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Quality Management in Hospital Departments

Empirical Studies of Organisational Models

STEFAN KUNKEL



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Abstract

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The general aim of this thesis was to empirically explore the organisational characteristics of quality systems of hospital departments, to develop and empirically test models for the organisation and implementation of quality systems, and to discuss the clinical implications of the findings.

Data were collected from hospital departments through interviews (n=19) and a nation-wide survey (n=386). The interviews were analysed thematically and organisational models were developed. Relationships among aspects of organisation and implementation were hypothesised and analysed with structural equation modelling.

The result was a new framework with three organisational aspects of quality systems each with two sub-aspects: structure (resources and administration), process (culture and cooperation), and outcome (evaluation of goal achievement and development of competence).

Strong positive relationships were confirmed among structure, process, and outcome. Quality systems could therefore be classified into three organisational degrees. For instance, quality systems of high organisational degree often had adequate resources and administration as well as positive organisational cultures and high cooperation among different professions.

Advanced designs required quality systems of high organisational degrees. Examples of such designs were coordination between departments, random check ups, and accreditation.

The organisationally demanding quality systems had been implemented through cooperative implementation, that is, directed by managers while at the same time giving opportunities for staff to participate in planning and designing.

The results can be useful to managers, quality coordinators, and clinicians when they describe, develop, implement, and evaluate the effectiveness and efficiency of quality systems in hospital departments.

Keywords: Quality Management, Organisational Models, Hospital Departments

Stefan Kunkel, Department of Public Health and Caring Sciences, Uppsala Science Park, Uppsala University, SE-75183 Uppsala, Sweden

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*I dedicate this thesis
to my mother and
to my father*

Papers

This thesis is based on the following four papers, which will be referred to in the text by their respective Roman numeral:

- I **A thematic comparison of seven quality systems at a university hospital. Different types and aspects of quality systems and their implications.**
Kunkel ST, Westerling R.
Health Policy 2006; 76(2): 125–33.

- II **The structure of quality systems is important to the process and outcome, an empirical study of 386 hospital departments in Sweden.**
Kunkel S, Rosenqvist U, Westerling R.
BMC Health Services Research 2007; 7:104.

- III **Quality improvement designs are related to the degree of organisation of quality systems: An empirical study of hospital departments.**
Kunkel S, Rosenqvist U, Westerling R.
Health Policy 2007; 84(2–3):191–9.

- IV **Implementation strategies influence the structure, process, and outcome of quality systems. An empirical study of hospital departments in Sweden.**
Kunkel S, Rosenqvist U, Westerling R.
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1 Introduction

The health care sector of today is a dynamic and exciting sector with many opportunities as well as challenges.

On one hand, there are *opportunities* to deliver high quality care to patients thanks to new technical, diagnostic, and therapeutic innovations.¹⁻⁶ On the other hand, there are *challenges* to decide which patients or groups of patients should be given priority as well as to keep up-to-date with innovations and developments.

On one hand, there are *opportunities* to adapt care and benefit from patient participation created by increasingly knowledgeable and informed patients.⁴ On the other hand, there are *challenges* to master the new skills that are needed to create and sustain successful relationships between patients and professionals.¹⁻³

This thesis is about quality systems in hospital departments. Quality systems can be the very tools for department managers and quality coordinators to master the challenges of achieving high quality of care in a complex ever-changing environment.

In this introductory chapter, the Swedish health care system and its stakeholders will be reviewed. Different concepts of quality and quality systems will be discussed and put into the Swedish regulatory context. Finally, the general and specific aims of this thesis will be outlined.

1.1 The Swedish health care system

There are several stakeholders participating in the Swedish health care system. These stakeholders will be further described below, but first a short summary of them:

The financing and production of health care are decentralised to publicly elected county councils. They decide how many resources should be available to health care and the number, type, and size of hospitals and primary health care centres. Private stakeholders, such as trade unions, patient associations, the mass media, or companies may try to influence these decisions.

Hospital directors and heads of hospital divisions decide how to organise the hospitals to provide good quality care, within budgets, while at the same time meeting the requirements of laws and regulations. Department heads and staff, as well as private stakeholders, may engage in this process.

Heads of hospital departments will need to decide on staffing, routines, and day-to-day priorities. Staffs and quality coordinators must prioritise among available quality improvement efforts, as must centrally placed hospital quality committees or directors.

County councils, managers, and staffs are bound by laws and regulations decided by The Swedish parliament and the National Board of Health and Welfare. These laws and regulations concern health care production as well as quality control.

1.1.1 County councils provide health care services

Sweden is administratively divided into 20 counties headed by politically elected councils that are responsible for providing health care to the people within their areas. For the island of Gotland, this responsibility is placed on municipal level instead. These 21 regions have populations of between 60,000–1,900,000 and range from small to very large in area size and their population densities vary from low in rural areas to high in urban areas.⁷

Each county council decides on their own taxes and patient fees. However, the Swedish Parliament has decided that patients do not have to pay more than a total of SEK 900 per year for health care.⁷

Every citizen is insured by a national health care insurance and should get access to care on the basis of needs only. The health care insurance is funded mainly by locally decided county taxes (71%) and only to a smaller degree by national government grants (16%) or income from sales, fees, and other similar sources (13%).⁷

There can be large differences in conditions between the regions, for instance, differences in size and geographical distribution of population, and the amount of resources available through taxation.

In total, there are roughly sixty hospitals in Sweden that provide specialist care and round-the-clock emergency care. Hospitals that provide basic specialist care are called *district county hospitals*, while hospitals that provide advanced specialist care are called *central county hospitals*. The most specialised care is provided by eight *regional hospitals* that also have medical research and education.⁷

The number of hospitals, their sizes, and their specialities are decided by each county council. The county councils can also decide on referral policies and rules.

The public hospitals are the main providers of specialised and emergency care in Sweden. There exist only a few private hospitals that offer specialised care. Even then, private hospitals do often have agreements with the county councils to provide care and are partially funded through the national health insurance system. Thus, the interaction and cooperation between hospital top management and the county councils is very important.

The county councils also decide how many resources they should devote to primary health care.

The Swedish Association of Local Authorities and Regions is an organisation where the counties and municipalities can cooperate to solve common issues. For instance, they have coordinated and supported about fifty national quality registers for outcomes of treatment of specific conditions, such as hernia or prostate cancer.

1.1.2 Private stakeholders influence policy and practice

There are several private stakeholders that influence, or try to influence, health care policy and practice. A very high rate of Swedish health care professionals are members of a trade union. The unions also have some responsibilities or authorities, such as the right to negotiate central agreements for salaries and other working conditions, or the right to confer with managers on the staff's behalf when larger changes are planned. Thus, the unions are a powerful force in Swedish policy making.

For instance, there is the Swedish Medical Association for physicians, the Swedish Association for Health Professionals for nurses, midwives, biomedical analysts, and radiographers, and the Swedish Association of University Teachers for professionals, researchers, and teachers employed at universities and colleges.

Other important stakeholders are associations of patients with certain diagnosis, the mass media which can affect public opinions, or companies that may be interested in selling health care services to the counties.

1.1.3 Managers and staff develop quality in hospitals

The quality improvement work at hospital level may be organised in several different ways. For instance, there may be a director of quality, a central quality committee, or a forum for cooperation and coordination among department quality coordinators.

Most hospitals are organisationally divided into departments according to medical specialities. Some large hospitals may have an organisational level above the department level, the division level. At the department level, short term planning and day-to-day health care production are performed.

Larger departments may have quality coordinators that are responsible for reporting of quality outcomes to hospital management and for advising other members of the staff how to conduct good and successful quality improvement work. In smaller departments, these tasks may instead be conducted by the department head or in some cases by the staff as uncommissioned assignments or volunteer efforts on an occasional basis.

1.1.4 Government agencies regulate and monitor quality

The National Board of Health and Welfare is the national government agency that regulates and monitors the quality of health care at hospitals. The Health Services Act (SFS 1982:763) contains the specific laws that regulate the activities of health service providers in Sweden.⁸ The Act requires that provided care should be of good quality (2a§) and that services should be organised to ensure high patient safety and good quality of care (28§). Furthermore, quality of service should be systematically and continuously developed and assured (31§).⁸

The National Board of Health and Welfare has issued regulations that require hospital departments to implement quality systems (SOSFS 1996:24M).⁹ The regulations state that hospital management should give directives and assure that all units of the organisation have purposeful quality systems with organisational structures, resources, routines, and methods that assure the quality of service.⁹

Department managers should, within budgets, develop and decide on a purposeful quality system to continuously control, follow up, develop, and document the quality of service to achieve set quality goals and to promote cost efficiency.

Staff should participate, and through systematic, continuous, and documented quality improvement work, ensure that set goals can be achieved.

Quality systems should be adapted to department specialities and sizes, include measurable goals and documented routines for quality assurance and evaluation of quality.

Routines that should be included in quality systems have also been specified in the regulations. There should be routines for:

- cooperation and communication among staff,
- implementation of new methods and abandonment of old ones,
- development of competence,
- procurement,
- risk assessment and incident reporting and handling,
- self check, follow-ups, and feedback, *and*
- handling of patient data.

New regulations have replaced to ones that have been described here.¹⁰ They were put into practice after the studies in this thesis had been conducted. However, these new regulations are very similar to the old ones in most regards. Thus, the new ones have not been separately described.

The National Board of Health and Welfare also monitors the hospitals through periodical visits and evaluations. Serious incidents that have been reported to the board, so-called Lex Maria incidents, may initiate further investigation.¹¹

Additionally, hospitals or departments that are accredited according to ISO-9002 or similar accreditations get periodically assessed by the national accreditation agency Swedac, which awards the accredited status as well as monitors compliance with certain standards. Swedac and the National Board of Health and Welfare are separate national government agencies.

Other important tasks of the National Board of Health and Welfare are to grant and withdraw certification of health care professionals, such as physicians and nurses.

1.2 Health care quality and quality systems

To determine if health care quality is good or bad requires decisions of which aspects should be included, reliable measurements of these aspects, and a comparison between measurements and standards. For instance, such aspects of quality could be that health care services should be safe and equitable. Measures can either be independent of personal opinions, often referred to as *objective* measures, or represent how things are perceived, often referred to as *subjective* measures.

Objective as well as subjective measures of quality can be used in health care. For instance, an objective measure of safety can be surgery complication rates and a subjective measure can be to ask patients if they are satisfied with the care.

To measure *objective* quality requires methods to measure a quantifiable characteristic that adequately reflect the aspect in question. For instance, surgeons can record the number and types of surgery complications, compare their measurements against the measurements of other departments, and conclude that quality is good or bad.

To measure *subjective* quality requires observers with appropriate knowledge, abilities, or qualifications to make *meaningful* statements of quality. *Subjective* quality can only be quantified in the sense that a certain proportion of qualified observers agrees or disagrees with the assertion that quality is good or bad. For instance, patient satisfaction surveys can be used as a subjective measure of quality.

The Swedish National Board of Health and Welfare has defined quality as "the degree to which an activity achieves decided criteria".⁹ It is an open definition that relates quality only to decided criteria. The criteria could be set to be objective as well as subjective measures. They are not limited in any way, neither by discipline and range, nor by ambition.

The Institute of Medicine in the United States of America has proposed a more detailed *definition of the quality of care*:

Definition of the quality of care: Quality of care 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.¹²

This definition is different to that of the National Board of Health and Welfare in several ways. It specifies that the activities in question are "health services" and that these activities should concern individuals as well as populations. Furthermore, criteria achievement is specified to be the degree to which the actions increase the likelihood of desired health outcomes. Moreover, the criteria should be decided with current professional knowledge in mind.

Thus, the definition from the Institute of Medicine takes into account not only that certain criteria are *fulfilled* but also that the criteria themselves are *consistent* with professional knowledge. Therefore, to maintain a certain level of quality, criteria will need to be changed when professional knowledge change or expand. Quality becomes a relative measure.

The definition of the National Board of Health and Welfare can be useful to assess quality of care. However, *quality systems* are not only about assessment but also about development. Thus, when studying quality systems it is useful with a concept of quality that not only takes criteria assessment into account but also criteria development.

Donabedian has developed a general model for analysing the quality of care by using three aspects: structure, process, and outcome.¹³⁻¹⁵ It has been extensively used as a framework to assess clinical practice.

Structure refers to attributes of the settings in which care occurs. It can be divided into three types. First, there are material resources, such as hospital buildings and equipment. Second, there are human resources, that is, the number of employees and their qualifications. Third, there are organisational resources, such as paths of authority and relations among organisational subunits.

