidentified studies and studies published up until June 1994.

B2. To identify papers on clinical guidelines defined according to the box, the following databases were searched: DHSS-DATA,[8] Embase,[9] Medline[10] and SIGLE[11] all since 1975; along with published bibliographies of related topics;[12-26] and citations in articles reviewed. Further references were provided by colleagues. Investigations of clinical guidelines were reviewed in depth if they were intended primarily for medical staff, used rigorous study designs to evaluate the effectiveness of guidelines in terms of the process of care or outcome for patients, and reported sufficient data for statistical analysis.

B3. Study design: In behavioural research, simple randomised controlled trials (RCTs) may be more susceptible to a range of biases than in other types of research,[27] although some form of RCT is still likely to provide the best evidence of the effectiveness of guidelines implementation.

B4. When evaluating guidelines in simple (patient) randomised trials there is a danger that the treatment offered to patients in the control group will be contaminated by doctors' knowledge of the guidelines, with the result that the evaluation may underestimate the true effect (eg[28]).

B5. In studies where doctors (or hospitals) are randomised to intervention or control groups, doctors randomised to the guidelines group may be subject to greater Hawthorne effects (the beneficial effects on performance of taking part in research)[29] than doctors in the control group, with the result that the evaluation may overestimate the true effects of guidelines.

B6. Cross-over trials (eg[30]), in which clinicians act as their own controls receiving different interventions in random order, can be a powerful design. However, because there may be contamination across periods due to (for example) learning effects, the evaluation may underestimate the effect of implementation. However randomised cross over trials may reduce Hawthorne effects.

B7. One of the most reliable trial designs for these types of interventions is one in which each participating doctor experiences both guidelines and the status quo simultaneously in a balanced incomplete block design based on two or more clinical conditions (eg[31]).

B8. Balanced incomplete block designs, randomised controlled trials randomising doctors either individually or in groups and randomised controlled cross over trials are considered to provide the most reliable (grade I) evidence (see Appendix).

B9. Before - after studies with non-randomised controls which compare changes in the targeted behaviour with control activities performed by study doctors but not targeted by guidelines (eg[32]) may provide useful though less reliable results. Before - after studies with non-randomised controls and simple RCTs in which patients are randomised are considered together as providing grade II evidence (see Appendix).

B10. Time series techniques have been used to analyze before - after studies in an attempt to detect whether an intervention has had an effect significantly greater than the underlying trend.[33] Non randomised studies in which the controls are selected in the belief that they may experience changes similar to those of the study populations (eg[34]) can also be useful. We reviewed before-and-after studies controlled by data from other sites, if: control and study sites were apparently similar; baseline characteristics and performance in control and study sites were similar; and data collection was contemporaneous in study and control sites during both phases of the study. These two designs are more reliable than the simple uncontrolled before and after study design where secular trends or sudden changes make it impossible to attribute observed changes to the intervention. The results from before - after studies controlled by site, and interrupted time series studies are considered to provide grade III evidence (See Appendix).

C. Do Guidelines Influence Clinical Practice?

Guidelines can change clinical practice and affect patient outcome. The methods of development, implementation and monitoring of guidelines influence the likelihood of adherence to clinical guidelines.

C1. 91 studies were identified covering a wide range of clinical settings and tasks. [28 30-122] They comprised 35 studies of clinical

The *Effective Health Care* bulletins are based on a systematic review and synthesis of literature on the clinical effectiveness, cost-effectiveness and acceptability of heath service interventions. Relevant and timely topics for review are selected by a Steering Group comprising managers, directors of public health and academics. Selection of topics takes into account the following criteria: resource implications, uncertainty about effectiveness, and the potential impact on health. The review and synthesis of the literature is carried out by a research team using established methodological checklists, with advice from expert consultants for each topic. The bulletins represent the views of the *Effective Health Care* research team.

care, 34 of preventive care, and 22 of prescribing, or the use of radiological or laboratory investigations. Only 14 studies were UK based including 4 of clinical care (hypertension,[62] common paediatric conditions,[51] infertility management and referral[51] dyspepsia[53]), 1 of preventive care (antenatal),[96] and 9 of investigations (of which 6 were radiological).[32,105,106,111,113,114,117,118,121]

C2. 81 of the 87 studies which examined effects on the process of care, as measured by adherence with recommendations of practice guidelines, reported significant improvements. 12 out of the 17 studies which assessed patient outcome reported significant improvements. All 14 UK based studies noted significant improvements in compliance with guidelines; the only UK study measuring patient outcome also reported significant improvement.[51]

C3. The evidence from those studies considered to provide more reliable (grade I) evidence confirm these findings. 43 out of 44 such studies report significant changes in process and 8 out of 11 show significant changes in outcome.

C4. The evidence from these rigorous evaluations suggests that properly developed guidelines can change clinical practice and may lead to changes in patient outcome.

D. Introducing Guidelines into Practice

Guidelines are more likely to be effective if they take into account local circumstances, are disseminated by an active educational intervention, and implemented by patient specific reminders relating directly to professional activity.

