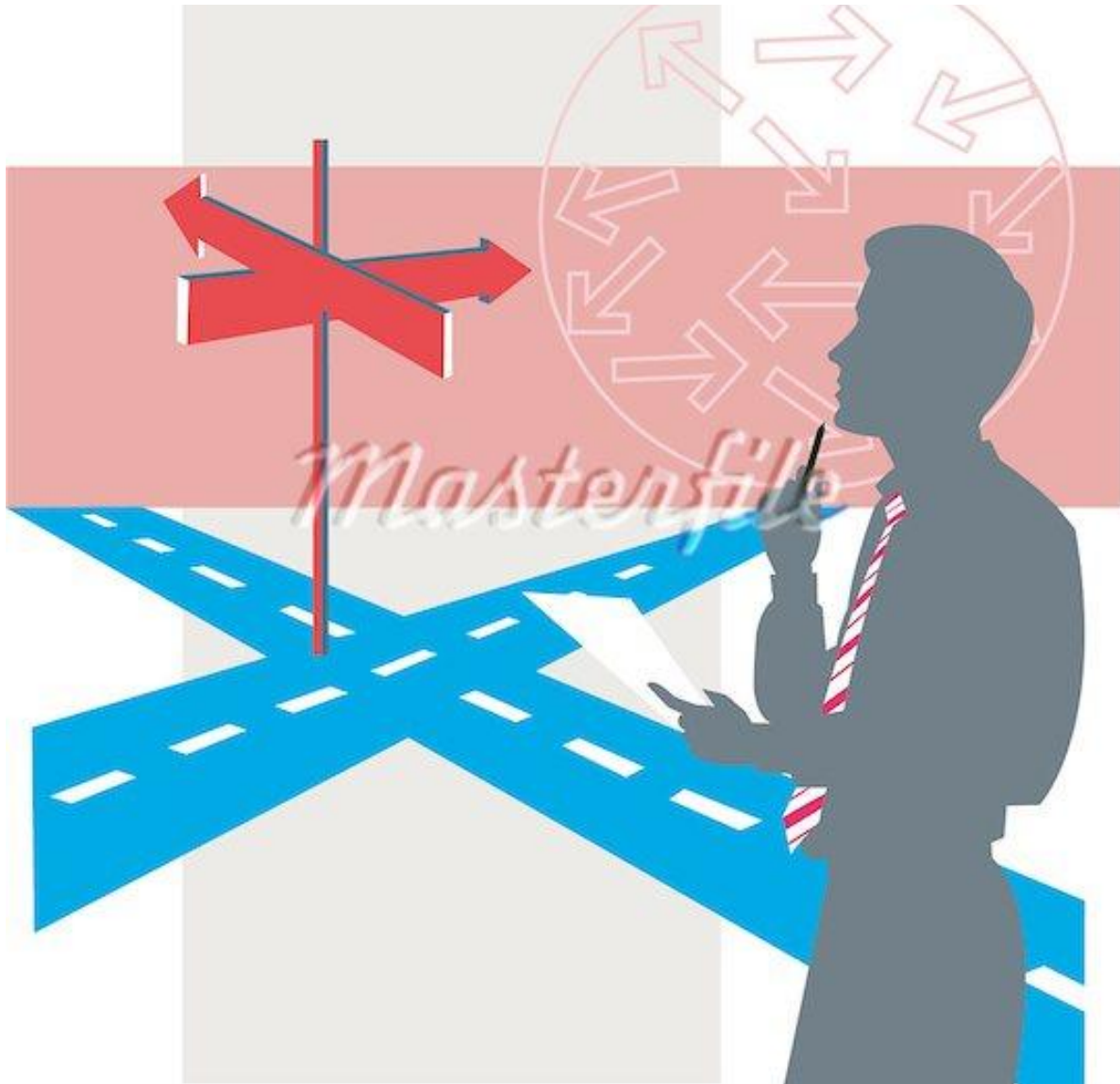


ON THE CROSSROADS



The future of supervision on healthcare in Europe

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With this thesis I complete nearly ten years of studying at the Erasmus University, first medicine and subsequently Health Economics, Policy & Law. During my earlier studies I felt that I wanted to get more involved with policy and as soon as I started my premaster I knew I was in the right place. This thesis forms the pinnacle of being involved with healthcare on a policy level. When I first started thinking about my thesis I knew I wanted to focus on supervision and Europe, albeit I did not know exactly what I wanted to research. I would like to thank dr. Den Exter for bringing this subject to my attention and for agreeing to supervise my thesis. He has been very supportive and when discussing the future of supervision we were often on the same page.

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Fons Cazius

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Abstract

Introduction

In this thesis I will discuss the current forms of cooperation as they exist within the EU. Subsequently I will describe the possibilities for improvement of the cooperation. This is all done to present a notion of the supervision of healthcare in Europe and how the future of supervision can be shaped.

Methods

My thesis will report on qualitative, investigative research into the cooperation between different European healthcare supervisors. I intend to interview several members of EPSO in order to discuss how their respective inspections cooperate with inspections from other European countries and under which circumstances. I want to conduct at least six interviews, the data from these interviews can be supplemented with observations done during the EPSO conference and discussions with the attending members. The interviews will be conducted in a semi-structured way. All participants, both in the interviews and at the EPSO conference will be asked for permission to tape the interviews.

Results

In the current existing configurations it is possible to identify two trends. On the one hand we have the formal circuit, but also the informal circuit plays an important role, perhaps even more so than the formal arrangements. The most relevant formal objects to consider are two European Directives, namely Directive 2005/36/EC and Directive 2011/24/EU. These Directives cover two different aspects of the supervision of healthcare. But there is also the Treaty on European Union and the Treaty on the Functioning of the European Union to take into account, which has a section specifically concerning public health, namely article 168.

Conclusions

Characterising the current situation of supervision is that it is difficult to distinguish what is happening, from the outside. This is because most arrangements are made on the informal circuit. Therefore, I consider the current situation something of an intersection, where the formal and the informal methods meet. To answer my main question on the shape of future supervision on healthcare in Europe. I think that it is useful that both the informal and formal roads remain present and coexist. Furthermore, I think that with the increase of cross-border

healthcare the need to establish guidelines on the recognition of rulings as well as on guaranteeing quality of care will continue to grow. In my opinion the cooperation through the national supervisors should expand to come to agreements on quality standards.

1. Introduction

In 2009 and 2010 reports were published about a Dutch neurologist, Ernst Jansen¹, who is currently being prosecuted for malpractice. Two separate committees were instated to investigate this case. The first report, published in September 2009, was written by the Lemstra committee. This committee reviewed the functioning of the neurologist in Medisch Spectrum Twente, the hospital where he worked². The committee concluded that the other specialists in the neurology department were aware that the professional actions of the neurologist Jansen were below standard. However, when the other physicians reported this to the hospital's Medical Board, the case was referred back to the department. The Board stated that the collegial relations were the departments own responsibility and referred the case back to them³.

The second report was written by the Hoekstra committee and published in May 2010. This report paid more attention to the role of the *Inspectie voor de Gezondheidszorg* (IGZ, Dutch Healthcare Inspectorate)⁴. The committee concluded that the IGZ should have investigated the malfunctioning of the neurologist Jansen much earlier than they did⁵. The Inspectorate waited four months before investigating a notification from a pharmacist that the neurologist wrote prescriptions for himself. Furthermore, according to the IGZ's own guidelines they should have reported the falsification of prescriptions and the theft of drugs to the public prosecutor. The final conclusion of the report is that the IGZ acts too reticent when it comes to complaints of patients or their next of kin⁶.

The case of the neurologist Jansen has led to much uproar in the Netherlands, because the Dutch public news discovered that he was working in Germany⁷. A discussion followed in the Dutch parliament about the exchange of information about this neurologist. There were several members of parliament that felt that there should be a database concerned with which physicians were either disciplinary or criminally prosecuted. This database should be accessible from different European countries in order to see whether a physician is allowed to

¹ Normally, the neurologist would have been anonymous, but the Lemstra committee decided to use to full name because it was already made public, for this proposal I have decided to follow that reasoning.

² W. Lemstra and others. 'En waar was de patiënt...? Rapport over het (dis) functioneren van een medisch specialist en zijn omgeving' (2009)

³ *ibid*

⁴ R. J. Hoekstra, *Angel en Antenne. Het functioneren van de Inspectie voor de Gezondheidszorg in de casus van de neuroloog van het Medisch Spectrum Twente* (, 2010)

⁵ *ibid*

⁶ *ibid*

⁷ NOS. 'Jansen Steur werkt in Duitsland' (2013) <<http://nos.nl/artikel/458279-jansen-steur-werkt-in-duitsland.html>> accessed 21 February 2013

work. An relevant question is whether the sharing of such information is allowed, or even required by the Member States of the European Union.

Apart from this particular case, rulings of the Court of Justice of the European Union (CJEU) also have played an important role in the development of regulations concerned with cross-border healthcare. One of the best known cases on cross-border healthcare is that of *Yvonne Watts versus Bedford Primary Care Trust*⁸. They refused to authorise a hip operation for Ms Watts in another Member State, which meant she would have to wait for a year to undergo the operation in the United Kingdom. Ms Watts went to France and paid the cost for the surgery herself, she subsequently proceeded to obtain reimbursement for the medical costs in the United Kingdom. The CJEU considered whether the treatment could be given to the patient in the Member State in which she resided within a reasonable time frame. Furthermore, in order to decide whether reimbursement was required the CJEU needed to balance the interests at stake. The CJEU ruled that if waiting time is reasonable it is allowed to refuse reimbursement, because otherwise it is possible that the planning and rationalisation of healthcare is put at risk. The CJEU decided that a system based on prior authorisation for hospital treatment provided in another Member State is necessary and reasonable. Furthermore, the CJEU ruled that the freedom to provide hospital services, even across borders exists⁹.

On the subject of cross-border healthcare several arrangements have been established over the last decade. The mutual recognition of degrees has been arranged in Directive 2005/36/EC of the European Parliament and the Council of the European Union¹⁰. Herein is stated that a physician is subject to the rules and regulations which apply in the host Member State. More specifically, it states in Article 8 that the Member State is required to cooperate and provide the host Member State with information concerning the conduct of a healthcare provider, and whether there are any convictions, either criminally, disciplinary, or both¹¹. It would seem that at least on a case basis it is possible to acquire information concerning the conduct of a specific healthcare provider, even if this conduct has taken place in another Member State.

⁸ *C-372/04 Yvonne Watts / Bedford Primary Care Trust, Secretary of State for Health, judgment of 16.5.2006* Watts 16 May 2006 (European Court of Justice)

⁹ *ibid*

¹⁰ European Commission. 'Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the Recognition of Professional Qualifications' (2005) 30(9) Official Journal of the European Union 2005

¹¹ *ibid*

Another relevant document is Directive 2011/24/EU which deals entirely with cross-border healthcare. It aims to provide regulations to facilitate the access to cross-border healthcare which is both safe and of high quality, while respecting national competencies¹². These two principles create tension between on the one hand the requirement of information and on the other hand respecting the autonomy of the EU Member States. In order to create a workable solution agreement between the Member States on the area of supervision of healthcare is required. This brings me to the main question of my thesis:

How should the supervision of healthcare in Europe be shaped?

In order to answer this question I will describe how supervision is arranged in six different EU countries, this is done in chapter 3. One of the most profound changes finds its basis in Directive 2011/24/EU, in article the Member States are required to establish a so-called National Contact Point (NCP)¹³. The Member States have been given 30 months to establish these NCPs, which means that the deadline is 25 October 2013¹⁴. Therefore, it is only possible to discuss the potential effects of this implementation, which can be found in chapter 6.

Other sub-questions which will help to answer the main question are:

- What forms of cooperation in the supervision of healthcare currently exist in Europe?
- Is it likely that a blacklist of malpracticing healthcare providers will be created, as was suggested by members of the Dutch parliament?
- Would it be possible to go even further and establish a European healthcare inspectorate?
- What legal basis exists within Europe for the cooperation on supervision of healthcare?

In the next chapter I will describe the methods I will use to obtain the data necessary to answer my questions. Subsequently, I will discuss how supervision is arranged in different EU Member States. In chapters 4 and 5 I will discuss my data and results. After discussing the National Contact Point in chapter 6, I will draw my conclusions and give some recommendations in chapters 7 and 8.

¹² Directive 2011/24/EU of The European Parliament and the Council of the European Union of 9 March 2011 on the application of patients' rights in cross-border healthcare 2011 Directive 2011/24/EU

¹³ *ibid*

¹⁴ Nathalie Chaze, 'A major step towards a Europe for Health Directive on patients' rights in cross-border healthcare' (2013)

2. Methods

My thesis will report on qualitative, investigative research into the cooperation between different European healthcare supervisors. At this moment no formal European supervision on the healthcare sector exists. I will study how the different supervisors cooperate at this moment and which legal framework exists that could be used to formalise a European healthcare inspection. Also, I will compare Directive 2005/36/EC and Directive 2011/24/EU. These two directives deal with the mutual acceptance of degrees and the free movement of patients. I will compare these in order to establish what legal framework exist for European supervision on healthcare. I will also look at what arrangements are laid down in the Treaty on the Functioning of the European Union. My selection is based on the directives concerned with the free movement of patients and the arrangements concerning cross-border healthcare. The objective is to identify which regulations exist to supervise healthcare providers, both on a national level as well as on a European level. Subsequently, do these directives and treaties give room to increase cooperation on supervision, or to centralise supervision.

In order to achieve this I will study how countries cooperate in the European Partnership for Supervisory Organisations in Health Services and Social Care (EPSO). The goal of this organisation is to improve the quality of healthcare in Europe and to make a connection both between supervising organisations and their individual members. EPSO aims to improve the exchange of ideas and information¹⁵.

I intend to interview several members of EPSO in order to discuss how their respective inspections cooperate with inspections from other European countries and under which circumstances. The countries I intend to interview are The Netherlands and Norway, because they were instrumental in the establishment of EPSO¹⁶. Also, The Netherlands are a forerunning country when it comes to supervision of healthcare. Other countries I intend to interview are Germany, Belgium (Flanders), England and France. I have chosen these countries because there is movement of patients and physicians between these countries and because all these countries have a functioning supervisory structure¹⁷.

