WORLD HEALTH ORGANIZATION
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What are the best strategies for ensuring quality in hospitals?

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EVIDENCE FOR DECISION-MAKERS

ABSTRACT

Health Evidence Network (HEN) synthesis report on the best strategies for ensuring quality in hospitals

Ensuring the safety of patients and personnel and improving quality have become important objectives for national health systems in developed and developing countries alike, in response to research highlighting poor quality, increasing patient expectations, and media reports. There is a general belief, supported by growing research literature, that there are effective methods to improve quality and safety.

This report is HEN's response to a question from a decision-maker. It provides a synthesis of the best available evidence, including a summary of the main findings and policy options related to the issue.

HEN, initiated and coordinated by the WHO Regional Office for Europe, is an information service for public health and health care decision-makers in the WHO European Region. Other interested parties might also benefit from HEN.

This HEN evidence report is a commissioned work and the contents are the responsibility of the authors. They do not necessarily reflect the official policies of WHO/Europe. The reports were subjected to international review, managed by the HEN team.

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Summary

The issue

Ensuring the safety of patients and personnel and improving quality have become important objectives for national health systems in developed and developing countries alike, in response to research highlighting poor quality, increasing patient expectations, and media reports. There is a general belief, supported by growing research literature, that there are effective methods to improve quality and safety.

Health care organizations are increasingly expected by governments, funders and patients to introduce quality control systems and outcome improvement strategies. Many health care managers and practitioners also believe that action should be taken, but are unsure of how to proceed, especially within resource constraints.

There are many approaches to improve quality and safety, and diverse strategies to encourage hospitals to do so. Which strategies are most appropriate and cost effective for a particular hospital in a specific situation? Which approach should a government or funder promote?

Findings

There is little research assessing the effectiveness of one or more hospital or national quality strategies that can be used to answer these questions. This lack of evidence does not show that strategies are not effective, but is rather due to the difficulty of evaluating interventions and of proving that the results are due to the strategy and not to other factors.

There is some research into local team projects which shows that "continuous quality improvement" approaches can be effective. There is also research indicating the conditions needed to support and encourage these approaches.

Many publications and reports describe different strategies, but few are well-designed research projects, or report scientifically valid evidence of results. There is an even larger quantity of literature by consultants, academics and commentators advising on the best approach; some is based on sound experience, but little is based on scientific research.

No single quality strategy cannot be recommended above any other on the basis of evidence of effectiveness, ease of implementation or costs.

Policy considerations

Some of the main recommendations from this synthesis of the literature are based on a few valid outcome studies and a critical assessment of the descriptive literature.

1. When reviewing types of strategies, hospitals and governments should question the claims of proponents of any one approach because there is no strong evidence of effectiveness.
2. Decision-makers should be aware that the same strategy applied in a different location or institution may well yield different results, even if fully implemented in exactly the same manner.
3. A chosen quality strategy should be reviewed regularly and adapted to the hanging situation and the responses of personnel. Efforts should be made to assess whether any lack of results is due to the wrong strategy, poor implementation, or the time necessary to observe results. Flexibility without sudden radical change appears to be important.
4. Quality experts with wide experience can be useful, but need to be chosen with care. One or more independent experts should be used to give independent feedback on a strategy for regular reviews.

5. Hospital quality strategies should include improving inter-service quality for different patients groups, and address hospital-community coordination of care issues. Patient experiences and outcomes are affected by how hospitals provide access, outreach and linking with non-hospital services.
6. It is possible that time and money that could be used for patient care is currently wasted on some strategies. There is a strong case for more independent and scientific research.
7. Fuller reviews of the evidence for particular strategies than were possible in this report should be carried out.

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Introduction

Research has shown significant avoidable patient injury occurring in hospitals, increasing the risk of adverse outcomes and higher costs (*1*). Poor health service quality wastes resources that could be used to treat more patients (*2*), and the public is becoming more critical of the quality of hospital care (*3*,*4*). Ensuring safety for patients and personnel and improving quality are national objectives for health systems in both developed and developing countries, in response to research highlighting poor quality, increasing patient expectations, media coverage, and a belief that there are effective methods to improve quality and safety. Health care organizations are increasingly expected by governments and funders to introduce quality systems and strategies. Some health care managers and practitioners also believe that action can and should be taken, irrespective of external pressures.

There are multiple approaches to ensuring safety and improving quality. Some think money should be invested in more personnel, others think that doing more of the same would not improve quality. Which strategies are most appropriate and cost-effective for a particular hospital in a specific situation? Which approach should a government promote?

This is not a systematic review of available research on multiple quality topics but a report synthesizing many types of research into hospital quality strategies. The aim is to enable decision-makers to better formulate, implement and evaluate strategies. Research puts competing claims made by proponents of each approach into perspective and can help avoid costly mistakes from choosing the wrong strategy or implementing it incorrectly. There is no strong scientific evidence of which strategies are effective. It is difficult to make valid comparisons among strategies. But there is useful research that gives partial assessments of results, describing different types of strategy, and suggesting means of implementation.

