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Guideline-Based Decision Support Systems for Prevention and Management of Chronic Diseases

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1. Introduction

One of the greatest challenges in today's health care is closing the gap between scientific evidence and medical practice. Keeping up with information in health care has never been easy, but with 500,000 clinical trials currently listed in the Cochrane Controlled Trials Register, and 75 clinical trials and 11 systematic reviews published daily (Bastian, 2010), physicians face unmanageable information processing tasks. It has been estimated that clinicians would have to read 20 papers a day to keep abreast of advances in biomedical knowledge (Shaneyfelt, 2001), and that it may take up to 20 years before findings from scientific studies are implemented in medical practice (Institute of Medicine [IOM], 2001). Medicine is not reaping the full benefits of research efforts, and much of the knowledge that is acquired in scientific studies is lost in translation.

The lack of success in translating research findings into medical practice is particularly prevalent in the prevention and management of chronic diseases (Lenfant, 2003). For instance, the protective benefits of beta-blockers for patients who are recovering from myocardial infarction were established in 1981 (β -Blocker Heart Attack Study Group, 1981), and confirmed by several later studies. Yet in 1996, beta-blockers were being prescribed for only 62.5 percent of patients who had had a myocardial infarction in the U.S. (National Committee for Quality Assurance, 1997). Similarly, in 1983 it was shown that aspirin is a highly effective therapy in patients with acute myocardial infarction and unstable angina, and as long-term, secondary preventive therapy in patients with established cardiovascular disease (Awtry & Loscalzo, 2000). Nonetheless, in the year 2000 aspirin was being prescribed for at most one third of patients with coronary artery disease for whom there were no contraindications to its use (Stafford & Radley, 2003).

Clinical practice guidelines are considered essential instruments to increase the application of scientific evidence to routine care (IOM, 2001). Guidelines summarize the available evidence for specific medical conditions, and provide cut-and-dried recommendations for common medical tasks such as screening, diagnosis, triage, treatment selection, and long-term management of patients. However, guidelines are often not followed in clinical practice. Implementing clinical practice guidelines in routine care has proved to be a challenging problem of its own. Computerised decision support is an effective means to solve this problem, as computers can provide, concurrent with care, reminders and advice

that are based on practice guidelines and tailored to the needs of individual patients. Decision support is also one of the central elements of the Chronic Care Model (Bodenheimer et al., 2002), an evidence-based conceptual framework that describes changes to the healthcare system that help practices to improve outcomes among patients with chronic illness.

This chapter presents an overview of guideline-based decision support systems for prevention and management of chronic diseases. Running example throughout the chapter will be the prevention and management of cardiovascular disease (CVD), which is discussed in Section 2. In Section 3, we review the literature on guideline implementation strategies. Section 4 discusses guideline-based decision support systems, and Section 5 presents an example in the field of cardiac rehabilitation. Section 6 summarizes the chapter and presents an outlook to future developments.

2. Prevention and management of cardiovascular diseases

Cardiovascular disease (CVD) is a family of chronic and highly prevalent conditions in Western countries that lead to life-threatening events (such as myocardial infarctions and strokes), multi-morbidity, disabilities, and death. All cardiovascular diseases are caused by atherosclerosis, an excess build-up of plaque on the inner wall of blood vessels, which restricts the flow of blood. Atherosclerosis may lead to coronary heart disease, cerebrovascular disease, abdominal aortic aneurysms, and peripheral arterial disease. As a result, CVD is the main cause of disease burden (illness and death) in the Western world (Murray & Lopez, 1997).

The lion's share of recent gains in life expectancy in the Western countries has come from reductions in mortality from myocardial infarction and stroke. In the U.S., life expectancy increased by six years between 1970 and 2000, and nearly two thirds of that increase can be attributed to reductions in mortality due to CVD. These reductions were due largely to improvements in pharmaceutical treatment, surgical techniques, and angioplasty. At the same time, demographic trends and unhealthy lifestyles have led to quickly increasing numbers of people with CVD, and it is estimated that the prevalence of CVD will increase by more than 40% over the decade (Murray & Lopez, 1997). So, while the disease has become less threatening in its acute phases due to technological developments, there exist major challenges for our health care system in preventing that more people get diseased and in managing CVD patients in the chronic phases of their illness.

In 2004 the Interheart study showed that 90% of myocardial infarctions can be attributed to a set of nine modifiable risk factors: abnormal lipids, smoking, hypertension, diabetes, abdominal obesity, psychosocial factors, low consumption of fruits and vegetables, alcohol intake, and lack of regular physical activity (Yusuf et al., 2004). Patients with atherosclerosis have an increased risk of a new vascular event in the same or different arterial beds. Several lifestyle measures (healthy diet, exercise, quit smoking) and treatment of risk factors with medication (antiplatelet agents, blood pressure-, and lipid-lowering agents, beta-blockers, and ACE-inhibitors) can strongly reduce the risks of future cardiovascular events. This knowledge provides important opportunities for improving CVD prevention and cardiovascular risk management, and procedures for optimal controlling these risk factors are nowadays described in all the prevailing guidelines. Unfortunately, these guidelines are poorly implemented in clinical practice

(Beaglehole et al., 2007). Many patients with coronary heart disease, cerebrovascular disease, abdominal aortic aneurysm, and vascular disease in general do not reach treatment goals (EUROASPIRE Study Group, 2001a, 2001b).

