Health system governance in Europe

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Health system governance in Europe: the case of hospitals

Timo Clemens

The research for this dissertation was performed at the Department of International Health within CAPHRI, the Care and Public Health Research Institute, Faculty of Health, Medicine and Life Sciences, Maastricht University.

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Health system governance in Europe: the case of hospitals

Dissertation

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Chapter 1

General introduction

1.1 Background

Health services in terms of their provision and financing are conceived by citizens and patients as a local or regional phenomenon. When we have the flu, we go to the local General Practitioner (GP) and get the medication in the pharmacy next door. For health checks and vaccinations we go to the health centre in our community. When we break our leg, we are admitted to a hospital close by. In the local newspaper we read about the mayor or local politicians to open a new or refurbished health facility or advocating not closing one. Ministers of health responsible for setting the regulatory frame for health services at national level, need to step down every now and then because of a health scandal or crisis.

However, the Tamiflu®, the anti-virus medication, the GP prescribes, the package handed out in the pharmacy, the purchase of vaccinations used at the health centre, the metal bar and screws used to fix your leg and the blood that is transfused during the operation, the label next to your hospital food, let alone the training schemes and working shifts of the doctors and nurses are all in some way or the other not only influenced by national policies but also by the European Union (EU). Nowadays, even the decisions to build or close a health facility can be subject to EU recommendations regarding national healthcare budgets. Even more, national health system reforms are nowadays informed by EU wide comparisons and good practice examples from other EU countries facilitated by systems of health monitoring and pooled expertise at EU level.

What has caused the EU to get involved with health services? Health crises that transcend over borders such as thalidomide, HIV/AIDS, BSE or the Swine Flu have led to an increased involvement of the EU in the area of healthcare. The establishment of the EU internal market with the core principle of free movement of goods, persons, services and capital (Article 26, TFEU¹) has led to the removal of travel and trade restrictions. Mobility of persons has necessitated that social security systems are coordinated to allow workers to move freely within the EU and still enjoy earlier accrued benefits; that tourists and ERASMUS students are granted access to emergency healthcare; and that citizens can access planned healthcare services in other countries under certain conditions. The free movement of goods has been applied to pharmaceuticals and medical devices in a way that the European Medicine Agency (EMA) evaluates new medicines for EU-wide market access and the controls and certification of medical devices in the EU follows a coherent procedure. Subsequently, the consumer rights agenda aiming at safe products and fair services within the EU internal market has been applied to patients more and more. It has raised issues such as adverse event reporting, clinical guideline development, healthcare acquired infections, antimicrobial resistance and, in general, patients' rights and quality of care to the EU's healthcare agenda. The regime of the Monetary Union of

¹ Treaty on the Functioning of the European Union (Lisbon Treaty)

the Euro in the context of the economic and financial crisis has brought the national expenses and performance of healthcare systems to the EU attention as they make up for 10% of Member States' governmental budget on average.

In this regard, national healthcare systems in the EU as “bounded space” (Ferrera, 2005) have become intertwined between the principles of EU market integration and competition law and the solidarity based organisation of social policy of Member States. Some commentators regard the EU to have a “ratchet effect” towards competition (Greer, 2009), limiting national policy options (Schmucker, 2010) or causing “cracks” to national health systems (Glinos, 2013). Others, regard a sheltered “healthcare edifice” to be possible as long as national healthcare policy is based on principles of good governance such as consistency, transparency and non-discrimination in the planning, stated objectives, procedures and regulation of health services (van de Gronden & Szyzszak, 2011).

Almost all of the instances of EU involvement described above and a couple of additional ones (Greer, 2009; McKee, Mossialos, & Baeten, 2002; Mossialos & McKee, 2002; Steffen, 2005) subject to EU regulation have been known at the start of this PhD thesis (2010) to a small but growing community of academics, civil servants, lobbyist and politicians. The European Court of Justice's (ECJ) Kohll² and Dekker³ cases on patient mobility, the inclusion of health services in the draft of the Bolkestein Directive⁴ and the implications of the Working Time Directive⁵ have been the most prominent and well-known examples that the EU is increasingly dealing with healthcare systems. While the single effect of each of the EU legislations or actions on how to organise parts of the health service provision could be traced, it was unclear at the time what the combined effect would be of the EU involvement on how healthcare systems in Europe will be governed. It was undecided whether in the future the EU will

- influence Member States directly in their decisions regarding organizing (parts of) healthcare services, or
- define some of the framework conditions of healthcare systems, or
- be the arena where national decision makers seek information and collaborations to shape developments regarding healthcare systems.

² Case C- 158/96 *Kohll v Union des Caisses de Maladie* [1998] ECR I-1931

³ Case C- 120/95b *Decker v Caisse maladie des employes prives* [1998] ECR I-1831

⁴ Draft Directive of 13 Januar 2004 on Services in the Internal Market COM (2004) 2

⁵ Directive 2003/88/EC of 4 November 2003 concerning certain aspects of the organisation of working time [2003] OJ L299/9

Hence, the questions remained

- (1) how the governance regarding healthcare systems has developed at the level of the EU, and
- (2) what are the effects thereof for the organisation of healthcare services by national governments.

This is at the heart of this PhD thesis where the focus will be on the hospital sector as a case of how of healthcare services are governed at the interplay of the EU and Member States. Hospitals are chosen because of their vital role in service provision, coordination of care, research and education of health professionals, of their financial significance and hospitals being a locus for health system reforms.

In the following, this introductory chapter provides a definition of governance as a starting point to understand, firstly, how the perception of the government's role (and beyond) has changed to control and steer public policy in general and health policy specifically. Secondly, the section addresses criteria for good governance and the EU's general rationale regarding governance. Section 1.3 turns to the question what a hospital and hospital policy is. In section 1.4, the evolvement of national healthcare systems is described during the 20th century to explain why governance questions regarding health and hospitals policy have come increasingly to the attention of decision makers in European Member States. On the basis hereof, the relevance of the European Union regarding the governance of hospitals is sketched moving initially from the regulation of insular issues linked to the free movement principles of the internal market towards a broader healthcare agenda. These parts form the basis to introduce the research questions and methodology towards the end of this chapter.

1.2 Defining governance

Governance is the leading concept and framework for analysis in this PhD thesis. Governance can be broadly understood as the "the general exercise of authority" (Michalski, Miller, & Stevens, 2001, p. 9). Questions of governance – of how to steer, pilot or direct (from the original meaning of the word) – have been discussed first in other areas of public policy before they have been applied to the health sector. According to David Levi-Faur, governance involves

*“the hybridization of modes of control that allow the production of fragmented and multidimensional order **within** the state, **by** the state, **without** the state and **beyond** the state. The plurality of modes of control reflect and reshape new ways of making politics, new understanding of institutions of the state and beyond the state [...]” (2012, p. 3, original emphasis).*

The concept of governance is now widely used in social sciences to analyse structure, process, mechanisms or strategies of governance (cf. Börzel & Risse, 2010). It assumes the shift “from hierarchical state to governance in and by networks” (Rhodes, 2012, p. 33) and reflects a turn of how public policy steering is performed. Initially, after World War II the formal government-led bureaucracy was central to pursue public policy which has been more and more replaced by the notion of more complex, dispersed and multi-actor networks being mandated to steer (Richardson, 2012). It follows that nowadays Member States, and the EU as well, apply various modes of control; hierarchy/authoritative decisions, market/competition and networks/negotiation are applied simultaneously and are mixed (Börzel, 2012). Table 1.1 provides a more elaborated confrontation of the characteristics of both notions with a focus on the state.

Table 1.1: Bureaucratic versus the post-modern state

Weberian bureaucratic state	A post-modern state
Government	Governance
Hierarchy (Weberian)	Heterarchy (networks etc.)
Power(1): zero-sum game	Power(1): positive-sum game
Power(2): concentrated	Power(2): diffuse
Elitist	Pluralist
Unitary, centralized, monolithic state	Decentralized, fragmented, hollowed-out state
Strong, central executive	Segmented executive
Clear lines of accountability	Blurred lines of accountability
State central control	State central steering
Single homogenous public service ethos	Heterogeneous service cultures

Source: (Richards & Smith, 2002, p. 36, Table 2.2)

The change of perspective from government to governance occurred parallel to the New Public Management (NPM) reforms of the public sector services during the 1980s moving from state led provision of public services predominantly in National Health Service (NHS) type of healthcare systems towards market forces and provision by third parties (Rhodes, 2012). At same time, reforms towards NPM principles focused on management by objectives, target setting or lean and efficient structures *within* governments. Although New Public Management and Governance vary on various aspects regarding focus or basic ideas (see Klijn, 2012 for a good overview), the concepts overlap for example regarding the salient issue of coordinating the network of actors (Klijn, 2012). Governance networks are understood as the

“more or less stable patterns of social relationships between mutually dependent actors, which form around policy problems and/or clusters of means [...]” (Koppenjan & Klijn, 2004, pp. 69-70).

The study of network governance is one strand or wave in the literature on governance. Network governance scholars have studied how governments relied more and more on other actors to achieve their policy goals and implement their policies, how those newly created networks grew. Moreover, studies have focused on how to steer those conglomerates of actors, how to manage the complex and growing networks effectively or on how to ensure that within established networks legitimacy and accountability do not dissolve (Rhodes, 2012).

Likewise, the concept of “good governance” – on a macro level – is concerned with aligned societal institutions such as rule of law, accountability, legitimacy, efficiency, and control of corruption to pursue public policies or public goods (Rothstein, 2012). While no unified understanding exists, the definition of the World Bank Research Institute is widely cited referring to “traditions and institutions” concerning

*“(1) the process by which governments are selected, monitored and replaced,
(2) the capacity of the government to effectively formulate and implement sound policies, and
(3) the respect of citizens and the state for the institutions that govern economic and social interactions among them”* (Kaufmann, Kraay, & Zoido-Lobaton, 1999, p. 1).

These criteria resemble broadly what has been put forward as criteria for good regulation (Baldwin, Cave, & Lodge, 2012) and from where Knill and Lenschow have derived the criteria for legitimising EU governance (2003).

Lately scholarly attention and reform efforts regarding health systems in Europe have shifted from (the analysis of) the attainment of health system outcomes towards understanding the processes and capacities in a health system to produce well-designed policies and decisions in

terms of health system reforms, crisis responses or implementation of routine tasks (Greer, Wismar, & Figueras, 2016; Saltman, Duran, & Dubois, 2011). Following the World Health Organization, health sector governance

“refers to a wide range of steering and rule-making related functions carried out by governments/decisions makers as they seek to achieve national health policy objectives that are conducive to universal health coverage” (WHO, n.d.).

The assessment of governance structures include public health policy and services (Kickbusch & Gleicher, 2012; Leppo, Ollila, Pena, Wismar, & Cook, 2013; McQueen, Wismar, Lin, Jones, & Davies, 2012), healthcare systems at large or the intersection of EU and national health policies (Mossialos, Permanand, Baeten, & Hervey, 2010; Sindbjerg Martinsen & Vrangbaeck, 2008; Steffen, 2005). More focused studies have addressed the division of powers and responsibilities between national, regional and local levels (Jakubowski & Saltman, 2013; Saltman, Bankauskaite, & Vrangbaeck, 2007) and the governance of public hospital boards (Saltman et al., 2011). Both, the EU and WHO Europe have issued a capacity assessment for public health services within their membership countries addressing governance and leadership aspects (Aluttis et al., 2013; WHO Regional Office for Europe, 2012).

Finally, the European Union is considered to be a regulatory entity almost exclusively tasked with law and policy making functions (Majone, 1994) coupled with relatively little budget and few executive tasks compared to the joint resources and the public service provision of all of its Member States. Rather the “efficiency of the EU politico-administrative derives from [...] externaliz[ing] the massive costs of governing the Union to member states” (Page, 2001, pp. 148-149). The EU’s administrative staff numbers are small compared to a national government apparatus. Running the EU with a small number of civil servants is possible because the transposition and implementation of EU laws and policies affecting national practices is the responsibility of Member States themselves. Moreover, the EU does not run hospitals, employ GPs or maintain a network of emergency medical services nor does the EU need to bother about the functioning of system-wide oversight, payment, human resource or monitoring structures (Greer et al., 2014).

1.3 What is a hospital? What is hospital policy?

Given, this thesis explores the influence of EU governance on healthcare systems using hospitals as a case, the institution of a hospital is systematically introduced. According to Miller a hospital is defined as

“an institution which provides beds, meals, and constant nursing care for its patients while they undergo medical therapy at the hands of professional physicians. In carrying out these services, the hospital is striving to restore its patients to health. Its goal – healing its sick patients – marks it off from institutions for the aged, from convalescent homes, and from nursing homes for the permanently disabled, [...]” (Miller, 1997, p. 4).