Process describes how the attributes of structure are put into practice, such as the processes of diagnosis and treatment, and how the care is received by patients.

Outcome refers to the results of the processes, for instance, the effects of therapies on the health status of patients. It can also include changes in patients' knowledge of their diseases or general health related behaviour.

1.2.1 Mission and aims of health care

It is important to decide what the general mission of health care should be to be able to develop meaningful criteria for evaluating quality. The Swedish Parliament has decided in the Health Services Act (SFS 1982:763) that the general mission of health care services should be to obtain good health on equitable terms for the whole population (2§). Health care services are defined as the medical services of prevention, diagnostics, and treatment of illness and injury (1§).⁸

The Institute of Medicine has proposed a similar but slightly more ambitious *mission of health care*:

Mission of health care: All health organizations, professional groups, and private and public purchasers should adopt as their explicit purpose to continually reduce the burden of illness, injury, and disability, and to improve the health and functioning of the people.¹⁶

Three important suggestions can be inferred by this mission statement. First, that it is important that the diverse stakeholders of the health care sector should have similar explicit purposes. Second, that these stakeholders should act to help people in need that are ill, injured by crime or accident, or disabled for some reason. Third, that they should work proactively and preventively as well as to react to the needs of people.

The two mission statements are similar but there are some differences. The mission statement of the Institute of Medicine explicitly acknowledges that public as well as private stakeholders have a role to fulfil in health care. The Health Services Act does not refer to stakeholders at all and does not indicate who will provide health services. Furthermore, the institute's mission also says "...to continually reduce the burden of illness..." which seems to be more specific than just "...to obtain good health...". The Health Services Act specifically states that equitable terms are desirable, which the institute does not state in the mission but only later as a more specified aim.

The Institute of Medicine further specified this mission into *six aims of health care*. According to these aims, health care should aim to be:¹⁶

- *safe*, to avoid injuring patients when providing adequate care,
- *effective*, to provide services based on science to those that are likely to benefit from them and not to those that are not,
- *patient-centred*, to provide care that is adapted to patient preferences, needs, and values during every stage of the caring processes,
- *timely*, to reduce waiting times for patients and staff,
- *efficient*, to avoid the waste of resources, *and*
- *equitable*, to provide care of equal quality regardless of the personal characteristics of the patients.

Similar aims have also been decided in Swedish laws. The Health Services Act mentions safety (2a§, point 1), patient-centeredness (2a§, points 3–5), timeliness (2a§, point 2), and equitableness (2§).⁸ The Health Services Professionals Act (SFS 1998:531) mentions effectiveness (2:1).¹⁷ The Public Administration Act (SFS 1986:223) mentions efficiency (7§).¹⁸

Such aims of health care have also been proposed by researchers.^{8-10 19}

1.2.2 Quality systems in health care

Health providers will need to develop strategies to achieve decided aims. One strategic decision will be to choose which measures that should be used to assess if safety, effectiveness, patient-centeredness, timeliness, efficiency, or equitableness have been achieved. It is a challenge since each aim can be measured in many ways. For instance, there can be several measures of effectiveness such as formal competence of physicians or availability of necessary equipment.

Another strategic decision will be to choose instruments that adequately reflect the intended measures. Examples of such instruments could be surveys, registers, or accounting systems. Target levels or points-of-comparison will need to be defined. For instance, a target for formal competence could be that at least 30% of all physicians at a department should be certified specialists.

The choices of measures and instruments are strategic since they can have great impact on which activities that managers and staff prioritise, especially if financial incentives are tied to these measures. Strategic decision making is the responsibility of hospital top management, but some of these decisions may be delegated to division or department management if the organisation is decentralised.

Measurements will need to be taken regularly, reported, and compared to the target levels. The measurement data need to be analysed, communicated to appropriate managers and staff and used to improve caring processes as well as to improve and develop the measures and instruments themselves.

There are many reasons to work with quality improvements in health care. Patients get well quicker and suffer less when they get appropriate care. Thus, it is a humanitarian interest that patients should be given high quality care. It is also often cheaper to do the right thing from the start and avoid additional therapy sessions that can be costly for caregivers as well as expensive for patients.^{5 6} Simply put, it can be good use of taxpayer money to improve health care quality.³

However, it can be easier said than done to set aside time to work with quality improvements. It can also be a challenge to know how to do it in practice, how to do it correctly, and how to avoid pitfalls that would only lead to waste of time and manpower. A more organised and systematic way to work with quality improvements can therefore help health care employees

to know when, how, and where to work with improvements. A quality system can be such a tool.

Quality systems can be used as tools for health care professionals to develop health care quality. Furthermore, the use of quality systems can signal to patients and politicians that hospital departments are working actively and systematically with quality issues. The collected and analysed data from quality systems could provide evidence that departments perform at high quality levels.

Quality systems can be defined as:

Definition of quality systems: Quality systems are quality assurance and quality improvement efforts that are designed and organised.^{12 14}

To be designed means that quality improvements are planned and executed according to accepted methods. To be organised means that efforts are managed and that employees work together towards shared goals.^{12 14}

According to this definition, quality improvements need to be ongoing and not limited in time to be considered quality systems. Naturally, improvement projects or programmes can be important parts of quality systems. However, they cannot by themselves – without coordination and plans for long-run implementation – constitute quality systems.

In practice, quality systems go by many different names. Quality improvement is a general term that can apply from everything from small locally developed systems²⁰⁻²⁵ to standardised systems such as Continuous Quality Improvement^{26 27}. A more specific term is quality assurance where quality measures are compared with outcomes in a structured manner, for instance, Total Quality Management or Balanced Scorecard.²⁸⁻³⁰ Quality accreditation denotes the case when the system has been approved by an external accreditation agency that regularly checks if the department complies with certain standards.^{31 32}

1.3 The aims of this thesis

The general aim of this thesis was to empirically explore the organisational characteristics of quality systems of hospital departments, to develop and empirically test models for the organisation and implementation of quality systems, and to discuss the clinical implications of the findings.

1.3.1 Main focus

There are four main organisational levels that were discussed earlier in this introduction: the national level, the county level, the hospital level, and the hospital department level.

In this thesis, only quality systems of *hospital departments* are studied. Thus, the national, county, and hospital levels were not examined. However, some background information about these levels was given to make it easier to understand the context in which hospital departments are embedded.

There are many different stakeholder perspectives that could be used to explore and analyse quality systems of hospital departments, for instance, the patient perspective, the profession perspective, and the manager perspective.

In this thesis, quality systems were studied from *the manager perspective*. Thus, the patient or professional perspectives have not been explicitly explored. However, managers of hospital departments in Swedish hospitals are most often also physicians, nurses, or members of other health care professions. Although focus was on the perspective of the persons that decide and are accountable for working with quality, this does however not mean that the professional perspective was totally excluded.

1.3.2 The specific aims of each paper

The specific aims of each paper were:

1. To study different quality systems, find the organisational aspects that are important for actors in those systems, use the aspects to construct types of quality systems, and discuss the implications of these various types for health policy makers (Paper I).
2. To analyse whether (the organisational aspects) structure, process, and outcome can be used to describe quality systems, to analyse whether these components are related, and to discuss the implications of these relationships (Paper II).
3. To analyse whether departments that work with specific quality improvement designs differ with regard to organisational factors, and to analyse whether departments with different organisational types of quality systems work with different quality improvement designs (Paper III).
4. To analyse whether the organisation of quality systems are related to how these systems were implemented (Paper IV).

2 Theory

The term *management* has often been used to describe the *people* that plan and decide what is done in organisations, for instance, managers or leaders, as well as the *processes* of how people organise. Thus, it has been used to denote managers as a collective as well as processes of organisation.

Organisations are created by people because there are limits to how much single individuals can achieve by themselves. They will need to *cooperate* to accomplish greater deeds. They will need to *engage* in the process of organising, to form organisations, and to create leadership functions to coordinate cooperation efforts. Classically defined, an organisation was described as "a system of consciously coordinated personal activities"³³.

In this chapter, general management theories as well as implementation research will be described. It is theories about how people organise and how to manage organisational change. But first, specific attempts to manage quality in health care will be depicted: early as well as recent attempts.

2.1 Quality management in health care

Since at least mid-nineteenth century there have been individuals committed to quality improvement. Some of them are well known even today.

The famous Florence Nightingale (1820–1910) was a nurse at the Scutari hospital in Turkey during the Crimean War (1854–1856). There the sanitary conditions were horrible for the wounded soldiers with dirty beds, clogged latrines, bad food and other filth, and 43% of the admitted soldiers died. In a well-known study, she hypothesised that bad sanitation was the reason for the high mortality rate, she had the hospital cleaned and sanitised, and noted that the mortality rate dropped to a mere 2%. It was a formidable success that probably also saved many lives.³⁴

The well-known Ernest Codman (1869–1940) was a Boston surgeon who started his own private hospital called The End Result Hospital. He recorded all errors and classified them into types such as lack of knowledge or skill, surgical judgment, lack of care or equipment, or lack of diagnostic skill. These results were then published in annual reports that were publicly available. Thus, he was a pioneer in the field of incident handling.³⁵

The renowned William Deming (1900–1993) was a mathematical physicist that specialised in statistical process control and the Plan–Do–Study–Act

model of organisational learning. This model is based on a cycle where solutions are continually implemented, evaluated, and modified. His services were first not appreciated in his home country so he went to work in Japan, where he became celebrated. Later he returned to the United States to complete a successful career in consulting within the health care sector as well as many other sectors.³⁶

Nightingale, Codman, and Deming, as well as many other pioneers not mentioned here, were often questioned or ridiculed when they first tried to do things differently. While some of them gained appreciation later during their lifetime some did not. That is the hard truth of being a pioneer ahead of your time.

More recent developments within the field of health care management research can be divided into three eras, beginning from approximately the 1970s, in chronological order:

- The standardisation of practice and policy approach was common in the 1970s and 1980s. It emphasised the key role of physicians in guaranteeing the quality of care and focused on development of professional practices and operational policies.
- The organisational approach was common in the 1990s. It aimed to create a commitment to quality in the organisation and to enable learning. An example of this type of approach was the Total Quality Management movement.
- The complex adaptive systems approach was discussed in the 2000s and still is. It is based on the premise that creating a few general rules of action for organisations and people will allow them individual flexibility of action but at the same time lead to outcomes that are congruent with decided goals.

2.1.1 Standardisation of practice and policy

In the 1970s, researchers started to notice that different health professionals could act very differently when confronted with identical clinical situations. These differences were considered to be potential quality problems and efforts were taken to evaluate professional practice and to reduce variability. Therefore, quality improvement efforts in American hospitals began to address professional practice and operating policies in the 1970s.³⁷

Professional practices are strategies for diagnosis and treatment, for instance, clinical guidelines. A clinical guideline is "a standardised and specific description of the best approach for a given pathological condition, developed on the basis of an analysis of the scientific literature and expert opinion".³⁸ Thus, clinical guidelines only deal with the technical aspects of the quality of care.

Operating policies consist of formal administrative standards, for instance, routines for admittance, safety regulations, and patient satisfaction survey standards.³⁷ However, operating policies only cover the documented standards and routines and not the informal parts of the organisation, such as tacit knowledge learnt through socialising with co-workers or through training.

Professional practices and operating policies are two methods to standardise health care processes. The first one, professional practices, is a domain where clinicians and medical researchers have traditionally had a strong influence because of their expert knowledge. The second one, operating policies, has more been the domain of managers and administrators.

However, strong professional independence for physicians has been, and is still in some respects, a defining feature of the organisation of health care. This has meant that physicians traditionally have had great freedom to decide how to diagnose and treat their own patients, as long as it was consistent with science and good practice.

These types of organisations are often called professional bureaucracies, that is, organisations where authority is based on professional affiliation and expertise rather than managerial position.

In professional bureaucracies, the independence of single professionals is great, although standards can also be set by external organisations, such as medical associations. In contrast, standards are usually set by senior management in traditional bureaucracies.³⁹

On one hand, professional practices could be seen as attempts to decrease this freedom for individual physicians. On the other hand, physicians might prefer professional practices over operating policies to maintain as much expert control over practice, on a profession-based scale, as possible.

There were those that opposed the trend towards standardisation because it would make work more routinised and less dependent on expert opinion. Thus, clinicians might prefer not to standardise professional practice to avoid routinisation of work, while medical researchers may want to promote their own research results by influencing and setting standards. Likewise, heads of hospital departments may wish to avoid standards that would decrease their influence over department work, while hospital senior management may prefer the opposite.