Insights into the risk factors of CVD and the growing number of patients have increased the importance of managing the non-acute phases of the disease. Patient-centred counseling and team-driven care, multidisciplinary collaboration, and continuity of care (follow-up arrangements) are required in these phases. These tasks are usually carried out by specialized nurses and other paramedical personnel. For instance, cardiac rehabilitation is a multidisciplinary therapy for outpatient recovery after hospitalization for cardiac incidents (such as myocardial infarctions) and cardiac interventions (such as heart surgery) (Ades, 2001). A typical cardiac rehabilitation programme lasts for 6-12 weeks, and may consist of exercise training, relaxation and stress management training, education about the disease and its consequences, lifestyle change interventions, and psychosocial counseling, mostly provided in group therapy. The aim of cardiac rehabilitation is to ensure that patients are in the best possible physical and psychosocial condition to return to and maintain their normal place in society and to reduce their future cardiovascular risk (World Health Organisation, 1993). To this end, cardiac rehabilitation teams usually include specialized nurses, physical therapists, psychologists, dietitians, social workers, rehabilitation physicians, and cardiologists.

3. Implementation of clinical practice guidelines

Clinical practice guidelines are systematically developed statements to assist medical practitioners in making decisions about appropriate care (Field & Lohr, 1990). They are designed to promote effective care and discourage the use of ineffective treatments, to reduce variations in care practice, and to make more effective use of health care resources. Guidelines are nowadays an intrinsic component of disease management programmes, increasingly applied to improve outcomes for patients with chronic illnesses such as cardiovascular disease (Ellrodt et al, 1997). Guidelines should provide clinicians with scientific knowledge in a readily digestible form without requiring that they search through large volumes of published material (Woolf, 1990). Increasingly, adherence to guidelines is considered a measure of quality of care (Epstein, 1995). While there may be debate about whether or not guidelines result in improved medical care (Brook, 1989), there is little question that they are a well-established and increasingly important part of medical practice.

Over the last two decades, it is increasingly recognized that dissemination of paper-based guidelines alone does not lead to the change in care practice. Instead, carefully designed methods for change are required for effective implementation of guidelines (Grimshaw et al., 2004).

3.1 Why clinical practice guidelines are not always followed in practice

Based on an extensive review of the literature, Cabana and colleagues (1999) developed a conceptual framework for barriers to physician adherence to practice guidelines. Starting from Woolf's (1993) distinction between knowledge, attitudes, and behaviour, the framework identifies *internal* (cognitive and affective) and *external* barriers to behavioural change. Cognitive barriers may consist of a lack of awareness that specific guidelines exist and a lack of familiarity with their details. Both may be caused by the overload of

information that is presented to health care professionals, a lack of time to keep up with new guidelines, and poor accessibility of the guidelines in question. Most guidelines are issued either as published articles, as specialized monographs or both (Woolf et al., 1999). In either case, such guidelines often have little impact on clinical practice either because clinicians are unaware of them or because the guideline is not accessible during the provision of care (Grimshaw & Russell, 1993; Lomas et al., 1989). Tunis and colleagues (1994) showed that physicians were poorly informed about the details of several well-established guidelines yet claimed knowledge of a non-existent guideline presented in the study as a control.

Affective barriers may consist of a lack of agreement with specific guidelines or guidelines in general, believing that one cannot perform the guideline recommendation, not believing that following the guideline recommendation will lead to the desired outcome, and a lack of motivation or inertia of previous practice due to habit and routines. When professionals do not agree with specific guidelines, this may be due to a different interpretation of the underlying evidence, because they believe that the guideline is not applicable for a specific patient, that it is not cost-beneficial, or because of a lack of confidence in the guideline developers. A general aversion against guidelines is typically motivated by stating that guidelines are "too cookbook", too rigid to apply, present a biased synthesis, challenge professional autonomy, or are not practical.

External barriers may be related to patients, to the environment, or to the guidelines themselves. Patient-related barriers include poor compliance with prescribed drugs, lack of time, financial constraints, and lack of motivation to make lifestyle changes (e.g., quit smoking). For instance, in a study examining the patterns and predictors of compliance with concomitant antihypertensive and lipid-lowering agents, only one third of the patients fully adhered to both medication prescriptions (Whelton et al., 1998). Environmental barriers, finally, may consist of organisational constraints, lack of resources, lack of reimbursement, or (perceived) legal constraints.

