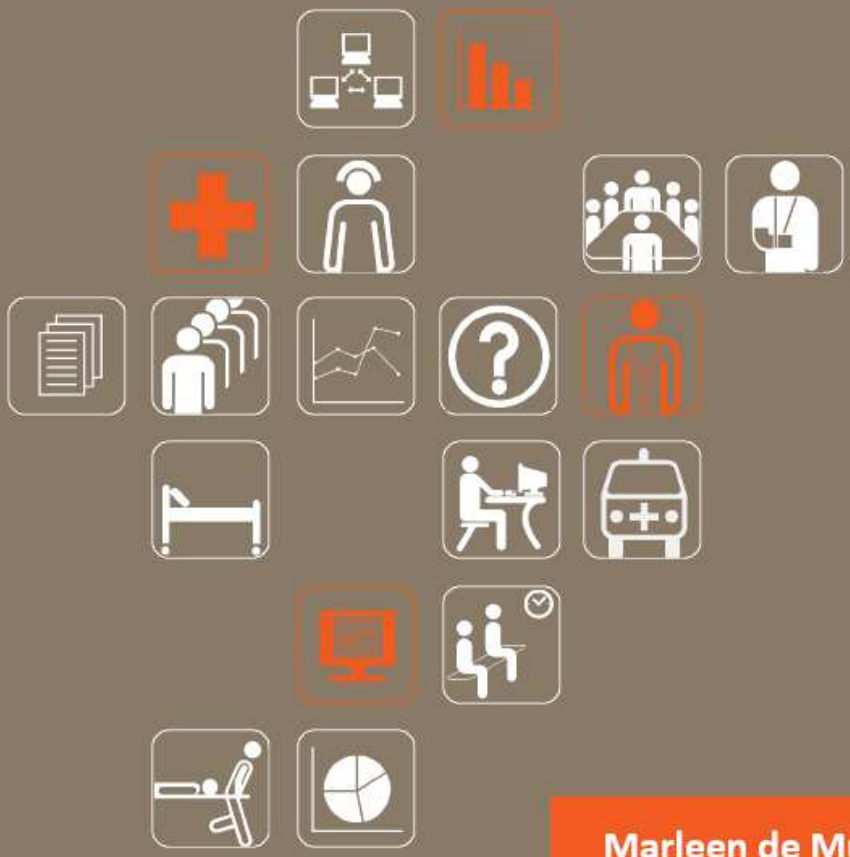
Managing Quality in Health Care

Involving Patient Care Information Systems and Healthcare Professionals in Quality Monitoring and Improvement



Marleen de Mul

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Involving Patient Care Information Systems and Healthcare Professionals in Quality Monitoring and Improvement

Het managen van kwaliteit in de gezondheidszorg

Over het betrekken van patiëntenzorginformatiesystemen en zorgprofessionals bij het bewaken en verbeteren van de kwaliteit

Proefschrift

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Publications

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Chapter 6

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Chapter 1 Introduction

It is no longer possible to ignore the issue of quality in health care. Care institutions strive to provide all patients with effective, efficient, safe, timely, patient-centered care. Increased attention for quality is also found in discussions regarding use of information and communication technologies (ICTs) in health care processes. In these discussions, ICT is almost always brought into a direct relationship with improving the quality of care, especially ICTs that professionals use directly in patient care, which are also known as patient care information systems (PCIS) [1-4]. Well-known quality reports from the US Institute of Medicine, such as To Err is Human [5] and Crossing the Quality Chasm [6], identify the lack of and delay in ICT development and implementation as a partial explanation for quality problems in existing healthcare systems. Both reports call for wider-scale implementation of PCIS, such as electronic patient records and computerized physician order entry (CPOE) systems. Such systems purportedly bring an end to illegible or lost records and forms, and thus reduce the number of mistakes made. Moreover, intelligent PCIS, such as decision support systems, would potentially support the care professional in making a diagnosis and determining the best course of action, which would make medical practice both more evidence-based and efficient [see also 3,7-10]. A large number of research projects also reflect these positive effects, but the conclusions of systematic reviews are mixed [11-16].

Although ideas regarding the quality-improvement potential of ICT are actually already decades old, limitations to realizing quality improvement are still evident in different areas of practice. ICT implementation does not necessarily automatically lead to better quality care. Much coordination work is necessary in order to integrate ICT systems in the complex setting of daily care [17-19]. Moreover, research has shown that ICT can also introduce new quality problems [20,21]. Koppel et al [20], for example, discuss the mistakes that can be attributed to use of CPOE systems, such as those related to the alteration or cancellation of medication orders, absence of a good overview of medication, and incorrectly-selected patients. Illegible handwriting is occasionally replaced by ‘illegible’ computer screens. Furthermore, the implementation of PCIS can be a problematic process: implementation takes much longer than is planned, costs more than is budgeted and, in the end, does not meet content needs and expectations [1,22-26].

Quality leaders have high expectations for ICT in health care. Despite the aforementioned critical reflections on ICT implementation, the predominant line of thinking in the field continues to suggest that there has been insufficient investment in ICT. In the Netherlands, for example, there is still much hope surrounding a national electronic patient record. In addition to the direct quality gains that are expected from, for example, the electronic patient record, quality leaders are also interested in the indirect gains that systems can deliver. Namely, making quality measurable as part of a broader-ranging process of quality *management* [27-34].

Quality management

"Quality begins with the intent, which is fixed by management."
W. Edwards Deming – Out of the Crisis [35]

The roots of quality management run deep. The origin is generally sought in the industrial revolution, because quality management is a result of the standardization of labor. Wilson and Goldschmidt [36] go even farther back in time, suggesting that quality management began with process controls around the building of pyramids in ancient Egypt. Modern quality management, however, began with the development of weapons during the Second World War. W. Edwards Deming (1900-1993) en Joseph Juran (1904-2008) are considered to be the founders of quality management (primarily known under the name Total Quality Management, or TQM) in post-World War II industrial society. Quality management was once more limited in meaning than it is today. In the past, quality management was about controlling the quality of products and was realized by standardizing entire production processes and implementing structured checks based on pre-determined norms. In this understanding of quality management, quality control also shares origins with Taylor's scientific management (that emerged in the late 19th century), which increased the efficiency of production processes by standardizing and division of labor.

Understandings of the concept quality control have been expanded, partially because of Deming en Juran's progressive insights regarding (total) quality improvement. This development is evident in Juran's works; his first book, which appeared in 1951, is all about quality *control*. His later works (for example, the standard "Juran's Quality Handbook") discuss quality *management*, which, according to Juran, comprises three core activities: quality planning, quality control en quality improvement [37]. Thus, quality control has been transformed from a synonym for quality management to one of several aspects of quality management. Planning, control, and improvement can also be related to post-Taylorian management, which is evident, for example in sociotechnical systems theory – a line of management that focuses on achieving effectiveness through teams that are responsible for carrying out, monitoring, and improving upon a common task [38,39]. The idea of a professional's responsibility to contribute to quality

management was first put forth by a Japanese author, Ishikawa, in his discussion of quality circles [40]. Although this approach was developed for an industrial setting, it has also been applied in health care.

In quality-related disciplines, the different approaches to quality are identified as different generations of quality thinking, which run parallel to the generations that are identified in management theories. The first generation focuses on quality control – guaranteeing a certain minimum standard (e.g. following those standards provided by the International Organization for Standardization, or ISO-norms). The second generation focuses on quality improvement that aligns with existing processes (e.g. using the plan-do-check-act cycle is one example of this generation). Much of the work of Deming and Juran can be placed in this second generation [see also: 41]. The third generation focuses on change and renewal as the results of a paradigm shift (e.g. business process redesign following the principles of patient-centered care). What is interesting about thinking in terms of generations is that it provides justification for change and progression: we must no longer think about controlling and maintaining what is already in place, but also about implementation and renewal. One caveat, however, is that each "preceding" generation has value in the current generation of quality management – even now. Quality must also be maintained, for example, within a redesigned work process that seeks to renew. Third generation quality thinking does not stand alone, but rather contains elements from the first or second generation. For this reason, and because all generations continue to receive attention in quality debates, we could also discuss quality management in terms of trends.

Quality management in health care

> *"Quality is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge."*
> *Institute of Medicine (2001, p.232) [6]*

The ideas put forth by Deming en Juran have been broadly adopted and adapted within health care, but there has also been attention for quality and quality management from within the field itself. Avedis Donabedian (1919-2000) is considered to have laid the foundation for quality and quality management in health care, what he referred to as, "quality assurance" and defined as, "all actions taken to establish, protect, promote, and improve the quality of health care" [42,p.xxiii]. Donabedian's primary contribution to quality in health care was theory formation [43-46]. For example, one of his early works from the 1960's introduced the now classic distinction between the structure, process, and outcome of health care [43]. The most renowned of today's quality leaders is Donald M. Berwick, a pediatrician, who is probably best known through his work for the American Institute of Healthcare Improvement, for which he is

currently the President and Chief Executive Officer. His first work on quality of care appeared in the late 1980's, when he argued that health care was in need of continuous improvement [27,47,48]. More recently, he has called for more fundamental healthcare system changes (on a global level), which he sees as necessary in light of current practice, where existing organizational structures are failing to deliver an acceptable level of quality [49,50].

The most acute reason for increased attention for quality and quality management in health care has been the continuous increase in costs since the 1960's [38]. Such surmounting costs have led, in many Western countries, to increased government surveillance of health care practices and, consequently, to a system where healthcare institutions strive for more efficacious practice. In the 1970s and 1980s, quality management in health care was a rather static concept, with quality being operationalized in systems that consisted of procedural norms and were used primarily by technical and support departments (e.g. norms for continuous temperature control of blood serums in a laboratory). In the Netherlands, the quality of medical professionals was controlled through (the admissions requirements for) medical education and the scientific/professional societies. In Dutch hospitals, special committees were established to address specific quality needs (for example, the incidents committee, the pharmaceuticals committee and the autopsy committee). Legislation made the establishment of some committees obligatory, while in other areas this was left to the professional groups. Hospital specialists had their own tools for addressing quality issues, such as audit, visitation and peer review [51].

Beginning in the 1990s, the influence of western governments in health care began to increase. In the Netherlands, a number of important health care-related laws were passed, such as the Medical Treatment Agreements Act (1995), the Care Institutions Quality Act (1996) and the Individual Health Care Professions Act (1997) – the medical disciplinary law had been in place since 1930. At that time, attention for evidence-based medicine (EBM) was also on the rise. EBM brought guidelines, protocols and other forms of standardization to both the institutional and national levels. A historic moment in Dutch governmental supervision was reached with the introduction of the basic set of hospital performance indicators, which first appeared in 2002. Other nationally-endorsed indicator sets for different care sectors, such as the long-term and mental healthcare sectors, soon followed. The Ministry of Health, Welfare and Sport (MinVWS) and various care-related umbrella organizations joined forces in 2003 to initiate health care quality improvement projects and develop national programs for hospitals and sub-sectors of care. A large number of organizations participate in breakthrough projects, wherein Deming's quality cycle is used to achieve measurable quality improvement in a short period of time, through the implementation of standards and transfer of best practices. A recent development within hospitals has been increased governance based on outcome, rather than process. This is linked to changing, more output-oriented financial structures, such as diagnosis-related groups,

and an increased responsibility for care units to keep quality and costs in balance with one another. Quality management becomes an attribute of individual departments and these are held accountable for (and through) outcome-related indicators. Through these developments, quality management becomes more integrated at the point of care.

Quality management by healthcare professionals

"Management of specialist care ideally integrates the medical goals for individual patients with the actual possibilities in terms of time and resources and evaluates the actual practice."
Niek Klazinga (1996, p.30) [51]

Donabedian places the healthcare professional at the heart of quality health care. First of all, quality of care refers to the technical and relational aspects of the care provided in the doctor-patient relationship. Secondly, external to that relationship are the more general quality demands, for which the management of an organization is also responsible. In operationalizing "quality of care", thus, Donabedian clearly takes the point of care and professional performance as points of departure. From this starting point, it is then logical that quality assessment is a task to be carried out by healthcare professionals themselves [52,53].

According to Klazinga, however, the concept of quality management leads to confusion among care professionals: "Management of a hospital is usually associated with the hospital administration, and hospital administration is mostly associated by physicians with constrains on their professional activities. It is quite understandable that the notion 'management of specialist care' is not very well recognized as a professional responsibility." [51,p.30].

This is also attributable to the dual structure of hospitals in the past, whereby doctors and managers not only had separate responsibilities, but also used their own tools for quality management. The medical profession is responsible for monitoring the content of daily health care practice, as well as how individual professionals function. Education, professional scientific societies, renewable registration, disciplinary committees, guideline development and peer review are all instruments used to this end [51]. Managers, by contrast, are held responsible for the organization as a whole and for creating the best circumstances for care professionals to do their jobs. Quality models and quality systems such as ISO, as well as the INK management model, were all made for managers. At the end of the 20th century, many quality-related activities in health care organizations, especially those related to supra- and inter-departmental quality issues, fell under the responsibility of specialized "quality" staff. These were either healthcare professionals with additional tasks, or non-clinical staff who provided support for the managers.

Still, the confusion about quality management and the responsibility of healthcare professionals illustrates that quality management by healthcare professionals is not self-evident. However, the developments in both information technology and quality management place healthcare professionals in a situation where it is not a question of whether or not they *have* a role in quality management, but rather about *how* that role is shaped: by themselves, by the information (systems) they use and by the organization. Related to these issues is the current interest in 'clinical governance', which is advocated and studied extensively in, for example, the United Kingdom and Australia [54,55].

Information

"Information is the life-blood of quality assessment (as it is of practice also)."
Avedis Donabedian (2003, p.78) [42]

Quality managers (whether they are care professionals or managers) need data for researching quality-related problems and measuring the effects of changes [27-30]. According to Blumenthal and Epstein, "quality improvement is … a painstaking and time-consuming business that depends for its success at least as much on our ability to modify the behavior of patients, purchasers, and providers of care as it does on the collection of good data about performance" [53,p.1330]. Quality managers have always used a variety of methods to collect the data that is necessary to their purposes. This has often meant "re-cycling" existing data, for example, administrative and billing information. For some quality issues, additional research has been conducted (e.g. employee satisfaction studies) or a sample of medical records was analyzed.

The quality management literature primarily addresses questions of how data must be transferred into quality-relevant information. Clinical data (data from the point of care) is the preferred choice of collected data because of its proximity to the actual care process. Quality gurus and authors of handbooks on quality management, however, are critical about such use of a (paper) medical record: "Even though the medical chart should be the primary source of clinical data, it is not the perfect source for QI data" [38,p.96]. The quality of (the data in) the medical record is considered to be insufficient. "…we know that the medical record is often incomplete in what it documents, frequently omitting significant elements of technical care and including next to nothing about the interpersonal process. Furthermore, some of the information recorded is inaccurate because of errors in diagnostic testing, in clinical observation, in clinical assessment, in recording, and in coding. Another handicap is that any given set of records usually covers only a limited segment of care, that in the hospital, for example, providing no information about what comes before or after." [52,p.1747].

Attention for ICT in quality debates is, as is mentioned above, relatively new. Many quality books were written in a period when information technology was on the rise, but was not yet an integral part of health care practice. In the Medline database, it is only since 2001 that we see a sharp increase in publications with combined use of keywords such as “quality in health care” and “medical informatics applications”. This rise was concurrent with the appearance of the first Institute of Medicine reports on these topics. Expectations for ICT in health care are high: "because information management will continue to improve, the future of quality in the health care delivery system is particularly bright” [38]. One expectation is that electronic medical records comprise more (and more complete) data/information than paper records. Another is that extracting this data for quality management purposes is also easier than reviewing paper records. In this regard, reference is often made to the – now classic – article, ‘Using information systems to measure and improve quality’, written by David Bates and colleagues, renowned in the area of medication safety [28]. This 1999 article provides examples of quality management activities using data from a PCIS (in this case, an electronic patient record) implemented in the Brigham and Women’s Hospital in Boston. In these examples, the authors distinguish three levels: (1) direct gains in quality through provision of extra information and decision support; (2) indirect gains in quality though identification of unintended events; and (3) overt measuring of quality aspects (for example, guideline adherence). The article places a strong emphasis on the value of measuring for the eventual improvement that is intended. Measuring is an essential step in quality management and information technology has the potential to play a large role in this process.

Aim and research questions

Many parallels can be identified in the concurrent developments in quality management and ICT, especially given changes over the past few years, where the words ICT and quality have increasingly been used in the same contexts. Much research has been done on the improvements in care processes and outcomes that have (or have not) been achieved through the introduction of ICT, as well as about how care professionals use ICT in practice. The intricacies of the mutual relationship between ICT and quality management – and the position of care professionals in this relationship – however, have hardly been addressed in structured research. This thesis hopes to fill this gap. The aim of this thesis is to explore how quality management is shaped by work practices and professional routines on the one hand and ICT developments on the other.

The following research questions are addressed:

1. How are information and communication technologies – specifically, patient care information systems – used in care organizations for quality management purposes?

2. What does this use mean for the role of healthcare professionals in quality management?
3. How is synergy between quality management, ICT use and the work of healthcare professionals achieved?

In order to answer these questions, a sharp focus on the three interrelated concepts – ICT, quality management, and the work of health professionals – is necessary. This thesis focuses on those ICT systems that have a direct relationship with patient care, in that they are used by healthcare professionals at the point of care. Throughout the text, the term patient care information systems (PCIS) is used to refer to the collective body of applications being researched. The best-known example of a PCIS is the electronic patient record (EPR). There are many different types of EPR, but they share a commonality: that care professionals are able to consult the record during contact with a patient (for example, in the examination room) for any information about that patient that is already registered within the care system (general practice or hospital), as well as to add new information.

In this thesis, quality management is defined as the work that is carried out and the techniques that are implemented in order to measure, monitor, and improve the quality of care. The focus is on quality management carried out by care professionals, either close to the point of care or using data from the point of care. Where I discuss care professionals, I am referring primarily to doctors, nurses and paramedic employees of hospitals and integrated care organizations. This focus on the care professionals working in these settings has consequences for the types of ICT and forms of quality management that are discussed in this thesis. The thesis looks primarily at quality management that takes place at the departmental or hospital level, using data from departmental and hospital information systems or systems that are designed for integrated care. In the context of primary care, where many professionals work alone or in small-scale partnerships, quality management can have a much different character. In the concluding chapter I will shortly discuss the relevance of my research for other contexts of care (e.g. primary care).

Theoretical Framework

In this thesis, a sociotechnical approach is used to answer the research questions listed above. The concept “sociotechnical” is used in different fields, including management theory and ICT research, where it has multiple meanings and interpretations. Because this thesis is situated at the intersection of (quality) management and ICT, it is relevant to explain “sociotechnical” from the perspectives of both disciplines, and to make explicit my own position in relation to these.

The best-known use of the term sociotechnical comes from business administration, where it forms a reaction to the line of thinking known as scientific management. Scientific management, of which Frederick Winslow Taylor is the founder, departs from the assumption that work processes must be intricately studied, in order to determine who is best suited to carry out which task. Through a division of labor, tasks can be standardized, or taken over by machines, leading to increased efficiency. Through the years, Taylor's ideas on scientific management have received much criticism because of the biased focus on efficiency, the desire for extreme mechanization and the lack of attention for the employee as a person. The sociotechnical approach is rooted in research from the Tavistock Group, which analyzed work processes in English coal mines in the 1950s. This group of sociologists discovered that a strict division of labor and too much mechanization led to a decrease in productivity. Workers were actually most effective, and most satisfied, when working in teams on a complex task with shared responsibilities. The researchers from the Tavistock Group demonstrated that the "technical" and the "social" are tightly interlinked with one another in a sociotechnical system. This form of sociotechnics is defined as: "the study and explanation of the way that division of labor and technical instrumentation are related to one another and to a given work environment, determine the possibilities for the production of internal and external functions, and lead to the application of knowledge by the design and redesign of production systems." [39]. The rules of development for effective organizations are also derived from this theory. The insights have been of great value for implementing new forms of work, human resources management, and the development of (information) technology [see e.g. 56].

The intricate relationship between "the social" and "the technical" is also a point of departure in the social sciences. The "sociotechnical approach" opposes technological determinism, which proposes that technology is an external actor that enters society and develops autonomously. For example, in Science and Technology Studies (STS), it is suggested that persons and technologies are in continuous interaction, whereby they also mutually shape one another. In STS, technology is more broadly interpreted – it is not only machines or apparatuses, but also ways of working, protocols, etc. In the field of information technology in health care, the term "sociotechnical approach" was re-introduced by Berg [18], who has also published STS research on the respective roles of paper and electronic medical records [57] and on technological decision-support [17].

This thesis utilizes the sociotechnical approach to ICT, as introduced by Berg. However this thesis also builds upon his insights by adding another dimension of study: in addition to the relationship between care professionals and ICT, quality management is also a subject of study. In this thesis, both ICT and quality management are considered sociotechnical phenomena in and of themselves. As ICT, quality management is also a type of interplay between people (care professionals, quality functionaries, and managers) and technology (data from medical records,

guidelines, indicators, and information systems) [58]. This is shown, for example, in research of De Bont et al. on the use of databases for governance of medication prescriptions by general practitioners [59].

In the sociotechnical approach, much emphasis is placed on researching the workplace and work practices. Anselm Strauss and other sociologists first unraveled the concept of care work in the book 'Social organization of medical work', which first appeared in 1984 [60]. On the basis of ethnographic research, the authors show that the work of doctors, nurses, and other employees of a care organization is complex and varied. It demands cognitive, technical, relational, empathic and organizational skills in order to "manage the patient trajectory", as they summarize medical work. Care professionals use apparatuses and techniques (machine work), must constantly be alert and pay attention to the safety of both the patient and themselves (safety work), regulate pain and discomfort (comfort work), be prepared to reassure the patient in cases of angst or uncertainty (sentimental work), and ensure coordination between actors for different parts of the care trajectory (articulation work).

Moreover, intertwined with these different types of work is communication with others and proper documentation in medical records, forms and files (information work). Berg's subsequent research has shown how articulation work and information work are supported by the (electronic) medical record. Berg [57] shows that information technology, much like the paper medical record, is a reading and writing artefact that fulfils an accumulating and coordinating function. By accumulation, Berg means that data from different sources are brought together in one record. This gives the healthcare professional a quick overview of the information that is necessary to make treatment decisions. The possibilities for ICT to present data both numerically and graphically, and to indicate changes over time, make the accumulation role of the electronic record stronger than that of a paper record. The coordinating role becomes evident when a patient is followed in a trajectory that spans a longer period of time. If the patient has appointments at more places, whereby he or she is treated by more care professionals, then the record provides insights into all of the actions that have been carried out, or that must be planned. Also in such cases, the electronic record reinforces the coordinating function, for example through allowing access to the record from more places at the same time. These roles of ICT, however, are not self-evident; the properties of ICT often appear to be in conflict with medical work, for example with respect to the level of standardization that the ICT requires, versus the (often) ad hoc nature of medical work. Berg argues, thus, that there is an issue of actively searching for synergy in practice [61]. Only then is ICT capable of strengthening medical work, whereby new activities, such as quality management, become possible.

In the contributions from both Strauss and Berg to medical sociology, the primary focus of analyses is direct care work in interaction with the patient. Doctors, however, also have tasks that extend beyond the level of individual patients. I argue here that quality work is an

additional component in the work of care professionals. The quality management work that was addressed earlier in this introduction is integrated with medical work. Strauss gives a prime example of this in his analysis of safety work carried out by professionals. Strauss describes in detail the processes related to administering a Swan Ganz catheter to a patient in the cardiac intensive care unit [60,p.82-84]. He shows that the tasks of doctors and nurses are coordinated such that they minimize the chance of risks. He also describes a process of constant reflection with respect to the performance of professionals, in order to identify mistakes and to test possible points of improvement. Furthermore, Strauss shows that safety is not only an issue of professional skill or of (failed) technique, but also of the organization of care. The observations from 1984 now form part of the shared understanding in the systems approach to patient safety as put forth by the IOM [5,6]. Strauss focused his ethnographic work on the description of medical work carried out at the lowest level (the doctor-patient relationship), but one can read between the lines that care professionals are also attuned to a higher level, that of processes and trajectories; in other words, the level of quality management. This is the reason that insights from sociologists, such as Strauss, regarding medical work are so important for researching quality management in health care: by examining medical work, one sees quality work. Moreover, where quality work comes into contact with ICT, there is the possibility of a tension between the two that is similar to that identified in relation to ICT and medical work. Therefore, the search for synergy between healthcare professionals and their work, quality management and ICT calls for a sociotechnical approach.

Methods

The choice for a sociotechnical approach to ICT and quality management also determines the methods employed in this research. Three basic principles of sociotechnical research are relevant in this regard [62-64]:

1. A thorough research of work practices. In this respect, sociotechnical research is about describing and analyzing what happens – what persons and technologies actually do. This actuality is often very different from the procedures that are described on paper, and from the technical description of an information system. An in-depth picture of work practice is only possible with qualitative methods, such as ethnography.
2. View users as a co-constructor of the technology [65]. In other words: see a constant exchange between a technique and its users, also during development processes. Users fulfill, for example, different roles: they are often involved in specifying technological functionalities, but also in testing phases and actual use in practice. Thus, during the 'implementation phase', technologies are further developed to align with the working practices of the users, leading to – what is called – participatory design [66].

3. Use insights from research during the development of the technology. The use of continuous formative evaluation and feedback from scientific insight to the work practice/research setting contributes to adjustments of the system and its implementation. Some sociotechnical research can even be classified as action research, whereby the researcher intervenes in the development process by being a part of it, too [e.g. 67,68].

The empirical data in this thesis stems from three research projects:

1. Evaluation of a PCIS developed for use in the emergency department of the Erasmus MC, Rotterdam;
2. Evaluation of two ICT-supported care innovation projects in Dutch eye care: the glaucoma project in Rotterdam initiated by the Eye Hospital and the diabetic retinopathy project in Zwolle initiated by Isala Klinieken;
3. Implementation and diffusion of a PCIS for the intensive care department of the Erasmus MC, Rotterdam.

Although these are three different projects, they nonetheless have several similarities. All three projects are about implementing ICT at the point of care in order to support care professionals, while at the same time targeting goals in the area of quality management. Data from the ICT systems was used to measure quality. These quality management goals only took shape in the course of the projects, however, because the ICT was initially developed with the sole purpose of being used at the point of care.

In the research projects, I used a combination of qualitative and quantitative methods, also known as mixed-methods research [69]. The term focuses on the combination of qualitative and quantitative research methods, which are more and more used in the fields of both medical informatics and health services research (including quality research) [62,63,70-72]. As Stoop shows in his thesis on the evaluation of ICT, the use of quantitative analysis can add depth to the qualitative analysis [70]. Stoop pleads for increased use of combined methods, whereby, ideally, the quantitative data is discussed in interviews and the results of interviews are used to interpret quantitative data. I used (participant) observation, interviews, and document analysis as qualitative research techniques and complemented this with analyses of the data from paper and electronic medical records and databases. The methods are further described in the individual chapters of this thesis.

Although there are important similarities between my research and a mixed methods approach, the distinction between qualitative and quantitative does not do justice to the research presented here. Information systems, most especially, the PCIS, played a central role in my research. The information systems were both objects of research and sources of data. By

analyzing the data from the systems, I could also observe and experience how ICT-supported quality management was given shape in the research projects. Quantitative research with PCIS data fulfils, thus, a double role: it is valuable in and of itself, but it turns into qualitative material when it is used during participant observation.

Outline

Chapter 2 primarily addresses the possibilities of quality management using ICT in intensive care. The purpose of this literature review is to present the wide range of quality management activities that are performed using (data from) PCIS, and discuss the issues related to ICT-supported quality management, such as data quality. The review shows that there is much activity in the area of quality management: measuring and reporting indicators, supporting quality improvement projects and tracking mistakes. Yet, quality management is still a complex interplay between people and technology. Individuals play an important role in defining quality, in translating data from the point of care into quality information, and in taking action on the basis of the results. Although the review focuses on research in ICUs, there findings also apply to other hospital departments and quality management on a hospital level.

While chapter 2 draws a picture of all topics of this thesis, in chapters 3 and 4, I take a step back and confine my attention to the ICT domain. In these chapters the sociotechnical approach to ICT development is introduced. Both chapters describe ICT systems that are used at the point of care. Chapter 3 analyzes the development of the PCIS that is used in the intensive care department of the Erasmus MC and further addresses the implementation of the systems and the local changes that have been made. During the implementation process, the value of a sociotechnical approach was revealed. By utilizing the analysis of work processes, the system aligned better with the wishes of the users with respect to content; by working with a multi-disciplinary project team, the implementation could be incorporated in different departments; and, the iterative process of developing, implementing and evaluating, created a cycle of learning. This chapter is based on an article from 2004, and consequently presents the state of implementation at that time. Since then, the PCIS has been upgraded several times, and implemented in other ICUs in the hospital. Additionally, a compatible system from the same vendor was implemented in the Operating Rooms and Post Anesthesia Care Unit.

Chapter 4 analyzes the development of a clinical data warehouse in the Erasmus MC. The PCIS used in the intensive care units served as the primary data source, and was supplemented with data from the hospital information system (HIS). Once again it becomes clear that the development of ICT, together with quality management, is an iterative process in which the different end-users (doctors, nurses, managers and researchers) play an important role. During

the development of this system, a method was used that allowed users to define in their own terms which 'key process indicators' should be included in the data warehouse. Because this chapter discusses the same PCIS that was discussed in chapter 3, this brings us full circle: a PCIS, implemented at the point of care, evolves to a data source for quality management.