However, despite these basic characteristics what appears to be a hospital can be very different and the notion what a hospital is and what services it provides has been changed over time.

First, in terms of its size and equipment the label of a “hospital” can be given to everything between a small ten bed building in a rural village in Russia without medical technical equipment and other basic infrastructure and the high-tech large scale university hospitals in western Europe hosting typically between 1000-1500 beds often spread over different buildings (McKee & Healy, 2002a).

Second, hospitals are discerned according to their level and scope of medical treatment they provide: primary hospitals providing basic medical services to a community; secondary hospitals providing comprehensive medical specialist services classically in a small or medium sized city and a tertiary hospital providing comprehensive and advanced medical specialist services to a region.

Third, defining hospitals by their buildings has limitations given that classically hospitals have been spread into different houses or campuses. More recently, the emergence of hospital chains and merger hospitals have led to organisational entities regarded as one hospital even being spread over different cities. Besides, hospitals providing ambulatory treatment and services via telemedicine do not limit hospitals to services within its walls (McKee & Healy, 2002a).

Finally, hospitals are classified further by whom they are owned. This can be public entities (the state, regions, cities), non-governmental organisations (e.g. religious organisations) and private companies. Moreover, hospitals are often discerned whether they are for profit or non- for profit.

Following Miller’s definition the core function of a hospital is to provide nursing and medical care to patients. However, depending on the characteristics of the hospitals there are other functions and roles hospitals fulfil according Healy and McKee (2002). These functions include besides patient care, also teaching, research, health system support, employment and a societal role. Departing from these various functions of hospitals it gets apparent that hospital policy – “a deliberate course of (in-)action [...] to achieve a certain outcome” (Versluis, van Keulen, & Stephenson, 2011, p. 11) – regarding the planning, financing, staffing and control of hospital is not limited to simply train doctors and nurses and pay them for the services provided. Areas of

hospital policy involve – but not limited to – decisions on investments and planning of facilities, incentives for cooperation, controls of hygiene, quality and patient safety standards, training of health professionals, rules for public procurement, competition law and merger control, funding of research, etc.

Figure 1.1: Function of hospitals (based on Healy & McKee, 2002) and areas of hospital policy

1.4 The evolution of governance of healthcare systems and hospitals in EU Member States

The historical evolution of healthcare systems and hospitals as we know them today reflects changing views towards the role of the state in healthcare and advancements in medical knowledge and technology since the mid of the 19th century. These discussions and reforms have been predominantly taken place in national spheres despite the fact that respective reforms have not been without international links as their occurrence in “waves” (Cutler, 2002) or “trends” (Dixon & Poteliakhoff, 2012) indicates. Until the end of the last century hospitals have come to the centre of healthcare systems during this evolution in terms of the setting

where increasingly medical treatments are provided, medical professionals work and healthcare resources are spent. In recent years, this is rather viewed as problematic given the high-cost, high-risk and medicalised hospital environment and efforts to move to “integrated” or “primary care led” healthcare systems are mounting (Council of the European Union, 2011).

The developments regarding governance of healthcare systems and hospitals will be described in the following according to three “waves” of healthcare reforms described by Cutler (Cutler, 2002)

- First wave: Universal Coverage and Equal Access (since mid-19th century),
- Second wave: Controls, Rationing and Expenditure Caps (from mid 1970s onwards),
- Third wave: Incentives and Competition (starting in the early 1990s).

First wave: Universal Coverage and Equal Access

In the middle of the 19th century the role of the state in healthcare was very limited. Care for the sick was provided within families, consultation of trained physicians – a number of medicine schools had been established already – or quack practitioners was hampered by the economic situation of large part of society. Licensing of medical professions had not been established on a large scale. Hospitals were rather hospices that cared for the sick (Starr, 1982) and were run traditionally by charities (McKee & Healy, 2002b). In the second half of the 19th century medicine developed towards a profession coupled with a rise of medical knowledge (e.g. surgery, hygiene) and technologies (e.g. antibiotics, vaccination, anaesthesia). At the same time, the hospital developed towards an additional setting where doctors were based next to the GP practices in the communities. At the end of the 19th century a few European countries started to establish health insurance funds for their workers but with limited population coverage and involving state subsidies to often voluntary schemes (Saltman, Busse, & Figueras, 2004). Hospitals became places for cure rather than care and were increasingly run by state institutions (McKee & Healy, 2002b).

The post-World War II period has witnessed a strong move towards expanding health insurance towards (almost) universal coverage and a greater role for the state in providing, financing and overseeing health systems. Some European countries introduced National Health Services (NHS) such as 1948 in the UK, Scandinavian countries in the 1950s and early 1960s and some Southern European countries in the late 1970s until mid-1980s. Others countries such as Germany, the Netherlands, Austria, and Belgium expanded their insurance schemes to cover not only workers but many other groups in the society. While the role of the government has been traditionally prominent in NHS systems as provider of care, extensive government regulation has been established to steer Social Health Insurance (SHI) systems as well (Saltman et al., 2004). Next to full coverage, the thrive to achieve equal access to care for all has led to – from today’s

perspective – broad basic benefit packages of covered services and a low level of required co-payments (Cutler, 2002) in the post war years. Both goals have been supported by massive financial investments into health and especially hospital infrastructure financed increasingly by larger shares of state budgets, because the economic boom in Western Europe in 1950s and 60s allowed for it. Compared to the pre-war era hospitals were owned to considerable degree by governments even in SHI systems. It has led to hospitals moving to the centre of healthcare systems.

Second wave: Controls, Rationing and Expenditure Caps

The investments of the 1950s/60s combined with medical technological innovations have considerably extended treatment options further since 1970s. These include improvements in diagnosis such as computer tomography, clinical laboratory or endoscopy and improvements in treatment including intensive care units, combination chemotherapy for cancer treatments, and coronary artery bypass or organ transplantation surgery (McKee & Healy, 2002b). It led to a massive increase of resources for health required by the state budget which by the time of the oil crises in 1970s was no longer paired with increases in GDP. In order to curb the increase of health expenditures during the 1970s – the percentage of GDP spent on healthcare rose from 5.3 to 7.1 (OECD Europe average) between 1970 and 1980 for OECD Europe countries (OECD, 1997) – governments introduced global budgets for physicians and especially hospitals care and cost-sharing measures during the 1980s (OECD, 1994, 1997). These reforms were intended towards macro efficiency⁶ in the health system and to counteract worrying signals of supply-induced demand.

Third wave: Incentives and Competition

Despite the taken measures there were concerns at the end of the 1980s and early 1990s that the cost control reforms would not be sufficient to limit health expenditures in the long run. Therefore, since the early 1990s micro-economic efficiency objectives⁷ came to the centre of attention. In the early phase the reform agenda has been dominated by introduction of market principles in healthcare including competition among providers (OECD, 1994, 1997). However, the targets for reforms went later well beyond this and included setting incentives for evidence based medicine tools, managerial efficiency of healthcare providers, deinstitutionalisation and Health Technology Assessment (HTA).

These developments in health systems itself have increased the complexity within the system and the need for coordination and well-established governance structures (Greer et al., 2016).

⁶ “health expenditure should consume an appropriate fraction of GDP” (OECD, 1994, p.14)

⁷ Given a share of GDP available for health, the selection of services that maximises health and consumer satisfaction. Increase of productivity.

The importance of addressing governance issues have been described among other for decentralisation tendencies (Costa-Font & Greer, 2013; Saltman et al., 2007), integrated care arrangements coupled with a moving emphasis from single acute to complex chronic care (Knai, Nolte, Conklin, Pedersen, & Brereton, 2014) or the introduction of healthcare “markets” and competition (Saltman, 2012). Moreover, new provider networks and partnerships (Barlow, Roehrich, & Wright, 2013) and the socio- political and economic necessities for an efficient performance of health systems call for monitoring systems to collect data on *inter alia* quality of care, patient safety and patient experience data as well as the establishment of respective response and oversight structures.

These system wide developments have been translated into a number of measures in the governance of hospitals. Newly applied governance tools in hospitals include the introduction of quasi-markets (Maarse & Normand, 2009), giving more decision latitude to hospitals’ management boards, moving towards activity-based funding schemes like the Diagnosis Related Groups (Kimberly, de Pouvourville, & D'Aunno, 2008) or publishing hospital “rankings” (Rechel et al., 2016). Moreover, hospitals started collaborations with other hospitals and providers towards establishing provider networks in some cases, to hire professional managers, extended their polyclinic services offers such as day surgery and outsourced auxiliary services such as laboratory facilities, cleaning or the hospital kitchen (Saltman et al., 2011, chapter 1).

From a conceptual perspective existing governance frameworks for health systems such as the NHS, SHI or private systems are being questioned because, in practice, many systems becoming mixed (Greer et al., 2016) and those models mirror macro level arrangements and principles that may not be useful to guide recent focal points for reforming health systems and hospitals. Regarding the former (mixed governance systems), Rothgang et al. (2010) have found that healthcare regulation in OECD countries has become more hybrid. Traditionally state led and corporatist systems have incorporated elements of competition. Whereas, private and corporatist systems use nowadays hierarchical modes of regulation as well (Rothgang et al., 2010). Regarding the latter (guiding reforms), in the same way the developments described in the section above, towards more complex hospital care processes and the increase of actors, call into question the government led bureaucratic notions of formal governance (Saltman et al., 2011).

1.5 The growing influence of the European Union on the governance of hospitals

Over the last two decades the role of the European Union in influencing domestic healthcare systems has moved beyond the regulation of insular issues regarding hospitals towards a broader agenda. The lines on which this has evolved include *increased applicability of EU laws, publishing reports providing data and intelligence on health system, inclusion of health system objectives in health and broader EU policy strategies and establishing fora* to discuss health system issues (cf. Paoli, 2012). Moreover, it is rooted in the applicability of the EU internal market principles to healthcare established by the European Court of Justice (ECJ) rulings, the growing perception of the healthcare sector as a contributor to economic development (Lisbon Strategy, Europe 2020) and the necessity for sustainable healthcare finances during the financial crisis.

The lines of activities resemble different modes of governance that have been described for the EU conceptualising types of EU regulation according to its bindingness, flexibility during implementation and actors involved (Knill & Lenschow, 2003; Treib, Bähr, & Falkner, 2007).

Table 1.2: A new typology of four modes of governance

Implementation	Legal instrument	
	Binding	Non-binding
Rigid	Coercion	Targeting
Flexible	Framework regulation	Voluntarism

Source: Treib et al., 2007, Table 3

Traditionally, the EU has regulated healthcare products such as pharmaceuticals⁸, medical devices⁹ and blood products, set minimum standards for the training of doctors, nurses and midwives¹⁰ and established a system of social security coordination in case of emergency care and for cross-border workers and pensioners¹¹ to ensure the free movement principles of the

⁸ Directive 65/65/EEC of 9 February 1965 on the approximation of provisions relating to proprietary medicinal products, [1965] OJ P022

⁹ Directive 90/385/EEC of 26 August 1992 on the approximation of the laws of the Member States relating to active implantable medical devices [1992] OJ L245

¹⁰ Directive 2005/36/EC of 7 September 2005 on the recognition of professional qualifications [2005] OJ L255/22

¹¹ Council Regulation 1408/71/EEC of 14 June 1971 on the application of social security systems to employed workers and their families moving within the community [1971] ECR 991

internal market. Health services have remained untouched from European integration as iterated in the Public Health article (Article 129) of the Maastricht Treaty (TEU). On the basis of the current Article 168(7), Lisbon Treaty (TFEU) it is obvious that the binding instruments regarding health systems remain limited.

Until 2000: European Court of Justice rulings as a trigger

The rulings of the ECJ of Kohll¹² and Decker¹³ in 1998 and subsequent cases¹⁴ have been a first line of actions increasing the EU's relevance for hospitals. Kohll and Decker and subsequent cases made clear that under certain conditions healthcare services are applicable to internal market principles and that patients can enjoy access to health services in other EU Member States and that likewise service providers can deliver their services to patients across borders (Lamping & Steffen, 2009). While the Kohll and Decker rulings were dealing with ambulatory care, and a strong prior authorisation regime for hospital services was held consistent with EU law due to planning and financing reasons, the subsequent ECJ rulings had a broader relevance for hospital services as well. First, hospital services were regarded as services according to the Treaty, an economic activity provided for remuneration. Second, existing waiting lists for hospital services – which many EU Member States handled at that time – could not be used as general escape from the principle of “without undue delay”¹⁵ (Mossialos & McKee, 2002, chapter 4).

