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Factors that Influence the Internal Effects of External Hospital Evaluation
Factors that Influence the Internal Effects of External Hospital Evaluation

PhD Dissertation

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1. Introduction

Stakeholders’ expectations towards hospitals have been growing in the last decades in all countries of Europe, among them in Hungary. Citizens’ and health policy makers’ requirements on accountability and transparency, and demand on an efficient and effective operation increased. Patients also demand detailed information about the health care services, about the hospital and the hospital care, too. Financing authorities or purchasers introduce new incentives to promote more efficient and more effective hospital operation. Stakeholders develop and apply new methods to achieve their goals related to hospital operation. These methods include external hospital evaluation methods. *External hospital evaluation methods are models and practically applied tools for systematic analysis that external stakeholders use to evaluate how hospitals achieve the appointed goals and objectives, and hereby how they satisfy their stakeholders’ demands and expectations.* External stakeholders include for example supervisory authority, financing authorities, accreditation boards, certification bodies or patients’ rights organizations.

This research focuses on the hospital evaluated by the external stakeholders using a certain method, which method effects on the behavior of the internal hospital actors. However, in many cases hospital actors’ reactions to the external evaluation differs from what external stakeholders expected, and this difference is evidenced by research. (See subchapter 4.3.) Despite such evidence, there is only little research that aims at revealing the reasons behind the different reactions and at examining the processes of the behavioral changes resulting from the effects of the evaluation.

1.1. Research objectives and the relevance of the topic

The aim of this PhD research is to propose a framework to classify hospital evaluation methods, and to explore the internal hospital effects of the external evaluation methods by trying to understand internal organizational processes and the reactions and interactions of hospital actors and by focusing on their relationship with hospital improvement initiatives. The aim of the research will be approached by the following *research question*: How external hospital evaluation methods affect the behavior of hospital actors and, as a consequence, the improvement initiatives of hospitals in the Hungarian health sector? The research aim and the research question were the result of a long process of approaching the topic. As a university student I was interested in the issues related to hospital evaluation, and I wrote my thesis about internal hospital evaluation methods. After the university I started to work for the National Health Insurance Fund Administration (NHIFA), where between 2002 and 2006 I was a member of the team developing quality indicator program for evaluating hospital care. Since 2006 I have been working for the Health Services Management Training Centre of the Semmelweis University, where I participate in projects on indicator development for health care (like the PATH project by the WHO\(^1\)). I also work as an

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1 The PATH project (Performance Assessment Tool for quality improvement in Hospitals) was launched in 2003 by the WHO, and the first six Hungarian hospitals joined the program in 2006. PATH can be considered as an internal hospital evaluation method, which supports quality improvement of hospitals.
expert for the development of a hospital accreditation system within the framework of an EU funded program. Working practice influenced the focus of my interest as a researcher, and oriented it from internal evaluation methods towards external evaluation methods. Meanwhile, besides trying to understand the effects of the evaluation methods on hospital care I turned my attention to understand the internal hospital mechanisms of these effects, which can be best approached by exploring and analyzing the perceptions and the reactions of hospital actors, and by analyzing the indirect effects of these perceptions and reactions. In order to achieve this objective, I opted for making an exploratory qualitative research in my PhD dissertation.

The relevance of the topic is evidenced by the fact that performance management and quality management tools have become widely spread in the 1980s and 1990s in the countries of Europe as a result of the New Public Management (NPM) movement (See subchapter 4.2.). These tools included some external evaluation methods, which also became used by health sector institutions. (Boland – Fowler, 2000; Wagner et al. 2006; Drótos – Révész, 2007)

The relevance of the research topic for the Hungarian health sector is shown by the fact that in the past two decades the certification according to ISO standards and SHC (Standards of Hospital Care) and later HHCS (Hungarian Health Care Standards) has become a widespread practice in Hungarian hospitals. According to a 2011 survey by the Institute for Health Care Quality Improvement and Hospital Engineering (EMKI), 72% of the hospitals had some kind of certification, 38% of which had ISO 9001 and HHCS, while 28% had only ISO 9001, and 6% had only HHCS certifications. (EMKI, 2011 survey, own calculations) The EFQM model was also included among the newly introduced external evaluation methods, as hospitals have the opportunity to apply for the National Prize for Quality for public organizations. Between 2008 and 2010 a hospital indicator system was also elaborated by the Health Insurance Supervisory Authority. The above mentioned TÁMOP (Social Renewal Operational Program) project aims at developing the hospital accreditation system in Hungary between 2012 and 2014.

The introduction of the external hospital evaluation methods raises many issues and sometimes contradictory requirements from hospitals not only in Hungary, but also in many other European countries. Who applies these methods and for what reasons? Do the applied external evaluation methods achieve their objectives? Which methods are effective and efficient? What are the effects and the adverse effects of these methods?

Since the 2000s several research projects have been launched to answer the above questions emerging from the practice. MARQuIS (The Methods of Assessing Response to Quality Improvement Strategies) was one of these projects between 2005 and 2007. This project was funded by the European Committee, and it investigated the effects of quality improvement strategies on hospital care in the EU.

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2 Project TÁMOP-6.2.5.A-12/1-2012-0001: To develop organizational efficiency in institutions affected by structural reforms: Establishing a unified survey system for outpatient care, inpatient care and pharmaceutical supplies.
3 Hospital is defined in my research as a publicly financed institution providing acute in-patient care. (See subchapter 4.1.)
4 Response rate among the hospitals was 96%.
5 TÁMOP-6.2.5.A-12/1-2012-0001 project aims at developing standards and a unified survey system not only for inpatient care providers, but also for outpatient clinics and pharmacies.
6 http://www.simpatie.org/marquis/Main, last access: 07.12.2010.
88% of the hospitals involved in the MARQuIS project were evaluated by an external organization\(^7\). The external evaluation was performed by accreditation institutes, certification institutes, patient or customer organizations or government inspection bodies. (Lombarts et al., 2009) Research results showed that internal and external evaluation methods had positive effects on hospital outputs. (Sunol et al. 2009)

MARQuIS research project leaders defined further research areas, such as the development and validation of a classification model for hospital quality improvement systems and the analysis of the associations of quality improvement systems and hospital outcomes (Gröne et al., 2009). Other studies also formulated further research questions related to the evaluation methods: Braithwaite et al. (2006) urge research on validity of accreditation, and on its impact and value. Gröne et al. (2008) propose further research on the costs and the effects of the indicator projects and on the background philosophies and the assumptions\(^8\).

It can be concluded that previous research mainly focused on the consequences of the evaluation methods (like how they affect output, outcome, what are the adverse effects).\(^9\) Only a few researchers focused on analyzing the mechanism of the effects. This PhD research does not only focus on the effects of the evaluation on the behavior of hospital actors, because this has been evidenced by other studies. The present dissertation aims at exploring the processes and factors that affect the perceptions, reactions, interactions and the interpretations of the role of external evaluation by the stakeholders of this evaluation (hospital actors and auditors).

In order to understand the scope of the validity of previous research and to be able to focus on undiscovered research areas it is recommended to classify the evaluation methods. The classification framework proposed as part of this dissertation is meant to achieve this aim and also to find the scope of the present research. In Hungary, despite the spread and support of the external hospital evaluation methods there are only a few studies analyzing their effects. (Makai et al., 2009; Dombrádi – Gődény, 2013) Considering all this and having in mind the focus of international research I opted for analyzing the inter-organizational effects of the Hungarian external hospital evaluation methods in this PhD research.

### 1.2. Research framework and dissertation structure

Theoretical background for this research is provided by areas describing external hospital evaluation and its methods on the one hand, and by theories describing the operation of health care and hospitals on the other. (See Figure 1.) External hospital evaluation can be considered as a specialized activity that is included in the scientific research field of evaluation as a cognitive process and as a profession. Furthermore the methods used by external hospital evaluation are mainly the methods of quality management and the methods of performance management. These three fields partially overlap, as it is shown in Figure 1. Chapter 2 describes the relevant features of these three fields. The understanding of these fields helps to describe the characteristics of the methods of external hospital evaluation. The

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\(^7\) The MARQuIS survey included hospitals from eight European countries. Criteria for hospitals included at least 100 acute care beds, and providing care for at least two of the three conditions selected for the study. From 1396 hospitals 389 answered the survey. (Lombarts et al., 2009)

\(^8\) Some of these assumptions are: that information systems continuously improve, clinicians use the data obtained and discuss the results, and patients use performance reports to select care provider. (Gröne et al. 2008)

\(^9\) The results of the empirical study on hospital evaluation methods are described in Chapter 4.
development and practical use of the evaluation methods is also influenced by the objectives and the explicit or implicit assumptions of the developer and the user of these methods. During the empirical research interviews with experts served to reveal what were the objectives of the developers and supporters of these evaluation methods. The theories of health economics and professional bureaucracy can support the understanding of the behavior of actors in hospitals. These theories (e.g. the particular features of the health care sector) are described in Chapter 3. The theoretical background for my PhD research is illustrated by the five fields on the top of Figure 1.

There are considerable differences between the assumptions on the interests and power of the stakeholders between the background theories of external evaluation methods (quality management, performance management and evaluation) and the theories related to the behavior of hospital actors (health economics, professional bureaucracy). (See e.g. Lozeau et al. 2002). This theoretical gap is described at the end of Chapter 3. The question is whether this gap can or cannot be experienced in practice, namely whether there is a similar difference after the evaluation between the behavior / practice expected by the external evaluators and the practice that the stakeholders perceive, or not. (See Figure 2.)

Following the theoretical Chapters 2 and 3, Chapter 4 is dedicated to describe the characteristics of the external hospital evaluation methods and to propose a classification framework for these methods. In the second half of this Chapter the results of the research on the effects of external hospital evaluation methods are summed up, as well as the results of the studies that focus on the internal hospital effects of these methods.

Chapter 5 offers a background for the empirical case study by describing the characteristics and introducing the principal stakeholders of the Hungarian health care system and the hospital sector. The Chapter also offers an overview of the relevant regulations and the external hospital evaluation methods applied in the Hungarian health care system.

The subsequent Chapters are dedicated to present the empirical case study. Chapter 6 gives a detailed description of the research questions and the research method. This is an exploratory qualitative research: the research questions were answered by using interviews with experts and case study methodology. The different points of view were compared, therefore semi-structured interviews were made with national experts who developed or supported the evaluation methods (5 people), the external
auditors of the hospital (2 people) and other hospital actors (30 people). Other data collection methods, such as observation and analysis of documents were also applied. Empirical research was restricted to certifications of system based on ISO 9001 and SHC/HHCS. Chapter 7 is dedicated to analyze the reasons and the objectives of the introduction of these external evaluation methods. This analysis is based on interviews with experts.

**Figure 2. Analytic framework for the case study**

![Analytic framework for the case study](image)

Source: own elaboration

Chapter 8 describes the hospital case study. In this Chapter the characteristics and the effects of the external evaluation (the certification and the related audits) are analyzed and described using the framework in Figure 2 (in detail see subchapter 8.1). The effect on the behavior of hospital actors and the perceived organizational change are influenced by many different factors. The Chapter also describes the identified influencing factors and the interpretations of the role of the certification and related audits in the hospital.

Results are summed up in Chapter 9, conclusions and comparison of the results with the literature are included in this Chapter. Chapter 10 provides summary and possible directions for further research.
2. Theoretical background: different approaches and interpretations of the concept of evaluation

According to my investigation the external evaluation of hospitals connects basically to three fields. The first is *evaluation* considered as an individual specialty (Guba – Lincoln, 1989; Scriven, 1991; Alkin, 2004; Radó, 2005), which has more subfields according to the type of the entity as an object of evaluation (Scriven 1998a), one of these subfields is institutional evaluation. The other two fields connected to external hospital evaluation are *quality management* and *performance management*. Although the methods applied by these fields have been developed in the business sector, they have become widespread in the public sector, and they effect on the methods applied during the external evaluation of hospitals as well. While the approach applied by the field of *evaluation* reveals the generic features of evaluation, *quality management* and *performance management* offer methods for external hospital evaluation. The way of how these three fields overlap (see Figure 1 in Introduction) will be described in the following Subchapter. The field of evaluation serves as broader framework for studying the phenomenon which is useful in analyzing the evaluation methods of quality management and performance management.

The first part of this chapter focuses on the evolution, types and application fields of the specialty of evaluation, as this field is only scarcely known in Hungary. The second part deals with the relevant tendencies and interpretations of the concept of evaluation as applied in quality management and performance management. Finally, the concepts of quality and performance will be discussed.

2.1. The specialty of evaluation

There are many different situations in life when we evaluate something or even someone. In some cases we are just expected to give our opinion, but in others we have to choose between alternatives that we had previously compared by using certain criteria. This is the situation, for example, when we evaluate a product or a service as consumers. In other situations a person or the individual performance is the subject of the evaluation, as when choosing our lifelong partner, or a leader for an institution, when teachers evaluate their students, or when a leader evaluates the performance of his subordinates. In many cases the object of the evaluation is the product made by a whole group, an organization or a whole country. In this dissertation the object of the evaluation is the hospital as an organization.

In Hungarian we use the term ‘értékelés’ equally for the English terms of ‘assessment’ and ‘evaluation’. According to the definitions given by Longman Dictionary (2000) ‘assessment’ means 1. calculating or deciding the value or amount of something, 2. judging the quality, importance or worth of something. ‘Evaluation’ means calculating or judging the value or degree of something. Both English terms include two possibilities of interpretation: they can suppose that we express the value or the amount of the thing

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10 Another relevant field is service management. However, this PhD dissertation does not focus on the service-related features of health care, but on the characteristics of the health sector. Therefore, I chose health economics and professional bureaucracies as a framework. Examples for the Hungarian literature on service management and service marketing can be found in Demeter – Gelei (2002); Kenesei – Kolos (2007), Becser (2007), Demeter (2009), and health-related issues of these fields are presented by Simon (2010) and Lantos – Simon (2007).
measured in numbers, or that we give an estimation of the worth, the importance or the quality of something (this is less expressible in numbers).

The term ‘evaluation’ can also refer to the scientifically based activity widely applied in practice and in many different scientific areas. According to this approach Scriven (1998a, p.85.) proposes the following definition of the term ‘evaluation’: „Evaluation is the process of determining the worth, merit, or significance of entities; and evaluations are the outcome of that process.” This definition is in accordance with that of the Longman Dictionary, and implies that Scriven (1991, 1998a) and many other authors (Guba – Lincoln, 1989; Alkin, 2004; Radó, 2005 etc.) handle the field of evaluation as a substantive specialty. The statements of this specialty can be applied to the research topic of the present dissertation. Scriven (1996, 1998a, 1998b, 1999b) and Davidson (2005) point out that the evaluation disposes of some specific characteristic features. Independently from its subject evaluation can be formative or summative, internal or external or mixed, qualitative or quantitative or mixed (for explanation see section 2.1.2).

According to the subject entity of the evaluation the following sub-fields can be distinguished: product evaluation (including technology assessment), performance evaluation (evaluation of performance of individuals), personnel evaluation, institutional evaluation, proposal evaluation, program and policy evaluation. This list can be complemented by two areas: the evaluation in scientific research (evaluation of hypotheses, data, results, applied methods and tools) and meta-evaluation, which refers to the evaluation of the evaluation itself. Some of the evaluation methods that were developed for one of the subdivisional areas may be applied for other areas, too. Most types of evaluations have considerable impact on the people involved, as they intrinsically feel that evaluation refers to the quality and value of their work. (Scriven, 1991, 1998a, 2001)

2.1.1. The development of the interpretation and application of evaluation

Guba and Lincoln (1989) identified three former generations of different interpretations of evaluation in the prior one hundred years, and described as measurement-, description- and judgement-oriented period of evaluation.

During the measurement-oriented period the interpretation of evaluation was especially influenced by student performance measurement in schools, for example. Tests have been applied for hundreds of years to measure students’ performance and knowledge in certain school subjects. School-related measurement applications also contributed to the development of IQ tests. This measurement-oriented interpretation was influenced by the raise of social sciences and scientific management (see Taylor, 1983), these fields resulted in influence on school testing. In this period evaluator had a technical role, his or her task was to measure variables under investigation.

The following, description-oriented period of the evaluation is characterized by listing the strengths-and-weaknesses pattern of the evaluated subject while attaining to achieve a certain goal or objective. In this case evaluation is not identified with measurement, and measurement is interpreted only as a tool of evaluation. In this period, during the 1960s (Scriven, 1991), the field of program evaluation was

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Scriven (1991, 1998a) even considers evaluation as an individual scientific area that belongs to the so called transdisciplines. Transdisciplines serve as a tool of studying for other disciplines, while at the same time having uniqueness as a discipline. They are primarily analytical sciences and not empirical sciences. Transdisciplines include statistics, probability, measurement, logic, evaluation. (Scriven, 1998a)
developed on the basis of curriculum evaluation. This direction of development was initiated by Ralph W. Tyler (1902-1994).

According to Guba and Lincoln (1989), the third phase of evolution is called judgement-oriented period. This is characterized by an even wider interpretation of evaluation offered by Robert Sake, who, in his 1967 study, defined the inclusion of judgement as a further step in the evaluation process. In this process the third generation evaluator adopts the role of a judge as an expert, besides exercising technical and descriptive functions.

Guba and Lincoln (1989) admit that the concept of evaluation enriched and became more sophisticated during the first three phases of development. The first generation developed the methods that allowed data collection about persons, the second generation began to apply evaluation on programs, organizational patterns or procedures, while the third generation redefined and extended the role of the evaluator. However, Guba and Lincoln in their book published in 1989 claim that the interpretation of evaluation has to be replaced because of three flaws of the previous generations. These are: a tendency to excessive manager-orientedness (managerialism)\(^{12}\), a failure to accommodate value pluralism and an over-commitment to the scientific paradigm of inquiry (using the paradigm of natural sciences when approaching evaluation).

Because of these flaws, Guba and Lincoln (1989) recommend a responsive constructivist evaluation alternative called negotiation-oriented evaluation. The authors suggest that the parameters and the scope of evaluation should be defined during an interactive negotiation process involving the stakeholders, instead of previous determination. As Pollitt and Summa (1997) point out, this fourth generation evaluation of Guba and Lincoln seems to be the summit of the development of a school of evaluation appeared from 1970s according to which cooperation and interaction with the subject of the evaluation are essential. This approach denies the objective external position of the evaluator. Since 1989 many different evaluation theories have appeared that also argue in favor of involving the stakeholders in the evaluation process and in decision making. The flaws of the first three generations of evaluation were reflected upon by the post-positivist author (Christie – Alkin, 2008), Scriven, who proposed to consider evaluation as a new branch of science (Scriven, 1998a). So, we can conclude that today there are two communities, both equally dedicated to the field of evaluation: those who accept the plurality of values and emphasize the importance of involving the stakeholders, and those (the ‘true believers’ community) who believe in scientific paradigm. (see Stake (1997) and Scriven (1997) in Chelimsky and Shadish (1997))

Development of the theories and the practice of evaluation is illustrated by Christie and Alkin (2008) by their ‘Evaluation Theory Tree’. The authors systematize and place evaluation theorists on this tree according to the main points and relationships of their theories. The Evaluation Theory Tree is being continuously revised, and the third version from 2006 is attached in Annex 1 of this dissertation. Importance of the field of evaluation is reflected by the fact that in the USA ten scientific journals focus on this topic and regularly publish articles on evaluation research (Weiss, 2005).

\(^{12}\) Managerialism is interpreted by Guba and Lincoln (1989) as the relationship between the client of evaluator (manager) and evaluator, and it insures the inviolability of manager, forces evaluator into a server position and makes the evaluation unfair for other stakeholders. (The recent interpretation of managerialism is different from this, see e.g. Kováts (2011).)
2.1.2. Some general typifications of evaluation\textsuperscript{13}

Although many different types of entities can become the subject of evaluation, there are some generally applicable typifications, as mentioned before. The role of evaluation can be circumscribed using several conceptual distinctions, such as formative vs. summative roles, or instrumental vs. conceptual roles. The methodology applied during evaluation can also be described following dichotomies like qualitative and quantitative, distanced and interactive evaluation. (Scriven, 1996; Patton, 1996) In the following these conceptual distinctions will be described, complemented by further classifications such as internal vs. external, outcome vs. process, or analytical vs. global evaluation.

2.1.2.1. Formative vs. summative evaluation

The terms of formative and summative\textsuperscript{14} were coined by and introduced in evaluation by Scriven (1966, 1967). The terms that were initially applied to curriculum evaluation can be interpreted for the evaluation of other subject entities as well. Scriven (1996) proposed the terms ‘formative’ and ‘summative’ to explain two distinct roles of evaluation.\textsuperscript{15} Formative evaluation centers on improving and supportive feedback supposing that the entity evaluated can be improved or modified, that it is not ‘finished’, but rather in process. Summative evaluation is summing up achievement. Summative evaluation can be effectuated to assess a closed procedure (like preparation of curriculum or production of prototype), but also in case of an entity in process (personnel or organization) when we evaluate a terminated phase as a ‘flash-like’ evaluation at a certain moment of this process.

Some authors apply these distinctions as the aim of the evaluation (see e.g. Patton, 1996), while according to Scriven (1966, 1996) these are in fact its roles. It is also true, however, that formative evaluation is usually strictly applied with the aim of improvement, while summative evaluation can be applied with different aims such as the aim of supporting decision making (e.g. choice between alternative) or the aim is simply to measure worth, excellence or importance of an entity without following decision. In my opinion, distinction between summative or formative evaluation reflects the approach of the evaluator to the subject of evaluation.

As Robert Stake summarizes the difference: „When the cook tastes the soup, that’s formative; when the guests taste the soup, that’s summative.” (quoted by Scriven, 1991 p. 169.)

Scriven (1996) claims that the use of formative and summative evaluation should depend on the context. Following the soup example: the guests’ evaluation is summative in the everyday context. But if the context is changed so that the evaluation given by the guests is continually used by the management as a feedback to improve the quality of the dishes, the evaluation becomes clearly formative. Contextual shifts play an important role. In the first case the entity evaluated is the dish and the evaluator is the guest, while in the second case the subject of the evaluation is the restaurant or the chef (and not the

\textsuperscript{13} This typification is used to support the classification framework for external hospital evaluation as proposed in subchapter 4.2.

\textsuperscript{14} When translating the English terms ‘formative’ and ‘summative’ into Hungarian I followed the tradition of their use in the field of education (Báthory, 2000; Golnhofer, 2004). When Carol Weiss’s work on program evaluation was published in Hungary in 2005, these terms were translated into Hungarian (‘támogató’ and ‘összegző’). However, this dissertation uses the more widely spread terms (‘formatív’ and ‘szummatív’) as used in the field of education.

\textsuperscript{15} According to some authors formative and summative terms do not cover all types of evaluation (see e.g. Patton, 1996; Chen, 1996) and they made an attempt to complement them with other terms. In his 1996 article Scriven defended the dichotomy.
dish), and the evaluator is the chef or the owner of the restaurant. (In the later case the evaluation made by the guest is considered as data.) Scriven argues that both types of evaluation are valuable under certain circumstances, and no one is superior to the other.

Formative evaluation is directed primarily to the internal members who are capable of assisting development, and it can be carried out by either internal or external evaluators (or a combination of both).

Summative evaluation is directed to an external 'public' or to decision makers, and can also be carried out by either internal or external evaluators, or both. (Scriven, 1991)

The terms of formative and summative evaluation are principally used in the field of education in Hungary (Golnhofer, 2004), and they are not really used in other fields of evaluation, yet.

2.1.2.2. Internal versus external evaluation

When evaluation is made by a member of the evaluated entity (e.g. organization, program), we talk about internal evaluation. External evaluation is carried out by evaluators who do not belong to the staff of evaluated entity. Scriven (1991) claims that internal/external do not represent two different types of evaluation, but rather a degree, and the combination of both may also take place in practice.

2.1.2.3. Outcome and process evaluation

Evaluation types are distinguished according to whether they refer to the outcome or to the process of the evaluated entity (e.g. program, organization). Scriven (1996) argues that in an ideal case evaluation includes both points of view. At the beginning of the development of the field of evaluation the focus was on the outcome, but later it was recognized that processes might not work as they had been previously planned (Weiss, 2005). Another reason for applying process evaluation is that it helps to assess outcome, although the cause-and-effect relationship between process and outcome variables can sometimes be ambiguous (Scriven, 1996).

2.1.2.4. Analytical versus global evaluation

In analytical evaluation only certain parts or aspects of the entity are evaluated, either as a tool of an overall evaluation or without the aim of a final synthesis. When parts are evaluated we talk about component evaluation, when the object is a certain aspect we talk about dimensional evaluation. On the contrary to analytical evaluation, in global evaluation the evaluated entity is characterized by a single final score or grade. (Scriven, 1991)

Both summative and formative evaluations can be an analytical or a global evaluation, which means that these concepts may overlap but they are not coupled pair. Formative evaluation is typically supported by analytical evaluation or sometimes by global evaluation. According to Scriven (1991) example for global formative evaluation can be a trial final examination, where students get a feedback in the form of a total score, but the result is not officially registered.

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Education distinguishes three types of student evaluation: besides summative and formative evaluation they apply diagnostic evaluation, where the aim is to obtain information about the conditions and preparedness of the student when they enter the educational process. (Báthory, 2000; Golnhofer, 2004)
Quantitative versus qualitative evaluation and the role of measurement

Before the 1980s the only quantitative evaluation was recognized as a reliable evaluation method, but from then articles and books have been published about the merits and advantages of qualitative methods, and as a result of these qualitative methods have also become legitimate, and nowadays there is nothing strange about applying both methods during the same evaluation process. (Weiss, 2005) Program evaluation is usually based on quantitative methods using measurement. Measurement is a common and sometimes large component of standardized evaluations; but a very small part of its logic, that is, of the justification for the evaluative conclusions.” (Scriven, 1991, p.226.)

The interactive constructivist approach by Guba and Lincoln (1989) and their followers question the role of measurement and they pose the problem of not measurable phenomena in many different fields of evaluation. For instance Báthory (2000) claims that educational evaluation is applicable for all educational phenomena and not only for the measurable ones.

Instrumental versus conceptual use of evaluation

According to Patton (1996) instrumental use of evaluation occurs when a decision or an action follows as a result of evaluation. Conceptual use does not require a decision or an action as a consequence of evaluation, but it serves to amplify knowledge and shape the ways of thinking. Scriven (1996) proposes the terms of action-oriented and research-oriented evaluation to describe the same types of use. Patton considers summative and formative evaluations as instrumental, while Scriven claims that summative evaluation can also be conceptual or, as he calls it, research-oriented.

Some application fields of evaluation

In the different phases of evaluation evolution different application fields were considered as dominant. In the middle of the 20th century student performance testing was dominant and practically all the evaluation literature focused on this field. In these days program evaluation has dominance in the United States. (Scriven, 2001)

The scope of evaluation has broadened within the different application fields, as well as in education. The object of educational evaluation can be the learners’ performance and development, the learning process, teachers’ performance, course materials, educational initiatives, curricula, schools or the educational system as a whole (Báthory, 2000; Goinhofer, 2004). Educational application of evaluation has an extensive use in Hungary. Báthory’s (2000, p.222.) wide scope interpretation of educational evaluation claims that „educational evaluation comprises the theory and practice of an organized and differentiated reporting on educational information”.

A possible object of educational evaluation is the institution (kindergarten or school), and according to Báthory (2000) another application field consists of the quality insurance system of the institutions. It is important to highlight this application field as the present dissertation also focuses on the evaluation of an institution (that is hospital) and I studied also quality management as one of the possible application field in health care (see subchapter 2.2.).

Scriven (1991) points out that another traditional and highly developed application field is product evaluation which also includes technology assessment (Scriven, 1999a). A related application field is

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17 According to Stevens, “...measurement, in the widest sense, is defined as the assignment of numerals to objects and events according to rules” (Stevens, 1946, p. 677)
health technology assessment\textsuperscript{18} which has also become widely used in the Hungarian health system, but it cannot be considered as an integral part of traditional technology assessment. There is a debate on whether health technology assessment can or cannot be considered as an individual discipline or just as a multidisciplinary method that is using the results of other disciplines (Gulácsi, 1999). Meanwhile, the representatives and practitioners of health technology assessment are facing the dilemma of whether their field can or cannot be interpreted as a subordinate field of Scriven’s discipline of evaluation (Reuzel – van der Wilt, 2000). Evaluated health technologies are classified in six groups, including management systems such as quality improvement systems (Gulácsi, 1999), which means that this sixth category includes hospital evaluation methods as well. According to this, my dissertation could belong to the field of health technology assessment, but the aim of this PhD research is not to give an overall view of the external hospital evaluation methods as the field of technology assessment would require, but to explore the effects and the mechanisms of effects that the application of external evaluation methods cause within the hospital.

The dominant application field of evaluation in the United States is program evaluation, which has also appeared in Hungary due to the assessment needs required by EU founded programs. Weiss (2005, p.16.) defines evaluation as „the systematic assessment of the operation and/or the outcomes of a program or policy, compared to a set of explicit or implicit requirements as a means of contributing to the improvement of the program or policy”.

Another field that my dissertation could relate to is program evaluation, as programs in a wider sense are considered as possible entities of evaluation, and according to some interpretations certain components of health care and hospital processes can also be considered as programs (see e.g. Weiss, 2005, p. 23.). However, the external hospital evaluation methods analyzed here were not developed according to the principles of program evaluation. Another possibility to relate my topic to program evaluation would be if external hospital evaluation methods were considered as programs. (This would be relevant under certain circumstances, like in the case of the indicator system developed by the Health Insurance Supervisory Authority.) The present dissertation, however, does not aim at applying the theory and models of program evaluation and the related evaluation research (Babbie, 2003; Weiss, 2005) or making a meta-evaluation (Scriven, 1999a). The aim of this PhD thesis is to acquire knowledge about external organizational evaluation and understanding the nature and the mechanism of effects of external hospital evaluation in an organizational context.\textsuperscript{19}

Therefore, my research topic is mainly related to the field of institutional evaluation defined as: „A complex evaluation, typically involving the evaluation of a set of programs provided by an institution plus an evaluation of the overall management, publicity, personnel policies, and so on of the institution.” (Scriven, 1991 p.196.) Scriven (1991) classifies accreditation as a form of evaluation of institutions, as this process is meant to prove that a certain institution is making efforts to comply with certain quality standards.

\textsuperscript{18} In Hungary the term ‘egészségügyi technológiaelemzés’ is used for health technology assessment (Gulácsi, 1999), as it appears in the name of the Health Economics and Health Technology Assessment Center within the Corvinus University of Budapest. (http://hecon.uni-corvinus.hu/).

\textsuperscript{19} The importance of the organizational context is increasingly emphasized in the literature on program evaluation, too. Rogers and Hough (1995) argue that program evaluations are based on inadequate hypotheses on operation of organizations, and they propose that organizational theories should be considered during program evaluation.
Scriven (2001) claims that the field of evaluation supports some fields of business administration (e.g. business & management, accounting) and other fields such as history, geography, informatics and education. According to this, evaluation can support with tools and methods the field of quality management and performance management. Scriven (1991) mentions quality control and quality assurance among the application fields of evaluation and considers these as a type of evaluation monitoring characterized as an internal, formative evaluation. Further overlap is accreditation which is usually mentioned among quality management models, but which is considered by Scriven as a type of institutional evaluation, as I mentioned before. There is also an overlap between performance measurement and evaluation: the emergence of performance measurement from the 1980s posed new challenge for the specialty of evaluation in the US and the United Kingdom (Chelimsky – Shadish, 1997). Wholey (1997) claimed that the representatives of the specialty of evaluation were also prepared to measure and evaluate institutional performance, which was in the focus of performance measurement, and therefore the activities of the representatives of these two fields overlapped. Considering all these we can conclude that the field of evaluation supports and overlaps with the fields of quality management and performance management.

The previous subchapter describes how the specialty of evaluation interprets and typifies the activity of evaluation and defines its application fields. The importance of this description for the present dissertation is that it offers a wider interpretation framework that can help to define and classify external hospital evaluations as well (see Chapter 4). In order to carry out this task it is also essential to get acquaint with the concepts of quality management and performance management, as the methods applied in external hospital evaluation derive basically from these areas.

### 2.2. Quality management and performance management

Hospital evaluation methods mainly use the concepts and tools of quality management and performance management. Therefore, the tendencies of their evolution and the relationship between these two fields, and their interpretation of the concepts of evaluation, quality and performance can have considerable relevance to the dissertation topic. The concepts and methods of these two management areas from business are altering and mixing when they are applied in public sector, e.g. in health sector.

The widespread application of quality management and performance management methods in the field of public services has lead to the conclusion that the methods of these two fields cannot be strictly separated in the field of public services (Aristigueta, 2008). Although both management fields have different approaches, recent tendencies are showing a convergence of these fields in public sector. Van Dooren (2008, p. 420.) points out that for public service applications „the implication is that conceptually, there no longer needs to be a barrier between performance management and quality management.”

In my opinion the analyzed external hospital evaluation methods cannot be unambiguously classified as quality management or performance management methods. What are the possible reasons behind the

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20 As a transdiscipline
The intertwining of these two areas in the public sector? When explaining this tendency in Section 2.2.1., I offer a brief history of the development of the two areas. Section 2.2.2. deals with the role and interpretation of evaluation according to the approaches of quality management and performance management. The interpretation of the concepts of quality and performance are also crucial to apply them for hospital evaluation methods, as these concepts determine which characteristics of the hospital will be evaluated. Section 2.2.3. shows how these two concepts are applied in the business sector, in the public sector and in the Hungarian health care system.

2.2.1. Tendencies in quality management and performance management approaches

The development of performance management and quality management has been described by several Hungarian publications and dissertations\(^{21}\) and will be only briefly referred to in the next section. However, comparison of the parallelsisms of the two areas is examined only by a few theorists (see e.g. Van Dooren, 2008). As in the public sector, and consequently in the health sector as a part of it, the two management areas can hardly be separated, this section will also focus on the similarities of the development tendencies of both.

The origins of quality management root in the scientific management by F. W. Taylor promoted at the beginning of the 1900s (although there are early proofs of the need for quality from the antiquity). The first phase of development was quality inspection, which was followed by quality control and then by quality assurance, when quality systems appeared. It was in the 1980s when the basics of TQM, Total Quality Management were settled. (Balogh, 1999; Topár, 2005; Sliwa – Wilcox, 2008; Demeter, 2008) The principal tendencies are: the broadening of the concept of quality; developing the approach to be applied to the organization as a whole; the emergence of integrated frameworks/models (such as the EFQM model); the integration of quality-related activities into management cycles (PDCA cycle\(^{22}\)); the emergence of a stakeholder-focused approach; organizational-strategy-orientedness (Balogh, 1999; Tenner – DeToro, 2001; Becser, 2007).

Financial indicators deriving from accounting have been used for a very long time and they can be considered as the first tools of performance measurement that is a part of performance management (Franco-Santos et al. 2007). The idea of quantification of organizational activities in order to enhance performance dates back to Taylor (1983)\(^{23}\) (Révész, 2010). In the 1980s there was a growing realization of the deficiencies of the financial measures and the traditional cost management methods, which was an important turning point in the development of performance measurement and management accounting systems. These deficiencies included: cost-based approaches are historical in nature, it provides little indication of future performance; it encourages short termism; insufficiency of financial and cost measures; lack of non-financial, operative indicators etc. (Kennerley – Neely, 2002; Wimmer, 2004). The realization of these shortcomings led to a subsequent revolution of performance measurement in the

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\(^{21}\) At the Doctoral School of Management and Business Administration of the Corvinus University of Budapest several dissertations were presented in topics related to performance measurement or management (Wimmer, 2000; Dolgos, 2000; Sajtos, 2004; Harangozó, 2007; Öndi, 2008) and to performance management in the public sector (Székely, 2005; Antal, 2005; Révész, 2010; Kiss, 2011). Somewhat less interest has been shown for the topic of quality management in the recent decades (Becser, 2007).

\(^{22}\) PDCA cycle or Deming cycle is an abbreviation for: plan, do, check, act. (Demeter, 2008)

\(^{23}\) It can be claimed that Taylor’s work is the meeting point of the three areas – evaluation, quality management and performance management - that relate to external hospital evaluation.
1990s, when overall, multi-dimensional balanced frameworks (including financial and non-financial indicators), such as Balanced Scorecards (BSC, Kaplan – Norton, 1992) or Performance Prism (Neely et al., 2004) appeared. The main tendencies in performance measurement are: making accounting data more relevant, use of non-financial indicators, a broader scope of the concept of performance (multi-dimensional), future-orientedness, linkage to strategies, integrated models, dynamism, stakeholder approach. (Kennerley – Neely, 2002; Wimmer, 2004; Wimmer, 2005)

According to these tendencies common features of quality management and performance management are:

- overall, integrated models (e.g. EFQM, BSC), with overlapping dimensions (Van Dooren, 2008),
- management cycles (e.g. PDCA-cycle, strategic and operative management cycles),
- the application of non-financial indicators (e.g. indicators on operational activities) and financial indicators, outcome and process indicators in both areas,
- holistic approach to organizational operations,
- strategy-relatedness,
- stakeholder approach.

According to Klazinga (2000) the quality management models applied in the public sector are convergent, while Van Dooren (2008) claims that they are also getting closer to performance management approaches. This convergent tendency can be illustrated as in the literature reference on models is often taken from the other management area, as we can find in Van Dooren (2008, p. 414.) „quality models, such as balanced scorecard”25. This also happens in literature on the business sector: Neely et al. (2004, p. 29.) refer to the Model of Business Excellence26 and to the Malcolm Baldridge Prize27 as performance measurement methods.

The difference between the two management areas still exist: according to Van Dooren (2008) quality management is characterized by dynamical leadership, shared responsibilities in planning and standardization, and empowerment. Quality management focuses on continuous improvement and on organizational culture (involvement of employees, leadership dedication), while performance management supports executive decision making, strategic management and goal setting (Kiss – Révész (2007). At the same time, dynamism (Kennerley – Neely, 2002), relationship with operational performance, value-based approach and the need for support in operational development have also appeared in performance management (Wimmer, 2004).

Differences and similarities of the two disciplines can also be observed in the interpretation of key terms. The following sections are dedicated to describe the changes and the tendencies in the interpretation of the terms of evaluation, quality and performance.

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24 We can find financial indicators in the dimension called key results of the EFQM quality management model, too. (Neely et al. 2002, https://sites.google.com/site/myfirststepwithefqmmodel2010/home/9-key-results)
25 Kaplan and Norton (1992) created the BSC (balanced scorecard) model, This model is principally related to performance measurement and management.
26 The Model for Business Excellence was established by the European Foundation for Quality Management (EFQM) in 1991 to serve as a basis for awarding the European Quality Award (Takács – Gulácsi, 2003).
27 The Malcolm Baldridge Prize was founded in the US to enhance quality improvement. Besides the Japanese Deming Prize, Malcolm Baldridge Prize was considered as an example to establish the European Prize for Quality. (Takács – Gulácsi, 2003)
2.2.2. The concept of evaluation as used in quality and performance management

Evaluation in quality and performance management can be narrowly interpreted as a single step in development and management cycles. In PDCA cycle the third step equals to evaluation (check, C), which evaluates whether a new solution has been effective or not (Demeter, 2008). A performance management cycle based on PDCA was introduced by Rolstadas (1995, quoted by Wimmer, 1999), where the third step consists of the activities of performance measurement and performance evaluation. The management control approach of performance management[28] differentiates between the phases of operational planning, forecasting; performance measurement; performance evaluation and feedback within the operational management cycle (Kiss – Révéész, 2007). In these management cycles measurement and evaluation follow each other, and evaluation does not include measurement.

Evaluation can have a wider interpretation both in quality management and in performance management, when we evaluate the organization as a whole, instead of evaluating an improvement activity or performance compared to a plan. An example within performance management is when a company evaluates the performance of a subsidiary based on the balanced scorecard model. Evaluation of organizations has a long tradition in quality management, for example self-evaluation or external evaluation based on EFQM excellence model. In the later case, evaluators trained by EFQM evaluate the organization that is applying for quality award. We also talk about external evaluation in the case of certification of an organization according to ISO 9001 system. Accreditation also counts as external evaluation, which can either assess the abilities of the certification institutes, or the organizations in the public sector (e.g. educational or health care organizations). These methods used by quality management and performance management to assess the organization also include measurement, so measurement is not separately handled.

2.2.3. The concepts of performance and quality

Tendencies in performance and quality management have led to modifications, broadening and overlaps of the concepts of quality and performance. These concepts and their interpretation have a key importance for external hospital evaluation, as these concepts define what kind of characteristics are going to be evaluated.

This section describes the interpretation of the concepts of quality and performance. The spread of management methods originated from business sector[29] have considerably influenced on how these concepts are used in the public sector and, therefore, in the health sector. Their interpretations and definitions used by the business and the public sector have been thoroughly described in the dissertation outline (Takács, 2012). Hereby only a brief summary is given. Similarities, differences and overlaps in the development of the two concepts will be highlighted in this section on the business sector as well as on

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[28] According to my realization two different approaches can be distinguished in the performance management literature: the authors who represent the approach of management control and controlling (like Otley, 1999; Bodnár, 1997 a,b,c; Bodnár, 2005; Anthony 2003; Anthony – Govindarajan, 2009) interpret performance management as an activity based on their field, and other authors (like Neely – Gregory – Platts, 1995; Wimmer, 2000; Kennerley – Neely, 2002) who consider performance measurement as an individual activity that supports development and decision making.

[29] In business sector the principal goal of organizations (e.g. enterprise, company) is to satisfy consumers’ needs while realizing profit in long term (Chikán, 2003). Organizations in the public sector are generally not profit-oriented. The public sector includes institutes of central government and local municipalities and organizations that are mostly publicly financed by the state or the local municipalities. The third sector for formal economic-social activities is non-profit sector. (Drótos, 2000; Drótos – Révéész, 2007)
the public sector and health sector. The terminology used in the Hungarian health sector will be compared to the terminology used in the business and in the public sectors, and I point out some consequences of the everyday use of these terms in Hungary.

2.2.3.1. The interpretations of quality and performance in the business sector

Literature on business performance measurement and management usually does not define explicitly the concept of performance; therefore, it is not easy to give a generally accepted definition. However, authors mostly agree that performance is a multi-dimensional term, and they usually point out two dimensions: effectiveness and efficiency. (Wimmer, 2000; Dolgos, 2000; Neely et al. 2004; Sajtos, 2004; Anthony – Govindarajan, 2009)

An example of this is found in Neely et al. (2004, p.11):

"Organizations achieve their objectives – perform – by satisfying their own and their stakeholders’ demands and expectations more efficiently and more effectively than their competitors. […] Effectiveness refers to the extent to which the outputs reach the requirements of stakeholders, while efficiency is an indication of how resources are used by the organization to reach a certain level of stakeholder satisfaction."

In terms of whose requirements and demands are met this definition offers much wider dimensions of performance as compared to the former definitions that referred exclusively to customers (see Neely et al. 1995).

Although there have been several attempts to define the concept of quality in the business sector, we cannot find a universally accepted definition (Becser, 2007). There are many different approaches and the concept itself is continuously changing and enriching. The most important thinkers of the topic (such as Crosby, Juran, Ishikawa or Shiba) mention the following levels of quality (Varga, 1998; Balogh, 1999; Topár, 2005; Erdei et al. 2010):

- conformance to specifications,
- conformance to expected use,
- meeting explicit customers’ requirements,
- meeting latent customer requirements,
- meeting social requirements.

The concept of quality has not only enriched in the sense of meeting many different levels of requirement and expectation but also in terms of the subject of quality. (Balogh, 1999) The concept has become used for the whole organization, its environment, its infrastructure and even for the entire society (Parányi, 2006). There has also been a shift from the hypothesis that "good quality is expensive" to the "economical quality" approach, which has also brought about the need for "immediately good one and well done" (Erdei et al. 2010, p.10.).

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30 Efficiency (‘hatékonyság’) is meant here in a narrow sense. For the wide and the narrow interpretation see Wimmer (2010). In my dissertation I will use ‘hatékonyság’ as the Hungarian translation of ‘efficiency’ instead of ‘gazdaságosság’ (efficiency in narrow sense) as the use of ‘hatékonyság’ is widespread in this sense in the Hungarian literature on public management, health economics and management (Id. Kiss – Révész, 2007; Evetovits – Gaál, 2005; Evetovits – Gaál, 2002; Belicza – Zékány, 1998).

The development of the concept of quality and performance used in the business sector shows several similarities. For example, both concepts broadened the scope of the stakeholders whose demands and requirements the entity wants to meet. Interpretation levels have also widened: both concepts are applied for example at organizational level and at the level of processes. The two concepts overlap when interpreted at the different levels: for example, the quality of a product or a service is among the features of operational level of business performance (Wimmer, 2001), while process performance is listed as one of the dimensions of business excellence which refers to organizational quality (Demeter, 2010) (see EFQM model).

There is a change of view regarding the concept of quality that the relationship between quality and costs is not based on a single trade-off, but quality improvement can bring about cost saving (for example by avoiding unnecessary waste), therefore we can conclude that quality and efficiency are not contradictory concepts. This implies that there is a correspondence between the concept of quality and the efficiency dimension of performance as well, while the effectiveness dimension of performance remains in close relationship with quality.

### 2.2.3.2. The interpretations of performance and quality in the public sector

The concept of performance is far from being unambiguous and from being consequently used in the public sector. According to Bovaird (1996, p.147, quoted by Bouckaert – Halligan, 2008) performance „is not a unitary concept, within an unambiguous meaning. Rather, it must be viewed as a set of information about achievements of varying significance to different stakeholders.” Bouckaert and Halligan (2008) make a distinction between the span and the depth of performance. The span of performance covers several dimensions of performance within and beyond the limits of an organization, including the dimensions of effectiveness and cost-effectiveness, too. The depth of performance refers to the level on which performance can be measured, such as micro level (individual public sector organization), meso level (level of a policy field or a product/service chain) and macro level (government performance) (Bouckaert – Halligan, 2008).

In the public sector the concept of quality is also lacking a standardized definition and it is changing continuously. It has been interpreted from many different aspects, such as conformity-based approach, system-based approach, strategic management approach or psychological approach. The viewpoint from which we approach quality is crucial in the public sector, as the different stakeholders may have very different levels of expectations and perceptions. The quality of some public services can be experienced at the level of the individual, but in the case of more complex services quality must be interpreted at the level of the society as a whole. (Bovaird – Löffler, 2009) While formerly quality improvement and productivity aims were considered as contradictory, as a result of a new approach these concepts are seen as complementary of each other in the public sector, too (Aristigueta, 2008).

The models of performance and quality in the public sector (Bouckaert, 1995; Bouckaert et al. 1997; Hatry, 1999; Bouckaert, 2002; Bouckaert – Halligan, 2008; Bouckaert – Van Dooren, 2009) can support a clearer understanding of these concepts. However, the use of the two concepts in practice is usually mixed-up. Both quality and performance can be interpreted at many different levels in the public sector: within the organization, at organization level, at the level of society. Most authors interpret both concepts following the basic input-output model (Bouckaert et al. 1997), and at the highest level both concepts are related to a superior goal, which is to enhance trust.
As management methods used in the business sector are more and more widely used in the public sector, the terms of quality and performance are used side by side (e.g. in indicator systems or in performance measurement or quality management models) (Aristigueta, 2008). This results in the blurring of the differences and a mixed-up use of the two concepts in practice\(^{32}\).

### 2.2.3.3. The interpretations of performance and quality in the Hungarian health sector

In the publications referring to the Hungarian health sector the concept of performance hardly ever appears in its wide sense\(^{33}\) as used in the business sector. A reason for this is that the term performance is mostly used in the context of a certain financing method introduced in Hungary in 1993. The so-called performance-based financing refers to HBCs-based (the Hungarian version of Diagnosis related Groups, DRGs) financing in in-patient care, and the fee-for-service payment in outpatient care.\(^{34}\) Therefore, the use of the concept is closer to the concept of ‘volume’, as the above mentioned systems measure outputs (Belicza – Evetovits, 2010). The National Health Insurance Fund Administration finances the institutions on the basis of type and volume of care (and the type of disease in case of HBCs), and the financing authority does not investigate the effectiveness and the efficiency of care.\(^{35}\) The use of the term ‘performance’ in the financing context is so widespread that it has to be taken into account in the case my PhD research.

The dimensions of the concept of performance in the business and public sector are used similarly, although in a narrower sense, in the Hungarian literature on health economics. Evetovits and Gaál (2005, p. 110.) propose the following terminology for health economics (considering translation problems):

- efficacy = ‘hatásosság’ (health gain that ideally can be achieved\(^{36}\))
- effectiveness = ‘eredményesség’ (health gain achieved in practice)
- efficiency = hatékonyság (comparison between input and output/outcome)”.

Besides the two dimensions usually applied in the business sector the dimension of efficacy appears, which is frequently used in the health literature (for example in case of controlled clinical trials). Efficacy differs from efficiency in that the former measures an ability, while the later measures the real effects. Although these three definitions derive from the field of health economics and are created to support health technology assessment, they harmonize with the definitions of performance used in the business sector, and with those used by the public sector to describe performance at organizational level. The main difference is that the definitions are health sector specific: effectiveness, for example, is related to the improvement in state of health. The interpretation at organizational (hospital) level can be wider, as

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\(^{32}\) An example for this is the OECD report from 1996, in which the term ‘service quality initiatives’ is what Aristigueta (2008) considers as the appearence of performance measurement movement.

\(^{33}\) See the translation issues of the term ‘pay for performance’ discussed by Belicza – Evetovits (2010); and see for wider sense Kiss – Révész (2005) and Kovácsy – Kiss (2009).

\(^{34}\) Financing methods are discussed in subchapter 5.2.

\(^{35}\) Analysis of effectiveness and efficiency of technologies are considered for the decision about reimbursement, however, once in the reimbursement system it is not examined or supervised how effectively or how efficiently these technologies are applied in practice by the providers. Still, this kind of performance-based financing is a step towards improving (technical) efficiency and is more correct than the previous system, where financing was based on the volume of the previous year (but it does not enhance allocative efficiency or quality). (for more details see section 5.2.3.)

