

Supervising the quality of care in changing healthcare systems

An international comparison

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Table of contents

Chapter 1. Introduction	3
1.1. Background	3
1.2. Theoretical perspective	3
1.3. Research questions	6
1.4. Research methods	7
1.5. Layout of the report	8
Chapter 2. The Netherlands	9
2.1. Health care organization	9
2.2. Quality assurance	10
2.3. Analysis	16
Chapter 3. Case studies	19
3.1. Introduction	19
3.2. Germany	19
3.3. Switzerland	24
3.4. Spain	28
3.5. France	33
3.6. England	36
3.7. Norway	41
Chapter 4. Analysis	45
4.1. Introduction	45
4.2. Changing governance modes	45
4.3. Country specific trends	46
4.4. Comparative analysis	49
4.5. Paradoxes	50
Chapter 5. Conclusions and summary	53
5.1. The research question and background	53
5.2. Theoretical perspective and case selection	53
5.3. Conclusions	54
5.4. Towards new arrangements for supervising the quality of care	56
5.5. Research agenda	57
Appendix 1. List of respondents	59

Chapter 1. Introduction

1.1. Background

The organization of healthcare in almost all European countries is changing rapidly. Faced with increasing challenges of an aging population and a rise in healthcare expenditures, European healthcare systems are implementing institutional changes, like the introduction of quasi markets. This changing context of healthcare delivery also means a redefinition of the role of the state in the traditionally highly state led healthcare systems in Europe. These and other changes often have direct consequences for the character and organization of the supervision on the quality and safety of healthcare. New supervisory tasks are added and the supervision of healthcare is organized in new ways. In England, for example, primary care trusts within the National Health Service (NHS) are no longer only supervised by 'traditional' NHS bodies, but also by a new organization, Monitor, that supervises the market functioning of primary care trusts at some distance from the NHS (Lewis, Alvarez-Rosete et al. 2006). Although the supervisory task of Monitor is not directly concerned with quality and safety of healthcare, its practical work necessarily touches upon these issues. In the Netherlands, a similar situation exists in the relation between the Healthcare Authority – erected to supervise the market functioning of healthcare organizations – and the Healthcare Inspectorate, traditionally focusing on the quality, safety and accessibility of health care. Next to that, in the Netherlands we see the rise of private parties, like health and risk insurers, that, albeit sometimes hesitantly, are taking on supervisory roles on the quality and safety of healthcare.

Against this background of changing tasks, responsibilities and organization of supervising the quality and safety of health care, the Dutch Health Care Inspectorate asked the department of Health Policy and Management (section Healthcare Governance), Erasmus University Rotterdam, to conduct a research. Financially, the research was also made available by the Dutch Health Care Inspectorate. The goal of this research report is to shed some light on the ways in which supervision is organized within a number of European countries, the changes and developments supervision is going through in these countries and what this means for the role of supervisory bodies. What kinds of dilemmas arise in the taking up of new roles by supervisors? What common trends can be observed and what strategies are taken? In this way, this report hopes to present somewhat of a mirror to supervisory bodies in the Netherlands.

The research question of this report is thus: In what way is the supervision on quality and safety of healthcare organized in a number of European countries? More specifically, the question we want to answer is *how* the supervision of quality and safety is organized – who is supervising, with what kind of resources, how do different supervisory organizations relate to each other, et cetera –, *which tasks* are performed by supervisors and what *formal competence* do they have? We conclude with some reflections and lessons for the Dutch Healthcare Inspectorate.

1.2. Theoretical perspective

In health care, governance relations are often complex. For a long time, healthcare was governed on the basis of two principles, state regulation and professional self-regulation. In the Netherlands, societal actors also have had a strong role in

governing health care. Since the mid-1980s, there has been a development of introducing 'regulated competition' into the Dutch healthcare system, introducing the market as a new governing mechanism. The concept of 'healthcare governance' tries to capture the complexity of steering relations in healthcare, pointing towards the shift from 'government' to 'governance' as has also been described in other domains (Bakker and Yesilkagit 2005; Helderma, Meurs et al. 2006; Rhodes 2007; Bal 2008). This shift emphasizes that (a) the state has become increasingly dependent on other (private and public) actors in regulating and supervising health care and (b) governing healthcare has taken more complex forms that no longer can be steered from a central position.

On the basis of a historical reconstruction of the governance of health care we can distinguish four ideal types of steering relations (and accompanying steering instruments), that can be characterized on the basis of (a) the level in which the state can function as a central steering actor and (b) the possibilities of private and societal actors to self regulate. A combination of these two criteria gives the following ideal typical institutional arrangements or modes of governance in health care: state, market, civil society and community (see table 1). These institutional orders are, moreover, linked to dominant governing mechanisms or instruments. Regulating is the dominant steering mechanism of the state; contract is the dominant steering mechanism for the market. For civil society the dominant steering mechanism is negotiation between representative parties, whereas for professional self regulation shared norms (laid down in guidelines and protocols) are the dominant steering mechanism.

		Level of self regulation of collective actors	
		-	+
Level of state intervention	+	State Regulation	Civil Society (Corporatistic) negotiation
	-	Market Contract	Professional self regulation Shared norms / protocols

Table 1. Ideal typical institutional arrangements and steering mechanisms

Characteristic for healthcare is in the first place that neither of these institutional arrangements are always dominant, but that they are present in changing constellations (Helderma 2007; Bal 2008). This is also true for the steering mechanisms that are linked to the institutional arrangements. Governing within healthcare is therefore always *mixed* or *hybrid* as it is made up of different mixtures of the four ideal types. The term 'regulated competition' already shows that state and market are present at the same time, and it should be noted that the other two institutional arrangements (civil society and professional self regulation) have not left the scene, albeit they may have taken up different roles. Professional bodies have, for example, been given an important task in defining Diagnosis Related Groups (the new 'products' that are sold on the 'healthcare market') and performance indicators (that are used by the Healthcare Inspectorate to assess the performance of healthcare organizations) are also developed in close cooperation with field actors such as professional bodies and healthcare organizations. Analyses of recent healthcare system reforms in other Western democracies have also shown that in these reforms, existing institutional orders and steering mechanisms are (partly) left in place (Oliver and Mossialos 2005), albeit that they sometimes transform their functioning. Secondly, healthcare governance necessarily involves several levels of

organization. These can range from the state (and increasingly also international organizations) to the level of the practices of care in which shared norms are given shape. Governance is therefore also always *layered*, connecting different layers of policy and organization. The impact of the European Union on healthcare in this regard has been significant, despite the fact that the European Commission formally has little say in national healthcare systems. Nevertheless, regulations of the EC and verdicts by the European Court of Justice on e.g. patient and professional mobility have had and are having a profound impact on national systems (Nys 2001; Greer 2006; Thomson and Mossialos 2007).

Within the discipline of healthcare governance, governance relations within and between these levels of organization are examined. How do the four ideal typical institutional arrangements and steering mechanisms relate in actual administrative and policy practices? In what ways can they strengthen or hinder each other? How do the hybrid arrangements develop and with what consequences? The central question is in what measure and in what way different mixtures of institutional orders affect the legitimacy, legality, efficiency and professionalism of healthcare arrangements. These questions again can be put on different levels of organization. At the level of the healthcare system, for example, a question is what the effects are of the introduction of the 'quasi market' for the relation between central actors. Which supervisory structures are necessary for accounting for public expenditures as well as for the accessibility and quality of care? At the level of the administration of healthcare organizations, questions can be targeted for example at the role of 'societal entrepreneurship'. At the level of concrete care practices, questions can be targeted at the changing patient-doctor relationship as a response to the introduction of 'steering by demand' mechanisms, or at the changing professional ethics in relation to the growing stimulation of entrepreneurialism of healthcare professionals.

Within the different 'modes of governance' (Gray and Harrison 2004), supervision of healthcare quality and safety can be organized differently. Supervision can for example primarily be organized by government, or professional organizations can perform a key role in supervision; also, market parties can supervise each other or supervision can be organized as part of civil society arrangements. Often, mixtures of such supervisory structures will be present and the question then is in what ways these relate to each other, whether they show overlap, which tensions arise because of the existence of multiple overlapping supervisory arrangements using different criteria and how these tensions are dealt with in practice.

Regarding supervision, the relationship between the supervisor and the supervised, as well as the forum within which they are held accountable, are central. Supervision has several characteristics: it is often obligatory, it is about the exchange of information between a forum and the supervised organization, it is about the explanation towards this forum about actions and their consequences (accountability), and it is about judging (and sanctioning or rewarding) this behavior and its consequences. Within the literature three dominant theoretical perspectives can be found regarding the way inspection and supervision take place and with what consequences that are relevant to analyze (De Bruijn 2001; Bovens 2005; Noordegraaf 2006).

First of all there is the 'democracy perspective', within which the accountability issue is focused at the democratic legitimacy of influencing quality policy, administration and organizational issues in healthcare. In the case of the quality of healthcare this perspective focuses on the relationship between the ministerial responsibility for the quality and accessibility of healthcare, and the tasks and responsibilities of the supervisory organization. Within this perspective, important instruments for

inspection and control are democratic accountability within representative forums. Next, the 'juridical perspective' focuses on the importance of inspection and control to create checks and balances in relation to organizations and professionals in healthcare. These organizations have to account for the way they practice their responsibilities and tasks given by law and regulation. Within this perspective, an important instrument for inspection is sanctioning in case rules and responsibilities are being neglected. Last, we distinguish a 'cybernetic' perspective within which inspection and control are mainly focused on learning and reflection. This perspective focuses on the ability of healthcare organizations and professionals to learn from practice, from mistakes and from dynamics in their environment. Accountability is a condition to learn and to reflect on behavior. Instruments within this perspective are communication and agreements on actions that have to be taken in order to improve the situation of quality and patient safety.

It is likely that supervision arrangements are related to the ways in which the larger healthcare system is governed, but supervision will probably also relate to the dominant values of quality, efficiency and accessibility that, in almost all countries, are dominant within healthcare sectors. The changing institutional structure as well as the changing relations (and administrative culture) in the wider society are also expected to put pressure on supervisory arrangements, putting more demands on supervision, as with the growing attention for patient safety (think of medical errors, complaints), efficiency (i.e. fraud, transaction costs), and accessibility (access times, the problem of the uninsured), supervisory bodies are often looked at for remediation. Little research has as yet been reported on the organization and functioning of supervisory arrangements ((Lewis, Alvarez-Rosete et al. 2006) being a notable exception). Further insight into the ways in which supervisory bodies relate, both to each other as well as to the public-private environment of healthcare, how supervision is given shape in practice and what its effects are, are therefore warranted. In this report we try to make a contribution to this by comparing the ways in which supervision is organized in a number of European countries.

1.3. Research questions

Against the background of the four ideal typical governance arrangements in health care and the associated hybrid and layered character of steering in health care, the central question of this research is *in what way the supervision of the quality and safety of healthcare is organized in different European countries*. This central question can be further refined with the following set of descriptive, explanatory and normative questions.

The **descriptive questions** are:

- Which functions are differentiated within the system of supervision and how are these organized? How does supervision of quality and safety of health care (e.g. through accreditation, visitation, quality assurance, regulation) relate to other forms of supervision (e.g. targeted at efficiency or competition)? Is there a difference in supervising care organizations and professionals and if so, how is this difference organized in the supervisory arrangements?
- What instruments can be employed by supervisory bodies? Next to sanctioning, one can think of e.g. financial and communicative instruments. How are these instruments used in practice?

- Which tensions and dilemmas are felt in the organization of supervision and how are influences of market mechanisms, state regulation and self regulation being dealt with?

Some **explanatory** questions are:

- How can we explain the way in which the supervisory arrangements are organized within a given country?
- How can we explain the tensions and dilemmas that are felt within the supervisory arrangements? Which roles do formal and informal institutions play in (dealing with) these tensions and dilemmas?

Some **normative** questions are:

- In what ways are the relationships between supervisory bodies, both in relation to the organizational structure of healthcare as in relation to the instruments for supervision, organized and which trends and focus points can be formulated for the future design of such arrangements?
- In what way can tensions and dilemmas in supervision – e.g. with regard to performance measurement and conflicting supervisory mechanism – be dealt with?

This research does not aim to answer all questions extensively for all countries researched, but rather aims at giving a general comparison. The questions above are the focus points for this general comparison.

1.4. Research methods

As a first step in this research we have further explored the Dutch supervisory arrangements, in order to sharpen the questions for the international comparison. For this exploration we have used existing literature and policy documents as well as interviews with key informants from supervisory organizations. Secondly, we have performed an international comparison looking at the following six countries: France, England, Spain, Norway, Germany and Switzerland. We have selected these countries on the basis of the four ideal types, aiming at a spread of the countries over the ideal types. Moreover, we have made sure to include both Beveridgean and Bismarckian healthcare systems and countries with a national and a regional organization of health care. On the basis of a first general analysis of healthcare systems, based on the literature, the countries can be classified in the following way:

Level of self regulation of collective actors		
Level of state intervention	-	+
	State/Regulation	Civil Society/Negotiation
	<i>France England Spain Norway</i>	<i>Germany</i>
	Market/Contract	Professional self regulation/Shared norms
	<i>The Netherlands</i>	<i>Switzerland</i>

Table 2. Classification of selected countries

As said, the comparison is performed at the general level. Countries have been researched using interviews with experts in healthcare policy and respondents from supervisory organizations (about two to three interviews per country), and analyses of websites and policy documents of supervisory organizations. Moreover, we have made use of publications of organizations such as the *European observatory on health systems and policies* as well as publications in professional and scientific journals. Interviews have been conducted partly by use of telephone or email and partly face to face and were targeted both at validating the description of supervisory arrangements as found in documents and the literature, and at exploring the formal and informal practices of supervising healthcare within the selected countries. Validation of findings have further been sought by discussing intermediate versions with informants from the Dutch healthcare inspectorate (particularly with Jan Vesseur and Paul Robben) and by presenting intermediate findings at a meeting of the European Platform for Supervisory Organizations (EPSO) in health care.

1.5. Layout of the report

In the next chapter, we present an analysis of supervisory arrangements in the Netherlands. Chapter three focuses on the supervisory arrangements in the six selected European countries. In chapter four we analyze our findings and compare the results between the different countries. Out of this comparison we discuss different trends and dilemmas in supervising healthcare. In chapter five we summarize our findings, give our main conclusions and reflect on them. We conclude with some notions about future supervisory arrangements and a research agenda.

Chapter 2. The Netherlands

2.1. Health care organization

The public-private mix in Dutch healthcare

Health care in the Netherlands can be described as a unitary system with Bismarckian features and has a public-private mix of provision and insurance. The Dutch healthcare system can be characterized by a mixture of steering mechanisms: from government steering, to professional/clinical and self-governance, and the market mechanism. Next to this, negotiations and consensus seeking between the 'societal partners' in healthcare (i.e. the state, professional bodies, healthcare providers, patients and insurers) has always been a dominant form of coordination in the Dutch 'polder model'. This means that there is a public-private mix at a system level. Central and local governments are constitutionally responsible for the quality, accessibility and efficiency of healthcare services, but dependent on privately owned organizations of providers and health insurers. These private organizations – on their turn – depend strongly on autonomous professionals with their own traditions, codes and regulations. Most organizations in this context can be characterized as hybrid organizations that have to deal with a variety of steering mechanisms. Most of them are privately owned, but serving public goals and using public means. They have to be responsive to the market, as well as society and government. This hybridism therefore refers to heterogeneous arrangements, characterized by mixtures of pure and incongruous origins, (ideal)types, 'cultures', coordination mechanisms, rationalities or action logics (Brandsen, Van de Donk et al. 2005).

The introduction of regulated competition

Despite the predominance of private ownership, Dutch government has gained a dominant role in regulating the health care system (Den Exter, Hermans et al. 2004). With the introduction of the Health Insurance Act in 2006, the health insurance system has been reformed. The traditional division between social health insurance and private health insurance has been replaced by a single (private) health insurance covering the entire population, aiming to make health insurance less complex and strengthening solidarity (Maarse and Ter Meulen 2006; Van de Ven and Schut 2008). Another development is the extension of market competition in health insurance. Health insurers must compete on premiums, quality of care and type of policy, since all insured have the right to choose their own insurer and policy type on a yearly basis and all insurers are obliged to accept applicants (Maarse and Ter Meulen 2006; VWS 2008). According to the new legislation, insurers must set a single flat premium rate for each type of health policy, and are forbidden to vary premium rates with age, gender or health risks. The government pays the premium for children under 18 and people with low incomes receive a government subsidy to maintain income solidarity (Maarse and Ter Meulen 2006).

With the introduction of market elements, health insurers are encouraged to negotiate favorable contracts with healthcare providers to reinforce their position on the health insurance market. The legislation allows insurers to sign contracts with only a limited number of preferred providers, including specific agreements on prices and waiting periods. Also, since the government seeks to achieve that market competition improves the quality, efficiency and access to health care, public constraints have been introduced. Examples are the obligation to every citizen to purchase health insurance, and the centralized decision-making structure concerning the health care benefits package (which is being determined by government) (Maarse and Ter Meulen 2006).

The role of transparency and quality assurance

Important conditions for regulated competition are the assurance of a level playing field between providers and insurers, adequate information and transparency about quality and efficiency, and consumer choice (Enthoven and Van de Ven 2007). The question is to what extent these conditions are and can be met in a hybrid context. In this report we focus mainly on the role of quality assurance in Dutch healthcare, which links directly to one of the crucial conditions of regulated competition in the Dutch context.

2.2. Quality assurance

Increasing attention for quality assurance

In the 1990s a series of three conferences was organized on the issue of quality management in health care. Present were all parties that had anything to say in the healthcare field, i.e. professional associations, associations of healthcare providers, insurers, patients, the Ministry of Health and the Healthcare Inspectorate. Central theme running through the conferences was the issue of self-regulation and how this should be accomplished. The idea of a 'quality system' for healthcare organizations was developed in the first conference and taken up by the Ministry in the 'Quality Act' of 1996 and in tandem the 'Act on professionals in healthcare' (*Wet Beroepen in de gezondheidszorg*, BIG). Whereas the former regulates quality assurance of healthcare organizations, the latter is focused on individual professionals. Central in the Quality Act is that healthcare organizations are responsible for having in place a quality management system to assure and improve quality of care. Much discussion in the course of the Leidschendam conferences was focused at what such a system should look like. For the healthcare system as a whole, schemes for accreditation and visitation were developed, which led to the founding of organizations like the HKZ (Harmonization Quality Care organizations) and the NIAZ (Dutch Institute for the Accreditation of Care Organizations) and the development of accreditation and visitation methods (Klazinga and Donker 1995; Klazinga 1996).