2000-2010: Enlarging the healthcare agenda

At the beginning of the 2000s, the Lisbon Strategy, the EU's strategy for growth and jobs in the first decade of the new millennium included the structural Healthy Life Years indicator as a marker for the “*contribution of growth and sustainable development*” (European Commission, n.d.). Moreover, the inclusion was regarded as a call

“...to invest in the health of their (European) populations, not only because (of) better health [...] but also because it is an important determinant of economic growth and competitiveness” (Suhrcke, McKee, Sauto Arce, Tsovolas, & Morgensen, 2005, p. 5).

By the Lisbon Strategy, the Open Method of Coordination in the area of health and long term care was initiated seeking to benchmark national care systems by information sharing and

¹² Case C-158/96 Kohll (n 2)

¹³ Case C-120/95b Decker (n 3)

¹⁴ Including Joined Cases C-157/99. *Geraets-Smits v Stichting Ziekenfonds VGZ* and *Peerbooms v Stichting CZ Groep Zorgverzekeringen* [2001] ECR I- 5473; Case C-372/05 *Watts* [2006], Joined Cases C-385/99 *Mueller-Faure v Onderlinge Waarborgmaatschappij OZ Zorgverzekeringen UA* and *van Riet v Onderlinge Waarborgmaatschappij ZAO Zorgverzekeringen* [2003] ECR I-4509; Case C-368/98 *Vanbraekel v. Alliance nationale des Mutalites Chretiennes (ANMC)* [2001] ECR I-5363; Case C-56/01 *Inizan v Caisse primaire d'assurance maladie des Hauts-de-Seine* [2006] ECR I-12403

¹⁵ *Ibid*, Cases C-157/99

monitoring according to commonly pre-agreed indicators following the overall goals of high quality of care, accessibility and financial sustainability (Commission of the European Communities, 2001). Member States were supposed to learn from each other regarding healthcare system organisation. Subsequently, data on a whole set of quantitative indicators and national reports were collected.

The ECJ rulings made Member States aware that their health systems cannot be sheltered from EU market principles. The Belgian and Spanish Presidencies in 2001 and 2002 put health systems on the agenda and the 2002 Health Council requested the European Commission (EC) to start a High Level Process of Reflection on Patient Mobility and Healthcare Developments in the European Union. In 2003 its recommendation included not only a comprehensive call for action at EU level but also for the establishment of a more stable structure to EU level cooperation regarding health systems. In 2004, the High Level Group on Health Services and Medical Care met for the first time. The High Level Group has been a forum for discussion between 2004 and 2006 and shortly relaunched activities in 2008. With the implementation of the Health Strategy (see below) the plenary meetings of the High Level Group have been ended although some of the working groups are still active today, such as the Working Groups on Quality of Care and Patient Safety or on the European Workforce for Health (Greer & Vanhercke, 2010; Hervey & Vanhercke, 2010).

The application of the European Working Time Directive¹⁶ to domestic hospitals came as a “fallout” because the horizontal directive impacted on the organisation of core hospital activities such as patient care and professional training. Hospital managers were forced to comply subsequently with a maximum 48 hours working week that clashed with normal hours doctors, especially in training, were used to work (often unpaid as exchange for a acquainting skills and practical experience). In terms of healthcare provision, the securing of continuous patient care by medical experts and the acquaintance of skills and experience were described as being threatened (Maxwell et al., 2010). Furthermore, process to improve the skill mix have been stimulated meaning replacement of doctors by nurse practitioners (Osborn, Jones, Gower-Thomas, & Vaughan-Williams, 2010) and sub-specialities by general specialities in on-call shifts (Hellawell, Kahn, & Mumtaz, 2005).

The EU’s Health Strategy *Together for Health*, agreed in 2007, included the Strategic Objective 3 on the support of “Dynamic Health Systems and new Technologies”. Under this objective the European Commission was tasked to develop a “*framework for safe, high quality and efficient health services*” and lending support to Member States for the implementation of “*innovations and e-health solutions*” (Commission of the European Communities, 2007, p. 9f). The Health

¹⁶ Directive 2003/88/EC (n 5)

Strategy ran from 2008 until 2013, prolonged until 2020 in 2011 as its objectives were evaluated by the European Commission to be still applicable. Next to the objectives and principles the Working Party on Public Health at Senior Level has been designated to support the implementation of the Health Strategy's objectives by structured cooperation. Moreover, the Working Party is a forum for discussion of non-legislative issues of common concern to Member States in order to review general developments and detect EU health policy topics. In recent years, the Working Party has been tasked to lead the reflection processes on chronic diseases and sustainable finances of health systems. The EU Health Programmes have been the main financial instrument to implement the Health Strategy (Council of the European Union, 2010, 2011). The current Third Programme for action includes two healthcare related overarching objectives on *innovative, efficient and sustainable health systems* and *access to better and safer healthcare*¹⁷. Actions such as collaborative projects, joint actions, commissioned studies and service contracts have been financed by the programme in the area of health systems and hospitals in particular (see hereunder the example of quality of care and patient safety).

The ECJ rulings on cross-border healthcare have broad quality of care and patient safety issues on the European agenda. Certain standards of quality of care and levels of safety in other Members States were regarded as prerequisite to allow and reimburse for cross-border care. The European Commission has subsequently started to finance comparative projects and networks particularly targeted at hospitals. These projects aimed

- to evaluate tools and instruments across countries (e.g. MarQuis & DUQUE projects for quality improvement strategies in hospitals),
- to develop sets of indicators (e.g. SimPaTHIE project for the safety of healthcare),
- to establish common principles (e.g. the EUNetPaS for patient safety programmes).

In 2009 these activities have fed into a Council Recommendation on patient safety¹⁸ and in the framework of the Patients' Rights Directive¹⁹ to the inclusion of transparency provisions (Article 4) and of a call for respecting good medical practice for quality and safety standards (Recital 20). The European Commission has supported the establishment and the transfer of scientifically agreed indicators and "best practices" by funding respective research activities and, subsequently, calling – albeit with only limited force – its Member States to implement these standards. In addition, the Patients' Rights Directive – codifying much of the case law on cross-border mobility of

¹⁷ Regulation (EU) 282/2014 of 11 March 2014 on the establishment of a third Programme for the Union's action in the field of health (2014-2020) and repealing Decision No 1350/2007/EC [2014] OJ L86/1

¹⁸ Council Recommendation C 151/01 of 9 June 2009 on patient safety, including the prevention and control of healthcare associated infections [2009] OJ C151/01

¹⁹ Directive 2011/24/EU of 9 March 2011 on the application of patients' rights in cross-border healthcare [2011] OJ L 88/45

patients – has paved the way for further collaboration on healthcare related areas like rare diseases, health technology assessment and eHealth²⁰ (Peeters, 2012; Sauter, 2011).

2010 until today: The crisis changing the narrative

With the first edition of the Health at a Glance Europe report in 2010 the European Commission in collaboration with the OECD collected quantitative health system data and provided analysis on the state of play of health systems throughout the EU (OECD, 2010). The EU tailored health report is since then published bi-annually (OECD, 2012, 2014; OECD/EU, 2016). Next to data on mortality and morbidity and on determinants of health, the report includes hospital data regarding infrastructures, provided services and various aspects of quality of care in hospitals. In the same year (2010), the Joint Report on Health Systems provided an in-depth analysis of differences in health expenditure in the context of the financial crisis to support efficiency. The report called for a shift towards primary care services, day surgery and concentration of hospital facilities. Moreover, better governance was called for to aim for improved policy coherence (European Commission & European Policy Committee, 2010).

The issues of sustainable finances and investments in health system have received increasingly attention at the European level as a response to the financial crisis. The European Commission has included health related Country Specific Recommendations in its European Semester Process since 2010 (Azzopardi-Muscat, Clemens, Stoner, & Brand, 2015; Baeten & Vanhercke, 2017). In 2012, the Commission established an Expert Panel on Effective ways to invest in Health to provide advice for health investments²¹. Its outcomes include evidence based recommendations relevant to the hospitals sector including opinions on access to care, hospital reforms, public-private partnerships, competition among healthcare providers or quality of care and patient safety. Although health is not a key target of Europe2020 strategy the relevance of good health for economic progress and social cohesion has been emphasised. The Communication Investing in Health advocates for assessing the efficiency of current health system structures and calls to reform systems to ensure better health, less inequalities and more efficiency as part of the Social Investment Package in the context of the Europe2020 agenda and the European semester (European Commission, 2013). Moreover, in his 2014 mission letter to the new Health Commissioner Andriuskaitis Commission, president Juncker included the priority “to develop expertise on performance assessments of health systems” to inform the European Semester process during the current Commission’s term (Juncker, 2014). As an outcome of the reflection process on modern, sustainable health systems the European Commission published a Communication in 2014 providing an overview of priorities, actions and tools to be used at EU

²⁰ Ibid, Directive 2011/24/EU, Chapter IV

²¹ Commission Decision 2012/C 198/06 of 5 July 2012 on setting up a multisectoral and independent expert panel to provide advice on effective ways of investing in health [2012] OJ C198/7

level to support Member States (European Commission, 2014). In the same year, the Commission, on initiative of Member States, set up a new Expert Group on health system performance assessment to provide support to and exchange experiences on national actions.

In sum, the EU has established quite a body of data, experts groups, fora for discussion, reporting instruments and strategies and lines of actions relevant to the governance of health systems and hospitals in particularly with potential influence on national policy makers predominantly in a non-binding way. Table 1.3 summarises the activities according to the modes of governance according to Treib et al. (2007) introduced above.

Table 1.3: EU modes of governance in the field of healthcare systems

Implementation	Legal instrument	
	Binding	Non-binding
Rigid	Coercion	Targeting
	Directive 2011/24/EU, on patients' rights, chapter I-III	Country specific recommendations (CSR) on health
	Directive 2005/36/EC on professional qualifications	Recommendation 2009/151/01 on patient safety
	Regulation 883/2004 on social security systems	
	Directive 2004/88/EC on working time	
Flexible	Framework regulation	Voluntarism
	Directive 2011/24/EU, on patients' rights, Chapter IV	Open method of coordination (OMC)
	Decision 1082/2013/EU on cross-border threats	Working groups
		The expert panel on investing in health
		Action programmes on health
		Council conclusions

Caption: This is a non-exhaustive list. The included EU governance instruments constitute prominent examples regarding healthcare systems.

1.6 Research questions

Over two decades the European Union has been increasing the applicability of its law principles to the national law governing healthcare (Hervey & McHale, 2004, p. 30; Mossialos et al., 2010). At the same time, the EU has established, over the years, an own comprehensive agenda for discussion to inform the future directions of national health systems. As a consequence, according to Greer, “[t]he European Union is a principal strategic challenge for EU health systems” (Greer, 2009, p. 159). Moreover, the transposition of EU legislation and the uptake of EU-level discussions into national health system policies are supposed to influence the domestic governance and design of healthcare systems.

As stated at the very beginning of the thesis, effects of individual EU legislations are already known and have been analysed. These concern for example the Patients’ Rights Directive²² (Baeten, Vanhercke, & Coucheir, 2010; Glinos, Baeten, & Maarse, 2010; Kostera, 2008; Sindbjerg Martinsen & Vrangbaeck, 2008), European Working Time Directive²³ (Collum, Harrop, Stokes, & Kendall, 2010; Hellawell et al., 2005; Maxwell et al., 2010), Professional Qualification Directive²⁴ (Glinos, 2012) and competition law (van de Gronden & Sauter, 2011). However, the combined effect of EU governance and of new governance tools in particular, on the governance of health systems in domestic arenas, is lacking so far. The objective of this thesis is to assess how the governance regarding healthcare systems has developed at the level of the EU and between the EU and its Member States and what the effects are for the domestic steering of healthcare systems.

In order to do so, the thesis focuses on the reforms needs and considered solutions at the level of the EU and Member States in the context of the crisis, the capacities for health system governance at EU level and current developments regarding health system governance at the intersection between the EU and Member States. The example of hospitals is taken as a case to map the interplay between the EU and domestic level.

In light of the research aim, the main research question is as follows:

How is health system governance developing in EU policies and what are the effects for domestic hospitals?

In order to evaluate the development of governance between the EU and Member States, this analysis evolves in three steps according to the output criteria for legitimising EU governance by

²² Directive 2011/24/EU (n 19)

²³ Directive 2003/88/EC (n 5)

²⁴ Directive 2005/36/EC (n 10)

Knill and Lenschow (2003) (cf. Baldwin et al., 2012) including

- the problem solving capacities,
- capacities for decision making,
- implementation and compliance at national level.