In chapters 5 through 7, the sociotechnical perspective is further developed. Chapter 5 describes the techniques that are used in the glaucoma screening project in Rotterdam. This refers to a form of telemedicine, where eye care customers are screened in the store by an optometrist for the eye disease glaucoma. The results of the screening (patient information, including an image of the eye) were evaluated in the hospital. In this chapter, I discuss the effectiveness and efficiency that was reached in this project. Chapter 6 builds upon the discussion of the eye care project in chapter 5 and addresses the question of what is necessary for achieving an optimal collaboration with respect to division of tasks and information technology. This chapter demonstrates how standardization is used in the two screening projects (glaucoma and diabetes, respectively) in order to create a fit between ICT and its users. In both projects, quality management is carried out using data from the PCIS. Chapter 5 is a quantitative study, while chapter 6 uses qualitative data. The articles show that more than one story can be told about quality improvement projects. Because of the different research questions and methodology, these chapters give different messages about the success of the glaucoma screening project. Based on the quantitative measures the project is efficient and effective; the qualitative data shows that the success of the project depends on another indicator: the flexibility of standards.
Chapter 7 uses both quantitative and qualitative methods to examine the completeness of paper records in the emergency department. Data items that are necessary for a national register of trauma patients are often missing from the paper record. This is one reason that hospital management wanted to switch to an electronic registration system. Analysis of work processes, however, showed that the system is too rigid for the context in which it is used.

Finally, chapter 8 discusses the most important findings of the work presented here and answers the research questions that are listed above.

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Chapter 2 Patient Care Information Systems and Quality Management in Critical Care[1]

Introduction

Due to increased attention for the quality of health care services, managing quality in health care is a topic that receives much attention. Quality management activities can have both an external focus (accountability to patients and society) and an internal focus (reflexivity of medical professionals) [1]. Quality management today encompasses many activities, and is shifting from a task solely belonging to hospital management to one that also involves doctors and nurses [2-4]. In critical care, the debate about quality spans more than two decades [5,6], specifically related to intensive care units. The focus on quality assessment and improvement might be explained by at least two characteristics of intensive care. First the nature of the care process, which is fast-paced and complex, while the patients are particularly vulnerable and often in need of complex and high-risk interventions and medication. For these reasons, the number of adverse events in intensive care units (ICUs) is higher than in other departments [7].

A second characteristic of intensive care that might explain the interest in quality management is that intensive care is very expensive, because it requires highly specialized staff and expensive technology. This situation calls for an efficient use of the ICU resources, and thus for measuring and assuring quality [8]. In many countries, this had led to national benchmarking initiatives and large research projects: The American Project IMPACT, the Netherlands Intensive Care Evaluation, the UK's Intensive Care National Audit and Research Centre Project, and the Australian and New Zealand Intensive Care Society Adult Patient Database [9-12].

Concurrent with this interest in quality of care has been the increasing visibility of information and communication technology (ICT) within health care organizations. IT-related discussions have focused on how these technologies influence the efficacy, efficiency and safety of care delivery. Reports from the US Institute of Medicine, such as "To Err is Human" [13] and "Crossing the Quality Chasm" [14], depict a strong relationship between ICT and quality management in

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care. The subsequent IOM report on patient safety [15] specifically deals with ICT-related issues, such as data standards and reporting infrastructures, and contains a recommendation for the "key capabilities of electronic health records" [16]. Such reports have proven to be strong catalysts for investing in ICT implementation and development in recent years; the implementation of ICT applications such as computerized physician order entry, decision support systems and electronic medical records is now considered to be a prerequisite for quality care.

Moreover, these patient care information systems themselves have evolved the last decades; apart from (clinical and administrative) data storage, many systems provide the users with integrated information, or even decision support. ICT systems are seen as tools to integrate evidence based medicine (e.g. through guidelines and critical pathways) in clinical practice. This makes ICT systems invaluable for knowledge management of health organizations. Intensive care departments were one of the first to use integrated patient care information systems (PCIS), often called clinical information systems or patient data management systems [17,18].

In an often cited article from 1999, David Bates and colleagues distinguish three ways that information systems have an impact on quality of health care [19,p.122]: "first they can be used to directly improve quality, by getting the providers the information and decision support they need when they directly interact with the information system in realtime. Second, efficiency and quality can be further improved by using event monitors to look for asynchronous events and communicate them to providers. Third, it will be possible to perform quality measurement using information systems in ways which will be less expensive yet more comprehensive and reliable than previous methods."

In critical care, and healthcare as a whole for that matter, most research focuses on the first role of IT: the direct impact on the quality of care [20,21]. The second and third roles distinguished by Bates et al. focus more on subpopulations of patients and on the organizational level. This is what we refer to as quality *management*, which is based on data aggregated at the level of patient groups (for example, all patients on ward X, in time frame Y). Because of the changing role of clinical governance, this type of quality management is becoming more and more important. However, while there seems to be much evidence about the direct benefits of PCIS, less is known about the use of PCIS to analyze patient data for adverse events or to measure quality of care.

The aim of this review is to identify types of quality management in critical care, using PCIS, and to discuss the challenges associated with PCIS-supported quality management. Our main focus is on PCIS used in intensive care units.

Methods

Because of the broad research question, a systematic, comprehensive review of the literature is not appropriate. We were interested in exploring the subject, rather than judging (the quality of) the evidence. Therefore, we chose a narrative review format, and a thematic presentation of the results.

This study is based on a literature search that was conducted on Medline in January-March, 2009. The search was restricted to English articles published since 1999. Both general text words and MeSH terms were used for the search, in various combinations (Table 2.1).

Table 2.1. Keywords of the search

Intensive care related keywords	***PCIS related keywords***	***Quality Management related keywords***
Intensive Care Units [MeSH] Intensive care Critical care	Medical records systems; computerized [MeSH] Registries [MeSH] (Clinical) information system Electronic (health / medical / patient) record Data warehouse Information technology Data mining (Patient data) management system	Quality of health care [MeSH] Safety management [MeSH] Quality assessment / assurance / control / improvement / management / monitoring / planning QA assessment Quality measure / indicator Benchmark Performance Adverse events Error reduction Decision support

For the exploration of the types of quality management, we included reviews, as well as studies and case reports, provided that they contained empirical data and a description of PCIS used. We excluded articles that were about other sub domains of critical care than ICUs. We also excluded articles about administrative information systems, research databases or registries that were used separately from the care process (because these are not *patient care* information systems), and articles about stand-alone decision support systems, that were not linked to the regular PCIS (clinical information system or physician order entry system). A manual search was conducted to supplement the automated search. Using the snowball method, we examined articles referenced by other articles, especially core articles that are necessary reference points in the current discussions about PCIS and quality management.

Results

A first, general finding is the types of PCIS used in intensive care units. Three groups of PCIS can be distinguished, although many systems can be classified in more than one group. The first group of PCIS includes those that are used for charting, medical notes, etc. Some ICUs use the hospital information system for charting and other recording activities. However, most automated ICUs have clinical information systems (CIS) or patient data management systems (PDMS) specifically designed for intensive care. A minority of these systems is an electronic copy of the patient chart; nurses must still manually record all real-time data from the monitoring equipment. Other PCIS are connected to the monitors and to the hospital information system for laboratory results [e.g. 22]. The second group of PCIS is computerized physician order entry systems (CPOE). CPOE systems are sometimes integrated in the clinical information system, but they can also be separate systems. Again, some are electronic versions of a paper medication prescription system, while others also provide reminders and decision support. The third group of PCIS used in the ICU is decision support systems. While most decision support is integrated in either the CIS or the CPOE, there are also examples in the literature of stand-alone decision support systems. These systems, however, are not discussed here.

The second general finding of the search is that databases, repositories and patient care information systems cannot easily be separated from one another. In some ICUs, databases are used during patient care to collect real-time patient data for the point of care and for analyzing purposes [23]. This approach was chosen in the cited case because the ICU did not have enough financial resources for a PCIS, but still wanted to be able to measure and monitor quality of care and patient outcomes. The SIC-IR repository, discussed by Golob et al., also served more than one purpose. It was not only a registry for retrospective infection surveillance, but also a PCIS during patient care [24,25]. These two systems are local systems, but some national registration databases seem to fulfill local quality management needs as well. For example, Stow et al. describe the database of Australia, which is not only used for benchmarking ICUs but also for analyzing local trends [12]. The ICUs are taught and stimulated to use the data collected for national reporting also on a local level.

In the subsequent sections, the three roles of Bates et al. will be used as a framework to present studies on the different types of PCIS-supported quality management in intensive care units. The studies discussed in the following paragraphs are also summarized in Appendix 2.1.

First role: Direct impact on quality of care

The provision of complete, timely information and decision support is expected to influence the quality of care directly. Compared to paper ICU records, there is evidence that PCIS improve

efficiency. First, some studies show that data recording takes less time [26,27], although others find no significant difference [28-30]. Second, the ICU record is more complete, for example contain more data elements needed to calculate quality indicators [29,30]. This completeness is, however, not self-evident. In a study from Oniki et al., reminders were used to improve completeness of end-of-shift documentation [31]. Third, the efficiency improvements of CPOE relate to reduced time intervals from the initiation to the completion of pharmacy orders and radiology procedures [32,33].

Another body of literature focuses on *patient safety* issues. Some studies show a reduction of adverse events after the implementation of a PCIS [34]. In one quality collaborative on reducing bloodstream infections it was suggested that the availability and usability of a PCIS was associated with better results [35]. Berger et al. describe a study on nutrition practices, comparing a unit with and without a PCIS, and before and after PCIS implementation [36]. In both units the same paper-based protocol was used, but the PCIS unit achieved an improved nutrition status of their patients. Because, the introduction of the PCIS shortened the time required for assessing nutrient delivery and energy deficiency due to automatic computing, it was easier for the nurses to follow the protocol. Claridge et al. [25] compared the sensitivity and specificity of a registry-system for infections (used real-time as a PCIS) with a traditional infection control team, and concluded that the system detected ventilator-associated pneumonia and catheter-related bloodstream infections with higher accuracy. Thus, infection surveillance can be accomplished without additional resources, while engaging the physicians treating the patient. Most studies on reducing medication errors focus on the effect of computerized physician order entry systems (CPOE) [37,38], although the improvements in pediatric ICUs are small compared to adults [39,40]; an increase in certain types of medication errors, and even mortality, has also been reported [41,42].

Patient safety and *effectiveness* are further improved by using decision support and computerized guidelines [17,43,44]. Rana et al. [45] demonstrate a new evidence based decision algorithm for blood transfusion, incorporated in the CPOE. This system led to a decrease of (inappropriate) blood transfusions and transfusion complications in three ICUs. Since the importance of strict glycaemic control in hospitalized patients has been stressed in the literature [e.g. 46], there have been some examples about the role of patient care information systems and decision support related to glycaemic control. Boord et al. report on the computerized protocol that is part of the CPOE system of a US university hospital [47]. Compared to the pre-implementation phase, when a paper version of this protocol was used, the implementation resulted in a reduction of time to insulin therapy initiation. In addition, more patients were within the target blood glucose range. However, the results of two other studies are less positive. Shulman et al. [48] developed and implemented decision support in a PCIS at a university hospital in the UK. In this computerized decision support system, the nurse inputs the

blood glucose measurement and the current insulin dose into the bedside computer. The decision support system uses this blood glucose value and the previous measurement to derive a new recommended insulin dose. The target blood glucose range was only achieved for a median of 23% of the time that the protocol was used. These authors conclude that the computerized protocol, by itself, is not enough to achieve tight glycaemic control. A study from Rood et al. [49] in a Dutch ICU did find statistically significant differences between the paper-based protocol and the computerized protocol, but these were too small to be clinically relevant. The authors explain this small difference by a cross-over effect during the study. Still, they conclude that computerized protocols may be preferred over a situation where there are no protocols, or just paper-based protocols, for complex therapies such as glycaemic control.

Second role: Tracking adverse events

This role is about patient safety. Because with voluntary reporting, only a minority of errors and adverse events is reported [50], automatic monitoring is seen as a valuable application of information technology. These monitoring systems analyze the databases of PCIS, using previously defined algorithms or triggers. The monitoring can be done retrospectively or in real-time. The latter type generates reminders to the medical staff, turning the system into a clinical decision support system that directly improves patient care (first role). In the last 10 years, the only studies in the ICU containing original data are from Hwang et al. and Pokorny et al. [53,54].

The study of Hwang et al. included ICU patients and patients from general wards in a Korean teaching hospital [51]. The study compared the specificity and positive predictive value of the adverse drug event (ADE) monitor to chart review by a pharmacist. The ADE monitor used data from the hospital information system, and compared laboratory data to medication profiles, discharge diagnoses and other patient information. It generated a list of alerts and corresponding patient data. A pharmacist trained in ADE verification review performed a targeted chart review for the patients who had ADE alerts, in order to assess whether the alert was associated with an ADE. The same pharmacist also performed a chart review for the patients who did not have ADE alerts to identify computer-unrecognized ADEs. The authors concluded that the ADE monitor was able to detect certain types of (serious) adverse events with high accuracy, but that other adverse evens were not detected. The study of Pokorny et al. about detection of nosocomial (hospital-acquired) infection in a Spanish ICU, used the hospital information system as a data source [52]. Three criteria for nosocomial infections were developed and applied to the data of a group of ICU patients that had suffered from nosocomial infections (gold standard). Almost all patients were detected when at least 2 criteria were met. However, the site of infection (urinary, etc.) could not always be determined because this information was missing in the hospital information system. Based on this retrospective study, the researchers proposed the use of the monitoring system in real-time, as an alert system for the hospital infection team.

Third role: measuring quality of care

The third role of PCIS in quality management is their contribution to quality measurement. In the literature we found examples of the (partly) automatic calculation of (nationally endorsed) quality indicators. The ICUs are not only interested in the figures, but they also act on the figures because they use them as a norm for quality of care. Related to this is the group of studies on the assessment of guideline adherence. As a guideline is also a norm, the distinction between these two bodies of literature is not straightforward.

The most widely used quality indicator for intensive care is the standardized mortality ratio, which relates observed death to predicted death. Severity of illness models, such as APACHE IV and SAPS are used to predict mortality for ICU patients. Automatic calculation requires complex algorithms. Junger et al. [53] demonstrate that a 'modified APACHE II score' can be calculated using routinely available PCIS data. Because some data elements were missing for many patients, especially manually entered neurology scores, a true APACHE II score could not be calculated. Today, more advanced PCIS offer 'automatic score calculation', but, as far as we know, the quality of this has not been studied. Still, this automatic calculation can only take place if all data elements are available in the database. Apart from the automatically recorded real-time variables, ICU staff must record other data elements (e.g. type of admission) manually.

Shabot [54] discusses how quality management in the ICU of an American hospital is accomplished with help from the CIS. His article focuses on the calculation of the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) Core measures on ventilator associated pneumonia prevention, stress ulcer disease prophylaxis, deep venous thrombosis prophylaxis, and central line associated blood stream infection. Following adjustments to the PCIS, the data elements for these core measures could be documented (or extracted from readily available data) on a specially designed, structured flowsheet. The severity of illness scores was calculated on a separate server, but the results were transferred back to the PCIS flowsheet. For multi-patient analyses, the data from the PCIS was transferred to a clinical data archive, and from there, to another database. Using complex algorithms, the Core Measures could be calculated on a patient and unit level. The results were tabulated for each ICU on a weekly and monthly basis, and were reported to physician directors, nursing managers and the quality department. The description by Wahl et al. [55] of the system used at a university hospital in the US has many parallels to Shabot. Every day printouts are made for the ICU staff, presenting current core measure status. The number of central line days and ventilator days are automatically calculated, and can be downloaded from the PCIS. In both studies, measuring quality indicators was part of a larger quality improvement project, to reduce nosocomial infections in the ICU. Both articles also report these results, and claim that measuring the quality indicators has resulted in quality improvement.

An example of a study using PCIS data for calculating other quality indicators is the study from Alban et al. on ICU readmission in a university hospital [56]. The researchers found that patients who were re-admitted to the ICU had a significant increase in length of stay and mortality, which was not entirely predicted by the APACHE II and SAPS scores. In the study, patient characteristics and outcomes were extracted from the PCIS of the ICU and hospital length of stay and mortality was extracted from the hospital's data repository. The aim of the study was not to investigate whether PCIS data can be used, but just to use it. The authors do not reflect on the usability or data quality of PCIS data. Hartmann et al. [57] describe using data from the patient data management system for review of antibiotic use in a German university hospital. The researchers conclude that knowing the reason for antibiotic prescription is important for being able to use prescription data from the patient data management system (PDMS) for quality assurance (e.g. outcome analysis). This implies the necessity of making the system more expansive. Also in the study from Rood et al. [49], discussed earlier, the PCIS automatically collected and processed all study data for measuring guideline adherence, such as time intervals between glucose measurements and insulin dosing.

These are just three examples of PCIS data use in practice for calculating quality indicators. Many others were not even included in our search because they were unspecific about the types of PCIS used, or did not even mention PCIS in the article's abstract.

Challenges for PCIS-supported quality management

When analyzing the literature, two fields of discussion emerged. The first discussion is related to measuring quality of care, and the second is related to data quality in PCIS.

The discussion about the calculation of quality indicators, specifically related to severity of illness, is as old as the development of these scoring systems. A central question, even in the current debates, is whether scores such as APACHE and SAPS can be used to compare performance of ICUs, since the same hospital can have a high score for APACHE and a lower score for SAPS at the same time [58]. The use of PCIS for calculation of these scores has placed the discussions on the validity of quality measures in a new perspective. For example, it is known that the sampling frequency of the real-time variables affects the calculation. With a PCIS that is connected to bedside monitor equipment, the frequency at which data elements are stored in the PCIS database is much higher than with manual data entry in a PCIS or paper chart. Consequently, with high sampling frequencies of PCIS the chance is higher that extreme values are tacked and stored. In a Dutch study by Bosman et al., predicted mortality increased by 15-25% when PCIS data was used instead of manual charts [59]. If one ICU has a PCIS and the other has paper charts, can these two ICUs be compared? And even within a single ICU, the sampling frequency affects the figures through time, and might bias the interpretation of the data [60].

Rubenfeld [61] brings other arguments to the discussion of PCIS use for quality management. He favors local use of the data, but for benchmarking and public reporting, he prefers the use of databases designed for this purpose. One of the limitations of PCIS is that only part of the wide range of quality indicators can be measured using PCIS data. For example, structure data is not available in a PCIS, as is patient-centered data, such as patient satisfaction or quality of life measures. As for process and outcome measures, data quality in PCIS may be inadequate or the recording of the data needed for the calculation is too complicated. For example, some of the JCAHO Core measures need binary data (a 'yes' or 'no', recorded in the PCIS), which can easily be computed. For other quality measures, for example those related to septic shock, data recording is more complex, as it requires bedside clinical judgment [55].

Many studies on the usability of PCIS for quality management include aspects of data quality in the study design. For example, Ward et al. [62] conclude that, when compared to other commonly used data sources for clinical research (such as the hospital information system, direct observation or chart review), a commercially available PCIS is an acceptable source of ICU patient data. Especially for the third role, measuring quality of care, not all data is available in a PCIS [53]. Automatic extraction of PCIS data will therefore not result in complete quality data. Arts et al. note in their study on data quality for the Netherlands Intensive Care Evaluation registry (NICE), that data from hospitals that automatically extracted their PCIS was less complete than the data from hospitals that had manually entered the data in the registry's module [10]. This incompleteness was explained by inconsistencies in the locally developed extraction tools, but was also related to the absence of data elements in the PCIS. As Oniki et al. [31] have shown, it can be useful to implement a reminder system to assure that the data needed for quality assessment is complete, accurate and timely.

Discussion

Patient care information systems are built primarily to meet the needs of healthcare professionals in their contact with individual patients. Advocates of using ICT in critical care have always proposed that more uses are possible, most notably pointing at potential for decision support and quality management [14,16,63]. In this review we elaborated on the roles of PCIS in quality management. Although we did not include all available literature and used a relatively short time frame of 10 years, we feel that the most important studies and viewpoints have indeed been discussed. The three roles of Bates et al. offered a good framework to explore quality management in intensive care, although their framework originated from physician order entry and medication safety, while our results reflect a broader use of PCIS.

The amount of literature indicates that IT-supported quality management in intensive care is a topical subject. This can be explained by the relatively long history of ICT developments and quality measurement and improvement in critical care. Especially in recent years, these two fields have merged: new ICT possibilities support real-time decision-making, bringing quality management close to the bedside. The literature gives more examples of 'realtime' quality management and direct quality improvement by PCIS than on the more retrospective types of quality management, such as calculating quality measures or analyzing care trajectories for patient groups. We found only a few studies on the automatic detection of adverse events. Apparently, this topic, which in our opinion holds great promise for learning from errors, has not been explored much in the ICU setting. Still, the articles used in this review, draw a picture of the many shapes of PCIS-supported quality management in intensive care, and give insight into discussions in the field about data quality and performance measures.

Intensive care departments are not the only pioneers in IT-supported quality management. For example, in other parts of critical care, the three roles of ICT can be revealed as well. Querying the databases of anesthesia information management systems and operating room information systems has been reported in several studies [64-70]. This querying is done for monitoring guideline compliance [64], detecting adverse events and complications [65,66], generating management information on logistics and costs [67,68] and calculating indicators [69,70]. Grant et al. [71] provide us with an example of quality management in the emergency department. The authors present the dashboard functionalities of a warehouse that is updated on a daily basis with data from the HIS. One of the dashboard reports shows the statistics of emergency department occupancy through time. Through rapid feedback, these reports are used to improve practice during patient care and retrospectively for quality management purposes.

Grant's example shows that quality management is not only a bottom up effort of individual departments, but also part of hospital policy and central ICT developments. Therefore, in order to understand quality management in intensive care it is also important to look at quality management on a hospital level. Not much research has been published on this level (the focus is more on administrative or financial systems than on PCIS), but some case descriptions of leading hospitals give insight in the current state of affairs and progression that has been made. For example, Neil and Nerenz [72] describe measuring efforts using examples from six US hospitals, and DeWitt and Hampton report on the local development of a data warehouse [73]. Both articles show that each organization must develop its own processes for collecting data and reporting on the basis of PCIS data. Choices for the types of measures are determined at the local level and can depend upon the patient population or strategy of the organization. Often, combinations are made with data from clinical information systems (including ICU-systems) and administrative systems, supplemented, for example, with patient surveys. These integrated

measures are then presented in tailored dashboards for the various management layers in the organization, including ICU management [see also 74-76].

It is striking that all examples in the literature of quality management that exceeds the individual patient level requires extra systems and tools next to the PCIS. Moreover, in many instances, the PCIS must first be adjusted to the data requirements for quality management, before quality management can take place. PCIS do not produce their own (quality) information or reports at the patient-group or organizational level. The value of the PCIS is primarily in the underlying database that contains detailed data at the individual patient level. It is thus not the ICT system, but rather the value of what it captures, contains and generates, which matters. PCIS are primarily used in quality management to *deliver data*. Queries of this data allow the transfer of tables to a statistical or graphical package, as well as the calculation of indicators and possible transfer of these to a dashboard structure. Because of the database structure of many PCIS in the ICU (most have a closed structure that does not easily allow data extraction and modification to the database) querying the database and extracting the results is complex and labor-intensive. Extra tools are almost always necessary to completing these tasks: tools to extract data from the database, statistical programs to work with the data, and business intelligence programs for reporting and/or synthesizing management information. The literature gives many examples of similar – partly automated, partly manual – processes, demonstrating that PCIS do not stand alone as quality instruments, but are used in conjunction with other databases and information systems. Moreover, because PCIS data is located in multiple databases within multiple information systems, a common approach to centralizing quality management is integrating that data within a data warehouse [77]. This enables different approaches to querying the data, such that reports can be tailored to individual quality information needs, while also meeting the needs of accessibility and flexibility. Currently, in order to meet quality management goals, use of other applications (such as analytical tools and statistical programs) in conjunction with the data warehouse is necessary.

A concluding discussion point is related to the question whether the insights from research can be translated to everyday quality management. These articles present the results of research projects mainly designed to answer ‘technical’ questions: is this information system suitable for decision support, detection of adverse events, calculating quality measures, etc? The organizational consequences of the study results are rarely addressed. Moreover, a research group is usually not responsible for daily ICU management. Thus, although these articles are useful for this review because they show the possibilities of using PCIS (data), it is unclear whether the activities noted in the research have further led to regular quality management activities. Indeed, we know that after a few studies on computerized decision support, the computerized tools were abandoned [17]. While research projects generally focus on one topic, in practice many quality-related issues are of interest to ICU management. In everyday

management and quality management of intensive care, both structural and ad hoc questions must continuously be answered. Does every type of quality management require its own systems and tools? What are implications for staff workload? Which employees are responsible for quality management? Who gathers and analyses data or makes reports? What is the necessary organizational structure to support these activities? [78]. It is striking that also the general case reports on IT-supported quality management in hospitals [e.g. 72,79] do not answer these questions. Quality management does not only need high quality information systems and data, but also a stable organizational context. More research is needed into these organizational issues.

Conclusion

In 1999 Bates et al. predicted: "In the future, almost all quality measurement will be done using information systems and will be seamlessly integrated into the process of routine care" [19,p.123]. And there are many expectations for the role that ICT can play in health care [80] and specifically in intensive care [5,81,82]. Although there are a lot of examples, many quality management processes still involve people and a lot of work. Several articles demonstrate that quality management is a combination of both automated and manual processes for coupling and controlling the data and making sure that these are complete enough to be presented in a meaningful way. Extra tools, such as data warehouses and applications for reporting, are also necessary to transform PCIS data into quality management data. In addition, the PCIS itself must be adjusted to incorporate new data elements. In the end, for quality management in the ICU, it is not the PCIS itself that matters, but the value of the data it captures, contains and generates. Turning the research findings into day-to-day quality management activities of busy ICU staff, remains a challenge, and is definitely not 'a mouse-click away'.

Nonetheless, investments in ICT as a channel for gathering data on different aspects of quality are slowly transforming not only ICT systems, but also the nature of quality management. Thus, the challenge seems to be in aligning quality management goals with PCIS use, and strengthening the role of healthcare professionals in the ICU. In the end, it is these professionals who will benefit most from the knowledge on quality of care that is generated from patient care information systems.

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Appendix 2.1. Summary of studies on the three roles of patient care information systems

APACHE II = Acute Physiology and Chronic Health Evaluation II; CPOE = computerized physician order entry; ICU = intensive care unit; JCAHO = Joint Commission on the Accreditation of Healthcare Organizations; PCIS = patient care information system; SQL = structured query language.

FIRST ROLE: Direct impact on quality of care

Study authors	*Topic of study*	*PCIS and other tools used*	*Description of study*	*Main results*
Donati et al. [26]	Impact of PCIS on charting time.	Commercial clinical information system	Before-and-after study in a general ICU, measuring time spent on documenting activities with paper chart and PCIS.	Decrease of the time spent on charting common ICU data from 37 minutes/day to 3 minutes/day (p< 0.001).
Wong et al. [27]	Impact of PCIS on nursing activities, including documenting.	Commercial clinical information system	Before-and-after study in a surgical ICU, measuring time spent on documenting activities with paper chart and PCIS.	Percentage of time spent on documentation decreased from 35.1% to 24.2% (p =.025).
Saarinen and Aho [28]	Impact of PCIS on nursing activities, including documenting.	Commercial clinical information system	Before-and-after study in a general ICU, measuring time spent on nursing activities, including documenting.	Increase of 3,6% (=15 minutes per shift) for documenting (not significant).
Menke et al. [29]	Impact of PCIS on charting time and quality of documentation.	Commercial clinical information system	Before-and-after time/motion study in a pediatric ICU, and review of nursing documentation.	No significant difference in time spent on charting and direct patient care; improved quality of documentation.

Study authors	*Topic of study*	*PCIS and other tools used*	*Description of study*	*Main results*
Apkon and Singhaviranon [30]	Impact of PCIS on charting time and quality (detail) of documentation.	In-house developed PCIS for recording purposes only; no automated charting, decision support or CPOE	Prospective observational time study and retrospective nalysis of records in a pediatric ICU; Comparison of paper vs PCIS was measured on alternate days, after the implementation of PCIS in the same user group.	The time spent on documentation decreased with 13% (not significant).
Oniki et al. [31]	Impact of computer-generated reminders on nurse charting deficiencies.	Hospital clinical information system; reminders were generated by Tabledriven Clinical Rules System	Trial; Study group (receiving reminders), control group and retrospective group in two specialized ICUs.	Decrease of charting deficiencies to 1.02 deficiencies per day per patient ($p<0.001$).
Thompson et al. [32]	Impact of CPOE on timeliness of urgent laboratory and imaging tests.	Commercial CPOE	Before-and-after study in a medical-surgical ICU.	Median time from ordering to obtaining laboratory specimens decreased from 77 to 21.5 mins, median time from ordering to laboratory result being reported decreased from 148 to 74 mins, and median time from ordering to imaging completed decreased from 96.5 to 29.5 mins ($p<0.001$).
Cordero et al. [33]	Impact of CPOE on medication errors and timeliness of orders.	Commercial CPOE	Before-and-after study in a Neonatal ICU; medication error rates, initiation to completion time intervals for pharmacy orders and radiology procedures were studied for selected drugs and procedures.	Reduction in medication turn-around times and medication errors for selected drugs, and a decrease in ancillary service (radiology) response Time ($p<0.001$).