The Leidschendam conferences were important in introducing a system-level, managerial approach to quality management in which quality assurance and improvement became a task, not only of individual professionals but of collective actors such as professional associations, and boards of hospitals. Much literature of the time uses a 'modernizing' discourse (e.g. (Harteloh and Verheggen 1994) in which quality management was to move away from a 'traditional' approach which is "marked by a medical perspective" towards the application of 'industrial' principles. At the same time, it was the field of healthcare itself that would have to do most of the work, not only in the actual improvement of healthcare, but also in the development of standards and assuring that these would be met. The aforementioned accreditation bodies – led by the 'parties' in the field of healthcare – would mostly be concerned with quality assurance of organizations and the development of accreditation schemes, whereas professional associations would organize visitations and develop clinical guidelines. The role of government was thought to be one of facilitating the process and assuring that the field would actually perform, that is, government would audit the auditors.

The foundation of the Health Care Inspectorate

During the time of the Leidschendam conferences, the Healthcare Inspectorate went through considerable changes. In 1995, the Health Care Inspectorate was founded by integrating the then Medical Inspectorate of Health, the Medical Inspectorate of Mental Health and the Inspectorate of Drugs (Kingma 2004; IGZ 2008a), in 1997

followed by the integration of the inspectors responsible for nursing homes. The new Health Care Inspectorate was well received in the field, yet internally conflicts kept arising as inspectors feared the loss of (regional) autonomy, the closing of their offices, and the rationalization of methods (Kingma 2004). Also, the three medical inspectorates had always been independent from each other, leading to different working methods and styles. In 1997, as a response to these problems, the Netherlands Court of Audit (Algemene Rekenkamer) decided to conduct an inquiry in order to reorganize the Health Care Inspectorate. The report was exceptionally negative towards the inspectorate. The main conclusions were that the Minister of Health would not be able to judge the quality of care on the basis of the information provided by the inspectorate, and that supervision by the Inspectorate proved to be insufficient for a number of crucial issues (Rekenkamer 1999). The findings led to concerns in Parliament, even more so because in the same period a parliamentary inquiry on the functioning of the Inspectorate during the 'Bijlmermeer disaster'¹ was being conducted, highlighting the mistakes the inspectorate had made. The main conclusion of that report, published in April 1999, was that the inspectorate had underestimated the situation and had reacted very slowly (Kingma 2004).

One important aspect the Audit Office lacked in the policies of the Health Inspectorate was a "risk analysis on the basis of which decisions can be made as to the distribution of supervision (...) over healthcare providers" (Rekenkamer 1999:17). It was the development of this form of surveillance based on "risk analysis" that was taken up in the committee that, after the report of the Audit Office, was installed to advise the Minister of Health about the strategy of the Healthcare Inspectorate (IGZ 2001). The committee, chaired by Hein Abeln of Twijnstra Gudde, one of the larger consultancy companies in the Netherlands, starts its report by stating that under the condition of a government that is 'retreating' from its centralizing role, inspectorates become more important in assuring quality of public services. This is strengthened moreover, in the light of "some recent disasters" (referring mainly to the Bijlmer disaster) in which governmental performance was central stage in public debate. Because of this, there is a great risk that "incidentalism" becomes dominant and planned general supervision is not realized.

The committee goes on to argue that the Inspectorate, after the merge of the inspectorates for the different healthcare sectors in 1995 had already put much energy in "strengthening central steering and the implementation of unified and planned working methods, which has gained speed in the last year". This process needs further attention, also because the intended self regulation of the healthcare field, in which agreements have been made on the setting up of quality systems by healthcare organizations (referring to the Leidschendam conferences discussed in the previous section), has not led to an "integral application of such systems". Because of this, the Inspectorate cannot restrict itself to an "audit of audit" but needs to be more actively concerned with the actual outcomes of healthcare work. While stressing that this needs to be done on the basis of a trust relationship with the field, the inspectorate has to assure that this trust is actually met. A system of "healthy trust" needs to be reached (p. 8), in which an independent inspectorate – independent both from the field of healthcare and from the Minister of health as "political interference (...) is unacceptable" (idem: 9) – has to assure that quality of care is actually guaranteed. To this end the legal position of the Inspectorate needs

¹ 4 October 1992 a cargo plane of El Al Airlines crashed into two apartment buildings in Amsterdam Bijlmermeer. Besides the four crew members of the airplane, 39 residents of the apartments died and 257 apartments were destroyed. Not long after the crash had taken place, residents of the area complained about their health and in 1998 the first patients were diagnosed with an autoimmune disease, possibly related to the effects of the crash.

strengthening,² and the Inspectorate needs to have more personnel (the 210 inspectors then employed by the Inspectorate needs to grow to a total of 350 to 400), but also the practice of the Inspectorate itself needs to become more standardized and transparent. The character of the IGZ as a 'silent service', however, "undoubtedly is functional and necessary at times" and "breaking the silence can bring unwanted damage to the credibility of health care" (idem: 47) which means that a balance has to be struck between transparency and secrecy. Nevertheless, acting within the secrecy that the Inspectorate has surrounded up until the 2000s is no longer possible, if only because so many other actors, formally or informally, have gained much knowledge about the performance of healthcare organizations. Rather than being a 'silent service', the IGZ needs to develop into a 'public service', one that is pro-actively engaged in informing both the public and the healthcare field about its ways of working, standards employed, advices and interventions, also to stimulate health care organizations "to take up their own responsibility for the care for quality".

For the internal functioning of the Inspectorate, this change of the way of working has considerable consequences. For one thing, according to the committee, a lot has to be invested in making inspectors to act "professionally" as inspectors. Rather than investing in medical training of inspectors, training has to be focused on "equipping inspectors with the competencies and abilities" to act as professional inspectors. Also the regional organization of the inspectorate needs to be reconsidered, according to the committee, as there is no substantive argumentation for this regionalization, and it sustains a "mental distance" between the regions, which stands in the way of developing a unified approach that also uses the knowledge gained in all settings. A centralized organization, with professional rather than regional sections, is preferable, also because this stimulates the sharing of knowledge between inspectors working in different sectors in the healthcare field which becomes increasingly important given the development of integrated care. Also the Inspectorate needs to consider moving its central office from The Hague to Utrecht, as this creates more distance from the Ministry and enables both the approachability of the Inspectorate by healthcare organizations and the central steering of the inspectorate. Introducing "account management" furthermore is needed to assure a good handling of inspections, possible complaints etc. In summary, the Abeln committee pleaded for an inspectorate that:

- puts citizens in the heart of supervision;
- is organized as a flexible knowledge organization;
- is embedded in legislation;
- is equipped with sufficient sanction instruments;
- uses a risk model to organize supervisory tasks;
- works in a uniform manner.

Tasks and working methods

These proposed changes made clear that the Health Care Inspectorate had to be equipped better and should improve its functioning. This was also needed by the more general Dutch healthcare reform of liberalization of healthcare services, the promotion of consumer choice and competition on quality of healthcare services. Several changes in the functioning of the inspectorate have therefore been implemented, although not all proposed changes have been effected. The growth of the Inspectorate for example has never come about; additional legal instruments, like the possibility to fine healthcare organizations, have however been developed as

² The committee amongst others pleads for the possibility of the Inspectorate to "advise the Minister publicly to 'order' a healthcare provider"; to be able to suspend activities or to suspend professionals and to give a penance to a care provider.

have more standardized ways of working, based on “risk management” strategies.³ At present, several working methods can be distinguished that are also endorsed in the longer term strategy of the Healthcare Inspectorate (IGZ 2007). Health care organizations can be visited in order to examine the safeguards that are in place to ensure provision of good quality care (IGZ 2008b). To prioritize these visits, a risk-based working method consisting of three phases has been introduced, in which each step along the supervision path acts as a filter to the next step (IGZ 2008b):

1. In the first phase, healthcare organizations report on their performance on the basis of a set of performance indicators;
2. In the next phase, those healthcare organizations are visited by inspectors that show poor performance on the basis of indicators (or, as is the case with acute care hospitals: all organizations are visited, but they are extensively asked on those indicators where they show poor performance);
3. In the last phase, the Inspectorate will take measures to restore good quality of care and products.

In all phases indicators for quality and output are crucial. A lot of effort is put into developing and improving quality measures and quality management. Performance indicators form part of the set of preventive research instruments that can be used for subsequent prioritization of supervision on the basis of risk assessment (IGZ 2005). Annually, a set of performance indicators concerned with patient safety and effectiveness is presented to all Dutch health care organizations, except for specialized institutions, independent treatment centers, and private clinics with a limited health care package (IGZ 2005). The performance indicators are in line with similar developments in other countries (Pollitt, Harrison et al. 2007) and are based on information obtained from reference literature on international indicator projects and subsequently set in close cooperation with organizations of professionals and healthcare providers. Health care organizations annually deliver the data requested in the set of performance indicators to the Inspectorate. Also, each organization is expected to make its own data available in the quality report, which is statutorily required and must be accessible to the public (IGZ 2005). The Inspectorate responds with its findings to each organization individually and compiles a report of the collected data, which is also publicly available (IGZ 2005). In 2007, a separate unit at the inspectorate was formed, the ‘Bureau for Transparency on Quality of Care’ (*Bureau zorgbrede transparantie van kwaliteit*). For every sector of healthcare, new performance indicators will be developed under the guidance of a steering group per healthcare sector in which all parties (insurers, professionals, patients, healthcare organizations, and the Inspectorate) participate. The new indicators should be ready in 2013, starting with medical specialist hospital care.

A second working method is intervention or crisis supervision in case of serious problems or calamities. In these situations, an in-depth investigation is conducted focusing on the cause of the problem, the consequences for the quality of care, and ways of avoiding recurrence in the future (IGZ 2008b). Thematic supervision is a third method and encompasses matters that overarch individual institutions (IGZ 2008b). Aim is to obtain a national overview of the effects of government policy or specific risks occurring in health care and to trace structural failures and problems in quality and safety. Last, public health supervision entails gathering information about the health status of the Dutch population, especially vulnerable groups in society (IGZ 2008b). Activities undertaken include the promotion of good mother and childcare,

³ It is clear that the standardization of work practices is an ongoing task however; research in 2006 for example still showed hugely diverging opinions about and practices of inspection Kist, S. and G. Hutschemaekers (2006). Beroep inspecteur in de gezondheidszorg. Den Haag, Inspectie voor de Gezondheidszorg.

the promotion of a healthy life style, and supervising preparations in order to avoid disasters.

The overview of instruments and working methods of the Health Care Inspectorate makes clear that a few theoretical perspectives are being combined. First of all, we recognize a learning perspective (cybernetic), which becomes clear in the effort that is put into tracing medical mistakes, improving working methods and quality over time. Next to that, we see a more hierarchical perspective of sanctioning and rewarding. The Abeln Committee also introduced a third perspective that put the clients/patients more centrally in the Inspectorate's focus, which could be called a more participative perspective. In other words, the Inspectorate's activities focus on different goals under different circumstances. In the long term strategy of the Inspectorate, these different functions can also be recognized (IGZ 2007)

However, the Health Care Inspectorate is not the only inspectorate controlling healthcare services. Since the introduction of the Health Insurance Act (ZVW) and the Health Care Market Organization Act (WMG) in 2006, supervision has also been rearranged. Multiple public and private supervisory bodies exist. These are described next.

Healthcare Authority

With the Health Care Market Organization Act (WMG) more competition has been introduced in the Dutch health care system. The Dutch government, however, still controls the public goals: quality, accessibility and affordability. The Healthcare Authority⁴ is the supervisory body for all healthcare markets in the Netherlands and operate under political responsibility of the Minister of Health, Welfare and Sport and was established on 1 October 2006 (NZa 2008a). Its tasks are laid down in the Act on Healthcare Competition (*Wet Mededinging Gezondheidszorg*, WMG) and the Healthcare Authority supervises both healthcare providers as well as insurers in the curative and the long-term care markets (NZa 2008a). Its tasks are to control total (macro) costs by funding healthcare providers and ensuring correct implementation of insurance legislation, and to pro-actively setting conditions for market forces to operate and enforcing these conditions (NZa 2008a). Aim is to provide consumers with accessible, affordable, and proper health care. This aim requires a proactive approach from the Healthcare Authority and therefore the Authority itself determines a large part of its agenda (NZa 2008b). In a way, the Healthcare Authority addresses two of the other crucial conditions for regulated competition: the improvement of transparency on quality and efficiency, as well as improving the level playing field. This means that the Health Care Inspectorate and the Healthcare Authority – together – play a crucial role in assuring the realization of public goals in a system of regulated competition.

A combination of tools is used to achieve this, aiming at effective supervision in a light and proportional manner that allows an optimum amount of room for individual freedom (NZa 2008b). If possible, methods of (regulated) market operation are used to achieve efficient market behavior. Monitoring is used to outline developments in markets and submarkets; it provides the basis for forming an opinion on the use of tools on markets (NZa 2008c). The Healthcare Authority also has an advocacy role, providing recommendations on request but also proactively about policy and regulations, in the interest of further developments of the healthcare system (NZa 2008c). It can further take action in individual cases, in case competitive conditions are distorted.

⁴ In Dutch: Nederlandse Zorgautoriteit (NZa)

For supervision of compliance, a combination of proactive and responsive behavior is used (NZa 2008c). The Risk Analysis Model (RAM) has been implemented to provide systematic insight into those sectors and markets in which market developments need intensive or less intensive follow-up (NZa 2008c). Further, signals from the market are important for maintaining supervision. The Healthcare Authority is also developing a vision on how control tools are to be used by consulting market parties with regard to the annual work program. This also includes the consultation of patients and consumers. For the development of tools, the Healthcare Authority works with consultation documents, vision documents and policy regulations so that the market parties are involved in the opinion-forming process and to provide clarity regarding the way in which powers are applied (NZa 2008c). This increases regulatory certainty, which is of importance for a good investment climate in healthcare markets.

Overall, as was the case with the Health Care Inspectorate, the Healthcare Authority either operates from a more hierarchical perspective in sanctioning market behavior and steering market relationships, or uses a more participative perspective when consulting stakeholders to create support for the Authority's activities, as well as a learning perspective in order to improve market behavior over time.

Other supervisory bodies

Both the Health Care Inspectorate and the Healthcare Authority collaborate with other supervisory bodies on the basis of cooperation agreements (NZa 2008d):

- The Food and Consumer Product Safety Authority (*Voedsel en Waren Autoriteit* VWA) protects human and animal health by monitoring food and consumer products to safeguard public health and animal health and welfare. Its main tasks are supervision, risk assessment and risk communication.
- The Labour Inspectorate (*Arbeidsinspectie*) monitors compliance with occupational safety and health legislation and regulation, and it investigates violations of worker safety, takes action and provides politically relevant information (arbeidsinspectie.szw.nl).
- The Netherlands Competition Authority (*Nederlandse Mededingings Autoriteit*, NMa) monitors fair competition and takes action against parties that form cartels and fix price agreements, as well as against parties that misuse a position of economic power.
- The Competition Authority also assesses mergers and takeovers in all sectors.
- The Dutch Central Bank (*Nederlandse Centrale Bank*) supervises the integrity and solvency of health insurance companies.
- The Netherlands Authority for the Financial Markets (*Autoriteit Financiële Markten*) has the task to supervise the behavior of financial institutions.
- Last, the Data Protection Board (*College Bescherming Persoonsgegevens*) supervises compliance with the Personal Data Protection Act.

Cooperation protocols between inspectorates

A lot of different public interests are at stake at the same time in healthcare. It is not only about the quality of care services, but also about the accessibility, efficiency, and solidarity in healthcare. Next to that, in a lot of cases social security and working conditions relate to healthcare, as well as environmental and hygiene issues. Besides, efficiency, financial solidarity and prevention of fraud are also at stake. Overall, a lot of different public interests are being supervised by different inspectorates and controlling bodies. The coordination of their activities, especially when different inspectorates have to make judgments about the functioning of the same organization or the supervision of the same care services, is very important in

order to prevent an increase in financial and bureaucratic costs and long procedures, but also in order to really weigh and prioritize the different public interests. Therefore, the Dutch government has developed protocols of cooperation in collaboration with these inspectorates. The Health Care Inspectorate, for example, has protocols of cooperation with the Healthcare Authority and the Food and Nutrition Authority. These protocols divide tasks and responsibilities, e.g. what kind of advice is given to each other in cases in which the quality of healthcare is at stake. They also arrange the exchange of information and expertise. In practice, these protocols are still being developed and have to be improved further. The Health Care Inspectorate further cooperates with the Netherlands Competition Authority, the Dutch Central Bank, the Inspection for Working Conditions, and the Environmental Inspection, however, without cooperation protocols.

One notable development is the development of the *Jaardocument Zorg* (Annual healthcare document) in which supervisory work together to coordinate both the questions they ask from healthcare providers and the timing of those questions. This development is part of the overall governmental strategy to decrease the administrative burden on society.

Non-governmental supervisory bodies

Besides these public bodies, private bodies exist that supervise healthcare providers. Among these are the two accreditation bodies that have been erected by the healthcare field itself (i.e. provider organizations, patient organizations and insurers) and that are increasingly influential, if only because of governmental and 'market' pressure to get accredited. The two dominant organizations are:

NIAZ is the Dutch Institute for Accreditation in Hospitals and is a private accreditation body for Dutch hospitals (although other segments may participate as well) and was founded by three umbrella organizations (hospitals, medical specialists and university hospitals) and an accreditation organization (NIAZ 2008). The 'Plan-Do-Check-Act cycle' is the basis of the NIAZ accreditation program.

HKZ: HKZ stands for *Harmonization of quality review in health care and welfare*, and is a Dutch initiative of health care providers, insurers and patients. Its mission is harmonization and accomplishment of quality management systems and external review of such systems. To achieve this goal, HKZ produces ISO 9001 compatible certification schemes for a variety of health care and welfare institutions. HKZ stimulates the implementation of these schemes (HKZ 2008). HKZ facilitates the Council of Experts in the Health Care Sector. All certifications are developed under the authorization of this council, which is acknowledged by the Dutch Board of Accreditation.

Next to these organizations, also patient and consumer organizations have become increasingly active in 'controlling' healthcare providers, e.g. by collecting and publishing performance information. Insurers, which are private organizations in the Netherlands, also have become very active in collecting information on quality of care from healthcare providers, as has the media, which publishes annual rankings.