These criteria are essential for EU health system governance given the limited mandate to act on health system (cf. Article 168 (7), TFEU), the dispersed responsibilities within EU institution on health issues (Greer et al., 2014), and the reliance on a multi-level system of national, regional and local governmental institutions as well as non-governmental and private actors for implementation. Based on the three output criteria the following sub-questions have been formulated:

1. What are the needs and problem solving capacities for health system and hospital reforms at EU and Member State level (chapter 2 & 3)?
2. What are the capacities for health governance at EU level (chapter 4)?
3. How do Member States comply with EU hard law and new governance tools (chapter 5 & 6)?

With the help of the three sub-questions, three detailed analyses will be performed at the level of the Member States, the EU and the interaction of Member States and the EU assessing the EU healthcare governance with regard to its policy content, its authority and efficiency.

1.7 Methodology: Hospitals and hospital policy as case

1.7.1 The method of a case study

This thesis uses a case study design *“the detailed examination of an aspect of a historical episode to develop or test historical explanations that may be generalizable to other events”* (George & Bennett, 2005, p. 5) in order to be able to trace links between the observed object of interest and its potential causes. Case study research is deemed appropriate when a variety of contextual factors are supposed to be present to cause the bounded phenomenon under study (George & Bennett, 2005; Rohlffing, 2012) which is certainly at hand in this research of health governance between the EU and its Member States. This single case study is focused on a detailed analysis of health policy as an example of a public policy in order to provide policy guidance by identifying the pathways and mechanism by which certain phenomenon occur or not – without too much of generalisation (middle–ranged theories). Hence, from a critical realist perspective the case of hospitals is seen as an instance of a “class of events” (George, 1982, p. 45). In this thesis other similar cases within the same “class of events” are considered to be

further health policy areas that are subject to a shared governance of the EU and its Member States. These further policy areas are supposed to share a number of similar conditions with the case of hospitals. In the Discussion chapter some inferences are made to the governance in other areas of the healthcare sector in Member States based on the findings regarding hospitals.

The method of case studies is criticised for lacking representativeness (external validity), involving selection bias of the case and, especially for single case studies, having no variance on the dependent variable (King, Keohane, & Verba, 1994). However, this criticism stems from a quantitative stance to (over-)generalise to entire populations and estimate an average level of causal effect. Nevertheless, these limitations will be addressed below when describing the case more in detail. To the advantages of case study research belong the ability to take into account complexity, equifinality (multiple paths to an effect), and multiple interactions when exploring relevant mechanisms (George & Bennett, 2005). A number of interaction effects arising from the complexity are inherent to, and have been described earlier for, the (EU) health policy field. Described interaction effects include path dependency (Immergut, 1992; Rico, Saltman, & Boerma, 2003), tipping points such as health crises, the introduction of the public health mandate or the ECJ rulings (Lamping & Steffen, 2009; Rosenkötter, Clemens, Sørensen, & Brand, 2013; Steffen, 2005) and sequential interactions (Trubek, Nance, & Hervey, 2009).

1.7.2 Hospitals and hospital policy as case

The choice to focus on hospitals as a case for the analysis of governance at the intersection of the EU and Member States has various reasons.

From a health policy perspective, hospitals still play an important role in domestic healthcare system they operate in. They provide secondary medical care from basic procedures to much specialised treatments in various medical specialities. The hospital setting is central beyond provision of care because of the referral function, training of professionals or clinical and health services research that takes place in hospitals. Furthermore, hospitals consume still a large share (35-70%) of the overall health budget (WHO Regional Office for Europe, 2008). Both factors make hospitals frequently subject to healthcare reform efforts despite the fact that hospitals are deemed quite resistant to change (Haycock, Stanley, Edwards, & Nicholls, 1999; McKee & Healy, 2002a).

Next to the hospital's importance several developments in the health system have fuelled the discussions on hospital service organisation at national and European level which McKee and Healy (2002b) called the "changing context" hospitals operate in:

- hospitals have to face ageing societies, changes in the disease patterns with life-style related chronic and new communicable diseases emerging, and increased expectations of its patients which changes the character of services that is demanded,
- innovative medical technologies (eHealth, mHealth) and changes in the health workforce (more part-timers, skill-mix) alter the way services will be offered,
- political tendencies to curb health and especially hospital expenditures and the increasing international aspects (migration, multi-national companies) belong to the socio-economic environment hospitals have to respond to (McKee, Healy, Edwards, & Harrison, 2002),
- more, recently a number of European countries have targeted over-capacities in hospital infrastructure and inefficiencies in the management as response to the financial crisis (Mladovsky et al., 2012),
- the European Union has addressed hospitals in the context of the European Reference Networks; EU wide cooperation of predominantly hospitals for highly specialised treatment of rare diseases. At the same time the 2011 Council Conclusions have called for “*moving away from hospital-centred systems towards integrated care systems*” (Council of the European Union, 2011).

However, the choice of hospitals as a case to explore how governance between the EU and its Member States has evolved should not only be guided by its importance but involves additional methodological considerations addressing the criticism raised above.

Firstly, in order to address the biases in case selection hospitals are regarded as a *most-likely case* (Eckstein, 1975) for an effect of EU governance on health policy in Member States based on the number of potential links between EU activities and hospitals. Taking into account the wide set of functions that hospitals fulfil including patient treatment, education of healthcare personnel, research activities and their role as employer or purchaser of (medicinal) goods (Healy & McKee, 2002), an array of EU activities influences – from health policy but well from other policy fields – are likely to affect them. For many other cases of healthcare policy – except where an explicit EU legal mandate exists – the number of potential links with EU activities is expected to be lower. More broadly, taking the Treaty mandate (Article 168 (7), TFEU) underlying theory would rather suggests the health sector at large to be a least-likely case for EU involvement in governance compared to other policy sectors.

Secondly, the case of hospitals in the context of EU governance and its Member States is delineated by a temporal, substantive and institutional boundary (cf. Rohlfing, 2012). The analysis of the interplay of governance for hospitals between the EU and Member States has

been limited temporarily to a period between end of the 1990s until today. As described earlier the joint effects of having a public health mandate in the Treaty, the establishment of the Directorate General for Health and Consumers (DG SANCO) in 1999 and the ECJ rulings regarding patient mobility have led to the EU becoming concerned with health system governance in the last 20 years in a systemic way rather than focusing on insular policy dossiers.

The substantive boundary covers the influence of governance on hospitals and hospital policy involving a variety of hospital activities in Member States not limiting it to a certain function such as treatment of patients or alike. Likewise, the analysis is taking into account that governance of hospitals is not just influenced by the Directorate General responsible for health but that relevant laws and actions originating from other Directorate Generals are relevant as well given the scattered health responsibilities at EU level. Moreover, focusing substantially on the outcome criteria for legitimising EU governance described by Knill and Lenschow (2003), a number of critical mechanisms to influence the governance of hospitals have been identified *a priori* and applied.

Institutionally, this analysis has been restricted on federal governments of EU Member States given they have the responsibility to transpose EU actions into national legislation and domestic political actions and are the prime interactor with EU institutions. However, thereby the role of regional and local entities which have responsibility of steering healthcare systems in some countries has been omitted. Likewise, this case study looked at the interactions and effects between EU countries and the European Union exclusively given the supranational powers the EU enjoys. The work and influence of other international organisations without legislative powers (WHO, OECD, World Bank, Council of Europe, etc.) regarding healthcare systems in Member States has not been considered. However, the EU finances or jointly commissions some relevant actions for health systems such as data collection from these international organisations.

1.7.3 Data collection

Finally, in order to ensure the trustworthiness of the findings this thesis has used a case study design to collect a variety of data on the phenomenon that could be triangulated. The research involved qualitative data of primary and secondary sources.

Primary data:

- 20 semi-structured interviews with key informants on the successes, failures and missed opportunities of EU health policy,
- 18 semi-structured interviews with hospital managers, advocates and decision makers on the influence of the EU in domestic hospitals and hospital policy in the Netherlands, Germany and Belgium,
- a content analysis of 24 National Contact Point websites combined with 13 structured short interviews with NCP office coordinators.

Secondary data:

- a narrative literature search in Medline via PubMed was performed using the MeSH term combination of 'Capacity Building' OR 'Health Resources' OR 'Health Policy' OR 'Legislation' OR 'Health Planning' AND 'European Union',
- a content analysis of EU official documents, including internal and external evaluations, reports, communications, strategic policy documents, minutes of EU level meetings, soft law documents and law proposals,
- published reports, scientific articles and (EU) policy documents that chart the implications of the financial crisis on health systems or on constituents thereof. Literature has been searched by screening the databases of Medline & Web of Knowledge, the volumes 2009 to mid-2013 of leading health policy journals and hand-searching the websites of institutions dealing with hospitals or the health effects of the crisis in Europe,
- a literature review on political science concepts of EU integration theories, Europeanisation, governance, policy transfer and learning.

1.8 Outline of the book

This thesis has seven chapters. This introductory chapter has presented the concept of governance, the object of study, the healthcare sector and hospital services, in particular, and the basic features of health system governance at national and European Union level including basic notions of its interactions. Furthermore, the chapter has presented the research framework involving the research questions, methodology and data sources.

As a starting point, chapter 2 and 3 address the problem solving capacities of EU governance regarding healthcare and hospital policy. **Chapter 2** focusses on the extent to which EU health policies are suited to address the challenges for health systems the crisis has exacerbated and the manner how national reform efforts are supposed to be supported by EU activities. The chapter presents five appraised areas of EU policies regarding their potential benefits or drawbacks in light of the crisis. The five policies involved (1) patient and health professional mobility, (2) the European Innovation Partnership on Active and Healthy Ageing, (3) the 3rd Public Health Action Programme, (4) Structural Funds (5) and the reflection processes in the area of health.

Chapter 3 addresses the questions how EU Member States align short-term and long-term pressures for hospital reforms in times of the financial crisis and to chart the ways the EU is influencing the context of these national reforms. A literature review and analysis of policy documents has been the basis for this research. The framework on policy responses to the

financial crisis by the WHO European Observatory on Health Systems and Policies has been applied to structure the findings.

Chapter 4 then turns to the decision making capacities at EU level. The chapter evaluates the functional capacities of the Directorate–General for Health and Consumers (DG SANCO) for policy making regarding its mandate for public health and health systems between 1999 and 2014. The chapter uses the United Nations Development Programme (UNDP) Capacity Assessment Framework to study the European Commission’s capacities for health policy making. A qualitative design has been used for this study based on three data sources: scientific literature, EU policy documents and interview data.

The degree of implementation and compliance with EU provisions is assessed in chapter 5 and 6. **Chapter 5** concerns the compliance of Member States with the legal requirements to establish a National Contact Point for cross-border healthcare (NCP) according to Directive 2011/24/EU. More specifically, to analyse what kind of information NCP websites provide and how the NCP offices have started cooperation. Research for this study included an analysis of the legal requirements stemming from the Directive to be checked against the practical implementation in Member States using primary data from a content analysis of NCP websites, an analysis of EU documents and meeting protocols.

Chapter 6 focuses on the impact of EU hard law and new governance tools for domestic hospitals and hospital policy in Belgium, Germany and the Netherlands. Interview data was collected from key informants to gather the perceptions of “experts” being aware of the national context in which EU hard law and new governance tools impact upon hospital policy. The research has been guided by concepts of Europeanisation and EU compliance research.

The concluding **chapter 7**, the General Discussion, provides a synthesis of results, then, turns to the implications for the governance regarding hospitals and health systems from a EU and Member State perspective using different scenarios. The chapter moves on to the limitations of the research and chosen perspective before devising some recommendations for policy makers and future research.

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Problem solving capacities

at EU and Member State level

Chapter 2

Supporting health systems in Europe

based on

Supporting health systems in Europe: added value of EU actions?

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Abstract

Since the start of the economic crisis, the European Union's (EU's) predominant discourse has been austerity and fiscal consolidation. The detrimental effects on Europe's health systems and the health status of its citizens are well described. However, little is known about the emerging EU level initiatives to support national health systems handle the challenges of efficient care provision and system reorganisation aimed to meet their future needs. This review analyses the manner, conditions and prospects of such EU support. First, health system objectives are increasingly entering the EU health policy agenda. Second, professional and patient mobility provisions may support Member States in coping with crisis related health challenges but can potentially exacerbate them at the same time. Third, in recent initiatives health system goals are more closely tied to the EU's economic growth narrative. And fourth, health system issues are taken up in existing EU-level structures for debate and exchange between Member States. In addition, the design of some policies may have the potential to intensify socioeconomic and health inequalities rather than ameliorate them.

