PIRKKO NYKÄNEN

Decision Support Systems from a Health Informatics Perspective

University of Tampere
Tampere 2000

Decision Support Systems from a Health Informatics Perspective

Acta Electronica Universitatis Tamperensis 55

ACADEMIC DISSERTATION
University of Tampere, Department of Computer and Information Sciences
Finland

Acta Electronica Universitatis Tamperensis 55
ISBN 951-44-4897-9
ISSN 1456-954X
http://acta.uta.fi

PIRKKO NYKÄNEN

Decision Support Systems from a Health Informatics Perspective

■

ACADEMIC DISSERTATION

To be presented, with the permission of
the Faculty of Economics and Administration
of the University of Tampere, for public discussion
in the Paavo Koli Auditorium of the University,
Kehruukoulunkatu 1, Tampere, on August 16th, 2000 at 12 o'clock.

University of Tampere
Tampere 2000

Abstract

Our theme in this study is decision support systems in a health informatics context. A decision support system can be approached from two major disciplinary perspectives, those of information systems science and artificial intelligence, which offer different conceptualisations of a decision support system. From an information systems science perspective, the approaches taken have been functionalist and development- and implementation-oriented, resulting in systems being developed mostly to support managerial decision making. In artificial intelligence-based approaches, on the other hand, the focus has been on modelling of an expert task and on implementation of that model as a knowledge-based system. Under these latter approaches, the focus has been on the design of systems to support individual decision making in tasks that are considered to require intelligence. In neither of these perspectives has the social and organisational contexts of decision support systems been given much attention.

We present in this study an extended ontology for a decision support system in health informatics. The ontology emphasises the need to cover environmental and contextual variables as an integral part of a decision support systems development methodology. With the addition of these variables, the focus in decision support systems development shifts from a task ontology towards a domain ontology. The variables presented have been further connected to a development and evaluation framework, which applies incremental development using evolutionary prototyping. The presented ontology and framework help the system developers to take the system's context into account through the set of defined variables which are linked to the application domain. This results in systems that support decision making in the health care organisational context and in the user's domain, application and knowledge contexts.

The presented ontology is founded on experience from related research fields, those of information systems science and artificial intelligence, as well as being informed by analysed five case studies. The result of this sudy is demonstration of a pragmatic approach for decision support systems development in health informatics domain. Further research is needed with the operationalisation of the developed ontology.

Preface

This work has been carried out in VTT Information Technology (earlier VTT Medical Engineering Laboratory) and in Tampere University, Department of Computer and Information Sciences.

I wish to thank warmly my supervisor, professor Pertti Järvinen, from Tampere University, who never lost his belief that this dissertation would finally exist. The reviewers, professor Jane Grimson from Trinity College and docent Mikko Korpela from Kuopio University gave valuable comments and feedback, for which I am deeply grateful. I thank professor Arie Hasman from Maastricht University for being willing to act as opponent for this dissertation. My colleagues at VTT deserve warm thanks, especially research professor Niilo Saranummi, research manager Jukka Perälä and group managers Jari Viitanen and Eija Kaasinen for their supportive attitude to my work. I want to thank also the personnel at Tampere University Department of Computer and Information Sciences for warm atmosphere and supportive attitude towards a visiting fellow. I thank Alena Sanusi for revising the language of the manuscript.

I want to thank all my co-authors in the presented case studies of this dissertation. The studies represent results from various European and Nordic projects during which we have had many thorough discussions and meetings on these matters. Without these projects and this cooperation with colleagues this dissertation would not exist today.

The work reported in this dissertation has taken some years from me. During these years my family has been encouraging and supportive towards my work, I thank you deeply for that. My friends have brought other interesting aspects to the life, theatre and literature discussions, holidays and travels. I thank you all for these memories.

This work has been financially supported by the Wihuri Foundation, the French-Finnish Technical Society, the Tampere Graduate School in Information Science and Engineering (TISE) and VTT Information Technology. The support is gratefully acknowledged.

Tampere, July 2000
Pirkko Nykänen

Contents

List of publications

This study is based on the following publications, which are referred to in the text according to their Roman numerals.

I Nykänen P and Nuutila P, Validation and evaluation of a system for thyroid disorders. *Int J Expert Systems with Applications, vol. 3, no. 2, 1991, 289-295*.

II Nykänen P, Boran G, Pince H, Clarke K, Yearworth M, Willems JL and O'Moore R, Interpretative reporting and alarming based on laboratory data. *Clinica Chimica Acta. Int J of Clinical Chemistry and Biochemistry, vol. 222, nos 1-2, 1993, 37-48.*

III Nykänen P, Chowdbury S and Wigertz O, Evaluation of medical decision support systems, *Int J Computer Methods and Programs in Biomedicine, vol. 34, no 2/3, 1991, 229-238.* Reprinted in: van Bemmel JH and McCray AT (eds.), *IMIA Yearbook of Medical Informatics 1992, Advances in an interdisciplinary science. Schattauer Verlagsgeschellschaft, Stuttgart 1992, 301-310.*

IV Brender J, Talmon J, Nykänen P, McNair P, Demeester M and Beuscart R, On the evaluation of system integration. In: van Gennip EMSJ and Talmon JL (eds.), *Assessment and evaluation of information technologies in medicine. Studies in Health Technology and Informatics 17, IOS Press, Amsterdam, 1995, 189-208.*

V Nykänen P, Enning J, Talmon J, Hoyer D, Sanz F, Thayer C, Roine R, Vissers M and Eurlings F, Inventory of validation approaches in selected health telematics projects. *Int J Medical Informatics, vol 56, no 1-3, 1999, 87-96*.

1. Introduction

Our current information society makes extensive use of information systems and technology. In the field of health care, information technology has been applied as long as computers have existed, and many types of information technology applications have been developed. However, there still exists a potential for growth of information technology in health care, as has been mentioned, for example, in the Bangemann EU report (1994). That report foresees that application of information technology will result in savings in health care costs, in better service accessibility, in more effective and efficient service delivery and in better support for elderly and home care. In fact, health information systems are even seen as an essential prerequisite for rational and effective decision making in health care. In Finland, the Ministry for Social Affairs and Health produced a strategic plan [Välimäki 1996] on how to better utilise information technology and systems in social services and health care. The visions driving this plan focus on the implementation of cost-effective, custom-oriented seamless care processes, networking of service production and delivery, and improvement of the well being of service providers, patients, clients and citizens.

Early information technology applications in health care were related to core areas of health care and were restricted in scope, having an impact on only a few professionals. They were mostly targeted at the automation of existing routines, to ration resources and to ensure quality. The shift to an information society has brought a qualitative change in this respect: The focus is now on the development of new information technology service products that can improve health care processes and their outcome, the organisation of health care, and the delivery and production of services. Current health care information systems and networks are large and have wide ranging impacts on people and organisations [Lorenzi *et al.* 1997].

An example of information technology applications in health care is decision support systems. A decision support system may in principle be any system that helps decision makers to make decisions. Shortliffe has defined a decision support system in health care to be any computer program that is designed to help health professionals to make clinical decisions [Shortliffe 1987]. In information systems science a decision support system (DSS) is defined as a computer-based information system that helps decision makers to utilise data and models to solve ill-structured problems [Gorry and Scott Morton 1971, Keen and Scott Morton 1978, Sprague and Carlson 1982, Iivari 1991, Turban and Aronson 1998]. Key features highlighted by this definition for a decision support system are that it is interactive, it incorporates data and models, and it supports, rather than replaces, human decision makers in semi- or unstructured tasks. In artificial intelligence based approaches applied in health care area a decision support system is defined as "an active knowledge-based system (KBS) that uses items of patient data to generate case-specific advice" [van Bemmel and Musen 1997, p.262].

Since the 1960's decision support systems have been developed in health care for such purposes as the interpretation of findings and test results in patient care, the selection of treatments, the choice of tests or protocols for the patient case at hand, the management of data and information, the control of work flow and the monitoring of patient care processes and their outcomes. Despite the long history of availability and the type and amount of resources used, the results achieved have been rather low and dissemination of systems into health care practices has progressed only slowly [Reisman 1996, Barahona and Christensen 1994]. Numerous prototypical decision support systems exist, but very few of them have entered routine use. Some studies [Wyatt 1987, Lundsgaarde 1987, Pothoff *et al*. 1988] showed that little more than 10% of medical decision support systems developed so far have been sufficiently developed to enter clinical use. In 1992 the 600 subscribers to the 'artificial intelligence in medicine' mailing list reported only six systems to be in routine use [Heathfield and Wyatt 1993].

Our theme in this study is decision support systems in health care context. Our motivation for this study arises from two major concerns. First, we are concerned to build on the only partly realised, but still great, potential of decision support systems for health care. And second, our results in the case studies I-V show the need to connect research and development of decision support systems to health informatics as a scientific discipline. Health informatics is seen as a science and as a practice of applying information technology in social and health care.

1.1 DECISION MAKING IN HEALTH CARE

The two major scientific approaches to the study of decision making are prescriptive and descriptive theories. Prescriptive, rationalistic theories aim at the specification of how decisions optimally should be made, and descriptive or behavioural theories aim at understanding how people behave in decision making

[Keen and Scott Morton 1978]. These two approaches provide a frame for the study of decision making from the following perspectives:

- Theory of rational decisions, where decision making is modelled as a three-phase process [Simon 1981]: intelligence, design, and choice. Implementation of the solution can be seen as a fourth phase, see Figure 1 [Turban and Aronson 1998]. This theory lends itself well in optimising and in situations where the variables are known and objective criteria for decisions can be found.

- Theory of bounded rationality, where a decision maker aims at finding a satisfactory solution among competitive alternatives and s/he uses heuristics to find the solution.

- Decision making as an organisational process where decision making is seen as a process participated in, contributed to and driven by many organisational units and the solution is found by consensus and by agreements between partners.

- Decision making as a political process where it is not the optimal goals, but instead competition and political relations between the parties involved that serve as the forces driving decision making.

- Decision making as an individual cognitive process where all individuals have their own problem solving and cognitive styles, which are reflected in decision making and decisions.

The phases intelligence, design, choice and implementation must be studied in decision making independent of whether any computerised decision support is planned or provided for the situation. Most computerised decision support developed focuses on the design and choice phases; little support has been offered for the intelligence phase [Dutta 1996].

In order to facilitate computerised decision support for the intelligence phase as well and to help in automating as many phases as possible, Stohr and Konsynski proposed to divide the decision making process into five phases instead of Turban and Aronson’s four: problem finding, problem representation, information surveillance, solution generation and solution evaluation [Stohr and Konsynski 1992]. In this approach problem finding and representation correspond to the intelligence phase, information surveillance corresponds to the design phase and solution generation and evaluation correspond to the choice and implementation phases.

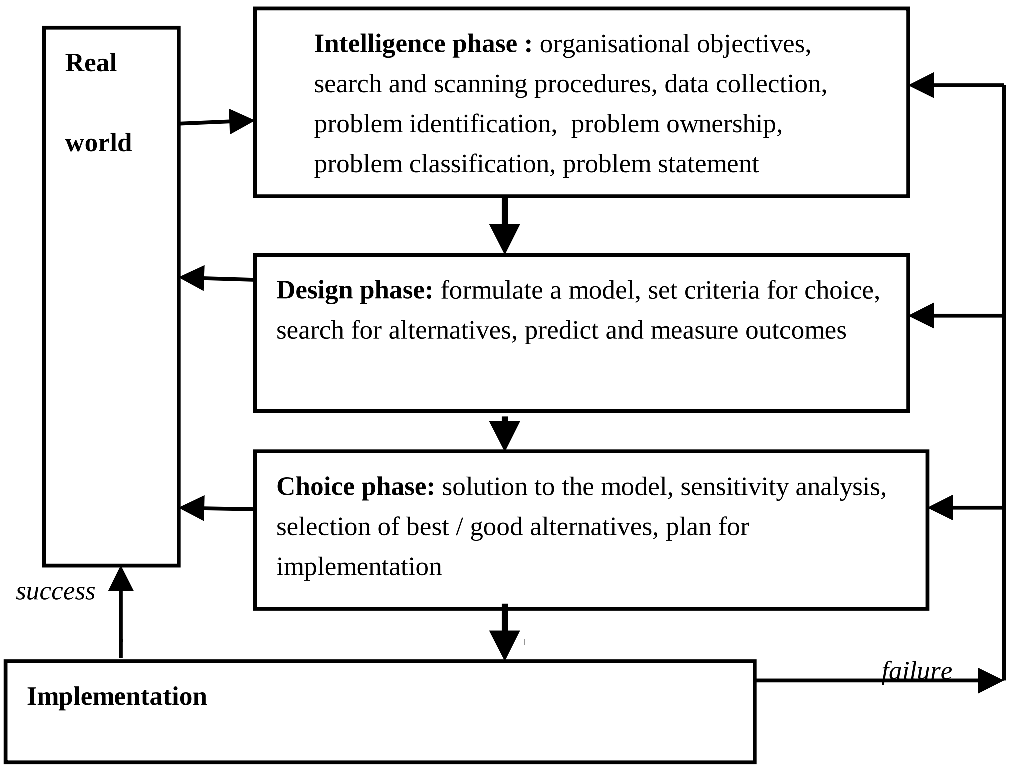

Figure 1: The decision making process [Turban and Aronson 1998]

The development of decision support systems is based on models of decision making and on computer implementations of these models. For implementation purposes decision making has been modelled using either psychological conceptual models like hypothetico-deductive models or inductive models, or computational models like mathematical and logical models, decision theoretical models and analytical or statistical models [Hoc *et al.* 1995]. The hypothetico-deductive model has been commonly used to model diagnostic decision making because of its power to convert an open problem, such as 'What is wrong with the patient?', into a set of closed problems, like 'Has he got disease X?', 'Has he got disease Y?'

In a real-life situation important dimensions of decision making are coordination, expertise and responsibility. The perspectives of the parties involved in decision making depend on their orientation to the situation and on their information interests. In addition, each decision maker has his/her own values and beliefs about the decision making situation [Turban and Aronson 1998]. In many real-life situations the decision making process is a network of both private and public actors, and the network includes both competitive and collaborative relations between the actors.

1.1.1 Organisational aspects of decision making

Health care services are provided by organisations like hospitals, health centres, nursing homes and other health services units. These organisations are complex, networked organisations formed from primary care organisations like health centres and from specialised care organisations like hospitals. Specialised care is normally divided into secondary care provided by local or regional hospitals and tertiary care provided by specialised units and university hospitals. Additionally there are connections to preventive services and third sector societies. Health care organisations are mostly public, non-profit organisations where strong humanitarian values exist. Professionals dominate in these organisations in a special way [Lorenzi *et al.* 1997], both in the definition and in the execution of the tasks. Health professionals may even dominate in the management of tasks.

Many health care organisations are facing problems today. For instance, cost-effectiveness is low and organisations are rigid in introducing changes [Timpka 1994, Koivukangas and Valtonen 1995]. In this situation there arise growing demands to improve effectiveness and measurable productivity. For meeting these demands information technology offers many possibilities, through enabling networking, integration and interoperability of existing systems and new solutions. Now, as health care organisations need to undergo fundamental structural changes in order to implement more efficient ways of rendering services (such as through seamless care processes), information technology is now even more widely required than in the past. As automatisation of routines or industrialisation of services can no longer solve all the existing problems, it has been suggested that improvements may be found in customer-orientation and in better quality, organisation and management of health care processes [Timpka 1994].

Information technology applications are, however, costly, and there are high risks related to implementation of successful large-scale information systems in health care. Technology transfer and implementation of systems requires that the organisational context, information needs and work practices of users be considered and understood [Southon *et al.* 1997]. Before information systems can be developed to support health care professionals, detailed knowledge is needed on their actual information needs. From these needs we can derive which data and knowledge is required to provide the needed information and then we can proceed to acquisition, formalisation, processing and delivery of information [Hasman *et al.* 1995]. A study [Forsythe *et al.* 1992] has shown that not only are the information needs of health care professionals broad, but they may not even be verbalised at all but rather communicated as information-seeking messages. Interpretation of these messages should never be done out of the context. The types of needed information are many and it is common to seek local or informal information, which is not easily captured or formalised for computational purposes. Forsythe *et al.* [1992] identified three types of information needs: currently satisfied needs, consciously recognised needs and unrecognised information needs. In another study [Timpka and Johansson 1994] it was shown that a number of the information needs of health professionals go unmet in clinical practice. An additional important issue for information is the value of information in a decision making context, i.e. what is the value of a piece, or an additional piece, of information in the decision making situation [deDombal 1996].

The health care environment also imposes special requirements for information technology applications, partly due to special conditions in decision making situations and partly due to high security, validity, and quality demands for data and information.

The decision making situations in health care organisations are many. Data and information is needed by clinicians, nurses, technicians, laboratory personnel and managers in a complex knowledge environment where logistics, information technology products, many types of equipment, manual procedures and personnel are contributing to the care process. In these situations it is important that correct data, information and knowledge be accessible where and when needed, to the right persons and in the right format.

The high data security requirements in health care are laid out in the data security legislation. Data validity and quality are principal issues in practice. Quality procedures including quality inspection, quality control and quality assurance have been well implemented, such as with laboratory information systems and biochemical robots. Unfortunately, a large part of medical knowledge is based on experience rather than on hard facts, and this type of knowledge is not very amenable to quality procedures.

The two aspects of information that are particularly important in an organisational context are equivocality and uncertainty [Daft and Lengel 1986]. An ideal situation would be one in which both aspects, uncertainty and equivocality, have low values, but it is easier to diminish uncertainty than equivocality. Uncertainty is best treated by improving management of masses of information. Group meetings, integrators and direct contacts are seen as the three best arrangements to reduce equivocality. Daft and Lengel recommend incorporating equivocality into information processing activities. For instance, two managers having different frames of reference on the same phenomenon could then get help from the same information system. But it is difficult to incorporate equivocality into traditional information systems. Information systems are normally designed under the assumption that such conflicts do not exist, assuming instead that a particular object has one and only one name in the whole organisation, e.g. a database schema.

1.1.2 Medical decision making

Clinical medicine today is data-intensive, but knowledge-based. Many health professionals spend much of their time processing information. Relations between the pieces of information may be complex in practice, and the appropriate expertise for interpretation is not always available where and when needed. The amount of knowledge and information relevant in a decision making situation is huge, even in restricted medical subspecialties. In this kind of information overload situation many clinicians may overlook or misinterpret abnormal findings because selection of relevant information is difficult [O'Moore 1990]. Health professionals are also confronted today with many types of information systems as the systems are networked and integrated with each other [Hasman *et al.* 1996]. Thus, they have access to huge amounts of data and information, which are not easily understood or interpreted, especially when captured outside their original context.

Diagnosis is often seen as a main task of the medical professional, and many attempts have been made to study the diagnostic process [Elstein *et al.* 1979, Kassirer *et al.* 1982, Shortliffe *et al.* 1990, Degoulet and Fieschi 1997]. These studies have concluded that physicians formulate hypotheses early, in limited numbers (from 5 to 7), and that physicians use a hypothetico-deductive reasoning method to rule out unlikely hypotheses and find probable diagnoses. A common interpretative error is over-interpretation, or the process of assigning new information to existing hypotheses more often than generating new hypotheses to deal with the new information. In this case, information may be used to confirm the strong hypothesis. The finding that a general hypothetico-deductive method is commonly used conflicts somewhat with other findings [Musen 1988] that experts use task-specific, context-specific reasoning methods. Both might be true: both general methods and task-specific methods may be applied depending on the problem case and situation, and it may actually be this dialectic application of both where the expertise shows.

On the other hand, diagnosis as a monolithic process is said not to exist [deDombal 1978], as each clinician has his/her own way of diagnostic reasoning and the way depends on many factors and vary from situation to situation. Cognitive science studies have emphasised the practice of medicine as a cognitive problem-solving activity where human cognitive skills are developed in interactive learning [Evans and Patel 1989]. Musen, for example, has presented a three-stage model of how expertise is developed [Musen 1988]. First, at the cognitive stage appropriate actions for the situation are identified, then at the associative stage learned relationships are practised through repetition and feedback, and finally at the autonomous stage the person compiles the relationships from the repeated practice to the point where they can be applied without consciously thinking of their application.

Studies have shown that medical experts reason more efficiently than novices [Evans and Patel 1989, Benner 1984, Pedersen *et al.* 1990], as they have more deep knowledge, tacit knowledge and wider approaches for strategic selections. Medical professionals are said to be capable of reasoning with incomplete and imprecise information [Miller 1994], which may be why medical care is sometimes said to be the art of making decisions without adequate information [Sox *et al.* 1988].

Most decision support systems in health care have been developed to assist in diagnostics. A study [Heathfield and Wyatt 1993] showed that 53% of systems dealt with diagnostic problems, but that clinicians asked for help in diagnostics in only 6% of the help queries from Medline literature database. 41% of the help queries asked for therapy planning problems, but only 19% of the developed medical decision support systems dealt with therapy planning problems. This indicates that the systems developed have not always been of that type that health professionals would have asked to be developed.

1.1.3 Knowledge aspects

Knowledge is an important aspect of expertise and decision making. Knowledge is classically defined as justified, true belief [see e.g. Armstrong 1973]. This definition emphasises the static nature of knowledge and truthfulness as an important attribute of knowledge. In an organisational perspective, however, knowledge has an active, subjective nature, and knowledge creation may be seen as an organisational process.

Basically two types of knowledge are involved in decision making: scientific and experiental knowledge [Nykänen and Saranummi 2000]. Scientific (deep) knowledge deals with the understanding of basic principles and relations, explaining and justifying empirical phenomena. Experiential (shallow) knowledge in health care originates from documented patient-cases and validated guidelines.

In decision making, scientific and experiential knowledge are interwoven. Thus, in a complex situation when equations cannot be solved, practical calculations can be based on shallow knowledge in form of linearisations and approximations. But deep scientific knowledge tells in this situation to which extent the approximations and simplifications make sense. Therefore, shallow algorithms must be viewed within a broader theoretical framework, which justifies them. In practice shallow theories and models produce best computational efficiency, but these models must be based on deeper theoretical knowledge of the domain [Pedersen *et al.* 1990].

From another perspective knowledge can be viewed either as tacit or explicit. Tacit knowledge describes the skills, i.e. knowledge has been operationalised to a level where one can no longer explicitly explain what one knows [Nykänen and Saranummi 2000]. Explicit knowledge is facts and items that can be explicated in some way, such as by being articulated verbally. Explicit or codified knowledge is defined by Polanyi as knowledge that is transmittable in formal, systematic language [Polanyi 1966]. Tacit knowledge has a personal quality, and it is action-oriented. Tacit knowledge has cognitive and technical elements, and it is hard to formalise and communicate. Cognitive elements refer to mental models formed by human beings that help them to provide perspectives on the world. Technical elements of tacit knowledge refer to skills and concrete know-how that can be applied to specific contexts. Additionally, Polanyi differentiates between focal and tacit knowledge [Polanyi 1966]. Focal knowledge is knowledge about the object or phenomenon that is in focus, and tacit knowledge is used as a tool to handle what is in focus. These dimensions, tacit and focal, are complementary.