2.3. Analysis

The Dutch case makes clear that within a unitary state, combined with a Bismarckian healthcare system, a lot of different stakeholders, institutions and instruments are being used to inspect the quality of healthcare services. On the one hand, this has got to do with the division of tasks between central and local government bodies,

which changes due to the decentralization of tasks towards local communities. On the other hand, this has got to do with the division of responsibilities between public, private and professional actors within the hybrid insurance based healthcare system, which also changes due to the introduction of competition and market incentives. In addition to the existing supervisory bodies, we see benchmarks, monitors and accreditation procedures being developed from within the sector itself (private, bottom up, self regulation), but also individual health care insurers start to monitor aspects of quality. In all, decentralization and liberalization do change the roles in healthcare and increase the amount of public and private actors and instruments involved with the supervision of quality. This also affects the role of the Health Care Inspectorate.

The national law on quality sets the general (minimal) goals for providers, insurers and professionals in healthcare. The activities of the Inspection are steered by these regulations. Yet, a huge variety of internal and external stakeholders and supervisors – such as politicians, patients, ministries, inspectorates and boards of trustees – also address aspects of quality assurance. With the decentralization and liberalization a growing set of public and private organizations are involved with quality assurance. Next to the variety of stakeholders, a huge variety of instruments for quality assurance and patient safety is also being used within the healthcare system. There is a mixture of vertically and horizontally focused inspection, but also a mixture of proactive and reactive instruments (prevention versus sanction), the so-called ‘gefaseerd toezicht’ (phased inspection) and thematic inspection.

In the center of this hybrid system we see the growing importance of clear relationships between the Health Care Inspectorate and the Healthcare Authority. In practice, a few cases are known in which judgments about quality and creation of a level playing field do not always coincide. In the case of mergers between healthcare organizations huge players in the healthcare market are created. This leads to discussions about guaranteeing a level playing field on the one side and the effects on quality and accessibility on the other side. A huge healthcare organization can be a monopolist, but does not necessarily have bad consequences for quality. Here we see that the cooperation between inspectorates is crucial in weighing public interests. The Healthcare Inspectorate and the Healthcare Authority both look at quality issues, yet the Inspectorate is merely focused on quality of care and the Authority on quality of information for patients and insurers about this quality and accessibility of care. Both inspectorates have intensified their relationships in the past years, in order to deal adequately with conflicting priorities. The relationships between the Authority and the Inspectorate are structured through a protocol of cooperation and regular meetings at all organizational levels. Meetings between the Board of the Healthcare Authority and the Inspector General take place regularly, as well as between researchers and inspectors. This does not mean that conflicts do not arise, such as in the recent Espira case, a merger between healthcare and housing organizations in the Netherlands. Different judgements about this merger led to a lot of confusion. This will probably influence the relationships between inspectorates and authorities in the future. So, in a changing healthcare system, also their relationships are part of a growing model.

This structuring and coordination of relationships is necessary due to the introduction of market incentives and the necessity to make quality of care more transparent on one hand, and due to medical crises and numbers about the increasing amount of incidents in healthcare organizations on the other hand. We see a trend from reactive towards proactive inspection, meaning a shift from sanctioning and rewarding afterwards to prevention of quality deterioration. Here, the role of severe incidents

has been crucial (such as in the Radboud Case the deterioration of quality of heart surgery, due to amongst others the communication between doctors). In these cases, it is increasingly important that both inspectorates use common figures about quality and work complementary in order to prevent conflicting judgments about market behavior. Yet, they also point to the fact that there is no such thing as a database with clear facts and figures to be used. Currently, there are debates about the forming of a 'Healthcare quality institute' that may perform this function, but it is still very unclear which tasks and functions this might have.

Chapter 3. Case studies

3.1. Introduction

After having described the Dutch case there is need for some comparison with other European countries. All European countries face – to a certain extent – the introduction of market incentives in health care systems. The urge for more transparency and the focus on output is increasing everywhere. Yet, not all countries deal with these pressures in the same way, and not in all countries they have the same consequences for supervising healthcare. Therefore, in this chapter, we describe six countries selected for comparison. As we mentioned in Chapter 1 we selected three federal states (Germany, Spain and Switzerland) and three unitary states (the England, France and Norway). This selection also reflects a mix of Bismarckian and Beveridgian healthcare systems. This means that we have the opportunity to study a broad range of country and health system related trends and strategies. For each country we will therefore describe the state structure, the health system characteristics and the function and position of healthcare supervision within that context. We analyze the findings about how these supervisory arrangements function and deal with the trends towards more transparency and output steering in healthcare. In chapter 4 we will compare the findings between the countries.

3.2. Germany

State Structure

Germany is a democratic federal republic. Since the reunification in 1990, when the former (East) German Democratic Republic (GDR) accessed the old Federal Republic of Germany, the Federal Republic of Germany (GDR) consists of sixteen federal states. The sixteen federal states have the legislative authority, except in areas for which this authority is explicitly given to the federal government. The Federation's legislative authority falls into three different categories (Busse and Riesberg 2004)(p.4)⁵:

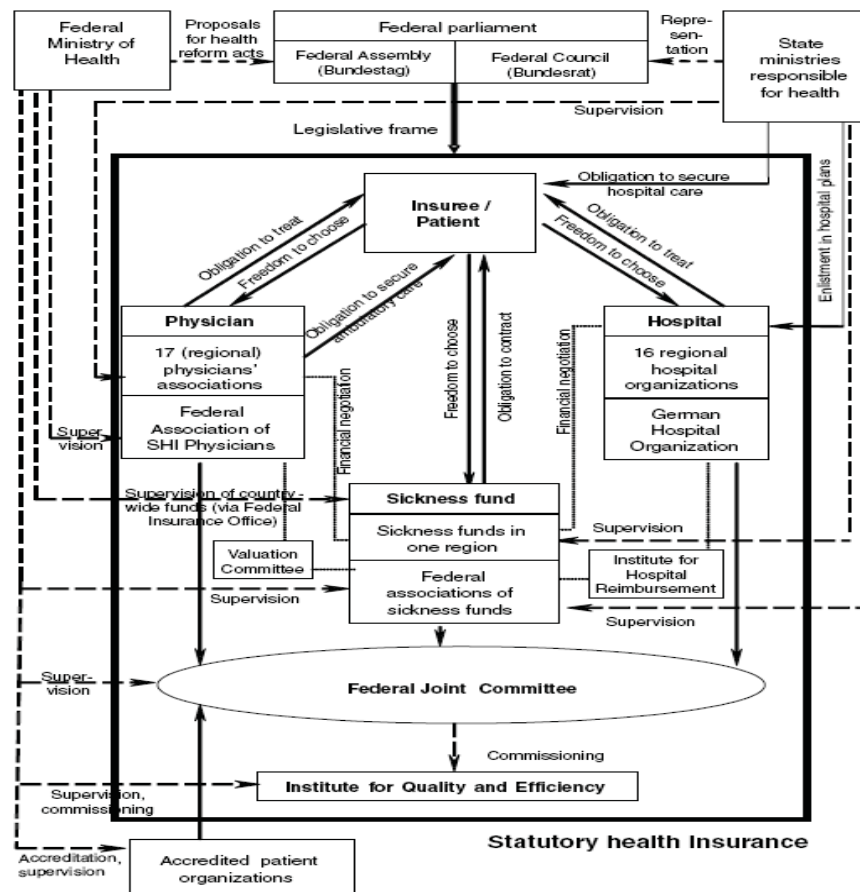
1. Legislation pertaining to foreign affairs, defense, monetary matters, air transport and some elements of taxation;
2. Legislation necessary to establish uniform laws for the whole country;
3. Framework legislation, though the states retain a considerable amount of legislative latitude.

The states can fill in any gaps left by federal legislation or in areas not specified by the constitution.

A fundamental facet of the political system in Germany – and the health care system in particular – is the sharing of decision making powers between the federal government, the federal states and the legitimized civil society organizations. In health care, national and regional governments traditionally delegate competencies to membership-based, self regulated organizations of payers and providers.

⁵ This section is largely based on Busse and Riesberg 2004.

Figure 1. German health insurance scheme



Source: (Busse and Riesberg 2004)

Figure 1 shows that the Federal Assembly, the Federal Council and the Federal Ministry for Health and Social Security are the key actors at national level. They are responsible for passing health care reforms concerning, among others, statutory insurance. The federal states are at their level responsible for planning inpatient capacities and financing investments in hospitals, nursing homes and institutions for social care and, in addition, they supervise corporatist actors and pharmaceutical manufacturers in their constituency. And thirdly, at the corporatist level non-profit, quasi-public sickness funds and their associations and umbrella organizations of SHI-affiliated physicians and dentists represented (Busse and Riesberg 2004).

Within the regulation of German health care services there is an important role played by the self-governing bodies of service providers and health insurance funds. Where the legislature creates the legal framework the medical self-governing bodies, formed by the national associations of doctors and dentists, the German Hospital Federation and the federal associations of health insurance funds, formulate and implement in detail which services will be provided and under which conditions (GBA, 2008). These various joint committees for the ambulatory sector, the hospital sector and dental care, working separately, or with their coordination committees have been

unified into the Federal Joint Committee⁶ (FJC) (Busse and Riesberg 2004). This Federal Joint Committee was established on January 1st, 2004 as mandated by a federal health reform law (GKV Modernization Act – GMG).

Health Insurance System

The German health care system is characterized by a predominance of mandatory Social Health Insurance (SHI) with many competing sickness funds and a private / public mix of providers. The system is a classical Bismarckian health care system, consisting of two parallel insurance systems: the SHI, covering about 90 percent of the population, and private health insurances covering about ten percent of the population. Germany accounts for about 250 private, non profit social health insurances and 52 private, for profit health insurances (Or, Cases et al. forthcoming). In the most prominent scheme, the SHI, sickness funds, their associations and associations of SHI-affiliated physicians have assumed the status of quasi-public corporations. These corporatist bodies constitute the self regulated structures that manage the financing and delivery of benefits covered by health insurance within the legal framework. They are based on obligatory membership and internal democratic legitimization (Busse and Riesberg 2004).

Healthcare Reforms

The Statutory Health Insurance Modernization Act of 2004 pushed many reforms a step further (Busse and Riesberg 2004). One aim behind the 2004 reform was to bring more competition into the healthcare system. A second aim was to introduce the dimension of quality in competition between sickness funds. Since the reform sickness funds are supposed to compete not only on contribution of care, but also on the quality of care as a means of diversification (Van Kemenade 2007). As part of the healthcare system reform and modernization, legislation called for the establishment of a new national institute for German health care. As a result, the Federal Joint Committee (FJC) was established and, in addition on June 1st 2004, the Institute for Quality and Efficiency in Health Care (IQWiG) was founded in the course of the health care reform as an institution of the Foundation for Quality and Efficiency in Health Care, to undertake commissions from the Federal Joint Committee and the Federal Ministry of Health. The several reforms of the German health care system have, together with the reliance on diffuse self regulatory mechanisms, hampered the emergence of a clear policy to assure quality (Lewis, Alvarez-Rosete et al. 2006).

Supervision and Responsibility

Quality assessment was already required under the 1989 Health Care Reform Act. But expert reports, like the Report of the Advisory Council for Concerted Action in Health Care in 2000, still described severe shortcomings in quality assurance (Hesse, Weinbrenner et al. 2004). Since those reports many policy changes were introduced to increase the level of quality: the Reform Act of 2000, the Case Fees Amendment Act of 2002 and the Social Health Insurance Modernization Act of 2004 were enacted for further actions to improve quality. To underscore the importance of quality in 2004, the responsibility for quality assurance moved to the Federal Joint Committee, the highest decision making board in the German self-governing health care system (Hesse, Weinbrenner et al. 2004).

Since 2004, the Federal lawmaker creates the legal framework for the Federal Joint Committee. The Federal Joint Committee, in turn, specifies the legal requirements in more detail and implements them (Hesse 2006). By doing that the Committee defines the benefit basket and decides whether a treatment or medical device will be reimbursed by the sickness funds and whether pharmaceuticals are subject to

⁶ In German: Gemeinsamer Bundesausschuss

reference prices (Hesse 2006). Therefore it is to say that it is the decision making body of the self governing bodies.

Despite of all the policy changes one of the respondents argued that quality assurance in Germany is still more or less in its infancy. This may especially be the case in the ambulatory care sector. However its is promising that the health care reform of 2007 initiates that quality measurement and assurance should be assimilated between the different health care sectors.

Since 2001, the Federal Institute for Quality Assurance (BQS⁷) leads and coordinates the external comparative quality assurance in German hospitals based on paragraph 137 of the Social Code Book V. This was done under the governance of the Federal Board of Trustees for Quality Assurance (Bundeskuratorium Qualitätssicherung) (Hesse, Weinbrenner et al. 2004). On the regional level the Regional Institute for Quality Assurance (LQS⁸) is commissioned with the external quality. The BQS and the LQS are both positioned under the responsibility of the Federal Joint Committee.

Quality assurance for hospitals now rests on a few important pillars (Hesse, Weinbrenner et al. 2004) (p.1):

- The requirement to provide internal quality assurance and quality management.
- Definition of a minimal volume for specific procedures and surgeries, such as liver transplantation; minimal volume must be met as a precondition for reimbursement.
- Requirement to provide data for the report on external quality assurance published annually by the Federal Office for Quality Assurance. Hospitals showing poor quality will face intensive dialogue including advice and support or even visitation by experts.
- Quality reports to be compiled by every individual hospital and published on the Internet by the sickness funds every two years. These reports comprise two parts: data on structural characteristics and services provided and description of the quality policy, the external quality assurance and the quality management of the particular hospital. Hospitals failing to prepare the first report (due 31 August 2005) will be visited by the SHI Medical Review Board every year.
- Finally, the evaluation of hospital procedures on the basis of scientific evidence is the prerequisite for reimbursement by the sickness funds.

On the national level the Federal Joint Committee defines the regulations, where the BQS develops the medical and methodological standards for hospitals. The LQS has the power and the opportunity for further specific regulations. And as explained earlier, in addition to the BQS and the LQS, the Institute for Quality and Efficiency in Health Care (IQWiG) is the other pillar of quality management under the responsibility of the Federal Joint Committee. The establishment of the IQWiG was part of an overall strategy to advance quality assurance in the total health care system. This was part of a strategy the national government had on its agenda since the beginning of the legislative period that started in 2002 (Hesse, Weinbrenner et al. 2004).

The IQWiG aims to foster quality and transparency in health care, and is responsible for the scientific evaluation of the effects, quality and efficiency of health care services. The work includes the assessment of pharmaceuticals, surgical procedures, diagnostic tests and clinical practice guidelines (Hesse 2006). The IQWiG reports its findings to the Federal Joint Committee. As commissioned by the FJC itself, any rejection of its advice must be accompanied by a written explanation

⁷ Bundesgeschäftsstelle Qualitätssicherung

⁸ Landesgeschäftsstelle Qualitätssicherung

towards the IQWiG. The Federal minister's agreement is not required to put into effect any proposal to extend coverage, but the minister is able to exercise a veto over any given decision (Lewis, Alvarez-Rosete et al. 2006). However, one of the respondents argued that this is more like tokenism: to show that the minister is the official supervisor.

A further, more profound level of interpretation of the strategy for quality assurance is provided by hospital management in deciding whether individual professionals meet the clinical requirements for the treatment. This is also subject to regulation by the Medical Review Board, a cooperative institute of sickness funds (Lewis, Alvarez-Rosete et al. 2006).

Ownership and financing of quality inspection

As said, a fundamental aspect of the German health care system is the sharing of decision making powers between the Federal government, the federal states, and the corporatist organizations consisting of sickness funds, physicians and dentists as well as other legitimized civil society organizations (Busse and Riesberg 2004; Van Kemenade 2007). The Federal Joint Committee has been institutionalized as a legal entity under public law. It has wide-ranging regulatory powers which are laid down in the Social Code Book that governs statutory health insurance (G-BA, 2008). The BQS and LQS are both positioned under responsibility of the Federal Joint Committee and thus under public law. The IQWiG, however, is established by the Federal Joint Committee as a foundation under private law and is financed through means of the Statutory Health Insurance (Hesse 2006).

Independency of quality inspection

One of the big issues within the debate about the inspection of quality is the independency of the IQWiG (Hesse 2006). The creation of the IQWiG in its current form was to a certain extent not consequential. It was planned as an independent, neutral player and 'regulator' in the system but it was politically not achievable to make it a state-run institute. This is still causing some difficulties and it will need more time for the institute to find its position in the system (Hesse 2006). One of our interviewed respondents even stated that as a result of this debate, the IQWiG became politicized and therefore there is resistance to work for the IQWiG. The opposition is also explained by the strong medical profession: the strong professional autonomy and paternalistic approach by the doctors, clarifying the resistance against controlling and re-controlling.

Out of their professional autonomy, the doctors are strongly opposing against any state- interference, arguing that they should be in power and that there cannot be any kind of 'state-medicine'. This is the reason that the IQWiG could not be placed under the Federal Government. Experiences from the first years of the IQWiG show that changes in the health care system are hard to apply because of the very heterogeneous structure of the system and the legions of lobbyists (Hesse 2006). Hesse (2006, p.7) argues that: 'It seems that the foundation of an independent institute is easier to realize in a state health system, than in Germany with its self governing body strongly defending its position'.

Procedures and Instruments

The German system of quality assurance has previously been characterized by confidentiality. However, the current system is opening up by making the results publicly available. The BQS system for hospital care provides indicators for internal quality management as well as for external quality comparison. These indicators are the basis for German hospital care management, the BQS performance measurement, resulting in the Hospital Quality Reports is mandatory. These Hospitals Quality Reports are published annually. The general standards are the

BQS indicators for hospital care. Within the system of gaining the quality information the hospitals send their data (indicators) to the BQS.

The administration still differs between the federal states, meaning that in practice, comparability is partly limited, although they strive for consistent modes all over the country.

Thus, the BQS defines indicators and data sets (IT- specifications), where the LQS provides the data analysis for the hospitals and performs the dialogue (Strukturierten Dialog) for suspicious results. Five percent of the hospitals will randomly be audited after the internal quality measurement, as well as the top-ends. By using performance indicators in the first phase, followed by a dialogue in the second the German inspection functions on a proactive basis.