2.1 Introduction

The financial and sovereign debt crisis has had implications not only on national health system policy but has also changed the way health system aspects are discussed at European Union (EU) level. At national level, the crisis has predominantly led to the adoption of retrenchment measures in health policy, which have been well-documented in terms of their public health and healthcare system effects (European Hospital and Healthcare Federation 2012, 2011; Garcia Rada 2011a, 2011b; Kentikelenis et al., 2011; Barros 2012; de Belvis et al., 2012; European Federation of Nurses Associations, 2012; Mladovsky et al., 2012). At EU level, health-system reforms towards austerity are additionally stimulated by economic adjustment programmes in some bailout countries (Fahy, 2012) and potentially by the stricter enforcement of the Stability and Growth Pact (Chalmers, 2012). Meanwhile, the initiation of discussions in support of health systems has included actions to back reforms and innovations inter alia in chronic disease treatment, hospital organisation (Council of the European Union, 2010b, 2011a), health investments or integrated care arrangements (Steering Group on the European Innovation Partnership on Active and Healthy Ageing, 2011; European Commission, 2012a). In addition, existing EU policies on health professional and patient mobility also have the potential to alleviate negative consequences from the crisis. Since both, new and existing EU health policies, have not been appraised with regard to their implications for health systems, this paper explores the positive or negative effects these policies have in light of the crisis.

Our analysis reveals that, first, the EU is increasingly and proactively discussing aspects of healthcare policies (Fahy, 2012). On the basis of the Treaty, public health policies have been the centre of the EU policy agenda and health systems were addressed rather reactively when influenced by spill-over effects from other policy domains. As health systems are facing increased pressures because of the crisis, more targets and objectives related to health systems have been on the EU agenda to add to national initiatives. Second, our analysis reveals that established EU provisions on patient and health professional mobility include chances to alleviate the negative effects of the crisis while simultaneously aggravating problems probably further. Individual patients and health professionals have the possibility to “escape” deteriorating health services and unemployment, respectively, by choosing the cross-border route. However, at the system level, this can exacerbate existing problems of securing financial viability and stable service provision by the loss of financial and human resources. Third, health systems are progressively regarded as loci for achieving economic growth. Whereas health goals have been seen as objectives of the Union in their own right or as prerequisites for economic growth, the current tendency is to link them more closely to the EU’s growth narrative (Borg, 2012). Fourth, Member States (MS) have announced to cooperate and exchange in a more enduring and tighter way on health systems than before.

To illustrate these findings, we appraise five areas of EU policies that comprise a health system dimension and explore their potential benefits or drawbacks in light of the crisis. The patchwork character of EU health policy¹ (Hervey and Vanhercke, 2010) implies that discussions are spread over different policy fields involving a diverse set of actors, instruments and applicable “ground rules” (Greer, 2008). The five policies under scrutiny include (1) patient and health professional mobility, (2) the European Innovation Partnership on Active and Healthy Ageing, (3) the 3rd Public Health Action Programme, (4) Structural Funds (SF) (5) and the reflection processes in the area of health. For each EU policy domain, the goal or the potential to contribute to the sustainability and efficient operation of national health systems has been reported. Moreover, the five policies address basic arrangements of European health systems as they are likely to affect supply and demand of services and stimulate broader innovations in healthcare services rather than looking into narrow policy issues. To analyse these policy areas, we draw on a review of EU policy documents including strategic policy documents, minutes of EU level meetings, soft law documents and law proposals addressing the policy design in the next financial framework of 2014-2020. In addition, from a review of the scientific literature, further insights into the EU health policy debates are gained.

Our findings raise additional questions to the broader “contradictions and challenges” of subsidiarity, the asymmetry of economic and social responsibilities and social cohesion that are inherent in EU health policy (Mossialos et al., 2010) which we will address in the “Discussion” section.

2.2 EU health policy in light of the crisis

The financial crisis has changed the degree and scope of pre-existing health systems challenges. This analysis discusses to what extent EU health policies, and the manner how national reform efforts are supposed to be supported, are suited to address the challenges for health systems the crisis has exacerbated.

2.2.1 Professional and patient mobility²

The potential influence of the financial crisis on patient and professional mobility demonstrates that the existing balance between free movement and the protection of health system goals can

¹ Article 168 TFEU circumscribes the EU competences to adopt harmonising legal provisions to very narrow areas in public health, for example, blood and organs or medicinal products. It gives a mandate for “soft” - coordinating and supporting - measures in many other fields including health systems. However, EU “hard” laws from other policy domains like internal market, employment or financial regulations are applicable to national health systems.

² These policies are based on EU Directives footed on a non-health rationale. However, the manner of EU health policy reactions to the crisis stays soft in these areas.

be distorted. The countries that are hit mostly by the crisis are potentially those that are suffering the most from the loss of health professional and resources. Increasing economic disparities are likely to increase health disparities propelled by incentives for professional and patient mobility. Currently, the opportunities of intensified cooperation between Member States on cross-border care and health workforce planning seem to be insufficient to alleviate additional disparities between countries.

Professional mobility

Since the 1970s, professional mobility of the health workforce has been subject to secondary EU legislation. However, in the last decade, health workforce questions have entered the European health policy agenda more prominently (European Commission, 2008, 2012c; Council of the European Union, 2010a) because of prognoses of increased professional mobility in an enlarged EU 27 and due to labour shortages in light of the demographic change. Easier access to other labour markets in an enlarged Europe with increased wage differentials has raised concerns of a brain drain (Bala and Lesniak, 2005; Starkiene et al., 2005). In addition, along with demographic change, the increasing demand for health professionals and the reduction of the number of people of working age, is leading to general health workforce shortages. Internal estimations by the European Commission expect a total shortage of 1 million health professionals by the year 2020. Professional labour mobility can be a partial solution for countries with an overall inflow of professionals but aggravate the problem in countries with a net loss of professionals.

The actual level of health workforce migration is diverse in the EU. All Member States recognise outflows of health professionals, whereas the level of inflow is considerable higher in many old Member States compared to new Member States. Looking at the pattern of workforce migration, western European countries like Belgium, Austria, France and Germany recruit their foreign professionals mainly from EU and European Economic Area countries, whereas the majority of foreign professionals in the United Kingdom is from outside Europe and in Slovenia from Balkan countries, respectively. Lastly, health professional mobility is particularly pronounced in border regions such as at the German-Austrian border, around the Baltic Sea or between the Benelux countries and France (Maier et al., 2011).

The current financial crisis has the potential to increase professional mobility among health workers in Europe particularly because a number of countries have introduced anti-crisis austerity measures with regard to health professionals namely dismissals, recruitment freezes, wage freezes or wage cuts (Houston et al., 2011; European Federation of Nurses Associations, 2012; Mladovsky et al., 2012). On the contrary, health systems and their professionals in some countries are not affected or have even increased resources. Thus, since there is no uniform

development, it is likely that wage differentials will widen throughout Europe (Mladovsky et al., 2012).

In addition, dismissed health professionals will seek job opportunities in countries other than their home country. Reports from Estonia, Latvia, and Romania already suggest that increased emigration of health professionals is likely (European Hospital and Healthcare Federation, 2011, 2012). An increase in mobility of highly qualified job seekers from Mediterranean countries to Germany has also been reported (Bundesagentur für Arbeit, 2012). In this regard, the revision of the Directive 2005/35/EC strives to ease professional mobility in Europe by the introduction inter alia of a professional card, common training frameworks or easier access to information on how to recognise qualifications in another Member State. However, to balance free movement rights and patient safety concerns the current proposal allows now for (systematic) language testing for health professionals³ (European Commission, 2011a).

To meet language needs in general multilingualism is advocated by the European Commission as an personal escape route out of the crisis and indications exits that more and more Southern Europeans are learning for example German. Therefore, those countries most affected by the crisis may suffer from an excess outflow of their health workforce. Hereby, future health workforce shortages are likely to intensify.

In light of the strive to facilitate professional mobility, health workforce planning need to be reappraised. First, the WHO Global Code of Practice on the International Recruitment of Health personnel, a voluntary code for ethical recruitment, is only partly applicable, since the free movement provisions of the EU's internal market prevail (Glinos, 2012). Second, proposals for extending the use of European Social Funds (ESF) resources for training and education of health professionals in the forthcoming financial framework could help partly to alleviate the effects of a brain drain. Third, the Commission's Joint Action on Health Workforce Planning and Forecasting to secure a sufficient number of health professionals in the future should incorporate crisis-related developments in human resources. Professional mobility and health workforce infrastructures are very likely to be affected by resource cuts caused by the crisis (Aluttis et al., 2013). An EU wide observatory on workforce planning providing sustainable coordination and support among Member States only has proposal status so far (Matrix Insight, 2012). In light of the right to move freely in the EU as a worker and the strong incentives present in some countries currently to use these rights, it can be questioned if the voluntary code for ethical recruitment, extended European Social Funds funding and Member State cooperation can sufficiently prevent the negative effects of anticipated, additional professional outflow.

³ The current Directive 2005/36/EC and its predecessors have not been explicit on the possibility for language testing (Peeters et al., 2010). It caused practical and legal insecurity whether language testing was possible or not. See, for example, Case C-424/97, *Haim II* [2000] ECR I-5123.

Patient Mobility

ECJ' s case law⁴ on patient mobility and cross-border care has established that healthcare systems are subject to the free movement provisions of the EU's internal market. At the same time, social protection goals have been accounted for by allowing to limit the right for treatment abroad for hospital treatment and limiting reimbursement to the level of their home country's social security tariffs. In addition, reimbursement of treatment abroad is only granted for healthcare services that are included in the domestic benefit package. This has recently been codified in the Patients' Rights Directive (PRD; European Parliament and Council of the European Union, 2011). The scope and linked costs of patient mobility have been estimated so far to be small, only <1% of the overall healthcare resources are spent on cross-border care (Rosenmöller et al., 2006). The crisis incorporates some drivers for increased patient mobility that can have detrimental as well as positive effects on health systems.

The character and scope of patient mobility may alter due to the financial crisis when policy responses in healthcare include increases of user charges, prolonging of waiting times and lowering the density of secondary care facilities (Mladovsky et al., 2012). As such, cuts in the benefit package of reimbursed health services, increased cost-sharing provisions and increasing geographical remoteness to healthcare and decreasing number of care providers have been identified as barriers to the access of health services within a country. At the same time these measures are described as motives for patients to consider health services in other countries (Busse et al., 2011). Since policy measures of retrenchment are not uniform across Europe (European Hospital and Healthcare Federation, 2011; Mladovsky et al., 2012), they create pressure to seek care across borders. The potential negative health system effects are threefold.⁵ First, by seeking (additional) care abroad domestic policy measures to save costs by restricting the supply of services (Glinos et al., 2006) or by the rationing of care are undermined. Second, patient mobility can incur additional costs for the home country because the availability of services or extent of care per patient increases, which would not be the case in a pure internal situation (Glinos and Baeten, 2006; Baeten, 2011). Third, the treatment of patients abroad is accompanied by an outflow of resources for health systems. Hence, a country's desire to invest in its own health system is further limited at a time when investment for restructuring is more urgent than before (Jesse and Kruuda, 2006; Baeten, 2011). Thus, there is a potential that the

⁴ Including Case C- 158/96 Kohll v. Union des Caisses de Maladie [1998] ECR I-1931, Case C- 120/95b Decker v. Caisse maladie des employes prives [1998] ECR I-1831, Joined Cases C-157/99 Geraets-Smits v. Stichting Ziekenfonds VGZ and Peerbooms v. Stichting CZ Groep Zorgverzekeringen [2001] ECR I-5473, Case C-372/05 Watts [2006], Joined Cases C- 385/99 Mueller-Faure v. Onderlinge Waarborgmaatschappij OZ Zorgverzekeringen UA and van Riet v. Onderlinge Waarborgmaatschappij ZAO Zorgverzekeringen [2003] ECR I-4509, Case C-368/98 Vanbraekel v. Alliance national des Mutalites Chretiennes (ANMC) [2001] ECR I-5363.

⁵ Given the restrictions to the right for reimbursement outlined in the PRD, patients might seek care abroad fully at their own expenses, because the type of treatment is not covered in their home country and/or is offered at a cheaper price. This type of patient mobility will have no direct budgetary impact on the domestic health system.

facilitation of patient mobility puts additional pressure on those health systems in Europe that are comparatively severely hit by the crisis.

However, so far the overall numbers of patients seeking care abroad is low and only a small share of overall healthcare resources is spent on cross-border care. Next to that, the PRD has increased Member States' control over cross-border care they reimburse. The PRD extends the prior authorisation rule from "hospital treatment" to treatment involving *"highly specialised and cost-intensive medical infrastructure or medical equipment"* [Article 8 (2)] on the basis of planning and cost reasons, which have been argued for the hospitals setting accordingly. Moreover, additional reasons for prior authorisation have been allowed for in Article 8 and it is clearly stated now in Article 7 that cross-border care is restricted to the basic package determined by Member States (European Parliament and Council of the European Union, 2011; Hatzopoulos and Hervey 2013).