What is a hospital quality strategy?

A regional or national hospital quality strategy is a long-term (2-5 year) programme to increase patient and personnel safety and improve hospital quality. This synthesis searched for evidence about the nature, implementation and results of both specific strategies in one hospital and strategies to improve quality in many hospitals.

A quality strategy differs from a quality tool in being an overall approach an organization takes over a period of time, rather than a specific method for a particular purpose. Thus, a programme for external inspection of hospitals is a strategy. A particular method for carrying out inspections is referred to by quality specialists as a tool. It is possible to pilot-test a tool, but not a strategy. Benchmarking is both a tool and a strategy. A separate WHO policy synthesis of research into quality tools is under work (*5*).

What is a "good" or a "bad" hospital strategy?

In evaluating strategies, it is necessary to identify alternatives and judge their effects, using evidence and clear criteria. Evidence in relation to the following criteria were sought to assess quality strategies: ease and cost of implementation, impact on health personnel, patient outcomes and cost savings. The

criteria used to assess the evidence are listed in Annex 1: "E1" indicates strong evidence, and "E6" no evidence of any kind.

Sources for this review

Research into hospital and national strategies can be found in many databases, from many sources. The following search strategy and sources were used.

- Electronic searches for systematic reviews and research were made of the databases listed in Annex 2, then a search of quality journals on web sites. The electronic search yielded 25 relevant journal papers and 3 books.
- Author's library: relevant literature collected since 1985 yielded journal papers (*21*), books (*6*), unpublished reports (*7*), master's and PhD studies (*2*), and reports from conferences (8). The synthesis also drew on an earlier overview of quality strategies for Swedish health care leaders.
- Search strategies followed by Scott, et al, (*6*) and the EPOC (Cochrane Effective Practice and Organisation of Care Group) report on how to review quality interventions (*7*) were useful models for identifying and reviewing research in this field.

This was not a full systematic review. There may be evidence which was not discovered or reported in this review due to the wide variety of sources and subjects which need to be searched.

Findings from research and other evidence

Which approaches could be used to improve quality and patient safety in hospitals?

Many strategies are reported in the literature, and are listed below. The research referenced refers to descriptions of the approach rather than to studies of effectiveness, which are considered later.

Increasing resources: increasing the financing, personnel, facilities or equipment used in a hospital or health system, with the aim of treating more patients or treating the same number faster, better and at lower cost-per-person.

Large-scale reorganization or financial reform: changing the structure of a hospital or health system so as to facilitate better decision-making or use of resources. Changes in financing methods are made as a way of improving quality.

Strengthening management: improving quality by increasing management responsibilities, authority or competencies. It is sometimes used as part of other types of strategy.

Standards and guidelines: formulating standards of what is expected from health providers, communicating, providing training in, and enforcing the standards. Examples are the United Kingdom's national standards frameworks (*8*), the Zambian national technical standards, and clinical practice guidelines for various health conditions (*9*). Most medical and clinical audits fall within this category (*10*), as well as some approaches called "quality assurance" (*11*) and "clinical pathways" (*12*).

Patient empowerment and rights: giving patients a voice, for example through complaints systems or patient satisfaction questionnaires, as well as publicizing what patients have a right to expect. There may also be methods to strengthen patient power through legal entitlement, advocacy or other institutions, such as a right to treatment within 30 minutes of arriving at an emergency room, and the United Kingdom "patients charter" of the early 1990s (*13*). A number of Nordic countries have patient guarantees as well as patient rights in law, and ombudsmen and other schemes to strengthen patient power (*14*).

Quality management system: defines responsibilities for quality and puts into place the structures and systems to ensure it. The International Organization for Standardization (ISO) issues guidelines used by some European hospitals to design quality management systems (*15*). The composition of such a system is interpreted differently from country to country in the absence of overarching standards.

Quality assessment and accreditation, internal or external: There are many assessment systems (*16*); the best known in Europe is the European Foundation for Quality Management system (*17*), based on the American Baldridge Award system (*18*). A related strategy is voluntary or compulsory external quality assessment by a third-party peer review organization, or governmental body (*16*). This may or may not involve issuing formal accreditation. Accreditation systems differ in which aspects of hospital operations are assessed and whether quality outcomes are considered in the assessment (*19*, *20*). Some experts argue that hospital accreditation programmes are not a good use of resources in low-income developing countries (*83*).

Total quality management (TQM) and continuous quality improvement (CQI): TQM is a set of principles and methods applied in many different ways, originating from organization-wide industrial quality programmes. This strategy focuses on attention of personnel and on providing the best patient experience and outcomes. Quality tools are used by multidisciplinary teams of workers to make changes, and the approach is generally thought to require strong management leadership. It is based on a view that quality problems are more often due to poor organization than to individual faults (*21*). CQI is the same as TQM in most literature, although it sometimes refers to a concentration on multidisciplinary project teams analysing work processes and using repeated cycles of testing small changes (*22*).

