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What are the advantages and limitations of different quality and safety tools for health care?

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ABSTRACT

This is a Health Evidence Network (HEN) synthesis report on the advantages and limitations of different quality and safety tools for health care. The term "quality tools" includes many safety and quality methods, frameworks, programmes or systems. Some are diagnostic methods to help decision-making, some are for intervention and change only, and some include both methods for diagnosis and intervention.

The main recommendations from this synthesis of the literature are based on a few studies which give weak evidence, and on a critical assessment of the descriptive research and practitioner report literature:
1) Simple continuous quality improvement (CQI) tools are useful for more effective everyday problem-solving, not just for quality improvement.
2) There is some evidence that guidelines, patient pathway methods, quality costing and statistical process control are effective in health care, when properly applied.

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Summary

The issue

The term "quality tools" is used in many different ways to refer to a method used by an individual, a team, an organization or a health system. It is most often used in a narrow sense in American texts to refer to a set of simple "continuous quality improvement" methods (CQI tools). More broadly, it includes many other safety and quality methods, frameworks, programmes or systems. Some are diagnostic methods to help decision-making, some are for intervention and change only, and some include both methods for diagnosis and intervention.

Findings

The simple tools most often reported to be used in continuous quality improvement include brainstorming, cause and effect diagrams, nominal group and Delphi technique, flow charts, histograms, control charts, Pareto diagrams, run charts, scatter diagrams, checklists, tables, and counts. Less often reported are the more complex tools: statistical process control (SPC), quality function deployment (QFD), and design of experiments study (DOE). These and other tools are also reported to be used within quality assurance or audit frameworks. The most commonly used systematic "approaches" are the continuous quality improvement plan-do-check-act (CQI PDCA) cycle, the Langley model, the team quality improvement sequence (TQIS), and different versions of the audit cycle and of patient pathway frameworks.

There is no clear evidence about which of the CQI, quality assurance or audit frameworks are most effective, but there is evidence that systematic and persistent use of a framework is necessary for results. There is evidence that statistical process control and quality costing methods are effective, but that the time and skills necessary to use them properly are greater than for many other tools. Both are disadvantaged in health care by the lack of quality data.

There are different views about whether guideline development and implementation is a quality "tool", but it is probably the most closely studied and most common method used in health care to make quality and safety improvements. Guidelines are used in CQI projects as a method of implementing a change to practice. They are most often used as a way to convert research evidence into practical rules to follow in a local setting. Other multi-method tools include benchmarking, reengineering, and patient pathway methods. There is evidence of positive results for all, although there are mixed results, higher costs and methodological questions regarding reengineering. The EFQM (European Foundation for Quality Management) organizational assessment method, some types of clinical audit and some structured peer review methods show weak evidence of positive results.

The most often used "safety tools" in health care are incident report data collection and analysis and root cause analysis methods. Other safety tools which could be used in health care are behavioural observation, crew resource management failure mode and effect analysis, and human factors engineering design methods. No studies were found that examined whether tools were used properly, or interventions to increase their effectiveness.

Policy considerations

The main recommendations from this synthesis of the literature are based on a few studies which give weak evidence, and on a critical assessment of the descriptive research and practitioner report literature:

1) Simple continuous quality improvement (CQI) tools are useful for more effective everyday problem-solving, not just for quality improvement. All health personnel should at least know what the simple CQI tools are, and should use reports and simple costing methods to assess whether to use a tool.

2) There is some evidence that guidelines, patient pathway methods, quality costing and statistical process control are effective in health care, when properly applied. More use should be made of these methods. However, the latter requires more training and guidance than other methods.

Type of evidence

Review of systematic reviews and critical assessment of descriptive research and other reports.

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Introduction

A systematic and fact-based approach to quality lies at the centre of the "industrial" quality and safety movement applied in health care in the last 20 years. A number of "tools" (or methods) are commonly used to carry out this approach. Some quality and safety tools have been developed and used separately, but are now being brought together within health care, and within specific projects. Hence this synthesis covers both sets of tools, referred to collectively as "quality tools". Some are "simple tools" such as brainstorming, some are "multiple-method tools" such as re-engineering and some are "frameworks" such as the plan-do-check-act (PDCA) and audit cycles. The tools are summarized in Table 1.

There is debate about the effectiveness, feasibility and costs of each of these tools in health care, and how much time health care professionals should spend learning and using them. Those using the tools also want to know when to use each and which is most effective in which conditions. What is the evidence from research about the benefits and limitations of each in a hospital or community setting? Have they been used and how? How easy and costly were they to use? What were the results?