3.2 Strategies for improving the implementation of guidelines

Following Davis & Taylor-Vaisey (1997), we will use the term *diffusion* for the distribution of information and the unaided adoption of recommendations, *dissemination* for more active communication of information to improve knowledge or skills, and *implementation* for active dissemination, involving strategies to overcome barriers. It is broadly agreed that diffusion of clinical practice guidelines is generally ineffective and, at best, results only in small changes in practice (Grimshaw & Russell, 1993; Oxman et al., 1995; Bero et al., 1998; Grimshaw et al., 2004). Nevertheless, it is probably the most common approach adopted by researchers, professional bodies, and health care organisations. The use of specific interventions to disseminate and implement clinical practice guidelines is less common, but many studies have pointed out that such interventions are necessary to ensure that practices change, and evidence suggests that more intensive efforts to alter practice are generally more successful (Bero et al., 1998; Grimshaw et al., 2004).

A wide variety of change interventions have been described in the literature. Roughly speaking, we can distinguish interventions orientated toward health care professionals, interventions orientated toward health care organisations, and those orientated toward health care consumers (Thorsen & Mäkelä, 1999). Here, we will focus on interventions directed at health care professionals. These interventions generally attempt to change professional behaviour by influencing the knowledge of professionals from preferred practice, changing their attitude toward preferred practice, or both (Bero et al., 1998). They can be classified into the following categories:

- educational interventions (distribution of educational materials, regional or national conferences, and/or small-group conference with active participation),
- outreach visits (use of a trained person who meets with professionals in their practice settings to provide information on preferred practice advocated by the guidelines),
- audit and feedback (providing summaries of recent clinical performance, obtained from medical records, computerised databases, observation, or from patients),
- assignment of local opinion leaders, nominated by their colleagues as 'educationally influential', to influence professional behaviour,
- local consensus processes (inclusion of care professionals in discussions on guideline recommendations and preferred practice),
- patient-mediated interventions, where information concerning professional behaviour is sought from patients or information about preferred practice given to patients,
- financial and regulatory incentives (fee-for-service, professional penalties; changes in medical liability, accreditation, or licensure),
- patient-specific reminders to physicians to perform a certain action, based on eligibility criteria described in the guidelines, and
- patient-specific, computerised decision support at the point of care.

Little or no effect was usually obtained with large-scale educational interventions. Audit and feedback interventions, assignment of local opinion leaders, local consensus processes, and patient mediated interventions have yielded variable results. Patient-mediated interventions do seem to improve the provision of preventive care, where baseline performance is often very low (Oxman et al., 1995). Small-group educational interventions, outreach visits, patient-specific reminders, and computerised decision support have consistently been shown to be effective implementation strategies across different studies. We note that patient-specific reminders can be either paper-based (i.e., consisting of memos, stickers, or slips of paper within the patient charts to remind physicians of preferred actions) or computer-based (i.e., consisting of automatic identification of eligible patients for specific actions, and provisions of prompts when the electronic clinical information system is accessed by the treating physician) (Dexheimer et al., 2008). The boundary between computer-based reminders and computerised decision support is not always clear-cut, and some authors consider them to belong to the same category.

Grilli and Lomas (1994) concluded that the choice of intervention should be guided by the characteristics of the guideline in question. Oxman and colleagues (1995) and Grol (1992) stated that it is important to identify local barriers to change before the actual intervention is started. Multifaceted interventions, i.e., combinations of two or more interventions such as participation in audit and a local consensus process, are more effective than single interventions (Wensing & Grol, 1994; Oxman et al., 1995). Grimshaw & Russell (1993; 2004) concluded that guideline-implementation interventions are most likely to be effective if they deliver patient-specific advice at the time and place of a medical consultation. Typically, this can be accomplished by computer applications. They can provide, concurrent with care, reminders and advice that are based on practice guidelines and tailored to the needs of individual patients. This insight has led to a broad consensus that clinical practice guidelines should be made available during clinical encounters through clinical information systems. During the last 15 years, the literature on the effects of deploying clinical guidelines has focused on computer based interventions (e.g., Rossi & Every, 1997; Ornstein, 2001; Subramanian et al., 2004). While many of these focus on simple reminder systems, many others represent increasingly complete presentations of entire clinical guidelines.

4. Guideline-based decision support systems

Since the invention of the digital computer, people have considered the application of computerized advice to improve the quality of medical decisions. In 1970s this led to the development of the first computer systems advising doctors in their clinical choices. Since that time, a large number of systems have been developed for a variety of clinical tasks and for a large number of clinical settings. Many of these have involved simple types of support like recognizing that a laboratory test result is out of normal range, or that a medication being ordered has a dangerous interaction with another one that a patient is taking, or determining that a patient is now due for an influenza vaccination. But also more complex systems have been developed, advising in advanced tasks such as diagnostic reasoning, diagnostic test selection, choice and planning of therapeutic actions, and prognostic assessment.