Furthermore, these countries are member of EPSO, which means they are in a position to attend the conference in Brussels in April 2013. Also, these countries form a good

¹⁵ European Partnership for Supervisory Organisations in Health Services and Social Care. 'Home: European Partnership of Supervisory Organisations in Health Services and Social Care' (2012) <www.epsonet.eu> accessed 6 January 2013

¹⁶ *ibid*

¹⁷ Dung Ngo and others. 'Supervising the quality of care in changing healthcare systems. An international comparison' (2008) Rotterdam: Institute of Health Policy and Management (IBMG)

representation of different system of healthcare and the supervision thereof. The Netherlands and Norway are founding members of EPSO, but they also are examples of a socio-democratic healthcare system. This is characterised by universal benefits cross-class solidarity. England is an example of liberal healthcare system, which is funded through taxes, but it also has to work with the other nations which together form the United Kingdom. France is conservative healthcare system characterised by benefit rules, but also a state-organised system¹⁸. Belgium and Germany are interesting, because they do have systems based on health insurance, but they are both federal states. This means that many responsibilities, also those concerned with healthcare and the supervision thereof, are not arranged at a national level, but they are delegated to lower levels of government. Together these six countries represent a nice mix of different views and healthcare systems as they exist across Europe. Furthermore, the local issues that may arise in the United Kingdom, Belgium and Germany might prove a useful tool to deal with the European differences and might enable the Member State to come to a unified approach on supervision, in the future at least.

I want to ask representatives of these countries how they feel about the creation of a database for physicians who have been convicted either criminally or disciplinary, or perhaps even further forms of supervision. I want to conduct at least six interviews, the data from these interviews can be supplemented with observations done during the EPSO conference and discussions with the attending members.

The interviews will be conducted in a semi-structured way. All participants, both in the interviews and at the EPSO conference will be asked for permission to tape the interviews.

¹⁸ Gøsta Esping-Andersen, 'Three Worlds of Welfare Capitalism' in C. Pierson and F. G. Castles (eds), *The Welfare State Reader* (Polity Press 2000) 154

3. Supervision in Europe

In order to come to cooperation between healthcare inspectorates in Europe it is relevant to look at the different ways in which oversight has been arranged in these countries. And what the powers of the different supervisors are. In 2008 Ngo et al. wrote a report on how the supervision on the quality of care was changing as a result of changes in the organisation of healthcare in European countries¹⁹. In their report they compared the IGZ with six other inspectorates.

In this chapter I will describe the functioning of the supervision in the countries I have used in my thesis, namely the Netherlands, England, Belgium, France and Norway. My description of healthcare inspections in these countries is largely based on the report of Ngo et al. however, it is supplemented by some of the observations I have made during my attendance of the EPSO-conference in Brussels in April 2013. For additional information concerning the different countries described here, I have used the International Encyclopaedia for Medical Law, edited by Herman Nys. While not a country I have chosen to describe EPSO also in this chapter. Because everyone I interviewed participates in EPSO and an important source of the data for my thesis the EPSO-conference in Brussels was, I thought it useful to add a description of that organisation at the end of this chapter.

The Netherlands

The healthcare system in the Netherlands is characterised by regulated competition. This means that there is a public-private mix of provision and insurance. Most Intramural healthcare facilities operate on a not-for-profit basis²⁰. As a result there is also a mixture of steering mechanisms, which ranges from government steering to professional and self-governing. In the 1990s there was a strong notion that the supervision of quality in the healthcare sector had to be improved. The *Ministerie van Volksgezondheid, Welzijn en Sport* (VWS, Ministry of Health, Welfare and Sport) developed this notion into legislation, namely the *Kwaliteitswet Zorginstellingen* (KWZ, Quality of Health Facilities Act) and the *Wet op de Beroepen in de Individuele Gezondheidszorg* (BIG, Professions in Individual Healthcare Bill). While the former regulates healthcare organisations, the latter is concerned with individual healthcare providers²¹.

¹⁹ Dung Ngo and others, 'Supervising the quality of care in changing healthcare systems. An international comparison' (2008)

²⁰ André Den Exter and Martin Buijsen, 'The Netherlands' in Herman Nys (ed), *International Encyclopaedia for Medical Law* (2012) 135

²¹ Dung Ngo and others, 'Supervising the quality of care in changing healthcare systems. An international comparison' (2008)

In article 48 of the BIG Act disciplinary measures concerning individual healthcare providers are mentioned²²:

- Warning;
- Reprimand;
- A fine, not exceeding €4500,-;
- Suspension of registration (conditionally or unconditionally) for one year at the most;
- Partial disqualification from practice in the field concerned, when the person has been registered;
- Striking off the register;
- Disqualification from medical practice.

The last two measures are usually for life, but restitution is possible²³.

Around the same time these two acts became effective the IGZ was revised. It was formed by combining and integrating the Medical Inspectorate of Health, the Medical Inspectorate of Mental Health and the Inspectorate of Drugs. Because these three supervisors had previously worked independently problems arose as a result of different methods and working styles. This led to a report in 1997 by the *Algemene Rekenkamer* (Netherlands Court of Audit). This report concluded that the Ministry of Health would be unable to judge the quality of provided care based on information from the IGZ. This and other conclusions showed that the IGZ had to be better equipped and its functioning should be improved. This has led to new legal instruments, for example the IGZ is allowed to fine healthcare organisations, and to a more standardised form of working²⁴.

The IGZ uses a risk management strategy, this means that the Inspectorate can visit organisations and make sure that healthcare of good quality is provided. In order to prioritise between providers their method is based on three phases²⁵:

- I. Performance, based on indicators, is reported by healthcare organisations to the IGZ;
- II. Healthcare organisations which are performing poorly, according to the indicators, are visited;
- III. The IGZ takes measures to ensure the improvement and restoration of quality.

²² André Den Exter and Martin Buijsen, 'The Netherlands' in Herman Nys (ed), *International Encyclopaedia for Medical Law* (2012) 135 173

²³ *ibid*

²⁴ Dung Ngo and others, 'Supervising the quality of care in changing healthcare systems. An international comparison' (2008)

²⁵ *ibid*

The IGZ also plays a role in public health measures. Local public health is concerned with the control of the outbreak of infectious diseases, the education on public health and on rearing children, and school health. In the Netherlands this task is carried out by the *Gemeentelijke Gezondheidsdienst* (GGD, local Health Care Service), which also covers the immunisation programs. The IGZ advises, supervises and monitors these task at a regional and national level²⁶.

The IGZ also works together with, among others, the food safety organisation. This is done from the aspect of controlling and supervising the quality of healthcare and the protection of health. The last few years a shift can be seen from a centralised approach to policies concerning public health to placing more responsibilities with the municipalities. One of the risks of this decentralisation such as a lack of coordination. However, several centralised, national public health programs remain in place²⁷.

Germany

Germany is a federation consisting of sixteen Federal States, each with its own constitution, parliament and government. The highest State authority lies with the Federal Government. An extensive network of social security exists in Germany²⁸. A key aspect of the political system in general and the healthcare system in particular is that the powers of decision making are shared between the federal government, the federal states and legitimised civil society organisations. Traditionally, powers are delegated by national and regional governments to self-regulated organisations of payers and providers. These organisations play an important role in the regulation of the German healthcare services. At a national level healthcare reforms are planned, while at state level lies the responsibility for the planning of care, financing institutions and the supervision of corporatist actors and pharmaceutical manufacturers. The detailed implementation of services is left in the care of the self-governing bodies²⁹.

In 2004, the responsibility for quality insurance was delegated to the *Gemeinsamer Bundesausschuss* (G-BA, Federal Joint Committee), which is the highest decision-making board in the German self-governing healthcare system. The G-BA specifies the legal requirements and implements them, based on the legal framework made on national level. The

²⁶ André Den Exter and Martin Buijsen, 'The Netherlands' in Herman Nys (ed), *International Encyclopaedia for Medical Law* (2012) 135

²⁷ *ibid*

²⁸ Tade Matthias Spranger, 'Germany' in Herman Nys (ed), *International Encyclopaedia for Medical Law* (2012) 159

²⁹ Dung Ngo and others, 'Supervising the quality of care in changing healthcare systems. An international comparison' (2008)

Bundesärztekammer (Federal Medical Association) maintains a *Ärztliches Zentrum für Qualität in der Medizin* (ÄZQ, Medical Centre for Quality in Medicine), and cooperates with institutions for quality assurance. An example of such an organisation is the *Bundesgeschäftsstelle Qualitätssicherung* (BQS, Federal Institute for Quality Assurance)³⁰. Together with the *Landesgeschäftsstelle Qualitätssicherung* (LQS, Regional Institute for Quality Assurance), they are positioned under the responsibility of the G-BA and the BQS and the LQS are tasked with the coordination of the external comparative quality assurance in German hospitals respectively on a national and on a regional level. The G-BA defines the regulations, with which the BQS develops the functional standard for hospitals. Subsequently, the LQS can further specify regulations³¹.

There is a third institution under the responsibility of the G-BA, namely the *Instituts für Qualität und Wirtschaftlichkeit im Gesundheitswesen* (IQWiG, Institute for Quality and Efficiency in Healthcare). This institute is responsible for the scientific evaluation of the effects, quality and efficiency of healthcare services. The goal of the IQWiG is to promote the quality and transparency in healthcare. The findings of this institute are reported to the G-BA. Because of their strong professional autonomy, physicians strongly oppose any state-interference³².

The BQS measurements result in mandatory Hospital Quality Reports. These reports are published annually. However, in practice comparability is very limited because the administration differs between the federal states. As a whole the German inspection functions on a proactive basis with performance indicators and dialogues³³.

Professional conduct of physicians is supervised by State medical associations. They can be contacted by patients both if the patient is under the impression that the physicians has acted in an unprofessional manner or if the patient has questions about the medical fee the physician charges. Subsequently, the medical association will investigate the claims and take steps if that is necessary. These steps can include calling on a professional court to rule on the consequence, which can range from administrative measures, to revoking the license of the physician or even banning the physician from the profession. Over the last few years the medical associations have been building an online database where physicians can report their mistakes anonymously. The aim is that by sharing their errors it can help prevent other

³⁰ Tade Matthias Spranger, 'Germany' in Herman Nys (ed), *International Encyclopaedia for Medical Law* (2012) 159

³¹ Dung Ngo and others, 'Supervising the quality of care in changing healthcare systems. An international comparison' (2008)

³² *ibid*

³³ *ibid*

physicians making the same ones. Furthermore, the medical associations hope to establish a more open error culture, because physicians are discussing their mistakes among each other³⁴.

France

France is a highly centralised state. The regulation and jurisdiction of health policy and the healthcare system is divided between the state, the parliament, government and various ministries, and statutory health insurance funds. Other parties that are involved, but to a much lesser extent, are the local communities, which mostly play a role at departmental level³⁵.

In France there are three inter-ministerial Inspectorates-General which play an embracing role over important areas in healthcare. The *Inspection Générale des Affaires Sociales* (IGAS, General Inspectorate of Social Affairs) is responsible for the supervision and quality assurance. Its most important role is to supervise the implementation of regulations and to make sure that providers comply with these regulations. Also, the IGAS verifies the proper use of public funds and donations. Furthermore, it provides decision-makers with an independent view of how their departments perform. And it evaluates the effectiveness of public policies and initiatives³⁶.

Responsible for the evaluation of the functioning of healthcare through inspection and control of safety in healthcare organisations, laboratories and pharmaceuticals in specific regions is the *Direction Régionale des Affaires Sanitaires et Sociales d'Ile-de-France* (DRASS, Regional Directorate for Health and Social Affairs of the Ile-de-France). This is a subdivisions of the *Ministère des Affaires sociales et de la Santé* (Ministry of Health and Solidarity). Secondly, there is the *Hauté Autorité de Santé* (HAS, National Authority for Health), which performs an accreditation procedure for health establishments. Hospitals are not obliged to be accredited, but hospitals which have an accreditation receive a higher reimbursement from health insurance companies³⁷.

Furthermore, it is responsible for the establishment of the status of information about medical strategies and for improving the safety of care. The HAS makes independent, scientific-based decisions on the quality of healthcare through an integrated, patient-oriented approach involving all stakeholders. HAS carries out programs for the improvement of the quality of care. Also, it has expertise in many fields of healthcare and produces guidelines for

³⁴ Tade Matthias Spranger, 'Germany' in Herman Nys (ed), *International Encyclopaedia for Medical Law* (2012) 159

³⁵ Dung Ngo and others, 'Supervising the quality of care in changing healthcare systems. An international comparison' (2008)

³⁶ *ibid*

³⁷ *ibid*

all stakeholders in the healthcare system. HAS advises the government, the national health insurance fund and healthcare practitioners, patients and users, and as a result holds a key regulatory position in the French healthcare landscape. The evaluation studies are mainly based on scientific literature and on the opinion of healthcare professionals³⁸.

The accreditation aims to ensure the quality of care and to promote improvement in care. The procedure for accreditation consists of four steps³⁹:

1. Auto-evaluation: the hospital receives a manual with 215 criteria that need to be met in order to receive the certificate, however hospitals are allowed to take action to meet these criteria;
2. Site-visit: expert of HAS pay a visit to the hospital to evaluate the organisation and the daily practice. During this visit the focus is on possible improvements;
3. Report: the hospital receives a report six months after the visit. This report discusses the decisions and recommendations of the HAS experts. Subsequently, the hospital board can react and object to certain results;
4. Diffusion: after acceptance and presentation to the hospital the regional agency makes the report publically available through their website.

Self-regulation also plays an important role. Doctors, dentists, and pharmacists have professional organisations at national and departmental level which govern professional ethics and right to practice. Doctors and the medical service of the health insurance fund monitor the compliance with the norms for hospital care which are determined by the Ministry of Health. The HAS is also involved in quality control. This includes the compulsory accreditation of hospitals, public as well as private, and the voluntary audit of self-employed professionals. A systematic evaluation for individual healthcare professionals does not exist. Professional associations and courts deal with patients' claims of malpractice⁴⁰.

A physician is not allowed to practice medicine unless he is a member of the *Ordre des médecins* (Order of Physicians), it is a professional association which can reject candidates who they do not deem desirable, or who do not meet the legal requirements. The requirement to register with the Order applies also for foreign physicians who want to work in France, if they meet the requirements of the Order. These physicians need to register with the local Order, i.e. the branch of the Order in the respective department. An exception is made for foreign physicians who maintain their practice in another Member State of the European

³⁸ *ibid*

³⁹ *ibid* Page 36

⁴⁰ *ibid*

Union, but who wish to provide medical services in France. However, they do need to make a declaration to the Order, except in emergencies, in which case a maximum delay of fifteen days is allowed. In the declaration is stated that the medical professional can perform their profession and is legally allowed to do so in their home Member State. This declaration needs to be accompanied by a notification of the relevant authorities of the Member State that the professional is in fact qualified and allowed to legally practice medicine in their home Member State⁴¹.

The IGAS and the DRASS governmental organisations and are financed by the Ministry of Health. While the HAS was set up by the French government it is an independent public body with an annual budget of €60 million.

England

The United Kingdom (UK) is in fact a union of four countries: England, Northern Ireland, Scotland and Wales. Each of these countries have their own parliament, also several executive tasks are delegated to these countries. One of these areas of responsibility is healthcare. Each of these four countries has their own supervisor for the NHS⁴². Because of the fact that the healthcare sector in the UK consists of independent NHSs I have chosen to focus on England, because it is the largest country of the four, and because many important decisions are taken in the United Kingdom Parliament in Westminster, London.

