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### Improving care of vulnerable elders through computerized clinical decision support

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# **Chapter 1**

## **General Introduction**

This thesis contains the groundwork for the Improving Care of Vulnerable Elders (ICOVE) project, which aims to improve the quality of care for elderly patients by providing computerized clinical decision support to both clinicians and patients. Computerized clinical decision support can be defined as any computer program which helps in making a clinical decision [1]. This can be a conscious decision, such as a patient choosing between treatment options, or an unconscious decision, such as a specialist remembering to send a letter to the general practitioner after a consult. Decision support is one of the most promising approaches to improving the quality of care [2], and is also an important tool in empowering patients to take a more active role in their own care [3]. However, not all decision support systems are successful at improving care [4–6]. The work in this thesis describes investigations into the underlying evidence that forms the knowledge base of the system, methods for transforming that knowledge into a formal description of a computer program, the needs and desires of both patients and clinicians who will use the system, and a theoretical approach to modeling the function and dysfunction of such a system.

### **Health care, the aging population, and patient empowerment**

The proportion of the population in the Netherlands that is over 65 years of age has increased from 7% in 1950 to 14% in 2010 [7], and is expected to reach 26% by 2040 [8]. As the average age of the population increases, in the Netherlands and throughout the world [9], health care for older patients becomes increasingly important. Care for older patients is often complex, as with age comes an increasing number of chronic diseases leading to multimorbidity, polypharmacy, functional and cognitive disability and the need to coordinate care between multiple providers. At the same time, older patients are often excluded from the clinical trials that provide the basis for evidence-based medicine. This can be due to explicit age requirements for inclusion, or through the use of inclusion criteria that tend to disproportionately exclude older patients such as excluding patients with comorbidities [10]. Recent initiatives have made efforts to ensure that older adults are included in studies [11], which means that the evidence base is changing rapidly. Specialist knowledge in geriatrics is often needed to keep up with the evidence and determine how evidence and guidelines for younger patients should be extrapolated to the oldest patients.

One of the major differences between care for the oldest patients and care for younger patients is that more often, older patients choose interventions to maximize quality of life rather than prolong life [12]. At the same time, older patients are often viewed by medical professionals and developers of decision aids as having less desire for involvement in medical decisions [13], possibly due to a lack of health literacy, and lower willingness or ability to use computer or internet-based resources [14]. Having adequate information to make informed decisions lies at the heart of participatory medicine and patient empowerment, thus it is essential to learn how older patients wish to be informed and can become more involved in their own care.

## Healthy, vulnerable, and frail elders

A “vulnerable elder” is a person aged 65 years or older who is at increased risk of death or functional decline in the coming years [12], and can be identified by scoring systems such as the Identification of Seniors at Risk (ISAR) score [15] or Vulnerable Elders Survey (VES-13) [16]. Functional decline can in turn reveal a state of frailty, which is the aging-associated decline in reserve and function across multiple systems, resulting in a decreased ability to recover from everyday stress and acute harm [17, 18]. Thus, age-related decline can be viewed as a progression from robust to frail, and likewise, healthy aging can be viewed as preventing or slowing this aging process, which Fries called “compression of morbidity” [19]. Many factors contribute to functional decline, but hospitalization is a significant risk factor, even when the problem leading to hospitalization is not one that would logically lead to increased disability [20]. Appropriate prevention, diagnosis, treatment, and follow-up care in vulnerable patients is particularly important, both to avoid hospitalization and to avoid iatrogenic harm during hospitalization or ambulatory care.

