Clinical Guidelines and Clinical Decision Support System

This article summarizes the current evidence-based guidelines and clinical decision support systems (CDSSs) development and proper usage of them in medicine.

During the post-World War II era there has been a huge boom in introduction of new medical therapies and in improvement of health care systems. New methods are used to increase the efficiency of medical treatment by combination of knowledge derived from the literature, clinical guidelines made on practice-based evidence, and a dialogue between healthcare professionals, clinicians and patients. And furthermore, the medical societies now focus on the different guideline programme, operating at a national level that incorporates both clinical and cost effectiveness and introduces to the discussion about the medical care a health economist, whose role is to monitor the cash flow.

The practice guideline demands processing of large amounts of diverse information, practitioners can accomplish having a working system only if they continually update their own medical knowledge and consistently place newly acquired knowledge in context with existing information to produce a beneficial impact on the clinical practice. You can be never sure if the guideline is still valid or whether it needs improvement.

Clinical decision support systems (CDSSs) have been hailed for their potential to reduce medical errors and increase health care quality and efficiency. At the same time, evidence-based medicine has been widely promoted as a means of improving clinical outcomes, where evidence-based medicine refers to the practice of medicine based on the best available scientific evidence. The use of CDSSs to facilitate evidence-based medicine therefore promises to substantially improve health care quality.

Medical guidelines

The words ‘guide’ and ‘line’ were first joined to refer to a physical object, such as a rope that marked the optimal course along a treacherous path. Using this help, the achievement of our aid is easier and time-saving.

Guidelines can be viewed as maps of common paths taken, derived from synthesis of past experience, with annotations that list advantages and disadvantages of reasonable alternatives. They will of course vary widely from one to another in their characteristics, just as characteristics of maps needed by a family on a trip to the nearest town will differ markedly from those needed by hikers on mountain trails. In other words, the formation of both maps and guidelines must respond to intended use.

The medical guideline is constructed by completing a task that may at first seem simple, but is in fact deceptively difficult. That task, in essence, is to formulate coherent statements of acceptable responses to common clinical situations. But those responses in most cases have been internalized by experienced providers to such an extent that they have become intuitive. These providers, when confronted with a familiar clinical scenario, have little difficulty pursuing a reasonable care plan that is derived from a professional lifetime of internalizing and structuring a large amount of information. Such plans have formed naturally as accumulating experience
combines with logic. That means even highly articulate practitioners can articulate these intuitively understood structures only with a reorientation and refocusing of thought.

How should the guideline look like?

The guideline has to be simple to understand, structured for better overview, logical and complex, all this forming a ‘user-friendly’ manual that facilitates the work. To summarize and organize the guideline algorithms can be used. The similar system is used in branching classification of animals with which are most people familiar. The ‘yes or no’ method, as it can be called, is simple enough and still well-structured, practical and logic to be used as a guideline.


These two figures show how the system works. While by focusing on special conditions we can distinguish a muskrat from a beaver (very important for zoologist but less effective for clinicians), the figure on the right show the approach to patient with sore throat (useful both for clinicians and sick zoologist).

Arrows are always one-way in the direction indicated by the arrowhead and are followed until an ‘answer box’, or terminal node, is reached. Some arrows may leave the algorithm to indicate that the information has to be searched somewhere else. The shape of the boxes follows commonly accepted criteria and depends on whether a question or answer is contained within the box.

An important part of the art of algorithm construction - whether for identifying animals or for diagnosing illness - is the careful selection, or identification variables that possess these two properties, i.e., user-friendliness and efficiency.
As illustrated by the previous example, algorithms are flow diagrams that consist of branching-logic pathways which permit the application of carefully defined types of some entity.

Management algorithms

Simple classification algorithm, including those designed to aid clinical diagnosis, require no action on the part of the user other than observation, including in the case of clinical medicine, patient examination and the noting of test results.

For some purposes, such algorithms are incomplete. Clinicians not only diagnose, they also provide treatment. Moreover, diagnosis and treatment often go hand in what is commonly referred to as a management strategy. Algorithms that include both diagnostic and treatment modalities are referred to as management algorithms. As an example, this figure depicts the approach to the unconscious heart attack victim.