2.1.2 The organisational approach

Professional practices and operating policies were successful as methods to improve quality.³⁷ However, the purely technical focus on quality that dominated during the 1970s and 1980s was criticised.^{40 41} It was argued that the actual implementation of policies had been neglected. Professional practices would only be of value if they could be effectively implemented in the organisation.

It can be difficult to implement professional policies. For instance, some physicians may not have the competence, training or motivation to conform to standards.

Moreover, even if professional practices could be successfully implemented, there would be no guarantees that they would be appropriate for every situation, for every clinician, or for every patient. Conformity with standards does not always correlate with good clinical performance.^{42 43}

There is also a risk that quality standards will be set to the bare minimum level of acceptable quality.⁴⁰ This is a risk because some physicians may be qualified and able to provide a quality of service that is higher than the standards require. Thus, requirements to conform to standards may in effect force these physicians to provide care of unnecessarily low quality.

According to the organisational approach, quality is not considered to be a function of medical expertise alone, but of complex processes that involve health care professionals as well as patients.⁴³ In fact, organisational processes could even be *more* important for overall quality than expertise.

Important and influential examples of the organisational approach to quality are the *Total Quality Management* and the *Continuous Quality Improvement* movements. They were based on the principles of the continuous search for improvement, the alignment between provided services and patient needs, and managers that involve the entire organisation in striving for quality.

The Total Quality Management method requires a detailed description of all processes of the organisation as a starting point. An important feature is the forming of teams that are called *quality circles*. A team should consist of all employees that are connected to the specific process in question. Such teams could thereby be interdisciplinary or interdepartmental. The task of the team is to analyse and improve the processes by using the tools provided by the method. The process should be carried out in a positive spirit where difficulties and mistakes should be seen as opportunities for improvement – not as problems to be punished.

Numerous hospitals have implemented Total Quality Management or Continuous Quality Improvement programmes but few implementations have been evaluated by scientific standards. Nonetheless, the principles that lie behind these movements have been very influential in many countries, for instance, in the United States of America and in France. Some of these programmes have also developed into straightforward accreditation systems to further reinforce their impact on the health care system.

The organisational approach to quality is rather different from the professional bureaucracy approach. In the organisational approach, physicians are still considered to play an important role for quality improvement, but their role is downplayed compared to their paramount role in the professional bureaucracy approach.

Physicians are naturally important actors since they have the professional expertise to diagnose and treat patients. However, all health care workers will need to contribute to achieve an overall high quality of care. Managers and administrators will have to plan and distribute resources, nurses and nursing assistants will have to provide patients with professional care, engineers will have to procure and maintain advanced technical equipment, cleaning staff will have to maintain antiseptic environments, and so on.

2.1.3 Complex adaptive systems

The total quality management approach and similar approaches have the advantage of trying to take many aspects of organisation and implementation into account when working to improve quality. However, the number of aspects and elaborate ways to work with quality improvements can quickly become too many and overwhelm managers and staff. Thus, working with quality improvements can become too complicated, inconvenient, or impractical.

The complex adaptive systems approach proposes a new way to cope with the complicated environment of health care. The approach is based on the adoption of simple rules in contrast to the two previously described approaches that are based on the adoption of more detailed procedures.

A simple rule can be summarised into a single or a few sentences but contains enough information to be useful to guide the managers and staff of health care. According to the approach, a set of a few simple rules could be adequate to guide the actions of managers and staff, to maintain freedom and flexibility of action, while still moving the organisation towards the decided aims and the mission of health care. For instance, the Institute of Medicine has proposed a set of simple rules (Table 1).¹⁶

According to theory, when an individual of an organisation follows simple rules, the specific outcomes of a single action may be unexpected and difficult to predict. However, when a collective of individuals follow simple rules, the overall outcome will be the expected and the predicted.

Thus, a single action may render unexpected results, but all actions together average out to the expected results. To have a state of predictive uncertainty of the outcomes of specific actions while at the same time achieving the expected outcomes of all actions together is called complexity. Organisations that exhibit these characteristics are called complex systems.

Another important concept is adaptivity which means that individual behaviour changes when characteristics in the environment changes. Thus, an adaptive system has the ability to change when necessary.

Table 1. *The set of simple rules proposed by the Institute of Medicine.*¹⁶

Simple rules to guide actions

01. Care is based on continuous healing relationships.
 02. Care is customized according to patient needs and values.
 03. The patient is the source of control.
 04. Knowledge is shared and information flows freely.
 05. Decision making is evidence based.
 06. Safety is a system property.
 07. Transparency is necessary.
 08. Needs are anticipated.
 09. Waste is continuously decreased.
 10. Cooperation among clinicians is a priority.
-

It has been shown that a hospital department can be viewed as a complex adaptive system in certain situations and as a traditional system in other situations.⁴⁴ For instance, in emergency situations where there is very little room for mistakes and few options for action, departments can operate as procedural, traditional systems. When the emergencies are over, the options to act may increase or become more flexible. Then the department could instead operate as a complex adaptive system.

2.2 General theories of management

A century of management research has resulted in several interesting theories, models, or perspectives on how people organise. This chapter will discuss two perspectives on organisation.

- The organisational culture perspective, in which culture is promoted as an important aspect that affects organisations and organisational performance.
- The organisational learning perspective, in which organisations are viewed as groups of people that learn and that these learning processes determine the development of the organisations.

2.2.1 Organisational culture

Inspired by the discourse of anthropology, the organisational culture perspective acknowledges the human dimension of work organisation.⁴⁵ It gained popularity during the 1980s and arose as a complement to the earlier organisation perspectives that focused mainly on the technical organisation of work. In *the organisational culture perspective*, culture is promoted as an important aspect that affects organisations and their performance.

There are three research traditions within this field: corporate culture, organisations as metaphors, and organisations as cultural expressions.

One way to define organisational culture is to treat culture as an organisational characteristic among other characteristics such as number of employees or company size. This tradition is often referred to as *corporate culture*. Within this tradition there are researchers and consultants that maintain that productivity can be increased by changing culture.⁴⁶

However, corporate culture is not the only way to define organisational culture. Organisational culture can also be used to describe what organisations are. In this tradition, culture is regarded as a *metaphor* for the organisation. As a consequence, culture as a concept is not to be used for managing organisations but rather as a method to describe or understand organising as a social phenomenon.⁴⁵

Organisations could be regarded as *cultural expressions* of larger societal processes.⁴⁷ This is perhaps the definition that most closely resembles what common people associate with the broad term culture.

This thesis is about the organisation of quality improvements in hospital departments. The metaphorical or expressive traditions would be more appropriate perspectives to study organisations within a societal context, not in the context of hospital departments. Thus, only the corporate culture tradition will be further discussed.

In the corporate research tradition, culture can be defined as a *pattern* of assumptions that *evolves* within a group while it *learns* to handle problems. For some reasons, these patterns of assumptions have been found *adequate* and are therefore *taught* to new members as *appropriate* ways to act when encountering specific problems.⁴⁶

The alternative term *organisational climate* is often used to describe the more direct experience of the work setting, in contrast to the more abstract concept of culture. However, the two terms can be and have been used synonymously.⁴⁸

An example of a corporate culture theory is the so-called Theory Z that was influenced by Japanese management ideas.⁴⁹ Students of organisation theory may remember the old Theory X that assumes that employees are lazy by nature and Theory Y that assumes that employees are lazy by being trained to be so.⁵⁰ According to these rather pessimistic views of human motivation, the task of the leader is to use whips or carrots to make the employees behave as requested.

Theory Z stands for a more optimistic view of mankind, where instead employees are assumed to have great potential and that a leader's task is to find ways to stimulate and unleash this potential. The secret to success, according to Theory Z, is to build trust and make everyone work towards shared goals.⁴⁹

2.2.2 Organisational learning

According to the organisational learning perspective, organisations are groups of people that learn and the way learning occurs also determines other characteristics of the organisation, such as organisational form or prosperity.⁵¹

There are two types of organisational learning research traditions. The first tradition, *organisational learning*, is more theoretically oriented and focused on general organisation processes, such as the processes of learning. The second tradition, *knowledge management*, is more focused on the characteristics of data, information, and knowledge.⁵¹ This thesis is about the characteristics of organisations rather than the characteristics of knowledge. Therefore, the knowledge management tradition will not be further discussed.

One important assumption of the organisational learning research tradition is that learning mainly relies on feedback, such as information about results of performed actions. Employees do not always act in the best or most effective ways but they can learn better ways to do things if given adequate feedback.⁵²⁻⁵⁴

However, to get adequate feedback is not enough. Employees also need proper knowledge and training to be able to reflect upon the feedback and know their options for alternative action. They must be prepared to change their ways of thinking and acting.

Two main processes whereby learning occurs has been proposed: single-loop learning or double-loop learning.⁵²

Single-loop learning occurs when a person gets feedback, reflects, and decides to take action or not, but without questioning the basis for reflection or action.⁵² For instance, a single-loop learner can ask the question: "How can I improve this routine?" However, this type of learning seldom includes making large changes to routines – just small continuous improvements. Other researchers have used the terms exploitation⁵⁵ or lower-level learning⁵⁶ for the similar process because *existing knowledge* are exploited and improved.

Double-loop learning occurs when the person also reflects upon the basis for reflection or action.⁵² For instance, a double-loop learner can ask the question: "Why am I doing this?" Thus, it opens up the possibility of making revolutionary or important discoveries with great potential for developing the organisation. Other researchers have used the terms exploration⁵⁵ or higher-level learning⁵⁶ for the similar process since it can result in the creation of *new knowledge*.

Some researchers⁵²⁻⁵⁴ claim that double-loop learning is superior to single-loop learning while others⁵⁵ claim that the two are equally important to the organisation. To always question procedure may be time-consuming and

inefficient when a job has to be done. Sometimes single-loop learning may prove to be more efficient, at least in the short run.

It has been proposed that four aspects affect the ability to achieve a higher-level learning capability: organisational structure, organisational culture, strategy, and the environment.⁵⁶ For instance, a decentralised organisation may support higher-level learning, as might a culture that is positive and rewarding to knowledge and improvements.

This rather abstract model has been developed into a more practically oriented model with five aspects: individual skills, compatible mental models among members, common and shared visions of the future, common learning, and system thinking.⁵⁷ Thus, learning organisations are characterised by members that continuously improve their abilities to achieve established goals, a high tolerance for new ways of thinking, and members that work and learn together.

2.3 Implementation research

Implementation is about realising change. It is one thing to plan and decide to change and an entirely different matter to actually change. It is often more complex and difficult than first expected.

Five phases⁵⁸ of an implementation process have been proposed:

- In the *initiation phase*, politicians, journalists, or other influential persons claim that change is necessary and try to convince others that their claims are justified.
- In the *analytic phase*, potential courses of action are invented and discussed. In the decision phase, decisions are made on which courses of actions should be taken.
- In the *administrative phase*, management and staff interpret policy and take appropriate actions.
- In the *evaluation phase*, the results of the implementation are assessed.

There are three perspectives on implementation that will be further described in this chapter:

- *the top-down model*, in which a linear hierarchic process is assumed, where policy makers plan and decide how and what to implement and the civil servants are expected to comply,
- *the bottom-up model*, in which highly independent civil servants, who can make independent decisions, are assumed, and last,
- *the cooperative model*, where policymakers and civil servants work together actively in a joint effort to design and implement the quality system.

Moreover, since this thesis is about quality systems in hospital departments, focus will be on the fourth phase of implementation: the administrative phase. Therefore, the chapter will end with a comparison of the three different models for administrative implementation, their advantages and disadvantages, and the prerequisites for successful administrative implementation.

2.3.1 The top-down implementation perspective

The top-down perspective proposes that the phases of implementation are carried out as linear and hierarchic processes.⁵⁹ They are linear because the phases follow each other. They are hierarchical since each organisational level is expected to obey the decisions of the next higher level: staff are expected to obey managers, who in turn are expected to obey policy makers.

Politicians or other policy makers define the existing problems and choose an appropriate method of change. Then the decisions are realised by managers, for instance, by allocating adequate resources and creating an effective organisational hierarchy. The implementation process is assumed to be initiated at the top and then carried out through each hierarchical level of the organisation.⁵⁹

To achieve a successful top-down implementation can be a difficult and complex process. It has been proposed that successful top-down implementations will need dedicated and skilful staff, support from managers and groups of interest, and favourable environmental or external conditions.⁵⁹

The dedicated and skilful staff need to have positive and supportive attitudes towards the specific changes in question.