\(^{36}\) Health gain: “improvement of state of health as a result of using health care services” (Evetovits – Gaál, 2005, p. 101.). That is to say, this definition of health gain is a health care specific definition of outcome.
besides the improvement of state of health the improvement of patient satisfaction, for example, can also be an important objective of a hospital, and patient satisfaction is influenced by other factors as well.

The concept of quality has wide interpretations in the Hungarian health literature, especially when detailing the dimensions of quality. Donabedian’s work (1966), in which he applied the concept of quality to the structure, processes and outcomes of health care, exercised the most important influence on the development of the concept of quality in health care (Belicza – Zékány, 1998; Orosz, 2001). Structure includes economic conditions, management, infrastructure (buildings, equipment), personnel (with their qualifications and experience) and regulatory systems (like quality management system). Processes include processes of health care (including decision making and execution) and related processes (such as communication). Outcome includes change in state of health, and also patient satisfaction and changes in health-related behavior. (Belicza – Zékány, 1998; Orosz, 2001)

According to Belicza – Evetovits (2010) the concept of quality can be applied to structure, professional and organizational processes, professional outcomes, patient perception and patient satisfaction. (These applications are in concordance with Bouckaert’s (1995) interpretation of the concept as applied in the public sector.)

According to the definition proposed in 1994 by the Consulting Center for Quality Improvement in Health Care (Egészségügyi Minőségfejlesztési Konzultációs Központ, EMIKK), „quality can be interpreted as the level of achieving certain goals and objectives” (Belicza – Zékány, 1998, p.26.). In 1995 Hungarian experts gave the following definition based on consensus: „The quality of a health service is a value judgement which expresses to what extent the expressed requirements of the stakeholders participating in the process of retaining, restoring and maintaining health are fulfilled.” (Belicza – Zékány, 1998, p.26.)

The most frequently listed dimensions of quality in health care are: effectiveness, efficacy, efficiency, appropriateness, timeliness, continuity, safety, accessibility, patient satisfaction. (Joint Commission, 1990; Gulácsi, 2000; Gődény et al. 2009; Belicza et al. 2010; Belicza – Evetovits, 2010) According to Belicza – Zékány (1998) the concepts of effectiveness, efficacy and efficiency are in concordance with the health economical interpretations described in the previous section.37 Belicza and Zékány (1998) point out that at the different levels of interpretation (e.g. system, organizational, service level) the weight of these dimensions may vary. (For example, at the level of the whole system equity is also proposed as an important dimension.)

The wide interpretation of quality in the health sector is not specific for Hungary only (see Øvretveit, 1999 or the definition by Leebov as quoted by Belicza – Zékány, 1998). Efficiency appears in most definitions of quality in health care, and it is considered as an integral part of quality (Gődény, 2007; Jenei, 2010).

As a result of the great variety of stakeholders in the health system many interpretations of quality are possible: Belicza – Zékány (1998) calls attention to the possibility of different interpretations by patients, health professionals and the management. Topár (2008) proposes to take into account the needs, requirements and goals of a wide stakeholder group, including patients, owners, financing authorities, health policy makers, governmental and local policy makers, management and personnel.

37 Gulácsi (2000) applies different translations from the ones used here, but the content of each definition is fairly similar.
In the Hungarian health care practice the interpretation of performance and quality are wider or slightly different from the interpretation used in business and public sector: the concept of performance in its wider sense is not used in the Hungarian health sector, as it is strictly applied to refer to the peculiarities of a financing method. On the contrary, the interpretation and use of the concept of quality is so wide, that it includes practically all the dimensions of organizational-level performance of business sector. When defining external hospital evaluation methods in subchapter 4.1., and when applying these concepts for the empirical study, these differences in the interpretation of the concepts were thoroughly considered.

This chapter pointed out the relevant features of the theories that are related to the external evaluation of hospitals, that as evaluation, quality management and performance management, on which the definitions of (see subchapter 4.1) and the classification of (see subchapter 4.2) hospital evaluation methods will be based. The next chapter offers a summary of the relevant basic statements of theories that describe hospitals and hospital environment that is the peculiarities of health sector and professional bureaucracies.
3. **Theoretical background: peculiarities of the health sector and hospitals**

This Chapter describes the context of my research topic, focusing on the peculiarities of hospital environment and the organizational characteristics of hospitals. Firstly, those consequences of the peculiarities of the health sector are presented that influence on hospitals. Secondly, the actors of the health sector. And thirdly, the hospital is characterized as a professional bureaucracy. Together with the theories of evaluation, quality management and performance management described in Chapter 2, the characteristics of the health sector and the theory of professional bureaucracies provide the theoretical background for this research. The relevant elements of these theories allow to have a better knowledge of the interests and relations of internal hospital actors, and to better understand their perceptions and reactions.

### 3.1. The consequences of the peculiarities of the health sector

The author of the present dissertation agrees with those economists who consider it important to take into account the peculiarities of the health sector when analyzing the situation of stakeholders in the health sector, and who claim that these peculiarities cannot be ignored just because similar elements appear and are analyzed in other sectors. According to Kornai – Eggleston (2004) the peculiarities of the health sector are the following: the value of health, the norm of equal access, uncertainty and the demand for security, the asymmetric nature of information, the problem of selection (adverse selection, risk selection), moral hazard, supply-side power and monopoly, the defenselessness of the patent and mounting costs. „The specificity of the health sector stems from possession of all these characteristics at once. Furthermore, some characteristics assert themselves with great intensity.” (Kornai – Eggleston, 2004 p.43.)

The present dissertation does not aim at describing all the characteristics of the health sector, as they are thoroughly analyzed in the publications on health economics by authors like Donaldson – Gerard (1992), Folland et al. (2007), and by Hungarian authors such as Orosz (2001), Kornai – Eggleston (2004), Brandtmüller – Lepp-Gazdag (2005), Lepp-Gazdag (2005). The most relevant consequences of these characteristics to the dissertation are: there are three intervening actors in the health sector (as contrary to the duality of the seller-customer roles); asymmetrical nature of the information can be observed between different actors (between patients and providers, or between insuree and insurers), which can have very serious consequences that are described below.

The modification of the roles of buyers and sellers in the health sector is due to the uncertainty of the demand for health care. In case of several health services the time and scale of needs cannot be predicted. This uncertainty explains the appearance of third actors, insurers / financing authorities. Therefore, customer’s roles (consumers and payers) are represented by two different entities (see Figure 3.).
These relationships are relevant to the dissertation topic, because under this constellation the self-regulatory mechanisms of a perfect competitive market seem not to work in the health sector. Therefore, in the health sector the failures of the insurance market (moral hazard, selection) generate a need for state intervention and bureaucratic coordination mechanisms, which mechanisms serve to mediate between the different actors, and which assure that the demands of these actors (patients, insurers, providers) will be met, although the actors are not able to force the fulfillment of these demands under the circumstances of an evident market failure. Asymmetric information can be mentioned as one of these failures.

Asymmetric nature of information can be experienced in the relationship between patient and provider (e.g. physician), between insurer and insure and between insurer and provider, too. The patient is much less aware of the subject of the transaction, that is, of the type of health care they really need, than the physician/provider. On the other hand, patients as insurees might have much wider knowledge of their condition (past and future health problems), than the insurer does. At the same time, the provider disposes of more detailed information on the benefits and the costs of a certain type of care, than the insurer or the financing authority does. The consequences of the asymmetric information are: the agent role of the provider, the defenselessness of the patient, moral hazard and provider-induced demand.

Considering that patients do not have enough information of what kind of care they need and when they need it, the physician (as provider) assumes the role of choosing between the alternatives (agent's role). This means that the provider, who represents the side of supply, influences on the demand. We are facing the principal-agent problem, where the patient has no sufficient information, and where, in most cases, it is not the patient who pays for the health care, and he has no significant control over the decision making process. Patients become defenseless. Although conscience and ethical norms are supposed to make physicians to represent patients' interests, it can happen that providers are influenced by the effects of certain incentives (financing techniques, e.g. fee for service), and they provide more care than necessary. This phenomenon is called provider induced demand. As a consequence of the characteristics of the insurance market patients may also be interested to use more expensive types of

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38 State intervention will evidently not solve all the problems as so called governmental failures also intervene. (see Orosz, 2001).
39 The Hungarian terms 'beteg' and 'páciens' are interchangeably used here for the English term 'patient'.

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care, as they do not directly experience the cost of care. This kind of insensibility is referred to by the term moral hazard, which can manifest both at the side of the physician/provider (provider induced demand) and at the side of the patient.

Why these characteristics are relevant for the present dissertation? These characteristics cause that the stakeholders of the health care system need enforcement, regulation and incentives to be able to meet social and individual requirements. While in the business sector effective purchasing power enforces the adequate supply, in the health sector this does not happen automatically. Hospitals, which are in the focus of this research, are forced by several factors, such as state regulations, supervisory authorities, financing techniques applied by insurance companies, and other stakeholders like patients (individuals or represented by patients’ rights organizations) also try to push through their requirements.  

External hospital evaluation methods serve in fact to mediate these requirements of the external stakeholders. While optional external evaluation methods like ISO or EFQM can serve as a communications tool applied by hospital management, however, they can also be introduced to meet external requirements. Therefore, it can be concluded that the introduction of external evaluation systems may serve very different purposes. The analysis of these purposes would lead to a detailed analysis of external evaluation methods, which is presented in Chapter 4.

Before beginning to describe the external evaluation systems in detail, the following subchapters will list the stakeholders of the health care system and will offer a description of the hospital as professional bureaucracy.

3.2. The actors of the health care system: the stakeholders of the hospital

Orosz (2001) offers a possible grouping of the actors of the health care system:

- patients/consumers (at the same time, they are those who pay tax and contributions),
- providers (individuals and institutions, including the owners and management of the latest),
- financing authorities (private insurers, compulsory insurers, state health authority),
- institutions carrying out education and research in health care,
- central government and municipalities,
- health workers’ professional organizations (chambers and unions),
- civil organizations that promote health and prevention, patients’ rights organizations,
- suppliers of health technology and equipment.

Considering these actors, external hospital evaluation methods can examine how hospitals perform and meet the requirements of the following stakeholders: patients (past, present and potential, that is, the whole population), patients’ relatives and adherents, patients’ organizations, the referring physician (e.g.

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40 In case of hospitals bureaucratic coordination mechanisms are not the only ones. Some situations are similar to business sector competition between providers (like quasi-markets mentioned by Orosz, 2001), while hospital personnel’s internal motivation and their willingness to fulfill with ethical norms can also work as a coordinating force.

41 They are also tools, like the financing techniques applied by the insurers / financing authorities. Moreover, external evaluation methods can be applied together with financial incentives. (see also Chapter 4.).

42 Suppliers of health technology and equipment are mentioned by Orosz (2001), but the author does not include them among the stakeholders of the health care system. The present dissertation includes them among the actors, as they are important stakeholders of hospitals, which are in the focus of this study.
GP), financing authorities, supervisory authorities (e.g. ministry, supervisory board), municipalities, partner organizations like outpatient clinics, ambulance, patient transportation organizations, educational and research institutions, professional organizations, civil organizations, suppliers and internal stakeholders, such as owners, management and employees. It is essential for the dissertation topic that the demands and expectations of the stakeholders of the hospital are considered as external hospital evaluation methods measure to what extent the hospital is able to reach these requirements (see definition in subchapter 4.1).

The emergence, spread and ‘extinction’ of external hospital evaluation methods rely on the value-based, interest-driven decisions made by the health care stakeholders. Orosz (2001) points out that in order to better understand the reforms and events in the health system it is essential to analyze the situation and the motives of the actors. According to Orosz, the actors’ situation is influenced by their share of power, by the available resources and tools, and it is also important to distinguish between their manifested aims and their real actions, and to try to find the reasons for the discrepancies. These considerations are relevant to the actual dissertation topic, too.

3.3. **The hospital as professional bureaucracy**

This dissertation focuses on understanding the internal hospital processes and the behavior of hospital actors. Therefore, this subchapter is dedicated to describe the characteristics of a hospital as an organization.

Some authors (Mintzberg, 1980; Mintzberg, 1991; Lozeau et al. 2002; Bertrand – de Vries, 2005) mention complex tasks and the dominance of highly trained professionals as the principal characteristics of the hospital as an organization. Professionals carry out complex tasks, they are usually trained for years outside the organization (at universities or other institutions), and then they are required to participate in further training according to the requirements of the organization. (Mintzberg, 1991) However, professionals do not only acquire professional knowledge and rules, but they also demand the right for shaping these rules (Kováts, 2012) and to decide on who can be considered a professional (e.g. by introducing compulsory chamber membership) (Kornai – Eggleston, 2004). Doctors are the professionals within a hospital. Complexity of tasks which requires several professionals is not only a characteristic of hospitals, but of other institutions as well, such as universities, accounting companies, consulting groups, architects’ and lawyers’ offices. Due to the similarities of their characteristics these organizations belong to the group of ‘professional bureaucracies’.43 This subchapter describes professional bureaucracies following Mintzberg’s (1991) study.

Mintzberg (1991) distinguishes seven different forms of organizations: entrepreneurial organization, machine organization, diversified organization, professional organization, innovative organization or

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43 Complexity of professional work also characterizes other fields such as complex scientific research, space research, petrol chemistry or even movie production. However, these fields are also characterized not only by the complexity of tasks, but also by a dynamically changing environment, which does not allow the organizations to operate within the framework of professional bureaucracy. Therefore, the typical organizational form for these organizations is adhocracy or innovative organization (see Mintzberg, 1991).
adhocracy, missionary organization and political organization. Mintzberg highlights that these are idealized types and simplifications, in practice we cannot find any organization that would be exactly like the ones he describes, and most organizations are a combination of, or a transition between the two models.

Another denomination for professional organization is ‘professional bureaucracy’, reflecting that the environment of these organizations is relatively stable, because relevant knowledge does not change as rapidly as in the case of adhocracies (innovative organizations), for example, which allows that standardization of skills can appear as a possible coordination mechanism. Mintzberg (1991) distinguishes six organizational coordination mechanisms: mutual adjustment, direct supervision, standardization of work processes, standardization of outputs, standardization of skills and standardization of norms. Standardization of skills generally takes place outside the organization: professionals who represent the operational core of the organization (see figure 4) arrive to the organization with their skills as an input. Coordination is possible, because during their studies physicians internalize the system of knowledge and norms and hereby the expectations towards each other. The work of professionals is complex and is based on complex skills, which makes standardization more difficult than in the case of machine bureaucracies. Output of professional work is hardly measurable, which means that standardization of outputs also results problematic. Therefore, standardization of skills becomes the dominant coordination mechanism on which these organizations rely.

Operation of professional bureaucracies is based on the work of professionals, who gain considerable power in decision making situations, including decisions on operational functions or on organizational strategy (horizontally decentralized organization). Power cannot only be used by professionals, but also by the institutions (universities, professional colleges and chambers) that train this powerful class of professionals, as in fact these institutions exercise control over the professionals they train (this control derives on the one hand from the determination and specification of the curriculum and professional guidelines / protocols and on the other hand from the enforcement of these). It is also true that this control is mainly exercised during the training period, or in certain cases (e.g. medical audit), but it does not directly influence on the daily practice. Therefore, autonomy of physicians is considerable, which means that they work independently from their other colleagues, but in close relationship with the customers (patients, in case of hospitals).

44 Mintzberg (1980) originally distinguishes five organizational forms responding to the first five categories enlisted here: simple organization, machine bureaucracy, divisional form, professional bureaucracy and adhocracy.
Figure 4.: Professional bureaucracy

![Diagram of professional bureaucracy](image)

Source: Mintzberg (1991), Figure 1, p. 332.

Figure 4 illustrates Mintzberg’s five structural elements of professional bureaucracies. In these organizations the principal element is the operating core. Due to the independence of professionals the management level (strategic apex and middle line) is small, while the level of operating core can be quite extended. Besides physicians the operating core includes nurses and health professionals, but physicians dominate and they define the way of care (Lozeau et al. 2002). Technostructure level, which includes analysts, is not strong in this structure, as their task consists of planning and supervising the work of the personnel, but this type of control (the standardization of the work processes and outputs) can hardly prevail. However, the expensive work of professionals is considerably supported by an extended support staff (laboratories, cleaning staff, maintenance, etc).

Considering all this, what are the characteristics of the operation of such a professional organization? According to Mintzberg, at the operational level professionals apply ‘pigeonholes’, standardized programs in case of familiar situations. Professionals match standardized programs to appropriate situation when they diagnose. 45 In case of physicians such standardized programs are based on professional guidelines applied in the form of concrete hospital protocols. However, despite standardization of knowledge and skills, the complexity of tasks deriving from the great number of and the great variety of influencing factors usually do not allow any routine application of ‘pigeonholes’.

Due to decentralized organizational structures, professionals do not only control their own professional work, but they exercise a kind of collective control over the decisions that affect their work, like the employment of new colleagues or the distribution of resources. Professionals gain such control by taking over part of the management tasks (administration), and by nominating their representatives to the most important positions of the management. This leads to a democratic structure, in which the coordination of administrative tasks requires mutual adjustment, and where temporary and standing committees are established to support organizational operation.

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45 Diagnosis is not necessary in machine bureaucracies, as standardized program series are initiated by a simple stimulus. On the contrary, in innovative organizations professionals face problems that require creativity to solve.
The work of support staff (patient admission, catering, cleaning, etc.) can be organized according to the characteristics of a top-down controlled machine bureaucracy, where standardization of work processes can be widely applied. This means that in a professional bureaucracy there are two coexisting hierarchical structures: a democratic, bottom-up hierarchic structure in case of professionals, and a top-down hierarchy in case of support staff.

Although the managers of a professional organization cannot directly control the work of their professionals, there are many other fields where they dispose of considerable direct power. Managers mediate in case of internal conflicts between professionals, and in conflicts between internal professionals and external stakeholders (e.g. government, financing authorities, patients’ organizations, etc) that exercise influence on the organization. External stakeholders usually expect an overall control over professionals from these managers, while professionals demand autonomy, so the balancing ability of managers becomes crucial. This means, that in professional bureaucracies power is held by those who can assume these managerial qualities, and even so, they will only be able to maintain this power if professionals consider that their interests are fully and properly represented.

According to Mintzberg, democratic structures and autonomy contribute to the motivation of professionals in professional bureaucracies, but at the same time democracy can also lead to typical problems affecting coordination, decision making or innovation. Standardization of skills is not a solution in all situations that require coordination. Coordination between professionals and support staff can be tricky when the later receive instructions from the management and from the professionals at the same time. Standardization of skills does not cover each of the everyday situations, which may lead to conflicts. Another problem is that in everyday organizational operation professionals have to make important decisions by themselves. The organization can work well only if professionals are competent and conscientious, and they consider the interest of both patients and the organization. The third problem is innovation. Innovation requires cooperation and collective action from professionals, but the complexity of the collective tasks usually results in that professionals are unwilling to cooperate and that they resist to innovation. However, changes are also present in professional organizations, but usually at lower levels of coordination: content of standardized programs is changing continuously, new pigeonholes are created as a result of collective decision making and the existing ones become restructured. Still, at a higher level these organizations are basically characterized by stability.

As a solution for these three problems stakeholders (others than professionals) propose external control. However, Mintzberg argues that standardization of work processes and standardization of outputs do not offer a solution because of the complexity of professional work. External control methods place responsibility for the provided services on a technostructure, and take it away from professionals, and this impedes effective operation, because it is not the government, the health system or the hospital that provides real care for the patient but the doctor. If doctors do not excel in their profession, no plan, rule or regulation can provide appropriate care. (Mintzberg, 1991) Mintzberg claims that changes in the performance of professional organizations can be reached by generating slow changes among professionals by the application of selection mechanisms, by the internalizing new norms and by further professional training in accordance with these norms.46

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46 Porter and Teisberg (2006, pp. 221-225.) also argue for the importance of redefining the content of physician training. In his case study on Hungarian hospitals Jenei (2009) also points out the possible effects of the system of medical education and training on organizational culture.
There is the question of whether the conditions of the existence of professional bureaucracies established by Mintzberg (complexity of tasks, stable environment) can be considered as relevant for all cases in the present and in the future? Nowadays, less complex tasks are not any more performed by physicians but by other health workers (e.g. nurses perform vaccination task). Is hospital environment really stable? Mintzberg (1991) mentions that the environment of university clinics is dynamic, which implies that new or modified organizational structures may appear. What effects will technological development have on hospital organizational operation and on the work of physicians? As a response to these challenges several authors propose new organizational structures for professional organizations and for hospitals (Mills et al. 1983; Quinn – Paquette, 1991; Lega – DePietro, 2005). Porter and Teisberg (2006) offer a solution to the problems of the health care system by introducing a value-for-patient system with the active participation of the health care providers including hospitals (‘value for patient’ strategy). These authors propose models restructure hospitals, while Mintzberg’s model of professional bureaucracy describes real, currently operating hospitals. Therefore, Mintzberg’s model is used as a theoretical background for the present dissertation.

### 3.4. Differences in assumptions of the background theories

Chapter 3 described the theories that characterize the environment, operation, interests and relationships of the stakeholders of the hospital examined in this research, namely the characteristics of the health sector and the theory of professional bureaucracies. There are considerable differences between the assumptions of these theories and the assumptions of the theories described in Chapter 2 referring to evaluation, quality management and performance management. Lozeau et al. (2002) have already pointed out theses discrepancies in a research that analyzes how Canadian public hospitals adapted business sector management methods, with special focus on quality management and strategic planning methods.

Lozeau et al (2002) labeled as ‘compatibility gap’ the differences between the theoretical hypotheses of management methods and the peculiarities of the organizational structure and operation of public hospitals. The relevant results of the analysis of this compatibility gap are summed up in table 1.
The ‘compatibility gap’ as described in Table 1 refers to theories. In practice the behavior of hospital actors and the assumptions of the developers and users of external hospital evaluation methods that influence on the characteristics of the applied method may considerably differ from the assumptions of the theories described in Chapter 3. This empirical study reveals the differences of interpretations by analyzing the assumptions and behavior of evaluators and of the internal actors of the hospital.

The first two chapters of the present dissertation described the theoretical background of the research on which the analysis of the external hospital evaluation is based. The next chapter is dedicated to make a proposal on the classification of external hospital evaluation methods, and to sum up research results on the effects of these methods.

<table>
<thead>
<tr>
<th>Table 1. Compatibility gap in theory</th>
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<tbody>
<tr>
<td><strong>Assumptions that lay behind the management methods applied in the business sector</strong></td>
</tr>
<tr>
<td><strong>External relations</strong></td>
</tr>
<tr>
<td>– ‘market’</td>
</tr>
<tr>
<td>Demand is represented by several stakeholders (patients, financing authorities), Patients’ influence is weak</td>
</tr>
<tr>
<td>– ‘institutional’</td>
</tr>
<tr>
<td>Institutional constraints: government, union and professional groups constrain choices</td>
</tr>
<tr>
<td><strong>Internal relationships</strong></td>
</tr>
<tr>
<td>– leadership</td>
</tr>
<tr>
<td>Diffuse leadership: strategy and operating processes are heavily influenced by key professionals (doctors)</td>
</tr>
<tr>
<td>– internal influence flow</td>
</tr>
<tr>
<td>Fragmentation, negotiated order: Strategic priorities and operations are defined locally via interaction of professionals and hierarchical power</td>
</tr>
</tbody>
</table>

Source: based on Lozeau et al. 2002.
4. Classification and effect of external hospital evaluation

This Chapter provides a definition for external hospital evaluation methods. Then a typification of hospital evaluation methods and their effects are described. Previous research results on hospital evaluation methods make it evident that a systematic model is needed to support comparison of previous research results, to define the scope of these results, and to define the aims of future research. This need has been expressed by several studies of international research. Therefore I make a proposal of the classification framework of hospital evaluation considering former classification attempts and the typifications in the area of the specialty of evaluation. The second part of this Chapter focuses on international research results on the effects of external hospital evaluation on hospital care and management and on the behavior of hospital actors.

4.1. Defining external hospital evaluation methods

Chapter 2 described how the relating fields of specialty of evaluation, quality management and performance management interpreted the concept of evaluation. Chapter 3 introduced the stakeholders of hospitals. The concepts used in these previous chapters serve as a basis to provide a relevant interpretation of organizational evaluation.

In the present dissertation organizational evaluation is defined as: a method-based analysis of the performance and/or excellence\(^{47}\) of an organization, and the comparison of the results with the explicit or latent expectations. The method applied can be based on quantitative measurement, or on a method that narratively describes the organization, without using quantitative measures.

This dissertation analyzes the hospital as an organization, therefore, external hospital evaluation is reckoned among organizational evaluation, which implies that the given definition prevails.

The term ‘hospital’ is used here for publicly financed Hungarian institutions providing acute in-patient care. This does not mean that the hospitals involved in this research provide exclusively acute in-patient care, but that they provide this type of care either exclusively or together with other types of care, like chronic in-patient care, outpatient clinic, etc. Therefore, the evaluation methods are not exclusively applied to in-patient care, but they may affect other types of care provided by the hospital, too. The number of hospitals between the years 2000 and 2009, and in 2012 is shown in Table 2.

<table>
<thead>
<tr>
<th>Table 2. Number of hospitals providing acute in-patient care</th>
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<tbody>
<tr>
<td>number of hospitals</td>
</tr>
</tbody>
</table>


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\(^{47}\) Organizational excellence is meant by organizational level interpretation of quality (See subsection 2.2.3.1.).
It is important to define which organizational aspects of the hospital are evaluated. **This research focuses on hospital evaluation methods that evaluate how the hospital achieves the proposed objectives and as a result how they meet stakeholders’ demands and expectations.** This definition is close to Neely’s et al. (2004) wider interpretation of performance (see subsection 2.2.3.1.), but it also includes the Hungarian interpretation of quality of services (see subsection 2.2.3.3.). The term ‘stakeholders’ can have a wide interpretation. The group of hospital stakeholders is described in subchapter 3.2. Subchapter 2.2. highlighted the dilemma of the different interpretations of the concepts of performance and quality, therefore, these terms are not referred in previous definitions. As the term ‘performance’ is used in a narrower sense, as an adjective of certain financing techniques in the Hungarian literature, I prefer using the term ‘quality’ in the present empirical study if it is needed. That is to say, interviewees were asked about external hospital quality evaluation methods. The examined hospital evaluation methods are not fully comprehensive in all cases, which means that they may focus on the demands and expectations of only a few stakeholders and they may assess only some of the services provided by the hospital, not all of them (like Standards of Hospital Care introduced in 2001 only referred to in-patient care within the hospitals). Sometimes the evaluation method applied does not cover all the possible dimensions of quality or performance, but only one of them (like efficiency or patient satisfaction) or maybe a combination of some dimensions.48

This dissertation focuses only on external hospital evaluation methods. In these methods one of the external stakeholders of the hospital evaluates the institution. The external evaluator stakeholders may be: authority, financing authority, patients’ organizations, accreditation board, or other independent evaluator (e.g. based on EFQM).49

Considering the above mentioned definitions of organizational evaluation, hospital and external evaluator stakeholders, the definition of external hospital evaluation methods is: **models and practically applied tools for systematic analysis that external stakeholders use to evaluate how hospitals achieve the appointed goals and objectives, and hereby how they satisfy their stakeholders’ demands and expectations.**

#### 4.2. Characteristics of the evaluation methods

External hospital evaluation preferably applies the methods used by performance management and quality management. Although some of the elements of these management areas had been formerly applied in public sector organizations, they became widespread due to the New Public Management (NPM) movement (see Zupkó, 2001; Jenei, 2004; Pollitt et al., 2007) that emerged in the Anglo-Saxon countries at the end of the 1970s. Following the organizational and the management reforms of the 1980s and the 1990s, the NPM became popular in other European countries as well. NPM involves all the initiatives that aim at promoting efficiency, effectiveness, accountability and transparency of public

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48 When evaluation does not globally assess the organization as a whole we talk about analytic evaluation (see 2.1.2.4.). Among analytic evaluation an example for component evaluation is when a hospital specialty is evaluated and an example for dimensional evaluation when we evaluate according to the dimensions of quality and performance.

49 Hospital stakeholders in Hungary, 2013, and the evaluator stakeholders are described in Figure 8. of subchapter 5.1.

50 The term is used since the 1990s due to the influential article by Hood (1991).
services. As a result of this movement the application of institutional evaluation methods has become widespread in several areas of the public sector (like public administration, education or health care). The methods applied may vary considerably according to their aim, tools and aspects. (Some possible aims of external hospital evaluation are for example: quality improvement; accountability; transparency; supporting patients’ decisions in choosing care by publishing reports; pay for performance/quality; allocating resources; supporting health policy decision making). In order to better understand the effects and mechanisms of the individual evaluation methods, it is recommended to classify them according to their principal characteristics. This classification framework also helps to define the scope of relevance of this research, and the characterization of the features of hospital evaluation methods studied in the empirical research details knowledge about a certain method.

The following section describes the characteristics and classification proposals in the literature that may be applied for classifying the organizational evaluation methods used in public sector. The second part of this subchapter is dedicated to highlight the important characteristic features of hospital evaluation methods and to construct the classification framework proposal. The content of this framework will be illustrated by foreign examples.

4.2.1. Classification of the evaluation methods in the literature

The need for a classification framework for evaluation methods has emerged several times in the literature on evaluation methods for public sector organizations and when the further research area is appointed (Boland and Fowler, 2000; Gröne et al. 2009). In the public sector literature the authors who make an attempt to propose classifications offer examples that are generally analog with the typifications proposed in Chapter 2 of this dissertation (see 2.1.2), although they usually do not refer to the field of evaluation. In the following the characterization used by the literature on public services in general will be described.

4.2.1.1. Internal vs. external evaluation methods

The principal consideration of public service evaluation systems is whether the evaluator comes from within or outside the organization. External evaluation of the organization is made by an external stakeholder, authority or an independent institution etc., while internal evaluation is performed by appointed members from within the organization. This distinction is used by Smith (1993) when he talks about internal and external regulatory systems in the case of performance indicator systems in public organizations51. This classification was used in the MARQuiS research project to classify hospital quality improvement strategies, and this was also used as a framework for empirical research in the project. The MARQuiS research project identified the most commonly used quality improvement methods by investigating quality policies and by interviewing leading professionals of 25 EU countries. (Sunol et al., 2009) The project classifies external evaluation methods as follows: accreditation / certification / license, governmental supervision or assessment, audit, ISO, indicator projects, benchmarking, EFQM model, national prize for quality and audit of laboratories (Spencer – Walshe, 2005). Further six methods were

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51 When referring to the literature I use the terms performance and quality according to the original sources. However, as it is described in section 2.2.3. their meaning usually overlaps.
classified as internal quality improvement strategies\textsuperscript{52} (Sunol et al., 2009). The ExPeRT\textsuperscript{53} research project supported by the European Committee distinguished four models of \textit{external} quality mechanisms, which are: accreditation, visitatie (based on the Dutch peer review model), EFQM model and ISO standards (Shaw, 2000). One of the dimension of the matrix proposed by Boland and Fowler (2000) also aims to distinguish external and internal evaluation methods. This matrix is described more in details in the following subsection.

4.2.1.2. \textit{Instrumental use of evaluation methods}

The instrumental or action-oriented evaluation type proposed by Patton (1996) and Scriven (1996), described in subsection 2.1.2.6, also appears in the literature on the evaluation of public organizations. An example for this is the study by Boland and Fowler (2000), where this method is one of the dimensions of the model proposed by these authors.

In their article that many other authors use as a reference (like Freeman, 2002; Veillard et al. 2005; Guisset, 2008), Boland and Fowler (2000) propose a two-dimensional matrix (see Figure 5.) to classify and analyze performance measurement tools and improvement initiatives in public sector organizations. The first dimension of the matrix is the \textit{control location} dimension, which distinguishes between the positions of the regulatory agent within or outside the organization (this distinction is also mentioned in the previous subsection). The second dimension is called the \textit{resultant action}, referring to the nature of controlling action, which, according to Boland and Fowler (2000) can be \textit{positive (supportive or beneficial)} or \textit{negative (threatening or punitive)}. Negative action supposes that for example the reasons for insufficient performance are an inappropriate usage of the resources, and, as a consequence, the controlling agent opts for decreasing the resources. Positive action in the same situation implies that the organization investigates the reasons for insufficient performance and it allocates resources to the problematic area, which implies the application of some organizational development strategy, like personnel training, for example. The authors claim that any performance measurement and improvement initiative of public organizations can be fitted into the matrix according to these two independent dimensions, and that the application of internal or external methods is necessarily followed by a positive or negative action. Therefore, these methods reckon among the so-called instrumental or action-oriented methods based on the typification of the specialty of evaluation.

\textsuperscript{52} Organizational quality management programmes (TQMs), audit and internal assessment of clinical standards, patient safety systems, clinical practice guidelines, performance indicators, systems for obtaining patients’ views.

\textsuperscript{53} ExPeRT = external peer review techniques, external method. The ExPeRT research project was carried out between 1996 and 1999.
Based on system theory approach Boland and Fowler argue that initiatives belong to external / negative quadrant „can easily lead to an overall worsening of public services rather than holistic improvement”, while the internal / positive quadrant „is the most desirable location for most public sector organizations, in terms of satisfying, in the long run, the needs of the majority of stakeholders.” (Boland – Fowler, 2000, pp. 423-424.)

However, in my opinion, the Boland – Fowler matrix is still not a really purified version for the classification of evaluation methods. On the one hand, the distinction of positive and negative actions used by Boland and Fowler (2000) involves value judgement in advance, and on the other, they mix and contract several possible distinctions in their classification. The distinction of positive (supportive or beneficial) and negative (threatening or punitive) resultant actions as presented in Figure 5 includes incentive types and the different approaches of evaluation role, too. The latest one is described in the following subsection.

Regarding the former one, that is the incentives related to methods used for performance measurement in health care were classified by Custers et al (2008). According to the authors the incentives can be financial or non-financial, and direct or indirect. (See examples in Table 3).

<table>
<thead>
<tr>
<th>Table 3. Examples for different incentive models</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>financial</strong></td>
</tr>
<tr>
<td>direct</td>
</tr>
<tr>
<td>– bonus,</td>
</tr>
<tr>
<td>– performance-based withhold,</td>
</tr>
<tr>
<td>– performance-based fee schedule,</td>
</tr>
<tr>
<td>– quality grants/performance fund,</td>
</tr>
<tr>
<td>– financial award</td>
</tr>
<tr>
<td>indirect</td>
</tr>
<tr>
<td>– cost differentials for beneficiaries</td>
</tr>
</tbody>
</table>

Source: Custers et al. (2008), Table 1.
In practice the evaluation methods of public organizations are followed by actions, decisions or incentives, according to which these evaluation methods are classified as instrumental use of evaluation among the types of instrumental vs. conceptual use of evaluation. (See subsection 2.1.2.6).

4.2.1.3. Formative vs. summative evaluation methods

The Boland - Fowler matrix has also been used by other authors to classify different methods. Veillard et al. (2005) applied the matrix to classify quality assessment systems54 with slight modifications in the original denomination of the dimensions (see Figure 6.).

Figure 6. Classification of quality assessment systems

<table>
<thead>
<tr>
<th>Source of control</th>
<th>Nature of expected actions</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>formative, supportive</td>
</tr>
<tr>
<td>Internal</td>
<td>e.g. WHO PATH program</td>
</tr>
<tr>
<td>External</td>
<td>e.g. accreditation</td>
</tr>
</tbody>
</table>

Source: Veillard et al. (2005), p. 488. Figure 1. (modified)

The new denominations are the source of control and the nature of expected actions. Furthermore, based on Freeman's article (2002) they introduce the terms formative and summative to characterize this later dimension. Veillard et al. (2005) clearly include the formative vs. summative distinction of the role of evaluation, but the authors do not separate these characteristics from the nature of the resultant action or incentive, although summative evaluation should not necessarily be followed by a punitive action, contrary to what is suggested in Figure 6.

Freeman's (2002) interpretation of summative evaluation refers to a situation when an overall, comprehensive picture is given, for example when organizations are compared and ranked. Meanwhile, formative evaluation supports organizational learning and development. This interpretation is in accordance with interpretations in the specialty of evaluation. Freeman (2002) carried out an extensive literature review on public performance indicator systems, which belong to organizational evaluation methods, and summarized their use pointing out two principal applications: summative mechanisms for external accountability and verification, and formative mechanisms for internal quality improvement. Thus, Freeman assigns summative and formative evaluation to certain goals and to the external/internal distinction as these are the most typical mechanisms, but this does not mean that they could not be matched with other goals or matched with other concepts within the matrix (Figure 6. contains examples for other possibilities).

54 Boland – Fowler (2000) postulated this matrix to classify performance measurement and improvement initiatives. However, it can be used to classify quality assessment systems, considering that Boland and Fowler used a wide interpretation of performance measurement and improvement, which also include quality systems. This is another example for the overlapping nature of the terms of quality and performance. (see section 2.2.3.).
4.2.1.4. The approach to knowledge

In his article Freeman (2002) points out an important characteristic of the evaluation systems used by public institutions. He claims that the two mechanisms of performance indicator systems used by public institutions differ in the level of need for information and in epistemology. Approach for accountability seek objective truth and claim „statistical validity and reliability” (Freeman, 2002, p. 129.), while improvement supporting approach uses additional data sources and local information to highlight relationships. This means that the former approach, which Freeman calls empirical, requires precise data, as its followers claim that statistical data processing can give an exact picture of the performance of a provider as compared to other providers. (Considering Freeman’s description this approach can be considered as a positivist one). According to the other approach, which Freeman calls interpretative, indicators serve as a starting point for further investigation about the circumstances and causes. Kazandjian’s (2003) remarks on interpreting organizational performance data and information also relate to the epistemological question of ‘how can we grasp reality’, in this case „how can we gain knowledge about the performance of an organization?” According to Kazandjian (2003) performance improvement is based not only on a visual culture, but also on an auditory culture. According to a visual culture „the message is best communicated through a visual display” (Kazandjian, 2003, p. 89.), which means by using tabular and graphical display of quantitative data. In this case we purely rely on the visual information supposing that it offers a complete picture of reality. Auditory culture, which is less developed in Western societies, claims that we need to observe the phenomenon and listen to additional information „in order to understand the reasons why a certain performance profile was observed”. (Kazandjian, 2003, p. 89.) There are types of information that cannot be quantified. These classifications are close to the typifications based on the distinction between quantitative vs. qualitative methods described in subsection 2.1.2. However, they can better highlight the difference between the methods, because they do not refer only to the way of data collection, but also to the assumptions of the evaluator about the way of having information of the performance of the evaluated entity.

4.2.1.5. Further aspects of classification

Gröne et al (2008) examined hospital performance indicator projects in an international review. After reviewing the literature they identified ten criteria: dimensions of hospital performance assessed by performance indicator project; number of individual indicators and of groups of indicators; the method for indicator development; compulsory or voluntary participation; number of participants; data collection method; public disclosure of reports or not; feedback mechanism, feedback time and budget. Among the ten criteria some may be applied to other fields of evaluation, such as to what extent the evaluation method covers the dimensions of performance and quality, or if participation in evaluation system is compulsory or voluntary.

The question of to what extent the evaluation method covers the dimensions of performance and quality refers to the dilemma of whether using analytical vs. global evaluation types (see subsection 2.1.2.4). When we use different dimensions within a method to assess the organization then we talk about analytical evaluation and final synthesis is not needed. Accreditation can be an example for global evaluation of public sector institutions, when the institution is ranked according to certain development categories. (However, the global evaluation of public institutions is really difficult to be carried out.)
Accreditation is also based on a group of standard dimensions, and it is hard to prove that all organizational areas are fully covered. Section 4.2.1 described classification models and features for evaluation methods used in the public sector as they appear in the literature, and it compared these classifications with typifications used in the specialty of evaluation (section 2.1.2). The next section presents a proposal for a classification framework based on the previous section, and with a view to support the present research.

4.2.2. Proposal for classification framework of hospital evaluation methods

One of the aims of this research is to propose a framework for the classification of hospital evaluation methods that is based on the models and typifications described in the literature, and which also supports the investigation of the present research. The scope of the present research is wider than that of other research projects and theoretical articles mentioned in the previous section, because this research does not make a distinction between quality and performance evaluation models. Distinction is neglected because many of the methods applied in real life practice cannot be unambiguously classified wether they are performance or quality evaluation methods, and the terms are used in overlapping way even in the literature.\footnote{In MARQuIS research project quality systems, strategies are used as a comprehensive category, while Boland and Fowler (2000) uses performance measurement and improvement as a comprehensive category.} The classification hereby proposed is wider also in the sense that can be applied not only to indicator projects (see Gröne et al., 2008), but also to standard-based systems\footnote{Indicator systems use measures to evaluate an organization, while standard-based systems – like accreditation or ISO system – compare organizational operation to statements, textual standards. „Standards describe an acceptable level of the performance of a health care provider or an individual”, and standards are „a general, but strict description of predefined requirements” (EUM, 2007, p. 127.).}. On the other hand, it is narrower, too, because this research focuses on external evaluation systems, and analyses exclusively their effects. The proposed framework is created principally for hospital evaluation methods, but it can be applied to evaluate other public sector organizations.

In the hereby proposed classification framework (see Figure 7) one of the dimensions describes the situation of evaluator distinguishing between internal and external evaluation. Another dimension is used to characterize the role of evaluation using the concepts of formative and summative evaluation. These two dimensions are used by the classification models of the evaluation methods of public sector organizations (Figures 5. and 6.). However, in the hereby proposed framework these terms are used with a clarified meaning, as described in section 2.1.2. This means that formative and summative characteristics are not handled together with the type/nature of the resultant action, but I use them to describe the role of evaluation as Scriven does (1966, 1991), who was the first to introduce these terms. The content of these typifications (internal vs external and formative vs summative) have been described in section 2.1.2.
The third dimension in the framework includes the different approaches of obtaining knowledge under the denomination of the approach to knowledge, these are referred in the literature, too (Freeman, 2002; Kazandjian, 2003). This dimension is containing the positivist and the interpretative approaches that refer to the epistemological questions of „how to grasp reality” (Gelei, 2007), and in this case ‘how to gain knowledge on the performance and excellence of an organization’. (Positivist and interpretative theoretical approaches are interpreted here with a view to practical applications, as it is also recommended by other authors (see Gelei, 2007).

When the term positivist is used in the proposed classification framework to characterize a method it means that the evaluation method is applied with the aim of objective measurement and assessment of the performance and excellence of the organization. The variables of the performance of the organization is explained and examined as elements of an external model. The typical methodology used is based on mathematical and statistical models, which are used to detect ‘real’ discrepancies in performance. Positivist evaluation methods use for example indicators or questionnaires. The underlying assumption is that the evaluation method does not have any effect on the evaluated organization, and that the evaluator can remain as an outsider, without influencing the evaluation results.

On the contrary, interpretative evaluation methods rely on locally available information and explanations, and consider that these support the evaluation process. These methods are based on the actors’ own interpretation of reality, and they do not try to fit phenomena into an externally established framework. They often use qualitative methods, such as interviewing or observation. In case they use indicators these only serve as a starting point for further investigation of the situation to explore real reasons. The evaluator is not an outsider here, but someone who has an influence on the organization and the evaluation process. Therefore, the result of the evaluation can be the product of both the evaluated organization and of the evaluator.

Freeman (2002) relates positivist (what he calls empirical) approach with the summative evaluation methods and the interpretative approach with formative evaluation methods when introducing the two
principal mechanisms of performance indicator systems. However, there are other evaluation systems (see BQS in the following section) that do not follow this scheme. In addition, the tendencies that prevail in practice show that evaluation methods tend to converge, and that they borrow several elements from each other, which results in the formation of mixed methods within the same dimension.

Besides the dimensions of the proposed classification framework, when we talk about hospital evaluation it is also important to take into consideration the nature of the resultant actions or incentives (see Figure 5. and Table 3.). The typification of these is also necessary, as their effect can be different in intensity (see Custers et al, 2008). One of the distinguishing features can be whether the resultant actions or incentives have a direct or an indirect effect (Custers et al, 2008), or whether positive or negative incentives are applied. Examples for actions and incentives are bonus, pay for performance (P4P) or public reports (see Table 3.). This latest can have an indirect effect through patients’ choice for providers, or a direct effect on the motivation of providers through publicity.

Other factors may also influence on the effects of external hospital evaluation methods, some of them are worth to take into account, such as:

- The evaluation method is applied for the whole organization or only for some areas of it, and which are the dimensions of performance and quality considered.57
- The use of the evaluation method is compulsory or voluntary.

The proposed framework (Figure 7.) serves to classify already established evaluation initiatives, because only the application of the models and methods can highlight how the political intents and the different interests of stakeholders influence on the functioning of the evaluation system (including the role of the evaluator or the approach to knowledge) and its effects. The same model, like an indicator system, for example, can be considered as summative or formative evaluation method regarding the role of evaluation, according to its practical application. It can also happen that the applied method is perceived differently by the different actors. This is the case, for example, when a voluntarily introduced external evaluation method is perceived by the participants as a compulsory task.

4.2.3. International examples for the different types of evaluation methods

Table 4. below illustrates the content of the proposed classification framework. The Evaluation and Quality Improvement Program (EQuIP) launched by the Australian Council on Healthcare Standards (ACHS) in 1996 can be considered as a formative method considering the role of the evaluation, and as an interpretative method, considering the approach to knowledge applied. The system includes standards, self-evaluation and systematic external peer review58, and it provides help for all kinds of health care providers to achieve and maintain high quality care and services and to prepare for ACHS accreditation.

57 These features relate to the typifications of global vs. analytical evaluation and within these types to the component and dimensional evaluation (see subsection 2.1.2.4.).
58 Peer review: Monitoring and evaluation of providers (GPs, dentists, nursing home physicians, physiotherapists, specialists, etc) and the discussion of results by professional groups in order to improve the quality of the services. (http://fogalomtar.eski.hu/)
Table 4. Examples of applied external hospital evaluation systems

<table>
<thead>
<tr>
<th>Example, country, year of start (- end)</th>
<th>The role of evaluation</th>
<th>The approach to knowledge</th>
<th>Extension/coverage (dimensions)</th>
<th>Participation</th>
<th>Sources</th>
</tr>
</thead>
<tbody>
<tr>
<td>EQuIP program by ACHS, Australia, 1996</td>
<td>formative</td>
<td>interpretative</td>
<td>the whole organization, several dimensions of quality</td>
<td>voluntary</td>
<td>Gröne et al. (2008), Braithwaite et al. (2006)</td>
</tr>
</tbody>
</table>


The benchmarking program of the German BQS (Bundesgeschäftsstelle Qualitätssicherung) institution is based on indicators, and their results are not published. BQS indicators are scientifically developed, tested and then applied in benchmarking of hospitals. The system is complemented by an active quality improvement program called structured dialogue, the aim of which is to identify problems and quality improvement activities. The BQS institute was responsible for the compulsory quality insurance program of German hospitals between 2001 and 2009. From 2009 AQUA institute took this task. (Gröne et al. 2008, http://www.bqs-institut.de/, http://www.aqua-institut.de). The BQS method can be considered as positivist in its approach to knowledge and formative in its role.

The indicator-based evaluation system used by the NHS (National Health Service) has been being developed since 1990s. An important episode in this process was the use of star rating between 2002 and 2003, which summed up indicator values based on certain method and ranked hospitals on a scale of 0-4 stars. The role of the evaluation was clearly summative, and the approach to knowledge can be characterized as a positivist one.

The proposed classification framework classifies the hospital evaluation methods used in practice, and also helps to determine the focus and scope of research. The following subchapter summarizes the results of international research on the effects of external hospital evaluation methods. The subchapter highlights the research gaps listing the questions that have not been responded yet.

60 http://www.bqs-institut.de/
4.3. International research results

This subchapter focuses on the international research results on the effects of the external hospital evaluation methods and intends to identify areas and topics for further research. Referring to research and literature reviews, the first section sums up and structures the effects on hospital care and management (e.g. effects on the output, quality improvement, adverse effects). The second section describes research results referring to the adaptation of external hospital evaluation methods and to the reactions of hospital actors.

4.3.1. The effect of the evaluation methods on hospital care and management

The spread of hospital evaluation methods raises several questions: who applies a certain method and with what aim is it applied? Did external evaluation methods reach their goals? Which methods are effective and efficient? What effects and adverse effects do they have? These questions raised in practice have been focused on by the researchers, as well. (Projects related to hospital evaluation method for example: ExPeRT 1996-1999, MARQuIS 2005-2007, ACCREDIT since 2007, DUQuE 2010-2013.) The present section of the dissertation describes research results that explore the effects and adverse effects of external hospital evaluation methods on hospital care and management.

The different research results are difficult to compare. One of the reasons for this is that although the need for a classifying model emerged in the 2000s, there is no classification framework that would make it possible to structure the research issues of hospital evaluation and to give comparable scope of research. Another reason is that professionals from different research areas such as quality management and performance management usually carry out investigations focused only on their area. In the following subsections research results are classified according to the effects of certain evaluation methods (like certification or accreditation), the effects of the characteristics of the evaluation methods (like related incentives), and the adverse effects of the evaluation methods in question.

4.3.1.1. The effects of hospital accreditation and ISO certification

The formerly mentioned MARQuIS research project supported by the European Commission is an exceptional example of a comparison of the effects of different hospital evaluation methods. The project investigated the relationship between hospital quality improvement strategies and the output of the processes of hospital care and found that „the implementation of internal as well as external quality improvement strategies in hospitals has beneficial effects on the hospital outputs” (Sunol et al., 2009, p. i62.). This research paid attention to both external and internal evaluation methods. The researchers analyzed the effects of the methods on hospital outputs, and they distinguished between clinical outputs, safety outputs and patient-centredness outputs. As part of the MARQuIS project, analysis of data collected by standardized data collection methods during the audits performed in 89 hospitals showed, that the presence of external evaluation significantly related to the outputs of safety and patient-centredness measured at hospital level. Among external evaluation methods voluntary and government

63 The presence of external evaluation (like certification, accreditation, peer review, authority supervision, EFQM model or external evaluation of laboratories) was measured by using the „external pressure index”.