This synthesis gathered and presents different types of evidence to answer these questions and aims to:

- note the different tools reported to have been used in health care;
- give references to the best descriptions of them; and
- present evidence about the tools, such as effectiveness reported in scientific research, or experience reported in an observational study, survey or project report.

The synthesis does not consider the use of tools together in a quality programme: this is reported in a complementary HEN report on quality strategies for hospitals *(1)*.

The definition of "quality tool" for this report is a specific method used by managers and workers to measure, ensure or improve the quality or safety of a product or service. An example is a simple paper checklist used by a nurse to record observations about patients not attending a clinic. The purpose of a quality tool is to make it easier correctly to complete a specific task in pursuit of an objective which contributes to "ensuring or improving the quality or safety of a product or service". There are a number of descriptions of these tools in health care *(2–12)*.

Methods and sources for this review

The aim of the search was to find descriptions of tools likely to be understandable to health personnel, and independent research showing their use in health care, emphasizing descriptions of how they have been used and evaluations of expected and actual results. The latter includes perceptions of results, as well as more objective before and after data.

Research into quality tools was found in different databases and in many different sources. Initially a limited definition of quality tool was used to refer to one of set of methods commonly used in total quality management, continuous quality improvement, quality audit or assurance cycles.

Research into these tools was identified from a search of the electronic data bases listed in Annex 1. The review concentrated on synthesizing evidence from these studies, but was broadened when little evidence was found to include evidence about other types of quality and safety methods applicable to health care. Electronic searches for systematic reviews and then other research were made of the databases listed in Annex 1, then a search of quality journals on web sites, yielding 27 relevant journal papers and 11 books. The author's library includes relevant literature collected since 1985, and yielded relevant five journal papers, nine books, three unpublished reports and three reports from conferences. Articles and books such as expository texts which did not give reports of the tools' actual use are referred to later in the synthesis.

Search strategies followed by Scott, et al. *(13)* and the EPOC report on how to review quality interventions *(14)* were found to be useful models for identifying and reviewing research in this field. This was not a full systematic review: there may be evidence not discovered or reported in it due to the wide variety of sources and subjects which need to be searched and the time limits allowed for the review. The method used to assess the advantages and disadvantages of each tool was to note relevant evidence and reports in research on tools and in reports of quality projects or activities.

Findings

What is a "quality tool"?

Research and other literature most often use the term "quality tools" to refer to the methods used in total quality management (TQM) or continuous quality improvement (CQI), to improve work processes. Examples are a "Fishbone" diagram, which is a way of showing different possible causes of quality problems, or a Pareto graph for displaying data to show the largest causes of a quality problem *(3)*. However, these same and other tools were reported to be used within other types of quality approaches, such as audits or quality assurance cycles aiming to correct deficiencies from standards or specifications.

The review found that studies used the term "quality tool" to refer to:

- methods for measuring, assessing, ensuring and improving both quality and safety;
- "systematic step frameworks" that guide teams in using methods in a series of steps, such as the plan-do-check-act (PDCA) framework *(15)*, team quality improvement sequence (TQIS) *(16),* Langley model *(17,18)* or clinical audit cycle *(19–21)*;
- quality and safety approaches involving multiple methods such as re-engineering *(22)*, patient pathways *(23)* and benchmarking *(24)*;
- organizational assessment methods such as the EFQM (European Foundation for Quality Management) system for quality awards *(25)*;
- quality management and assurance systems such as those designed to meet ISO 9000 (International Organization for Standardization) standards *(26);*
- generic interventions used to improve quality or safety, such as clinical guidelines, automated drug dispensing, computer decision-support systems, or manual systems to remind a secretary to contact a patient for a follow-up visit;
- national quality policies or strategies such as patient guarantees.

"Quality tools" was thus used in the literature to refer to methods used by individuals, teams, organizations or health systems. The term is used narrowly to refer to a set of between seven and thirteen continuous quality improvement (CQI) tools, or more broadly to include many other safety and quality methods, frameworks, programmes or systems. The review concentrated on evidence about quality and safety methods used by individuals and teams, rather than organizations, systems and programmes.

The term "tools" is most often used in American literature, to describe simple methods used within a CQI framework, the most common being the PDCA (plan-do-check-act) and process improvement frameworks *(18)*. The term is little used in European literature before 1992, which follows quality assurance or audit cycle frameworks.

Most often used quality and safety tools in health care

One study provides evidence of the frequency of use of different tools by quality projects in United States Veteran's Administration hospitals. The study listed 13 "commonly reported techniques" that distinguished continuous quality improvement (CQI) from other methods: brainstorming, cause-and-effect diagrams, nominal group technique, delphi, flow charts, histograms, control charts, Pareto

diagrams, run charts, scatter diagrams, checklists, tables, and counts (27). It noted that in 1995, there were no research studies "that have empirically investigated tool use and its relationship to actual improvement of performance".