Study authors	*Topic of study*	*PCIS and other tools used*	*Description of study*	*Main results*
Fraenkel et al. [34]	Impact of PCIS on quality of care and staff perceptions.	Commercial clinical information system	Longitudinal observational study in a general ICU.	The system was associated with significant improvements in key quality indicators, positive nursing staff perceptions, and some positive resource implications.
Amaransingham et al. [35]	Impact of level of ICU automation on outcomes in a multi-institution quality collaborative.	-	Cross-sectional study with a survey for the medical directors of 19 Michigan ICUs participating in a state-wide quality improvement.	A 10 point increase in the 'CIT score' is associated with 4.6 fewer catheter related infections per 1,000 central line days for ICUs who participate in the quality improvement intervention for 1 year.
Berger et al. [36]	Impact of PCIS on nutritional support.	Commercial PCIS with nutrition flowsheet; paper based nutrition protocol	2-phase observational study, comparing units with and without PCIS, and one unit before and after PCIS implementation in a surgical/burn ICU.	Decrease of time required for writing and computations ($p<0.0001$); nutrient delivery was closer to target values. In burn patients, the better data visibility was associated with a significant improvement in nutrient delivery.
Claridge et al. [25]	Impact of PCIS on infection surveillance	In-house developed registry/PCIS	Prospective analysis in two surgical and trauma intensive care units, comparing the SIC-IR system to an infection control team.	The SIC-IR had a sensitivity and specificity of 97% and 100%, respectively, for identifying ventilator associated pneumonia
Colpaert et al. [38]	Impact of CPOE on medication errors.	Commercial PCIS with incorporated CPOE	Prospective trial in a paper-based general ICU versus a computerized general ICU in one hospital.	Decrease in the occurrence and severity of medication errors in the ICU ($p<0.001$) and in adverse events following these errors ($p<0.01$).

Study authors	*Topic of study*	*PCIS and other tools used*	*Description of study*	*Main results*
Walsh et al. [39]	Impact of PCIS/CPOE on medication errors.	Commercial PCIS with integrated CPOE	Before-and-after study in a Pediatric ICU, Neonatal ICU and general prediatric ward.	Decrease in the rate of nonintercepted serious medication errors by 7% (p=0.0495). There was no change in the rate of injuries.
Taylor et al. [40]	Impact of CPOE on medication administration variances.	Commercial CPOE	Before-and-after study in a NICU.	Decrease in the rate of medication administration variances (significant), but still variances in 11% of all medication administrations.
Rana et al. [45]	Impact of CPOE with a computerized decision support tool for red cell transfusion	In-house developed evidence-based decision algorithm for red cell transfusion integrated into commercial CPOE.	Before-and-after study in general ICUs in one hospital, before and after introduction of the algorithm.	Decrease of (inappropriate) red cell transfusions (p<0.001) and of transfusion complications (p=0.015).
Boord et al. [47]	Impact of CPOE with an integrated insulin protocol on glycaemic management.	In-house developed intravenous insulin protocol integrated into a in-house developed (now commercialized) CPOE.	Before-and-after study in a surgical ICU, comparing paped based and computerized protocol.	Reduction of time from first glucose measurement to initiation of insulin protocol; more glucose readings in the ideal range; improved control in patients on intravenous insulin.

Study authors	*Topic of study*	*PCIS and other tools used*	*Description of study*	*Main results*
Shulman et al. [48]	Impact of computerized decision support system on glycaemic control.	In-house developed computerized decision-support system as part of a commercial PCIS	Before-and-after study in a general ICU in mechanically ventilated patients.	The target tight glycaemic control band (4.4 to 6.1 mmol/l) was achieved for a median of 23.1% of the time. Nearly half of the time (median 48.5%), blood glucose was within the band 6.2 to 7.99 mmol/l.
Rood et al. [49]	Impact of computerized decision support system in a PCIS on glycaemic control.	Commercial clinical information system; decision support software module; custom-made Visual Basic application	Three phase off-on-off study in a medical-surgical ICU, combined with intervention and control group in the on-study (control group had paper guideline only)	Significant improvement of glucose regulation (timeliness, and regulation) compared to absence of guideline. However, no clinically relevant differences with paper-based guideline, due to crossover effect.

SECOND ROLE: tracking adverse events

Study authors	*Topic of study*	*PCIS and other tools used*	*Description of study*	*Main results and conclusion*
Hwang et al. [51]	Evaluation of a computer-based adverse-drug-event (ADE) monitor.	In-house developed hospital information system (data) + in-house developed ADE monitor system	Retrospective analysis in 2 ICUs and 5 general wards, comparing ADE monitor to chart review by a pharmacist.	The positive predictive value of the computer monitor was 21% (148 of 718). The computer-based ADE monitor successfully identified most of the ADEs and almost all of the severe ADEs.
Pokorny et al. [52]	Impact of computer-based surveillance system on the automatic detection of patients with nosocomial infection.	Hospital information system (data) + automated system (algorithm)	Validation study in a general ICU, using a group of ICU patients with confirmed infection as a gold standard.	The combination of 2 criteria demonstrated the most satisfactory sensitivity (94.3%) and specificity (83.6%). The positive predictive value was 55.9%; the negative predictive value was 98.5% The system could assign a site of infection for 90.4% of the nosocomial infections detected.

THIRD ROLE: measuring quality of care

Study authors	*Topic of study*	*PCIS and other tools used*	*Description of study*	*Main results and conclusion*
Junger et al. [53]	Automatic calculation of APACHE II scores.	Commercial PCIS; SQL software	Validation study in a surgical ICU	A prediction model based on completely automatically calculated 'modified APACHE II scores' can be constructed using data collected with PCIS.
Shabot [54]	Automatic calculation of JCAHO quality measures.	Commercial clinical information system; clinical data archive for extraction; Oracle database	Case report	PCIS can automatically gather most of the data required for quality and outcome measures and make it available for analysis and reporting.
Wahl et al. [55]	Automatic calculation of JCAHO quality measures.	PCIS (computerized flowchart)	Observational study in a surgical ICU.	PCIS can automatically gather most of the data required for quality and outcome measures and make it available for analysis and reporting. Moreover, an increased number of patients met target levels of the ICU measures.
Alban et al. [56]	Re-admission to the sugical ICU.	Commercial clinical information system; In-house developed clinical data warehouse	Prospective observational study in a surgical ICU.	Readmission to the ICU significantly increases the risk of death ($p<0.001$) and length of stay ($p<0.001$).
Hartmann et al. [57]	Antibiotic drug use.	Commercial patient data management system; SQL software	Prospective observational study in a surgical ICU.	Antibiotic drug therapy can be analyzed in detail using PCIS data (for example, number of drugs, duration of therapy).

Chapter 3 Implementation of a Patient Care Information System in the ICU[2]

Introduction

The use of patient care information systems in critical care has increased exponentially the last few years [1-5]. These systems, often called clinical information systems (CIS) in critical care, provide medical and nursing staffs with up-to-date patient data and have the potential to improve quality by reducing errors and supporting evidence-based medicine through their built-in guidelines and protocols [5-8]. The Erasmus Medical Center, the largest University hospital in the Netherlands, has been using a clinical information system from Picis, CareSuite (Picis, Wakefield, MA) (http://www.picis.com) on five intensive care units for a period of one to four years. The CareSuite system is considered to be a success; users are satisfied with the system they regard as a step forward in high quality care. We address what factors made CareSuite a success in the Erasmus MC. Apart from a description of the system itself, we will also discuss the implementation process, which–despite all the challenges–contributed to the success. In addition, we describe the functionality of the system and briefly evaluate the impact of the system on the work practices in the intensive care units (ICUs). Finally, we discuss the lessons learned during the implementation of the PCIS.

Implementation of CareSuite

Implementation pilot

The implementation of the CareSuite system in the Erasmus MC was the first large scale implementation of Picis in the ICU environment in Europe. It was a cooperative effort between the hospital and the Dutch division of Siemens Medical Solutions, supported by technicians from Picis Europe (Barcelona, Spain). The preparations for the implementation of CareSuite 5.0

[2] This chapter has been published as: De Mul M, Berg M, Hazelzet JA. Clinical Information Systems: CareSuite from Picis. Description of a system and the implementation process. *Journal of Critical Care* 2004; 19:208-214.

started in January 1998. A multidisciplinary project team–consisting of doctors, nurses, technicians (both information technology and medical technology) and a representative of Siemens–was responsible for the implementation. The nurses were to be the change agents on their units, the ones leading the change process. A pilot for two units was planned: a pediatric ICU and a surgical ICU. These units had great variation in patient population, medical devices and corporate culture. Initially, it was estimated that CareSuite 5.0 would be up and running in both units within nine months. Due to performance problems, it turned out to be a process of two years instead. The pediatric ICU has been using CareSuite since September 1999, the surgical ICU has been fully operational since January 2000.

What follows is a description of three key activities of the project team, which had a sequence in time, but also overlapped.

Configuring of the system

The CareSuite 5.0 system was purchased with a nearly empty database and the project team used a "priming tool" to fill all tables. This took a few months, longer than expected. The processes on the ICU had to be analyzed (actions performed on an ICU, current data collection, available devices to be connected to CareSuite 5.0, authorization issues) and tuning with other departments was needed (e.g. pharmacy, on the list of medication and doses to be put in the system). All this work on the configuration was done by hospital staff: technicians from the IT department and two nurses, who had been trained by Picis. They used a configuration tool for the screen content and layout. The configuration and interface are largely similar for both units, but there are some small differences based on different working practices, patient characteristics and preferences of the staff.

Testing of the system

CareSuite 5.0 was tested throughout the implementation. There were technical tests for every driver that was installed for the connection between CareSuite and a monitor or other bedside device, and tests for the connection between CareSuite and the Hospital Information System. Finally, CareSuite was tested at the start of the actual implementation on the units, during three days parallel to the charting on paper.

Training of the users

The project team paid much attention to the training of future users. They developed a training program, a user manual and several protocols. In total, the nurses trained for two days, but several nurses received extra training in (technical) problem solving; they became the "superusers". The dedicated nurses trained medical staff as well. Training was a continuous process, because of the turnover of nurses and residents, but also because the system changed through time (small system enhancements and several major program updates).

Going "Live"

The CareSuite 5.0 system went "live" in the early summer of 1998, but when only a few beds were transferred from paper charts to CareSuite, the performance decreased dramatically (response time of more than one minute). The implementation was aborted and both units returned to using their paper charts. The slowness of the system proved to be caused by the long stay of the patients. CareSuite was based on the Chart+ module for Anesthesia; it could handle real-time patient data for a few hours or a few days maximum. However, many patients on the pilot ICUs stayed there for a week or even a few months, which caused performance problems. For example, the system automatically calculated the fluid balance for the complete admission period, every time the fluid balance sheet was opened. For the long stay patients, this took much time and the users were unsatisfied that they had to wait for a calculation that was not even useful for them. A new version of CareSuite (5.1) and the change from SQL Server to Oracle was the solution to this problem. After extensive testing and training of the users, CareSuite 5.1 was implemented on both units in May/June 1999 but it took until January 2000 before the technicians had tackled all technical problems and the system was fully operational. In March 2000 the project group evaluated user satisfaction by means of a questionnaire. A new, improved version of the system (CareSuite 6.0) with higher performance and ease of use was implemented in October 2000. This version was faster and had less bugs. In spring 2001, the pilot officially ended with a second evaluation of user satisfaction and a round of interviews and observations. This resulted in some configuration changes and extra training for all nurses.

Roll out

The roll out to the three other ICUs were less problematic, thanks to the experience gained in the pilot and technical improvements of the CareSuite system. Configuring the system was easier, only a few new devices needed a driver and the training of users could be planned more efficiently. For practical reasons, the implementation on the internal medicine ICU had already started during the pilot and was finished in January 2001. The implementations on the neurological ICU and pediatric surgical ICU were completed in August 2002. At the moment all five ICUs have CareSuite 6.3, and the new version 7.0 will be implemented early 2004.

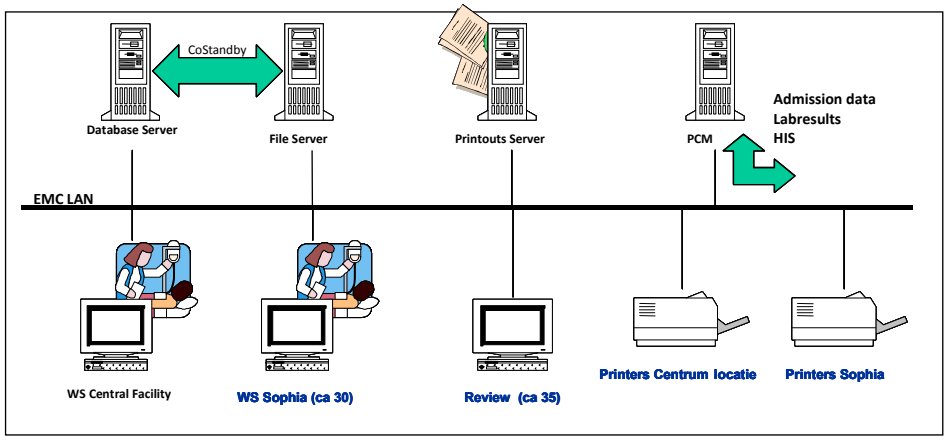
CareSuite: Description and evaluation of the system

The 6.3 version of CareSuite consists of two modules: Chart+ and Visual Care, the features of which are described below. In CareSuite 7.0, which will be implemented in the hospital in January 2004, both modules are integrated.

Technical description

CareSuite 6.3 runs as a client-server database application on a network of standard Windows 2000 workstations (Figure 3.1). Two servers, the database server and the file server, are mirrored constantly. Two other servers, CPS and PCM, facilitate reports and communication with external systems, respectively. CareSuite recommends a dedicated network, but in the Erasmus MC it is used on the regular hospital network, without noticeable effect on performance. The database (Oracle) gets its input directly from the workstations, which are connected to the various devices (monitor, ventilator), from manual input and from the hospital information system for patient identification and lab results (Torex Hiscom, Leiden, the Netherlands).

Figure 3.1. Network architecture



Picis has three tools for tailoring CareSuite: the priming tool that was used only once for filling the static (reference) tables of the database; the configuration tool to design the lay out; and the database touch up tool to keep the static (reference) tables up to date (new users, new medications). These tools are used by the technicians from the IT department and by the dedicated nurses. Major changes of the database (such as structure changes to accommodate new features in a new version) are delivered by Picis.

Training of the users, testing of new drivers, adaptations of the configuration, system upgrades or even beta testing takes place within a separate testing environment, with a separate database and eight workstations. This testing database contains real-time patient data, to make the testing as realistic as possible. However, changes in this database will not affect the real patient data in the “production” database.

CareSuite 6.3 configuration

The CareSuite system is highly configurable to the wishes of the users. Figures 3.2 and 3.3 show two sheets of Visual Care and Chart+, respectively, as they are used in the Erasmus MC. In Tables 3.1 and 3.2, all flow sheets and windows of the two modules are listed.

Figure 3.2. Visual Care sheet: Present medication sheet

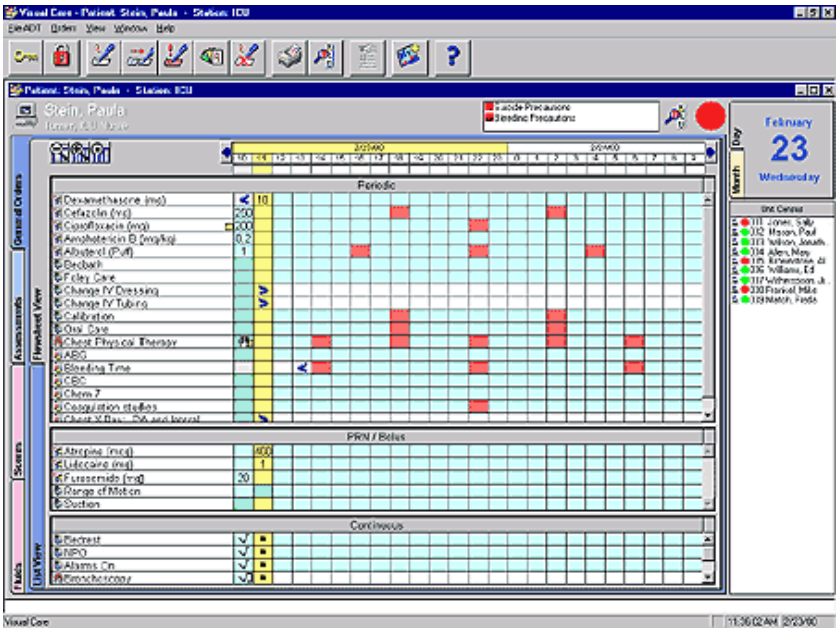


Table 3.1. Sheets and windows in the CareSuite 6.3 configuration at Erasmus MC: Visual Care module

Visual Care	
General orders sheet	Overview of all orders regarding medication, infusion pumps, blood, general care, and lab orders
Nursing assessment sheet	Careplan with skin care, hygiene
Fluids in/out sheet	Input/output flowsheet for urine, infusion, and blood
Scores	Customized scores or assessments, e.g. comfort score
Ordering windows	Order management tool for medication, fluids & additives: to prescribe medication, extend current prescriptions and stop orders
Validation windows	For nurses' validation of generals orders (medication)

All CareSuite sheets can be printed, but the system also produces printed weekly reports, discharge reports, and summaries of patient data that are relevant for reporting to national critical care registries.

Figure 3.3. Chart + sheet: Overview table and graphs

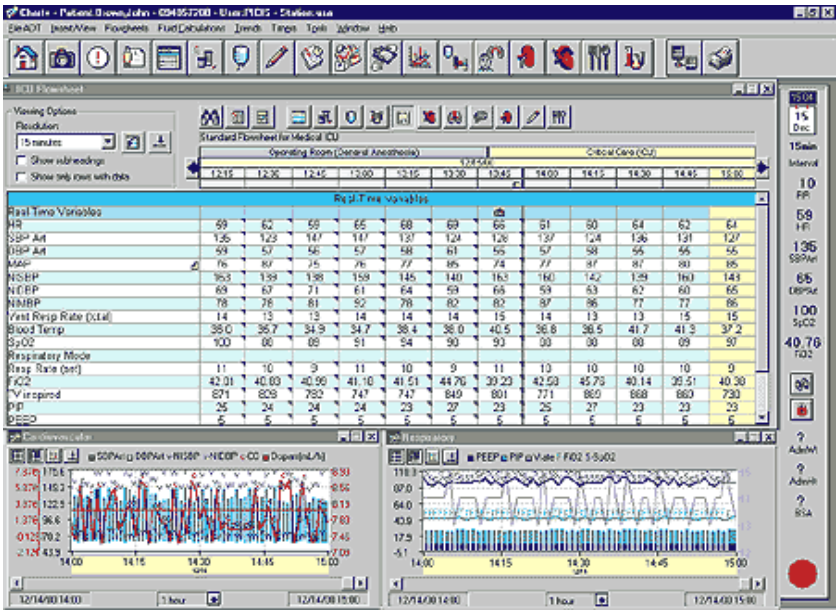


Table 3.2. Sheets and windows in the CareSuite 6.3 configuration at Erasmus MC: Chart+ module

Chart +	
Basic parameter flowsheet	All real-time data from the monitor, ventilator and other devices, like heart rate and blood pressure
Fluid flowsheet	Input/output flowsheet for urine, infusion, and blood
Laboratory flowsheet	All data from the hospital lab before and during admission on the ICU, e.g. blood cell count, bacteriological cultures
Medication flowsheet	Arranged by medication group (non-infused medication)
Composite flowsheets	For specific patient overviews of real-time numerical data and/or trends (parameters, medication, infusion and lab): e.g. cardiovascular, breathing, respiratory and infection
Admission window	Patient administrative data, admission weight, allergies, diagnosis (specific lists and ICD-10)
Fluid balance window	Daily/weekly overview of total balance in a barchart
Events window	e.g. intubation, x-ray
Patient summary window	Shift reports and summary of events and vital signs
Trends window	Correlates physiological parameters with medication, fluids and lab result data. All graphs are adjustable by the users
Validation window	For validating real-time data in Chart+

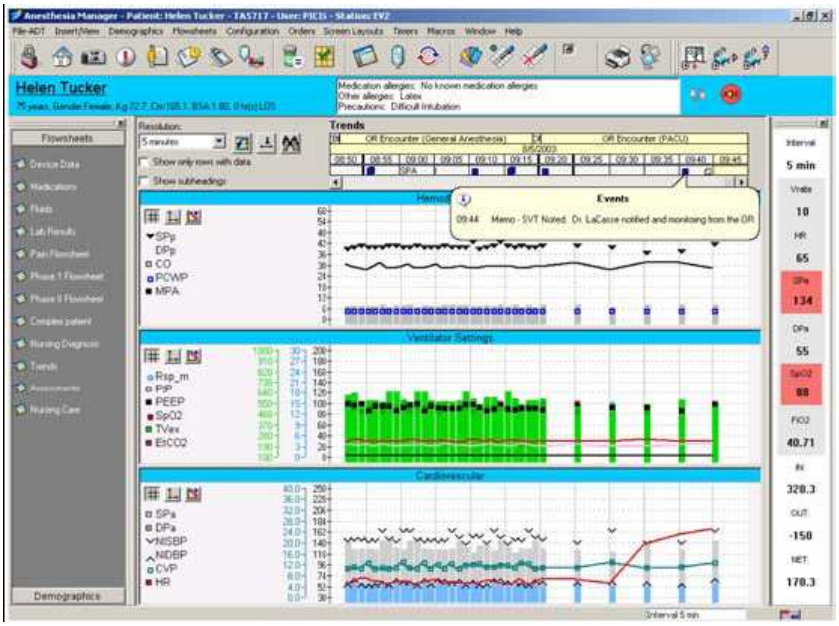
Order management

Medication order entry in the ICU is restricted to the ICU doctors only, as the ICUs of the Erasmus MC, like many other in Europe, have a closed format. The intensivists are the first responsible doctors for ICU patients, and the other disciplines are consulted if necessary. A few windows guide the doctor in the prescription process, providing him or her with information on standard doses, sets of medication for specific conditions, and drug infusion calculations. The two pediatric ICUs have their own satellite pharmacy that has direct access to CareSuite. The other ICUs have most medication available on the unit. They use a daily printout of the medication list to collect the medication they need. CareSuite 6.3 has no direct alerts for allergies and drug incompatibilities.

CareSuite 7.0

New features and enhancements to CareSuite, in version 7.0, will facilitate improved processing of information from physiologic monitors, fluids in an out, assessments, scores, labs, and orders (e.g. relate cardiac physiological parameters to physical assessment of patients to promote informed decisions), decrease training time and increase ease of use by merging Chart+ and Visual Care in one (Figure 3.4), improve usability of the system, and decrease the number of servers needed (interface engine does not need to be installed in a dedicated machine).

Figure 3.4. CareSuite 7.0 flowsheet



Future developments

Plans for the very near future are to use the system as a quality tool (incorporating protocols), and use the available data in the database for medical research and quality assessment. To use the production database for this purpose means compromising the performance of the database. A better approach is to transfer the data to a data warehouse. Picis has already built such a tool for the OR environment, and is busy with the same architecture for the ICU, ready beginning 2004. A big step forward would be to connect the infusion devices (pumps etc.) directly to the Picis system. That would mean that a syringe with medication (e.g. dobutamine) is prepared in the satellite pharmacy and delivered to the unit supplied with a label with text and barcode showing the content of the syringe. By means of a barcode reader, pump and syringe are linked to the PCIS and the settings of the pump as well as the content of the syringe are compared with the given order. In case these are not in accordance with the order, this is observed and reported. Every change in the settings is registered, including bolus infusions.

Discussion: the value of a sociotechnical approach to PCIS implementation

Developing and implementing information technology in health care organizations is difficult. Often, implementations fail, or succeed at high extra investments in time and money [9-10]. More and more it is recognized that social, political and organizational aspects determine the success of ICT in healthcare [11-13]. The unique character of healthcare work (e.g. the complexity, fluidity and socio-cultural aspects) and its implications for ICT development and implementation is stressed specifically within the so-called socio-technical approach [14]. Implementing ICT is not just installing a PCIS in an ICU, but creating new work practices in which the PCIS is thoroughly intertwined. Implementing a PCIS is, by nature, an organizational change process, and should be managed as such [13,15-17]. Three issues that are typical for this socio-technical approach have proven to be crucial for the implementation of ICT in healthcare and for the implementation of CareSuite in the Erasmus MC. Analysis of work practices, the role of the users, and implementation as an iterative process. These are discussed below.

Analysis of work practices

This is very important and requires more than making a workflow diagram or an inventory of user specifications, which is often done by the vendor of a PCIS. The nurses and doctors of the ICU were the obvious experts to transfer tacit knowledge about “how things go around here” to the content and configuration of the CareSuite system. Moreover, it became clear how context dependent work processes are, and that ICUs differ from country to country and even within a single hospital. The discrepancy between Picis’ notions of ICU work practices and the actual work processes on the ICUs of the Erasmus MC became visible when CareSuite 5.0 was implemented: the performance was very poor, especially for the long stay patients. For Picis, this

problem was new, as they only had experience with CareSuite in short stay postoperative ICUs. This example shows the importance of a thorough analysis of work practices to the detailed level of the unit that is about to implement a PCIS. When planning the implementation, the project team had not taken into account the amount of work involved with analyzing these ICU processes. However, this extra investment in time resulted in a system that has a much better "fit" with ICU work, which is crucial to its success in daily use.

Role of the users

User participation has been stressed by many authors [e.g. 15,18-19] and there are many ways to put this into practice. The importance of user participation was clear from the start of the implementation of CareSuite. The multidisciplinary project team consisting of users and technicians was very valuable. Implementation could not be left to the IT department alone; participation of doctors and nurses was crucial. For the project team, this attention to user participation was one of the keys to the success of CareSuite in the end. Especially the nurses who tailored CareSuite to the characteristics of their units fulfilled an important role. These nurses had longtime experience on ICU and were highly respected by their colleagues. For them, it was easier to get commitment from the ICU staff, even in times of technical problems. All users played an important role in the evaluations throughout the implementation: their comments were appreciated and suggestions for improvement were, if possible, implemented. Apart from active user participation, communication to the users is also important. Throughout the process, the project team kept the users informed by means of newsletters.

Implementation as an iterative process

An implementation process is by no means a step-to-step, linear process. In practice, system development, implementation, and evaluation merge into a continuous cyclic process [14,16]. At the onset, the project team was not prepared for this: the project plan had clear-cut phases and a linear course. In practice, however, there was a constant alternation of developing, testing, and configuring. Sticking to the unrealistic project plan turned out to be frustrating and de-motivating. The socio-technical approach of ICT implementation also stresses the need for continuous evaluation. First, it stimulates an internal learning process, which is crucial for a good "fit" between the system and the work practice. Second, the results of an evaluation are valuable for others who are thinking about implementing ICT. Although several evaluations of PCISs for critical care have been published over the last few years [20-23], many PCIS implementations end without an evaluation. The project team of the Erasmus MC was interested in satisfaction and used questionnaires, interviews, and observations to evaluate this aspect. Due to limitations of space, the results of this evaluation are not presented here. However, there are many other relevant evaluation questions in the different phases of an implementation [24-25].

Conclusion

The success of Picis, CareSuite in Erasmus MC can be explained by the fact that the system, after an extensive tailoring process, meets the most important wishes of the users (nurses and doctors). It presents patient data well organized, it has a good module for ordering medication, and the system is stable and uses an open database. Although the ICUs have more wishes regarding functionality and ease of use, the current version of CareSuite can be regarded as a big step forward in delivering 21st century critical care. The implementation process has contributed to the success of CareSuite as well. The constant user involvement and adaptation to the actual work processes on the ICU, has made CareSuite a part of the organization the ICUs cannot do without.

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Chapter 4 Development of a Clinical Data Warehouse from an Intensive Care Patient Care Information System[3]

Introduction

Information technology in health care is still a topical subject, and reports like IOM's *Crossing the Quality Chasm* have stimulated developments in physician order entry, decision support systems and shared patient records [1]. Despite all the efforts, many health care organizations still have stand-alone information systems that do not communicate with each other. Therefore it remains an enormous task to use data collected at the point of care or in the supporting administrative processes for other purposes than they were collected for (e.g. management information, quality assessment and research).

Data warehousing is one of the techniques that seems promising for healthcare information systems. Use of data warehouses in healthcare is not new – they have developed slowly through the years and received much attention in the past. In its simplest definition, a data warehouse is a copy of transaction data specifically structured and optimized for query and analysis [2]. The architecture, life cycle, and the end-users of a data warehouse are different from those of transactional systems (such as electronic medical records), and for performance reasons, it is recommended to develop data warehouses separately from the transactional environment.

There are relatively few organizations that have developed clinical data warehouses, containing patient data from the point of care. Because of the various care practices, data types and definitions as well as perceived incompleteness of clinical information systems, the development of a clinical data warehouse is a challenge [3]. Some vendors of health care information systems have developed data warehouses for their products, which contain administrative data only. But

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there are also hospitals that develop their own (clinical) data warehouse. An advantage of this last strategy is that data from several information systems can be combined in the data warehouse and that the end-users can be involved more extensively in the developing process. This will lead to data warehouses that are tailored to local needs.

Intensive care units (ICU) might benefit from clinical data warehouses, as they can be characterized as information-rich environments with a high degree of automation and information technology (IT). The last decades many ICUs especially in the larger university and teaching hospitals have implemented patient care information systems (PCIS), which are often called clinical information systems (CIS) or patient data management systems (PDMS) in critical care. These systems sample and store data from the monitors and other bedside devices, as well as manually entered observations and lab results. PCIS are used for charting, fluid balance, medication lists and care planning. Some PCIS also have physician order entry functionalities. Since these systems are designed for the point of care, the aggregation of data for management and research is limited. Querying the database of a PCIS requires technical skills and knowledge of the database structure. Competences which most managers, doctors, and nurses lack. Moreover, querying can be a burden for the operational database because it slows down performance [3].