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accreditation was significantly related to safety outputs and to the clinical outputs measured in the units of internal medicine, and voluntary accreditation also had significant relationship with cross-border patient-centredness. ISO certification was related to patient-centredness outputs, but it has no significant relationship with clinical and safety outputs. (Sunol et al., 2009) The MARQuIS project also identified and analyzed the differences of the quality management of the hospitals which were accredited or certified by ISO. The criteria examined during the audit were classified using six dimensions. There were significant differences in all dimensions, except patient rights, between the hospitals that were accredited or certified and hospitals that were not. When comparing accredited and certified hospitals, there was a significant difference in favor of the accredited hospitals considering the dimensions of management, patient safety and clinical practice. However, even the authors ask for a cautious interpretation of these results, because the sample was relatively small, and the effects of the external evaluation methods could also be influenced by differences in application of methods within and between countries. (Shaw et al., 2010) The MARQuIS research project was followed by the DUQuE project (2010-2013) (Gröne et al., 2010), the results of which started to be published at the same time when the present research was carried out (see e.g. Secanell et al. 2014). This project also analyzed the effects of the accreditation and of the ISO certification on the quality management, and these effects were measured using four composite measures (specialized expertise and responsibility, evidence-based organization of pathways, patient safety strategies and clinical review). In case of hospitals which were either accredited or certified significant relationship could only be found with one measure in the case of stroke care (accreditation was significantly positively related to clinical review, and ISO certification with patient safety strategies in stroke care). Using both accreditation and certification had significant positive relationship with specialized expertise and responsibility, patient safety strategies and with clinical review in more different fields of care (AMI, stroke, hip fracture), but they had no significant relationship with evidence-based organization of pathways. (Shaw et al. 2014)

Further research investigates the effects of certain methods. Braithwaite et al. (2006) propose a research design to investigate the effects of accreditation, and they used the ACHS (Australian Council on Healthcare Standards) as an example. Related to this research Greenfield et al. (2007) reviewed research on accreditation and they concluded that accreditation programs promoted changes that „are related to standardizing the organization and decision making processes for care” (quoted by Sunol et al., 2009, p. i67). Based on the literature review it can be concluded that accreditation supports organizational changes and professional development (Greenfield – Braithwaite, 2008, quoted by GYEMSZI, 2011). Sack et al (2011) used a questionnaire to explore the relationship between patient satisfaction and accreditation, but they found no significant relationship. Australian researchers launched the ACCREDIT project to examine the effects of accreditation (Braithwaite et al. 2011). The study protocols of this project were already published (Greenfield et al. 2012; Hinchcliff et al. 2012; Mumford et al. 2013). According to Shaw et al. (2014), besides the above mentioned examples the effects of the ISO certification on health care organization has not been analyzed.
4.3.1.2. The effects of public reporting and other incentives

Several studies focus exclusively on certain characteristics of the evaluation methods. Many projects investigated the effects of public reporting \(^{64}\) of performance and quality evaluation results. Some of these studies focused on specific areas, for example, on the effects of programs evaluating cardiological care in the USA, where the results were that high risk patients were refused and referred to other institutions, and that data recording discipline worsened (data manipulation) (Jacobson et al. 2003), mortality was higher and more adverse effects took place (Mannion and Goddard, 2003).

Hibbard et al (2003) examined the effects of public reporting at hospital level. They used an experimental design to analyze the effects of publishing hospital performance results in the form of indicators. They found that public reporting encourages quality improvement activities in hospitals as compared to hospitals receiving private reports and to a control group (no report), especially when reported performance was poor. It was also revealed that public reporting generated negative attitudes, anger and distrust. It is also worth mentioning that 15% of hospitals responded „that they would improve only because of changes in coding practices” (Hibbard et al., 2003, p.92.). Hospitals in public reporting group thought that public reporting may influence their image, but not their market share.

Contradictory statements have been published about the effects of public reporting on quality improvement. Some authors claim that public reporting does not have significant effect on care and on providers’ behavior. (Schneider – Lieberman, 2001; Vallet et al. 2006) Others claim that among hospital with worse indicator results public reporting had a positive effect on quality improvement. (Scott – Ward, 2006) Some research found deterioration of quality due to the fact that reports distract attention and resources from other fields of hospital operation. (Davies – Marshall, 1999; Mullen, 2004; Scott – Ward, 2006)

Werner and Asch (2005) argue that public reporting can contribute to the improvement of the quality of care by encouraging providers to change their practice or to provide only care with high performance score, or to fire employees providing low quality service. However, the conclusion was that public reporting worsens the quality of care due to its adverse effects. The authors also call the attention to the fact that there are some important aspects of public reporting such as accountability and transparency, and they also emphasize the importance of distinguishing various goals and taking them into account when developing different systems.

Studies based on literature review claim that public reporting may have undesirable adverse effects such as selecting patients (rejecting admission and refer to another institution), modifying data reporting, higher costs of care (defensive medicine), resource reallocation from areas not measured to areas that are evaluated, earlier discharge, neglecting patient preferences and clinical opinion (in order to encourage physicians to reach target values). (Werner – Asch, 2005; Belicza – Takács, 2007)

Not only the effects of public reporting, but also the effects of other measures and incentives related to external hospital evaluation have been researched. Custers et al. (2008) reviewed literature with the aim of summarizing information on the effectiveness of incentives\(^ {65}\). They found evidence for effectiveness in the case of public reporting, but only in the evaluated performance area and only in case of using direct

\(^{64}\) Public reporting mostly refer to publishing indicator results, like league tables that show ranking based on scores, while publishing of accreditation results can also be considered as public reporting. Public reporting is used in NHS star rating mentioned in section 4.2.3 and in the Hungarian indicator system of EBF mentioned in section 5.3.2.

\(^{65}\) In this case effectiveness is the ability to achieve the objectives expected by the financing authorities.
incentives enhancing intrinsic motivation of providers. There is no evidence for indirect effects of public reporting, because patients either do not use this information, or they do not have the opportunity to choose between providers. (Shekell (2009) came to the same conclusion when examining direct and indirect effects of public reporting). Custers et al (2008) found some evidence of the effectiveness of bonus systems, but evidence for other incentives were limited or not found.

4.3.1.3. Adverse effects of external hospital evaluation

Adverse effects of indicator-based systems were noticed already in the ‘90s (see e.g. Smith, 1993). Custers et al. (2008) classified the adverse effects of incentives related to external hospital evaluation methods (not only to indicator systems) as follows: gaming (maximization of the measured outputs without achieving expected goals), multitasking problem (distorting efforts from unmeasured objectives) and finally incentives related to external evaluation can undermine the intrinsic motivation of health care workers.

Boland and Fowler (2000) argue based on systems-theory that in the health care sector characterized by delays, inertia and nonlinearity the introduced measures may result in unintended, undesirable effects with behavior that contradicts intrinsic motivation. According to the authors this is not only true for public reporting, but also to the case when external evaluation based on indicators or audit is followed by re-allocation of resources: organizations performing "well" receive more resources and are able to perform even more higher level, while "bad" organizations drop behind and survive only with difficulty.

The summary of the literature shows that only a few researches (like the MARQuIS project) have compared the effects of different evaluation methods. It can also be concluded that most research focused on the effects of incentives related to evaluation (such as public reporting, bonus or resource allocation). In the past ten years research was mainly focused on the effects of public reporting among the possible incentives. Other incentives like pay for performance/quality have only been considered recently (Belicza – Evetovits, 2010).

Several researches highlight the nonintended negative effects. Studies based on literature review (Freeman, 2002; Werner – Asch, 2005; Belicza – Takács, 2007) conclude that some evaluation methods (like public reporting) may have negative effects on hospitals due to unintended consequences. One of the responses to the adverse effects of evaluation is that the evaluation method has to be improved (by considering goals, interest of the stakeholders, and the peculiarities of the system). The other response is that the evaluation methods are correct, but hospitals have to develop in order to properly adapt them, therefore, organizational culture should be changed. However, in my point of view the principal question is whether the assumptions behind the methods are correct or not.

How can we explain that hospital actors do not produce the expected reactions to external evaluation (e.g. gaming instead of improvement)? The mechanism of the effects of external evaluation in hospitals and the reactions and behavior of the hospital actors have hardly been researched. The studies dealing with this topic are presented in the following section.
4.3.2. Effect of external evaluation on the behavior of internal hospital actors

Considering the failures of the practical use of external hospital evaluation methods, some authors (Klazinga, 2000; Werner and Asch, 2005; Hibbard et al., 2003; Custers et al. 2008) propose to develop evaluation systems with a view to the aim of its application and so that it fits to the organizational environment. Custers et al. (2008) emphasize that the effectiveness of incentives depends on the environmental factors and that the values and goals of the health care system should be considered. Klazinga (2000) also points out that the choice and application of a certain model are much more influenced by political intents in health care systems and the power and interests of the stakeholders than on rationality. Furthermore, it is possible that the original assumptions may fail during the implementation therefore the assumptions behind methods should be investigated (Gröne et al., 2008). This problem is described by the compatibility gap theory, according to which there can be discrepancies between the assumptions behind the formation and application of an evaluation method and the dominant forces that influence real organizational action.

Lozeau et al. (2002) examined the use of the methods of quality management and strategic planning in public hospitals, and based on literature review and on an empirical study they concluded that the compatibility gap between the assumptions that lay behind the methods and the everyday practice of public hospitals was significant. In their empirical study they intended to find out which of the four possibilities of handling compatibility gap is realized by hospitals as a result of the different relations in power and interests.

The four possibilities are:

- Loose-coupling: management tools are applied superficially and the application is pure formality. Compatibility gap remains and becomes tolerated.
- Transformation: the gap is closed by the organization adjusting to the extent that its functioning fits the assumptions of the theory behind the method.
- Customization: closing the gap by adapting the method and adjusting the organization while it also transforms.
- Corruption or co-optation: the management tool is corrupted, and the original power structure and roles are reproduced. The gap is closed by bringing the method closer to the organizational pattern.

Lozeau et al. (2002) assume that the bigger the compatibility gap, the more organizations tend to corrupt management techniques. The analysis of case studies and interviews suggests that the dominant pattern for both management techniques (quality management and strategic planning) was loose coupling or corruption. Only a few outliers were identified, where customization or transformation was the case.

The study by Lozeau et al. (2002) has particular relevance to the topic of the present dissertation because their case studies and interviews were carried out in an environment (Quebec, Canada) where hospital accreditation as a form of external hospital evaluation method is widely used. The authors concluded that the examined management programs were mostly introduced under the pressure of the Canadian Council for Hospital Accreditation (CCHA), because introduction was required by accreditation standards. Although accreditation was not compulsory it was important for hospitals as supposed to improve their image. A typical effect of accreditation was that the intensity of quality improvement

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66 See former subsection on adverse effects.
67 Assumptions influence for example on establishing different systems, choosing the methods and defining objectives.
activities suddenly increased about six months before, and decreased immediately after the accreditation. Quality-related activities focused more on documentation than on real quality improvement. This reaction did not affect the power structure within the organization. It was usually a nurse coordinator who was appointed to make the preparation for accreditation, with much less lobbying power in the organization than physicians or managers. It seems that managers and the CCHA and also managers and employers tacitly agreed that accreditation requirements will only formally be fulfilled that also supported sustaining the original relations, circumstances. Lozeau et al. (2002) found only one outlier case regarding quality management where there was customization, that is the method was adapted while the organization also changed. A more detailed analysis of the case revealed that even in this case quality management programs affected only one operational department which remained isolated from the rest of the organization. This „island” belonged to the support staff of the hospital where, as Mintzberg (1991) points out, control mechanisms characteristic of machine bureaucracies like standardization of work or outputs can prevail.

In France the effects of accreditation were analyzed by Pomey et al. (2004). The authors carried out a longitudinal exploratory case study in a university clinic during the preparatory phase of the accreditation (self-evaluation), after this type of external evaluation was made compulsory in the country. The researchers used quantitative and qualitative data collection methods and applied more analytical levels. One of the conclusions of the study was that the preparation for the accreditation affected differently the different professions within the hospital. The management of the clinic was especially interested in the success of the accreditation process as they were personally affected and because the preparatory phase allowed them to exercise direct supervision over the professionals. This brought about changes in the power structure, which may be a source of conflict and can hinder the inclusion of other health care personnel. After the initial impetus physicians realized that it was much more about organizational and operational issues than about medical profession, and their participation in the preparation became much less active than that of the nurses, who were much more interested in operational issues. One of the most interesting conclusions was that the preparation opened new channels of communication between the different areas and the different hierarchical levels of the hospital, which offered an excellent opportunity to establish social relationships and social capital. Researchers also observed changes in the attitude of the employees, such as patient-centredness became more focused, and the culture of written regulation appeared. (Pomey et al. 2004)

The mechanism of effects of external hospital evaluation methods and the effect of these methods on the actors have been scarcely researched in the context of hospitals. However, the question has emerged in research on other public organizations. Starting from the theory of reactivity, Espeland and Sauder (2007) and Sauder and Espeland (2009) used the indicator-based ranking of higher education institutions as an example to illustrate how evaluation, observation and measurement affect the behavior of the stakeholders. The authors identified effects that were similar to the adverse effects described in the previous section (e.g. resource allocation to the measured areas, reorganization of processes, gaming) in the case of evaluation using rankings of higher education (law) institutions. Searching for the reasons behind this phenomenon they identified the mechanisms of self-fulfilling prophecies and commensuration. The former means that the actors react to public ranking in a way that will indeed verify the original expectations and assumptions transmitted by the indicators. The later, that is the commensuration in the case of rankings canalizes and focuses attention by using simplified, integrated
information and by creating relations between institutes. This research carried out in the education sector shows that the typifications of the classification framework should be taken into consideration when analyzing the mechanism of the effects of the evaluation methods, because according to the dimensions of the framework the method of ranking has different characteristics than for example the method of accreditation.

Chapter 4 described the aspects of classification for external hospital evaluation methods and proposed a classification framework that may help to describe practically applied methods and to define the scope of research. The second part of this chapter presented research results which prove that external hospital evaluation may affect the output of hospital care and may have adverse effects, and that it affects organizational actors’ behavior. The question of how and through which mechanisms these methods can reach the desirable result or produce an undesirable adverse effect has scarcely been dealt with. Therefore the empirical study hereby presented focuses on the research gap that how external evaluation methods affect the behavior of hospital actors.
5. The Hungarian environment: characteristics of Hungarian hospitals and the external hospital evaluation methods

This PhD dissertation examines the effects of external hospital evaluation methods in the context of the Hungarian health care system. This Chapter describes this context and the external hospital evaluation methods used in Hungary. The first subchapter focuses on the external stakeholders of hospitals and highlights those that are eligible to perform external hospital evaluation according to the definition. The next subchapter is dedicated to the principal characteristics of the Hungarian hospital sector. The third subchapter describes the legal background of the regulation of external hospital evaluation and the applied methods.

5.1. External stakeholders of hospitals in Hungary

Figure 8. shows the situation of the stakeholders listed in subchapter 3.2 as it corresponds to the situation in Hungary in 2013. (Data collection for the case study was made in 2013). The figure focuses on the stakeholders that are relevant for the present research.

Figure 8.: External stakeholders of hospitals in Hungary in 2013


In Figure 8 arrows show which external stakeholders evaluate or could evaluate the hospital using the
defined external evaluation methods. The methods are thoroughly described in subchapter 5.3. (The
Health Insurance Supervisory Authority mentioned in subchapter 5.3 does not appear in Figure 8
because it ceased to exist in 2010.)

5.2. Characteristics of the hospital system in Hungary

Besides the owner structure and financing methods of the hospital sector this subchapter describes the
financing techniques that affect organizational behavior and the behavior of the actors within the hospital.

5.2.1. The ownership structure of hospitals in Hungary

Kornai and Eggleston (2004) classify health care providers according to the holder of ownership rights as
follows:

- state ownership: organizations owned by the central government and municipalities,
- non-profit, not state-owned organizations (e.g. church or foundation ownership),
- profit-oriented private organizations.

Kornai and Eggleston notice that there can be transitional ownership forms, too, and that ownership
types may be combined.

Most Hungarian hospitals are state-owned institutions, and until 2012 municipalities disposed of
ownership rights in case of town-, county- and capital city hospitals. In 2012 hospital ownership was
centralized: from the 1st of January 2012. 46 hospitals (43 after integration) that formerly belonged to
counties and the capital city, and from the 1st of May 2012. further 54 in-patient institutions that formerly
belonged to the municipalities became state-owned. From the 1st of January 2013. another 10 in-patient
care providers became state-owned. (Borbás – Mihalicza, 2011) The ownership is practiced through the
National Institution for Quality- and Organizational Development in Healthcare and Pharmaceutics
(GYEMSZI). GYEMSZI was founded in 2011 integrating five former central institutions (EMKI, OGYI,
ESKI, ETI, OSZMK)69. GYEMSZI has a wide range of activities, it belongs to its responsibility “to create
quality improvement and patient safety strategies, elaborate methodological background for development
of different levels of health care, organize patient pathway strategies and to create development
strategies” (http://www.gyemszi.hu).

During the period of municipality ownership and operation in 2000’s functional privatization offered a new
alternative and many hospitals became operated by profit-oriented private companies. Between 2007
and 2009 there were 10 to 12 privately operated hospitals in Hungary. (Dózsa, 2010) Later a
restructuration began and continued even in 2011, and some of these hospitals returned to municipality
and later to state ownership (Borbás – Mihalicza, 2011).

69 EMKI – Egészségügyi Minőségfejlesztési és Kórháztechnikai Intézet, Institute for Health Care Quality Improvement
and Hospital Engineering; OGYI – Országos Gyógyszerészeti Intézet, National Institute of Pharmaceutics; ESKI –
Egészségügyi Stratégiai Kutatóintézet, Health Care Strategy Research Institute; ETI – Egészségügyi Szakképző és
Továbbképző Intézet, Institute for Training of Health Workers, OSZMK – Országos Szakfelügyeleti és Módszertani
Közpunkt, National Centre for Healthcare Audit and Inspection.
In Hungary the number of hospitals owned privately or owned by churches and foundations is small, as well as their weight in care. They are mostly specialized institutions. (Dózsa, 2012)
The centralization process of the past years can have several effects on the research topic of the present dissertation. As a result of this process GYEMSZI, the institution with ownership rights, has become also responsible for hospital development.

5.2.2. Financing methods of hospital care

Kornai and Eggleston (2004) classify hospital financing methods as follows:
- state financing, where tax-incomes are the main source of financing,
- compulsory insurance with the following possibilities:
  - insurance is provided by a single state institution or regional institutions (monopolies),
  - insurance companies compete for insurees,
- voluntary insurance: individuals can decide whether to buy private insurance provided by insurance companies or not,
- direct payment to the provider.

In case of financing we can also find examples for combination of methods.
The operational costs of hospital care are financed from the National Health Insurance Fund handled by the National Health Insurance Fund Administration (NHIFA) (compulsory public health insurance, a single state institution). The income of the Health Insurance Fund derives from contributions of employers and insurees, from the percental health care contribution, from public health product tax, from accident tax and other contributions of central state budget. (Borbás – Mihalicza, 2011)
From the middle of the 90s the legal environment is favorable for sector-neutral financing in Hungary, which means that the NHIFA can sign a contract with the providers independently from ownership and the legal form of the company (Dózsa, 2010).
The legal forms of direct payment for hospital care are not typical in Hungary. However, illegal direct payment affects one part of hospital employees.

5.2.3. The effects of financing techniques on hospital operation

In Hungary outpatient care provided by hospitals receives fee for service financing, acute inpatient care receives case-based financing and chronic care receives daily fees from the Health Insurance Fund. The so-called German score system is used in the financing of outpatient care, while Hungarian DRGs (diagnosis related groups) are applied in the financing of acute inpatient services. These two are called performance-based financing in Hungary. Since the 1st of January, 2004 a so called ‘performance volume limit’ has been used in inpatient and outpatient care to avoid excessive volume reporting (Dankó et al. 2006). The regulations for this performance volume limit have changed several times, and since the introduction of digressive strip financing in 2011 the rules alleviated strict performance volume limitations (Borbás – Mihalicza, 2011).

70 Until 2012 all development / investement costs beyond operational costs had to be financed by the municipalities with ownership rights, but the changing ownership modified this situation.
71 Since 2012 called as social contribution tax.
72 A smaller proportion of the incomes of the Health Insurance Fund come from other operational income, assets taken from the Retirement Fund, and property incomes (GYEMSZI, 2011).
73 Following the American DRG model.
There is considerable evidence that financing methods have important effects on the quantity and quality of health services (Kornai – Eggleston, 2004, p.68.) Certain financing techniques bring about undesirable and distorting effects beside their positive effects. The negative effects in the case of Hungarian system are summed up below.

In outpatient care the score system, as well as other pay-for-service systems, can motivate higher volume of services, while it does not necessarily contribute to increase hospital income. The certain services have a fix score value, and in case of budgetary limitations this can result lower amount when expressed in monetary terms. Providers try to bite a bigger part of the „budgetary cake” at other providers’ expense. Another disadvantage of pay-for-service systems is that it does not enhance quality improvement.

The DRG system is favorably applied in acute inpatient care. Among its beneficial effects we can mention that it contributes to increase technical efficiency and cost-awareness. However, it may have the following undesirable effects: early discharge of patients, substituting outpatient care with inpatient care, data overcoding. And it also does not seem to enhance quality improvement. In chronic care daily fees can result in longer hospital stay. (Orosz – Ellena – Jakab, 1998; Kornai – Eggleston, 2004; Dózsa, 2010)

The relevance for the research topic is that it is proven that these incentives have a number of undesirable effects, which may be also relevant for the incentives related to external evaluation methods. To sum up, it can be claimed that the financing techniques applied in Hungary do not really enhance quality improvement.

5.3. **External hospital evaluation methods in Hungary**

At the beginning of the 1990s the operation of hospitals in Hungary went through significant changes. There were changings in the ownership structure, and many hospitals came under municipality ownership. There were changes in the financing system: the financing based on the costs of the previous year was changed by performance-based financing (see section 5.2.3.). Hospital management had to face new challenges that the new health care system brought about and this attracted attention to management science and to quality assurance (Ajkay – Szabadfalvi, 1992). Controlling and quality assurance systems began to spread. The first quality assurance initiatives emerged in the beginning of the 1990s due to a project launched by the European Commission (Makai et al. 2009), and also proposed by several professional organizations. Certification according to ISO standard was the first among external hospital evaluation methods, and the first hospital (Zala county hospital) was certified by ISO 9001 in 1995 (Tihanyi – Tompa, 2000; Belicza – Kullmann, 2003).

This subchapter focuses on the regulatory context of external hospital evaluation. It also lists the methods used in Hungary that concord with my definition of external hospital evaluation given in the

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74 Orosz (2001, p.19.) comes to a similar conclusion.
75 The term quality is used here for quality of services. (See Kenesei – Kolos, 2007)
76 Like The Quality and Accreditation Committee of the Ministry of Welfare, the Consulting Center for Quality Improvement in Healthcare, The Hungarian Association for the Improvement of Quality and Efficiency in Healthcare, the Quality Committee of the Hungarian Hospital Association, the Hungarian National Committee of the European Organization for Quality.
previous chapters. The methods which are relevant for this research are thoroughly described in subchapter 5.4.

5.3.1. Legal regulations and the spread of hospital certifications

In the beginning of the 1990s many government decrees were dedicated to regulate quality assurance and quality assurance of each sector of the national economy was assigned to the ministry of the sector. In 1991 the Ministry of Welfare funded the Quality and Accreditation Committee to establish quality policy for the health sector. The law on the accreditation of laboratories and institutions certifying health care organizations was passed in 1995. (Belicza – Zékány, 1998) However, quality improvement activities of Hungarian hospitals were not regulated until 1999. It was in this year when paragraphs 119-124 of the 1997. CLIV law on the quality of health services came to force. (Szy – Sinka, 2004). The law forced all health care institutions to establish an internal quality assurance system, but the use of external systems was not compulsory. The law did not include detailed requirements relating the content of quality systems. Content definition was supported by the guidelines of the Ministry of Health, Social and Family Affairs published in 2003 about „The quality systems of health care providers and their consequences” (Szy et al. 2003). The guideline regulated internal quality systems and the application of external systems (like certification according to ISO) was still not required (Kullmann, 2004). However, between the end of the 1990s and the beginning of 2000 the number of hospitals certified according to ISO 9000 standards grew considerably in Hungary (See Table 5). According to an expert of the Ministry of Health, Social and Family Affairs this trend is because in that time there was no other system besides ISO standards to meet the requirements of the law on internal quality systems (Szy et al. 2003).

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<td>63%</td>
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Note: Data from 2004 was collected in February 2004.

The Ministry’s reaction to the application of not always clearly interpreted ISO standards was that in 2003 it edited a „Recommendation for the application of ISO 9001-2000 standard in health care organizations” and it promoted development of specific standards for inpatient care which was published as Standards of Hospital Care (SHC) in 2001 (Szy et al. 2003). According to these standards the certification of hospitals became possible (although they were originally meant to support accreditation). As it is shown in Table 5 from 2001 hospitals could voluntarily choose whether to use ISO or SHC or both. According to a survey made in February, 2004 76 hospitals had ISO and 18 had SHC certifications, while 14 hospitals of them disposed of both. This means that altogether 80 hospitals, 59% of the respondents had a certification in 2004. (Szy – Sinka, 2004)

As a reaction to the different options the sectorial quality policy claimed that its aim is „to establish an integrated quality management model for health care organizations” (Szy et al. 2003, p. 20.). Based on

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77 The table includes all the respondent hospitals, independently of whether they fit the definition given in Chapter 4.1.
the initiatives launched by the Ministry the SHC were developed for other areas, such as outpatient care, GPs and district nurse in mother- and childcare (EÜM, 2007). These standards were integrated, compiled and published in 2007 as Hungarian Health Care Standards (HHCS) and this made it possible to certify health care providers according to these standards. The standards of the HHCS and other systems (like ISO 9001:2000 standard or EFQM model) were meant to support integrated quality management systems. (EÜM, 2007). By 2008 the rate of ISO, SHC or HHCS certified hospitals78 reached 71 % (EBF (2008) indicator system, own calculations).


5.3.2. The applied external hospital evaluation methods in Hungary

Besides certifications, there are other external evaluation methods that have become used in the Hungarian health sector. The external evaluation methods that correspond with the definition proposed in subchapter 4.1 are the following:

- Certification by ISO 9001 standard since 1995,
- Standards of Hospital Care (KES) (2001-2007), Hungarian Health Care Standards (MEES) since 2007,
- Indicator program of the National Health Insurance Fund Administration (OEP) (2002-2006),
- Indicator program by the Health Insurance Supervisory Authority (EBF) (2008-2010),
- National Prize for Quality in public organization category since 2006 (based on EFQM).

Besides these methods there were also other initiatives like the indicators of the Ministry of Health, Social and Family Affairs, national surveys on patient satisfaction, clinical audit, which do not belong to external hospital evaluation methods according to my definition. The place of the data referred to all questioned and respondent hospitals that means, to more hospitals than those fitting into the definition of hospital given in subchapter 4.1. The subchapter 6.2 offers exact data on the hospitals that correspond to the definition.

Hospital management was given feedback on the results of the indicators proposed by the Ministry of Health, Social and Family Affairs, external evaluation results based on these indicators were available only at a more aggregated level. Patient satisfaction surveys introduced by external stakeholders of hospitals have not become regularly applied and the results have not been published at hospital level. Clinical audit cannot be considered as external hospital evaluation method according to my definition, because it evaluates professional work and not the organization. (See Annex 2.)
methods in their practical usage can be different. For instance the place of the certification according to ISO or HHCS has to be tested.)

**Figure 9. Hungarian external hospital evaluation methods in the proposed classification framework**

Not all evaluation methods that are situated in the classification framework could be examined during the empirical case study carried out in this research. The indicator programs of the National Health Insurance Fund Administration and of the Health Insurance Supervisory Authority had ceased to exist by the time this research was carried out. External evaluation based on EFQM model, that is National Prize for Quality has been launched recently for public organization, and has only affected a few hospitals until today. As ISO and HHCS certifications are widespread in Hungarian hospitals these are the methods that will be studied in this research and thoroughly presented in subchapter 5.4.

**5.3.3. New strategy and regulation on quality improvement in Hungarian health care**

When empirically examining external hospital evaluation methods we have to consider how health policy initiatives influence on hospital quality improvement. Therefore, this section describes health policy quality plans. When the new government came to power in 2010 the National Institution for Quality- and Organizational Development in Healthcare and Pharmaceutics (GYEMSZI) funded in 2011 became responsible for establishing quality improvement strategies for the health sector. The four goals of the National Quality for Health and Patient Safety Strategy are:

1. to improve patient safety,
2. to improve organizational operation and processes,
3. to improve professional activities of health care providers,
4. to improve coordination of providers and care.

Goals 2 and 4 include the aim of establishing an accreditation system for health care organizations and carrying out patient satisfaction surveys. (Belicza et al. 2011) According to the plan accreditation will be voluntary, and will be based on currently used standards (like HHCS) and ISOua requirements (Belicza, 2012). In the summer of 2012 the legal regulation on the quality system of health care providers was changed. The elements of internal and external quality system under the title „Assuring quality of health services” are described in paragraphs 119-124 of the currently used 1997. CLIV. Law (updated on 1st
July 2012). Internal systems are henceforward compulsory for the institutions. External quality system includes authority supervision, assessment of professional work, accreditation and certification, where the two latest are voluntary. Paragraph 124 regulates accreditation and certification, claiming that „Accreditation proves that health care providers work according to specific standards for the type of care they provide“, and „certification is the supervision and recognition of the provider’s quality management system based on national or international standards“.

These regulatory modifications created a legal background for accreditation of hospitals. The development of the accreditation system is supported by an EU project80 from 2012 and the accreditation system is expected to fully function from 2015.

5.4. ISO and SHC/HHCS certifications

This subchapter is dedicated to describe how ISO standards have become widespread among Hungarian hospitals and how health care specific systems appeared. To illustrate the Hungarian experience with these systems some survey results will be presented.

5.4.1. ISO 9000 standards and hospital certifications

ISO 9000 standards were first published in 1987 by the International Organization for Standardization, and since then it has become the most widely used standard system in the world. Formerly, there were several types of standards in use, like those used by NATO or by car factories since 1945. The development of ISO standards was based on the British BS 5750 series of standards. The different countries adjusted their systems to ISO, and as a result of such harmonization the MSZ EN ISO 9000 standards were established in Hungary. (Bernáth et al. 2000)

The goal of ISO standards is to assure customers that the quality of the product or service they receive meets the requirements of the system and the customer demands. The way to assure all this is that standards are used to define the characteristics of the managing and regulatory systems. This means that the ISO system does not regulate directly the basic activities of an organization. Therefore, it can be applied to products and services independently from sector or industry. The system and operation based on ISO standards can be certified by accredited institutions. (Demeter, 2008; Erdei et al. 2010)

The hospital certifications according to ISO standards spread in the 1990s and many countries elaborated guidelines to support its adaptation for health care. (Gulácsi et al. 2000) When the first hospitals in Hungary started to develop their quality systems, ISO 9000:1994 was the valid reference. The new standards released in 2000 (ISO 9000:2000)81 were fully expected (Nagyné Tarr, 1999; Bernáth et al. 2000) because, as compared to the previous version, it seemed more process-oriented, the principle of continuous improvement dominated, and its language was more applicable to services.

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80 TÁMOP-6.2.5.A-12/1-2012-0001 project on the „Improvement of organizational efficiency in institutions affected by structural changes: Establishing a unified external supervisory system for outpatient and inpatient care and for pharmacies“

Communication and relationship with customers became a principal focus, and it was based on the eight principles of TQM philosophy. (Bernáth et al. 2000; Demeter, 2008; Erdei et al. 2010) All these characteristics made it more applicable to health care organizations than the former version. Hospitals considered it as a success when they received their ISO certification (Nagyné Tarr, 1999; Tihanyi – Tompa, 2000). The first hospitals had many different aims when they decided to go through the certification process. Some of the aims were: racionalization of processes, traceability, continuous improvement (Tihanyi – Tompa, 2000), costumer-centeredness, best practice in quality management (Nagyné Tarr, 1999); and surviving in a rapidly changing environment (e.g. competition or privatization) (Gombos, 2002). Regulations and their communication were not clearly understandable for hospitals, which lead to misinterpretations\(^{82}\) (Nagyné Tarr, 1999). The expectations towards the certification of quality systems were: quality improvement of services, decreasing costs, growing trust of patients, bigger market share (Nagyné Tarr, 1999; Gombos, 2002). The enthusiasm and communication of the first certified hospitals probably raised the expectations of other hospitals towards ISO.

Although in 1998 the content of quality activities for hospitals was not defined by any regulation, according to a survey made by the Hungarian Hospital Association already eight\(^{83}\) of the 95 respondent hospitals (62.9% response rate) had ISO certification. According to the survey the development plans and aims were also directed towards ISO among quality systems, and in 1998, 32 hospitals were planning to obtain certification. There was a demand for material and professional support for the preparation for the certification, a need for a stable regulatory background, for qualified external professionals, informatics development and moral recognition. Hospitals pointed out that they would expect financial incentives and more favorable financing for certified hospitals. (Belicza et al. 1998) The second survey by the Hungarian Hospital Association was made in 2002. The number of certified hospitals increased, 47 of 103 respondents had a certification (67.3 % response rate) (regulation was already in force). Hospitals mentioned that they expected more favorable financing, and that professional attitudes and work did not change as a result of certification. (Belicza – Kullmann, 2003). „It can be said that hospitals mostly just wanted to receive the good diploma.” (Kullmann, 2004, p. 37.)

5.4.2. Health care specific systems

Initial enthusiasm dampened when expectations were not fulfilled, and the beginnings of the 2000s brought about changes. The Ministry called for proposals to elaborate a system that can be better interpreted by hospitals. Then in 2001 the Ministry published specific hospital standards for inpatient care (SHC), and in 2003 it published a material entitled „Recommendation for the application of ISO 9001-2000 standard in health care organizations”.

The SHC was based on the hospital standards of the Joint Commission International. During the elaboration of standards the experiences of a trial study were considered. The trial study was made between 1997 and 1998 and it examined the applicability of the standard system of the American Joint Commission on Accreditation of Healthcare Organizations (JCAHO) with the participation of seven

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82 An auditor working in an ISO 9001 certified hospital wrote in 1998: "...the 1997./ CLIV. Law on health care institutions made quality management systems and their external supervision compulsory from the 1st of January 1999." (Nagyné Tarr, 1999, p. 180.) – This statement is false, because the law only made internal systems compulsory, but not external certification.

83 Data is different from the survey of the Ministry shown in Table 5. The reason can be the different time of data collection and different respondents.
Hungarian hospitals. (Belicza – Zékány, 1998; Csídei et al. 2004) These standards could serve as a basis for the accreditation of health care institutions, but when SHC was introduced the result was that the same institutions became eligible for certifying hospitals according to these standards that were eligible for making ISO certifications.

Following the introduction of SHC hospitals disposed of several methods, but legal regulation was not clear about the content of quality systems. The several possibilities have lead to the integration of the different quality systems. In 2003 the recommendations published for the health care application of ISO 9001-2000 aimed at finding the linking points between ISO, SHC and EFQM-based systems and developing an integrated quality management system. (ESZCSM, 2003). Hajnal et al (2004, p. 12.) refers to the 2004 conference of the Ministry where it was claimed that „...the requirements of the Law [1997.] are fulfilled by a quality management system based on ISO 9001 standard and complemented by the requirements of SHC, therefore, the establishment of an integrated ISO 9001 – SHC system is recommended for health care organizations.” The summit of the integration process was the publishing of HHCS (Hungarian Health Care Standards) in 2007. The manual for HHCS claimed that its standards together with ISO 9001:2000 or the EFQM model aim at supporting the creation of an integrated quality management system. The certification of health care providers became possible since 2007 based on the HHCS that substituted former Standards for Hospital Care (SHC). (EÚM, 2007)

The integration of methods was first applied when the Szent János Hospital was certified based on ISO and SHC in 2004 (Hajnal et al. 2004). Hajnal et al (2004) considered the application of an integrated system as a milestone, as it enhanced internal commitment while at the same time maintaining the priority of patient care. They emphasized the importance of a specific method for system development. They considered that the organization of interdisciplinary teams and increasing the weight of internal audits were the most important elements of such development.

Radnai and Ivanova (2004) and Széll (2005) also claim the importance of considering the peculiarities of health care. Radnai and Ivanova (2004) argue that a consultation between the physician and the patient has such relevance for quality that its characteristics should be considered as an individual dimension of quality according to the structure-process-outcome system as proposed by Donabedian. Széll (2005) calls the attention to the fact that while the establishment of quality systems in the business sector brings about rationalization, better customer satisfaction and related cost savings, in health care these advantages cannot be so directly experienced. The number of patients is influenced by several other factors (e.g. referral system), and financing regulations may also distort the effects.

5.4.3. Experiences about ISO and SHC/HHCS systems

Széll (2005) reminds that there is considerable lack of trust, fear and resistance towards quality systems. There was no exact information about how general these feeling are among Hungarian hospital workers therefore Széll (2005) made a survey to examine attitude of hospital workers towards quality systems. 14 hospitals participated in the survey. 10 of these hospitals had ISO or integrated SHC/HHCS certifications. The respondent hospital workers\(^{84}\) opinion about quality systems was almost neutral. Respondents considered it as an advantage that quality systems contributed to a more regulated and more transparent institutional operation. The over-optimistic character of the expectations towards quality systems is

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\(^{84}\) The proportion of non-certified hospitals was lower among the respondents, which means that they were under represented in the survey.
shown by the fact that in non-certified hospitals more hospital workers (87%) expected better transparency than it was recognized by workers of already certified institutions (73% in ISO hospitals, 71% in SHC/HHCS hospitals). It is also considered as an advantage that quality systems provide legal protection, and that clear instructions help routine work and internal communication. Significant number of respondents complained about over-documentation (82%) and extra work (82%), nurses and skilled workers more than physicians. Many of the respondents could not form an opinion about the effects of quality management systems on costs (or they claimed that the system increased costs), and they did not notice any increase in the number of patients.

Wagner et al (2006) and Makai et al (2009) also published a study on research about quality systems in Hungarian hospitals. In a survey made in 2000 Wagner compared the maturity of hospital quality management systems in three countries, considering the peculiarities of the regulations and the incentives applied. In another survey carried out in 2005 (Makai et al. 2009) the authors examined the relationship between the maturity of quality management systems and ISO or SHC certification with patient safety. They found a weak correlation between the maturity of quality management systems and patient safety, but there was no correlation between certification and patient safety. The case study by Jenei (2009) is also related to the quality management of Hungarian hospitals, he analyzed the relationship between lean management and TQM in a Hungarian hospital with quality prize.

Table 6 contains the assumed characteristics (those that will be empirically tested in this research) of ISO 9001 and HHCS certification, the two systems described in this subchapter.

<table>
<thead>
<tr>
<th>External evaluation, Starting Year</th>
<th>The Role of Evaluation</th>
<th>The Approach to Knowledge</th>
<th>Scope/Coverage</th>
<th>Participation</th>
<th>Sources</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO 9001 certification, Since 1995</td>
<td>Formative</td>
<td>Interpretive</td>
<td>Quality management system, production, managing and supportive processes</td>
<td>Voluntary</td>
<td>Hungarian Standard MSz EN ISO 9001</td>
</tr>
<tr>
<td>HHCS certification, Since 2007</td>
<td>Formative</td>
<td>Interpretive</td>
<td>Processes of patient care, diagnostics, managing and supportive processes</td>
<td>Voluntary</td>
<td>HHCS handbook (EÜM, 2007)</td>
</tr>
</tbody>
</table>

Abbreviations: HHCS: Hungarian Health Care Standards

Chapter 5 described the principal characteristics of the Hungarian hospital system, and it presented hospital stakeholders who are most probable to use external hospital evaluation methods as hereby defined. The second part of the Chapter analyzed the regulatory framework and the spread of the most widely used methods. In Hungary the most widely used certifications are ISO and SHC/HHCS, and my empirical research focuses on these certifications, and the research questions formulated in the following Chapter will also focus on these.
6. The introduction to the empirical research

Before describing the case study, in this Chapter I refer back to the research objectives and the research questions described in the Introduction of the dissertation. This research question is detailed and highlighted by presenting some secondary research questions. The second subchapter describes the research methodology including the phases of data collection and analysis of the case study and of the expert interviews. The last subchapter characterizes the empirical case study according to the aspects of the quality of the research.

6.1. Aim of the empirical research and research questions

One of the research aims was to propose a classification framework for hospital evaluation methods. Section 4.2.2 of Chapter 4 described this proposed framework, elaborated on the basis of theoretical and systematic articles. This framework served as a basis for the empirical study. Empirical research was restricted to analyze the effects of ISO 9001 standard and SHC/HHCS, which are the systems most widely used by the hospitals in the Hungarian health sector. Therefore, the aim of the empirical research was to explore the effects of the ISO 9001 and SHC/HHCS systems (considering their place in the proposed framework) by understanding the internal organizational processes, and the reactions and interactions of hospital actors, while focusing on their relationship with hospital improvement initiatives.

It was supposed that the effects of the external evaluation methods were principally influenced by the perceptions and the reactions of the external and the internal stakeholders of the organization, and that to be able to answer the principal research question it is essential to understand these perceptions and reactions. (This refers to my approach as a researcher, too.) Therefore, the phenomenon to be understood includes the processes that the application of an external evaluation method induces among the hospital actors, which can enhance or hinder improvement initiatives of the hospital.

This focus was kept in mind when the research question was restricted to the following: How do ISO 9001 and SHC/HHCS certifications affect the behavior of hospital actors and, as a consequence, the improvement initiatives of the hospital in the Hungarian health sector? The question word how refers not only to the possible changes, but also to the processes themselves that result in these changes, including the perceptions and the interpretations of the role of external evaluation by the stakeholders and the reactions and interactions induced.

Both the research question and the research aim reflect that the focus is on analyzing the mechanism of the effects on the improvement initiatives of the hospital. One of the initial questions is whether it is among the objectives of any of the external stakeholders to use the external evaluation methods to enhance (quality/performance) improvement in hospitals, as it was originally assumed in subchapters 5.3 and 5.4? The question is relevant because these external hospital evaluation methods can also be used to achieve other aims than this. Therefore, one of the secondary research questions is:

0. What were the reasons and the objectives that motivated the introduction of ISO and SHC/HHCS systems in hospitals in Hungary?
The dissertation makes an attempt to answer this question by making interviews with experts and by examining the case study hospital. During this attempt three more sub-questions raised, which are illustrated in Table 7.

The characteristics of the certification by ISO and by SHC/HHCS are analyzed according to the aspects of the proposed classification framework (See section 4.2.2). Related to this topic the following research questions were asked:

1. Is the situation of ISO and SHC/HHCS in the classification framework for evaluation methods, that is their characteristics evidenced by the assumptions, perceptions, aims and reactions of the auditors and the hospital actors?

This research question was subdivided according to the dimensions and other factors (see section 4.2.2) of the classification framework (see Table 7).

The how question of the principal research question was complemented by the following question:

2. What kind of mechanisms of the effects did result from ISO and SHC/HHCS, and what responses did they generate within the hospital?

The further research questions related to this topic are included in Table 7.

The methods applied to answer the research questions is described in the following subchapter.

### Table 7. Detailed description of secondary research questions

<table>
<thead>
<tr>
<th>0. secondary research question</th>
<th>1. secondary research question</th>
<th>2. secondary research question</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.a) What are the aims that the developers and the supporters of these evaluation methods want to achieve?</td>
<td>1.a) Certifications by ISO and by SHC/HHCS and the related audits are formative or summative in character?</td>
<td>2.a) How do hospital actors perceive and interpret external evaluation?</td>
</tr>
<tr>
<td>0.b) What are the aims of the certification by ISO and SHC/HHCS according to the auditors?</td>
<td>1.b) What is the approach to knowledge applied by certification by ISO and by SHC/HHCS?</td>
<td>2.b) How do hospital actors react to external evaluation?</td>
</tr>
<tr>
<td>0.c) What do hospital actors think were the aims and reasons when the hospital opted for introducing ISO and SHC/HHCS certifications?</td>
<td>1.c) According to the perceptions of the hospital stakeholders the implementation of the certification was voluntary or compulsory?</td>
<td>2.c) What kind of interactions prevail between the hospital actors as a result of the internal mechanism of the effects of the certification?</td>
</tr>
<tr>
<td></td>
<td>1.d) Which hospital areas are affected by the ISO and the SHC/HHCS certifications?</td>
<td>2.d) Are there any differences between the perceptions, interpretations and reactions of the different hospital actors according to their interests and their place in the hospital power structure (position in the hierarchy, scope of activity: nurse, physician, supporting personnel, etc)?</td>
</tr>
</tbody>
</table>

2. e) Does the certification enhance the improvement initiatives, and does it result in real improvement, according to the interpretation of the hospital actors? 2. f) What other (not expected or adverse) effects do these evaluation methods bring about?

Source: own elaboration
6.2. Research methodology

The empirical research was based on an exploratory qualitative research. The nature of research questions (see subchapter 6.1) required the application of such methods, which also complied with my own attitude as a researcher. This method can be successfully applied when the researcher does not only focus on the events and on the behavior of the participants, “but also in how the participants in your study make sense of this and how their understandings influence their behavior” (Maxwell, 1996, pp. 17.), and when the aim is to understand the processes behind the events and the actions. Qualitative research methods are also beneficial when the research aims not only at evaluation but at giving support for development and at improving the current practice. (Maxwell, 1996) The present research is characterized by these research aims.

This research was based on a hospital case study and on interviews with experts. The following sections give a detailed description of the methods applied.

6.2.1. Case study

For the case study I chose a Hungarian hospital that obtained both ISO 9001 and SHC (Standards of Hospital Care) certifications at the beginning of the 2000s. For the case study semi-structured interviews were made, documents were collected and an audit was observed.

The following subsections describe the applied methods: firstly, it describes the justification of the methods, and secondly, it presents the data collection and the data analysis methods.

6.2.1.1. Justification of methodology

The aim of this research was a deep understanding of a phenomenon, as it is reflected by the research aim and the research questions. Therefore, the case study research method was chosen, because it allows to deeply know the perceptions, interpretations and reactions and interactions of hospital actors and of the external auditors. According to Yin (2009), the case study is a form of empirical research that uses several data sources to observe the phenomenon in its natural environment, because the phenomenon cannot be clearly separated from its environment.

Yin (2009) compares five research strategies, including the case study method, using three questions for three different aspects, and these questions serve as a guideline to decide which method to choose. Yin (2009) claims that the application fields of the three research strategies cannot be clearly separated, and that they overlap, but the situation always shows which strategy is more beneficial. „For the case study, this is when a “how” or “why” question is being asked about a contemporary set of events, over which the investigator has little or no control.” (Yin, 2009, p. 13.)

Considering this research the following answers are given to Yin’s (2009) questions:

a) What type is the research question posed? – Most of the research questions of the present research are “how” questions, reflecting that I am interested in how things happen, and I focuses on understanding a phenomenon, and not on the frequency or the incidence of a phenomenon.

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85 Yin (2009) compares five research strategies: experiment, survey, archival analysis, history and case study.
86 The latter topics are characterized by the research questions containing „who”, „what” and „how many”, where the proposed methods by Yin (2009) are survey or analysis of archives.
b) The extent of control an investigator has over actual events? – Considering that the unit of the analysis is the hospital, which I wanted to observe in its natural context and in its complexity, I had practically no control over the events. This excludes experiment as a research method, but supports the choice of the case study method.

c) The focus is on contemporary or on historical events? – The phenomenon of ISO and SHC/HHCS certifications and the related audits are an ongoing process in many Hungarian hospitals, and the organizational effects can be continuously observed, which means that the phenomenon can be considered as contemporary. This is also corroborated by the fact that I was not primarily interested in the past effects of the certification, and the research question can be better answered by the perceptions and reports of the hospital actors. Case study method also allows to use many different data collection methods, which implies that historical events (e.g. archive documents, memoires) and contemporary events (e.g. observation of the audits) can be analyzed at the same time.

Within the case study method Yin (2009) distinguishes four possibilities, illustrated by a 2x2 matrix (Figure 10). One of the aspects is whether the research is based on one single case or on more cases, and the other aspect is whether the case study is holistic or embedded.

Figure 10. The basic types of case study and the type applied during the present research

<table>
<thead>
<tr>
<th></th>
<th>single-case designs</th>
<th>multiple-case designs</th>
</tr>
</thead>
<tbody>
<tr>
<td>holistic</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>(single-unit of analysis)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>embedded</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(multiple units of analysis)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Source: Yin (2009), Figure 2.4, p.46.

Although Yin (2009) remarks that if the sources and the situation make it possible it is recommended to base our research on multiple-case design, he also claims that the study of a single case may also be justified in case of: a critical case, extreme or unique case, representative or typical case, revelatory case, longitudinal case or pilot case. The other aspect (see Figure 10) distinguishes between holistic and embedded case studies. Holistic case studies analyze a case as a whole, while embedded case studies focus on more than one analytical units, and both the whole case and the lower-level units can be analyzed. The analytical units of the embedded cases allow more detailed research and can compensate the weaknesses of a single case.

This research is based on an embedded case study of a single case (see the ‘x’ in Figure 10), because the aim of this research is to have a deep understanding of the phenomenon, and this method allows a more detailed analysis, more cases would provide opportunity for a more superficial analysis. The phases of data collection and data analysis were also defined according to this choice. (The embedded cases (hospital units) are not described in detail for reasons of limitation of extension.)

When choosing the hospital for the case study I intended to elect a ‘typical’ hospital as it is a possible argument for single-case study according to Yin (2009). The available resources also oriented the choice towards the single-case study. The choice of embedded case study made it possible to compare more analytical units and to study emerging topics on more than one hospital units.