3.3. Switzerland

State Structure

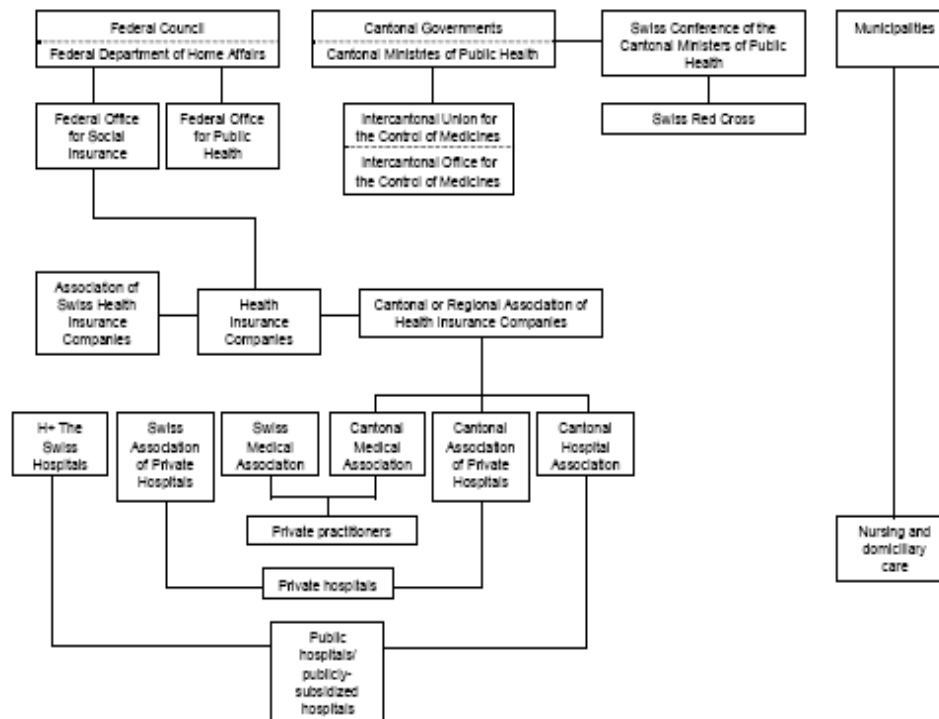
Since 1979 Switzerland is a federal republic made up of 23 cantons, three of which are divided into demi-cantons. Therefore Switzerland comprises 26 entities that are sovereign in all areas that are not specifically designated the responsibility of the Swiss Confederation by the federal constitution (Van Kemenade 2007). Each canton and demi-canton has its own constitution and a complete body of legislation stemming from its constitution. The legislative authority is a unicameral parliament that in most cantons is elected by proportional representation. Like the Swiss Confederation, the cantons have an executive body consisting of between five and nine members. In contrast to the Federal Council, the members of the cantonal decision making bodies are directly elected by popular vote. Similar to the Federal Council, the individual members of a cantonal executive take part in the collective decisions of the regional government and also take responsibility for one or more administrative departments (Minder, Schoenholzer et al. 2000).

The Swiss Confederation can legislate only when explicitly empowered to do so by constitution. Over the health system, the constitution only grants limited powers to the Confederation. The health service is one of the areas of government activity in which the cantons have a decreasing but still relatively high degree of independence. The 26 entities are acting autonomously in the organization of healthcare in their region – specifically cantons are charged with regulation, hospital accreditation and finance along with disease prevention and health education (Minder, Schoenholzer et al. 2000). The result is 26 slightly different systems.

Most cantons operate their own hospitals by having a seventy five percent ownership. There are also some cantons that subsidize private hospitals and there are also private clinics that do not receive any state support. The revised health insurance law (the LAMal) enacted in 1996, requires the cantons to draw up plans for providing hospital care according to need and to produce a list of hospitals and nursing homes that are eligible for reimbursement under compulsory health insurance. It is the cantons that define which hospitals are reimbursed. Opposing is the system of reimbursement of ambulatory care, where reimbursement by the health insurance always will take place. This strict separation between in-house and ambulatory care is one the main characteristics of Swiss health care system.

Preferences of (potential) patients determine the structure of the (cantonal) public services to a degree found in just a few other countries. The over seven million residents are directly involved in the political process, through seemingly continual referenda. Regarding health care, this means that patients really do influence the system – by voting on local hospital enlargements for example (Jacobs and Goddard 2000).

Figure 2. Organizational chart of the Swiss healthcare system



Source: (Minder, Schoenholzer et al. 2000)

Bismarck vs. Beveridge System

Switzerland's health care system is largely financed through compulsory health insurance premiums. Switzerland has more or less a Bismarckian health care system. Since the revised health insurance law (LAMal) came into force all permanent residents are legally obliged to purchase obligatory health insurance policies (Minder, Schoenholzer et al. 2000).

Like in most developed countries, the Swiss healthcare system is funded through both public and private sources. However, the percentage of expenditure from public sources is one of the lowest in the European region (Jacobs and Goddard 2000). In Switzerland, characterized by liberalism, social health insurance is financed through per capita premiums and social transfers from the regions (Helderman, Henke et al. forthcoming). The insurance providers who comply with the requirements of the health insurance law and are registered with the Federal Office for Social Insurance may provide compulsory health insurance (Minder, Schoenholzer et al. 2000).

For the in-house patients fifty percent of the medical bill will be paid by the canton, the other fifty percent will be paid by the social insurance company. As a patient you will only be reimbursed if you are treated in your own canton. Only for medical reasons you will get access and reimbursement for treatments in other cantons.

Reforms

The new law on health insurance (LAMal) is a federal law and therefore it had to come in force in all cantons in 1996. It was a long process before the new law was implemented, and it had to survive a popular referendum.

The law introduces a degree of competition into the health care system that is comparable to the Netherlands and Germany. Switzerland has been continuously attempting to reform its health care system in the last ten years, and the principal aim of all policy changes was to reduce health care costs which have been rapidly rising

since 1970. Consequently, the LAMal was an answer to the inflation in health care (Helderman, Henke et al. forthcoming). By the law incentives were introduced on the demand side to increase self-responsibility, as well as on the supply and financing sides to act in a competitive way. However, in practice the competition elements are bound by the cantonal barriers, including cantonal ownership and cantonal reimbursement criteria.

An OECD report of October 2006 described that the suppression of the cantonal barriers is an inevitable part of a reform process making the Swiss health care system more cost-effective (OECD 2006). Reasoning out of this report the National Council amended in March 2007 the draft bill of the Council of States and decided to remove cantonal boundaries step by step. Aim of this draft bill was to improve the cost-effectiveness of the system and to improve the quality of care by introducing market principles in the health care system. The cantons were without doubt the stakeholders who opposed the free choice of hospitals most (Crivelli 2007). The element of the draft bill that the cantons opposed to is the so-called principle of 'Cassis de Dijon', in the context of hospital care establishing the freedom for patients to choose any hospital which appears in the planning scheme of at least one canton and, as a result, diminishing the constraint of cantonal territoriality. The regions, however, would favor the maintenance of the principle of cantonal territoriality. If the National Council's solution were confirmed, it cannot be excluded that the cantons would decide to set up a referendum (Crivelli 2007).

Supervision and Responsibility

Since as long ago as 1877, when the federal law on freedom of medical personnel in the Swiss Confederation was enacted, the national government has been responsible for the accreditation of 'scientific professions' (Minder, Schoenholzer et al. 2000). This term covers doctors, dentists, veterinarians and pharmacists; they are all required to pass an exam, and having done so they are awarded a diploma that guarantees them freedom to practice anywhere in Switzerland, providing they also apply for a license to practice from the cantonal authorities. Since the introduction of the law on health insurance quality of health care has evolved to a progressively more important issue within the Swiss health care system. The importance of quality in health care has increased for several reasons. The most important factor is the variation in health care outcomes that cannot be explained by differences in patient characteristics (Luhti 2002). In the LAMal articles about quality of care are included. However, they are enclosed in the purpose of being reimbursement criteria (efficiency, effectiveness and appropriateness), and therefore they are not very specified.

The federal government can, after meetings with interested organizations, arrange scientific evaluations in order to ensure quality in health care. However the notion of quality is not further specified. A common understanding of what quality is or should be in health care lacks in Switzerland, and this makes the inspection of quality rather difficult. Quality assurance is a shared responsibility between the cantons and the federal government. Where the federal law on health insurance deals with quality only in broad terms (efficiency, effectiveness and appropriateness), the cantons have their own quality criteria. Cantonal responsibilities are laid down in their own, far more detailed, cantonal laws. Almost all cantons have their own cantonal laws, except for some small cantons, which work together to reach a harmonization of laws (e.g. the Central Switzerland region). One of the interviewed experts explained that, as a result, supervision is not only very heterogeneous, but also that the shared responsibility between the federal government and the cantons has led to power game between the cantons and the federal government.

Besides that, the cantons are involved in the paying scheme and contracting of the hospitals, and therefore the cantons are much empowered in the implementation of quality regulations in in-house care in their own canton.

At the moment, quality inspection is mainly conducted by private supervisory (certification) bodies, which are mandated by the public government (mostly cantonal governments). Next to that, a lot of professional umbrella organizations inspect their own professionals. This is another reason the system is very blurred. To deal with this heterogeneity the Interkantonalen Verein für Qualitätssicherung und –Förderung in den Spitalern (IVQ) was founded in November 2007. In this association for the in-house care, cantonal authorities, insurance companies and stakeholders from the health care providers are represented. The association is currently supported by 23 cantons. The aim of the association is to measure quality indicators based on a common strategy, to deal with the unstructured, heterogeneous and underdeveloped quality supervision in health care in Switzerland.

Critical incidents in health care have increased the attention of patient safety much more than the importance of quality of health care. One of respondents elaborated that incidents are used to convince and explain to the public the importance of patient safety aspects. Another respondent argued that by focusing publicly on patient safety it becomes an issue 'coming from the street'.

Ownership and financing of quality inspection

In the current system, the Federal Office of Health collects quality related data at the national level. And at the cantonal level the similar Cantonal Office of Health collects the regional data. Besides those offices there are many privately owned certification and accreditation bodies, like Verein Outcome, EQUAM, sanaCERT, et cetera. These private bodies are mandated by the public (cantonal and federal) governments and are therefore public-private partnerships. Next to that the various umbrella organizations (SanteSuisse, H+, FMH) want to control and supervise their own institutions.

Independency of quality inspection

Independency is an important factor in the system of quality inspection. First of all, there is a debate going on and questions are being raised about the independency of the professional umbrella organizations inspecting their own organizations. Secondly, there was a debate prior to the foundation of the IVQ. The cantons and other stakeholders were afraid of losing some of their powers; in essence they were afraid that a national authority would be established. This debate eventually led to the creation of the IVQ, where cantonal authorities, insurance companies and stakeholders from the health care providers are represented.

Procedures and Instruments

At the moment, quality inspection is mostly conducted by private supervisory (certification) bodies mandated by the public government (most cantonal governments). Next to that, a lot of professional umbrella organizations inspect their own professionals. Because the canton is the owner and the contractor of the hospitals (DRG system) the outcome of quality inspection will be the input of contract negotiations between cantons, hospitals and insurers. Thus, the quality system is using the outcomes of quality measurement more in a reactive way.

In Switzerland, there is a new trend towards publication of the results of the inspection; those are published by the supervisory bodies and by the cantons. This is a new phenomenon in Switzerland. And at the moment all different supervisory bodies tend to publish their own quality reports and this might question its value for the public.

3.4. Spain

Spain is a parliamentary monarchy. The Constitution of 1978 ended a long period of dictatorship, after which the country underwent a major change of the State and of its political structure and its legal framework (Rico, Sabes et al. 2001; Duran, Lara et al. 2006). One of the main elements of this transformation has been the profound political decentralization of state structures incrementally implemented since the beginning of the transitions of democracy. Territorially, the political organization of the Spanish state is made up of the central state, seventeen regions (Autonomous Communities) with their respective governments and parliaments, fifty provinces, and almost 8000 municipalities (Rico, Sabes et al. 2001)⁹.

Each of the seventeen Autonomous Communities has one basic law (Statute of Autonomy). Together with the 1978 Constitution, these basic laws comprise the constitutional framework of Spain. However, this does not automatically mean that Spain is a federal state and some respondents stated that it is better defined as a system decentralized into regional autonomies. But, the distinction between *symmetric* and *asymmetric federalism* should be recalled here. As Rico et al (2001, p.21) explain: 'symmetric federalism consists of a territorial division of powers which gives all regions the same constitutional powers. Asymmetric federalism, on the contrary, refers to a territorial structure of the state allowing for maximum political self-government by some Autonomous Communities alongside only administrative decentralization by the rest of the regions' (Rico, Sabes et al. 2001). The prevailing power-sharing scheme in the healthcare sector directly results from the partial agreement reached between the defenders of both institutional alternatives during the democratic metamorphosis and the drafting of the constitution. In some of the Autonomous Communities with characteristic cultural traditions and language (and most notably in Catalonia and the Basque Country), there are strong nationalistic groups and political parties with self-governing interests, which stand for asymmetric federalism. In the rest of the Spain, on the other hand, there tends to be support for symmetric federalism.

Healthcare and social security are shared areas of responsibility, although to very different extends in the different Autonomous Communities. This is the result of the asymmetric federal system.

The basis for the current organizational structure of the healthcare system in Spain was formed during the transformation to democracy. From 1986, the transition to a National Health System involved a reform of financing, which has transformed the former insurance-oriented system into a system financed by taxes, with almost universal coverage. The reform towards decentralization was completed successfully in 2002 (Duran, Lara et al. 2006). Within this decentralized system, the national government has the responsibility for promoting coordination and cooperation in the health sector.

The Ministry of Health and Consumer Affairs is responsible for the management of health policy and retains some exclusive competencies, while the system is highly decentralized to the regions. The relationship between the National Ministry of Health and the Autonomous Communities is through the Interterritorial Council (Consejo Interterritorial), a body where all of the autonomous governments are represented. The Interterritorial Council of the NHS acts as the coordinating body for the state and the regions in health care, with advisory functions only.

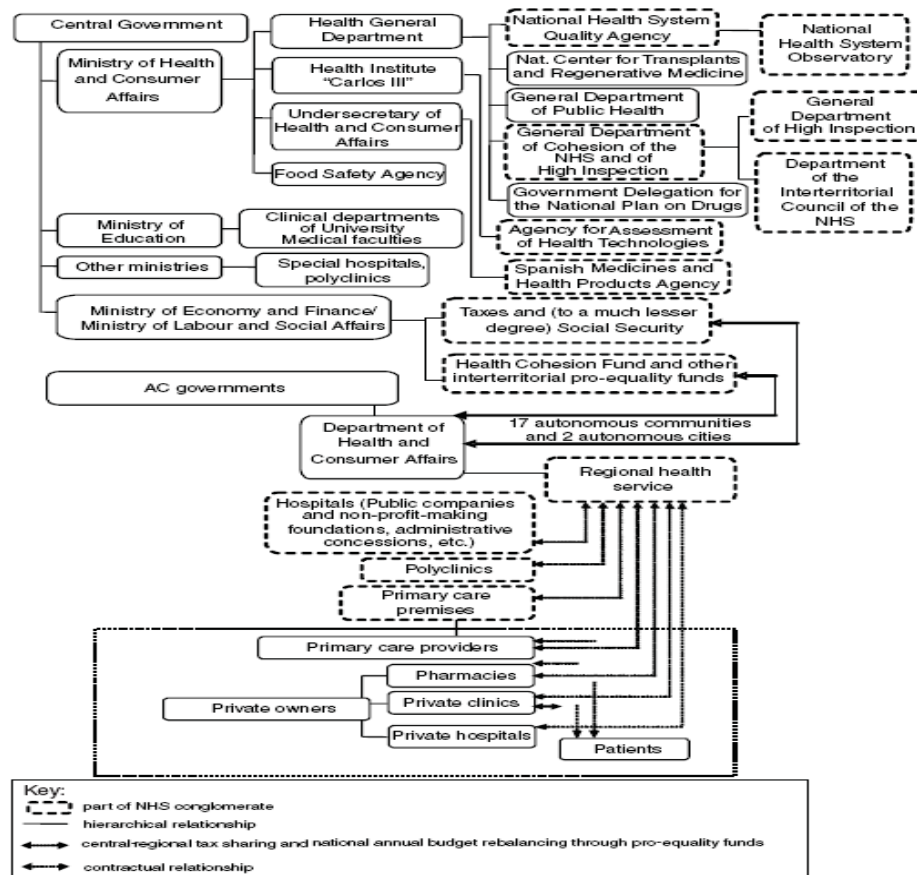
⁹ This section is largely based on Rico, Sabes and Wisbaum 2001.

Partly owing to the way in which the process of decentralization took place, the transfer of services was carried out under different conditions, which resulted in a complicated system of health care financing and, ultimately, in major problems regarding control of global health care expenditure (Duran, Lara et al. 2006).

Catalonia

Catalonia was the first autonomous community in Spain to take on healthcare responsibilities in 1981. The healthcare system in Catalonia is a special case in Spain, because of the clear separation between the purchasing and the provision of functions. The Catalan Health Authority purchases services from providers, regardless of whether they are publicly owned (Van Kemenade 2007). Thus, unlike the rest of Spain, the Catalan Health Service makes use of both public and private providers. Public provision is through the Catalan Health Institute (Instituto Catalan de Salud, ICS); and, in turn, the ICS receives an annual budget directly from parliament (Duran, Lara et al. 2006).

Figure 3. Organizational chart of Spanish healthcare system



Source: (Duran, Lara et al. 2006)

Bismarck vs. Beveridge System

The 1986 General Health Care Act outlines the main principles for the Spanish National Health System (NHS). This Beveridgean system, created from the social security health services and providing universal coverage with free access to health care, is publicly funded – mainly through taxation – and has a decentralized organizational structure (Duran, Lara et al. 2006). Governance of the system is

decentralized, with local organization in each of the 17 Autonomous Communities, which comprise the Spanish state. The general principles of the National Health System as defined by the 1978 Constitution and the 1986 General Health Care Act are (Rico, Sabes et al. 2001)(p.17):

- Universal coverage with free access to health care for almost all citizens;
- Public financing, mainly through general taxation;
- Integration of different health service networks under the National Health System structure;
- Political devolution to the Autonomous Communities and region-based organization of health services into health areas and basic health zones;
- Development of a new model of primary health care, emphasizing integration of promotion, prevention and rehabilitation activities at this level.

Catalonia

The public health care system in Catalonia is, similar to the national system, a National Health Service, free at point of use. It provides universal coverage for all citizens of Catalonia. There is a single purchaser of health care services – a 1990 law established the Catalan Health Service (CatSalut) to purchase, finance, coordinate and evaluate health services (Lewis, Alvarez-Rosete et al. 2006). Despite the arm's length position of CatSalut, which is established as an autonomous body, there is high degree of integration between the CatSalut and the Catalan Ministry of Health. CatSalut is governed by a council chaired by the minister and works closely with the Ministry of Health. Twenty five to twenty eight percent of the Catalan population has double -public and private- coverage. In many cases the reason for having a dual coverage is for comfort reasons and to avoid waiting lists in case of minor health problems, such as minor surgery.