In an organisational context three different theories on how to create knowledge are relevant to our purposes. First, Nonaka has emphasised the dialogue between tacit and explicit knowledge [Nonaka 1994, Nonaka and Takeuchi 1995]. According to this theory organisational knowledge creation can be represented as a spiral model, which describes the modes of knowledge conversion in the dialogue between tacit and explicit knowledge: socialisation, combination, externalisation and internalisation (Figure 2).

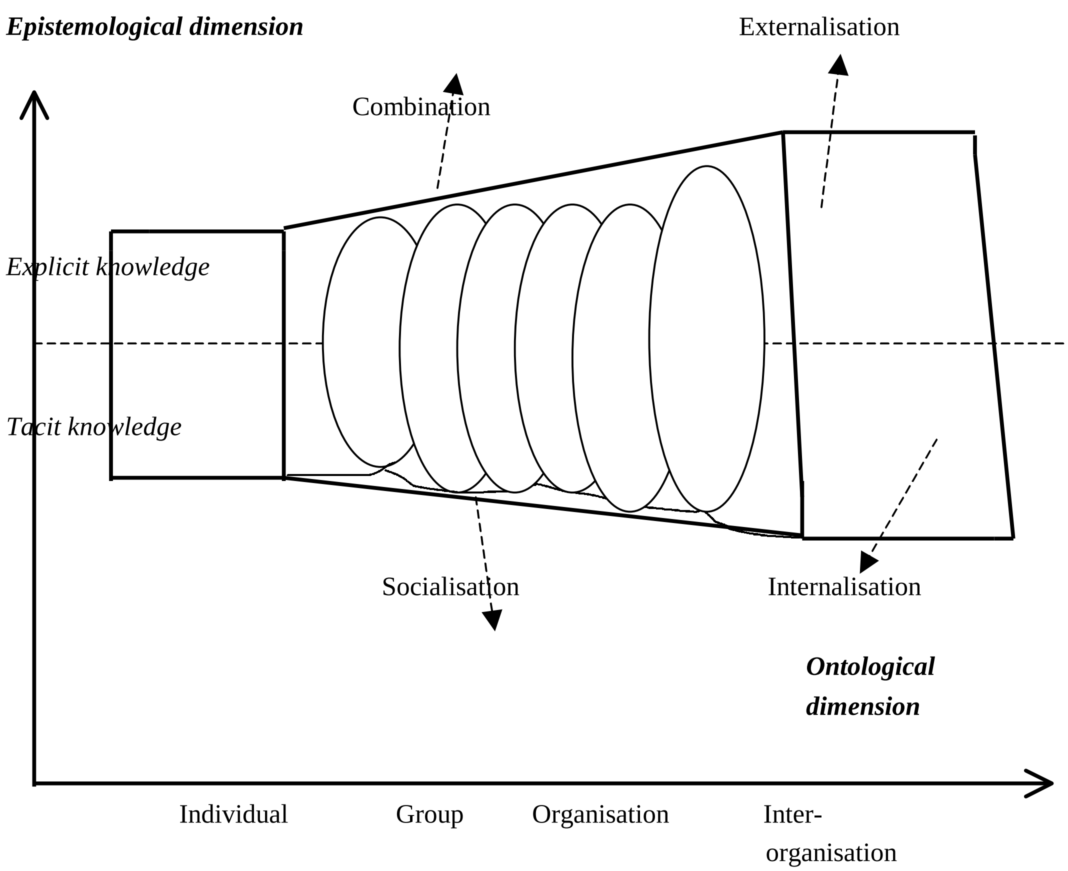

Figure 2: Spiral model of organisational knowledge creation [Nonaka 1994, Nonaka and Takeuchi 1995]

The epistemological dimension in Figure 2 describes where and how explicit knowledge is created. In these processes (combination and externalisation) new ideas and concepts are created. The ontological dimension describes how and where within the organisation tacit knowledge is created. In these processes (socialisation and internalisation) tacit knowledge is developed and shared. Thus knowledge creation in an organisation starts from an individual, proceeds to collective group level, and to organisational level, maybe even to inter-organisational level.

Second, Boland and Tenkasi argue that producing knowledge requires the ability to make strong perspectives within a community, as well as the ability to take the perspectives of the others into account. They created the term "community of knowing" to apply to a group of specialised knowledge workers [Boland and Tenkasi 1995]. Knowledge work of perspective making and perspective taking requires individual cognition and group communication. They present two models of language, communication (language game and conduit) and cognition (narratives and information processing) for amplifying our thinking. These models can assist in the design of electronic communication systems for perspective making and perspective taking. This view of cognition, emphasising the rational analysis of data in a mental problem space and the construction of deductive arguments, must be supplemented by recognising that humans also have a narrative cognitive capacity. We narrativise our experiences almost continually as we recognise unusual or unexpected events and construct stories which make sense of them.

Third, Brown and Duguid have found that conventional descriptions of jobs mask not only the ways people work but also the significant learning and innovation generated in the informal communities-of-practice in which people work [Brown and Duguid 1991]. For example, they tell the story of how a technician with a maintenance man solved a real new problem concerning a certain failure using an iterative approach, and the two created a story about this case and shared the new knowledge through telling the story to their co-workers.

These aspects of the creation of organisational knowledge have not yet been given much consideration in the development of decision support systems in the health care context.

Knowledge may also be categorised as declarative, procedural and metaknowledge. Declarative knowledge is descriptive: it tells facts, how things are. Declarative knowledge is shallow, and human experts normally are able to explicate or verbalise it. Procedural knowledge is methodological in nature: it describes how things are done. Declarative knowledge has to be transformed into procedural knowledge in order to develop cognitive skills. Metaknowledge is knowledge about knowledge, so that, for example, as applied to decision support systems, metaknowledge would be knowledge about the system's knowledge, or knowledge about where knowledge is to be found [Davis 2000].

Blackler has recently presented an interesting classification of knowledge into five types: embrained, embodied, encultured, embedded and encoded knowledge [Blackler 1995]. His motivation for this classification is the identified importance of expertise in achieving competitive advantages. In Blackler's typology embrained knowledge means knowledge that is dependent on conceptual skills and cognitive abilities. Embodied knowledge is action-oriented and is only partly explicit. Encultured knowledge refers to processes of achieving shared understandings. Encultured knowledge is dependent on cultural symbols, socialisation, and language. Embedded knowledge is found in systemic routines, and in encoded knowledge information is conveyed by signs and symbols. This classification of knowledge can be used to characterise organisations and types of knowledge used. He presents a hospital as an example of an expert-dependent organisation where emphasis is on embodied competencies of key individuals [Blackler 1995]. That means that the role of tacit knowledge is important in a health care organisation. Also Blackler, like Polanyi, emphasises that it is better to talk about knowing than about theory of knowledge. Knowing is an active process which is mediated, situated, provisional, pragmatic, and contested.

The importance of knowledge management in the health care environment is increasingly understood, and now medical textbooks, journals, patient records and other reference materials are widely consulted in the development of care guidelines and treatment protocols in order to compile medical knowledge into operational form. These efforts aim to develop harmonised guidelines, which may be applied and used according to the specific needs of the case. Evidence-based medicine is an initiative which aims at the development of operational probabilistic models based on experiences in medical practice. These are all efforts to try to capture, to explicate and to share tacit knowledge. The developed guidelines and templates need, however, to be locally adapted to be applicable on the local patient population and disease panorama [Nykänen and Saranummi 2000], because patient data are highly context-sensitive, considerably unstructured, and subject to variability and inaccuracy. Though medical knowledge is universal, clinical practice is local.

1.2 COMPUTERISED DECISION SUPPORT IN HEALTH CARE

Early computerised decision support in health care was based on Bayesian statistics and decision theory. As early as the 1950's it had already been demonstrated that medical reasoning could be made explicit and represented in a decision theoretical way [Ledley and Lusted 1959]. Ledley and Lusted showed that both logic and probabilistic reasoning were essential components of medical reasoning.

During the 1960's and 1970's, many data-driven programs, such as those using pattern recognition techniques, were developed for diagnostic problems. These showed that impressive diagnostic accuracy could be achieved if the computer programs were supported with reliable data. However, access to reliable data in medical practice is problematic. A good example of these early data-driven applications is the program that helps determine the necessity for acute surgery based on the analysis of acute abdominal pains [deDombal 1978, Ikonen *et al.* 1983]. In the 1970's this program was planned for use in the emergency clinic and is still in restricted use. When developed, it was used widely in clinical sites. The program was successful in practice because it had a large and reliable database available and, more importantly, because it was focused on a restricted classification problem where all needed variables could be easily and quickly defined and measured, without time-consuming examinations, in the emergency situation.

From the 1970's onwards, decision support in health care and medicine has been mostly related to artificial intelligence-based approaches [Blum 1986, Shortliffe *et al.* 1990, Miller 1994, Aliferis and Miller 1995]. Several groups, first in USA and later also in Europe, started in the 1970's to work with expert systems, knowledge representations, reasoning methods, uncertainty management and models of decision making, among others. The early work resulted in many well-known prototypical medical expert systems, such as MYCIN [Shortliffe 1976] and INTERNIST [Miller *et al*. 1982]. These rule- and frame-based systems demonstrated that domain-specific knowledge could to some extent be captured and represented, but still there remained problems such as that of tacit knowledge. As these systems were based on shallow rules, managing only narrow routine situations according to predefined patterns, they were brittle. They could not give explanations for the conclusions achieved because there was no deep knowledge available in the system. The problems with knowledge acquisition showed that elicitation and representation of knowledge was the bottleneck problem. It was understood that much of human expertise and experience is in a form of tacit knowledge which can be acquired by doing or by interacting, not by interviewing. Experts were capable of neither articulating nor explicating their knowledge and thus the resulting knowledge bases were restricted [Shortliffe *et al.* 1990, Barahona and Christensen 1994].

Many of these expert systems failed: they could not be used routinely. According to Wyatt and Spiegelhalter, the reasons for the failure of these expert systems were that they had poor human-computer interface, they were cumbersome to use, they asked too many questions from the user, they were slow in drawing conclusions and they were not able to give explanations [Wyatt and Spiegelhalter 1990]. Typical of these expert systems was that they tackled restricted medical problems that were characterised by generalisation rather than by complexity. Many systems were developed to test researchers' theoretical models; they were not developed for health care purposes. Systems were developed using expensive and specialised hardware and software, which made their integration with the health care environment difficult, or even impossible. In 1993 Heathfield and Wyatt listed these major reasons for failures with clinical DSS's: major mismatch between real problems and the problems tackled by the systems, the failure to define the role of systems, the non-existence of a coherent development philosophy and disregard for organisational issues [Heathfield and Wyatt 1993].

During the 1980's the evolution of hardware and software caused changes in application domains and in the technologies used. It became easier to develop expert systems because of microcomputers and of software for interface development. Also, local and wide area networks offered new possibilities for connectivity and integration. The two trends in late 1980's were the demand for high performance systems for routine use and for a system's capability to manage qualitative, deep knowledge [Summers and Carson 1995, Kulikowski 1995].

During the 1990's artificial intelligence approaches and methods have gradually become integrated with traditional information technology, especially with multimedia and Internet technologies. As a continuum for probabilistic approaches, the connectionist data-mining approaches including machine learning, artificial neural networks and genetic algorithms have received widespread interest, being applied in health care and medicine for decision support.

The early decision support and expert systems in health care mostly implemented the Greek Oracle model, in which the user played a passive role, merely inputting data to the system, which inferred a diagnosis or other conclusions and passed them back to the user [Miller 1994]. This was an unrealistic situation because a decision support system can never know all that should be known about the complex case at hand, and the user should be intellectually in control of the system's functioning. This attitude changed during late 1980's, first to critiquing systems and later to understanding of the co-operative situation between a user and a system. Today we do not develop expert systems to replace experts in high-level decisions, but we do, or at least we ought to, develop systems that draw advantages from the strengths of both the user and the system.

In our country decision support system activities in health care have been quite pragmatic and in many cases technology-driven. Our advanced information technology infrastructure in health care with sophisticated programs, wide networks and advanced telecommunication facilities have offered many challenges for applications. Statistical approaches have been applied for classification problems since the 1970's and some systems were developed, such as Data-ECG applications in Kuopio and a system for classification of bone tumors in Turku University Hospital. Artificial intelligence-based approaches have resulted in prototypical systems for various restricted medical problems. Examples are: Microbe [Valluy *et al.* 1989], Thyroid [I], Incare [Autio *et al.* 1991], Sleep Expert [Korpela 1993], Headache Expert [Pelkonen *et al*. 1994], and One [Auramo 1999]. The connectionist approach has become active in recent years and today there exist applications in anaesthesia [Vapola *et al.* 1994], acute abdomen [Pesonen *et al.* 1994], aphasia [Tikkala *et al.* 1994], myocardial infarction [Forsström and Eklund 1994]. Also some cognitive engineering based approaches have been applied, including an orientation-based approach on an anaesthesiologist's activity [Klemola and Norros 1995].

1.3 NEED TO EVALUATE DECISION SUPPORT

The use of decision support systems in health care results in changes in health care practices, processes, and outcomes. The aim of this development is to improve health care delivery. Users in health care are asking for useful systems, i.e. systems that provide users with information and knowledge that support their work and actions in their working environment.

However, such change and impact may also be negative, changing the relation between the patient and the physician, or linking the decision to an individual instead of linking it to a professional group, or limiting professionals’ possibilities for independent problem solving [Pothoff et al.1988, Shortliffe 1989, Pitty and Reeves 1995]. Another important issue is the legal implications of decision support systems in health care. Some health professionals think that it is less harmful to use computer applications than not to use them [Hafner *et al.* 1989]. An accepted interpretation today is that decisions suggested or supported by computer systems are always the responsibility of the medical professional who puts them into effect.

Information technology applications, like decision support systems, are not dictating changes in health care, but all changes should be planned and designed at the organisational level to ensure that information technology actually does support and facilitate the changes. Therefore, in all situations with decision support systems and other information technology products, evaluation should be carried out during development and before introducing the systems into use. Evaluation studies are one means to control the system's development and to ascertain that the desired results are achieved, and that undesirable effects are avoided.

Evaluation of decision support systems is important also because DSS’s are domain-dependent, even domain embedded software [Giddings 1984] that are normally developed in such a way that a sequence of prototypes is developed and these prototypes are redefined step by step. During these steps evaluation is needed to provide feedback for the successive prototyping in relation to the problem statement. Also, domain dependent software products often function as catalysts for change when introduced into the use environment. These changes may exceed those planned by software developers. Therefore, evaluation is also required to follow unanticipated changes and their impacts on the environment and on the problem statement.

The importance of evaluation is growing as information systems and technology are widely used in complex, networked environments for data management, for communication, for information enhancement and for support in decision making. It is important for health administrators, for health professionals, and for patients and citizens to have information on the qualities of information technology products and their functioning.

Evaluation is concerned with development of criteria and metrics and with assessment against those criteria [March and Smith 1995]. Evaluation can be either subjectivist, based on unbiased observations, or objectivist, based on measurement of items from which judgements for unobservable attributes can be made [Friedman and Wyatt 1997]. Friedman and Wyatt present a broad perspective for evaluation, which emphasises the importance of five major aspects in evaluation:

- The clinical need that the information resource is intended to address,
- The process used to develop the resource,
- The resource's intrinsic structure,
- The function the resource carries out, and
- The impacts of the resource on patients and other aspects of health care environment.

Friedman and Wyatt also consider evaluation difficult because of multiple approaches and because multiple impacts of information resources on health care systems need to be considered from the viewpoints of health care structure, health care processes and outcomes of health care. No single definition for evaluation is seen to exist, nor does a generally accepted practical methodology. Every evaluation study is seen as a specific case where a tailored mindset is needed and methods and methodologies are applied to the case following the general rules of technology assessment and scientific research and experimentation [Friedman and Wyatt 1997].

In our article [Kinnunen and Nykänen 1999] evaluation of information technology in health care is also seen in the framework of general assessment principles and methods. Evaluation requires that the stakeholders be defined so as to identify their information interests, and the objectives and criteria of the evaluation study need to be carefully considered to select the strategies and methods for the study. The approaches that can be applied in an evaluation study may be combinations of four major perspectives:

- *Goal-oriented perspective* which aims at operationalisation of the goals of the information technology project and through measurements provides information on the resources needed and used to achieve these goals.

- *Standardised perspective*, which applies standards or other normative rules or guidelines as a frame of reference.

- *Effectiveness-based perspectives* where cost-effectiveness, cost-benefit or cost-utility are measured with various value-based measures.

- *Stakeholder-based perspective* where the perspectives of many stakeholders may be combined to derive criteria for evaluation and thresholds used in qualitative assessment of models and in their valuing.

From the multiple perspectives presented briefly above it is seen that evaluation and assessment of information technology in the health informatics context is a field where application of expertise from many disciplines is required. Evaluation should give us information on how information technology influences health care organisations and their outcome, professionals and patients in these organisations, as well as information concerning the economic and technical aspects of information systems and technology. To obtain this information we need to know what to measure, how to measure and why to measure, and how to design and carry out professionally an evaluation study.

Various definitions have been suggested for evaluation [see e.g. Wyatt and Spiegelhalter 1990, Lee and O'Keefe 1994, Friedman and Wyatt 1997, van Bemmel and Musen 1997]. We consider evaluation as a three-step process [Nykänen 1990, Clarke *et al.* 1994, Brender 1997, Turban and Aronson 1998]:

- The first step is *verification,* or assessing that the system has been developed according to specifications. This means that we are assessing whether the system has been built according to the plan.

- The next step is *validation,* which means assessing that the object of evaluation is doing the right thing, i.e. that the right system has been developed for its purpose. Validation refers to assessing the system's effectiveness.

- The third step, *evaluation,* means assessment that the object of evaluation, e.g. a decision support system, does the right thing right. This has to do with the system's efficiency within its use context. Evaluation is a broad concept, covering usability, cost-effectiveness and overall value of the system.

Normally in the verification phase the system is assessed as a standalone system, whereas during validation it is assessed in a restricted use situation, such as in a laboratory type environment. During evaluation the system is assessed in a real- life, or nearly real-life, situation.

Evaluation can be either formative (measurements and observations are performed during the stages of development) or summative (measurements are done on the performance and behaviour of people when they use the system) [Friedman and Wyatt 1997]. Constructive evaluation emphasises the need to give feedback on design and development during formative evaluation.

Evaluations have not been often performed for health information systems, and the studies reported in the literature have been carried out without generally accepted objectives, methodology and standards [Clarke *et al.* 1994, Brender 1997, Friedman and Wyatt 1997]. Traditionally evaluations of health information systems have been done following an experimental or clinical trials model.

Reported evaluation studies focus mostly on a system's performance, diagnostic accuracy, correctness, timeliness and user satisfaction. For instance, Pearson's user information satisfaction measure has been applied in evaluation of a hospital information system [Bailey and Pearson 1983, Bailey 1990] and of a DSS [Dupuits and Hasman 1995]. Broader human issues, such as interaction with the user and impacts on the organisational environment, have been little studied [Brender 1997]. Some studies exist on evaluation of the impact of an information system on decision making, particularly on diagnostic and therapeutic decisions [Maria *et al.* 1994]. In one study [van der Loo *et al.* 1995] 76 evaluative studies of IT systems in health care were analysed for the criteria used in evaluation. The three most often investigated system effect measures were performance of the user (23%), time changes in personnel workload (17%) and the performance of the information system (13%). Only 10 of the 76 studies had performed some type of economic evaluation. This study also showed that, surprisingly, user information satisfaction measures were not used in evaluating these information systems.

A market study was performed in the VATAM project [Hoyer *et al.* 1998] to analyse the situation in evaluation of information technology in the health care environment. The results showed e.g. that a surprisingly number of IT suppliers, in fact more than half of those interviewed, did not see evaluation as part of their business. IT suppliers felt concerned only with project work and did not see the significance of evaluation. When we looked at the aims of reported or planned evaluation, a different picture was shown. The most important aims of evaluation were organisational impacts and user satisfaction, while efficiency and patient health were a minor concern (Figure 3). The reasons for this might be that the managers and the leaders in health care might be distinct groups. The decisions taken on (and the perception of) information systems are largely dominated in health care by the physicians, not by the managers. Before decisions to implement, then, it is the physicians who have to be convinced, which can be done with the results of evaluation. The observed focus on user satisfaction and organisational effects support this view. The low score on patient health is most likely related to difficulties in measuring the impacts of information systems on patient health.

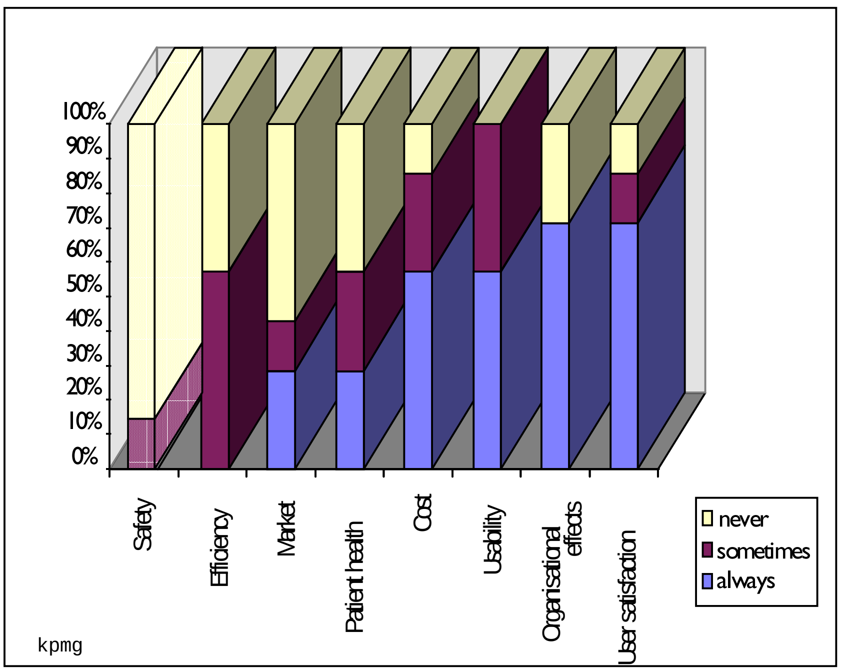

Figure 3: Aims of evaluation [Hoyer et al. 1998]

In this market study, decision support systems were the most often evaluated IT systems, as seen in Figure 4. An explanation of this may be that DSS's in use are rather restricted, small systems and it is important to evaluate their capabilities, limits and effects. Evaluations of IT systems have been mostly done in implementation and software development stages, and not for applications in use. So, evaluation is triggered by problems in development and implementation of systems, but it is not used as often for marketing of applications [Hoyer *et al.* 1998].