The study used data from 168 quality projects in 36 hospitals. The most commonly used tools were brainstorming (used by 90% of the teams), flowcharts (68%) cause-and-effect diagrams (45%), and nominal group technique (21%) and the "data management tools" checklists (28%), tables (28%) and Pareto charts (20%). Run charts and control charts, which theorists propose as essential tools, were used by 8% and 6% of teams respectively. Another survey of 92 American teams (convenience sample) found flow-charting to be the most frequently used tool *(28)*.

Beyond these two surveys no evidence was found of the actual frequency with which different quality and safety tools are used in health care, and no such evidence is given in the many general theoretical and expository texts. Thus, in the absence of other evidence, this review formed an impression from reports of quality projects describing the methods used, and from the number of studies found reporting specific methods.

In Western health care the most commonly used CQI (continuous quality improvement) tools reported across a range of studies are: brainstorming, cause-effect diagrams, flow diagrams, data collection tools such as forms for recording observations, and data display or analysis tools, the latter being, in decreasing amount of use, histograms, Pareto diagrams, scatter diagrams and control charts *(3)*. CQI tools less often reported in health care were statistical process control (SPC) *(29–32)*, benchmarking, quality function deployment (QFD), design of experiments study (DOE), and the theory of constraints *(33)*. Guidelines, protocols and organizational procedures were the most commonly reported generic tools, either for implementing the latest research, or as part of CQI projects to institutionalize changes tested by project teams *(34)*.

This synthesis found incident report data collection and analysis *(35)*, root cause analysis *(36)*, and crew resource management *(37)* to be the most often reported in health care.

What is the research evidence about each tool?

There are no systematic review of quality tools, but one unsystematic review was found, carried out by the International Society for Quality Assurance (ISQA) for WHO in 2001 *(38)* which lists and discusses studies reporting different tools. A compendium in French by ANAES of 20 tools with case studies in health care is also available on the internet (*10*).

The research evidence about each tool is listed below by grouping tools under their use for six different purposes: 1) measurement and data gathering; 2) problem prioritization and writing problem statements; 3) data analysis and presentation; 4) change planning and implementation; 5) change evaluation and 6) multi-method tools, frameworks, or tools for other uses.

Tools for measurement and data gathering

These are tools for gathering data to make an assessment of the size of a quality problem in order to decide action, or to monitor whether changes reduce the problem. The simplest reported is a check-sheet for recording observations of events, and the most often reported are patient feedback tools and quality indicators. Descriptions of measurement tools for health care are available with examples *(39–44)*. One study noted how only 17% of teams in their survey used sampling for collecting data, which would have been more efficient *(29)*.

One of the most often commented-on shortcomings of much health care quality improvement is the lack of actionable quality and safety data. This is supported by project reports and survey research. The mentioned Veterans' Administration study of 168 teams reported that those who use and analyse

data are more likely to report perceived improvement than those who do not *(28)*. More use is being made of methods for gathering data about errors or adverse events *(45)*.

Patient feedback tools

The disadvantages of only collecting patient complaints were reported by a number of early health care studies *(46,47)*. This method is one of the most frequently used ways of gathering feedback from patients, and improved schemes have been reported, but not rigorously evaluated. Many patient satisfaction surveys are neither valid nor reliable, according to one analysis of 195 studies *(48)*. Most guidance texts emphasize the need to base surveys on a pre-study of what is import to patients and to pilot a survey first. There are advantages and disadvantages to mailing, telephone and in-service administration of questionnaires *(49)*.

Before 2000, the feedback tool most often reported in health care research was the SERVQUAL method *(50)*. An increasingly used method is the Picker Questionnaire *(51)*, because it provides more actionable data than many other standard questionnaires. It is based on and validated by research *(52)* and the Picker company provides data processing and comparative analysis. It is used for comparative data in the United Kingdom National Health Service *(53)*. Independent American research found high patient satisfaction scores associated with reduced complications and mortality and low scores with lower health status in acute myocardial infarction patients *(54,55)*.

The literature shows that focus groups are increasingly used to gather patient and carer expectations and perceptions of services *(56)*. This method needs skilled facilitators and careful analysis of data to be valid. It does not give representative data, but does indicate issues about which selected patients feel strongly. Critical incident technique is less often used *(57)*. Further details may be found in another HEN report *(58)*.