The main structural difference between management algorithms and simple diagnostic algorithms is the presence of boxes (nodes) containing instructions (e.g., ‘Begin rescue breathing’). In contrast to question nodes (which always have two exit arrows - one for ‘yes’ and one for ‘no’), instruction nodes have only one exit arrow.

Management algorithms appear to differ from the algorithms discussed above in that they seem to go beyond the classification and identification tasks associated with those algorithms. This is not the case, however. Management algorithms also classify patients into separate subgroups according to differences it needs (and appropriate management strategies).

The primary function of management algorithm is to identify patients who stand to benefit (or not benefit) from a particular management strategy (or range of strategies).

Judgments of expected benefit are tricky, of course, and in effect constitute outcome predictions with their own degree of sensitivity, specificity, and predictive value. Outcome studies are essential if these
judgments are to be as accurately as possible.

Having defined management algorithms, we shall now look at their potential advantages and disadvantages, particularly with respect to their use in conjunction with the development of clinical guidelines.

**Advantages of algorithms**

- Algorithms serve to organize the guideline.
- They facilitate the translation of guidelines into computer formats.
- They can show how different sections of guideline relate to each other.
- Algorithms have been shown to result in faster learning, higher retention, and better compliance with established practice standards than prose text.
- Algorithms have also been used successfully for retrospective quality review activities in a variety of settings.
- One of the most valuable features of algorithms is that they identify situations in which testing is unnecessary.

With the algorithm approach, testing is incorporated in the flow of patient evaluation only if ‘downstream’ management strategies depend on test results.

Properly constructed algorithms help guideline developers specify appropriate indications for particular management strategies. For example, the first node in figure asks whether a patient is at high risk for a particular condition.

Importantly, this question is tantamount to asking ‘What are the appropriate indications for testing?’ and so on. The selected phrase must then be specifically defined within the algorithm’s annotation into specific criteria.

Which patients, exactly, are at high risk? What are the findings (e.g. symptoms, signs) that distinguish high-risk patients from those at low risk (and who, therefore, should not be tested?)

The use of decision-relevant questions within the algorithm boxes is an
important feature in the construction of management algorithms. Properly phrased, these questions compel guideline developers to define clearly the types of patients who should or should not be considered to receive particular interventions or who should or should not be managed in a defined manner.

**Disadvantages and criticism of algorithms**

- Algorithms can seem to impose lockstep rigidity on physicians, turning them into ‘robots who do not think’.
- Patients are too variable and using the guideline without proper knowledge can be harmful and dangerous.
- Insufficient effort has been expended to link algorithms to the literature in order to ensure maximum possible clinical validity.
- Incomplete literature can cause consequent uncertainties.
- Additional counseling is almost always required.
- Algorithms put clinicians into a pressure, just yes/no answers are accepted, there is no space for *maybe, possibly* and *I have no idea*.

**Guidelines and algorithms**

This is an example of the guideline, the draft of management algorithm for patients with heart failure. There are some situations that are not covered, referring to other sources. But it still contains quite a lot of instructions, and therefore it is quite complicated. It is a very good algorithm figure, well-structured, easy to follow and logical.

Draft of management algorithm for patients with heart failure [2]
The creation of algorithm that can serve as the guideline is an art. Much of this art lies in looking for ways to reduce clutter. The priority is the handiness.

Several methods can be used to form a proper guideline algorithm:

› Nodes should be selected with care, limited to those that either represent a significant decision point or else apply to a significant proportion of patients (e.g. 20-25%) flowing through that particular pathway.

› Another way to reduce clutter is to include within testing nodes the principal question to be answered by this test, rather than using two nodes for this purpose.

› Multiple, redundant nodes and arrows can often be collapsed into a more parsimonious structure. For example, the section of an early version of the heart failure algorithm shown in previous figure can be collapsed into the four nodes like this.
As discussed above, selection of nodes and corresponding identification parameters should be based in large part on discriminatory power. In pursuit of the objective, the yes-or-no questions should capture the essence of the clinical decision-making process.