On the contrary, the PRD and cross-border care arrangements could help towards a more efficient and cost-effective organisation of healthcare. Baeten (2011) discerns in this regard three ways how "steered" patient mobility can be financially beneficial. First, tasks and infrastructure can be shared across borders. Second, co-financing of highly specialised treatment facilities can be organised across borders (Glinos and Baeten, 2006). Third, "outsourcing" of treatments to other countries is an option when the low number of patients to be treated does not justify a country investing own resources in the build-up of professional skills and care infrastructures (Azzopardi Muscat et al., 2006; Baeten, 2011). However, Baeten describes how cross-border arrangements can involve expensive administrative costs, which make them less attractive. In addition, the setting up of cross-border arrangements might need some additional start-up investments, which can be hard to realise when resources are scarce.

Additionally and beyond the direct facilitation of patient mobility, the PRD foresees various types of national cooperation which offer solutions for more general questions of healthcare re-organisation in light of the demographic change and financial crisis. Intensified Member State cooperation in areas such as rare diseases, eHealth and health technology assessment (HTA) can help to provide healthcare more efficiently and cost-effective. The establishment of European Reference Networks on rare diseases would allow exploiting economies of scale for diseases of which the prevalence is low by organizing the training of specialists and the supply of specific infrastructure on a European scale rather than nationally. The introduction of eHealth applications like telemedicine, data management and tele-monitoring in healthcare on a wider scale is expected to deliver care more cost-efficient and more convenient for patients. Lastly, the incorporation of HTA findings in health policy decision making supports the goals of safe, effective and efficient health (care) interventions and organisation.

In sum, the crisis involves incentives for increased patient mobility which in turn could have potentially detrimental effects at the health systems level. Faced with a potential outflow of resources, current provisions protect health system goals but can certainly not deprive patients of the right to seek healthcare abroad. On the contrary, it remains unclear whether or not benefits through economies of scale and additional national cooperation can be realised.

2.2.2 European Innovation Partnership on Active and Healthy Ageing

Since the European Innovation Partnership on Active and Healthy Ageing (the partnership) is part of the Europe 2020s flagship initiative *Innovation Union*, it ties health priorities – a two years increase in healthy life years – very much with economic priorities of growth and support to European enterprises. While the initiative should be welcomed to address structural challenges linked to demographic change, a number of flaws and difficulties are worth noting. First, the partnership is criticised for its narrow (technological) approach to achieve health system goals and an increase in healthy life years (Ahtonen, 2012) which corroborates the economic objective of the partnership. Second, the lack of dedicated resources within the partnership when budgets are tight is problematic. Third, establishing the link with growth and business solutions will be hard to realise in healthcare systems in a period of austerity. This could even lead to the uneven use of funds and increase differences between systems even further.

As stated in the implementation plan, a “triple win” is sought by the partnership including improved population health, a reduced burden on healthcare systems and increased growth and market potential for European enterprises. The partnership concentrates on three thematic pillars: (1) prevention, screening and early diagnosis, (2) care and cure and (3) active ageing and independent living. Health system issues are addressed in all pillars but are central in pillar 2 where innovative approaches to professionals’ training, tackling multi-morbidity and integrated care arrangements are supported (European Commission, 2012d). However, the proposed areas for actions are regarded as less (cost-)efficient than a comprehensive focus on health promotion. The EU is encouraged to consider regulatory and policy interventions across various sector to promote healthy lifestyle changes on diet, physical activity and smoking. For a more inclusive approach adaptations are envisaged to among others the Common Agricultural Policy, the Horizon 2020 proposal, educational, social and employment policies (Ahtonen, 2012).

However, since the partnership aims to lend support to health industries as innovative approaches should be converted to marketable business solutions (European Commission, 2012d) the promotion of a healthy lifestyle and adequate care for the frail is sought by financing focused (technological) innovations (Ahtonen, 2012). In addition, the emphasis on marketable business solutions raises the question of who will pay for these innovations once on the market

and if they are likely to make the provision of care less or more costly. Moreover, there is a risk that the health systems and health industries hit hard by the crisis may not be able to demonstrate the growth and business dimension to profit from the partnership.

The partnership has no discrete funding but aims at synergy effects by inviting other existing funding schemes to take on the proposed targets of the partnership. The European Commission wants to ensure that the priorities of the partnership will be taken into consideration including the allocation of budgets in the other EU funding schemes such as the Public Health Action Programme, Structural Funds, Framework Programme7/Horizon 2020 or INTERREG (European Commission, 2012e). It involves the risk that resources are shifted from pre-existing and agreed funding priorities in the schemes which are still relevant. Additionally, the Commission seeks to support marketable business solutions and incentives for private firms to invest by adapting relevant EU legislation such as EU data protection, public procurement, research funding and EU standardisation provisions (European Commission, 2012d). It remains to be seen how the overall ambitious goals of two healthy life years gained by 2020 will be reached with a limited scope for actions and without dedicated funding resources. This is especially so in times of economic decline when financial resources are scarce.

2.2.3 Structural Funds

Current developments in European Structural Funds suggest that by streamlining the Structural Funds objectives with the growth targets of the Europe 2020 agenda, health targets are subsumed under economic goals. Moreover, while efforts to increase the effectiveness of Structural Funds investments in health by *conditionalities* are incorporated, it remains unclear if Structural Funds resources can alleviate regional differences when overall national austerity measures run counter to them.

EU Structural Funds aim at regional development in Europe by stimulating economic growth and social cohesion in and among European regions. Thus, welfare is re-distributed between economically stronger and weaker regions in Europe. In the past, EU enlargement has widened not only economic inequities but also health inequities throughout Europe. It has led to the inclusion of health targets in the Structural Funds policy in the current financial framework 2007-2013 in which ~5 billion euros have been dedicated for direct health investment. So far, the resources of the European Regional Development Fund have been predominantly used for health infrastructure investment to (re)construct healthcare services. Projects have focused especially on hospitals and eHealth applications. In addition, European Social Funds' resources can be used to train healthcare personnel and create healthy workplaces (Watson, 2009). The financial crisis is likely now to accelerate regional differences in economic performance as countries have been affected to varying degrees. This makes the attainment of regional cohesion

harder, but demonstrates at the same time that the goals of the Structural Funds are even more relevant than before.

In light of the crisis, the proposal for a Regulation regulating the use of Structural Funds for the next programming period 2014-2020 has defined the objective in accordance with the overall Europe 2020 strategy. This implies that Structural Funds resources used for health are not ring-fenced anymore, but need to be justified in support of Europe 2020s growth narrative. In addition, the proposal foresees the introduction and enforcement of *conditionalities* to ensure higher effectiveness of investments for regional growth and social cohesion. This affects the pursuit of health targets within Structural Funds, too. Starting from 2014, *conditionalities* have to be fulfilled by Member States when submitting their Operational Programmes specifying the use of Structural Funds resources in their country. These *conditionalities* link envisaged actions funded by the Structural Funds with domestic regulatory provision that need to be in place. With regard to the pursuit of health goals, these include, first, in case of eHealth objectives, outcome targets for eHealth in the domestic innovation strategies. Second, for the national Operational Programmes addressing active and healthy ageing challenges, actions need to be drafted according to the EU Employment guidelines (Council of the European Union, 2010c). Third, for other health objectives, the existence of a domestic strategy for health to guarantee quality and sustainability of health services is required including action to promote efficiency and the use of, among other things, technological innovations (European Commission, 2012f).

Proposed changes to the Structural Funds Regulation demonstrate a closer link between growth goals and health. Furthermore, the *conditionalities* make sure that Structural Funds funding is embedded in a supportive environment of existing national and EU policies. The envisaged consistency is sought to ensure higher overall effectiveness of investments. Hence, health policy objectives such as health equity are more closely coupled with the overall goal of promoting regional growth. Despite ongoing and future EU investments in health infrastructure, it is questionable if national austerity measures such as the closing of care facilities, dismissal of personnel or the introduction of co-payments are limiting access to healthcare overall and increasing health inequities further.

2.2.4 3rd Public Health Action Programme

The proposal for the 3rd Public Health Action Programme for the period 2014-2020 addresses health systems in light of the financial crisis. In the explanatory memorandum of the European Commission attached to the legislative proposal, first, the European Commission argues that the crisis has made questions of sustainability and cost-effectiveness more pressing. Moreover, it is stated that ensuring accessibility and quality of care is a delicate task when resources are limited. Therefore, in the proposal for the 3rd Action Programme two entire objectives are

dedicated towards healthcare system issues: one aiming at innovations to secure sustainability and the second to promote access to and safety of healthcare (European Commission, 2011b). It implies a considerable shift towards healthcare related objectives, since healthcare has not been a primary objective but was only moderately addressed in the 1st and the 2nd Action Programme (European Parliament and Council of the European Union, 2002, 2007).

Second, the proposal very much connects health targets and economic growth *“to a greater extent than the previous programmes”* (European Commission, 2011b: 2). The health sector is regarded as a *“driver for growth”* due to its potential for (technical) innovations such as eHealth solutions. Within its programme, the European Commission intends to encourage financial sustainability by setting incentives for *“the most innovative and valuable products and services, which at the same time offer the best market potential and cost savings in the longer term”* (p. 4). Although the notion of a healthy population as a prerequisite for economic growth is mentioned, it is not the leading rationale in the explanatory memorandum. Comparing the framing of the connection between health and economic growth to the one in the EU Health Strategy, it reveals a shift from health predominantly regarded as prerequisite for growth towards the health sector as a contributor to economic growth (Borg, 2012).

The Action Programme is supposed to influence discourses or political agenda and thereby to influence potentially healthcare practice and the organisation of national healthcare systems (Hervey and Vanhercke, 2010). The actions financially supported by the Action Programmes include the cooperation among Member States' health systems and a greater coordination and knowledge exchange between national health policy makers at the European level. It involves the supply of comparative health data, benchmarking and the facilitation of policy learning using best practice exchange and co-ordination efforts⁶. However, evaluations of the EU Health Strategy and EU Action Programmes have reported little impact on national practices so far (European Court of Auditors, 2009; Public Health Evaluation and Impact Assessment Consortium, 2011a, 2011b). Given the comparable small budget of the programmes, the unfavourable, overall economic situation and competing national and European policy initiatives for retrenchment, its potential influence can be questioned even more.

Nevertheless, the proposal for the 3rd Action Programme and the shift towards health system objectives should be welcomed, since the healthcare reforms have become more difficult because of the crisis and are of major concern to national health decision makers. The Public Health Action Programme can certainly stimulate greater cooperation and coordination on health system-related issues among Member States. At the same time, the framing of health

⁶ Examples from the past include cancer survival rates, maternal and perinatal mortality rates, HIV infection rates where comparative data on EU level stimulated countries 'at the bottom of the table' to review their current policies in these respective areas.

system objectives is more closely tied to economic goals. It remains to be seen if the Action Programme can influence national discourses and if so, can set the right incentives for health system reform.

2.2.5 Reflection processes

The reflection processes reveal the intention of Member States to cooperate and exchange knowledge on health system matters more than before. Compared with the Commission's growth approach to health system, issues of cost-effectiveness, questions of management and investment decisions are central topics of national concerns in light of the crisis. Although the reflection process is intended mainly for Member States cooperation, there is involvement by the European Commission as well, as it delivers input to meetings and chairs subgroups of the reflections process or organises the expert panel on health investments.

Both the Council Conclusions on "Innovative approaches for chronic diseases in public health and healthcare systems" and "Towards modern, responsive and sustainable health systems" (Council of the European Union, 2010b, 2011a) called for the introduction of reflection processes to identify responses to the challenges of chronic diseases and of sustainable finances of health systems. The reflection process is a more durable engagement with these themes under the auspices of an existing EU forum for national exchange, the Working Party Public Health at Senior Level. Reports indicating the areas of Member States' interest and recommendations for further actions are the envisioned output of these activities.

Based on the Council Conclusions, the reflection process on innovative approaches for chronic diseases aims to give recommendations for better chronic disease management including health promotion and prevention, healthcare, and research (Council of the European Union, 2010b). The concern about an ageing European population and the cost-effectiveness of chronic disease treatment has increased since the start of the crisis. It is identified by the Working party as one of the topics to be addressed in this reflection process (Council of the European Union, 2011b). A first output of the reflection process will be a report summarising the key areas of concern regarded by Member States and suggesting further activities within the reflection process and beyond. The themes have been narrowed towards innovative approaches in health promotion and disease prevention and chronic disease management and good practice exchange. An initial questionnaire among all Member States based on a consultation paper has helped to identify the areas of most interest (Council of the European Union, 2012a). An interim report has been discussed in September 2012 and Member States supported the report's suggestions for the establishment of a Joint Action on chronic diseases targeting (1) mechanisms to validate good practice, (2) a case study on diabetes care and (3) actions on care pathways for multi-morbid patients. Second, Member States were in favour of a mapping exercise on patient

empowerment in chronic disease management (Council of the European Union, 2012b). Both actions, the Joint Action and the mapping exercise, have been included in the Work Programme 2013 of the second Action Programme on Public Health (European Commission, 2012b).