4.1 Computerized decision support

Based on Wyatt & Spiegelhalter (1991), we define computerized decision support (CDS) systems as knowledge-based reasoning systems which use two or more items of patient data to generate case-specific advice. This definition excludes systems that only retrieve patient information or medical knowledge without performing reasoning steps with these data, and systems that merely help to focus attention by performing range checks (e.g. alarm systems in anaesthesia and intensive care) or by warning for potential drug-drug interactions. This is not to say that these tools are not useful or effective – they simply form belong to different classes of systems.

Two types of CDS system were developed and thoroughly evaluated in the 1970s en 1980s: *Bayesian diagnostic systems* and *expert systems* (Shortliffe et al., 2003, Ch. 20). In Bayesian diagnostic systems, the knowledge base typically consisted of statistical associations between clinical parameters and medical disorders, and (pseudo-)Bayesian probabilistic inference was used to calculate posterior probabilities for each of the disorders included in the system, given a set of clinical observations. Cognitive psychological studies had shown that people, including experienced physicians, tend to make systematic errors in this type of reasoning (Kahneman et al., 1982). Bayesian diagnostic systems assisted physicians in proper reasoning with probabilities when establishing a diagnosis. A disadvantage of these systems was the fact that the results were sometimes counter-intuitive, and that these systems could not provide an explanation of their reasoning. Expert systems, in contrast, aimed to capture the nuances of human expertise and reasoning, by building a heuristic model of the knowledge from clinical experts. Reasoning in these systems was primarily symbolic (e.g., based on IF-THEN rules), and would aim to follow the line of thinking of human experts. Expert systems often had extensive facilities for justifying their advice to the user.

Several authors have defined characterizing features of CDS systems (Shortliffe et al., 2003, Ch. 20; Kawamoto et al., 2005; Garg et al., 2005). Table 1 lists 10 features that have been investigated in the scientific literature and are often associated with effectiveness. We note that these are not independent features. For instance, active systems have more effects on decision making behaviour than passive systems, which require users to recognize situations when advice would be useful and then must make an explicit effort to access the CDS system. It is only possible, however, to create an active CDS system when it is integrated with the electronic clinical information infrastructure. The same holds for the

requirement that no additional data entry is needed from the user. Consultation and critiqueing are generally considered to be complementary models. System integration, advice at the point of care, active system, and absence of the need for additional data entry all point in the same direction: At best, the decision-support element should be embedded within the users’ professional routine—thus making decision support a by-product of the practitioners’ ordinary workflow.

system feature	explanation
system integration	CDS system is integrated with the clinical information infrastructure, e.g. the system is connected the electronic patient record system, laboratory system, and CPOE system.
advice at point of care	Decision support is provided at time and location where decisions are actually made, e.g. during clinical encounters with patients or during multidisciplinary team meetings.
active system	CDS system does not wait for its users to ask for assistance but automatically provides advice as part of clinician workflow.
actionability of advice	CDS system advices in what to do for the patient (e.g., What test should be ordered?, Which treatment should be initiated?) instead of in what is true about a patient (e.g., What is the correct diagnosis? or What is the risk of developing specific disorders in the future?).
consultation model	CDS system serves as an advisor, accepting patient-specific data, possibly asking questions, and generating advice for the user about diagnosis or management.
critiqueing model	The clinician has a preconceived idea of what is happening with a patient or which therapy would be appropriate, and the system acts as a sounding board, expressing agreement or suggesting alternatives.
no need for additional data entry	All information that is necessary to generate advice is automatically extracted from patient records.
justification of advice	Advice is justified to user by explaining the reasoning steps or by provision of underlying research evidence
ease of use	The system has a clear and intuitive user interface with prominent display of advice; the system is fast, saves clinicians time or requires minimal time to use.
additional change interventions	CDS is accompanied by educational interventions, periodic performance feedback, active involvement of local opinion leaders or other change strategies.

Table 1. Characterising features of CDS systems, based on Shortliffe et al. (2003; Ch. 20), Kawamoto et al. (2005), and Garg et al. (2005).

Another characterizing feature, not included in the table, is the system’s underlying reasoning process, i.e. the logic or algorithms that are used to generate advice. A wide variety of techniques has been used to do this, predominantly stemming from Bayesian probability, decision analysis, and artificial intelligence. After evaluations showed a poor uptake of expert systems (Miller & Masarie, 1990) and modest benefit of diagnostic systems

(Berner et al., 1994), emphasis has shifted towards the implementation of clinical practice guidelines and protocols. These systems generally build on computer-interpretable models of the guidelines or protocols in question, and are described in Section 4.2.