A logical flow must be maintained within the algorithm. It is important to ensure that all events and decisions depend on the answers to the questions and observations that precede them.

Algorithms are extremely effective as guidelines, easy to understand and deal with. Although there is debate about the appropriate place of guidelines in clinical practice, guidelines can be seen as one way of assisting clinicians in decision-making. Given the likely diversity of opinion that any group of people may display when considering a topic, methods are needed for organizing subjective judgments.

Although a considerable amount of research has been carried out, many aspects have not been investigated sufficiently. For the time being at least, evidence on those aspects has, therefore, to be based on the user’s own commonsense and the expertise of those who have used or participated in these methods. Even in the long term, some aspects will not be amenable to scientific study. Meanwhile, adherence to best practice will enhance the validity, reliability and impact of the clinical guidelines produced.

Ideally, guidelines should be based on evidence from large, well conducted studies, but often such research does not exist and, where it does, how the results might be applied to particular patients can be unclear. But there is a progress in this part of medicine.

The interventional procedures programme produces guidance on the safety and efficiency
Many clinical guidelines can be presented as recommendations, based on the best available evidence, for the care of people by healthcare professionals. In general, clinical guidelines have been defined as: ‘systematically developed statements to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances’, although they are also relevant to health service managers.

These guidelines are expected to promote both clinically effective and cost-effective care. Good clinical guidelines change the process of healthcare, ensure more efficient use of healthcare resources and improve outcomes for patients. For example, well-constructed and up-to-date clinical guidelines:

› provide recommendations for the care of patients by healthcare professionals
› can be used to develop standards to assess the clinical practice of healthcare professionals (for example, by professionals themselves, NHS trusts, health authorities or primary care groups)
› can be used in the education and training of healthcare professionals
› can help patients to make informed decisions
› can improve communication between the patient and healthcare professionals
Conclusions for practice

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- can help patients to make informed decisions, and improve communication between the patient and healthcare professionals.

The scope of a guideline provides a framework within which to conduct the development work. Its content briefly describes the background epidemiology relevant to the disease or condition and defines the aspects of care that the guideline will cover in terms of:

- population to be included or excluded – for example, age groups or people with certain types of disease
- healthcare setting – for example, primary, secondary or tertiary care
- interventions and treatments to be included and excluded – for example, diagnostic tests, surgical, medical and psychological treatments and rehabilitation, lifestyle advice.

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Developing clinical questions

Once the final scope of the guideline is agreed, the next stage is to refine it into structured clinical questions. These questions vary depending on the scope, but must be clear, focused and closely define the boundaries of the topic. They are important both as the starting point for the subsequent systematic literature review, and as a guide to facilitate the development of recommendations by the guideline developers (GDs). It is important to describe how clinical questions are selected, how they are formulated and how they are agreed. There may be different types of question that are usually required.

Number of questions

The exact number of clinical questions required for each guideline depends on the topic and the breadth of the scope. However, it is significant that the number of questions is of a manageable size for the GD to handle, especially in relation to the agreed timescale. For guidelines taking 18 months to develop, about 30 questions would be a reasonable number. If a guideline topic requires a larger number of questions it may be necessary to divide it into subtopics.
**Selecting questions from the scope**

Clinical questions should address all the areas covered in the scope, and should avoid introducing new aspects not specified in the scope. They will, however, contain more detail than the scope, and should be seen as building on the fundamental framework of the guideline as laid out in the scope.

The questions are usually drafted by the technical experts. They should then be refined and agreed by all GDs through discussions. The different perspectives of GDs ensure that the right questions are identified, thus enabling the literature search to be planned efficiently. Often, however, the main questions need refining once the evidence has been searched, and this may generate subquestions. Questions may also be submitted by stakeholders for the GDs to consider. The GDs be explicit about the rationale it uses for selecting questions and should keep a detailed record of the proceedings leading to the decisions made.