Managers are in a challenging position. On one hand, too rigid or specific implementation directives that do not take practice into account can hold back the staff and obstruct implementation. On the other hand, too much freedom for the staff may lead to unexpected or unwanted implementation solutions from the policy maker's perspective.

Instead of deciding on very specific implementation directives, a solution could be to try to infuse values, norms, and interests into the staff to increase the likelihood that they will use their freedom in ways that comply with the overall goals of implementation.⁶⁰

An alternative course of action could be to select certain loyal employees that are known to be positive to the implementation in question and put them on key positions in the organisation.⁶¹

Support only from managers in charge, such as department heads, will not be enough for successful implementations.⁵⁹ Support from other influential groups of interest will also be needed, for instance, support from local or national professional associations and hospital senior management. They will also need the resources or means to implement the changes in practice.

The success and failure of implementations will also depend on how society at large is developing.⁵⁹ For instance, if newspapers write positively about quality assurance or if quality is debated in boardrooms and among managers, then it might be easier to gain support for quality improvement efforts than if quality was not debated.

2.3.2 The bottom-up implementation perspective

The bottom-up perspective is a critique against the hierarchical and linear top-down perspective.⁵⁹ According to the bottom-up perspective, the process of implementation is neither hierarchical nor linear.

Policy makers do decide on formal policies but these formal policies will then have to be interpreted by managers and the staff. The results of these interpretation processes may or may not be consistent with the original intentions of the policy makers. Thus, implementation is not about obeying orders alone and policy is not created by policy makers alone. Policy makers are but parts in a complex process where the implementation phases can be revisited several times before the process has been completed.

The street-level bureaucracy model is a well-known example of a bottom-up model.⁶² Street-level bureaucrats are defined as public servants that work directly towards citizens, for instance, social workers, school teachers, and physicians.⁶³ They often have some sort of professional competence that citizens need and are thereby allowed to influence policy within their areas of expertise, not only through professional associations, but most importantly, through individual action.⁶⁴

Thus, street-level bureaucrats are in fact creating policies rather than just implementing them.⁶² On one hand, this could mean that the implemented processes become well adapted to the actual clients and situations in practice. On the other hand, the implemented processes may be quite different from the original intentions of the policymakers and possibly coloured by the motives and interests of a few street-level bureaucrats.

2.3.3 The cooperative implementation perspective

The cooperative implementation perspective could be said to represent a combination of the top-down and bottom-up approaches to implementation.

In top-down models, the importance of hierarchies and linear implementation process are emphasised. The top-down approach can have the advantage that changes can be quickly implemented. However, it requires familiar problems so that the staff *understand* what to do and that they have the right competence to be *able* to implement the requested changes. Moreover, the staff will need to be motivated to really *want* to implement the changes.⁶⁵ There is also a risk that the implemented policies will not be adapted to the particular conditions at the specific department.

In bottom-up models, the importance of the professionals in the staff is emphasised and policy making is decentralised. The bottom-up approach can have the advantage that changes will become more adapted to the requirements of specific cases at a department. However, it requires a staff of competent professionals that can by themselves correctly identify problems, *understand* what to do, *want* to perform necessary actions, and that are *able* to develop and implement policies to solve these problems.⁶⁵ Moreover, there is a risk that centrally decided policies are not implemented at all or in ways that are not in line with the original intentions of these policy makers.

It has been suggested that top-down or bottom-up models may be equally adequate or useful but in different contexts. The top-down model can be useful in contexts where a strong central authority exists, while bottom-up models may be more appropriate when such authorities are lacking.⁶⁶ This is a *contextual* view of implementation where the suitability of a certain perspective depends on the situation.

However, it has also been suggested that top-down models may overemphasise the role of central actors, while bottom-up models exaggerate the importance of contextual low-level actors.⁶⁶ This is a *synthetic* view of implementation, since aspects from several perspectives are integrated into one model that is suitable for all, or at least most, situations. An example of this would be a cooperative model.

In cooperative models, the importance of *cooperation* between managers and the staff is emphasised. Thus, central actors, such as managers, and contextual actors among the staff, are both considered important actors in implementation processes. Cooperative models have incorporated elements from top-down as well as bottom-up models. Thus, cooperative models represent a synthetic view on implementation.

A cooperative approach can have the advantage of creating solutions that are adequately adapted to the problems of the specific department while at the same time likely to be relatively quick to implement.

Just as the two other models, the cooperative approach requires a staff that *understand*, *want*, and are *able* to implement changes.⁶⁵ However, in

addition to these prerequisites to implementation, the successful applications of the cooperative approach also require that the managers and the staff are able to *cooperate*. Thus, the implementation will have to be discussed and planned in a joint effort by the managers and the staff.

The initiator can be *top-down oriented*, for instance, the department head, senior hospital management, or politicians. The initiator could also be *bottom-up oriented*, for instance, someone in the staff.^{59 62} Patients, associations of patients, and institutional purchasers of care could be considered indirect initiators since they cannot by themselves initiate implementation. Initiation could of course also occur as a result of efforts from two or more initiators, for instance, a *cooperative effort* between a manager and the staff.⁶⁷

In the cooperative implementation perspective, policymakers, managers, and the staff are assumed to interact and cooperate with each other to jointly create and implement policies. However, this does not imply that each member or coalition is equally important or influential in the implementation process. The influence of specific members or coalitions will be determined by the context of a specific implementation situation.^{67 68}

Street-level bureaucrats can be assumed to influence policy because of their expert knowledge but, in contrast to in the street-level bureaucrat model, managers and policymakers can also be assumed to have considerable opportunities to influence the implementation process by using their position in the organisational hierarchy. This has, for instance, been proposed in the power equalisation model⁶⁹

3 Methods

3.1 Exploratory, bridging, and confirmatory phases

This thesis has been methodologically divided into three phases: an exploratory phase, a bridging phase, and a confirmatory phase (see Table 2 below). Each of the phases will be presented in separate chapters in this thesis. Each chapter will describe the methods and results of that phase.

The first phase was the exploratory phase in which the organisation of quality systems of hospital departments in practice was explored qualitatively. It is represented in this thesis by Paper I.

The second phase was the bridging phase – the bridge between the exploratory and the confirmatory phases. In this phase, models to describe and analyse the organisation of quality systems were developed, hypotheses were stated, and instruments for measurement were developed and piloted. This phase has only been briefly discussed in the Methods section of each of the included papers (Paper II–IV). Therefore, a more detailed description has been given in this thesis to more clearly illustrate the connections among the papers.

The third phase was the confirmatory phase. In this phase, the instruments for measurement were assessed and the hypotheses were tested statistically. It is represented in this thesis by Paper II–IV.

3.2 Inductive and deductive approaches to science

There are several ways to gain insights in how the world works and how its inhabitants interact. Two main ideal types are frequently mentioned: the inductive approach and the deductive approach.⁷⁰ Researchers often use a combination of the two approaches during the research process.

With an inductive approach, the researcher begins to empirically observe and notice interesting patterns and then formulates tentative hypotheses and develops a theory. The exploratory phase of this thesis was mainly designed with an inductive approach.

With a deductive approach, the researcher begins to formulate a theory, states specific hypotheses that can be tested, collects data by empirical observation, and ends by hopefully confirming the hypotheses. The confirmatory phase of this thesis was mainly designed with a deductive approach.

Table 2. *The three phases of research in this thesis*

Phase	Design	Sample	Data collection	Analysis
<u>Exploratory phase</u>				
Explore quality systems in practice (Paper I)	Cross-sectional qualitative multicase	Criteria based strategic (non-random)	Semi-structured interviews n=19	Thematic analysis
<u>Bridging phase</u>				
Specification of hypotheses (Paper II–IV)				
Development of a measurement model (Paper II–IV)	Pilot questionnaire	Criteria based strategic	Pilot to informants and peers n=13	Questions adjusted according to feedback
<u>Confirmatory phase</u>				
Questionnaire assessment (Paper II-IV)	Cross-sectional survey	Simple random	Questionnaire* n=600 386 responses	Exploratory and confirmatory factor analysis
Hypothesis-test H1 (Paper II)	Cross-sectional survey	Simple random	Questionnaire* (see above)	Structural equation modelling
Hypotheses-test H2a and H2b (Paper III)	Cross-sectional survey	Simple random	Questionnaire* (see above)	Cluster analysis ANOVA, χ^2 -tests Structural equation modelling
Hypothesis-test H3 (Paper IV)	Cross-sectional survey	Simple random	Questionnaire* (see above)	Structural equation modelling

* The studies use different subsets of the same questionnaire.

The inductive and deductive approaches complement each other well. With the inductive approach, the researcher can explore the world without first deciding on theoretical frameworks – these frameworks will be developed during the research process. Thus, the developed frameworks will be firmly anchored in the empirical reality. However, the researcher may neglect to take into account important aspects that by chance or research design were not present in the collected data. For instance, you will not find whales if you go fishing in small lakes!

The researcher can overcome this limitation with the deductive approach. All available information can be used to try to formulate models and hypotheses: theoretical propositions, results from previous empirical research, as well as logically derived arguments. Thus, the models may include elements and relations that have not yet been observed or proved empirically. However, there is a risk that the models will then include too many aspects

that are empirically irrelevant and thereby unnecessarily conclude that the proposed models are not valid.

Therefore, by combining the two approaches as has been done in this thesis, the researcher can benefit from both the inductive advantage of firmly empirically anchored models as well the deductive advantage of including aspects or relations that have not yet been identified or proven empirically.

Formal ethical approval for the studies included in this thesis was not needed.⁷¹ However, steps were naturally taken to assure compliance with general ethical principles for conducting research. Respondents were informed of the purposes of the studies. Participation was voluntary and no gifts or other rewards were promised to responders. Interviews and responses will be kept confidential.

4 The explorative phase (Paper I)

In this chapter the methods and results of the explorative phase will be described.

4.1 Methods: a qualitative study

To explore how quality systems may be organised in hospital departments, a multicase cross-sectional design was chosen.^{72 73} Data were collected through interviews of 19 strategically sampled informants and analysed with thematic analysis.

The criteria for selection of informants were position (manager with staff responsibility or quality coordinator) and type of hospital department (medical, surgical, laboratory, or diagnostic). If possible, both a manager and a quality coordinator were selected for each quality system to find potential differences in perspectives. In initial telephone contacts, the 19 informants were found to represent a total of seven quality systems.

The interviews were conducted face to face using a semi-structured interview guide with the general opening question: "How do you work with quality at your department?"

A thematic analysis was conducted to identify *organisational aspects* that could be used as a framework to describe each of the seven quality systems.⁷³ The quantitative counterpart to this thematic analysis would be exploratory factor analysis, for instance, to identify questionnaire *items* that are related and group them into variables or *factors*.

The quality systems were then grouped into *types* with the help of similarities and differences in the descriptions of the organisational dimensions. The quantitative counterpart to this method would be cluster analysis, for instance, to identify *cases* that are similar and group them into types or *clusters*.

Thus, two results were expected from the thematic analysis. First, the identification of organisational aspects of quality systems that could be used as a framework to describe and analyse all quality systems. Such *aspects* could be considered organisational *variables* that all quality systems could be described with, but to varying levels, for instance, high level or low level. Second, the characterisation of *types* of quality systems by using the variation within each identified aspect among the seven studied systems.

Table 3. *The six identified aspects, the three types of aspects, and their definitions.*

Aspects	Definitions
STRUCTURE	The organisational prerequisites that are necessary to be able to work with quality improvements.
Resources	The amount of financial resources and time available to staff and managers for working with quality improvements and if they have the right competence to do so.
Administration	The organisational hierarchy and available administrative support for working with quality improvements.
PROCESS	The organisational aspects that affect the ability to work with quality improvements.
Culture	The attitude towards accepting new quality improvements and reporting incidents among staff and managers.
Cooperation	The attitude towards participating in, supporting quality improvement initiatives, and cooperating with other professions.
OUTCOME	The organisational states that are desired as results of a quality system.
Evaluation of goal achievement	The frequency and methods of evaluation of achieved quality goals.
Development of competence	The methods for staff and managers to increase their competence in quality improvement.

4.2 Results: characteristics of quality systems

There were two interesting results that will be described below:

- a framework with aspects to describe quality systems, *and*
- a classification scheme to categorise types of quality systems.