The English NHS can be divided into two sections. There is one which deals with strategy, policy and managerial issues. The second one deals with all clinical aspects of care, which means primary, secondary, and tertiary care. Recently the distinction between these two sections is fading. A shift is visible in which the organisation is moving toward a more localised approach with very little barriers between primary and secondary care. Patient choice will also be increased⁴³.

Public health, social care, and the running and improving of the NHS is done by the Department of Health. National standards, investments in the service and strategic direction are provided by the NHS. The management of the NHS at a local level and the feedback to the Department of Health is done by the Strategic Health Authorities. Local health services are supported with improvement of performance and the integration of national priorities into local health plans. They also monitor the performance of the Primary Care Trusts (PCT) to

⁴¹ Gérard Mémeteau, 'France', *International Encyclopaedia for Medical Law* (1998) 152

⁴² David Price, 'United Kingdom' in Herman Nys (ed), *International Encyclopaedia for Medical Law* (2002) 162

⁴³ Dung Ngo and others, 'Supervising the quality of care in changing healthcare systems. An international comparison' (2008)

make sure that they meet predetermined targets. The task of the PCTs is to plan and improve primary and community services in their own region. PCTs have the freedom to develop their own targets and frameworks within nationally set standards. While the local trusts are accountable to the Strategic Health Services they are mainly self-governing. The PCTs held their own budgets. Which meant that no money was paid directly to them by the Secretary of State for health, instead PCTs had to make sure that their revenues were sufficient to cover their expenses⁴⁴. The Primary Care Trusts were abolished on 31 March 2013.

The improvement of the quality of patient care in the NHS is done by the Healthcare Commission. The task of this commission, also known as the Commission for Healthcare Audit and Inspection (CHAI), is to visit every NHS trust and health authority every four years. This is done through peer reviews to improve the process of clinical governance. NHS performance ratings and indicators for hospitals and trusts based of a rating scale, are publicised. These rating can either lead to more autonomy and additional funding, for achieving three stars, or support from the Modernisation Agency, in case the provider receives zero stars. Furthermore, the CHAI also handles formal complaints against the NHS, in case disputes could not be resolved at a local level⁴⁵. In 1999 the Health Act was established which enforces every health authority, PCT and NHS Trust to arrange a system for monitoring and improving the quality of healthcare which they provide to individuals⁴⁶.

There are three other supervisors in the NHS. Firstly, the Audit Commission, which is an independent organisation which aims to improve outcomes by driving economy, efficiency and effectiveness in local services. This commission focuses on the financial aspect of healthcare and publishes independent reports to show both risks and good practice. The aim is to continuously improve the financial management in the health services. It conducts an audit of NHS bodies, e.g. PCTs, which are not permitted to appoint their own auditors^{47,48}.

Secondly, there is an independent regulator of NHS Foundation Trusts, Monitor. Its goal is to ensure the autonomous functioning of NHS Foundations Trusts. NHS Foundation Trusts are accountable to their local communities, Parliament, and Monitor. Thirdly, a new regulator

⁴⁴ David Price, 'United Kingdom' in Herman Nys (ed), *International Encyclopaedia for Medical Law* (2002) 162

⁴⁵ Dung Ngo and others, 'Supervising the quality of care in changing healthcare systems An international comparison' (2008)

⁴⁶ David Price, 'United Kingdom' in Herman Nys (ed), *International Encyclopaedia for Medical Law* (2002) 162

⁴⁷ *ibid*

⁴⁸ Dung Ngo and others, 'Supervising the quality of care in changing healthcare systems. An international comparison' (2008)

has been created in 2007, which should register all healthcare providers, whether inside or outside the NHS⁴⁹.

Furthermore, the National Clinical Assessment Authority (NCAA) has been established. This was commissioned to work with both doctors and employers specifically to address incompetence and underperformance. It is possible for employers to refer professionals to the NCAA in order to assess the performance. Subsequently, a course of action for both the employer and the doctor will be recommended. The most serious cases will be referred to the General Medical Council. The main goal is to tackle a problem before is situation escalated, so an approach more focussed on prevention. Apart from the NCAA , the National Patient Safety Agency was established within the NHS. Its task is to collect and analyse data on undesired incidents, so that solutions to prevent harm in the future can be developed. Within this approach emphasis is placed on the prevention of blaming⁵⁰.

The Health Commission is a non-departmental public body whit the task to inform the Secretary of State about the provision of healthcare and to give advice on matters concerning healthcare by the NHS or by independent providers. Also the other two supervisory bodies: the Monitor and the Audit Commission are considered independent⁵¹.

Apart from these supervisors exists the General Medical Council (GMC), which was created in 1858. With the Medical Act, of the same year, supervisory and power of self-regulation were delegated formally to the GMC. They control aspects of practice, such as access, medical education and training. The GMC consists entirely of physicians, while pressure exists to allow representation by lay member and other⁵² professionals. The GMC also has branches four each of the four nations of the UK⁵².

Employers also have the possibility to discipline and even fire employees, but only under specific circumstances. Misconduct can be legitimate grounds to dismiss a professional. However, this does not apply to GPs, who are not employed. It does affect professionals employed by NHS Trusts, as well as those employed by health authorities and private health organisations and health insurers. Furthermore, the Royal Colleges, which are professional organisations also have the authority to discipline their members. This includes the power to

⁴⁹ *ibid*

⁵⁰ David Price, 'United Kingdom' in Herman Nys (ed), *International Encyclopaedia for Medical Law* (2002) 162

⁵¹ Dung Ngo and others, 'Supervising the quality of care in changing healthcare systems. An international comparison' (2008)

⁵² David Price, 'United Kingdom' in Herman Nys (ed), *International Encyclopaedia for Medical Law* (2002) 162

exclude them from the relevant College. But they also have authority over the registration of the professional, in the case of doctors the relevant professional organisation is the GMC⁵³.

Norway

The Norwegian health state is characterised by three levels of decision-making, namely state, health regions and municipalities. National health policy is outlined at state level by the *Helse- og omsorgsdepartementet* (Ministry of Health and Care Services). Further, the Ministry occupies itself with the preparation of reforms, proposals for legislation, monitoring of implementation, and assisting the government in decision-making. The responsibilities of the counties includes public health, and in cooperation with municipalities the organisation of public dental care. The municipalities are further responsible for primary care, both prevention and curative care, in the form of provision as well as funding, and social services. Specialist care, including somatic and mental health institutions, is supervised by five different health regions⁵⁴.

Supervision is carried out at national and at county level, the following supervisory authorities are in place⁵⁵:

- *Statens helsetilsyn* (Norwegian Board of Health Supervision), the short name, often used, is Helsetilsynet;
- Norwegian Board of Health Supervision in the Counties, which is concerned with health service and healthcare personnel. Since 1 January 2012 this has been integrated with the County Governors;
- Offices of the County Governors, which deals with child protection services and social services.

Helsetilsynet works at the national level and falls under the responsibility of the Ministry of Health and Care Services. Helsetilsynet has the oversight over the supervisory organisations that work at the county level⁵⁶.

Even though decision-making has been split up into three different levels, the oversight on healthcare, both the governance and regulation of quality, is predominantly organised at a national level. The responsibility for the general supervision of health has been delegated to a national supervisory organisation, the Norwegian Board of Health. Local supervision is

⁵³ *ibid*

⁵⁴ Dung Ngo and others, 'Supervising the quality of care in changing healthcare systems. An international comparison' (2008)

⁵⁵ European Partnership for Supervisory Organisations in Health Services and Social Care, *Report of a peer evaluation of The Norwegian Board of Health Supervision (Statens helsetilsyn)* (2012) Page 2

⁵⁶ *ibid*

carried out by the Governmental Regional Board, which reports to the National Board of Health. Both these authorities are independent organisations, however, they are both financed by the Ministry of Health and Care Services. Financial oversight is carried out by the Office of the Auditor General, which since 2002 has a department for health services⁵⁷.

There are several instruments at the disposal of the Norwegian Board of Health Supervision. There are supervision teams which make assessments and system audits concerning dangerous areas in healthcare. The basis for the assessment and improvement of provided services is to ask healthcare providers to use reports about nationwide and local supervision. To motivate providers to meet the requirements that have been set a fine can be given, but the Board does not view this as a form of punishment, but as a means of coercion. There is also a national system to monitor adverse events when they occur in hospitals. The goal of this system is to find out how such an event could occur and to prevent it in the future⁵⁸.

On the level of the individual provider there are different acts which provide standards according to which care should be provided. The Norwegian Board of Health can take measures of increasing severity from warning to the revocation of license to practice, in case of malpractice⁵⁹.

Belgium

Over the last decades Belgium has transformed slowly into a federal State. Belgium is divided into linguistic regions: Flanders (Dutch speaking region), Wallonia (French speaking region), Eupen-Malmedy or East Cantons (German speaking region), and the bilingual Brussels-Capital region. All these regions have their own Council or Parliament and Executive, which are elected directly. The different regions have a great deal of autonomy and they are responsible for healthcare and the supervision thereof in their own region⁶⁰. Because only Flanders participates in EPSO I have chosen to only discuss the Flemish region.

In Flanders the *Zorginspectie* (Healthcare Inspection) has two core tasks to inspect and to report. They inspect both facilities, which are recognised, subsidised or authorised by the *Departement Welzijn, Volksgezondheid en Gezin* (WVG, Department of Welfare, Public Health and Family), and persons who receive individual benefits. After an visit the Healthcare

⁵⁷ Dung Ngo and others, 'Supervising the quality of care in changing healthcare systems. An international comparison' (2008)

⁵⁸ *ibid*

⁵⁹ *ibid*

⁶⁰ Herman Nys, 'Belgium', *International Encyclopaedia for Medical Law* (2012) 209

Inspection reports its findings to the WVG. The Department decides whether there are consequences for the authorisation or subsidies⁶¹.

The Healthcare Inspection provides knowledge to support the development of policy. Besides reporting on single facilities, the Inspection also provides an image of an area of healthcare based on findings from inspections. The Inspection also uncovers defects in regulation. Furthermore, the Inspection aims to inform citizens. This is to create transparency on the quality of care delivered by the providers⁶².

The Healthcare Inspection is an independent authority. Inspections are carried out on their own initiative. The frequency of inspections is related to the risk of substandard quality. During an inspection the daily practice with a provider is compared to framework in which the provider should operate, this entails quality standards, regulations and frames of reference. Besides quality inspections, the Healthcare Inspections also carries out financial inspections. Inspections are carried out announced, however financial inspections can also occur unannounced. After the inspection the provider can reply to any ambiguities or inaccuracies in the report. Complaints about provisions or providers cannot be filed with the Healthcare Inspection.

The *Orde van geneesheren* (Order of Physicians) is divided into provincial councils which maintains the rules for professional conduct of medical professionals. The provincials councils are responsible for disciplining misconduct carried out by members of the Order. The provincial council can impose sanctions: warning, censure, reprimand, suspension of the right to practice for a period not exceeding two years, and being struck of the list of the Order. How a violation is sanctioned is the prerogative of the council⁶³.

Responsible for the evaluation of the quality of medical practice is *Institut national d'assurance maladie invalidité - Rijksinstituut voor ziekte- en invaliditeitsverzekering* (INAMI-RIZIV, National Institute for Sickness and Disability Insurance). It uses accreditation and peer review to oversee the system of continuous training of doctors. The system of quality accreditation, which was introduced in 1995, has three objectives⁶⁴:

1. To promote quality and cost awareness of care and the quality and efficiency of interaction between doctors and dentists;
2. To prevent the duplication of work through the exchange of patient data;
3. To promote the quality of care through continuous training of physicians.

⁶¹ Zorginspectie. 'Onze opdracht' (2010) <www.zorginspectie.be> accessed 15 February 2013

⁶² *ibid*

⁶³ Herman Nys, 'Belgium', *International Encyclopaedia for Medical Law* (2012) 209

⁶⁴ *ibid* Page 91

Responsible for the management of the system of peer review is the National Council for Quality Promotion. This Council also determines recommendations for good medical practice and it gives feedback to doctors⁶⁵.

EPSO

In this last paragraph I will describe how the European Partnership of Supervisory Organisations in Health Services and Social Care (EPSO) functions. I have discussed the role of with both Paul Robben and with Jooske Vos. I think in order to understand the current cooperation in Europe concerning the supervision of healthcare it is necessary to understand what EPSO is and how it functions.

Originally, EPSO was formed in 1996 by the IGZ and the Norwegian inspection, in this year also the first international meeting was held in Noordwijk. The aim of establishing EPSO was to establish a European network of the supervisors and monitors of the quality of healthcare in their respective countries. Over the next few years several conferences were organised and different activities in the member states were carried out⁶⁶. This lasted until 2004 when there was an intermezzo until 2008 when EPSO was revitalised by EURinspect⁶⁷.

Jooske Vos told me about EURinspect when I interviewed her. It is a foundation which researches cross-border regulation in Europe. Technically EPSO is not an independent organisation, but a project of EURinspect. This is because there is no funding for this kind of work⁶⁸. At this moment EPSO is a fairly loose organisation which meets two times a year, when it holds a conference. Its membership is more or less open to every organisation, for example at this moment Turkey is examining whether it will become a member, but they were already present at the conference I attended in Brussels. A small membership fee has to be paid, from which the secretary is paid. However, the main problem why some countries cannot participate is because they do not have a supervisory organisation. This is the case for several Eastern European countries⁶⁹. It is even possible to participate without being a member. The role of the different member organisations also differs, some are healthcare inspections, on individual provider level, while others have a more supervisory role, and others perform accreditations.

⁶⁵ *ibid*

⁶⁶ Jooske Vos. 'European Partnership of Supervisory Organisations in Health Services and Social Care - About EPSO' (2013) <www.epsonet.eu/about-epsa.html> accessed 2 July 2013

⁶⁷ Jooske Vos. 'Presentation 4: Role of healthcare supervisory organisations and of the European Partnership of Supervisory Organisations (EPSO)' (European Accreditation Network Durham 24-25 September 2012)

⁶⁸ Jooske Vos, 'Interview with Jooske Vos' (2013)

⁶⁹ PBM Robben, 'Interview with Paul Robben' in U. A. Cazius (ed) (2013)

4. Data

In order to obtain a good picture of the possibilities of supervision of healthcare in Europe, I visited the biannual EPSO-conference, which was held in April 2013 in Brussels. In preparation of my visit I spoke with Jooske Vos, who is the head of the EPSO secretary⁷⁰. In advance I e-mailed her my questions, and I also requested contact information of the ESPO member states I wished to interview. She e-mailed me her preliminary answers and invited me to discuss them in a personal interview. Unfortunately, this meeting also meant my first drawback. In my research proposal I had made a selection of countries, of which I wanted to interview representatives. Of this list, I considered Germany interesting in particular, because not only does this country shares remarking similarities with the Netherlands when looking at the system of health insurance, it is also the country where the neurologist Jansen went after he resigned in the Netherlands. In the Dutch media there was quite a lot of commotion over this fact, because it was felt that his background had not been properly checked by the German hospital.