Quality collaboratives: a national and regional strategy in Australia, Norway, Sweden and the United States, promoted by United Kingdom's National Health Service, and being tested in middle-income developing countries (*23*). The strategy is to bring together project teams from many different hospitals. The teams typically meet every 3 months over 9 months to learn and apply quality methods and to report their progress (*24*). It was devised to provide an economical way to learn models of effective practice and quality methods, to stimulate enthusiasm and get faster results than are usually obtained by CQI/TQM strategies (*25*).

Re-engineering: uses some of the TQM methods, but includes a more radical redesign of "production processes" than the TQM approach, which normally involves small-scale and incrementally tested changes (*26*).

Quality indicator comparison: seeks to motivate patients, clinicians and others to use information about quality to make improvements, but is not prescriptive. It can be used by one hospital taking part in a comparative data gathering programme (*27*), or as a voluntary or compulsory strategy for hospitals in an area to collect and report the same data. Some comparison systems are public and promoted to encourage both patients and providers to take action to improve quality (*28*).

Benchmarking: uses comparative information about quality with additional methods to help providers decide how to improve quality. There are specific methods for identifying, documenting and applying the best practices (*29*, *30*).

Risk management and safety: identifies high risk procedures or situations that put the hospital at financial risk from patient claims (*31*). It includes methods for diagnosing causes of adverse events. Patient safety strategies often include risk management and a wide range of methods from other industries for collecting and analysing adverse event or near miss reports with a view to prevention (*32*).

What is the evidence about hospital quality strategies?

There is no conclusive evidence of effectiveness for any of the strategies. There is some evidence from surveys of provider's expectations or perceptions of results, and some descriptive evidence of strategies, although most of the latter are self-reports. This search found evidence of different types for each type of strategy. Time prevented a full review of each type. A report below of "no evidence" means that no strong scientific evidence was discovered. It does not mean that there is no evidence of

any type: most reports are by practitioners or project leaders who provide some evidence, but not of the quality required for a scientific study (noted as "self-report E5").

Systematic reviews: There are no systematic reviews of hospital quality strategies, but there are some reviews of interventions which could be used as part of a strategy. Distributing educational materials to professionals has little effect, according to one review (*33*), but other reviews suggest that this approach is more effective if combined with audit and feedback (*34*), computerized prompts (*35*) or "academic detailing" (*36*). Other single studies support the value of combined approaches. Research in United Kingdom primary care found significant changes in provider behaviour through clear leadership and a set of financial and professional incentives (*37*, *38*).

Reviews of interventions to change physicians' practices suggest that a multi-intervention approach is likely to be most effective (*39*, *40*). Other reviews of guideline implementations and audits are noted below.

A review of target payments in primary care found they led to some improvements in health outcomes, but also noted that financial incentives could cause efforts to be switched from interventions for which reimbursement systems are harder to develop (*41*).

Increasing resources: There is some evidence that increasing resources can reduce waiting times (*42*), but there are disagreements about whether the reductions were due to the extra resources and whether waiting times should be considered a quality characteristic at all. There is some evidence that reducing resources does affect quality. A full review of research about this subject was not possible in this synthesis.

Reorganization: There is no evidence that large scale structural reorganization can improve quality. There is limited evidence (E3) that quality for some specialties is higher above a certain volume of patients (*43*, *44*), and that a merger can increase volume, but no studies showing conclusively that a merger improves quality. Small reorganizations for process changes by teams can improve quality and the evidence on this is reported below under TQM/CQI. There is no evidence that changes in financing methods can improve quality, although there is some evidence it can reduce quality. A full review of evidence about large reorganization as a quality strategy was not possible in this synthesis.

Strengthening management: There is no evidence that increasing management responsibility for quality, authority or competencies improves quality, but it is still sometimes carried out as part of other types of strategy, especially in the United Kingdom NHS through clinical governance (*45*). A full review of this subject was not possible in this synthesis.

Standards and guidelines formulation and implementation: Many individual audit projects report positive results but do not meet scientific standards of evidence (noted as "E5" self reports). No evaluations of auditing as a hospital-wide or national strategy provide strong evidence of results. A literature review of 93 studies concluded that auditing could be "a valuable assistance" to any quality programme, but would need a "coherent strategy aimed at nurturing effective audits". Perceived benefits of auditing included improved communication and patient care, increased professional satisfaction, and better administration. Disadvantages were perceived as diminished clinical ownership, fear of litigation, hierarchical and territorial suspicions, and professional isolation. The main barriers were lack of resources, lack of expertise in project design and analysis, problems between groups and group members, lack of an overall plan for auditing, and organizational impediments. Key facilitating factors were modern medical records systems, effective training, dedicated staff, protected time, structured programmes, and a dialogue between purchasers and providers (*46*).

A systematic EPOC (Cochrane Effective Practice and Organisation of Care Group) review of evaluations of guidelines for nursing and therapy professions cautiously concluded that guidelines can be used to get positive changes in process and outcomes to care. No differences were reported between nurses and doctors following protocols for skill substitution in the studies reviewed (E2, *47*). One large well designed, randomized, controlled trial found that guidelines based education for detection

and treatment of depression in primary care in the United Kingdom did not produce expected benefits (*48*).