In this paper we report on the in-house development of an ICU patient data warehouse at Erasmus Medical Center, Rotterdam, The Netherlands. This data warehouse uses data from the PCIS installed at the ICUs.

Data warehousing at Erasmus MC

Erasmus Medical Center, Rotterdam, is a University hospital with 1200 beds and 37.000 admissions per year. Divided over three locations there are three ICUs with 104 beds in total (34 adult, 36 pediatric, and 36 neonatal). The ICUs have implemented their clinical information system, Critical Care Manager/CareSuite (Picis, Wakefield, MA, USA) in the period 2000-2006 [4]. The CIS database contains 75 GB of data and grows 15 GB each year.

The hospital has experience with data warehousing since 2000, and in several increments the scope of the data warehouse has broadened. First, a financial data warehouse was developed, which contained data on costs, production, personnel and absence through sick leave. From 2002, a data warehouse for the operating rooms was developed externally. Since 2004 a DRG-data warehouse and a patient logistics data warehouse were developed by staff of the IT department, supported by external parties. All these data warehouses used (administrative) data from modules of the Hospital Information System (HIS) (iSoft, Leiden, Netherlands).

In 2005 a start was made with the in-house development of a patient data warehouse; a data warehouse that was to contain patient information from clinical information systems and parts of the hospital information system (e.g. the laboratory module of the HIS). To date, three increments have been completed: the intensive care data warehouse, the radiology data warehouse and the laboratory data warehouse.

Intensive Care data warehouse (ICU-DWH) development

The ICU-DWH project started in September 2005, and was supported by Atos Origin. For modeling, the Atos Origin Metadata Frame was chosen as method. This method is based on *fact* and *communication* oriented thinking and uses FCO-IM (Fully Communication Oriented Information Modeling) - the most modern form of complete communication-oriented information modeling [5]. For the development of data warehouses, the Metadata Frame method fully supports the design principles of Multi-dimensional modeling, as advocated by Kimball [2]. In fact, the creation process of the required dimensional models is fully automated under the Metadata Frame method. The method is relatively new; it was developed in the Netherlands in the 1990s [5]. The Erasmus MC data warehouse is the first large scale application of the Metadata Frame method in health care. This method was chosen for several reasons. The first reason was the focus of this method, which places end-users like doctors, nurses, and researchers, as experts of the domain, in a central position. The second reason was that the method also supports the maintenance of metadata. Because of the large amount of tables and data elements in a (clinical) data warehouse, technical and functional maintenance is a precarious matter. Extensions and changes in the models have to be implemented integrally throughout the data warehouse structure in order to maintain internal consistency. Because of the several increments of the data warehouse, this was an important issue for Erasmus MC.

The development of a data warehouse is often referred to as a life cycle with several stages [2]. Each of the steps in the life cycle which were passed in order to realize the ICU-DWH is described in more detail below.

Phase 1. Preparing

At Erasmus MC, a multidisciplinary project team was installed, consisting of two metadata experts, one data warehouse developer, two domain experts (one ICU doctor and one researcher), and three experts on the PCIS (both technical and functional), of which two were also ICU nurses. They met regularly during all the phases, to provide the DWH developers with the necessary input for their work.

At the start, the DWH project leader and the Atos Origin consultant interviewed key users of the PCIS: doctors, nurses, and (clinical) researchers, and the head of one of the ICU departments (n=7). These interviewees had experience with analysis of the PCIS database, and therefore were potential users of the data warehouse. The interviews focused on current use of the PCIS database, and wishes for future use of the data warehouse. The interviews were analyzed, which resulted in lists of the organizational units and processes involved, the required and desired reports for research and for mandatory national registries for ICU patients, all relevant (key) performance indicators ((K)PIs), and globally assessed subjects that can be connected to these (K)PIs. These subjects are candidate dimensions in a dimensional design. The (K)PIs were further defined, grouped and classified in a 'bus matrix' by the project team. The bus matrix was visualized using a spreadsheet (Microsoft Excel). In this bus matrix, the (K)PIs were assigned to the various processes, the reports that Erasmus MC needed, and the candidate dimensions. At the end of the preparation phase, thus, both the clinical staff and the IT staff had a clear picture of everything that had to be modeled.

Phase 2. Modeling

In the second phase of the ICU DWH development, examples were made for each of the items in the bus matrix and for the types of data available in the PCIS (starting from the charts, screens and flow sheets used by ICU staff). These examples, which were formally verbalized with the domain experts are called 'fact expressions' in FCO-IM. Fact expressions are complete sentences in common language. Again, a spreadsheet was used to present the examples and share them in the project team. The fact expressions were presented together with the charts of the PCIS containing the original data. This enabled the domain experts in the project team to understand the examples, correct verbalizations (if necessary) and validate the facts expressed in the sentences. Special care was given to ensure that the examples and their verbalizations contained all pieces of information at their 'natural lowest grain' (e.g. single events, nursing activities, and applied medications) and not just arbitrary aggregations of these facts. By these activities, data supply and information demand were brought together. It became clear which of the items defined in the first phase could indeed be made available in the DWH and which ones not, because they required (additional) recording in the PCIS first. The team decided to model all items, whether available in the PCIS database or not, in order to meet future needs. When all the sentences were validated, CaseTalk™ software (BCP Software, Utrecht, Netherlands) was used to create the conceptual models. An example of the fact expressions and their transition in CaseTalk™ is presented in Appendix 4.1.

Phase 3. Building

The data model in CaseTalk™ was automatically transformed into an entity-relationship model and transferred to an Entity-Relationship tool (ERwin). The final database model was implemented in the database using Oracle Designer. For the ETL (extract, transform and load) process, the Extelligence® Critical Care Export Tool was used, which was an extraction tool developed by the PCIS vendor, Picis. This had two advantages. First, it saved a lot of developing time, because the vendor had the knowledge of the database necessary for making complicated extractions and calculations relatively easy. Second, the extraction tool will be updated with every new release of the PCIS, which guarantees future data quality and usability. Data elements that were not in the extraction tool were extracted by Erasmus MC. Oracle Warehouse Builder was used to fill the tables of the data warehouse with the extracted data.

The ICU-DWH consists of 24 dimensional star models, containing 49 different tables and 578 attributes. Central Fact tables and the approximate number of facts (data entries) are presented in Table 4.1.

Table 4.1. Fact tables of ICU-DWH and the number of facts they contain

Facttable name	***Number of facts (approximately)***
Blood product administration	77.000
Catheter day fragment	197.000
Fluids per hour	10.0 million
ICU admission	24.900
Medication task	3.3 million
Medication administration per hour	7.9 million
Nursing activities	618.000
Observation item recording	6.5 million
Patient event	531.000
Real-time measurement	81.9 million
Scores item recording	1.6 million
Ventilation hour fragment	1,2 million

Phase 4. Testing

The test group consisted of staff from the Department of Information Technology and 12 end-users (managers, researchers, doctors and nurses). In this phase, the Division of Medical Information was intensively involved. This division resides under the Department of Information Technology, and one of their tasks is to support hospital management, researchers, students and doctors with data. They have much experience with the Business Objects (BO) tool, which is used to create reports from all Erasmus MC data warehouses, including ICU-DWH.

The test phase lasted almost 2 years. This was partly due to the limited availability of the end-users, but more importantly, to some major problems with the ICU-DWH that were encountered during testing and had to be solved first.

One of the problems was related to the metadata and the hospital information system. In all data marts of the Erasmus MC data warehouse, the location of the patients (and thus an admission in a specific department) was derived from the hospital information system (HIS). The times of admission and discharge, however, did not match the time recorded in the patient care information system of the ICU. This was problematic because many patients were admitted to the ICU, while they were not administratively discharged from a ward. The ICU-DWH only extracted data from the PCIS within the boundaries of HIS-admission and HIS-discharge. Because the first few hours of an ICU admission are important for data collection, a lot of data will be missing in the ICU-DWH. Moreover, the HIS uses old codes for the ICU departments, while in the past few years two large organizational changes have occurred: the specialized surgical, internal and neurological/neurosurgical ICUs have merged to one intensive care department with two general units, and the pediatric and pediatric surgical ICU have merged to one pediatric ICU. The users of the ICU-DWH want to zoom in at the level of their units (or even a bed-level), but this amount of detail requires a complex query.

During the test phase, the ICU-DWH was frequently used to generate reports or collect data for research. Many imperfections were discovered during these activities, which helped the ICU-DWH team to improve the data model and data extraction. Some of these reports will be discussed, as examples of (future) use of the ICU-DWH.

- A simple report was made for the secretaries of the pediatric ICU listing all children that were admitted and discharged in the previous week. In the past, they made these lists by hand, which was time consuming and introduced errors.
- A report for X-ray ordering was built. In the adult ICU it was a standard procedure to order Chest X-rays for all ventilated patients, but new efficiency policy states that these photos are only to be ordered if indicated. To monitor the effects of the new policy on X-ray ordering practice, a query was made that extracts for each day the number of patients that were both ventilated and had a Chest X-ray ordered, between 9.00 and 10.00 a.m. (the time of the daily rounds). This is compared with all ventilated patients in that time frame, and the results are presented in a Business Objects report. When building this report on chest X-rays, imperfections in the ICU-DWH were encountered, when length of ventilation was calculated. These were related to both modeling errors, limitations in the PCIS, but also to improper quality of the manually entered data.
- The ICU-DWH was used to calculate ventilation time, which is one of the mandatory quality measures each ICU has to report to the Dutch healthcare Inspectorate.
- An example of the use of the data warehouse for research questions is the NGAL study. At Erasmus MC, a study is performed on detecting kidney damage with NGAL proteins in blood and urine. Before the data warehouse was implemented, the

research team collected all data by hand. Now, for each ICU admission that is included in the NGAL study, data on fluids and medication is extracted from the data warehouse, and collected in a Business Objects report, in the format that the researchers need (for example divided in 24 h timeframes).

- The ICU-DWH has been used by researchers in the pediatric and neonatal ICUs to select patients eligible for studies, or retrieve specific real-time data.

Although, at first, it seemed easy to test the ICU-DWH, the testing phase turned out to be a long trajectory. Because the problems were related to frequently used data elements (admission time, ventilation), the ICU-DWH could not be implemented before these were solved. Even though there are still wishes for improvement and extension of the data warehouse, this requires substantial changes of the data model, and thus, resources (investment from the ICUs and development time from the Department of Information Technology).

Discussion

The development of an organizational data warehouse should be regarded in the light of the strategic position of the healthcare organization [6]. According to DeWitt and Hampton: "Investment in a data warehouse is an investment in the future of the organization. The strategic value of the data warehouse is … in the knowledge derived from the data warehouse and the application of that knowledge to obtain improved outcomes" [7,p.1019]. At the Erasmus Medical Center, the choice was made to develop the data warehouse incrementally, in order to deal with managerial and clinical information needs, as well as educational and research aims that are important in the setting of a university hospital. In this paper, we described the development of the ICU Data Warehouse, which is one of the data marts of the hospital wide data warehouse. The data warehouse contains various types of information: automatically generated real time monitor data, patient characteristics, observations and medication orders and delivery. Since the data warehouse was modeled on the lowest grain of data available in the clinical information system, the data can be used for research questions on various levels of detail; from the patient group or department level up to the individual patient level.

For further organizational embeddings of the DWH (and related IT projects), Erasmus MC is preparing a Business Intelligence Center. This center aims to support the ICU-DWH users with – mainly – their knowledge on Business Objects, while key users (e.g. research nurses) support their colleagues with their knowledge on ICU processes and PCIS data. Thus, part of the functional maintenance is decentralized, with the key users being 'linking pins' to the Business Intelligence Center. In other hospitals, similar organizational solutions have been implemented [e.g. 8-10]. Just like DeWitt and Hampton noted in their organization, we learned that the scope

of DWH projects should be broad from the start: not only focusing on the technical aspects. They admit in their paper that "Our original objective was the development of a data warehouse, but not the full range of services required for the delivery of analytical services. We should have anticipated and built the full scope of services required to optimize the use of the data warehouse, including the creation of custom applications and reports, the provision of user training, and business analysis expertise." [25,p.1024)

Relation to other DWH projects in the literature

The first articles on data warehousing date from two decades ago. In the period 1995-2000, it was a topic in healthcare management journals, but many articles provided only viewpoints, and lacked technical and empirical data [e.g. 11,12]. Certainly back then, the focus was on financial data warehouses, and data warehouses are still used for research into in-hospital costs [e.g. 13-15]. Since then, the focus has shifted somewhat to data warehouses for the bioinformatics domain [e.g. 16]. To date, there are but a few published examples of clinical data warehouses, using data from electronic patient records, that are implemented and in use. Interestingly, many of the data warehouses discussed in the medical (informatics) literature tend to focus on clinical research questions rather than (clinical) management questions. For example, data warehouses are used to select a group of patients for a study or retrieve similar cases [17]. Sometimes the data warehouse alone provides enough data for a study, but often additional data is needed from (paper) patient records. The main reason is that only few health organizations keep an entire patient record in the data warehouse [3]. Data warehouses are also used for data mining, which– again – has a research focus [18,19].

However, there are some publications on (quality) management related issues. Grant et al. [20] provide one interesting example of the dashboard functionalities of a warehouse that is updated on a daily basis with data from the hospital information system. The dashboard reports show – among other things – the statistics of emergency department occupancy and laboratory test ordering through time. Through rapid feedback, these reports are used actively to improve practice during patient care and retrospectively for quality management purposes (e.g. identifying bottlenecks and making improvements).

Collins and Wagner [21] discuss quality management in a non-profit health system, where an electronic medical record (EMR) and a 'mini business intelligence system' called AIM (Analytical Information Manager) are used. AIM is a data-driven business intelligence system with a data warehouse structure. The data warehouse is regularly updated with data from the EMR, but data can also be imported from the financial data warehouse. Dashboard reports are used for presenting data from AIM. For each type of question, a different report is created. One example is a charting compliance dashboard where the user can select the unit(s) of interest and report column(s) that s/he wants to view. It is also possible to create an overview of all patients that

meet a given criterion (eligibility for additional research, following a certain treatment/medicine, etc.). These dashboard reports are used for both management objectives and patient care. The latter is possible because the reports can be generated almost in real-time. (See [22] for more examples of near-real-time use of AIM for clinical workflow analyses).
Welch et al. [23] describe the use of the Emergency Department (ED) data mart, as a part of the organization's data warehouse. The ED data mart is filled with several administrative and clinical sources. Reports from the ED data mart revealed a number of patterns, for example admission rates and turnaround times by hour of day, which were used to improve patient flow. Other examples of clinical data warehouses include a data warehouse that is used as an infection control system [24], and a data warehouse that was used to assess adverse drug reactions [25]. In these data warehouses, information systems from the pharmacy department and laboratories were used as a data source, as well as other systems. The literature shows that, in some data warehouses, both clinical and administrative data sources are included. Moreover, usually extra data sources (e.g. paper records); analytical tools (statistical packages); and presenting tools (the produce reports) are needed in conjunction with the data warehouse, in order to meet quality management goals.

Rubenfeld promoted the use of computerized medical databases to measure and improve the quality of intensive care [26]. However, there is still little evidence in the literature of the presence and use of data warehouses containing ICU data. For example, in the studies by Nishi et al. [27] and Alban et al. [28], on early readmission and mortality after readmission, respectively, data from the PCIS was combined with data warehouse data but the last was administrative data from the hospital information system on length of stay and mortality. This is also the case for the study by Byington et al. [29] on pneumococcal empyema in children: the hospital data warehouse, containing administrative and diagnosis data was queried for all patients with a certain ICD-9 code. After that, data was combined with the (paper) medical records of the patients and electronic data from the microbiology laboratory. In the study by Dasta et al. [30] on costs and outcomes of acute kidney injury following cardiac surgery, financial and clinical data from the hospital's data repository was matched to APACHE III data from the ICU's clinical information system.

Brammen et al. [31] provided the only example of a data warehouse that uses ICU data as a source. They describe how their hospital is using a data warehouse for scientific research on the interface of intensive care and genetics. The paper does not delve into the technical details of the development, but it is clear that this data warehouse has a specific and narrow focus that fits current research interests but is not prepared for future needs. From this we conclude that data warehousing in intensive care is emerging, but not yet documented very well.

Methodology

In the development of the ICU-DWH, the multidimensional modeling method as advocated by Kimball was applied [2]. In the literature discussed above, we found one hospital that used the same methodology [8]. At the Erasmus Medical Center, the organization-wide DWH was built in several increments, adding new data marts along the way. Multidimensional modeling with tools such as CaseTalk™ and Oracle Designer, was necessary considering the magnitude and complexity of the DWH. Compared to the DWH described by Ebidia et al. [32], using Microsoft Access, the DWH has far more tables and dimensions, requiring more powerful hardware and software.

Although the data warehouse is complex, its development process was transparent for the users of the data warehouse (managers, doctors, researchers), because all elements of the DWH were defined using their own language. This was experienced as the main advantage of the methodology used (Metadata Frame, based on Fully Communication Oriented Information Modeling).

A critical note to the methodology, however, is the focus on the end products of the DWH: reports with fixed data elements, produced for a defined user group in the organization. This focus can be explained by the origin of the data warehouse as a managerial tool. However, the ICUs had mainly ad hoc research questions with a clinical focus. Therefore the interviewees and the domain experts in the project team wanted to put all data types at the lowest grain in the data warehouse, including free text. Except for the free text, all data elements were indeed modeled in the ICU-DWH, but the lack of a clear standard report (and the large amount of data elements) complicates the testing of the DWH. Testing now is an ad hoc activity that can always reveal inconsistencies and errors. This is one of the reasons why the testing phase has lasted almost as long as all of the other phases together.

Lessons learned

1. The preparation phase is crucial, but takes a lot of time. This was partly caused by the complexity of the clinical information system and the amount of wishes expressed by the domain experts, but it was also caused by the intensive user participation in the project team. Active user participation has proven its value in the past, when the clinical information system was implemented in the ICU [4], but there is also a risk. Compared to IT-driven, top-down projects in health care, projects like these, which place end users in a central position, are highly dependent on input from doctors. Their work in the ICU, and the continuous availability to the clinic sometimes conflicted with the linear structure of the DWH project management and planning of team meetings. For the benefit of continuity, a spreadsheet was used to exchange updates of the bus matrix in the project team. All members could add their input at the time

that was most convenient, allowing the project to proceed without the regular attendance of clinical domain experts.

2. It is crucial to train the users of the data warehouse in using the analytical and reporting tools, and to provide them with the tools and support they need. While the managers are more familiar with Business Objects, because they already use it for other parts of the data warehouse, the clinical staff and the researchers experience difficulty with the software. Most doctors are familiar with a statistical software package, but not with On-Line Analytical Processing tools, such as Business Objects. In the complex ICU-DWH a complex query cannot be built through simple trial and error, but it has to stem from a clear and unambiguous (research) question. Because of the complexity of the data model, it is recommended that the key users check the queries of researchers. A report that appears valid, might still present misleading or wrong data. Moreover, the users of (performance) reports need to learn how to interpret the data because its format is different from the medical data presentations they are familiar with [33]. We propose that a course on ICU-DWH and Business Objects is offered a few times a year, for those nurses and (junior) doctors who want to do research in the ICU.

3. Developing clinical data warehouses places data quality high on the agenda. Streamlining data is challenging because definitions for individual items must be clear and unambiguous throughout the organization, while in practice shared data elements have alternative definitions, owing to a range of different (clinical and administrative) users with a variety of different information needs [3]. Thus, the data warehouse development raises new questions about system integration, definitions and data quality. Especially data warehouses that use manually entered patient data face quality problems regarding completeness, accuracy, timeliness, and so forth. The DWH is fully dependent on the data in the source systems. For example, regarding the issue of the chest X-rays, mentioned earlier. Currently, only a simple monitoring query can be made, producing a report showing that fewer X-rays were ordered. The DWH reports cannot show whether these X-rays were ordered for the right patients (that is, the patients that had medical reasons for a chest X-ray) if there is no data in the PCIS (and consequently in the DWH) on this. Health care staff is usually not aware that the data they enter in an electronic record is used for other purposes. However, if professionals learn what they can and cannot do with the data, they will probably be more motivated to improve their recording practices. That way, the DWH can be a catalyst for data quality improvement, and so for *information* quality improvement. This takes, however, continuous effort.

Data warehouse development for clinical environments such as the intensive care seems valuable and promising. It is crucial for the developers to use clinical expertise, and to manage this complex development process collectively.

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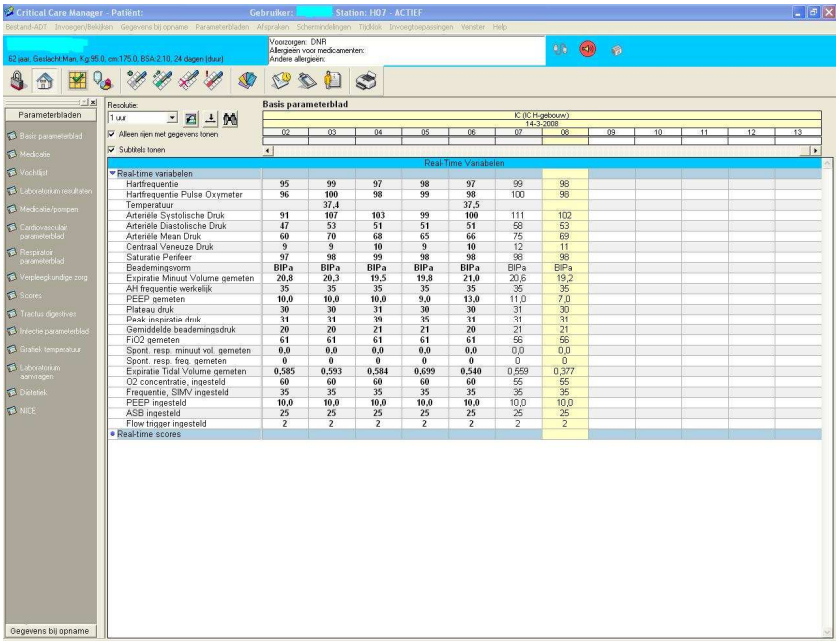
Appendix 4.1. Modeling with FCO-IM

The patient chart in the PCIS, showing Realtime Measurements from the bedside monitors (Figure 4.1).

Figure 4.1. Patient chart in Critical Care Manager/CareSuite



Fact expressions on Heart Frequency were defined as examples for the project team to validate…

- For patient 587801 on 14-03-2008, 5:00:00 h for heart frequency a value of 98 has been recorded.
- The measurement for patient 587801on 14-03-2008, 5:00:00 h for heart frequency has beats per minute as a unit.
- Has the measurement for patient 587801on 14-03-2008, 5:00:00 h for heart frequency been validated by a nurse or doctor? 1.

In CaseTalk™, the first fact expression is ‘grammatically’ analyzed as is shown in Figure 4.2, and the result of this analysis is presented in what is formally called an ‘information grammar’, shown in Figure 4.3.

Figure 4.2. Expression tree in CaseTalk™ for the fact type Real-time measurement with result

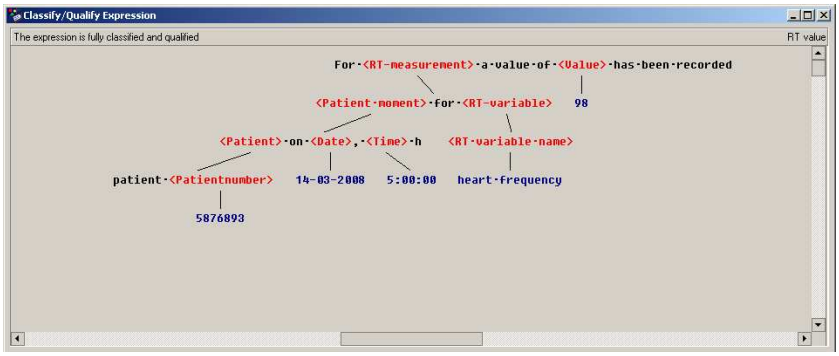
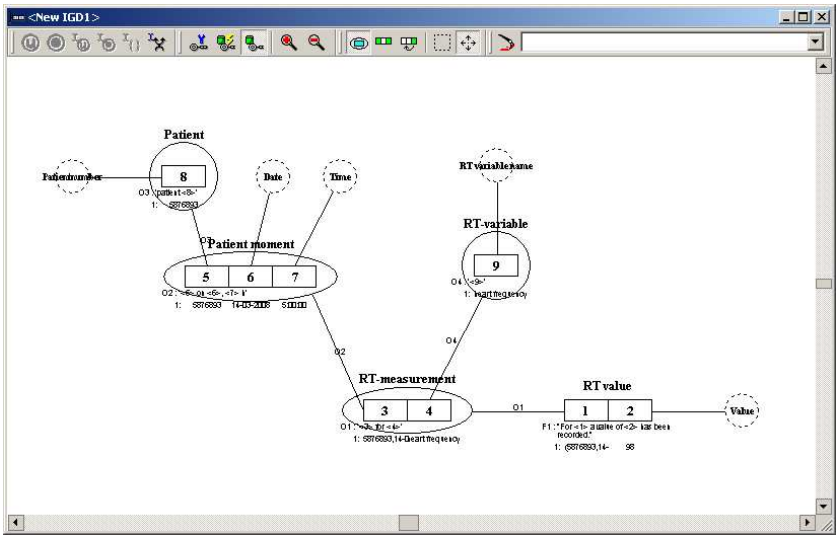


Figure 4.3. The elementary information grammar for Real-time measurement with result



When all relevant facts from all the concrete examples are analyzed in the same way as in Figures 4.2 and 4.3, CaseTalk™ can derive a complete information model from these facts, with the minimum number of tables needed to contain all information corresponding to the relevant facts. The fact type in Figure 4.3 appears in this model as part of the table shown in Figure 4.4.

Figure 4.4. The table Real_time_measurement as emerging from the algorithm of CaseTalk™

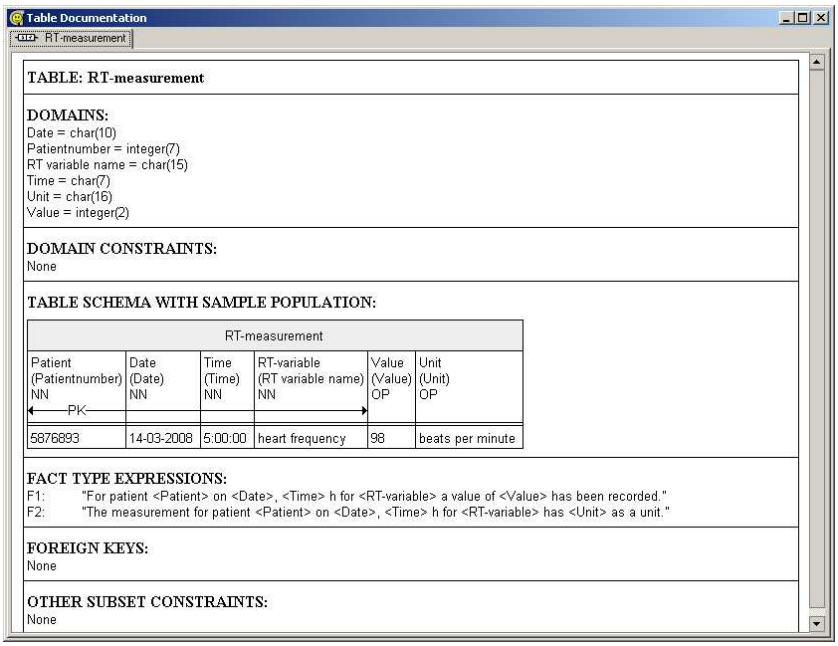


Table Documentation

RT-measurement

TABLE: RT-measurement

DOMAINS:
Date = char(10)
Patientnumber = integer(7)
RT variable name = char(15)
Time = char(7)
Unit = char(16)
Value = integer(2)

DOMAIN CONSTRAINTS:
None

TABLE SCHEMA WITH SAMPLE POPULATION:

RT-measurement					
Patient (Patientnumber) NN	Date (Date) NN	Time (Time) NN	RT-variable (RT variable name) NN	Value (Value) OP	Unit (Unit) OP
←PK→					
5876893	14-03-2008	5:00:00	heart frequency	98	beats per minute

FACT TYPE EXPRESSIONS:
F1: "For patient <Patient> on <Date>, <Time> h for <RT-variable> a value of <Value> has been recorded."
F2: "The measurement for patient <Patient> on <Date>, <Time> h for <RT-variable> has <Unit> as a unit."

FOREIGN KEYS:
None

OTHER SUBSET CONSTRAINTS:
None

Chapter 5 Improving the Quality of Eye Care with Tele-ophthalmology: a Case of Shared-care Glaucoma Screening[4]

Introduction

Information and communication technology (ICT) can play a key role in care innovations like task redesign and shared care [1]. ICT is well suited to the coordination and information exchange that such redesigned work practices require. In addition, it can help to structure the work of non-physicians so that they can perform 'medical' tasks safely, responsibly and satisfactorily [2]. Tele-ophthalmology uses new (digital) diagnostic devices, information exchange technologies and sometimes shared electronic patient records to provide eye care at a distance. So far, however, publications about tele-ophthalmology have reported mainly small pilot studies, focused on the technical or clinical feasibility of tele-ophthalmology [3-6]. Reports on routine telemedicine services in ophthalmology (as in other parts of healthcare) are still rare [7,8].