D1. The successful introduction of a clinical guideline is a complex process with three important stages - developing the guideline, educating clinicians about the guideline and ensuring clinicians act upon the guideline. In this bulletin, the term "educational strategy" is used to describe interventions that aim to influence targeted professionals' attitudes to, and awareness and understanding of, a guideline; and "implementation strategy" to describe interventions that aim to translate knowledge into changes in practice. Whilst this distinction is helpful in exploring the process of guideline introduction, some interventions are designed to achieve both education and implementation.

D2. **Developing guidelines:** Guidelines can be developed by clinicians who will be using the guidelines in practice (end users), or by groups without end user representation.[123] Studies have shown that significant improvements in the process of care can be obtained through implementing guidelines which have been developed across the spectrum of end user involvement.

D3. It is often assumed that end user involvement, in part by increasing ownership, improves the implementation of guidelines. However only two[42,51] of the four[40,42,47,51] studies identified showed this to be the case. The behavioural factors involved in the development of guidelines which influence adherence are very complex, and guidelines produced locally by professional end users may at times be seen as less credible than those produced by locally respected clinicians (opinion leaders) or national experts.[40]

D4. Although some interventions based on the more passive reception of information (eg publication in professional journals and mailing to relevant groups) have been shown to influence professionals' awareness[33] and knowledge of guidelines,[65] they are usually insufficient to change professional behaviour by themselves. However, three UK studies of local general practitioner guidelines for radiological investigations found improved compliance following targeted mailing without any supporting implementation strategy.[32,105,106]

D5. Educational interventions requiring more active participation by professionals (including targeted seminars, educational outreach visits and the use of opinion leaders) are more likely to lead to changes in behaviour. There is some evidence of the effectiveness of educational outreach visits by trained personnel who meet professionals in their practice settings to influence prescribing behaviour [54,104,116] and of the role of opinion leaders - professionals identified by their colleagues as influential.[49] Because these interventions require the investment of valuable resources it is important that their cost effectiveness is rigorously evaluated before their widespread use.

D6. **Implementation strategies:** These are more likely to be effective when they operate directly upon the consultation between the professional and the patient. Such strategies include: restructuring medical records,[52,74,83] patient specific reminders during the consultation[69,70] and patient mediated interventions[79] (in which the aim is to affect professional practice through informing patients). Strategies operating outwith the consultation that have been rigorously evaluated include patient specific feedback[73] and aggregated feedback on compliance with guidelines,[66] financial incentives,[108, 109] explicit marketing[30] and professional peer review.[114]

D7. Several studies have compared different educational and implementation strategies.[45,46,48,49,55,58,73,75-7,79,82,84,85,89,91,93-6,100,114] This research suggests that educational interventions requiring active professional participation, and implementation strategies that are closely related to clinical decision making are more likely to lead to successful guideline implementation.[123] In other words, implementation strategies which are nearer the end user and integrated into the process of health care delivery are more likely to be effective. However, there is insufficient evidence to reach conclusions about the relative effectiveness of different educational and implementation strategies in different contexts.

D8. Other reviews of the research on professional behavioural change, some not including explicit guidelines, also provide insights into methods of implementing guidelines. Lomas[125] reviewed different behavioural change theories and concluded that five types of intervention were worth further evaluation - opinion leaders, educational outreach visits, patient specific reminders, continuous quality improvement and mass marketing. Wensing and Grol[126] compared single and multiple interventions and concluded that multiple interventions were more likely to lead to changes in practice especially if they included individual instruction, feedback and reminders. Johnston et al[24] reviewed trials of the effects of computer-based clinical decision support systems and found evidence that such systems could improve clinician adherence to guidelines. All this evidence reinforces the findings of the specific evaluations of guideline implementation that implementation strategies which are nearer the end user and more integrated into the process of health care delivery are most likely to be successful.

E. Desirable Attributes of Clinical Practice Guidelines

Guidelines should be based on the systematic identification and synthesis of evidence of clinical and cost effectiveness. Recommendations should be explicitly linked to the available evidence.

E1. Eleven characteristics of high quality clinical guidelines are summarised in Table 1. If guidelines are to be effective they should fulfil most if not all of these criteria. Few current UK based guidelines satisfy them.

Table 1 Desirable attributes of clinical guidelines

Attribute	Meaning
Validity	Correctly interpreting available evidence so that when followed valid guidelines lead to improvements in health.
Cost effectiveness	Guidelines lead to improvements in health at acceptable costs.
Reproducibility	Given the same evidence another guideline group produces similar recommendations.
Reliability	Given the same clinical circumstances another health professional applies them similarly.
Representative development	All key disciplines and interests (including patients) contribute to guideline development.
Clinical applicability	Target population is defined in accordance with scientific evidence.
Clinical flexibility	Guidelines identify exceptions and indicate how patient preferences are to be incorporated in decision-making.
Clarity	Guidelines use precise definitions, unambiguous language, and user-friendly formats.
Meticulous documentation	Guidelines record participants, assumptions and methods; and link recommendations to the available evidence.
Scheduled review	Guidelines state when and how they are to be reviewed.
Utilisation review	Guidelines indicate ways in which adherence to recommendations can be sensibly monitored.

Source: Adapted from Grimshaw & Russell[126] and Field and Lohr[6].