Quality and safety indicators

Indicators are considered by some texts as a quality or safety tool and nearly all refer to the importance of data for quality and safety improvement. There is a wide range of literature about which data could indicate low or high quality or safety in health care *(59)*, which indicators to use *(60)* and outcome measurement tools *(41-43)*. There are a few studies about methods for developing indicators *(43)* but little research describing how personnel have done this in health care or the results. There are some studies giving an overview of a range of indicators and comparative data methods *(61)*.

Other measurement tools

Standards are a tool for measurement in the sense that they give guidance about what to measure and make it possible to assess the significance of the level of performance achieved. Standards are the starting points for audit, quality assurance, accreditation and inspection methods. A number of texts discuss formulated health care standards and how providers might formulate them *(62,63)* and clinical guidelines *(64)*.

The balanced scorecard refers to both a set of measures and methods intended to help managers give their organization a strategic market-oriented direction *(65)*. There are a number of reports of its use in health care and some evidence that it is effective for these purposes *(66–69)*.

Studies have found that research observation and patient record reviews yield more accurate safety measuring data about adverse incidents than personnel-made reports. However, blame-free and near-miss reporting systems are thought to be essential for gathering data about patient safety problems *(70,71)*, notwithstanding problems of professional culture and confidentiality. One report described implementing such data gathering methods as part of a clinical risk management strategy *(71,72)*.

Other comprehensive assessment systems, such as EFQM (European Foundation for Quality Management) and Baldrige, are sometimes described as tools for gathering data about the quality status of an organization. Research reporting their use is noted later, as are methods for gathering quality costing data.

Tools for problem prioritization and writing problem statements

Choosing the right problem to address and describing it correctly are reported to be difficult for project teams, often accounting for their lack of success *(13)*. One study was found that used a review of research to suggest how teams might improve their choice and definition of problems, by defining them in terms of customer experience and from different perspectives as well as breaking them into smaller parts *(73)*.

Methods teams can use to list and prioritize problems include simple multi-voting and group ranking and Delphi and nominal group techniques *(3)*. Choosing problems that are truly important to patients and management, and writing problem statements are described *(29,17)* as is asking the right questions *(40)*.

Tools for data analysis and presentation

The literature consistently emphasizes the need for visible presentation of data. Tools most often reported for both presentation and analysis are histograms, scatter diagrams, Pareto diagrams and, to a lesser extent, control charts. Flow diagrams and patient pathways are also methods of presenting data collected about the actual flow of materials, information or patients. There are a number of descriptions and illustrations from health care *(3–13)*, but no systematic research about their effectiveness or when they are applicable.

Tools for change planning and implementation

There are more methods reported for quality analysis than for making changes. Methods reported for change planning or implementation are generic change management methods, including force field analysis, project management, and strengths, weaknesses, opportunities and threats analysis (SWOT).

Reports of experience show many to be valuable, but there is little strong evidence of their effectiveness. One summary notes methods most likely to be of use *(74)* and one review gives summary descriptions and evidence reports of various change management techniques *(75)*. The difficulty of change in health care is much commented on, especially in quality strategies founded on evidence-based practice *(76,77)*. Most of the relevant empirical research has been carried out on strategies for guideline implementation *(78,79)*.

A tool for assessing whether a quality change is likely to be successful and allows for re-planning before and during implementation has been reported *(80)*. Change concepts are tools that have been usefully applied, mostly in breakthrough collaboratives *(81)*. They are concepts summarizing changes that have successfully improved processes, such as parallel processes to save time by performing tasks simultaneously *(19)*. Tools for spreading proven changes within one organization or across a health system have been described *(82,83)*, but were reported to be used by a minority of teams in a survey of 92 projects *(28)*. No term studies have been undertaken to assess whether personnel continue to use the tools or sustain the results of change; a review of tools for sustainability has been published *(84)*.

The most commonly reported tool for implementing clinical change is clinical practice guidelines *(34)*, but most research is about guideline dissemination and implementation strategies rather than the guidelines themselves. The most recent systematic review is of 235 rigorous evaluations of implementation strategies, covering up to 1998 *(85)*. It reported that most of these strategies resulted in small to moderate improvements in care, with the greatest shown with reminder systems, less effect

with educational materials alone (which may be short-lived), less with audit and feedback, and still less with multifaceted interventions involving educational outreach, which were previously thought to be effective. The review, however, reported large variation in the effects within interventions (reminder effect varied from –1.0% to +34.0%), and uncertainty about whether the effects would be found in other settings.