4.2.1 Aspects of quality systems

Six organisational aspects of quality systems were identified in Paper I: resources, administration, culture, cooperation, evaluation of goal achievement, and development of competence (Table 3).

The six organisational dimensions were classified as three types of aspects: structure, process, or outcome aspects of quality systems. This classification was inspired by Donabedian's framework for assessing quality.⁷⁴ However, rather than evaluating quality, the framework was used to evaluate quality systems. Thus, it could be said to be a meta-level application of Donabedian's framework.

Table 4. *The three identified types of quality systems.*

Aspects	Local quality systems	Centralised quality systems	Integrated quality systems
STRUCTURE			
Resources	lack of resources: time and staff	lack of resources: time and staff	available and integrated
Administration	individual initiative	structured, bureaucratic	structured and integrated
PROCESS			
Culture	negative	mostly positive	very positive
Cooperation	low	medium, hierarchical barriers	high, all professions
OUTCOME			
Goal achievement	lack of evaluation	occasional evaluation	periodical evaluation
Development of competence	limited	voluntary	compulsory

4.2.2 Types of quality systems

The seven quality systems were classified into three types of quality systems by using the variation within the six organisational aspects (Table 4). They were called local, centralised, or integrated quality systems in Paper I. These names were derived from differences in the description of the administration aspect.

An interesting result was that the aspects seemed to be related to each other. For instance, lack of resources for quality improvement efforts, negative attitude towards quality improvements, low cooperation between professions, and lack of evaluation, all seemed to be related.

Moreover, if resources and administrative support were available, then the attitude towards quality improvements was positive instead, cooperation was high, and there were periodical evaluations of goal achievements.

5 The bridging phase

In the bridging phase, aspects of *organisation* and *implementation* were defined and models and hypothesis were developed from the results of Paper I. An instrument of measurement was developed to measure the defined aspects and a pilot questionnaire was administered to previously interviewed subjects as well as to fellow researchers.

5.1 Specifying hypotheses

The aspects were defined using the results from Paper I and from organisational research.^{75 76} The aspects were the *organisational aspects* structure, process, and outcome, and their sub-aspects resources, administration, culture, cooperation, evaluation of goal achievement, and development of competence, and the *implementation aspects* implementation prerequisites, cooperative implementation, and sources of initiative.

Relationships between aspects were specified in form of *hypotheses* that were possible to test statistically.

Moreover, other concepts were defined to enable the hypotheses to be tested. For instance, the three types of quality systems were described and it was decided which quality improvement designs to include.

Quality improvement designs were included that fulfilled three criteria. The included designs should be theoretically as well as empirically founded. Thus, designs were included that were mentioned in the *regulations* from the National Board of Health and Welfare,⁹ as well as present in the quality systems that were studied in *Paper I*.

5.1.1 Hypothesis 1 (Paper II, organisational aspects)

The three main aspects structure, process, and outcome were developed in Paper I as a framework to describe and analyse quality systems (Table 5, below).

Structure aspects represented the organisational prerequisites that were necessary to be able to work with quality improvements, for instance, adequate resources, an organisational hierarchy, and supporting functions. Structure aspects are necessary, but not sufficient, aspects.

Table 5. *The model development definitions of the organisational aspects.*

Aspects	Definitions
STRUCTURE	The organisational prerequisites that are necessary to be able to work with quality improvements.
Resources	The amount of financial resources and time available to staff and managers for working with quality improvements and if they have the right competence to do so.
Administration	The organisational hierarchy and available administrative support for working with quality improvements.
PROCESS	The organisational aspects that affect the ability to work with quality improvements.
Culture	The attitude towards accepting new quality improvements and reporting incidents among staff and managers.
Cooperation	The attitude towards participating in, supporting quality improvement initiatives, and cooperating with other professions.
OUTCOME	The organisational states that are desired as results of a quality system.
Evaluation of goal achievement	The frequency and methods of evaluation of achieved quality goals.
Development of competence	The methods for staff and managers to increase their competence in quality improvement.

Two structural aspects were defined in this thesis. First, *resources* was defined as the amount of financial resources and time available to staff and managers for working with quality improvements and if they have the right competence. Second, *administration* was defined as the organisational hierarchy and other available administrative support for working with quality improvements.

Process aspects represented the aspects that affect the ability to work with quality improvements. They complemented the structure aspects by making it easier, more effective, or more efficient to work with quality. For instance, a positive attitude towards working with quality and towards working in teams with different professions may make it easier to achieve good results from quality improvement efforts.

Two cultural aspects were defined and used in this thesis. First, *culture* has been defined as the attitudes towards accepting new quality improvements and reporting incidents among staff and managers. Thus, it is an indicator of what is acceptable to *think* in a department. Second, *cooperation* has been defined as the attitudes towards participating in, supporting improvement initiatives, and cooperating with other professions. Thus, it is an indicator of the degree to which something is considered valid to *do* in a department.

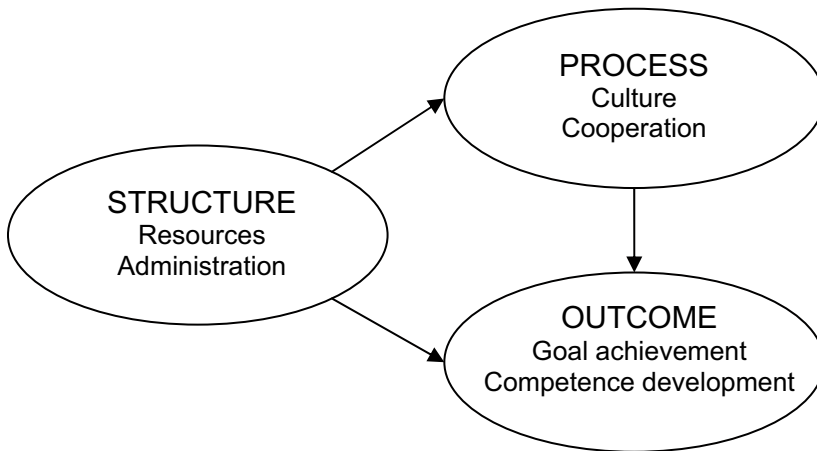


Figure 1. The first hypothesis

Outcome aspects are aspects that describe the organisational states that are desired as results of a quality system. An important reason for the existence of quality systems is that they should lead to individual and organisational learning to improve processes and, in the end, improve the health status of patients. For instance, evaluation of goal achievement and development of competence could be used as indicators of organisational learning.

Two learning aspects were defined. First, *evaluation of goal achievement* was defined as the methods of evaluation of achieved quality goals. Thus, it is an indicator of organisational *feedback*. Second, *development of competence* was defined as the methods for staff and managers to increase their competence in quality improvement. Thus, it is an indicator of the *competence* to reflect upon feedback.

The results in Paper I indicated that the structure, process, and outcome of quality systems were positively related. For instance, quality systems with adequate resources and administrative support had staff and managers that were more positive towards quality and that cooperated to a higher degree than systems with inadequate resources.

Moreover, quality systems with managers and employees with positive attitudes were more often evaluated and had more opportunities for competence development than systems with negative attitudes to quality improvements.

Therefore, it was hypothesised that the structure, process, and outcome of quality systems are positively correlated. Similar relationships among the structure, process, and outcome of the quality of care have been suggested by Donabedian, and this thesis was inspired by his framework.⁷⁷

Thus, the first hypothesis was specified as follows (Figure 1):

Hypothesis 1: The structure of quality systems has a positive effect on the process and the outcome of quality systems. Given the influence of structure, the process of quality systems has a remaining positive effect on the outcome of quality systems.

5.1.2 Hypothesis 2a (Paper III, types of quality systems)

Three types of quality systems were categorised and described in Paper I by using the aspects, resources, administration, culture, cooperation, evaluation of goal achievement, and development of competence.

For instance, for the evaluation of goal achievement, three levels were identified: lack of evaluation, occasional evaluation, and periodical evaluation.

Three levels that were reasonably well separated from each other could be described for most aspects.

Of course, each of the seven studied systems was unique in some way. Thus, it would have been possible to identify as many levels as there were systems. However, the differences between the levels would then have been much smaller and maybe not relevant in practice.

The three-level nomenclature was used to categorise the systems into three types of systems, or in other words, three degrees of organisation. The aspects of quality systems of the first degree of organisation were mostly at lower levels. For instance, local systems had few evaluations of goal achievement and few opportunities for competence development. Similarly, aspects of quality systems of the second degree (centralised) were mostly at intermediate levels. Finally, aspects of quality systems of the third degree (integrated) were mostly at higher levels.

Limiting the number of organisational degrees to three would make it easier for non-researchers to distinguish among the degrees. This will hopefully make the nomenclature more useful in clinical practice. The hypothesis was specified as follows:

Hypothesis 2a: Quality systems can be of at least three organisational degrees, type A, type B, and type C. Type A is characterised by having aspects at high levels. Type B is characterised by having aspects at intermediate levels. Type C is characterised by having aspects at low levels.

Table 6. *The quality improvement designs.*

Number	Design descriptions
Design 1	Reporting and follow-up of incidents and undesirable events
Design 2	Availability improvements for patients
Design 3	Patient satisfaction surveys
Design 4	Quality registers for certain diagnosis
Design 5	Random check-ups for selected processes
Design 6	Coordination of the quality improvement work with other departments
Design 7	Quality accreditation

5.1.3 Hypothesis 2b (Paper III, organisational designs)

The *quality improvement designs* were defined to describe what specific methods a department uses. For instance, one department may only report incidents while another department may be certified according to ISO9002. Thus, the departments could be said to use quality systems of different designs (Table 6).

In the interview study (Paper I), different designs were found to be used in different types of quality systems, except for incident reporting which was used in all systems. Availability improvements and patient satisfaction surveys were used in local systems. Quality registers, random check-ups, and coordination were used in centralised systems. Accreditation was used in integrated systems. This indicated the existence of relationships among organisational degrees and quality improvement designs.

Thus, the hypothesis was specified as follows:

Hypothesis 2b: Quality systems with a high organisational degree (type A) will use more sophisticated designs than quality systems with intermediate or low organisational degrees (type B or C). Quality systems with an intermediate organisational degree (type B) will use more sophisticated designs than quality systems with low organisational degree (type C).

5.1.4 Hypothesis 3 (Paper IV, implementation strategies)

The aspects of implementation were chosen based on implementation research.

The *sources of initiative* that were thought to be most important at the *department level* were hypothesised to be the managers (a top-down oriented initiator), the staff (a bottom-up oriented initiator), and the external institutional purchasers of care (an indirect initiator) (Table 7).

The *implementation prerequisites* aspect was defined as the degree to which the implementation got adequate resources and positive and competent staff. Thus, adequate resources will have to be assigned for the implementation so that managers and staff are *able* to implement the new system.

Table 7. *The model development definitions of the implementation aspects.*

Aspects	Definitions
Source of initiative	From whom the initiative for implementation came: the staff, the manager, or the institutional purchasers of care
Cooperative implementation	The degree to which the design and planning of the implementation were done in cooperation with the staff.
Implementation prerequisites	The degree to which the implementation got adequate resources and positive and competent staff.

The staff will need to be positive to implementation, expect that the quality system will provide value, and be *willing* to solve problems that may arise during the process. Finally, the staff will have to possess the right skills, training, and competence so that they *know* how to effectively implement quality systems.

The *cooperative implementation* aspect was defined as the degree to which the design and planning of the implementation were done in cooperation with the staff.

It was proposed that to implement more sophisticated quality systems, that is, quality systems at higher levels of structure, process, and outcome, would require implementation prerequisites at higher levels, as well as cooperative implementation at higher level, than less sophisticated systems. The sources of initiative were also proposed to affect the levels of structure, process, and outcome of going quality systems.

The hypothesis was specified as follows:

Hypothesis 3: The levels of structure, process, and outcome of going quality systems are positively related to the levels of implementation prerequisites and cooperative implementation, and also related to the source of initiative.

5.2 Methods: developing an instrument

A questionnaire consisting of three parts were developed. The first part included questions about professional affiliation and organisational position of the responder, and about which designs were used by the department. This part was unproblematic from a measurement perspective. All variables were categorical or dichotomous (yes/no) and they were also clearly defined. For instance, either you are a physician or you are not, either your department perform random check-ups or it does not.

The aspects of organisation and implementation were latent variables, that is, variables that cannot be observed directly. Thus, questions were developed to reflect these latent variables.^{75 76} It has been proposed that three to five reflective variables are adequate to represent a latent variable.⁷⁵ Three to

four questions were developed to reflect each latent variable except one, where two questions were considered adequate.