Kawamoto and colleagues (2005) conducted a systematic review and meta-analysis of randomised clinical trials that assessed efficacy of decision support systems in improving clinical practice. They included both computerized and non-computerized systems, e.g., manual systems for attaching care reminders to the charts of patients needing specific preventive care services. From 70 studies that were included in the review, 48 (68%) significantly improved clinical practice. Four features were identified as independent predictors of improved practice, from which “active system” was by far the strongest. The other features were computerized (vs. manual) decision support, advice at point of care, actionability of advice. In another systematic review of the literature, Garg and colleagues (2005) summarized findings from 100 studies evaluating the effects of CDS systems, in both randomised and non-randomised controlled trials. From 97 studies that assessed improvement in clinical practice, 62 (64%) found statistically significant effects. Garg et al. also found that active systems are more effective than passive systems. In addition, studies in which the evaluators developed the CDS system themselves more often found positive effects than studies where the evaluators were not the developers. CDS was particularly effective for provision of preventive care (reminder systems), drug dosing and drug prescribing, and chronic disease management, but not for diagnosis. The success of CDS in prevention and chronic disease management is probably explained by the fact that in these areas, CDS is an effective means to transfer tasks from busy physicians to nurse practitioners and other paramedics (Jones & Peterson, 2008).

4.2 Computer interpretable guideline models

A variety of approaches has been used to computerize guidelines (Sonnenberg & Hagerty, 2006). At the most rudimentary level, these are merely electronically readable versions of text guidelines (e.g., in PDF), made available through hospital intranets or through the Internet. Computerized reasoning with documents in natural language is not feasible. So, to provide genuine guideline-based CDS, it is imperative to translate guidelines to a format in which they can be reasoned with by computer algorithms. These translated guidelines are called computer interpretable guideline models.

One of the earliest attempts to translate clinical practice guidelines into a computer interpretable format was used in systems for raising context-sensitive alerts and reminders, with so-called *situation-action rules*. The most widely used format for specifying such rules is the Arden Syntax (Hripcsak, 1994), an Health Level Seven (HL7) and ANSI standard, an example of which is given in Fig. 1. A rule interpreter processes the rules, scanning the patient database for relevant situations that trigger rules and evaluating whether the condition part of the rule holds. If so, the CDS executes the action part of the rule, which often consists of displaying an alert or reminder to the user.

Situation-action rules are suited for systems that need to issue simple, one-time reminders and alerts, such as reminder systems. Investigators have demonstrated significant enhancement of adherence to preventive-care guidelines, such as those for the administration of pneumococcal and influenza vaccinations, by integrating simple reminders with clinical information systems (Dexheimer et al., 2008). The success of these systems is probably explained by the fact that they provide actionable advice at the point of

care, they are easy to use, well integrated with other systems, and there is no need for additional data entry.

```

CHD_discharge := event {discharge
                        where dx = myocardial_infarction or
                              treatment = CABG or
                              treatment = PTCA}

NYHA_class := read_last {HF_NYHA_class}

;;

evoke: CHD_discharge ;;

logic:

if exist(NYHA_class) and (NYHA_class > 2) then conclude false
else conclude true;

endif;

;;

action:

write
"Patient should be referred to cardiac rehabilitation"

;;

```

Fig. 1. Example of a situation-action rule expressed in the Arden syntax. This rule prints a warning whenever a patient is discharged after hospitalization for myocardial infarction, coronary artery bypass grafting (CABG) surgery, or percutaneous transluminal coronary angioplasty and the patient does not have severe heart failure (NYHA class III or IV), that this patient should be referred to outpatient cardiac rehabilitation.

Situation-action rules are however not suitable to model more complex guidelines (Peleg et al., 2001). Development and maintenance of large rule bases can be difficult because interactions among rules may have unanticipated side effects. Rule-based models also do not support the application of elaborate procedures with multiple steps and procedures that extend over long periods of time, as is necessary for the support of the care of patients with chronic diseases. A final limitation of the Arden Syntax is the fact that it mixes representation of decision logic with specification of connections to other information systems (exemplified by the “event { ... }” and “read_last { ... }” statements in Fig. 1). Situation-action rules that are written in Arden Syntax therefore cannot be shared between institutions, as specifications of connections to other information systems depend on the local situation. This is often called the “curly braces” problem in the literature (Shortliffe et al., 2003, Ch. 20). For these reasons, the Arden Syntax is no longer in use to build guideline-based CDS systems.

Since the late 1990s, a number of more expressive guideline representation formats have been developed. Examples are GLIF (Ohno-Machado et al., 1998), PROforma (Fox et al.,

1998), ASBRU (Shahar et al, 1998), GASTON (De Clercq et al., 2001), GUIDE (Quaglini et al., 2001), and SAGE (Tu et al., 2007). Most of these representation schemes share a number of elements that solve the limitations of the Arden Syntax (Peleg et al., 2003, De Clercq et al., 2004). To describe multi-step procedures and procedures that extend over long periods of time, they represent guidelines in graphical flowcharts called task-network models. Each node in such a network model represents a single step and is either targeted at data input, performing calculations, flow control, executing a subguideline, or data output; examples are given in Table 2. Furthermore, a medical concept model (ontology) and virtual medical record are used to separate decision logic with the specification of connections to other information systems, rendering guideline models sharable between institutions. For most representation schemes, toolsets exist to create computer-interpretable guideline models and verify their consistency and completeness. In addition, execution engines have been developed for building decision support systems that are linked to clinical information systems and use these models to provide patient-specific advice to care professionals (Isern & Moreno, 2008).