**Formulating and structuring clinical questions**

A good clinical question is clear and focused. It should be formatted in terms of a specific patient problem because this helps identify the clinically relevant evidence. Its exact structure will depend on the question being asked, but it is likely to fall into one of three main areas: *intervention, prognosis and diagnosis.*

**A. Questions about interventions**

Questions about interventions usually represent the majority of questions for a particular guideline. Each intervention listed in the scope is likely to require at least one clinical question, and possibly more depending on the populations and outcomes of interest.

A helpful structured approach to formatting questions about interventions is the patient intervention comparison and outcome (PICO) framework. This divides each question into four components: the patients (the population under study); the interventions (what is being done); the comparisons (other main treatment options); and the outcomes (the measures of how effective the interventions have been).

Features of a well-formulated question on effectiveness intervention – the PICO guide
**Patients/population:** which patients or population of patients are we interested in? How can they be best described? Are there subgroups that need to be considered?

**Intervention:** which intervention, treatment or approach should be used?

**Comparison:** what is/are the main alternative/s to compare with the intervention?

**Outcome:** what is really important for the patient? Which outcomes should be considered: intermediate or short-term measures; mortality; morbidity and treatment complications; rates of relapse; late morbidity and readmission; return to work, physical and social functioning and other measures such as quality of life; general health status; costs?

For each question, the GDs should take into account the various confounding factors that may influence the outcomes and effectiveness of treatment. Once the question has been framed, key words can be identified as potential search terms. The most appropriate study design to answer a question relating to an intervention is likely to be a randomised controlled trial (RCT). Further information on the side effects of a drug may be obtained from a cohort study.

**B. Questions about diagnosis**

Questions relating to diagnosis do not involve an intervention designed to treat a particular condition, therefore the PICO framework is not a helpful structure. Questions should still be clear and focused, but they have to pick up key issues specifically relevant to diagnostic tests, for example their accuracy, reliability, safety and acceptability to the patient.

Examples of clinical questions on diagnosis. Questions used in the development of the guideline on lung cancer.

What is the diagnostic accuracy of:

- MRI compared with CT in assessing invasion of mediastinal structures and chest wall invasion in patients with potentially curable lung cancer?
- MRI compared with CT in assessing the presence of cerebral metastases in patients with stage III disease?
- PET compared with the histological results or follow up of more than 6 months in the detection of distant metastases (in brain/bone/adrenals/liver) in patients with lung cancer?
- abdominal ultrasound compared with the reference standard (histological results or follow up of more than 6 months) in the detection of distant metastases (in adrenals/liver) in patients with lung cancer?

The most appropriate study designs to answer a question relating to diagnosis are likely to be cross-sectional cohort studies or blind prospective comparisons of the investigation with a gold standard.

**C. Questions about prognosis**

In some situations the prognosis of a particular condition is of fundamental importance, over and above its general significance in relation to specific interventions. Areas where this is particularly likely to occur relate to assessment of risk, for example in terms of behaviour modification or screening and early intervention.
Examples of clinical questions on prognosis.

- Does family history discriminate patients who should be referred?
- Which are the symptoms, signs and other features that raise a suspicion of cancer in women, and those that make cancer less likely as a diagnosis?
- Which are the symptoms, signs and other features that raise a suspicion of cancer in a man presenting with a breast abnormality, and those that make cancer less likely as a diagnosis?
- Does trauma have a role in initiating breast cancer?

The most appropriate study designs to answer a question relating to prognosis are likely to be cross-sectional cohort studies or blind prospective comparisons of the finding with a gold standard.

D. Questions about service-delivery guidance

In general, clinical guidelines do not cover issues of service delivery.

Examples of clinical questions on service-delivery guidance

- Is nurse telephone consultation in out-of-hours primary care effective and safe?
- What is the impact of home-based support in early labour on the rate of Caesarean and instrumental birth?
- Which types of in-patient care produce better clinical and social outcomes for young people with mental health problems?

Ideally the most appropriate study design to answer these questions is an RCT. However, a wide variety of methodological approaches and study designs have been used.
Clinical Decision Support System (CDSS)

CDSS have been introduced in medicine to simplify the work of clinicians and to improve the medical care. Decisions based on previous experiences have higher probability to be successful in dealing with variable diseases and problems. These support systems can be presented by guidelines advising proper pathways of medical treatments.