The second part included nineteen questions reflecting the identified *organisational aspects* (latent variables). This part was developed mainly from the results from Paper I.

The third part included ten questions reflecting *implementation aspects* (latent variables). This part was developed through studies of organisational and implementation research.

The pilot questionnaire was tested in a cross-sectional pilot study. All three parts of the pilot questionnaire were peer reviewed by researchers, senior researchers, physicians, and a statistician.

In addition, the second part of the pilot questionnaire was administered to seven of the previously interviewed informants. These seven were strategically chosen to include informants working in all three types of systems that were identified in Paper I.

5.2.1 Results from the pilot questionnaire

The results from the pilot questionnaire showed that informants from the different types of quality systems responded on the aspects as proposed in the results from Paper I. Type A systems had higher total aspect levels than type B systems and type C systems, and type B systems had higher total aspect levels than type C systems.

In conclusion, the results from the pilot questionnaire indicated that the three types of systems that were found in Paper I could also be identified in the questionnaire, and that the questions seemed to be able to capture differences in aspect levels among different quality systems. See Appendix A for the English version of the final questionnaire.

6 The confirmatory phase (Paper II–IV)

In this chapter, the methods and results from the confirmatory phase will be described.

6.1 Methods: assess questionnaire and models

In this section, the methods used to assess the questionnaire and to test the hypotheses will be described.

6.1.1 Assessing the final questionnaire

A simple random sample of 600 out of 1757 hospital departments in Sweden was provided.⁷⁸ The final questionnaires were addressed to the head of the respective department, with an option to delegate the task to a quality coordinator to increase the response rate if possible. These two groups were chosen since they were thought to possess a more detailed knowledge of quality systems.

Two reminders and a non-responder questionnaire were sent when necessary. The questionnaires were coded, entered into a dataset file, and checked.

The questionnaire was analysed with factor analysis with the LISREL software suite. Factor analysis is a way to analyse which variables are mathematically related, that is, which variables have values that vary in the same way. It is a way to analyse if the questions are valid and reliable reflections of their intended aspects.^{76 79}

First, three exploratory factor analyses were conducted (PRELIS 2.72). Variables that did not load significantly (loading < 0.300) onto their intended factor were considered inadequate reflections of their factor and were therefore removed.^{75 76}

Second, confirmatory factor analysis were conducted with the remaining variables (LISREL 8.72). In confirmatory factor analysis, the researcher specifies which questions should be related to which factors and statistically tests if the questionnaire seems to measure what it was intended to do. This process is called testing the measurement model.

Three measurement models were tested separately in the factor analyses mentioned above: the first organisational aspect model (structure, process, and outcome), the second organisational aspect model (resources, admini-

stration, culture, cooperation, goal achievement, and development of competence), and the implementation aspect model (cooperative implementation and implementation prerequisites).

A good model fit is indicated by a non-significant p-value ($p > 0.05$), by a low root mean square error of approximation ($RMSEA < 0.08$), and by a high comparative fit index (CFI close to 1.00). The estimated parameters were evaluated with t-tests to test if the variables adequately reflected their intended factor (convergent construct validity). Factor correlations were evaluated by calculating 95% confidence intervals to assess if the factors were separated from each other (discriminant construct validity).

Cronbach's alpha scores were computed and used as a complementary indicator of reliability (SPSS 14). Cronbach's alpha values above 0.70 have been regarded as evidence of reliable questions.⁷⁵

Factor scores were computed in PRELIS for the aspects that were found to be adequately reflected by variables. To compute factor scores is a way to aggregate many variables into fewer variables, such as to aggregate indicator variables into latent variables.

Intra-class correlations were computed to analyse potential cluster effects since some of the departments were located in the same hospitals. Intra-class correlations below 0.25 are considered low, indicating unimportant multi-level effects.

6.1.2 Assessing the models

When the questionnaire's measurement models have been analysed and found to be a valid and reliable representation of the dataset, the analysis of relationships between the latent variables, or factors, can begin.

Two conceptually different ways to test hypotheses were used in this thesis: the rejection method and the confirmation method.^{75 76}

The rejection method was used to test hypotheses of relationships between two aspects or to compare single aspects among different groups. For instance, it was used to test if the relationship between two organisational aspects were statistically significant. For instance, such hypotheses were stated as follows:

Null hypothesis: The correlation coefficient between aspect A and aspect B is zero ($\rho = 0$, a relationship *does not exist*)

Alternative hypothesis: The correlation coefficient between aspect A and aspect B is *not zero* ($\rho \neq 0$, a relationship *does exist*)

The alternative hypothesis is the one that is expected to be true. If the statistical test shows that the correlation coefficient is not zero, a significant

relationship between the two aspects is empirically supported, and the *null hypothesis is rejected* in favour of the alternative hypothesis.

The concept of "significant relationship" is often expressed as a p-value. A *p-value of 0.05 or less* is often accepted as evidence enough to reasonably reject a null hypothesis. A low p-value indicates that the tested relationships probably do exist and that the results are probably not due to chance.

The rejection method was also used to test for differences in aspect levels among different types of quality systems. Such hypotheses were specified as follows:

Null hypothesis: The difference between group 1 and group 2 for aspect A is zero ($D=0$, there are no difference among groups)

Alternative hypothesis: The difference between group 1 and group 2 for aspect A is *not zero* ($D\neq 0$, there are no difference among groups)

In this thesis, tests for differences between groups were conducted by using the chi-square test of independence to test for differences in frequencies among three groups, analysis of variance (ANOVA) to test for differences in aspects among three groups, and post hoc test after ANOVA to test for differences in aspects between two groups. All of these tests were conducted in Paper III.

Relationships between aspects were tested with structural equation modelling in Paper II and IV.

It is only practical to use the rejection method when there are few variables, few relationships, or few groups to be compared or tested. Moreover, the rejection method does not allow all relationships to be tested at the same time and cannot simultaneously test whole models.

The confirmation method was used to test whole models, that is, to test with one single statistical test if a model with several specified relationships was a reasonable representation of empirical data. Confirmation method tests provide somewhat weaker evidence than rejection method tests but they are the only practically available methods for testing whole models.

Even if a model is confirmed to be valid, it does not rule out the possibility that there exist other models that would also fit the empirical dataset equally well or better than the tested model. This is why the method can be considered somewhat weaker. However, with good theoretical as well as empirical evidence for the specified hypothesis this risk can be minimised.

Hypotheses are formulated differently when using the confirmation method:

Null hypothesis: There are *no significant differences* between the model and the empirical dataset. (The proposed model is *good*)

Alternative hypothesis: There *are significant differences* between the model and the empirical dataset. (The proposed model is *bad*)

With the confirmation method, the null hypothesis is the one that is expected to be true. Thus, hopefully the statistical test will result in a p-value that is *0.05 or higher*, indicating *no significant differences* between the relationship coefficients predicted by the model and the coefficients that are calculated using the empirical dataset. Structural equation modelling is the only confirmation method test that has been used in this thesis (Paper II and IV).^{75 76}

When using confirmation method tests, individual relationships between aspects were also tested by rejection method tests, such as t-tests. That way, individual relations as well as complete models were examined. This increases the strength of the confirmation method hypothesis tests.^{75 76} Hypotheses 1, 2b, and 3 were tested with these types of tests.

Structural equation modelling is similar to multiple linear regression but can include several dependent variables rather than just one single variable. The method also permits the researcher to freely specify or omit relationships between aspects.

A good model fit is indicated by a non-significant p-value ($p > 0.05$), by a low root mean square error of approximation (RMSEA < 0.08), and by a high comparative fit index (CFI close to 1.00). The estimated relationship parameters were evaluated with t-tests to test if they significantly differed from zero, indicating that they in fact existed.

The structural equation models were analysed in LISREL 8.72 with the robust maximum likelihood method which does not require data normality.

Since the questionnaire was found to be valid and reliable in the developmental phase, the same sample of 600 hospital departments was also used to test the hypotheses.

6.2 Results: hypotheses were confirmed

In this section, the results from the confirmative phase will be presented:

- the assessment results of the questionnaire,
- the tests of Hypothesis 1: the relationships between structure, process, and outcome (Paper II),
- the tests of Hypothesis 2a: the relationships between types of quality systems and organisational aspects (Paper III)
- the tests of Hypothesis 2b: the relationships between quality improvement designs and organisational degrees (Paper III), *and*
- the tests of Hypothesis 3: the relationships between implementation aspects and organisational aspects (Paper IV).

6.2.1 A valid and reliable questionnaire (Paper II-IV)

Out of the 600 departments, 82 should not have been included in the sample since they were either closed down or associated with larger departments. Thus, responses were expected only from a maximum of 518 departments.

In total, 386 valid responses were obtained. The adjusted response rate, 386 out of 518, was 75%.

Out of the non-responding 132 departments, 63 stated a reason for not responding to the main questionnaire. The most common stated reason was lack of time. However, there were no significant differences between responding and non-responding departments in size of hospital ($p=0.07$) or speciality of department ($p=0.19$).

Partially missing data accounted for less than 1% of total data and were mostly limited to a single missing value per incomplete case. Multiple imputations were performed as recommended to compensate for partially missing data. It has been shown that multiple imputations introduce least estimation bias compared to just deleting whole cases.⁷⁵

First, the organisational variables were examined. Almost all variables (14 out of 18) had factor loadings above 0.300 on their intended factor. However, two process variables (B2 and B3) related to organisational culture did not load significantly at any factor and two outcome variables (C5 and C6) related to the development of competence did not load significantly onto their intended factor. They were therefore removed from the following analyses. Factor scores were calculated for structure, process, and outcome.

Second, the more detailed model with six factors was examined. The first five aspects were adequately reflected, but not the last aspect: development of competence. Moreover, the resource-competence variable A3 cross loaded onto the administration factor and the administrative help variable A6 cross loaded onto resources. Thus, factor scores were computed for the five organisational factors resources, administration, culture, cooperation and goal achievement.

Third, the six implementation variables were examined and found to be good reflections of their two factors. Factor scores were computed for cooperative implementation and prerequisites for implementation.

Questionnaire reliability was excellent for all aspects (Cronbach's alpha scores of 0.78–0.86). Intra-class correlations were low (correlations <0.10), indicating that multi-level models would not be needed to adequately represent the data.

6.2.2 Structure, process, and outcome (Paper II)

The test of hypothesis 1 confirmed the proposed relationships between structure, process, and outcome of quality systems (Figure 2):

Hypothesis 1: The structure of quality systems has a positive effect on the process and the outcome of quality systems. Given the influence of structure, the process of quality systems has a remaining positive effect on the outcome of quality systems.

Structure aspects, such as available time and staff with quality improvement competence, seemed to be strongly related to other aspects of quality systems, as did the presence of documented and highly available administrative support.

First, structure was related to process characteristics, for instance, supportive colleagues that participated actively in suggested quality improvements.

Second, structure was also related to outcome characteristics, such as clear and unambiguous quality goals, periodical evaluations, documentation of the results of the evaluations, and feedback to the staff.

Third, process was also related to outcome independent of structure. This means that while structure aspects, such as resources and administration, were important, work to improve process aspects could further improve outcome aspects. For instance, creating a positive organisational climate for working with quality could make it easier to evaluate the goal achievements.

The model implies that, for instance, adequate time to work with quality improvements (structure) would increase the chance of supportive colleagues (process), and the chance that improvements are evaluated (outcome).

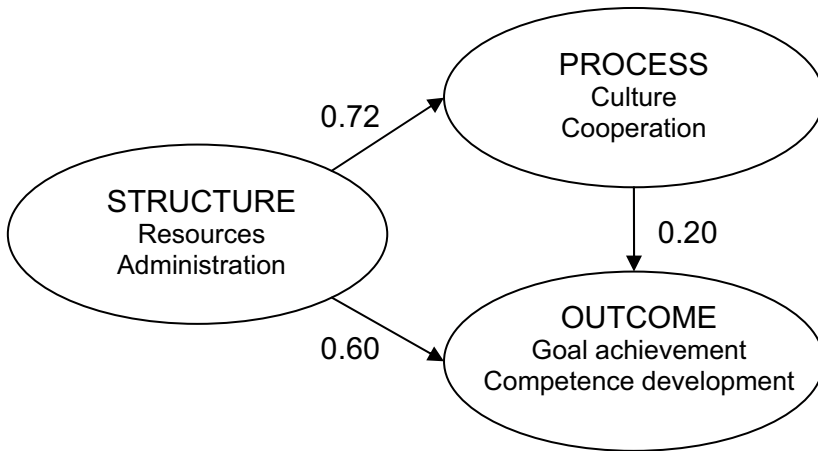


Figure 2. The result of the test of hypothesis 1.