E2. **Validity of guidelines:** Guidelines are valid if, when followed, they lead to improvement in patient outcome at acceptable costs. Validity depends on how well evidence is identified, synthesised and incorporated into the guideline and therefore, on how and by whom the guideline is developed.[126]

E3. In the United Kingdom, few national guidelines fulfil the criterion of validity. Guidelines are still being developed by 'expert' panels without formal systematic literature reviews. This approach relies too heavily on panel members' knowledge of published work. Unfortunately published expert recommendations often lag behind evidence[127] and may reflect individual enthusiasm. Furthermore, guidelines relying on literature reviews that are not systematic are potentially biased because they may fail to take account of important evidence on effectiveness.[128,129]

E4. These biases may be overcome if guideline developers adopt a systematic approach to identifying and synthesising evidence. Systematic reviews use explicit standards to judge the scientific validity and clinical applicability of evidence, ensuring that conclusions are drawn only from methodologically sound studies.[130] Reviews are more likely to be rigorous and systematic if carried out using established and evaluated techniques by personnel skilled and experienced in their use. Guidelines based on reviews that identify, synthesise and interpret evidence systematically are more likely to be valid.

E5. Since local groups may lack the resources and skills needed to develop evidence based guidelines,[124] care must be taken to ensure that any increased acceptability due to local guideline development is not achieved at the expense of their potential to improve patient outcomes.

E6. There are many methods of guideline development, including peer groups, nominal groups, Delphi techniques and consensus conferences.[131-4] All these methods have potential biases and there is little evidence on their relative merits. It is important to pilot guidelines in several sites to ensure their applicability and relevance. The experience of patients as well as professional users should be taken into account.

E7. Practice guidelines should not be solely concerned with clinical effectiveness, but should also pay regard to the costs of treatments if they are to maximise improvements in health status.[5,135,137] Guidelines should explicitly take into account the costs of interventions so that the limited resources available are used most efficiently. If guidelines ignore the issue of cost effectiveness they might recommend practices which result in large increases in cost but with little corresponding improvement in health. Unfortunately guideline development has largely ignored the issue of costs. Since costs of treatments may vary across sites, local guideline development will need to consider local factors which may influence cost effectiveness.

E8. Guidelines should clearly indicate the basis of each recommendation and the degree to which it is supported by good research evidence. The target patient population and circumstances under which the recommendations apply should also be clearly stated. Clarity of definitions, language and format is essential to ensure that different users interpret and apply them in essentially the same way. In particular, guidelines should use clinical terms precisely and avoid ambiguous or vague statements.

E9. There is little information in the literature on the effect that style and format have on the adoption of guidelines. Guidelines with a wide range of styles and formats have been shown to be effective in changing practice.

E10. **Scheduled review:** Guideline developers should specify how their guidelines should be monitored to identify major changes in knowledge and how the guidelines should be routinely reviewed to incorporate such knowledge to maintain validity. Guidelines should also indicate ways in which adherence to recommendations can be monitored (utilization review).

E11. **Critical appraisal of clinical guidelines:** Unfortunately few published guidelines give enough details about development for their validity to be confidently assessed.[138] Guideline developers should provide enough information to allow potential users to make an informed judgement about validity and relevance to specific circumstances.[139] A guide for structured abstracts for guidelines encouraging the publication of details of development has now been published.[140]

F. Medico Legal Issues

Compliance with clinical guidelines is unlikely to prove decisive in a medical negligence action, unless the intervention concerned is so well established that no responsible doctor acting with reasonable skill would fail to comply with it.

F1. Clinicians' concerns about the legal status of guidelines and potential litigation resulting from non compliance may be a barrier to guideline implementation. Guidelines are subject to the Bolam test which will remain the legal standard for the foreseeable future.[141]

F2. The Bolam test uses the criterion of common professional adoption, rather than that of evidence-based health care, as the basis for negligence.[142] This would require a guideline to have achieved professional acceptance and use by a responsible body of doctors before it could be accepted as evidence of the required standard of care in a court of law. Thus guidelines which fail to

reflect customary practice, however scientific, are likely to fail the Bolam test. Compliance with, or deviation from, a clinical guideline is unlikely to prove conclusive in a medical negligence action, unless it can be shown that the guideline is so well established that no responsible doctor acting with reasonable skill would fail to comply with it.[143] Therefore, medico legal issues do not, in principal, represent a barrier to guideline implementation.

F3. There have been suggestions that the Bolam test might be challenged in the future by evidence based practice which does not reflect customary professional practice.[144,145]

G. Guidelines and Commissioning

National initiatives are required to help provide the evidence base which can be incorporated into national and local guidelines. The development and introduction of national and local guidelines should be adequately resourced. Priority should be given to the introduction of guidelines which address local needs and where nationally produced rigorous guidelines exist or where the evidence base is readily available.

G1. Guidelines can be used in a wide range of settings to promote effective and efficient health care; for example: at the primary/secondary care interface to improve the appropriateness of referral;[52] to guide the introduction of new procedures or services; to promote effective health care in primary or secondary care settings (eg[55]); to encourage the adoption of cost effective interventions (eg[63]); to improve the timing and processes of the discharge of patients (eg[63]); to structure and encourage patient participation in clinical management decisions (eg[79]); to inform the development of criteria and standards for monitoring the quality of care, in particular through clinical audit.[146]

G2. **Developing guidelines:** Resources should be made available to help provide the evidence base which can be incorporated into guidelines. Resources should be available for the national development of valid evidence based guidelines, their local adaption, or the production of local evidence based guidelines.