This research based on a single case does not aim at generalizations, however by describing the context it can serve as a basis for comparison with cases deeply known by others.
6.2.1.2. Case selection

The principal analytical unit, or ‘the case’ of the empirical study is a hospital, which can be considered as ‘typical’ from the aspects which are relevant to the research, namely from the aspect of its quality practice, and it represents a bigger group of Hungarian hospitals according to its size and functions. The selection of the case was not based on random sampling, but on theoretical sampling (Glaser – Strauss, 1967, quoted by Eisenhardt, 1989), because there was only one case to be chosen (Yin, 2009) and because it is an exploratory research.

Subchapter 4.1 defined the term ‘hospital’ as a publicly financed institution providing active in-patient care. When the selection was made in Autumn 2012 (after the structural change of hospital system) there were 93 hospitals matching this definition. The research required a ‘typical’ hospital, so the following aspects were considered:

- hospital size: 300-1000 acute beds, 450-1500 total bed number,
- number of specialties: between 10-19,
- hospital type: excluding special hospitals and university clinics,
- ISO or/and SHC/HHC certification,
- date of obtaining the certification, continuity of the maintenance of the certification.

A detailed analysis of the criteria for the first three aspects are described in Annex 3. After reducing the number of the possible hospitals by using the first three criteria, only bigger town hospitals, capital city hospitals and county hospitals remained.

The other aspects of selection referred to the quality related work of the hospitals. Selection was based on hospital data on ISO and SHC/HHC certification (Szy–Sinka, 2004; EBF 2008-2010; EMKI 2011) of the 93 hospitals that worked with publicly financed active beds in the second semester of the year 2012. Institutional data were available for five years, which are represented by Figure 11.67

![Figure 11. The number of hospitals disposing of ISO or/and SHC/HHC certifications by years](image)


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67 There were only aggregated data on the survey results of the previous years (Szy-Sinka, 2004), so I could not work with information on the 93 hospitals for these years.
Figure 11 shows that there was no year when data were available for all the 93 hospitals (see “no answer” 88). However, it can be seen that at least 60% of the 93 hospitals (56 hospitals) disposed of a certification in 2004, and the proportion of certified hospital was growing in the following years, resulting in that in 2011 at least 72% of the hospitals (67 hospitals) disposed of a certification (in this year the number of respondents was also high). The EBF survey in 2008 also reveals the date of the year when the certification was obtained. (See Figure 12)

This Figure shows that in the beginning of the 2000s there was a boom of certifications, although it was not compulsory for hospitals. Between 2000 and 2004 almost the half of the hospitals (44) obtained a certification. One of my case selection criteria was that the hospital obtained its certification in the period between 2000 and 2004. The other criterium was that the hospital has maintained the certification without any interruptions.89

All the criteria was met by 15 hospitals. From these hospitals I chose those four hospitals that was possible to regularly visit in the case study period. The websites of the hospitals were checked and letters were sent to the quality managers asking for information about the validity of the certification of the institutions and about when the next audit was due. Three of the four hospitals had both ISO and HHCS certifications, and one had only ISO and therefore was put at the end of the list. The institutions that had both kinds of certification seemed more attractive. As Figure 11 shows, the number of institutions having both types of certifications were slowly increasing, and in 2011 more than one third of the 93 hospitals (at least 35) disposed of both certification types.

The remaining three hospitals were ordered according to availability, and in Autumn 2012 the first letters asking for participation were sent out. The first two institutions rejected participation in the research, but the third hospital accepted it. The letter for this hospital was sent out already in 2013, and data collection was also performed in this year. (More detailed data about the hospital is not included for reasons of respecting anonymity.)

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88 Data from 2004 does not show how many hospitals responded that they did not have a certification, neither that how many of the 93 hospitals did not respond at all.

89 As not every hospital responded in each year, I could only exclude hospitals that did not renew their certification.
6.2.1.3. **Data collection methods**

According to Yin (2009) and Eisenhardt (1989) case study method allows both quantitative (survey) and qualitative data collection methods. This research is based exclusively on qualitative data collection methods, because these methods support understanding of the phenomenon (Eisenhardt, 1989). (See the justification of the research methods at the beginning of this Chapter and the relevance of these methods for the research aims and the research questions.)

Yin (2009) claims that the most widely used data sources used for case studies are: documentation, archival records, interviews, direct observation, participant-observation and physical artifacts. According to the original research plan interviews were made, documents were collected and direct observation was performed. The data collection period lasted three and a half months in 2013 (see Annex 4).

**25 semi-structured interviews** were made with hospital actors and **2 semi-structured interviews** were made with the external auditors. The 25 interviews mean that 30 interviewees were involved, because one interviewee (the quality manager) was involved in two interviews, while two interviewees participated in the same interview, and there was an interview with seven participant interviewees, one of them also giving an additional personal interview. The interviews with more than one participant were not planned. In one of the cases a head nurse spontaneously joined in responding to the invitation by the interviewee (head physician). In the other case the Economy Director proposed to make a group interview with the heads of the economy/technical units, which I accepted, although it was not planned.90

According to the original research plan an interview was made with the top hospital managers, including the former Director General, with the quality manager and other personnel involved in quality issues (process coordinators, internal auditors, some quality workers), and also with other personnel from different levels of hospital hierarchy who were not involved in quality issues. (The distribution of the interviewees is shown in Table 8.) In Figure 13, which represents the hospital, small circles show the interviewees. It is also shown which hierarchy level and which hospital field is represented by the interviewees (e.g. supportive fields, technostructure, etc.)

<table>
<thead>
<tr>
<th></th>
<th>physician</th>
<th>nurse, skilled health worker</th>
<th>diagnostics</th>
<th>economic / technological</th>
<th>technostructure</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>top managers</strong></td>
<td>3</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>5 (16.7%)</td>
<td></td>
</tr>
<tr>
<td><strong>middle and lower managers</strong></td>
<td>3</td>
<td>4</td>
<td>1</td>
<td>5</td>
<td>2 (6.7%)</td>
<td>15 (50%)</td>
</tr>
<tr>
<td><strong>non-managers</strong></td>
<td>4</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2 (6.7%)</td>
<td>10 (33.3%)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>10 (33.3%)</strong></td>
<td><strong>7 (23.3%)</strong></td>
<td><strong>1 (3.3%)</strong></td>
<td><strong>8 (26.7%)</strong></td>
<td><strong>4 (13.3%)</strong></td>
<td><strong>30 (100%)</strong></td>
</tr>
</tbody>
</table>

Source: own elaboration

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90 Eisenhardt (1989) claims that if a new possibility of data collection emerges, the researcher can change the original data collection plan. „This flexibility is not a license to be unsystematic. Rather, this flexibility is controlled opportunism in which researchers take advantage of the uniqueness of a specific case and the emergence of new themes to improve resultant theory.” (Eisenhardt, 1989, p. 539.)
The first interviews were made with managers involved in quality issues and with the top managers of the hospital. The first interviewees were also asked about who else they recommend to make an interview with. Later on this snowball method of interviewing was not applied for many reasons (e.g. anonymity, authenticity).

Later, units were selected for the embedded cases. First I asked the quality manager and some other interviewees which units are active or passive in quality issues. Following this step, three patient care units were chosen, two of which can be considered as active in quality issues (see units A and B of Table 9), and one that was considered as passive (unit C) by the interviewees. During the data collection period it became clear that the supportive units had very different characteristics from the patient care units, and therefore further two supportive units (D and E) were selected for the analysis.
Table 9. Data collection for the embedded cases

<table>
<thead>
<tr>
<th></th>
<th>A patient care unit</th>
<th>B patient care unit</th>
<th>C patient care unit</th>
<th>D diagnostics unit</th>
<th>E economical / technical unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>data collection: interviews (within the embedded case unit)</td>
<td>4 interviewees: head physician and head nurse, nurse employee and a skilled health worker</td>
<td>4 interviewees: head physician and head nurse, nurse lower manager, physician employee</td>
<td>4 interviewees: head physician, nurse lower manager, two physician employees</td>
<td>1 interviewee: head physician</td>
<td>1 interviewee: head of the unit</td>
</tr>
<tr>
<td>data collection: other*</td>
<td>documents, observation</td>
<td>documents</td>
<td>documents, observation</td>
<td>documents, observation</td>
<td>documents, observation, interviews with auditors</td>
</tr>
</tbody>
</table>

*The relevant parts of the interviews made with other interviewees outside the embedded units were also used for the analysis of the embedded cases.
Source: own elaboration

Including the embedded cases the interviewees represented more than one third of he hospital units. To ensure anonymity, the interviewees were requested via e-mail or printed letter, attaching the approval of the Director General. This was effective in case of the managers, but it was more difficult to approach non-manager employees. Hospital website and other documents provided less information about their contact parameters. First I turned to the head of a unit to help me contact with an employee, and one of the interviewees was chosen with her help. However, during the interview my fears that the way of the request may have influenced on the interviewee’s behavior were proven, because the interviewee came prepared for the interview and with a clear wish to meet some supposed requirements. Therefore, this method of interviewee selection was not applied in more cases. This meant that I had to come over several difficulties to contact with the interviewees at the different levels of hospital hierarchy, but at least the answers were less distorted and more spontaneous.

Some of the interviews were made before observing the audit, and another part was made after the audit (see Annex 4). The data collected during the observation of the audits also influenced on the selection of the further interviewees and on the questions asked. For the same reasons, one of the external auditors was interviewed before, and the other after the audit. The draft of the hospital interviews is attached in Annex 5, and the draft of the auditor interviews in Annex 6.

Interviews with three of the requested interviewees could not be made, none of them rejected the interview, but they could not find a convenient date because of lack of time. These three requested interviewees were the Director General, a head of a unit and a unit physician.

The interviews took 30-90 minutes each. The lower the position of the interviewee was in hospital hierarchy, the shorter the interviews were.91 If the interviewee agreed, interviews were recorded by a dictaphone to save data precisely. If the interviewee denied to record the interview, I opted for taking notes (three cases). In one of the cases it turned out at the end of the interview, that it was not recorded, so I took notes from memory immediately after the interview.

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91 This usually happened when employees who were less involved in quality issues gave short answers to my questions.
Beside the interviews there were several consultations with the quality manager of the hospital, and she informed me about the important events in the hospital (like management review or audit). The quality manager provided me with 73 hospital documents, which were complemented by others downloaded from the internet (22 documents). (For the list of the documents see Annex 7.) These documents included the external audit reports, the records of the management review, the documents on the internal audits, the organogram of the hospital, the quality handbook and other documents. (Documents are referred to by using codes like JK for records.)

The researcher also had the opportunity to collect data by direct observation. The event observed was a two-day external audit in the hospital, including participation in the opening and the closing meeting, and participation in visiting hospital units accompanying one, and later the other auditor; and the observation of part of the audit with the quality manager, including the phase of documentation checking. This means that I had the opportunity to take parts in all of the events of the audit, except those that went on simultaneously. During the audit detailed notes were taken.

A research diary was kept during the data collection period, in which I took notes of the circumstances and experiences in the hospital, and why I considered them relevant for the study. These records defined the direction of further data collection (e.g. interviewees, questions). Any observation relating the case was written down.

The phases of data collection and data analysis were not separated, which is also admitted by Eisenhardt (1989). The initial analysis carried out in the data collection period can help to find a clearer focus of research. I also intended to direct data collection towards new hospital units, research questions and documents that may clarify aspects of the research questions that had been formerly ignored. Therefore, as Yin (2009) and Eisenhardt (1989) point out, during a case study research flexibility is very important, which means that if new aspects and questions raise it is recommended to change the original research plan. However, this flexibility cannot hinder consistency of the research. Therefore, data collection and initial data analysis, used hand in hand, contributed to find proper answers to the research questions.

6.2.1.4. Data analysis

The application of several different data collection methods supports triangulation, which strengthen research results and conclusions. Triangulation in this case study meant that data deriving from the semi-structured interviews, from the documents and from the observation were compared, and the characteristics and effects of the certification and audit were also examined from different aspects by asking not only the hospital actors, but also the external auditors themselves. In case of some research questions these data sources were also compared to data provided by interviews with experts (see following section).

The interviews recorded by dictaphone were transcribed by an experienced secretary. This secretary typed each sound of the text, and even breaks and other reactions (like laughing) were documented. Interviews, notes, observations records and documents were analyzed by NVIVO 9 software.
For the analysis of hospital and auditor interviews, documents\textsuperscript{92} and observations the method of open coding was applied (Strauss – Corbin, 1990). For the first two interviews a detailed analysis was made (to the level of words and expressions), following the guidelines by Strauss – Corbin (1990). A passage can have several interpretations, so it was listed among more than one codes if necessary. The consistency of coding was checked by repeated coding after a week, neglecting the former coding system, and the new code system was compared to the original one. The discrepancies were analyzed, and coding was refined. The hierarchically structured coding system was complemented by further codes during the coding of the later interviews, and the structure was also refined. After coding the half of the interviews the structure could be called as stable. When new codes appeared or when the coding system was modified the previous interviews were recoded according to these modifications. The first two levels of the final coding system\textsuperscript{93} are included in Annex 8.\textsuperscript{94}

The analysis and the interpretation of the coded textual passages was a cyclic process, according to the logic illustrated by Huberman – Miles (1994, 27.2. Figure in p. 433.). This means that after my first analytical and explanatory texts I returned to the coded data, and applied further questioning to support deeper understanding of the phenomenon and the relationships. The queries were made according to the embedded cases (e.g. by codes and interviewees), and according to the groups of the interviewees (e.g. physicians and other patterns). As a result of these cycles the first, rough analysis of the coded texts were made, including the exact codes of the data sources that were used for the analysis. Based on this, further analysis made it possible to formulate the first case report, which helped to make some conclusions. In order to present a material that can be understood by the public, these conclusions had to be restructured.\textsuperscript{95}

During the analysis of the data the original research questions served as guidelines, but new ‘discoveries’ were made during the overlapping phases of data collection and initial data analysis, which would have been avoided if I strictly follow the original research plan. During the analysis I intended to make my preconceptions explicit, and to make the analysis independent from these preconceptions.

### 6.2.2. Interviews with experts

Besides the case study, the other method applied was making interviews with experts. Besides revising the publicly available documents (e.g. regulations, articles, presentations) on the quality improvement in health care in Hungary (see subchapters 5.3 and 5.4), semi-structured interviews were made with the developers and the supporters of the external evaluation methods analyzed (ISO and SHC/HHCS), in order to have a better knowledge of the wider context of the case. These interviewees are called ‘experts’ in the dissertation. This data collection method helped the understanding of the intentions of the developers with the supported systems, and it also contributed to have a more complex view of the history of these systems.

\textsuperscript{92} 95 documents were revised and 50 were coded. The others were analyzed by using different methods (as an example see Table 11 and Table 12 for the distribution of quality personnel in the hospital). (For the list of the documents see Annex 7.)

\textsuperscript{93} The consistancy of the coding system was continuously improved as I realized that a certain passage may belong to more than one codes.

\textsuperscript{94} The first two levels of coding systems presented in Annex 8 were generally used in analysis, in answering of some questions the third-level codes were also useful.

\textsuperscript{95} In Chapters 7 and 8 the quotations taken from the interviews are in italics, and the quotations from the documents in normal letters. Interview quotations are grammatically corrected.
The selection of the expert interviewees was oriented by the aim of obtaining as much information as possible about the history and development of these systems (since the 1990s), and to find the most influential experts in quality. The experts were also asked about who they recommend to make an interview with, and their answers influenced further selection. From those who met the above mentioned criteria five interviewees were chosen, including professionals who were responsible for quality in health care in the Ministry, the developers of methods (like standard systems) and the developers of background materials (like for ISO 9001:2000 (ESZCSM, 2003)).

The interviews with the experts were made preceding the data collection for the case study, in Autumn 2012. The draft of the interviews is included in Annex 9. This draft was adjusted to the individual experts according to the fields of their expertise. The expert interviews took 1 or 2 hours each. During the data analysis phase these interviews were coded using previously defined categories. The categories were selected from the coding system established during the analysis of case study data, considering which categories are relevant. A new code was also introduced, named ‘how it works: experts’ assumptions’. The codes applied for the analysis of the expert interviews are included in Annex 10.

Interviewees are referred to as I1, I2, I3, I4 and I5. (For the description of the expert interviewees see Annex 11.) The expert interviews were used in Chapter 7 on the characteristics of ISO and SHC/HHCS certification in case of the hospitals in Hungary, and expert opinions and experiences were also compared to some characteristics of the present case in Chapter 8.

6.3. **Validity, reliability and generalizability of the research**

The factors undermining validity of the research (Maxwell, 1996) were fought by using the following strategies:

A diary was kept, recording not only the time and method of data collection, but also every little event that happened during the case study, and even impressions and other experience. The diary also recorded the circumstances of data collection, and, if it could be perceived, how the behavior of the participants influenced by me as a researcher. (For instance, there was such a case during the observation.) These recorded notes were also taken into consideration when analyzing data.

In the phase of data collection and initial data analysis I used auto-reflection to try to identify the filters I unintentedly used. I tried to maintain openness for different approaches in both the phases of analysis and data collection. This attitude helped to surpass initial assumptions (like the aim of the method is improvement), and be able to accept other interpretations.

It was also intended to try to perceive if the interviewees want to meet some of my expectations they assume. In the initial phases of some interviews this behavior was identified, which I intended to avoid by openness and honest communication. One of the interviewees had previous knowledge of my former career, and it could be observed that this information influenced on the interviewee’s behavior. As a reaction, I pointed out that this research was independent of my former workplace, and that I was fully open to know opinions.

The interviews started by introducing myself, by assuring anonymity, and by offering to send interviewees a copy of the final dissertation. I was eager to consider feedback and to avoid misunderstanding.

During data collection it was an aim to collect controversial data and negative examples as well, and to consider alternative explanations. Triangulation (comparison of interviews, documents, observation and
different aspects) supported the validity of the research. The first versions of the case study were consulted with a participant who had an extended knowledge of the case, and with a researcher who was not an expert in the topic. Their feedback was taken into consideration when elaborating the final version of the case study.

In order to enhance reliability, the researcher documented every steps and events related to the elaboration of the case study. Data (recordings, notes, documents, etc) were stored in a systematic way and they are retrievable. The written materials that was made during the analysis are based on each other, and so the sources of the statements are retrievable.

In case of the applied method, the case study, the criteria for the quality of the research is not statistical generalizability, but analytical generalizability (Yin, 2009; Eisenhardt, 1989). The conclusions are compared to the theories of the literature and to former research results (see subchapter 9.2). This strategy supports generalizability of the research.

However, it was not a principal aim of this research to be generalizable, because it focuses on the understanding of a phenomenon in its real-life context. Maxwell (1996) claims that this focus of the qualitative studies does not exclude generalizability of the results, because the theories formulated can be extended to other cases as well. With the presentation of the case study it was an aim that it can be compared to other cases, and that conclusions can be drawn from these comparisons by considering the similarities and the differences of the particular circumstances.

Chapters 7 and 8 describes the analyses of the empirical research. Chapter 7 analyzes the objectives, roles and reasons of the certifications on the basis of expert interviews, while Chapter 8 presents the results of the hospital case study.
7. Experts’ opinion on ISO and on SHC/HHCS certifications

The history and the spread of certification according to ISO 9001 standard and to SHC/HHCS were described in the subchapter 5.3. Subchapter 6.1. detailed the research questions for this study, and it called the attention to the importance of the question of what were the reasons and the aims of introducing these systems in Hungarian hospitals. In this Chapter the objectives of the application and the roles of these quality systems are examined from the point of view of Hungarian system developers and supporters, and the reasons of why hospitals decided to go through the process and obtain a certification are given based on experts’ opinion. The statements of this chapter are formulated after analyzing and comparing the five interviews with expert professionals.

7.1. The objectives and the role of quality systems

Subchapter 5.4 points out that the introduction of quality systems and certifications was not forced by any legal regulation in hospitals, so in health policy terms we cannot talk about external objectives, but about general objectives related to the application of quality systems. In the following expert opinions are given about what kind of declared objectives were behind the introduction of the different quality systems (ISO, SHC/HHCS) and the attached external evaluation methods. Real life experience about the realization of these objectives and the fulfillment of the requirements will also be described.

7.1.1. Declared objectives of quality systems

Health policy leaders of the 1990s strictly followed WHO recommendations, and this lead to the declaration of quality improvement as an objective and "they declared that the quality of care has to be improved and this improvement has to be supported by proper quality systems." (I5 96). The same expert commented that health policy leaders did not take the effort to thoroughly explore the possible consequences of the introduction of the systems. More experts agreed that health policy leaders were committed at the level of their declarations, but operation of health policy was dominated by economic restrictions, therefore quality ceased to be a priority. (I2, I5)

According to an expert who took part in the adaptation of JCI (Joint Commission International) standards to Hungarian hospitals (developing SHC) the system of objectives was not clearly defined, which had negative results for the future development of these standards. (I3)

Interviewees agreed that there were no clear health policy objectives behind the introduction of ISO system and the development of SHC, and developers did not perceive the objectives as clearly as they may do it now. Still, quality improvement appeared as a declared objective at institutional level (I2), although it was usually pure rhetoric, while institutional leaders did not really understand the practical operation of quality systems:

"This is a two-faced issue. Quality documents of the institutions clearly declare commitment of the executives to quality improvement. However, and maybe my words are a bit strong, institutional...

96 Expert interviewees are referred to as I1-I5. For description and characteristics of interviewees see Annex 11.
leaders have very little idea about what quality means and what could be expected from these systems." (I5)

7.1.2. The role of quality systems and of certification

The opinion of experts about the role of ISO system and SHC/HHCS system are summed up in Table 10.

Table 10. The role of quality systems based on experts’ opinion

<table>
<thead>
<tr>
<th>ISO 9001 standard</th>
<th>SHC/HHCS system</th>
</tr>
</thead>
<tbody>
<tr>
<td>regulation;</td>
<td>regulation;</td>
</tr>
<tr>
<td>serve as a framework;</td>
<td>serve as a framework;</td>
</tr>
<tr>
<td>decision making tool for</td>
<td>patient and worker safety, defense;</td>
</tr>
<tr>
<td>the management;</td>
<td>cost savings;</td>
</tr>
<tr>
<td>quality improvement</td>
<td>changing of operation;</td>
</tr>
</tbody>
</table>

Source: own elaboration

Regulation is mentioned in case of both systems. „ISO requires that I describe what I do and that I do what I described.” (I1), and standards are defined as „the regulation of the processes of health care and of other key processes, according to certain criteria” (I3).

Talking about ISO quality management system most expert interviewees pointed out the role of serving as a framework (I1, I2, I4, I5). One of them gave an interpretation: „[…] I consider ISO as a cupboard with many systematically arranged drawers in it, where we can fill the drawers as we want to.” (I1) This framework can be filled with specific health care procedures (I5), professional procedures (I1). Another role of the ISO system is to serve as a management support tool with the opportunity of continuous monitoring. (I4)

According to one of the experts (I3) one of the functions of standard systems (like SHC) is to improve safety, but developers had not seen this so clearly. Through improving patient safety and worker safety standard systems also contribute to defending the institutions in case of trials or denouncements. (I3)

One of the aims communicated when SHC was introduced was that it enhanced cost savings (I3). Furthermore, as compared to ISO system, SHC also aimed at changing the operation of the institutions, as SHC standards contained requirements referring directly to the institutional operation.

Both quality systems had as an aim to improve quality. SHC says: „there was a separate group of standards to ensure that internal quality improvement programs could work and could change a static system”. (I3) All experts agreed that one of the aims of ISO system was to improve quality.

ISO and SHC/HHCS systems can complement each other if we consider their strengths and weaknesses. According to the experts interviewed one of the weaknesses of ISO is that it is not health care specified, health care processes do not appear, while they do appear in SHC/HHCS. This is the reason while some of the experts decided to take part in the elaboration of an interpretation of ISO 9001 standard for health care (ESZCSM, 2003) (I1, I2). More experts (I1, I2, I4) miss from SHC/HHCS a systematic approach that could serve as a guideline for the management on how to apply and operate these systems, and it does not reflect the operation of the PDCA cycle like ISO quality management system does (I1).

Three of the experts (I1, I2, I5) agreed that ISO and SHC/HHCS complemented each other and could be applied together in an integrated way.
"It is something like form and content. ISO is like a very strong framework, in which health care specific requirements can be embedded. Some institutions even made an excellent matrix matching ISO standard and HHCS standards" (I5)

When creating HHCS it was among the aims to integrate the logic of ISO into the system of these health care standards (I2). In accordance with the opinion of the three experts who argued for an integrated application of the standard systems, another expert with auditory experience also claimed that HHCS could complement ISO by supporting the evaluation of patient care units (I4). The fifth expert (I3) agreed that the two systems could complement each other, although not by using a mixture of both standards for external evaluation, but by using HHCS for evaluating patient care and ISO for the supportive background fields, as its scope does not always include the profession of health care. Originally the two systems are very different in concept. While ISO evaluates the quality management system and the processes of how rules are set in an organization, SHC focuses directly on institutional operation (I3). This interpretation suggests that the two systems (ISO and SHC) represent two different external evaluation methods. This approach is distorted by the fact that SHC can only be achieved through a certification procedure the method of which is based on ISO. One of the experts claims that in practice the implementation of HHCS is strongly determined by the fact that external evaluation is made according to ISO requirements. She claims that in this way a system based on operational requirements (SHC) has been implanted into a quality management system (ISO) which is disadvantageous for the implementation of the health care standards (I3).

7.1.3. Practical experiences of the application of ISO and SHC/HHCS systems

Even the experts mentioned that the original aims and roles of quality systems are not necessarily fulfilled during their practical application. In some cases even the developers of these systems failed to transmit the key messages. Many of the experts emphasized the failures of practical application (I1, I3, I4). However, there are also some positive experiences, and three of the experts claimed that ISO system was a tool to make some order (I1, I2, I5):

"Posteriorly most institutional leaders say that ISO has been an excellent tool of ‘tidying up’ the organization, because now we all know what to do, and everybody knows their place." (I5)

"Hospitals that elaborated their own processes, maintain them regularly and control fulfillment are considerably better in maintaining order in their institutions" (I2)

According to one of the experts providers that have longer experience in using these quality systems and have some committed professionals, can enjoy the benefits of the systems and that these systems have a positive regulatory function in practical operation (I3). Meanwhile, for providers that bought the ready-made system and did not take part in its development, it is mostly only one more among the thousands of institutional documents (I2) to prove fulfillment of legal requirements (I1).

Two of the experts agreed that ISO system did not contribute to quality improvement in practice, because providers did not fully exploit the opportunities offered by the model (I4, I1), and that this was due to the characteristics of the current auditory practice (I4). The current practice is to introduce ISO in order to fulfill requirements of the authorities, "this is the unpretentious version, while we are talking about the luxurious version, of course". (I4)

Related to practical application experts mentioned some disadvantages for both systems: according to some experts (I1, I3) ISO requires too much documentation, and one of them claimed that it was nothing
else but this (I3). About SHC it was clear from the beginning that it could not be surveyed by audits. (I2) Another expert thought that SHC/HHCS were easier to implement due to their focus on health care procedures: „HHCS focuses on patients and on medical procedures, which makes it more acceptable than ISO.” (I5) At the beginning the elaboration of the content for the ISO framework was extremely difficult and mostly only formal, while SHC provided the appropriate content (I5).

Experts also described the systems according to in which hospital field they can be useful or advantageous as compared to the other system. Experts mostly agreed that the scope of ISO system extends to the organization as a whole, but it does not affect professional work of the different hospital units (I1, I3, I4), but it properly regulates background services (I3, I4). Meanwhile, SHC and HHCS focus on patient care units, although they also fail to properly regulate professional work in its strict sense (I3, I4).

7.2. The reasons of undertaking external evaluation

All of the expert interviewees received feedback from hospital leaders, and three of them had their own hospital experience. (See Annex 11.) According to the experts hospitals undertook certification for the following reasons:

- to fulfill legal requirements,
- lack of experience,
- perception of ministry requirements,
- it is among the requirements to be able to submit tenders,
- expecting advantages in financing,
- fashion.

Although obtaining a certification has not been compulsory, institutions obtained it to fulfill legal requirements. (I1, I5) One of the experts explained:

„Institutions thought that obtaining the certification was as important as managing a quality system. They wanted to be able to show that they had a good quality system.” (I5)

This means that the certification justified that the institution met legal requirements and it had an operating (internal) quality system.

Another reason that led to obtaining a certification was that health care institutions did not have any experience in establishing a quality system and they asked an external certifying institution to do that. (I1, I5)

A lot depended on how hospital leaders perceived ministry’s expectations (I3, I5), although having a certification has never been an explicit requirement (I2, I5). However, the Ministry published a guideline for internal quality systems,97 which was

„a kind of simplified, ISO-based requirement system. [...] The hospital started to deal with it, and the leaders realized that if they start working on the implementation of all those requirements, then why not undertake an audit and obtain the certification to show up with.” (I2)

97 Guideline on the internal quality system in health care providers and requirements published by the Ministry of Health, Social and Family Affairs (valid until 1 of December 2005., validity of the modifications: 31 of December 2009.)
Besides perceiving certain expectations another reason for obtaining a certification was that it was a compulsory element of tender requirements (I1, I3, I4).

According to the experts hospital leaders might have supposed that obtaining a certification would have more favorable financing as a consequence. (I1, I2, I3) There was „an initiative of the Ministry that the National Health Insurance Fund gives a kind of bonus to the certified institutions.” (I3) However, this initiative failed to go through even the ministerial phase of the process. (I2) Despite its failure, hospital leaders knew about this initiative and they had continuous expectations towards its realization, and that certification would have some positive consequence for their institutions, which has not become fulfilled. (I3, I4, I5)

Another factor that influenced hospitals when applying for certifications was that there were more and more institutions that had obtained one (I2, I4): „Therefore, quality issues became a fashion by the end of the 1990s, and those who did not want to stay behind obtained a certification for their institution.” (I2)

As far as intrinsic motivation is concerned experts claimed that most institutions only needed the document (I1, I2, I3, I5) to prove fulfillment of legal requirements and to be able to submit tenders. Most experts also agree (I2, I3, I4) that there were some institutions where the importance and the advantages of these systems were recognized. Some of these advantages could be that they could achieve a regulated operation or better quality. (I2, I4) One of the experts claimed that according to his experience hospital leaders consider certification as a burden, they do not enjoy its benefits, as the system is used as pure formality. They are characterized by a short-term perspective and they refer to scarce resources when they fail to finance the operation of the system. (I1)

Experts also highlighted why hospitals chose for one or the other system. At the beginning ISO was the only system available, hospital leaders were uncertain, while certifying institutions faced a glutted market in the private sector.

„ISO seemed to be at hand, with good references in the private sector, offered by companies with a convincing international background that provided training and certification at the same time. And these were companies that had been accredited by the NAT98, so they were embedded in an officially accepted structure and this seemed to provide security for hospital managers.” (I5)

The systems of SHC and HHCS could be chosen because they were health care-focused systems and could be more easily interpreted by hospitals. (I3, I4, I5) SHC and later HHCS certification was rarely obtained without ISO. According to an expert a reason for this is that these systems did not provide instructions on the implementation, which made it difficult to prove them in audits, while ISO contained guidelines on these issues. (I2) Another expert said that although SHC and HHCS seemed more beneficial, but institutions that had already had ISO certification preferred to integrate standards (see form and content). (I5)

Many experts agreed that integrated systems were applied by institutions devoted to quality improvement. On the one hand, „They were those who realized that something was missing from ISO.” (I2) On the other hand, an integrated system is more costly. (I1)

The news about the hospital accreditation system that is currently being developed can also influence institutions in their decisions of obtaining a certification, therefore, I asked some experts about how this

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98 NAT: Nemzeti Akkreditáló Testület (National Accreditation Board)
new influences decisions about taking up or maintaining certification. Experts agreed that hospital leaders are waiting to see which way the cat jumps (I1, I2, I3, I5), and that this is not beneficial for the maintenance of the current systems (I5). However, maintenance is also hindered by an unfavorable economic background (I2) and by changes in the institutional system (I5).

As a conclusion it can be claimed that according to the experts interviewed Hungarian health policy makers in the 1990s supported quality systems, but they failed to communicate clear goals and objectives. Experts agree that the practical application of quality systems and certifications have not necessarily produced the desirable beneficial effects.
8. Hospital case study

The message of this motto is important because it reveals that even the quality manager admits that the final system established as a result of the certification process reflects only one possible interpretation of the integrated application of ISO 9001 and HHCS, and that the resulting system is shaped hand in hand with the leading auditor as an external evaluator. It is also possible, that working with another auditor would completely change the interpretation of the role of certification.

The case described below can also have different interpretations. This Chapter focuses on the interpretation that I consider relevant for the research questions of the present dissertation. The following subchapter offers an analytic framework that supports also the understanding of this chapter.

8.1. Analytic framework of the case study

While analyzing hospital and auditor interviews, documents and data collected during observation, the following categories seemed to be useful to describe the phenomenon in question:

- mechanism of the effects, including the reactions and interactions of the stakeholders (auditors and hospital actors) in relation to external evaluation, and the effects of these reactions and interactions within the organization,
- external evaluation including the characteristics of the certification and the related audits, which is one of the factors that influence on the mechanism of effects,
- other factors that influence the mechanism of effects,
- interviewees’ interpretations of the role of certification for the hospital.

Figure 14 illustrates this analytic framework.

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99 Originally the quotation included the name of the leading auditor of the hospital, and this has been substituted here.
Figure 14 illustrates that both auditors and hospital actors have their own perceptions of hospital operation, of other actors' work and their behavior (perceived practice), and of the auditor's expectations towards these factors, and, therefore, they have an idea of the discrepancy (GAP) and of the level of appropriateness. Auditors detect this gap by applying audit (external evaluation) methods, and the characteristics of this method have an influence on the reactions and interactions of hospital actors and of the auditors. The reactions and interactions that are the consequences of the process of the certification and the audit are called mechanism of effects, which mechanism is also influenced by other factors. All these effects shape the perceptions that hospital actors have at the end of the process about the role of the certification in their institution. These interpretations of roles again have a secondary effect on the reactions and interactions through the behavior and attitude of hospital actors, and through these mechanism on the possible and perceived changes.

Chapter 8 has the following structure: when describing the methodology (subchapter 6.2) the criteria for hospital selection were given. Therefore, subchapter 8.2 focuses on a brief description about the principal characteristics of the hospital, giving more details about the quality system. Then a summary is given about why this hospital undertook the certification process (see subchapter 8.3). Using the analytic framework of Figure 14 subchapter 8.4 analyzes the characteristics of the audit related to the external evaluation (in this case: of the certification), and examines the reactions and interactions of hospital actors and auditors as a result of the external evaluation (here: the mechanism of effects) (subchapter 8.5). Subchapter 8.6 systematizes the perceived effects of the evaluation on the organization, as perceived by hospital actors. The different interpretations of the interviewees about the role and effects of the certification process and of the audits are analyzed in subchapter 8.7. The factors that were revealed to influence on the mechanism of effects are summed up in subchapter 8.8.

Influential factors can have different origins and may interact with each other, so they will be illustrated as a jigsaw puzzle-form in Figure 15. The groups of influential factors identified in the empirical study are as follows:

![Figure 14. Analytic framework for the case study](source: own elaboration)
– theoretical factors,
– external evaluation factors,
– external factors,
– organizational condition factors,
– indirect effect factors,
– factors at individual level.

The information on and interpretations of ISO and SHC/HHCS system available to hospital actors and the interpretations and messages of the developers of these quality systems as described in Chapter 7 are considered as theoretical factors. The elements of the other factors that were identified during the case study are described at the end of the subchapter 8.2, 8.3, 8.4, 8.6.1, while individual factors are presented in subchapter 8.8, and their validity will be proven by analyzing some embedded cases. The final subchapter is dedicated to the analysis of how certification and related audits could affect improvement initiatives in the case studied here (subchapter 8.9).

8.2. Case description

Subchapter 6.2 described the principal characteristics of the case hospital. In order to respect anonymity publishing of more details was not allowed. The hospital is middle-sized (acute bed number between 300 and 1000, total bed number between 450 and 1500). Basic specialties are all represented (number of specialties altogether between 10-19), which means that the institution is a general Hungarian hospital (not a specialized hospital and not a university clinic).

Hospital leadership is committed to professional and infrastructural development of the institution. According to the former director of the hospital, the implementation of the quality system and the certification process was also considered as one of the series of measures aiming at institutional development. This subchapter describes the quality system of the institution, the initial phase of the certification process, the hospital roles relevant to this study and the changes that took place during the certification process.

8.2.1. Obtaining a certification

As mentioned among the selection criteria, the hospital obtained ISO 9001 certification at the beginning of the certification wave in Hungary. This certification has been continuously renewed, and meanwhile the institution also obtained SHC and later HHCS certification. The hospital was using an integrated version of ISO/HHCS at the time when this case study was made.

The susceptibility of the management is shown by the fact that the hospital was among the first ones to establish a quality system according to the available ISO standard, and the idea of the certification was part of a clear strategic concept represented by the Director General, “which was accepted and...”
understood by the decision makers in the hospital.” (interview, person for quality\textsuperscript{100}). The Director General assigned the responsibility of quality management to his vice medical director.

The certification was preceded by a one year preparation period, dedicated to system implementation and preparation of the regulatory documents (e.g. descriptions of procedures, operating rules of departments, job descriptions). This period also included a preparatory training for the quality manager, the secretary responsible for quality issues, the process keepers, the internal auditors and the quality workers. (interviews, JK17) Each department appointed a responsible who elaborated regulations at the level of the department. Leaders involved in quality issues claimed that the elaboration of the basic elements and adaptation took a lot of time and efforts.

At the beginning it was difficult to interpret ISO terminology and apply them for the context of the hospital. Even certifying companies had little or no experience in the field of health care. One of the physician head interviewees overtly criticized the certifying company that used the business term ‘customer’ when they worked with patients.

The first certifying audit was preceded by several internal audits and trial audits organized by the company responsible for the preparation, and this was followed by a pre-audit performed by the certifying institution. Then feedback was given to the hospital units about the failures, and exceptional unit meetings were held to carry out the necessary modifications. According to the records, the actual situation of the quality system and the necessary measures was a topic of practically all of the unit meetings. (JK17, JK16, interview) All this process was followed by the certifying audit where the hospital obtained the certification. The certification of this hospital is always made by the same institution. Every three years they make a renewal audit, and in the interim two years they have a so called supervisory audit, which means that auditors come to visit the hospital every year.\textsuperscript{101} (interviews, reports) Not only the certifying institution is the same since the beginnings, but also the auditors themselves.\textsuperscript{102} At the time of this study the leading auditor of the hospital was a qualified nurse who worked for another hospital as quality manager, and the other auditor was a practicing physician.

As the hospital was among the first to start an ISO-based quality system, when SHC became available the situation was already given. According to the present quality manager it was evident that the hospital would integrate SHC into ISO system, as a separated application would have involved much more documentation. The difficulties derived from the fact that the two systems were not always compatible. The introduction of SHC required the elaboration of some new regulations that had not been used before.

\textquote{This meant extra work, but it was not as deterrent as for the first time, but well, the birth of a first child is always more difficult. [laughs] When it is there, and have to do something with it, the second one cannot be a problem. Well, this was the case with ISO and SHC}. (interview, top manager)

According to the records (JK11, JK12) SHC was also preceded by an intense preparatory period including random supervisions, nursing visits, internal audits, handling of inadequacies, trainings,

\footnote{\textsuperscript{100} Section 8.2.3 introduces the personnel responsible for quality management („person for quality”), including the quality manager, quality secretary, coordinator, process keepers, internal auditors and quality workers.}

\footnote{\textsuperscript{101} In the case study the term ‘auditor’ refers to external auditors. When talking about internal auditors it is always done explicitly.}

\footnote{\textsuperscript{102} At the beginning a third auditor was also present.}
changing of regulations. After the preparatory period SHC was introduced in two weeks, „due to the excellent commitment of the management and all the hospital workers” (JK10).

8.2.2. Reception of ISO and SHC in the hospital

Interviewees who presented at the introduction of ISO (7 interviewees) pointed out that the interpretation and adaptation of the system was difficult because it was not health care specific. Some of the examples of the early reactions:

„At the beginning it sounded as if it was from another planet. What? An assurance system for manufacturing? Because ISO was developed for this. From purchasing of the material to the customers’ evaluation? Well [smiling], this did not seem to be the thing for health care.” (interview, quality manager)

„I had a disapproval, because I could not understand how on earth we have to adapt an ISO-type model to health care when it was not developed for it.” (interview, top manager)

„When we introduced this quality system it was clear that it had nothing to do with health care. […] All the concepts were different, suggesting that it was all conceived to control procedures like baking bread or something like that.” (interview, quality manager)

Physician head interviewees who worked as heads of patient care units agreed that this system, which had been developed to control business and manufacturing procedures, could hardly be applied for health care. (three interviewees)

As it has already been mentioned, ISO had already been established by the time SHC appeared as a possibility. Interviewees considered the introduction of SHC as indispensable, because SHC was health care specific, but they also wanted to maintain ISO:

„Many years of hard work could not be annulled, and institutions that had obtained ISO could not be punished, so although we all knew that SHC was better and health specific, we opted for not to begin from nothing […]”. (interview, former Director General)

This attitude was also supported by the quality manager. However, besides its health specific nature SHC also had its weaknesses, which were compensated by HHCS (such as standards for outpatient care) according to the opinion of quality manager. Another person for quality also had some critical remarks:

„It seemed that the developers of SHC did their job in an ivory tower, and although they tried to do their best to find an answer to every detail the result was an extremely complicated system […]”

„There were passages that we were unable to interpret, and when an auditor company came we turned to them for answering our questions. And we relaxed when, well, when they also replied that they could not interpret them either.” (interview, person for quality)

None of the interviewees mentioned that SHC would have brought about any significant changes in the hospital. Introduction and implementation of SHC meant a lot of extra work for the personnel involved in quality issues, as SHC regulated health care procedure in a more detailed manner than ISO did. According to the quality manager the difficulty was that „SHC were hospital specific standards, while ISO

103 Quotations from documents are in normal letters, quotations from the interviews are in italics.
standard were not. Which meant that they had to be integrated, and this required extreme efforts.”
(interview, quality manager)
The nurse director, who took an active part in the introduction of both systems, said about the effects of
ISO and SHC:

“For me ISO seems more vivid than SHC, but this may only be because I spent a lot of time and
effort on its introduction. We also apply SHC, but mostly as an extended, more refined version of
ISO.” (interview, nursing director)

It was mentioned before that the interpretations given by the auditors can also contribute to the effects of
SHC and HHCS on the hospital. According to one of the auditors the standard system „simply requires
that institutions meet legal requirements. So, why to establish a new system for this is incomprehensible.”
(interview, auditor) The first SHC audit reports followed the structure of ISO reports, where important
elements of standards such as measurable quality aims, indicators did not appear. (Jelentes7b, Jelentes6b).
The effect of SHC on hospitals is characterized by the fact that interviewees hardly ever used the term
SHC or HHCS, but they usually referred to ISO. Hospital actors did not distinguish between the two
systems, and ISO-related attitudes dominated. Therefore, the following parts of the present case study
will also write off the distinction between ISO and SHC/HHCS, as the effects of these systems cannot be
separated in the hospital.

8.2.3. Certification and audit-related hospital roles

In relation to audit, interviewees claimed that quality manager, middle managers (heads of departments,
physician heads of departments, nurse heads of departments, head operation room nurse) and top
managers (the management) play an important role. The same stakeholders were mentioned by the
leading auditor of the hospital, and she also pointed out the importance of internal auditors. Hereinafter
these and some other quality-involved hospital roles will be introduced.

8.2.3.1. Persons for quality in the hospital

Seems trivial that the personnel involved in the implementation of the quality policy of the organization
(called persons for quality, hereafter) have an important role in relation with the audits. Interviewees
mostly mentioned the quality manager, and some of them also mentioned the internal auditors among the
personnel involved. However, there are other personnel responsible for quality like quality secretary,
“quality coordinator” 104, process keepers, and quality workers. First the role of the quality manager will be
described.

The first quality manager of the hospital was the vice medical director as mentioned before. When he
retired, the former Director General had to decide whom to appoint for the position: a top manager also
qualified in his profession, „who is able to communicate the results more successfully, and documentate
them in a proper way towards the public.” (interview, former Director General); or someone from below,
„who can better identify with the opinion and feelings of most hospital employees.” (interview, former

104 The title of „the quality coordinator” is in quotation mark, because she was not assigned for this position, but the work
she performed can be corresponded to the work of a quality coordinator.
He decided for the last one, and a nurse professional with several other qualifications was appointed as quality manager. This quality manager was in charge when the present case study was made.

The official position of the quality manager differs from her real position. According to the auditory report: “The quality manager is a full member of the hospital management and takes part in its meetings.” (Jelentes5a) This official position is reflected in the former organogram of the organization. Despite this, the quality manager did not consider herself as a full member of the hospital management. This is reflected in what she said about her fellow quality managers in other institutions: “They work as quality directors, and they are in fact members of the management, and not only in the facade.” (interview, quality manager) When the Director General changed, the position of the quality manager changed too, and she became explicitly not part of hospital management, as it was reflected in the new organogram of the institution.

However, the job of the quality manager would require participation at management meetings, because in this way she could be informed about organizational changes. (2 interviews, persons for quality) Interviews also suggest that participation at the meetings would not only be important to be well informed, but also because more support from the management could be obtained for more effective operation. One of the top managers’ remarks: “I have to confess that the quality manager is sometimes left alone with her work.” (interview, top manager)

The quality manager sums up her role as follows: “Well, it would take weeks to describe my tasks. But, principally, I have to coordinate quality system – let this be enough for now.” (interview, quality manager)

Hospital workers (four interviewees) referred to the quality manager as the know-all of quality issues, whom they can ask any time, and she can always give an answer, which is very important during the audits as well. In accordance with the importance of the quality manager during the audits she sees her role as follows:

“[question] What do you think about your role in the result of the evaluation and in what decisions are made?

[reply] I think my work has an effect on this. The failures committed by a department are not serious failures if there is a committed quality management behind. My job is to be committed in this respect. My job is to be professional, and try to represent everybody’s interest, with special focus on the institution and on the patients. And I also have to consider economic situation, the burdens of my colleagues and the attitude of the management, which are many people. So I think that I have an important role, as if my work is not as good as it should be, any mistake would seem much bigger. […] The opinion about the institution is in accordance with how I present things.” (interview, quality manager)

The quality manager has many coordination tasks besides audit (10 interviews) some of them are: control regulations, to be able to transmit them to other workers. She takes part in the implementation of the measures introduced as a result of the audit, so if stakeholders cannot immediately adapt to the new measures she can give them support. One of the top managers sums up the role of the quality manager as follows: “She is the one who is able to see what is needed, what is to be done, he can help the departments to do things, and without her many things would be neglected.” (interview, top manager)

The importance of the work of the quality manager is recognized even by other top managers of the hospital.
Internal auditors are hospital staff members especially trained for this job. (Jelentes3a, JK3, JK10, JK11, interviews) Besides qualifications, internal auditors have to dispose of some special skills to perform this task. According to my interviewees it is important that they can ask good questions, and that they have to have an overall view of institutional operations. The quality manager also considered important the role of the internal auditors, and it is the quality manager who appoints the internal auditors, as she works in close cooperation with them.\footnote{The work of internal auditors is coordinated by the quality manager.} It was an aim that internal auditors come from different areas of hospital operation.

The role of the internal auditors is to support organizational units during the preparation for the audits. Internal audits reveal the gaps and mistakes that still can be corrected. (6 interviews, dok3, dok4, dok5, JK2, JK3, JK8, JK9) One of the auditors describes their task as follows:

\[\text{I always joke that I may find something to get them hot under the collar. Anyway, if I find something, it will have no serious consequences, but it offers an opportunity to improve until the external audit comes. […] So it is not for fun when I say that I have found something, and sometimes my colleagues even smile and say thank you, because in this way they can correct their mistakes. If we find something, it also serves to prevent more serious failures.} \] (interview, internal auditor)

Internal auditors do not only play an important role in the organization as a whole, but they can also give considerable support to their own department. Internal auditors know more than any other colleagues about the requirements of an external audit. (5 interviewees) Although the quality manager claimed that nurse heads of departments were the best informed, and they often held the position of internal auditors as well, interviews suggested that an internal auditor could be better informed about the quality system than a nurse head if the nurse head is not in the position of internal auditor. The role played in supporting a department is illustrated by the following quotation:

\[\text{If we did not have an internal auditor within the department we would feel left alone, and we would not know what questions to expect, and we could not properly prepare for either internal or external audits.} \] (interview, internal auditor)

The quality secretary, quality coordinator, process keepers and quality workers also participate in the operation of the quality system. According to the interviews and to the records, the quality secretary played more important role at the beginning when the system had to be implemented, rather than at the time when the case study was made.

The current quality manager had previously worked as quality coordinator, but the position of quality coordinator was not filled during the period of the case study. However, there was an assistant working with the quality manager whom I will call as “quality coordinator”, because she was the one to keep contact with the departments during the audits, she transmitted them regulatory requirements, and she coordinated modifications of department rules, too. (interviews, observation) It was also her task to manage quality related documents.