To enable better understanding, we write here a short list of definitions useful for further reading.

- **Evidence-based medicine.**

  Evidence-based medicine is the management of individual patients through individual clinical expertise integrated with the conscientious and judicious use of current best evidence from clinical care research. This approach makes allowances for missing, incomplete, or low-quality evidence and requires the application of clinical judgment.

  The scientific literature is the major source of evidence for evidence-based medicine, although literature-based evidence should often be complemented by local, practice-based evidence for individual and site-specific clinical decision making. Evidence-based medicine is conducted by the health care provider and may or may not be computer-assisted.

- **Clinical decision support system (CDSS).**

  In this paper, we define clinical decision support systems to be software designed to be a direct aid to clinical decision-making, in which the characteristics of an individual patient are matched to a computerized clinical knowledge base and patient-specific assessments or recommendations are then presented to the clinician or the patient for a decision.

- **Evidence-adaptive CDSS.**

  We focus on a subclass of CDSSs that are evidence-adaptive, in which the clinical knowledge base of the CDSS is derived from and continually reflects the most up-to-date evidence from the research literature and practice-based sources.

  For example, a CDSS for cancer treatment is evidence-adaptive if its knowledge base is based on current evidence and if its recommendations are routinely updated to incorporate new research findings. Conversely, a CDSS that alerts clinicians to a known drug-drug interaction is evidence-based but not evidence-adaptive if its clinical knowledge base is derived from scientific evidence, but no mechanisms are in place to incorporate new research findings.
Process

The track consisted of three panels and two break-out discussion sessions. The first panel addressed the role of information technology in the dissemination and critical appraisal of research evidence, the technical challenges and opportunities of evidence-adaptive computerized decision support, and the organizational and workflow issues that arise when effecting practice change through information technology.

The second panel presented two case studies of evidence-based quality improvement projects and summarized the status of the GuideLine Interchange Format, a developing foundational technology for distributed evidence-adaptive CDSSs.

Finally, a commentator panel expanded on some of the pitfalls to changing practice through technology and on the information-technology funding agenda of the Agency for Healthcare Research and Quality.

Interspersed with these panel presentations were two moderated break-out sessions, in which participants worked to identify the research and policy needs and priorities for effective computer-supported practice change.

All conference sessions were audiotaped. Using these audiotapes, we distilled five central areas of activity that are essential to the goal of increased adoption of CDSSs for evidence-based medicine.

- Capture of both literature-based and practice-based research evidence into machine-interpretable formats suitable for CDSS use
- Establishment of a technical and methodological foundation for applying research evidence to individual patients at the point of care
- Evaluation of the clinical effects and costs of CDSSs, as well as how CDSSs affect and are affected by professional and organizational practices
- Promotion of the effective implementation and use of CDSSs that have been shown to improve clinical performance or outcomes
- Establishment of public policies that provide incentives for implementing CDSSs to improve health care quality
The Role of Evidence in Evidence-adaptive CDSSs

Clinical decision support systems can be only as effective as the strength of the underlying evidence base. That is, the effectiveness of CDSSs will be limited by any deficiencies in the quality or relevance of the research evidence. Therefore, one key step in developing more effective CDSSs is to generate not simply more clinical research evidence, but more high-quality, useful, and actionable evidence that is up-to-date, easily accessible, and machine interpretable.

Literature-based Evidence

Only about half the therapeutic interventions used in inpatient and outpatient care in internal and family medicine are supported in the research literature with evidence of efficacy. The other half of the interventions either has not been studied or have only equivocal supportive evidence. Several problems exist with using the research literature for evidence-based medicine.

First, the efficacy studies of clinical practice that form the basis for evidence-based medicine constitute only a small fraction of the total research literature. Furthermore, this clinical research literature has been beset for decades with study design and reporting problems - problems that still exist in the recent randomized trial, systematic review, and guidelines literature. As the volume of research publication explodes while quality problems persist, it is not surprising that most clinicians consider the research literature to be unmanageable and of limited applicability to their own clinical practices.