6.2.3 Types of quality systems (Paper III)

The tests of hypothesis 2a confirmed that quality systems can be categorised into three organisational degrees, each with aspects at different levels (Table 8).

Hypothesis 2a: Quality systems can be of at least three organisational degrees, type A, type B, and type C. Type A is characterised by having aspects at high levels. Type B is characterised by having aspects at intermediate levels. Type C is characterised by having aspects at low levels.

Quality systems of type A had aspects at higher levels than type B or C, and type B had higher aspect levels than type C, just as proposed by the hypothesis.

Due to the design of the questionnaire that was used in the Paper III, it was not possible to identify the same differences in the administration aspect as was done in Paper I. Qualitative studies usually have deeper and more detailed descriptions of discovered aspects than it is possible to capture with a questionnaire. Thus, the reader should be aware that cluster A systems cannot automatically be considered integrated quality systems, cluster B systems centralised, or cluster C systems local.

Table 8. *The result of the test of hypothesis 2a.*

Variable	Difference between clusters		
	cluster	factor score	95% Confidence Interval
Resources	A - B	**0.949	(0.729; 1.168)
	A - C	**1.264	(0.957; 1.570)
	B - C	*0.315	(0.022; 0.609)
Administration	A - B	**1.151	(0.954; 1.348)
	A - C	**1.744	(1.513; 1.975)
	B - C	**0.593	(0.370; 0.817)
Culture	A - B	**0.604	(0.364; 0.844)
	A - C	**1.192	(0.889; 1.496)
	B - C	**0.589	(0.288; 0.889)
Cooperation	A - B	**0.800	(0.607; 0.993)
	A - C	**1.900	(1.678; 2.122)
	B - C	**1.100	(0.899; 1.300)
Goal achievement	A - B	**0.862	(0.662; 1.061)
	A - C	**1.891	(1.677; 2.106)
	B - C	**1.029	(0.826; 1.233)

**p<0.01, *p<0.05. Effect is large for resources and culture ($\eta^2>0.21$), and very large for the other variables ($\eta^2>0.50$). A factor score difference of 0.7-0.9 corresponds to a difference of 1 unit in the questionnaire (approximately).

6.2.4 Designs of quality systems (Paper III)

The test of hypothesis 2b confirmed that quality systems of type A used more sophisticated designs than type B or type C systems, and type B systems used more sophisticated designs than type C.

Table 9. *Percentage of responding departments that use a specific design, the same percentages for clusters A-C, and the χ^2 test of independence for differences in percentages among clusters (in order of increasing differences)*

Design	Cluster				χ^2
	A (%) n=152	B (%) n=152	C (%) n=82	Total (%) n=386	
Incident reporting	98	98	99	99	(n.s.) 0.2
Other	28	24	21	25	(n.s.) 1.5
Availability improvement	69	81	72	74	*6.4
Quality registers	55	69	61	62	*6.8
Patient satisfaction surveys	71	83	67	75	*9.0
Coordination between depts	61	43	32	48	***20
Random sampling/check ups	47	23	15	31	***33
Accreditation or similar	31	6	5	16	***45

(n.s.)=non significant, *p<0.05, ***p<0.001. The χ^2 tests have 2 degrees of freedom

Table 10. *The structural equation coefficients from the test of hypothesis 2b.*

Designs	Resources	Admin	Culture	Coop	Goal ach	R ²
Availability improvement	+0.03	*-0.20	+0.01	**+0.12	-0.03	0.03
Quality registers	+0.01	*-0.28	-0.04	+0.04	**+0.18	0.06
Patient satisfaction surveys	-0.04	*-0.18	-0.07	**+0.11	+0.09	0.03
Coordination between depts	+0.04	**+0.16	**+0.10	**+0.14	+0.04	0.13
Random sampling check ups	**+0.16	**+0.15	-0.05	+0.09	**+0.23	0.21
Accreditation or similar	**+0.13	**+0.48	*-0.11	-0.03	**+0.25	0.42

*p<0.05 (|t-value|>1.96).

Admin=administration, Coop=cooperation, Goal ach=goal achievement.

Hypothesis 2b: Quality systems with a high organisational degree (type A) will use more sophisticated designs than quality systems with intermediate or low organisational degrees (type B or C). Quality systems with an intermediate organisational degree (type B) will use more sophisticated designs than quality systems with low organisational degree (type C).

Most quality systems included incident reporting (Table 9). This design is compulsory according to Swedish regulations, which might explain this outcome.

Quality systems with a high degree of organisation included designs such as coordination between departments, random sampling of selected processes, and accreditation more often than systems with other degrees of organisation (Table 10). These designs were also relatively more common in systems with higher administrative support than in systems with lower administrative support.

Accreditation designs were relatively more common in quality systems that had dedicated time for working with quality, adequate administrative support, and routines for systematic evaluation of quality related processes. Surprisingly, the attitude towards quality work seemed lower in these departments, indicated by a negative coefficient for culture.

Quality systems with an intermediate degree of organisation included designs such as availability improvements, quality registers and patient satisfaction surveys more often than systems with other degrees of organisation. Interestingly, these designs were relatively more common in systems with lower administrative support.

6.2.5 Implementation of quality systems (Paper IV)

The test of hypothesis 3 confirmed that there was a relationship between implementation aspects and organisational aspects (Figure 3).

Hypothesis 3: The levels of structure, process, and outcome of going quality systems are positively related to the levels of implementation prerequisites and cooperative implementation, and also related to the source of initiative.

First, the results showed that quality systems with high scores on structure and process also had high scores on implementation prerequisites. Thus, systems that were implemented with adequate resources for implementation, problem-solving capacity, adequate competence, and high expectations, developed into quality systems with adequate resources and administrative support for working with quality, positive attitude towards the system and high cooperation between professions.

Second, the results showed that implementations with a high level of cooperation between managers and staff had high scores on process and outcome. This may indicate that cooperation between managers and staff in the implementation process may improve the attitude towards the quality system and increase the chance that goal achievement is systematically evaluated.

Surprisingly, implementation prerequisites were not found to be related to the outcome of quality systems. Thus, the ability to implement systematically evaluated quality systems that offer good learning opportunities for the staff does not depend on implementation resources but rather on cooperative implementation. Cooperative implementation, on the other hand, was not related to the structure of active quality systems.

Third, the results showed that implementations initiated by managers were reported to result in quality systems with high scores on structure and outcome. High manager initiative might therefore lead to quality systems that are adequately funded and systematically evaluated.

However, process was not related to manager initiative. Thus, the results indicated that it did not matter for the attitude towards the quality system or for the cooperation in the running quality system whether it was the manager that initiated the implementation or not, as long as the implementation had been done in cooperation with the staff.

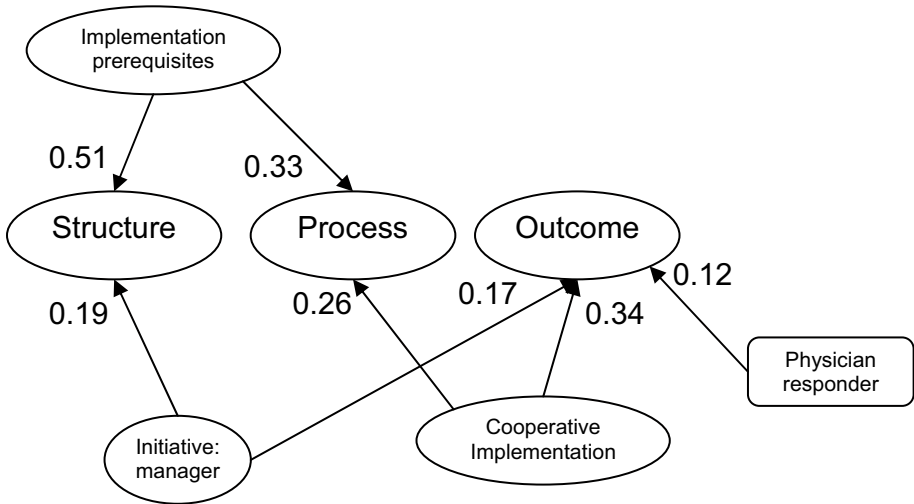


Figure 3. The result from the test of hypothesis 3.

7 Discussion

This thesis has resulted in three new models to describe and analyse quality systems at hospital departments:

- *Organisational aspects* – a general model to describe and analyse the organisation of quality systems with the three aspects structure (resources and administration), process (culture and cooperation), and outcome (evaluation of goal achievement and development of competence). This model describes the aspects that can be used to describe all quality systems.
- *Organisational types and designs* – a model that describes three types of quality systems by using differences in aspect levels among structure, process, and outcome, and that links these three types of systems to the use of specific quality improvement designs. Quality systems with high aspect levels did use more sophisticated quality improvement designs.
- *Implementation of quality systems* – a model that describes the relationship between the implementation of quality systems (implementation prerequisites and cooperative implementation) and the organisation of these systems (structure, process, and outcome). Operating quality systems with high aspect levels were also implemented with high aspect levels on certain implementation aspects.

It is also an example of how to use advanced quantitative methods to explore organisations and implementations:

- *Large scale model testing* – the use of a quantitative approach with structural equation modelling of a large sample of hospital departments to test organisational models and implementation models.

7.1 To *improve* quality improvement

Quality systems at hospital departments could be described, analysed, and evaluated with a framework of six aspects: resources, administration, culture, cooperation, evaluation of goal achievement, and development of competence. Thus, the same aspects could be used to describe and analyse the organisation of quality improvements across departments of different medical specialities or in hospitals of different sizes.

One of the reasons for having quality systems is to make the process of quality improvement better and thereby hopefully improve quality of care. Therefore it is necessary to evaluate results to analyse if goals have been achieved. Furthermore, it is important to communicate the results of the evaluations throughout the organisation so that staff and managers know what to improve.

In the organisational learning model, adequate feedback of the results from actions has been proposed as an important way to enable learning.⁵²⁻⁵⁴ The two outcome aspects evaluation of goal achievements and development of competence could be seen as indicators of feedback to enable organisational learning.

Moreover, the organisational learning model suggests that organisational structure as well as organisational culture support learning.⁵⁶

Indeed, the results of this thesis showed that departments with structure and process aspects at high levels also had outcome aspects at high levels. For instance, departments that evaluated quality to a high degree and communicated the results to the staff had:

- assigned adequate resources for quality improvements,
- employees with adequate qualifications, responsibilities, and training,
- an organisational culture in which working with quality improvements was seen as positive, and
- a high level of cooperation among professions

The aspect evaluation of goal achievement should probably be seen as the base aspect to further single-loop learning, that is, to make small continuous improvements of existing quality improvements processes. It might also be important to consider the aspect development of competence to facilitate double-loop learning, that is, to develop new ways to work with quality improvements.^{52 55 56}

In organisational learning, *feedback* on performed actions as well as *competence* to reflect upon feedback are considered important for learning.⁵¹⁻⁵⁷

Thus, to make good quality improvement better, the results of this thesis indicated that departments will need to develop all organisational aspects. Structure will need to be developed to provide opportunities for reflection and action. Process will need to be developed to facilitate interaction and sharing. Outcome will need to be developed to provide a basis for increasing and maintaining knowledge. Moreover, these results support the propositions of the organisational learning model.

7.2 To choose *appropriate* improvement designs

Three organisational aspect levels were identified, high, intermediate, and low aspect level, and the corresponding types of quality systems, type A–C.

Many departments used similar designs or cluster of designs, such as reporting and follow-up of incidents and undesirable events, availability improvements for patients, patient satisfaction surveys, quality registers for certain diagnosis, random check-ups for selected processes, coordination of the quality improvement work with other departments, and quality accreditation. However, not every department used every design or the same pattern of designs. Thus, there were similarities among departments as well as differences.

For instance, quality systems with an intermediate degree of organisation included designs such as availability improvements, quality registers and patient satisfaction surveys more often than systems with other degrees of organisation.

Interestingly, designs such as availability improvements, quality registers and patient satisfaction surveys were relatively more common in systems with lower administrative support. Some of these designs might have been more applicable to certain specialities. For instance, surgical departments may have more use for quality registers than other departments.