Standards or guideline strategies are simple, easily understood and largely accepted, but are quite resource intensive and standards may be formulated without regard for resource requirements or variations in settings. This and failure of management supervision, action or sustainability can lead to loss of credibility (*48*).

Patient empowerment and rights: There is no evidence supporting any strategy of this type. There is no strong evidence of the impact or costs of patient satisfaction questionnaires. One review of 195 studies found few of the studies were valid and reliable (*49*). The most detailed research description is of a California programme, showing methods of involving and empowering underserved populations (*50*, self-report E5).

Quality management system: Although this is one of the most popular strategies in Europe, there is no evidence of results. Some self-reports call the European Foundation for Quality Management framework a "quality management system", and report benefits, especially awareness-raising about a comprehensive approach to quality (*51*, *52*). The United Kingdom clinical governance programme requires a quality system, as does the Norwegian quality strategy, but though there is much discussion in the literature, there is no research evidence.

Quality assessment and accreditation, internal or external: A comprehensive summary of accreditation programmes by ISQA for WHO in 2001 found that 14 accreditation programmes operated in 12 European countries (*82*), and noted that half are funded by government and increasingly used for regulation and accountability, rather than for voluntary self-development.

A 1990 study found no association between the United States' HCFA mortality rates and hospital quality as measured by accreditation performance (*53*). There is no more recent research that takes account of changes to accreditation systems, some of which include outcome performance assessments (*54*).

There is no evidence of results for the American Baldridge or the European Foundation for Quality Management framework or other systems, but there are many reports of positive experiences using these systems as part or all of a strategy (*55*, *56*).

Total quality management (TQM) and continuous quality improvement (CQI): Most evidence in this field covered strategies identified as this type by hospital managers or practitioners. However, there is no strong evidence of results. One American interview survey concluded: "None of the quality experts could identify a healthcare organization that has fundamentally improved its performance through CQI (or any other means). There simply are no organization-wide success stories out there" (*57*).

An American study of 67 hospitals using TQM found that, after two years, patient outcomes were not significantly different compared to hospitals just starting TQM/CQI programmes (*58*). A study of 61 American hospitals found that TQM programmes had largely failed to address professional quality issues. After an average 3.6 years, fewer than 30% had examined clinical quality, and only 14% of physicians had taken part in the training within 43% of sampled hospitals (*59*). A later study commented, "Although there is a growing descriptive and prescriptive literature ... no systematic evidence exists as yet to demonstrate CQI/TQMs superiority to existing or alternative approaches to quality assurance and improvement" (*60*).

Few public health services in the United States or Europe have introduced full TQM programmes, although there are many smaller-scale initiatives which are often called TQM programmes (*61*). One of the few reported long-term evaluations is of selected hospitals and community health services taking part in the United Kingdom National Health Service / Department of Health and Social Security TQM pilot programme (*62*). This study found that:

- three of the 20 services had relaunched their quality programmes two years after starting, and are now using a Deming TQM approach;
- many services had not introduced a full TQM strategy, but were encouraging small-scale initiatives in different departments and professions;

- there were some changes in personnel's understanding of quality methods and attitudes in nearly all sites;
- investment in the TQM quality programme was between 5% and 10% of that in two comparable non-health organizations;
- little training was done in basic quality awareness, quality methods or process improvement;
- only one site perceived any improvement, but had little measurable evidence of changes in processes or outcomes;
- only four services in the sample had been able to involve physicians; and
- most programmes had dwindled due to personnel turnover, restructuring, too few resources and poor programme management.

Similar findings were reported for a four-year study of six Norwegian hospitals. They noted the difficulties managers and enthusiastic physicians had devoting the time necessary for such a programme (*63*).

A review of the clinical application of CQI in the United States found 41 single and 13 multi-site studies mostly using practitioner before-and-after measures (*64*). Accepting the scientific weaknesses of the studies, the review concluded that there was some evidence that improved quality and economic efficiencies were achieved. It noted the effort and costs to create these results, the publication bias of the journals, and that "evidence has yet to emerge of an organization-wide impact on quality." One policy evaluation of a 24-pilot United Kingdom national CQI-based improvement programme explained the wide range of short-term and long-term results as due to "the power of physicians, the inertia built into established ways of working and the effort needed to implement new work processes" (*65*). Recommendations included stimulating change at individual, team, organization and systems levels simultaneously, and pointed out the need for personnel to feel that they, too, as well as patients, benefit from improvements.

Other studies proposing explanations of why TQM/CQI appears difficult to apply in public health systems have noted financial disincentives, three different management hierarchies of nursing administration and medicine - as opposed to the one found in industry - and professional resistance to management control of quality at the expense of autonomy (*66, 67, 68, 69*).

Quality collaboratives: One report of two American collaboratives for end-of-life care reported that 47 teams "made key changes to improve care", for example a 60% reduction in patients with pain greater than 5 on a 10-point scale (*70*). Other studies report similar improvements (*71*), but the quality of evidence is questionable as data were collected by practitioner project teams, not often meeting scientific standards for data collection or for control of confounders.