At the beginning process keepers were responsible of preparing descriptions of the principal hospital processes (like inpatient care, outpatient care or diagnostics) and they are responsible for their maintenance and modification. Some of the process keepers were top managers. According to one of the
interviewees it was of key importance at the beginning that the personnel appointed to process keeper were capable of understanding this complex task and took it really seriously. Quality workers were also mentioned by some of the interviewees, but not as key figures during the audits, although according to the document that describes the competencies of quality workers (dok10) they are supposed to play an important role in the quality system of the hospital. Their competencies include “... to be familiar with, promote and control the fulfillment of quality related regulations in all hospital units and departments.” (dok10) Theoretically quality workers are responsible for the quality training of new employees, as it is reflected in the job descriptions and in the interviews. Interviews also revealed that the intensity of the activities of the quality workers was different in each hospital unit. There was a unit where employees did not even know who the appointed quality worker was, while in another unit employees unanimously praised the quality worker’s performance. According to the physician head of the latter department, audits and their consequences meant much less burden on the employees in this unit as there is this enthusiastic quality worker. In this unit the quality worker revealed problems, prepared the employees for the external audits, and she informed unit staff about the importance of the recommended changes and the proposed quality elements (like operational rules of department, description of competences), and, together with the nurse head of the department, they also made development proposals. As I mentioned before, in some cases besides the quality worker an internal auditor was also present within the same unit and took part in the quality work. None of the quality workers considered it their task to train new employees in quality matters. Quality workers – except in the department where the employees could not name who it was – usually participated in the audits (8 interviews, observation, dok17), as included in their job description (dok10). Quality workers were not trained for this job106, but they received a competence description when they were appointed to the task, and therefore some of them felt that they had not been properly informed about their tasks. One of the interviewees, who was an internal auditor and a quality worker at the same time, claimed that she used his knowledge obtained during his work in other departments as an internal auditor, and her skills obtained in internal auditor trainings during his job as a quality worker. The quality manager said that it was not her who appointed the quality workers but the heads of the units, because quality workers had to cooperate principally with them. The quality manager usually writes a memorandum or, less frequently, organizes a meeting with the quality workers of the hospital if she wants to push through a message to the employees. Most quality workers were doctors (57,5%) (See Table 11). The quality manager claimed that even if the quality worker is a physician, quality related tasks are always performed together with the nurse head of the departments. The reason for not mentioning quality workers as important participants in quality issues may be that in one-third of the cases the heads of departments107 hold the position of quality worker, too (See Table 12), and they were mentioned in other context. One fourth of the quality workers were internal auditors at the same time, and all the nurses and skilled workers appointed as quality worker were internal auditors, too.

106 Although before the certifying audit even quality workers had a training as reflected in one of the documents (JK17).
107 If we do not calculate with those whose position is not known (12,5%), approx the half of the quality workers are in a position of head of department.
Tables 11. and 12. Distribution of quality workers by professional groups and organizational positions

<table>
<thead>
<tr>
<th>Profession</th>
<th>Proportion by profession</th>
</tr>
</thead>
<tbody>
<tr>
<td>physician</td>
<td>57.5%</td>
</tr>
<tr>
<td>nurse, skilled worker</td>
<td>17.5%</td>
</tr>
<tr>
<td>economic, technical</td>
<td>15.0%</td>
</tr>
<tr>
<td>other</td>
<td>7.5%</td>
</tr>
<tr>
<td>no data</td>
<td>2.5%</td>
</tr>
<tr>
<td>Total</td>
<td>100.0%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Position</th>
<th>Proportion by position</th>
</tr>
</thead>
<tbody>
<tr>
<td>vice top manager</td>
<td>2.5%</td>
</tr>
<tr>
<td>head of department</td>
<td>32.5%</td>
</tr>
<tr>
<td>vice head of department, group leader</td>
<td>10.0%</td>
</tr>
<tr>
<td>senior physician</td>
<td>20.0%</td>
</tr>
<tr>
<td>assistant professor</td>
<td>7.5%</td>
</tr>
<tr>
<td>specialist (physician)</td>
<td>5.0%</td>
</tr>
<tr>
<td>other non-manager</td>
<td>10.0%</td>
</tr>
<tr>
<td>no data</td>
<td>12.5%</td>
</tr>
<tr>
<td>total</td>
<td>100.0%</td>
</tr>
</tbody>
</table>

Source: dok17, dok14

8.2.3.2. The management

The members of the management play an important role in the certification process. The term management is used here to refer to top managers, the General Director, other directors (physician-, nurse-, and economic directors) and their substitutes. In this case study when management is mentioned the quality director is not included, because although officially she belongs to the management, the interviews suggest that in fact it is not the case (see the description of the role of the quality manager).

Hospital management plays a key role in making employees accept the changes, and this was verified by hospital employees (7 interviews) as well as by top managers (3 interviews). External auditors with expertise in other hospitals also agreed that the example and the commitment of organizational management are essential for the success of the quality systems. It is when they return to a certain hospital after a few years and there have been changes in the top management that they see how important management commitment is. One of the hospital interviewees commented that they could see from the management’s commitment that the case of quality was so important for this hospital. However, the change in the position of the General Director brought about changes in the situation of the quality system within the hospital (interview). According to the quality manager the General Director had the most important role in the quality system, „because by articulating that quality is important, he delegates me the right to work for it.” (interview, quality manager)

During the audits the management plays an important role at the opening and at the closing meetings, where they inform the auditors about the situation, and they listen to the auditors’ report. (5 interviews, observation) The previous General Director claimed that an active participation in these meetings was essential, and that overt and honest communication with the auditors was needed in order to have reasonable recommendations and measures as a result. The General Director may also influence the character of these meetings. Some interviewees commented that since changes have occurred in the position of the General Director there also have been changes in the length and content of the meetings. (3 interviews)

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108 Each hospital unit has an appointed quality worker. The number of hospital units and the number of quality workers is not published for reasons of anonymity of the hospital.
Besides the audits the management with the quality manager, the secretary and the coordinator have at least one management review meeting per year. According to the records of these meetings the management determines the quality aims for the next year and they evaluate the achievements of the previous year. (records) (In the following parts of the dissertation I will write about how quality aims are defined and evaluated.)

The General Director also has an important role in making certain decisions and introducing new measures as the results of audit, especially when the quality manager does not have the leave to take measures. (interview, JK2, JK3, JK11) The other management member whom the hospital interviewees considered of crucial importance was the nurse director. The nurse director took part in the implementation of the quality system from the beginning, she established a committee for quality improvement that worked on a regular basis, and participated in the elaboration of nursing protocols and competencies. She participated in the opening and closing meetings during the audits, and she also accompanied one of the auditors during their visit to the departments. She also took part in the implementation of the measures that were taken as a result of the audit. The vice medical director also had a role in the quality system: he was responsible of managing complaints.

Although this role was not mentioned among the most important ones, many interviewees referred to the so called „auditor escorts“. This role consisted of accompanying the auditors to the hospital units during external audits, and this role was performed by one of the management members or by the quality manager. (five interviews, observation) The presence of an escort can certainly influence on the audit, although interviewees considered it as a neutral and purely secondary role. The presence of a management member may have a relaxing effect on the employees audited, and it also suggests that management support audits by their presence. Although escorts did not directly answer auditors’ questions instead of the employees, sometimes they gave extra information about issues they knew more about (interview, observation), and they used gestures and eye-contact to tranquilize the audited employees109 (observation, 2 interviews). Auditor escorts also informed the auditors during break times between two unit visits and during informal talks. (observation) Audit escorts also took part in correcting errors, and there are examples when some small corrections were made even on the spot during the audit. (interviews, observation) Many top managers commented that audit escorting experiment was useful for them because they could personally see what the problems were.

8.2.3.3. Middle managers

Interviewees also mentioned middle managers (heads of departments, physician and nurse heads of departments) as important stakeholders in the certification process. When auditors visit departments they are usually received by the head of the department, and in inpatient care units the physician head and nurse head of department take part in the audits together with the quality worker of the department, who usually holds one of the head positions. (observation, 15 interviews) Many interviewees agreed that the head of the department sets an example by taking part in the audits and he emphasizes the importance of the event. Heads of departments considered it useful to see where the weaknesses are. (3 interviewees).

109 There was a case when the behavior of the auditor escort was not supportive but rather demanding.
Heads of departments not only have an important role during the audits, but also in the fulfillment of the requirements, which has an effect on the result of the audits as well. One of the top managers says: “The style of the physician head is reflected in the style of the whole department.” (interview, top manager) The other department leaders (nurse head, head operating nurse) can also do a lot to assure meeting of the requirements. According to the quality manager the nurse heads play a key role. A lot depends on what the heads of the units demand, for example, if they demand strict documentation or not. (12 interviewees)

8.2.3.4. Non-managing employees

The employees do not take part in the auditory visits, but they are informed about the event (five interviewees). Their role is to prepare documentation and hand them to the head of the department. (four interviews, observation) Six of the interviewees claimed that auditors hardly ever meet the employees. "Well, very rarely although theoretically they can address anyone, and there were some examples for this, but very few and recently perhaps none." (interview, physician head)110

Heads of departments and quality workers transmitted the information to the employees concerning the audits and the quality system.111

8.2.4. Time dimension: changes during the period of the certification

There had been significant changes in the hospital since the first certifying audit took place: both the Director General and the quality manager were replaced. As it was previously mentioned, the preparatory steps were taken and the first certifying audit was made during the leadership of the former Director General. By that time the vice medical director held the position of quality manager, and when he retired the former quality coordinator was appointed to this position, and she was still in charge at the time of the study. This means that at the beginning a medical professional held the position of quality manager, who was later replaced by a nurse professional. According to the experiences of an external auditor, it is also common in other hospitals that a top manager is followed by a "worker" who had already worked in the quality system. At the beginning hospitals tried to appoint the quality responsible from among medical professionals and nurses at the same time. In the case hospital there was also an attempt to achieve this, because after the changes the vice medical director also took part in quality issues by being responsible for handling complaints, but his weight was considerably less than that of the former vice medical director.

Curiously, similar changes can be observed among the external auditors of the hospitals while they were the same people during the period: at the beginning the leading auditor was medical professional, while later the nurse professional replaced him as leading auditors.

The proportion of medical professionals among the internal auditors of the hospital also lowered.112 By the time of the case study most internal auditors (66%) were nurses or skilled health workers. (See Table 13.) More than the half of the nurses and skilled health workers who started to work as internal auditors at the beginning of the certification period were still in this position when the study was made, while there

110 During the observation in an outpatient consulting room and in a diagnostic unit there were examples of the auditor addressing directly the employees and not the managers. (observation)
111 Another interviewee reported that in the hospital where she formerly worked employees had been more involved in quality issues (there were trainings for them, for example).
112 The previous section (8.2.3) highlighted the importance of the role of internal auditors.
was only one of the medical professionals who started to work as an internal auditor at the beginning and was still in this position at the time of the study. One of the reasons of this change in the proportion of medical and nurse professionals can be that it is the quality manager who appoints the internal auditors. The quality manager says:

„I need an auditor who can certainly perform this task. I do not need one who does not do that because he hurries to a patient, or because he does it without having his heart in it. Or, because he does not dare to do it. A nurse goes more easily to a head physician during an audit and says what were the mistakes than another physician who is lower in rank. Nurses have the advantage that they are outside the strict hierarchical system of physicians.” (interview, Quality Manager)

The quotation also reveals that physicians may not like doing this job, and this can also be a reason behind the lower rate of physicians among internal auditors of the hospital. (Physicians’ opinion about the certification is described in following parts of the dissertation.)

<table>
<thead>
<tr>
<th>profession</th>
<th>at the beginning of the certification period</th>
<th>during the case study period</th>
</tr>
</thead>
<tbody>
<tr>
<td>physician</td>
<td>35%</td>
<td>6%</td>
</tr>
<tr>
<td>nurse</td>
<td>27%</td>
<td>38%</td>
</tr>
<tr>
<td>skilled health worker</td>
<td>19%</td>
<td>28%</td>
</tr>
<tr>
<td>technical or economic</td>
<td>8%</td>
<td>9%</td>
</tr>
<tr>
<td>other with a degree</td>
<td>8%</td>
<td>13%</td>
</tr>
<tr>
<td>person for quality</td>
<td>4%</td>
<td>6%</td>
</tr>
</tbody>
</table>

Source: dok14, dok15

Table 13 illustrates the distribution of internal auditors among the different fields of the hospital, and we can conclude that most auditors come from units directly involved in patient care, which reflects the weight of this units within the hospital. However, diagnostics is a field that is overrepresented by auditors (double of the initial proportion). Therefore, the weight of diagnostics in the quality system of the hospital increased as compared to the beginning years. It is also worth mentioning that most auditors organizationally belong to the Nursing Directorate, and this was so at the beginning as well as during the case study period. There were no changes in the individuals performing the tasks of internal auditors belonging to the Nursing Directorate, but other organizational units were not characterized by such a level of continuity.

113 The number of internal auditors equals to the number of hospital units, which is not given to respect anonymity of the hospital.
### Table 14. Distribution of internal auditors according to the hospital fields

<table>
<thead>
<tr>
<th>field of care</th>
<th>at the beginning of the certification period</th>
<th>during the case study period</th>
</tr>
</thead>
<tbody>
<tr>
<td>patient care fields</td>
<td>62%</td>
<td>50%</td>
</tr>
<tr>
<td>diagnostics</td>
<td>8%</td>
<td>16%</td>
</tr>
<tr>
<td>economic, technical</td>
<td>8%</td>
<td>6%</td>
</tr>
<tr>
<td>other supportive</td>
<td>12%</td>
<td>16%</td>
</tr>
<tr>
<td>unit for quality management</td>
<td>8%</td>
<td>6%</td>
</tr>
<tr>
<td>management (top leaders or deputies)</td>
<td>4%</td>
<td>6%</td>
</tr>
</tbody>
</table>

Source: dok14, dok15

There were also other changes in the quality work of the hospital during the certification process:

According to the records and to the audit reports, at the beginning of the certification period there were management reviews before and after the audits, or even more times during the year, but later there was only one preceding the audit in the year. However, the timing of these management reviews became fixed, as well as that of the audits.

There were also some changes in the size of the quality team of the hospital: according to one of the audit reports (Jelentes12a) in the first years the team consisted of four members (quality manager, quality secretary, quality coordinator and a secretary). However, when the quality manager retired the team reduced to three members.¹¹⁴ From the three members only two, the quality manager and his assistant (“quality coordinator” – see above) performed quality related work on a daily basis.

Subchapter 8.2 described the characteristics of the hospital that are relevant for this case study. These characteristics also function as factors that can have an influence on the effects of certification and related external audits, and these factors mostly belong to the factor groups called organization condition factors and indirect effect factors. The factors of the two groups cannot be strictly separated, which is illustrated by a jigsaw puzzle, as the factors of the group called indirect effect factors are also organizational characteristics; moreover, they are factors that emerged and became parts of the organizational structure due to the certification process. (For more details see section 8.6.1.) Figure 16 illustrates the influencing factors that have been identified in this subchapter.

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¹¹⁴ As the former quality coordinator was appointed in the position of quality manager, but the position of quality coordinator remained unfilled, although a secretary also takes part in the coordination of quality-related work.
Organizational condition factors include the role of the management and of the middle managers, the existence of responsible and/or experienced person for quality issues in the organization and at the level of organizational units, and the antecedents of the organization with similar functions to certification (like existence of ISO certification before SHC or HHCS). The organizational factors that became parts of the organization due to certification (indirect effect factors) are the roles of the quality manager, of internal auditors and of other persons for quality and the presence of audit escorts during audit. The two groups of factors intertwine because the responsible or experienced staff members are covered by the roles included in the indirect effect factors.

At the end of subchapter 8.2 I would like to point out the importance of the management and of the middle managers as influencing factors. According to the interviews (10 interviews) the most important factor was the attitude and the commitment of the direct leaders, which determined the behavior and work of the employees and the operation of the unit. By direct leaders we not only mean heads of the units, but in case of the other directors the direct leader is the Director General, and in case of middle managers the direct leaders are the directors. In units where the head of the unit demanded certification requirements (auditors’ requirements), the employees less perceived the effects of certification, and the process went more smoothly.

"I think that our department is well managed, even in documentation we try to be precise. So, I think, it would be difficult to find too many errors here." (interview, nurse head)

The requirements of the direct leader and the effects of the certification can support each other if the leader understands and accepts the requirements of the certification: "I understand why we have to do it and I make my nurse colleagues to do it." (interview, nurse head) The same nurse head commented that certification may have bigger effects in units where the head would not require the same things without
the certification. This nurse said that if the certification did not have to be renewed every year, "[…] we would not change anything, but perhaps in other places they would. Where this is considered as a burden, and where they would not do it by themselves, quality would immediately deteriorate." (interview, nurse head) The role of the leadership becomes emphatic when the established system does not produce the expected results: "if somebody resist only a strong decision at the directorial level can enforce changes." (interview, person for quality)

Subchapter 8.3 continues to describe the quality history of the hospital and it is trying to highlight why the hospital undertook the certification.

8.3. The objectives and the importance of the certification in the hospital

Subchapter 7.2 already explained some of the possible reasons of taking on the certification process. This subchapter highlights what extrinsic and intrinsic motivational factors and what extra-organizational factors influenced the role of the certification in the case study hospital.

8.3.1. By internal need or by external force?

According to interviewees who were in top-manager positions when the hospital decided to participate in the certification process the management was fully committed to this:

"I think there was an ambition to be up-to-date, and it was unquestionable, not like now, and we believed that the objectives of our quality strategy were justifiable. The objective was to have an operation based on scientific research and international practice, adapted to our hospital." (interview, former Director General)

"It was an internal need, nobody demanded it. […] as we did not know what we did wrong. We wanted to compare ourselves to something. And to avoid failures." (interview, top manager)

The mission of the hospital says that their objective is to achieve a high quality regulation and continuous improvement of the operation and the quality management system of the hospital in order to meet patients’ requirements and to provide quality care in accordance with EU requirements. (dok18)

The previous Director General also mentioned that there was a demand for introducing the system by the municipality owner, and health sector leaders also promised support. The hospital leaders who participated in the implementation of the system considered external demand in a more emphatic way:

"We felt a kind of obligation, as official media and statements by health policy leaders also suggested that it was a strong demand […] So there was a kind of forcing power by many sources, such as health policy leaders, direct authorities, the media […] Some hospitals were ahead of us, some were behind us, and some had no idea of what the whole thing was. But we accepted it internally." (interview, person for quality)

Leaders also suspected, although it was not communicated, that the NHIFA (OEP) would not sign their contract or the National Public Health and Medical Officer Service would not give the license for the operation if the hospital does not have a certification – but such thing was never communicated in writing.
The current quality manager of the hospital claims that the wish to meet external requirements played a crucial role in initiating the certification process:

„Everybody wants to be the best." […] „Our hospital has a good reputation, and we were eager to meet the requirements. I think it is like children, who develop best if they are eager to meet requirements and learn.” (interview, quality manager)

Interviewees who were not part of the management also had different perceptions of the reasons why their hospital decided to obtain a certification: we wanted to reach an international, a Western-European level (4 interviewees); our leaders „recognized” that certification was a minimum requirement of hospitals (4 interviewees); perhaps there was also an intent to improve internal operation (like more transparent and organized operation, improving work processes) (4 interviewees). Non-manager employees had less idea of why the hospital wanted to go through the certification process. One of them confessed: „Well, not much was said to us about this.”

As I referred to it in previous parts of my dissertation, there was no legal force to obtain a certification. Besides external demands the management of the hospital considered it a voluntary decision to go for the certification. However, some of the interviewees perceived it differently:

„No, this choice was not voluntary at all. It is like when the market forces you to have it.” (interview, person for quality)

Further 6 interviewees claimed that it was voluntary, while 4 interviewees claimed that it was a forced decision. One of them pointed out the complexity of the issue:

„There were many different factors. There were the demands by our ‘bread and butters’, the health policy makers, there was the self esteem of our hospital leaders, there was the conception of our Director General, the loyalty of his top and middle managers, and so on. There was the suspect that there come a time when you cannot drive without a license, so you cannot run a hospital or you cannot cure without a certification, so many factors were involved.” (interview, top manager)

Therefore, in the case study hospital the decision of opting for the certification was voluntarily initiated by the management. This was strengthened by one of the auditor interviewees, too. However, besides intrinsic motivation there was the perception of some external demands (by the owners, health sector leaders, etc.), and these factors were also mentioned by the former Director General, and they were also experienced at lower levels of hospital hierarchy.115 However, the maintenance of the certification may be influenced by other factors, such as the resources available through tendering or prestige. (interviews) By this latter we mean the case when it would be a loss of prestige if the hospital did not renew its certification, as external stakeholders and the media would react negatively.

8.3.2. The importance of the certification and the audits for the hospital

The following quotation illustrates the weight of certification and audits in the case hospital:

115 Interviewees mentioned other extrinsic motivations such as the news about extra resources accompanying certification, fashion at the beginning of the 2000s and marketing activities of the certifying companies. However, it is not very probable that these factors had an influence on managerial decision in this hospital. Still, these factors could influence other hospitals, and interviews and the auditors also claimed that hospital leaders had some news and were talking about extra financing related to certification, and many shared the opinion that institutions without certification would be negatively distinguished.
“It has some special importance for us. Hospital leaders always highlight this, and refer to it as something essential for our institution, something that we cannot live without.” (interview, head of department)

A top manager expressed: „employees as well as leaders know that it is indispensable”. (interview, top manager) Some stakeholders (8 interviewees) thought that the requirements of the certification and of the audits did not have much importance, because there were other regulations (laws, authority directives, protocols) that they had to follow in their work. „The whole process is well regulated, so ISO is just one more among the regulations.” (interview, physician head) They think that due to the presence of other regulations, if the hospital did not renew its certification it would not have any effect on the internal operation of the institution. This view was supported by the physician heads of the patient care units (3 interviewees) and the heads of the economic and technical units (5 interviewees). The quality manager also agreed that in patient care the professional directives, guidelines and protocols rule, while quality system plays much less role in the level of patient care. (h14)

According to a top manager, who otherwise recognized the importance of process regulation, in the present environment characterized by brain drain and insufficient financing the role of the certification becomes secondary: „You know, when you just want to keep alive in the middle of the sea you don’t worry much about your swimming style.” (interview, top manager)

However, even those who had a critical opinion agreed that certification was needed in order to meet external requirements (e.g. prestige, tender requirements). There was no organizational member who told that there was no need for certification.

One of my research questions was if improvement was among the objectives of external evaluation. Interviewees agreed that ISO and SHC/HHCS systems aimed at improvement, and that this aim was declared in the quality policy document of most Hungarian hospitals.

In the case study hospital improvement was among the objectives of the management when they decided to introduce the quality system and obtain a certification, but not all the employees were aware of this aim.116 Most employees think that obligation or meeting external requirements were the dominant motives of obtaining the certification, while top managers claim that the aim of the certification is to support development:

„We always emphasized that it was not l’art pour l’art, but it could contribute to improving care and quality.” (interview, top manager)

Besides improvement the hospital had other aims with the certification, too. Subchapter 8.3 reveals that besides intrinsic motivational factors117 there were also other „forces” that worked. These forces are classified among the external factors (Figure 17), which in our case are: perceived expectations of owners and health policy leaders, possible extra resources (e.g. by tenders) and example of other certified hospitals which may effect in different ways (e.g. fashion, waste of prestige if the hospital is not reaudited, becoming a general requirement). Based on the hospital interviews the perception of the importance and weight of the certification is influenced by other external factors: existing external

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116 It was only the quality manager and another active participant in quality issues besides some members of the management who explicitly claimed that improvement was among the aims of going for the certification.

117 This appears as an organizational condition factor (see subchapter 8.2 the role of the management).
regulations (such as legal regulations, authority requirements\textsuperscript{118}; professional guidelines and protocols), and other health sector related issues (e.g. shortage of labor and of resources). Interviewees pointed out (8 interviews) that shortage of labor and fluctuation evidently influences the reactions given to the certification and the audits and it also influences the interactions (as a result of extra burden of work, weight of administrative work).

**Figure 17. External factors**

![Diagram showing external factors](source: own elaboration)

Another important external factor that affects the hospital and the employees is trials and denouncements, highlighted by 5 interviewees. Interviews made it clear that one of the results and effects of trials and denouncements is a more detailed documentation (6 interviews): „due to trials and denouncements it became clear that every little step has to be properly documented.” (interview, top manager) This can provide protection for the hospital.

The previous subchapters described the hospital and the history of its quality system. The following subchapter focuses on the method of external evaluation (subchapter 8.4), its mechanisms of effect (subchapter 8.5) and on its effects on the organization (subchapter 8.6).

\textsuperscript{118} Legal regulations and authority requirements are important influencing factors because their modifications can influence audit requirements and quality system regulation, and the system must be continuously adapted to them. (3 interviews, reports)
8.4. **Method of audit as an external evaluation in the hospital**

This subchapter is dedicated to the analysis of the characteristics of the ISO and SHC/HHCS integrated audit methods\(^{119}\) as applied in the case study hospital, as described by hospital actors and auditors of the hospital during interviews, and based on the analysis of observation and documentation. First, the auditory „market“ and auditors’ attitudes are examined, and then the approach to knowledge (e.g. gaining information, evaluation criteria) are analyzed.

From the influencing factors this subchapter describes the external evaluation factors, and characterizes the audit method according to the dimensions of classification framework introduced in section 4.2.2.

8.4.1. **Consequences of a long-term relationship**

As it was mentioned when describing the quality history of the hospital, the certifying company and the individuals who performed the audits have not changed since the beginning of the certification process. (See subchapter 8.2.) This was perceived by the managers and by most of the persons for quality, too. (11 interviews, observation) However, this does not mean that the same hospital unit always meets the same auditor, because they visited the departments interchangeably, and there was a head of unit, for example, who had not met one of the external auditors until the case study audit.\(^{120}\)

The relationship between hospital members and auditors was good and even friendly (interviews with hospital actors and auditors, observation), which was due to their long lasting relationship: „*If they come from the same company year by year it is normal to meet them as friends.*“ (interview, top manager)

According to one of the auditors as a result of the long-term collaboration „*this relationship is more a friendship than just a working partnership.*“ (interview, auditor)

There can be many reasons for this stability in the collaboration with the same certifying company and the auditors. Auditors claim that it is a general phenomenon, and clients and quality managers want them back personally and not the company. The quality manager highlights the two sides of the coin:

> „*It is good because they are flexible, which is good for me and good for employees. But it’s not good for the organization, I think. For the organization it would be better if the people who come did not know me or them, but they just see a new organization and decide whether it works well or not.*“ (interview, quality manager)

According to the interviewees, having previous contact with the same auditors is tranquilizing because they do not seem so terrifying for the employees. Some of the interviewees thought that auditors' positive attitude may also be due to their fears that the hospital may choose another certifying organization next year, as companies are competing with each other in the market and the hospital has the opportunity to choose.\(^{121}\)

The leading auditor and some of the hospital members agreed that having new auditors would have some advantages. According to the quality manager:

\(^{119}\) Integrated audit is not an established methodology here (See Tarr, 2007), but the practice of the case study hospital of performing ISO 9001 and HHCS audits during the same audit session.

\(^{120}\) This was the case in the diagnostics unit, which is often audited, and in a technical-economical unit where the head of the unit had not had an external audit since he was in charge (8-9 years).

\(^{121}\) During the observation period the hospital asked for bids as a result of its economic situation, but at the end they opted for the previous certifying organization.
“They would notice things that now they do not or they don’t want to, because they respect our friendship. Yes, you don’t point out every little mistake in a friend’s house, while you easily criticize in a neutral place.” (Interview, quality manager)

If auditors are too familiar with the hospital, they may not notice little things and the audit may become formal. (Interviews) According to an interviewee who had experiences with another hospital: „Audit is a little bit too light here.” (Interview, manager)

8.4.2. The attitude and the role of the auditors

Hereby I describe the attitudes and the role of the auditors as perceived by the auditors, by hospital actors and by the researcher (me) during the observations. This will support the classification of the applied audit method as formative or summative according to the ‘role of the evaluation’ dimension of the classification framework presented in section 4.2.2.

8.4.2.1. Auditors’ opinion about their attitudes

One of the auditors conceives the role of audit as that of an exam, and himself as a type of examiner who is curious of what the examinee knows. He is interested in how to help and how to support improvement. He thinks that if their attitude would be strict and they would merely stick to the requirements then people would hate the whole procedure and would see them as enemies. They have to find the golden mean. The other auditor agreed that an assertive attitude works best, and this attitude enjoys support of the hospital workers.

According to what auditors say they do not aim at looking for errors. If they point out the errors or faults it is to support improvement, and not to punish the responsible. They intend to help by offering their own experiences.

The work of the auditor is also to keep contact with people: „During the audit the auditor is in a position that makes other people feel subordinate and defenseless. It depends, some would misuse this power.” (Interview, auditor) The auditor interviewed wanted to help, and not to punish them. About proper documentation he also commented that it could serve as a protection for the employees. Both auditors mentioned that it was important to see how the audited person reacted, and they had to adjust communication to these reactions. One of them considered it important even when giving recommendations: „I have to see if I did it well, if they accepted it or not.” (Interview, auditor) If she feels that there is no interest in what she says, she may not give certain recommendations.

8.4.2.2. Auditors’ attitudes as perceived by hospital actors

Hospital workers considered auditors’ attitude as supportive and constructive (7 interviewees, JK15), objective (not biased), honest, overt and correct. The former Director General said: „honest, constructive partners, they actuate so that we don’t feel the need to hide anything or cheat.” (Interview, former Director General)

This good relationship does not mean that auditors set aside their task of directing attention to the mistakes. Interviewees agreed that auditors were not failure-focused, but they wanted to help, which is accepted positively by the employees. If auditors find a mistake, they give reasonable advice: „… this is
not like an ÁNTSZ\textsuperscript{122} supervision where they are looking only for failures." (interview, head of department)

Only the level of rigor was criticized in the attitude of the auditors. Even the quality manager claimed that a little bit more rigor would do well for the employees who not always take audits seriously. One of the managers who also work as auditor escort during the audits observed that:

„They are nice and friendly, but when they ask questions they do it absolutely seriously. So they do not concede just because we have known each other for years. They take what they need.” (interview, top manager)

This statement is congruent with my own observations during the audits, where auditors showed considerable rigor when pointing out failures by questioning.

8.4.2.3. The roles of the auditors

Interviews made with hospital employees and with auditors and my observations\textsuperscript{123} also corroborate that auditors may have very different roles. Table 15 shows the roles identified according to the source of information.

<table>
<thead>
<tr>
<th>roles played by the auditors</th>
<th>data source</th>
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<tbody>
<tr>
<td></td>
<td>hospital interviews</td>
<td>auditor interviews</td>
<td>observation</td>
</tr>
<tr>
<td>educator, examiner</td>
<td>X</td>
<td>X</td>
<td></td>
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<tr>
<td>counselor</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>external observer</td>
<td>X</td>
<td>X</td>
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<td>interpreter</td>
<td>X</td>
<td>X</td>
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<tr>
<td>convincing power</td>
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<td>X</td>
<td>X</td>
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<tr>
<td>inspector</td>
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<tr>
<td>collector of evidences</td>
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<td></td>
<td>X</td>
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<tr>
<td>spokesman</td>
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<td>X</td>
<td></td>
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<tr>
<td>anti-stress actor</td>
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</table>

Source: interviews, observation

One of the auditors of the hospital identified himself more with the role of the educator and examiner, while the other with that of a counselor. The content of the roles are described below.

Educator: Reflecting to the long-term collaboration with the hospital where the auditors had the opportunity to participate in the development of the quality management system one of the auditors said that:

„Sometimes I feel like an educator who spends 8 years educating children in the same class. Like a teacher who can see how much they have developed.” (interview, auditor)

\textsuperscript{122} ÁNTSZ: Állami Népegészségügyi és Tiszteletvosi Szolgálat (National Public Health and Medical Officer)

\textsuperscript{123} Observation is not an adequate form of gaining information about all the auditors’ role, so if I found no evidence for the existence of a role it does not mean that the role does not exist.
Examiner: The same auditor considers that "audit is a kind of exam" (interview, auditor), and he describes himself as an examiner who is interested in what the pupils know and who wants to help them. It is important what type of examiner the auditor is, what attitudes they have, because this role can also be misused. The exam metaphor was also used by hospital employee interviewees.

Counselor: Counseling is officially when auditors assist system planning and system implementation, or when in later periods the organization asks for help with the interpretation of some concepts. However, both auditors mentioned their role as a counselor during the audit as well. One of them claimed that it is important to make proposals because they can help to correct failures. This auditor was really active in their role as a counselor and in making proposals, which could be observed during the audits and could also be followed in the documents. (interview, observation, audit reports) Auditors think they can help to find good solutions because they have gained a lot of experience working in other hospitals. The role of counselor involves making proposals and guidelines for hospital actors involved in the quality system. (interviews) During the observation of an audit I also experienced this supportive role while observing the communication between the auditor and a top manager. (observation)

External observer: According to the quality manager the certification of the quality management system is important because an external observer may reveal things that those who are submerged in routine work do not notice:

"For a good operation of the system outsider observers are essential, who did not participated in the planning of the system, and who do not personally know the stakeholders, but who has an unbiased view of the system and who can judge if our aims and our interpretation is correct or not." (interview, quality manager)

This role is interpreted as error correction in narrower sense and as the evaluation of the quality management system in broader sense, and is considered as constructive criticism. According to the quality manager external observer is not really effective when employees know the auditors from the beginning and they have worked together for years developing the system. Auditors also agree that an external observer can more easily find the weaknesses. One of the auditors claimed that if an organization obtained the certification long time ago, then the aim is not to reveal mistakes – this is the task of internal auditors -, but the supervision of the elements of the quality management system, such as the supervision of internal audits.

Interpreter: Auditors may help hospital actors to interpret the standard systems.

"[…] he is there to show to all of the employees why is ISO more than they think. To show what it can be for the cleaning assistant and what for the physicians and for the economic director. If the auditor can explain this in training or during the audit, or he can make employees understand why the auditor is there, it is positive." (interview, auditor)

According to the quality manager, she and the leading auditor are representing only one possible interpretation of the system and they represent one possible direction of quality work. (See motto at the beginning of Chapter 8.)

124 Although one of them mentioned that audit is taught as exploratory, something that does not contain counseling.
125 It can also be a form of counseling when the auditor leaves their role, and gives advice on how is it proper to prepare for the audits (what kinds of documents to prepare, etc.) This kind of counseling occurred during the audit as well as during informal talk following the audit. (observation) This kind of supportive behavior can make audit lighter.
Convincing power: Auditors have the opportunity to convince hospital workers of the importance of a document (e.g. job description) or of the importance of a signature or a seal, or to demonstrate why it is important to appoint the responsible. (auditor interview, observation)

Inspector: Some hospital leaders call auditors inspectors. (3 interviews) One of these interviewees said that auditors have no right or knowledge to question the correctness of the operational procedures. Another leader told about the role of the auditors that they simply checked whether the seal is put on the documents or not.

Collector of evidences: The role of the auditors can be conceived as someone who collects evidences on the spot to prove that the organization works according to the standards. The importance of collecting evidences was also mentioned by the interviewees and was observed by me, for example when the auditor spent time on writing down the identification numbers of the documents, while employees were watching, or when the auditor is asking for written evidences of the documentation of quality related tasks.

Spokesman: Both auditors mentioned that they may be considered as spokesmen for quality. For example, if they see that the case of quality or the quality manager personally do not get enough support they can communicate it towards the management during the closure meeting.

Anti-stress actor: I observed that auditors had several communication tools to cope with employee stress during the audits. One of the auditors usually told jokes or anecdotes during the audits or during department visits. These jokes usually followed a stressful situation when the auditor seriously pointed out some deficiencies, so the jokes had a clear anti-stress function. Perhaps an example of the same relaxing manner was when after delicate situations the other auditor informed the employees of what she was writing down in her notebook. It also happened that after a department visit the auditor gave a relaxing feedback, like „It was a pleasure. Thank you.” or „Thank you, I think you are quite o.k.” (observation)

The dimension of ‘the role of evaluation’ of the classification framework proposed in section 4.2.2 distinguishes between formative and summative evaluation methods. Due to the constructive and supportive attitude of the auditors the audit methods used in the case study hospital were clearly formative, which is supported by the ‘confessions’ of auditors, by the perceptions of hospital actors and by my observation.126 This makes it not evident that all audits made in hospitals are formative in character. As one of the auditors remarked they knew a colleague who wants to strictly demand the fulfillment of the requirements, and that this attitude is all right, but it deters the participants and the effect may be adverse.127

126 Only the role of ‘inspector’ does not fit into the characteristics of formative methods, but only some of the interviewees perceived this role of the auditors.

127 Hospital actors do not have too much other experiences, although some of them participated in the first audits and these actors claimed that changes were positive. One of the first auditors are remembered as rigorous and aggressive.
8.4.3. The approach to knowledge

Hereby the audits are analyzed from the point of view of how the method applied gains information about the organization, and how the result of the audit is born. This analysis of the audits supports the classification of the audit method according to the dimension called approach to knowledge of the classification framework proposed in section 4.2.2.

First the random-like process of the audit is described, and then the information gathering methods of the auditors is analyzed using three main sources (interviews with auditors, interviews with hospital employees and observation) and I examine how the final evaluation is made.

8.4.3.1. The audit process and the participation of hospital actors

Audit starts with an opening meeting with the participation of the auditors, the hospital management and the quality manager. The Director General has a great influence on the character of the opening and closing meetings and on who participate in them. On the first day of the audit in the morning the leading auditor collects information from the quality manager about the operation of the quality management system in the presence of the ‘quality coordinator’. Meanwhile, the other auditor starts visiting the departments accompanied by an escort. When the leading auditor finishes talking with the quality manager they also start visiting departments in other departments, also assisted by an escort. As mentioned when describing hospital roles, auditors are received by the heads of the department and the quality worker, the participation of other employees is limited to preparing the necessary documentation.

In the afternoon of the last day of the audit the auditors revise patient documentation, and after a short discussion between the two auditors the audit is closed by a meeting. (interviews, observation)

8.4.3.2. Random selection

One of the characteristics of the audits is that auditors do not check overall hospital operation but they randomly select the processes and the units they want to visit. (interviews, observation). The audit report points out: „While comparing the quality system with the standard it is not required to reveal each and all of the discrepancies.” (Jelentes14a) However, as one of the auditors pointed out, it is important that relevant recommendations are made at the end of the audit.

Random selection is different from sampling in the way of determining timing of the audit and the selection of the departments, although one of the interviewees used this term (sampling) to describe the process. Timing of the audit is adjusted to the certification supervision deadlines and it is defined together with the management. (observation) The selection of the departments is influenced by different factors: patient care and diagnostics units are revised in a rotator system, but the order is influenced by the wishes of the quality manager and the Director General.128 Some of the economic and technical units (like human resources unit or purchasing unit) are audited every year and some of them more rarely. (interviews, observation) Sometimes the heads of department try to influence on the scheduling of the audits, because they want to be present on the audit of their department and the quality coordinator usually takes this into account. (interview, observation)

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128 According to my observation hospital actors did not try to hide the problems, but they asked auditors for their opinion (‘external observer’) or influence them (‘inspector’), and the auditors seemed to be partners in this.
The documents are also chosen randomly, which is also influenced by other factors (like whether the document is directly available in the spot or not, how long does it take to make them available). The document choice method used in case of patient documentation cannot be considered as sampling, either.129 (interviews, observation)

8.4.3.3. How do auditors collect information?

This subsection focuses on the information sources and on the methods of collecting information used by the auditors in the hospital. The different stakeholders see this process from different points of view. Table 6 and the description below highlights the role and the importance of the information sources (documents, interviews, observation) according to the views of the auditors, hospital actors and the observation.

<table>
<thead>
<tr>
<th>sources of the audit</th>
<th>research source</th>
<th>research source</th>
<th>research source</th>
</tr>
</thead>
<tbody>
<tr>
<td>documents</td>
<td>„The whole department can be audited using one patient documentation.“ (interview, auditor)</td>
<td>revision of modified regulatory documentation and other quality management documents; typical data collection method during department visits; separate patient document revision; checking authenticity certification and calibration of technical equipment and machines;</td>
<td>observing documents during department visits and taking notes; in patient care units: asking promptly for documents; in supportive units: asking for process related documentation; separate patient document revision</td>
</tr>
<tr>
<td>interviews</td>
<td>asking about the processes; careful listening to hospital actors' reports; useful for „more theoretical“ issues (e.g. improvement)</td>
<td>interviews with the quality manager; using list of questions at the units, questions about documentation; listening to the reports of the heads of departments</td>
<td>questions about changes and the characteristics of the unit; in supportive (economic, technical, diagnostic) units questions about processes; careful listening to hospital actors and taking notes</td>
</tr>
<tr>
<td>observation</td>
<td>not important</td>
<td>observing work of a department is not typical (except in diagnostics); checking store and refrigerator of medicines</td>
<td>observing medicine store, equipments and machines; observing work of a unit is not typical, except in diagnostics unit</td>
</tr>
</tbody>
</table>

Source: interview, observation

129 During the audit observed patient documentation was required at the beginning of the visit only in one unit, the other units provided it later on during the audit.
According to the auditors and their reports:

Auditors use different methods to collect information, but what is evident is when they take notes during the opening meeting or about the fulfillment of standards during the department visits. One of the auditors claimed that the method of collecting information was not defined for them. The report made by auditors contains the following about what the auditors check: "It was checked to what extent the requirements of the system documentation and the related regulations were fulfilled, and to what extent the system was efficient." (Jelentes1a)

One of the auditors commented that they shared work with each other, and while one of them checked fulfillment of standard requirements (purchasing, documentation of the quality management system at the quality manager) the other goes to the hospital units. During the audit of an unit one can follow different principles. According to one of the principles they check standard requirements (e.g. measuring instruments). The other type of audit is different:

"Auditors can choose not only to check fulfillment of standard requirements, but also to get information about the processes and check fulfillment of requirements in the light of these processes." 
... the best is to follow this, because I can say that I audited a unit if I understand their processes." (interview, auditor)

The auditor can start by asking the head of the department to talk about what they do and listen to them carefully and taking notes. Then he can ask further questions about the processes and check if the documents reflect what was said, and if not, try to find out the reason and whose fault it was (individual or system error).

At the same time one of the auditors said: "The whole department can be audited using one patient documentation." and "an outpatient document sums up what happened." (interview, auditor)

They take notes of the identification numbers of the checked documents and equipment to have evidence of the audit. They are obliged to ask for a certificate of the correction of serious errors and they also check if recommendations were implemented or not (interviews, Jelentes12a)

More "theoretical" issues like the commitment of the managers or improvement is more difficult to document, so in these cases "we just listen." (interview, auditor) If the auditors are familiar with the place they usually only ask for the changes that happened since the last audit was performed. The content of the auditors’ reports also reflect that in order to prove responsibility of the managers they refer to the oral reports made by the audited actors during audit. (Jelentes7a, Jelentes9a)

As hospital actors perceive it:

The employees involved in quality related work can comment on how auditors revise quality documentation. At the beginning all the quality related documents were read by the auditors. Now, auditors mostly remember these documents "They remember that the regulation was correct." (interview, person for quality) They ask for the important documents (e.g. handbook, regulations) that have been modified.

In the morning of the first day of the audit the leading auditor collects information from the quality manager about the operation of the quality management system. As the quality manager comments, the auditor usually revises the following: first they ask if former recommendations have been implemented into the system. They check the scheduling and the documentation of the internal audits, randomly check
the documentation of handling nonconformities and patient complaints and whether regulations are up-to-date.

For hospital actors the most visible form of information collection by the auditors is the revision of the documents during visiting the different units. (11 interviews) In a patient care unit they usually ask for example for the medical record, nursing documentation and the surgery records. Hospital actors sometimes only perceive that the auditor checks the seals and signatures on the documents, while others also noticed that they had compared certain documents. The phase of checking patient documentation is described by an audit escort as follows:

„Then they come down to this room, we try not to disturb them and they look at the documents, whether everything is there, signed and ordered, signed by the physician, signed by the nurse, the patient was given their medicine. Well, this is how they work, I don’t see the point, I only know that this is what they do in an institution.” (interview, auditor escort)

The other type of documentation the auditors ask for is related to the employees (like job descriptions). Another form of information gathering is questioning. Many people commented that the auditors arrived at the institution with their lists of questions. Some think that the questions refer to the documentation, but others mentioned typical questions that were not in connection with documentation. According to some interviewees it is not the same who answers auditors’ questions, because not everyone can give a detailed answer. Top managers, audit escorts, the quality manager or the internal auditors may have some information that can be important in influencing the auditors’ opinion of the institution.

Hospital actors also perceived that auditors not only gained information by asking questions, but also by just listening to what managers said, and perhaps they also used information from this. Hospital actors had different opinions about the interviews made during the department visits: some interpreted that while auditing the managers the attention of the auditors can be manipulated. Others said that the auditors wanted to understand the logic of how the unit in question operated. However, a nurse manager commented that the auditors were not able to see into the operation of the unit, but they arrived with their schemes and they only noticed what did not fit, and it made no sense to try to explain them the reasons.

In the patient care units the auditors are accompanied by the nurse heads but they do not observe work processes. More heads of department mentioned that the auditors have never entered the surgery room. One of the auditor escorts said that „it didn’t seem to me that they were going around eager to find something” (interview, auditor escort). At the same time the quality manager says that auditors sometimes observe work in a unit, and she mentioned some examples for this: in one of the cases they went to see a new unit after they revised the operational rules of the unit; the other case was when they asked for the job description from a nurse who was just administering an infusion. This is a good example of how auditors combine observation with document revision. In patient care units 7 interviewees mentioned that auditors check documentation of drugs and medicines, their expiry dates and their storage (stores, refrigerators). Some also mention the checking of handling hazardous waste.

Hospital actors from the economic and technical departments also mentioned the checking of documents and the checking of the authenticity certification and calibration of the equipment. According to the

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130 Although one of the interviewees described a case when the auditor entered the surgery rooms but avoided those where surgery was going on.

131 Among the other interviewees only one, a nurse remembered that their job (washing hands, treating a patient and communicating with them) was observed by an auditor.
interviews in these fields, auditors mostly talked to the heads of the units and there was no observation. Only the head of one of the diagnostic units said that „we are rarely left out, because this is something spectacular” (interview, head physician).

The researcher’s observations

In all of the places (opening meeting, hospital units) the auditors asked about the changes (what happened since then? any development? any purchasing? any modification in the operation?), or about the general characteristics of the unit (number of personnel? specialties? obligations in care? patient numbers? how work is organized in economic units?). During the presentation of the Director General or the heads of departments about the changes and development the auditors were taking notes. During these reports auditors also received information about the problems of the unit (e.g. shortage of labor, infrastructure) and they carefully listened. In informal talks outside the units they could also gain information about the changes in the organization, of the circumstances and of the difficulties of quality related work. Sometimes auditors asked questions about other units as well. In some cases they followed certain processes (e.g. purchasing) of other units by asking for the documentation and by listening to the explanations.

When auditors are interested in a process or in an activity (purchasing, training, etc.) they usually ask for the documentation and they take notes. In the economic, technical and diagnostics units they also asked questions about the processes and they listened to how the work in this unit was usually performed. In patient care units they ask directly for the documentation (e.g. medical record, job description, operational rules, licenses), and according to my observation they did not question about the processes of patient care. Sometimes they asked questions about the ways of internal communication and its documentation. There were some less typical questions like when the auditor asked if there was any quality improvement, and the head of the unit replied that they planned physician training in the form of competence development. During the observation the auditor only once asked an audited person (an assistant) about how she performed a concrete task.

In hospital units the auditors mostly looked at the documentation and took notes. If auditors found any discrepancy or a problem they asked for explanation and listened to the answer. In the phase of checking patient documentation they revised the documentation of five patients from each of five units.

Auditors usually go round the units, which means: in patient care units they go into the nurse room and they check how drugs and medicines are stored, how often nurses checked expiration dates, sometimes they asked about the state and the documentation of the equipment. During the observed audit the auditor articulated that they would not go into the surgery rooms, and he only asked about sanitation inspection. Sometimes they visited a consulting room or a medical treatment room, but during the observation there was only one case when in these places there was a treatment going on. Auditors also checked and took notes about documents and equipments (e.g. identification numbers) in nurse rooms, and in treatment rooms.

In one of the diagnostics unit the auditors followed the processes while the head of the unit explained what was going on. The auditor also took notes of the documents, observed the equipment, asked about the calibration, authenticity and maintenance of equipments, the treatment of hazardous waste and its documentation. The auditor theoretically had all the opportunities to observe real work in this unit. In the economic and technical units no observation was made, but auditors met the head of the unit or the responsible in his room.
During the visitations of 10 hospital units which I observed there were two places where the auditor had the opportunity to observe the work of the unit. I have information of only one case when the auditor took advantage of this opportunity and in fact observed the work process: it was when in a diagnostics unit the auditor asked something from an employee about the process that she was doing.

Comparison of the three data sources

Based on the different interpretations and perceptions of the three information collecting methods of the auditors we can conclude the following. The methods of the auditors are observed from outside by those who are audited, and they not always understand why auditors ask the questions they ask, and what is the „point” in checking the documents. (See the quotation above by the audit escort.) Auditors also admitted that information gathering is not always perceivable (sometimes they only listen). Most hospital interviewees perceive the dominance of the documentation and the related feedback (e.g. missing signature, seal, discrepancies of two documents). It seems that those who participated in the quality work of the hospital perceive more (e.g. they also mention that auditors observe processes).

Comparing the three perceptions of the information gathering methods of the auditors we can find interesting differences according to hospital fields. According to the observations, auditors ask process-related questions and match documentation checking to these questions principally in the supportive (diagnostics, economic, technical) units. In the diagnostics unit the auditor also observed a process in the presence of the head of the unit. It can be due to this that the interviewees from these fields mentioned that auditors check the work processes. In the patient care units processes were not mentioned, but I could observe document checking and examination of certain fields (e.g. medicines), and one of the auditors mentioned that the whole unit can be audited from a single medical record. Maybe this influenced that in these units employees perceived that audit equals to document checking (see subchapter 8.7 for role interpretations).

The observation of work processes was not perceived by the hospital actors, even the auditors did not mention it as a principal tool in their work and I also did not observe it as typical (except in diagnostics). Therefore, it can be concluded that auditors supervised the fulfillment of the requirements of regulations by checking documents, by asking questions and by listening to reports.

ISO system supposes that fulfillment of requirements of regulations can be supervised by document checking and documentation is prescribed. (interview, Hungarian Standard MSz EN ISO 9001) However, the dominance of information gathering from the documentation has an effect on how hospital actors perceive the role of the certification and audit in the organization and its effects. (See subchapters 8.6 and 8.7.)