type of step	examples
data input	<ul style="list-style-type: none">• reading the latest serum cholesterol values from the laboratory information system• prompting the user whether or not the patient smokes
calculation	<ul style="list-style-type: none">• computing the patient’s cholesterol ratio from total cholesterol and high-density lipoprotein cholesterol values
flow control	<ul style="list-style-type: none">• choosing the next node to execute, based on whether the cholesterol ratio is above the threshold for initiating medical treatment• iterating over all patient records in the laboratory information system
execute subguideline	<ul style="list-style-type: none">• determine the correct dosage of cholesterol lowering drugs, based on the patient’s age, body weight, and kidney function
output	<ul style="list-style-type: none">• setting a warning flag in the electronic patient record• writing the drug dose determined to the electronic patient record• displaying a message on the computer screen

Table 2. Typical steps of task-network models.

Clinical practice guidelines often contain ambiguities, inconsistencies, and logical errors that hamper their translation to computer interpretable guideline models. The models are often more precise than the original guidelines, with crisp thresholds where the guidelines tended to be vague and recommendations for situations that were originally overlooked. These discrepancies are unintended side effects of the translation, and may lead users of the CDS system to become suspicious of its advice. Goud and colleagues (2009a) have proposed a strategy where development of the paper guideline and development of the computer interpretable guideline model take place concurrently, exchanging information at crucial steps. With this strategy, it is possible to ensure perfect consistency between the paper guideline and the CDS model.

4.3 Using CDS for guideline implementation

In 1999, Shiffman and colleagues (1999) performed a systematic review of 25 studies of guideline-based CDS systems. Adherence to guidelines was improved in 14 of 18 studies

that evaluated it. Shiffman et al. also identified a set of eight information management services that foster uptake of such systems. However, not all guideline-based CDS systems have been successful. In a later study by Tierney and colleagues (2003), primary care physicians and pharmacists used a sophisticated electronic health record system with evidence-based cardiac care suggestions. The intervention had no effect on physicians' adherence to the care suggestions (23% for intervention patients vs. 22% for controls), and there were no improvements in quality of life, medication compliance, health care utilization, costs, or satisfaction with care. Physicians viewed guidelines as providing helpful information but constraining their practice and not helpful in making decisions for individual patients. Ansari and colleagues (2003) found no benefit from computerized physician reminders to use beta blockers in patients with heart failure. Montgomery and colleagues (2000), finally, investigated the prescription of blood pressure lowering medication in primary care when physicians received patient-specific cardiovascular risk charts and guideline-based CDS. Unaided physicians poorly assessed cardiovascular risks and this was significantly improved by risk charts. CDS did however not provide additional benefit.

5. Example: The CARDSS project

This section describes the development and evaluation of CARDSS, a guideline-based decision support system for cardiac rehabilitation and secondary prevention of cardiovascular disease. CARDSS (acronym for CARDiac Rehabilitation Decision Support System) was developed by the University of Amsterdam in collaboration with the Netherlands Heart Foundation and the Netherlands Society of Cardiology, with the aim to stimulate implementation of the Dutch national guidelines for cardiac rehabilitation. The system was used in approximately 40 Dutch outpatient rehabilitation clinics. Section 5.1 gives a brief overview of the Dutch guidelines for cardiac rehabilitation and the development of CARDSS, and Section 5.2 describes the results of two evaluation studies.

5.1 Development of the CARDSS system

To improve the quality of care in cardiac rehabilitation and secondary cardiovascular prevention, national guidelines were published in the Netherlands in 2004 (Rehabilitation Committee, 2004). These guidelines state that all patients with established coronary artery disease should be offered an individualised rehabilitation programme, built up from four possible group-based therapies (exercise training, relaxation and stress management training, education therapy, and lifestyle change therapy) and if needed, different forms of individual counseling (e.g. by physical therapists, psychotherapists, or dietitians). Patients should only receive therapies and forms of counseling that they really need, and not others. For instance, to decide whether a patient should receive exercise training, the patient's desired level of exercise capacity should be compared with the results of a maximal exercise capacity test.

The guidelines' recommendations with respect to assessing patient needs and selecting the appropriate therapies for individual patients were summarized by a clinical algorithm. In total, the needs procedure requires 15 to 40 data items concerning the patient's physical, emotional, and social condition and lifestyle to be gathered. It generally takes place two weeks after discharge from the hospital, after which, during weekly meetings, the multidisciplinary team formally decides on the content of the patient's rehabilitation

programme. The clinical algorithm consists of nine decision trees. When following the decision trees, each of their branches leads to one or more therapeutic goals and indications. To stimulate implementation of the guidelines, it was decided to develop a CDS system that would assist cardiac rehabilitation professionals in conducting the needs assessment and therapy selection procedure as described by the clinical algorithm (Goud et al., 2008). CARDSS consists of an EPR for outpatient CR, a structured dialogue module for gathering the information that is required to assess patient needs, a decision support module that generates guideline-based therapy recommendations, and several information management services. The EPR and information management functionalities were developed in Microsoft's .NET framework with an SQL server database that is accessible to multiple CARDSS clients within the same clinic. The structured dialogue and decision support modules were developed in GASTON (De Clercq et al., 2001). The system facilitates a genuine multidisciplinary needs assessment, where different clinical users can start, interrupt, and continue the structured dialogue at any time. Fig. 2 displays a sample CARDSS screen with therapy recommendations.