However, Mrs. Vos told that it would not be possible to talk to a representative of Germany. The reason for this is something for which I had been warned earlier by professor Robben. As a result of the fact that Germany is a federal state there is no single healthcare supervisor. The German *Länder* (states) can each develop their own policy. Furthermore, a lot of regulation is left to the professional associations, which are also organised regionally. These professional associations have a lot of influence and are for a great deal responsible for supervising individual healthcare providers⁷¹.

This manner to make the acquaintance of differences in the supervision of healthcare is characteristic for the situation in Europe as a whole. The manner in which healthcare in general, and supervision in particular is organised varies greatly between different countries. This is something which was also indicated by prof. Robben in his interview. He remarked that there are some countries, particularly in eastern Europe, which do not have any supervisory organisation⁷². This closely fits the intentions of EPSO, which is the sharing of knowledge, and exchanging methods of best practice between the members. But also in countries which have a supervisory organisation there exist great differences⁷³. For example, in the United Kingdom there is a different supervisor for each of the different NHSs, namely England, Scotland, Northern Ireland, and Wales. But also in Belgium a similar situation

⁷⁰ Jooske Vos, 'Interview with Jooske Vos' (2013)

⁷¹ PBM Robben, 'Interview with Paul Robben' in U. A. Cazius (ed) (2013)

⁷² *ibid*

⁷³ Jooske Vos, 'Interview with Jooske Vos' (2013)

exists, because it has three different supervisors, one for each of the three language regions, Dutch, French, and German.

Focus group meeting

The differences in the approach to supervision became very clear in the first meeting I attended while visiting the EPSO-conference. This was a focus group meeting concerned with ‘*Identifying best practices to deal with impaired and incompetent health care professionals*’. The discussion was focussed around two different examples⁷⁴.

Case A:

A healthcare professional smells alcohol of a fellow colleague while they were working. This is the third time this month. This fellow is functioning properly and behaves just as always.

This focus group provided me with the opportunity not only to observe some of the countries I intended to use for my research, but also other countries which attended this meeting. It became immediately clear that the manner of organisation of healthcare and the authorities of the supervisory bodies play a crucial role in the manner in which the cases were approached. In the focus group I attended were among others Northern Ireland and Ireland present, both of these countries have a National Health Services (NHS), which means that healthcare is mainly provided by the state. As a result most individual healthcare professionals are in civil service. The representatives of these countries noted that in dealing with such problems a large role is played by the employers of the healthcare professionals. The members of the Flemish delegation noted that their main focus lies on healthcare provider at the level of the organisation. The Flemish *Zorginspectie* (Healthcare Inspection) is not allowed to discipline individual healthcare professionals⁷⁵.

The differences in the approach of supervision in their own countries becomes even more visible when I discussed their views on the future of supervision in Europe. Besides (Northern) Ireland and Flanders, the focus group was made up of France, the Netherlands, Turkey, Slovenia, England, Sweden, Finland and Belgium. When discussing Case A, the representative of Slovenia responded by describing that there is split of responsibilities between Social Services and the Ministry of Health, the former can only report the situation to the latter. But the Ministry of Health has no inspection. The representative further told us that there are medical chambers which deal with such a situation. Also, employees are to report

⁷⁴ European Partnership for Supervisory Organisations in Health Services and Social Care. '15th EPSO conference' (Brussels 18 - 19 April 2013)

⁷⁵ *ibid*

something like this to the direction of the institute. The Belgian delegation recognised what was described by the Slovenians. In Belgium there is no inspection for the individual healthcare professional, but a control system is in place which can eventually revoke a license of an institution. Apart from the Zorginspectie another professional body exists which is a central report system⁷⁶.

England and Northern Ireland consider this primarily a problem for the institution as the employer of the physician. Northern Ireland said that primary action should be taken through work-based regulation. However, physicians also have the professional and legal duty to report a malfunctioning professional. This is the last step before formal intervention by the General Medical Council (GMC)⁷⁷.

Subsequently, the chair of the focus group asked the question how to deal with “sick” employees or colleagues, such as alcoholism or mental disorders? England considers this a task for the employer and the system regulator. A Swedish delegate replied that a healthcare provider is obliged to report if they think a professional is endangering patients. This is first handled at a local level, there lies the responsibility for the overall patient safety. This responsibility was established with an act which became effective in 2010. This gives formal obligation to providers. Finland has a similar system to Sweden. The Finish representatives stated that when patient safety is compromised it is reported swiftly. These reports go to a central organ, which is called in when someone is concerned with the safety of patients. Before they conduct an inspection they first issue a written warning to the employer. The employer has to act towards the professional, in practice this means suspending the specific professional. The Swedes also note however, that as a result of different systems such an approach cannot be copied everywhere. Furthermore, they ask the question: do you act immediately, or do you first talk about it with the professional⁷⁸?

Next, a member of the Dutch researchers who chaired the focus group, asked whether healthcare providers would cover for each other, i.e. not divulge misconduct. He continued to say that if this were the case a supervisory body would not know it. One of the Swedish delegates nodded in agreement. The representative for Northern Ireland replied that doctors might have a certain degree of tolerance before they act, which means that they will not immediately report misconduct. The representative went on to say that it is possible to provide

⁷⁶ *ibid*

⁷⁷ *ibid*

⁷⁸ *ibid*

for protective disclosure. This means that the identity of the one who reports the misconduct is kept secret. However, such an event has not occurred since 2009⁷⁹.

One of the Swedish delegates said that they hardly take any disciplinary measures. After an investigation the institution falls under a special inspection regime for three years. Through reorganising the institution they are given the chance to rehabilitate themselves. Also, tests are conducted to see whether the problem is being dealt with. The English representative continued by saying that a healthcare professional can be registered (for a period of time), so a specific person is supervised⁸⁰.

Case B:

A healthcare professional (A) is covered by a colleague (B) during a week off. During this week, B notices that his colleague causes serious avoidable damage while treating several patients by inappropriate care provision. B discusses this observation after the week off. However, A isn't accessible for critical assessment. After a second time of replacing A, B concludes that A still makes serious errors in which patient safety was threatened.

A delegate from Ireland began by saying that a healthcare provider has the obligation to report such an incident to the supervisory organisation. He continued to say that there is quite a high reporting rate. One of the representatives of the Zorginspectie said that they are not competent to inspect individual treatment. They can inspect the institution, during which the Zorginspectie might discover a case as the one in the example. Professionals are only reported through peer group organisations, these organisations might retract the license of the healthcare provider.

A representative of Northern Ireland stated that both professional A and B have a professional and legal responsibility to bring such a case to the attention of the management. If they do not do this both A and B can be considered culpable. The employer is capable to deal with the situation effectively, if this is the case the supervisor would not even know of the incident. He further raises the question what would happen if there is no regulator? An English delegate agrees with the Northern Irish: it is the responsibility of the employer, to provide professional regulation. He furthermore states that the question is whether or not there is an adequate system. Subsequently, it is the task of the regulator to see whether this system is in place. One of the Belgian delegates asks how to deal with independent specialists in hospitals. A situation similar to the one in the Netherlands where many medical specialist are

⁷⁹ *ibid*

⁸⁰ *ibid*

organised in independent partnerships within hospitals. Northern Ireland asked how a supervisor should deal with reports from vengeful, fired providers. One of the Swedish delegates said that patients can file a direct complaint with the supervisor. This would lead to an assessment, this is apart from the report from a professional.

The chair of the focus group asked whether there is public disclosure of information about physicians? A representative from Northern Ireland replied that the NHS does disclose information, but this differs per country. Subsequently, the representative asked when the shift occurs from professional impairment to criminal conduct?

Next, the discussion turned to prevention. The delegate from France told that healthcare professionals have to continue training their entire professional life. However, the interval differs, yearly evaluations are not obliged by law, but they are required for the accreditation of hospitals. Shortly thereafter the meeting ended, while only one hour was reserved for the focus group, it lasted a little over eighty minutes.

Interviews

Both in preparation as well as while attending the EPSO-conference in Brussels in conducted several interviews with representatives of EPSO and its respective member states. The interviews were divided into two parts, first I e-mailed my written questions to the representatives, subsequently I talked to them in person during the EPSO-conference. While I had selected the countries, I was advised about who to contact by Joeske Vos, the general secretary of EPSO. I asked these people about their views on the current cooperation on the supervision of healthcare in Europe, but also how the supervision should be shaped in the future. The people I interviewed are:

- Geir Sverre Braut (Norway): deputy director general of the *Helsetylsinet* (NHBS, Board of Health) and chairman of EPSO;
- Paul Robben (the Netherlands): inspector with the *Inspectie voor de Gezondheidszorg* (IGZ, Healthcare Inspectorate) and board member of EPSO;
- Neil Prime (England): Head of Analytics of the *Care Quality Commission* and board member of EPSO;
- Bruno Lucet (France): deputy head of the accreditation department of the *Haute Autorité de Santé* (HAS, National Authority for Health);
- Krist Debruyne (Belgium): inspector with the *Zorginspectie* (Healthcare Inspectorate).
- Joeske Vos (the Netherlands): general secretary of EPSO.

Besides these people I was able to talk to several more people at the EPSO-conference during the intermission between parts of the program.

Current cooperation in Europe: strengths and weaknesses

EPSO is a platform which enables its members to share best practices and experiences concerning the supervision of healthcare. What struck me most during my visit was the openness with which problems were discussed and experiences were shared. There is a great desire to learn from each other and to share knowledge. According to Geir Sverre Braut one of the strengths of the current form of cooperation is:

“An increasing, mutual willingness between a considerable part of the governmental supervisory organizations to collaborate around professional practices related to supervision and control (through EPSO).”

This was also reported by other respondents. What they consider most positive about the cooperation through EPSO is the good will and energy of its members. The EPSO-network provides the members with the opportunity to share experiences. The EPSO-conferences are a place to obtain ideas. The network is a source of high profile expert advice. Neil Prime, who works for the Care Quality Commission, mentioned five different positive aspects of the cooperation through EPSO: (1) there is a great deal of good will and energy, (2) it is a good source of information, (3) a lot of experience exists inside EPSO and its wider network, (4) often the members find that they have to deal with similar issues, and (5) they can develop their links together, without having to rely on central EU structures⁸¹.

There are also downsides to the cooperation through EPSO. One of the largest problems are the differences in Europe concerning the supervision of healthcare. There are different requirements on safety and quality laid down in national legislation. Furthermore, different organisations for supervision exists throughout Europe. Neil Prime also noted that issues raised in EPSO meetings are sometimes not followed up. He stated that if meetings were more structured this would not occur⁸². Also, as a result of the loose organisation of EPSO it is up to the individual supervisory organisations whether they use obtained knowledge or not, according to Paul Robben⁸³.

However, it may not be easy for national supervisors to incorporate what has been learned in their daily practice. As Geir Sverre Braut has pointed out large differences exist

⁸¹ Neil Prime, 'Interview with Neil Prime' (2013)

⁸² *ibid*

⁸³ PBM Robben, 'Interview with Paul Robben' in U. A. Cazius (ed) (2013)

between different European countries concerning requirements for safety and quality⁸⁴. Furthermore, in several countries there is no uniform inspection. As I mentioned earlier in Germany supervision is arranged at the level of Länder, but also in the United Kingdom and in Belgium not a single supervisor exists. In the UK each of the nations has its own NHS and takes care of its own supervision, in Belgium the division is based on the linguistic border. This means that a independent Flemish, Walloon, and German supervisor exists. According to Joeske Vos each one considers the others backward⁸⁵.

Because there is no formal contact between EPSO and the European Commission local problems which are discussed at conferences are not lifted to a higher level. But also at a national level these items are not easily picked up, because there is a lot of resistance; different mechanisms are in place to keep healthcare policy a national matter, according to Paul Robben⁸⁶.

Views on the future of supervision in Europe

The question than is how to move forward from the existing situation. This is where some differences became visible in the opinion of the members. While Geir Sverre Braut and Bruno Lucet refrained from presenting a strong opinion, Paul Robben and Neil Prime have a clearer vision on the future of supervision of healthcare in Europe.

Sverre Braut stated that he did not have a sharp opinion, but that lessons could be learned for, for example, the food safety regime. Which also forms a cooperation of different European supervisors⁸⁷. Bruno Lucet felt that EPSO could be structured more, which was of course also considered a weakness by others, but he stressed that the development of minimum standards should be avoided. When I asked him about this, he told me that he was afraid that the posing minimal requirements would result in a situation in which countries would only strive to meet these requirements, instead of opting for optimal performance⁸⁸.

Paul Robben and Neil Prime both said that they expected the situation might be more formalised in the future. Robben referred to the 'blacklist', which was proposed by members of the Dutch parliament. He expects this list to become a reality in a few years time⁸⁹. Neil Prime also has a practical standpoint. He thinks that because the health market in Europe is

⁸⁴ Geir Sverre Braut, 'Interview with Geir Sverre Braut' (2013)

⁸⁵ Joeske Vos, 'Interview with Joeske Vos' (2013)

⁸⁶ PBM Robben, 'Interview with Paul Robben' in U. A. Cazius (ed) (2013)

⁸⁷ Geir Sverre Braut, 'Interview with Geir Sverre Braut' (2013)

⁸⁸ Bruno Lucet, 'Interview with Bruno Lucet' (2013)

⁸⁹ PBM Robben, 'Interview with Paul Robben' in U. A. Cazius (ed) (2013)

growing and becomes more complex, the need arises to formalise the existing links. He also considers it necessary for EPSO to expand more, in spite of the present growth⁹⁰.

Joske Vos said that there is no desire among any of the EPSO members to formalise the cooperation. A formal organisation would mean involvement of all EU Member States, setting a budget and establishing duties and powers which are to be exercised by EPSO. Furthermore, she told me that no one in EPSO wants an overarching European Inspectorate. In her opinion the success of EPSO is the result of the informal character, the voluntary participation and the enthusiasm of the participants. She also pointed out that EPSO's format allows for the discussions to go much deeper. In a formal EU setting this would not be possible. She stated⁹¹:

“probably 27 formal representatives without any knowledge would meet and would mainly discuss the division of money and not share knowledge and interesting developments.”

However, she does envision that the EPSO will continue to grow into a network of cooperating inspectorates, supervisors and monitors. Furthermore, EPSO will seek out organisations which focus on quality and safety improvement, and cooperate with them. Also, the exchange of information with the formal European circuit is merely on a personal basis. The only formal project in which EPSO takes part is a French initiative, Joint Action, but this does not go any further than sharing information⁹².