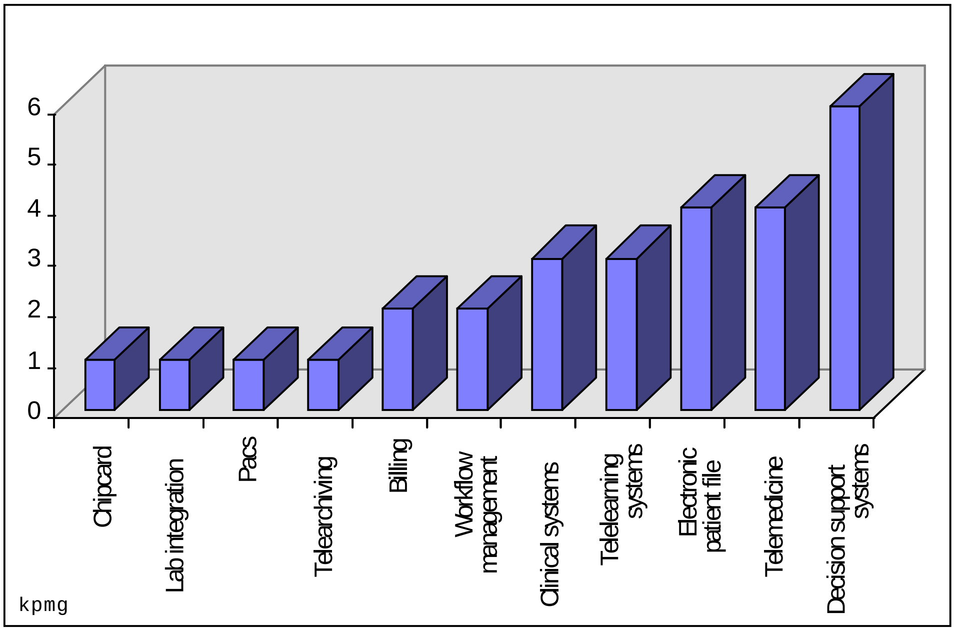

Figure 4: Evaluation in relation to the type of information system [Hoyer et al. 1998]

Most successful among the decision support systems in the health care environment have been those that have offered support for data validation, data reduction and data acquisition [Van Bemmel and Musen 1997]. In most cases these systems function in the laboratory medicine domain where support has been offered to manage information, to focus attention or to interpret patient data, among others. The successful systems have often been able to combine well two things: identified users' need and application domain. A good fit of these two seems to be vital for successful development of DSS in health care environment [O'Moore 1995]. In an organisational context George and Tyran surveyed factors and evidence on impacts of expert systems [George and Tyran 1993] and they also found that the most critical factors for successful implementation of expert systems were assessment of user needs (71%), top management support (67%), commitment of expert (64%), and commitment of user (64%).

1.4 THIS STUDY

For a long time the author's work and research interests have been focused on development and evaluation of information and decision support systems in the health care context. Many of the solutions developed have involved decision support components – either as stand-alone decision support systems or as integrated decision support modules. These developments across the years have been based on many various approaches and theories, and developed systems have been implemented using different technological principles and methodologies. The applied methodologies and implementations have each reflected the thinking models and dominant theories of the time.

The results, developed decision support systems and decision support modules, have to some extent proven to work in practice, but have not proceeded in their lifetime beyond the prototype phase. Mostly, the developed prototypes have in the end only been demonstrators of the applied methodological approach or technological implementation. We can say that partly these developments have proven successful in that the results have demonstrated, at least to some extent, the feasibility of the applied methodology or technology. However, we can also say that these developments have not been successful in so far as the results have not proven feasible and usable in practice, which, somewhat ironically, has mostly been the final goal of their development and implementation.

1.4.1 Research questions and objectives

The development of decision support systems that are successful from both the theoretical and the practical viewpoints, is the focus of this study.

We are searching for answers to the following research questions:

- What are decision support systems in a health informatics context? Are they somehow different from information systems or knowledge-based systems?

- Do we need a special conceptualisation for a decision support system in health informatics as compared to those presented in related research areas?

- Is health informatics a special field for application of decision support systems? Do we need special approaches and methodologies to develop and evaluate decision support systems in health care context?

The context of this study is a combination of three areas:

- First, our scientific foundation is information systems science where decision support systems represent a subclass of information systems with a long history and rich research tradition.

- Second, an additional justification for a decision support system is given by knowledge-based systems in artificial intelligence, especially in the field of medical artificial intelligence.

- Third, our domain is health informatics, the application of information technology or information systems science in social and health care. Health informatics is considered here both as a scientific discipline and as a practice.

To find answers to the questions above, we analyse our own work with decision support systems as described in the publications I-V. In addition to our own work, we use in the analysis conceptual definitions of a DSS and a KBS as presented in information systems science and in artificial intelligence. The purpose of this analysis is to identify relations between the theoretical approaches applied and practical implementations that could help to explain the successes and failures of our work.

Our objectives in this study are:

- To present a conceptualisation of a decision support system in health informatics, and

- To outline a framework for development and evaluation of decision support systems in health informatics.

The study is conceptual-analytical in nature. Conceptually we are searching for a deeper understanding of the concept ‘decision support system’, especially understanding of its conceptualisation within health informatics. Analytically we aim at building a framework for development and evaluation of decision support systems.

We hope with this study to contribute to health informatics, both research and practice, through provision of a framework and proposals for the research agenda. We hope to contribute also to the recognition of health informatics as a scientific field of its own in our country.

The study targets people working in the health informatics area, with a background in health informatics, medicine or health care or information systems science.

1.4.2 Study outline

This study consists of five original publications (I-V) and a monographic presentation of unpublished results. The study is structured in two parts.

Part I Summary consists of five chapters as follows. Chapter 1 gives an introduction to the themes and background of the study. Chapter 2 presents the disciplinary contexts of the study: information systems science, artificial intelligence and health informatics. In chapter 3 we summarise our case studies (I-V): Problems, methods, results, and remaining problems. Chapter 4 is a monographic presentation of unpublished results. We elaborate a synthesis based on our work reported in (I-V) and on analysis of the concept of decision support system, derive a framework for development and evaluation, and discuss the significance, validity and applicability of our work. In chapter 5 we draw conclusions.

Part II Papers consists of the original papers (I-V) in their published format. All papers (I-V) deal with the theme of decision support systems in the health informatics context, but each with a slightly different emphasis:

- **Paper I** reports development and evaluation of a system for interpretation of thyroid disorders in the field of clinical chemistry. Evaluation has been performed using a four-phase evaluation methodology.

- **Paper II** reports development and evaluation of three decision support systems, which are targeted to improve utilisation of laboratory results in clinical decision making. Developed systems have been encapsulated with an open laboratory information system architecture, especially with post-analytical functionalities of the laboratory system.

- **Paper III** connects two additional perspectives of evaluation to the four-phase evaluation methodology. The two perspectives are knowledge acquisition validation and user-system integrated behaviour.

- **Paper IV** discusses use of the developed four-phase methodology for the evaluation of the integration of medical decision support systems with a hospital information systems infrastructure. The focus in evaluation of integration is on the evaluation of the feasibility and relevance of the various integrated prototypes and on the evaluation of the integration process itself.

- **Paper V** reports the results from an inventory performed on some health telematic projects with the purpose of identifying the needs and problems encountered in applying evaluation methodologies on health telematics systems and on their development. The inventory is based on a three-dimensional approach to evaluation.

Author's contribution to the papers (I-V) is the following:

– **Paper I**: The present author performed the evaluation study, and prepared the paper. DrMed Pirjo Nuutila collected the patient cases and performed the validity checking of the THYROID system with real patient cases.

– **Paper II**: Reports the results of a group work in the post-analytical functionalities workpackage of the OpenLabs project (EU-Programme Telematic Systems for Health Care, Project A2028). The present author was responsible for the work, actively participated in it, and prepared the paper using input from the other authors.

– **Paper III**: Reports evaluation methodology results from the shared effort in the KUSIN-MED programme (Kunskapsbaserade system in Norden - Medicinska delen). The author is responsible for the extensions of the evaluation methodology and for the preparation of the paper using input from the other authors.

- **Paper IV**: Reports work by the group of the ISAR-project (EU-Programme Telematic Systems for Health Care, Project A2052). The author's major contribution is on the impact phase of the evaluation methodology.

- **Paper V**: Inventory work performed in VATAM (Validation of Telematic Applications in Medicine, HC1115HC) project in EU Telematic Applications Programme. The author has been responsible for the paper and has actively participated in the performance of the inventory work.

2. Disciplinary contexts of decision support systems

In this chapter we review the disciplinary contexts of this study: decision support systems in information systems science, knowledge-based systems in artificial intelligence and health informatics.

2.1 INFORMATION SYSTEMS

Our first disciplinary context for decision support systems is information systems science. Decision support systems are an important and recognised subfield of information systems [Sprague and Carlson 1982, Iivari 1991, Turban and Aronson 1998].

Information systems science (IS) studies development and use of information systems, including different approaches for designing, constructing, and institutionalising, as well as the evolution of, information systems [Ives, Hamilton and Davis 1980]. Information systems science may be defined either in terms of observed information systems in organisations or in terms of functions of systems planning, development, management and evaluation [Davis 2000].

Ives, Hamilton and Davis see a complete information system as a collection of subsystems defined by functions or organisational boundaries. It is important to note that IS deals with organisations and information systems, that is, with phenomena which can be both created and studied by humans [March and Smith 1995]. The purpose of information systems development is to result in a planned change in the functional, organisational and social contexts of the system [Iivari 1991]. The change may occur in management practices, in workflows, or in the organisation of work.

In information systems science are found different schools [Iivari 1991, Iivari and Hirschheim 1996]: software engineering, database management, management information systems, decision support systems, implementation research, sociotechnical approach, interactionist approach, speech-act based approach, soft systems methodology, trade unionist approach and professional work practises. Each school has a different emphasis. Software engineering, for example, focuses on programs as software products, while the professional work practises school puts the focus on actual work before trying to improve it using information technology. During the 1960's in Scandinavia [Bansler 1989, Dahlbom 1995] the systems theoretical approach emphasised that the aim of information systems development was to improve the organisation's efficiency. The sociotechnical approach introduced in 1970's the ideas of joint-design and user participation, i.e. that in information systems design and development humans and their roles need to be considered. Information systems were no longer seen just as technical systems. Later, the critical tradition proceeded even further in demanding that information systems should be developed to promote the workers' skills and quality of the work [Iivari 1991].

Korpela analysed the social classifications of approaches to information systems development by identifying which social group was the prime actor and whose needs were to be served by information systems [Korpela 1994]. His results show that early information systems (1950-1965) were technical systems with system developers as prime actors, and system developers were also the users of these early systems. Later (1965-1980) designers were the prime actors, but systems were developed to serve the needs of managers. The next phase from 1980's onwards brought a shift towards users: business-directed systems were developed for managers, other systems were developed applying user-centred design approaches, and systems were also developed using co-operative design with end-users as prime actors. Currently we have organisation environment constraints that lead to market-oriented, or strategic information systems, and service-chain systems that focus on services. The focus of end users has shifted from work process to production of service. The changes in focus and orientation have resulted in new information system architectures, like object-oriented component-based architectures, and design methods. Also the systems theoretical approach of the 1970's has been re-implemented as business process re-engineering which is based on the idea that organisational systems decay and should therefore be periodically re-engineered, sometimes radically [Davis 2000].

Research in information systems has mostly been conceptual-theoretical in nature and only from the 1980's onwards have empirical and environmental issues of information systems received more attention. The Ives, Hamilton, Davis model [Ives, Hamilton and Davis 1980] was the first to show that environmental variables and their relations to process and information system variables have to be considered in design and development. They argued that major reasons for failures with information systems were due to insufficient understanding of the social nature of information systems. The social aspects, they claimed, could be seen in system developers' attitudes, for example.

These problems were further studied by Hirschheim and Klein through an analysis of the assumptions taken by system designers and how these assumptions were reflected in the resulting information system [Hirschheim and Klein 1989]. They proposed that there are other paradigms in information systems design besides functionalism, which had been by far the dominant paradigm. The functionalist paradigm is being realised in a situation where a designer is an expert who develops an information system following advice from managers. In this paradigm, system design is a technical process. Other possible paradigms include social relativism, radical structuralism and neohumanism. Social relativism emphasises systems development as a sense-making process where the system designer is a consultant who helps the user to understand the new information system and its environment. Radical structuralism advises the developer to select one side, either the user's side or the manager's side, because this selection defines the needs to be served and benefits achieved with the information system. Neohumanism is a theoretical construction where systems development is seen as emancipation through rational discourse. This analysis [Hirschheim and Klein 1989] was important because alternative paradigms were found, their assumptions and application situations were discussed, and it was understood that they lead to different practises.

Iivari further analysed the assumptions underlying the construction of information systems [Iivari 1991]. He found that the DSS approach as a subclass of information systems showed some antipositivist epistemology as opposed to the other information system classes studied. The DSS approach emphasised human interpretation and understanding. Iivari's conclusion was that the DSS approach is focused on developing systems for specific problems, so there is only weak support for systems design and use because the focus is on the development, implementation and maintenance phases [Iivari 1991].

All these paradigmatic analyses found that functionalism with a positivist epistemology had been the major paradigm applied in information systems science. Progress in searching out alternative approaches and in their application has contributed to the evolution of pluralistic approaches and orientations such as computer-supported co-operative work, developmental work research and cognitive engineering approaches. In some of these, the role of information technology is seen through a tool metaphor: Information technology is a means used in information systems development to result in IT tools. These IT tools may enlarge a user's skills and capabilities to master a larger set of tasks, and hence reduce the number of people needed to perform a long sequence of tasks. They will therefore reduce the need for the division of labour and for unnecessary hierarchy, too.

The analyses discussed above also showed that information systems development has been in many ways problematic. Lyytinen, taking a critical social theory viewpoint, analysed the reasons for failures [Lyytinen 1987] and found two types of problems: development problems and use problems. According to him development problems may be related to goal of development, technology used, economy or development process. An important source of development problems is that the impact, both positive and negative, of the system on the working environment and the organisation and users are not taken into consideration nor planned for. Problems in the use of information systems may arise, according to Lyytinen, from technical, data or conceptual sources. Use problems may also be due to the user's negative attitudes, changes in power structures caused by the system or the deskilling of users as impacts of the system's use.

2.1.1 Decision support systems

A major goal of decision support systems research is to develop guidelines for designing and implementing systems that can support decision making. A decision support system is built from components for dialogue management, data management, model management, communication and knowledge management, and DSS architecture, Figure 5 [Sprague and Carlson 1982, Turban 1993].

In Figure 5, the DSS architecture component is the mechanism and structure for integration and interoperability of the components as a system. The dialogue management component builds the user interface to the DSS. The data management component builds connections for databases and data warehouses where data is accessed and stored. The model management component makes it possible to use models to analyse the case at hand. The knowledge management component makes it possible to utilise knowledge and knowledge bases, and it also enables management, storing and delivery of knowledge to other DSS systems and other information systems in the environment. This makes knowledge sharing possible as well as organisational learning and intelligence. It is not necessary for all decision support systems to include all the described components.

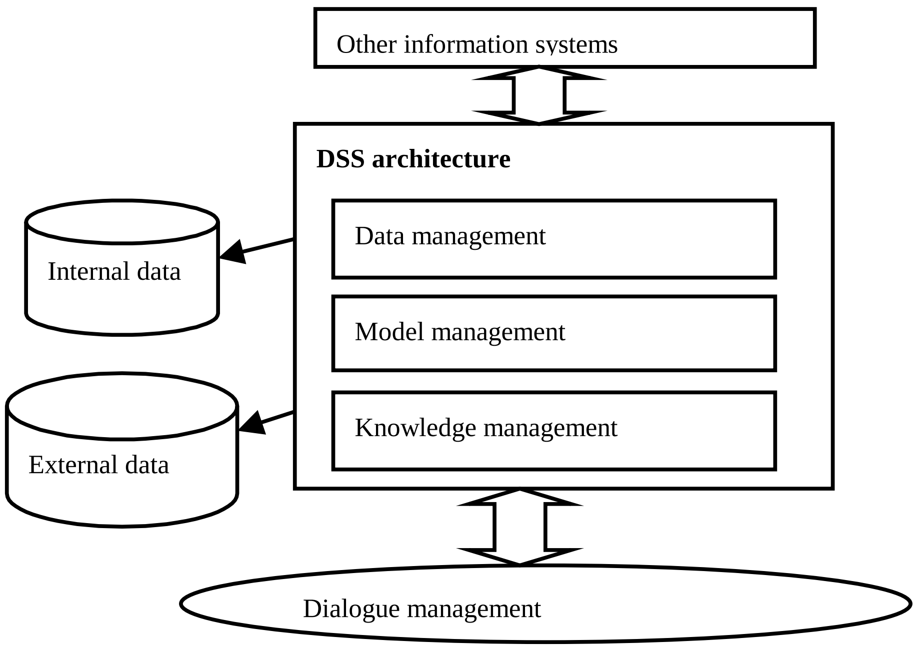

Figure 5: Conceptual model of a decision support system

Decision support systems can be designed and developed using different approaches and methods. A life cycle approach on development methodology is often used and user-participation in the development is emphasised. A life cycle development methodology basically includes the following principal steps [Keen and Scott Morton 1978, Turban and Aronson 1998]:

- <u>Planning phase</u>: needs assessment, problem diagnosis, definition of system objectives and goals, including determination of the decisions to be supported;

- <u>Research phase:</u> identifying the approach used to address users' needs and available resources, definition of the DSS environment;

- <u>System analysis and conceptual phase:</u> selection of best construction approach, definition of resources needed, conceptual design and feasibility study;

- Design phase: design of system components, structure, interfaces, dialogue, model base, database, knowledge management;

- Construction phase: technical implementation, integration, testing;

- Further development phase: testing and evaluation, demonstration, orientation, training and deployment; and

- Maintenance, documentation and adaptation: documentation, changing environment and evolving users' needs cause changes and the process needs to be repeated to maintain the system.

There are, however, problems with life cycle development methodology, because it does not support well the typical design situation where users do not quite know their needs at the beginning and developers do not quite understand users' needs. Adaptive design or incremental design using an evolutionary prototyping approach is often more suitable for DSS development because it supports learning during the development process. The evolutionary prototyping approach normally includes [Turban and Aronson 1998] the following steps:

- Selection of a problem to be solved.

- Development of a small but usable prototype system.

- Evaluation of the developed prototype system by both user and builder at the end of each step. Evaluation is here an integral part of development, a means to control the development process.

- Refinement, expansion and modification of the system in subsequent analysis, design, construction, implementation and evaluation steps.

Generic DSS tools, such as general building blocks like graphical packages, data base management systems, statistical tools etc., can be used for development. DSS generators are more advanced combinations of hardware and software for DSS development. General programming languages are useful development tools, because they support integration of resulting software with the information systems environment.

2.1.1.1 DSS history

As early as 1970 Little described a decision calculus as a model-based set of procedures to assist a manager in his decision making [Little 1970]. He aimed at better utilisation of management science models through effective computer implementations of these models. He stressed the importance of the model interface and argued that interface requirements had implications for model design. Little was even then able to list the requirements for a successful decision support system: simple, robust, easy to control, adaptive, complete on important issues and easy to communicate with.

Scott Morton described in 1971 how computers and analytical models could support managers in decision making. He developed a pioneer DSS for marketing and production planning [Scott Morton 1971]. Together with Gorry he gave the first definition for a decision support system [Gorry and Scott Morton 1971]. Their DSS framework maps the potential for computer support in management activities along two dimensions: structuredness of the task and level of managerial activity (Figure 6).

Gorry and Scott Morton saw that, based on this framework, decision tasks can be divided between a human decision maker and a computer system in many ways. In a structured situation all phases of decision making are structured and potentially automatable, and therefore the resulting systems are decision making systems. A semi-structured case is one where one or more of the intelligence, design and choice phases are unstructured. The unstructured case corresponds to the Simon’s unprogrammed situation [Simon 1981]. In the semi- and unstructured situations there is a need for decision support in order to extend the capabilities of a decision maker or to improve the quality of the decision making process. Some researchers see that a DSS as useful only for the structured parts of decision problems, but humans must solve unstructured parts. The line between structured and unstructured situations moves over time when problems are understood better, bringing structure to them.

From the early 1970’s decision support systems research has grown significantly, and many definitions have been presented. Mostly, these definitions have paid attention to the task structuredness and the problem of distinguishing decision support systems from other management information systems or operations research models. Sprague and Carlson brought into the discussion the organisational context of a DSS [Sprague and Carlson 1982]. They provided a practical overview on how organisations could build and utilise a DSS.

	Operational control	**Management control**	**Strategic planning**
Structured		*Decision making systems*	
Semistructured		***Decision support systems***	
Unstructured		***Decision support systems***	

Figure 6: The Gorry-Scott Morton framework for decision support systems

Recently, executive information systems (EIS) for executives and group DSS (GDSS) to support group decision making have evolved. Today, even enterprise-wide DSS's exist, supporting large groups of managers in networked client-server environments with specialised data warehouses [Power and Karpathi 1998].

A recent classification of decision support systems [Power 1999] presents eight classes of systems: data-driven systems, model-driven systems, suggestion systems referring to data mining and expert systems, document-driven systems, inter-organisational systems, group systems, and function-specific systems referring to systems for specific tasks and web-based systems. Another type of classification is given in [Mirchandani and Pakath 1999] where decision support systems are classified in a knowledge-oriented way into four classes: symbiotic systems, expert systems, adaptive systems and holistic systems. Symbiotic systems are static systems where used knowledge needs to be fully and explicitly predefined. Expert systems are also static and reason using explicit or implicit knowledge in form of rules. Adaptive systems are dynamic systems that use inductive inferencing to generate new knowledge. Finally, holistic systems, dynamic systems that are capable of holistic problem processing, are the most advanced.

In information systems science, research on decision support systems has been tightly focused on the DSS systems and models themselves rather than on the contextual aspects of the decision making processes in organisations. Development has been based on hard quantifiable data and information rather than on soft qualitative information. The goal has often been to find generic solutions. Matching the type of the problem and the task of the system has been the major approach applied. Support has mostly been offered for individual decision making; only quite recently has support been offered enterprise-wide or for group decision making.

DSS research has been criticised for its putting major effort into studying the choice phase in decision making and much less effort into producing support for the intelligence and design phases. Winograd and Flores [Winograd and Flores 1986] claim that focusing on the choice phase in decision making is dangerous because it may mean selection of a solution without really thinking what the right solution might be. They advise that more attention in the study of DSS's should be paid to communication as a central element in organisational decision making.

2.1.1.2 Concepts used in defining a DSS

In Table 1 we summarise the definitions of a decision support system as found in information systems science textual sources.

In many of the definitions in Table 1, the problem type as well as system function and user (e.g. through usage pattern, interface or user behaviour) are explicitly included, but some definitions focus only on problem type and problem occurrence. Effects of interface characteristics on system design were emphasised early on, in 1970 [Little 1970]. Sprague noted [Sprague 1980] that a DSS is developed for a specific task in a knowledge worker's environment, and that information technologies are a means to developing a DSS. Moore and Chang noted that the structuredness concept in the Gorry-Scott Morton framework cannot be general because structuredness is always in relation to the specific user [Moore and Chang 1980]. In Keen's definition [Keen 1980] a DSS is seen as a product of a process where a user, a developer and a system itself exert mutual influence through adaptive learning and evolution. Eierman *et al.* [Eierman *et al.* 1995] pay special attention to the environment construct, which refers to the organisational context of the system's development and its use. This is a noteworthy addition to the Gorry-Scott Morton framework. Eierman defines eight constructs (see Table 1) and 17 relations between these constructs. Eierman's [Eierman *et al.* 1995] constructs also attend to the social and organisational aspects of system use, such as attitudes and motivation of the user as well as actions taken by the user. However, the focus in Eierman's analysis has been on two issues: system implementation and system use.