For effective local use of guidelines, a number of studies emphasize the importance of local critical assessment of them *(86)* and the need to pay attention to organizational and other barriers to change when developing an implementation strategy *(87)*. Evidence about computerized decision support systems for implementing guidelines is conflicting: a meta-analysis and two systematic reviews found some limited evidence that some systems were effective in changing practice *(88–90)*, but some studies showed no effect *(91–94)*. The evidence shows such systems are difficult to implement but can be effective and do allow for efficient updating of guidelines, when "integrated into the clinical workflow" and presenting "the right information, in the right format, at the right time, without requiring special effort" *(94)*.

More patient safety improvement interventions have been reported since 2000, but there is very little evidence of effectiveness, apart from evidence about specific safety practices *(95)*.

Tools for change evaluation

There is little research describing or assessing methods for teams, managers or purchasers to evaluate the results of quality changes. The method most often used is a simple before-and-after comparison, using the plan-do-check-act (PDCA) model, which usually involves collecting baseline data and using the same measure again after the change to collect data. The evidence suggests this method is feasible for improvement projects and some management purposes and is the minimum required. However, for more rigorous evaluation, and certainly for research evaluation, the method is inadequate as it cannot exclude a variety of explanations apart from the quality change intervention *(96)*. More rigorous methods require comparing data with other organizations, or other time series or comparative controlled designs *(97)*.

Tools for evaluating a national and local quality strategy are presented in an annex of the publication by the International Society for Quality Assurance *(98)* and discussed in Tsavaras et al. *(99)*. Methods for evaluating quality interventions are described e.g. by Harvey and Wensing *(100)* and by Øvretveit *(97)*.

Multi-method tools

Methods which themselves involve the use of a number of tools are reported in health care. Most reports are about the patient pathway development methods benchmarking and reengineering. Patient pathway tools involve a number of methods for tracing patient progress through an organization or health system, identifying problems or standards for each part, and for planning and introducing changes to reduce delays or errors. There are reports and some evidence that pathway mapping can improve quality *(101–103)*. Methods within the same category are integrated care pathways, which are structured multidisciplinary care plans, and critical paths, which are commonly used in the United States to define actions to be carried out each day of a patient's stay *(104)*. A related set of "flow development" tools are used within operations research; these are described with case studies in one text *(105)*.

The term "benchmarking" is loosely used to refer to making a comparison of performance or process with another organization *(106)*. However, the term has been defined as a sophisticated method for finding best practice in any industry, analyzing the process, and seeking to reproduce key aspects locally. Reports of benchmarking have found some value to this method, but note the skills and time needed to make it effective, which have been underestimated in health care *(107,108)*. Reengineering

is like patient process improvement but far more radical: more like taking down a house and rebuilding it rather than renovating an old house. There are evaluations of this approach in health care, which have shown mixed results *(109,110)*.

Frameworks

Frameworks or cycles are models of steps to follow in diagnosing and resolving a quality problem. The model is sometimes called a tool, and it indicates when other tools should be used in different phases of quality improvement. The most commonly used in health care are the PDCA (plan-do-check-act), the FOCUS PDCA, the Nolan model, and versions of the audit or quality assurance cycle. No research has compared the effectiveness of these different models, which are in widespread use. One study was found of interventions that theoretically could improve the effectiveness and speed of quality improvement teams *(111)*. Peer review, where assess other professionals' practice, often uses the model of an audit cycle *(112–115)*.

The collaborative breakthrough method, although based on ideas from industry, is specific to health care. It could be classified as a model under this heading, or as a multi-method tool *(116)*. One review of evaluations of this method concluded that teams using it could achieve significant results within nine months, but a number did not, or did not maintain the results. It concluded that cost-effectiveness depended on sustainability and that assistance with data gathering and analysis, management support and physician involvement were needed to enhance the chances of success *(82)*.

Organizational Quality Assessment Tools

A number of tools began to be used in the early 1990s to assess quality in whole health care services, and are based on experts' opinions about the actions an organization needs to take to ensure quality services. No similar organizational safety assessment systems are reported in widespread use.

There are a number of reports of the use of the EFQM (European Foundation for Quality Management) tool for assessing whether an organization is doing the things necessary to achieve excellent results, and the actual results *(117)*. It was originally designed for assessing organizations for a quality award competition and is similar the American Baldrige quality award method *(118)*. Most reports in health care are of its use for educational or self-assessment purposes in order to help formulate a quality strategy. More recently, studies have also assessed other tools for accreditation and external quality assessment: a summary of the European Union ExPeRT project on EFQM, ISO (International Organization for Standardization), visitation and accreditation methods reported that a review of published literature in 2000 found no evidence of effectiveness for any of these methods *(119)*.