We have carried out an evaluation of a tele-ophthalmology service in the Netherlands, namely the Rotterdam Shared-Care Glaucoma Screening Project. In this project, task redesign (including delegation of tasks from ophthalmologists to optometrists) was supported by ICT to provide high-quality glaucoma screening for that part of the Rotterdam population that is at increased risk of glaucoma. The project now provides a routine service. Our research question concerned the quality of care realized in this service: the quality of work, and the efficiency and effectiveness of the screening process. We have also investigated the interdependency of ICT and task redesign in the organization of this shared-care service.

[4] This chapter is published as: De Mul M, de Bont AA, Reus NJ, Lemij HG, Berg M. Improving the quality of eye care with tele-ophthalmology: a case of shared-care glaucoma screening. *Journal of Telemedicine and Telecare* 2004;10:331–336.

Background

Glaucoma is a group of conditions that cause a gradual loss of vision, initially without symptoms. This vision loss is caused by damage to the optic nerve, and is often (but not necessarily) related to high intraocular pressure (IOP). In The Netherlands, people at risk for glaucoma are screened only when they visit an ophthalmologist, or when a high IOP is found during a visit to an optician. Any form of structured screening for people at high risk would be an improvement but, because of the shortage of ophthalmologists, this would be impossible, unless other professionals such as optometrists provided such a service [9].

Scanning laser polarimetry, featured in the commercially available GDx equipment (Laser Diagnostic Technologies, Inc., San Diego, CA, USA), is a new approach for glaucoma detection [10,11]. A scanning laser polarimeter estimates the thickness of the retinal nerve fiber layer (RNFL) using the polarization properties of nerve fibers; differences in retardation of the polarized laser light correspond to differences in RNFL thickness. GDx measurements are presented in several ways: as fundus images, as thickness maps and as graphs, showing the various indices of the RNFL. The Rotterdam Eye Hospital was involved in the development of the GDx nerve fiber analyzer (GDx NFA) and has had much experience with this imaging system.

Glaucoma screening project

The Shared-Care Glaucoma Screening Project was initiated in 1999 by staff at the Rotterdam Eye Hospital and 10 optometrists in the Rotterdam area. These optometrists were trained by the hospital and equipped with a GDx NFA.

From their retail optician stores, the optometrists are linked to a network that connects the GDx computer to a server in Germany, where all the data are stored (Medstage, Siemens Medical Solutions, Munich, Germany). The participating optometrists offer an extensive ophthalmic examination to clients at increased risk for glaucoma. The principal risk factors are:

1. age ≥40 years;
2. IOP ≥24 mmHg (1mmHg=133 Pa)
3. difference in IOP between fellow eyes ≥5 mmHg;
4. a family history of glaucoma

First, the optometrists perform a routine ophthalmic examination, which includes taking the medical history, IOP measurement and examination of the optic nerve head. In addition, they take measurements with the GDx NFA; they assess the quality of the GDx images and judge the GDx results to be either ‘normal’ or ‘suspect’. After that, they record their observations on an electronic patient form. They attach the matching (uncompressed) digital GDx images to this form.

In the hospital, all data submitted by the optometrists are assessed by technicians who work in the perimetry department, the department of the hospital where the visual field is assessed. These technicians, who are experienced GDx users, assess all data submitted by the optometrists. They also access the server, open the electronic forms and download the GDx images. They reassess the quality of the images and the GDx results. When in doubt, the technicians consult a physician. Based on the GDx results and the examination carried out by the optometrists, the technicians recommend further tests at the hospital, or follow-up by the optometrist. They record their assessment and advice on the same electronic form. Finally, the optometrists check the hospital's response on the server and inform the client accordingly.

Methods

To evaluate the quality of delivered care in the tele-ophthalmology service, we focused on those aspects of quality that were most critical to the screening process:

1. The quality of work of the optometrist - their capability to produce the GDx results and to interpret them correctly;
2. Efficiency - whether the transfer of screening tasks from the hospital to the optometrist represented an efficient use of hospital resources;
3. Effectiveness - whether this new screening process detected patients who would probably not have presented themselves at a normal ophthalmologists' appointment because their IOP was within normal limits or because there was no history of glaucoma in their family.

We defined a set of measurements for these aspects of quality (Table 5.1). All measures, except for sensitivity, could be derived from the patient data routinely collected throughout the screening process. To estimate sensitivity, we invited 200 patients to re-attend who were previously deemed normal, and took pictures of the optic disc with a non-mydriatic fundus camera. These pictures were judged by a glaucoma expert. If the discs were suspicious, the patients were called for additional testing at the hospital.

Table 5.1. Selected measures of quality of care

Aspect of quality	*Measures employed*
Quality of the optometrist	Quality of the GDx image according to the hospital technician[a]
	Proportion of agreement between optometrist and technician on classification of the GDx images
Efficiency of the screening process	Percentage of patients not requiring further testing in the hospital
	Percentage of patients with risk factors[b] not consulting the ophthalmologist
	Positive predictive value of a suspect GDx measurement
Effectiveness of the screening process	Number of glaucoma patients detected without risk factors [b]
	Sensitivity of the GDx

[a] This judgment was based on the centering of the optic disc on the image, as well as image focus, any inadvertent eye movements and the exposure of the image.
[b] The specific risk factors were IOP >24 mmHg and relatives with glaucoma (all patients screened were at high risk).

Results

At the time of the study, a total of 2300 people had been screened in the project. We excluded the first 500 patients from our analysis, because during the first months of the project, technical problems in the electronic data exchange hindered routine data collection. In total, we analyzed data from 1729 patients.

Quality of work of the optometrist

According to the trained technicians of the perimetry department, 11% of all GDx images from the 1729 patients were of poor quality, generally either because of eye movement during image acquisition which gave rise to motion artefacts or because anatomical characteristics of the patients' cornea led to erroneous GDx measurements. Most images were judged to be of satisfactory (76%) or even high (13%) quality.

In the 1532 cases in which image quality was at least satisfactory, the optometrists judged 39% of the images as suspect, while the technicians considered only 26% of them to be so (397/1532). Technicians and optometrists agreed in 81% of the cases ((888+351)/1532) about whether the image was normal or suspect (kappa=0.57) (Table 5.2). The agreement on suspect images was 88%; the agreement about normal images was 78%. This reflects the caution of the optometrists: if they had any doubts about an image, they judged it to be suspect. We also found that the proportion of agreement rose with time, from 77% in 2000 (kappa=0.52) to 88%

in 2003 (kappa=0.75) (*P*=0.005). Of the 46 patients whose images were classified as 'suspect' by the technician and normal by the optometrist, one patient turned out to have glaucoma.

Table 5.2. Agreement on classification of the GDx images between optometrists and technicians

		Assessment by hospital technician		
		Normal	Suspect	Total
Assessment by optometrist	Normal	888 (58%)	46 (3%)	934 (61%)
	Suspect	247 (16%)	351 (23%)	598 (39%)
	Total	1135 (74%)	397 (26%)	1532 (100%)

Percentages are of total (*n*=1532)

Efficiency of the process

We found that 70% of the 1729 patients did not require further testing for glaucoma at the hospital (Table 5.3). About one-third of these patients were advised to visit their optometrist for follow-up in the next five years. Of these, 8% had an IOP of 24 mmHg or more and 37% had a family history of glaucoma. Because of their increased risk, monitoring by the optometrists was recommended every one to three years.

Table 5.3. Advice of the hospital regarding all study patients

	No	***%***
No follow-up required	705	41
Follow-up within 1-5 years at optometrist	508	29
Further testing at perimetry department	471	27
Direct referring to ophthalmologist's outpatient clinic	39	2
Missing	6	0.3
Total	*1729*	*100*

Of all patients, 27% were advised to attend the perimetry department for one of several reasons:

1. they had suspect images;
2. they had poor-quality images, which made a reliable assessment impossible;
3. they had normal images but other risk factors for glaucoma.

The technicians called these patients for a second measurement with the GDx NFA, and testing of their visual fields at the perimetry department. Not all patients attended; in total 431 (25%) patients did so. Most of these patients were sent back to the optometrist or were advised to visit the perimetry department again in a year or two. Of this group, 10% had an IOP of 24 mmHg or more, and 39% had a family history of glaucoma.

A total of 162 patients were subsequently referred to the ophthalmologist. Thirty-nine patients were referred directly to the ophthalmologist without a visit to the perimetry department, because their examination had revealed a narrow anterior chamber angle or a very high IOP.

Some patients failed to attend, resulting in 188 ophthalmologists' referrals (11% of all screened patients).

We found a positive predictive value of the GDx measurement of 18%, which means that two out of 11 patients with a suspect GDx image (as assessed by the technician) had glaucoma or suspected glaucoma.

Effectiveness

Most patients were classified as normal, either because the ophthalmologist diagnosed them as normal (for those patients referred), or because their eyes were deemed normal or only slightly suspect by the technicians (Table 5.4). Of the 1729 patients, 80 (4.6%) had established glaucoma. Of these, 63% had an IOP less than 24 mmHg, and 45% had no family history of glaucoma. Within the group of glaucoma patients, there were 41 cases of open-angle glaucoma and 39 cases of narrow-angle glaucoma. Apart from glaucoma, several cases of suspected glaucoma (probable optic nerve changes without glaucomatous field defects) and ocular hypertension were found. All these patients received further ophthalmologic treatment and monitoring.

In the sample of 200 patients with normal GDx results who also underwent optic disc photography, two more cases of glaucoma (1%) were detected. The estimated sensitivity of the GDx in this screening process was 82% (4.6/[4.6+1.0]).

Table 5.4. Diagnosis of all patients included in our study

	Number	***%***
Normal	1518	88
Established open-angle glaucoma	41	2
Established narrow-angle glaucoma	39	2
Suspected glaucoma	24	1
Ocular hypertension	29	2
Other eye disease	13	1
Missing/drop-outs	65	4
Total	*1729*	*100*

Discussion

The present study has answered three important questions about the optometrists' competence, and the effectiveness and the efficiency of the screening process. First, the results of our study indicate that the optometrists fulfilled their task in glaucoma screening adequately. The majority of the images were of at least satisfactory quality, and the optometrists' ability to distinguish normal from suspect images improved with time, as they gained experience.

Second, scanning laser polarimetry in a primary care setting made the screening more effective than traditional methods available to Dutch optometrists, such as IOP measurement [12]. More cases of glaucoma were detected, and many people at increased risk for glaucoma could be monitored outside the hospital. The proportion of patients with open-angle glaucoma in our study (2.4%) was considerably higher than the prevalence of this type of glaucoma in the Dutch population (0.8%) [13]. This is not surprising as we only screened people at increased risk for glaucoma. In our study, the estimated sensitivity of the GDx was 82%. This is lower than was reported in a controlled study of subjective analyses of complete GDx results [14], but higher than several other studies that focused only on the GDx parameters [15]. At present, the hospital uses a GDx with a variable corneal compensation (GDx VCC), which has a reportedly higher diagnostic accuracy than the GDx NFA [16]. The participating optometrists may switch to this device in the next few years.

Third, the screening process was shown to be efficient. Many people at increased risk for glaucoma – and therefore requiring ophthalmology care – could be monitored without consulting an ophthalmologist. The positive predictive value of a suspect GDx result was not very high (18%). This was as expected, because of the low prevalence of glaucoma in the screened population. As the GDx can only detect glaucomatous damage and not eyes merely at a high risk of contracting the disease (such as eyes with narrow chamber angles, capable of closure), a standard examination which includes IOP measurement and ophthalmoscopy remains important. Although many unnecessary visits to the hospital could be prevented, there would be numerous false positive referrals. The next step would be to improve the process, for example by repeat testing before referral [17].

Since the mid-1990s, shared care in ophthalmology has increased, especially in the UK with shared care in screening and follow up of glaucoma and retinopathy. Positive patient outcomes were found in a large randomized controlled study in Bristol that involved monitoring glaucoma patients and glaucoma suspects by community optometrists [18]. In this program, however, no electronic information systems were used. The Rotterdam Shared Care Screening Project is one of the first initiatives involving shared eye care in The Netherlands; it began when the Dutch Ministry of Health and the associations of ophthalmologists and optometrists jointly promoted cooperation and task redesign. It is an example of a service that successfully integrates shared care between primary and secondary care workers, and uses ICT.

In our view, the integration of ICT and task redesign described in this service is more than just a happy coincidence. Information technology and task redesign are deeply interdependent. It is the *interrelation* of the two that provides for care innovation, which in turn contributes to improving the quality of care. Usually, task redesign implies that work tasks are split up between different professionals, who do their work separately in space and time. Task redesign, then,

often increases the needs for coordination and information. ICT can facilitate shared-care glaucoma screening in several ways. First, it supports data collection and data exchange. In our screening service, the electronic form supports structured reports of the optometrist, while the Internet facilities provide communication with the hospital. Second, ICT facilitates the transfer of a substantial part of the screening process outside the hospital, in a primary care setting close to the patients' homes. The Internet platform here functions as a means of coordination [19]. The technicians can see which new cases have been sent, while the optometrists can check whether the images of their clients have been assessed yet. Third, the database of the Internet platform functions as a quality system, since the data are used to assess the quality of the images and the other examinations of the optometrists [20]. In this setting, then, ICT not only supports the screening process, but also facilitates professional-centered, total quality management [21]. Finally, ICT provides a basis for trust between ophthalmologists and optometrists in the service. This is especially important in The Netherlands, where highly educated optometrists, practicing in a commercial setting, are a relatively new phenomenon. By screening in a structured way (using standardized electronic reporting forms, for example) optometrists can prove and improve their competence and knowledge, and win the trust of ophthalmologists.

As ICT and task redesign are highly interrelated, it is obvious that the technical and organizational issues are equally important in order to realize shared-care-telemedicine that will yield significant benefits and prove feasible in the long run. The present glaucoma service has proved to be a fruitful first step towards cooperation between hospitals and optometrists in The Netherlands.

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Chapter 6 ICT-supported Skill-mix Change and Standardization in Integrated Eye Care[5]

Introduction

Health care is faced with a number of challenges such as an ageing population, the rise of costs and shortages of skilled health care workers. Skill-mix change of the healthcare workforce is presented as one of the solutions for the problems healthcare is facing [1]: by reallocating tasks among professionals, scarce resources could be used more efficiently, without compromising quality. Several developments have attributed to the current interest in skill-mix: the professionalization of nurses and paramedics in the 1970s [2,3], periods in which the efficient use of resources was needed, such as that of the lack of doctors in the 1980s [4], a transformation from supply-driven to demand-driven patient centered health care of the 1990s [5], and the breakthroughs in medical technology [6,7]. A well-known example of the latter is the development of X-ray technology, which resulted in radiology as a new specialty in medicine [8]. The potential for substitution is increased if new technologies make tasks simpler than the old technologies [9].

Skill-mix change can be brought about through, for example, task substitution (across professional divides, e.g. from physician to nurse), task delegation (from more qualified to less qualified staff within the same professional group), or task innovation (new tasks for new professionals). On a service level skill-mix change can be brought about through transfer of tasks from a hospital to the community [1]. Therefore, it is closely related to the development of integrated care. Skill-mix change, the focus of this paper, is now one of the key elements of (integrated) care programs and pathways for groups of patients with a particular disease [10].

[5] This chapter is published as: De Mul M, de Bont A, Berg M. IT-supported skill-mix change and standardisation in integrated eyecare: lessons from two screening projects in The Netherlands. International Journal of Integrated Care 2007;7:e15.

In this context, the rise of information technology (IT) may also contribute to skill-mix change. The integration of skill-mix change and use of information technology seems, at least in theory, very effective. For example, information systems could be used to organize all types of data collected during the course of a patient's trajectory and could add structure to it, thereby enhancing its information content. Information systems, like shared electronic records, could also sequence and structure activities, and so facilitate coordination among more professionals and/or in more locations [11]. However, little is known about the promises and problems of ICT-supported skill-mix change in everyday practice [10]. In many instances, skill-mix change and ICT can do without each other. However, we suggest that for the system's change that is needed to take health care to a next level – as proven in several reports of the American Institute of Medicine [12], ICT-supported skill-mix change is a concept that needs serious exploration and research. Despite all attention for information technology and skill-mix change, the two domains are hardly ever connected in the literature.

Standardization seems to be the core binding concept in discussions about the problems and promises of ICT-supported skill-mix change. Both information technology and skill-mix change require standardization of work processes, decision criteria and terminology to be effective. However, standardization can also stand in the way of high-quality health care work, when the wrong processes are focused on, or when standardization is pursued too rigidly. Thus, although their complementary values seem obvious at first glance, in practice a happy marriage between ICT and skill-mix change might not be self-evident at all [13].

In our research we explored the possibilities of creating an optimal fit between skill-mix change and ICT through standardization. We evaluated two well-known screening projects in eye care in the Netherlands on behalf of the Dutch Society of Ophthalmology (NOG). In both projects, aimed at retinopathy and glaucoma respectively, tasks were reallocated among professionals, and integrated-care was introduced. ICT was used to facilitate the care process. Eye care is one of the aspects of health care in which the rise of new technologies and new professionals has led to discussion about substitution of tasks [14]. In eye care, substitution of tasks is related to the development of new imaging techniques that require less specialized skills than traditional instruments like the slit lamp and lenses [15,16]. These developments led to new professionals in Dutch eye care: the technician as an assistant to the ophthalmologist, and the optometrist with a bachelor's degree in optometry, practicing in optician stores or hospitals [14]. They were also the grounds for delegating tasks outside the ophthalmologic domain, for example, to nurses of diabetic patients.

The structure of this paper is as follows. First, we will briefly describe the two skill-mix projects in eye care, and the methodology of our evaluation study. In section three, we will explicate our theoretical assumptions about the relationship between skill-mix change, information

technology and standardization. After that, we will present our findings when studying standardization in the two screening projects, and thereby show the tensions that exist between the design of an optimal match of ICT and skill-mix change. In the discussion portion we will answer the question, what is needed for an optimal co-operation of skill-mix change and information technology?

Methods

The setting

The main characteristics of the two integrated care projects for glaucoma and retinopathy are briefly described in Table 6.1 and 6.2.

Table 6.1. Description of Glaucoma project

Glaucoma project	
Setting	The Rotterdam Eye Hospital and 10 optician's stores in the Rotterdam area.
Aim	Detecting cases of glaucoma in the population at risk. Glaucoma is an eye disease related to high intraocular pressure.
Prior to task redistribution	People at risk for glaucoma were referred by the primary care physician to the ophthalmologist for tests and a physical examination.
Professionals involved	Ophthalmologists, technicians, and optometrists. Optometrists have a bachelor's degree in optometry, and are specialized in eye health. Technicians assist the ophthalmologist; they perform several visual tests under supervision of the ophthalmologist.
Technologies used	Nerve Fiber Analyzer, Internet server.
The new process	Trained optometrists use a Nerve Fiber Analyzer to test the condition of the eyes. This camera produces an image and estimates the thickness of the nerve fiber layer using polarized laser light. The images are saved on the Internet in a database that is also accessible to the ophthalmologists and their trained technicians at the hospital. After the assessment, they decide whether a referral to the hospital for ophthalmic evaluation is necessary. This glaucoma screening service has become part of regular care in 2003.

The participants and data collection

Our evaluation of the two screening projects had a multi-method design, combining quantitative and qualitative methods. We used a sociotechnical approach to collect our data, which implied that both the healthcare professionals and the technologies (cameras, recording forms, and protocols) were the objects of our study and analysis.

Table 6.2. Decription of Retinopathy project

Retinopathy Project	
Setting	Isala Clinics, Zwolle
Aim	Regular screening of all patients with Diabetes Mellitus (DM) for retinopathy, a complication of DM related to micro vascular damage of the eye.
Prior to task redistribution	The ophthalmologist was responsible for screening diabetes patients every 1-2 years.
Professionals involved	Ophthalmologists, diabetes nurses. Diabetes nurses perform routine tests every year and educate their patients.
Technologies used	Non-mydriatic retina camera, local hospital network, and electronic patient record.
The new process	Trained diabetes nurses make digital images of the back of the eyes of their patients with a non-mydriatic retina camera. The images are saved in the hospital's network, which is also accessible to the ophthalmologist. The ophthalmologist examines the blood vessel pattern and decides whether a consultation is necessary.

Unfortunately, the projects had already begun when we commenced the evaluation. Therefore, a before and after design was not possible. Instead, we analyzed administrative and patient data to assess the quality of care realized in these projects. These findings were published in the Journal of Telemedicine and Telecare, in 2004 [17]. Parallel to this quantitative evaluation, we conducted 37 formal, semi-structured or informal interviews with all ophthalmologists, optometrists, nurses and ICT-experts involved in the two projects. Data collection took place between April 2001 and November 2003. Key informants were interviewed several times. For the retinopathy project, the key informants were the internist, the ophthalmologist and one of the diabetes nurses. In the glaucoma project the key informants were the ophthalmologist, one of the technicians and two optometrists. For the interviews topic lists were used, including the themes cooperation between the professionals, communication patterns, satisfaction with the ICT used, and perceived effectiveness and efficiency of the care program. The interviews were audio taped and transcribed. In addition, we had email contact with our informants, attended project meetings, joined meetings for (re)training and visited the key informants at their workplace several times to observe their work. All research activities are summarized in Table 6.3.

We analyzed our empirical data for instances of standardization, and the interaction of the professionals and the technologies in these situations. The data was clustered by emerging themes to answer our research question: "What is needed in these projects for an optimal match of ICT and skill-mix change?"

Table 6.3. Research activities

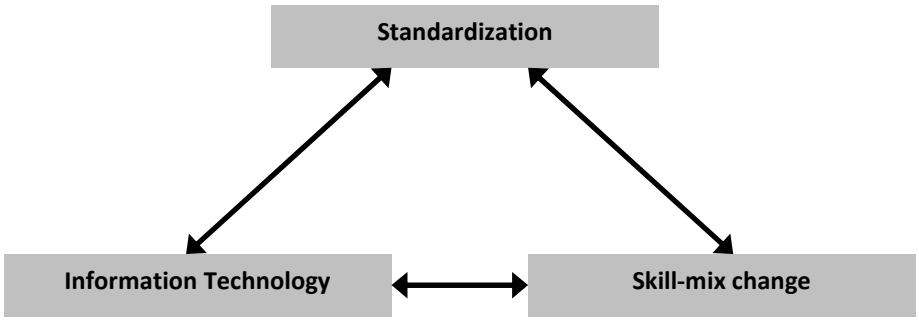
Time frame	*Research activity*	*Subjects in Retinopathy project*	*Subjects in Glaucoma project*
July – October 2001	Observation and unstructured interview		3 Optometrists 1 Technician 1 Ophthalmologist
November 2001	Semi-structured interview	1 Ophthalmologist	
December 2001	Observation and group interview	1 Ophthalmologist 1 Internist 1 Diabetes nurse 1 Researcher	
March – June 2002	Semi-structured interview	1 Ophthalmologist 1 ICT-developer 1 Diabetes nurse	1 Project manager 10 Optometrists 1 Technician 3 Ophthalmologists
March – April 2003	Observation and unstructured interview		4 Optometrists 1 Technician 1 Ophthalmologist
August 2003	Semi-structured interview	1 Ophthalmologist 1 Internist 1 ICT-developer	
July 2001 – October 2003	Email & telephone contact	All professionals involved	Project manager
July 2001 – October 2003	Attending project meetings	Project team	Project team
July 2001 – October 2003	Attending training sessions		Project team & attending optometrists

Skill-mix change, information technology and standardization

IT and skill-mix change share an important precondition: standardization of work processes. The relationship between these three concepts is presented in Figure 6.1.

The use of information technology is valuable in redesigned clinical work processes, because it fulfils two roles. First, information systems can be used to organize all types of data collected during the course of a patient trajectory and can add structure to it, thereby enhancing its information content. Second, information systems, like shared electronic records, can sequence and structure activities; it can make synchronous coordination possible; and it can facilitate coordination between more locations [11,18]. Because of these features, ICT has the potential to significantly support task delegation and reallocation in skill-mix change projects.

Figure 6.1. Relationship between skill-mix change, information technology and standardization



At the same time, redistribution of tasks is often necessary for information systems to optimize their potential impact. For example, structured, detailed recording forms are a prerequisite for electronic patient records that allow support of the decision-making process, or plan all activities in a care trajectory. Yet physicians are often not the best candidate for such detailed and structured data entry tasks: their (relatively expensive) time is better used for tasks that require their clinical expertise. A specialized nurse or clerk, with specific time allotted for such a task, is often both more efficient and more disciplined in the data entry than a physician [10,19].

Standardization refers to the 'process of rendering things uniform'. Guidelines, protocols or other procedural standards are both the means and the outcome of standardization [20]. Therefore, we have to look at the process of standardization in practice (and not only to a specific procedural standard) to fully understand its impact on the care process. From the skill-mix perspective, standardization is often used to assure the quality of the work of the 'new professionals' who take over from the physicians. In protocols and practice guidelines, the physicians set down (in detail) what should be done. And conversely, if it is possible to standardize certain (clinical) tasks, it is easier to delegate these tasks from physician to non-physician. In many care programs efficiency and quality benefits can be realized by delegating tasks to nurses, secretaries, receptionists, etc [10]. These 'new' professionals have to develop the skills to actively use the standards, which implies that they have to know when to discard or adjust the standards according to the individual patient. This proficiency required for a standard to be effective, is at odds with the notion expressed in the literature that standardization leads to "cookbook" medicine. The professionals involved have to submit themselves to the standards, which is not equivalent to passively following the rules, but to actively allowing the standards to affect their work [20].

In addition, ICT requires standardization as well. The roles of coordination and accumulation [11] can only be fulfilled if professionals align themselves with the standards of the system. For example, these standards can relate to the terminology used in the system (e.g. diagnosis codes), and the procedures incorporated in the system (e.g. sequence of documentation). This property of ICT – that it requires standardized use – can be optimally utilized in situations where standardized work is required. It can be a deliberate choice to use ICT instead of paper records and forms in skill-mix change as this enables standardization.

Standardization plays an important role in ICT-supported skill-mix change. It is not a matter of more or less standardization than in the 'old' situation, but about creating an optimal fit. Unfortunately, this fit is not fully modifiable. Sometimes there are conflicts of interest between or within the professional, clinical, technical and organizational domains. In those situations, tensions can arise when designing standardization and this often results in standards that are experienced as 'too strict' or 'unpractical' from the perspective of the 'new' professional. For example, the extent to which standards allow flexibility and diversion often depends on the amount of trust non-physicians (nurses, optometrists) have gained from the physicians that delegated their tasks. However, there can also be clinical considerations leading to a choice for strict standards. For example, protocols for chemotherapy have to be meticulously followed by oncology nurse practitioners, not because the oncologists question their proficiency, but because otherwise the therapy will be ineffective or perhaps even harmful.

Results

Both eye care screening projects can be seen as examples of task innovation and task delegation. "Screening" was split up into "gathering information & examination" and "assessment". The new diagnostic techniques facilitate skill-mix change, because they replace physical examinations of a specialized ophthalmologist. The (non-mydriatic retina) camera allows the nurse, or whoever is using the camera, to make images of the back of the eye, where changes in the blood vessel pattern (which can be caused by the diabetes) can be detected. The software in the nerve fiber analyzer, the camera used in the glaucoma project, estimates the thickness of the nerve fiber layer and calculates the probability of glaucoma. The results of the measurements, the digital images, are accompanied by an anamnesis performed by the optometrist or nurse. The ophthalmologist and the technician use these data to assess the images and to recommend follow-up. In the retinopathy project, the local hospital network is used for data exchange between nurse and physician. In the glaucoma project, a secure Internet connection is used to facilitate data exchange to and from a password-protected server.
These screening processes with delegated tasks could only be designed with the use of (information) technology. In our analysis we focus on three parts of the care process, where

(standardized) use of ICT plays an important role: performing clinical tasks, documentation, and communication between the professionals. In these areas tensions arose during the course of these projects with regard to standardization.

Standardization of clinical tasks

In both projects paper-based protocols were created that stated which tasks had to be performed by the nurse and the optometrist, and how this had to be done. The most important clinical task was the production of high-quality images with a digital camera. The protocols explained the use of this camera both for the process (how to prepare for the measurement, how many images to make) and the outcome (what is a high quality image and how many of these images are requested). That way the images produced by different optometrists and nurses with different cameras would be comparable.

In the glaucoma project the standard stated that six images of each eye had to be made by the optometrist, which would take about 10 minutes. In practice, the optometrists could not always follow this standard. In several interviews the optometrists explained why the standard did not work in practice and their strategy to deal with this. If a patient had difficulty in keeping his eyes still, or if he had an eye disease, such as cataracts, it was impossible to produce six high quality images within a reasonable time and with reasonable amount of effort. Either, the optometrists made many more images than six per eye (which was more time-consuming), and then chose the best, or the optometrists decided to make fewer images, because they knew from experience that six images would be impossible within the time limits or because of the patient's condition. The optometrists would then send in fewer images, or images of lower quality. However, if the technician strictly followed the standard, she would have to reject these images and request new ones. In some instances this actually happened, which created extra work for the optometrists. Some optometrists resigned to the situation:

> "*They [the technicians, MM] will know, they have more experience (interview optometrist B, March 2002*).

Other optometrists, however, were very uncomfortable with this situation:

> "*If they [the hospital, MM] respond that the image has to be made again, I have my doubts. I don't see added value in asking my client to come again. There just cannot be a better image" (Interview optometrist G, March 2002).*

In the data we analyzed, we found only a few cases in which images were sent back, so quantitatively the problem seemed small. However, in the experience of the optometrists it was a significant problem that caused dissatisfaction. They regarded it as unfair criticism of their work. The optometrists discussed this with the ophthalmologist and the project team decided to set a new standard: at least one image per eye had to be sent to the hospital, provided that it was of high quality.