G3. If guidelines are to achieve their potential they should be adequately resourced and should be introduced through partnerships which may include clinicians, providers, purchasers and the public.[147] The purchasers' role in this process may involve identifying the best evidence of effectiveness and cost effectiveness or valid national guidelines, and prioritising areas for the introduction of local guidelines. They also have a role in sponsoring the development of local guidelines; incorporating guidelines into service specification (referenced in contracts); supporting providers in implementing guidelines; monitoring and evaluating development and implementation, in particular the achievement of standards specified.

G4. **Prioritising areas for local guideline introduction:** The number of guidelines that can be assimilated by health care professionals or provider organisations at any time is limited. Local activities should be coordinated to prioritise the guidelines that professional groups are asked to implement. Greater priority should be given to the introduction of guidelines which address important local need, in fields where rigorous national guidelines or research evidence are available, and where current practice diverges from best practice thus providing the potential for significant gains in health.

G5. The choice of clinical condition may influence the success of guideline implementation. Guidelines relevant to clinical conditions where recommendations require the acquisition of new skills and where evidence on effectiveness is counter to widely accepted practice may need additional resources for implementation and specific skills based training packages.

G6. **Local guideline development:** should be multidisciplinary if at all possible including representatives of all key clinical disciplines, providers and purchasers, as successfully implementing guidelines normally requires changes in the behaviour of more than one discipline.[127,148,149]

G7. Local guidelines may include more operational detail than national guidelines. Additional tasks for local groups include analysis of the local resource consequences of guideline introduction, identification of barriers to guideline introduction, discussion about appropriate implementation strategies and agreement upon criteria and standards for monitoring. Public involvement in guideline development may enhance implementation especially where public expectations influence practice. Guidelines and their associated criteria and standards may be detailed within a service specification and referred to in the contract. However, by itself, contracting is unlikely to be sufficient to implement guidelines.

G8. **Local guideline implementation:** New guidelines should be introduced through active educational programmes for all personnel whose work is targeted by the guideline. Regular reinforcement through personalised feedback and review and through continuing professional education may be beneficial. It is important to identify which health care professionals are involved in the care targeted by the guideline and the context in which that care is provided. Methods of prompting the professional to follow the guideline during the consultation (the most powerful implementation strategy) should be identified where possible. Patient mediated interventions may enhance implementation especially where public expectations influence practice. Complementary strategies will usually be required to ensure the successful introduction of guidelines.

G9. **Monitoring of standards:** Purchasers and providers need to agree upon criteria for the review of practice based upon guidelines. These standards should be monitored through the commissioning process to ensure that the guidelines achieve a quality of care consistent with the evidence upon which they are based. Clinical audit groups may be well placed to co-ordinate and resource the development of local guidelines and should be encouraged to develop expertise in leading and facilitating local guideline development groups. Ideally relevant patient outcomes data should be collected and analyzed routinely to explore how guideline implementation may be influencing the quality of care.

H. Research Issues

A coherent programme of research is needed to ensure that clinical practice guidelines are used to their full potential.

H1. **Research into effectiveness:** Guidelines can be used to promote cost effective health care. However, guidelines are not the most appropriate tool for all circumstances. It is important to study the optimal contribution that guidelines can make and their limitations to ensure that they are used only in areas most likely to encourage effective and efficient health care.

H2. **Research into guideline development:** Research is needed to identify the most cost-effective methods for developing valid and reliable national and local guidelines. This should include research into methods for deriving recommendations and into the effects of different formats and styles of guidelines on their adoption. Research to examine ways of better incorporating costs into guidelines so that they help promote cost effective health care is required. It is also important to develop valid instruments for critically appraising guidelines.[138]

H3. The Health Technology Assessment programme of the NHS Research & Development Initiative has identified research into the

use of consensus development panels for assessing health technologies and producing practice guidelines as a priority.

H4. **Research into guideline implementation:** Research is required to examine barriers to the adoption of guidelines and to devise and test appropriate strategies to overcome these. Although there is some evidence on the effectiveness of different educational and implementation strategies these are still poorly understood in the UK. Further research is needed to ensure that resources made available for the implementation of guidelines are used cost effectively.

H5. The new Cochrane Collaboration on Effective Professional Practice will provide up to date reviews of rigorous research on the effectiveness of different approaches to implementation.[150] Future research should build upon the existing knowledge base, and its implications and limitations.

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Appendix – Evidence from rigorous studies of guideline introduction. Categorised by clinical area and grade of evidence