Re-engineering: There is no evidence of a hospital wide re-engineering programme. No multi-hospital strategies using this approach have been reported. There are some early reports of successful projects using this approach but the full costs and benefits were not reported (*72*). The best scientific study in health care of a United Kingdom re-engineering strategy found some benefits but also reported the importance and difficulty of getting continual support from doctors (*73*). This finding is echoed on many studies of different strategies (*25, 62, 63, 64*).

Quality indicator comparison: A review of issues in the use of comparative data to assess quality concluded that many variations among hospitals were a data artefact[1] rather than a real quality difference (*74*). The most recent unsystematic review of all published comparative data systems in the United States concluded that the cost and validity problems were not worth the benefits (*28*).

These and other studies of data sets used in comparative systems suggest that routine quality data is not yet adequate to be used as a strategy for improving quality. However there is agreement about the need for valid and credible data about quality. One United Kingdom hospital reported using the Maryland system (*27*) and expected positive results from this strategy.

[1] Something artificial from the data

Benchmarking: There is little evidence about benchmarking strategies. One American study describes the experience of eight hospitals and the problems of getting physician involvement (*75*), but without strong evidence of results.

Risk management and safety strategies: No scientific evidence of the effects of these strategies was found, although there are some descriptions and also estimates of results by extrapolation from other industries (*76, 77*).

National quality strategies: The search revealed a number of national strategies for quality, but no systematic evaluations appear. The United Kingdom 1998 strategy is the most extensive documented programme (*78*), and the Norwegian is the longest-running, since 1995 (*79*). Some of the range and breadth of possible strategies is shown in the United States' 1990 Medicare quality assurance strategy (*80*). The recent Institute of Medicine "framework for action" does not give a plan but a set of objectives, principles and rules for American health systems (*81*). A comprehensive descriptive review of different strategies was compiled by International Society for Quality in Health Care for WHO in 2001 (*82*), with an appendix on "questions for a national strategy in developing countries".

Is there evidence that one type of strategy is better than another for improving quality and patient safety in hospitals?

There is no scientific evidence that one type of strategy is better than another. There is little research assessing the effectiveness of one or more hospital or national quality strategies. The lack of evidence is largely a result of the difficulties of evaluating this type of intervention and of proving that the results are due to the strategy and not to other changes.

There is some research into local team projects which show that "continuous quality improvement" approaches and some others can be effective, but the projects are small-scale, not hospital-wide, and some of the reports contain short-term results collected by practitioners and some are not scientifically designed.

There are many publications and reports describing different strategies, but few report valid evidence of results. There is an even larger body of literature by consultants, academics and commentators advising on the best approach, some of which is based on sound experience, but little is based on scientific research.

In sum, no one quality strategy cannot be recommended over another on the basis of evidence of effectiveness, ease of implementation or costs.

Gaps in evidence and conflicting evidence

The search revealed several points.

- There are a wide variety of sources, subject areas and topics which included relevant discussions and research. The material is widely spread and difficult for policy- makers and managers to find, access, and to assess for scientific quality or applicability to their setting.
- Many articles are commentaries by experts or consultants, usually with a particular opinion or financial interests.
- There has been little empirical research either describing a strategy or attempting to evaluate it systematically. Although the main studies were identified, a full review of each type of strategy was not possible within the constraints of this HEN synthesis: some gaps might be filled with a more extensive search.
- There is considerable variation in the scientific quality of the empirical research, especially regarding the few studies which assessed results. The research varied from 12-person interview surveys to large surveys combined with qualitative interviews, data on outcomes and multidimensional analysis.

- Most research was carried out in the United States and mostly concerned private hospitals or health systems. Caution should be used in transferring conclusions from this research to other countries and to public health systems.

The lack of high-quality evidence in part explains conflicting claims about TQM/CQI approaches. Some commentators report a lack of evidence, but others claim that effectiveness and cost-effectiveness have been shown (*84*), although they can only cite projects in parts of a hospital and data collected by project teams which may not meet scientific standards (*85*).

A recent influential quality journal editorial noted that, "From what we know, no quality improvement programme is superior and real sustainable improvement might require implementation of some aspects of several approaches - perhaps together, perhaps consecutively. We just do not know which to use, when to use them, or what to expect" (*86*).

One conclusion of the synthesis for future research is that researchers need to pay more attention to describing the strategy actually carried out, assessing the depth of implementation and considering alternative explanations for the apparent results of a strategy. A combination of research designs could contribute to better strategies. Strong evidence of results is difficult to establish in this field, even with expensive long-term designs, and generalizations to other situations are uncertain. Research employing a variety of methods to assess results from different perspectives, documenting the actual evolving strategy and its context would be most useful. Another approach would be to identify "successful" strategies and retrospectively study how these were implemented and the conditions which accounted for success.