As for EFQM reliability, one study noted variations among assessed score values and tested a checklist intervention to increase assessor reliability *(120)*. It found that inexperienced assessors using the checklist made almost the same scores as those of experienced assessors without the checklist. The evidence from this study was that rater-scores vary due to different interpretations of criteria, different assessments of the evidence, and the experience of the assessor. The study suggests that score variations would be greater on a team with a mix of experienced and non-experienced assessors.

There is no evidence of associations between EFQM ratings and indicators of patient outcomes, or of other aspects of quality. The evidence of associations found in other sectors is not strong and cannot easily be generalized to health care *(121,122)*. A survey of the use of EFQM in the Netherlands found no evidence that its use led to better outcomes or other results *(123)*. A German study concluded that the method had a high "face validity", that is, that the subjects scored would appear to cover important aspects of organizational quality *(124)*, and proposed it was not specific enough to cover all areas of health care, and should therefore be used with clinical standards assessments, for example those using peer review methods. Another study noted that EFQM's lack of specificity might account for its

popularity: it could be adapted to different settings for different purposes *(125)*. In addition, it found that the reported positive judgements about EFQM were subjective, that there was no evidence of its usefulness, and more research was needed into the method.

This lack of strong evidence about whether EFQM or Baldrige is associated with better patient or other outcomes is not itself evidence that using them does not improve results, but it does suggest that there is no certain clear and simple effect. Studies have commented on the different ways organizational quality assessment methods are used. No studies have assessed a method for its use for development compared to its use for inspection and or regulation. There is evidence from some studies of confusion and differences in view between assessors and those assessed about whether a method is being used for development, or inspection, or both. This may make the method less useful for either purpose *(126)*.

Quality costing

Quality costing is a method for monetarily quantifying waste and poor quality. It can also be used to estimate the savings or speed of return from investments. The costs of poor quality are thought to be high in health care and the evidence for this is increasing, with more economic studies of medical error or adverse events. One review of quality costing methods and studies has been undertaken for health care, which found that the method is little-used but would enable managers to better assess the value of potential interventions *(127)*.

The most commonly described quality costing method in the literature is to calculate the "costs of failure" and compare these with the costs of prevention and appraisal *(128)*. Another method is for managers to assess or predict the cost savings of a quality project by estimating the cost of the problem, the spend-cost for a 50% solution and the annual savings. Very little research has been carried out into the use of these methods by health care providers, although two studies reported positive results *(17,129)*. Available evidence does suggest that if quality costing methods show savings of which some part can be kept by the saving unit, motivation is increased, even if investment resources are provided from other sources *(128)*.

Facilitation tools

Much of the literature emphasizes the importance of team or project facilitators with expertise in quality methods, including those for ensuring productive meetings, such as distributing an agenda before a meeting, getting views on issues before the meeting and postponing evaluation of ideas *(74)*. A number of texts give general guidance *(130)* and two studies reports experiences of quality facilitators in health care *(131,132)*.

Conditions for effective tool use

The literature suggests that individual tools are best used in combination, following a structured framework, usually by a project team (combining diagnostic, measurement, analysis and intervention tools). There is also evidence that project teams or multiple-method approaches need certain conditions to be used successfully. The mentioned study of tools used by projects in the United States Veterans Administration hospital provided some weak evidence that involvement of top and middle managers, training, and a prominent role for a top level quality council contributed to the ability of teams to use the methods effectively *(28)*.

A review of 55 mostly American quality improvement studies found little or no evidence of success and concluded that success was more likely where there was a receptive context, involved leadership, training and support, measurement and data systems, and protection from over-regulation *(133)*. A study of six Norwegian hospital quality programmes came to similar conclusions, and found physician involvement to be another critical condition for results *(134)*. One British review of 93 publications on auditing found the main barriers to be lack of resources, lack of expertise or advice in project design

and analysis, problems among group members or groups, lack of an overall plan for the audit, and organizational impediments *(135)*. The same review reported facilitating factors to be modern medical records system, effective training, dedicated staff, protected time, structured programmes and dialogue between purchasers and providers.

Mixed success for project teams in collaboratives was attributed in one review to the ability to work as a team, the ability to learn and apply quality methods, the strategic importance of the work to the home organization, the culture of the home organization, and the type and degree of support from management *(82)*. Research into reengineering projects found the following conditions contributed to successful change: preparation and training, a clear and consistent vision, multiple communication efforts, strong support and involvement, mechanisms to measure progress, and involving physicians *(136)*.

The right organizational culture is increasingly reported by the literature to be necessary for effective tool deployment *(137)*. There is little evidence of which specific culture is necessary and whether culture can be effectively changed. Some tools for diagnosing culture or safety climate in order to decide strategies for change have been reported *(138)*. More recent research suggests that combined interventions at different levels are needed for quality tools to be used successfully *(139)*.