Table 1: Concepts used to define a decision support system in information systems science (further elaborated on the basis of Turban 1988).

Source	**DSS defined in terms of**
Little 1970	System function, interface characteristics
Gorry and Scott Morton 1971	Problem type, system function
Alter 1980	Usage pattern, system objectives
Sprague 1980	Task, users (knowledge workers), means (information technology)
Moore and Chang 1980	Usage pattern, system capabilities
Bonczek et al 1981	System components
Keen 1980	Development process
Turban 1988	Problem type, usage pattern, system capabilities, system objectives
Sprague and Watson 1989	Problem type, problem occurrence
Klein and Mehlie 1990	System capabilities, system function (support), application tasks
Adam et al. 1995	Problem occurrence, problem specifiability
Eierman et al. 1995	Environment, task, system capabilities, implementation strategy, system configuration, user, user behaviour, performance

To summarise, DSS approaches in IS have been closely focused on development and implementation and on hardware and software issues rather than on decision makers and on decision processes [Power and Karpathi 1998]. Keen has noted that the system, but not the decisions or the support, have been the focus in building the DSS's [Keen 1997]. DSS technologies should not be the focus, but rather taken to be a means to develop better contexts for decision makers and DSS's.

Use of qualitative information in decision support systems and handling of unstructured, semistructured, novel or complex problems has been the major motivation for artificial intelligence-based computerised decision support.

2.2 KNOWLEDGE-BASED SYSTEMS

Our second disciplinary context for decision support systems is artificial intelligence (AI). The goals of AI are to study human intelligence and to build computational models that can simulate intelligent behaviour [Nilsson 1974, Lenat 1975, Newell and Simon 1976]. Artificial intelligence is both theoretical research, i.e. the study of intelligent behaviour, and technology, i.e. knowledge engineering where models are implemented as computer programs, knowledge-based systems (KBS). Knowledge-based systems may also be called expert systems (ES). AI can be seen as a science that studies solutions to complex or ill-structured problems using heuristics [Aliferis and Miller 1995].

Weak AI sees computers as tools to develop computational models that show intelligence. Strong AI sees computers as means to develop and test theories of human intelligence. The two branches of strong AI are classical and connectionist. Classical AI sees mental systems as physical symbol systems and explains that intelligence originates from manipulation of symbols. Symbols and search are essential for intelligent behaviour and provide the necessary and sufficient means for general intelligent actions (Physical Symbol System Hypothesis) [Newell and Simon 1976]. Connectionism is a statistical data-driven approach where mental systems are modelled as connectionist neural networks or genetic algorithms.

Research in AI has for decades followed the divide-and-conquer strategy [Hayes-Roth 1995] so that the field has fragmented and diverted from the original aim of building intelligent agents. Despite the fragmentation, solutions to some challenging theoretical problems have been found and also some commercial successes met. The core problem of AI, according to Hayes-Roth, is that achieved component solutions are not easily integrated with the whole, and thus comprehensive agent architectures have not yet been found [Hayes-Roth 1995].

2.2.1 Medical knowledge-based systems

Medical artificial intelligence (AIM) is a subfield of AI that focuses on modelling expert knowledge and on developing systems and tools that can be used to improve health care and medicine. Medical knowledge-based systems can combine information from patient data sources, from a patient record, for example, with general medical knowledge, i.e. empirical or evidence-based knowledge. Throughout its history AIM has been the most active subfield of AI. The historical phases of AIM with their characteristic issues are described in Table 2.

The early years of AIM were quite technology-driven, and medicine provided AI with set of restricted and isolated problems as a playground for AI methods and tools. The AI languages, tools and machines of the 1970's and 1980's proved to be slow, expensive, difficult to understand and use, and difficult to integrate with other information systems and the environment.

Nowadays AI has been mostly integrated with or embedded in research in other fields like biology, cognitive science, psychology, information technology, communication and organisation theories. Results have been achieved with methods and approaches to study human reasoning and cognition, with knowledge representation formalisms, with knowledge acquisition methods and with analysis of knowledge types and structures.

In many AI projects the goal has been to develop a model of a specific expert's expertise and to implement this model as an expert system. The object of such study has mostly been an expert task at individual level decontextualised from the environment, and in most developments the social and organisational contexts of the decision making of the expert have not been considered.

Discussion on AI-based decision support systems, knowledge-based systems, or expert systems, has largely concentrated on methodological aspects of decision support, asking such questions as: Is it better to use model-based or data-driven approaches to model and implement decision making algorithms? Today the discussion has intensified even more around these issues because of the growing number of possibilities in methodologies, technologies, telecommunication networks and software facilities.

Table 2: Historical phases of AIM (developed on the basis of Summers and Carson 1995, Kulikowski 1995)

Era	**Phase**	**Characteristics**
1950-1967	Non-AI applications	Statistical methods, Bayesian decision analysis, decision theory
1968-1976	First phase of AI	Analysis of decision making in terms of problem-solving characteristics, knowledge intensive frameworks for representation of medical reasoning, causal networks, modular rule-based reasoning, hierarchical networks, frames
1977-1982	Second phase of AI	General frameworks, shells for expert systems, knowledge acquisition, learning, categorical reasoning
1983-1987	Transitional period	Research on medical reasoning, critiquing approach, qualitative models, rule refinement, neural networks
1987-	Present	Development of knowledge-based representations, knowledge level abstraction paradigms, qualitative reasoning, temporal reasoning, relations to statistical methods, influence diagrams, probabilistic causal networks, neural nets and fuzzy logic, machine learning, deep knowledge

The future of AIM in health care depends on whether medical and health problems will become a driving force for AI and whether significant positive impact on health care can be demonstrated. Additional potential for AI can be found in integration with other information technology approaches and methods and in integration with the Internet. Actually in the Internet environment, many AI-based approaches are used to manage, update and represent knowledge and information. Also, exploitation and delivery of results may be done through the Internet; medical software and decision support systems can be made accessible, even world wide, via the Internet.

2.2.2 Concepts used in defining a KBS

Concepts used to define a decision support system in AI are presented in Table 3 as derived from textual sources. We have studied primarily the knowledge level abstraction paradigms, because knowledge level modelling has been the major approach applied in expert systems to generalise and structure domain and task knowledge. Additionally, we have included two additional approaches, which represent extensions and pragmatic guidelines for KBS development.

The core of Newell's knowledge level hypothesis is that knowledge is an abstraction that can be separated from symbols that are used to represent the knowledge [Newell 1982]. Knowledge level analysis of a problem specifies actions needed to solve the problem in the world, the symbol level analysis specifies the computational mechanisms needed to model these actions. This means that the design of the conceptual architecture of a system at the knowledge level can be separated from the implementation of the architecture at the symbol level [Newell 1982]. The specifications at these two levels are different: at the knowledge level they are semantic, whereas at the symbol level they are mostly syntactic. If a system can be described at the knowledge level, it can be described at the symbol level in terms of representations, data structures and processes.

The knowledge level paradigms are: heuristic classification [Clancey 1985], distinction between deep and shallow knowledge [Keravnoe and Washbrook 1989], the problem-solving method [McDermott 1988] and generic tasks [Chandrasekaran 1986]. Heuristic classification focuses on the inference structure that underlies expertise, while the deep/shallow knowledge distinction focuses on the theoretical structure and contents of domain knowledge. The problem-solving method focuses neither on inference structure nor on domain knowledge, but instead on characterisation of the sequence of actions that enable a KBS to execute a certain task in a specific domain. A problem-solving method can be seen as the generation of possibilities and as selection from these possibilities. The generic tasks paradigm is based on the idea that there exist classes of generic tasks, e.g. interpretation, classification, diagnosis and so on. All these tasks, it is proposed, can be decomposed into simpler subtasks, and the relations between them can be described.

These paradigms have made strong assumptions about domain knowledge, and therefore developers often had first to select the problem- solving paradigm and then define domain knowledge in terms of the method. Slowly, there has emerged the need to capture general concepts independent of what problem-solving method would be used. These efforts in AI have gradually led to scalable architectures where reusable problem-solving methods and domain ontologies can be used. This kind of approach makes a distinction between the foundational domain concepts and the inferences and problem solving that might be applied to those concepts [Musen 1999]. A good example of this approach is the KADS model for knowledge engineering [Schreiber *et al.* 1993].

Additionally, we present in Table 3 the epistemological model [Ramoni *et al.* 1990] and the development philosophy approach [Heathfield and Wyatt 1993]. In the epistemological model the term knowledge level has been replaced with epistemological level, because inference structures, problem-solving methods and task features are also seen as elements at the knowledge level, in addition to domain knowledge. This approach proposes that a KBS contains two types of knowledge: knowledge about the domain (ontology) and knowledge about inference structures that are needed to execute a task to exploit the ontology. Therefore, in building a KBS we need to focus on the definition of the domain ontology and on the definition of the underlying inference structure.

The development philosophy approach is a pragmatic view covering all aspects of DSS development, from requirements analysis to evaluation, and includes values and beliefs.

The connectionist approaches of AIM have not been included in Table 3 because of their different nature.

The concepts detailed in Table 3 indicate that in AIM a knowledge-based system or a decision support system is mostly understood to be a system that supports an individual's cognitive processes. The major focus in development has been on mimicking an individual human's intelligent behaviour by modelling tasks and knowledge and inference processes. The development philosophy approach aims at utilisation of software engineering approaches and experiences in KBS development in such a way that a professional, systematic methodology is used. However, the domain problem is still seen as an isolated and decontextualised one.

Table 3: Concepts used to define a KBS

Abstraction paradigm or approach	**KBS defined in terms of**	**Source**
Heuristic classification	Feature abstraction, heuristic match, solution refinement	Clancey 1985
Deep and shallow knowledge	Deep knowledge, causal relations, shallow knowledge	Keravnoe and Washbrook 1989
Problem-solving method	Problem decomposition, domain independent strategies, sequencing inferences	McDermott 1988
Generic tasks	Problem type, problem decomposition, task, ordering of tasks	Chandrasekaran 1986
Epistemological model	Ontology, inference model, medical tasks	Ramoni *et al.* 1990
Development philosophy	Need, development methodology, methods, metrics, tools, integral evaluation, professional approach	Heathfield and Wyatt 1993

The object of a knowledge-based system has been construed as an expert task at an individual level decontextualised from the environment. Medical knowledge based systems are mostly expert systems developed to solve isolated medical decision making problems. The decision making context, i.e. the social and environmental variables, has mostly not been considered at all in the systems developed. The focus in the decision making process has been on the choice phase, and this has resulted in AI-based approaches in which problems have been matched to available tools. This way of proceeding puts the focus on the choice instead of on intelligence. The choice phase problems have been challenging for AI researchers and developers, but these choice phase problems may not have been driven by the interests and needs of health care professionals.

2.3 HEALTH INFORMATICS

Our third disciplinary context for the study of decision support systems in the area of health care is health informatics, or medical informatics, which focuses on information processing in the health care environment, on methodologies to develop information systems for health care and medicine, and on evaluation and understanding of the changes brought by these systems and technology in the health care environment.

2.3.1 A science

Both terms, health informatics and medical informatics, are used. Mostly they are used as synonyms, sometimes distinctions are made in their meanings. The differences in interpretation may arise from different cultural traditions or from restrictions in the scope of the definition given [Hasman *et al.* 1996]. We prefer to use the term health informatics instead of medical informatics, because to our mind health informatics refers clearly and widely to health care and its processes as a whole, whereas medical informatics may be interpreted as referring only to medical science and medical care.

Some approaches to the task of defining the concept are presented in the following. In the Handbook of Medical Informatics [van Bemmel and Musen 1997] the terms *medical informatics* and *health informatics* are used as synonyms. *Medical, or health informatics,* is defined as "art and science where methods and systems are developed and assessed for acquisition, processing, and interpretation of patient data using knowledge obtained from scientific research" [van Bemmel and Musen 1997, p. XXXIII]. Computers are vehicles to realise these goals. Van Bemmel and Musen propose that the domain of health informatics is the entire domain of medicine and health care, and some areas are more fundamental and some have more applied character.

Health informatics is defined [Hasman *et al.* 1995, p. 55] "as a discipline of systematic processing of health related data, information and knowledge by computers". According to Hasman *et al.* health informatics focuses on the study of information-processing principles and deals with providing solutions to information-processing problems in health care. In these information-processing problems formal methods and tools taken from information systems science are used to design, develop and evaluate systems [Hasman *et al.* 1995]. Haux defines

[Haux 1997, p. 10] *medical informatics* "as a discipline concerned with the systematic processing of data, information and knowledge in medicine and health care". According to Haux, the domain of medical informatics covers computational and informational aspects of processes and structures in medicine and health care. Coiera defines [Coiera 1997, p. xxi] *medical informatics* "as a logic of healthcare, as a rational study of how medical knowledge is created, shaped, shared and applied". Coiera proposes that medical informatics concerns also the study of the way we think about patients, of how treatments are defined and selected, and, finally, of how we organise ourselves to create and run health care organisations. This definition clearly emphasises the organisational dimensions of health informatics.

From the definitions above we can see that the three key aspects of health, or medical, informatics are [Haux 1995, Hasman *et al.* 1996, Haux 1997]:

- Study of processes, functions, data, information and knowledge of health care and medicine,

- Design and development of information systems to support health care processes,

- Study of changes brought about by information systems and technology.

Can health informatics be considered as a scientific discipline? Do we have scientific and theoretical knowledge, and do we as health informaticians apply it to our work? Or, should health informatics be classified as a profession? These issues are being debated in a lively ongoing discussion [see Heathfield and Wyatt 1995, Giuse and Miller 1995, Protti 1995, Nöhr and Andreassen 1995, Scherrer 1995, Haux 1995, Hasman and Sosa 1995, van Bemmel and Musen 1997, Hasman 1997, Haux 1997, Cesnik 1999]. In the Handbook of Medical Informatics [van Bemmel and Musen 1997] health informatics is classified as a scientific discipline because the domain can be defined (domain is intersection of medicine or health and informatics or information), it is both an applied and a theoretical science, and the general goal is to collect generally applicable knowledge that can be used in a particular domain: health care.

Also, other researchers consider health informatics as a scientific community and a discipline of its own [see e.g., Shortliffe 1993, Korpela 1994, Friedman 1995, Pryor

1995, Hasman *et al.* 1995, Heathfield and Wyatt 1995, Hasman *et al.* 1996, Coiera 1997]. They justify this stance by pointing out the existence of academic chairs and health informatics education programs in such countries as Sweden, Denmark, the Netherlands, Germany, the United Kingdom, France, the United States, Japan and Canada. Additionally, there exist a number of scientific journals (e.g. *Methods of Information in Medicine*, *Medical Informatics*, *Computer Methods and Programs in Biomedicine*, *Artificial Intelligence in Medicine*) and a number of professional societies and regular scientific conferences (e.g. *European Federation for Medical Informatics, International Medical Informatics Association, Artificial Intelligence in Medicine Europe, Medical Informatics Europe)*. Some researchers [e.g. Heathfield and Wyatt 1995] see that health informatics also fulfils the criteria for a profession because theoretical foundations have already been established in some areas and in others researchers are starting to address them. Health informaticians apply these theories in their work. Some researchers [Protti 1995] are more suspicious and propose that, although health informatics is approaching the professionalism phase, it is not yet a profession.

In Finland we do not have academic chairs in health informatics at the end of the 1990's, although health informatics has been an active area in our country, both in research and in practice, for a long time. For example, the first information systems had already been installed in Finnish health care organisations by the end of the 1960's. Still, some networked organisations have been established to improve the research and education facilities in the field [Saranto and Korpela 1999]. Examples of these networks are HC-ICE (Health Care Informatics Centre of Excellence in Satakunta), MIRCIT (Medical Informatics Research Centre in Turku), CHIRDEK (Centre for Health Informatics Research, Development and Education in Kuopio) and OSKE (Centre of Excellence for Information and Communication Technology in Welfare and Health) in Helsinki. These organisations are networked through OSVE (Network of Excellence Centres for Social Welfare and Health Care). OSVE also functions as a means of communication in implementation by the Ministry of Social Affairs and Health of its strategy on the utilisation of information technology in social and health care services. Implementation of the defined strategy [Välimäki 1996] will most likely play a part in the recognition of health informatics as a scientific discipline as well in our country.

The subfields of health informatics can be represented as a tower [Friedman 1995] (Figure 7).

Means		**What to study?**
Evaluation studies	**Study of effects**	-Effects on resoning and behavior of HC professionals, on organisation and delivery of health care
Organisation and ecology	**Systems installation**	-Install systems and make them work reliably in functioning health care environment of the work place
Design approaches and methodologies, theories and facts	**Systems development**	-Innovative systems using models that deliver information and knowledge to HC professionals
Scientific theories	**Model formulation**	-Models for acquisition, representation, processing, display, transmission of knowledge and information

Figure 7: Tower of achievements in health informatics [Friedman 1995]

The tower structure indicates that the levels build on one another. At the first level, model formulation focuses on very basic and scientific problems following scientific principles of abstraction and generalisation. At the next level, system development is concerned with building reliable systems that deliver information or knowledge, and accumulating knowledge on the development of effective and efficient information systems. The third level, the system installation level, focuses on how the system affects the structure of the work and, conversely, on how the work creates constraints on a system. At this level an in-depth understanding of the organisation and ecology of the health care services is required. The highest level, the level of the study of effects, focuses on the effects of the information systems on the quality of health care. At this level, empirical evaluation studies are performed with the purpose of providing information for the improvement of work in the other levels and to assess the results achieved in the framework of the stated objectives. All four of these levels, as well as vertical integration across the levels, are important for a health informatics system, for a health informatics project, and for health informatics.

A recent Delphi study [Brender *et al.* 1999] showed that active management of change in health care organisations should be a research issue in health informatics. This is important since the application of information technology, or any new technology, imposes changes on the structure and organisation of health care. The study identified the current major research needs in health informatics as follows (their top ten priorities are listed here from highest to lowest):

- Research on how information technology changes the way health care is delivered (Business process re-engineering)

- Research on the infrastructural support needed for the sharing of the contexts of care episodes between clinicians (Electronic patient record)

- Development of methods and tools for up-to-date reporting on public health status (Management, policy and financial aspects)

- Research on measures of well-being (Quality of life, compensating physical andicaps, bioengineering)

- Research on medical decision making and representation of medical treatment plans (evidence-based medicine, clinical guidelines)

- Research on the context for application of decision support systems, i.e. how to integrate knowledge-based decision support with clinical process (Utility of decision support and knowledge based systems)

- Development of self-learning intelligent systems (Knowledge extraction from clinical data and free text)

- Research on virtual worlds for consultation on diagnosis and treatment in general (Education),

- Research on operational costs (Telemedicine)

- Research on patients' access to their own patient record in particular and to medical knowledge in general (The informed patient)

In this list, contextual and organisational aspects of health information systems are given higher priorities than they have enjoyed in the past, and as important research issues are seen the context of decision support systems, and the integration of decision support with clinical practices.

2.3.2 A practice

Computational and informational aspects of processes and structures in medicine and health care are the domain of health informatics. These structures and processes may be of different types, and they may be communicating with or integrated with each other. Health informatics aims at developing models of these processes and structures and at implementing these models as different types of information systems [Hasman *et al.* 1996].

The types of information systems in health care can be classified using the relationship of information systems to health care processes as a classification criteria (Figure 8) [van der Loo *et al.* 1995]. Health care processes consist of both auxiliary processes and care processes. Auxiliary processes, such as financial and personal management, administration and cleaning services, are those processes that create conditions for effective and efficient care processes. Care processes are the core processes of health care: curing and caring for patients. The care process itself can be divided into a supporting process and a medical care process. Supporting processes form the conditions for medical care. Examples of supporting processes are medical research and laboratory services. The medical care process is directly connected to diagnostics, treatment or therapy and nursing. Types of information systems related to the health care processes may be (Figure 8):

- *Communication* systems between processes,
- Systems for the *integration of processes,*
- Systems that *support a health care process*. These may be systems that *support the auxiliary process*, or the *care process*. Care process support systems may either *support the medical care process (e.g. laboratory information systems)*, or *concern the medical care process itself*, i.e. they are *diagnostic systems, treatment and therapy support systems* or *supporting systems for nursing.*

In the health care environment, decision support systems function clearly to support health care processes and/or its subprocesses. This includes support to communication and integration of health care processes, or auxiliary processes, not only to clinical decision processes. Thus, clinical decision support systems represent a subclass of decision support systems, they support medical care process.

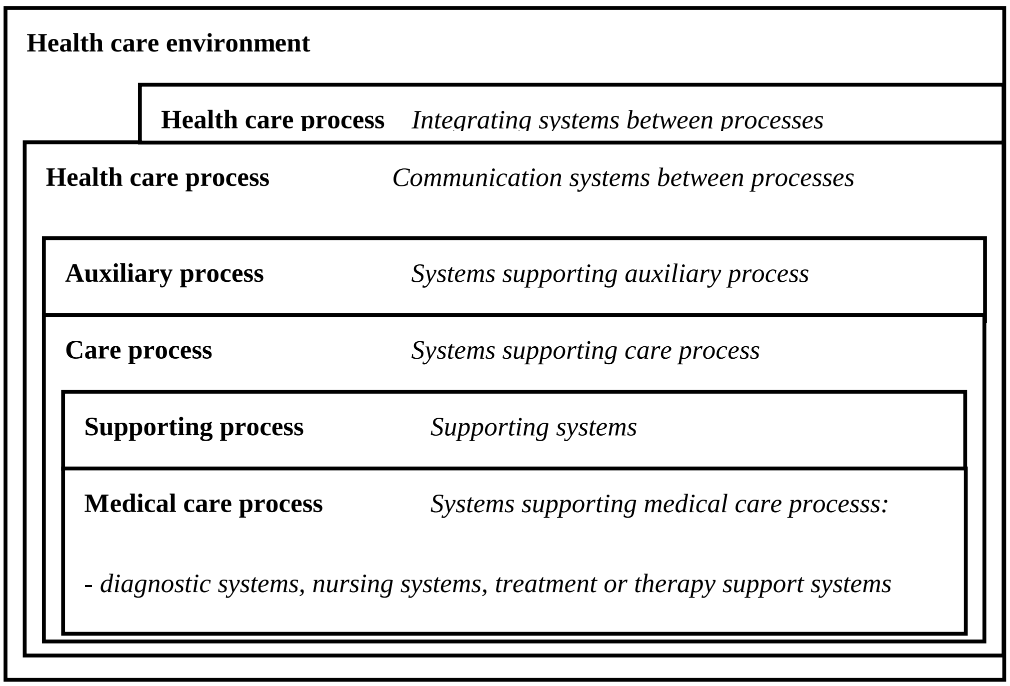

Figure 8: Types of information systems in health care environment [van der Loo et al. 1995]

The biggest achievements by far in health informatics practice have been obtained with health information systems, documentation, signal processing, image processing, laboratory automation, knowledge-based support and molecular bioinformatics [Haux 1997]. Today's health information systems are complex, often networked and integrated systems that support activities in administrative and diagnostic service departments. Their volume for information processing is huge, they are mission-critical systems which should always function. Various health professionals, such as physicians, nurses, laboratory personnel and administrative staff, use these systems. They are integrated with other applications in the hospital via networks, and they may even have connections to remote systems in other countries. The integration is both technical and functional, requiring consistent and shared terminologies and agreed-upon concept taxonomies and classifications. Service delivery via networks also emphasises importance of human factors, usability and utility of systems. On the other hand, this kind of networking makes the health information systems' infrastructure complex, and therefore clumsy to use, and also vulnerable to applied technology, as for example, the interoperability of network components may be disturbed easily by new components.