## Assessing Care of Vulnerable Elders

In 1966, Donabedian described the quality of care in terms of two major aspects: technical quality and interpersonal quality [21]. Technical quality was defined in terms of structure (whether the resources and facilities are available to provide high-quality care), process (whether the correct procedures are followed that should lead to good outcomes) and outcome (the result of care, in terms of survival and health); interpersonal quality is the ability of the doctor to gather information about his patient and communicate instructions to his patient, but also his ability to educate, to counsel, and to comfort his patients. The 1999 Institute of Medicine report “*To Err Is Human: Building a Safer Health System*” informed us that the outcomes of health care were not always positive: 1.7% of hospital admissions in the US resulted in a preventable adverse event [22]. Similar studies in the Netherlands [23] and elsewhere [24] yielded similar results. Furthermore, quality of care tended to be lower in older patients [24]. The Assessing Care of Vulnerable Elders (ACOVE) project aimed to develop a comprehensive set of process-oriented quality indicators to assess and guide care in this population [12]. The quality indicators were formulated by an expert panel evaluating evidence using a Delphi method, and resulted in a set of 236 “clinical rules” in the form of “If *condition* then *action*” (392 in ACOVE-3) [12, 25]. In addition to being assessed specifically for their applicability to older patients, the recommendations were phrased to give clear instructions as to what to do in particular situations, and were intended to describe the minimal care that should be offered [26]. In the initial assessment of the quality of care in the ACOVE study, appropriate care was provided according to the quality indicators 53% of the time [27], meaning that when a patient met the conditions of a rule, the action recommended by the rule was taken 53% of the time. Although the adherence rate varies widely per condition, overall, similar results have been found in subsequent studies [28, 29]. Furthermore, the assessed quality of care was shown to be significantly associated with 3-year survival [27].

## **From assessment to improvement**

In an intervention based on the ACOVE quality indicators, the quality of care for falls, urinary incontinence, and dementia showed modest improvement through the use of a paper checklist inserted into the patient record [30]. Interestingly, improvement occurred in both the intervention and control arms of the study [30]. A probable explanation was that in screening patients to determine which qualified for the intervention, patients were called before their appointment and asked about falls, urinary incontinence, and cognitive symptoms. This screening likely acted as an intervention, underscoring the importance of patient activation and information in the care of older adults. The authors suggested that to see greater improvements, an intervention should be incorporated into the electronic patient record system [30]; in other words, that we should use computerized clinical decision support.

## **Computerized clinical decision support**

The field of clinical decision support began in the 1960's, with experimental diagnostic systems such as the Leeds Abdominal Pain system [1]. The 1990's saw the introduction of rule-based systems in clinical practice, such as the LDS Hospital's HELP system, which generated alerts such as allergy warnings. Both of these systems used mainly experts as their source of clinical knowledge. Around this same time, clinical practice guidelines were being introduced as a way to help clinicians keep up with current recommendations and reduce unwarranted variation, but it quickly became clear that simply publishing a guideline was not sufficient to see it adopted in practice [31]. Guideline-based decision support systems were employed to help move guideline recommendations from paper to practice. Currently, most decision support systems are based on either guidelines or expert knowledge, which is formalized (translated from natural language to a formal language suitable for specifying a computer program) and encoded into a decision support system.

Two systematic reviews published in 2005 found that the use of decision support resulted in improvement in clinical practice in 64% and 68% of controlled trials, respectively [5, 6]. Effectiveness was associated with automatic provision of support [5], giving recommendations on what to do rather than assessments [5], providing support at the time and place of decision-making [5], and integrating support with the electronic patient record or order entry systems [5, 6].

However, clinical decision support is far from a silver bullet. Much as the *To Err is Human* report exposed the harm that can result from medical interventions, the 2004 paper *Some unintended consequences of information technology in health care* and its follow-up studies exposed the potential harm from information technology interventions, including decision support [32, 33]. A 2006 review of overriding of drug safety alerts found that 49-96% of drug safety alerts were overridden [34], despite the fact that drug prescribing and management is the domain in which decision support is most effective [4, 35]. There are many reasons why alerts may be overridden. In a study reviewing the reasons for override, 96% of overrides were appropriate, and 39% of the alerts were incorrect [36]. A

high percentage of incorrect alerts can also contribute to “alert fatigue,” the tendency to ignore all alerts when faced with too many or too frequent alerts [37]. A 2012 review showed that, in contrast to the results from the 2005 reviews, alerts integrated into the electronic patient record were less effective than those from standalone systems – an effect likely attributable to alert fatigue [4]. In addition, cognitive overload and interruption (either of the clinical process by a poorly-timed alert from the system, or errors during use of the system by the inherently interruptive nature of clinical work) can lead to clinical errors [32, 38].