Reforms

After the transformation of the state, many reforms took place. The objectives of the health reforms of the 1980s were to extend and rationalize the public health sector and to improve coverage and access to health care, while the focus of reforms during the 1990s was on cost-containment (Duran, Lara et al. 2006). After that, during 2001-2003 a number of other reforms took place. Towards the end of 2001 health care issues were included for the first time in the new financial system for the autonomous communities approved by law. At the same time an agreement was reached to complete the decentralization process and shift the responsibility for health powers and resources to the ten autonomous communities.

Having achieved full decentralization of the health administration, the need to clarify and strengthen responsibilities in the collaboration between public administration departments had become more urgent than ever. The law on Cohesion and Quality of the NHS approved May 2003 sets up the framework for ensuring cohesion and quality in the NHS in response to a new context of increasing need for coordination and collaboration within the NHS. The main points of the act are (Duran, Lara et al. 2006) (p.160):

- Citizens' right throughout the whole NHS.
- Maximal time taken in accessing services in autonomous communities.
- Right to choose a physician and obtain a second opinion.
- Equality in conditions and guarantees for patients moved from one region to another.

Supervision and Responsibility

Interest in quality and patient safety is the result of the fact that the number of patient claims (in general and judicial claims in particular) has increased considerably, as

well as patient dissatisfaction with the NHS system or some doctors. One of the reasons might be that citizens are now more aware of their rights and are also better educated and informed, and their expectations of health services have increased as well (Martinez-Garcia 2006a).

At national level there is a mandatory system of quality accreditation for public providers run by the Ministry of Health and Consumer Affairs. Quality accreditation of providers is the primary responsibility of a department within the Ministry of Health (Lewis, Alvarez-Rosete et al. 2006). This scheme sets national care standards for all providers. Although the national government is responsible for the accreditation scheme, the assurance of quality is mainly a regional responsibility, with a trend towards more decentralization in Catalonia. To set a common strategy, the Ministry of Health and Consumer Affairs has founded the National Quality Plan to share experiences among regions and for fostering certain measures related with health care policies through financial support. However, in any circumstances those policies are mandatory.

Different ideas and measures to increase patient safety and reduce medical errors are being debated in Spain. Some of the measures are included as objectives and measures in the National Quality Plan, to be further developed and specified in the near future, and others have come from other administrations and institutions (Martinez-Garcia 2006a). The National Quality Plan considers patient safety as one of the strategic objectives of the Spanish NHS. With a budget of €50 million, and managed by the Ministry of Health and Consumer Affairs through the National Health System Quality Agency, this Quality Plan will deal with some of the key challenges of the NHS (Duran, Lara et al. 2006). The most important part of its role, with a budget of €33.8 million, will be devoted to financial measures and projects on the improvement of efficiency within the NHS, and on patient safety and reduce clinical errors. Other objectives are to reduce the costs of the insurances of professionals (which cover their errors), and increase professional guarantees and patient guarantees. The plan includes different measures to be implemented, such as (Martinez-Garcia 2006a)(p.1):

- Studying different aspects of patient safety: e.g. on adverse effects, on how health professionals perceive patient safety and what they think about it.
- The creation of strategic associations between the NHS and universities, medical and scientific associations.
- Information campaigns on this issue, symposiums and seminars, addressed to health care managers and health professionals.
- Designing clinical management tools for increasing the safety for health professionals.
- Providing a quality guarantee for procedures, services and health institutions through the establishment of basic regulations on quality accreditation. Currently, different accreditation systems exist for example in Catalonia; they are now in the process of also including management accreditation and external evaluations.
- Establishing a national system of notification of adverse effects.
- Creating and implementing (together with the autonomous regions) projects to increase and evaluate safe practices in different areas (e.g. thrombosis, nosocomial infections, and drug administration errors).
- Improving information for doctors on drug effects and other relevant information on drugs.

Hospitals have a commission – specified in the contract, where possible incidents are examined. An annual memory of the activities developed by the commission is

delivered the Health Region (CatSalut in Catalonia). Critical incidents, such as death in elective surgery are published in the media, and this may cause a change in methods.

Catalonia

In Catalonia, 'Opening Permissions' are required for all health care providers. Those permissions are regulated by the Catalan Ministry of Health (Lewis, Alvarez-Rosete et al. 2006). Next to that, the national mandatory system of hospital accreditation for public providers is being effective. The Catalan accreditation process therefore provides national care standards. This accreditation system is based on the Model of the European Foundation for Quality Management. The accrediting body is the Ministry of Health of Catalonia itself, which also uses standards set by a commission of experts. After an initial self-evaluation, hospitals undergo technical audits for the accreditation committee to make the final decision. The Ministry of Health has recently tendered the services of some independent audit agencies to perform the inspection process (Lewis, Alvarez-Rosete et al. 2006). At this moment, the accreditation system is compulsory for hospitals, but still voluntary for primary health care services. Nevertheless, the CatSalut is launching a new plan for primary care and one of the measures is to have a mandatory accreditation system.

The Catalan health authority has started the process of increasing the quality of health services also by taking into account patients' views on the quality of health services in 2005. The way to do so has been to take quality objectives into some of the contract negotiations between the administration (the purchaser) and providers. The quality aspects included -as well as the methods used to monitor them, are established in agreement between the payer and the provider. Included programs are aimed at increasing the perceived quality by patients on issues such as waiting lists, processes, information, access to primary care, et cetera. A non-fixed (variable) payment to providers is linked to the attainment of quality objectives. The new agreement between providers and payers should increase the quality level. The process seems to be a good one since part of the payment to providers is linked to the quality of the services they provide, and at the same time it seems that there are good relations between the purchaser and providers (Martinez-Garcia 2006b).

In addition to these accreditation and contracting schemes, the Catalan Agency for Health Technology Assessment has been founded to report to the CatSalut and is responsible for advising on the adoption of new technologies (Lewis, Alvarez-Rosete et al. 2006).

Ownership and financing of quality inspection

In Catalonia the accreditation body is the Catalan Ministry of Health and, in addition, they recently tendered the services of a number of independent audit agencies to carry out the inspection process. The before mentioned Catalan Agency for Health Technology Assessment has been created as a public not-for-profit company, which is responsible for advising on the adoption of new technologies (Lewis, Alvarez-Rosete et al. 2006).

Independency of quality inspection

In Catalonia, there are no fully independent regulatory bodies. In general, regulatory functions are executed by informal relationships between the Ministry of Health, the quasi-independent CatSalut and a mix of independent and state-owned providers. Furthermore, CatSalut uses a voluntary quality assurance scheme for hospitals based on 'consensus indicators' (Lewis, Alvarez-Rosete et al. 2006). The Catalan Health Service (CatSalut) has its Board of Directors (Consell de Direccio) consisting of representatives from political parties, trade unions, consumers and health

professionals associations. The health plan of Catalonia and the annual budget of the Catalan Health Service are approved by this board (51% of the votes belong to the autonomous government).

Procedures and Instruments

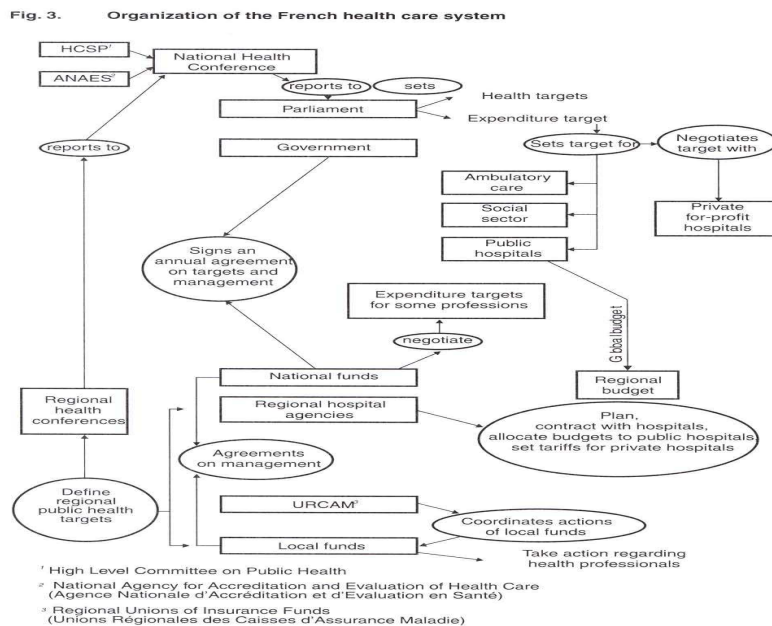
The purpose of inspection on quality is more pro active in Catalonia, but, of course, in case of incidents it is also reactive. Two main instruments of inspection on quality are being used. The first instrument is accreditation and the other one is by contracting between CatSalut and health care providers. Between one and five percent of the total budget that providers (both hospitals and primary care) receive from CatSalut is related to the achievement of health goals, many of them related to quality assurance. The quality related outcomes are used in different ways: communicatively is the first step; for instance, discussing the results with a hospital. Financially, there are two options: (1) not contracting a type of surgery anymore to this hospital, and (2) possibility of a fine. In extreme situations a centre can be closed.

3.5. France

State Structure

France can be characterized as a unitary state. Jurisdiction in terms of health policy and regulation of the health care system is divided between the state (parliament, government and various ministries), statutory health insurance funds and, to a lesser extent, local communities, particularly at the department level (Sandier, Paris et al. 2004). The institutional organization of the system was highly affected by the Juppé reform of 1996. In addition to introducing parliamentary control over the health care system and its resources, the reform significantly reinforced the role of the regions, creating new institutions at the regional level. At national level, the Parliament and the Ministry of Health are responsible for health policy and health care expenditure (see figure 4).

Figure 4. French healthcare system



Source: (Sandier, Paris et al. 2004)

Since the reorganization of the Ministry of Health, the following structures have been included: a general directorate of health responsible for health policy; a directorate of hospital and health care responsible for the management of resources; a directorate of social security responsible for financial matters and supervision of social security organizations; and a general directorate for social policy responsible for the social aspects of health care. Since the 1990s, a process of regionalizing the organization and management of the health care system has begun. Nowadays, regional hospital agencies (ARH) are responsible for hospital planning, financial allocation to public hospitals and adjustment of tariffs for private for-profit hospitals. The regional unions of the health insurance funds (URCAM) bring together the three main health insurance schemes at the regional level. They coordinate the work of the funds and give impetus to a regional policy of risk management¹⁰.

Bismarck vs. Beveridge System

The French health care system has its origin in a Bismarckian system. It is predominantly funded through tax revenues and social health insurance contributions from employers and employees. All legal residents are covered by public health insurance, and the population has neither choice to opt out nor any choice of insurer (Sandier, Polton et al. 2002). All residents are automatically affiliated to a health insurance scheme on the basis of their professional status and place of residence:

- The general scheme covers salaried employees (and their families) in commerce and industry (84% of the population)
- The agricultural scheme covers farmers and employees (7%)
- The scheme for non-agricultural self-employed people (5%)
- Small schemes for certain categories, such as miners and seamen (4%)

(Sandier, Polton et al. 2002; Sandier, Paris et al. 2004).

Further, patients have free choice of provider, meaning they can visit any GP or specialist practising privately or working in hospital outpatient departments, without referral or any limit on the number of consultations. They can also be hospitalized in the public or private hospital of their choice. Only 1% of patients have agreed to sign up with a referring GP with the incentive not having to pay for consultations up front (Sandier, Polton et al. 2002).

Supervision and Responsibility

With regard to supervision and quality assurance, the Inspection générale des affaires sociales (IGAS) is one of France's three inter-ministerial Inspectorates-General carrying out an all-embracing role – not just inspection – over key areas in health care (IGAS 2006). It was established in 1967 and its core responsibility is to ensure compliance with and implementation of regulations and to verify the proper use of public funds and donations. It also fulfils an advisory role, by providing decision-makers with an independent overall view of the performance of their departments, and by evaluating the effectiveness of public policies or initiatives (IGAS 2006).

The Direction Régionale des Affaires Sanitaires et Sociales d'Ile-de-France (DRASS) is a subdivision within amongst others the Ministry of Health Care and is responsible for regional healthcare. It analyses the need for healthcare, determines the priorities in public health and evaluates the functioning of health care by inspecting and

¹⁰ Parts of the texts in this paragraph are mainly derived from Sandier, S., V. Paris, et al. (2004). Health care systems in transition: France. *Health care systems in transition*. S. Thomson and E. Mossialos. Copenhagen, WHO Regional Office for Europe on behalf of the European Observatory on Health Systems and Policies.

controlling safety in health care organizations, laboratories and pharmaceuticals in their own region (Peltier 2003).

Another important institute, the Agence nationale d'accréditation et d'évaluation en sante (ANAES), was created in 1997 and was responsible for establishing the status of information about medical strategies, for contributing to improvement in quality and safety of care, and for performing the accreditation procedure for health establishments (Sandier, Paris et al. 2004). However, the National Health Insurance Reform Act in 2004 created a new institute, the Haute Autorité de Santé (HAS), taking over the responsibilities of the ANAES (HAS 2007). HAS is an independent, scientific, public authority with its own legal identity. It makes independent, scientific-based decisions on healthcare quality through an integrated, patient-oriented approach involving all stakeholders. Furthermore, it has expertise in many fields of healthcare and produces guidelines for all stakeholders in the health care system. HAS has a key regulatory function in the new French healthcare landscape created by the national health insurance reforms: it advises the government, the national health insurance fund and healthcare practitioners, patients and users (HAS 2007).

Ownership and Financing of Quality Inspection

Doctors, dentists, and pharmacists are self-regulating through their professional organizations at national and department level, in terms of professional ethics and the right to practice. The Minister of Health determines the norms for hospital care, while compliance is monitored by doctors at regional and department level, and by the medical service of the health insurance fund. Institutions and professionals can also be involved in the procedures for quality control by the HAS, including the compulsory accreditation of public and private hospitals and the voluntary audit of self-employed professionals. HAS also prepares practice guidelines that are issued to the entire medical profession, most of which are voluntary in nature. Systematic evaluation at the level of individual health care professionals does not exist. Malpractice giving rise to patients' complaints are dealt with by professional associations and courts (Sandier, Paris et al. 2004).

Since IGAS is one of France's three inter-ministerial Inspectorates-General, it is financed by the Ministry of Health. This is also the case for DRASS, the (regional) subdivision within the Ministry. HAS was set up by the French government, but it is not a government body. Indeed, it is an independent public body with financial autonomy. However, it receives an annual budget of 60 million Euros (HAS 2007).

Independency of Quality Inspection

IGAS and DRASS are (sub)divisions within the Ministry of Health Care and thus are not totally independent organizations. HAS, however, does have an independent, scientific and public status.

Procedures and Instruments

The traditional inspection functions of the IGAS are intended to produce a better control of all institutions which contribute to the implementation of policies relating to public health, social security and provision, work, employment and professional training (Malle, De Cherge et al. 2003). The purpose of these control functions is in-depth investigation of compliance with the regulations and proper use of public funds. A report is produced after all controls and the final version of the report, after discussion with the managers of the controlled organization, is sent to the Minister (Malle, De Cherge et al. 2003). However, the reports are not made available publicly.

DRASS is responsible for inspection and quality assurance at a regional level. Their mission is to control public health, to improve social cohesion and social

development, and to control welfare. Instruments that are used are evaluations, controls, regional prevention programs, and a mortality and morbidity surveillance system (SUMMO) (DRASSIF 2005).

In the field of public health, evaluation is an objective assessment of the effectiveness of medical strategies in order to provide better choice for the patient. It also provides the elements for improving the health care system. HAS conducts evaluation studies, mainly on the basis of analysis of scientific literature and on the opinion of health professionals (Malle, De Cherge et al. 2003). It identifies recommendations for clinical practice and gives its opinion on the list of treatments or services reimbursed by health insurance companies, except for pharmaceuticals. It further carries out evaluations of professional practices, training for clinical audit and programs for improvement of the quality of care (HAS 2007). Accreditation is a second instrument being used by HAS, with the purpose to ensure quality of care and to promote ongoing improvement in care. The accreditation procedure for hospitals consists of four stages (HAS 2007):

1. Auto-evaluation: the hospital receives a manual with 215 criteria that need to be met prior to receiving the certificate. Hospitals are allowed to take action in order to meet with these criteria.
2. Visit: experts of HAS visit the hospital and evaluate the organization and the daily practice. They focus on possible improvements.
3. Report: six months after the visit, a report is sent to the hospital. The report consists of decisions and recommendations of the HAS experts concerning accreditation. The hospital board is allowed to comment and object on the findings.
4. Diffusion: the report has been accepted and is presented to the hospital, the regional agency and the public by making it publicly available on the website.

Accreditation for hospitals is not obligatory. However, hospitals that have been accredited receive higher reimbursement from health insurance companies.

3.6. England

State Structure

England, with its national health system, is a second example of a unitary state. The NHS can be divided into two sections: one dealing with strategy, policy and managerial issues, and the other dealing with all clinical aspects of care, i.e. primary care, secondary care, and tertiary care (RCGP 2004)¹¹. However, the divisions between these sectors are becoming less distinct, with structural changes taking place within the NHS. Particularly, the organization is moving towards local decision making, breaking the barriers between primary and secondary care, and enabling greater patient choice. The NHS structure can be described as follows (see figure 5).

¹¹ This section is largely derived from RCGP (2004). The structure of the NHS, RCGP.

Figure 5. Structure of the NHS in England

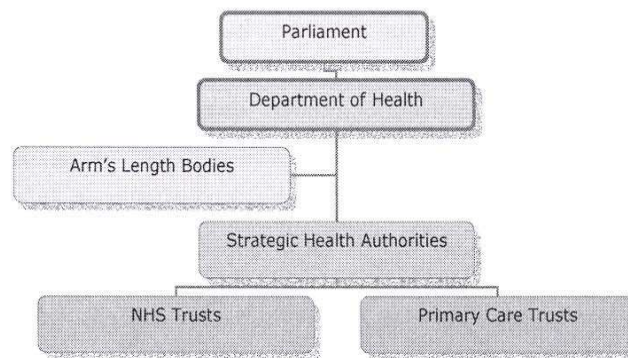


Diagram 1: The Structure of the NHS in England

Source: (RCGP 2004)

The government allocates funds to the NHS in England via taxation. The Secretary of State for Health decides how these funds will be spent and is accountable to Parliament for the overall performance of the NHS in England. The Department of Health is responsible for running and improving the NHS, public health and social care in England. The organization provides strategic direction, secures resources, sets national standards, and invests in the service. Arm's Length Bodies are independent organizations, sponsored by the Department of Health to undertake its executive functions. They are accountable to the Department of Health and, occasionally, to Parliament. Strategic Health Authorities manage the NHS at local level and act as a link back to the Department of Health. They support the efforts of the local health service in improving performance, integrating national priorities into local health delivery plans, and resolving any conflicts that cannot be resolved between local NHS organizations. Strategic Health Authorities also monitor the performance of Primary Care Trusts and ensure they meet targets. Primary Care Trusts are charged with planning, securing and improving primary and community services in their local area. The Department of Health has given Primary Care Trusts freedom to develop their own targets and frameworks within a set of national standards. NHS Trusts employ the majority of the health service workforce. The trusts are largely self-governing, but are accountable to Strategic Health Authorities for their performance management.