The desire to intensify the cooperation between different supervisors through EPSO was illustrated by Joske Vos. In March 2012 a report was published by EPSO of a review of Helsetylsinet, this audit was conducted on the request of the Norwegian supervisor. In March 2011 the Director and Deputy-Director of Helsetylsinet wrote a letter to EPSO requesting a peer evaluation of the Norwegian Board of Health Supervision. The aim of the evaluation was to determine whether the practice of the NHBS could be regarded as good. The request was made to respect the formal working conditions of the NHBS. Subsequently an international team was formed to conduct this inspection⁹³. Joske Vos told me that the review was conducted satisfactorily for both Helsetylsinet and for EPSO⁹⁴.

⁹⁰ Neil Prime, 'Interview with Neil Prime' (2013)

⁹¹ Joske Vos, 'Interview with Joske Vos' (2013)

⁹² *ibid*

⁹³ European Partnership for Supervisory Organisations in Health Services and Social Care, 'Report of a peer evaluation of The Norwegian Board of Health Supervision (Statens helsetilsyn)' (2012)

⁹⁴ Joske Vos, 'Interview with Joske Vos' (2013)

5. Results

When considering the results of my research, several aspects have to be taken into account. I distinguish two aspects, firstly, there is the current situation. This entails both cooperation as it presently exists in Europe, but also the European directives concerned with healthcare. To consider the practical results of these directives it is imperative to review to national legislation based on thereon. Secondly, there is the future of supervision in Europe. It is possible to discern two different results, there is the practical side which can be considered as the continuation and expansion of existing policies and there possibilities and preferences to consider.

Existing configurations

In the currently existing configurations it is possible to identify two trends. On the one hand we have the formal circuit, on the other hand exists the informal circuit. Perhaps this plays a more important role than the formal arrangements. The most relevant formal objects to consider are the European directives, namely Directive 2005/36/EC and Directive 2011/24/EU. These directives cover two different aspects of the supervision of healthcare. Apart from these there is also the Treaty on European Union and the Treaty on the Functioning of the European Union to take into account, which has a section specifically concerning with public health, namely article 168⁹⁵.

Article 168 forms the legal basis for Directive 2011/24/EU throughout the directive references are made to the specific article, furthermore it places more emphasis on the role of the European Union (EU) as a whole, rather than the individual Member States. This article states that the Union shall take action aimed at improving public health. In section 2 it reads that the EU shall encourage cooperation between the Member States in the areas of the improvement of public health. Furthermore, if necessary the EU will support and complement Member States in the improvement of providing cross-border health services. Important to note is that the Member States shall coordinate among themselves their policies concerning public health, but in this process they will confer with the EU. However, the EU is also allowed to take the initiative to promote coordination, particularly those aimed at establishing guidelines and indicators and organising the exchange of best practices. Important to note is section 7 of Article 168, which states that the EU will respect the responsibilities of the Member States in defining health policy⁹⁶.

⁹⁵ Consolidated version of the Treaty on European Union and the Treaty on the Functioning of the European Union 20122012/C 326/01

⁹⁶ *ibid*

Directive 2005/36/EC deals with the recognition of professional qualifications. This is not limited to the medical professionals, but also entails other professionals. The objective of this Directive is to remove obstacles which might exist for professionals to freely move inside the European Union and provide professional services in the EU Member States. The background of this directive is the ability of, in this case, doctors to move freely. Directive 2005/36/EC is based on an economic standpoint, its aim is to remove any barriers between Member States preventing the free movement of persons and services⁹⁷. Healthcare is a service which can be provided in another EU Member State than the Member State of residence. This is something confirmed by the Court of Justice of the European Union in the Watts-case⁹⁸. But this is also based on the Treaty on European Union and the Treaty on the Functioning of the European Union, which has the objective to establish an internal market⁹⁹.

The results are twofold, on the one hand this allows doctors to exercise their profession in another member state than where they were trained. On the other hand it gives the receiving member states a certain guarantee that a professional is sufficiently trained to carry out their profession. The Directives even goes on to specify that the recognition should not only be automatic, but also be without prejudice. Furthermore, the recognition of qualifications must be the same for professionals for whom the Member State functions as host as well as for nationals, trained in this Member State¹⁰⁰.

However, the host Member State is allowed to ask for evidence that the professional is entitled to perform services in their country. In order to establish proof, the following documents, among others, may be requested, according to Directive 2005/36/EC¹⁰¹:

- a) Proof of nationality;
- b) A testimonial that the professional is legally allowed to provide the relevant services and that he is not prohibited, not even temporarily, from practising at this moment;
- c) Evidence of professional qualifications;
- d) The professional has provided these services for at least two years over the past ten years.

⁹⁷ European Commission, 'Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the Recognition of Professional Qualifications', vol 30 (2005)

⁹⁸ European Court of Justice, 'C-372/04 Yvonne Watts / Bedford Primary Care Trust, Secretary of State for Health, judgment of 16.5.2006' (2006)

⁹⁹ European Union, 'Consolidated version of the Treaty on European Union and the Treaty on the Functioning of the European Union' (2012)

¹⁰⁰ European Commission, 'Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the Recognition of Professional Qualifications', vol 30 (2005)

¹⁰¹ *ibid*

In order for the host Member State to verify the legality of the documents provided by the professional the competent authorities of the host Member State are allowed to ask the competent authorities of the Member State of origin for any relevant information. This information can concern both the establishment of good conduct as well as the absence of any disciplinary or criminal sanctions of a professional nature. In article 56 of Directive 2005/36/EC these competent authorities are specified. It is stated that the competent authorities from both the host as well as the Member State of residence shall work in close cooperation and that they will ensure that the information is handled confidentially. Furthermore, it is stated that all information which might be relevant for the provision of services by the professional will be shared. In section three of this article it states that all member states shall appoint an organisation to give out and receive the relevant evidence¹⁰².

Subsequently, article 57 continues by stating that each Member State will also designate a contact point to provide both citizens and contact points of other member states the necessary information to value the recognition of professional qualifications. Also, these contact points will share information with the European Commission at its request¹⁰³.

With the provision of information for patients it is possible to turn to the second existing directive I will discuss here. This is Directive 2011/24/EU on the application of patients' rights in cross-border healthcare. This directive applies to individual patients who seek healthcare in another Member State, than is their own. Furthermore, it aims to promote cooperation on healthcare between EU Member States¹⁰⁴.

In part Directive 2011/24/EU is the result of the ruling in the Watts-case in 2006. While this is not directly mentioned, elements of the ruling can be found in the directive, as was summed up in the press release¹⁰⁵. The Court of Justice of the European Union (CJEU) ruled that patients are allowed to receive healthcare abroad and to be reimbursed for their costs. This made it necessary to create a directive to regulate the rights of patients in cross-border healthcare. Particular attention is paid to Articles 114 and 168 of the Treaty on European Union and the Treaty on the Functioning of the European Union¹⁰⁶. Article 114 states that

¹⁰² European Commission, 'Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the Recognition of Professional Qualifications', vol 30 (2005)

¹⁰³ *ibid*

¹⁰⁴ European Parliament and the Council of the European Union, 'Directive 2011/24/EU of The European Parliament and the Council of the European Union of 9 March 2011 on the application of patients' rights in cross-border healthcare' (2011)

¹⁰⁵ Consilium Council of the European Union. 'Directive on cross-border healthcare adopted' (2011) <http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lisa/119514.pdf> accessed 16 June 2013

¹⁰⁶ European Parliament and the Council of the European Union, 'Directive 2011/24/EU of The European Parliament and the Council of the European Union of 9 March 2011 on the application of patients' rights in cross-border healthcare' (2011)

provisions laid down by the European Parliament and the Council have as objective to establish a functioning internal market. While Article 168 is concerned with public health, but also gives the Union the responsibility to promote cooperation between Member States when it comes to public health, particularly in cross-border areas. Furthermore, it gives the European Commission the prerogative to promote initiatives aimed at the exchange of information. However, it is relevant to point out that it also states in Article 168 that the European Commission, when taking initiative, shall respect the Member States and their responsibility concerning the establishment of their system of healthcare¹⁰⁷. It would seem plausible that that is the reason why the choice has been made to direct the Member States to appoint a National Contact Point, rather than a European umbrella organisation.

The aim of Directive 2011/24/EU is to promote cooperation between Member States and to set rules in order to facilitate the access to cross-border healthcare of high-quality, while respecting the autonomy of the Member States. Furthermore, it also applies, among others, to Directive 2005/36/EC, which has been discussed earlier. However, it is up to the Member State where the treatment is provided to deliver care of good quality, hereby EU legislation and standards have to be taken into account¹⁰⁸. It is important to note that the directive does not specify the quality standards which have to be met, or even that the provided healthcare has to be of the same quality, or meet the same standards, across Europe.

Moving forward

Now that it is clear how the supervision of healthcare is currently organised it is possible to consider how the future of supervision might be seen. I discussed this with the people I interviewed, who have different views on this matter. It is possible to discern different possibilities of supervision of healthcare. The most important distinction is between formal and informal, because as Paul Robben told me, there is no formal contact between EPSO and the European Commission¹⁰⁹. This was confirmed by Joeske Vos who said that any contact with the formal Brussels organisations is on a personal title¹¹⁰.

At this moment mostly the informal circuit is active: EPSO. But this organisation is very open and accessible for member states or organisations which wish to join. The downside of this informal character is that the results of the EPSO conferences are most often nothing

¹⁰⁷ European Union, 'Consolidated version of the Treaty on European Union and the Treaty on the Functioning of the European Union' (2012)

¹⁰⁸ European Parliament and the Council of the European Union, 'Directive 2011/24/EU of The European Parliament and the Council of the European Union of 9 March 2011 on the application of patients' rights in cross-border healthcare' (2011)

¹⁰⁹ PBM Robben, 'Interview with Paul Robben' in U. A. Cazius (ed) (2013)

¹¹⁰ Joeske Vos, 'Interview with Joeske Vos' (2013)

more than the exchange of information and best practices. There are no agreements on how to deal with situations or how to proceed with new developments.

Now it is time to turn to the formal approach. As I mentioned before, at this moment no formal arrangements are made concerning the supervision of healthcare in Europe. However, it is possible to take other, past experiences and envision the possibilities on the formal level. I can imagine four potential developments to formally arrange the supervision of healthcare. Firstly, it would be possible to formalise the existing cooperation of EPSO. The advantage would be that it could build on the existing organisation, with the experience of the present member. The downside is that not all EU Member States have a supervisory organisation. Furthermore, the powers of the various member organisations differ. The last disadvantage is something that Joeske Vos told me. In our interview we discussed formalising supervision and she explained that as soon as something becomes formal in Brussels all Member States want to be present and the discussion is mostly concerned with money¹¹¹.

Secondly, an attempt could be made to formalise agreements of EPSO. The best practices, once agreed upon, are laid down in directives which are subsequently implemented into national legislation of the Member States. For example the audit which was conducted last year of the Helsetilsynet. A formalised EPSO might come to an agreement on how a supervisory organisation should be shaped. Subsequently, it could impose the need to have the national supervisors reviewed. Another example would be that of the two cases discussed in the focus group meeting during the EPSO conference. While at this moment the discussion ends with the conclusion that large differences exist in Europe, a formalised organisation would want to come to an agreement and a uniform approach for such cases. The advantage would be that the professionals would remain involved and decide together upon the best approaches. The disadvantages of this approach would be that it is quite substantial and time-consuming. As becomes clear for the description a lot of steps are involved. Other downsides are that also in this method all EU Member States would want to be involved, as a result the process of decision making would take a lot of time in order for everyone to agree. Furthermore, there is a disadvantage which can be observed already when implementing European directives, the implementation into national legislation also costs a lot of time.

Thirdly, a European healthcare inspection could be established. The authorisation could be found in Article 168 of the Treaty of the Functioning of the European Union. Herein is stated that the Commission can support initiatives to improve public health, in particular in

¹¹¹ *ibid*

cross-border regions¹¹². However, additional legal basis is hard to find and in order for this European Inspectorate to function the EU Member States would have to give up autonomy in the arrangements for the healthcare system. The advantages would be that it will not be necessary for all EU Member States to reach an agreement, but this independent organisation could form guidelines, for example based on best practices already agreed upon by EPSO. Another advantage would be that regulations can be developed by professionals, so that knowledge and expertise is not lost. Furthermore, the discussion could be shifted away from money and instead focus on what needs to be achieved. The disadvantages of this approach would be that it is required harness a new organisation, which would probably be very bureaucratic. Also, in the development of this European inspection all Member States would want to be involved to decide on the budget and the powers of this inspection. Furthermore, many Member States would be reluctant to grant authority over healthcare over to a European organisation. The EU Member States are very protective on maintaining the control over the arrangements of healthcare in their respective countries. I did discuss this option during my interviews, but apart from Bruno Lucet from France no one mentioned this as a potential option for the future of European supervision on healthcare¹¹³.

Fourthly, it is possible to look at existing directives and consider the possibilities given by these documents. The directive which immediately comes to mind is Directive 2011/24/EU which requires the Member States to establish a National Contact Point (NCP)¹¹⁴. It could be considered an obvious candidate because the EU Member States already have the obligation to establish it. Furthermore, because it is established on a national basis the threat of losing control over their own system of healthcare would probably appear or even be smaller. Also, it does not require the establishment of an additional autonomous body for supervision. While the directive was established in 2011 the NCP will not have to be established until 25 October of this year, because the Member States have been given a period of 30 months to establish the NCP¹¹⁵. The advantages of using the NCPs would be that the Member States are already obliged to implement them, it does not require additional arrangements. Furthermore, the objective of the NCP is, according to Directive 2011/24/EU, to allow easy access to information concerning healthcare providers. Another advantage is that because of

¹¹² European Union, 'Consolidated version of the Treaty on European Union and the Treaty on the Functioning of the European Union' (2012)

¹¹³ Bruno Lucet, 'Interview with Bruno Lucet' (2013)

¹¹⁴ European Parliament and the Council of the European Union, 'Directive 2011/24/EU of The European Parliament and the Council of the European Union of 9 March 2011 on the application of patients' rights in cross-border healthcare' (2011)

¹¹⁵ Nathalie Chaze, 'A major step towards a Europe for Health. Directive on patients' rights in cross-border healthcare' (2013)

establishing a NCP in each Member States, there is no need to give up any autonomy over the arrangement of healthcare. Also, because each Member State is entitled to designate their own NCP it is not necessary to create a similar supervisory organisation, with similar powers in each Member State. However, this also has a downside, because of the differentiation between Member States it is unlikely that mutual guidelines will be developed. Furthermore, there is no possibility for a central enforcement of guidelines, because each Member State has their own NCP. It is important not to neglect Directive 2005/36/EC in this context, because this directive is concerned with the recognition of diplomas and the supervision of professionals: whether or not they are allowed to practice. This also results in another advantage, it would mean that both directives are executed by a single organisation. A downside is that the tasks of the NCPs are not yet fully crystallised. Particularly the role of quality of care will play is still uncertain, in order for the NCPs to play a role as an umbrella organisation it is necessary that also the aspect of quality is addressed sufficiently.