The goal of the reflection process on modern, responsive and sustainable health systems is to support the re-organisation of health services towards more effective systems and to use limited budgets efficiently (Council of the European Union, 2011a). The Council Conclusions explicitly refer to the combined problem of increased costs linked to the demographic change and reduced available budgets connected to the crisis. Moreover, the Council Conclusions recognise that the crisis has changed the “scale and urgency” to safeguard health system objectives and in case they remain unaddressed, can alter the economic and social conditions in the EU (Council of the European Union, 2011a). The reflection process has been organised by dividing five different sub-groups working on (1) the presentation of health in the National Reform Programmes led by the Commission, (2) effective health investments and financing including the use of SF, (3) the cost-effective use of medicines, (4) integrated care models and better hospital management and (5) measuring and monitoring the effectiveness of health investments. Subgroups 2 to 5 are led by Member States with the Commission having the role of a coordinator guiding the process of the subgroup. Each subgroup plans to submit a report by the end of 2013 including recommendations for further actions (Council of the European Union, 2011c, 2012b).

In addition to the initiation of the reflection process, the Council Conclusions of 2011 state that the European Commission should support the reflection process by offering tools such as health system performance assessment, new ways of European level funding for health systems and expert advice on health investments (Council of the European Union, 2011a). Providing expert advice on health investments has resulted already in a Decision to set up a *multi-sectoral and independent expert panel* on effective ways of investing in health (European Commission, 2012a). The expert panel is to provide expertise and compile knowledge on how to invest most effectively in health systems. The field of expertise covers comprehensively a broad range of issues in healthcare and public health and organisational aspects of health systems (see Annex 1 of the Decision). The panel is organised by the Commission and is expected to run until 2015 with the possibility of being extended. It is emphasised that advice is non-binding and provided only upon request of Member States (European Commission, 2012a). Nevertheless, since several Member States have resorted to health system reforms because of reduced financial resources, an expert panel will be available to support national health reform initiatives by giving Member States access to 12 European experts. To some extent, the expert panel and the other plans of action demonstrate that Member States are willing to allow for more involvement of the

European Commission in facilitating cooperative actions and policy learning on health systems at the EU level.

As these Council Conclusions are a declaration of intent by national ministers of health, they reflect a greater willingness of Member States to engage in a more structured and continuing exchange at the EU level on specific healthcare-related topics. Compared with earlier EU Council Conclusions, the introduction of a reflection process is intended to enable strategic discussions among Member States on these important issues and alleviate the problem of changing agendas because of rotating Council presidencies. The reflection processes offer possibilities for mutual learning among Member States and for taking joint efforts on the problems health systems face during the crisis. However, due to the need to factor in diverging national priorities, the production of the reports seems delayed. Moreover, in what way the recommendations will be taken up or lead to concrete actions remains unclear so far.

2.3 Discussion

Previous studies on the effects of the financial crisis and the role of the EU in health policy have focused on the negative impact on both health and health systems of retrenchment responses (e.g. Kentikelenis et al., 2011; Mladovsky et al., 2012) and the narrowed policy leeway for national decision makers because of tighter EU fiscal governance (Chalmers 2012; Fahy 2012). These contributions have largely focused on the national level and have been mostly inattentive to the potential of EU health policies in light of the crisis. Using a review of EU policy documents and scientific literature, we identified a number of EU health policies potentially supportive of national health systems. An assessment of these EU policies has been performed incorporating current developments connected to the financial crisis.

The concentration on health system objectives at the EU level has increased during the crisis. The European Commission has adopted several initiatives on questions of health system organisation. Further, Member States have expressed their intention to collaborate more intensively than before on health systems on the EU level. Emerging health policy initiatives contain proposals for more stable cooperation structures on chronic disease management and health investments to exploit benefits from mutual learning and information exchange on pressing health system issues. Moreover, established network and joint action structures are also used increasingly to collaborate in this area. The framing of health system goals, especially in the Commission's financing instruments, shows a stronger emphasis and closer link between health goals and economic targets. Health policy is not only regarded as a pre-condition for economic growth, in fact, it is increasingly considered as the locus where business interests and economic growth can be realised. The potential benefits of existing policies on patient and

health professional mobility to alleviate the crisis-induced problems of unemployment and reduced access to care must be weighed against growing problems of brain drain and resource outflow for those countries most affected by the crisis.

Broader “contradictions and challenges” of subsidiarity, power asymmetry between economic and social goals and social cohesion (Mossialos et al., 2010) are likely to be touched by these developments. First, subsidiarity⁷ as a political principle means that the EU may only act in health policy when there is clear added value to single Member State actions. Whenever the EU becomes progressively involved in policy areas such as health system policy one can question if a shift in competence distribution in favour of the EU is taking place. Despite a growing healthcare agenda at EU level, the subsidiarity principle seems to be untouched from a health policy perspective. Financing schemes provide “incentive measures” which include multiple opportunities for national decision makers to change or block the incentives set by the EU. Other instruments outline a role for the European Commission rather as a facilitator or an arena for the cooperation and exchange of Member States. Member States will stay in the “driving seat” of healthcare organisation. Nevertheless, by having the opportunity to frame agendas and steer discussions, this can change national policies and align national practices increasingly in a way that the ground for future hard laws might be prepared (Hervey and Vanhercke, 2010). Member States do not perceive a higher efficiency in regulating healthcare system aspects at EU level to be so high that they would give up their regulatory competences in health system organisation.

Beyond the EU’s healthcare agenda, potential pressures on the subsidiarity principle in health policy might arise from the emerging fiscal governance framework. The strengthening of the Stability and Growth Pact involves inter alia stricter and independent monitoring of national households and a limit to the structural deficit by 0.5% of the gross domestic product. Additionally, “peer pressure” is encouraged by the “European Semester” to improve macroeconomic coordination among Euro countries. The practical relevance of establishing a EU fiscal union for health systems cannot be fully estimated at the time of writing. However, discussions have started on what degree budgetary control will impinge on national health system budgets and thereby affect the subsidiarity principle in place (Lamping 2012). Consequently, from a health policy perspective, it appears that the EU’s responsibilities in healthcare organisation will remain limited in the near future.

Subsidiarity affects another contradiction inherent in EU health policy relating to the asymmetry between economic and social responsibilities at EU level. Market integration and liberalisation have been successfully Europeanised, but EU social integration has been limited by the diversity

⁷ “The “principle of subsidiarity” regulates authority within a political order, directing that powers or tasks rest with the lower-level sub-units of that order unless allocating them to a higher-level central unit would ensure higher comparative efficiency or effectiveness in achieving them” (Føllesdal, 1998:190).

of national social security systems (Scharpf, 2010). To identify the uptake of supportive health objectives as a move towards social priorities is tempting because of the increasing pre-occupation with health policy targets at the EU level. However, the attainment of healthcare policy goals is very much linked to economic goals. The replacement of the Lisbon Agenda by the EUROPE 2020 strategy in 2010 was accompanied by a shift in balancing the economic versus the environmental and social pillar of the Union with a changing emphasis in favour of the former. The Lisbon Agenda regarded social and environmental objectives in addition to economic objectives as goals in their own right, but nevertheless connected – as prerequisites for growth and employment objectives. In contrast, with EUROPE 2020 regarded as an “exit strategy” from the crisis are *“social and sustainability concerns now explicitly put at the service of growth as growth enhancing factors”* (Bongardt and Torres, 2010: 139). This has certainly influenced the formulation of new health policy initiatives at the EU level as we have seen with the proposals for a Structural Funds Regulation and the 3rd Action Programme starting in 2014. Despite growing attention for health and social priorities, it is sought to achieve economic goals at the same time. Thus, asymmetry is still in place in the formulation of EU health policies.

Moreover, since the effects of market liberalisation are supposed to differ across regions, economic integration has necessitated the promotion of social cohesion. EU cohesion policy with regard to reducing regional disparities, has addressed health inequities by supporting health system and public infrastructure. As the crisis hits countries to a varying degree, the achievement of social cohesion in the European Union is becoming more difficult. Moreover, the EU policies on free movement and financial schemes to be applied in health systems might even intensify socio-economic differences. First, free movement of health professionals and patients might hit economically weaker countries more and benefit economically stronger countries. Second, those regions and countries most affected by the crisis will find it comparatively more difficult to demonstrate the benefits for businesses and the economy in the application for EU funds. In a situation where national austerity measures incorporate major cuts in health system and other public expenditure and general tax increases, the prospects of health system strengthening and economic growth will be hard to make. This runs counter the actual need for public and private investments to be made in those regions and countries. Hence, it remains doubtful if health policies can make a difference to growing economic and health inequalities despite social cohesion goals incorporated in EU policies.

2.4 Conclusions

Fahy has asked “Who is shaping the future of European health systems?” (2012). We have provided an initial analysis of how health systems will be influenced by the EU’s health policy agenda in the future. Financial support and the facilitation of an arena for cooperation by the European Commission are not neutral. EU involvement adds new layers to the discussion of health policy such as questions of subsidiarity or EU wide social cohesion. In addition, national and EU agendas on healthcare systems differ in the degree to which economic and social goals are balanced. The discussion and comparison on the EU level of measures to counteract health-related effects of the crisis and additional EU funding opportunities for health system should be welcomed. Nevertheless, EU involvement can add biases and problems previously unknown at national levels. This is not only important for the response to the crisis but also in light of more long-term discussions on and challenges to redesigning health system in addressing the effects of the demographic change. Every policy needs further careful attention concerning its added value and potential drawbacks in later stages of the policy process.

In addition, our analysis raises questions on the implications for EU health policy as such. Do we witness the emergence of a critical juncture as Greer (2008) has described earlier for EU health policy? The predominant narrative for discussing health system issues on EU level is still undecided. A health rationale has co-existed so far with a social and economic policy perspective at EU level and the crisis has likely added a financial consolidation rationale to it. The financial crisis might lead to one of them becoming the prevailing discourse for health policies discussions and alter the institutional design of health policy at EU level. This could indicate the current patchwork character to dissolve and EU health policy to be more coherently addressed from a health – or from one of the alternative logics. However, a path-dependent route continuing with multiple logics for health policy making cannot be precluded so far.

Finally, what does this mean for the regulators, providers, purchaser and patients in European healthcare systems? The increasing occupation with health system goals at EU level can lead via networking, learning and consensus building among decision makers in Europe to very practical effects (Greer and Vanhercke, 2010). Although it is too early to see them now, we might have entered a long term process “From Cooperation to Convergence” (Peeters, 2012: 56) towards a Europeanisation process of health systems in Europe.

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Chapter 3

Aligning cost containment needs with plans for structural redesign in European hospital reforms

based on

European hospital reforms in times of crisis: Aligning cost containment needs with plans for structural redesign

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Abstract

Hospitals have become a focal point for healthcare reform strategies in many European countries during the current financial crisis. It has been called for both, short-term reforms to reduce costs and long-term changes to improve the performance in the long run. On the basis of a literature and document analysis this study analyses how EU Member States align short-term and long-term pressures for hospital reforms in times of the financial crisis and assesses the EU's influence on the national reform agenda. The results reveal that there has been an emphasis on cost containment measures rather than embarking on structural redesign of the hospital sector and its position within the broader healthcare system. The EU influences hospital reform efforts through its enhanced economic framework governance which determines key aspects of the financial context for hospitals in some countries. In addition, the EU health policy agenda which increasingly addresses health system questions stimulates the process of structural hospital reforms by knowledge generation, policy advice and financial incentives. We conclude that successful reforms in such a period would arguably need to address both the organisational and financing sides to hospital care. Moreover, critical to structural reform is a widely-held acknowledgement of shortfalls in the current system and belief that new models of hospital care can deliver solutions to overcome these deficits. Advancing the structural redesign of the hospital sector while pressured to contain cost in the short-term is not an easy task and only slowly emerging in Europe.