Discussion

Gaps in evidence and conflicting evidence

This field is theory-rich and evidence-poor. Very few studies have been carried out of what health personnel actually do when they use quality methods or of the results. Little of the large guidance literature is based on health care experience, and even less is based on sound independent scientific research. Most is from the United States and might not translate to other health systems.

Much of the evidence for CQI (continuous quality improvement) tools and many of the other mentioned methods consists of descriptions by health or quality practitioners as part of a larger report of a quality project. There is almost no evidence about the results of using specific tools. Only two empirical studies were found that made a reasonably comprehensive assessment of the frequency of use of different CQI tools *(28,29)*. The picture is similar for research evidence about frameworks and multi-method tools. Studies of guidelines are mostly about specific interventions for disseminating or implementing guidelines.

Only one publication was found that studied the effectiveness of different CQI quality tools, in one health system in one region of the United States in 1995 *(28)*. This was an "exploratory study" and relied on leaders' perceptions of the success of their project. No studies have been carried out controlling for other explanations of apparent results. The search could find no evidence from experimental controlled trails about the effects of using specific tools, unless specific methods for implementing guidelines are considered a quality tool. No study has satisfactorily assessed the time and money costs of learning or applying different tools.

There were other types of evidence about the results of using tools, including perceptions of users about expectations or results. There were also descriptions of how tools were used, and some reports or discussions about the conditions under which tools could be most effective. This evidence was presented in both scientific research and in practitioners' reports, the latter not meeting scientific criteria for valid and reliable evidence.

That there is no strong evidence of results is not evidence that there are no results. It is possible that there is scientific research in other industries that does show results. It is unlikely that these tools would be widely used in industry if they did not produce results and do so cost effectively. However,

unless they have been proven to work in health care, acceptance is low. Practitioner reports are accepted as proof by some, but often not by doctors, whose involvement is thought to be necessary if these methods are to be widely used.

Current debate in this field

In the absence of clear evidence, the debate in the literature about the cost and effectiveness of different quality and safety methods comes as no surprise. One debate concerns the relative merits of frameworks underpinned by a process-improvement approach, and those founded on a standards-correction approach. The former is proposed as promoting continuous improvement and as emphasizing organizational deficiencies rather than those of individuals. The latter is simpler to understand, but depends on explicit standards, and tends not to direct towards continually improving performance or to enhance capacity to change systems of care.

A more recent debate is about the extent to which methods can be considered independently of their context, either the framework in which they are used or the organizational and health system context *(95)*. This is related to research debate about how best to evaluate the methods, and about the need for multiple interventions at different levels.

There is also a recurring debate about whether health care differs from other industries in ways that make the application of many tools more difficult and less effective. Many characteristics of health care have been offered as explanations of tools' slow adoption and of the mixed evidence of effectiveness. It has been observed that the methods are better for analysis than for change, and that the rational engineering focus assumes that evidence of problems or of an effective change will be enough to persuade others to make changes. The failure of the methods to engage with social factors such as politics and organizational and professional culture has been noted.

Barriers to greater use of the methods most debated are lack of physician involvement, lack of data, the leaders role *(140)* and how much time clinical professionals should be spending on improving organization rather than clinical practice. Poor computer systems in health care are often blamed for a lack of quality and safety data, and for the often prohibitive amount of time needed for clinical staff to collect data.

Conclusions

There is a much literature describing quality tools in general texts, but few empirical studies describing how they were actually used in health care, and even fewer reporting results or even experiences. Most of the evidence is from reports showing that a method was used, and sometimes describing its use. There are some indications that results depend on the conditions under which the methods are used, and that an organization's competence at adopting and applying the method is important.

There is no strong evidence from health care about whether continuous quality improvement/process improvement frameworks are more effective than assurance or audit standard checking and correction frameworks. No systematic empirical research comparisons were found of these two types of frameworks. There is some evidence from evaluations in health care of multi-method tools, notably re-engineering and patient pathway methods, in the form of descriptions of the use of the tools and of some of the results. The evidence suggests that patient pathway tools are more effective and easy to apply than re-engineering. Most effectiveness research appears to have been carried out into methods for implementing and disseminating clinical practice guidelines, showing some methods to be moderately successful, but there is uncertainty about whether similar results would be experience in all settings. More patient safety improvement methods have been reported since 2000, but there is very little evidence of effectiveness, apart from specific safety practices.