The quality of the evidence used in the synthesis

There is a lack of strong evidence about the results of quality strategies in individual hospitals, and about national strategies to improve hospital quality. Where evidence is reported, it is mostly informant's assessments of results, or of results of projects in part of a hospital. In the few studies where outcome quality or costs were reported, causation was not conclusively established and alternative explanations could not be ruled out. Within quality journals there appears to be a publication bias favouring positive findings and few studies of failed strategies.

As regards the most studied strategy, TQM/CQI programmes, an unsystematic review of 41 reports of American hospital quality programmes and those of 12 hospital systems concluded that:

> More comprehensive and comparative case studies of successful implementation would be helpful...also elaborate studies, which detail the steps in building a successful TQM system in the health care industry and which outline specific performance measures in evaluating health care systems are necessary. Data from such studies should be obtained from on-site observation, questioning, and performance data analysis, which will lead to hypotheses to be measured by questionnaires sent to hospital administrators who have been successful in implementing TQM. (*87*)

Another review of 127 reports from the United States found that many only described quality activities in one department. It found that, "articles that focus primarily on how to implement are generally vague, providing little direction to managers", and that evidence of the effectiveness of total quality management programmes was lacking:

> Despite a considerable body of literature, very little data exist confirming the claims made on behalf of TQM, including improved performance, quality or competitiveness. No comparative research has been published, and with few exceptions the numerous case studies are anecdotal. The literature lacks well-designed empirical studies that investigate the effect of TQM....There is a noticeable lack of evidence that hospitals are able to create systematic change through the organization, or that they are able to sustain such change or benefits over time. (*88*)

It is debatable whether the lack of evidence of results is due to a lack of results, failure to publish them, or an absence of rigorous quasi-experimental designs with controls.

Current debate in the field

Given the lack of evidence and the money at stake, it is not surprising that there is considerable debate within this field about which strategies are or could be effective. One debate concerns "generic" versus "specific" strategies: would more resources carefully allocated do more to raise quality than a specific quality strategy? Many professionals take the view that increasing personnel, equipment and training is the best strategy. Quality proponents argue that "doing more of the same" can sometimes harm patients, and that applying quality methods systematically within a strategy is more cost-effective in the long term. This is the most fundamental debate in the field. The debate is especially acute in developing countries, where there is similarly poor and conflicting evidence of the results of different approaches. It is increasingly recognized that quality strategies in these countries supported by donors have not been sustained, just have they have not been at times in the high-income countries. There is debate about programme costs and possible savings or benefits, but no research into the economics of different strategies.

Another debate concerns individual versus organizational approaches. Some strategies concentrate on individual practitioner change, such as training or guideline implementation, and others on organizational changes. Adherents of the latter argue that changes in work organization and procedures are needed to get significant quality improvement, and that traditional profession-specific approaches do not change the system. However, professional training is quicker, easier to implement and can be made more effective by supervision. In part this debate reflects competition between management and professional "ownership and control of quality" and that quality strategies involve significant political issues (*89, 67*). In practice, individual-oriented strategies depend on and effect change in the organization, and organizational-change approaches apply training and guidelines on the individual level.

There is also debate about incentives and a "climate" for quality. One view is that quality is best improved by an open and honest discussion of gaps between current and acceptable quality, by publicizing the best results and how they were achieved, and rewarding hospitals for improving their performance over time. Another view is that this takes too long, that poor quality providers are the least likely to participate in voluntary programmes, and that national governments have a duty to ensure minimum standards and to protect people from poor or unsafe care. This view supports compulsory inspection or accreditation, with sanctions for poor quality and rewards for improved quality. The alternative view is that this damages the open and positive climate thought to be most effective for quality improvement.

There are numerous arguments for and against "police, punish and reward" approaches, and "inspire and develop" approaches. Many governments use both, causing problems for the agencies expected both to apply sanctions and to encourage open sharing of quality performance information. Related to this is the issue of publicizing quality performance data. Critics argue that the data are misleading, easily misinterpreted and subject to falsification by providers, and that internal, anonymous distribution is more likely to be effective with professionals. Others argue that public release of data will improve the quality, and that researchers and the state have no right to withhold data about poor quality that the public needs to protect itself and make informed choices.

A further debate is about the appropriateness of applying "industrial" quality strategies to health care. Many differences have been cited which are thought to prevent easy transfer (*67, 88, 89*). With growing acceptance of the methods in health care, the debate has shifted to how they are best translated or adapted. There is recognition by quality experts that a strategy has to be tailored to specific circumstances, and debate about the point where adaptation looses the "active ingredient" and results in reduced effectiveness.

Another type of adaptation debate concerns the use of specific quality strategies in non-Western countries with comparable income levels. It has been proposed that many quality methods are based on Western assumptions about rational management, authority and employee participation that do not apply in some countries. A debate is beginning about the cultural preconditions for a quality strategy to be effective, either within a country or an organization. As regards the latter, it is generally agreed

that a strategy has to change the culture of an organization to be effective. However, there is debate about what a quality-culture or safety-culture is, how to measure it and how to change it.