In the retinopathy project, the use of the retina camera was standardized, but along the way, new standards were introduced that caused resistance with the diabetes nurses. The camera that was purchased for the project was a so-called non-mydriatic camera, which meant that, in principal, the camera did not need dilated pupils to produce well-exposed images. This type of camera was chosen because it would be easy to use and no extra work was involved. According to the standard, dilation with medication was only necessary if the first series of images were too dark, for example because the patient had small pupils. Because dilation of the eyes leads to temporary blurred vision, the diabetes nurses were hesitant to dilate their patients' eyes:

> *"If we have a reason not to dilate our patient's eyes, then we don't…the ophthalmologist knows why we don't use dilation, but he disagrees with our arguments, that's the issue here" (Interview diabetes nurse, May 2002).*

According to the ophthalmologist, the nurses did not conform to the standard. Too many images could not be assessed, because they were too dark, and according to the ophthalmologist this could have been prevented if more patients' pupils had been dilated. The nurses disputed this, as the large majority of images could be assessed without problems. They wanted dilation to be an exception, not a rule.

Still, the ophthalmologist wanted to change the standard: as a precaution, all patients with small pupils and all patients that previously had dark images would require dilation. The nurses protested; they wanted to dispose of the eye examination altogether. In their opinion, the eye examination should be easy and should not produce a great deal of work for them or too much discomfort for the patient. Their work with the patient involved more than the eye examination: they also needed time for discussing blood glucose levels, the patients' life styles and time for examination of the feet. If the ophthalmologist knows best, then why doesn't he make the images himself, or have someone do it at the ophthalmic department, they argued. The ophthalmologist was not sensitive to the arguments of the diabetes nurses. He did not understand why these nurses were so reluctant to dilate their patient's pupils, and approached the 'problem' from a different perspective:

> *"That stuff is not dangerous, I would drink it myself! Maybe they are afraid that something goes wrong, and that they are responsible, but that is nonsense. If I ask them to do this, it is my responsibility, not theirs" (Interview ophthalmologist, September 2001).*

In both projects, the diagnostic instruments are easy to use, according to the ophthalmologists:

> *"I could teach you [the interviewer, MM] to make and interpret the retina images in two days" (Interview ophthalmologist retinopathy project, September 2001)* and *"Anyone can learn to make images in two weeks" (Interview ophthalmologist glaucoma project, May 2002)*.

Standards were designed to prescribe the use of the nerve fiber analyzer and the retina camera. In practice, however, tensions arose among the physicians who made the protocol and the optometrists and nurses who had to use it. These tensions were due to poor or unfunctional

standardization. In the glaucoma project the standard was updated to allow for more flexibility. This improved the workability of the standard. In the retinopathy project the standard was changed in an unexpected way as the technology now had to be used differently than intended (i.e. for dilated pupils only, while it was designed for non-dilated pupils). While this flexible approach in the glaucoma project resulted in more satisfaction for the optometrists and technicians, the strict approach in the retinopathy project caused dissatisfaction and even discussions about the skill-mix change itself.

Standardization of data recording

In both eye care projects, the transfer of information between the professionals about their separate tasks was important for the screening process as a whole. For this, the recording of data had to be standardized; the protocols codified which information was expected from which professional, in which format and at what time. In the glaucoma project, the patient file was a structured recording form on the Internet, which had to be filled out completely, before the data could be saved in the database. This mandatory character was beneficial for the hospital, since availability of all the data they needed for reviewing a patient's status was guaranteed.

For the optometrists, however, these structured procedures had some disadvantages, and they had to find alternatives to manage them. Firstly, since the structured recording form was derived from the clinical protocol, diversion from the protocol (as we saw in the previous paragraph) could lead to problems with the data recording. For example, behind the protocol lied the assumption that a patient has two eyes, and that both eyes needed to be tested by the optometrist. Therefore, the form requested two files per patient. However, there could be several reasons for an optometrist to confine him- or herself to examining only one eye: a patient may have been blind in one eye; or have one-sided cataract or another eye disease that made it impossible to analyze the nerve fiber layer with the camera. The most common reason, though, might be that the hospital requested that, for a particular eye, new images were made because of low quality. From our observations, we know that the optometrists found an alternative when dealing with this situation. They either attached the file with images from the one eye two times, or they used old images or false images and added an explanatory note to the form.

Secondly, the optometrists were not satisfied with the pre-structured forms, from which they had to choose from a limited list of options, for example regarding the perceived quality of the images.

> *"The options are very black-and-white. Often, an image is neither bad nor average. It's somewhere in between. How should I record that?" (Interview optometrist C, March 2002).*

They also lacked the option “best image possible”. The system’s feature to attach notes in free text was not used very often. As one of the optometrists confessed:

> *“I often forget to add a note that this image was the best image possible” (Interview optometrist E, March 2002).*

The third disadvantage was related to the technology used in the glaucoma project. The recording form on the Internet only allowed for complete entries. In the interviews, optometrists affirmed that this feature was useful, knowing that they were likely to forget things if the form did not guide them. However, they also experienced a downside: if one or more items were missing, the electronic form could not be saved, and the data would not be stored in the database. In fact, all data would be lost and the optometrist had to fill out the form once again. It is not practical to fill out the form during the patient examination, as not all data is available at that moment. Most optometrists wanted to review the images thoroughly after the patient had left, so they usually filled out the electronic form at quieter times, or after their store had been closed. We observed that, as a workaround, they used a paper form during the examination, or made notes on a piece of paper. Although this meant double work, the optometrists expressed to us that it was more efficient than using the Internet server only.

These three examples from the glaucoma project show that a structured recording method required by the information technology can be a barrier for the users and for the care process. The required completeness and the inaccuracy are examples of technological design failures that can, at least partly, be solved by building in more flexibility. If the optometrist can save incomplete recording forms in the database or send in only one set of images, he does not need the workaround. And if the list of choices for image quality matches the definitions of the users (good, average, moderate, bad) they will be more satisfied. However, for the project team, complete and structured patient records might be preferred to allow for continuous quality assessment by calculation of indicators like ‘% images of high quality’. The managerial or quality domain might conflict with the interest of the optometrists, who want an easy-to-use recording form that is tailored to their specific needs.

Standardization of communication

In both projects, the professionals who performed part of the eye screening were situated in geographically separated places. In the retinopathy project, the diabetes nurses worked at the outpatient diabetes clinic and in a few remote nursing homes, while the ophthalmologist was situated in the outpatient clinic of the ophthalmology department. In the glaucoma project, the optometrists were situated in optician shops throughout the extended Rotterdam area. As the professionals did not normally come into contact with each other, formal communication had to be arranged. In both projects, the communication was mainly the transfer of clinical and administrative data like the images, the visual parameters and the advice for follow up. For this,

they used the Internet and the hospital network, and thereby standardized the communication. Oral communication with the hospital seemed to be unnecessary: when the ophthalmologists or technicians saw a new case in the database, they knew that their assessment was expected.

However, there are also drawbacks to standardized communication. Firstly, as explained in a previous paragraph, there is the risk that the context of the data collection will be lost from view. There is a risk of jumping to conclusions, especially if the images are of low quality, For example, in the glaucoma project one of the optometrists received feedback from the hospital stating “Low quality! Send us new images”. Because the person who assessed the images (the technician), was not there when the image was made, he or she interpreted the image from a different perspective: "the image is too dark” or “the image is blurred" and therefore the optometrist had to do his work again. The optometrist, in turn, gave another interpretation:

> *“We always try to make the best image. ‘Better’ is not possible, under those circumstances… it is not realistic that the hospital asks us to make that image again” (Interview optometrist G, March 2002).*

A second risk follows naturally from the de-contextualization of data: the tone of the communication. Feedback from the technician in short notes like “Low quality! Send us new images”, can be (mis)understood by the optometrist as a negative or critical remark:

> *“The last few months, we noticed that the feedback from the hospital is sometimes very unfriendly… they use terms that are not always appropriate” (Interview optometrist A, March 2002)*.

The lack of other ways of communication (outside the standardized form) can lead to deterioration of the communication and dissatisfaction with each other’s work. For example, some of the optometrists did not feel appreciated for their work of making a good image with the nerve fiber analyzer, when they received ‘negative’ feedback.

> *“When is an image good enough? There are no agreements on this… we often doubt whether the image is good enough, but we decide to send it because it is the best result we can get” (Interview optometrist A, March 2002).*

It is striking that at the inception of the project, the ophthalmologist and technician expected that the optometrists would call if they were unsatisfied, or if they had questions regarding the feedback from the hospital. In practice only a few of the optometrists used the telephone as a regular communication tool alongside the Internet system. Those optometrists who called frequently, were satisfied with the communication. However, most optometrists said in the interviews that they hardly ever had telephone contact with the hospital. They confessed that this was due to lack of time or interest:

> *“We don’t contact the hospital, especially if a client is assessed as normal, while we thought he was suspect” (Interview optometrist D, March 2002)*.

Others had a negative experience:

> *"I got the feeling that my calls were not appreciated, because of the tone used by the technician." (Interview optometrist F, March 2002).*

Thus, for most optometrists, the main contact between the hospital and the optician stores was through the electronic recording form.

In the glaucoma project, the electronic recording form was used as a standardized communication tool between the optometrists, the technicians and the ophthalmologists in the Rotterdam area. However, not only geographical, but also professional boundaries had to be crossed. This 'social distance' between the professionals was one of the causes of dissatisfaction about the communication. This was also one of the main reasons why the communication problems in this project could not be solved with technical adjustments.

Discussion

In this chapter the role of ICT in skill-mix change has been explored. ICT can be used to accumulate information and to coordinate tasks. However, we demonstrated that it is more than a tool, because ICT also standardizes and transforms data and tasks. To understand what ICT does in skill-mix change, we examined the way ICT transformed skill-mix, while at the same time we showed that ICT was highly dependent on the healthcare professionals to become embedded in daily practice. In both eye care projects, for example, data recording had to be standardized to transfer information among the professionals about their separate tasks. Protocols codified which information was expected from which professional, in which format and at what time. As the patient file was a structured recording form on the Internet, which had to be filled out completely, before the data could be saved in the database, all data the hospital needed to review a patient's status was guaranteed.

The way standards are designed and used highly influences the 'success' of ICT-supported skill-mix change. Firstly, we demonstrated that standardization of clinical tasks can interfere with the work practices of optometrists and diabetes nurses, and can lead to tensions in daily practice. A more flexible approach to the use of protocols seemed to be a solution for this dissatisfaction [20,21], but then the physicians should support this development. In one of the projects this was not the case. Secondly, we showed that structured recording, although desirable for skill-mix change, needs workarounds. Professionals have to play an active role in matching the technology to their work [20]. Thirdly, we showed a change in communication patterns in these projects, when recording forms replaced informal, personal contact. Unintentionally, this affected teamwork [22,23]. Especially for the glaucoma project it seems important to restore the 'old' communication patterns.

Strategies for standardization can only be recognized and valued if the 'whole picture' is taken into account; that is, if we look at ICT and people (the professionals and users of the technology) together. Moreover, standardization was a valuable concept to show the co-construction of ICT and skill-mix change. Both in research and practice, focusing on only one aspect of skill-mix change has many shortcomings. By isolating technology and focusing on ICT-solutions, it is hard to circumvent technologically determinist accounts. The "embeddedness" of ICT in and dependence upon work practices and the professionals that use ICT, is easily lost from view. By looking at the processes 'behind the tools', for example the standardization process, the interrelation of the technical and the social becomes visible. Similarly, if the only focus is on the professionals involved in skill-mix change, there is the risk of overlooking ICT as an essential element of the process. In many skill-mix change projects, discussions about standards can be rephrased as discussions about proficiency and trust, as we saw in these two cases as well, regarding the administering of dilation medication and the complete recording forms. Only if we consider ICT as well, we see that trust is redefined in these projects. Trust is not (only) a matter of knowing each other and recognizing each other's skills, but it is shaped by and incorporated in the technology; the standardized cameras, the recording forms, and the data exchange that were crucial in these skill-mix change projects [24].

Recognizing the interdependency of skill-mix change and information technology is not only relevant for research into skill-mix change [25], but also for those who are actively involved in (developing) skill-mix change projects and integrated care programs. They should be interested in more than functional, technical and implementation issues of ICT. ICT can highly influence and transform work practices. Hence, it is important to know the possibilities and pitfalls of ICT in advance, as well as the organizational context in which ICT is going to be used.

Conclusion

IT is not only a tool that can be used in skill-mix change projects to accumulate information and to coordinate tasks of the various professionals involved in the care process. ICT also standardizes and transforms data and tasks. Therefore it has to be carefully integrated with the work of the healthcare professionals involved in skill-mix change. Developing ICT-supported skill-mix change by means of standardization is a matter of tailoring standardization to fit the situation at hand, while dealing with the local constraints of available technology and clinical and organizational context. It is a challenge to combine the best of both worlds.

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Chapter 7 Completeness of Medical Records in Emergency Trauma Care and an ICT-based Strategy for Improvement[6]

Introduction

The position of the medical records of Accident & Emergency departments has been affected by two developments during the last decades: the rising attention to the quality of care and the booming field of Information and Communication Technology (ICT). Compared to other parts of health care, the link between ICT and quality aspects like effectiveness, efficiency and safety may be even more important in emergency care, since emergency health care workers are among the most information intensive of healthcare professionals [1]. This is partly because they are involved in (life-and-death) situations that need a rapid response, and partly because in emergency care many disciplines cooperate. Quality assurance depends for a large part on information gathered at the point of care, found in the medical record. Consequently, the quality of the medical record itself is discussed: can we use the medical record for quality assessment? The outcome of these discussions is usually that the (paper) medical record cannot provide accurate quality information because of its incompleteness [2].

Quality of care has gained much interest on all levels of the health care system. The Committee on Quality of Health Care in America states that there is a chasm between what the overall quality delivered should be and what it actually is [3]. This sub-optimal quality of care reveals itself in inefficient care practices, medical errors, lack of evidence-based medicine, and a lack of patient-centeredness. With the call for improved quality of care, the quality of record keeping receives much attention as well. In fact, the quality of the medical record is often, directly or indirectly, associated with the quality of care: good records are seen as a sign of good quality of care and bad records as a serious threat to quality [4]. As an example, if healthcare professionals have to base their decisions on incomplete or inaccurate data in the medical record, there is a

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risk of wrong decisions and errors, leading to sub-optimal, or potentially even harmful, patient care. Also from a wider perspective, incompleteness (and other recording inadequacies like variance in documentation) is a quality problem, because it is difficult to use the record as a reliable source for quality information [2,5-7]. As insight in the quality of care is a first step to improving that care [8], the inability to use patient data for quality monitoring may also affect quality in the long run, as an important data source remains unused.

Patient Care Information Systems (PCIS) and other types of Information Technology are often seen as a silver bullet for the quality of emergency care in several ways. First, the PCIS is regarded as a means to produce high quality medical records: legible, accessible, and complete [9]. Second, these complete electronic records are seen as an ideal data repository for quality information and clinical performance measures [5]. Third, ICT itself leads to better quality of care, it is claimed, since ICT can support clinical decision making, improve efficiency in test ordering and prevent medical errors [10-13]. In discussions about PCISs, these three arguments usually go hand in hand. Many managers and other decision makers feel that, when they 'get rid of the bad and incomplete paper records' and implement an electronic patient record or other electronic registration device, record completeness and quality of care will improve. Research from social scientists, however, challenges this assumption, because they show that there can be good reasons for incomplete records [14,15].

We investigate the (impossibilities) of IT-based solutions for these issues and, by elaborating on the nature of completeness of medical records, propose a strategy to tackle the perceived problem of incompleteness. We studied the completeness of paper trauma records of the Accident & Emergency Department (AED) of a large University Hospital. For the management of the AED incompleteness of the paper records was a serious problem for several reasons. First, they feared that incompleteness of the medical records had a negative impact on the quality of care, as potentially vital information would be missing at the point of care. In addition, from a legal perspective, completeness of the medical record was also seen as important. Most trauma patients who are treated in the AED have had an accident, therefore the AED staff is often involved in legal procedures related to questions for guilt and damage. Third, the Minister of Health had designated this University Hospital in 1999 as one of the ten Dutch trauma centers. She had initiated the development of a national quality system for these trauma centers. The quality system consisted of a trauma registry, through which the quality of this expensive and high-risk care could be monitored, and the trauma centers could be benchmarked [16]. This situation implied that the AED had to produce and report data about their trauma patients.

Methods

We studied the completeness of paper trauma records of the Accident & Emergency Department (AED) of a large University Hospital. For this, we used a multi-method approach [17,18]. By integrating qualitative and quantitative methods, it was possible to gain a thorough understanding of the dynamics of health care practice, medical records and ICT implementation, and to approach the issue of incompleteness from different perspectives.

Qualitative study

The aim of the qualitative study was to investigate staff's perceptions of their record keeping, and to observe their recording practices. Moreover, we were interested in their ideas about electronic medical records.

First we carried out observations in the AED to gain an overview of the dynamics of the department and the way the records were produced and used in the daily work of the professionals. These observations were carried out during the day shift, by one observer, for a period of 2 weeks. After that we carried out a small quantitative analysis of the completeness of the records (see below). Throughout the project (2000-2001) semi-structured interviews were carried out with the staff of the department, both doctors and nurses, on subjects like current practice of documentation, what completeness meant to them and what they thought of patient care information systems (n=8). These interviews were recorded on tape and transcribed.

Quantitative study

The aim of the quantitative study was to investigate completeness of the AED records for serious trauma patients. We selected the medical records of a group of trauma patients who visited the department between November 1999 and August 2000, based on three criteria: (1) patients suffering from severe trauma; (2) patients who needed care urgently; and (3) patients who were admitted to the hospital after their visit to the AED. The selection resulted in 226 records.

As the measure for completeness, we selected those items of the paper record that had to be reported to the national trauma registry at the time this registry was implemented. The Dutch dataset of the registry is based on the original dataset from the Major Trauma Outcome Study (MTOS), which had been carried out in the US in the 1980s [17]. This original dataset is expanded with some data on pre-hospital and post-AED care, and is called MTOS+ (Appendix 7.1). The items we selected for our study were: patient name, address, gender, date of birth, hospital ID, time of arrival in the AED, systolic blood pressure, respiratory rate, Glasgow Coma Score (GCS), and Revised Trauma Score (RTS). Although diagnoses are recorded on the AED chart, we decided to leave them out of our checklist, because these diagnoses were free text while MTOS+

requires specific diagnosis from a predefined list of codes. In addition, we expanded our checklist with three items: time of departure or transfer of the patient, discharge destination, and name or signature of the doctor.

Findings

Quantitative study

Of the MTOS+ data set, some items are always recorded, while others appear only occasionally on the trauma chart (Table 7.1).

Table 7.1. Completeness of trauma records (n=226)

Item	***Present***
Patient name	226 (100.0%)
Patient address	226 (100.0%)
Gender	226 (100.0%)
Date of birth	226 (100.0%)
Patient ID	226 (100.0%)
Time of arrival patient	226 (100.0%)
Systolic blood pressure at arrival	205 (90.7%)
Respiratory rate at arrival	115 (50.9%)
Glasgow Coma Score (GCS) at arrival	142 (62.8%)
Revised Trauma Score (RTS) at arrival	33 (14.6%)
Time of departure/transfer patient	211 (93.4%)
Discharge destination	224 (99.1%)
Signature or name of doctor	205 (90.7%)

All items related to patient identification are complete, because these are copied from the Hospital Information System's admission data. A tag with this patient information is placed on every chart. However, 18 patients (7.9%) had two tags on their chart, because the first tag was incorrect (for example, the name of the patient was 'Trauma'). This was the case for major trauma patients whose name was unknown at the time they arrived at the AED.

Physiological parameters and scores are more likely to be missing. For example, in many of the analyzed records of severe trauma patients, respiration and patient scores like Glasgow Coma Scale (GCS) and Revised Trauma Score (RTS) were absent. As the Revised Trauma Score is derived from other parameters (respiration, blood pressure and Glasgow Coma Score), the absence of one of these parameters leads to the absence of an RTS on the charts.

Qualitative study

In this section we describe two contexts in which the trauma record is used: the point of care and quality assessment. Both these contexts impose a norm for completeness on the medical

record and the staff producing that record. Our descriptions of the use of the trauma record are based on the observations and interviews carried out throughout our study.

The point of care

The trauma record is produced during the point of care and for use in that process. But even at the point of care, the trauma record served more than one purpose. We focus on direct patient care on the AED and patient transfer from the AED to other departments in the hospital.

Much more than in a regular outpatient clinic, medical work in an AED is teamwork: nurses and doctors of various disciplines are together in the same surgery while examining and treating the often critically ill and unstable patient. Oral communication is very important; nurses and doctors inform each other in the staff room, in the hallway and of course in the surgery. Because of these characteristics, it regularly makes perfect sense for professionals to prefer a colleague to the written medical record, if they need up to date information. As a consequence, keeping the medical record up to date has no first priority. We observed that doctors and nurses turn to the record in quiet moments, for example when they have to wait for the X-ray results. Many doctors even write their observations and actions down afterwards, in the staff room, when the patient is stable and awaiting transfer. Sometimes the record is written after the patient has left. Writing and signing the medical record and putting it on a pile with the rest of the medical records is a closing ritual, an administrative task.

The medical record does not seem to serve the purpose of providing up-to-date information on everything that has been done in the AED. Moreover, the interviews made clear that incompleteness is not an issue for the medical staff: they know the context in which the data were recorded (or omitted) and can reconstruct that if they have to. For example, a missing GCS could indicate that the patient was conscious and alert, and therefore the physician thought it irrelevant to subject this patient to a neurological score. One of the nurses gave another example:

> *"According to the chart, we should record two scores, at arrival and at departure of the patient – and I also feel we should do this – but in practice, a missing score at departure usually means that the score was the same as the first one".*

Thus, notions of clinical relevancy and efficiency explain why medical records are incomplete.

Another purpose of the trauma record is informing other professionals about the condition of the patient, specifically doctors and nurses from other departments. When a patient is transferred to an Operating Room or an Intensive Care Unit, the trauma record changes from a mere 'internal' record to a transfer document. With this transformation, another type of patient data is needed, such as an overview of the physical state of the patient in the AED, the tests that have been ordered, the treatment that was started, and the first responsible doctor. When the

purpose of data collection and data use changes, the definition and norm of completeness change as well. In the interviews, the medical staff mentioned several items that are important to record when patients are transferred, regardless of the medical discipline involved: patient history, physical examination, vital parameters such as heart rate and blood pressure, and a diagnosis. Our quantitative study showed that these 'essential' transfer data were missing in many cases. According to a trauma surgeon:

> *"When I'm in the OR [operating room, MM] and a patient comes from the AED, I want to know exactly what I have to do. It is the responsibility of the staff that was present at the AED to document a treatment plan, as specific as possible. Just 'Admission' or 'OR' is not a treatment plan to me"*.

The trauma record did not fulfill the role of transfer document very well. Therefore, beside the emergency chart, a new record was introduced for the junior surgeons who examined a (trauma) patient in the AED before they were transferred to the Surgery Department. The senior surgeons were happy with this record, because (1) it had been written by their own staff, which they trusted; (2) they were sure that the information they needed had been recorded; and (3) it had the same (free text) format as a surgical record. This additional record had a negative impact on the trauma record. Aware of the duplication involved, the staff of the AED became less motivated to complete their own records. Consequently, the trauma chart of the AED as a transfer document was becoming (even more) incomplete and unsatisfactory. As one AED doctor confessed:

> *"A treatment plan is not important for the AED, because the junior surgeons record it now. It is for the surgery department, so they have to write it down. Then it is not a big deal that our chart is incomplete, because the patient is not coming back"*.

Assessment and monitoring of trauma care

The trauma record also serves as a data source for issues such as financial control, research or quality monitoring. Such purposes are usually called 'secondary use' or external use [20]. In this chapter we will only focus on the use of data for quality purposes, and more specifically for the trauma registry.

For benchmarking it is essential to use a strict norm and clear definitions of the dataset, because otherwise data from different centers cannot be compared. The MTOS+ dataset focuses on assessment of the severity of illness in the first hours after the accident and patient outcome (dead or alive). With these data, both input and output of the trauma centers can be compared nationally. The throughput, the treatment at the AED or other hospital departments, is beyond the scope of MTOS. Following the MTOS+ norm, the records of trauma patients in our study were highly incomplete: both vital signs and scores were missing many times, and absence of only one item posed problems on calculating clinical scores like RTS. Consequently, the items of

the MTOS+ dataset cannot be structurally extracted from the trauma charts, and much extra work would be needed to prepare these records for benchmarking.

Part of this extra work relates to the interpretation of missing values. As we saw in the previous section, the assumption that the medical record is a written one-to-one reproduction of the care process is not true. Healthcare professionals do not record their actions with external use in mind. If a heart rate is missing, this could indicate that a doctor or nurse forgot to write it down, but it could also mean that the heart rate was never measured, or that recording the heart rate was seen irrelevant (because it was within the boundaries of 'normality'). In many registries, and for calculation of severity scores, missing data are regarded as normal data. In these instances incompleteness can also affect data *accuracy*, as the calculated scores may not represent the true state of the patient at that time. Since the patients that suffer from severe trauma, as were selected in our study, usually have abnormal physiological parameters, a proper understanding of missing items in the chart is crucial. According to one of the clinical managers of the department:

> *"The norms that are imposed upon us by the government, because we are a trauma centre [that is: recording and reporting the MTOS+ dataset, MM] do not match with our current recording practices. We perform very badly. . . The solution will be an electronic record that will force us to be complete"*.

Discussion: Improving completeness with ICT and organizational change

Medical records are not complete or incomplete by nature. Completeness is a relative concept; it can only be assessed in the light of a purpose, and with the use of a norm derived from that purpose.

For the point of care, these norms are mostly implicit and incompleteness does not seem to be a problem in the context of the care work itself. When we take into account the internal usability of the medical record, missing data can be functional. For the AED staff, missing items in the record have meaning in their own right; this means that nothing noteworthy changed during a patient's stay at the AED. This observation is in accordance with a study by Berg and Goorman, who described how ICU doctors only recorded deviant observations and deliberately omitted normal observations. This practice made perfect sense to the professionals of that department, and was even seen as efficient and a sign of competence and experience [15,21]. Moreover, AED staff prefers other communication patterns to the written paper record, which is usually produced at quiet moments or after the patient has left. Therefore, we disagree with authors who claim that incomplete records are a disgrace for the medical profession, and that only

complete records (containing everything that happened with the patient) deserve the stamp of science [22,23].

However, when we regard completeness in a different context, for example patient transfer, we see problems arise. Data are missing, and this might affect patient care as diagnostic tests are duplicated and time is lost [24]. If the data from the AED records are used for external purposes, like the national trauma registry, the problem of incompleteness is even more profound. According to the norm of the MTOS+ data set, almost all paper records were incomplete. Even items that would seem to be essential in the handling of every serious trauma, such as the Glasgow Coma Score, were not recorded in several records. These findings are in accordance with other studies on completeness of medical records in AEDs [e.g. 25-28].

Improving the quality of trauma care is an important goal, and the contribution national registries could make to this goal is undisputed [29]. However, the work processes of the Accident and Emergency Departments, as in our study, often cannot cope with these demands. What is needed, then, to improve the quality and completeness of trauma records?

As stated in the introduction, information technology is often presented as a solution to illegible and incomplete medical records and as a silver bullet for quality monitoring and quality improvement [5,30]. More than a structured paper chart, electronic records enforce the users to be complete, for example by making it impossible to go to the next screen if the previous screen is not completed [27,30-33]. During the last two decades many new electronic applications for emergency and trauma care have been introduced: from electronic patient records [34-36] to clinical information systems [37-38]. These applications all contributed to more complete electronic patient records, compared to handwritten paper emergency records.

The studies show that PCISs and other forms of ICT can improve the quality of the medical record, but still the large majority of AEDs are behind on ICT implementation [39]. There can be financial or organizational reasons for this delay in ICT adoption, but it also has to do with the quality of the PCIS itself. Still many systems are designed without thorough study of the context in which it will be used. Designers should be aware of, and deal with the 'conflict between the fluid cooperative and necessarily "messy" nature of work practice and the formal, standardized and comparatively rigid functioning of IT' [40]. In order for a PCIS to be used satisfactorily in an AED environment, there has to be a balance between the efforts of the user to produce a structured record and the direct user benefits compared to a paper record. Therefore, the PCIS should be equipped with functionalities that make manual data entry as easy as possible, or even unnecessary. For example, by linking the system to the heart monitor, vital parameters would be automatically generated, leaving more time for the staff to record other items. For this purpose, a Patient Data Management System, often used on intensive care units, could be useful

for the AED [38,41]. Techniques like language processing, digital pens and bar coding have also proven to facilitate data entry in PCISs [23,42-44]. In addition, integration with other information systems is important. Many AED visits, including those of trauma patients, represent a single episode. However, there are also patients who visit the AED more than once during a care trajectory, for example chronic cardiac patients with acute episodes of heart failure. For these patients it is even more important that the information systems used in the AED be linked to, or integrated with the hospital information system.

We can conclude that much can be expected from well-designed ICT systems, and studies show that extraction of data from PCISs in order to report to national registries is technically possible. The quality of these data, however, strongly depends on the way the users of the PCIS deal with the data definitions and criteria imposed by the registry [45]. More generally speaking, users of PCIS have to align themselves with the demands of the tool, and these demands may well conflict with current recording practices [40]. When we look at the daily practice of recording in the AED, it is obvious that just replacing the paper chart by an electronic system is not a solution. Staff will use this system in the same way as their current paper chart: at a time that is convenient, not at the time that the data have to be collected (for example, upon arrival of the patient), introducing the risk of errors. In addition, they will only record data that have meaning and relevance, unless, for example, they are forced by the PCIS to record a Glasgow Coma Score for every patient. Moreover, they will likely be frustrated by the structure of the system if it conflicts with the way they perceive and perform their clinical and recording work. Consequently AED staff has to spend much more time recording as they are now obliged to fill in data that were deliberately not recorded previously, but also because electronic recording takes more time compared to paper charts [46].