Bismarck vs. Beveridge System

The United Kingdom (UK) has a national health care system, the National Health Service (NHS), founded in 1948. It is a free, comprehensive health care service, available to the entire population. The NHS is mainly funded through general taxation, with an additional element of national insurance contribution paid by employers and employees (Van Kemenade 2007)¹². Further funding for social services is available through local taxation. The rates of local taxation vary between local authorities and are banded according to the value of the property within the authorities. Budgets are set every three years as part of the general public expenditure planning process. For-profit and non-profit companies provide private health insurance. Private health insurance premiums are risk-related and vary

¹² This section is largely based on Van Kemenade, Y. W. (2007). Healthcare in Europe 2007. The finance and reimbursement systems of 11 European countries. Maarssen, Elsevier Gezondheidszorg.

between group policies and individual policies. Premium levels are not regulated. The majority of the private health insurance policies are group policies purchased by employers. The NHS covers all legal UK residents. Services are mostly free at the point of use, with no charges for GP consultations or inpatient hospital stays. Co-payments are required for long-term and private care, dental care, pharmaceuticals and ophthalmic services.

Primary care is the first point of contact for most patients and is delivered by a wide range of professionals. Most primary care in England is provided by GPs in group practices. A patient must be a resident of a specific area in order to register with a GP. GPs act as gatekeepers in the system, and a referral is required to gain access to specialist services. In England, 152 Primary Care Trusts (PCTs) are at the center of the NHS and control 80% of the total NHS budget. They are responsible for purchasing or commissioning health care services from other organizations in the NHS, as well as independent providers. Because they are local organizations, they are in the best position to understand the needs of their communities. All GPs are required to join a PCT. As of 2007, parts of GP's incomes depend on achieving a high level of satisfaction among their patients.

Secondary care is provided in general NHS trusts and small-scale community hospitals. Hospitals are managed by NHS Trusts, also known as Acute Trusts. Their wide-ranging services are commissioned or purchased on behalf of patients by PCTs and, increasingly, NHS Trusts are being commissioned by PCTs to provide services in the community closer to where people live. NHS Trusts employ most of the NHS workforce. NHS Foundation Trusts are a new type of NHS hospitals, run by local managers, staff and members of the public. Only the highest performing hospitals can apply to become NHS Foundation Trusts, a status which gives them more freedom in running their services than other NHS Trusts.

Supervision and Responsibility

Regarding quality of health care, England has dealt with several developments. In 1999, the government introduced the Commission for Health Improvement (CHI), aiming at improving quality of patient care in the NHS and examining systems and processes of clinical governance through peer review without autonomous powers (Gott 2003; Bevan and Cornwell 2006). Tasks of CHI were to visit every NHS trust and health authority, including primary care groups, local health groups, and general practices on a program every four years (Gott 2003). Further, CHI investigated serious service failures in the NHS. However, in 2002 the government announced that from April 2004 CHI would be abolished and tasks would be taken over by a new organization, the Healthcare Commission, also known as the Commission for Healthcare Audit and Inspection (CHAI) (Bevan and Cornwell 2006)p.23).

The Healthcare Commission is responsible for the regulation and inspection of the NHS. Its role is developed to include publication of NHS performance ratings and indicators for hospitals and trusts, based on a rating scale of zero to three stars. Trusts achieving three stars are given autonomy and extra funding, while trusts gaining no stars are given support from the Modernization Agency. The Healthcare Commission also handles formal complaints against the NHS, resolving disputes that have been unsuccessfully tackled at local level.

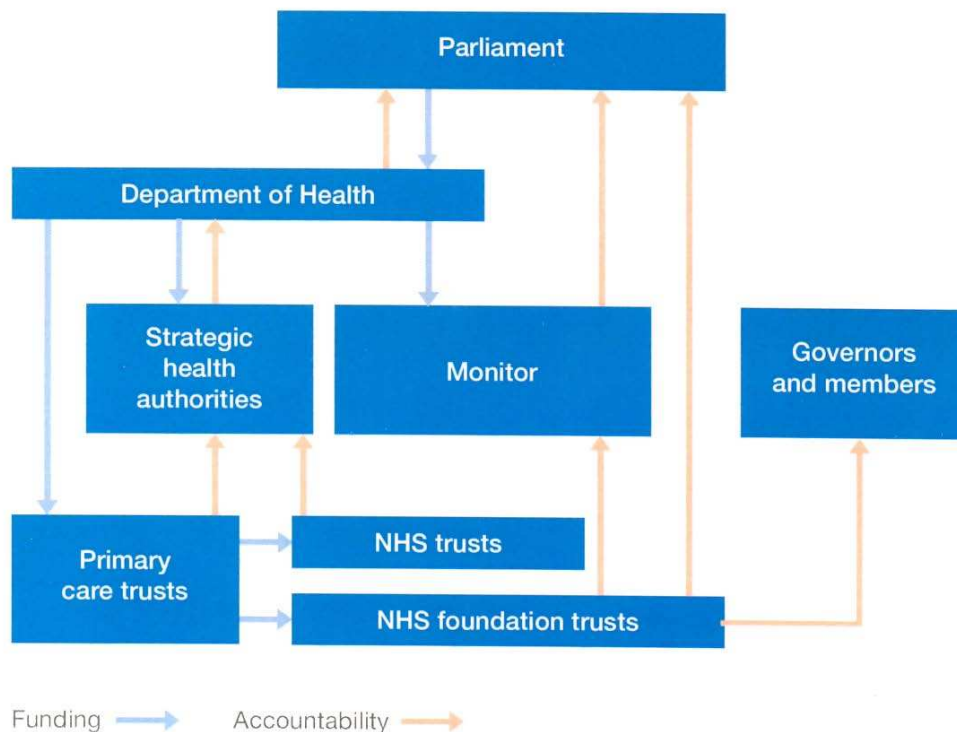
The Audit Commission is an independent watchdog, driving economy, efficiency and effectiveness in local public services to deliver better outcomes for everyone (AuditCommission 2007). Tasks include auditing NHS Trusts, PCTs and strategic health authorities to review the quality of their financial systems and work with foundation trusts. The Audit Commission also publishes independent reports which

highlight risks and good practice to improve the quality of financial management in the health service and encourage continual improvement in public services including in the field of public health and health inequalities. The Audit Commission further works closely with partner organizations in health audit and regulation (AuditCommission 2007).

Monitor is an independent regulator of NHS Foundation Trusts, established in 2004 (Monitor 2008)(p.2). Its role is to ensure that NHS foundation trusts are able to operate effectively as autonomous organizations, and are well managed, legally set up and run, with their finances in good order. NHS foundation trusts are free from central government control and are accountable to their local communities, through governors and members, to Parliament, and to Monitor (p.4). Monitor works with a network of organizations, such as the Healthcare Commission, the Health Protection Agency, the Department of Health and the National Patient Safety Agency, to ensure access to a broad range of information on NHS foundation trust performance and expert advice (p.7). Figure 6 shows the working relations of NHS foundation trusts and the funding flow.

In October 2007 the government announced the introduction of a new regulator, replacing the Commission for Social Care Inspection, the Mental Health Act Commission and the Healthcare Commission by April 2009 (CHAI 2007)(p.16). The new regulator should register all healthcare providers, NHS or independent, by 2010. Also, the new registration system will build on the current registration and inspection system in the independent sector, and the core standard elements of the annual health check in the NHS (p.17).

Figure 6. Working relations NHS and funding flow



Source: (Monitor 2008): (p.4)

Ownership and Financing of Quality Inspection

The Healthcare Commission is a non departmental public body, established under the Health and Social Care (Community and Health Standards) Act 2003 (CHAI 2004)¹³. The Commission has a duty to keep the Secretary of State informed about the provision of healthcare by or for any NHS body and to give advice on any matters connected with the provision of NHS or independent healthcare. The amount of the grant-in-aid to be paid to the Commission, and any conditions to be attached, will be determined and approved by the Secretary of State, in consultation with the Assembly, before the financial year in question. Any requests to the Department or the Assembly for additional funding will be supported by a separate business case. The Department and the Assembly will consult the Commission about its need for funding before making any financial planning assumptions for future years, and decisions are made in light of the Department and the Assembly's overall priorities. Monitor, being an independent regulator of NHS Foundation Trusts, is funded by Parliament and the Department of Health (see also figure 7). The Audit Commission is classed as a Public Corporation and is sponsored by the Department for Communities and Local Government (AuditCommission 2007).

Independency of Quality Inspection

In England all three inspection bodies are considered to be independent: the Healthcare Commission, Monitor and the Audit Commission.

Procedures and Instruments

The regulation of foundation trusts is undertaken by an independent regulator, Monitor. Monitor is responsible for licensing new foundation trusts, for monitoring their performance and for intervening in the management of the foundation trusts (Gott 2003).

The Audit Commission Act of 1998 requires the Audit Commission to prepare, and keep under review, a code of audit practice prescribing the way in which auditors are to carry out their functions under the Act, and which embodies what appears to the Commission to be the best professional practice with respect to standards, procedures and techniques to be adopted by auditors (Gott 2003).

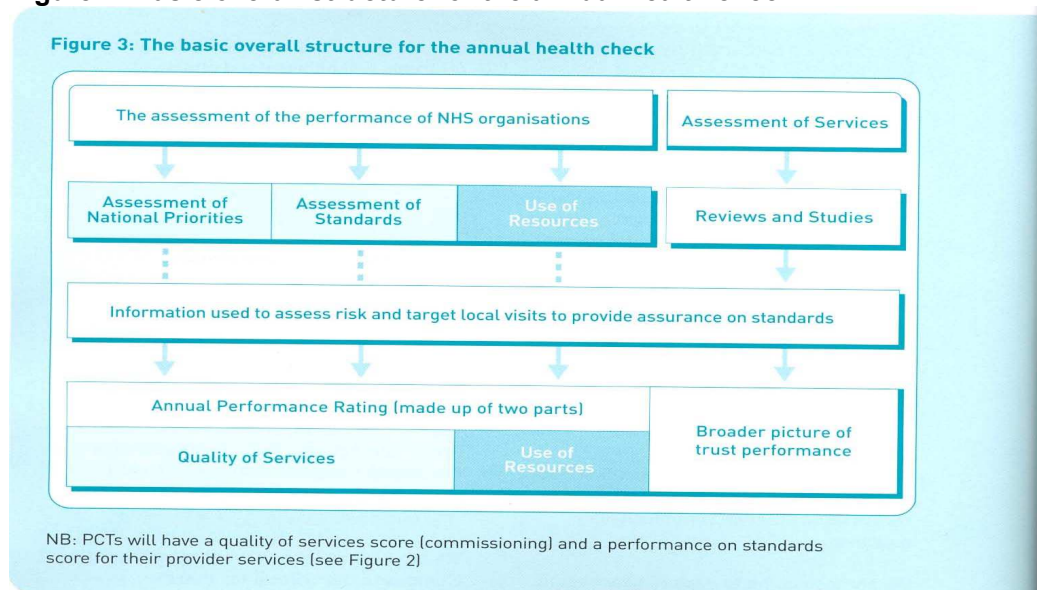
Trust boards are responsible for ensuring that the governance and services provided by their trust comply with the standards laid down by the government (CHAI 2007)(p.31)¹⁴. Each year the Healthcare Commission publishes the criteria used for the assessment against the standards. In 2007/2008 the Healthcare Commission has published, for the first time, a small set of benchmark indicators to show the position of the trust relative to similar trusts on aspects of safety, quality, health and wellbeing and patient focus. Declarations made by trust boards are cross-checked against nationally available data, including the set of indicators. Next, the trusts that are considered to be most at risk of not meeting the standards are identified for inspection. A second group of trusts, randomly identified, are also selected for an inspection. The aim of the inspections is primarily to detect areas of non-compliance that have not been declared by trusts, and in doing so, safeguard the interest of patients (p.32). The Healthcare Commission proactively follows up these areas of non-compliance, working with strategic health authorities and Monitor whose responsibility is to manage the performance of trusts. Throughout the year, the

¹³ This section is largely based on CHAI (2004). Commission for Healthcare Audit and Inspection Management Statement (part 1), Healthcare Commission.

¹⁴ This section is largely based on CHAI (2007). Developing the annual health check in 2008/2009. Have your say, Commission for Healthcare Audit and Inspection.

Healthcare Commission keeps the information up-to-date with new sources of information as they become available and by feeding in the views of patients and the public through local representatives. Figure 7 shows the basic overall structure for the annual health check.

Figure 7. Basic overall structure for the annual health check



Source: (CHAI 2007)(p.30)

Monitor is responsible for the regulation of NHS foundation trusts. Once authorized, every NHS foundation trust is assigned to a Monitor relationship manager (Monitor 2008)(p.5). NHS foundation trusts are asked to assess their own compliance with the terms of their authorization, as part of Monitor's risk-based approach, and they have to submit an annual plan, quarterly and ad hoc reports. The actual performance is then monitored against plans and potential problems are identified. Monitor assigns three quarterly risk ratings (highest risk category – concerns over service performance – lowest risk category) on finance, governance and mandatory services, and identifies steps that need to be taken to address problems. NHS foundation trusts at risk are monitored more regularly, and updated action plans are required and reviewed (p.11). In case an NHS foundation trust has failed to comply with the terms of its authorization, Monitor has statutory powers to intervene (p.6). Measures that can be taken are closing a specific service in case of serious concerns, requiring a board to take a specific action, requiring a board to obtain external advice on a particular issue, or removing any or all of the directors or governors and appointing replacements (Monitor 2008).

3.7. Norway

State Structure

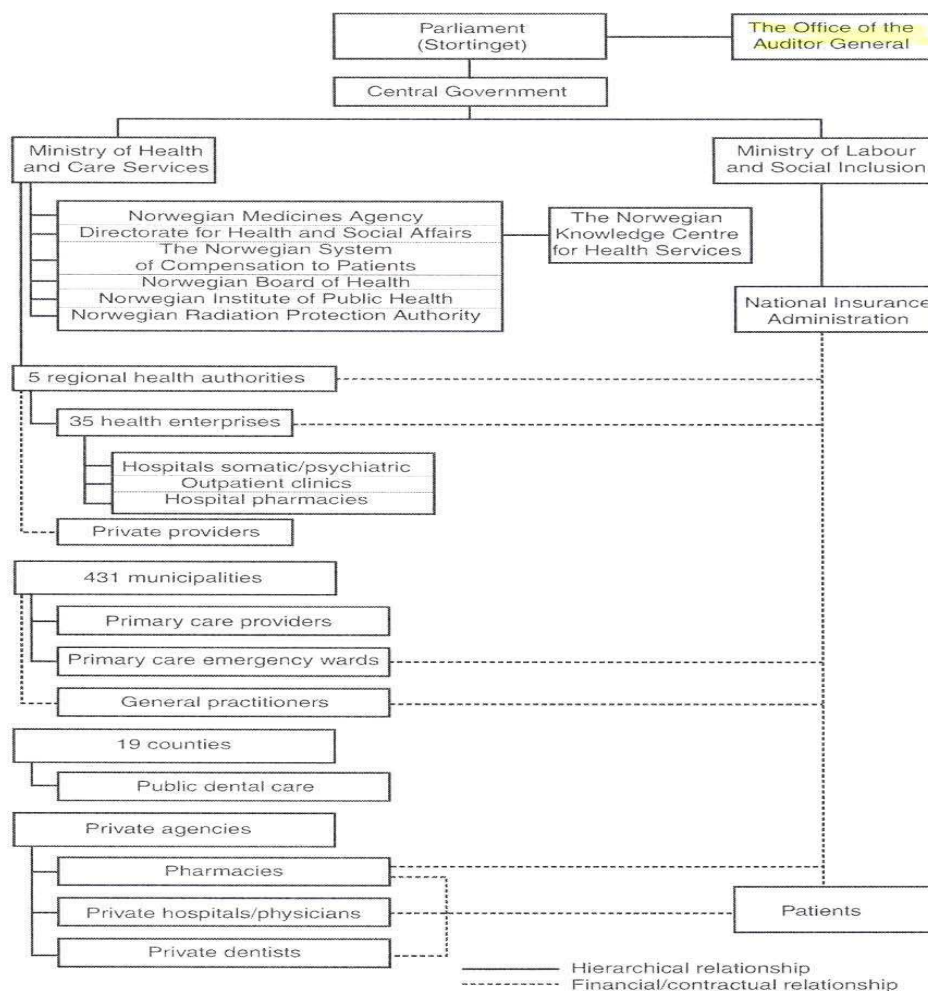
Norway can also be characterized as a unitary state, but to a lesser extent. The Norwegian health care structure namely consists of three levels of decision-making: state, health regions and municipalities (see figure 8).

At state level, the Ministry of Health and Care Services outlines national health policy, prepares major reforms and proposals for legislation, monitors

implementation, and assists government in decision-making (Johnsen 2006)¹⁵. The Ministry is further responsible for administering primary health care, specialized health care, public health, mental health, medical rehabilitation, dental services, pharmacies and pharmaceuticals, emergency planning and coordination, and nutrition and food safety. Since the hospital reform of 2002, counties lost their responsibility for specialist health care. Currently, their responsibilities include organizing public dental care in cooperation with municipalities. The counties also have some responsibilities with regard to general public health. The four regional health authorities have gained responsibility for the provision of specialized care, including both somatic and mental health institutions, as well as other specialized medical services since 2002. The 430 municipalities are responsible for the provision and funding of primary health care, including preventive and curative care, and social services.

Figure 8. Overview of the Norwegian healthcare system

Fig. 1.1 Overview chart on health system



Source: (Johnsen 2006)

¹⁵ Parts of this paragraph are based on Johnsen, J. R. (2006). Health systems in transition: Norway. Health systems in transition. V. Bankauskaite. Copenhagen, WHO Regional Office for Europe on behalf of the European Observatory on Health Systems and Policies.