There is widespread recognition that conditions surrounding a quality initiative are important for its success, but debate about which conditions are most important. Comparative research into implementation of complex change has found that success depends on a range of local factors (*90*). The only generalizations that can be made from these comparisons are which factors appear to be important and which decision-makers need to pay attention to in implementing changes: there is no general model or series of steps which will guarantee success in all situations.

A hospital quality strategy creates conditions to encourage initiatives and projects within the organization: there is some evidence that CQI projects require physician and management involvement, managers to allow personnel time, and good data support to be effective (*59*). There is no evidence of the conditions needed to encourage hospitals to improve quality but much debate, especially about the financial incentives, disincentives and priorities which conflict with both short-term and long-term quality improvement (*60*). It is likely that different conditions would be important for different types of strategy, but there is no research that could be recommended to help leaders to choose a strategy for their unique conditions.

Considering the value placed on evidence by the "quality movement", this lack is remarkable, and has been noted by commentators in the field. But there is debate amongst researchers about which types of evidence are possible or desirable and about appropriate methods for evaluating quality strategies. There are clear differences in views between those advocating quasi-experimental controlled studies and those arguing for more naturalistic social-science case studies or comparative studies (*90, 7*). Current thinking advocates combining data on strategy outcomes with data on implementation processes their context. How far positivist and naturalistic paradigms can be combined remains to be seen.

Other aspects

Probably the most ambitious strategy is that of the United Kingdom NHS (*78*). Since 1998, this has involved generic strategies of extra resources and restructuring. Specific strategies include national guidelines and standards for clinical care, national inspection and public quality performance reporting, a law giving all NHS organizations with a "legal duty of quality" and requiring them to implement a quality improvement strategy, clinical governance quality management systems, and a national system for reporting and analyzing adverse events. No evidence of results or costs is reported and no research to gather such evidence is planned.

One study in 2000 of about 20% of all United Kingdom NHS provider organizations found that nearly all had educational programmes, local guidelines, improvement groups, and peer assessment methods, with half using feedback of performance data. Fewer than half replied that educational and guideline programmes were effective (*38*).

The 1995 Norwegian quality strategy was reviewed as part of the development of a new strategy, due in 2003, but no reports have been published (*79*). An expert group has compiled a set of principles to guide national quality strategies, based on experience with quality initiatives in the United Kingdom NHS since 1985 (*91*).

The longest running hospital strategies in Europe, and the most successful according to self reports, are those of Reinier de Graaf in Delft and Maastricht The Netherlands, Haugesund, Kristiansand, Tromsø and Trondhiem hospitals in Norway, Danderyd and Huddinge in Stockholm, Leicester Royal Infirmary United Kingdom, one hospital system in Munich, Germany, and Padua and Reggio Emilia Hospitals in Italy (*66*). A ten-year follow up study of six Norwegian hospital's quality strategies is underway (*63*).

More research on the economics of quality is also needed (*92*). In commercial services a number of studies have been undertaken with implications for health and models such as "return on quality" (*93*) which help assess the costs and savings of a strategy and return on investment.

One study carried out a literature review of methods for evaluating quality assurance strategies in developing countries, but this was not reported in the publication. The study did give research-based guidelines for internal or external evaluations of such strategies. It describes steps for carrying out an evaluation and set of tools for evaluators (*94*).

Conclusions

Little useful, accessible scientific research has been undertaken into the effects of hospital quality strategies. Some research has been carried out that is helpful for identifying, planning and implementing an appropriate strategy. Two studies give scientifically-acceptable evidence of results of TQM-type strategies, but these show little impact after two years.

There are some reviews of interventions such as guideline implementation suggesting that multiple strategies are more likely to be successful. No evidence exists to suggest one "best" strategy. This overview of the available research suggests that a strategy is more likely to be successful if it is chosen with a knowledge of alternative approaches, adapted to the situation, reviewed and adjusted to changes and pursued consistently by committed management. It is possible that a policy and financial context that rewards greater safety and quality is important, as is active and transparent management of the balance of quantity, cost and quality of service.

Policy options

The main recommendations from this synthesis of the literature are based on a few valid outcome studies and a critical assessment of the descriptive literature.

1. Hospitals should decide which approach to adopt after making an assessment of their quality and safety status and listing the different strategies which might be appropriate to their situation.
2. When reviewing types of strategies, hospitals and governments should question the claims of proponents of any one approach because there is no strong evidence of effectiveness of any strategy. They should recognize the value of extensive experience as a form of evidence, but also the commercial nature of the growing "quality industry" in health care.
3. Decision-makers should be aware that the same strategy applied in a different place may well yield different results, even if fully implemented. Attention needs to be paid to financial, cultural and other conditions surrounding implementation.
4. Having chosen one type of quality strategy, one should review it regularly and adapt it to changing situations and the responses of the interested personnel. Efforts should be made to assess whether any lack of results is due to the wrong strategy, poor implementation, or the time required for results to become measurable. Close monitoring using a range of types of information can assist this assessment.
5. It is possible that applying a consistent quality strategy over time is more likely to be effective than changing to another approach. Flexibility without sudden radical change appears to be important. "It ain't what you do, it's the way that you do it."
6. Quality experts with wide experience can be useful, but need to be chosen with care. One or more independent experts should be used to give independent feedback for regular reviews of a strategy.