Examples of current health information systems in our country are hospital information systems (HIS), computer-based patient record systems (CBPR) and various clinical information systems in intensive care, nursing and clinical decision making. Additionally there are numerous information systems that support health care service production, such as laboratory information systems, embedded software in equipment, radiology systems, pharmacy systems and resource management and workflow systems. Data and information documentation and image and signal processing methods are used to access and analyse data from existing enormous databases and data warehouses in the networked environment. A good example of our current, advanced situation in health informatics practice is the Satakunta Macro Pilot project where a seamless, regional health care network is developed to serve clients of the social services, patients of health care organisations, health care professionals and citizens in the whole region. High technology methods and products are used in the Macro Pilot to enable an efficient and high quality service production and delivery regionally [www.makropilotti.fi].

By far the weakest features of health information systems are the lack of full integration of systems and their poor interoperability. They do not support well cooperative work of health care professionals, and reporting does not always support health care quality. Also, the management of complex and heterogeneous large information systems and networks in health care organisations has proven problematic [Haux 1997]. An interactive dialogue between research and practise in health informatics is needed so that scientific innovations could be disseminated into practise while practical projects would provide research with feedback and experiences from real world problems and their solutions.

Health informatics has, however, already contributed considerably to the quality of the whole health care system as well as to education and research in medicine and the health sciences, especially through interdisciplinary projects [Haux 1997].

Today, health professionals would find it impossible to keep track of clinical research and its implications on clinical practise without information technology support.

We are facing currently a paradigmatic shift in health care from institution-centred care to citizen-centred care where informed citizens take responsibility for their health [van Gennip and Lorenzi 1999]. In the health care delivery system the change is towards continuity of health services with seamless and integrated care processes and towards evidence-based medicine. The focus in computerised decision support has also changed to improvement of health care processes, their organisation and outcome. Decision support has become more and more embedded into health care information systems as opposed to the stand-alone systems of the past. Offered decision support can sometimes be seen as a by-product of data management activities. An example of these kinds of systems are integrated DSS components in the laboratory information systems or embedded components in biochemical robots which in many cases were the first systems to include decision support components in health care practice. In the future health informatics may be moving more and more towards provision of telematic services and use of information and knowledge via the Internet.

Though much progress has been achieved in health informatics, some important fields remain poorly covered. One such important field is education and training, which is incomplete, or even lacking, in many European countries, e.g. in Finland [Hasman and Sosa 1995, Hasman *et al.* 1995, Cesnik 1999].

When education and training in health informatics are not well organised, health care professionals lack both knowledge on information systems and technology and practical skills of participation in the design of information systems. Health professionals' having knowledge about and skills in information technology would reduce errors, increase individual work productivity and allow more adaptability in the face of new challenges. Knowledge of health informatics would also help health professionals to give feedback to system developers, and more importantly, they would have valuable insight into the possibilities, and also to the limitations, of information technology in health care [Vimarlund *et al.* 1999, Hasman *et al.* 1995]. This lack of education will hopefully be rectified in the near future, because the importance of education has been widely recognised and training programs are in fact emerging. In many cases these programs utilise results from the shared EU research programmes such as the Telematics Applications Programme.

3. Summary of the case studies (I-V)

The papers I-V present our case studies on development and evaluation of decision support systems in the health care context. In this chapter we review the work presented in the papers: problems addressed, methods used and results achieved.

3.1 PROBLEMS

Research problems addressed in I-V are of two types. First, there is a **user's problem**, an underlying real world problem which may be a medical problem, a health problem or some other type of problem in the health care environment. The existence of this user's problem is the major motivation for the solution developed. Second, there is a **developer's problem**, the methodological choices made in order to provide a solution to the user's problem.

The problems in I-V are presented briefly in the following using this two-type problem typology.

- ***Paper I: User's problem:*** For the management of information overload in a data-intensive environment, support is needed for interpretation and utilisation of laboratory data in clinical decision making, both in primary and secondary care**.** ***Developer's problem****:* Development of a system for routine clinical and laboratory use using a commercial expert system shell and interfacing the developed system with the traditional information systems environment. The resulting system should satisfy the settled validity criteria and be acceptable for the users.

- ***Paper II: User's problem****:* Massive amounts of data are produced in clinical laboratories and intensive care, so support is needed to interpret and utilise this data in clinical decision making. Post-analytical functionalities in a laboratory deal with enhancing and interpretation of data in such a way that useful and understandable information can be delivered to users of laboratory services at different levels of health care. ***Developer's problem****:* To develop generic modules for interpretation, enhancement and delivery of information in such a way that harmonised approaches and standards are used and the modules can be integrated with traditional legacy systems and extended when needed.

- ***Paper III: User's problem**:* Decision support systems are needed to support decision making in complex situations, which are specific to individual users. Users are not involved in the development of the systems, and when evaluations of systems are performed (which is rarely), the results are either not reported to users or are incomprehensible to them. ***Developer's problem**:* Evaluation and development of knowledge-based systems should be integrated with each other and result in successful systems for routine use.

- ***Paper IV*: *User's problem**:* Integration of external systems with an existing hospital information system environment in such a way that the systems function correctly in the integrated environment and are useful and usable. ***Developer's problem**:* Is the four-phase evaluation methodology feasible for evaluation of the integration, i.e. evaluation of integration of the prototypes and evaluation of the integration process itself?

- ***Paper V: User's problem:*** Guidance and methods to evaluate and validate health information systems, or health telematic systems, are needed. ***Developer's problem:*** Evaluation methods should be integrated with development projects, and there should be a repository of methods and information on how to make these methods accessible.

In the next two sections we present a summary of how these problems have been dealt with in each of the papers I-V.

3.2 METHODS

Building and evaluating information technology artefacts have design science intent according to March and Smith [March and Smith 1995]. Where natural sciences and social sciences try to understand reality, design science attempts to create artefacts that serve human purposes. Design science is technology-oriented, and consists of two basic activities, build and evaluate. Building, or development, is a process of constructing an artefact for a specific purpose. Evaluation is a process of determining how well the artefact actually performs.

In the next two subsections we consider both development and evaluation methods.

3.2.1 Development methods

Two types of development methods have been applied for decision support systems in the papers I-V: a life-cycle development method with integrated four-phase evaluation methodology and an open distributed process model approach.

The life-cycle development method proposes that the development of a decision support system proceeds through the following phases (in parentheses: the integrated evaluation phase): Phase 1: User requirements and functional specifications (preliminary exploration); Phase 2: Development and prototyping (validity); Phase 3: Further development and testing (functionality); and Phase 4: Maintenance (study of effects and impacts).

This life cycle methodology integrates a sequential development approach and an evolutionary prototyping approach. The methodology integrates development and evaluation as well, in such a way that feedback is collected at each phase in defined steps, and this feedback is used throughout the lifecycle to improve development. Figure 9 presents the lifecycle methodology.

The life-cycle development methodology was applied in the development of the thyroid system (I), with evaluation integrated with each development phase. The joint consortium in the EU research projects KAVAS (A1021) and KAVAS-2 (A2019) [Clarke *et al.* 1994] developed the methodology.

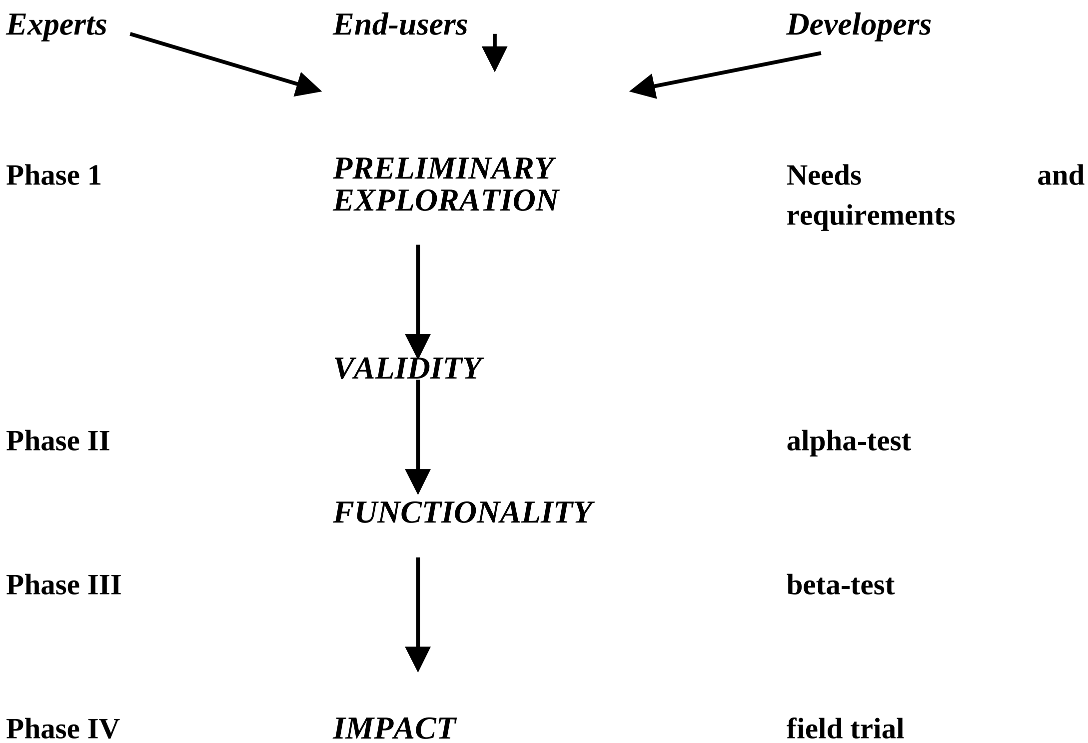

Figure 9: The lifecycle development methodology [Clarke et al. 1994]

The open distributed process reference model [ODP 1993] was used as a frame of reference in development of post-analytical functionalities modules (II) in the Openlabs project (A2028) [O'Moore *et al.* 1996]. The ODP model provides five viewpoints on the development process, helping to maintain focus during development so that at each level of abstraction the focus on development is different. Use of ODP model simplifies the design and development of a complicated system. The ODP viewpoints are presented in Figure 10.

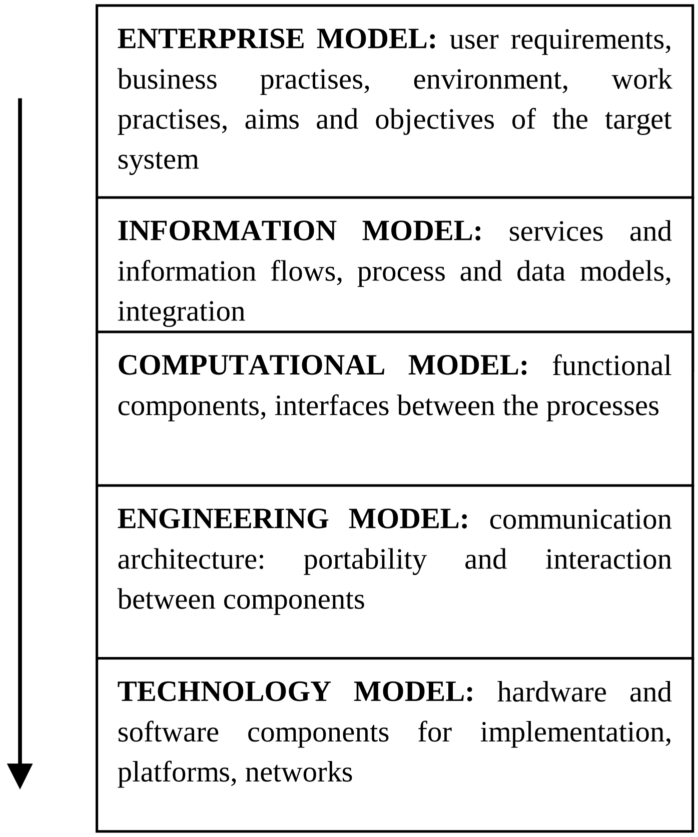

Figure 10: The ODP viewpoints [ODP 1993]

The developed post-analytical models have been encapsulated with the open laboratory information system architecture, and the data flows have been defined in a generic way so that integration of any add-one functionality would further be possible [II, Grimson *et al.* 1996].

3.2.2 Evaluation methods

Two types of evaluation approaches have been used in the papers: a four-phase evaluation methodology integrated with development (I, II, III, IV) [KAVAS-methodology, Clarke *et al.* 1994], and validation guidelines (V) [VATAM guidelines, Talmon *et al.* 1999] which describe perspectives and dimensions for the evaluation of telematic applications.

The KAVAS methodology (I, II, III, IV): The four-phase evaluation methodology for knowledge-based systems (applied in I, II and IV and further developed in III) consists of the following phases: preliminary exploration (phase 1), validity (phase 2), functionality (phase 3) and impact (phase 4). The purposes of evaluation in each of the phases 1 to 4 are:

- *Phase 1*: To assess that documentation of users' requirements and system specifications are in agreement with the users' needs, expectations and requirements. Requirements need to be documented in such a way that they are understandable for the users.

- *Phase 2*: To assess that the developed model corresponds at the desired level to the real problem. Additionally, validity of the model implementation is tested in operation in a test case environment.

- *Phase 3*: To assess the system's functionality, usability and utility in a restricted user environment.

- *Phase 4:* To assess the impacts of the system, impacts of its use on user environment and effects of applied technology on environment and users. Impacts and effects analysis requires that the developed system have been used in a real-life situation for some time. The impact study must be planned carefully so that desired effects and impacts can be detected and also undesirable impacts are somehow recognised. In the impact assessment phase we have to remember that impacts may be affected by the measurement situation, e.g. Hawnthorn effect, carry-over effect or checklist effect.

The VATAM guidelines (V): The guidelines have the purpose of providing evaluators with a structured approach for what to evaluate, how to evaluate and when to evaluate.

The three axes used to approach evaluation are:

- *Stakeholder*, or actor: the party whose interest is the main point in evaluation. Stakeholders can be found at the following levels: macrolevel (e.g. governmental policy makers), mesolevel (e.g. national health care organisations) and microlevel (e.g. actors in health care institutes and suppliers, including medical, nursing, administrative, professional, management, industry).

- *Use of the system*: the type of the system, which is being assessed. Classification of types of systems is based on the taxonomy described in section 2.3.2, Figure 8 [van der Loo *et al.*1995].

- *Phase of the system life-cycle*: the phase of development or use. The life-cycle is divided into five phases: 1) user requirements, 2) functional design, 3) technical design and implementation, 4) validation, which consists of two consecutive steps: verification (technical verification and user acceptance testing) and demonstration (large scale testing and use), and 5) exploitation of the system.

These three axes help the evaluator to identify from whose viewpoint the system is to be assessed, what type of system is under assessment and in what phase of the lifecycle the system under assessment is.

From these identification steps we can proceed to an evaluation study. The dimensions applied are the following:

- *Effects on IT development*: concerns how evaluation contributes to the development process, and how evaluation results are fed back into product development.

- *Quality of the IT solution:* concerns how the developed IT solution meets the general standards for quality, how quality is defined and how quality of the results is ensured.

- *User requirements*: ask who are the users are, who the potential buyers of the technology are, what the information needed for decision making is, what user assessment tests are to be performed, etc.

- *Health technology assessment*: concerns the scope, design, methods and targets of the assessment study and items to be studied, e.g. costs, improved efficiency, effectiveness, satisfaction, impact on quality of care or quality of life.

- *How should the product be marketed*: market analysis and marketing plans.

A set of questions was defined for each of these dimensions to collect the needed information and to design the evaluation study (V).

Finally, in order to proceed to perform an evaluation study, we have developed in VATAM [Talmon *et al.* 1999] a repository of information needed to conduct an evaluation study. The repository is an information source including references to literature, to evaluation projects, to tools that can be used, to questionnaires and to terms and their definitions [www-vatam.unimaas.nl].

3.3 RESULTS

3.3.1 Support for thyroid disorders (I)

Our first case is a DSS developed for the interpretation of thyroid disorders. In evaluating the DSS the preliminary exploration phase (phase 1) showed that the documents specifying user requirements worked well as a frame of reference in qualitative terms, but not well quantitatively. The specifications were incomplete; system performance, documentation and maintenance requirements were not documented at all in these specifications. Feasibility of the specifications was poor because of the lack of practical mappings from user requirements to software specifications. Neither cost-effectiveness nor viability of the system were considered at all.

Validity in application (phase 2) did not rate highly. The system correctly classified 98.6% of the test cases with suspected thyroid disease. This was less than the target correctness rate (99%). The failures were due to errors in data, in inputting data and in definition of too broad diagnostic categories for classification. Broad categories were used because we would have required more detailed data and clinical information from the patient to be able to proceed to a more qualified classification. As a result, all those cases that could not be classified correctly were assigned to the class of non-specific thyroid disorders. A commercial expert system shell was used in the development of the system, and the knowledge base was not checked for its validity.

Functionality and usability (phase 3) of the thyroid system turned out to be poor, and the user acceptance of the system was also poor. The reasons were the poor user interface and the lack of navigation, inspection and updating options for the knowledge base. The system was very brittle, transferable for use only to an organisation where the same fixed strategy was in use for thyroid diagnostics.

In the impacts phase (phase 4) it was found that a training effect was the major positive impact caused by the system. The training effect was seen in improved diagnostic accuracy in primary care and in the accumulation of knowledge on thyroid diagnostics in secondary care, especially in borderline and difficult cases. The training effect was caused by interpretative reports, which were sent by normal mail or email to the primary care organisation. From these reports primary care physicians learnt more about thyroid diagnostics and became more knowledgeable in the selection of tests to be performed. When the test selection strategies gradually became more accurate, the number of tests performed could be reduced. This resulted in better cost-effectiveness because the costs of tests were rather high and resources could be saved when only those tests were performed that were useful in the specific clinical situation.

The four-phase development and evaluation methodology proved not to function well in this case, because the problems with the system were detected only in phases 2 and 3. Errors should have been detected earlier; it would have saved time and resources. The methodology was not well suited for the development of knowledge-based systems because the knowledge acquisition phase and its validity checking were not explicitly included in the development life cycle. The system was connected with the laboratory information system, but the connection was very slow, difficult to use for the health care professional, and it worked only in one direction. The connection was needed in order to transmit the measured laboratory test results from biochemical analyzers to the thyroid system for analysis and interpretation. The system did not satisfy the stated correct classification criteria, and user acceptance was poor in the laboratory.

Nevertheless, the thyroid system helped users in primary care to deepen their understanding of thyroid diagnostics and to better select the tests to be performed. It also helped the specialist in the laboratory to concentrate on the borderline and difficult cases because the majority of the samples were normal and were correctly classified by the system. Though the acceptability of the system to the laboratory specialist was poor, the acceptability of the interpretative reports by the general practitioners was good. Our other study [Nuutila *et al.* 1991] on the clinical value of the system showed that in health centres 99% of the users read interpretative reports regularly and 60.4% considered these reports useful. In comparison, of the internists

79.5% read the reports regularly and 55.9% considered them useful. For these reasons clinicians considered the system a valuable support in their work.

3.3.2 Support for post-analytical functionalities (II)

In our second case three DSS modules were developed for interpretation of laboratory test results and for alarming in the intensive care environment. The modules developed were integrated with an open laboratory information system architecture. The systems were evaluated in an experimental hospital setting.

Evaluation of the thyroid system with more than 3000 requests in a 4-month period found that interpretations could be generated by the system for at least 90% of all requests. The remaining requests needed to be interpreted by a human expert.

Interpretation of acid-base disorders was based on utilisation of the laboratory measurement results together with data recorded in the intensive care unit. Evaluation of the accuracy of the system resulted in 92.8% correct classifications with a test set of 194 cases. The accuracy was also tested by two independent experts; levels of agreement between the independent expert, the system and between the different experts were found to be similar.

The generation of alarms and alerts in intensive care using laboratory data and clinical information proved to be a complex task due to the many variables that need to be included, due to the temporal aspects of the recorded data and due to high safety requirements. A prototype system was developed and interfaced in a hospital with the laboratory information system, but no evaluations were carried out at this stage and the system was used only in an experimental setting,

These developed DSS modules provided users of laboratory services, both in a specialised hospital unit and in primary care, with interpretations and suggestions on how to proceed with the specific patient case. The interpretations served as high quality decision support for users. The modules were integrated with a telecommunication network, though they were originally designed as stand-alone systems. Integration was done using standardised components and open architecture specifications. An important aspect of these specifications was the standardised definitions for data and information exchange messages. When integrated with the laboratory information system, the developed systems did not add to the laboratory workload, but showed promise of improving laboratory efficiency.

3.3.3 Extending the evaluation methodology (III)

In our third case the previously used (I, II) evaluation methodology was extended to better cover the development of knowledge-based systems. This involved the suggested addition of two perspectives to the evaluation process: knowledge acquisition validation and user-system integrated behaviour.

Knowledge acquisition validation emphasises knowledge acquisition as part of a system's design and development. With knowledge-based systems knowledge acquisition is a critical phase where a domain model is developed. Quality and validity of the resulting knowledge-based system depends strongly on the domain knowledge model developed. Therefore, validation of knowledge acquisition should be done integral with development. The approach to knowledge acquisition validation was developed by [Benbasat and Dhaliwal 1989], and in (III) this approach was integrated with the evaluation methodology.

It was proposed that validation be done at the following levels: first, conceptual validation for the conceptual, domain model for its correctness and reasonability, and second, elicitation validation for the knowledge models for their representational validity, i.e. representation comprehensibility and accordance with standardised terminologies and taxonomies. These validation steps result in a domain model in an appropriate representational formalism for implementation. Key characteristics for this implementation model is that it captures the essential contents of the domain, is understandable in representation, and can be communicated. If machine learning or connectionist approaches are used in knowledge acquisition, then statistical methods would be needed in knowledge validation to assess the database contents and the decision making logic.

The user-system integrated behaviour perspective emphasises the need to develop and evaluate the system as part of the integrated knowledge environment of the user. An important part of the user requirements documentation and system specifications should be a model of the user-system integrated behaviour. This model describes the task and role of the system in the user environment and through that explicates the need for the system. Thus, the domain model should represent also contextual aspects of the task. Consequently, the validity of the system concerns the validity of the system in performing a task with the user, man plus machine. This implies that evaluation and validation have to be performed along two lines: *a priori* and *pragmatic*. The term *a priori* highlights the understanding of the framework where the system is to be integrated, whereas the term *pragmatic* emphasises the role of the experience and utilisation of realistic methods in a system's design, development and evaluation.

These extensions indicated that when developing a decision support system a domain knowledge model has to be built and this model is gradually transformed into such a representational formalism that can be used for computation. Checks for the validity of the model transformations are performed at each level. In this process of model development, the target environment, the user and the use of the system by the user have to be included in the domain knowledge model characteristics.