Authors	Setting	Clinical area	End user involvement in guideline development?	Interventions to promote use of guidelines	Design	Effect on process	Effect on outcome
A. Studies of Clinical Care							
Grade I Evidence – Balanced incomplete block designs and randomised controlled trials randomising doctors							
McDonald (1976)[35]	US ambulatory care	Various medical conditions	No	Local guidelines implemented by computer generated reminders	X-over	+ + +	–
Sanazaro and Worth (1978)[36]	US hospital care	1 paediatric, 2 surgical and 4 medical conditions	No	National guidelines approved by local staff and placed in patients' notes	RCT-Dr	+	0
Hopkins et al (1980)[37]	US emergency room care	Hypotensive shock	No	Local guidelines distributed by brief educational programme and implemented by general reminders	RCT-Dr	+ + + +	+ +
Linn (1980)[38]	US hospital care	Management of burns	No	National guidelines distributed by specific educational programme and implemented bygeneral reminders	RCT-Dr	+	+ +
McDonald (1980)[39]	US ambulatory care	Various medical conditions	No	Local guidelines implemented by computer generated reminders supported by bibliographic citations on request	X-over	+ +	–
Sommers et al (1984)[40]	US ambulatory care	Unexplained anaemia	i. Yes ii. No	Guidelines implemented by aggregated feedback: i. developed by end users ii. developed without end users	RCT-Dr	i. 0 ii. + +	–
Norton and Dempsey (1985)[31]	Canadian general practice	Cystitis and vaginitis	Yes	Guidelines implemented by aggregated feedback on baseline compliance	BIB	+ + +	–
Palmer et al (1985)[41]	US ambulatory care	4 medical and 4 paediatric conditions	Yes	Guidelines implemented with aggregated feedback on baseline compliance	BIB	+ +	–
Putnam and Curry (1985)[42]	Canadian general practice	5 medical conditions	i. Yes ii. No	Guidelines distributed by mail and personal educational package, implemented with aggregated feedback on baseline compliance: i. developed by end users for 2 conditions ii. developed without end-users for 2 conditions	RCT-Dr	i. + + + + ii. + + +	–
Winickoff et al (1985)[42]	US ambulatory care	Hypertension	No	National guidelines modified locally and implemented with patient specific feedback outwith the consultation and physician specific feedback	RCT-Dr	+	0
McAlister et al (1986)[44]	Canadian general practice	Hypertension	No	Provincial guidelines distributed by mail and implemented with computer generated patient specific feedback	RCT-Dr	0	+ +
Wirtschafter et al (1986)[45]	US community hospitals	Neonatal respiratory distress syndrome	No	Local guidelines: i. distributed by specific educational programme ii. i + implemented with guidelines embedded in paper medical record	RCT-Dr	i. 0 ii. +	–
Vinicor et al (1987)[46]	US ambulatory care	Diabetes mellitus	No	Local guidelines: i. distributed by individual patient education ii. distributed by intensive physician education and implemented by aggregated feedback, hot-line to diabetic specialists and computer generated reminder iii. i. + ii	RCT-Dr	–	i. + ii. + iii. + +
Putnam and Curry (1989)[47]	Canadian general practice	Hypertension	i. Yes ii. No	i. guidelines developed by endusers ii. guidelines distributed by targeted mailing	RCT-Dr	–	i. 0 ii. 0
Mazzuca et al (1990)[48]	US ambulatory care	Diabetes mellitus	No	Local guidelines distributed by seminar and implemented by: i. computer generated reminder ii. i. + clinical materials iii. ii + diabetes patient education service	RCT-Dr	i. + ii. + iii. +	–
Lomas et al (1991)[49]	Canadian obstetric care	Caesarean section	No	Consensus Development Conference provincial guidelines distributed by mailing to targeted clinicians and implemented by: i. aggregated feedback ii. local opinion leader	RCT-Dr	i. 0 ii. + +	–
Margolis et al (1992)[50]	Israeli paediatric care	3 paediatric conditions	No	Local guidelines implemented by computerised protocol	PBIB	+ + +	–
North of England Study of Standards and Performance in General Practice (1992)[51]	UK general practice	5 paediatric conditions	i. Yes ii. No	Guidelines implemented by feedback on baseline compliance: i. guidelines developed by end users ii. guidelines developed without end users	BIB	i. + ii. 0	i. + + + + ii. 0
Emslie et al (1993)[52]	UK general practice	Infertility	Yes	Guidelines distributed by mail and implemented with guidelines embedded in paper medical record	RCT-Dr	+ + + +	–
Jones et al (1993)[53]	UK general practice	Dyspepsia	Yes	Guidelines distributed by targeted mailing and implemented by a general reminder of the guidelines	RCT-Dr	+ +	–
Soumerai et al (1993)[54]	US hospital care	Blood transfusion	No	Local guidelines distributed by lecture, printed materials and individual doctor educational outreach visits	RCT-Dr	+ + +	–
Anderson et al (1994)[55]	US hospital care	Prevention of deep vein thrombosis	No	NIH Consensus Development Conference national guidelines: i. distributed by CME ii. distributed by CME and implemented by quality assurance program	RCT-Dr	i. + + + ii. + + +	–