The full promise of CDSSs for facilitating evidence-based medicine will occur only when CDSSs can "keep up" with the literature—that is, when evidence-adaptive CDSSs can monitor the literature for new relevant studies, identify those that are of high quality, and then incorporate the best evidence into patient-specific assessments or practice recommendations. Automation of these tasks remains an open area of research.

In the meantime, the best electronic resources for evidence-based medicine include the Cochrane Library, Best Evidence, and Clinical Evidence, resources that cull the best of the literature to provide an up-to-date solid foundation for evidence-based practice. The drawback to these resources is that their contents are textual and thus not machine-interpretable by present-day CDSSs.

In contrast, if the research literature were available as shared, machine-interpretable knowledge bases, then CDSSs would have direct access to the newest research for automated updating of their knowledge bases. The Trial Bank project is a collaboration with the Annals of Internal Medicine and JAMA to capture the design and results of randomized trials directly into structured knowledge bases and is a first step toward the transformation of text-based literature into a shared, machine-interpretable resource for evidence-adaptive CDSSs.
Practice-based Evidence

Although the research literature serves as the foundation for evidence-based practice, it is not uncommon that local, practice-based evidence is required for optimizing health outcomes.

For example, randomized trials have shown that patients with symptomatic carotid artery stenosis have fewer strokes if they receive a surgery called carotid endarterectomy. If complication rates from the surgery are greater than about 6 percent, however, the benefits are nullified. Despite this, only 19 percent of physicians know the CEA complication rates of the hospitals in which they operate or to which they refer patients. For clinical problems with locally variable parameters, therefore, developers of CDSSs should place a high priority on obtaining local practice-based evidence to complement the literature-based evidence.

Practice-based evidence may also be useful for the development of practice guidelines. Although the evidentiary support for individual decision steps in a guideline comes primarily from literature-based evidence, as discussed above, a guideline's process flow is usually constructed on the basis of expert opinion only. With more practice-based information on clinical processes and events, however, guideline developers may be able to improve the way they design process flows.

As useful as practice-based evidence may be, it is often not easy to come by. The informatics community can foster this much-needed research by developing information technologies for practice-based research networks to automatically capture clinical processes and events in diverse outpatient settings. Many research and policy issues concerning these research networks—from the standardization of data items to data ownership and patient privacy—are active areas of inquiry.

Patient-directed Evidence

The Internet and other sources of research evidence have provided patients with many more options for obtaining health information but have also increased the potential for patients to misinterpret or become misinformed about research results. As a result, patients are now less dependent on clinicians for information, but still trust clinicians the most for help with selecting, appraising, and applying a profusion of information to health decisions.

Clinical decision support systems can support this growing involvement of patients in clinical decision making through interactive tools that allow patients to explore relevant information that can foster shared decision making. Systems that provide both patients and clinicians with valid, applicable, and useful information may result in care decisions that are more concordant with current recommendations, are better tailored to individual patients, and ultimately are associated with improved clinical outcomes. The actual effects of these CDSSs on care decisions and outcomes should be evaluated.
Recommendations

The gap between the current state of CDSSs and the full promise of CDSSs for evidence-based medicine suggests a research and development agenda. On the basis of the expert panels and discussion sessions at the Congress, we recommend the following steps for researchers, developers, and implementers to take in the five areas of activity essential to increasing adoption of evidence-adaptive CDSSs.

➤ Capture of Literature-based and Practice-based Evidence

If clinical research is to improve clinical care, it must be relevant, of high quality, and accessible. The research should provide evidence of efficacy, effectiveness, and cost-effectiveness for typical inpatient and outpatient practice settings. If CDSSs are to help translate this research into practice, CDSSs must have direct machine-interpretable access to the research literature, so that automated methods can be brought to bear on the myriad tasks involved in “keeping up with the literature.” Thus, the establishment of shared, machine-interpretable knowledge bases of research and practice-based evidence is a critical priority. On the basis of discussions at the conference, we identify six specific recommendations for action:

➤ Conduct better quality clinical research on the efficacy, effectiveness, and efficiency of clinical interventions, particularly in primary care settings.