Because the NCPs are currently being developed it is not yet known what their impact will be. Therefore, I will describe the development of the NCP on a European level as well as the introduction in the Netherlands in the next chapter. I will also discuss two possible scenarios of how the use and the role of the NCP could become over the next few years.

6. Implementing the National Contact Point

With the adoption of Directive 2011/24/EU Member States are required to establishment of a National Contact Point (NCP) to enable patients to obtain information about healthcare providers abroad¹¹⁶. The implementation of this directive could prove to be a turning point for the use of cross-border healthcare. Up until now the Member States of the European Union have been very protective about the arrangements of healthcare. There is great reluctance to give up any autonomy on the provision of healthcare. This is in spite of several rulings of the Court of Justice of the European Union (CJEU). But effectuating the NCPs could have large effects on all stakeholders in the healthcare sector. Therefore, I will give my view on the influence establishing a National Contact Point can have on the stakeholders in the healthcare sector.

Zooming out in the application of patients' rights in cross-border healthcare

In this section I will take the text of Directive 2011/24/EU and subsequently zoom out to consider it in a broader view. This allows me to observe how the Directive came to be and what its intentions are.

Based on, among others, the ruling in the Watts-case obliged the European Union to establish ground rules concerning the use of cross-border healthcare. The purpose of Directive 2011/24/EU is to enable patients to seek healthcare abroad. They are entitled to be treated in another Member State of the European Union, in principle without having to seek prior authorisation for planned healthcare. This applies for healthcare which does not require an overnight stay. Patients can simply request to be reimbursed for the costs when they return home. In the situation in which the patient is required to stay overnight in order to make use of the treatment, he is obliged to ask permission from his health insurer¹¹⁷.

Zooming in again on the Directive, it shows that the establishment of the Directive also provided patients with a new entitlement. Patients have the right to adequate information on cross-border healthcare. The Member States are therefore obliged to create a National Contact Point (NCP)¹¹⁸. In Article 6 of the Directive is stated that each Member State shall designate at least one national contact point for cross-border healthcare. These NCPs have to deliberate with patient organisations, health insurers and healthcare providers. The intention is that these NCPs should enable the exchange of information on healthcare providers. This is both

¹¹⁶ *ibid*

¹¹⁷ European Patients' Forum, *EPF Guidance on Cross-Border Healthcare* (2013)

¹¹⁸ *ibid*

information concerned with the provider, but also information on patients' rights, for example complaint¹¹⁹.

There are several catches concerned with the exchange of information. Firstly, how should this exchange take place? In these digital times access via the internet would seem most obvious, also because it would allow for easy access to citizens. However, several issues are to be reckoned with, particularly the issue of privacy is relevant. This is almost one of the remarks Henriette Roscam Abbing made in her 2009 article about the right of patients to quality healthcare¹²⁰. In article 56, section 2 is stated that the Member State can exchange information digitally, but when doing this they have to take into account the Directives concerning the protection of personal data and privacy¹²¹. Secondly, when should the exchange take place, should this be done on request, or should the NCPs do this by themselves, proactively? On request would allow for specific, up-to-date information, but proactively would mean that it is easier to compare different Member States, because information can be gathered by a NCP.

Roscam Abbing states that large differences in Europe exist in the arrangements made by Member States concerning the system for the supervision of healthcare. Some of these differences can be observed in my description of the countries I studied, described earlier in this thesis. Furthermore, she writes about the lack of agreement about how Article 56 of Directive 2005/36/EC should be interpreted¹²². Article 56 concerns the cooperation between the home Member State and the host Member State, on the exchange of information about healthcare providers¹²³. Roscam Abbing argues that the use of a smart card might be helpful, because it allows for the electronic identification of whoever accesses the information about a specific provider. Also, this allows for electronic verification of the credentials presented by the healthcare provider¹²⁴.

¹¹⁹ European Parliament and the Council of the European Union, 'Directive 2011/24/EU of The European Parliament and the Council of the European Union of 9 March 2011 on the application of patients' rights in cross-border healthcare' (2011)

¹²⁰ Henriette DC Roscam Abbing, 'Editorial: Problem Doctors and Patients' Right to Good Quality Care in the European Union' (2009) 16(4) European Journal of Health Law 301

¹²¹ European Commission, 'Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the Recognition of Professional Qualifications', vol 30 (2005)

¹²² Henriette DC Roscam Abbing, 'Editorial: Problem Doctors and Patients' Right to Good Quality Care in the European Union', vol 16 (HeinOnline 2009) 301

¹²³ European Commission, 'Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the Recognition of Professional Qualifications', vol 30 (2005)

¹²⁴ Henriette DC Roscam Abbing, 'Editorial: Problem Doctors and Patients' Right to Good Quality Care in the European Union', vol 16 (HeinOnline 2009) 301

Scenarios for the National Contact Point

At this point in my thesis I will focus on the National Contact Points. The purpose of the NCPs is to create an informed patient. Its goal is to provide patients with all relevant information on cross-border healthcare to help them make an informed choice¹²⁵. In my opinion this could result in two situations.

First scenario I, it is possible that the NCP collects all national information concerning healthcare providers and also information concerned with patient rights. Subsequently, when a national from another Member State would like to receive treatment in the Netherlands, information concerning the healthcare provider could be obtained via the NCP. Secondly, it could be the case that the NCP collects information from abroad, about the provision of healthcare in other Member States of the EU. Then, when a Dutch national would like to use healthcare in another Member State he could obtain information via his Dutch NCP about the provider elsewhere.

Both approaches have their upsides and their downsides. In scenario I, in which the NCP only collects national information, the advantages are that the NCP collects “local” information. This means that the NCP works in its own environment, where it is familiar with the ways and means of the healthcare system. Furthermore, there is no language barrier, because the NCP and the providers speak the same language. Another advantage is that the NCP only has to collect information about one country, which is less work.

The advantages of scenario II, are that it is easier to compare providers from different countries, because information from all EU Member States can be accessed simultaneously. Also the NCP can provide all the information in the language of the Member State, this allows for better comparison. The disadvantages are that the NCP will have to collect information from all other EU Member States, which might prove too much work, especially for the smaller Member States of the EU. Furthermore, it will be harder to keep the information up to date, particularly if there is a delay before the data from a country is actually available in the Member State. Also, it might be harder to advise patients on which provider to choose, because there exists no inside information on specific providers. Finally, if only a limited number of people use the NCP, its work could be considered of minor importance and as a result become neglected, which leads to outdated information.

¹²⁵ Nathalie Chaze, 'A major step towards a Europe for Health. Directive on patients' rights in cross-border healthcare' (2013)

Stakeholder analysis

Zooming out from Directive 2011/24/EU, allows for an overview on the different actors in this process. The relevant stakeholders can be seen already in the text of Article 6: “Member States shall ensure that the national contact points consult with patient organisations, healthcare providers and healthcare insurers”¹²⁶. I will now focus on the different actors and discuss how they could perceive the development of a National Contact Point. It is important to realise that because the NCP does not exist, it is difficult to establish precisely what result the implementation will have and what the effects on the stakeholders will be. In this section I will discuss my own views and opinions concerning the effects of the establishments of the NCPs on the stakeholders. As a result the situation I draw can be seen as utopian.

The State

Based on Article 6 of the Directive, the State has first of all the responsibility to establish the NCP. When Directive 2011/24/EU became effective on April 24th 2011 the Member States were given 30 months to set up this NCP. As a result on October 25th of this year each Member State should have designated a NCP¹²⁷.

In order to find out how far along this was I contacted the Dutch Public Information Service line via telephone number 1400. The operator was unable to answer my question as to where the NCP would be situated in the Netherlands, but he did refer my question to Ministry of VWS. When I received no answer after two weeks I called again. My request was once again referred to the Ministry of Health. Shortly thereafter I received an e-mail from ministry in which they informed me that they are talking with the *College voor Zorgverzekeringen* (CVZ, Health Care Insurance Board). According to the ministry, the CVZ is best equipped to form the NCP. In order to give the CVZ the proper authority to form the NCP the *Zorgverzekeringswet* (Zvw, Health Insurance Act) needs to be changed. The Ministry of Health informed me that it will not be possible to alter the Zvw before October 25th, but according to them this will not be a problem.

However, by delegating the NCP to the CVZ the State is not relieved of its responsibilities. The State is obliged to ensure that the different actors contact each other. This requires a coordinating role, in which they have regular contact with all other stakeholder to

¹²⁶ European Parliament and the Council of the European Union, 'Directive 2011/24/EU of The European Parliament and the Council of the European Union of 9 March 2011 on the application of patients' rights in cross-border healthcare' (2011) Page 57

¹²⁷ Nathalie Chaze, 'A major step towards a Europe for Health. Directive on patients' rights in cross-border healthcare' (2013)

ensure that each one of them feels sufficiently involved in the process. This is also necessary to ensure that no one actor outflanks the others and is able to get a hold over the NCP. Furthermore, the NCP has to provide patients with information concerning their rights, but also about procedures for complaints and solutions when patients are not happy with their treatment. According to section 3 of Article 6, this requires the State to make sure that these arrangements are laid down in national legislation. This gives additional responsibilities for to the State, but the State also becomes a party for information, which should be provided to the NCP. Most of these tasks are regardless of which scenario becomes reality. Only the scope to where information has to be provided becomes larger in scenario II.

The Ministry of Health indicated that to establish the NCP at the CVZ the Health Insurance Act needs to be changed. By altering the Zvw the establishment of the NCPs ventures into the domain of the health insurers. In the next section I will discuss the role of the health insurers in the functioning of the NCP.

The health insurers

The role of the health insurer will most likely change with the establishment of the NCPs. Until now, their role was mainly to sell health insurance policies to citizens and negotiate with healthcare providers about arrangements concerning treatments and costs. However, one of the aims of the Directive 2011/24/EU is to help patients make an informed choice thanks to the NCP¹²⁸. When patients want to use healthcare abroad the health insurers will get an additional task. It will be required of the insurers to provide information concerning the provider in another Member State and to make an informed decision whether or not the treatment abroad will be reimbursed. Their decision will have to be justified to the insured.

This new role with greater responsibilities fits the trends in the Netherlands over the last decade. With the implementation of the Zvw in 2006 a greater role with larger responsibilities for health insurers became a reality. The NCPs give the health insurers the possibility to obtain information about the quality of healthcare providers. Depending on which scenario becomes will unfold. These healthcare providers can either be domestic or be active in other Member States. This creates an interesting situation, because according to article 29, section 1 the work area of a health insurer is the Netherlands¹²⁹. But in order to arrange healthcare abroad, health insurers will have to negotiate with foreign healthcare providers.

¹²⁸ *ibid*

¹²⁹ Zorgverzekeringswet 2005

It is also possible that the establishment of the NCPs effects what care insurers are willing to reimburse. According to the article by Niezen et al. from 2007, conditional reimbursement is considered an effective means to establish which pharmaceutical care is reimbursed, based on specific criteria¹³⁰. Conditional reimbursement was developed as a tool to promote the appropriate use of medical drugs. The conditions aim to promote both effective, efficient healthcare and the quality of care.

In the article four types of conditions are identified¹³¹:

- Restrictions of the indication;
- Referral to professional guidelines;
- Prescribing only by treating specialist and/or specific demands on the requested expertise of the prescribing physician or the treating facility;
- Prior authorisation must be obtained from the health insurance company.

The fourth point is similar to one of the points in the Directive: for hospital care prior authorisation is required before using cross-border healthcare. However, it is possible to imagine that health insurers will use the information from the NCPs to decide whether or not to approve the use of healthcare abroad. This was also confirmed in the Watts-case where the CJEU ruled that for the reimbursement of hospital care obtaining prior authorisation is legitimate. The argument was that otherwise the planning of the healthcare system might be damaged¹³².

This could have two effects, firstly health insurers use this information to steer patients away from healthcare providers of insufficient quality. This could mean that patients have an important say in which provider they choose. Subsequently, when they seek approval from their insurer there is no problem, unless the insurer deems the quality insufficient. The second effect could be that health insurers will actively steer patients to specific providers. Their motivation might be cost-based: in order to reduce the costs of healthcare insurers aim to steer patients towards providers who charge lower costs. However, these lower expenses might be the result of lower quality. In either case the problem is that it is difficult for health insurers to assess the quality of healthcare. One of the reasons is the large differences in Europe where the system of healthcare is concerned, this was also noted by Roscam Abbing¹³³. It seems

¹³⁰ Maartje Niezen and others. 'Conditional reimbursement within the Dutch drug policy' (2007) 84(1) Health Policy 39

¹³¹ *ibid* Page 41

¹³² European Court of Justice, 'C-372/04 Yvonne Watts / Bedford Primary Care Trust, Secretary of State for Health, judgment of 16.5.2006' (2006)

¹³³ Henriette DC Roscam Abbing, 'Editorial: Problem Doctors and Patients' Right to Good Quality Care in the European Union', vol 16 (HeinOnline 2009) 301

likely to expect that large differences will also exist in their respective systems for measuring quality. It is than really possible to compare the quality of different providers across Europe. Furthermore, it is still unclear whether and how the NCPs will provide quality information, because this is not specified in Directive 2011/24/EU¹³⁴. If this information is not provided will health insurers be able to obtain and asses this information themselves? I think that the task is too laborious for health insurers, which means that it is unlikely that they will undertake this task.

When health insurers will actively steer patients this could be opposite the intention of both Directive 2011/24/EU and the Dutch Zvw, which both aim to provide patients with ample opportunities to choose where they use healthcare^{135 136}. Furthermore, one of the aims of the Zvw is to give more choice and responsibility to the insured. Both choice and responsibility are taken away if insurers would actively steer patients towards providers. This could be the case in both scenario I and II, however in scenario II it will be much easier to compare different providers. It also depends whether the NCP will also collect information about the costs of healthcare. Certainly, an additional administrative burden will be placed on the insurers to keep up with the data from all different Member States, regardless of which scenario is implemented.

The actions of the health insurers could have large effects on the ability of patients to choose their provider. However, other effects can also be identified. Therefore, I will describe what might be the consequences for the patients when the NCP becomes active in the next section.