3.3.4 Applying evaluation methodology to evaluation of integration (IV)

In our fourth case the evaluation methodology was applied to the integration of various knowledge-based systems with the hospital information system. The systems were developed in EU research programme projects whose purpose was to assess whether these kinds of stand-alone systems could really be integrated, both technically and functionally, and used routinely in a hospital environment.

The evaluation of the integration focussed on two aspects: on integration of the prototypical knowledge-based systems and on evaluation of the integration process itself. The interesting questions in the prototype integration were the feasibility, relevance and success of the integration. In evaluation of the integration process we were interested in finding out whether the integration process itself fulfilled the users' needs and expectations. The ultimate goal of our work was to assess whether our evaluation methodology could be successfully applied on this type of problem.

The focus in the prototype integration was not the prototype itself, but how the prototype could be integrated with the environment. Evaluation of the prototype integration did not cause any changes or problems with the evaluation methodology.

Assessment of the integration process itself brought some extensions to the evaluation methodology. In the exploratory assessment (phase 1) the frame of reference for evaluation was defined to be the expectations of the project managers, representatives from the projects and users in the evaluation site. In the validity assessment (phase 2) it was understood that this phase covered the whole implementation period, i.e. the whole prototype integration. In the functionality assessment (phase 3) the focus was not the functionality of the integrated prototypes, but the functionality of the evaluation methodology in guiding the integration process. The impacts assessment (phase 4) was seen as particularly important as the core idea behind this work was to show that prototypes developed in other sites can be transferred and used in a real hospital environment, with positive impacts. The impacts evaluation was focused on dissemination, and practically speaking, this assessment could be performed only after the integrated systems had been functioning for some time.

Application of the evaluation methodology on this integration problem proved rather simple, but new formalism was needed to identify the information needs at individual stages, and new metrics and measures had to be developed for the integration assessment.

3.3.5 Dimensions of evaluation and validation (V)

In the fifth case, an approach for validation and evaluation was developed and applied to evaluate some running projects in the TAP programme. The focus of evaluation was to analyse the approaches and methods used in these projects for evaluation of the project itself and its results.

The results showed that evaluation and validation were seen as integral parts of the development process. Validation was seen as an important tool to give feedback to the development process. However, confidentiality, data security and data protection aspects were not handled by the used validation methodologies, neither did they cover change management aspects of development. Quality aspects were mostly measured against users' needs and expectations. It is difficult to measure quality against users' needs because users' needs may be implicit, they cannot always be successfully elicited and there may be problems understanding users' needs or there may be a lack of criteria for quality measuring. Software standards mostly deal with technical issues and not with users' needs and therefore are not sufficient for measuring quality in health telematics applications. Total quality assessment with quality assurance, control and inspection should be incorporated into a health telematics project in order to identify reasons for failures and deviations from plans. Quality information should be used throughout the lifecycle to guide the development process.

Evaluation along the user dimension showed that communication and understanding between the users and IT system developers should be improved. Experiences from projects, achieved benefits and shortcomings should be disseminated to the users and developers so that mutual learning is possible.

The finding along the technology assessment dimension was that many different approaches and methodologies were used in assessment depending on the situation at hand. Only a limited number of effects were considered in the assessment, mostly clinical effectiveness and use of the system. The study settings were not well planned. For example, none of the projects randomised the samples, and none had tested the data collection instruments for their validity either.

Marketing was not a real concern in most projects, although the Commission had especially asked for plans for exploitation and dissemination of results. Marketing plans should have been included in the project business plan and been included in the project planning documentation. The importance of marketing planning appears not to have been well understood.

An important issue raised again in this inventory was the lack of unified terminology for assessment, evaluation, validation, verification and demonstration. A terminology glossary, therefore, forms part of these guidelines.

3.4 DISCUSSION

Here we discuss briefly some problems that are related to the findings of these case studies. First, did we find problems in serving the user's and developer's problems, and second, do we still have some problems left that were not considered during the work.

3.4.1 User's problems

The developed, and to some extent evaluated, decision support systems in our case studies can be classified as knowledge-based systems, and they were targeted to support the clinical decision making of health professionals. They proved successful for the users in the management of information overload and in the interpretation of information in such a way that it could be better utilised in clinical practice (I, II). Various users at different levels of health care were served through these systems. Specification of the systems' function was based on the users’ needs in the problem at hand. The major function of the developed systems was to enhance information from data, which was measured or collected in specialised units, and to transfer it to other health care units or primary care where expertise for interpretation was not available.

The evaluations performed in these case studies (I, II, IV) were restricted and were not reported to the users. No special attention was paid to how the evaluation studies and their results were documented so that users could understand them. In this respect users' needs were not served. On the other hand, users were involved in evaluation to some degree, and they received information and could give feedback for system developers on identified failures and needed improvements in the systems' functioning. Users, however, got no training or guidance for the future on how to evaluate decision support systems and which criteria and methods of evaluation to use, though there was a real user's need for that.

Evaluation methodology modifications proposed in (III, V) were based on users' needs to have practical methodologies and guidance for evaluation. Extensions were needed also to cover knowledge acquisition aspects of knowledge-based systems evaluation (III).

3.4.2 Developer's problems

Developer's problems were mostly methodological. First, in developing decision support systems the planned use environments determined the constraints for software and methodological choices in (I) and (II). Use of a research-oriented, combined evaluation and development methodology and use of commercial expert system shells as software environment were not quite successfully combined in (I). We were in a situation where the problems were matched to the tools and not vice versa, as it should have been done. Problems were especially encountered in interfacing the developed systems with the existing health care information systems environment.

Second, developer's problems were related in (II) and (IV) to the problem of how to integrate evaluation with the selected development methods. The four-phase methodology used integrates two different types of heuristics: that of sequential development and that of iterative development through prototyping. Integration was performed by defining checkpoints at different phases in development where pre-specified success or failure variables were measured and compared with the determined reference criteria in order to decide on how to continue. Measurement information was used to guide further steps in development.

As developers we were facing problems in this kind of situation. Although there were many technical and methodological possibilities and alternatives to choose from, the use environment imposed strict requirements and constraints for the selection of software and technology options. These requirements were in some degree even conflicting. Additionally, development was done in an evolving world, and emerging technologies were available and new modalities were arising. Therefore, we tried to apply as much as possible conventional approaches and standards so that the modules could be integrated with traditional legacy systems. This was not, however, always successful.

3.4.3 Remaining problems

Though user's and developer's problems were in the main quite successfully served in our case studies, there still remained some problems which needed attention, but which were not recognised as problems while we were carrying out these case studies.

The first problem is that a decision support system was only implicitly conceptualised in the five papers. There was no explication of the concept. The contents of the concept 'decision support system', particularly the type of system and the requirements for this type of system, have not been explicated. This means that the task of the system and the role of the system in supporting decision making remain undefined. This seems to be one big issue behind the problems met in the work described in (I-V).

The second problem is a natural consequence from the first, and it is also the same as with early expert systems: decontextualisation of the system from its environment. While developing the system, the focus was on modelling the specific expert's expertise, or a few experts' expertise, in a defined task and that model was then implemented as an expert system. In the modelling and implementation processes, the decision making context and its social and environmental variables were not considered. From this it followed that the resulting system functioned well when seen as a problem-solver for the specific problem, but when seen as a system in real environment used by a human user, the system did not function well. This was because those system characteristics that would consider the environmental and use contexts of the system, as well as the organisational context for knowledge and its use, were missing.

The third remaining problem has to do with evaluation and development methodologies. One feature integral to the development methodology is the need for evaluation during all development phases. Developing decision support systems for semi- and unstructured problems puts strenuous demands on development methodology and may even, depending on the type of the system, make it necessary to bring in additional developmental phases like knowledge acquisition, knowledge modelling, knowledge management, and knowledge validation. Also, another big problem is the lack of a generally accepted evaluation methodology, as noted in papers (I-V). We lacked theoretical assumptions on how to connect evaluation and development successfully in the health care context. This caused problems in (I-V), both from the developer's and from the user's viewpoint.

These remaining problems have motivated us to perform further work, which is reported in the next chapter.

4. Approaching synthesis

In this chapter we elaborate a synthesis based on the findings in the literature review and in our case studies (I-V). In the synthesis an extended conceptualisation of a decision support system in health informatics is derived and discussed. Additionally, we discuss the development and evaluation framework for a DSS.

With this work we aim at defining an ontology for a decision support system in health informatics. Definition of an ontology for a DSS means identification of concepts and relations and logical structure for these concepts. Ontology is interpreted as an agreement about a shared conceptualisation [Guarino 1998]. Ontology should provide us with a domain of discourse that is understandable and clearly bounded, and which can be used to develop and evaluate decision support systems that contain detailed descriptions of some health informatics application areas.

4.1 EXTENDING CONCEPTUALISATION

Our experience in performing case studies (I-V) highlighted the problem that a decision support system concept was not explicitly defined in the studies and, therefore, the resulting systems did not have defined contextual aspects. This failure to define contextual aspects largely accounts for the failures in the case studies. On another level, this is also a problem with DSS's in general, as the contextual variables are mostly lacking from the DSS definitions (Tables 1 and 3). This is especially the case with medical expert or knowledge-based systems.

As contextual variables have not been considered during the development of decision support systems, the resulting systems have been brittle: they have functioned only in their development environment, and they have not been transferable to other organisational environments.

Our case studies (I-V) highlighted the need to consider the contextual aspects of decision support systems. In health care, decision support systems are developed and used as part of the environment and as part of the knowledge environment of the user. Therefore, we need such a conceptualisation for a DSS that it covers the contextual aspects in system's development, evaluation and use.

4.1.1. Reference model for information systems research

Ives, Hamilton and Davis presented in 1980 a model for information systems research in their article [Ives, Hamilton and Davis 1980] (Figure 11). In the model, three information system environments (operations, development and user environments) and three information system processes (use, development and operation processes) and the information subsystem itself must be taken into consideration. All these exist within an external and organisational environment.

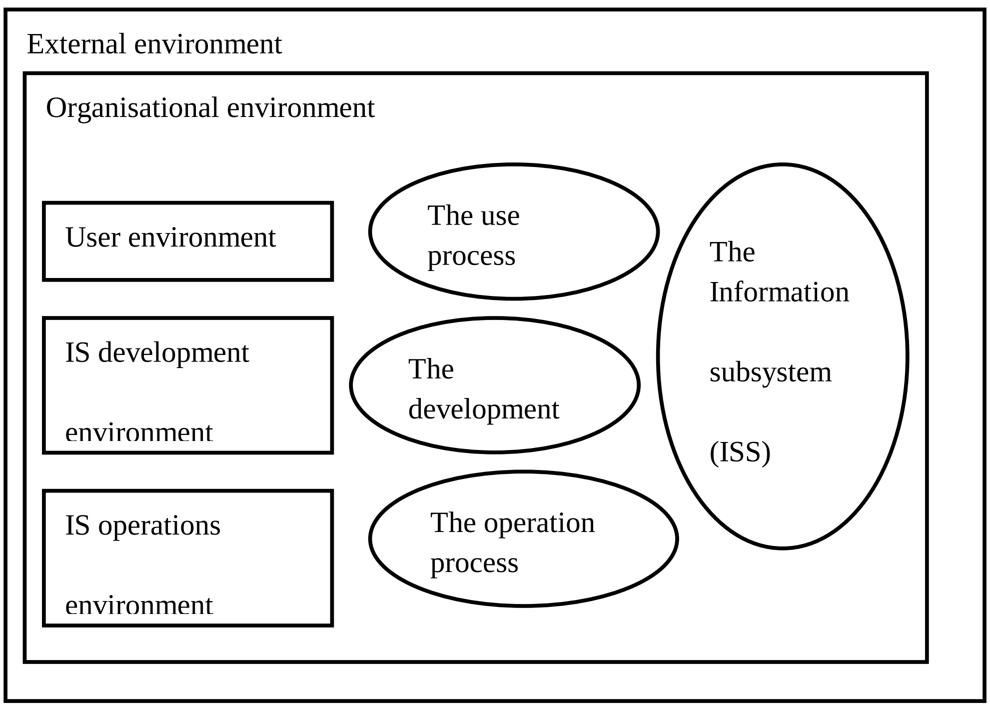

Figure 11: A model for information systems research [Ives, Hamilton and Davis 1980]

In this model, variables that need to be considered in the development of an information system were defined. These variables are described briefly in the following [Ives, Hamilton and Davis 1980].

Environment variables define the resources and constraints for the scope and form of an information subsystem.

    - External environment: Legal, social, political, cultural, economic, educational, resource and industry considerations
    - Organisational environment: Organisational goals, tasks, structure, volatility and management philosophy
    - User environment: The user, user's organisation, user's task
    - IS development environment: Development methods and techniques, design personnel and their characteristics, organisation of development and maintenance
    - IS operations environment: Resources necessary for IS operations, software, hardware, database and operations personnel
- **Process variables** comprise interactions between the information system and the environment
    - Use process: usage of the ISS by the primary user, measured through task accomplishment and effects on productivity, decision making quality, information satisfaction, quality of work life
    - Development process: organisational resources are selected and applied to result in an ISS
    - Operations process: physical operation of the ISS
- **Information subsystem** is the output of the development process.
    - ISS content: dimensions of both data and decision models that are available through use of the ISS
    - Presentation form: methodologies to present information to the user
    - Time of presentation: time dimension, e.g. reporting interval, processing delay.

This model has exerted a big impact on information systems research because it can be used to understand and classify research approaches and to generate research hypotheses. What is important about this model is that it showed that the environmental variables and their relations to development, use and operation processes need to be taken into account in information systems development. We use this model as our reference when discussing the relevant variables and development and evaluation processes of decision support systems in the next subsections, though the model is very abstract and has not been operationalised to a practical level. The model, however, helps us in identifying the relevant variables and in demonstrating the signifigance of environments and processes.

4.1.2 Decision support system in health informatics

When comparing the Ives, Hamilton and Davis model to the DSS and KBS approaches discussed in chapter 2, we see that in information systems science, decision support systems research and development has been development- and implementation-oriented, but covering environment, process and information subsystem variables. The major focus has, however, been on development and user environment. In artificial intelligence, decision support systems research and development has been focused on IS development environment and on information subsystem variables.

As a result of our case studies and of the analysis of definitions we propose that the Ives, Hamilton and Davis framework be applied to the development of DSS in health informatics. And we propose to include some additional variables to the conceptualisation of a health informatics decision support system (Table 4). These additional variables will be discussed in this subsection. From the variables of the Ives, Hamilton and Davis model we have left out the operation environment and operation process variables which are not today as essential to information systems. They are even less relevant in the case of decision support systems as their operation is included in user environment and use process variables.

Table 4: Variable groups and variables for a decision support system

Environment variables	▪ ***External environment*** legal, social, political, economic, educational, resources, industrial environment of the system ▪ ***Organisational environment*** organisation's aims and objectives, tasks, structure, instability, management style and philosophy ▪ ***IS development environment*** development methods, techniques, development and design personnel with their assumptions and characteristics, organisation and management of the development work, user-system integrated behaviour ▪ ***User environment*** users and their environment, users' characteristics, users' tasks, organisation of users
Process variables	▪ ***Development process*** resources and costs, participation, support and satisfaction ▪ ***Use process*** system usage, usage pattern, effects and impacts of system use on work performance and on productivity, on quality of decision making and work, user satisfaction
Information system variables	▪ ***Content*** information and knowledge achievable through the system, *Domain* describing vocabulary of the domain ▪ ***Representation*** formalisms, media and visualisation techniques ▪ ***Scale*** timestamps for representations ▪ ***Knowledge*** types, sources, validity of knowledge ▪ ***Application*** specialisation of the domain and task in the specific application.

The environment variables presented in [Ives, Hamilton and Davis 1980] are essential for decision support systems, as systems are used by decision makers to support tasks and actions in a contextual situation, and they are developed with the express purpose of having effects and impacts on the environment. We propose to pay special attention to *user-system integrated behaviour* as part of the IS development environment. This variable emphasises the need to design and develop the system as part of the integrated knowledge environment of the user.

Environment variables have not been well covered in IS-based DSS approaches. For instance, in the Gorry and Scott Morton framework for decision support systems [Gorry and Scott Morton 1971] only a user environment variable was explicitly included, and implicitly development and operation environment variables were covered. Eierman drew attention to the environment construct [Eierman *et al.* 1995] with a DSS emphasising the need to consider the organisational and environmental context of system's development and use. Eierman *et al.*,however, did not include designer's or developer's attitudes in the presented constructs, neither problem type nor the system function were included. Eierman *et al.* results strenghen our analysis results that environmental aspects like organisational environment and structure, task characteristics and context have to be considered in the DSS design and development.

In AI task-specific approaches have been recently used in order to separate problem-solving methods and domain concepts, and to be able to represent domain vocabularies and concepts as reusable ontologies [Musen 1999]. However, these task-specific approaches have not paid much attention to the contextual and environmental aspects of the task. Rather, domain ontologies have been used to represent fundamental domain concepts like classifications and taxonomies. In Table 3 describing AI approaches, only the development philosophy approach [Heathfield and Wyatt 1993] has drawn attention to the context of domain problem and its modelling.

In information subsystem variables, the *content* should specifically consider the *domain* that describes the domain vocabulary not included in the other variables in that group.

Domain consideration is needed because from the DSS conceptualisations in IS and AI we found that definition of the problem that the system is planned to support is essential for a decision support system. Each DSS needs to have a problem to address, which represents the existing need for the system. The purpose of DSS development is to have a system that solves or supports the solution of the underlying problem. This problem is contextual and domain-sensitive and characteristics of the problem are reflected in the resulting system. The domain defines the purpose for developing the system and its use from the environmental perspective.

An awareness of domain allows for the possibility that the focus in DSS development should be moved from the task analysis more to the direction of the domain analysis. The possibility that a task ontology is an insufficient ontology for decision support systems has been raised also by Guarino [Guarino 1997, Guarino 1998] in his studies of ontology-driven information systems. He concluded that there is a need to cover also the aspects of domain and application area: a clear implication of our analysis of AI approaches. A DSS should not be an implementation of an expert task that is decontextualised from the environment, or from the domain, as has been the case with most medical expert systems developed, as we found also in our case studies.

In the information subsystem variables group we propose to add two new variables: knowledge and application.

The *knowledge* variable indicates the characteristics of knowledge, i.e. type, sources, validity and acquisition method. Knowledge aspects are emphasised in AI-based approaches as seen in Table 3. A health informatics decision support system is not only managing data and information, but also knowledge. Knowledge models are developed during knowledge acquisition and the quality of the system depends on the quality of knowledge, type of knowledge and validity of knowledge.

The organisational context of knowledge is important to consider in the health care environment as knowledge is created and shared through various communication, learning and conversion processes [Nonaka 1994, Boland and Tenkasi 1995, Brown and Duguid 1991]. When concepts are created and made explicit, they can be modelled and shared, first at the domain level and further at the application level. In a health informatics context, decision support systems are often targeted to function as means or facilitators for organisational knowledge creation, sharing and accumulation in the decision making context. A decision support system, developed through a development process in an environmental setting and used by users in their environment, should reflect through its characteristics, e.g. through an implemented knowledge model, its contextual and situational environment.

As an information subsystem variable, the *application* variable specialises the domain environment in the specific application. The application variable is needed to take the contextual aspects into account at the system variables level. A DSS is an application which has a domain specified at a more general level, but the concepts relevant for this specific application need to be considered at the system level. For example, in our thyroid diagnostics case (I) the environmental domain and task is an internal medicine and interpretation task, and at the system level the application is thyroid interpretation.

Without specialising the domain and task to the system level through application, we would not be able to use shared concepts from the domain in the application and thus we would not have enough information for successful system development.

The discussed extensions to conceptualisation of a DSS present an ontology for a health informatics decision support system.

4.2 FRAMEWORK FOR DEVELOPMENT AND EVALUATION

Now we have presented the variables important for a decision support system, and can proceed to discussion of these variables in connection with development and evaluation methodologies.

The four-phase development and evaluation methodology applied in our case studies (I, II, III, IV) proved not to function well with knowledge-based systems. This four-phase methodology actually integrated the sequential development and iterative development heuristics. Adaptive design or incremental design using an evolutionary prototyping approach would be a more suitable development methodology for DSS because it supports learning during the development process [Turban and Aronson 1998]. The VATAM approach presented in (V) is not as such an evaluation methodology, but rather gives perspectives and dimensions to approach an assessment study.

The need for a change in emphasis, from a product-oriented view to a process-oriented view, in software engineering has been discussed by Floyd [Floyd 1987, Floyd *et al.* 1989]. The product-oriented view is close to the life-cycle development, implying that software development starts with a top-level specification document, proceeds to successive defining of specifications, which are finally transformed into executable programs. The process-oriented view, on the other hand, emphasises the need to view software development in connection with human learning, work and communication. Programs are seen as tools or working environments for people, and they are developed in learning and communication processes to fulfil human needs. The process-oriented view of development enables such a development process where the user can intervene to enhance the system's functionality in the context of his/her own work.

In our opinion the process-orientation paradigm should be applied to the development of DSS in the health informatics context. A sufficient development methodology ought to fulfil the following criteria:

- It covers the environment, process and system variable groups as described in the section 4.1;
- It enables adaptive, incremental development; and
- It enables integration of evaluation with development during the system's development and use.

These criteria have been derived from the results of our case studies (I-V) and from the analysis of the DSS and KBS conceptualisations in the literature, as discussed in chapter 2 of this study.

A methodology framework is outlined in Table 5. The term *framework*, according to Webster's Dictionary (Internet version) refers to a basic structure (as of ideas), a skeletal, an openwork, or a structural frame. When a framework is described, it has its applicability assumptions and limitations which are related to the contextual domain where it is defined. Our outlined framework should be seen as a structural frame or a skeletal, it has not been operationalised neither tested with DSS development or evaluation. The purpose of this framework presentation here is to demonstrate the conceptual extensions in relation to the development and evaluation activities.

The outlined framework applies incremental development using evolutionary prototyping. The major point is connection of the IHD-model variables to development and evaluation of decision support systems. The framework describes the development phases and focuses on evaluation during these phases. In order to develop a DSS in the health informatics context following this framework, we proceed through the phases: problem, small prototype, prototype evaluation and refinement, expansion and modifications in an incremental fashion. The framework supports co-operation processes during development and thus learning and communication is enabled.

Table 5: Framework for development and evaluation of decision support systems

Development phase	Evaluation focus	Variables to be considered
Problem	Problem description, task and domain description	**Environment:** external, organisational, development, user
Small but usable prototype	Prototype development, prototype use, prototype qualities	**Process:** development process, use process **System:** content, representation, scale, knowledge, application
Evaluate the prototype		
- by user	Validity, functionality, usability	**System:** content, representation, scale, knowledge, application
- by developer	Development methods and tools, development process	**Process:** development process, use process **Environment:** external, organisational, development, user
Refine, expand, modify	Analysis, construction, implementation, evaluation	**Environment:** external, organisational, development, user **Process:** development process, use process **System:** content, representation, scale, knowledge, application

The framework suggests that we consider environment variables from the very first (problem) phase, then with the system to be evaluated and on to system modifications and refinements. Consideration of the environment variables from the problem phase establishes the context for the system's development. The small prototype can be evaluated from the development perspective, i.e. focusing on validity and functionality, but the environment variables are reflected in this prototype and its functioning. Both development and evaluation need to focus on environment variables throughout the development and use of the system.