8.4.3.4. Evaluation criteria and results

The quality manager mentioned as one of the aspects of the evaluation of quality management system that „everything has to be easy to identify and easy to follow” (interview, quality manager). One of the top managers perceived that auditors are only interested in the documentation, and therefore the role of the regulations is to make hospital operation easy to follow for external observers, and auditors demand that the documentation describes what people have in their minds, and not inversely. However, 8 manager interviewees mentioned that the auditors compare documentation with real operation. In deed many audit reports begin: „During the audit it was examined to what extent regulations have been put into practice and how efficient they are." (reports)
The hospital does not receive the certification if any of the standard requirements is unfulfilled, so if there are serious discrepancies between the regulations and real practice found by auditors, which may hinder the operation of the system. Such a serious nonconformity[^132] is that, for example, if there is no quality policy, or no internal audits, or no documentation on the calibration and authenticity of measuring equipments. If such serious discrepancies are found the organization is given a week to solve the problem and the result is checked during an extra audit session. (interview, auditor) Audit reports list the nonconformities and statements[^133] according to their importance. If the auditors cannot find any discrepancies they have the opportunity to give recommendations[^134] which the organization is not obliged to follow. As it was described in the section on information gathering, the correction of the discrepancies (nonconformities, statements) has to be checked by the auditors. They also ask about the implementation of their recommendations, but they also accept negative answers (for example if the conditions were not adequate) according to one of the auditor.

When describing auditors’ attitudes and the long-term relationship between the auditors and the hospital (sections 8.4.1 and 8.4.2) it was mentioned that according to many hospital actors the auditors were not rigorous enough, a reason of which may be that they think that if they react more rigorously then the hospital chooses other auditors for the next audit. According to one of the persons for quality this is one of the reasons why the auditors did not refer to the discrepancies during the later audits, and they mostly focused on providing recommendations. However, the auditors claim that this is due to the development of the quality management system, and recommendations also dominate in other hospitals, as year by year fewer discrepancies are found.

In the passages describing the information collection methods it was also pointed out that in case of discrepancies the auditors have to find out whose fault it was, an individual’s or of the system. The quality manager commented that the auditors do not consider any discrepancy serious, although it could be serious, if they see that the hospital disposes of a quality management system that is able to screen for such discrepancies, and if auditors experience commitment and controlled operation. Therefore, the quality manager considers that a lot depends on how she presents the operation of the quality management system, because the final judgment is mostly based upon this. (See quotation in section 8.2.3 describing the role of the quality manager.)

One of the auditors said that they also considered the factors that cannot be influenced by the hospital in their final evaluation. Even audit reports contain phrases that refer to the understanding of the circumstances (financing problems, human resource shortages, change of the person of quality manager, etc.) and that they take them into consideration when giving their final evaluation. (Jelentes5a, Jelentes7a)

Interviews and observation suggest that the final statements given by the auditors (e.g. about discrepancies, deficiencies or recommendations) are not unilateral, but the result of an interactive process between the auditors and hospital actors. Auditors asked for the details of some deficiencies during the audits and they also listened to the explanations given by the audited hospital actors[^135]. They

[^132]: Nonconformities „Have to be corrected before the certification is given.” (Jelentes9a)
[^133]: Statements „Have to be corrected until the following audit.” (Jelentes9a)
[^134]: Recommendations „Do not refer to nonconformities between standard and practice. They refer to the optimization of QM documentation or / and the QM system.” (Jelentes9a)
[^135]: The opinion of one of the auditor escorts contradicts to this when she claims that during unit visitations the auditors do not talk about the discrepancies revealed, but other interviews, observation and reports do not corroborate this opinion.
usually made their recommendations during their visitations to the units, and hospital actors had the opportunity to respond directly. At the closure meeting the auditors also reported the deficiencies and their recommendations to the top managers, which means that the statements that were written in the final report could also be influenced by the reactions and recommendations of the top managers. (observation, interviews with hospital actors and auditors, reports) According to the former Director General communication between the management and the auditors was essential, and the opening and the closure meeting are needed to discuss audit recommendations. This is considered very useful by one of the auditors, too. (interviews, observation)

Based on the section 8.4.3 the audit method used by the case study hospital can be classified as an interpretative method according to the approach to knowledge (for the classification framework see section 4.2.2). The audit was not unilateral, the auditors not only gathered and analyzed information and gave feedback, and hospital actors reacted, but auditors and hospital actors interacted, influencing each other’s perceptions and interpretations, and, therefore, shaping together the final result of the evaluation. The description of the discrepancies and recommendations was the result of interactions between hospital actors and auditors (e.g. discussing discrepancies and recommendations during unit visits and closure meeting). The phases of the information gathering process cannot be separated. Auditors listen to the explanations of hospital actors, and they intend to understand the processes and the reasons of the discrepancies (e.g. individual fault or fault of the system), and they also consider the circumstances. Although some of the interviewees mentioned sampling as an information gathering method – which would be in concordance with a positivist approach – this was not characteristic of the auditor method used in the case study hospital, because the units and the documents were used randomly, but influenced by many other factors such as choosing the problematic fields following the recommendations of the hospital actors. Therefore, auditors were not independent evaluators, but their participation influences the final evaluation result which is shaped together with the hospital actors.

If hospital audits are analyzed from a different point of view, several critical remarks can be made. Some hospital actor interviewees claimed that auditors’ opinion could be manipulated. According to a manager participating in quality work the fields of the audit and the questions are calculable:

„Audit is still a kind of a shop window. We can go through the audit so that there is surely no mistake found. This is because I can find out what they are going to ask, not because they tell it beforehand, but it is simply calculable, and then we can prepare to avoid mistakes.” (interview, person for quality)

While some of the interviewees talked about the possibility of an open communication, some of them perceived that it not only had the form of a constructive communication, but sometimes hospital actors pushed through their opinion and made it accepted by the auditor. (interviews)

Some interviewees thought that the audit method was not proper to assess the quality of the hospital and to compare it with other hospitals. A top manager mentioned several times that he could not judge whether the method of the audits (e.g. frequency, level, details) was good or not. The same top manager also perceived that sometimes audits focused on a particular case (case to show). He expressed criticism of the eventuality of the audit methods and of the quality management system (e.g. patient satisfaction, patient complaints) and he thought these methods were not objective and they could be manipulated. One of the interviewees explicitly missed concrete numerical data or scoring, because he
perceived only counting of the mistakes. This interviewee considered audit as a subjective method where auditors make decisions based on their own impressions.

According to these critical remarks the auditor is not an independent evaluator, because they can be manipulated and their reactions are calculable, and they are not able to assess objectively the quality of hospital operation. Therefore, audit does not correspond to the requirements of a positivist method.

It can be concluded that the judgment of the audit method depends on what criteria we use (interpretative or positivist).

During studying the case several aspects of the audit as an evaluation method were identified, which factors influence the reactions and interactions that the audit has on hospital actors and which factors influence on what consequences the audit brings to the hospital. (Figure 18)

![Figure 18. External evaluation factors](image)

The initial conditions are determined by the market of the certifying organizations ("auditor" market), which favors long-term relationships as described in section 8.4.1, but according to the interviewees it also influences auditors’ attitudes. Auditors’ attitudes and their role (see section 8.4.2) is another important influencing factor. Auditors have some roles (interpreter, convincing) that refer to the fact that the way auditors interpret the role of the certification also influences its interpretation by hospital actors (auditors' interpretations and their messages). A good example for this is that the interpretation of SHC and HHCS by one of the auditors could have contributed to the effect that these systems lost their importance in the hospital. This auditor meant that HHCS could not be audited separately from ISO, and that

"[…] HHCS requirements are nothing else but a law translated into statistics. It does not contain any constructive and productive requirement that would enhance health institution development or improvement. It simply requires that health care institutions meet the requirements of the law and that's all. Why to operate a system for this? I don’t understand." (interview, auditor)

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138 Leading auditor when SHC was introduced.
During studying the case I also found evidence that not only the aspects and the results of the evaluation (e.g. revealing errors, feedback on recommendations) influence reactions and interactions of hospital actors, but also the methods of information collection (through documentation, for example). (section 8.4.3)

8.5. The mechanism of the effects of the certification and the audits in the hospital

The certification and the related audits induce various reactions and interactions not only among the hospital actors, but also between hospital actors and the auditors, as we could see as a result of the method presented in the previous subchapter. These are called the mechanism of effects of the certification and the related audits. The mechanism of effects is illustrated hereinafter through the steps called preparation, emotional effects (“exam nerves”), error correction and supervision.

8.5.1. Preparation

The subchapter describing the history of the hospital audit (subchapter 8.2) reveals that the first audits (trial audit, certificating audit) were preceded by an intense preparatory phase including a situational analysis, the training of hospital employees (e.g. quality manager, process keepers, internal auditors) and the planning of the quality management system. One of the top managers mentioned situational analysis as an aim, and this is what the auditors consider as an initial step:

"The establishment of a new system is preceded by a situational analysis which examines hospital operation and says what is good and what is wrong. In order to be ready for the certification these thing have to be clarified." (interview, auditor)

Trainings were commented on by one of the internal auditors:

"I had to be aware of what are the criteria to be met in order not only to obtain, but also to be able to maintain the certification." [...] it was during long months that we had lectures here in our classroom, and we had to take exams, and not easy ones. All this after work, in extra hours or taking time from our working time, which was not easy either." (interview, internal auditor)

After the trainings during the preparatory phase the basic elements of regulation (e.g. process descriptions, operational rules) and documentation system were established, and parallel the responsibilities (e.g. job descriptions) were also arranged. (interviews, Jelentes4a, Jelentes14a) Hospital operation had to be illustrated by process descriptions made by the process keepers:

"It seemed very difficult at the beginning, but then we realized that we have a solution for everything within the institution and we in fact solve everything, but it is just not written down." (interview, process keeper)

They had to prepare each employee’s job description according to the new scheme (interview, JK17), all the documentation had to be registered, „which was not an easy task, in fact, it was an extremely lot of work.” (interview, top manager) They also had to develop a document management system. Although many things had been previously documented (e.g. nurse documentation, medical record), and checked
(e.g. expiration of medicines), but not everything was written down, so new documentation had to be introduced. Operational rules, process descriptions and documentation schemes also had to be prepared at the level of the different units. One of the diagnostics units was ahead of the other units, because it had previously adapted international trends, and they “always had to be precise in documentation” (interview, physician head), and here the documentation requirements did not mean any new burden, because it had been introduced during the 1990s.

Hospital actors remember that the initial period was difficult because “there was a strong rejection”, “aversions and non-understanding of why we need it” (interview, top manager) As one of the hospital actors who participated in the introduction of the system comments: „resistance was huge, employees seemed determined to resist.” (interview, physician head) At the beginning employees did not understand

“[…] why to take so much extra tasks. It was difficult to convince them that it was nothing more than what they had done before, but now we just give everything a name and we tell them where to write it down. And then they have to do what they have written down. So it was like write down what you do, and do what you have written down. So, it took a lot of time to explain it to everyone that it is not about asking them to do more work.” (interview, person for quality)

Not only the first audit was preceded by a preparatory phase, but hospital actors prepared every year for the new audit, as it is documented in the management review records (JK12, JK3, JK8, JK9, JK10). Interviews point out the importance of the internal audits in the preparation for external audits, because internal audits reveal the discrepancies and they can be corrected on time. Preparation has a cyclic scheme, which means that the period preceding the external audits is always busy with internal audits, management review and document revisions.

“ISO requires a lot of administration. We are always up-to-date, of course, but not all of the units are. So this is the period of revising all the documents and everybody tries to recover their unit.” (interview head of unit)

Their cyclical character of the preparation is seen negatively by some hospital actors:

“I think that all this should not be left for the last minute, when there is no time to concentrate ...” (interview, internal auditor)

Many assessed this effect as positive, something that gives energy.

“Yes, it is interesting, but everybody was tense and almost panicked before these audits. I don't really understand why, since we go on working as we did before. [sighs] Yes, maybe this is useful.” (interview, head of unit)

This means that some hospital actors do not consider it negative that they invest extra energy in arranging things, and these actors do not emphasize the temporary effects, but they focus on how it can inspire employees to make order, to adjust and to be more disciplined.

During the preparation phase units revise their documents (e.g. job descriptions, competence descriptions, medical records) and storage of medicines. Besides quality workers other employees of the unit also participate in this work, and – as commented when describing the roles of the stakeholders – internal auditors also help in their units.

Persons for quality arrange documents at hospital level, too, and they arrange remaining tasks (like nonconformity reports). Meanwhile they constantly renew regulations to follow the changes of the
external environment (e.g. laws and decrees) and the changes of organizational operation. (interviews, reports, records) According to one of the top managers, audits play an important and positive role in following organizational changes by regulating the processes. In audit reports the sections called „Documentation requirements” and „Document handling” auditors follow the changes, and they also make suggestions for further requirements (see e.g. Jelentes1a). Therefore, audit does not only has an effect through the preparatory phase (JK1, JK2), but some regulations are modified due to the requirements of the auditors (interviews, dok1, Jelentes11a, records).

8.5.2. „Exam nerves”

Almost all interviewees admitted that they were more nervous and tense than the normal before the audits and during the events. A non-manager employee remarked:

„I don’t know, but ISO is like APEH for ordinary people. We just say ISO and I see the panic on people’s face, so, I don’t know.” (interview, skilled health worker)

According to the interviewees' opinion about themselves and about their colleagues nervousness affects both managers (nurse heads and physician heads) and employees, except a few who claimed that they were not nervous at all. One of the top managers admitted that he was also nervous about the first audits, because they seemed important and unknown. For the quality manager it was also embarrassing if something wrong was found during the audits: „There was an interesting case, and I almost got a heart attack during an audit.” (interview, quality manager)

According to the interviews the reason for nervousness is that employees fear that auditors find a mistake and that somebody would be called to account. One of the auditor escorts says: „What I see on my colleagues’ face is that they turn pale when auditors’ pen starts moving.” (interview, auditor escort)

Negative feelings about the audits also emerge because some employees think it is a time consuming or waste of time that takes attention from daily routine. (interviews)

Hospital actors and auditors agree that nervousness was more intense during the first audits, because employees did not know what to expect and what was going to happen if an error is found.

8.5.3. Error correction

As it was mentioned when describing the audit method, if auditors detect a discrepancy they report it according to its weight as a nonconformity or a statement. If the problem cannot be considered as a discrepancy, then auditors „only” make recommendations, which the hospital is not obliged to realize.

The discrepancies are revealed and the recommendations are formulated during an interaction between auditors and hospital actors, and feedback is not only given in a final report, but also during and after the audit, which means that hospital actors have an informal and a formal way of receiving auditors’ evaluating reactions.

When auditors reveal an error, correction is possible at the different stages of the evaluation process. There are errors that hospital actors reveal and correct before any formal revelation by the audit. (interviews) There were also other errors that were revealed by the auditors and which could be easily corrected during the audit due to the quick reaction by the quality manager „who got into contact with the

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137 APEH: Adó- és Pénzügyi Ellenőrzési Hivatal (Tax and Financial Control Administration)
responsible head of the unit and he took the necessary measures to immediately correct the error." (JK1)

Some of the errors corrected during the audit process appear in the audit report as recommendations, but others are not formally mentioned (observation, interviews, Jelentes1a). After the audit hospital actors try to find a solution for the problems revealed even if these problems are not mentioned in the official audit report. If auditors find serious discrepancies they may set a deadline for correction and asks for feedback from the hospital. In these cases the auditor must check error correction, and in these cases a responsible is appointed and a deadline is set. (Jelentes13a, Jelenetes12a)

In the case study hospital there was no discrepancy mentioned in the recent reports, but there were some not compulsory recommendations that, according to the interviewees (6 interviews), hospital actors tried to adapt. The two auditors, the quality manager and the audit reports corroborated that the adaptation of the recommendations was supervised during the following audit. This means that the recommendations made by the auditors are taken into consideration:

"Well, I try to consider auditors’ recommendations. They usually say that it would be better if... Well, they are not compulsory, but still it is good to take them into consideration. I also implemented a documentation that made no sense, but I simply could not say no to the auditors." (interview, quality manager)

Some hospital actors (6 interviewees) think that auditors’ recommendations do not make much sense. As auditors do not have an overall view of hospital operation, not all the recommendations they make are relevant (interview with internal auditor). There were recommendations that were neglected by the hospital, because the quality manager considered that the existing practice was more reasonable. (JK1)

Error correction and the adaptation of the recommendations is realized through management hierarchy and by individual measures taken by the quality manager. In some cases these two coincide.

After the audit the quality manager sends a memorandum and gives feedback on the results of the audit in meetings for top managers and middle managers, and they say thank you to everyone. The quality manager takes the necessary steps to adapt audit recommendations, or if she is not assigned to do so, she asks for the intervention of the Director General and other directors. (interviews, records, dok1, dok2)

At the level of the units the discussion of audit results is mostly informal, except in case of discrepancies which are consulted in unit meetings where measures are taken to correct errors. In case of concrete recommendations by the auditors the quality manager discusses them with the head of the relevant unit. (interviews)

Besides these ‘official’ mechanisms there are also spontaneous ones. Spontaneous mechanisms are those measures that are taken by the hospital actors to correct errors even if these errors are not mentioned by the audit report. These reactions are interesting because there is no obligation of providing feedback, but the problem is considered important by the hospital actors themselves and they take the necessary measures to modify the regulations.

It is worth mentioning the case of repeated recommendations, when auditors make recurrent recommendations with very similar content (reports), which means that the auditors repeated their recommendations when they were not taken into consideration and they considered them important.139

138 An example was when an employee was performing a task that was not part of their job description. The auditor perceived this but it was not mentioned in the report.
139 An example was the sequence of the recommendations on the introduction of a checklist for medical records. (Jelentes2a, Jelentes3a, dok1, JK1)
The recurrent character of the recommendations also suggest that the applied error correction methods were not always successful. In order to enforce measures the mechanism of the effects of the certification and the audits, that is, the reactions and the interactions of the actors, resulted in more intense supervision, which is described in the following section.

8.5.4. Regular supervisions

The quality manager is assigned to supervise and check if the necessary measures were taken in order to correct errors signaled by the auditors. The results of these measures were checked during internal audits and there were also other supervisions (e.g. nurse visits) and direct checking.140 (interviews, records)
The frequency and the process of these supervisions were variable, as it is illustrated by the two cases below.

8.5.4.1. „Action”

According to the report of the employees of a certain unit, if their unit had a problem it always brought about consequences. Audits revealed that in some medical records the signature and the seal of the physicians was missing. The quality worker could not solve this problem, so the quality manager and the nurse head were asked to help, and together they achieved that the physicians signed and sealed the documents.

„But it needed many of us. It was not enough when I went to them alone. They said it was not in the directive given by the director. Well, the directive is not always needed, because the regulation by the ISO must be enough, independent of the director’s directive. But physicians said no, because they only obey to the director, and so on… Yes [laughs], it was like that.” (interview, quality worker)

According to this interviewee physicians’ practice was changed by acting together, but other factors could also influence. These factors will be mentioned in subchapter 8.8.

8.5.4.2. „Campaign”

In another hospital unit several revisions and warnings were made to correct errors. After an external audit feedback of the errors revealed was given to the unit by the quality manager, an internal revision was made and the quality manager sent back the revision documentation to the head of the unit and also to the Director General, and a top management meeting was held to discuss the necessary measures. „The Director General called the attention of the head of the unit to the importance of precise documentation.” (JK2) Then another internal audit followed, and the next year the unit was again visited by the external auditors. The quality manager claimed that auditors usually go to the units every two years, but this unit was audited every year. (reports)
The effect of the revisions on the unit were the following: the physician head considered it good that he could also participate in the audits and could see what the problems were with the administration. The

140 Nurse visits were used to check correction of errors revealed by the audits (e.g. expiration of medicines). (interview)
An example for direct checking was when the application of the thermometers in the refrigerators was checked after a trial audit. (JK16)
physician head was responsible for the errors, and he was warned to take measures. He took the following measures:

"I ordered to take all the medical records since the beginning of the month and check them all. My colleagues said that they were not willing to do this, only if they are assisted by an administrator, because they already worked 12 hours instead of 8 to do their job." (interview, physician head)

Two physicians of the same unit commented: "now we get a huge amount of medical records to arrange." (interview, physician) The other physician said: "Well, sometimes the head of the unit warns us that something is missing, and the people try to correct it." (interview, physician)

After the external audit the discrepancies revealed in this unit had some further consequences: random supervisions were extended to other units as well.\textsuperscript{141} (dok1, dok2, JK1, JK2) The result of the overall supervision was that it was recognized that the ordering of medicines was not standardized within the hospital, and the elaboration of new regulation was required. (JK2) This example shows that external audits cannot only contribute to generate supervisions to avoid revealed errors, but also to discover new problems and induce new regulation.

The above mentioned examples illustrate that the effects of the external audits as regular supervisions can be strengthened by generating further internal supervisions. The effects of the certification on the control mechanisms of the organization is described in detail in section 8.6.1.

Subchapter 8.5 described what effects audits have on the reactions and interactions of hospital actors (preparation, emotional effects, error correction and supervisions). The results of the subchapter 8.4 claiming that audits consisted of individual events of evaluation rather than of an independent and unified evaluation process has been corroborated by the present subchapter. There was no clear boundary line between the evaluation and its effects, and the evaluation process cannot be separated from the reactions and other consequences, but they complement each other.

Based on the subchapter 8.5 it can be concluded that one of the important aspects of the mechanism of effects of the audits is the regular supervisions. This means that the effects of the evaluation are not the result of a single event, but hospital actors are aware that the next time they will also have to face auditors’ requirements. Therefore, the reactions of hospital actors are strongly influenced by the resultant action, which usually consist of internal supervisions and the audit of the following year. (The nature of the resultant action as a further classification aspect has been already mentioned in section 4.2.2.)

The preparation and the emotional reactions described refer to the exam-like character of the audits, which was a metaphor used by some interviewees. This exam-like character suggests that the audits are considered as something important that make hospital actors to carry out certain modifications to avoid discrepancies. The exam-like character was especially perceived in case of the very first audit, which had been preceded by an intense preparatory period. Exam-like character together with regular supervisions have a cyclic effect which is perceived in various ways by the hospital actors. Many hospital actors consider that this effect is positive because it makes

\textsuperscript{141} The fact that one of the consequences of external audits is the intensification of supervisions and the introduction of random supervisions was corroborated by an interviewee who observed this in their previous workplace, too. (interview)
hospital actors adjust and be more disciplined. Periodicity is also considered as positive by the auditors themselves. Recurring audits also enhance implementation of auditors’ recommendations. Besides periodicity it is important to point out that in this case certification and the related audits have been exercising their effects for a long time in the organization. Long term relationship may also influence the reactions of hospital actors and the overall effects.

Many factors that influence the mechanism of effects have been described at the end of the previous subchapters. However, reactions and interactions are also influenced by factors at individual level described in section 8.8.1. This means that the mechanism of the effects exercises an influence on the organization together with these influencing factors. The resulting changes are classified in the following subchapter.

8.6. The effects of the certification and the audits on the organization (perceived changes)

This subchapter classifies the changes as perceived or documented based on the analysis of interviews with hospital actors and the relevant documentation. Hospital actors have different opinions about whether certification and the related audits caused any changes in hospital operation. Section 8.3.2. on ‘The importance of the certification and the audits for the hospital’ signaled that three physician heads of three different patient care units pointed that certification did not have any significant effect on the internal operation of the hospital, because external regulations (laws, professional protocols) had already established the framework for operation, and they claimed that audits did not affect their professional work. Other interviewees claimed that there were significant changes in hospital operation, especially in the initial period of the audits. 9 interviewees agreed that these changes had long-lasting effects, although the changes that took place in the initial period were more essential than the later ones.

“I think that it was at the beginning that we had to do everything differently. Because we were not used to it. Now we can only change little things.” (interview, top manager)

Hospital auditors also agreed that a functioning quality management system only has to follow the changes of the external environment and the changes of the organization, which means that the system becomes reactive.

8.6.1. The system established as a result of the certification

The certification and the audits are evaluation methods that require the establishment of a quality management system in the institution as a condition of the certification. The elements of such a system were implemented during the preparation period for the first hospital audit (JK15, JK16). The elements of the system are: the regulatory and documentation system and elements related to the PDCA cycle. These elements are described below in the context of the case study hospital.
8.6.1.1. Regulation and responsibilities

Experts and auditors agreed that in case of a good system better regulation of the processes can be one of the positive effects of certification. According to those who knew the original situation, hospital operation became better regulated as a result of the certification (5 interviewees).\(^{142}\)

What does better regulation mean for the hospital? On the one hand the establishment of a unified regulatory system. Before the certification there had been several separately emitted directives, but they were not harmonized. There were units that did not have written operational rules and there were no process descriptions. Therefore, a new, standardized system of the documentation of the processes, operation rules and job descriptions was established in the whole organization as a result of the audits. Mainly due to the audits these regulations are continuously updated and adapted to external and internal changes. (interviews, dok7, reports, records)

What does the new regulation mean for the hospital actors? Do people read the regulations and act accordingly? This is not necessarily so. In fact, when the system was established the principle was to write down the existing practice, and then not to deviate from what is written. One of the physicians commented on the application of the new regulations:

> „[…], well, in fact, you can deviate, but you have to be able to say why. And if you are obliged to say why, you will think it twice to deviate or not. If someone deviates, but they can reason why, then it’s ok. Not all the steps you take can be regulated.”(interview, physician)

Regulations have many advantages for the hospital: they can serve as a reference during supervisions and as a reference for other units. When handling complaints it is also useful to have regulations at hand and be able to refer to them. They can be used when hospital actors, either managers or employees, want to have information from a less well-known operational area. It is also useful for new employees that they can use regulation documents to know more about hospital operation. One of the top managers characterized the system as follows:

> „I wouldn’t say all hospital workers, because we are not all super-devoted and fully committed individuals, but those who are leading others, or leading units, or the nurses, or those in diagnostics can use it really beneficially. It is great that we always know where to turn to. […] And that it is surely written there, and if it is written, we have to act accordingly. I think it’s important.” (interview, top manager)

Regulation affects responsibility and accountability. Rules can lower individual responsibility of choices, because if someone acts according to these rules then they are protected in the context where these rules had been introduced and legitimated. Regulation offers a framework which protects hospital actors who act accordingly. They can alleviate responsibility burden in situations where the regulation can offers a solution. One of the effects of the certification was that it regulated responsibilities and accountability. (interviews with 7 hospital actors and two auditors) Moreover, standardized job descriptions were also prepared during the initial period, which later were complemented by competence descriptions. (interviews, records, dok1, dok10, Jelentes2a) Accountability was supported not only by clear job descriptions, but also by the documentation of work done or not (e.g. unconformities).

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\(^{142}\) Only one of the interviewees emphasized that operation did not become more regulated.
8.6.1.2. Documentation

ISO 9001 requires action documentation which requirement is clearly transmitted by the auditors (observation, interviews, Hungarian Standard MSz EN ISO 9001). Documentation is double-edged: on the one hand if someone commits an error, he becomes accountable. (5 hospital leaders, one auditor) According to the quality manager the obligation of documenting actions resulted in significant changes.

“It must be documented. Responsibility only exists if there is documentation. Oral commitment does not involve responsibility or accountability.” (interview, quality manager)

Documentation can also be used to prove that certain work was performed, and therefore it can protect hospital workers. (interviews with 6 hospital actors and one auditor) Hospital actors have different opinions about the importance of the documentation:

“Its role is that I can prove what I have done. In nursing, I think, this is the point.” (interview, nurse)

“…during the years it became clear that I would never be able to prove that I did something if it was not documented. Anyway, in such a place it is a little bit disappointing that you can’t prove that you did something, only by showing the papers.” (interview, top manager)

Certification had an effect on documentation and administration (20 interviewees, records, Jelentes1a, dok1). During the preparatory phase the former documents were registered, unified and systematically arranged, and as a result of audit recommendations further documentation of the activities and checklists have been introduced (interview, Jelentes2a, JK1, JK2, JK15, JK16).

Many of the interviewees formulated the statement that certification only brought about administrative changes. (7 interviewees) The opinions about these changes were different. Many claimed that these changes had a positive effect on documentation discipline and that documentation of patient records became more precise and detailed. Some hospital actors in patient care units claimed that changes in the administration only had negative effects: it is a burden that is „hindering“ their professional work (3 interviewees).

8.6.1.3. Supervision

When describing the mechanism of the effects of the audits in subchapter 8.5 it was shown that audits also had an effect on the supervisions in the hospital. New forms of supervisions were introduced and the role of former supervision types was strengthened. (interviews, dok1, records, reports) Many hospital actors claim that regular supervision has a positive effect (10 interviewees), because it helps to maintain discipline. Others (5 interviewees) think that without these supervisions discipline would become loose and people would not take things seriously. It is also possible that these are only needed in units „where originally there were some problems“ (interview, nurse head), and where only these supervisions have some forcing power.

Most audit recommendations – especially during he second phase of the certification period – refer to the documentation. (A detailed analysis has been made on the content of audit recommendations, which is not included in the dissertation for reasons of limitations of extension.)
8.6.1.4. Other system elements

Other quality management system elements are also required by the certification, and these elements were also introduced during the preparatory phase (JK15, JK16). For example, the patient satisfaction survey, which formerly did not exist (interview). Auditors check the existence of the quality management system elements, which are the following beyond the regulatory system and the documentation system: quality objectives, management review (and its documented record), patient complaints, patient satisfaction surveys, internal audits, nonconformities reports. (interviews, observation) Audit reports also point out the importance of these system elements among the evaluation criteria. (audit reports) The result of the application of these system elements is a series of cyclic tasks:

„Because they have a year to perform an internal audit, to elaborate the patient satisfaction questionnaire, to perform management review, and they have to do it every year to meet system requirements that they have set for themselves.” (interview, auditor)

Quality management system elements are classified as indirect effect factors: the auditors’ expectations about these system elements are perceived by the quality manager, which means that the effect of the application of these elements according to audit requirements can be considered as an indirect effect of the audits. Several audit statements and recommendations referred to the application of these system elements, and in this way they influenced on their effects on the organization. (reports, records)

Therefore, the system elements presented in section 8.6.1. belong to the indirect effect factors, as well as the quality-related roles of hospital actors shown in section 8.2.3. (See Figure 19.) The complementary elements of the group of the indirect effect factors are: regulation and documentation system, supervision system, and the elements of a possible PDCA cycle (like establishing the objectives, nonconformities reports, internal audits, satisfaction surveys, management of complaints, management reviews).

Figure 19. Indirect effect factors

Source: own elaboration

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The role of the indirect effect of the established system in decreasing the gap between requirements and practice is summed up by one of the auditors as follows:

"[…] all this shows that the systems are improving, the aim is to minimize discrepancies and I think if the organization does it well, then it is reflected during the audits." (interview, auditor)

So while these roles and quality management system elements were established and are continuously improving as a result of the audits, they also contribute to the changes of the organization. However, not all the factors have the same intensity in influencing the organization: while documentation had an important effect on accountability and protection, some of the elements of the PDCA cycle did not appear with the same weight in hospital operations. The quality manager is responsible of continuously adjusting the system to the changes of the external environment and to the changes within the organization (?Plan), and the necessary measures are taken according to the auditors’ recommendations (Do), which are regularly checked by the auditors (during internal audits, for example) (Check), and new actions are implemented if necessary (Act).

However, the quality manager claimed that patient satisfaction surveys did not have any serious consequences, even if they revealed that there were serious problems in the field of, for example, cleaning. (interview, JK1) This means that the opportunities offered by the analysis of these elements (results of internal audits, patient satisfaction surveys, analysis of patient complaints) were not properly used, and the objectives were not formulated on the basis of such analysis, and the systematic evaluation of the achievement of the aims also failed. According to this we can conclude that the Planning phase of the PDCA cycle failed, which resulted in a reactive maintenance of the system, but the proactive and developing potential of the system was neglected or misused by the hospital management. (The effects of the indirect effect mechanism on development will be analyzed in subchapter 8.9.)

According to the interviewees the system changes shown in section 8.6.1. had several effects. One of the effects of the certification was that it made order and hospital operation became more transparent and arranged (4 interviewees, including two top managers).\footnote{144 Only one interviewee (a physician head) signalled that he did not agree with this.} This effect was also corroborated by the auditor interviewees. Order is reflected in the availability of key regulations and activity documentations, and everything is at hand if information is needed.

One of the effects of the certification (6 interviewees) was that it improved protection of the hospital, which is an advantage in legal cases. A person for quality claimed:

"I think it is like the crutch for a cripple if there is a problem, because denouncements are inevitable here as well as in other hospitals. In most cases the petitioner think that something was going wrong in the hospital. In this case we can take the documentation that proves that everyone did their job, and the hospital becomes more defendable against lawyers’ tricks." (interview, person for quality)

One of the top managers could serve with an example of how the system could defend the hospital and its employees against a denouncement. Two other hospital actors (a top manager and a person for quality) were less optimistic: they admitted that the system established as a result of the certification played some role in defending the hospital, but they claimed that it was far from being enough to provide overall protection.
8.6.2. Perceived changes in hospital operation

When talking about hospital operation I refer to the basic functions like patient care, and the supportive functions like diagnostics, economic and technical operation. Under 'its changes' I mean the changes that affect the work processes (general changes, like changes referring to regulation and documentation are not included). During the analysis of the interviews and the documentation I found much less examples for changes affecting basic hospital operation than for changes that affected the system or the documentation. These changes in hospital operation affected the following fields: stocktaking, culling (e.g. checking expiration of medicines), storage (e.g. meeting the requirements, thermometers in the refrigerators, handling and storage of hazardous waste); registry, authenticity and calibration of equipments, their technical conditions. (interviews, records) These former changes were typical in the first period of the certification, and although some of the changes took place in the patient care units (storage of medicines, handling hazardous waste), most of the changes affected the supportive areas (technical, storage). According to the perception of the interviewees, their own professional work was not affected by the changes induced by the audits neither in the patient care units, nor in the supporting units. (The reason for this in the supportive fields may be that the interviewees who worked in economic and technical units during the research period had not been worked there in the initial period when certification was introduced, and therefore they did not have the opportunity to perceive these changes.) According to the quality manager the use of the checklists in the patient care units assures that no step is missing from a process, which is also important for the patients, but only one interviewee of those working in patient care units mentioned also this aspect. Two top managers had completely different opinion about in which fields the certification had an effect: one of them claimed that the certification affected every operational areas, while the other claimed that the audits did not have any effect on the work processes.

At the same time many agreed (the former Director General, another top leader, the quality manager, physicians and nurses who take active part in the quality system) that certification had an effect on the quality of care. This does not necessarily mean that there have been concrete changes in the work processes, but the effect could also be the result of the changes that happened at the level of the whole system.

„I think that certification is a key element of hospital quality, which proves that the hospital disposes of a certain level of organization of its processes. Organization of the processes supports patient safety, and in this respect it is essential. The certification also contributes to improve quality, but it is far from being a unique element of professional excellence.” (interview, top manager)

8.6.3. Effects on stakeholders

This section focuses on two aspects where the changes induced by the audits were perceived differently by hospital actor interviewees. One is the aspect of the effects of the audits on hospital actors; the other is the effects of the certification on the patients.

145 One of the auditors claimed that this was generally true to the effects of the audits, even in other hospitals.
8.6.3.1. Effects on hospital actors

Stakeholders had different perceptions of whether the certification had any effects on hospital actors (their behavior, their work or their attitudes) or not. According to 11 hospital interviewees certification had an effect on their work and on the attention they pay to their work. Although at the beginning it was difficult to pay attention to the changes introduced, but hospital employees got used to these changes (like handling hazardous waste), and later they became part of the daily routine. (5 interviewees, JK8, Jelentes9a). One of the effects of the audits is that people pay more attention to their work (like stock-taking, disposal of assets, thermometer in the refrigerators, patient documentation – these are all fields that auditors usually check according to the interviewees). (5 interviewees)

6 interviewees have a different opinion and they claim that certification did not have any effect on their behavior or their work. One interviewee claimed that certification had a negative effect on hospital actors, because the burden of extra documentation made them frustrated. The burden of extra documentation was also experienced by other interviewees and by the quality manager of the hospital, who said the following about the employees:

„They are impatient, yes, because they have to write everything down. Routine does not help, because it takes a lot of time anyway. It takes time away from patient care. And patient care tasks are not less than before, and if they want to perform their tasks well, it is extremely frustrating when there is no time for this.” (interview, quality manager)

It can also be mentioned among the effects on the hospital actors that there have been some changes in their attitudes. At the beginning they resisted, but this resistance changed, as interviewees commented. According to many top managers the resistance decreased because managers realized the importance of the certification, and they transmitted it to the employees who understood it, and their attitudes changed. However, resistance is still present among hospital actors, although in some cases it could be eliminated by similar measures (like convincing them about the importance of the changes). The effect of the audit can also be adverse. As one of the physician heads said, they were full of expectations towards the certification, but after the first audit they felt disappointed.

8.6.3.2. Interviewees’ opinion about the effects on the patients

Most of the interviewees (7) from patient care units and the quality manager agreed that certification did not affect patient care or treatment and the relationship with the patients. Certification does not have any effect on how patients perceive quality of care and it does not influence them when choosing a hospital.

„Patients do not choose a hospital on the basis of whether the hospital has a certification or not. Patients don’t even know what certification is. It has only importance for us. Patients feel something, but they cannot explain what it is. The patient says he wants Dr. X, because in his unit care was O.K., the ward was clean. Quality management system is not a point. If it would not exist, I personally think that there would be more denouncements, because patients see it differently. But patients do not ask if all this is certified or not. If they don’t get the treatment they expect they feel disappointed and now they can make a denouncement. This is how things have changed.” (interview, quality manager)

The quotation also reveals that the quality manager considers that the certification contributes to prevent denouncements, and she concludes that certification may have an effect on patient satisfaction. One of the changes related to the patients was that patients had an opportunity to express their opinion through patient satisfaction surveys and by writing complaints or praise in notebooks placed in the wards. From
the aspect of the patients many interviewees (5) claimed that extra documentation burden had a negative effect on the patients, because it took time from care and form communication. Meanwhile a nurse person for quality expressed that documentation was also useful for the patient because they receive and can dispose of a precise documentation of their treatment.

8.6.4. Negative effects

Some of the negative effects of certification have been mentioned in the previous sections. Hereby these negative effects will be summed up and complemented.

13 interviewees mentioned the documentation burden as a negative effect of the certification, but 6 interviewees found it reasonable, because they also saw the advantages, and they considered that when these changes become part of the routine they cease to be a burden. Five interviewees (three physician heads, a nurse manager and a physician) found documentation burden unquestionably negative, and they considered extra documentation unreasonable and redundant. Three of the interviewees who shared this opinion worked for the same hospital unit. One of the nurse manager of another unit agreed that documentation had some unreasonable elements. Duplication was one of these unreasonable elements mentioned in both units, when physicians and nurses had to document the same thing. Another negative effect of the administrative burden was that employees became frustrated and that they had less time for patient care. Extra documentation also increased paper consumption. (According to the economic manager this burden was significant at the beginning, but later it was stabilized.) To the ‘yes or no’ question of whether audits had any negative or adverse effects 12 interviewees and all those who participated in a group interview answered no, or that they could not mention any adverse affects.

Subchapter 8.6 classified the perceived and documented changes induced by the audits. These changes were significant at the beginning of the certification process and affected organization level and transparency of the institution. The changes affecting the work processes were also mostly perceivable at the beginning, and these changes mostly affected the supportive activities of the hospital. The changes related to the extra documentation have been perceived during the whole certification period, and had positive (accountability, protection) and negative (documentation burden) effects according to most of the interviewees.

8.7. The role of the audits and of the certification in the hospital

The previous subchapters described the characteristics of the audit methods, their mechanism of effects in the hospital and the perceived changes that audits induced within the organization. These effects are influenced by other (external and internal) factors, some of which have also been described. The next question to be answered is that as a result of all these effects what kind of image is formed by the hospital actors about the role of the audits in the hospital. These role interpretations affect the attitudes and the reactions of hospital actors, and, therefore, react upon the whole mechanism of effects and the organizational changes. (See Figure 14 in subchapter 8.1.)

Subchapter 8.7 is dedicated to classify the interpretations of the role of the audits by the hospital actors, and these interpretations are compared to the interpretation given by the auditors and the professional expert interviewees.
8.7.1. Interpretation of the role of the certification by hospital actor interviewees

Table 17 sums up the interpretations of hospital actor interviewees of the role of the audits and of the certification within the hospital. This table shows that hospital actors gave many different interpretations, some of which can be considered as dominant, and some of which characterize a certain group of hospital actors. The basic interpretations will be described in the sections below.

<table>
<thead>
<tr>
<th>Interpretation of the role of the audits and/or certification</th>
<th>number of hospital actor interviewees</th>
<th>characteristics of hospital actor interviewees</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exam (metaphor)</td>
<td>2</td>
<td>managers</td>
</tr>
<tr>
<td>Supervision: document-checking process supervision</td>
<td>12</td>
<td>physician heads of patient care units, physicians, nurse managers, and two top managers</td>
</tr>
<tr>
<td></td>
<td></td>
<td>persons for quality and heads of supportive hospital units</td>
</tr>
<tr>
<td>Regulation</td>
<td>9</td>
<td>mixed (from many different hospital areas and different levels of hierarchy)</td>
</tr>
<tr>
<td>System</td>
<td>5</td>
<td>mixed</td>
</tr>
<tr>
<td>Order and discipline</td>
<td>9</td>
<td>managers, persons for quality from the beginning (no physician from patient care units)</td>
</tr>
<tr>
<td>Protection for the hospital and for the employees</td>
<td>3 (+4)</td>
<td>person for quality, top managers, physician heads</td>
</tr>
<tr>
<td></td>
<td></td>
<td>nurses, quality manager</td>
</tr>
<tr>
<td>Revealing, correcting and avoiding errors</td>
<td>6</td>
<td>mixed</td>
</tr>
<tr>
<td>Improvement</td>
<td>3</td>
<td>physicians (two of them are top managers)</td>
</tr>
<tr>
<td>„Degree“</td>
<td>4</td>
<td>managers</td>
</tr>
<tr>
<td>„Gap in the system“</td>
<td>6</td>
<td>physicians</td>
</tr>
</tbody>
</table>

Source: own elaboration

8.7.1.1. Exam

Interviewees used several metaphors to refer to the audits. Some of them were „exam“, „experiment“, „shop-window“ or, referring to the certification as a „degree“. The effect of the audits is also suggested by the terms „impersonal manager“, „springtime cleaning“ or a „shoe“. These metaphors highlight the different aspects of the audits and the certification, and they will be analyzed below. Two of the interviewees consistently referred to the audits by using the „exam“ metaphor, which properly describes the emotional effects of the audits (see section 8.5.2), and it also refers to the final result, the certification. One of the managers said:

„Well, I’m proud of it, you know... It is like passing an exam or solving a problem and you feel proud and satisfied.“ (interview, head of a diagnostics unit)

8.7.1.2. Supervision

Certification and the audits involve regular supervision for the hospital employees. „Audit is a form of supervision, as I see.“ (interview, top manager) Five of the interviewees considered it important to have certain control within the organization and that auditors represented this control. Some of the managers also admitted this role of the audits, but one of them was skeptical about whether audit was the most
adequate tool for such control. This manager claimed that a lot depended on managers. Another manager, who agreed with the later, claimed that audit functions like a kind of "impersonal manager".

"The effect of the audit can be compared to the situation of if we had another, impersonal manager, who always demands, but is never present." (interview, head of a unit)

![Figure 20. Document-checking versus process supervision according to hospital actor interviewees](image)

Source: own elaboration

**Document-checking**

The dominant interpretation among hospital actors (12 interviewees) was that audit was a kind of document-checking, and that it aimed at checking the documents. (See Figure 20.) Many interviewees highlighted this administrative role while pointing out that audits did not enhance professional work. This was the opinion of the physician heads and the other physicians of the patient care units, except one physician who had been active for years in quality. (7 interviewees) Most of the physicians of patient care units criticized audits for merely checking signatures and seals on the documents. (5 interviewees) The document-checking role of the audits was considered as negative by all the three physician heads of the patient care units.

Nurse manager interviewees (4 interviewees) also highlighted the document-checking role of the audits, but they did not consider it as negative. One of the nurses mentioned the administration burden as a negative effect, but even this nurse admitted that administration was needed. Other three pointed that
they usually do not have problems during the audits and they think that administration must be taken seriously anyway.146

Among the top managers there were two interviewees who attributed document-checking role to the audits, but they did not consider this role as essential or dominant during the audits.

**Process supervision**

The process controlling role of the audits was mentioned by much less hospital actors (7 interviewees). (See Figure. 20.) Mostly the persons for quality of the hospital and the heads of the supportive fields (diagnostics, economic, technical) claimed that the certification and the audits played a role in regulating and supervising the work processes. However, both the heads of the economic and technical units emphasized the role of documentation during supervision. The head of the diagnostics unit said that the audits supervised the processes but not the professional work.

**8.7.1.3. Regulation**

Interviewees from different hospital activity areas and from different levels of the hierarchy (9 interviewees) mentioned that audits supervise whether hospital actors do their work according to the regulations or not, therefore, audit plays a role in the regulation. The quality manager claims that the system established as a result of the certification makes it possible that everyone knows what to do and when to do it, and they can also expect it from each other (h14):

“[…] it helps the employees by providing a direction, so they don’t have to deal with that. Therefore, if the rules are given, employees have less to worry about.” (interview, quality manager)

Some of the persons for quality mentioned that the audit reflects the point of view that *practical operation has to be fixed in order to draw a pathway that we follow and from which we do not deviate* (interview, person for quality), which means that they describe how the hospital operates, and then they follow these descriptions. According to one of the physician heads one of the disadvantages of this system is that it does not enhance development and improvement of the processes. Another physician head distanced from the rule makers when answering the question about the role of the certification and the audits in hospital operation: *I suppose they want to check whether we meet the requirements of their regulations.* (interview, physician head) A physician said the following about the role of the regulations:

“They told us that ISO would be implemented, and we had to write a lot of stupid staff, and we were also told that we had to fulfill a number of requirements that we and they impose.” (interview, physician)

The head of an economic and technical unit thought that the operation would be the same without the certification as well, although he found regulations useful:

“I think the aim of the hospital with the ISO is the same as the aim of establishing ISO, namely to regulate the processes and make them easy to follow for the users and for the supervisors. To make processes easy to follow and accountable. Thing have to be clearly and objectively described, so that they are easy to supervise and to perform, of course.” (interview, head of unit)

146 One of the limitations of this research is that only a few non-manager nurses and no administrator were involved in the interviews. This may be the reason why negative interpretations of the role of the audits is not really emphasized.
Two of the physician heads, although they considered certification as important, did not have a positive opinion about the established system. One of them thought it brought about extra documentation, and the other commented that operation did not become more regulated, although it was one of the aims of the certification. One of the persons for quality of the hospital commented that regulation was important, but she thinks it was not efficient, and thinks that certification is the necessary evil. All these opinions illustrate that there are several different opinions about the regulation role of the certification in the hospital.

8.7.1.4. The system
Certification and audits have a role in establishing "the system". Interviewees did not use the term ‘quality management system’ (except the quality manager), but they used "the system" when referring. (5 interviewees) "We had everything before, but things were not in a system as they are now due to the audits." (interview, top manager) The system serves as a framework which makes hospital operation more transparent. There was a physician head who commented that the hospital could easily operate without the system, but "from the aspect of the managers or external supervisors the system makes it much easier to have an overall view of hospital operation". (interview, physician head) One of the top managers also claimed that, due to the system hospital operation became more transparent, and this was not only beneficial for the management but also for the employees (like new employees for whom it will be natural). This role of forming a tradition was also referred to by other hospital actors, who emphasized its importance under the circumstances of high level of fluctuation.

8.7.1.5. Order and discipline
9 interviewees agreed that audits had a role in establishing order and discipline in the hospital.

"Looking back I think that it really made an order in the system." (interview, top manager)

"It decorated the house, and keeps the decoration on." (interview, person for quality)

One of the unit leaders used the metaphor of "springtime cleaning" to describe the positive effects of the audits. This cyclic effect enhances adjustment and discipline.

Management members agreed that certification and audits helped to make order. This opinion was supported by other original participants of the quality system of the hospital. However, the physician heads and the physicians of the patient care units (6 interviewees) did not mentioned this role. Although interviews and their employees corroborated that some of their managers also consider order and precise work essential, but these managers did not think that audits had any effect on this.

8.7.1.6. Protection for the hospital and for the employees
Hospital managers who took an active part in establishing the quality system of the institution (3 interviewees) pointed out the benefits of the certification in the protection of the hospital and the employees. This protection is provided by regulated and controlled processes and by a management system that is legitimate by the certification. Some hospital actors believed that the system could serve to prevent complaints and trials by assuring that processes meet all the legal requirements. Some of the physicians (2 top managers and 2 middle managers) also thought that it could provide protection against trials. However, the efficiency of the system in this area was not corroborated by the same interviewees.
The system offers protection for the employees by documenting that the activities have been performed according to the requirements and regulations. (h14, 3 interviewees) Most of the nurse interviewees also agreed with this. According to one of the heads of an economic and technical unit: „[…] the whole thing looks like as if I tried to defend myself by the papers I make.“ (interview, head of unit)

8.7.1.7. Revealing, correcting and avoiding errors

Six interviewees pointed out that the role of the audits was to reveal and correct errors in the hospital. The records about the management meeting after the first hospital audits also reveal that „[…] the trial audit revealed many errors and offered a new opportunity to channel energies to correct them. […] It was very useful, and it helped to focus our activities to the correction.“ (JK16) „I think that the most preventive measure we have is our integrated quality management system based on the audits and its efficient functioning.“ (JK11) (This record was signed by the former quality manager.) The present quality manager commented:

„And supervision aims at revealing if we deviate or the results are different, and it warns us to intervene and understand why we have not achieved what we wanted, and it urges us to correct errors.“ (interview, quality manager)

One of the internal auditors claimed that the system was able to command attention, to reveal faults and errors and to provide opportunity for correction, „[…] we have to admit that it is useful, and it helps to keep your gunpowder dry.“ (interview, internal auditor)

One of the top managers expresses it as „… the best experiment with evidence at hand within two days. We get a final report, so of course we react.“ (interview, top manager) He adds that he agrees with the principle, although in practice external audits sometimes fail to perform this error revelation role.