7. Hospital quality strategies should include improving inter-service quality for different patient groups, such as older people, and address hospital-community coordination of care issues. Patient experiences and outcomes are affected by how hospitals provide access, outreach and linking with non-hospital services in systems of care.

8. It is possible that time and money that could be used for patient care are currently wasted on some strategies. Considering the large amount of resources invested in quality strategies, the high costs of unsuccessful strategies, and the interests of the "quality industry", there is a strong case for more independent and scientific research.

9. Researchers need to pay more attention to describing the strategy actually carried out, assessing the depth of implementation, and considering alternative explanations for the apparent results of a strategy.

10. A combination of types of research could contribute to better strategies. Strong evidence of results is difficult to establish in this field, even with expensive long-term designs, and generalizations to other situations are uncertain. Research employing a variety of methods to assess results from different perspectives, documenting the actual evolving strategy and its context would be most useful. Another approach would be to identify "successful" strategies and retrospectively study how these were implemented and the conditions which accounted for success.

11. Fuller reviews of the evidence for particular strategies identified in this report should be carried out, as there may be evidence which was not discovered in this review due to the wide variety of sources which need to be searched.

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Annex 1. Grading of evidence

E 1. Strong evidence of results: consistent findings of results in two or more scientific studies of high quality.

E 2. Moderate evidence of results: consistent findings of results in two or more scientific studies of acceptable quality.

E 3. Limited evidence of results: only one study available giving results, or inconsistent findings of results in several studies. Studies of results in the form of users' perceptions were graded E3 if the latter were collected and analysed according to accepted scientific methods using an appropriate design.

E 4. Evidence of implementation only: description of implementation collected and analysed according to accepted scientific methods using an appropriate design.

E 5. No scientific evidence: no study of results of acceptable scientific quality available. These include practitioner self-reports.

E 6. No evidence of any type.

Studies presenting results, descriptions of implementation and descriptions of context were noted as "complete descriptions" (CE).

Studies giving evidence of the influence of specific context factors on results were noted as E3/CE.

Annex 2. Sources and methods for review and synthesis

Databases were searched for the following key terms: hospital quality strategy, hospital quality programme, quality strategy, quality assurance.

The search covered from 1991 to 2003 and concentrated on the following databases: PubMed, Medline/Ovid, Web of science, Swemed, Miks and Libris, Cochrane Library, Campbell Collaboration, Best Evidence (ACP Journal Club), York Database of Abstracts of Reviews of Effects (DARE), Bandolier management.

The search strategy was to allocate 25% of the time for the synthesis to searching for relevant journal articles, reports and books. The search strategy included:

1. Clarifying the initial questions to be answered and possible sources, so as to be able to judge quickly if a book or paper would be relevant. The relevance/exclusion criteria used were whether the item:
    - described a national, local or individual hospital strategy for improving quality
    - discussed issues and considerations of one or more hospital strategy for improving quality
    - discussed issues directly relevant to quality strategies for hospitals in those cases where the entities studied were not hospitals.
2. Assembling all papers and books relevant to the question collected since 1985 in the author's library.
3. Conducting an initial search of electronic databases and above sources for any systematic or unsystematic reviews of the subject or of similar areas, and ordering the key papers.
4. Carrying out searches of the following databases, in order:
    - Medline, CINAHL, Kings Fund (www.Kingsfund.org) United Kingdom, HELMIS & Dh Data. These were reported by Scott, et al. (2003) as covering "all of the major English language management journals with an emphasis on health services research."
    - Pubmed
    - European clearing house on health systems reform http://www.leeds.ac.United Kingdom/nuffield/infoservices/ECHHSR/dbase.html
    - Bandolier management http://www.jr2.ox.ac.UnitedKingdom/bandolier/booth/booths/mgmt.html
    - http://www.shef.ac.United Kingdom/uni/projects/wrp/seminar.html Emerald DB
    - http://www.sosig.ac.United Kingdom/
    - http://www.psycinfo.com/ web of science http://www.isinet.com/isi/products/citation/wos/ wisdom centre.
    - http://haly.emeraldinsight.com/vl=2154875/cl=13/nw=1/rpsv/index.htm Elsiver (via KI) http://www.sciencedirect.com/ OVID USA http://www.ovid.com/site/index.jsp and http://erc.msh.org ("the managers resource").
    - For journal titles, see reference list.

Review and synthesis method
The assembled literature was read, assessed again for relevance, for the scientific nature and status of descriptions and outcome data, and classified in terms of subject and main findings. Parallel to this, the WHO HEN guidelines were used and a possible set of headings for the report were compiled

which covered the main issue or findings discussed in the literature. An outline set of headings was created which allowed sub-headings to cover key issues and findings and gave a logical and readable structure. The summaries of each item were then used to compile the report, and whilst doing this key practical recommendations which followed from evidence were listed, as well as research issues and gaps in the literature. The review was completed by rewriting the recommendation and redrafting following comments from colleagues.