Authors	Setting	Clinical area	End user involvement in guideline development?	Interventions to promote use of guidelines	Design	Effect on process	Effect on outcome
Grade II evidence – randomised controlled trials randomising patients, crossover trials and before and after studies controlled by activity not targetted by guidelines							
McDonald (1976)[56]	US ambulatory care	Diabetes & other medical conditions	No	Local guidelines implemented by computer generated reminders	RCT-Pt	+ + +	–
Coe et al (1977)[57]	US ambulatory care	Hypertension	Yes	Guidelines implemented by computer generated reminders	RCT-Pt	–	0
Restuccia (1982)[58]	US Hospital care	General medical conditions	No	National guidelines implemented by nurse coordinator providing: i. Direct feedback to attending physician ii. Feedback to physician adviser iii. Feedback at nurse's discretion	RCT-Pt	–	i. + + ii. 0 iii. + +
Rogers et al (1982)[59]	US ambulatory care	Hypertension, obesity and renal disease	Yes	Local guidelines implemented by computer generated reminders	RCT-Pt	+	+ +
Barnett et al (1983)[60]	US ambulatory care	Hypertension	No	Local guidelines implemented by computer generated patient specific feedback	RCT-Pt	+ + + +	+ +
Thomas et al (1983)[61]	US ambulatory care	Diabetes	No	Local guidelines implemented by computer generated reminders	RCT-Pt	+ +	0
Brownbridge et al (1986)[62]	UK general practice	Hypertension	Yes	Local guidelines discussed with participants and implemented by paper based or computerised protocol	CBA-A	+ +	–
Weingarten et al (1990)[63]	US hospital care	Chest pain	No	Local guidelines implemented with patient specific reminder	RCT-Pt	0	+ + + + +
Grade III evidence – before and after studies controlled by site and time series analysis							
Barnett et al (1978)[64]	US ambulatory care	Streptococcal sore throat	Yes	Local guidelines 'determined' by clinic staff and implemented by patient specific feedback	TSA	+ +	–
Kosecoff et al (1987)[55]	US hospital care	Breast cancer, caesarean section, coronary artery bypass grafting	No	NIH Consensus Development Conference national guidelines distributed by publication in professional journals, no further attempt at implementation	TSA	0	–
Lomas et al (1989)[65]	Canadian obstetric care	Caesarean section	No	Consensus Development Conference provincial guidelines distributed by publication in professional journals and mailing to targeted clinicians, no further attempt at implementation	TSA	+	–
Durand-Zaleski et al (1992)[66]	French hospital care	Hypovolaemia	No	Consensus Development Conference national guidelines distributed by specific educational meetings and implemented with monthly feedback and discussion of compliance	TSA	+ + + +	–
Sherman et al (1992)[67]	US hospital care	Localised prostatic carcinoma	No	NIH Consensus Development Conference national guidelines distributed by publication in professional journals, mailing to targeted clinicians, no further attempt at implementation	TSA	0	–
B. Studies of Preventive Care							
Grade I Evidence – Balanced incomplete block designs and randomised controlled trials randomising doctors							
Cohen et al (1982)[69]	US ambulatory care	8 preventive tasks	No	Local guidelines distributed by intensive educational intervention and placed in patients' notes	RCT-Dr	+ + + +	–
McDonald et al (1984, 1992)[69,70]	US ambulatory care	9 preventive tasks and 6 laboratory tests	No	Local guidelines implemented by computer generated reminders	RCT-Dr	+ + +	+ +
Winickoff et al (1984)[71]	US ambulatory care	Colorectal cancer screening	Yes	Local guidelines distributed by specific educational programme and implemented by comparative feedback of individual doctor performance	X-over	+ +	–
Cohen et al (1985)[72]	US ambulatory care	13 preventive tasks	No	Local guidelines distributed by mail, residents received credit at university book shop after reading guidelines	BIB	'Modest' improvement in compliance	–
Tierney et al (1986)[73]	US ambulatory care	11 preventive tasks	No	Local guidelines distributed by internal mail and implemented by: i. computer generated reminder within consultation ii. patient specific computer generated feedback	BIB	i. + + ii. +	–
Cheney and Ramsdell (1987)[74]	US ambulatory care	12 preventive tasks	No	National guidelines implemented by age-sex specific checklist placed in patient's notes	RCT-Dr	+ +	–
Cohen et al (1987, 1989)[75,76]	US ambulatory care	Smoking cessation	No	National guidelines distributed by specific educational program, implemented by: i. patient specific reminders ii. nicotine gum iii. patient specific reminders and nicotine gum	RCT-Dr	i. + + + + ii. + + + + iii. + + + + +	–
Wilson et al (1988)[77]	Canadian family practice	Smoking cessation	No	National guidelines: i. implemented by nicotine gum ii. distributed by specific educational intervention and implemented with nicotine gum	RCT-Dt	i. + + + + + ii. + + + + +	i 0 ii. +
Cummings et al (1989)[78]	US ambulatory care	Smoking cessation	No	National guidelines distributed by specific educational program and implemented with reminders	RCT-Dr	+ +	+
McPhee et al (1989)[79]	US ambulatory care	7 preventive tasks	No	National guidelines implemented by: i. Audit and feedback ii. Cancer screening reminders iii. Patient education	RCT-Dr	i. + ii. + + iii. + +	–
Turner et al (1990)[80]	US ambulatory care	6 preventive tasks	No	National guidelines implemented with computer generated reminder (control group). In addition study group patients received reminders	RCT-Dr	+ +	–