Patients

As I described above, both the Zvw and Directive 2011/24/EU aim to create informed patients who are able to seek information concerning providers and make a rational decision based on that information. Before 2006 Dutch patients who needed hospital treatment first went to their general practitioner (GP) who subsequently referred them to a specialist. If they were not sure about the advice, or proposed treatment of the specialist they could go back to their GP and obtain a second opinion. With the introduction of the Zvw the role of the health insurer has become larger, which means that patients sometimes do not have a choice where

¹³⁴ European Parliament and the Council of the European Union, 'Directive 2011/24/EU of The European Parliament and the Council of the European Union of 9 March 2011 on the application of patients' rights in cross-border healthcare' (2011)

¹³⁵ Ministerie van Volksgezondheid, Welzijn en Sport, 'Zorgverzekeringswet' (2005)

¹³⁶ European Parliament and the Council of the European Union, 'Directive 2011/24/EU of The European Parliament and the Council of the European Union of 9 March 2011 on the application of patients' rights in cross-border healthcare' (2011)

they can go, for example if their health insurer has only contracted a limited number of hospitals for a particular treatment. With the establishment of Directive 2011/24/EU the possibilities for patients have been enlarged. Patients have the opportunity to go abroad for their treatment, with only the need to obtain prior approval from their health insurer in the event of hospital care.

How easy would it be for patients to use healthcare abroad? Probably they will not be able to ask their GP for advice on a foreign healthcare provider, because he does not know them. An advantage of the NCPs is that the information the patient can obtain is provided by the country in which the treatment is provided, in scenario I. This allows the patient to receive treatment which is very up to date. However, several disadvantages exist in scenario I. A patient who wishes to receive information about treatment abroad will have to travel abroad, where he might run into language problems. Especially if the NCP does not provide its information in all languages of the EU. But also if a patient wishes to compare providers from different Member States he will have to contact the different NCPs and subsequently compare the information himself. Scenario II would be much more convenient for the patient: he could access the information in his own country, and language. Furthermore, it would be easier to compare providers from different countries, because the data would be available in one location. However, if countries or providers are slow to update information, the patient would be uncertain as to how accurate and timely the information is. Furthermore, is the information comparable: are the same parameters used, or the same period for measuring, for example. This is unknown to the patient and perhaps also to the NCP.

Furthermore, it is not an option for all patients to travel abroad, because to do this the patient would have to possess the necessary resources. This could lead to a division between patients: those who have the intellectual and financial capabilities to go abroad for healthcare and those patients who lack these possibilities. Potentially, this could result in unequal treatment, because those who go abroad might be treated sooner and faster than those who do not go abroad. Also, because travelling expenses will most likely not be reimbursed by health insurers. It is possible to take a Rawlsian standpoint on this. Because when some patients travel abroad to receive healthcare, it results in shorter waiting lists in their Member State of residence. Which means that patients unable to use healthcare in another Member State, whether this is for financial or other reasons does not matter, will remain on a shorter waiting list. This is considered Rawlsian, because at least one person is better, the patient who travels

abroad, and none are worse off, because those who remain are left with a shorter waiting list¹³⁷.

The last issue I wish to discuss here is what happens when the patient is not satisfied. According to the text of Article 6 the patient is also informed by the NCP of his rights and how to file complaints, however the reality might be more difficult. If complications occur sometime after a treatment, when the patient has returned to his own country it might be difficult to complain. His national supervisor might argue: treatment was received abroad, so that is where your claim belongs, while the supervisor in the country where the treatment was received could say: you are a citizen of another country, so you have to file your complaint there.

As I mentioned above, patients will come with new questions at their GP's office concerning healthcare providers in other countries. In the next section I will discuss the possible effects of the establishment of an NCP for physicians.

Physicians

The establishment of a NCP will have several consequences for physicians. Firstly, their role with patients will change, as I have mentioned above. Patients will have questions concerning both treatments and providers in other Member States. While treatments will most often be the same as in their own country, providers will likely be unknown. In the current situation GPs will refer most of the time to a local specialist, who they know. If the specialty is rarer and not available in the immediate vicinity of the GP, he will also likely know the specialist, because of their limited number in the Netherlands. However, in the whole of Europe their number will be much larger and because they will not have been trained together the GP will not know the specialist. As a result the GP is less able to advise his patient as well as is possible in the current situation.

There is also another thing which comes into play, namely that physicians will have to compete with providers abroad. The objective of Directive 2011/24/EU is to help patients make an informed choice. It aims to ensure that patients are able to choose their provider from all over Europe. Furthermore, if large differences exist between the costs of a treatment it is possible that health insurers will actively try to steer patients towards a cheaper provider. Providers will have to try and distinguish themselves from providers across the border. Physicians might feel pressured from different sides: from the State to provide care of high

¹³⁷ Johan Polder and Werner Brouwer. 'Tien woorden gezondheidseconomie' (2008) 86(2) TSG: tijdschrift voor gezondheidswetenschappen 63

quality, from the insurers to keep the costs low, and from foreign providers who could be cheaper. Also, physicians might feel pressure from insurers that they are no longer able to refer patients freely, as they have done until now. But it could also have a positive outcome: if a physician is aware of a new treatment abroad, he could refer a patient to that foreign specialist, easier than is currently the case.

Another aspect the physician will notice in his practice will be an administrative one. The task of the NCP is to provide patients with information concerning healthcare providers. And according to section 3 of Article 6: “on request, information on a specific provider’s right to provide services or any restrictions on its practice”¹³⁸. As a result physicians, or at least the organisation in which they work, will have to provide accurate up-to-date information on their services. This would place an additional administrative burden on the physician and/or organisation for which he works. Also the places a responsibility with the NCP to check whether the information is, and remains accurate. In order to effectively compete with providers from other Member States physicians will have to obtain information about providers, their quality, prices, and additional services they provide.

It seems that from a competition aspect scenario II holds the most advantages for the physicians, because they will most easily be in a position to compare their foreign competitors. However, in case of scenario II physicians would also have more administrative work providing information to all NCPs. Furthermore, they might be forced to provide data in a specific format, requiring additional administrative work.

It seems that both scenarios have (dis)advantages, in the next section I will draw some conclusions. Furthermore, I make some recommendations concerning the implementation of the Dutch NCP as well as the future of supervision in Europe.

¹³⁸ European Parliament and the Council of the European Union, 'Directive 2011/24/EU of The European Parliament and the Council of the European Union of 9 March 2011 on the application of patients' rights in cross-border healthcare' (2011) Page 57

7. Conclusions

In this thesis I have described the current status of supervision on healthcare in Europe and discussed the future of that supervision. In order to answer my main question I have drafted several sub-questions, two of which have been answered in their own chapters. Namely, the different arrangements of supervision in the various EU Member States in chapter 3. And my thoughts about the establishment of the National Contact Points in chapter 6. In this chapter I will discuss my remaining sub-questions which will lead to an answer of the main question of this thesis.

Current forms of cooperation

The current situation of supervision resembles an intersection, where the formal and the informal circuits meet. Most striking about the current situation is the differences which exist throughout Europe. Particularly the differences in powers between the various existing supervisory bodies. This dissemination is sometimes caused by different ways of organising the healthcare system. I shall give some examples, the British system is characterised by two important features. Firstly, the NHS is a state-organised healthcare system, this means that basically all doctors are civil servants. As a result their approach to physicians who do not function properly is to have the employer deal with it. This became clear during the focus group meeting I attended in Brussels¹³⁹. The second aspect is that the United Kingdom is in fact made up of four different nations¹⁴⁰. This means that each one is responsible for their own supervision. As a result they are not all represented in EPSO, but also they do not have their own unified standpoint. A similar situation exists in Belgium, where different supervisors exist for each of the linguistic areas. Furthermore, the Zorginspectie does not have the authority to take action against individual healthcare providers¹⁴¹. While in Germany supervision is not arranged at a national level and where professional organisations play a large role in disciplining healthcare professionals¹⁴². These countries do not have a single domestic healthcare supervision, how can it be expected that a single European agreement on supervision exists? On top of that, the Member States of the European Union are very protective when it comes to the arrangements concerning their healthcare system. The Member States are reluctant to give away any autonomy in this field.

¹³⁹ European Partnership for Supervisory Organisations in Health Services and Social Care, '15th EPSO conference' (Brussels edn 2013)

¹⁴⁰ David Price, 'United Kingdom' in Herman Nys (ed), *International Encyclopaedia for Medical Law* (2002) 162

¹⁴¹ Herman Nys, 'Belgium', *International Encyclopaedia for Medical Law* (2012) 209

¹⁴² Tade Matthias Spranger, 'Germany' in Herman Nys (ed), *International Encyclopaedia for Medical Law* (2012) 159

Because of these differences it is difficult to come to a unified form of cooperation. As Paul Robben discussed when I interviewed him local initiatives do exist. An example is dealing with the MRSA-bacteria, which differs greatly in incidence between Germany and the Netherlands. Therefore, both countries try to cooperate to reduce the prevalence on the different sides of the border. However, such initiatives rarely seep out to the main European playing field¹⁴³. As a result no single approach for this challenge is formulated and cooperation remains at a local, bilateral level. Next, I will discuss what views exist on the idea which surfaced in Dutch parliament about a blacklist for healthcare professionals.

From blacklist to European Healthcare Inspectorate

I asked the people I interviewed whether they thought it likely that a blacklist of malpracticing healthcare providers would be established. I subsequently went even further and asked them if they thought it possible that in the future such an organisation as a European healthcare inspectorate might be formed.

Paul Robben stated that he expected that in time a blacklist would be established. However, he also remarked that establishing a blacklist is not as easy as it might seem, this is the result of different attitudes in various European countries. To give an example: in the Netherlands euthanasia is, though strictly regulated, allowed when the necessary conditions are met and the relevant precautions are taken. While in a country such as Italy this would probably be unthinkable. This means that a physician who carried out euthanasia in the Netherlands could be blacklisted in Italy¹⁴⁴. This means that the desire of the politicians to establish a blacklist might not be as easy as it is perceived or it might not be as clear cut as thought, based on the case of the Dutch neurologist. This is something which is also noted by Henriette Roscam Abbing, she refers to different cultural and religious backgrounds which can reflect sanctions, for example for carrying out an abortion. Furthermore, she raises the issue of how to deal with pending cases. Because on the one hand the suspicion or investigation could be reason enough to inform other Member States. But on the other hand this restricts something of a fair trial, because making this information public might make a healthcare professional seem guilty even when he is not convicted¹⁴⁵. In spite of these potential drawbacks, it seems probable that in the future a blacklist, at least for convicted

¹⁴³ PBM Robben, 'Interview with Paul Robben' in U. A. Cazius (ed) (2013)

¹⁴⁴ *ibid*

¹⁴⁵ Henriette DC Roscam Abbing, 'Editorial: Problem Doctors and Patients' Right to Good Quality Care in the European Union', vol 16 (HeinOnline 2009) 301

healthcare professionals, will be established. Particularly considering the current political desire to do so.

Apart from these issues, the only one of the people I interviewed in favour of a single European healthcare inspectorate was the French delegate Bruno Lucet¹⁴⁶. Also, other people I spoke with at the EPSO conference in Brussels did not think that the establishment of such an organisation would be a good idea¹⁴⁷. These people share the sentiment expressed by Joeske Vos, who stated that when such an organisation would be formed all EU Member States would want to be involved and the main topic would be financially oriented¹⁴⁸. Furthermore, they thought that it would probably create a large and bureaucratic organisation. In the next section I will further deepen what legal infrastructure exists or is missing to base the future cooperation on.

Legal basis for future cooperation

In order to answer the question of what the supervision of healthcare in Europe should look like it is relevant to establish what legal basis currently exists in Europe. In my thesis three European documents play an important role: the Treaty on European Union and the Treaty on the Functioning of the European Union, Directive 2005/36/EC, and Directive 2011/24/EU. Of particular interest of the Treaty is Article 168, which is concerned with public health. All these three documents have a different approach and as a result they both overlap as well as leave voids. Important to note is that in particular the Treaty and Directive 2005/36/EC are concerned with establishing an internal market: arrangements are made to promote the free movement of persons and services. This is something which Directive 2011/24/EU also picks up, namely the free movement of patients across borders to receive treatment. As a result providers of healthcare are allowed to provide services across borders. What is missing in these three documents is the quality and supervision of healthcare. Quality is mentioned, but the standards are left to the individual Member States, rather than imposed, or obliging the Member States to come to an agreement.

Nevertheless, Directive 2011/24/EU forms an improvement compared to the earlier Directive 2005/36/EC, because in the 2005 directive the exchange of information was not mandatory, something which was also noted by Roscam Abbing¹⁴⁹. However, apart from the

¹⁴⁶ Bruno Lucet, 'Interview with Bruno Lucet' (2013)

¹⁴⁷ European Partnership for Supervisory Organisations in Health Services and Social Care, '15th EPSO conference' (Brussels edn 2013)

¹⁴⁸ Joeske Vos, 'Interview with Joeske Vos' (2013)

¹⁴⁹ Henriette DC Roscam Abbing, 'Editorial: Problem Doctors and Patients' Right to Good Quality Care in the European Union', vol 16 (HeinOnline 2009) 301

establishment of the NCPs it remains unclear how the exchange of information should take place in practice. Furthermore, how should information concerning providers and regulations in Member States become available to individual patients? Also the extent of the information is not laid down. Should the information for example be made available through a publically accessible website? Which of course has security risks, also what happens after a sentence, whether criminal or disciplinary, has been served. When the name is removed from the website, who will guarantee that it is not available somewhere online and can be found through a search engine?

As I mentioned earlier tension exists between easy, open access and privacy and protection of professionals suspected of malpractice. I think that the full extent will become visible in the coming years, but I also think that differences between European countries will be visible in the availability of information. One of the issues where this already can be seen is the manner in which is being dealt with healthcare providers who are charged with malpractice: will Member States publish information about these professionals, or will they respect their privacy, or even will these Member States attempt to keep it quiet which would give the provider the opportunity to set-up practice abroad?

The Treaty on the Functioning of the European Union gives with Article 168 the Commission the opportunity to take the initiative in establishing a single European healthcare inspectorate. Particularly, if the NCPs do not provide the desired result in cross-border healthcare. Through Article 168 the Commission is allowed to take the initiative in such matters. However, in section 4 of Article 168 the quality of care is not mentioned when objectives are summed up. For medical products and devices it is specified that measures are taken to set high standards for quality and safety. What would further limit the establishment of a European healthcare inspectorate by the European Commission is section 7 of Article 168. Herein it is stated that the Union shall respect the Member States when defining health policy as well as the organisation and delivery of healthcare¹⁵⁰.

To answer this question, the legal framework to exchange information, establish a blacklist and potentially even a European healthcare inspectorate is in place. However, it seems unlikely that the Commission would go as far as setting up a single European supervisory organisation. Furthermore, what is also missing at this moment is the legal basis for unified quality standards. This is left to the Member States, but there is no binding requirement to come to such an agreement.