8.7.1.8. Improvement

The role of the audits in hospital improvement was mentioned by three physicians who had been participating in the establishment of the system since the beginning. Two of them are members of the hospital management:

„There is the aim to improve. This should be the principal and declared aim of the audits and their mission, I think. Otherwise it would not serve, and we could not talk about aims and results.“ (interview, top manager)

„[…] the point is that we should not stop, but we should go on improving what we accepted“ (interview, other top manager)

The third interviewee commented: „Well, audit is good because we learn to write down how hospital operation can be optimized. The closer we come to this in practice, the better […]“ (interview, person for quality) This and other fragment of the interview makes me suggest that this interviewee, unlike others, thought that regulations do not necessarily have to document the current practice of hospital operation, but they have to describe optimal operation in order to encourage improvement. This reflects the opinion of one of the physician heads who told that it did not enhance improvement if they described how the hospital was working. Among the other interviewees only one mentioned improvement among the roles of the audits.
8.7.1.9. „Degree”

According to some hospital managers (4 interviewees) the principal aim of the certification is to show that the hospital has it.

„It is just an obligation, like when someone must have a degree to apply for a job.” (interview, person for quality)

At the beginning there were rumors about that certification would be necessary for National Health Insurance Fund Administration or National Public Health and Medical Officer Service permits, and later certification became a necessary requirement of submitting tenders. Many of the leaders thought that certification was good for the prestige of the hospital. „It is the sign of a kind of ambition that the institution has obtained the certification.” (interview, top manager)

8.7.1.10. „Gap in the system” – what is not covered by the certification

Many of the interviewees commented on some unfulfilled expectations in relation with the audits (6 interviewees). These expectations were either related to their own working areas, or reflected overall expectations about the results of the certification. All these interviewees were physicians. According to their opinion, audits did not impose new requirements and did not supervise quality in hygiene, surgery rooms or communication. The disappointment about unfulfilled expectations is reflected in the following quotation:

„[…] I don’t know, but I think it’s disappointing, and I think it is not correct that the surgery rooms have never been visited.” (interview, physician head)\textsuperscript{147}

Another interviewee pointed out that audits and the system would be reasonable if it aimed at rationalizing and optimizing operation, but that it was not the case. Some felt frustrated about calling audits as quality supervisions, while they had nothing to do with judging the quality of hospital operation. Another gap was that audits did not focus on professional aspects. (8 interviewees) This was mostly mentioned as a fact but not as an expectation. The interviewees were physician heads and physicians who were not members of the management and who did not take an active part in the operation of the quality management system. This also reflects that professional aspects are mostly important for the physicians. It is also worth mentioning that some heads of economic and technical units also mentioned that their professional processes were not supervised by the audit, but they added that they did not expect it either.

8.7.2. Organizational patterns

The appearance of the role interpretations shows a certain organizational pattern. This section describes the groups of interpretations that usually characterize a certain group of hospital actors: those who have taken an active part in implementing the quality system and are “appreciative”, and those who are “discontented”. Besides these the section also describes the interpretations given by the management and the quality manager, because they play a critical role in what effects the certification has in the hospital.

\textsuperscript{147} According to the interviews there was a unit where the auditors visited the surgery room.
All the management members agreed with the order-making role of the certification and the related audits, although the level of agreement was different. Besides order-making, two management members agreed that it enhanced discipline, and another two that it makes hospital operation more regulated and more transparent. Two of the top managers considered that certification and audits contributed to improvement, but the two other top managers claimed that audits played rather a role in checking the documentation.

According to the quality manager of the hospital the role of the certification and the related audits was to provide a regulatory framework for the employees. This helps them know what to do and when to do it, and they can also expect the same from their colleagues. It provides protection for the employees against denouncements if they can prove by documentation that they acted according to the requirements. (interview, h14) The quality manager considers it important to fulfill legal and other requirements, and she claimed that the quality system could help to decrease the number of complaints and trials. She also emphasized that the auditors were outsiders, which enhanced reactions of discipline, fulfillment of requirements, while they were also more probable to notice things that routine workers did not notice. She said that audits helped to reveal discrepancies and errors that can be corrected.

The analysis of the interpretations of the roles revealed that interviewees who took active part in implementing the quality system of the hospital (7 interviewees) agreed in many interpretations. Considering that they are the hospital actors who experienced the certification process from the beginning and who actively participated in the establishment of the quality system of the hospital we can call them “APPRECIATIVE”.148 These actors could make a comparison between the periods before and after the certification. They thought that the certification and the audits contributed to establish order and discipline in the organization. The three interviewees who considered that the certification played a role in defending the hospital by preventing denouncements were also in the group of the “appreciative”, similarly to those three who considered that it contributed to hospital improvement. As it was mentioned before, the interpretation of the role of document-checking dominated, but none of this group of interviewees thought that the audits had this kind of role. These characteristics exclusively prevail for this group of interviewees.

There was another homogenous group of hospital actor interviewees, namely the group of the six physicians working in patient care units, who did not take an active part in the quality system. This group can be called as the “DISCONTENDED”, because none of them thought that the certification would have contributed to establish order and discipline, or to correct errors, and all of them agreed that certification equaled to document-checking. The discontented who were present during the implementation of the system think that there are some deficiencies (”gaps in the system”). All of them mentioned that the audits did not affect professional work, and they also remarked that they did not expect audits to do so.

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148 One person for quality from the group of the APPRECIATIVE was different, because although he agreed with the others, he also formulated slight criticism towards the quality system, pointing out the gaps of the system and also using the term ‘degree’ for the certification. The other six members of this group could be named not only as ‘appreciative’, but also ‘fully committed’.
8.7.3. Comparison between the interpretations given by the auditors and by the hospital actors

Auditors highlighted the role of the audits in establishing order, and making hospital operation more transparent and regulated. One of them thought that these arrangements were done during the preparatory phase, and produced changes at the beginning, which is only true for adequately operating systems. Many hospital actor interviewees also attributed this role to the certification, among them the top managers of the hospital, especially those who took an active part in the implementation of the system.

Certification had a role in “being able to expect from the employees that they work according to the regulations”. (interview, auditor) Both auditors claimed that the system supported the managers by enhancing responsibilities and accountability. One of the auditors also claimed that in nursing this is also encouraged by the documentation. The other auditor pointed out that proper documentation of the activities provided protection for the employees. These advantages were acknowledged by the quality manager, too.

The error-revealing and error-correction roles of the audits were interpreted differently by the two auditors: one of them mentioned the importance of making recommendations, while the other auditor did not consider the revealing and correcting of errors as the principal aim of the audits, but “the proper implementation of an operating quality management system” (interview, auditor). This latter auditor claimed that during an external audit it is essential to evaluate the internal audits of the organization.

Both auditors agreed that the certification affected the organization and the control of the processes: “ISO controls processes that are reproducible, controllable and measurable” (interview, auditor). They consider process improvement important. One of them thinks that auditors can support this improvement by giving recommendations. The other auditor considered that they could influence process improvement by examining and improving the quality management system, because this system is responsible of implementing the PDCA cycle to enhance hospital decision makers to continuously seek for solutions to the problems. Auditors assessed the attitude of hospital management to improvement as positive (Jelentes7a, Jelentes7b). The three hospital interviewees who emphasized the role of the audits in hospital improvement admitted that development was not exclusively generated by the audits, but also by other factors, some of them interlocking with the effects of the certification.

8.7.4. Comparison between the interpretations given by the experts and by the hospital actors

Experts agreed that one of the principal roles of the ISO and SHC/HHCS systems was regulation, which only was effective where commitment was strong towards the establishment and the operation of the system. In the case study hospital the regulatory role of the certification was clearly perceived by many hospital actors. According to the experts, the other opportunity that the certification may offer is quality improvement, although only a few hospital actors mentioned it among the aims of the system established as a result of the certification. This does not contradict experts’ opinion, because many experts think that in practice this role is not performed in most of the hospitals. Experts mentioned the order-making role of the certification, and in the case of ISO the documentation burden. These effects were also mentioned by most of the hospital actors.

Many experts pointed out that ISO offered a framework that SHC/HHCS standard systems can fill with health-specific content. In this respect SHC and HHCS are considered as positive examples. The case
The study does not corroborate this kind of symbioses, because although the introduction of SHC had some effects on the quality system, hospital actors did not perceive these effects, due to the dominance of the effects of the formerly established ISO system.

The roles of supporting decision making, improving patient safety or cost savings mentioned by experts did not emerge in the studied hospital, but one of them emerged the role of protection.

Hospital interviewees mentioned many different roles of the certification and the audits that in some aspects coincided with the roles mentioned by the auditors and the experts. We could also ask who is right about the role of the certification and the audits. My answer is that each actor is right from his point of view. The role they conceive depends on their position in the organization and in the quality system, (see section 8.2.3 on hospital roles), and it also depends on what individual-level factors affected them. These factors at individual level, which may offer some explanations for the different interpretations, are analyzed in the next subchapter.

To sum up we can conclude that all the perceived roles characterize the hospital to some extent. The metaphor of “the onion” may serve to illustrate this phenomenon: the onion is the role that the certification and the audits play in the hospital. The scale leaves of the onion correspond to the certain role interpretations. Depending on their position, some only see the possibilities of an external interpretation (external leaves, like document-checking), while some who are closer to the certification may also see the deeper content (e.g. role of protection).

8.8. Influencing factors

The subchapters of Chapter 8 have already identified some factors that influence on the effects of the certification and the audits in the organization (mechanism of effects) and also on the organizational changes. The next section is dedicated to the analysis of a group of factors that manifest at the level of the individuals, affecting not only the reactions of the individuals, but also the interpretation they give of the role of the certification. Later, using the embedded cases of the case study, the effects of the influencing factors will be described.

8.8.1. Influencing factors at individual level

Hospital actors react differently and with different intensity to the effects of external evaluation (certification, audits), and they have different perceptions of its role in the organization. Many factors influence the extent to which individual hospital actors contribute to the fulfillment of external requirements. (Figure 21.) Some of them accept the role of certification and audits they perceive and this acceptance supports the fulfillment of the requirements. However, there are some who criticize some aspects and elements of the certification or the audits, but still think that hospital actors had to meet their requirements. In this case fulfillment of requirements is formal and superficial.
The reaction of hospital actors is influenced by how they perceive the difference between real and expected behavior. It has been mentioned that according to many interviewees when the system was established the regulations documented the work processes as these processes were usually performed in practice. "If all was well written, everybody thought that there was nothing new, it was how we had always done it." (interview, person for quality) In this case hospital actors did not perceive any difference between real practice and the expectations. One of the top managers interpreted the auditors’ expectations as these expectations also referred to documenting in the regulations what the real practice was.

The difference between expected and real behavior is not only relevant for the regulations, but hospital actors also perceive the expectations by the auditors and the feedback of recommendations after the audits. The reactions of the hospital actors (implementing recommendations) reflect that these perceptions act as important influencing factors.

Acceptance and fulfillment can be reinforced by understanding, which means that hospital actors think that they understand the role and the objective of the certification and the audits. At the same time if hospital actors do not understand the objectives and do not see the reason of the measures to be introduced as a result of the evaluation, this can hinder acceptance and fulfillment. It is important to point out that individual hospital actors may interpret differently the role of the external evaluation, but this individual understanding will also support acceptance and fulfillment of the requirements.

The importance of understanding was also emphasized by the quality manager. She expressed her opinion that at the beginning no one understood the operation of the system, and auditors and internal trainers tried to make hospital actors understand why it was important. According to one of the top
managers only those understood it who were present when the system was introduced. The importance of understanding was illustrated by a top manager as follows:

“[…] we realized that it was good to put on shoes to avoid pebbles hurting our bare feet, and we had to convince employees to put on shoes, but later they also realized that it was good that pebbles did not hurt their feet.” (interview, top manager)

According to the auditors the preparatory phase and even the later phases were proper to convince employees about the importance and sense of the quality management system and the audits (for example of why it is important to check measuring equipment). During the audits discussions can help to convince employees of the usefulness of implementing auditors’ recommendations. Following the observed audit one of the hospital actor interviewees referred back to the auditors’ explanations about a certain recommendation admitting its importance. Most top managers and the quality manager also agreed that asking questions during the audits can also support understanding of the system.

Two internal auditors also commented that employees do not always understand why certification and modifications of the regulation are needed.

“For an elderly nurse who learned how to care for the patient it is a burden to understand more and they do not want to understand more. Because this should be understood, as well, I think.” (interview, internal auditor)

In case of later modifications and measurements introduced as a result of the recommendations by the auditors it is also important that employees understand why these changes or extra administration is needed. The report of a nurse manager highlights the problem:

“No, when we don’t know what it is for, then we don’t know what to do with it, and it’s just a paper more, and it’s a burden for the nurses or for the physicians, and I think this is nonsense.” […] “The worst is when we don’t know what it is for, but we are obliged to do it. But what for? And why is it compulsory? But if it’s compulsory, then we have to make a try. But it doesn’t mean that for the next audit it will be perfect.” […] of course we try to explain it, write it down, and say that from now on it must be so. But if we don’t understand the reasons, then how could we explain it to others? […]” (interview, nurse manager)

If they do not understand the point, then they conceive it as a burden, and they cannot explain it to the other employees. Even if somebody understands the importance of the whole system (an internal auditor, for example), it is irritating if they do not understand any element of the documentation, that why is it necessary (why to make a nursing diagnosis, when the physician consults the patient, or why to print so many documents, when it is a waste of paper). One of the quality workers also uses the practice of enhancing understanding in their communication:

“[…] and then I try to explain, that your medicine is not given if there is no signature on the prescription, and this is like making a prescription. So, they understood and they sign it.” (interview, quality worker)

149 The auditor told me how he convinced a physician of the sense of the system during the preparatory phase when the physician had the opportunity to experience the benefits of his recommendation by trying it out in practice.

150 The quality manager shared an example of how employees understood the importance of the expiration checklist for medicines: when expired medicine was found during the audits it was highlighted how important it was to be able to find who failed to check the expiration dates.
A physician from another unit questions why ISO determines where to put a seal and where to put a signature on a temperature chart, so why to introduce such requirements when it had never been a problem before. One of the nurses commented that they can receive audits positively if they understand the motives, for example if auditors make reasonable suggestions. This nurse could also understand the need for the documentation:

„At the beginning we felt that it was a burden, especially when we had to come in from vacation. But if you give it a thought, maybe you admit that there are special cases when it is acceptable. Acceptable, because if we document, check and write it down, then it is easy to follow, controllable, and it can defend us, too." (interview, nurse)

The acceptation of the external evaluation and of the measures introduced as a result of this evaluation is supported if hospital actors consider legitimate the evaluation and its methods. If hospital actors experience that at higher levels of the hierarchy the director general and the other directors (medical director, nurse director, etc.) consider it important to meet the requirements of the certification and the audits, then they become more willing to accept the system themselves. However, if employees do not experience such commitment from the part of their leaders they easily question the importance of the system. An example of the lack of legitimacy was when a quality worker tried to convince the physicians to put their signature and seal on the documents „where ISO requires“ (interview, quality worker). Despite ISO requirements the physicians replied that „it was not in the directorial decree. […] And that they are physicians and they are lead by the director and nothing else. ” (interview, quality worker) The quality worker conceived that she could achieve that physicians accepted the requirements of the new system by convincing them (see the quotation on the previous paragraph), and by demonstrating power (asked support from the quality manager and the nurse head). However, a physician interviewee from the same unit claimed that they only obeyed to the physician head when they accepted the new rules about seals and signatures, which means that the new rules became legitimate by the approval of their leader who stood higher in the hospital hierarchy.

Preceding the first audits hospital actors had some expectations towards the audits and the new system. The acceptation of the external evaluation and the system is hindered if these expectations are not fulfilled. The report of one of the physician heads is an example:

„We thought it was good and we had a lot of expectations. We expected that this system would arrange thing better and regulate things. But when the audits came it resulted that it was not like that, but they only wanted papers and seals. This was disappointing.” […] „You didn't have that happy feeling that you have done something good and useful, not at all.” […] „So, well, I think, I know it sounds terrible, but I think that not too much have been done." (interview, physician head)

The three head physicians of the three different units had different opinions, but all of them had some expectations that were not fulfilled, and therefore they mostly conceive the system as a burden. Hospital actors also differ in whether they conceive the system changes as essential or redundant. If they consider it redundant, they only see the burden of it, and do not perceive the positive things, therefore, they are reluctant to accept the system and feel less motivated to adapt. The physician heads of the patient care units judged the system as redundant, as something that did not affect professional work, which was the most important for them.

The quality manager also agreed that real changes can be reached if they affect a serious problem (like denouncements with costly consequences), because in these cases everybody pays more attention and
attitudes may also change. In case of minor issues (like rules were not hung on the walls) it was less
probable that the audits would change practice. In this interpretation it is significant how the quality
manager judges the gravity of a problem. If the problem is considered as serious by the quality manager,
she pushes the button, and influences the hospital actors (e.g. by internal supervision, besides other
factors).
The reactions of the hospital actors also depend on whether the system established as a result of the
audits brings about anything new, and if this novelty is experienced as positive or negative.
Documentation burden is mostly mentioned among the negative experiences. If there was no
documentation burden, the resistance against the changes would be much weaker. Besides
understanding, these reactions are also influenced by the experiences of the hospital actors.
In the units where the requirements introduced by the certification, like detailed documentation, had been
previously fulfilled, these requirements did not mean any extra burden and they were accepted as
natural. This can be the consequence of the demands imposed by the head of the unit, or the result of
the intrinsic characteristics of the unit. Diagnostics is an example for this: „Administration has always
been tough, and we got used to it, [...] so I always had to do it.” (interview, physician head) If this
requirement is not considered as a burden, then hospital actors may mostly perceive the positive side of
the certification (more systematic, transparent, accountable operation), and they are more willing to
accept the changes.
In other units where it was not typical, documentation was a burden, and if actors do not see the point,
they consider it redundant: „I think that it is the characteristic of our unit, where we are not used to
document everything.” (interview, top manager) Many interviewees agreed that changes meant a burden
only in the beginning, later they become part of the routine and experience leads to acceptance. For
employees who started working in this system with the same requirements it has become fully natural.
(„tradition”).
Experience does not only mean a habit or a tradition, but it can also lead to a quicker acceptance of the
system: for example if hospital actors experience the benefits of the changes (like transparency,
accountability or protection). This cannot only be the result of a spontaneous process, but the revelation
can also be supported by the intervention of the external auditors or the internal persons for quality.
A strong wish to fit in can also motivate changes. An example for a strong wish to fit is commented on by
one of the auditors:

„[...] let us handle physicians and skilled workers separately. Skilled workers are like another race.
Skilled workers, and especially nurse heads have a bad conscience if not everything is in order.
When a small problem is found, they seem to die of remorse.” (interview, auditor) 151

A top manager also corroborated that meeting audit requirements enhanced professional self-esteem:

„I remember that many years ago an infusion bag was found in the passage. The nurse head almost
had an attack of remorse, it was shocking to see. [...] Some feared that she would commit a suicide,
so ... her professional self-esteem was so deeply hurt.” (interview, top manager)

151 Auditors experience corroborated that if a head nurse found a fault they were more probable to call the auditors than
the head physicians, because for them it was more important to arrange the case.
The wish-to-fit-in factor takes us to the world of individual psychology, which also influences on the reactions given to the effects of the certification (like the reactions of a disciplined individual), as many of the interviewees remarked.

Fitting external requirements does not always require an acceptance of the evaluation method and of the established system.

Hospital actors who were critical towards the certification, the audits or the resulting changes could also contribute to meeting its requirements if they perceived that the certification was needed to meet the requirements of other external stakeholders (e.g. tender requirements). To the question of whether the certification has reached its objectives a physician gave the following answer: „Yes, if we consider that we can hang the certification out on the wall, and it is extremely important for the outside world.” (interview, physician head) This physician thought that the hospital could not work without the certification, because media reactions would bring about serious consequences. Another top leader also agreed that certification was a kind of demonstration to the public.

In these cases the only objective is formal (see “shop-window” metaphor), and the focus is on obtaining the paper-format document (“degree” as a role, see section 8.7.1).

Depending on to what extent the audits are perceived as an external force, audits also enhance fitting and adjusting by being iterative and by having an exam-like character. One of the top-managers commented: „It is also important that we know that they use several forms of supervision.” (interview, top manager) According to some interviewees many units only fulfill the requirements because they know that they would be supervised, but if external audits became lighter, discipline would surely become lax. The exam-like character is illustrated below:

„The auditors are in a much higher position during the audits. [...] It is a test for the hospital, an exam where everybody is nervous. And after passing the exam there’s a relief. But during the exam the examiner seems different.” (interview, auditor)

The circumstances of the audits (preparation, nerves) also suggest that hospital actors take audits as seriously as an “exam”, but individual attitudes may differ, as the quality manager also pointed out. During the audits not only the auditors collect information about the organization, but hospital actors also perceive (observe and listen to) the auditors’ requirements, due to the fact that they would like to fit in and to meet these requirements. Considering that it is a reiterative “exam”, the hospital actors try to meet the auditors’ perceived requirements by relying on the mechanism of effects described in subchapter 8.5. According to one of the auditors periodicity has a forcing power that results in fulfilling the requirements for the next audit.

Appraisal and punishment mechanisms used by the organization may also contribute to enhance or to hinder meeting of the requirements. This was referred to by the quality manager when she mentioned that employees felt frustrated when they did not have time to perform the task they undertook because of the extreme documentation burden, and they feared they would be punished if documentation is missing.

The motivational power of punishment is far from being evident. One of the nurse heads commented, that although they accepted administration as necessary, they conceived it as a punishment to receive a final report after the supervisions. A physician head said: „Well, we never get an appraisal, but we are punished if something is wrong.” (interview, physician head) One of the physicians remembers that in the beginning they even received a notice: „if somebody makes a mistake they will be punished this and that way. But now it isn’t so serious, because the system is established and routinely functioning.” (interview,
physician) No example was found for the effectiveness of appraisal and punishment during the case study.

Including the above described individual influencing factors chapter 8 listed the influencing factors identified during the case study. These factors are summed up in Table 18 (featured similarly to Figure 15). The following section illustrates the effects of these factors through embedded cases.

### Table 18. The influencing factors explored in the case study

<table>
<thead>
<tr>
<th>External evaluation factors:</th>
<th>Theoretical factors:</th>
</tr>
</thead>
<tbody>
<tr>
<td>“auditor” market</td>
<td>Information available about ISO and SHC/HHCS system, interpretations and messages by developers and supporters</td>
</tr>
<tr>
<td>auditors’ attitudes and their role</td>
<td>aspects and results of evaluation</td>
</tr>
<tr>
<td>auditors’ interpretations and their messages</td>
<td></td>
</tr>
<tr>
<td>methods of information collection</td>
<td></td>
</tr>
<tr>
<td>Factors at individual level:</td>
<td>Indirect effect factors:</td>
</tr>
<tr>
<td>perception of real and expected behavior</td>
<td>role of the quality manager</td>
</tr>
<tr>
<td>acceptance</td>
<td>role of internal auditors</td>
</tr>
<tr>
<td>understanding</td>
<td>role of other persons for quality</td>
</tr>
<tr>
<td>legitimacy</td>
<td>auditor escorts</td>
</tr>
<tr>
<td>fulfillment of expectation</td>
<td>operation of the quality management system:</td>
</tr>
<tr>
<td>essential vs. redundant</td>
<td>o regulation system</td>
</tr>
<tr>
<td>experience</td>
<td>o documentation system</td>
</tr>
<tr>
<td>strong wish to fit</td>
<td>o supervision system</td>
</tr>
<tr>
<td>perception of external requirements</td>
<td>o PDCA cycle</td>
</tr>
<tr>
<td>external force</td>
<td></td>
</tr>
<tr>
<td>appraisal, punishment</td>
<td>Organizational condition factors:</td>
</tr>
<tr>
<td></td>
<td>role of the management</td>
</tr>
<tr>
<td></td>
<td>role of middle managers</td>
</tr>
<tr>
<td></td>
<td>responsible / experienced person</td>
</tr>
<tr>
<td></td>
<td>antecedents with similar functions to certification (like existence of ISO certification before SHC or HHCS)</td>
</tr>
<tr>
<td></td>
<td>External factors:</td>
</tr>
<tr>
<td></td>
<td>perceived expectations of owners</td>
</tr>
<tr>
<td></td>
<td>perceived expectations of health policy leaders</td>
</tr>
<tr>
<td></td>
<td>possible extra resources (e.g. by tenders)</td>
</tr>
<tr>
<td></td>
<td>other certified hospitals</td>
</tr>
<tr>
<td></td>
<td>shortage of labor, fluctuation</td>
</tr>
<tr>
<td></td>
<td>trials, denouncements</td>
</tr>
<tr>
<td></td>
<td>professional guidelines, protocols</td>
</tr>
<tr>
<td></td>
<td>legal regulations, authority requirements</td>
</tr>
</tbody>
</table>

Source: own elaboration

### 8.8.2. The effects of the influencing factors on the embedded cases

The analysis of the case study hospital was carried out not only at the level of the organization, but it also focused on some organizational units as embedded cases. The detailed presentation of this analysis is not included in the dissertation for limitations of extension. However, these units are used to illustrate the possible effects of the influencing factors. As it was mentioned in the Chapter on the research methods, five units were chosen as embedded cases, three of which are patient care units and two are supportive units (diagnostics and economic/technical). Table 19 highlights some influencing factors related to the five embedded cases.
Table 19. Analysis of the embedded cases

<table>
<thead>
<tr>
<th>Characteristics of the audit: method of information gathering</th>
<th>A patient care unit</th>
<th>B patient care unit</th>
<th>C patient care unit</th>
<th>D diagnostics unit</th>
<th>E unit on economic / technical area</th>
</tr>
</thead>
<tbody>
<tr>
<td>documents, interviews</td>
<td>documents, interviews</td>
<td>documents, interviews</td>
<td>documents, interviews</td>
<td>observation documents, interviews</td>
<td>documents, interviews</td>
</tr>
<tr>
<td>Effect mechanism</td>
<td>regular supervision, exam</td>
<td>regular supervision, exam (e.g. voluntary action)</td>
<td>more regular supervision, exam (e.g. campaign)</td>
<td>regular supervision, exam</td>
<td>less regular supervision, exam</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Influencing factors</th>
<th>- heads of unit</th>
<th>- responsible / experienced person</th>
<th>- understanding</th>
<th>- fulfillment of expectations</th>
<th>- essential, useful vs. redundant</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>committed (nurses)</td>
<td>supportive</td>
<td>non supportive</td>
<td>committed</td>
<td>neutral</td>
</tr>
<tr>
<td></td>
<td>yes (2)</td>
<td>yes (1)</td>
<td>no</td>
<td>yes (2)</td>
<td>(no data)</td>
</tr>
<tr>
<td></td>
<td>(among nurses)</td>
<td>(among nurses)</td>
<td>(among nurses) no</td>
<td>(among nurses) not fulfilled</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(among physicians)</td>
<td>(among physicians)</td>
<td>(among physicians)</td>
<td>(among physicians) not fulfilled</td>
<td>(no data)</td>
</tr>
<tr>
<td></td>
<td>not fulfilled</td>
<td>disappointment</td>
<td>not fulfilled</td>
<td>fulfilled</td>
<td></td>
</tr>
<tr>
<td></td>
<td>useful (nurses), not important (physicians)</td>
<td>useful (nurses), not important (physicians)</td>
<td>not useful (nurses), redundant (physicians)</td>
<td>useful</td>
<td>does not affect the unit</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Interpretations of the role of the certification and the audits within the hospital, based on the interviews</th>
<th>A patient care unit</th>
<th>B patient care unit</th>
<th>C patient care unit</th>
<th>D diagnostics unit</th>
<th>E unit on economic / technical area</th>
</tr>
</thead>
<tbody>
<tr>
<td>nurses: document-checking (positive), error correction, protection</td>
<td>nurses: document-checking (positive), regulation, order and discipline, error correction</td>
<td>nurses: document-checking (negative), „degree“, „gap in the system“</td>
<td>physicians: document-checking (negative), „degree“, „gap in the system“</td>
<td>physicians: document-checking (negative), „degree“, „gap in the system“</td>
<td>process supervision, regulation, order and discipline</td>
</tr>
<tr>
<td>physicians: document-checking (negative), „degree“, „gap in the system“</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>no role</td>
</tr>
</tbody>
</table>

Source: own elaboration

Two of the patient care units could be considered as active in quality work, while unit C was rather passive (interviews). Table 19 shows that the expectations of the physician heads of these three units were not fulfilled, and one of them was explicitly disappointed. A reason for this is the experiences they had during the certification and the audits. Considering that audits did not affect professional work, physician heads in all the three patient care units considered them as lacking importance. The physician head of unit C expressed that audits were redundant for the operation of their unit. Therefore, we cannot consider this physician head as a supporter of the system of audits and certification. The physician heads of the three patient care units had very similar interpretations of the role of the certification within the institution. The main difference among the three units is in the presence of the lack of a responsible or an experienced staff member, and there is also a difference among the nurses. Unit C did not have an
appointed quality worker, and the employee interviewees did not even know who was responsible for quality issues. Unit C did not have an appointed internal auditor either. A nurse manager interviewee from this unit commented that it was difficult to transmit to the employees the changes related to the certification, because she personally also had problems of understanding the point in introducing these changes that bring about a lot of documentation burden. Therefore, this nurse manager did not consider these changes as relevant or useful. According to my experiences, the attitude of the other nurses of unit C was also negative towards the certification. These factors may have contributed to a negative opinion about the document-checking role of the certification, while the same role was considered as positive in units A and B by nurses. The role interpretations and the influencing factors experienced in unit C led to a different mechanism of effects of the audits, which means that the reactions of the employees and the reactions of the other persons for quality (like quality manager, internal auditor\footnote{The internal auditors play similar role at the level of the units that the external auditors at the level of the whole organization.} and their interactions were different from other units. An example of the reactions of the employees is that changes that were considered as “minor” in other units were commented as „One cannot ask things like this. It’s nonsense.” (interview, physician head) An example for the interaction with hospital actors are the more regular supervisions in this unit (see „campaign” in subsection 8.5.4.2). Just to compare, in unit B the voluntary action (see subsection 8.5.4.1.) was an initiative by the quality worker of this unit, which is also a sign of the vigorous quality-related activity that characterized this unit.

The reactions to the effects of the certification and the audits were completely different in the supportive units. In the diagnostics unit (D) even the information gathering methods used by the auditors were different, in this unit observation was a typically applied method. Unit D disposed of several experienced staff members who were active in quality, and had a thorough understanding of the system. In unit D the process-supervision role of the audits dominated.

Considering the influencing factors the situation was also different in the economic/technological unit E. In this unit the audit observed during the case study was the first in the past 8-9 years, since the head of the unit had worked in the hospital.\footnote{This statement refers to the external auditors, internal audits were regular in this unit.} Therefore, the head of the unit shared the opinion of other heads in the economic/technological units that certification and audits did not affect them, but were focused on the patient care units of the hospital.\footnote{This can be influenced by other than individual factors, such as the dominant role of legal regulations or authority supervisions in these units.} The mechanism of the effects of the certification also differed in unit E, which difference was manifested in less regular supervisions (external audits). This means, that the hospital actors in this unit had little experience about the audits (experience is also an influencing factor that does not appear in Table 19), which resulted in that hospital actors in this unit shared a common belief that the certification had no role in their unit.

Of course, there are probably some other influencing factors that have not been revealed by the case study. For example, it cannot be excluded that in case of the embedded cases the labor shortage and fluctuation also have an effect, but the data gathered during the case study does not provide sufficient evidence for these effects.

The analysis of the case hospital provided some answers to the research question of how ISO 9001 and SHC/HHCS affect the behavior of hospital actors within the organization. Meanwhile, the analysis also
focused on how the reactions and the interactions of the hospital actors as a result of the certification affected the organizational changes. The original research question focused on improvement initiatives as organizational changes, but there were some changes related to the certification that hospital actors did not perceive as improvement. The following subchapter analyses how hospital actors interpret the term of improvement.

8.9. The role of the certification in improvement

The mechanism of the effects of the certification and the related audits (subchapter 8.5) and its effect on the hospital (subchapter 8.6) suggest that certification can contribute to hospital development in many different ways.

On the one hand, the organization experienced significant changes during the preparatory period and during the initial implementation of the “system”. Organizational management became equipped with a new regulatory system and a related documentation system, while controlling mechanisms of the organization also developed. Responsibilities and job descriptions became clarified, which enhanced accountability and protection. Hospital functioning became more transparent from the point of view of the hospital leaders, and most of those who followed the changes from the beginning considered that processes became better organized.

On the other hand, changes are also produced as a response to the requirements and the recommendations of the auditors, which can also result in improvement.

At last, some elements of the system can also contribute to improve development potential of the organization through indirect mechanisms (see section 8.6.1).

The question is whether these changes can be considered as improvement. This depends on how we define the term ‘improvement’.

Looking at the “facts” reflected in the documents, the certification and the related quality system had a positive effect on improvement: „The system is continuously improved. The recommendations of the auditors are implemented. The management benefits from the opportunities to improve.” (Jelentes2b)

Interviews with hospital actors do not reflect such a direct relationship between the certification and improvement. When asked about audit-related improvement, three interviewees associated on high-scale development, like development of technology or infrastructure. Interviewees who had spent a long time working for the hospital (3 interviewees) claimed that hospital management always supported improvement, and that this attitude characterized the whole institution. The leading auditor also claimed that audits and improvement are handled as one, and that the improvements of the former years form part of the quality system. This interpretation allows parallel consideration of certification and improvement.

Although during their visits auditors asked about changes and improvement, hospital actor interviewees did not mention this as an important part of the audits. The former Director General pointed it out, but according to his report he also failed to perceive the relevance of it for the certification. Only one of the other interviewees (head of unit) and the quality manager said that auditors mainly asked them about the changes and they always asked about the implementation of the recommendations. I observed that auditors’ questions about improvement were usually very general, and they did not try to reveal whether
the quality management system played any role in the improvement. This implies that the employees of the hospital units did not conceive the relationship between these questions and the role of the certification and the quality management system, as this was also reflected by the answers given to my interview-questions about changes and improvement.

During the interviews (9 interviewees) and the observations of the audits many improvement initiatives were mentioned that were independent of the audits and the quality management system. Former reports contained some generalized, schematic description of hospital development plans. (records) This means that these development elements were not the result of the certification or the related quality system, but still, they were mentioned during the audits and in the audit-related documents. Moreover, at the beginning of the audit reports there was a reference to the implemented or planned infrastructural development, to the development plans of the management, and the purchasing of new equipment was also mentioned as development. (reports)

Three interviewees who attributed an important role of the certification in hospital development (see section 8.7.1) had different interpretations of the relationship between certification and improvement. The former Director General said that certification and quality improvement “always go hand in hand because this is their nature.” (interview, former Director General) According to another top manager, who claimed that the aim of the certification is to enhance improvement, hospital development (infrastructural, technological) and the effects of the certification intertwine, complement each other and an improvement step is a result of many different factors. According to the third interviewee, who also admitted that certification enhanced improvement, infrastructural development made it possible that the hospital can meet the requirements of the quality system.

“Office work, documentation and administration discipline were all things that only work on paper, but that could not be solved in the physical environment. To write process regulations about these sounded like a joke. Why to write down how to do things, when they could not be done in practice?” (interview, person for quality)

This person for quality thought that certification enhanced improvement by formulating requirements that were necessary for development. This was contradicted by the experience of one of the physician heads:

“The opinion about the ISO was that they will check what we write down, so we had better write down things that we can fulfill, and then there is no urge to improve.” (interview, physician head)

Eight interviewees pointed out that audits do not improve professional processes of patient care. They mentioned different reasons for this: professional processes go on well without the audits; it does not depend on them; professional rules and development are external factors and they adapt to them; certification was developed for industrial organizations and could not be applied for health care institutions.

“It does not affect our professional work. Professional protocols do not care about ISO, they are written by professional committees, and we read, apply, and work according to these protocols.” “[…] a head of a unit performs well their job if they improve in these professional things, and they progress with other professionals. ISO has never supported my work in this respect, never.” (interview, physician head)

One of the internal auditors who is also heading a unit said when answering my question about the effect of the certification on improvement:
"I don’t know to what extent are audits related with improvement. That’s a good question, anyway [laughs] I’ve never been thinking about it. Yes, we always learn something new. However, I couldn’t grasp any concrete relationship between improvement and the audits. That’s interesting, but I can’t mention any." (interview, internal auditor)

However, some of the top managers and heads of units (3 interviewees) even mentioned examples of how certification enhanced hospital development: regulation of processes, developing documentation and supervision processes, which contributed to a better protection of the hospital. These examples were mentioned in relation with the initial changes that took place at the level of the whole system. The other two mechanisms of the effects (auditors’ requirements, direct mechanism of effects) are analyzed below.

The role of auditors’ requirements in improvement:
The leading auditor promoted improvement via recommendations, because she considered her role as a kind of consultant. This auditor also proposed beneficial changes during the audits. In her recommendations she tried to rely on previous experience gained in other hospitals. „Let’s see if they like it." (interview, auditor) Both auditors agreed that the aim of their proposals and recommendations was to support improvement of the quality system implemented as a result of the certification. (interview, dok6)

“[…] if the auditor’s attitude is supportive and they want offer their help to improve the system, then it can be considered as a successful audit.” (interview, auditor)

One of the auditors pointed out that a sign of system improvement is that they find less discrepancies year by year. The improvement aim of the recommendations is also emphasized by the title under which these recommendations appear in the reports: “Guidelines for further improvement”. (reports) Despite all this, only a few interviewees conceived recommendations as improvement opportunities. One of the nurses belonged to these few, and they usually discussed with the quality manager „What mistakes have been revealed, and what can we learn from them, how could we improve.” (interview, nurse head) Another nurse agreed that audits contribute to „face our mistakes and to try to correct them, and they also propose long-term objectives to improve.” (interview, nurse) At the same time, when giving an example of improvement (treating patients) this latter nurse interviewee admitted that this improvement was not the result of the certification, but it was the result of an initiative by the nurse head and their team. The opinions of the internal auditor nurses reflected insecurity about the relationship between the audits and improvement. Meanwhile they commented that there were improvement proposals made by the hospital unit personnel and most of them were welcome and accepted.

“If the head nurse and I make a recommendation that it would be better or easier this and that way, doctors usually consider it and it works.” (interview, nurse)

Interviews corroborated that most of these improvements was not the result of the audits or of the quality management system.

The role of indirect mechanism of effects in improvement:
One of the auditors referred to the indirect effects of the audits on hospital improvement. According to this auditor the advantage of ISO over SHC and HHCS is that it demands that the health care provider improves their system. This auditor claimed that the motor of this improvement is the PDCA cycle, which he described as follows:
"The PDCA model includes information of many management elements or quality elements. I think this makes the whole system move. This assures that I don’t make ad hoc decisions, but first I check the processes. Numerically or not, it’s the same. But I try to have an objective view either by a compulsory internal audit, or by a compulsory patient satisfaction survey. Or by handling customer complaints, it is also a way to get information about the system. And then I can take this information to the management and say well, this is how we work, independent of the financing methods, independent of the area of care, independent of many other things. This is how the system and our processes work. This can also be changed. And we make decisions. And if these decisions are good, and the feedbacks are good, then it works, and this is the difference between ISO and the other standard systems like HHCS, that ISO requires continuous problem solving." (interview, auditor)

This means that through the PDCA cycle the certification can have an indirect effect on the improvement of the organization as a whole. This interpretation supports the role interpretation given by one of the expert interviewees who claimed that the system can be considered as a management supporting tool.

Section 8.6.1 has already pointed out the logic of the PDCA system among the indirect effect factors, according to which the established quality system operated. That section highlighted that the "plan" phase of the cycle did not work properly, because the analytical opportunities offered by the quality management system were not used by the top managers of the hospital. Although the records contained next year’s objectives, the evaluation of fulfillment and also the summaries of the information on some quality elements (like patient satisfaction surveys, handling complaints and internal audits), but records did not refer to how objectives related to the analytical tools. The objectives were defined outside the quality management system, and were not based on the analysis of the information offered by the system elements, but reflected the intents of the top management. An evidence for this is a recommendation formulated following the audit I observed: „the tasks related to quality improvement should be listed under the heading of ‘quality objectives’.” (Jelentes1a) This recommendation was included in the report because the several improvement objectives were not mentioned among the quality objectives included in the management records. Therefore, this recommendation aimed at including the aims and objectives defined by the management in the records, although these aims and objectives were not defined as a result of the operation of the quality management system.

However, certification may have had some effect on the definition of the objectives: According to one of the top managers the relationship between the certification and hospital improvement is that certification requires that the organization regularly formulates its objectives and its strategy, although strategy planning took place independently of the audits. Moreover, the recent records already included some proposals and objectives based on the experiences of the quality manager, and these were mentioned among the examples for improvement by one of the internal auditor interviewees.

To conclude it can be claimed that the certification had an improving effect on the organization in the initial period of its implementation. The direct improving effects of the audits (like auditors’ recommendations) mainly affected the established system, and hospital actors mostly perceived only changes related to the documentation, but they did not really consider these changes as an improvement. The indirect effects of the certification (through the system) did not result in enhancing a proactive improvement potential of the organization, but it induced reactive behavior, which means that it helped the organization to adapt to other kinds of changes, either external to the organization (e.g. change in legal regulations), or changes influenced by other factors (like top management improvement decisions). Therefore, certification did not function as a motor of improvement, but it involved the changes that were the result of other development into the organizational regulation system, and as a result it fixed and transmitted the changed situation.
9. Summary of the research results

Chapters 7 and 8 described the analysis of the empirical study. The conclusions are summed up in subchapter 9.1. In subchapter 9.2 research results are compared to the literature.

9.1. Main conclusions

This subchapter sums up the main research results and the conclusions that can be supported by the analyses described in the previous chapters. It is important to mention that in the case investigated the effects of the ISO 9001 and SHC/HHCS certifications cannot be separated. Interviewees claimed that the effects of the previously implemented ISO system were dominant, and the integrated ISO-HHCS system has been applied for many years by the case hospital, so the conclusions do not refer to two different external evaluation methods, but to a single case when a mixture of these methods was applied.

According to the dimensions of the classification framework described in section 4.2.2., the certification and the related audits in the case investigated can be considered as interpretative and formative external evaluation methods.

**According to the ‘approach to knowledge’ dimension, the certification in the studied hospital case can be considered as an interpretative evaluation method.** This statement is supported by the following:

- Audit related information collection and evaluation are not happen in clearly separated phases in succession, but ‘moments’ of evaluation and giving feedback happen during information collection (in the audit process itself), and this influences on the content of the information obtained.
- The result of the audit is not just a fully objective external evaluation given by the auditor, but hospital personnel also participate in the evaluation process, for example, they actively react to the proposals and recommendations made by the auditors, and the auditors’ constructive attitude also allows to discuss the relevant topics.
- Audit as a method makes it possible for the auditors to take into account the circumstances, explore the causes, carefully listen to the explanations given by hospital personnel, and auditors take advantage of these opportunities.
- The audit method is not based on sampling, but it is a random process, which is influenced by the different points of view of the auditors and of the hospital actors.

Another dimension of the classification framework is the **role of the evaluation**, which is **formative** in the studied case. This statement is supported by the following:

- Although auditors usually tend to survey the appropriateness to standards, their attitude is mainly influenced by helpful and supportive purpose.
- Auditors consider that the audit is valuable if it contributes to the development of the system.
Hospital actors usually find auditors' attitude helpful and constructive. They perceive that auditors are not necessarily seeking for errors, but they want to help and make supportive recommendations if they find errors.

According to hospital actors the role of the certification among others is to reveal, correct and prevent errors and to enhance improvement.

Certification as external evaluation is inadequate for summative role in this case. Although the term 'degree' appears among the role interpretations, referring to the fact that the hospital must be able to show the certification in order to have access to other opportunities (e.g. tenders), which implicitly supposes that it is the result of a summative evaluation. However, many hospital actors, even those who used the term degree, claimed that the certification cannot serve as a basis for comparison between hospitals. This means that although certification is required to submit tender proposals, according to hospital actors and the auditors it is not proper for making a summative evaluation or its role is not this. (The fact that some external stakeholders use the certification to make judgments on the abilities of the hospital does not necessarily mean that the certification is a proper tool for this, and that it is a summative form of evaluation.)

These statements evidence that the classification framework proposed in section 4.2.2. can be used to classify the applied external evaluation methods. Further research is needed to test the validity of the framework.

This research has made me understand that methods should not be merely classified as ‘interpretative’ or ‘positivist’ on the basis of the dimension of the approach to knowledge, but the methods can be assessed using both approaches, and we can decide whether from the one or the other point of view the method is acceptable or not. It does not mean that we want to hide the weaknesses of the method. The interpretative point of view also reveals several failures of the method, like in the studied case the fact that auditors do not take advantage of all the possible data collection methods: beside dominant documents and interviews they could use more observation to corroborate the validity of their conclusions. Moreover, a more intense comparison of the information obtained from the different data sources (like documents and interviews) would also make the audit results more valid (see triangulation).

One of the proposed additional classification aspects described in section 4.2.2 is the distinction between voluntary or compulsory external evaluation. The studied case reveals the complexity of this question, because according to the top managers the decision to undertake the first certifying audit was voluntary, although the wish to meet certain requirements also played an important role, even in case of the first audit. According to more hospital interviewees the maintenance of the certification was considered as an inescapable path, because not renewing the certification would cause loss of prestige to the hospital. Expert interviews corroborate that meeting external requirements (like tender requirements) can also play an important role in opting for taking up certification, which is a forced decision, rather than the result of intrinsic motivation (e.g. organizational development). This suggest that the evaluation methods cannot be unambiguously classified as voluntary or compulsory, as it is not a dichotomous variable, but rather a scale extending from intrinsically motivated voluntary decision to a compulsory evaluation method (legal, for example) that may even bring about punishment (if not fulfilled).
One of the aims of the research was to reveal the mechanisms of the effects of the certification and the related audits by understanding the organizational processes, the reactions and interactions of the participants. As a result the following statements can be formulated.

The characteristics of the mechanism of the effects of the certification and the related audits as revealed by the hospital case study:

1. **Regular supervisions**: According to the proposed additional classification aspects of external evaluation described in section 4.2.2, this characteristic can be considered as a resultant action or incentive. That is the feedback following the audits can affect the organization, because regular follow-up supervisions motivate error correction and implementation of the recommended changes. Audit-related regular supervision does not only include external audits, but internal audits, too, which are expected by the external auditors. Other direct forms of supervision have also appeared. These supervisions strengthen the effect of other control mechanisms applied by the organization.

2. **Exam-like character**: This is manifested in intense preparation before audit and emotional effects (e.g. nerves) signing the importance of the event in the hospital case. The exam-like character of the audits motivates hospital actors to prepare for the event, and this together with the reiterative character result in a cyclical effect. The exam-like character is also manifested independent from the reiteration. It is illustrated by the preparation for the first audit, which brought about the most significant changes in the organization compared to other audits, as hospital actor and auditor interviewees remembered.

In my opinion these characteristics of the mechanisms of the effects of the certification, together with a formative character, can result in an efficient organizational learning process. Due to the implementation, supervision and reiterative supervision of supportive recommendations the changes become part of the organizational routine. The mechanism of the effects of the certification and related audits revealed in the studied case is worth to compare to the theories of learning (see for example Argirys, 1994; Bakacsi, 2000) in further research.

Based on the case study it can be claimed that the characteristics of the method applied and the perceived changes both have an influence on how hospital actors interpret the role of the certification (role interpretations). These role interpretations by the auditors and by the hospital actors also come down to affect their reactions and interactions, that is, role interpretations also affect the mechanisms of the effects, and, as a result, the perceived changes. (Figure 22)
Among the information collection methods used by the auditors, document checking is clearly perceived by most of the hospital actors, and most of the perceived changes are also those that are related to the documentation, and hospital actor interviewees claimed that the certification affected only the documentation elements of professional work. ISO system was originally developed to regulate the basic main processes of the organizations, and the health care related, Hungarian interpretation of the ISO 9001 published in 2003 also refers to the need for the identification, planning and regulation of the professional processes of the health services (diagnostics, therapy, rehabilitation, nursing, screening) (ESZCSM, 2003). Despite this, hospital actors and even the auditors accept it as normal that the certification does not affect the professional processes, and the document-checking role dominates among the role interpretations given by the hospital actors about the audits. However, this is not surprising if we consider the characteristics of the applied method (e.g. the principal method of information collection is document checking) and the perceived changes.

The ideas of the participants about the role of the certification also affect the mechanism of the effects and the perceived organizational changes. For example, certain elements of SHC/HHCS cannot prevail if the auditor does not transmit them as a requirement towards the organization because auditor thinks that the standards demand only what is required by the legal regulations, too. Furthermore, auditors think in vain that the role of the certification to enhance organizational development (through the PDCA cycle), if the top management fails to recognize the role of the certification as a decision support tool.

Several influencing factors have been identified as a result of the case study, which affect the mechanism of the effects of the certification method and, therefore, the perceived changes (Figure 22.), and, due to the back-and-forth effects described above, these influencing factors also affect the interpretations of the role of the certification. The classified and identified influencing factors are described in Figure 18 at the end of the section 8.8.1. Some of the influencing factors are highlighted below:

- professional guidelines and protocols,
- legal regulations, authority requirements,
- role of direct leaders,
- denouncements and trials,
- role of the management,
the presence of a responsible or experienced person,
understanding and experience,
interpretations and messages by developers and supporters.

The findings of this research harmonize with certain statements on professional bureaucracy (e.g. hospital) by Mintzberg (1991). The professional guidelines and protocols in the group of external factors are also included among Mintzberg’s (1991) coordination mechanisms, considering that professional protocols and professional training correspond to the coordination mechanism called standardization of skills. The dominance of this coordination mechanism makes hospitals belong to professional bureaucracies. The case study corroborates the importance of this external regulatory force for the physicians of the hospital. There are also other important external regulatory forces, like legal regulations and authority requirements, especially in the economic and technological support area. The interviewees working in these fields claimed that legal regulations cover their activities to the extent that certification and the related regulatory system does not affect their work, while authority supervisions play a more important role.