Authors	Setting	Clinical area	End user involvement in guideline development?	Interventions to promote use of guidelines	Design	Effect on process	Effect on outcome
McPhee et al (1991)[81]	US family practice	11 preventive tasks	No	National guidelines implemented by computer generated reminders	RCT-Dr	+ +	–
Ornstein et al (1991)[82]	US ambulatory care	5 preventive tasks	No	National guidelines distributed by intensive educational intervention and implemented by: i. physician computer generated reminder ii. patient reminder iii. i + ii	RCT-Dr	i. + ii. + iii. +	–
Cowan et al (1992)[83]	US ambulatory care	7 preventive care tasks	No	National guidelines placed in patients' notes	RCT-Dr	+	–
Dietrich et al (1992)[84]	US ambulatory care	10 preventive tasks	No	National guidelines: i. distributed by specific educational intervention ii. implemented by practice facilitator iii. i + ii	RCT-Dr	i. + + ii. + + iii. + +	–
Headrick et al (1992)[85]	US ambulatory care	Cholesterol	No	National guidelines distributed by lecture, implemented by: i. guidelines placed in notes ii. patient specific computer generated prompts	RCT-Dr	i. + ii. +	–
Litzelman et al (1993)[86]	US ambulatory care	3 preventive tasks	No	National guidelines modified locally implemented with computer generated reminders (control) vs physicians required to respond to computer generated reminders	RCT-Dr	+	–
Mayefsky and Foye (1993)[87]	US ambulatory care	Well child care	No	National guidelines implemented by individual physician feedback	RCT-Dr	+ +	–
Grade II evidence – randomised controlled trials randomising patients, crossover trials and before and after studies controlled by activity not targetted by guidelines							
Morgan et al (1978)[28]	US hospital care	Antenatal care	No	National guidelines discussed locally, implemented by computer generated reminders	RCT-Pt	+ +	–
Rodney et al (1983)[88]	US family practice	2 adult immunisations	No	Local guidelines distributed by educational programme and implemented by redesign of medical record to encourage two adult immunisations	CBA-A	+ +	–
McDowell et al (1986)[89]	Canadian family practice	Influenza vaccination	No	National guidelines implemented by: i. computer generated reminder to the doctor ii. telephone reminder to the patient iii. reminder letter to patient	RCT-Pt	i. + + ii. + + + iii. + + +	–
Prislin et al (1986)[90]	US family practice	2 preventive tasks	No	Local guidelines distributed by specific educational conference and implemented by flowsheet placed in patients' notes	RCT-Pt	+ + + +	–
Becker et al (1989)[91]	US ambulatory care	9 preventive tasks	No	National guidelines implemented by: i. reminder to physician ii. reminders to physician and patient	RCT-Pt	i + ii. + +	–
Chambers et al (1989)[92]	US family medicine	Mammography	No	National guidelines implemented by computer generated reminders	RCT-Pt	+ +	–
McDowell et al (1989)[93]	Canadian family practice	Blood pressure screening	No	National guidelines implemented by: i. computer generated reminder to the doctor ii. telephone reminder to the patient iii. reminder letter to patient	RCT-Pt	i. + ii. + iii. + +	–
McDowell et al (1989)[94]	Canadian family practice	Cervical screening	No	National guidelines implemented by: i. computer generated reminder to the doctor ii. telephone reminder to the patient iii. reminder letter to patient	RCT-Pt	i. 0 ii. + + + iii. + + +	–
Rosser et al (1991)[95]	Canadian family practice	Smoking cessation	No	National guidelines implemented by: i. computer generated reminder to the doctor ii. telephone reminder to the patient iii. reminder letter to patient	RCT-Pt	i. + + + ii. + + + + + iii. + + + +	–
Lilford et al (1992)[96]	UK hospital care	Antenatal care	Yes	Local guidelines implemented by: ii. structured papaer record ii. interactive computerised questionnaire	RCT-Pt	i. + ii. +	–
Rosser et al (1992)[97]	Canadian family practice	Tetanus vaccination	No	National guidelines implemented by: i. computer generated reminder to the doctor ii. telephone reminder to the patient iii. reminder letter to patient	RCT-Pt	i. + + ii. + + iii. + + +	–
Grade III evidence – before and after studies controlled by site and time series analysis							
Thompson et al (1983)[32]	US prepaid health plan	Investigations in 'routine' physical examinations	Yes	Local guidelines distributed by intensive educational programme and implemented with feedback on performance	CBA-Dr	+ + +	–
Robie (1988)[98]	US ambulatory care	6 preventive tasks	No	National guidelines distributed by lecture implemented by chart reminders	CBA-Dr	+ + +	–
Schreiner et al (1988)[99]	US ambulatory care	4 preventive tasks	No	National guidelines implemented by patient specific reminders	CBA-Dr	+	–
Nattinger et al (1989)[100]	US ambulatory care	Mammography	No	National guidelines implemented by: i. audit and feedback ii. visit-based intervention (including patient reminder and completed request form)	CBA-Dr	i. + + ii. + +	–
Tape et al (1993)[101]	US ambulatory care	8 preventive tasks	No	National guidelines, distributed by continuing medical education and implemented by flowsheet in paper record (control group). In addition study group received computer generated reminders.	CBA-Dr	+	–