In order to integrate evaluation with these development phases, we have the evaluation focus defined for each phase. Methods and metrics for evaluation can then be defined based on theoretical and practical experiences and technology assessment research. Evaluation then benefits from the use of multiple methods, because the effects of systems have diverse and diffuse nature. Multiple methods are needed also because the final evaluation results may be combinations from sets of data and information which each may provide partial answers to evaluation questions. Numerous methods and data collection techniques can be applied, such as cost-benefit analyses, critical incident logs, document analyses, experiments, interviews, observations, simulations and surveys [Friedman and Wyatt 1997, Kaplan 1997]. For instance, the dynamic assessment methodology [Brender 1997] is an extended and advanced presentation of the four-phase evaluation methodology we used (I, II, III, IV) and can be applied to the evaluation of DSSs. However, this methodology relies on the life-cycle model of development, actually on a modified waterfall model, and therefore it would require modifications to enable its integration with incremental evolutionary design. Another possible methodological approach for evaluation of a DSS would be that of [Lee and O'Keefe 1994] which applies a spiral life-cycle model, including requirements analysis, knowledge acquisition, prototype development, clinical integration and impact considerations.

4.3 DISCUSSION

We have presented an ontology for a decision support system in health informatics and outlined a framework for development and evaluation that takes into account the defined variable groups. It was necessary to extend variable groups as the contextual aspects had not been sufficiently considered in the case of decision support systems. Failure to attend to these aspects was identified as a major reason for failures in our case studies (I-V).

The need to understand the contextual aspects of health information systems has been emphasised very recently by IMIA Working Group 13: Organisational aspects of medical informatics [see e.g. Lorenzi 1999, Aarts and Peel 1999, Berg and Goorman 1999]. Aarts and Peel emphasise the need to understand the context of clinical work as a prerequisite for successful implementation of an information system in health care [Aarts and Peel 1999]. If such an understanding exists, then it is reflected in the developer's work and, through his/her efforts, in the resulting system. Berg and Goorman emphasise, among others, that development of information systems in the health care context has a sociotechnical nature, and therefore successful development requires that developers understand the practises in the environment in which the systems are destined to function [Berg and Goorman 1999]. Information in health care is in relation to the context where it is produced.

Also, a previously refereed Delphi study [Brender *et al.* 1999] identified as important area in future health informatics research the study of the context for application of decision support systems, i.e. how to integrate knowledge-based decision support with the clinical process. We can say, that it is not only the clinical process, but the health care processes overall, that are related to computerised decision support, depending on the case, and these processes we need to consider and understand.

We have emphasised that evaluation is important and integral to the development of decision support systems. Respectively, evaluation is important in relation to this study, there is now a need to evaluate the work we have presented, the ontology and the outlined framework. Generally any new derivation should be somehow better than its best challenger. This kind of comparison has to be performed in every study [Järvinen 1999]. Therefore, we compare our result, the new theory or approximation of a new theory, with the old theories, and study the sensitivity of our results to describe and explain the phenomenon under study. We will evaluate our work in the next subsections.

4.3.1 On the ontology

An extended conceptualisation for a decision support system was developed in this study. Does the presented ontology enable us to master such aspects of decision support systems that the other studied approaches are not able to cover? Does it provide us with better support for development, perhaps with better usability? And further, how valid and applicable is our ontology of a DSS?

We used as our reference the Ives, Hamilton and Davis model. This model has been largely applied on information systems science, and it has proven to be useful in understanding problems. It has been widely accepted in the IS research community to classify past research and to give directions for the future (Lyytinen 1987, Järvinen 1999), though it is rather abstract and not operationalised.

The presented conceptualisation of a DSS applying the Ives, Hamilton and Davis-model gives us possibilities to cover those aspects of DSS's which have not been covered by earlier IS-based or AI-based approaches. The contextual aspects of domain, application and knowledge are covered. When the focus is moved to the direction of these issues, it means that domain and application characteristics, as well as knowledge creation and sharing aspects, are considered at every phase of development.

The presented conceptualisation gives better support for development because from it follows that a more thorough problem analysis will be performed. The environment and the domain are considered right from the beginning of the development. A more thorough problem analysis, on the other hand, means that more qualified resources may be required for development. However, with inclusion of domain, application and knowledge aspects in the development of a DSS, we are more likely to be able to produce more successful systems because their contextual environment is taken into consideration in system development, and the characteristics of the environment are reflected in the system characteristics. One part of the IS development environment is the user-system integrated behaviour which puts the focus on the aspects of the integrated knowledge environment of the user.

When considering how valid and applicable our conceptualisation of a DSS is, we need to think about how the variables were found and how they were selected. When studying a particular phenomenon, we are trying to find the most essential features and relationships of that phenomenon. There are always a large number of factors affecting the part of reality under study. In practise we cannot include all those factors or variables into our study. In selecting the variables into consideration, we make far-reaching decisions [Järvinen 1999].

The variables that have been selected for our conceptualisation of a DSS originate from three sources. First, they have been selected from the known variables of the Ives, Hamilton and Davis [1980] model. Second, variables have been selected on the basis of our analysis of how a decision support system has been defined in areas of information systems science and artificial intelligence. This analysis found that some variables that are not present in the Ives, Hamilton and Davis model should be included in the decision support system model in health informatics. Third, the results from our case studies (I-V) confirm the need to include these additional variables. On this basis we have decided that the environmental and contextual variables do have an influence on the phenomenon under study, i.e. on development and evaluation of decision support systems in health informatics. In this kind of decision, there is, of course, a possibility that we have forgotten some important variable that has not shown up during this experiment. We have classified this variable as unknown: it is interpreted as not having a big enough influence on the phenomenon under study. If the situation occurs that an unknown variable becomes known, then the conceptualisation should be modified on this basis, or new experiments carried out. This possibility would be a call for further research on the application of the ontology we have presented on DSS development and evaluation.

4.3.2 Framework applicability and limitations

Based on the ontology of a DSS, we have outlined a framework for the development and evaluation of decision support systems in the health informatics context. This framework applies a process-oriented paradigm for development, considers essential variables, and enables integration of development and evaluation. How far is this developed framework applicable? Where are the limits of its applicability?

The framework presented in Table 5 is a skeleton which relates evaluation to the development phases and suggests where to pay attention in evaluation at each of these phases. An important aspect in the framework is its process orientation, in which no exact path from requirements to final executable code is foreseen, but rather, a system's development is a process of re-design, re-implementation and re-evaluation, and at each phase a system version can be (re-)evaluated in the context of the user. What is new about this development and evaluation framework is that we have connected the variables from our DSS conceptualisation to this development framework. These variables should be seen as guidance on what issues and aspects should be considered during the development of an information system. Concerning decision support systems, we anticipate that consideration of the environment variables would improve results in the development of decision support systems in a contextual environment.

The presented framework is not intended as a complete theoretical construction. Referring to Weick [Weick 1995] we can say that theory approximations take at least four forms: (1) General orientations in which broad frameworks specify types of variables people should take into account, without any specification of relationships among those variables; (2) Analysis of concepts in which concepts are specified, clarified and defined but not interrelated; (3) *Post-facto* interpretation in which *ad hoc* hypotheses are derived from a single observation, with no effort to explore alternative explanations or new observations; and (4) empirical generalisations in which an isolated proposition summarises the relationship between two variables but further interactions are not attempted. While none of these four is a complete theory, they can, however, serve as means for further development.

Our framework for research and development of decision support systems falls in category (1): it points out variables that should be considered. The applicability and limits of the framework follow from this broad orientation. With the step of complementing the framework with the ontology we have developed, we proceed a little bit further to defining concepts and relationships between concepts. However, we have not operationalised our framework and it has not been applied on real DSS development and evaluation. So far, empirical results on applicability and limits do not exist.

4.3.3 Health informatics perspective

How does the presented ontology and framework contribute to health informatics research and practice?

To find answer to the question above, we first look at the ontology and the framework in relation to the tower model of health informatics presented earlier in this study in Figure 7 [Friedman 1995]. To recap the structure of the tower: At the first level, model formulation, models are developed for knowledge and information; at the second level, systems are built that use the developed models; at the third level, system installations are delivered into health care organisations and environments; and at the fourth, study of effects level, effects and impacts of systems on reasoning, on organisation and delivery of health care are studied.

Our DSS ontology builds a model of a DSS in health informatics and contributes to theory formulation in health informatics. The framework for development and evaluation is interrelated to the other levels, i.e. to levels two, three and four. The framework does not, however, provide a methodology for development, installation or evaluation, but rather gives guidance on how to find a way in climbing up the tower.

When developing a decision support system in health informatics practice, important aspects to be considered are health care organisational context, and domain, application and knowledge aspects, as discussed earlier in this study. The ontology and framework help in drawing attention to these aspects during the problem formulation, development and evaluation phases.

Next, we look at our results in relation to the design science intent of information technology as discussed in [March and Smith 1995]. They describe that in information technology artefacts are created that serve human purposes. Design science products are of four types: constructs, models, methods and instantiations. Constructs or concepts form the vocabulary of the domain, a model is a set of propositions or statements that express relationships among the constructs or concepts. A method is a set of steps, an algorithm or a guideline, used to perform a task. An instantiation is the realisation of an artefact in its environment. Building, or development, is a process of constructing an artefact for a specific purpose. Evaluation is a process of determining how well the artefact performs.

In this study we have produced the following research findings, in the terms of [March and Smith 1995]: DSS conceptualisation represents constructs, DSS conceptualisation (ontology) represents also a model as it describes the relationships between the defined constructs. The framework for development and evaluation can be interpreted as a method, or rather as a guideline. Instantiations, realisations as artefact are not represented in our findings.

The DSS conceptualisation identifies relevant constructs and thus presents a vocabulary of a DSS in health informatics domain. Are the created constructs better than the old ones, i.e. those presented in conceptualisations in IS and AI areas? Our DSS conceptualisation gives a wider and a more dense classification for concepts than the other conceptualisations discussed, and its application domain is health informatics. The DSS conceptualisation is also a model which describes the situation as problem and solution statements. Is this model better than the other ones discussed, e.g. the abstraction paradigms of AI? The DSS conceptualisation represents essential concepts and gives a structure to the presentation. The model can be used to build instantiations. If the model helps both user and developer to better understand the problem at hand, or the developer to develop better instantiations based on better understanding, and the user will have a useful and usable system at his/her disposal, then we can obviously judge that the utility is better than that of the model we are comparing with. The development and evaluation framework seen as a guideline, does it have better utility than the other methods discussed? We may answer to this in two ways. The method's potential utility is better because it forces all concerned to consider aspects that need to be considered to achieve good results. On the hand, potential utility may be deemed poor, as use of this method requires more work, more qualified resources.

The presented ontology for a DSS in health informatics and the outlined framework for development and evaluation, contain more variables and viewpoints than those presented and discussed earlier in this study. Thus they may guarantee a more thorough analysis of the problem case, but they do have negative consequences, too. While forcing a deeper analysis, we increase the work of system developers and users. This might mean that system's development requires higher intellectual qualifications and a larger consumption of human resources. These requirements may not be easily met in a real-life situation. However, these results in their part support our earlier findings that education and training in health informatics is an important issue to be covered.

5. Conclusions

5.1 RESULTS

Our major goals in this study were to present a conceptualisation for a decision support system in health informatics and to outline a framework for development and evaluation of DSSs in health informatics. We were searching for answers to the following questions: What are decision support systems in health informatics context? Are they somehow different from information systems or knowledge based systems? Do we need a special conceptualisation for a decision support system in health informatics as compared to those presented in related research areas? Is health informatics a special field for application of decision support systems? Do we need special approaches and methodologies to develop and evaluate decision support systems in health care context?

Our answers to the questions are:

- Decision support systems in health informatics context are information systems or knowledge based systems that are developed to support decision making in an organisational context. They may be developed using information systems science approaches, or artificial intelligence based approaches, or other, e.g. management information systems approaches.

- We do need a broad conceptualisation for a decision support system in health informatics, because the contextual aspects (e.g. health care environment and domain, knowledge and application characteristics) have to be considered with a system. We presented an extended conceptualisation for a DSS that draws attention to the contextual aspects of development and domain, knowledge and application characteristics of the system. The conceptualisation builds on health informatics as a scientific discipline, both as theoretical and applied science, where health care, medicine and informatics provide the subject and general methods are applied to produce knowledge and systems.

- Decision support systems development and evaluation does not need special methodologies as compared to those used in information systems and artificial intelligence. But it is important to focus on all variable groups throughout the whole development and evaluation phases. A process-oriented paradigm with adaptive, incremental development seems to be a better candidate for decision support systems than the traditional life-cycle development methodology as it supports learning and communication during development. However, we do not have empirical results on application of this development approach.

Our major results achieved with this study are summarised:

- Connection of environment, process and information subsystem variables to a decision support system conceptualisation,
- Inclusion of domain, knowledge and application to the decision support system variables,
- Outlining a framework for development and evaluation of decision support systems in health informatics context.

5.2 IMPLICATIONS, FUTURE RESEARCH

The results of this study have some implications on research and development of decision support systems in health informatics:

- Focus on decision support systems development is proposed to be moved from a task ontology towards a domain ontology.
- Systems development is seen as a sense-making process, where system designer helps the user to understand the system. This is needed to achieve an understanding of the domain problem and the purpose of the planned system.
- Consideration of environment, process and system variable groups during development and evaluation, and especially focusing on environmental variables, means that we are not any more developing isolated decision support systems, but systems that support decision making in health care organisational context, and in the user's domain, knowledge and application context.
- Development and evaluation of information technology products, e.g. decision support systems, in health informatics requires information and knowledge on the domain and methods of health informatics. Research and practice are the

essential components of health informatics, and dialogue between these two is needed, and they both should be included in health informatics education.

We have concentrated in this study on decision support systems from conceptualisation, development and evaluation perspectives. These issues were raised by our case studies and the literature review. The issues of human interaction, i.e. the user's and use perspectives, have not been that much covered in this study. Further research would be needed with these issues in relation to the presented ontology.

Further work would also be needed with operationalising the presented ontology and framework. Developed constructs, models and guidelines have not yet been applied on a real decision support systems development and evaluation, and thus we would require to focus on empirical research and development using the presented constructs and guidelines.

References

[Aarts and Peel 1999] Aarts J and Peel V, Using a desriptive model of change when implementing large scale clinical information systems to identify priorities for further research. Int J of Medical Informatics 56, nos 1-3, 1999, 43-50.

[Adam et al. 1995] Adam F, Murphy C and Fahy M, Cumulative research in decision support systems – A practical example. In: Doukidis G, Galliers B, Jelassi T, Kremar H and Land F (eds.), Proceedings of the 3rd European Conference on Information Systems, Greece, 1995, 1221-1233.

[Aliferis and Miller 1995] Aliferis CF and Miller RA, On the heuristic nature of medical decision support systems. Methods of information in Medicine, 34, 1995, 5-14.

[Alter 1980] Alter S, Decision support systems: Current practice and continuing challenges. Addison-Wesley, Reading, Mass, USA, 1980.

[Armstrong 1973] Armstrong RM, Belief, truth and knowledge. Cambridge University Press, Cambridge, UK, 1973.

[Auramo 1999] Auramo Y, Construction of an expert system to support otoneurological vertigo diagnosis. Tampere University, Department of Computer Science, Report A-1999-2, Tampere, 1999.

[Autio et al. 1991] Autio K, Kari A and Tikka H, Integration of knowledge-based system and database for identification of disturbances in fluid and electrolyte balance. Int J Computer Methods and Programs in Biomedicine, vol 34, nos 2-3, 1991, 210-210.

[Bailey 1990] Bailey JE, Development of an instrument for the management of computer user attitudes in hospitals. Methods of Information in Medicine, 1, 1990, 51-56.

[Bailey and Pearson 1983] Bailey JE and Pearson SW, Development of a tool or measuring and analysing computer user satisfaction. Management Science, 5, 1983, 530-545.

[Bansler 1989] Bansler J, Systems development research in Scandinavia: Three theoretical schools. Scandinavian Research in Information Systems 1, 1989, 3-20.

[Barahona and Christensen 1994] Barahona P and Christensen JP (eds.), Knowledge and decisions in health telematics. IOS Press, Technology and Informatics 12, 1994.

[Benbasat and Dhaliwal 1989] Benbasat I and Dhaliwal JS, A framework for the validation of knowledge acquisition. Knowledge Acquisition 1989; 1: 215-233.

[Benner 1984] Benner P, From novice to expert. Excellence and power in clinical nursing practice. Addison Wesley, USA, 1984.

[Berg and Goorman 1999] Berg M and Goorman E, The contextual nature of medical information. Int J of Medical Informatics 56, nos 1-3, 1999, 51-60.

[Blackler 1995] Blackler F, Knowledge, knowledge work and organisations: An overview and interpretation. Organisation Studies, vol 16, no 6, 1995, 1021-1046

[Blum 1986] Blum B, Clinical information systems. Springer Verlag, USA, 1986.

[Boland and Tenkasi 1995] Boland RJ and Tenkasi RV, Perspective making and perspective taking in communities of knowing. Organisation Science 6, no 4, 1995, 350-372.

[Bonczek et al. 1981] Bonczek RH, Holsapple CW and Watson AB, Foundations of decision support systems, Academic Press, NY, 1981.

[Brender 1997] Brender J, Methodology for asssessment of medical IT-based systems in an organisational context. IOS Press, The Netherlands, 1997.

[Brender et al. 1999] Brender J, McNair P, Nöhr C, Research needs and priorities in health informatics – early results of a Delphi study. In: Kohol P (ed.), Proceedings of Medical Informatics Europe 99 (MIE’99), IOS Press, 1999, 191-196.

[Brown and Duguid 1991] Brown JS and Duguid P, Organisational learning and communities-of-practice: Toward a unified view of working, learning and innovation. Organisational Science 2, no 1, 1991, 40-57.

[Cesnik 1999] Cesnik B, The future of health informatics. Int J of Medical Informatics, vol 55, 1999, 83-85.

[Chandrasekaran 1986] Chandrasekaran B, Generic tasks in knowledge-based reasoning: High level building blocks for expert systems. IEEE Expert, Fall 1986, 23-30.

[Clancey 1985] Clancey W, Heuristic classification. Artificial Intelligence, December 1985, 27, 289-350.

[Clarke et al. 1994] Clarke K, O'Moore R, Smeets R, Talmon J, Brender J, McNair P, Nykänen P, Grimson J and Barber B, A methodology for evaluation of knowledge based systems in medicine. Int J Artificial Intelligence in Medicine, vol 6, no 2, April 1994, 107-122. Reprinted in: van Bemmel JH and McCray AT (eds.), IMIA Yearbook of Medical Informatics 1995. Schattauer Verlagsgeschellshaft, Stuttgart, 1995, 513-527.

[Coiera 1997] Coiera E, Guide to medical informatics, the Internet and telemedicine. Arnold, UK, 1997.

[Daft and Lengel 1986] Daft RL and Lengel RH, Organisational information requirements, media richness and structural design. Management Science 32, no 5, 1986, 554-571.

[Dahlbom 1995] Dahlbom B (ed.), The infological equation. Essays in Honor of Börje Langefors. Gothenburg Studies in Information Systems, Report no 6, Gothenburg University, Sweden, 1995.

[Davis 2000] Davis GB, Information systems conceptual foundations: Looking backward and forward. In: Baskerville R, Stage J and DeGross JI (eds.), Proceedings of the IFIP TC8 WG8.2 International Working Conference, Kluwer Academic Publishers, The Netherlands, 2000, 61-82.

[deDombal 1978] deDombal FT, Medical diagnosis from a clinician's point of view. Methods of Information in Medicine 1978, 17, 28-35.

[deDombal 1996] deDombal FT, Assigning value to clinical information - major limiting factor in the implementation of decision support systems. Methods of Information in Medicine, 35, 1996, 1-4.

[Degoulet and Fieschi 1997] Degoulet P and Fieschi M, Critical dimensions in medical informatics. Int J of Medical Informatics 44, 1997, 21-26.

[Dupuits and Hasman 1995] Dupuits FMHM and Hasman A, User satisfaction of general practitioners with HIOS+, a medical decision support system. Int J Computer Methods and Programs in Biomedicine, 2, 1995, 183-188.

[Dutta 1996] Dutta A, Integrating AI and optimisation for decision support: A survey. Decision Support Systems 18, 1996, 217-226.

[Eierman et al. 1995] Eierman MA, Niederman F and Adams C, DSS theory: A model of constructs and relationships. Decision Support Systems, 14, 1995, 1-26.

[Elstein et al. 1979] Elstein AS, Shulman LS and Sprafka SA, Medical problem solving. An analysis of clinical reasoning. Harvard University Press, USA, 1979.

[Evans and Patel 1989] Evans DA and Patel VL, Cognitive science in medicine. Biomedical modeling. MIT Press, USA, 1989.

[Floyd 1987] Floyd C, Outline of a paradigm change in software engineering. In: Bjerknes G, Ehn P and Kyng M (eds.), Computers and democracy. A Scandinavian challenge. Avebury Gower Publishing Company, UK, 1987, 193-210.

[Floyd et al. 1989] Floyd C, Reisin FM and Schmidt G, Steps to software development with users. In: Ghezzi C and McDermid JA (eds.), Proceedings of the 2nd European Software Engineering Conference, Lecture Notes in Computer Science 387, Springer Verlag, Berlin, 1989, 48-64.

[Forsström and Eklund 1994] Forsström J and Eklund P, Using neuro fuzzy tool to support medical decision making. A case study on the diagnosis of myocardial infarction. In: Carlsson C, Järvi T and Reponen T (eds.), Multiple paradigms for artificial intelligence. Finnish Artificial Intelligence Society publications STeP-94, Turku, 1994, 75-80.

[Forsythe et al. 1992] Forsythe DE, Buchanan BG, Osheroff JA and Miller RA, Expanding the concept of medical information: An observational study of physician's information needs. Computers and Biomedical Research 25, 1992, 181-200.

[Friedman 1995] Friedman CP, Where is the science in medical informatics? JAMA 2, no 1, 1995, 65-67.

[Friedman and Wyatt 1997] Friedman CP and Wyatt JC, Evaluation methods in medical informatics. Springer Verlag, New York, 1997.

[George and Tyran 1993] George JF and Tyran CK, Expert systems and organisations: Predictions and evidence. Accounting, Management and Information Technology, vol 3, no 3, 1993, 173-189.

[Giddings 1984] Giddings RV, Accommodating uncertainty in software design. Comm of ACM, May 1984, vol 27, no 4, 429-435.

[Giuse and Miller 1995] Giuse DA and Miller RA, Potholes in the road to professionalism in medical informatics. Methods of Information in Medicine 1995, 34, 434-440.

[Gorry and Scott Morton 1971] Gorry GA and Scott Morton MS, A framework for management information systems. Sloan Management Review, vol 13, no 1, 1971, 55-71.

[Grimson et al. 1996] Grimson W, Brender J, Grimson J, Groth T, Hermanson B, Yearworth M, Wade V, Specifying an open clinical laboratory information system. Int J Computer Methods and Programs in Biomedicine 50, 1996, 95-109.