Bismarck vs. Beveridge System

The Norwegian health care system is also characterized by a Beveridge structure. It is built on the principle of equal access to services. To fulfill this aim, the organizational structure has three levels that mirror political tiers: the national/state level, the five health regions, and the 431 municipalities. The role of the state is to determine national health policy, to prepare and oversee legislation, and to allocate funds. The parliament (Stortinget) is the political decision-making body and the Ministry of Health and Care Services has the overall responsibility for the health care sector. The five health regions are mainly responsible for the provision of health care services for specialist health care, while the municipalities are responsible for primary health care, including nursing care. The 19 counties are responsible for dental care. Further, GPs act as gatekeepers and agents with regard to health services provision.

The health system is predominantly tax based. All persons who are either residents or employees must be insured under the National Insurance Scheme (NIS). Insurance is also compulsory for certain categories of Norwegian citizens working abroad. All insured persons are granted free stay and treatment, including drugs, in public hospitals. Patients pay part of the costs of GP or specialist treatment as an outpatient, for the prescription of certain drugs, and for transportation costs related to examination or treatment. The municipality and/or the National Insurance cover the major part of the expenses.

Integrated purchaser-provider relations are dominant in the health care system. In 2004, 40 of the 431 municipalities had introduced a purchaser-provider model. Contracts between municipalities and private providers are a very important tool in guaranteeing good quality for service users, and in securing good cooperation with other parts of the health system. Currently, no purchaser-provider model exists between municipalities and regional health authorities.

Supervision and Responsibility

Although decision-making takes place at three levels, governance and regulation of quality are mainly organized centrally. The Norwegian Board of Health is a national supervisory authority with responsibility for the general supervision of health and social services (Helsetilsynet 2002; Johnsen 2006). In the counties, the Governmental Regional Board carries out supervision, and reports to the National Board of Health.

The Office of the Auditor General is the supreme audit institution and the supervisory body of the Parliament, and has independent agency status. The main task is to monitor public assets and ensure they are used and administered according to sound financial principles. Since 2002, the Office of the Auditor General has established a department for health services.

Ownership and Financing of Quality Inspection

Both the Norwegian Board of Health as well as the Regional Board are financed by the Ministry of Health and Care Services. The Office of the Auditor General is the supreme audit institution and supervisory body of the Parliament and is thus financed by the Parliament.

Independency of Quality Inspection

The Norwegian Board of Health and the Regional Board are independent supervision authorities. The Office of the Auditor General also has independent agency status.

Procedures and Instruments

The Norwegian Board of Health Supervision uses several instruments to ensure quality and safety in health care. One method is to set up supervision teams that make assessments and system audits about dangerous areas in health care. A thorough assessment of client's needs, wishes and suggestions is essential, in order to provide services that the client can gain maximum benefit from (Hanssen 2007)(p.7). Health care organizations are asked to use the reports about countrywide supervision and local supervision as the basis for assessing and improving the services they provide (p.11). In September 2007 the Norwegian Board of Health Supervision decided to impose a coercive fine, as a result of failure to follow instructions to meet statutory requirements related to health services (Helsetilsynet 2007). The purpose of the fine is not to punish the organization, but to compel them to meet the statutory requirements, and a fine can thus be avoided by following instructions. The fine can be imposed for every day, week or month after the deadline, until the requirements are met (Helsetilsynet 2007). Also, the fine can be given as a single amount. Further, since 1993 Norway has established a national reporting system for adverse events occurring in hospitals. The main aim of the reporting system is to clarify the background for the event and to prevent similar events happening again.

Health care professionals should provide care of a sound professional standard according to the Health Personnel Act, the Specialized Health Services Act, and the Municipal Health Services Act. In case of malpractice, the Norwegian Board of Health can use the following instruments: warning; revocation of or limitation of authorization, or of license to practice; revocation of certificate of completion of specialist training; revocation or limitation of the right to prescribe addictive medication; and suspension of authorization (Helsetilsynet 2007).

Chapter 4. Analysis

4.1. Introduction

In this chapter we analyze our research findings, reasoning from the conceptual framework presented in chapter two. First, we will address the main general and country specific trends in the supervision of health care quality across the different countries. Next, we will analyze the most important issues or dilemmas as a result of these trends. We will compare them between the different countries and conclude with some remarks about the way these countries try to deal with these issues. To conclude, we will reflect on our findings in formulating a research agenda and some possible strategies.

4.2 Changing governance modes

Increasing market influences ask for a new balance between inspection mechanisms

In a state-led version of governance, government steers by command and control mechanisms and hierarchical ways of supervision. Such governance mechanisms have become rare however and increasingly other modes of governance are enacted to accomplish societal coordination and steering. The 'market' is one of the dominant ways to which coordination is relegated. Markets are steered by the exchange of supply and demand and are thought to be controlled by clients that have the information to judge on price and quality (transparency). Societal mechanisms for inspection and control have got to do with loyalty and trust towards representative bodies and organizations that account for the realization of public goods. Self regulation by codes and commitments plays an important role as the professional domain has its own set of protocols, regulations and supervisory arrangements (Putters 2001; Van der Kraan 2006). In all selected countries we see, in one way or the other, a stronger emphasis on transparency of quality, agreements on output in contracts and the exchange between price and quality at the 'market' of healthcare. Therefore, market influences have to be coordinated with government steering and professional self regulation. New balances have to be found in supervision and inspection on quality, accessibility, solidarity and efficiency. This is shown in changes of the focus of inspection and accountability (what is being inspected), as well as in the locus (who is inspecting).

The changing focus of healthcare inspection

The introduction of market principles, and the increasing urge for transparency and consumer choice, also changes the work in healthcare inspectorates. In a way, it increases its burden, especially in countries in which self regulation and trust have been important principles in organizing inspecting 'at a distance'. Due to the influence of information technologies and growing media and public attention for issues of quality and patient safety more possibilities for being transparent about costs, quality and patient safety are being created. The switch to risk-based approaches in supervision would for example have been impossible without the possibility to statistically analyze large databases as well as the possibility to 'extract' data from (electronic) patient records. Besides, the public debate about the output of healthcare organizations, and the quality of professional work as well as the right of patients to good quality, have put more emphasis on supervision and inspection as well. This directly relates to the trend of increasing influence for patients and clients in healthcare (more patient centeredness). The introduction of websites and other ICT

applications have increased the possibilities to gather information about the quality of healthcare by patients themselves and/or to make available information on health providers in order to facilitate choice. In addition, in a lot of countries new instruments of accreditation and codes of good governance have to assure that patients are being empowered and quality is being assured. In all, the focus of healthcare inspection moves from learning and creating trust in professionals and organizations, towards increasing transparency of output, costs, quality and safety, and public accountability for that.

The changing locus of healthcare inspection

This directly relates to the changing locus of healthcare inspection: who is inspecting and within which institutional setting? Parallel with the trends of liberalization and the introduction of market principles in healthcare we experience an ongoing trend of governments decentralizing responsibilities from central administrative levels to lower levels, such as local communities, regions or administrative bodies. In unitary states such as the Netherlands this is seen with e.g. the new Social Support Act (*Wet Maatschappelijke Ondersteuning*). Local governments become responsible for home and elderly care, while other parts of healthcare are relegated to the market. In federal countries this reflects the historical struggle between federal and regional/state responsibilities. In a lot of situations we see that central government remains responsible for the quality, accessibility and efficiency of healthcare services, which ensures an ongoing interference with what is happening at local and regional level. In unitary states this can be interpreted as a form of 'recentralization'. In federal states it is a changing balance between government levels. Due to the paradigm of increasing transparency and public accountability for quality and safety recentralization is being stimulated. There are increasing expectations from healthcare inspectorates to guarantee quality and patient safety, even when other public and private organizations have increasing responsibilities for those themselves.

4.3 Country specific trends

All three described trends are present in our country case studies, but their intensity and focus differ. This is strongly related to the institutional setting of each of the selected countries. The trends, therefore, cannot be separated from the institutional settings in which they are embedded. For this reason, we describe the trends for each of the countries separately.

Germany

One of the aims behind the 2004 Statutory Health Modernization Act was the introduction of more competition on quality in German's health care system. This reform also caused the foundation of the Federal Joint Committee and the IQWiG to move competition on quality a step further. However, the relation between competition and quality is not very present in the current system. This absence is mainly caused by a lack of real competition mechanisms and because of the geographical characteristics of the country. For instance, when the nearest hospital is eighty kilometers away, the quality outcomes of a hospital may become a remote factor for choosing a hospital.

The second trend is a very hot topic in Germany at the moment. The German system was always characterized by its confidentiality. However, since public disclosure of the hospital outcome reports is introduced, the reputation of the health care provider or professional is made into a market themselves to further the rights of

patients to have more insight in the outcomes on performance of healthcare providers. Especially in Germany with its very strong medical profession, this was a big change. The BQS has developed indicators for public disclosure.

Despite being a federal state, the German system of quality assurance is centralized, and it is carried out centrally and decentrally, but following a same scheme. The Federal Joint Committee is responsible for quality assurance and patient safety and under the FJC the BQS, LQS and IQWiG are positioned. Also in this matter the influence of the medical profession was present; because of the professionals the responsibility for quality assurance was not positioned under the state government, arguing that this would lead to 'Staatzmedizin'.

Switzerland

Competition in health care is a hot topic in the political debate at the moment. One of the main problems for introducing competition in the Swiss health care system is the existence of the cantonal barriers. Because of the cantonal boundaries and the canton-related reimbursement criteria for the health insurance there is no free movement of patients possible in the current situation. Therefore competition in health care is not really feasible. The health care providers who are taking the lead in implementing quality management measurements (quality certification, quality circles) are the health care providers who are advocating more competition in the current situation, with the cantonal barriers, like HMOs.

In 2007, the National Council amended the draft bill of the Council of States and decided to remove cantonal boundaries step by step. The cantons opposed the intended free choice of hospitals most vigorously.

According to the second trend, Switzerland, like many other countries, is developing a system of more public disclosure at the moment. This is quite a breakthrough within the Swiss health care system, and many supervisory bodies use this opportunity to publish all their specific outcome reports.

In Switzerland a direct link between competition and quality supervision is not yet achieved, and competition is still not well developed because of the cantonal barriers. One could argue that Switzerland at the point of competition in health care is stuck in its own institutional framework. To overcome this institutional problem in the field of inspection on quality of care, the Interkantonalen Verein für Qualitätssicherung und –Förderung in den Spitalern (IVQ) was founded in November 2007. The organization's main goal is to strive for a common strategy to assure quality of care among the cantons.

Spain (Catalonia)

Having a Beveridgean health care system, Spain is not directly striving for more competition in health care. Reforms have been aimed at the accomplishment of complete decentralization and cost containment. Supervision of quality developed incrementally over time, adapting to the reforms and institutional setting.

The two main instruments of quality control are accreditation and contracting by the Autonomous Community, using their outcomes in the specific ways.

In 2002 an agreement was reached to complete the decentralization process and to shift the responsibility for health powers and resources to the ten Autonomous Communities. But having achieved full decentralization of the health administration, the need to clarify and strengthen responsibilities in the collaboration and cooperation between public administration departments has become more urgent than ever. For that reason the law on Cohesion and Quality of the NHS was approved in 2003. And, in the current situation, within the framework of legislation

and with the National Quality Plan applying for the entire country, the trend is towards more decentralization on common grounds.

France

Since the reforms in France, the country has experienced a shift towards state-led managed care. It seeks to modernize the health care sector and increase quality of care, while controlling costs by increasing efficiency of resource allocation within targeted expenditure limits. This reinforces the powerful role of the central state, which aims at overseeing vast institutional renovation, applying administrative and IT to health care and designing incentives and regulations to improve quality. However, limitations do exist in the centralization of policymaking and the successful resistance of the medical profession. Also, France tries to avoid two popular ideas in health care reform – consumer choice and price competition – since they believe that freedom of beneficiaries to choose among all providers should exist and that competition would lead to privatization.

In 2006, the health insurance reform was implemented, encouraging a coordinated treatment pathway in which the preferred doctor would play an important role, i.e. gatekeeping was introduced. Against the background of free choice of provider, financial incentives were introduced to stimulate patients to enter the referral system. Referred patients receive higher reimbursement than patients consulting doctors/specialists directly. Research has shown that the financial incentive has stimulated 44% of patients to register with a preferred doctor. The research also shows that 82% of referred patients felt no changes in follow-up and quality of care.

Supervision has also slightly changed. Since the establishment of HAS in 2004, health care organizations have financial incentives to become accredited: with accreditation they receive higher reimbursement by health insurance companies. Financial incentives are thus important for the health care system to function as proposed. Because of the shift towards state-led managed care, supervision also remains quite reactive.

England

Since 2000, England is working through a ten-year program of reforms aiming at providing high-quality care for every patient, responding to need instead of ability to pay. For the reforms to be successful, patients should be fully engaged in decisions and choices about their own health and healthcare. The role of the NHS then would be to give more attention to the prevention of illness, by tackling inequality of access and by empowering people to make choices that improve and protect their own health. The reform program thus seeks to embed the right balance of incentives, patient choice, plurality and transparency in the system. Four connected streams of work exist:

1. Demand-side reforms: more choice and stronger voice for patients;
2. Supply-side reforms: more diverse providers with more freedom to innovate and improve services;
3. Transactional reforms: money following the patient, rewarding the best and most efficient, giving others incentives to improve;
4. System management reforms: system management and decision making to support quality, safety, fairness, equity and value for money.

IT and supervision play an important role in achieving these goals. Access to information is crucial in order to support patient choice (e.g. by using benchmark websites), and to help supervisory bodies to track quality and performance. Also, for providers to meet the required quality standards, a licensing or accreditation system should be used. These reforms stimulate a proactive supervisory approach.

Furthermore, by 2010 a new regulator shall be introduced, replacing the existing regulators.

Norway

The health care system in Norway is often characterized as a decentralized NHS model, in which local and county governments play an important role in allocating resources. Since the hospital reforms, the system changed from a decentralized to a semi-centralized NHS model with responsibility for primary and secondary care being divided between different governmental levels. Further, health regulation plays an important role in determining the functioning and tasks of regulators and health care providers (see also chapter 4). The requirements laid down in laws and regulations are central elements when health services are planned, provided and evaluated. The Norwegian Board of Health Supervision has the task to ensure that health and social services are provided in accordance with these statutory requirements. Supervision in Norway is very proactive, since the Norwegian Board of Health Supervision believes that the results of supervision should point out areas that need to be developed. New methods have been introduced to achieve this goal, e.g. the implementation of a coercive fine and the national reporting system for adverse events.

4.4 Comparative analysis

In table 3 we summarize important empirical results concerning the changes in governance arrangements within the different countries. We have seen that overall the arrangements between state, society, medical profession and market are changing rather rapidly. The trends appear to be the same, but the responses are path dependent, that is, they reflect the more general organization of healthcare within each country.

Country	Changes in governance mode	Problem issues
Germany	Increasing control by shared decision making bodies; erosion of the power position of professionals.	Coordination problems between central and decentral steering/control (federal/regional).
Switzerland	More market competition and self regulation by health care providers (in assessing quality measures).	Diffusion of tasks between cantons and federal state.
Spain	Maintenance of traditional relationships between controlling state (top down supervision).	Coordination problems between central state and regional autonomy.
France	Increasing state control (state led managed care), but changing instruments: more financial incentives & accreditation.	Quality inspection is mainly reactive. How to transform this to more pro-activeness and transparency?
England	Focus on more consumer choice, transparency and competition at cost of the role of the state. Change of instruments (accreditation).	Transition phase: from reactive to proactive quality inspection and problems adapting to new, more market oriented, context.
Norway	Maintenance of state led system, with room for more consumer choice. Quality inspection is organized in a proactive manner.	The adaptation of the system to more transparent and output oriented ways of working.
Netherlands	Introduction of regulated competition and market incentives. Focus on transparency, output and contracts.	Coordination between different supervisors (on quality, on effectiveness, on level playing field).

Table 3. Summary of trends in the 7 countries

In general, this table makes clear that all countries have to deal with increasing patient empowerment, an increase of market incentives that stimulate transparency (in different intensities and forms) and more technological possibilities for accounting and supervising. Yet, the countries do not respond in the same way. An important part of the explanation for that is the path dependency of health care systems, and more specifically of the supervision of health care quality. This means that it does make a difference whether a Bismarckian or a Beveridgean system is at stake or whether central or decentral governments are in the lead. Within the Bismarckian system we see an increase of influence of self regulation by the field of healthcare (providers/insurers), and a government that is searching for a new role in the relationship with new market parties. A very clear example in the Netherlands is the introduction of new commercial organizations within the sector, causing problems with the supervision of quality by government bodies. Within the Beveridge systems we see the same struggle but focused on the division of tasks between the central and decentral government layers. In all cases, the power position of patients is increasing. Giving them more information and choice leads to a focus on transparency and changing relationships between governments, organizations and patients. This changes the governance arrangements rapidly, which is reflected in several dilemmas in inspection practices.

4.5 Paradoxes

The scheme from the last paragraph shows that due to changing relationships between public, private and professional supervision systems several issues and dilemmas arise. We showed that the trends of marketization and decentralization within health systems, and the urge for increasing transparency on costs and quality, have caused a change in focus and locus of healthcare inspection. The focus is more on optimizing the information on costs, quality and patient safety than on optimizing trust and reflexive learning. The locus is more on individual responsibilities, but at the same time creating new centralized arrangements that guarantee quality and patient safety. These changes lead to several dilemmas in health care inspection.

1. *The information paradox*

The need for information about healthcare services changes. More information about price, quality and patient safety of healthcare services is asked for by clients and the market. A lot of emphasis is put on increasing transparency. This leads to more insight in costs and quality, but also to an emerging information paradox. This means that on one hand due to the focus on transparency and measurable figures about the quality, safety and efficiency of healthcare services the exchange on the market is more and more being steered by measurable assets. Yet, it is difficult to include the quality of e.g. the communication, dialogue and trust between doctors and patients. As a result, whereas transparency would suggest that the public is given an insight in existing performance, the activities and performances of healthcare providers actually are transformed in the process of making them transparent, creating somewhat of a distorted picture.¹⁶ Besides measurable figures about price and

¹⁶ This dilemma has been described in the literature extensively, see e.g. Power, M. (1997). *The Audit Society. Rituals of Verification*. Oxford, Oxford University Press.

, Tsoukas, H. (1997). "The Tyranny of Light." *Futures* 29(9): 827-843.

, Noordegraaf, M. and T. Abma (2003). "Management by Measurement." *Public Administration* 81(4): 853-871.