Hospital departments are staffed with employees that have been educated and trained in similar ways. For instance, the education to become a physician includes similar theoretical elements across different universities, as does the clinical training that is compulsory to get certification. This could explain why some designs were relatively common among departments.

Moreover, there are regulations on what to include in quality systems, for instance, the regulations from the National Board of Health and Welfare. Managers and staff may feel obligated to fulfil these requirements because they approve of the regulations or because they want to avoid criticism.

Managers, quality coordinators, and staff may also cooperate among hospitals or departments and thereby learn new ideas, designs, and ways to work with quality improvements from each other.

On one hand, departments can quite easily imitate the designs that they feel are relevant to their department. On the other hand, departments might also want to be perceived as somewhat unique and therefore try to differentiate themselves from other departments.^{80 81} Such ambitions could act as a barrier against sharing successful quality improvement designs.

However, modern hospital departments are embedded in a context where they are dependent on the needs, wants, and wishes of many different stakeholders, internal or external to the departments. Furthermore, the departments have limited resources to work with quality improvement. Thus, their opportunities to create or invent entirely new ways to work with quality improvements may be limited.

Instead of creating entirely new ways to work with quality improvements, it may make more sense for departments to copy successful ideas and designs from other departments and modify these according to their own specific conditions. This modification process has been called editing.⁸²

7.3 To make improvements *needed* and *implemented*

Structure aspects of quality systems were found to be very important to the process and outcome aspects of quality systems. Such structure aspects were available resources and administrative support, and they were significant to enable managers and staff to work with quality improvements

However, given the effects of the structural aspects on the outcome aspects, there were still remaining effects from the process aspects. Thus, it may be beneficial to stimulate culture and cooperation to make it desirable to work with quality improvement. It should be a good career move to work with quality improvements.

In the corporate culture tradition, culture can be used to describe what is considered valid to *think* or *do* in an organisation.^{46 48 49} Learning organisations are characterised by members that continuously improve their abilities, a high *tolerance* for new ways of thinking, and *cooperation* among members.⁵⁷ Thus, the culture and cooperation aspects are important since they can make it easier to work with quality improvement.^{46 48 49}

Managers face difficult challenges when trying to create a tolerant and cooperative environment. Authority barriers between professions can make it difficult to share information or to report opportunities for improvement. Externally or internally set career advancement criteria can make it more worthwhile for managers or staff to excel in other areas than just quality improvements.

However, to make quality improvement needed, managers must try to conquer these barriers. For instance, managers and staff could cooperate to modify or remove routines that lead to unnecessary separation of work among different professions. They could try to anonymise sharing of sensitive information and officially acknowledge good ideas. Furthermore, they could try to introduce financial incentives that promote working with quality improvements.

The results also showed several interesting things regarding the implementation of quality systems. Organisationally sophisticated quality systems were to a higher degree initiated by managers. These systems were also to a higher degree implemented in a cooperative fashion and with an adequate amount of resources for implementation than less sophisticated systems.

The implementation of more organisationally sophisticated quality systems is probably a very challenging venture to undertake and therefore also put special demands on implementation.

First, adequate resources must be assigned for the implementation so that managers and staff are *able* to implement the new system. Second, the staff need to be positive to implementation, expect that the quality system will provide value, and be *willing* to solve problems that may arise during the process. Third, the staff will have to possess the right skills, training, and competence so that they *know* how to effectively implement quality systems. The results are supported by research that proposes that implementation prerequisites are important to achieve successful implementations.⁶⁵

For instance, to implement an ISO-9002 certified system, all processes and routines at the department will first need to be documented, assessed to determine compliance with standards, possibly reworked, and continuously kept up-to-date and available to accreditation inspectors. Moreover, the staff may need training to learn new procedures or perhaps be persuaded that changes are necessary. This has to be done while at the same time running business as usual – patients still need care during the implementation period.

Sophisticated quality systems also required implementation prerequisites at higher levels than less organisationally sophisticated systems. Thus, when implementation complexity increases, such as when implementing quality systems with structure, process, and outcome at higher levels, it becomes increasingly more important that the staff understands what to do, that they want to do it, and have the right knowledge to do it.

Change requires learning, and learning, especially double-loop learning, requires that managers and staff have the knowledge to come up with new creative ways to solve problems. The results that complex implementations require implementation prerequisites at high level are therefore consistent with the organisational learning perspective.^{52 55 56}

Moreover, cooperative style implementation was more common when implementing more sophisticated quality systems. This was indicated by the combination of managers that to a higher degree initiated the implementation and staff that were allowed to influence the planning and design of the system to a higher degree.

Maybe the implementation of sophisticated quality systems requires that managers and staff adapt the design of their quality system to the specific conditions at their departments, as well as to policies determined at higher organisational levels. That would be consistent with the cooperative implementation model.^{67 68}

7.4 New *original* models and methods

Most studies of quality systems focus on a single organisational aspect or a single quality system of a single hospital department.

There are many studies of quality systems that focus on a particular aspect. For instance, common aspects to study are organisational culture, participation, and competence management.⁸³⁻⁹²

Moreover, there are several single-case studies, studies of single departments, or studies of quality improvement efforts at single hospitals. For instance, it has been common to analyse or evaluate quality systems such as Total Quality Management, ISO-9002, or Continuous Quality Improvement as well as studies of very small local quality initiatives.²⁰⁻³⁰

Thus, there have been very few studies that have integrated experiences from *a wide range of quality systems* and *a wide range of organisational aspects* at the same time.

The integrative perspective is one of the greatest strengths of this thesis, since such perspectives are uncommon in research. Thus, there are good chances of bringing together knowledge that could be beneficial to managers, clinicians, and other health care professionals. However, the integrative approach does have the disadvantage of not allowing the researcher to delve too deep into each aspect or quality system.

Naturally, it is not possible to study everything at once. Thus, patients and patient associations were excluded. However, it was thought that they rarely initiate quality improvements by themselves. They have rather been assumed to indirectly influence staff, managers, and institutions to initiate implementations of quality improvements. In this thesis, the focus is on the managers, the staff, and their options for organising and implementing quality improvements.

Many qualitative research studies have been conducted within the field of quality improvement research. For instance, interview studies with managers and staff to assess a specific quality intervention. There have also been studies that describe and analyse differences through rather standard statistical methods. Some of the published studies have had more in common with regular development than with organisational research.

This thesis is an attempt to use the most sophisticated statistical methods available to test models in a field with very few advanced quantitative studies. The study was designed with a large sample size, about a third of the available hospital departments in Sweden. The response rate was an impressive 75%. The data were analysed with the cutting edge structural equation modelling suite LISREL 8.72.

There are limits to what is possible to achieve even with the most advanced quantitative methods. Some phenomena are better explored by qualitative methods. However, to test models with constructs structural equation modelling is the preferred method.

It would have been interesting to do a multi-level analysis of differences in aspect levels, relationship coefficients, or models among hospitals or types of departments. On one hand, the analysis of intra-class correlations indicated that multi-level effects were very small. On the other hand the sample of this study was not selected with a multi-level analysis in mind. It is probable though, with these results in mind, that a larger sample of cases per department will have to be selected to find potential multi-level effects.

8 Conclusions

In this thesis, new models to describe, analyse, and implement quality systems have been introduced.

First, the organisation of quality systems can be described and analysed with the three main aspects structure, process, and outcome. The description and analysis could be further enhanced by using the sub-aspects resources, administration, culture, cooperation, evaluation of goal achievement, and development of competence. This framework could be used by managers, policy makers, or researchers for establishing a baseline before an organisational change or intervention. It could also be used to evaluate the results of such changes or interventions.

Second, quality systems can be classified into three types of quality systems according to organisational aspect levels: high, intermediate, and low aspect level quality systems. An interesting result was that aspect levels were often similar on all of the aspects within quality systems.

Third, quality systems with high organisational aspect levels more often used more sophisticated designs. Availability improvements, quality registers and patient satisfaction surveys were more often included in quality systems with an intermediate degree of organisation. Coordination between departments, random sampling of selected processes, and accreditation were more often included in quality systems with a high degree of organisation. Thus, managers and health policy makers need to consider that the implementation of sophisticated designs may require sophisticated organisations.

Fourth, health care policy makers and managers that wish to implement organisationally demanding quality systems should probably direct and lead the implementation process, while assuring that the staff get opportunities to contribute to the planning and designing of the new system.

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Appendix A: The questionnaire

The questionnaire consisted of three parts:

- Part 1: Responder characteristics and quality systems designs
- Part 2: Organisational aspects of quality systems, *and*
- Part 3: Implementation aspects of quality systems.

The original questionnaire was written in Swedish. The English translation of the questionnaire has been included in this Appendix.

Part 1. *Responder characteristics and quality systems designs*

Labels	Questions
PART 1	RESPONDER CHARACTERISTICS & QUALITY SYSTEM DESIGNS
Profession	Which is your current professional affiliation? (scale: 5 categories: physician, nurse, physiotherapist, biomedical analyst, or other)
Position	Which is your position? (scale: 3 categories: head of department, quality coordinator, or other)
Designs	How do you work with quality improvements at your department? check alternatives that are used in your department (may be many) (scale: 2 categories: yes or no)
Design 1	Reporting and follow-up of incidents and undesirable events
Design 2	Availability improvements for patients, for instance, projects to shorten queues
Design 3	Patient satisfaction surveys
Design 4	Quality registers for certain diagnosis
Design 5	Random check-ups for selected processes
Design 6	Coordination of the quality improvement work with other departments
Design 7	Quality accreditation according to ISO or similar
Design 8	Other, please describe

Labels and headlines were not included in the original questionnaire. They have been added to make it easier for the reader to follow.

Part 2. *Organisational aspects of quality systems*

Labels	Questions
PART 2 ORGANISATIONAL ASPECTS (scale: ordinal 7 steps)	
STRUCTURE	
<u>Resources</u>	
A1	Do the clinic's employees and managers have time to work with quality improvement?
A2	Are there enough employees to implement new quality improvement methods?
A3	Do the clinic's employees and managers have the right competence for working with quality improvement?
<u>Administration</u>	
A4	Are the clinic's routines documented in a quality manual or similar? (Such as filing system with routines for treatment, quality development or evaluation.)
A5	Are there documents on which employee should do what in quality improvement?
A6	Does the clinic have administrative support for working with quality? (Such as access to computers, secretaries or advice on how to work with quality improvement.)
PROCESS	
<u>Culture</u>	
B1	In general, is it easy to get support from the clinic's colleagues when trying to implement new organisational improvements?
B2*	In general, is it easy to get support from the clinic's managers when trying to implement new organisational improvements?
B3*	Are the clinic's employees positive to reporting incidents?
<u>Cooperation</u>	
B4	Are members of all professions participating actively in working with quality?
B5	Are most of the clinic's employees participating actively in working with quality?
B6	Do members of different professions co-operate regarding quality related work?
OUTCOME	
<u>Goal achievement</u>	
C1	Does the clinic have precise quality related goals for the clinic?
C2	Does the clinic periodically evaluate if the quality related goals are accomplished?
C3	Are the results of the evaluations documented?
<u>Development of competence</u>	
C4	Are the results of the evaluations communicated to the employees?
C5*	Are new employees introduced to the clinic's routines for working with quality?
C6*	Do the clinic's employees get opportunities to educate themselves in how to work with quality improvement?

Labels and headlines were not included in the original questionnaire. They have been added to make it easier for the reader to follow. The instruction to responders was: *How do you work [with quality] at your department today?*

* These variables were later found to be inadequate reflections of their factors and were removed.

Part 3: *Implementation aspects of quality systems*

Labels	Questions
PART 3	IMPLEMENTATION OF QUALITY SYSTEMS (scale: ordinal 7 steps)
	<u>Initiative</u>
I1	Did the implementation initiative come from the staff?
I2	Did the implementation initiative come from the managers?
I3	Did the implementation initiative come from the institutional purchasers of care?
	<u>Cooperative implementation</u>
Q1	Was the design of the quality system discussed with the staff?
Q2	Was the implementation planned in cooperation with the staff?
	<u>Implementation prerequisites</u>
Q3	Did the implementation have adequate resources?
Q4	Were the expectations high about what the quality system could accomplish?
Q5	Was there adequate competence for the implementation?
Q6	Was it easy to resolve any implementation difficulties

Labels and headlines were not included in the original questionnaire. They have been added to make it easier for the reader to follow. The instruction to responders were: *The questions above were about how you work today with quality related issues. The questions below are about how this way to work with quality was implemented at your department.*

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