➤ Continue to develop better methods for synthesizing results from a wide variety of study designs, from randomized trials to observational studies.

➤ Develop shareable, machine-interpretable repositories of up-to-date evidence of multiple types (e.g., from clinical trials, systematic reviews, decision models).

➤ Develop shareable, machine-readable repositories of executable guidelines that are linked to up-to-date evidence repositories.

➤ Define and build standard interfaces among these repositories, to allow evidence to be linked automatically among systems for systematic reviewing, decision modeling, and guideline creation and maintenance.

➤ Develop an informatics infrastructure for practice-based research networks to collect practice-based evidence.

➤ Introduce a inter-communication between healthcare professionals and a net of information flow to produce the up-to-date accessible evidences prepared for usage.
Establishment of a Technical and Methodological Foundation

The figure depicts the informatics architecture that we suggest is needed for CDSSs to facilitate evidence-based practice. In this architecture, CDSSs are situated in a distributed environment that comprises multiple knowledge repositories as well as the electronic medical record. Vocabulary and interface standards will be crucial for interoperation among these systems. To provide patient-specific decision support at the point of care, CDSSs need to interface with the electronic medical record to retrieve patient-specific data and, increasingly, also to effect recommended actions through computerized order entry. Evidence-adaptive CDSSs also need to interface with up-to-date repositories of clinical research knowledge. No longer should CDSSs be thought of as stand-alone expert systems.

In addition to establishing standardized communication among CDSSs, electronic medical records, and knowledge repositories, we also need better models of individualized patient decision making in real-world settings. Formal models of decision making such as decision analysis are not commonly used; much methodological work remains to be done on mapping real-world decision-making challenges to tractable computational approaches.

We identify several additional priorities for evidence-adaptive CDSSs in particular. These priorities include the development of methods for adjusting for the quality of the
evidence base, and efficient, sustainable methods for ensuring that CDSS recommendations reflect up-to-date evidence.

Recommendations for Researchers and Developers

➤ Continue development of a comprehensive, expressive clinical vocabulary that can scale from administrative to clinical decision support needs.

➤ Continue to develop shareable computer-based representations of clinical logic and practice guidelines.

➤ Develop tools for knowledge editors to incorporate new literature-based evidence into CDSS knowledge bases; specify the clinical context in which that knowledge is applicable; and customize the literature-based evidence for local conditions.

➤ Explore and develop automatic methods for updating CDSS knowledge bases to reflect the current state and quality of the literature-based evidence.

➤ Develop more flexible models of decision making that can accommodate clinical evidence of varying methodological strength and relevance, so that evidence from randomized trials is accorded more weight than evidence from case reports or expert opinion.

➤ Develop models of decision making that can simultaneously accommodate the beliefs, perspectives, and values of multiple decision makers, including those of physicians and patients.

➤ Develop methods for constructing and selecting among decision models of scalable granularity and specificity that are neither too general nor too specific for the case at hand.

Recommendations for Current CDSS Developers

➤ Adopt and use standard vocabularies and standards for knowledge representation as they become available.

➤ Incorporate into the CDSS knowledge based on the current best literature-based and practice-based evidence, and either provide mechanisms for keeping the knowledge base up-to-date or explain why keeping up with the evidence is not applicable.

➤ Describe care delivery setting and clinical scenarios for which the CDSS is applicable.

➤ Integrate CDSSs with electronic medical records and other relevant systems using appropriate interoperability standards (e.g., HL-7).

➤ Develop more CDSSs for outpatient settings. Approximately 60 percent of US. physicians practice in outpatient settings, where an aging population is requiring increasingly complex diagnostic, treatment, and supportive services.

Recommendation for Policy Makers, Organizations, and Manufacturers
Evaluation of Clinical Decision Support Systems

Despite the promise of CDSSs for improving care, formal evaluations have shown that CDSSs have only a modest ability to improve intermediate measures such as guideline adherence and drug dosing accuracy. The effect of CDSSs on clinical outcomes remains uncertain. Thus, more evaluations of CDSSs are needed to produce valid and generalizable findings on the clinical and organizational aspects of CDSS use. A wide variety of evaluation methods is available, and both quantitative and qualitative methods should be used to provide complementary insight into the usage and effects of CDSSs. All types of evaluation studies, not just randomized trials, deserve increased attention and funding.