, Pollitt, C. (2006). "Performance Information for Democracy: The Missing Link?" *Evaluation* 12(1): 38-55.

quality (and on complaints about the quality of healthcare), also less measurable aspects should be taken into account, such as trust, professional authority and adequate communication. The different countries deal in a varied way with this dilemma. Some countries focus on more detailed protocols (Germany, Norway) and accreditation procedures (England, France, Spain), while others focus on more sharp regulations. An interesting conclusion is that all – in a way - focus on rationalizing healthcare: improving information infrastructures (e.g. the Dutch attempts with DBC's, performance indicators etc.), improving and detailing regulations. That means that a risk in the inspection of quality remains: the lack of addressing trust, dialogue and learning.

Referring to our theoretical perspectives as introduced in Chapter 1, the *cybernetic* perspective of reflexive learning, for which trust and dialogue are rather important, appears to become less important in inspecting healthcare quality due to the dominance of contracts, output and measurable assets of transparency. This then also means that healthcare systems in which this trend is dominant risk losing possibilities for learning.

2. The regulation paradox

The first dilemma already introduced the second one. Due to the increasing possibilities of gathering information, and the political and public urge to do so, new government regulations arise on the issue of quality and patient safety. This is contradictory to the trends in the context of healthcare inspection, like marketization and decentralization of responsibilities. The big difference with former regulations is that trust in bureaucracy (bureaucratic competence and obedience) is exchanged for trust in infocracy, which means that clients and supervisory bodies ask for information on output. We saw that regulations on transparency and consumer choice are being stimulated in all selected countries.

There is no real difference between federal and unitary states, or between Bismarckian and Beveridge systems on this regard. However, there are some differences in the way they deal with increasing transparency and publicity. In general, negative publicity as result of incidents occurring in health care has led to reorganizations, new regulations and even reforms within supervisory bodies. Incidents with important consequences for quality and patient safety get a lot of attention in the media and enforce public accountability of professionals and managers for their behavior. Examples are the Bristol case in England and the contaminated blood case as well as the case of the heat wave in France; in the Netherlands the Bijlmer disaster would be an example of a crisis that has been influential in transforming supervisory arrangements. As a result new regulations arise. England has reformed its inspection system as a response to strong critique after several incidents took place. More consumer choice has become an important focus point nowadays, while at the same time intensifying regulations on quality and patient safety.

Referring to our theoretical perspectives the *juridical* perspective is rather dominant in current inspection practices: the debate is about centralizing or decentralizing responsibilities, which is all about checks and balances between government levels and between public and private domains. We see that government regulations become rather important in guaranteeing quality and safety in a market like setting. So, whereas discourses in almost all countries centre around different versions of liberalizing healthcare provision, it is the implementation of these policies that lead to a reemphasis of the role of the state (compare (Klein 2003)).

3. *The paradox of responsiveness*

Due to the information paradox and the regulation paradox the systems' responsiveness is at risk. On the one hand the need for more transparency steers inspection activities. On the other hand market incentives and decentralization give responsibilities for healthcare quality to other public and private organizations and bodies. On top of that politicians often introduce new hierarchical and top down supervision instruments in this context of marketization and decentralization (especially when incidents in the sector take place). When trust in supervising and inspection bodies is low we face ongoing political attempts to recentralize and regulate top down in a sector that it is for a large part based on self regulation and professional mechanisms. Due to this recentralization reflex it can become rather diffuse who is responsible for what part of quality assurance and patient safety. This threatens the systems' responsiveness and challenges the trust that the system is able to detect low and bad quality and act on it to improve these situations. The paradox is that where the urge for transparency is meant to increase the systems' responsiveness, the diffusion of responsibilities and the political reflexes bear the risk to realize the opposite.

Interestingly, we see that the selected countries deal with this dilemma of responsiveness very differently. The federal states all struggle with the relationships between centralized and decentralized government, yet there is an overall attempt to centralize back to the federal state. This is done e.g. by the top down formulation of more detailed patient rights at federal level (Germany), and the increasing federal influence on quality of healthcare by the enduring possibilities to sanction bad quality (Spain). In unitary states we clearly see more market influence, but also state led managed care (France/Norway) and the introduction of new accreditation instruments on state level (France/England). In the Netherlands, we also see new market incentives and decentralization of responsibilities, but more governmental influence on the quality of care, in formulating patient rights and in systems of transparency.

Referring to the *democratic* perspective on accountability and inspection we see that on the one hand individual patients get more opportunities and possibilities to be informed, influence healthcare services and make choices. On the other hand we conclude that political interference from the public domain does not improve the responsiveness of the system, because its top down and regulative dominance interferes with traditional influences and responsibilities of stakeholders from the professional and private domains of healthcare.

Chapter 5. Conclusions and summary

5.1 The research question and background

Faced with increasing challenges of an aging population and a rise in healthcare expenditure, European healthcare systems are implementing institutional changes, like the introduction of quasi markets. The role of the state is being redefined in traditionally highly state led healthcare systems. These and other changes have direct consequences for the character and organization of supervision on the quality and safety of healthcare. With this changing context in mind, this research has focused on the following question: In what way is supervision on quality and safety of healthcare organized in a number of European countries? More specifically, *how* is the supervision of quality and safety organized, *which tasks* are performed by supervisors and what *formal competences* do they have?

5.2 Theoretical perspective and case selection

On the basis of a historical reconstruction of the governance of health care we have distinguished four ideal types of steering relations (and accompanying steering instruments), that can be characterized on the basis of (a) the level in which the state can function as a central steering actor and (b) the possibilities of private and societal actors to self regulate. A combination of these two criteria classifies four different ideal-type modes of governance with different steering mechanisms. Regulating is the dominant steering mechanism of the state; contract is the dominant steering mechanism for the market. For civil society this is negotiation between representative parties, whereas for professional self regulation it is about shared norms (laid down in guidelines and protocols). On the basis of these ideal types different countries have been studied. We also varied along Beveridgean and Bismarckian healthcare systems and nationally or regionally organized healthcare systems:

Level of self regulation of collective actors		
Level of state intervention	-	+
	State/Regulation	Civil Society/Negotiation
	<i>France</i> <i>England</i> <i>Spain</i> <i>Norway</i>	<i>Germany</i>
	Market/Contract	Professional self regulation/Shared norms
	<i>The Netherlands</i>	<i>Switzerland</i>

Table 4. Classification of selected countries

In our empirical research we have studied the governance modes of each of the selected countries, as well as its consequences on the inspection arrangements concerning quality and patient safety. We came to conclusions about the way these inspection arrangements work, as well as how and why their responses to system changes differ. In the next section we give our results and conclusions.

5.3 Conclusions

In this section we answer the descriptive and explanatory questions we posed in the first chapter. The Chapters 3 and 4 have discussed the topics thoroughly. This section can therefore be seen as a summary. We will address four main conclusions. The first conclusion is about the inspection arrangements across countries, their changing functions, the division of responsibilities and the instruments being used. The second conclusion formulates the three paradoxes we found in the practice of these inspection arrangements. The third conclusion gives some explanations for these paradoxes and for the way health systems respond to them. These explanations come from our conceptual model of governance modes and the different cybernetic, juridical and democratic perspectives on inspection and accountability. The fourth conclusion shows that inspection arrangements can be changed by following our theoretical model. Suggestions for future changes will be found in the next section.

1. The focus and locus of inspection arrangements are changing

We studied the way supervision on quality and patient safety is organized in different countries, which tasks are performed and what formal competences inspectorates have. We concluded that the governance arrangements in which this is embedded differ a lot and change quickly due to several trends in healthcare. In all countries we see the increasing dominance of transparency at the market and the growing responsibilities for healthcare at a decentral level. This causes changes in the *focus* and in the *locus* of healthcare inspection arrangements.

The focus is changing due to increasing technological possibilities for creating new forms of accountability (political, public and professional) and transparency. Also the public and political debate is about increasing transparency. This causes some problems for inspectorates, because the quality of healthcare also is about trust and dialogue between patients, professionals and inspectors. We conclude that there is a shift in the focus of inspection arrangements from trust in bureaucracy and professional competences towards trust in output information and actual behavior. Next to that, also the locus of healthcare inspection changes (who is inspecting and on what level). The philosophy of decentralization and individual responsibilities means that more responsibilities for quality and patient safety are shared by different (local, regional and central) stakeholders. Yet, at the same time we conclude that new regulations and measurement methods are created top down in order to strengthen the political grip on the quality of healthcare.

The conclusion therefore is that, although discussions about the inspection of health care quality are often dominated by the urge to choose between the ideal types of governance, the different steering mechanisms appear to be communicating vessels. They lead to different mixes and hybrid arrangements in practice. Although, not surprisingly, a high level of state interference in unitary states causes a low level of self-regulation of collective actors and intensifies the role and functions of governmental supervisory bodies, we conclude that new supervisory tasks are added, e.g. concerning the inspection of commercial care in state led systems, and the balance between professional self regulation, state regulation and market forces changes rapidly. It leads to less professional influence, more output and contract steering and enforcing state control at the same time.

2. Changing governance modes cause paradoxical inspection practices

Due to the changing locus and focus of inspection arrangements within the healthcare systems we found three paradoxes in current inspection activities: an information paradox, a regulation paradox and a paradox of responsiveness. Market incentives and decentralization are strengthened on the one side, but centralization

in regulations on the transparency of quality and on contracts on output are strengthened as well. This again causes more centralization, regulation and instrumentalization of healthcare inspection, while decentralization and deregulation were promoted. This is what we call the *regulation paradox*.

Next, reflection, learning and improvement from the bottom are equally important for improving quality. Yet, the dominant focus tends to be on optimizing transparency and measurability, although we know health care quality and patient safety is not all about measurable assets. Traditions, codes and commitments have a lot of influence on inspecting healthcare. They steer the role of communication, dialogue, reflexive learning and creating trust. The suggestion that optimizing transparency and measurability creates safety and quality is contestable. It also concerns attitude, communication and dialogue. The dominant focus on transparency therefore causes an information paradox.

The last paradox addresses the responsiveness of inspection systems. On the one hand new checks and balances are sought in decentralizing responsibilities to organizations and consumers. At the same time politics tends to intervene with hierarchically oriented strategies. The dominance of these strategies causes diffusion about who is responsible for what, while most healthcare systems can be characterized by a mix of self-regulation, market incentives and state led regulation. The attempts at political steering cause the paradox of responsiveness: it appears to increase grip on quality and patient safety, but it neglects the needs and responsibilities coming from the professional and private domains of healthcare.

So, inspecting the quality of healthcare is not only about measuring and steering towards quantifiable results. It is also about creating trust, improving organizational learning and balancing public, private and professional responsibilities for quality and safety. Supervisory arrangements have to address this in order to be effective and legitimate.

3. Informal institutions and inspection styles can be decisive

The conclusion that follows is that the existence of these paradoxes can be explained by system characteristics only partly. We found that informal institutions play a decisive role in effective and legitimate quality assurance. Although different system characteristics determine the role and function of supervisory bodies, a lot of variety was found between systems in the same groups of countries. Also, a lot of variety was found between public and private actors and at different levels of administration. This cannot be explained by the set of formal institutions only. Informal institutions such as the style (authoritative or negotiating), conflicting trends and policies (decentralization versus centralization) and different types of instruments (proactive versus reactive) provide crucial explanations for the effectiveness and legitimacy of quality assurance through supervisory bodies. The same can be said about the role and position of regulations of complaints and the insight in the amount and severity of complaints (e.g. in Norway a lot of knowledge is available about complaints due to the proactive style of inspection in order to prevent complaints in the future).

4. Inspectorates, you have a choice!

That brings us to our last conclusion: countries do have a choice in organizing the inspection on quality of healthcare. Partly this organization is determined by state and health system structures, which have developed in a path dependent way. History – of course – steers current and future arrangements. But, partly it is also steered by the way the inspectorates, politicians, patients and professionals deal with the paradoxes caused by current trends in healthcare. This has got to do with style, leadership, vision and creativity. Therefore, to conclude, we will explore some possibilities for new arrangements for inspecting healthcare.

5.4 Towards new arrangements for supervising the quality of care

In this section we look to the future. What can we learn from our study and analysis? Our prescriptions address the normative research questions we posed in the first chapter.

Accept and 'use' the hybridity of supervision arrangements

The implementation of different strategies depends on the state and health system structures in different countries. We can for example not say that the decentralized organization of the inspection of health care quality is better than organizing it centrally; research on the effects of supervision are hard to find and comparing effectiveness between countries is an almost impossible task. Yet, we can conclude that within decentralized models more options for organizing trust can be created in cooperation with professionals and managers. At the same time, in the context of increasing market influences in healthcare systems, it is equally important that quality inspectorates play a more centrally organized role in supervising healthcare services as market authorities do on effectiveness and controlling the level playing field. Obviously, we think mixtures of instruments on decentral and central levels of health care systems need to be addressed. Most health systems are in a way hybrid, characterized by a mixture of self regulation by professionals and organizations, state led inspection and market instruments like benchmarks and monitors. It is more productive to accept them as complementary as to introduce ideal type inspection models that deny these practices.

Create a more balanced policy mix to prevent 'over-instrumentalization'

Therefore we concluded that quality cannot be assured by introducing regulations and contract alone. Most governance arrangements can be characterized by mixes of the four modes of governance. The trends we described tend towards more contract and output steering, based on quantifiable information about quality. This leads to an instrumentalization of inspection activities. Technology enables this but does not assure the organization of trust, changing culture and clinical leadership. Regulative and financial instruments should therefore be complemented with communicative instruments such as reflexive evaluation, and the organization of trust. Also new forms of self regulation and commitment by the field of healthcare can be mentioned such as the introduction of all kinds of sectoral codes for good governance, the creation of improved information systems on quality and patient safety, the use of benchmarks and monitors and the increasing attention that is being given to reputation management by healthcare organizations and professionals. We also saw that patients, both individually and collectively, play an increasingly important role and force health systems to be more transparent and guarantee quality. Not only in judging quality on the basis of available information on price, quality and patient safety and choosing healthcare services on the basis of that information (using their right to 'exit'), but in voicing their preferences for the organization of care policies and practices as well.

Cross border care urges European inspectorates and authorities to cooperate

We also see some changes in the formal relationships between governmental supervisory bodies. The coordination between them is rather important and is all about the importance and priority that is being given to quality and efficiency in healthcare. In systems in which the professional self regulation has been dominant in inspecting the quality of healthcare, the introduction of market incentives creates new forms of control and inspection. It is therefore necessary to coordinate the activities of these different inspectorates. Especially with cross border care this has to be

taken into account. Europe is characterized by very differently organized health systems. We have distinguished between centrally and decentrally organized systems, as well as between Beveridge and Bismarck systems. Next to that, we saw that the involvement of private (and commercial) organizations is of increasing importance. For the inspection of the quality of cross border care we conclude that it is more important to focus on the functions that all these different organization have, rather than too much on these organizations themselves; functions can, as we have seen, be institutionalized quite differently between countries. Cooperation should take place across borders between organizations that practice the same functions of inspecting health care quality. They can learn from each other and show best practices and norms of good care. This will be increasingly important to guarantee the quality of cross border care. We advise the different European inspectorates to cooperate more intensively to create a mix of instruments to assess the quality of cross border care in a better way.

5.5 Research Agenda

The research leaves us with several questions, of course. Little research has been conducted so far on inspecting the quality of cross border care, of comparing health quality systems between countries and of assessing the role and functions of inspectorates in order to learn from international experiences. Our research agenda should be focused on that. We have provided the first step of comparing inspection systems and addressing the dilemmas of inspecting health care quality in public/private settings. After having done this, we would advise the Inspectorate to study more thoroughly a selected set of case studies in order to get more insight in the way roles and responsibilities work out in practice. Doing this in an international comparison would provide the different inspectorates with alternative models, very practical lessons and best and worse case scenarios. We have provided the framework for these in depth cases studies with this report.

Next to that, specific issues that should be addressed are, firstly, the relationships and cooperation between supervisory bodies. In a context in which market forces, transparency and output are becoming increasingly important in all countries, the cooperation between supervising bodies becomes increasingly important as well. They all focus on one or two public interests, but their public and political contexts also address other interests. Therefore, the supervisory bodies have to agree on how to exchange information, judgments and advice. Of course, too much cooperation would threaten a precise judgment on the quality of care, but a lack of cooperation threatens each supervisor's impact on health practices. Secondly, further research could provide more insight in what makes the assessment of health care quality really effective. What is the effectiveness of quality inspection? Is it the amount of advice a hospital implements, or is it the internalization of new and better practices on the long run? And how to assess and monitor this? On these issues international comparisons are very valuable and should be carried out to further professionalize the inspection of quality in European health systems. Micro-level studies of healthcare organizations coping with different inspection regimes would also be a valuable source of analysis here.

Although in this research we have tried to address both the formal organization and practice of supervision, it is clear that we have not been able to do this extensively. Further research into inspection practices and the interplay of different instruments of supervision would be helpful in designing better strategies for quality assurance and improvement. Especially the use of 'information' strategies (i.e. through the use of

performance indicators and the like) in combination with other types of supervision could be researched more. Given the pervasive use of such strategies, research into this topic seems much needed.

Appendix 1. List of respondents

Germany

- Ms. Dr. S. Schlette – Bertelsmann Foundation
- Dr. med. K. Döbler – Federal Institute for Quality Assurance

Switzerland

- Dr. med. G. von Below - Swiss Society for Quality Management in Healthcare
- Dr. med. A. Meer, MHIM – Swiss Medical Association FMH, Medi24, and University of Fribourg.
- Ms. S. Moresi-Izzo – University of Fribourg

Spain

- Dr. J. Argimon – CatSalut
- Representative of CatSalut
- Representative Institute Avedis Donabedian

France

- Ms. C. Mayault – Haute Autorité de Santé
- N. Gerk – French Embassy on behalf of Dutch Ministry for Health
- Representative of HAS – Haute Autorité de Santé

England

- Prof. dr. G. Bevan – London School of Economics and Political Science
- Ms. Prof. dr. L.M. Wallace – Applied Research Centre, Health and Lifestyle Interventions
- Representative of CHAI – Healthcare Commission

Norway

- M. Oulie – Norwegian Board of Health
- Delegate of Helsetilsynet – Norwegian Board of Health

The Netherlands

- Prof. dr. T.E.D. van der Grinten – Erasmus University Rotterdam
- Dr. M.E. Homan – Dutch Healthcare Authority
- E. Boersma – Dutch Healthcare Authority
- Prof. dr. G van der Wal – Inspector-general for healthcare
- Mw. Drs. C. van Beek – Dutch Healthcare Authority

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