¹⁵⁰ European Union, 'Consolidated version of the Treaty on European Union and the Treaty on the Functioning of the European Union' (2012)

Shaping the future of European supervision on healthcare

Now I come to the answer to my main question: *how should the supervision of healthcare in Europe be shaped?* Characterising the current situation of supervision is that it is difficult to distinguish from the outside what is happening in ways of cooperation. This is because most arrangements are made either bilaterally or on the informal circuit: for example the European Partnership of Supervisory Organisations in Health Services and Social Care (EPSO). An organisation of which I had never heard before I started with this thesis. But while it may not be very well known, it is certainly not an inaccessible organisation. EPSO is certainly open, this can be seen from the fact that they are expanding, taking on new members. Also, perhaps even as a result thereof, EPSO is becoming more important, for example by carrying out peer review, such as the audit of the Norwegian healthcare supervisor. In my opinion this could mean that eventually EPSO might become a formalised European organisation. Several people I interviewed, considered a formalisation of EPSO a development which is to be expected, and perhaps even required. There was agreement among all the people I interviewed that something is happening, but the Dutch, Paul Robben and Joeske Vos, whom I interviewed were more cautious. Joeske Vos said that she did not expect EPSO to formalise, but did think that it would continue to expand with supervisors, regulators and monitoring organisations¹⁵¹.

Meanwhile, it is possible to distinguish changes on the formal side of supervision of healthcare. Two events are the cause for that, firstly, from 25 October 2013 Member States of the European Union are obliged to have an NCP. This became mandatory with the establishment of Directive 2011/24/EU, which gave the Member States 30 months to establish the NCPs. Secondly, the case of the Dutch neurologist Jansen who, after making a deal with the IGZ to never work in the Netherlands again, went to work in a German hospital. This caused a great deal of uproar in the Netherlands¹⁵². However, it also created momentum, particularly in the Netherlands, to establish a blacklist of malpractising physicians¹⁵³. When I spoke with a Dutch civil servant a few weeks ago, who was involved with the negotiations on the mutual recognition of diplomas (Directive 2005/36/EC) at the height of the case Jansen. He told me that this case made it much easier to act, because there was a lot of political willpower to do something.

¹⁵¹ Joeske Vos, 'Interview with Joeske Vos' (2013)

¹⁵² NOS, 'Jansen Steur werkt in Duitsland' (<http://nos.nl/artikel/458279-jansen-steur-werkt-in-duitsland.html> edn 2013)

¹⁵³ NOS. 'EU-politiek wil snel artsenregister' (2013) <<http://nos.nl/artikel/458463-eupolitiek-wil-snel-artsenregister.html>> accessed 3 July 2013

What is missing in the current cooperation on supervision are the professional organisations, such as representative organisations of medical specialists. As I have described earlier they play an important role in many European countries, both in the establishment and implementation of supervision as well as in a disciplinary role for providers who do not meet their standards. In medical practice often a consensus exists on both generally accepted treatments as well as the best available treatment. In order to reach this a lot of research is done into the best approach, but also there is discussion among professionals about what is considered to be generally accepted. Therefore professionals have experience in reaching agreements across borders. I think it could prove useful to involve these professional organisations, at least to some extent, in order to help establish cross-border guidelines on how to conduct treatment. For example, through the *Nederlands Huisartsen Genootschap* (NHG, Dutch College of General Practitioners) I came to the website of Wonca Europe which works together to develop guidelines for the prevention of coronary vascular disease¹⁵⁴. Another example is the *Comité Permanent des Médecins Européens* (CPME, Standing Committee of European Doctors). This organisation works to shape the future of practice in healthcare and public health, but it also represents the view of the medical professionals. Furthermore, it cooperates, together with EU Member States, in EU funded projects. These projects are among others concerned with patient safety¹⁵⁵.

I think that the expansion of EPSO will continue, hopefully with the inclusion of professional organisations. I have noticed during my visit to the Brussels conference that there is a lot of enthusiasm among the participants to share experiences and to cooperate. Furthermore, it can be seen that an interest exists from other countries to join and to learn through EPSO, for example Turkey, which is not an EU Member State, but who were present in Brussels and would like to continue to participate in EPSO. In my opinion this is also a demonstration of the a-political character of EPSO. In any formal EU meeting it would be unlikely that Turkey would be able to participate so easily. The downside of the open character of EPSO is that it really depends on the motivation of organisations whether or not they join. For example, there was no representative from Germany and from Belgium only Flanders participates in EPSO. This means that it would be difficult for EPSO to establish a uniform European standpoint on supervision, because it does not represent all EU Member States. Furthermore, the desire to form a unified front does seem to exist within EPSO, at least

¹⁵⁴ Wonca. 'Wonca Europe' (2013) <<http://www.woncaeurope.org/library/documents>> accessed 16 July 2013

¹⁵⁵ CPME. 'Comité Permanent des Médecins Européens - History' (2013) <<http://www.cpme.eu/about/history/>> accessed 16 July 2013

from my observations. Everyone I spoke with emphasised the openness and the motivation of each individual participant. This allows for everyone to take knowledge with them depending on whatever they deem useful, rather than that a certain practice is imposed on them. Another disadvantage for EPSO is that apart from the different powers the supervisory organisations have, not all members are supervisors. For example Bruno Lucet, the French representative works for the French accreditation organisation. However, I do think that the role of EPSO for its members will grow, and with that the influence it (indirectly) has. The review EPSO did in 2012 of the Norwegian supervisor, at their own request, was successful and received positively. It is very well possible that in the future more audits of member organisation will take place. This could eventually lead to a more uniform approach for the supervisors.

To answer my main question on the shape of future supervision on healthcare in Europe. I think that it is useful that both the informal and formal roads remain present and coexist. Furthermore, I think that with the increase of cross-border healthcare the need to establish guidelines on the recognition of rulings as well as on guaranteeing quality of care will continue to grow. In my opinion the cooperation through the national supervisors should expand to come to agreements on quality standards. In the next chapter I will give my recommendations continuing forward from these crossroads.

8. Recommendations and discussion

As I discussed in the conclusions, the supervision of healthcare in Europe is at a crossroad at this moment. While a crossroad might seem like an ideal place for the two paths, the formal and the informal, to meet up and continue together, I would advocate that these two directions should continue parallel and remain separate. The reason for this is that each of the two has its own worth and advantages.

First, the informal track headed by EPSO. The strength of EPSO lies in its informal character. As a result thereof the motivation of the individual people drives their actions. The persons present at the conferences want to learn and share their knowledge, so that other people may learn. What particularly struck me was how friendly everyone behaved. This was not only to the other participants, but also to me, even though it was the first time I attended and I knew almost no one present. The goals of those attending is to take in best practices, as was mentioned by several people I interviewed^{156 157 158}. An example of a topic which is regularly discussed is the whether a supervisor should conduct announced or unannounced visits. While no consensus is reached it does allow those present at the conference to hear arguments for both approaches and perhaps arrive at new insights about their own approach to site visits. I consider it a positive development that EPSO conducted a peer review of Helsetilsynet. I would recommend that these audits are carried more frequently in the future. It allows for the auditors to see other practices of supervision and learn from them. It also allows for the reviewed organisation to hold their process up to the light and reconsider their purpose and function.

Furthermore, it seems that EPSO appeals to others, continuously new organisations wish to join, even from outside Europe. I think it would be a waste to discard the network as it exists, as well as the knowledge from people who actually work in the field of supervision. Because they occupy themselves with best practices, rather than money or politics. While the formal regulations, as laid down in several European directives, are aimed more at the internal European market. This entails both the freedom of movement for people as well as the freedom of movement of services, which means the possibility for healthcare providers to offer their services abroad, rather than merely domestically as is currently the case. Furthermore, as I noted in the conclusions professional medical organisations are absent at this moment in the EPSO conferences. I think it would prove useful to reach out to these

¹⁵⁶ Bruno Lucet, 'Interview with Bruno Lucet' (2013)

¹⁵⁷ Joeske Vos, 'Interview with Joeske Vos' (2013)

¹⁵⁸ Geir Sverre Braut, 'Interview with Geir Sverre Braut' (2013)

organisations and let them assist with the implementation of cross-border agreements on practices and on disciplinary matters.

However, agreement on disciplinary measures for healthcare professionals has its own difficulties. Firstly, under what type of law do these disciplinary rulings fall, for example in the Netherlands it is part of Administrative Law, while in other countries it could very well be part of the Criminal Law. Secondly, how are the arrangements concerning the procedures of these disciplinary rulings? Do all parties get a fair hearing, are the procedures public or are they held behind closed doors? All these factors determine whether or not there can be established if there has been a fair trial. This necessary otherwise it is unlikely that other Member States will blindly follow such a ruling.

I would also recommend separate development of the formal and informal track, because the formal regulations are relatively new. Over the last few years there has been the development of Directives 2005/36/EC and 2011/24/EU, but these are not even fully implemented in national legislation. As I have shown the establishment of an NCP as required by the directive on cross-border healthcare has only just begun. Even though the existence of the NCPs is mandatory from 25 October 2013 onwards. I think it would be a good idea to watch the development of the official regulations concerning the supervision of healthcare in Europe and to let it take form for itself. Also, because of something I referred to in the chapter about the NCPs, namely the Rawlsian approach that if patients go abroad for treatment no one is worse off. However, it is very much possible that the public opinion will not share this view. In their eye it could appear that people who have the capabilities, financial or otherwise, to use healthcare in another Member State have an unfair advantage over those who are unable to travel abroad for treatment. I think that if the public opinion would pick up on this political parties will swiftly be inclined to discourage or even ban, as much as possible, the use of healthcare abroad.

But I also have some comments on my own research and recommendations for further study. Because of the time I had, it had to limit the extent of the number of countries I studied. Furthermore, I would like to have been able to include Germany in my thesis. But the discord in the different Länder results in a situation in which the country as a whole not is absent at the EPSO-conferences, but it even lacks a federal policy on the supervision of healthcare. Another problem I encountered was that while everyone I met and talked with at the EPSO-conference in Brussels was very friendly and helpful some were reluctant to reply on my written questions, whether these questions were e-mailed in advance or afterwards. I always made several attempts if there was no reply, but I chose to refrain from further attempts after

three unanswered e-mails. Perhaps if I had had more time I could have chosen to try and arrange either a face-to-face meeting with them to ask my questions, or attempt to get hold of another contact person for that organisation or Member State. Furthermore, some of the data of the Member States and their arrangements on supervision are outdated. Partially, this is the result of the literature I used, the International Encyclopaedia for Medical Law, of which some updates were from more than a decade ago. Of course I could have attempted to try and find out the current state of affairs, but as a result of my planning I chose not to pursue this course of action.

I also noticed that I felt a bit disappointed when I learned that the Dutch government was still in a very early stage with the establishment of the NCP, even though the original directive allowed for a period of 30 months to make the necessary arrangements. As a result I did not have the opportunity to see how the practical implementation of the National Contact Point had taken place. Furthermore, I think that an entire thesis might be written about the establishment and functioning of the NCPs across Europe. It would be interesting to see what differences exist in the way the EU Member State give substance to the NCP, but also to discuss how the exchange of information takes place in practice. Furthermore, I wonder whether citizens are in fact able to find the NCP and whether the use of cross-border healthcare will increase. Also, I think it would be interesting to see which citizens use the NCP, what is their background and socio-economic status. In my thesis I assumed that the situation might arise that a shift in the population occurs between those citizens which have the capabilities to use cross-border healthcare and those who do not. And does this subsequently cause discontent among the general public, which could lead to political measures to create more equal access to cross-border healthcare. Something which was intended with the creation of Directive 2011/24/EU.

Also, how will the purchasers of healthcare fit into this new system? There are large differences between the roles purchasers, such as health insurers, play in Europe. For an example I turn again to the Netherlands, as I did in the chapter about the NCPs. Over the last few years the health insurers have been given a greater part in the arrangement of healthcare. Also, they will have to approve overnight healthcare received abroad. I have argued that health insurers might focus on the cheapest option without paying attention to quality. While it remains uncertain whether anyone, including health insurers, will be able to distinguish quality differences with different providers from separate Member States, it is also possible that they will behave as a good health insurer and take their responsibility, because they consider it their duty to care. That they will attempt to deliver high quality care and will steer

patients to different providers across Europe depending on where the best treatment is available.

Furthermore, it is not yet clear what action should be taken if a citizen is not satisfied with the provision of healthcare in the Member State of treatment. In particular when he has already returned to his home Member State. I already briefly mentioned this problem in the chapter about the NCP. The most obvious course of action would be to complain to your domestic supervisor. However, is that organisation authorised to act in another Member State? That is probably not the case, which means that the supervisor should contact the supervisory organisation of the visiting Member State, which would have to deal with this complaint. Also Roscam Abbing refers to this issue in her article. She states that the Member State in which the treatment was received remains responsible for the quality and safety of the treatment. Furthermore, she writes that the NCPs are responsible for providing information on quality and safety¹⁵⁹. This means that such information from different countries should be comparable, currently no arrangements have been made to establish that. But as I have shown the powers of the different European supervisors differs. Some of them are not allowed to act against individual professionals.

Recently, there has been an interesting development, on 9 July the Dutch newspaper *NRC Handelsblad* reported the Dutch *Ministerie van Volksgezondheid, Welzijn en Sport* (VWS, Ministry of Public Health, Welfare and Sport) has made a deal with England, Sweden, Finland, Luxemburg, Denmark, Ireland and Norway to share information about malfunctioning physicians. The article implies that the action of VWS precedes European regulations as a result of the distress the actions of the Dutch neurologist Jansen created in the Netherlands¹⁶⁰. VWS has chosen to report professionals who have been convicted. Furthermore, it is interesting that the choice was made to make bilateral agreements, rather than an open system in which the information is available for all these countries. It would seem that privacy is an important issue because the choice was made to only share information concerning convicted professionals and to make bilateral arrangements. This means not all reported providers are universally shared and that the information is not easily available for everyone. But the website of the BIG-register is now also available in English and the Netherlands will share a list of convicted professionals monthly. This means that the choice has been made to take a proactive standpoint. In the chapter about the NCPs I raised

¹⁵⁹ Henriette DC Roscam Abbing, 'Editorial: Problem Doctors and Patients' Right to Good Quality Care in the European Union', vol 16 (HeinOnline 2009) 301

¹⁶⁰ Lex Boon. 'Europese landen gaan elkaar waarschuwen voor falende artsen' *NRC Handelsblad* (9 July 2013 2013)

the question how the NCPs would function, whether they would only collect national information or rather information from abroad. It seems that the choice has been made the collect national information, but to actively share it, rather than on request of the respective Member State.

I think that in the future it is possible to expect that the situation will occur in which a patient is not pleased with their treatment and will want to file a complaint against a healthcare provider. I think that eventually someone will litigate, ultimately to the Court of Justice of the European Union. This is similar to what happened in the Watts-case. Subsequently, the EU will have to deal with such a ruling. I think that at that moment it can be very useful to have a informal organisation, like EPSO, to discuss such an event and to share knowledge about how to deal with that complaint. This means that they will continue to move in the same direction, but along different roads.



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