In many instances the work process in the AED has not evolved to deal with external demands from registries. Therefore ICT ‘in itself’ will not solve the issue of incomplete data. Not only does the tool have to change, but so does the practice. The introduction of a new PCIS requires (re)organization of the recording practice in the AED. The extent to which practices have to change, strongly depends on the purpose of the (electronic) recording system. A patient care information system that has to be used in real time patient care has other requirements than a registration system to be used retrospectively. Organizing real time data entry in the AED for both internal (patient care, transfer) and external (trauma registry) purposes is complicated. As we saw that the AED staff has neither the time nor interest to record in real time, a new ICT system is unlikely to have the desired effect on completeness.

A way out of this problem is the introduction of a clerk. This can be either an administrative clerk or a clerk-professional, a doctor or nurse who is designated for documentation. The choice for one of these options depends on the amount of data that an AED wants to collect electronically,

and the clinical knowledge that is needed to ensure data accuracy. Mostly, administrative clerks are trained secretaries, who are stationed at the reception and the telephone. In some hospitals they also have a role in patient triage [47]. The tasks of these clerks could be expanded with managing the (electronic) trauma record, either by completing the items that were not recorded by the doctors or by recording everything themselves, following orders of the doctors and nurses. Several studies show the value of administrative clerks for recording tasks [47-50]. If nurses or doctors are designated for the recording work, they have to be temporarily released from direct patient care in order to use the PCIS. Some authors are critical about this solution, as it places expensive, highly trained professionals in the data-entry role [51]. But from a different perspective, we can also claim that recording one's actions is part of *being* a professional. This claim is supported by recent developments in professional standards. For example, in the UK's code of conduct for nurses and midwives, responsibility for complete, accurate and timely documentation in the medical record is explicated in a separate paragraph [52]. Even though the tension between the responsibility of doctors and nurses to document their work and the other tasks they have to perform cannot easily be solved, a first step could be to regard recording work as *part* of medical work. From that starting point strategies can be designed to facilitate this work. In that respect, the demand for easy-to-use AED technology is still strong [53]. For example, if clerks are equipped with handheld information systems with Personal Digital Assistant (PDA) technology, they can complete the documentation more accurately than if they are to use a traditional desktop workstation, which is often situated in the corner of an examination room or at a central desk in the AED. In pre-hospital emergency care, and for triage and medication ordering there is already some experience with mobile devices [54-56].

We were unable to find studies that report on the combination of ICT implementation and organizational change with relation to data quality. Since many hospital departments have moved on to electronic patient records, and since many experience difficulty in producing and extracting complete and useful information for quality assessment [2,6,57,58], there is a large research field yet to be explored.

Conclusion

The medical record receives much attention from both healthcare professionals and parties interested in quality of care. This is logical, since its content and quality influence health care practice in many ways. It is also a valuable data source for quality-assessment and quality-improvement initiatives. At the same time, the (paper) medical record is negatively evaluated because of incompleteness. In this chapter we have shown that it is important to define completeness in its specific context. For the trauma record to be usable for internal and external quality assessment drastic change is needed. But also in at the point of care, incomplete records

could affect quality of patient care. Yet, the AED work processes have not evolved to deal with these demands of quality assessment.

It is widely acknowledged that information technology has the power to improve completeness and to facilitate quality assessment. However, it also imposes structure and inflexibility to the users of the system. In the AED environment, but also in other parts of health care, structured recording is hard to enforce. The standardization necessarily associated with ICT and the complexity and fluidity of trauma care as well as the current recording practices of AED staff do not match. In order to improve completeness of data to be able to report to the national trauma registry, just implementing ICT is doomed to fail. We propose a strategy with two elements: introduction of a, preferably mobile, patient care information system and a restructuring of the recording process by introducing a clerk (administrative or professional). This combination is the most powerful strategy to improve complete records, to release doctors from registration tasks, but also to leave the recording activities where they should be: that is, as a part of patient care.

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Appendix 7.1. MTOS+ dataset

MTOS+ dataset	Available on AED chart?
Name	Yes
Address / postal code patient	Yes
Date of birth	Yes
Gender	Yes
Patient ID code	Yes
Date and time of accident	No
Number of ambulance service	No
Time of arrival at AED	Yes
Type of injury: blunt or penetrating	No
Systolic blood pressure at arrival	Yes
Respiration frequency at arrival	Yes
Glasgow Coma Score at arrival	Yes
Revised Trauma Score at arrival	Yes
Diagnosis (AIS-90)	No [a]
Injury Severity Score	No
Length of stay on intensive care	No
Date and time discharge hospital	No [b]
Outcome: dead or alive	No [c]
Autopsy	No

[a] Diagnosis available, but in free text, not classified according to AIS-90
[b] Only discharge time AED
[c] Because of our selection (patients admitted to the hospital), all patients in the sample were alive when they left the AED and thus excluded from our analysis

Chapter 8 | Conclusion

The aim of this thesis was to explore how quality management is shaped by work practices and professional routines on the one hand and ICT developments on the other. This exploration was guided by three research questions:

1. How are information and communication technologies – specifically, patient care information systems – used in healthcare organizations for quality management purposes?
2. What does this use mean for the role of healthcare professionals in quality management?
3. How is synergy between quality management, ICT use and the work of healthcare professionals achieved?

ICT and quality management

"In the future, almost all quality measurement will be done using information systems and will be seamlessly integrated into the process of routine care."
David Bates (1999, p.124) [1]

Patient care information systems, such as electronic patient records, are built primarily to meet the needs of healthcare professionals in their contact with individual patients. However, advocates of using IT in health care, such as the Institute of Medicine, have always proposed that more uses are possible, most notably pointing at potential for quality management – for monitoring and improving care [2-4]. But are they right?

The literature review in chapter 2 provided an overview of the different types of quality management activities that are being conducted using PCIS. The chapter deals with PCIS used in intensive care units, but these results can also be extrapolated to other departments and the hospital level. PCIS were used for calculating quality indicators, making dashboard reports, tracking errors and monitoring guideline adherence. The literature gives many examples of similar – partly automated, partly manual – processes, demonstrating that PCIS do not stand alone as quality instruments, but are used in conjunction with other databases and information systems. Moreover, all studies show that PCIS-supported quality management is more than a

mouseclick away; much work must to be done to adapt the sytems, both to generate and to process quality data. The future predicted by Bates and colleagues is underway, but we still have a long way to go, and recent progress in ICT offers some new perspectives for quality management. For example, a common approach to centralizing quality management is integrating data from clinical and administrative information systems within a data warehouse [5]. New generations of PCIS are also of interest. These systems have more functionality options, such as decision support and reminders. This 'intelligence' has direct benefits for the point of care, as well as also for quality management, because the databases of these systems contain new types of data. With this data, quality indicators, which were previously unknown or demanded too much manual labor, can now be calculated. A simple, but clear, example is guideline adherence. In the old situation, retrieving all data-elements from the PCIS database and combining these with the guideline norms involved a good deal of work. If, in the new generation of PCIS, guidelines are part of the record, then deviation from a guideline will be more visible and, as such, traceable in the database. Because research in ICT use is usually a few years behind ICT development, I expect to see more examples of PCIS with integrated quality management functionality in the next decade.

The literature review further showed that few systems produce their own information or reports at the patient-group or organizational level. The connection between PCIS and quality management might not be as straightforward as the IOM reports suggest. Many of the systems used in health care today have complex data structures that are difficult to disclose because the developers are not eager to release the programming code. I observed that the nontransparency of PCIS and data warehouses makes care professionals and managers cautious in using the data on an aggregated level. They put more trust in data on individual patients, presented at the point of care, than in a query on the database. Naturally, this trust will come in time, but current practice suggests that although quality information systems (including business intelligence tools) are often in place, their active use is not self-evident.

The value of the PCIS for quality management is, I claim, in the patient data that it contains. It is exactly for this reason that it is important to monitor the quality of the data being produced at the point of care [6]. And, indeed, electronic medical records are often incomplete, or contain errors, as we saw not only in chapter 7 with respect to the trauma records, but also in the articles reviewed for chapter 2 [7]. There are researchers who point to problems with data from PCIS (or paper medical records, for that matter) as justification for recommendations against using this data for quality management purposes [8,9,10]. I, however, agree with Blumenthal and Epstein, who state, "the fact that the data quality managers propose to collect may be imperfect, does not mean that the alternative – collecting no data about the quality of care – is preferable" [11,p.1330]. This is not to say that discussions on data quality are irrelevant. On the contrary, data quality should be part of the discussions on quality management, but only in the

context of a specific quality issue. The most successful route toward improving data quality is not through imposition (for example, by pressing for use of a given information system), but rather through stimulation of the intrinsic motivation of care professionals. The quality of documentation improves when the one doing the documenting sees the importance of the act, and, preferably, has a vested interest in the documentation. Rather than trying to improve overall data quality, there should be a focus on those parts of the record that are relevant to a current quality theme, preferably a theme that forms a shared interest between managers and care professionals. Using the example of mortality figures in the ICU: because this has direct consequences for admission and discharge policy, and thus also for capacity, utilization and costs of care, this theme is relevant for both managers and ICU staff. It is easier to find a basis for improving data quality when quality issues reflect shared interests.

Additionally, it is important to realize that data quality itself is a contextualized concept: there are different norms for judging the data, depending on the purpose for which the data is being used. A medical record is, therefore, not per se (in) complete or (in) accurate [12]. For these reasons it is not fruitful to judge data quality in general, or to use general strategies to improve completeness, as is presented by Wilson and Goldschmidt when they firmly state that “clinical information is such a vital component of quality management that the clinical information (medical record) function should come under the jurisdiction of the quality management department and the medical record administrator should report through the quality manager to the hospital manager. All too frequently in large hospitals a separate medical record department falls under the jurisdiction of medical administration. Unfortunately, this arrangement merely ensures that traditional attitudes become enhanced and opportunities for change remain marginal.” [13,p.517]. It is striking that other authors do not explicitly connect quality management to data quality. They only briefly express their dissatisfaction with the quality of data in medical records [14,p.291; 15,p.78], but fail to translate the implications of this statement to other parts of their handbooks. For example, in practical chapters it appears that there *is* such a thing as ‘perfect data’ that is available to quality managers and care professionals for making flowcharts and diagrams.

One of the shortcomings in the discussion on data quality is that it is reduced to a technical concept (notably, objectively determinable completeness and accuracy of data) and to an issue that is resolvable using ICT. Currently there are, indeed, possibilities for increasing completeness within ICT; for example, by coupling files or through checks and reminders [6,16,17], or by connecting information systems to each other in a data warehouse structure [18]. The issue of data quality, however, is still only partially resolved. This is because there are not only technical, but also social components to the problem, for it is the healthcare professionals themselves who document many of the patient data in the PCIS. Thus, data quality is a result of their habits and values; their ‘recording culture’. Moreover, quality management requires human interpretation.

Employees with knowledge on care processes are necessary to interpret the data extracted from the PCIS and to make sensible decisions based on this interpretation. What Caceres argued in 1978 with respect to the relationship between humans and technologies holds true today: “We must not forget the necessary presence of a human being in any system in the conversion of data to information. The human in an information system is assisted by various technological components, but the human is the essential part of an information system.” [19,p.7]. Database queries must be built by database managers, and the data must be interpreted both in the context of the point of care [20], and the quality theme at hand. Shifting the absolute responsibility, as Wilson and Goldschmidt propose, will not be a solution to this problem. After all, healthcare professionals (and the administrative support staff) themselves have a first responsibility, as they are the ones who use the patient care information systems.

Involving healthcare professionals

“The active engagement of all clinicians with quality improvement is essential but, as yet, largely unrealised.”
Huw Davies et al. (2007, p.36) [21]

I stated that care professionals have the first responsibility for data quality in their information systems. Yet, the attitude of care professionals toward these systems is ambivalent. On the one hand, professionals willingly use ICT in cases where it provides direct support for their work and offers advantages in accumulation and coordination over paper information systems. Doctors in the intensive care have reached a point where they can no longer do without their medication order entry system and the nursing staff can no longer miss the nursing plan and fluid balance found in the patient care information system. The impact of a PCIS on care work only becomes truly clear at the point that employees are forced, through, for example, a technical glitch, to return to paper-based (manual) documentation [22]. On the other hand, professionals experience use of the PCIS and other information systems as a (administrative) burden, because these systems introduced more registration work for managerial purposes and external parties (Health Inspectorate, insurance companies). Actually, this was also the case with paper records and forms. In this respect, the arrival of the computer has not changed professional opinion and practice. Examples are the diagnosis-related groups for billing, but also the documentation of complications and adverse events. Quality management is often the victim of this ambivalence toward PCIS, because it hopes to use both ‘routinely’ recorded data and extra data that are specific to quality management goals. Quality management is, thus, too easily relegated to the category of extra administrative burden, and dissociates from the point of care and professionals’ own care work. Several studies confirm that care professionals are not ‘engaged’ with quality [21,23], and one of the reasons for this might be the unjustified distinction care

professionals tend to make between their daily work (at the point of care) and quality (measurement/improvement) activities.

The ambivalence towards PCIS is undesirable in the light of the quality movements described in Chapter 1. Care professionals can no longer ignore issues of quality; quality management should become part of medical treatment. Developments in the organization and content of health care have led to a strengthened position of doctors and other care professionals when it comes to quality management. In addition, the introduction of care paths also brought quality issues such as standardized tasks, efficiency and patient logistics, closer to the care process – and thus also closer to the roles fulfilled by professionals. What is more, external forces, such as the introduction of a basic set of performance indicators for Dutch health care institutions, were catalysts for change in quality management in health care organizations. Collecting the data was a huge task for all hospitals, and a lot of effort was put into improving completeness and accuracy of data in paper and electronic systems. However, (nationally endorsed) performance indicators do not automatically lead to quality improvement [24,25]. Clemmer states that: "Much of the higher level monitoring and benchmarking activity has not proven to be effective in improving outcomes and may represent waste in our systems. However, when used at a lower level, where there is a vision, commitment, and a culture of improvement, the monitoring and use of relational databases is very useful and effective in improving outcome. To be effective, these databases should be developed and controlled at the level where change is to occur, and the closer to the frontline, the better" [26,p.235].
Still, all these internal and external developments lead to reformulating what quality management *is*, and to the need for instruments other than those traditionally used in medicine, such as education, professional societies, re-registration, disciplinary action, guideline development and peer review [27]. These new developments from inside and outside the care process have indeed influenced the role of care professionals in quality management.

At the same time, quality management also becomes distanced from care professionals. As is described above, this is partially attributable to the fact that doctors experience quality management and related data collection as a task that is external to provision of care – that is, an administrative burden. This experience is often reinforced through use of information systems that are unable to carry out quality management activities. Other systems and tools are usually necessary; data from the PCIS must be channeled to a central data warehouse, or to statistical and business intelligence packages. The data is then literally removed from the care process. This also contributes to the impression that quality management is external to the point of care and thus not necessarily a logical task for the professional. Direct patient care "at the bedside" takes precedence and administration (which includes quality management) is secondary. Quality management, then, belongs to the rubric of ad hoc work, which is only done

when doctors have time for it, or in reaction to an incident or newly published performance indicators.

As a result, we see a dualism when it comes to the relationship between quality management and care professionals. One side is that quality management comes increasingly closer to the point of care, because it aligns with questions regarding the organization of care processes. The other side, however, is the creation of distance between the care process and quality management as a result of the centralization of data and the association of quality management with administrative burden. It is therefore crucial that care professionals begin to realize that they are central to quality management and that quality management, as quality work, is a fundamental part of care practice [28]. In daily practice, this can play out in various ways, but it is nonetheless still important that certain quality management tasks fall under the responsibility of the right professionals and support staff. Then it must also be logical that the intention is not that medical specialists waste their time registering sundry additional data on forms or in computer applications, but that it is their responsibility to keep their own (electronic) medical records in order and – where possible – use standard terms to improve comparability of data (e.g. regarding diagnosis). The pivotal position of care professionals in quality management is then best fulfilled when quality management takes place at the point of care. For this to happen, quality work must become better embedded in both care work and the care organization.

Quality management should be a 'local' activity of a group of care professionals (a department, unit, or microsystem) within a central framework, to assure comparability within the organization. Quality figures come to represent a real meaning for care professionals, when these figures are derived from and can be placed in the context of professional work. Once again, analyzing mortality rates in the ICU provides us with a good example. Such analysis can be done with locally-gathered data on the case mix, and then transformed into a validated score such as APACHE II (in other words, data is extracted from the point of care). If it then becomes evident that there are more patient deaths than would be expected on the basis of the APACHE II score, then doctors can further address the issue by reviewing a number of records, searching for mistakes and, where possible, initiating concrete steps for improvement (in other words, data is reincorporated at the point of care).

The search for synergy

"The potential synergy between PCIS and professional work can only be found in careful unraveling of care processes…"
Marc Berg (2003, p.341) [29]

As the above discussion shows, synergy between care professionals, their work, information systems and quality management does not happen automatically. It should not, however, be seen as an impossible goal, but rather as a state of affairs that is reached through additional work. A future of ICT-supported quality management by healthcare professionals is, in my opinion, not a utopia. Synergy is often reached through a few small changes. I will show this below using quality management examples from the preceding chapters.

The search for synergy in intensive care

Chapters 1 to 3 addressed information technology used in one of the most information-rich settings in a hospital: intensive care. ICUs have long had a higher permeation of technologies (monitors, machines that regulate or replace bodily functions, etc) and since the 1980s, clinical information systems (CIS) have also gradually replaced medical charts. In the Erasmus MC, a PCIS was implemented starting in 1995. Although the system was a so-called 'off the shelf' package, the care professionals played a large role in adjusting this system to local practice, as was described in chapter 3. These adjustments were crucial, partly because the system that was originally implemented did not align with the organization of (Dutch) intensive care units. The system performed badly for patients that stayed longer than one week in the ICU, because the system was designed from the vendor's knowledge on operating processes and short-stay postoperative care in surgical ICU's.

The PCIS is not designed for quality management. Questions such as, "how many days were patients hospitalized in period X and how many days did patients receive artificial respiration?" can not be directly answered using the PCIS. Such questions must be directed to the database manager, who then develops and runs a query. He provides the applicant with a spreadsheet that is full of data on individual patients who meet the criteria of the query, and that must then be analyzed further. Despite this cumbersome route for gathering information, much use has been made of database queries over the last few years. There were so many that the PCIS managers had to develop a triage procedure for the requests they received. The need for queries was related to the fact that the Erasmus MC is an academic hospital, where the PCIS is also used for scientific research and smaller research questions for medical education purposes. Another reason is that an increasing number of requests for data were received from external

players, such as the Healthcare Inspectorate. For both of these reasons, there was a need for better tools for retrieving and analyzing data from the PCIS.
These tools came through the development of a clinical data warehouse for the intensive care (IC-DWH). This data warehouse was built locally, using different PCIS as sources, for example, the CIS from the intensive care units and the hospital information system. Once again, care professionals played an important role in the development: the workgroup consisted of a number of doctors, nurses, and researchers, who determined which items were to be included in the data warehouse.

The arrival of a data warehouse implies that the tasks of the IT department shifts to care professionals and managers. The tools are indeed made for non-technicians: there is no additional knowledge of the database structure necessary, but there is a need for a clearly defined question. In other words, one must have a clear conception of the sub-selection and items that one wishes to review in the report.

Despite the fact that the data warehouse was built using expert knowledge from the point of care, and despite the fact that the tools were more accessible for care professionals than the PCIS database, use of the data warehouse is still neither an automatic nor a self-evident process. Currently, the managers and professionals from the ICU lack the knowledge necessary to using the tools most effectively, and they are also not so eager to learn. This means that the synergy at this moment is also less than ideal.

This is mostly attributable to the implementation. The IC-DWH development was a technical project for the IT-department, as an answer to questions coming from ‘the ICU’. The project plan largely addressed the technical realization of the system and the implementation phase concerned the delegation of system control from the IT-department to the medical administration department. This implementation was thus not approached as an organizational change for the care professionals and managers who were to use the data warehouse. Although this is a much smaller group than the users of a PCIS, attention for communication, training, and other interventions that orient people with the system and actually motivate them to use it are also important here. Thus, also in this situation, synergy should be strengthened, using multiple strategies.

One of these strategies is integrating the system with the point of care. Otherwise, there is a good chance that the system will only be used in an ad hoc manner by a select group; that is, by the ones who made the effort to get familiar with ‘business intelligence’ tools. Demonstrating how the data warehouse can be used to provide insights on a given problem or question, can motivate care professionals to use the system for their own questions. This also holds true for managers. For this reason, it is important to begin with questions and subjects that are relevant

to professionals and managers. In Intensive Care, for which the data warehouse was first developed, there are many examples of such questions. For example, questions regarding mortality rates and admission/discharge policy (which patients should be admitted and which ones discharged) are interesting for both professionals and managers, as they relate to clinical considerations, logistics and financing.

Another strategy to strengthen synergy is paying extra attention to how the data warehouse is embedded in the organization. This is already being addressed by the hospital: a business intelligence center is being established. This may appear to be a rather large intervention (creating a new department within the hospital), but this IC-DWH does not stand alone. There are other data warehouses and other systems that contain quality information and 'business intelligence'. For a large hospital, such as the Erasmus MC, creating a help-desk for managers and professionals who are dealing with quality management is a logical step. Specifically with respect to the IC-DWH, they must ensure that employees of the intelligence center have sufficient knowledge of the point of care. Employees familiar with data warehouses tend to have more financial and logistical expertise, because the first data warehouses were primarily used for administrative purposes.

The search for synergy in emergency trauma care

Chapter 7 discussed the implementation of an electronic medical record for trauma patients. This case is an example of a failed implementation: the computer was literally placed in a corner in the examination room and was further ignored. The purpose of the electronic record was to record part of a national dataset for measuring the quality of Dutch trauma care, and for benchmarking the individual trauma centers. Thus, it primarily had an external purpose. The ICT system was also developed to this end. Although the goal was to have AED doctors use the system at the point of care, it was still set-up primarily as a registration system.

In this situation, there is clearly no indication of synergy. On the contrary: the technology failed to align with care activities and was ignored by professionals for this reason, consequently leading to a lack of the very data that was needed by department heads for the requisite quality management.

In this case, part of the problem is related to the design and purpose of the system. This was related to a form of quality management emerging from the needs of the head of the department and was dictated by national policy on trauma centers. This was not a primary concern for care professionals and was seen as a top-down decision that was changing practice. Quality management was not a discernable part of their daily work, yet. The system was, in principle, sufficient for the purposes of quality management, but it was not designed to fit in

with the point of care. Thus, the system did not sufficiently align with other aspects of medical work.

For this reason, we proposed to make not the entire trauma team, but just one doctor or nurse responsible for registration by designating him or her as “clerk”. This redistribution of tasks would increase completeness and timeliness, thus meeting the needs of management and demands of the government. In addition, registration by a “care professional-as-clerk”, as opposed to an administrative clerk, contributes to securing the overall quality of the data content.

However, in order to further move toward synergy in this case, it will be even more important to strengthen the existing relationship between care professionals and quality management. This could be achieved, for example, through letting professionals analyze the datasets themselves, and letting them make subsequent recommendations for improvement. This implies that the information system must also be open to change. It can possibly be improved in ways that make it align better with daily practice and enable further development of the system, from a registration system into a patient care information system with quality management options.

The search for synergy in eye care

Chapters 5 and 6 discussed two projects for the redistribution of tasks in eye care, focusing on glaucoma and diabetic retinopathy. Ophthalmologists delegated part of their tasks to optometrists and diabetes nurses. In both projects, ICT was used to communicate, to coordinate care and to monitor quality. The central systems used were the database with screening images and digital forms.

Quality management in these projects served different purposes. First of all, there was the purpose of monitoring quality within the project. This sometimes led to an adjustment of the standards for carrying out risky treatments (e.g. dilation of the eyes), for diagnostic testing (making the image), judging the quality of the image, and registering the findings. Secondly, quality management had an external purpose: both projects were innovative approaches to eye care and were being followed (both with interest and warily) by insurers and the rest of the Dutch eye care community. The projects were thus so-called pilot experiments for improving quality in eye care, with respect to creating more efficiency in the organization of care, without losing medical quality and effectiveness. The projects were therefore expected to answer questions such as: can less expensive professionals also carry out certain screening tasks? And, does an image provide the same level of information as a physical eye examination? In order to answer these types of questions, quality management had to be incorporated into the care trajectory. To this end, quality indicators were part of the care process from the very beginning of the redistribution of tasks.

For quality management, “routine” data from the point of care was used in both projects. Extra data necessary to the quality management was also collected at the point of care, whereby it became part of the care process. In the diabetes project, for example, extra data was added on whether or not dilation medication was used. In the glaucoma project, the optometrist’s decision regarding the quality of the pictures was monitored. In so doing, both the optometrist and the hospital employee responsible for (re-)assessing the images (the technician) recorded their evaluation on the requisite form.

Because the technology was fairly simple, that is, a digital form, its most important function in this process was data delivery. The underlying database had to be exported to Microsoft Excel or SPSS in order to research the data on a level higher than that of the individual patient. The database from the glaucoma project could then be used to compare the work of optometrists, in relation to one another, and also across a given time period. Data from the diabetes project was used to identify the link between the presence or absence of administered dilation medication and the quality of the image by the ophthalmologist. In both projects, quality management had a structural character. The data was analyzed at specified moments, and at least once per year.

At first glance, there appears to be a good synergy between the work of the care professionals, the use of ICT and quality management. Data from the point of care was used for measuring quality indicators, and was discussed with the project members. Sometimes, adjustments to the care process were made (e.g. more flexible standards, extra training). However, there are two points that demand additional attention. First, both cases are projects that were initiated by the hospital and the ophthalmologists, whereby quality management primarily had the characteristics of quality control. The ophthalmologists controlled the work of the optometrists and diabetes nurses, for example with indicators such as “the quality of the image”. This situation sometimes led to tensions within the projects, at moments that improvements had to be made on the basis of this quality control. Some optometrists and diabetes nurses had the feeling that there was an insufficient level of trust (from the doctors) in their ability to function adequately according to their own professional insights. Quality management, thus, did not align optimally with the work and values of some of the care professionals.

Second, the two research questions underlying these projects were answered during the projects: redistribution of tasks, supported by new medical technology and ICT is indeed effective and efficient. The manner of working introduced in the glaucoma project has even become regular care. This new situation has consequences for quality management, which should take on a different character. It is no longer only about the quality of tasks carried out by the optometrists and nurses, but about the entire care trajectory from the community to the outpatient setting (and beyond). It is also no longer only an issue of quality control, but also of quality improvement. This could mean that new indicators should be used, to monitor the

quality of care. As a conclusion, the case of eye care shows that synergy is neither a self-evident, nor a permanent outcome.

Lessons for research and practice

Because care professionals, their work, ICT and quality management are continuously shaping one another, the final destination in the search for synergy – or better stated, the final shape of synergy – is not known in advance. Therefore, the search for synergy is not a perfectly drawn pathway from A to B, but rather a journey filled with trial and error. Instead of providing a route for the journey, I have decided instead to list three insights to pack for the road. These three insights are also lessons for researchers interested in quality and information technology in health care, because it is important that we continue to develop research concepts in this area.

1. Remove counterproductive distinctions between primary and secondary work activities

Publications often discuss care work in terms of primary and secondary activities, where the primary activities relate to the point of care (most specifically, to the individual patient, and to quality management while caring for that patient) and secondary activities to everything else (including quality management for the 'aggregated' patient, for example a subpopulation of patients or a department). However, we can question the relevance of this distinction when discussing quality management. In this thesis, I have shown that quality work is one component of care work. To do so, I used a broader definition of care work and refuted a view of care work that is, in my opinion, too narrow (e.g. that of Strauss [30] and certain authors using the sociotechnical perspective). Where a narrow definition of care work is used, a situation is created where other work (including, but not limited to, quality work) is easily disqualified by doctors (and researchers!) as less important. And, because it is less important, it is not allowed to disturb "real" care work. This means that gathering data for quality management or controlling and adjusting records for purposes of quality management are less important tasks that cannot, without consequence or consideration, be placed under the responsibility of care professionals [20,31]. In my opinion, both care and quality management would benefit by removing this distinction between primary and secondary care activities. Moreover, the position of healthcare professionals towards PCIS would have to change. We have patient care information systems that support individual patient care, but the majority of systems are not designed for patient care in the broad definition of the term. What we need are systems that allow multiple views of the data they store: following a patient, or a patient group, or an organizational entity (hospital, department, microsystem); presenting overviews in real-time, but also trends through time or even forecasts. The current lack of these PCIS might be related to technological limitations, but I also feel that the call for these new PCIS from the professional domain is not strong enough, because of this dualism towards patient care and quality

management. We could paraphrase Don Berwick [32] and say “every patient care information system is perfectly designed to achieve the results it achieves “. To sum up, do not discuss quality in terms of a primary process (the point of care) and secondary process (quality management), but see both sets of activities as part of the point of care. This is not to say that all activities performed by care professionals are primary work. There is still a lot of secondary work, for example administrative work, that is distanced from the point of care. Much of this work can be automated, but that is beyond the scope of this thesis.