Among the organizational condition factors the role of the direct leaders can also be found among the coordination mechanisms by Mintzberg (1991) under the denomination of direct supervision. The case study evidenced that the requirements of the direct leaders dominate over the effects of the certification. Many hospital actor interviewees claimed that the operation of a hospital unit depends on the requirements transmitted by the head of the unit. The requirements of the ISO (quality management) system in the hospital is only considered legitimate by some of the hospital interviewees if the direct leader supports it. According to Mintzberg the regulatory role of the quality management system belongs to the coordination mechanism called standardization of work processes. This means that the coordination mechanisms of ‘direct supervision’ and ‘standardization of work processes’ compete, and the question is whether hospital actors accept the later without the reinforcement of the former. The two coordination mechanisms can also support each other, as shown by the example when a head nurse considered the requirements of the quality system important, and they transmitted this message to their employees through their own requirements as a direct leader. There were some leaders who had already represented some of the requirements of the quality system even before the system was implemented (like precise documentation), and in this aspect ‘ISO’ did not add much novelty to the operation of these units.

Among the external factors, denouncements and trials also influenced on the interpretation of the internal role of the certification. Due to the fact that these external factors may have serious consequences on the organization (e.g. costs), the related requirements have a special weight. Many hospital actors claimed that the system established as a result of the certification protects the hospital because it helps to prevent problems that can result in complaints, denouncements and trials. The hospital actors who agreed with this role interpretation also agreed that appropriate documentation plays an important role in prevention, while it contributes to accountability and to the protection of employees at the same time.

Among the organizational condition factors the role of the management is important in the interpretation of the role of the certification and of the related system. Literature on quality management lays special emphasis on management commitment. This commitment is also examined during the audits, and the auditors make statements about management commitment in their reports. However, it is important to define what we mean by management commitment. Management commitment does not only mean that
the leaders decide for the certification and delegate the related tasks, but also that the behavior and the communication of the Director General reflect to the other hospital actors that it is important to meet these requirements. The case study proved that such an attitude, which characterized the former Director General of the hospital at the time of implementing the quality system, can bring about changes in the organization. The case also served to prove that the role of the Director General and the management is not only this, but it is also important how they interpret the role, the aims and the mechanism of the method. If the hospital leaders do not implement and do not take advantage of the opportunities offered by the method (e.g. objective setting based on analysis or evaluation of its realization), then their effects (e.g. on improvement through the PDCA cycle) cannot prevail. To sum up, the effects of the certification are significantly influenced by how the important actors like the management or the Quality Manager interpret the role and function of this method in the organization.

Among the organizational factors it is also important to highlight the presence of a responsible/experienced person. The case proves that it makes a big difference if in the organization or within an organizational unit there is a hospital actor who is responsible of operating the quality system and/or has some experience with the audit methods. The embedded cases evidenced that in the units where there was an appointed internal auditor it was much easier to meet the requirements of the external audits, while in the unit where there was no responsible staff member or an appointed internal auditor the requirements could not be properly interpreted, which made adaptation even more difficult for the employees. At the level of the units the internal auditors are the most familiar with the method, which allows them to help to interpret the new changes (why are they needed). As during the internal audits they also visit other units than their own, they have more experience of how audits work. Internal auditors also enhance organizational leaning by dispersing best practice. This logic could also work at organizational level, if there was a hospital actor who would work as an external auditor for another hospital, and they could bring best practice of others into the hospital. One of the external auditors of the hospital who works as quality manager for another hospital corroborated this.

Among the individual factors I has to mention the importance of understanding and experience. A frequently mentioned negative effect of ISO is that it brings about a great documentation burden, as pointed out also by the experts interviewed. However, the case study revealed that this documentation burden is not always perceived, because hospital actors who think that they understand why documentation is needed can accept it, and once it becomes part of the daily routine it is not perceived as a burden anymore. It was also not perceived as a burden if they had to fulfill similar requirements before (e.g. requirements of a direct leader), or if they experienced that it made sense to document things (e.g. accountability), these factors are included in the influencing factor called 'experience'. This means that the case does not evidence that ISO certification would impose extra documentation burden that provokes resistance of the hospital actors. As an influencing factor it is much more significant if hospital actors see the point in the changes introduced (e.g. in documentation) as a result of the certification or not, which factor is described here by the term of 'understanding'. Understanding means that the hospital actors consider that it makes sense to implement the changes induced by the certification. It is not necessary that all hospital actors agree about what the point is, but the important is that they all consider that there is a reason, and then they accept the changes more easily. However, if they do not see the point in the new method and they only perceive that it is a burden, then they will not accept the method, and even if they try to meet the requirements by external force, fulfillment will be more difficult (see embedded case unit C in section 8.8.2.). The presence of the factors of understanding and experience
does not mean that any documentation burden will be accepted, which is shown by the fact that even those who understood its importance criticized the elements that they could not understand (e.g. duplication in the documentation). There are also other influencing factors that were identified during the case study. (See subchapter 8.8.)

With so many influencing factors there is the question of how the original ideas of the developers and supporters on the role of the certification can prevail at all during the application of the method? The history of ISO and SHC/HHCS described in the dissertation illustrates that the understanding and the interpretations of the developers and supporters of the systems can have also significant effect on their operation. The history of the Hungarian SHC system, based on accreditation standards, is a good example for this, because it supported the spread of only one element of the accreditation system, namely the regulatory standards, while another important element, the supervisory system, which was based on a logic different from the supervisory system applied by ISO, was completely ignored, because at that time the developers and the health care quality policy makers did not realize its importance. They should have understand the essence of the evaluation method and the basic differences between ISO and the new system, be able to communicate them, instead of interpreting standards on their own.  

This influencing factor is called the interpretations and messages by the developers and supporters.

The original research aim and the original research question focused on analyzing the effects on the improvement initiatives. The case study revealed that in the hospital case improvement was among the declared objectives of taking up the certification, but it was not its primary role. Expert interviewees also corroborated that in Hungary the improvement role of the ISO and SHC/HHCS systems do not prevail, although there can be many ways in which the certification and the related audits could contribute to enhance improvement. The changes introduced by the effect of the preparatory phase and the first certifying audit, like more regulated and more disciplined operation, were changes perceived as improvement by most of the hospital actor interviewees experienced these changes. Meanwhile, the certification can also enhance improvement through the recommendations made by the auditors as they can prevail through the described mechanism of effects, however most of the hospital actor interviewees did not perceive these recommendations as an improvement. The case study showed that the quality system established as a result of the certification could enhance improvement through the PDCA cycle, this is hindered by some influencing factors (like the role of the management). (See subchapter 8.9 for detailed analysis.) Whether hospital actors consider the perceived changes as improvement does not only depend on if these changes are positive or negative, but also on whether hospital actors perceive them at all, or whether they consider them essential or not. The certification and the related audits can bring about organizational changes, but the content and the importance of these changes is also influenced by how the auditors and the hospital actors interpret the role of the certification. To conclude it can be claimed that in the studied case the indirect effects of the certification did not result in generating a proactive improvement potential for the organization, but it induced a kind of reactive behavior, which means that it helped the organization to adapt to changes resulted by other

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155 Chapter 7 reveals that there were no clear objectives and messages about the aims and the role of the quality systems. The experts try to learn from this experience, and, by a deeper understanding of the method, to elaborate the new accreditation system with much clearer objectives. The question still remains: will the new method be an adequate tool for achieveing the objectives? This can be the topic of further research.
factors, and modified the regulatory system according to these changes, and as a result it fixed and transmitted the new state.

9.2. **Comparison of the research results with the literature**

The results of the empirical research were compared to the literature presented in the theoretical chapters of the dissertation. The following subchapter summarizes my statements related to the theory on the professional bureaucracies by Mintzberg (1991), to the theory of the compatibility gap (Lozeau et al. 2002) and to the characteristics of the health sector.

The standardization of the work processes, as physicians and nurses see it

Some of the relationships between the influencing factors revealed by the case study and the coordination mechanisms by Mintzberg (1991) were already described in the previous subchapter 9.1. The certifications by ISO and SHC/HHCS, which external evaluation methods were focused in my empirical research, demand a coordination mechanism of the organization that can correspond to the standardization of the work processes. Mintzberg claims that in professional bureaucracies like hospitals six coordination mechanisms are present, and the standardization of the work processes is not the principal mechanism, but the standardization of skills dominates. According to Mintzberg the role of the technostructure responsible for the standardization of the work processes is minor in professional bureaucracies.

In fact, in the case study hospital there are professional guidelines, protocols and trainings that influenced and determined the work of the physicians. Interviews reflected upon this claiming that ‘ISO’ does not affect professional work of physicians, because this is regulated by the professional protocols. This means that in the case of the physicians the standardization of skills prevailed. However, when Mintzberg (1991) refers to the characteristics of professional bureaucracies, he does not separate physicians and nurses within the operational core of the organization, although both the studied case and also the auditors’ general experiences corroborated that nurses take a more active part in the operation of the quality system. It is unquestionable, that the role of the physicians dominates in patient care, and they dispose of much more power within the hospital hierarchy, but the nurses and the other skilled health workers also form their own hierarchical structure, which plays an important role in patient care, too. Therefore, among a considerable part of the operational core the standardization of work processes can prevail, as it was supported by the studied case.

In an article about hospitals Mintzberg (1997) publishes an analytical framework, which can explain this phenomenon. In this model Mintzberg distinguishes between the two different worlds of physicians and nurses, but also between the worlds of the management and the directorate. The four worlds represent four different points of view, and four different ways of seeing organizational issues. Nurses in the world of ‘care’ provide continuous care, and the coordination of the work of professionals is a central problem for them, and therefore they incline to think in terms of coordinating the work processes. However, physicians work in the world of ‘cure’ and think about their own profession, and their work are performed
in curing episodes.\textsuperscript{156} All this is relevant to the present case study because it suggests that nurses can have an overview of the work processes and they more easily perceive the problems than physicians do, and therefore nurses are more motivated to propose measures to standardize work processes. Physicians in their world of ‘cure’ are less susceptible to these problems in coordination. The case offered another possible explanation for a more receptive attitude experienced among nurses and skilled health workers towards the methods: certain trainings of nurses and skilled health workers already include some knowledge on patient documentation and quality, as many of the interviewees motioned. Moreover, the position of the nurses in the hierarchy (e.g. subserviency), in the decision making process and other factors can also serve with an explanation to the phenomenon. In case of the physicians it would be instructive to analyze how the content of their training affects their attitudes for example towards documentation. The division of labor is also influenced by the ideas and the beliefs of the nurses and of the physicians (for instance: whose task is documentation? administrators’, nurses’ or physicians’?).\textsuperscript{157} The analysis of the role of the different factors like the special position in the decision making process (world of ‘care’ vs. world of ‘cure’), training and other factors can serve as a topic for further research.

The importance of the different role interpretations and the compatibility gap

Based on the results of the case study the hospital can be analyzed from the aspect of how the hospital and the hospital actors reacted to the certification-related requirements and it can be examined that how can this behavior correspond to the alternatives adapted to react to the compatibility gap, as described by Lozeau et al. (2002).

The certification did not affect the professional work of the physicians, neither according to the role-interpretation (see section 8.7.1 on the “gap in the system”), nor according to the perceived changes. Meanwhile, the dominant role-interpretation was documentation-checking, and documentation-related changes were perceived by most of the interviewees. If we consider the theoretical role of the certification based on ISO 9001 (that is, it is applied to the principal activities of the hospital, too), then we can claim that the method was ‘corrupted’, which is one of the possible reactions described by Lozeau et al. (2002). One of the assumptions behind the empirical case study was that the role of the external evaluation methods was to enhance improvement. Considering this assumption the case can also be conceived as the ‘corruption’ of the method.

However, if we base our judgment on the interpretation given by the external auditor who is an expert of the method, the conclusion is not so unambiguous. One of the auditors claimed that ISO does not aim at regulating the professional processes, because that is what professional protocols do. Following this interpretation which considers the particular circumstances of the hospital the case could be classified in the group of ‘customization’ (Lozeau et al. 2002). The role-interpretations given by the auditors corresponded to the role-interpretations of the management and the Quality Manager. (see subchapter 8.7).

\textsuperscript{156} There are specialties where physicians also continuously take part in patient care, like GPs. In this case physicians also face the problems of coordinating the work processes.

\textsuperscript{157} I think that training plays an important role in influencing on the beliefs that are strengthened by hospital experience. Therefore, training does not only affect the standardization of skills, but also the standardization of norms within each profession, which can define the attitude of the physicians towards their patients or towards other specialties. (see stereotypes, Mintzberg, 1997). These statements should be tested by further research.
Analyzing the realization of SHC and HHCS it can be concluded that the original role (see experts’ interpretations) and the practical use of the method in the hospital can be characterized by the term of “loose-coupling” coined by Lozeau et al. (2002), because next to ISO the effects of SHC and HHCS did not really prevail, although the hospital obtained both of these certifications.

The question is whose interpretations to consider, because even developers of the methods (see expert interviews on SHC) have different interpretations of their role. If hospital actors thought that ISO system made sense (e.g. it is worth applying it for reasons of protection, which is supported by documentation), then it suggests that practice corresponds to their role interpretations. The problem is when some hospital actors have different interpretations of the role of the certification – maybe influenced by the developers, supporters or by the auditors -, and as certification does not fulfill their requirements they conceive it as a burden, which can lead to resistance and passivity, which was the case of the hospital studied, where the different role interpretations did not correspond to each other. In such a case it is worth considering an intent to harmonize the different interpretations and to modify the method applied.

Assumptions of the external evaluation method and the characteristics of the health sector
In the context of health care ISO 9001 is usually criticized for not being specific for health care, because it had been developed for business (and even manufacturing) organizations. The application of ISO standards was supported by the Ministry by offering interpretations of the different terms for the health care services that is already helpful. (ESzCsM, 2003) (Meanwhile, international development also supported the health care application of ISO 9001. (Shaw et al. 2010) The ISO 9001-based standard on the quality management systems for health care services (EN 15224:2012) was published by the European Committee for Standardization (CEN), and it became available in Hungarian translation in Spring 2014.) The case study hospital had to face the difficulties of its adaptation alone, because when this hospital implemented the standard the above mentioned supports were still not available.

The health care-related interpretations of the terms of ISO standards are still far from being enough for the smooth adaptation of the system. It is also necessary to analyze the (implicit) assumptions by the stakeholders (e.g. developers, supporters, preparatory companies, appliers). It is important to consider the peculiarities of the services compared to production and the peculiarities of the health care sector (see Chapter 3) in the case of a public health care organizations, because these peculiarities can be completely different from the assumptions that are valid in the case of an ISO system introduced for business and manufacturing companies. One of the elements of ISO system to be considered is customer focus, because it is not enough to change the name for client or patient focus, but influencing forces should also be revealed. While in the business sector the customer is the consumer and the financer of the service (or product), in health care these two roles are separated (see Chapter 3), and the patient cannot influence on the hospital activities by paying for the service. Patient empowerment is also restricted by other characteristics of the health sector: (see Chapter 3) It is to be answered how the patients could represent their interests. One of the possibilities is to choose another provider. This possibility is limited in Hungary (strict referral criteria, compulsory territorial coverage by providing care), and this choice is viable only for limited types of care and only in certain regions (like Budapest with many hospitals). Therefore, it was not by chance that protection from trials and denouncements became one of the principal interpretations of the role of certification in the studied hospital, because these are the patients’ requirements that the hospital directly experiences. However, denouncements and trials are
motivated by many different factors, which make them not a really adequate tool of patient empowerment.

In this context the most relevant question for the dissertation is how an external evaluation method like certification can contribute to patient empowerment, if the hospital really wanted to adapt ‘customer focus’. ISO system disposes of elements like patient satisfaction surveys or handling of complaints, which probably produced significant changes in the attitudes of susceptible recipients through the presence and application of these tools in hospitals. However, the studied hospital case shows that the application of these tools does not necessarily bring about better consideration of the interests and demands of the patients. In order to achieve this several other conditions should exist, for example, hospital actors should recognize and accept this role of the certification (the role of patient empowerment), and the tools applied to seek for patients’ opinion (like patient surveys) should be properly analyzed and used to support decision making. Still, all this may be insufficient as the main force towards customer/patient focus would be lacking. In my opinion, a well-constructed and -operated external evaluation system that would also represent patients’ interests could enhance this process, because one of the results of the empirical case study evidences that hospital actors (management, other leaders and employees) take external requirements seriously and these requirements affect their decisions. (For instance, if the owners or the health policy makers require the implementation of a system, then the hospital is ready to implement it; or if the auditors make recommendations and they check their implementation, then the hospital will implement these recommendations.) Still, it is important to find a commonly shared interpretation about the aim and the role of the method, and about how this method operates and contributes to achieve the desired objectives.
This research focused on the internal effects of external hospital evaluation methods. The relevance of the topic is evidenced by the fact that external hospital evaluation methods have been widely applied in many countries and since 2000 in Hungary, too, as a result of which hospitals can be assessed by several external stakeholders at the same time, each of them using different evaluation methods. This practice has raised controversial issues in practical usage as well as among the researchers, concerning the aims and the effectiveness of these evaluation methods. Research on hospital evaluation methods boomed since the middle of the 1990s. In the 2000s research mainly focused on the effectiveness of the methods, that is their effects on hospital output and outcome, and several researches focused on the adverse effects of some of the methods. (Research results on this topic is summed up in subchapter 4.3) As a result of researches it became clear that a framework to classify hospital evaluation methods is necessary. Little research and theoretical study were found that focused on how external hospital evaluation methods achieved the desired effects, or what were the reasons behind the adverse effects. The aim of this research was to explore the internal hospital effects of the external evaluation methods by trying to understand internal organizational processes and the reactions and interactions of hospital actors and by focusing on their relationship with hospital improvement initiatives. It was not the aim of this research to assess the effectiveness of the external evaluation methods, but to analyze the effects of these methods in the organization. The other research aim was to propose a framework for the classification of the external hospital evaluation methods, in order to support comparison of different research results, which is only possible if the methods are classified according to their principal characteristics.

The classification framework has been proposed based on the review of the scientific articles on the systemization of the external evaluation methods, and on the aspects generally used in the field of evaluation. The dimensions of the framework are the situation of the evaluator (external or internal), the role of the evaluation (formative or summative) and the approach to knowledge (positivist or interpretative). Other classification aspects are suggested, like what kind of actions or incentives are applied as a result of the evaluation; which organizational fields are affected by the evaluation or whether evaluation is compulsory or voluntary. The proposed framework can be applied not only for hospitals, but also to classify the evaluation methods of other public organizations. The framework was developed to classify the practically applied evaluation methods, considering that there can be a big difference between theory and practice (for example, in the resultant actions and incentives). The applicability of the classification framework was tested by the empirical case study, which proved that the applied evaluation method of the studied hospital could be classified and characterized based on the dimensions of the proposed framework.

The empirical research was restricted to analyze the organizational effects of the hospital evaluation methods used in Hungary. These methods are ISO 9001, Standards of Hospital Care (SHC) and Hungarian Health Care Standards (HHCS). The research question of the exploratory empirical research was: How do ISO 9001 and SHC/HHCS certifications affect the behavior of hospital actors and, as a consequence, the improvement initiatives of hospitals in the Hungarian health sector? To answer this research question a qualitative method was applied based on interviews with experts and on a case study. From the opportunities offered by the case study method the analysis of one single case
with embedded cases was chosen, because it seemed proper for the exploratory character of the research, and it supported deeper understanding of the phenomenon. The choice of the method is justified by the fact that the analyzed phenomenon cannot be clearly separated from the organizational context, while the case study method allows taking context into consideration. (Yin, 2009) The choice for a qualitative method is justified by the exploratory character of the research and by the research question, which focuses on the deeper understanding of a phenomenon. (Eisenhardt, 1989; Maxwell, 2006) To be able to compare different points of view, semi-structured interviews were made with Hungarian experts who participated in the development of the methods or supported them (5 interviewees), with the external auditors of the hospital (2 interviewees) and with hospital actors (30 interviewees). In order to increase validity, different data collection methods were applied (semi-structured interviews, documents, observation) in the case study (triangulation). The analysis of the embedded cases made it possible to make comparisons at the level of the different hospital units. (5 embedded cases) Data were coded using NVivo 9 software (using open coding for interviews with hospital actors and auditors (Strauss – Corbin, 1990), and using mixed coding for interviews with experts (Miles – Huberman, 1994)), and a reiterative analysis was made to come to the presented research results. The methodology applied was very time-consuming, but it fully supported exploratory research. The results of the empirical study are the following: In the studied case the ISO 9001 and the SHC/HHCS certifications, which were situated in the proposed classification framework, can be considered as formative evaluation methods according to the dimension of the role of the evaluation, and interpretative according to the ‘approach to knowledge’ dimension. The case study hospital operated an integrated system of ISO 9001 and SHC/HHCS, and the evaluation of these methods is not separated during the audits. Therefore the research analyzed this integrated system and certification as the effects of the two methods were not separable. The role of the certification and the related audits was formative as the attitude of the auditors was constructive, supportive, and hospital actors perceived the improvement role of certification, while this role cannot be considered as summative. The certification and the related audits are interpretative methods, because both the auditors and the hospital actors take part in the process of the evaluation, and data collection is not separated from evaluation feedback, which results in that the moments of evaluation affect the content of the information collected, and auditors also take into consideration the explanatory circumstances in the evaluation. The method does not correspond to several requirements of a positivist method. The mechanism of the effects of the certification in the hospital was also analyzed, including the reactions and interactions of hospital actors and auditors. As a result it can be claimed that the principal characteristic of the mechanism of the effects of the certification in the studied hospital was regular supervision and the exam-like character. Further research could be directed to analyze what kinds of organizational learning process results from the mechanism of the effects of the certification. The empirical case study revealed factors that influence the reactions and interactions of the hospital actor. These factors were classified in the following groups: theoretical factors, external evaluation factors, external factors, organizational condition factors, indirect effect factors, factors at individual level. The effects of the influencing factors were corroborated by the analysis of the embedded cases, too. The comparison of these influencing factors with other theories, like the reactivity theory (Espeland – Sauder, 2007) or the theory of organizational learning by Argyris (1994) can be the topic of further research.
There is a back-and-forth effect between the mechanism of the effects (reactions and interactions) influenced by the above mentioned factors and the interpretation of the role of the certification. The different groups of hospital actors had different interpretations of the role of the certification and the related audits. Most perceived the role of documentation-checking. The most discontented group with the role of the certification was the group of physicians working in patient care units. However, according to hospital actors who participated in the implementation of the system and who were more familiar with the methods, certification played an important role in establishing order and discipline, and in contributing to the protection of the hospital by preventing denouncements and trials. Some of these hospital actors also claimed that the certification played a role in hospital improvement. To conclude, it can be claimed although improvement was among the declared objectives of taking up the certification, but it was not its primary role in the hospital, although in the beginning phase it also enhanced development (e.g. regulation, transparency); but the system established as a result of the certification mostly only reacts upon external and organizational changes.

The detailed and exploratory presentation of the case study in this dissertation offers a possibility of comparison with other cases, although the research did not aim at generalizing its results. The results are also proper to be compared to theories in the literature. The results have already been compared to the theories described in the dissertation.

The results are in accordance with the professional bureaucracy model by Mintzberg (1991), considering that in case of the physicians standardization of skills is the principal coordination mechanism. However, I also found that in the case of the nurses the standardization of the work processes, which was affected by the certification, can also be a characteristic coordination mechanism. An explanation for this can be found in Mintzberg’s (1997) model on the worlds of ‘cure’ (physicians) and ‘care’ (nurses). The other influencing factors (like different decision-making position, training, professional culture, standardization of norms) of the attitudes of physicians and nurses towards regulation serve as a topic for further research.

The studied case was compared to the study by Lozeau et al (2002) analyzing how hospital actors reacted to the requirements imposed by the certification process. It can be claimed that according to the interpretation of which participants (developers, auditors, hospital actors) we compare the perceived practice, we come to different conclusions (corruption, customization, loose-coupling). It is important whose interpretation is taken as a basis, depending on the wish whether to improve the method or the practice.

The analysis of the attitudes and the roles of the external evaluators (e.g. auditors, supervisors), or the analysis of the effects of the external evaluation methods on the “culture of errors” can also serve as topics for further research. (During the case study it was typical to call “error” every discrepancy between the expected and the real practice. It is to be revealed whether this has negative (punishment) or positive effects (error correction) related to the certification). Another possible research question is that how the assumptions of the developers of the external hospital evaluation methods affect the structure and the practical effectiveness of the methods. This question would be worth analyzing in case of the currently developed hospital accreditation system.

The research presented in the dissertation is continued by the analysis of the effects of the currently developed hospital accreditation system. The project performed by a group of researchers of the Health
Services Management Training Centre of the Semmelweis University analyzes the effects of the accreditation on organizational culture related to patient and staff safety. The research results of this dissertation may also be used during the development of the hospital accreditation system. The identified influencing factors can support the understanding of the different attitudes of nurses, skilled health workers and physicians towards the regulation. These influencing factors are worth considering when developing and implementing standards for hospitals. The research corroborates that an intense communication between the different stakeholders (developers, auditors, hospital actors) is essential. Giving a common interpretation to the aim and the role of the accreditation and the assumptions related to its operation can be crucial for the future success of the method.

Besides its theoretical and practical results, the research has also contributed to my personal development. On the one hand, it offered a better understanding of the studied phenomenon, and on the other hand it served as an experience in using different data collection and data analysis methods, which can be useful in further research.
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https://sites.google.com/site/myfirststepwithefqmmodel2010/home/9-key-results, last available: 09.02.2014.

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Annexes

Annex 1. The evaluation theory tree

Source: Christie and Alkin (2008), p. 133.
Annex 2. Other external hospital evaluation methods and other initiatives in Hungary

National hospital indicator projects in Hungary

At the beginning of the 2000s national hospital indicator development projects were launched by the Ministry of Health, Family and Social Affairs (Ministry) and the National Health Insurance Fund Administration (NHIFA, OEP). The indicators developed by the Ministry were published in 2003 in the Hungarian Health Policy Review and recommended to use and measure together with the ISO and SHC systems and during the internal audits. The aim of the experts of the Ministry was to create a nationwide indicator-database to support the development of the quality management systems of the health care providers. (Szy et al. 2003) The value of twelve of the indicators published in the Health Policy Review (2003) was calculated during the years between 2004 and 2006, using the financing data that the hospitals regularly send to the NHIFA. The results of this national data processing were published as aggregated indicators (at the level of regions and groups of institutions) on the website of the Ministry. The hospitals had the opportunity to process their own data by using computer software. (EÜM, 2005a, b; Lóránth, 2007) However, the indicator program of the Ministry cannot be considered as external evaluation, because the hospital level data processing was made by the hospitals themselves, while the external experts analyzed and published aggregated data.

The NHIFA launched its indicator development program in 2002, with the aim of making care more transparent, enhancing quality improvement and supporting certification and accreditation programs. (Belicza et al, 2004a, 2004b). The indicators were calculated using the NHIFA financing database. Experts were also consulted during the development of the indicators. The first hospital-level indicators were published in 2005 on the website of the NHIFA158, without publishing the names of the hospitals. The indicators were published with individual institutional codes that only the developers of the indicator system and the hospital itself could identify. (The NHIFA sent each hospital its own institutional code.) The reason for this was that the development of the indicator system was still not completed, and the aim of the program was not to inform patients, but to support quality improvement of the hospitals. The indicator program of the NHIFA functioned intensely until 2006, and then it finished for lack of financial support. Therefore, the program was more like a development project to test the ability of the NHIFA database to process indicators. It also served as a useful experience for later indicator programs.

When the new government came into power in 2006, the Health Insurance Supervisory Authority (HISA, EBF) took over the development of indicators from 2007. In 2008, 2009 and 2010 the HISA published the indicator values on its website as part of its quality indicator program, including the names of the hospitals and other information. The aim of the HISA indicators was to inform the patients and the insurees and to support quality improvement of health care providers. (Kovácsy – Kiss, 2009; Gémes et al. 2011) The HISA indicator system is described in the draft of the dissertation. (Takács, 2012)

Parallel to the system developed by the HISA, in 2008 the Institute for Quality Improvement and Hospital Engineering (IQIHE, EMKI) also planned to launch its own indicator program, and in 2009 made a preparatory survey. (EMKI, 2009). After the new government came into power both indicator programs

158 http://www.oep.hu/portal/page?_pageid=35,36252&_dad=portal&_schema=PORTAL
died. The HISA ceased to exist in September 2010, and the IQIHE was renewed under a new name and integrating many different institutions (GYEMSZI). In the recent years a new indicator development project was launched by the new institution (GYEMSZI), which is based on data collection through the supervisory system, and the aim of which is to enhance quality improvement in the data provider institutions.\textsuperscript{159}

Nationwide patient satisfaction surveys
There was several patient satisfaction surveys carried out among the hospitals in Hungary. The first survey was ordered from Szonda Ipsos by the NHIFA in 1999 (Nagy, 1999). The second survey was also ordered by the NHIFA in 2001 and it was carried out by TÁRKI (Nagy – Boncz, 2001; Boncz – Nagy, 2002). The Ministry of Health first ordered a patient satisfaction survey in 2004 in the field of inpatient care (Borbás, 2012), and the second in 2005 for outpatient care. The results were published on the website of the Ministry. (EMKI, 2009). The patient satisfaction surveys did not become a regular practice, and the external evaluators processed and published results based on aggregated level. Although there are no regular patient satisfaction surveys in Hungary (the National Institution for Quality- and Organizational Development in Healthcare and Pharmaceutics is planning it), hospitals usually make their own patient satisfaction surveys.\textsuperscript{160} According to a survey by the IQIHE, in 2008 86\% of the hospitals made a patient satisfaction survey (EMKI, 2009), while according to 2010 data of the HISA 90\% of the institutions has at least once made a patient satisfaction survey (EBF, 2010). These are not considered as external hospital evaluations, because the external stakeholder, namely the patient only offers data, but the analysis is made by the hospital itself.

“\textquote{The Hospital of the Year}” prize
In 2005 HáziPatika.com launched the internet-based voting for the title “\textquote{The Hospital of the Year}”. On an internet webpage participants can assess five aspects of Hungarian hospitals using a five-tone scale. The five aspects were: medical and professional care; nursing; infrastructure; treatment; environment and overall cleanliness. The result was published based on the visitors’ votes and the absolute winner could dispose of the title “\textquote{The Hospital of the Year}” during a year. (www.hazipatika.com)

EFQM excellence model
During the 2000s Hungarian hospitals also showed interest for the self-evaluation method based on EFQM excellence model. The first EFQM-based self-evaluation was performed by the Zala County Hospital between 2000 and 2001. (Takács et al. 2002). In 2001 an international conference on the adaptation of the EFQM model in health care was held in Balatonaliga (Szy et al. 2003). According to a survey by the Ministry, the EFQM-based self-evaluation was applied by 10\% of the respondent hospitals (Szy – Sinka, 2004). The EFQM evaluation is complemented by external evaluation if the hospital applied for the National Prize for Quality. Since public institutions can apply for this prize two hospitals have won it: first the Zala County Hospital in 2006 (Kránitz, 2007), and in 2007 the Jósa András Teaching Hospital Health Care Provider Non-profit Ltd. of Nyíregyháza (Vancsó – Csikai, 2010).

\textsuperscript{159} Based on a written notice by Éva Belicza.
\textsuperscript{160} About patient satisfaction and measurement see Simon (2010).
Clinical audit: professional evaluation

Among the Hungarian evaluation methods it is worth mentioning the clinical audit, which is „a multidisciplinary method to systematically analyze routine professional practice”, „focusing on what you do and how you could do it better” (Horváth et al. 2003, p. 36.). The introduction of the clinical audit was decided in 2001 by the Ministry, when planning a development direction based on reforming the inspection by head physicians. (Szy et al. 2003). From 2002 an evidence-based professional guideline was developed, and pilot clinical audit projects were performed. (Horváth et al. 2003) As a result the guideline for clinical audits was published by the Ministry (Mogyorósy – Mogyorósy, 2004). From 2008 the development of the clinical audit system was the responsibility of the National Centre for Healthcare Audit and Inspection (OSZMK), which worked under the direction of the National Public Health and Medical Office Service until 2011. Later the OSzMK merged with GYEMSZI.

According to the two different approaches of the clinical audit it can serve as a measure of control and inspection for the health policy authorities on the one hand, and it can support self-evaluation and autonomous improvement of professional work on the other. In Hungary both approaches prevail. (Vereckei et al. 2007) Gödény (2012) distinguishes between internal and external clinical audits on the basis of the relationship between the evaluator and the evaluated entity. However, neither of the two approaches, not even the external clinical audit can be considered as an external hospital evaluation method according to the definitions of the dissertation, because although the evaluation can be performed by an external group of experts (inspector, peer), the subject of the evaluation is the professional work, and not the hospital as an organization.
Annex 3. Analysis for case selection

The analysis of the population of the Hungarian hospitals was made in September 2012 to support case selection decision.161 This means that the results of the structural changes imposed in Summer 2012 could be taken into consideration, and which also influenced the determination of the characteristics on which the selection was based. In the first phase of the selection I had to filter the hospitals that matched the definitions that is those hospitals that were publicly financed institutions with acute inpatient beds. After the structural changes in 2012 there were 93 hospitals that matched this definition. The distribution of these hospitals according to the acute bed numbers are shown in Figure 1. The statistics on the acute bed numbers are shown in Table 1.162 In Figure 1 the ellipses illustrate the group of hospitals to which I narrowed the potential cases: the ellipse below is for the hospitals with 300-1000 acute beds, and the ellipse above for hospitals with 450-1500 acute and chronic (total) bed numbers.

Figure 1. Distribution of hospitals according to bed numbers in the end of 2012

![Graph showing distribution of hospitals by bed numbers](image)

Source: OEP, 2013

<table>
<thead>
<tr>
<th>Table 1. Basic statistics on hospital bed numbers</th>
</tr>
</thead>
<tbody>
<tr>
<td>max: 2097</td>
</tr>
<tr>
<td>3rd quadrant:</td>
</tr>
<tr>
<td>average:</td>
</tr>
<tr>
<td>median:</td>
</tr>
<tr>
<td>1st quadrant:</td>
</tr>
<tr>
<td>min:</td>
</tr>
</tbody>
</table>

Source: OEP, 2013

161 The first analysis was made using preliminary data, because the NHIFA published its data in 2013 with the title of 'Data on hospital bed numbers and number of patient visits, 2012' (OEP, 2013). This publication was referred in the dissertation as it is already publicly available.

162 According to the acute bed numbers the specialized hospitals and chronic care hospitals usually belong to the lower quadrant of the 93 hospitals. These hospitals, although they match the definitions because they have publicly financed acute beds, are not typically acute care hospitals.
Figure 2 shows the distribution of the 93 hospitals according the active specialties represented by the institutions. During the case selection the hospitals with only a few specialties were excluded, and it was aimed that the principal specialties (e.g. internal medicine, surgery, maternity ward) are represented. Based on these criteria the number of the hospitals was restricted to the institutions with 10-19 specialties. University clinics were also excluded, because these institutions have several special activities (like training and research) and special characteristics related to my research topic (they are accredited as training hospitals).

**Figure 2. Distribution of the hospitals according to the number of specialties represented at the end of 2012**

Source: OEP, 2013
## Annex 4. Data collection timetable

<table>
<thead>
<tr>
<th></th>
<th>Monday</th>
<th>Tuesday</th>
<th>Wednesday</th>
<th>Thursday</th>
<th>Friday</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1(^{st}) week</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>first meeting with the quality manager of the hospital</td>
</tr>
<tr>
<td><strong>2(^{nd}) week</strong></td>
<td></td>
<td></td>
<td>second meeting with the quality manager of the hospital, collecting documents</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>3(^{rd}) week</strong></td>
<td></td>
<td>2 interviews: quality secretary, quality manager</td>
<td></td>
<td>interview: medical director</td>
<td></td>
</tr>
<tr>
<td><strong>4(^{th}) week</strong></td>
<td></td>
<td></td>
<td>2 interviews: head of an economic-technological unit, nurse head (internal auditor)</td>
<td></td>
<td>2 interviews: vice medical director, nurse director</td>
</tr>
<tr>
<td><strong>5(^{th}) week</strong></td>
<td></td>
<td>interview: nurse</td>
<td>3 interviews: economic director, physician head and nurse head, physician</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>6(^{th}) week</strong></td>
<td></td>
<td>group interview (economic-technological area): 4 heads of unit, 3 non-managers</td>
<td>interview: external auditor</td>
<td>interview: former Director General</td>
<td></td>
</tr>
<tr>
<td><strong>7(^{th}) week</strong></td>
<td></td>
<td>observation: audit</td>
<td>observation: audit</td>
<td>2 interviews: physician, physician head</td>
<td></td>
</tr>
<tr>
<td><strong>8(^{th}) week</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>9(^{th}) week</strong></td>
<td></td>
<td></td>
<td></td>
<td>interview: external auditor</td>
<td></td>
</tr>
<tr>
<td><strong>10(^{th}) week</strong></td>
<td></td>
<td>4 interviews: physician head (diagnostics), head of an economic-technological unit, nurse head, nurse head assistant</td>
<td></td>
<td>interview: physician</td>
<td></td>
</tr>
<tr>
<td><strong>11(^{th}) week</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>12(^{th}) week</strong></td>
<td></td>
<td></td>
<td></td>
<td>2 interviews: quality manager (second interview), physician head</td>
<td></td>
</tr>
<tr>
<td><strong>13(^{th}) week</strong></td>
<td></td>
<td>interview: quality manager (continuing the second interview)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>14(^{th}) week</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>15(^{th}) week</strong></td>
<td></td>
<td>interview: physician</td>
<td></td>
<td>interview: &quot;quality coordinator &quot;</td>
<td></td>
</tr>
<tr>
<td><strong>16(^{th}) week</strong></td>
<td></td>
<td>interview: skilled health worker</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Annex 5. Semi-structured interviews with hospital managers\textsuperscript{163}: topics and questions\textsuperscript{164}

Warm-up:
\begin{itemize}
  \item Introduction
  \item Brief summary of the research objectives
  \item Methodology: interviews with professionals and case study
  \item ANONIMITY
  \item How much time they have for the interview?
  \item May I record it by dictaphone? I will also take notes.
  \item Any questions before we start?
\end{itemize}

The recent history of external evaluations in the hospital
\begin{itemize}
  \item What kinds of external hospital evaluation methods have been applied in your hospital in the recent years? (explanation, orientation)
\end{itemize}

If they had a former workplace, ask when relevant: the situation of this hospital as compared to your former workplace…?

Focus on certification

The history and the process of evaluation
\begin{itemize}
  \item Could you describe how evaluation happened? What preceded the evaluation?
  \item What was the aim with the certification? Why did the hospital decide to take it? What were the reasons? (initial, integrated, renewal)
    \begin{itemize}
      \item Would it mean anything in hospital operation if the certification was not renewed?
      \item Was improvement among the aims?
    \end{itemize}
  \item Was it a voluntary decision?
  \item How did the evaluation process happen? (evoke concrete events)
\end{itemize}

Questions about the participation of the interviewee
\begin{itemize}
  \item What role did you play in the evaluation process? In what ways did you participate?
  \item Was your role decisive in the evaluation process?
  \item Was your work evaluated by the auditors?
\end{itemize}

According to the interviewee, how did the other hospital actors take part in the evaluation
\begin{itemize}
  \item What do you think how did the other hospital actors experience the evaluation?
  \item What was their attitude like?
  \item Were there any hospital actors who played a decisive role in hospital evaluation? Why?
\end{itemize}

According to the interviewee, how did the external evaluator perform their task, what was their role, attitudes and effects
\begin{itemize}
  \item What kind of relationship did you have with the external evaluator? Why?
  \item How do you think the evaluator performed their task? What was their attitude like?
\end{itemize}

\textsuperscript{163} There were originally two versions of the drafts for interviews with hospital actors, one for the managers and another for non-managers. Some question were added if the researcher was interested in other roles, like the role of the internal auditors, or in relation with the experiences about the audit observed.

\textsuperscript{164} The questions in italics were added following the analysis of the first interviews.
What do you think: what kind of information sources were the evaluation based on, and how this information was collected?

The effect of the external evaluation according to the interviewee
- What do you think were the effects of the external evaluation on the hospital?
- What effects did it have on the hospital actors and their behavior? (in a long run)
- Do you share your experiences about the audits?
- Were there any changes in the hospital as a result of the evaluation? Can you mention examples? Which hospital areas did these changes affect?
- Does/did certification affect on how you treat the patients or on your relationship?
- What events happened in the hospital as a result of the evaluation?
- Were new decisions or measures taken?
- What do you think about these changes/Measures or decisions? Were they positive?
- Did the evaluation have any undesirable or adverse effect?

Improvement initiatives as a result of the evaluation (if it is necessary to ask in the light of the answers to the former questions)
- Were there any decisions or measures to enhance improvement as a result of the evaluation? Can you say concrete examples?
- What happened to these improvement initiatives? Did they change hospital operation? If yes, were the changes long-lasting and desirable? In which fields of operation?

To what extent were the aims defined by the interviewee achieved by the external evaluation and why
- Do you think that external evaluation could achieve its aim? (if necessary: ask again for the aims)
- Why could it? – What were the reasons? What should have been done differently?

According to the interviewee, what role did the concrete external evaluation play in the hospital operation
- To sum up: What do you think was the role of this external evaluation in the operation of the hospital?
- Is there anything you may wish to add? (comment, question)

following the interview: Have you got any questions or request?
Annex 6. Semi-structured interviews with external auditors: topics and questions

Warm-up:
- Introduction
- Brief summary of the research objectives
- Methodology: interviews with professionals and case study
- ANONIMITY
- How much time they have for the interview?
- May I record it by dictaphone? I will also take notes.
- Any questions before we start?

Introduction:
- Could you please tell me how did you become an auditor? Why did you choose this job?
- What kind of audits do you do? ISO, HHCS or integrated?

Objectives and reasons:
- What do you think are the objectives of the ISO certification of the hospitals? And the objectives of HHCS?
  - Improvement?
- Why do you think hospitals decide to obtain the certification? (at the beginning, in the 2000s and today)

The audit and the role of the auditors:
- Could you describe how audit happens? What is its process?
- What do you think the role of the auditor is in this process?
  - Does it make any difference who performs the external audit?
    - Why?
- How do you think auditors should behave during the audits? What is the attitude you consider as adequate?
  - Does the auditor’s attitude make any difference?
- What requirements did you have to face as an auditor, if any?
- What difficulties does an auditor have to face?
- What kind of information is collected during the audits and how this information is collected?
  - What “senses” participate in the information collection?
  - Are you interested in the explanations, or you collect facts only?

The relationship with the hospital:
- What kind of relationship do you have with the hospital actors (management, quality manager, employees)?
  - What are the reasons behind?
- According to your experience, is there any difference in the attitudes of actors of the different hospitals? (management, quality manager, employees) What are the possible reasons?
- How do hospital actors react during the audits? What effect does the audit have on them?
  - What are the consequences of this behavior?

The effects of the certification and the audits:
- What effects do the audits and the certification have?
  - on the hospital actors?
Which hospital operational field is the most affected by the certification? Is there any difference between ISO and HHCS in this respect?

In which ways do you think the audits affect the organization?

Through which actors, events or decisions?

What do you think: is there a key hospital actor during the audits or who influences the effects?

When you return to the same institution for a supervisory or a renewal audit, do you experience any changes that can be attributed to the previous audits? Can you tell me an example?

Have you ever experienced any undesirable or adverse effects of the audits? Can you tell me an example?

Do you think that ISO and HHCS certifications achieved their original aims?

+ Why? / - Why not?

What should be different in order to assure that the systems achieve their aims? (from the aspects of the auditor and the hospital)

Can you mention any aspects of the method or the assumptions that fail to be valid?

Could you please sum up what is the role of the certifications by ISO or HHCS in hospital operation?

Is there anything you wish to add? (comment, question)

After the interview. Have you got any questions or any request?
Annex 7. The list of the documents collected to the case study

<table>
<thead>
<tr>
<th>analyzed by coding</th>
<th>analyzed by other methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>20 external audit reports (reference codes: Jelentes1a - Jelentes14a, Jelentes2b – Jelentes7b, or reports)</td>
<td>17 internal audit schedules and diary (reference codes: baut1 - baut11, baut12a, baut12b, baut13a, baut13b, baut14, baut15)</td>
</tr>
<tr>
<td>17 records on management review (reference codes: JK1 – JK17, or records)</td>
<td>3 lists of internal audits (reference codes: dok14, dok15, dok16)</td>
</tr>
<tr>
<td>3 internal audit reports (reference codes: dok3, dok4, dok5)</td>
<td>1 list of quality worker (reference code: dok17)</td>
</tr>
<tr>
<td>3 letters (reference codes: dok1, dok2, dok6)</td>
<td>1 quality management handbook (reference codes: dok18)</td>
</tr>
<tr>
<td>2 organizational organogram (reference codes: dok12, dok13)</td>
<td>1 unit operation rule (reference code: dok19)</td>
</tr>
<tr>
<td>5 other (reference codes: dok7, dok8, dok9, dok10, dok11)</td>
<td>21 internal newspapers and 1 brochure (reference codes: h1-h21, dok20)</td>
</tr>
<tr>
<td><strong>total: 50 documents</strong></td>
<td><strong>total: 45 documents</strong></td>
</tr>
</tbody>
</table>

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Annex 8. Coding formed during the empirical case study

This coding system was used for the analysis of the interviews with hospital actors and auditors, documents and observation.

the reasons for the certification or the audit
  motivation
  volunteering
  reason for maintenance
  reason for integrated application

objectives
  certification- and audit-related objectives
  achievement

the history of the certification or the audits, precedents
  preparation, training
  difficulties of implementation

the interpretations and the roles of the certification or the audit
  associations about the certification and the audits
  the certification and the audits as evaluation
  the importance of the certification and the audits
  gap in the system

audit
  preparation
  the audit process, steps
  evaluated field by audit
  characteristics of the audit
  attitude, participation and motivation
  method of information collection
  method of evaluation
  audit results
  relation to other forms of supervisions, evaluations
  stories

auditors
  the relationship with the auditors
  the role of the auditors
  their attitudes
  companies, market
  expectations
  preparatory company
  changing practice
  carrier, experience
  training
  motivation
  difficulties
  qualifications

consequences, effects of the audit
  characteristics
  direct reactions
  following reactions
  interactions
  perception of the expectations of the auditors
  auditors’ recommendations and proposals
  the role of regular supervisions
  changes
  reputation
  paper (degree)
  protection of hospital (denouncements, trials)
  the patient’s perspectives
  responsibility
awareness
quality system
negative effects

improvements
audit vs. improvement
improvement independent from the audit

error
classification
revealing errors
handling, correcting errors
preventing errors

quality system
internal audit
surveys
quality committee
involvement of employees
handling complaints
its changes, improvement
management review

other influencing factors
external conditions
perception of external requirements
trials, denouncements
professional protocols
organizational conditions
new director general
direct leaders

other evaluation methods
the interpretation of quality
standard, standard systems
characteristics of ISO
characteristics of SHC and HHCS
dispersion

roles
relevant stakeholders
management
quality manager
persons for quality
auditor escort
internal auditors
head of unit
non-managers
own role interpretation
the researcher’s role as an observer
Annex 9. Expert interviews (draft)

Warm-up:
- Brief summary of the aims of the research
- Plans: expert interviews, hospital case study
- How much time do they have for the interview?
- May I record the interview by dictaphone?

Questions:
- Could you please tell me when and how did you first get into contact with quality management systems for hospitals?
  (When they stop:
  - Later on, in the development of which hospital quality management system did you participate?)

This research focuses on the ISO and SHC/HHCS certifications, so the questions that follow will refer to these two systems.
- Can you recall how ISO and SHC/HHCS were first received by the health care organizations?
- What do you think were the reasons behind hospitals introducing the ISO and/or SHC/HHCS and asking for certification of their quality systems? What were the reasons in the 1990s, and what are the reasons in the 2000s?
  - Were there/are there any incentives that promoted their introduction?
  - Were there/are there any subsequent incentives introduced or measures taken by external stakeholders?
- What do you think were/are the aims of introducing the ISO and the SHC/HHCS systems?
  - (Whose aims are these?) [explicit and implicit aims]
  - Quality improvement?
- What kind of circumstances or conditions do you think are necessary to assure that ISO and SHC/HHCS achieve their objectives? How do they work?
  - [Reveal the assumptions related to hospital actors.]
- Could you describe the role you played in relation with the ISO and SHC/HHCS systems?

Actual situation
- To what extent do you think hospitals are well informed about the development that is being carried out by the GYEMSZI (National Institution for Quality- and Organizational Development in Healthcare and Pharmaceutics) in relation to the accreditation, in your opinion?
  [depending on the answer to the previous question]
- To what extent does this information influence the behavior of the hospitals in their choice between the former external hospital evaluation methods, in your opinion?
- What expectations do you think hospitals have about external hospital evaluation systems, in your opinion? (positive, optimistic, neutral, etc.)

Closing
Annex 10. Codes applied for the analysis of expert interviews

- history of the certification or the audit, precedents
- objectives
- reasons for the certification or the audit
- the role and the interpretation of the certification and the audit
- improvement
- standard, standard systems
- other evaluation methods
- characteristics of the auditors (auditors: companies, market)
- how does it work? (experts’ assumptions)

Annex 11. Characteristics of expert interviewees

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<th>developer of an external evaluation method or additional material</th>
<th>leader in quality related function in the Ministry of Health or in a nationwide organization</th>
<th>hospital experience</th>
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The Author’s publications on the topic

Foreign refereed publication


Other foreign language publication


Hungarian scientific book or book chapter


Hungarian refereed review

Takács Erika [2015. 1st quarter]: Szervezeti értékelési módszerek a közszolgálati szektorban. [Organizational evaluation methods in public sector.] *Vezetéstudomány* (accepted for publication)


Other publications in Hungarian