5.2 System evaluation

There exist several potential sources of bias when empirical studies are carried out with CDS systems (Friedman & Wyatt, 2006):

- “Hawthorne effect”: human performance may improve as a result of attention from investigators, a psychological phenomenon;
- “carry-over effect”: clinical decisions may be influenced by earlier system advice given to the same professional or to a colleague from the same clinic;
- “checklist effect”: the structuring of information (e.g. dialogue structure) by an information system may improve the quality of decision making of its users;
- registration bias: information entered into the system may reflect socially desirable behaviour and not actual clinical practice; and
- “clustering effect”: observations on decision making that were made within the same clinic may be correlated.

In contrast to uncontrolled studies and before-after studies, randomised controlled studies do not suffer from the “Hawthorne effect” because this will cancel out when the study groups are contrasted. It was therefore decided to evaluate the effect of CARDSS on concordance to the Dutch cardiac rehabilitation guidelines in a randomised trial (Goud et al., 2009b). To avoid “carry-over effects” resulting from professionals or teams learning from CARDSS, a cluster randomised design was chosen (Donner & Klar, 2000). Participating clinics worked with either of two versions of the system: an intervention version (having full functionality) or a control version which comprised the EPR, needs assessment dialogue, and information management services but did not provide therapeutic recommendations. This design controlled for the “checklist effect”, because the structuring of information was equal for both groups. During the trial, one or more members of the multidisciplinary rehabilitation team, usually a specialised nurse or therapist, recorded needs assessment data into CARDSS during a 30-60 minute meeting with the patient. The data were subsequently used as input for the weekly multidisciplinary team meeting, where all decisions about the patient's rehabilitation programme were made. In intervention clinics also the guideline-based therapy recommendations from CARDSS were available during such meetings. Teams recorded their final therapeutic decisions in CARDSS at the end of the meetings.



Fig. 2. Screen from the CARDSS system in which the rehabilitation programme is formulated based on therapy recommendations by the guidelines. The pop-up window displays the explanation why the system recommends giving exercise training for this particular patient.

From 44 Dutch clinics that used CARDSS, 31 clinics agreed to participate in the trial. Fifteen clinics were allocated to work with the control version of CARDSS, from which four discontinued participation. After the trial, data audits were conducted in all participating clinics to assess the quality and completeness of record keeping in CARDSS. The results of these audits were used to correct for registration bias. Four intervention clinics were excluded from the analysis because of discrepancies between the information recorded in CARDSS and the information recorded in an independent source. In addition, three intervention clinics had not recorded all their clinical decisions properly into CARDSS, and one clinic had too much missing data. These clinics were also excluded from the analysis. One control clinic, finally, accidentally erased its database and was also excluded. The resulting data set from 21 centres (12 intervention, 9 control) comprised 2787 patients (1655 intervention, 1132 control). The numbers of patients enrolled per clinic ranged from 78 to 171; the median number of patient per month per clinic was 14. The mean (SD) age of patients was 60.8 (11.4), and the number of male patients was 2060 (73.9%). The main reasons for referral to cardiac rehabilitation were heart surgery (n=1104, 39.6%), acute coronary syndrome (n=1086, 39.0%), and hospitalisation and treatment for stable angina pectoris, including percutaneous coronary intervention (n=454, 16.3%). Table 3 lists the results of the trial in terms of concordance to the guideline recommendations.

Therapy	Concordance (intervention)	Concordance (control)	Crude difference	Adjusted difference [95% CI]
Exercise training	92.6	84.7	7.9	3.5 [0.1 to 5.2]
Education	87.6	63.9	23.7	23.7 [15.5 to 29.4]
Relaxation	59.6	34.1	25.5	41.6 [25.2 to 51.3]
Lifestyle change	57.4	54.1	3.3	7.1 [-2.9 to 18.3]

Table 3. Results of trial: differences in concordance with guideline recommendations between intervention and control clinics. Values are percentages.

Concordance was generally high for exercise training and education therapy, and low for relaxation therapy and lifestyle change interventions. To control for “clustering effects”, the differences between intervention and control groups were statistically analysed with generalised estimation equations (Zeger & Liang, 1986). CDS increased guideline concordance for exercise training, education therapy, and relaxation therapy, but not for lifestyle change interventions. Both cases of over- and undertreatment were reduced by CDS, but reduction in undertreatment (i.e., not receiving guideline-recommended therapy) occurred more often. Concordance with recommendations for lifestyle change interventions was poor across both study arms: only 26% of the patients for which it was recommended actually received it. Similarly, despite the positive effect of the CDS, there remained still considerable undertreatment for relaxation therapy. In addition, there was a large variation between clinics in their levels of guideline concordance for all four therapies, in both intervention and control groups.