2. Remove counterproductive distinctions between primary and secondary use of data

Following this, it is also important not to refer to primary and secondary uses of data, but just about ‘using’ data. There is an old rule from Van der Lei that asserts, ‘data should be used only for the purpose they were collected’ [33]. With this rule, Van der Lei problematized the secondary use of data from the point of care. There are two ways that I could respond to this assertion. The first reaction would be the argument that the rule is outdated. Quality management has become so important, also for care professionals, that it is highly inefficient and ineffective to establish a separate process for collecting data next to the one that is already in place with the (electronic) medical record. A second reaction is that the rule is actually (still) correct, but that the definition of ‘purpose’ used by Van der Lei is too narrow. Quality management is part of care work, and therefore, the data that are collected at the point of care are also per definition usable for quality management. Both reactions can be defended using cases from this thesis. I prefer the second line of argumentation because it assumes that quality management is not just a trend, but rather that healthcare professionals have always been involved in quality work of some kind (see Chapter 1). Nonetheless, I feel it is important to reformulate Van der Lei’s proposition, because it is otherwise too tempting to continue using the rule as justification for inhibiting all forms of secondary use of data from the point of care, including quality management. As an amendment to Van der Lei’s rule, I propose ‘Data collected at the point of care should be used for providing, monitoring and improving patient care’. This new rule gives room for using data at the point of care to provide, monitor and improve care for the individual patient of whom the data is collected. But the rule gives also room for using that data on an aggregated level for a number of purposes, related to efficient, effective, timely, patient-centered, save and equitable care. We can learn from this individual patient, and apply that knowledge to improve care for other patients. What’s more, the ‘should’ in the rule also points at an imperative: if we have access to data that gives us more insight in quality of care, then we have to use it. This is not to say that quality management using aggregate patient data is one mouse-click away; several chapters of this thesis show how much work is involved in translating data from individual patients to quality information of patient groups or organizational units.

Related to this, it is interesting to discuss another 'rule' of medical informatics that was introduced by Berg as an elaboration of Van der Lei's rule: 'secondary use of data implies extra work'. I agree with Berg, but I also want to nuance this rule. It is indeed true that much work is needed to collect, control, and process data for quality management or other purposes. However, by using the word 'extra' again a division is made between 'primary' and 'secondary' activities. The 'usual documenting work' is part of the point of care, and all other documenting is 'extra'; extra time, extra effort, extra annoying. Berg claims that care professionals should be rewarded for this extra work, or that the work should be delegated to lower-skilled staff [20]. Following what I have claimed so far, this is problematic. The rule of Berg clearly stems from a narrow definition of care work. If quality work (both for individual patients and 'aggregated' patients) is part of the point of care, collecting quality data it is not 'extra work', but just 'work' that should be rewarded with enough time and resources, just like operating or running an outpatient clinic. Of course, (some) recording tasks can be delegated to clerks or secretaries, as long as care professionals are responsible for the overall quality (completeness and accuracy) of their data.

It is noteworthy that in the past few years, part of the medical informatics society has picked up the discussion on reuse (or secondary use) of data and published two white papers on this topic, in which they argue to abandon this distinction between primary and secondary use [34,35]. As Berg and Goorman showed, both data collection and data interpretation are situated within a given context [20]. Data is not merely an anatomical package that can just be moved from one context to the other. On the contrary, every context (medical and quality work) has its own characteristics, as well as its own demands for data quality and completeness. These sociotechnical insights are an enriching contribution to the debate on data quality that can be found in literature on quality and/or ICT, where a primarily technical, anatomical definition of data quality is used.

3. Regard quality management as a shared responsibility

Care professionals are not single-handedly responsible for quality management; the same is true for department managers and other non-medical employees. They are all part of a quality management network [36]. Furthermore, as is the case in health care work, tasks and responsibilities should be carefully (re)structured; that is, when possible, delegated from doctors to nurses and from care professionals to non-professionals [37]. At first sight, the easiest route appears to be to remove quality management from doctors, either because they have little time or motivation, or because quality functionaries have been appointed or because a quality assurance department exists. However, if quality work is viewed as part of care work, then this demands extra attention for the division of labor, as was demonstrated in the case of the redistribution of labor by eye care screening, addressed in chapters 5 and 6. From this perspective, it is undesirable to delegate the responsibility 'away' from the medical professional.

Pierce [38], for example, is very firm in his argument regarding the proper place for safety management: according to him, this falls under the domain of care and must not be delegated to staff or contracted to a quality department. This implies, however, that there are already professionals or managers on the work floor who have attention for quality, or at least one aspect thereof. Preferably, these individuals are regular managers or doctors and nurses who, where necessary, have received or reserved time for carrying out this type of work. By utilizing these content experts, quality management remains closest to the point of care. The nurse-as-data-collector that we envisioned in chapter 7 fulfills a role in quality management, but one can also think in his case of health scientists and others who are knowledgeable about quality management. Which professionals would be most appropriate for carrying out these tasks, would depend upon the organization and the type of quality management in question. It is thus not necessary for a medical specialist to query the data warehouse for him/herself, but that he or she does discuss the resulting report with colleagues and takes the initiative to initiate improvement. That way, care professionals can put their clinical governance role into practice [39]. It goes without saying that care professionals must learn quality improvement methodology in order to be able to fulfill their pivotal role.

Especially in the next few years, technical knowledge will also be a necessary part of quality management, because more and more systems will be incorporated in management processes. This has implications for the tasks and position of IT-departments in health care institutions. Weir et al. [40] show with their research that within the VHA, a step was made to transform the IT department from “a computer office to a full-scale clinical partner” [40,p.391]. Munsch [41] also gives an example of a health care organization where a new “clinical data department” was created in order to support care professionals in quality improvement projects, measuring indicators, and a number of other activities requiring data from (electronic) medical records. The business intelligence center in the Erasmus MC is also an example of the organizational structure needed to *support* care professionals and researchers. In my opinion, these types of centers should by no means take over the responsibility and expert knowledge of care professionals.

There is, again, an important role for social scientists in evaluating these transitions in quality management: how do care professionals fulfill their ‘new’ role in quality management? Following a sociotechnical approach, social scientists will discover many quality management activities that care professionals themselves did not qualify as such. Sociotechnical research demonstrates that quality work is inextricably bound up with care work. These insights do not only enrich the quality management debate, but they can also be used as an argument for care professionals to demand extra support (in time and money) from their organization, or to call for restructuring care and recording processes in such a way that quality management is truly incorporated at the point of care.

Rounding up

All parts of healthcare are confronted with the quality movement, by some authors even called a quality *imperative* [42]. Therefore, the themes explored in this thesis as well as the three insights listed above, are valuable not only for quality management in a hospital setting, but also in other areas of health care, such as primary care, mental healthcare, or public health. Obviously, a 'translation' is needed to this new setting, in order to optimize synergy. For example, general practitioners of small primary care practices already have a double role as care professionals and managers of their practice, thus giving another dynamic to quality management efforts (e.g. in selecting topics or assuring data quality). As another example, public health is (generally speaking) behind on ICT implementation, but it has much experience in using patient data for reporting and (epidemiological) research. These external demands for data have implications for PCIS design in this setting.

Today's quality movement encompasses several generations of quality management: quality control, quality improvement, change, and new understandings on patient centered care. Patient care information systems have influenced all these generations. The issue of using ICT for quality management is not so much about the technology in question, but about creating a space where medical concerns and quality concerns can be brought together—as part of medical work, and where PCIS can be optimally used to support this work. This is a continuous search for synergy.

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Summary

Quality is one of the omnipresent themes in healthcare. All care institutions strive to deliver effective, efficient, safe, timely, patient-centered and equitable care to their patients. The attention for quality of care permeates the development of information and communication technology (ICT), specifically in the patient care information systems (PCIS) that healthcare professionals use at the point of care. There are many expectations of the quality gains of these systems, which are confirmed in scientific research. For example, that improved legibility results in fewer medication prescription errors or improved access by multiple professionals on multiple locations results in better coordination of care and information exchange. Other research points to the quality threats of ICT, because it also introduces new types of errors. Apart from the direct quality gains of PCIS, there is also an interest in the indirect contribution to quality of care, namely in making quality measurable and thereby manageable. The expectations of PCIS are equally high at this point, because these systems contain patient data for calculating indicators or measuring the effect of certain quality interventions.

The purpose of this thesis is to investigate how quality management is shaped by both the work practices of healthcare professionals and ICT developments. For this, a sociotechnical approach is used, in which the interplay of people and technologies is the focus of research. Quality management is considered to be an integrated part of healthcare work, and not an outside-activity.

Chapter 2 provides an overview of the literature on PCIS and quality management in the context of intensive care. The review shows that there is more evidence on the direct impact of PCIS on quality of care, than on quality management (e.g. calculating quality indicators). In addition, there are debates in the literature about how quality of intensive care should be measured and if data quality of the PCIS is sufficient for calculating quality indicators. PCIS often provide the data for quality management, but they are not designed to deliver aggregated data to care professionals. Although there are numerous examples, many quality management processes in intensive care involve people and a lot of work.

Chapter 3 describes the implementation of a PCIS on the intensive care units of Erasmus MC, while chapter 4 focuses on the developments of a data warehouse using the PCIS data. Both chapters demonstrate the importance of a sociotechnical approach to ICT development and implementation, with a focus on user participation. This results in information systems that have a better fit with working practices. The data warehouse of the ICU is one of the few examples of data warehouses containing clinical data. This field is still in development, and is restricted by the current disadvantages of PCIS, which often cannot be easily queried on an aggregated level.

Chapters 5 and 6 present examples of ICT supported quality management in two shared-care projects: the shared-care glaucoma project and shared-care retinopathy project. The data recorded with ICT applications were continuously used to measure quality and to inform the dialogue between various professionals involved in the projects: ophthalmologists, optometrists, and diabetes nurses. Chapter 5 reports on the effectivity and efficiency of the project, and the quality of work of the optometrists. In addition, several roles of ICT are distinguished: data collection, data exchange, facilitating skill-mix change, generating quality information and creating trust between care professionals. Chapter 6 explores what is needed for optimal synergy of skill-mix change and ICT. Using examples from both projects, it is argued that a fit is not automatic. Rather, flexible standards should be used in an intelligent manner to create and hold the trust between various professional domains.

Chapter 7 deals with the completeness of paper trauma records in the accident and emergency department of the Erasmus MC. Although the records were often incomplete, the solution introduced by the management – a new electronic registration system – turned out to be a poor strategy. This system was too rigid in use, because it is aimed at external accountability using a standardized data set, and not sensitive to the ad hoc working practice of trauma teams. Thus, a counterproductive distinction was created between healthcare work and quality management, which eventually led to a boycott of the system.

Conclusion

ICT and quality management

PCIS fulfill an important role in quality management. However, few systems can switch from the individual patient level to the aggregated level of patients groups or departments. The literature only shows only a few examples, because PCIS are primarily developed for supporting direct patient care. Developments in PCIS point to an increase of PCIS that facilitate quality management and in a few years, the results of these developments can be found in the scientific literature. So far, the most important role of PCIS is delivering data. Extra tools are necessary for making PCIS data usable for calculating quality indicators, such as data warehouses that collect and store data from multiple information systems, and business intelligence tools that generate reports. Moreover, there is a crucial role for the users of these systems: they must decide which quality information is useful to collect; they make the queries for the data warehouse; they add incomplete data and interpret the results; and they are responsible for taking action on the results of the measurement. Quality management with PCIS, thus, is not the push of a button, but a complex interplay of people and technology.

Involving healthcare professionals

PCIS and healthcare professionals play an important role in quality management, but the interrelation is complex. On the one hand, quality management comes closer to healthcare professionals, because it is increasingly occupied with (and interfering with) the point of care. On the other hand, quality management is excluded from the point of care by healthcare professionals. Quality management is unleashed from care, which is even enforced by ICT (data warehouses and management tools). Quality management is then easily classified as non-medical or administrative, and as a burden and threat to healthcare work. This opinion directly affects the responsibility felt by healthcare professionals for managing quality. One of these reponsibilities is recording and managing data in PCIS, so that the data can be used (by the professionals themselves) for quality management. Therefore, when optimizing quality management, it is wise to start with those quality themes that are both relevant and interesting to healthcare professionals and at the same related to management issues. When healthcare professionals and managers have a shared interest in visualizing a certain quality theme, there is a stronger base to collect and use PCIS data, and – if necessary – motivate healthcare professionals to record additional data and improve data quality in the PCIS.

The search for synergy

Using examples from the empirical chapters, it becomes clear that creating synergy between quality management, ICT use and the work of healthcare professionals is indeed possible. Often, synergy can be reached with some small adjustments to the process; for example, by re-arranging tasks, using more flexible standards, and integrating information systems (including data warehouses) at the point of care. Sociotechnical research into work practices offers an important contribution to discovering possible issues for optimization.

Lessons for research and practice

The thesis ends with three lessons for research and practice:

1. Remove counterproductive distinctions between primary and secondary work activities;
2. Remove counterproductive distinctions between primary and secondary use of data;
3. Regard quality management as a shared responsibility.

The development of ICT in healthcare has influenced quality management in many ways. The issue of using ICT for quality management is not so much about the technology in question, but about creating a space where medical concerns and quality concerns can be brought together as part of medical work, and where PCIS can be optimally used to support this work.

Samenvatting

Kwaliteit is een begrip in de gezondheidszorg waar we niet meer omheen kunnen. Zorginstellingen streven ernaar om effectieve, efficiënte, veilige, tijdige, patiëntgerichte zorg te bieden voor al hun patiënten. De aandacht voor kwaliteit van zorg werkt ook door in de ontwikkeling van informatie- en communicatie technologie (ICT) die zorgprofessionals gebruiken in de directe zorgverlening, oftewel patiëntenzorginformatiesystemen (PZIS). Er zijn veel verwachtingen van de kwaliteitswinst die het gebruik van deze systemen oplevert, en deze worden (zij het ten dele) ook in wetenschappelijk onderzoek bevestigd. Door betere leesbaarheid worden bijvoorbeeld minder medicatiefouten gemaakt; doordat een dossier door meerdere professionals opvraagbaar is op verschillende locaties, verbetert de informatie-uitwisseling, etc. Naast de directe kwaliteitswinst van PZIS-en is men ook geïnteresseerd in de indirecte bijdrage die ICT levert aan de kwaliteit van de gezondheidszorg; namelijk in het meetbaar maken van kwaliteit, ten behoeve van kwaliteitsmanagement. De verwachtingen van PZIS-en zijn ook op dit punt hoog, omdat zij zoveel gegevens bevatten die gebruikt kunnen worden om indicatoren te berekenen, of het effect van een bepaalde kwaliteits-interventie te meten.

Het doel van dit proefschrift is te onderzoeken hoe kwaliteitsmanagement wordt vormgegeven door de werkpraktijk van zorgprofessionals enerzijds en ICT ontwikkelingen anderzijds. Daarbij wordt een sociotechnische benadering gehanteerd, waarbij het samenspel van mensen en technieken focus van onderzoek is. Kwaliteitsmanagement wordt daarbij beschouwd als een onderdeel van het zorgwerk, en niet als een activiteit daarbuiten.

Hoofdstuk 2 geeft een overzicht van de literatuur over PZIS-en en kwaliteitsmanagement in de context van intensive care. Het laat zien dat er meer bekend is over de directe impact van PZIS op kwaliteit van de intensive care zorg, dan over het gebruik voor kwaliteitsmanagement (bijvoorbeeld berekenen van indicatoren). Daarnaast wordt er in de literatuur gediscussieerd over hoe kwaliteit van intensive care gemeten kan worden, en of de kwaliteit van data in een PZIS voldoende is voor deze metingen. PZIS-en leveren vaak wel de data voor kwaliteitsmanagement maar zijn zelf niet in staat om de zorgprofessionals informatie te geven op geaggregeerd niveau. Hoewel er veel voorbeelden zijn van ICT ondersteund kwaliteitsmanagement, wordt duidelijk dat het veel werk kost en dat dit niet zonder de inzet van de zorgprofessionals zelf kan plaatsvinden.

Hoofdstuk 3 beschrijft de implementatie van een PZIS op de intensive care afdelingen van het Erasmus MC en hoofdstuk 4 de ontwikkeling van een data warehouse dat gebruik maakt van de gegevens uit dit PZIS. In beide hoofdstukken wordt het belang zichtbaar van een sociotechnische

benadering van ICT-ontwerp en implementatie, waarbij de gebruikers nauw betrokken zijn. Dit maakt dat systemen beter aansluiten op de werkpraktijk. Het data warehouse van de IC is een van de weinige voorbeelden van data warehouses die klinische gegevens bevatten. Dit terrein is nog volop in ontwikkeling en wordt ingegeven door de beperkingen van de huidige PZIS-en, die niet gemakkelijk benaderd kunnen worden met vragen die het individuele patiëntniveau overstijgen.

Hoofdstuk 5 en 6 geven voorbeelden van kwaliteitsmanagement met behulp van ICT in twee transmurale projecten: het Transmuraal Glaucoom Project en het Diabetische Retinopathie Project. De gegevens die worden verzameld in de ICT-applicaties worden voortdurend gebruikt om de kwaliteit te meten en gebruikt in de dialoog tussen de verschillende professionals die bij het project betrokken zijn: o.a. oogartsen en optometristen resp. diabetesverpleegkundigen. Hoofdstuk 5 rapporteert over de effectiviteit en efficiëntie van het project en de kwaliteit van het werk van de optometristen in het glaucoomproject. Bovendien wordt duidelijk dat de ICT verschillende rollen speelt in het project: gegevensverzameling, gegevensuitwisseling, het faciliteren van taakherschikking, het genereren van informatie voor het kwaliteitssysteem en het creëren van vertrouwen tussen de zorgprofessionals. In Hoofdstuk 6 wordt ingegaan op de vraag wat er nodig is voor een optimale synergie van taakherschikking en informatie technologie. Aan de hand van voorbeelden uit beide projecten wordt betoogd dat er niet automatisch een goede fit wordt bereikt en dat je op een slimme, flexibele manier gebruik moet maken van standaarden om vertrouwen tussen verschillende beroepsgroepen te creëren en vast te houden.

Hoofdstuk 7 gaat in op de compleetheid van papieren dossiers van trauma-patiënten op de spoedseisende hulp van het Erasmus MC. Hoewel de dossiers inderdaad vaak onvolledig zijn, is de oplossing van het management – een nieuw elektronisch registratiesysteem – geen goede strategie. Dit systeem blijkt te rigide in het gebruik, omdat het teveel gericht is op externe verantwoording van een gestandaardiseerde dataset en te weinig de ad hoc werkpraktijk van een traumateam in ogenschouw neemt. Hierdoor wordt dus een contraproductief onderscheid gecreëerd tussen zorgwerk en kwaliteitsmanagement, wat uiteindelijk leidde tot boycot van het systeem.

Conclusies

ICT en kwaliteitsmanagement

PZIS-en vervullen een belangrijke rol in het kwaliteitsmanagement. Maar weinig systemen kunnen omschakelen van het niveau van de individuele patiënt naar een niveau daarboven (de afdeling, een patiëntengroep). In de literatuur zien we daar nog maar weinig voorbeelden van, omdat PZIS-en ook primair gebouwd zijn voor ondersteuning van de directe patiëntenzorg. Ontwikkelingen in de ICT duiden er wel op dat het aantal kwaliteitsmangement-faciliterende

PZIS-en toeneemt. Over een paar jaar zal daarvan ook meer terug te vinden zijn in de wetenschappelijke literatuur. Tot zover is de belangrijkste rol van PZIS-en het leveren van data. En zijn er extra tools nodig om de data uit PZIS-en geschikt te maken voor bijvoorbeeld het berekenen van indicatoren, zoals data warehouses die data uit verschillende informatiesystemen samenbrengen en business intelligence tools die rapportages genereren. Bovendien is er een belangrijke rol voor de gebruikers van deze systemen: zij moeten bepalen welke kwaliteitsinformatie nuttig is om te verzamelen; zij stellen de query van het data warehouse op, vullen onvolledige data aan en interpreteren de resultaten; en zij zijn verantwoordelijk voor de (verbeter)acties die erop volgen. Kwaliteitsmanagement met PZIS-en is dus zeker geen druk op de knop, maar een complex samenspel van mens en techniek.

Het betrekken van zorgprofessionals

PZIS-en en zorgprofessionals spelen een belangrijke rol in kwaliteitsmanagement, maar hun posities ten opzichte van elkaar zijn complex. Zo komt kwaliteitsmanagement enerzijds steeds dichter bij de zorgprofessionals, omdat het zich steeds meer bezig houdt met (en wil ingrijpen in) de directe zorgverlening, maar wordt het anderzijds door de zorgprofessionals zelf ook weggehouden uit de directe zorgverlening. Kwaliteitsmanagement wordt losgekoppeld van de zorg en dit wordt nog eens versterkt door de ICT die gebruikt wordt (data warehouse en management tools). Het wordt dan gemakkelijker om kwaliteitsmanagement af te doen als niet-medisch of administratief, en als een last voor het zorgwerk. Dit heeft direct gevolgen voor de verantwoordelijkheid die zorgprofessionals zelf ervaren voor kwaliteitsmanagement. Zo is een van die verantwoordelijkheden het goed beheren van de data in het eigen PZIS, zodat de data (door henzelf) gebruikt kan worden voor kwaliteitsmanagement. Om kwaliteitsmanagement te optimaliseren, is het verstandig om met die kwaliteitsthema's te beginnen, die voor de zorgprofessionals zelf interessant zijn, en die ook aanknopingspunten bieden voor managers. Als zorgprofessionals en managers er gezamenlijk belang bij hebben om de kwaliteit op dat betreffende thema inzichtelijk te krijgen en te verbeteren, biedt dat een goede basis om data te verzamelen vanuit het PZIS en om de zorgprofessionals te motiveren om extra gegevens vast te leggen in het PZIS, of de kwaliteit van de routinematig ingevoerde gegevens te verbeteren.

De zoektocht naar synergie

Aan de hand van voorbeelden uit de empirische hoofdstukken wordt duidelijk dat het creëren van synergie tussen kwaliteitsmanagement, het gebruik van ICT en het werk van zorgprofessionals geen onmogelijke opgave hoeft te zijn. Vaak is de synergie al met een aantal kleine aanpassingen te versterken. Bijvoorbeeld door taken anders te verdelen, door flexibeler om te gaan met standaarden en door de informatiesystemen (ook systemen als data warehouses) beter te integreren in het primaire proces. Sociotechnisch onderzoek naar de werkpraktijk levert een belangrijke bijdrage in het ontdekken van mogelijkheden voor optimalisatie.

Lessen voor onderzoek en praktijk

Het proefschrift eindigt met drie lessen voor onderzoek en praktijk:

1. Hef het onproductieve onderscheid tussen primair en secundair zorgwerk op;
2. Hef het onproductieve onderscheid tussen primair en secundair gebruik van data op;
3. Maak kwaliteitsmanagement tot een gezamenlijke verantwoordelijkheid.

De ontwikkeling van ICT in de zorg heeft het kwaliteitsmanagement op allerlei manieren beïnvloed. Het gebruik van ICT voor kwaliteitsmanagement is echter niet zozeer een zaak van de techniek zelf. Het gaat vooral om de ruimte die gecreëerd wordt voor kwaliteitswerk als onderdeel van het werk van zorgprofessionals en om de synergie die bereikt kan worden als PZIS-en op een goede manier worden ingezet.

Dankwoord

Op allerlei manieren heb ik mij gesteund gevoeld bij het schrijven van dit proefschrift.
In de eerste plaats door mijn promotor en copromotoren. Marc, tijdens mijn eerste functioneringsgesprek sprak je de verwachting uit dat ik vier jaar later met een proefschrift binnen zou komen dat je nauwelijks had hoeven begeleiden. Deze opmerking was illustratief voor onze verstandhouding toen en sindsdien. Ik deed alles het liefst zelf en vroeg weinig om hulp. Dat deze sterkte ook echt een zwakte is, blijkt wel uit het feit dat ik er twee keer zo lang over heb gedaan als je toen voorspelde. De kinderen die tijdens het promotietraject geboren zijn en mijn parttime aanstelling lijken legitieme verklaringen, maar ik vind het te gemakkelijk om het volledig daarop te gooien. Ik vond het altijd moeilijk om prioriteit te geven aan het proefschrift, aan de 'wetenschappelijk output'. Koppig als ik was om op mijn manier en in mijn tempo te promoveren, had ik echter wel iemand nodig die met me 'meeliep' gedurende de weg. Toen jij vertrok naar Plexus nam Antoinette de begeleiding over als co-promotor. Het tweede deel van je voorspelling kwam daarmee wel uit. Jij bleef op afstand. Een betrokken afstand overigens, want je was altijd bereid om mee te denken over de lijn van de artikelen en om stukken te lezen. Voor die begeleiding in de afgelopen negen jaar ben ik je erg dankbaar.
Antoinette, je gaf me precies op het goede moment de feedback die ik nodig had. Of het nu om de inhoud van het werk ging, mijn twijfels over het promoveren, of om het combineren van werk en privé, door jouw betrokkenheid heb ik het kunnen en willen afmaken. Soms wees je een weg die ik niet direct op wilde gaan, maar achteraf had je wel steeds gelijk. Ik heb je begeleiding niet ervaren als een aan het handje lopen, gelukkig! Je was vooral op gehoorafstand. Als ik vastliep was je dichtbij en had je tijd voor me om naar me te luisteren. Deze vorm van begeleiden heeft voor mij erg prettig gewerkt. Veel dank!
Jan, ik wil jou danken voor de mogelijkheden die je mij gaf om de intensive care te leren kennen en om betrokken te zijn bij allerlei interessante ontwikkelingen op het gebied van ICT en kwaliteit in het Eramus MC. Je maakte het ook financieel mogelijk om onderzoek te blijven doen in het Erasmus MC. Ik bewonder je optimisme bij het uitdragen van je visie op informatisering en standaardisering in een organisatie die nog steeds bestaat uit vele kleine koninkrijken.

In de tweede plaats wil ik de leden van de promotiecommissie bedanken voor het lezen en beoordelen van mijn proefschrift. In het bijzonder wil ik Roland Bal bedanken voor de feedback op eerdere versies van de artikelen en zijn betrokkenheid bij de afronding van het proefschrift. Jan Bakker ben ik dankbaar voor de mogelijkheid om op zijn afdeling onderzoek te doen naar de kwaliteit van zorg.

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voor de ruimte die ze gaven om dit proefschrift af te ronden, naast alle onderwijs- en onderzoektaken. Ik heb vele deadlines niet gehaald, maar kreeg gelukkig steeds de kans om vooruit te komen. Anne, ik wil jou bedanken voor je heldere overzicht op al mijn onderzoeksactiviteiten en artikelen. Jij was het die de term kwaliteitsmanagement introduceerde als overkoepelend thema van mijn onderzoek.

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Dicht bij huis wil ik mijn paranimfen Leontien Laterveer en Marco van Apeldoorn bedanken voor hun steun tijdens de promotie. Ik dank mijn ouders en schoonouders voor de zorg voor de kinderen, zodat ik extra schrijftijd had. Peter, Sofie, Emma en Rosa wil ik danken voor hun geduld, relativeringsvermogen en liefde.
Dit proefschrift draag ik op aan mijn oma Johanna Toben-Lindner, die vorig jaar overleed aan dementie. Als kind schreef ik kookboeken voor haar. Ach, zo groot is het verschil ook weer niet.

Gouda, 12 juni 2009

Curriculum Vitae

Marleen de Mul was born January 15, 1977 in Eindhoven, the Netherlands. In 1995 she graduated from the Jacob-Roelandslyceum in Boxtel. She studied at Leiden University for one year, and attained a propedeuse in Religious Studies. From 1996 to 2001 she studied Health Sciences at the Institute of Health Policy and Management at the Erasmus University in Rotterdam. She followed extra courses on health information management, and graduated in 2001. Since 2001 she has been working as a researcher at the Institute of Health Policy and Management, and has been involved in many ICT and quality of care projects. She developed a particular interest in use of data from the point of care for quality management. For the past two years she has supervised the course “Quality in health care”, and has been involved in several other courses on quality, health information technology, organizational change, and the social medical sciences.

Marleen the Mul is married and is expecting her fourth child in October 2009.

PhD Portfolio Summary

PhD student	Marleen de Mul
Department	Institute of Health Policy and Management
PhD period	2002-2009
Promotor	Prof.dr. Marc Berg
Supervisor	Prof.dr. Joris van de Klundert

1. PhD training

	Year	Workload (Hours)
Presentations		
- Kennis Beter Delen	2003	8
- ICT & Knowledge Society	2005	8
International conferences		
- ISQUA	2004	8
Seminars and workshops		
- Internal workshop with Lucy Suchman	2002	16
- Kennis Beter Delen	2003, 2006, 2008	40
- Seminar evidence based medicine	2004	8
- Conference IQ healthcare (start research centre)	2008	8
- Conference health logistics (start expert centre)	2008	8
Didactic skills		
- Presenting skills (individual training)	2005	40
Other		
- Course English conversation	2004	20
- Course Business Objects	2006	20
- Presenting and discussion skills	2008	16

2. Teaching activities

	Year	Workload (Hours)
Lecturing (lectures and tutoring)		
- Zorginformatiemanagement	2002-2003	8
- Medische Technologie	2002-2003	80
- Sociaal medische Wetenschappen	2003-2004	40
- Veranderen en Vernieuwen	2003-2005	160
- Kwaliteitskunde	2004-now	300
- Kwaliteit en Doelmatigheid	2005-now	260
- Public Health	2008-now	8
Supervising theses		
- Supervising Master's thesis (2 students)	2008-now	80
- Supervising Bachelor's thesis (9 students)	2004-now	360
Other		
- Supervising course Kwaliteit en Doelmatigheid	2007-2008	40
- Supervising course Kwaliteitskunde	2007-now	135
- Stagebegeleiding	2004-2005, 2007-2008	40