Authors	Setting	Clinical area	End user involvement in guideline development?	Interventions to promote use of guidelines	Design	Effect on process	Effect on outcome
C. Studies of prescribing, laboratory and radiological investigations							
Grade I Evidence – Balanced incomplete block designs and randomised controlled trials randomising doctors							
Marton et al (1985)[102]	US ambulatory care	Biochemistry and drug monitoring investigations	No	Local guidelines: i. distributed by educational materials ii. implemented by individual physician feedback iii. i + ii	RCT-Dr	i. 0 ii. 0 iii. + + + +	–
Chassin and McCue (1986)[103]	US hospital care	Pelvimetry in pregnancy	Yes	Local guidelines distributed by educational meetings and mailed educational materials	RCT-Dr	+ + +	–
Landgren et al (1988)[30]	Australian hospital care	Antibiotic prophylaxis in surgery	No	Local guidelines distributed by with anti-advertising campaign and implemented with aggregated feedback of baseline compliance	X-over	+ + +	–
Avorn et al (1992)[104]	US residential care	Psychoactive drugs	No	Local guidelines distributed by lectures to non medical staff, educational materials to all doctors and educational outreach visits to high prescribing doctors	RCT-Dr	+ + + +	–
Bearcroft et al (1994)[105]	UK general practice	Chest X-rays	No	Local guidelines distributed by post	RCT-Dr	+	–
Oakenshott et al (1994)[106]	UK general practice	4 X-ray investigations	No	National guidelines distributed by local department	RCT-Dr	+ + + +	–
Grade II evidence – randomised controlled trials randomising patients, crossover trials and before and after studies controlled by activity not targetted by guidelines							
Eisenberg et al (1977)[107]	US hospital care	Biochemistry investigations	No	Local guidelines implemented with physician specific feedback about over utilisation	CBA-A	0	–
De Vos Meiring and Wells (1990)[32]	UK general practice	9 radiological investigations	No	Local guidelines distributed by mailing to targeted clinicians, no further attempt at implementation	CBA-A	+ + +	–
Grade III evidence – before and after studies controlled by site and time series analysis							
Brook and Williams (1976), Lohr and Brook (1976)[108,109]	US ambulatory care	Injectable antibiotic prescribing	No	State guidelines distributed by targeted mailing and practice visits and implemented with financial incentives (payment was denied unless care complied with guidelines)	TSA	+ + + +	–
Wong et al (1983)[110]	US hospital care	Biochemistry investigations	Yes	Local guidelines: i. distributed by mailed educational materials ii. i + implemented by change in request form	TSA	i. 0 ii. + + + + +	–
Fowkes et al (1984)[111]	UK A&E care	Skull X-rays for patients with head injuries	No	National guidelines distributed by specific educational programme, implemented by structured head injury card	TSA	+ + + +	–
Novich et al (1985)[112]	US hospital care	Biochemistry investigations	No	Local guidelines implemented by i. requirement for general justification of test ii. requirement for specific justification for test	TSA	i. + + + + ii. + + + + +	–
Fowkes et al (1986)[113]	UK hospital care	Biochemistry and haemotology investigations	No	Local guidelines distributed by specific educational meeting and implemented by weekly feedback	TSA	+ + + +	–
Fowkes et al (1986)[114]	UK hospital care	Preoperative chest X-rays	No	National guidelines implemented by: i. utilisation review committee ii. feedback on individual compliance iii. structured CXR request form iv. review of requests by radiographer	CBA-Dr	i. + + ii. + + iii. + iv. + +	–
Ray et al (1986)[115]	US outpatient practice	Diazepam prescribing	No	State guidelines distributed by educational outreach visit	CBA-Dr	+ +	–
Avorn et al (1988)[116]	US hospital care	Dosage of intravenous antibiotics	Yes	Local guidelines distributed by lecture and printed materials, unadvertisements and posts, implemented through a structured ordering form.	TSA	+ + + +	–
Bareford and Haying (1990)[117]	UK hospital care	Haematological tests	No	Local guidelines distributed by specific educational programme and implemented by aggregated feedback and cancellation of inappropriate expensive tests	TSA	+ + +	–
Clarke and Adams (1990)[118]	UK A&E care	Skull X-ray requests in patients with head injuries	No	Local guidelines distributed by specific educational programme, implemented by general reminders	TSA	+ + +	–
Everitt et al (1990)[119]	US obstetric care	Prophylactic antibiotics for complicated caesarean section	No	Local guidelines approved by senior medical staff, distributed by pamphlet and departmental meetings and implemented through a structured ordering form	TSA	+ + + + +	–
Raisch (1990)[120]	US Health Maintenance Organisation	Anti ulcer treatment	No	Local guidelines distributed by educational outreach visit	CBA-Dr	0	–
Gama et al (1992)[121]	UK hospital care	Cardiac enzymes	No	Local guidelines distributed by specific educational programme	TSA	+ + + +	–
Soumerai et al (1993)[122]	US hospital care	Antibiotics	No	Local guidelines implemented with a structured ordering form	TSA	+	–

KEY

Effect sizes (Average effect size of significant results)

–	Not measured
0	No significant effect
+	Absolute effect between 0-9%
+ +	Absolute effect between 10-19%
+ + +	Absolute effect between 20-29%
+ + + +	Absolute effect between 30-39%
+ + + + +	Absolute effect greater than 39%

Designs

Grade I evidence

BIB	Balanced incomplete block design
PBIB	Partially balanced incomplete block design
RCT-Dr	Trial randomised by individual doctor, team, unit or hospital
X-over	Crossover study

Grade II evidence

RCT-Pt	Trial randomised by patient
CBA-A	Before and after study controlled by untargeted activity

Grade III evidence

CBA-Dr	Before and after study controlled by 2nd site
TSA	Time series analysis

End user involvement in guideline development?

Yes	End users involved in guideline development
No	End users not involved in guideline development

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