While randomised clinical trials can be used to study the magnitude of change in decision making behaviour, they do not provide insight into the reasons why professional behaviour changes. For this reason, it was decided to also study the effect of CARDSS on factors that hamper guideline implementation with qualitative research methods (Goud et al., 2010). This study consisted of in-depth, semi-structured interviews with end-users of the system, focusing on reasons for improved concordance or persistent non-concordance to the guidelines after successful adoption of CARDSS. Interviews were transcribed verbatim, and all remarks regarding guideline implementation were extracted, and classified using the conceptual framework from Cabana and colleagues (1999) that was described in Section 3.1. Twenty-nine rehabilitation nurses and physiotherapists from 21 Dutch clinics were interviewed, resulting in the identification of eighteen barriers. Seven barriers had vanished since the introduction of CARDSS. Table 4 lists five examples, including the barrier type, whether or not the barrier was removed by CARDSS, and a sample comment.

Interviewees reported that CARDSS increased their familiarity with the guidelines’ recommendations and decision logic, stimulated them to abandon their conventional way of reasoning, and helped them to apply the guideline in practice, for example by calculating and interpreting of quality-of-life scores. If the system’s recommendations were shared with patients, these were more often willing to participate in psychosocial therapies. Interestingly, none of the participants reported that their decision making for exercise training and education therapy had changed because of the introduction of CARDSS. However, these were two of the three therapies for which the trial had shown that the CDS increased concordance to guideline recommendations. Many clinics lacked the facilities and resources to offer all patients all recommended therapies. This fact explained the considerable undertreatment of patients with lifestyle change interventions and relaxation

therapy. Similar problems existed with lacking reimbursements and difficult collaboration with other departments. CARDSS was not effective in solving these organisational barriers.

Barrier	Type	Effect	Sample comment
Guideline complexity	External	r	"We now use the quality-of-life questionnaire with every patient."
Lack of familiarity	Internal	r	"Since CARDSS we focus more on [lifestyle related] questions."
Inertia to previous practice	Internal	p	"We don't offer lifestyle change interventions in this clinic. We haven't thought about it yet. I think that is just because of a lack of time."
Lack of resources	External	p	"[Exercise training] is currently full due to a lack of accommodation. The physiotherapist says he just wants five patients in his group, because otherwise the hall is too small for sports activities."
Lack of reimbursement	External	p	"The insurance companies do not reimburse relaxation therapy."

Table 4. Examples of reported barriers to following the cardiac rehabilitation guidelines, with barrier type, effect of CARDSS (r = reduced, p = persistent), and sample comment from interviews.

6. Summary and conclusions

Clinical practice guidelines are well-established instruments to bridge the gap between scientific knowledge and clinical reality. This is crucial in many medical areas, but especially in the prevention and management of patients with chronic illnesses, such as cardiovascular disorders. These disorders are the main cause of disease burden in the Western world and responsible for quick increases in care consumption. Substantial changes in the provision of medical care are needed to anticipate this problem. Many important insights into the factors that are responsible for the development and progression of CVD have been laid down in practice guidelines, urging physicians to initiate preventive therapies in early phases of the disease and provide proper management in later phases. However, guidelines are often not followed in practice, and during the last decade attention has therefore shifted towards implementation of guidelines in clinical practice.

Barriers to guideline adherence vary from knowledge and attitude of individual clinicians to environmental factors which reside in the organisation of care, lack of resources or reimbursement, legal constraints, and in patients that refuse to make the necessary changes to their lifestyles. Different strategies for improving the implementation of guidelines have been used to address these barriers, with variable success. CDS has proven to be among the most effective among these strategies, but is limited to tackling cognitive and affective barriers. In the CARDSS project, for instance, CDS improved guideline implementation by increasing the knowledge of guideline recommendations, by reducing inertia to previous practice, and by reducing guideline complexity. However, CARDSS was not effective when

organisational or procedural changes were required that users considered to be beyond their tasks and responsibilities. It has therefore become clear that in many situations CDS must be combined with other strategies into a multi-faceted intervention, to tackle all the existing barriers.

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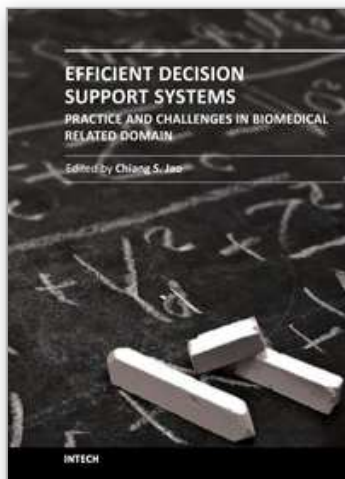
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