Current research has exposed the problems that can arise when implementing decision support, but to date we know little about how to solve them. Efforts have been made in improving drug safety alerts, particularly by stratifying alerts based on severity (the probability and seriousness of adverse clinical effects if the alert is not followed [39, 40]). However, it remains difficult to predict what effect a decision support intervention will have on the cognitive processes of the clinician, the overall clinical workflow, and consequently the quality of care.

### **The ICOVE project**

The goal of the ICOVE project is to provide decision support to improve the quality of care of older patients. We have three groups of users: general practitioners, hospital clinicians, and patients. Given the aforementioned difficulties encountered by others in implementing effective decision support, we chose to adopt the strategy of consulting with the users, under the premise that the user is best able to advise on his or her own information needs and workflow and thus could help us design systems that could and would be used within that workflow. Thus, the core question underlying this work is, “How do we provide effective support for clinicians and patients, while avoiding adverse unintended consequences?” This question will not be answered completely by any one research project, but it leads to the research questions addressed in this thesis.

### **Challenges and research questions**

One of the main challenges in the field of decision support is understanding what characteristics define successful systems, as opposed to systems that are not effective or not used. Consequently, the field needs a framework for understating the underlying functionality of the systems and their effect on their environment. Chapter 2 addresses this question, and presents the Two-Stream Model (2SModel) that can be used to organize the factors which influence the effectiveness of a system.

As is illustrated in this model, one of the important factors underlying the quality of the system is the quality of the knowledge upon which it is built. In the ICOVE project the ACOVE clinical rules form the knowledge base, but it was not yet known whether clinicians wanted support for some rules more than others, and if so, why. Chapter 3 presents a study in which general practitioners are surveyed to learn which rules they want supported, and why. Chapter 4 investigates the quality of the knowledge base from the angle of the applicability of evidence to older patients. As demonstrated above, evidence from

younger patients cannot always be applied directly to older patients. This applicability had recently been brought into question with the use of proton-pump inhibitors to prevent gastrointestinal complications related to the use of non-steroidal antiinflammatory pain medications in older patients. Although this preventative treatment is recommended in the ACOVE clinical rules, insurance companies in the Netherlands had withdrawn payment for this therapy. Thus, in Chapter 4 we address the question “Is the recommendation to coprescribe proton-pump inhibitors with non-steroidal anti-inflammatory drugs in older patients supported by the observational evidence?”

As illustrated in the 2SModel, the next step in creating a decision support system is to encode the clinical knowledge into formal knowledge that can be used by the computer to reason about the patient. Previous work on formalization of clinical knowledge has focused on the formalization of guidelines [41], but formalization of clinical rules differs in that guideline recommendations have explicit relationships (in terms of time and patient population) that must be preserved, where clinical rules often have implicit relationships that must be discovered. Chapter 5 addresses the question of how we formalize clinical rules into a specification for computer-interpretable code.

As suggested by the 2SModel, providing correct information is only half of the story. To successfully support decisions, the information must also be provided in a place where the user will easily find it when they need to make a decision, and in a form that they are comfortable using for the decision at hand. Chapters 6 and 7 address this challenge for the main user groups in ICOVE: patients and physicians. As mentioned above, earlier studies have questioned whether information provided via internet will be used by older adults. In Chapter 6 we present the results of a survey which asked, “What resources do seniors use and trust for health information, and when and what types of information are sought?” With respect to clinical decision support for clinicians, as mentioned above, recent studies have suggested a trend toward more interruptive forms of support. However, the 2SModel suggests that the type of support should be tailored to the type of task, and thus less interruptive support may be successful for tasks which do not have to be done immediately. In Chapter 7 we present a randomized controlled trial of a simple email reminder system to remind clinicians to write letters to the general practitioner, thus addressing the question, “Can a simple email reminder provide effective decision support for writing patient letters?”