[Guarino 1997] Guarino N, Understanding, building and using ontologies: A commentary to "Using explicit ontologies in KBS development". Int J Human and Computer Studies, 46, 1997, 293-310.

[Guarino 1998] Guarino N, Formal ontology and information systems. In: Guarino N (ed.), Formal ontology in information systems. IOS Press, Amsterdam, 1998, 3-15.

[Hafner et al. 1989] Hafner AW, Filipowicz AD, Whitely WP, Computers in medicine: Liability issues for physicians. Int J Clin Monit Comput 6, 1989, 185-194.

[Hasman 1997] Hasman A, Challenges for medical informatics in the 21st century. Int J of Medical Informatics, 44, 1997, 1-7.

[Hasman and Sosa 1995] Hasman A and Sosa M, Review of the state of the art in education and training of health informatics in Europe. Int J Computer Methods and Programs in Biomedicine, vol 48, nos 1-2, 1995, 183-188.

[Hasman et al. 1995] Hasman A, Albert A, Wianwright P, Klar R and Sosa M, Education and training in health informatics in Europe. State of the art, guidelines, applications. IOS Press, Amsterdam, Technology and informatics 25, 1995.

[Hasman et al. 1996] Hasman A, Haux R and Albert A, A systematic view on medical informatics. Int J Computer Methods and Programs in Biomedicine, 51, 1996, 131-139.

[Haux 1995] Haux R, Medical informatics: A key to the future of medicine and health care? Methods of Information in Medicine 1995, 34, 454-457.

[Haux 1997] Haux R, Aims and tasks of medical informatics. Int J of Medical Informatics 44, 1997, 9-20.

[Hayes-Roth 1995] Hayes-Roth B, Agents of stage: Advancing the state of the art of AI. Stanford University, Knowledge Systems Laboratory, Report no KSL-95-50, 1995.

[Heathfield and Wyatt 1993] Heathfield HA and Wyatt J, Philosophies for the design and development of clinical decision support systems. Methods of Information in Medicine, 1993, 32, 1-8.

[Heathfield and Wyatt 1995] Heathfield HA and Wyatt J, The road to professionalism in medical informatics: A proposal for debate. Methods of Information in Medicine 1995, 34, 426-433.

[Hirschheim and Klein 1989] Hirschheim R and Klein H, Four paradigms of information systems development. Communications of the ACM, vol 32, no 10, 1989, 1199-1216.

[Hoc et al 1995] Hoc J-M, Cacciabue PC and Hollnagel E (eds.), Expertise and technology. Cognition and human-computer cooperation. Lawrence Elbaum Associates, USA, 1995.

[Hoyer et al. 1988] Hoyer D, Thayer C, Eurlings F, Castadena G, Talmon J, Enning J, Vissers M, Nykänen P, Roine R, Final market study report on tools, methods and services for assessment of IT in health care. Deliverable D05.3, of the VATAM (Validation of Telematic Applications in Medicine, HC1115) project, EU R&D Programme TAP (Telematic Applications Programme), 1998.

http://www.makropilotti.fi/ Satakunta Macro Pilot: Social Services and Health Care Development Project, July 6, 2000.

http://www-vatam.unimaas.nl/ Welcome to VATAM; your guide to validation of Health Telematics Applications, July 6, 2000.

[Iivari 1991] Iivari J, A paradigmatic analysis of comtemporary schools of IS development. European Journal of Information Systems, vol 1, no 4, 1991, 249-272.

[Iivari and Hirchheim 1996] Iivari J and Hirschheim R, Analysing information systems development: A comparison and analysis of eight development approaches. Information Systems, vol 21, no 7, 1996, 551-575.

[Ikonen et al. 1983] Ikonen J K, Rokkanen P U, Grönroos P, Kataja J M, Nykänen P, deDombal F T and Softley A, Presentation and diagnosis of acute abdominal pain in Finland: A computer-aided study. Annales Chirurgiae et Gynaecologiae 72, 1983, 332 -336.

[Ives, Hamilton and Davis 1980] Ives B, Hamilton S and Davis GB, A framework for research in computer-based management information systems. Management Science 26, no 9, 1980, 910-934.

[Järvinen 1999] Järvinen P, On research methods. Opinpaja Oy, Tampere, 1999.

[Kaplan 1997] Kaplan B, Addressing organisational issues into the evaluation of medical systems. Journal of American Medical Informatics Association, vol 4, no 2, Mar/Apr 1997, 94-101.

[Kassirer et al. 1982] Kassirer JP, Kuipers BJ and Gorry GA, Toward a theory of clinical expertise. American Journal of Medicine, 73, 1982, 251-258.

[Keen 1980] Keen PGW, Decision support systems: Translating useful models into usable technologies. Sloan Managament review, vol 21, no 3, 1980, 33-44.

[Keen 1997] Keen PGW, Let's focus on action not info. http://www2.computerworld.com/home/cwlaunch.nsf/launch?RealForm&/home/print9497.nsf/ November 17, 1997.

[Keen and Scott Morton 1978] Keen PGW and Scott Morton MS, Decision support systems. An organisational perspective. Reading, Mass. Addison-Wesley, 1978.

[Keravnoe and Washbrook 1989] Keravnoe E and Washbrook S, Deep and shallow models in medical expert systems. Int J Artificial intelligence in Medicine, 1989; 1: 11-28.

[Kinnunen and Nykänen 1999] Kinnunen J ja Nykänen P, Terveydenhuollon tietotekniikan arviointi. In: Saranto K and Korpela M (eds.), Tietotekniikka ja tiedonhallinta sosiaali- ja terveydenhuollossa. WSOY, Helsinki, 1999 (in Finnish).

[Klein and Mehlie 1990] Klein M and Mehlie LB, Knowledge-based decision support systems with applications in business. John Wiley et Sons, UK, 1990.

[Klemola and Norros 1995] Klemola U-M and Norros L, An orientation-based approach to the anaesthetist’s activity: Realistic versus objective orientation. In: Norros L (ed.), Proceedings of the 5th European conference on cognitive science approaches to process control. VTT Symposium publications 158, Espoo 1995, 213-226.

[Koivukangas and Valtonen 1995] Koivukangas P and Valtonen H, Hyvinvointiklusteri. Sosiaali- ja terveydenhuollon palvelujärjestelmän, teollisuuden ja tutkimuksen verkko. STAKES Raportteja 181, 1995 (in Finnish).

[Korpela 1993] Korpela L, Computer-aided decision making for epilepsy and sleep disorders. Acta Neurologica Scandinavica, Supplementum no 144, vol 87, Copenhagen 1993.

[Korpela 1994] Korpela M, Nigerian practice in computer systems development. A multidisciplinary theoretical framework applied to health informatics. Helsinki University of Technology, Research report A31, 1994.

[Kulikowski 1995] Kulikowski CA, History and development of artificial intelligence methods for medical decision making. In: Bronzino JD (ed.), The Biomedical Engineering Handbook, CRC Press and IEEE Press, USA, 1995, 2681-2698.

[Ledley and Lusted 1959] Ledley RS and Lusted LB, Reasoning foundations of medical diagnosis. Science 1959, 130: 9-211.

[Lee and O'Keefe 1994] Lee S and O'Keefe RM, Developing a strategy for expert systems verification and validation. IEEE Transactions on systems, man and cybernetics, 24, no 4, 1994, 643-655,

[Lenat 1975] Lenat D B, The ubiquity of discovery. Artificial Intelligence 9, 3, 1975, 257-285.

[Little 1970] Little JDC, Models and managers: The concept of decision calculus. Management science, vol 16, 1970, 466-485.

[Lorenzi 1999] Lorenzi N, IMIA Working group 13: Organisational impact of medical informatics. Int J of Medical Informatics 56, nos 1-3, 1999, 5-8.

[Lorenzi et al. 1997] Lorenzi NM, Riley RT, Blyth AJC, Southon G and Dixon BJ, Antecedents of the people and organisational aspects of medical informatics. Review of the literature. JAMA, no 2, Mar/Apr 1997, 79-93.

[Lundsgaarde 1987] Lundsgaarde H P, Evaluating medical expert systems. Social Science and Medicine 24, 10, 1987, 805-819.

[Lyytinen 1987] Lyytinen K, Different perspectives on information systems: Problems and solutions. ACM Computing Surveys 19, no 1, 1987, 5-46.

[March and Smith 1995] March ST and Smith GF, Design and natural science research on information technology. Decision Support Systems 15, 1995, 251-266.

[Maria et al. 1994] Maria BC, Lambay FA, Dankel IID, Chakravarthy S, Tufekci S, Marcus R, Kedar A, XNEOr: Development and evaluation of an expert system to improve quality and cost of decision making in neuro-oncology. JAMA, 1994, 678-683.

[McDermott 1988] McDermott J, Preliminary step toward a taxonomy of problem-solving methods. In: Marcus S (ed.), Automatic knowledge acquisition for expert systems. Kluwer Academic Publishers, Boston USA, 1988, 225-254.

[Miller 1994] Miller RA, Medical diagnostic decision support systems - past, present and future: A threaded bibliography and brief commentary. JAMA, 1, 1994, 8-27.

[Miller et al. 1982] Miller R A, Pople H E and Myers J D, Internist-1: An experimental computer-based diagnostic consultant for general internal medicine. N Eng J Med 307, 1982, 468-476.

[Mirchandani and Pakath 1999] Mirchandani D and Pakath R, Four models for a decision support system. Information and Management 35, 1999, 31-42.

[Moore and Chang 1980] Moore JH and Chang MG, Design of decision support systems. Database, vol 12, nos 1 and 2, Fall 1980, 8-14.

[Musen 1988] Musen M A, Generation of model-based knowledge acquisition tools for clinical-trial advice systems. PhD-thesis. Stanford University, USA, 1988.

[Musen 1999] Musen MA, Scalable software architectures for decision support. Methods of Information in Medicine 38, 1999, 229-238.

[Newell 1982] Newell A, The knowledge level. Artificial Intelligence 18, 1982, 87-127.

[Newell and Simon 1976] Newell A and Simon H, Computer science as an empirical inquiry: Symbols and search. (1975 ACM Turing Award Lecture), Comm ACM 19, 3, 1976, 113-126.

[Nilsson 1974] Nilsson N, Artificial intelligence. In: Rosenfeld JL (ed.), Information Processing 1974, North-Holland, Stockholm, 778-901.

[Nonaka 1994] Nonaka I, A dynamic theory of organizational knowledge creation. Organisation Science vol 5, no 1, February 1994, 14-37.

[Nonaka and Takeuchi 1995] Nonaka I and Takeuchi H, The knowledge creating company. Oxford University Press, New York, 1995, USA.

[Nuutila et al. 1991] Nuutila P, Irjala K, Viikari J, Forsström J, Välimäki M, Nykänen P and Saarinen K, Clinical value of the decision support system for the assessment of thyroid function. In: Adlassnig KP, Grabner G, Bengtsson S and Hansen R (eds.), Proceedings of Medical Informatics Europe 1991, Lecture Notes in Medical Informatics 45, Springer Verlag, Berlin 1991, 389-393.

[Nykänen 1990] Nykänen P (ed.), Issues is evaluation of computer-based support to clinical decision making. Report of the SYDPOL-5 Working Group. Oslo University, Institute of Informatics, Research Report 127, 1990.

[Nykänen and Saranummi 2000] Nykänen P and Saranummi N, Clinical decision systems. In: Bronzino JD (ed.), The Biomedical Engineering Handbook. CRC Press and IEEE Press, USA 2000, 183-1...183-8.

[Nöhr and Andreassen 1995] Nöhr C and Andreassen S, Theory and practice of medical informatics professionally balanced in problems and projects. Methods of information in medicine 1995; 34: 446-449.

[ODP 1993] ISO/IEC JTC/SC21/WG7. ODP Basic Reference Model of ODP – Parts 1 to 4. New York: ISO/IEC. 1993: IOS/IEC/JTC1/SC21/WG7 N10746-1 to 4.

[O'Moore 1990] O’Moore RR, Decision support based on laboratory data. Methods of Information in medicine 27, 1990, 187-190.

[O'Moore 1995] O’Moore RR, The conception of a medical computer system. In: van Gennip EMSJ and Talmon JL (eds.), Assessment and evaluation of information technology in medicine. Studies in health technology and informatics 17, IOS Press, Amsterdam, 1995, 45-49.

[O'Moore et al. 1996] O’Moore R, Groth T, Grimson W, Boran G, The openlabs project. Int J Computer Methods and Programs in Biomedicine 50, 1996, 85-86.

[Pedersen et al. 1990] Pedersen SA, Jensen PF and Nykänen P, Epistemological analysis of deep medical knowledge in selected medical domains. Public report of the KAVAS-2 (A2019) project of Telematic systems in Health Care, Commission of the European Communities, 1990.

[Pelkonen et al. 1994] Pelkonen P, Korpinen L, Frey H and Järvinen P, Headache expert - A medical decision support system. In: Carlsson C, Järvi T and Reponen T (eds.), Multiple paradigms for artificial intelligence. Finnish Artificial Intelligence Society publications STeP-94, Turku, 1994, 90-94.

[Pesonen et al. 1994]Pesonen E, Juhola M, Ikonen J, Eskelinen M, A tentative automatic diagnosis of acute abdomen using neural networks. In: Carlsson C, Järvi T and Reponen T (eds.), Multiple paradigms for artificial intelligence. Finnish Artificial Intelligence Society publications STeP-94, Turku, 1994, 59-66.

[Pitty and Reeves 1995] Pitty DC and Reeves PI, Developing decision support systems: A change in emphasis. Int J Computer Methods and Programs in Biomedicine, vol 48, nos 1-2, 1995, 35-38.

[Polanyi 1966] Polanyi M, The Tacit Dimension, Routledge & Kegan Paul, London, UK, 1966.

[Pothoff et al. 1988] Pothoff P, Rothemund M, Schwebel D, Engelbrecht R and van Eimeren W, Expert systems in medicine. Possible future effects. Int J of Technology Assessment in Health Care, no 4, 1988, 121 – 133.

[Power 1999] Power DJ, Management information and decision support systems. http://dss.cba.uni.edu/dssresourcesbook, December 1999.

[Power and Karpathi 1998] Power DJ and Karpathi S, The changing technological context of decision support systems. In: Berkeley D, Widmeyer G, Prezillion P, Rajkovic V (eds.), Context sensitive decision support systems. Chapman & Hall, USA, 1998, 41-54.

[Protti 1995] Protti DJ, The synergism of health / medical informatics revisited. Methods of Information in Medicine 34, 1995, 441-445.

[Pryor 1995] Pryor AT, Hospital information systems: Their function and state. In: Bronzino JD (ed.), The Biomedical Engineering Handbook, CRC Press and IEEE Press, USA, 1995, 2615-2622.

[Ramoni et al. 1990] Ramoni M, Stefanelli M, Magnani L, Barosi G, An epistemological framework for medical knowledge based systems. Pavia University, Research report RIDIS-41-90, July 1990.

[Reisman 1996] Reisman Y, Computer-based clinical decision aids. A review of methods and assessment of systems. Int J of Medical Informatics, vol 21, no 3, 1996, 179-197.

[Saranto and Korpela 1999] Saranto K and Korpela M (toim.), Tietotekniikka ja tiedonhallinta sosiaali- ja terveydenhuollossa. WSOY, Helsinki, 1999 (in Finnish).

[Scherrer 1995] Scherrer J-R, “The road to professionalism in medical informatics: A proposal for debate” a reaction to Heathfield’s paper. Methods of Information in Medicine 1995, 34, 450-453.

[Schreiber et al. 1993] Schreiber A, Wielinga B, Breuker J (eds.), KADS: A principled approach to knowledge based systems development. Academic Press, London, 1993.

[Scott Morton 1971] Scott Morton M, Management decision systems: Computer-based support for decision making. Harvard University Press, Boston, 1971.

[Shortliffe 1976] Shortliffe EH, Computer-based medical consultations: MYCIN. Elsevier Publishing Company, USA, 1976.

[Shortliffe 1987] Shortliffe EH, Computer programs to support clinical decision making. JAMIA 258, 1987, 61-66.

[Shortliffe 1989] Shortliffe EH, Testing Reality, The Introduction of Decision Support Technologies for Physicians. Editorial. Methods of Information in Medicine 28, 1989, 1-5.

[Shortliffe 1993] Shortliffe EH, Will the adolescence of AI come of age? Artificial Intelligence in Medicine, vol 5, no 2, 1993, 93-106.

[Shortliffe et al. 1990] Shortliffe EH, Perreault L E, Wiederhold G and Fagan L M, Medical Informatics: Computer applications in health care. Addison-Wesley, New York, 1990.

[Simon 1981] Simon HA, The sciences of the artificial. MIT Press, Cambridge, 1981.

[Southon et al. 1997] Southon FCG, Sauer C and Dampney CNG, Information technology in complex health services: Organisational impediments to successful technology transfer and diffusion. JAMA, vol 4, no 2, Mar/Apr 1997, 112-124.

[Sox et al. 1988] Sox HC, Marshal AB, Higgins MC, Marton KI, Medical decision making. Butterworths, USA, 1988.

[Sprague 1980] Sprague RH, A framework for the development of decision support systems. MIS Quarterly, vol 4, no 4, 1980.

[Sprague and Carlson 1982] Sprague RH and Carlson ED, Building effective decision support systems. Prentice Hall, Englewood Cliffs, NJ, 1982.

[Sprague and Watson 1989] Sprague RH and Watson HJ (eds.), Decision support systems. Putting theory into practice. Prentice Hall, USA, 1989.

[Stohr and Konsynski 1992] Stohr EA and Konsynski BR, Information systems and decision processes. IEEE Computer Society Press, USA, 1992.

[Summers and Carson 1995] Summers R and Carson ER, Non-AI decision making. In: Bronzino JD (ed.), The Biomedical Engineering Handbook, CRC Press and IEEE Press, USA, 1995, 2660-2667.

[Talmon et al. 1999] Talmon JL, Enning J, Castadena G, Eurlings F, Hoyer D, Nykänen P, Sanz F, Thayer C, Vissers M, The VATAM guidelines. Int J of Medical Informatics 56, nos 1-3, 1999, 107-115.

[Tikkala et al. 1994] Tikkala A, Juhola M and Laine M, Simulation of aphasic naming errors: Properties and result analysis of the method. In: Carlsson C, Järvi T and Reponen T (eds.), Multiple paradigms for artificial intelligence. Finnish Artificial Intelligence Society publications STeP-94, Turku, 1994, 67-74.

[Timpka 1994] Timpka T, The health care crisis: End or beginning of the heyday of medical decision support systems? Methods of Information in Medicine, 33, 1994, 332-335.

[Timpka and Johansson 1994] Timpka T and Johansson M, The need for requirements engineering in the development of clinical decision support systems: A qualitative study. Methods of Information in Medicine 33, 1994, 227-233.

[Turban 1988] Turban E, Decision support and expert systems. Management Support Systems. Macmillan Publishing Company, First edition, USA, 1988.

[Turban 1993] Turban E, Decision support and expert systems. Management support systems. Macmillan Publishing Company, Third edition, USA, 1993.

[Turban and Aronson 1998] Turban E and Aronson J, Decision support systems and intelligent systems. Prentice Hall, USA, 1998

[Valluy et al. 1989] Valluy L, Nykänen P, Rantanen J, Salmela J, Grönroos P and Lumio J, An approach to combine knowledge validation and evaluation with development in medical AI. In: Linnainmaa S. and Jaakkola H. (eds.) Proceedings of the Second Scandinavian Conference of Artificial Intelligence, Tampere University of Technology, Tampere 1989, 865-875.

[van Bemmel and Musen 1997] van Bemmel JH and Musen MA (eds.), Handbook of Medical Informatics. Bohn Stafleu Van Loghum, The Netherlands, 1997.

[van der Loo et al. 1995] Van der Loo RP, van Gennip EMSJ, Bakker AR, Hasman A, Rutter FFH, Evaluation of automated information systems in health care: An approach to classifying evaluative studies. Int J Computer Methods and Programs in Biomedicine 48, 1995, 45-52.

[van Gennip and Lorenzi 1999] van Gennip EMSJ and Lorenzi NM, Results of discussions at the IMIA 13 and 15 working conference. Int J of Medical Informatics, vol 56, nos 1-3, 1999, 177-180.

[Vapola et al. 1994]Vapola M, Simula O, Kohonen T and Meriläinen P, Monitoring of an anaesthesia system using self-organising maps. In: Carlsson C, Järvi T and Reponen T (eds.), Multiple paradigms for artificial intelligence. Finnish Artificial Intelligence Society publications STeP-94, Turku, 1994, 55-58.

[Warner 1995] Warner HR, Medical informatics: A real discipline ? JAMA, vol. 2, no 4, 1995, 207-214.

[Weick 1995] Weick KE, What theory is not, theorising is. Administrative Science Quarterly 40, no 3, 1995, 385-390.

[Vimarlund et al. 1999] Vimarlund V, Timpka T, Hallenberg N, Health care professional's demand for knowledge in informatics. Int J of Medical Informatics 53, 1999, 107-114.

[Winograd and Flores 1986] Winograd T and Flores F, Understanding computers and cognition. A new foundation for design. Addison-Wesley, USA, 1986.

[Wyatt 1987] Wyatt J, The evaluation of clinical decision support systems: A discussion of the methodology used in the ACORN project. In: Fox J, Fieschi M and Engelbrecht R (eds.), Proceedings of the Artificial Intelligence in Medicine, Lecture Notes in Medical Informatics 33, Springer Verlag, Berlin, 1987, 15-24.

[Wyatt and Spiegelhalter 1990] Wyatt J and Spiegelhalter D, Evaluating medical expert systems: What to test and how? Medical Informatics 15, 1990, 205-217.

[Välimäki 1996] Välimäki K, Sosiaali- ja terveydenhuollon tietoteknologian hyödyntämisstrategia. Sosiaali-ja terveysministeriön työryhmämuistioita 27, 1996 (in Finnish).

Papers I-V

PAPER I

Pirkko Nykänen and Pirjo Nuutila,
Validation and evaluation of a system for thyroid disorders.
Int J Expert Systems with Applications, vol 3, 1991, 289-295.

PAPER II

Pirkko Nykänen, Gerard Boran, Hilde Pince, Kevin Clarke, Michael Yearworth, Jos L Willems, Rory O'Moore,
Interpretative reporting and alarming based on laboratory data.
Clinica Chimica Acta 222, 1993, 37-48.

PAPER III

Pirkko Nykänen, Shamsul Chowdhury and Ove Wigertz,
Evaluation of decision support systems in medicine.
Int J Computer Methods and Programs in Biomedicine, 34, 1991, 229-238.

PAPER IV

Brender Jytte, Talmon J, Nykänen Pirkko, McNair Peter, Demeester Michel and Beuscart Regis,
On the evaluation of system integration.
In: EMSJ van Gennip and JL Talmon (eds.), Assessment and evaluation of information technologies. IOS Press, Amsterdam, 1995, 189-208.

PAPER V

Pirkko Nykänen, John Enning, Jan Talmon, Dirk Hoyer, Ferran Sanz, Christine Thayer, Risto Roine, Marieke Vissers, Fabienne Eurlings, Inventory of validation approaches in selected health telematics projects. *Int J of Medical Informatics 56, 1999, 87-96.*

ISBN 951-44-4874-X
ISSN 1457-2060