In light of the current focus on errors in medicine, a special class of evaluation study deserves particular mention. These studies are ongoing, iterative reevaluations and redesigns of CDSSs that identify and amplify system benefits while identifying and mitigating unanticipated system errors or dangers. The rationale for these types of studies is that automation in other industries has not always been beneficial, and indeed, automation can interfere with and degrade overall organizational performance.

Clinicians and health care managers must be continuously vigilant against unforeseen adverse effects of CDSS use.

Recommendations for Evaluators

- Evaluate CDSSs using an iterative approach that identifies both benefits and unanticipated problems related to CDSS implementation and use: all CDSSs can benefit from multiple stages and types of testing, at all points of the CDSS life cycle.

- Conduct more CDSS evaluations in actual practice settings, including ambulatory settings.

- Use both quantitative and qualitative evaluation methodologies to assess multiple dimensions of CDSS use and design (e.g., the correctness, reliability, and validity of the CDSS knowledge base; the congruence of system-driven processes with clinical roles and work routines in actual practice; and the return-on-investment of system implementation). Qualitative studies should incorporate the expertise of ethnographers, sociologists, organizational behaviorists, or other field researchers from within and without the medical informatics community, as applicable.

- If preliminary testing suggests that a CDSS could improve health outcomes, the CDSS should be evaluated to establish the presence or absence of clinical benefits. Any randomized clinical trials that are conducted should have sufficient sample sizes to detect clinically meaningful outcomes, should randomize physicians or clinical units rather than patients, and should be analyzed using methods appropriate for cluster randomization studies.
Establish partnerships between academic groups and community practices to conduct evaluations.

Promotion of the Implementation of CDSSs

Relatively few examples of CDSSs can be found in practice. In part, this limited adoption may be because CDSSs are as much an organizational as a technical intervention, and organizational, professional, and other challenges to implementing CDSSs may be as daunting as the technical challenges.

Recommendations for CDSS Implementers

- Establish a CDSS implementation team composed of clinicians, information technologists, managers, and evaluators to work together to customize and implement the CDSS.

- Develop a process for securing clinician agreement regarding the science underlying the recommendations of a CDSS. For evidence-adaptive CDSSs, a process is also needed for maintaining clinician awareness of and agreement with any changes in CDSS recommendations that may result from new evidence.

- Plan explicitly for work flow re-engineering and other people, organizational, and social issues and incorporate change management techniques into system development and implementation. For example, a CDSS that recommends immediate angioplasty instead of thrombolysis as a new treatment option for acute coronary syndromes will necessitate a major restructuring of the hospital's resource use and work practices.

Establishment of Public Policies That Provide Incentives for Implementing CDSSs

Significant financial and organizational resources are often needed to implement CDSSs, especially if the CDSS requires integration with the electronic medical record or other practice systems. In a competitive health care marketplace, financial and reimbursement policies can therefore be important drivers both for and against the adoption of effective CDSSs. As more evaluation studies become available, policy makers will be better able to tailor these policies to promote only those CDSSs that are likely to improve health care quality.

Recommendations for Policy Makers

- Develop financial and reimbursement policies that provide incentives for health-care providers to implement and use CDSSs of proven worth.

- Develop and implement financial and reimbursement policies that reward the attainment of measurable quality goals, as might be achieved by CDSSs.
Promote coordination and leadership across the health care and clinical research sectors to leverage informatics promotion and development efforts by government, industry, AMIA, and others.

**Conclusions**

The coupling of CDSS technology with evidence-based medicine brings together two potentially powerful methods for improving health care quality. To realize the potential of this synergy, literature-based and practice-based evidence must be captured into computable knowledge bases, technical and methodological foundations for evidence-adaptive CDSSs must be developed and maintained, and public policies must be established to finance the implementation of electronic medical records and CDSSs and to reward health care quality improvement.
Literature:


3. Health Technology Assessment: Methods of developing clinical guidelines, 2001, 4-6