Table 1: Summary of quality and safety tools

Quality and Safety Tool	Comments
Tools for measurement and data gathering (lack of data is one of the most commonly reported explanations for failed application of quality and safety projects)	
Patient feedback tools	Includes complaints methods. Many criticisms of questionnaire surveys reported. SERVQUAL and Picker surveys most often used and cost-effective with computer processing and comparisons.
Quality and safety indicators	A wide range of literature about which data could indicate low or high quality or safety in health care *(141)* and guidance about which indicators to use *(34)* and about outcome measurement tools *(41–43)*.
Other measurement tools	Standards are the starting points for auditing and other methods. The "balanced scorecard" is for developing a strategic direction *(85)*. For safety measurement, observation and patient record review yield more accurate data about adverse incidents than personnel reports.
Tools for problem prioritization and writing problem statements	
Problem formulation guidelines, simple multi-voting and group ranking and Delphi- and nominal group techniques *(3)*	Choosing the right problem and describing it correctly are reported to be difficult for project teams, and often account for their lack of success *(13)*.
Tools for data analysis and presentation	
Forms for recording observations, and for data display: histograms, Pareto diagrams, scatter diagrams and control charts *(3)*	Less often reported in use in health care are statistical process control (SPC) *(86–89)* benchmarking, quality function deployment (QFD), design of experiments study (DOE), and theory of constraints *(90)*.
Tools for change planning and implementation	
Generic methods for change planning: force field analysis, project management	
Guidelines for implementation	Guidelines need to be developed for local use with implementation carefully planned and carried out *(85,87)*
Tools for change evaluation	
Before-and-after comparison using plan-do-check-act (PDCA) model	The more rigorous methods require comparing data with other organizations, or other time series or comparative controlled designs *(91)*.
Other tools and methods	
Frameworks: CQI (continuous quality improvement) team frameworks, Quality assurance or audit cycle frameworks	
Multi-method tools: pathway development, benchmarking, re-engineering	
Organizational assessment methods: EFQM (European Foundation for Quality Management), Baldridge award, ISO 9000 (International Organization for Standardization) quality system standards and	

process for assessment	
Quality costing	The cost-spend-save method is for assessing a quality intervention. A general method is to assess the costs of failures, inspection and prevention.
Facilitation tools	These are methods used by facilitators, for example to assist quality project teams or practitioners to follow evidence based practice.
Specific safety tools: incident report data collection and analysis *(92)*, root cause analysis *(93)* and crew resource management *(94)*	

Annex 1: Sources and methods for review and synthesis

Databases were searched for the following key terms: quality tools health care, quality methods health care, safety methods health care. The electronic search covered 1991–2003 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) and Bandolier Management. The search strategy was to allocate 25% of the time for the synthesis to searching for and getting relevant journal articles, reports and books. The search strategy included:

- 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 according to whether the item described a single or multiple quality or safety method, discussed issues in using a method or covered organizations other than health care;
- assembling all papers and books collected since 1985 in the present author's library which were relevant to the questions and subject;
- searching the named sources for any systematic or unsystematic reviews already carried out of the subject area or of similar areas, and ordering key papers referred to by such reviews;
- searching the following databases, in order: Medline, CINAHL, Kings Fund www.Kingsfund.org.uk, accessed 4 October 2005 and HELMIS & Dh Data, Pubmed, Bandolier management http://www.jr2.ox.ac.uk/bandolier/booth/booths/mgmt.html, accessed 4 October 2005;
- searching indexes of *Quality and Safety in Health Care, Health Policy, Journal of Health Services Research and Policy, Journal of Health Organization and Management (previously Journal of Management and Medicine), International Journal for Quality in Health Care, International Journal of Health Care Quality Assurance, International Journal for Quality in Health Care, Milbank Quarterly, Quality Management in Health Care, Joint Commission Journal on Quality and Safety, European Journal of Public Health, Total Quality Management, International Journal of Health Planning and Management, International Journal of Public Sector Management, International Journal of Public Sector Quality, Health Services Research and Journal of Health Services Research and Policy;*
- searching:
  http://www.shef.ac.uk/,
  http://www.sosig.ac.uk/,
  http://www.psycinfo.com/,
  http://www.isinet.com/isi/products/citation/wos/,
  http://www.emeraldinsight.com/Insight/,
  http://www.sciencedirect.com/,
  http://www.ovid.com/site/index.jsp, and
  http://erc.msh.org ("the managers resource").
  (accessed 5 October 2005)

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 Health Evidence Network (HEN) guidelines for synthesis authors were used and a possible set of headings for the report were compiled which covered the main issue or findings discussed in the literature. The summaries of each item were then used to compile the report, listing key practical recommendations following from evidence, along with research issues and gaps in the literature. The review was completed by rewriting the recommendation and redrafting following comments from colleagues.

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