3.1 Introduction

The current financial and sovereign debt crisis has accelerated questions of efficiency and sustainability in the healthcare sector at large. A decline in tax revenues and the volume of social security contributions against the background of pre-existing cost drivers of increasing demand for health services due to ageing societies, higher patient expectations and costly medical innovations presents a challenge to the maintenance of the current scope of service provision in many EU Member States. It has therefore given new impetus to reform efforts for cost savings and efficiency gains in the hospital sector [1]. Early analyses of the impact of the crisis on health systems anticipated the use of short-term measures to control costs and the need to improve efficiency in the long run [2, 3]. Both contributions have suggested specific reforms for the hospital sector, such as reduction of overcapacities, change of payment systems, or better co-ordination of care.

Although reforms are not limited to the hospital sector, there is a need to take a closer look at hospitals for several reasons. First, they are prone to (short-term) cost control measures because of the considerable share (20-50%) of the overall health budget they consume [4] and, second, the assumed potential for reducing inefficiencies due to variances in cost and outcomes [5, 6]¹. Third, because hospitals are still the central nod in the provision of care, any reform of specialised or pathway type of care arrangements will involve hospitals. Moreover, the move from hospital-centred systems to integrated care systems will require a different type of hospitals to serve the needs of European populations. In that regard, to plan the right long-term policy decisions is of equal importance. Short-term reforms are not sufficient to address underlying cost drivers, more profound reforms are needed to secure sustainability [2, 3]. Secondly, strategic decisions (e.g. capital spending) will impact on the way hospital *and* non-hospital care is delivered for the decades ahead, for example, patients are increasingly treated within pathway care models that transcend different in- and outpatient arrangements [7].

Two kinds of reforms are discerned in the analysis. Following up on Schneider [2], short-term reforms are aiming at reducing health expenditure while leaving the structures – the logics of organisation and regulation – of providing, financing and paying services – in the health systems unchanged. Examples include, delaying investments, reducing administrative costs and lowering the remuneration for providers and producers [2]. In contrast, we regard long-term reforms as those reforms aiming at increased performance of health systems in the long run by altering the structures, relationships and institutions within existing systems. Structural reforms involve for

¹ Some variance is accounted by factors outside the healthcare sectors (e.g. socio-economic situation of a country, lifestyle of population) and may reflect as well certain choices (inputs into the healthcare system). A considerable part of variance can be linked to variation in medical practice (even within countries).

example the move to deinstitutionalised care provision or new models of provider payment to contain the rise of expected health costs, to adapt services to changing needs and expectations and to secure a sustainable base for financing care in the future. As stated above, both, short-term and long-term reforms are important, even more so, as the current financial crisis exacerbates the problem of immediate budget constraints and questions the sustainability of healthcare system on the background of increasing future needs in the long run.

The aim of the study is to analyse how EU Member States align short-term and long-term pressures for hospital reforms in times of the financial crisis and to chart the ways the EU is influencing the context of these national reforms. With the help of a literature and documentary analysis this paper first assesses what kind of hospitals reform strategies have been embarked on in EU Member States during the current crisis. Second, we describe current EU policies linked to the current hospital reform agenda and assess the potential influence of this process.

3.2 Methods

Our findings are based on a growing stock of published reports, scientific articles and policy documents that chart the implications of the financial crisis on health systems or on constituents thereof. Literature has been searched by screening the databases of Medline & Web of Knowledge, the volumes 2009 to mid-2013 of leading health policy journals and hand-searching the websites of institutions dealing with hospitals or the health effects of the crisis in Europe. Comparative works covering the entire EU as well as single country analyses written in English have been considered. The retrieved sources have been analysed for the data on hospital reforms using the framework applied in two linked WHO European Observatory studies on policy responses to the financial crisis for the entire health systems [10, 11].

This framework charts the policy responses according to (1) the decision on the level of expenditure, (2) the policy domains to implement the envisaged changes and (3) their effect on health system goals. First, general decisions are taken to alter or preserve the level of public expenditure for health within the overall governmental budget when tax revenues decline in times of crisis. Governments are faced with the question whether or not to cut resources for the health sector (vis-a-vis other public domains) and if so, in which domains of the health sector (primary, secondary care, prevention, long-term care, etc.). Second, the policy tools to implement the envisaged general expenditure changes are subdivided according to financing and contributions, volume and quality of care and cost of care. Third, the effect of reforms can be analysed in relation to the fulfilment of health system goals. According to the WHO European Observatory framework these goals include health status, financial protection, efficiency, equity, quality, responsiveness, transparency and accountability. The described framework supports the

description of health system responses according to the outlined three facets, however, it does not imply a linear sequencing of actions [10].

Because we focus explicitly on hospital care services in EU Member States we provide an overview of changes to expenditure levels, then we screen the reform efforts to establish how they are directly and/or indirectly affecting the operations of hospital services and discern them according to the WHO European Observatory framework [10] by:

- *financing and reimbursement*: hospital budgets, user charges and provider payment,
- *volume and quality of hospital services*: scope of the basic benefit package, waiting time,
- *operational costs*: prices of medical goods, health professionals, capital investments, re-organisation of the hospital system.

Lastly, we describe the implications of reforms efforts for health system goals as far as they are already reported in the literature.

3.3 Hospital reforms in times of crisis

More and more hospitals are facing budget cuts and efficiency initiatives as a growing number of Member States react to the continuing pressures on their economies. For some, immediate cuts were triggered as early as 2008/09 as the crisis unfolded. Others followed or deepened their austerity measures for their health systems in 2010 [12]. Interestingly, some of the EU countries (Greece, Ireland, Estonia) with the most pronounced cuts in general health spending between 2009 and 2011 had comparably higher health expenditure growth rates in the years since 2000 [54]. It is presumed that those health systems had problems already prior to the crisis and, therefore, were even more vulnerable to the implications of the crisis [62]. The work of Reeves et al. suggests that the level of debt, the strength of recession and political party colour (right vs. left) is not consequential for health budget cuts. Instead, they found an association between greater reductions in health budgets and the country receiving IMF loans, even after controlling for selection bias [66]. Although most countries have attempted to minimise financial impact there is clear evidence of budgetary reductions in the hospital sector in some Member States. In some instances, a graduated approach was followed by reducing hospital volumes, prices and/or wages. Many also sought to realise efficiency and productivity gains in the operation of their hospital systems. However, the picture is diverse throughout the EU. Countries facing similar economic difficulties have reacted differently in terms of their health budgets [66].

Moreover, the analysis of crisis-related implications is blurred by the fact that some reform projects existed prior to the crisis but were likely to be accelerated to bring forward improvements in the cost efficiency and effectiveness of service delivery [1, 10]. Likewise, there is a growing debate – predominately US focused – whether the financial crisis being the single reason for the recent slowdown of healthcare expenditures or not. While some of the potential alternative explanations are typical for the US context, the introduction of Obamacare, move to paying physicians by salary, others, such as slower diffusion of technological and pharmaceutical innovations, cost sharing and increase of efficiency in providing services, may be valid also in Europe. This is in so far important to expect health expenditures to move to their original growth paths or not once economic growth resumes [55-58].

3.3.1 Policy tools aimed at hospitals

3.3.1.1 Financing and reimbursement of hospital services

Several countries report changes to the financing and reimbursement of their hospital services. Scope and characteristics of measures differs widely between Member States. In some instances, reforms have been moderate, like lowering growth rates, or indirect, such as the change of payment system. In other countries, Spain, Latvia, Greece and Portugal for example, changes have been direct and considerable involving sizeable reductions in the resources available. The latter two countries face cuts in response to the requirements of their bailout agreements. A detailed overview of reform introduced or planned can be retrieved from Table 3.1.

Table 3.1 Reform (plans) on financing and reimbursement of hospital services

Tools	Description of reform (plans)	Country	Reference
Hospital budgets	Reduced budget by 2% in 2011	Czech Republic	
	Reduced budget by almost 1% in first half of 2010	Slovenia	[1]
	Decreasing budget in absolute terms in 2011	Austria	
	Intended savings of €200M in 2012 further 5% planned for 2013	Portugal	[30]
	8% cut in 2012 foreseen	Greece	[16]
	Frozen budget for 2011	Hungary	[13]
	Lower growth 2,5% limit in 2011 instead of more than 4% previously	The Netherlands	[1]
	Lower growth 3% instead of 5%	Luxemburg	
	Frozen NHS budget (incl. hospital sector)	UK	[61]
User charges	Co-payments increased or introduced for hospital services	Portugal	[50]
		Czech Republic, France, Ireland, Romania, the Netherlands and Italy	[10]
Provider payment	Lowered tariffs paid to providers	Estonia, Ireland, Romania, Slovenia	[10]
	DRG prices reduced	France	[13]
	DRG system planned to be implemented	Bulgaria	[51]
		Czech Republic	[10]
		Cyprus	[52]
	Introduction of pay for performance in 2010	The Netherlands	[13, 43]
	Plans to introduce pay for performance	Italy	[10]
	Non reimbursement of emergency readmission within 30 days	UK	[53]

3.3.1.2 Volume & quality of hospital services

Only minor exclusions of hospital care services from the basic package were reported. In the Netherlands reimbursement for IVF treatments has been lowered. Portugal excluded cosmetic surgery from the package [10]. A plan for new Danish treatment guidelines aims to reduce the amount of surgery by encouraging alternative – and less expensive – methods of treatment where possible [13]. Beyond minor exclusions of hospital services from the basic benefits package, additional services are moved outside the hospital setting using outpatient facilities as described in section 3.3.1.3 under *Re-organisation of the hospital system*.

Increases in waiting times as an explicit policy are reported for Estonia where the maximum waiting time for outpatient specialists' visits has been raised from four to six weeks [10], for Denmark where plans to lift the four weeks guarantee for patients to be treated in private hospitals exist [1] and Catalonia where the Ministry of Health indicated that the maximum waiting time of six months was going to be extended to twelve months [14, 15].

3.3.1.3 Operational costs of hospital services

Prices of medical goods

Reducing the prices for pharmaceuticals, medical devices and other apparatuses has been reported as a common strategy to cut in the costs of health systems including hospitals. To lower the price paid for pharmaceuticals, Austria, Belgium, Ireland and Spain renegotiated the contracts with pharmaceutical producers. In France, Hungary and the Czech Republic greater use of generics has been stimulated. Malta and Slovakia introduced a reference price system and Romania reformed its system. Whereas in the Baltic States, Portugal, Slovenia, Catalonia, Greece, Spain and Poland a whole package of different measures to reduce costs of drug prescription has been indicated [10].

In the area of medical goods and equipment, Austria concluded long-term contracts for imaging scanners and other medical aids involving price reductions. Belgium introduced a new reimbursement scheme for implants and medical goods with lower prices. In the Czech Republic auctions were introduced for procurement of medical equipment and drugs in 2011. In Bulgaria reforms for the purchasing of medical devices are anticipated [10]. Moreover, Slovenia reduced the prices paid for goods and equipment by 20% [1].

Health professionals

Cutting the general salaries of health professionals including hospital staff has been applied in Cyprus, Greece, Ireland, the Baltic States, Romania, Spain and Portugal [1, 10]. Moreover, wage freezes have been adopted in the UK (excluding low wage earners), Portugal and Slovenia and a

reduced rate of wage increase was advocated in Denmark [10]. For Portugal and Catalonia, additional cuts in the remuneration of overtime are reported [10, 15]. Greece was required to save EUR 100M in the expenditures for wages and fees by the introduction of new payment system in 2012 [16].

The reduction of the number of health professionals through redundancies including direct dismissals have been stated for France, for some regions in Denmark, for some hospital managers in Portugal [13] and Catalonia [14]. Ireland, Italy, Greece [17], Slovenia, Portugal, Cyprus and Spain reduced number of personnel by non-replacement of terminated contracts or retired staff, and hiring cuts or freezes [13]. A few Member States report that nurses are replaced by less skilled (the Netherlands, UK) or un-skilled (Slovakia) workers [18].

Capital investments in the hospital sector

Some countries have put on hold or revised their investment plans for the hospital sector; others however have put extra resources into the system to accelerate reform in a reaction to the crisis. Romania stopped plans to build eight new hospitals and Ireland reduced the number of planned new health facilities by 25% [10]. Spain reduced its investments by 25% in 2010 [13]. In the region of Catalonia, even all investments plans were abandoned [14]. In the UK, the building of a new hospital in North East England has been cancelled [13] and the NHS's general capital spending budget for 2011 to 2014 has been reduced by 17% [10, 19]. In contrast, extra investments in the hospital infrastructure were made in Cyprus for the building of two new hospitals and in Germany as part of a general economic investment package [1]. In Latvia, commitment persisted to invest in aligned eHealth technology [10] as strategy to make healthcare provision more efficient and safe. Likewise, Greece and Portugal are pushed to implement eHealth applications following the agreed economic adjustment programs [16, 30].

Re-organisation of the hospital system

The broader re-organisation of hospital care provision involving ways of centralising hospital care provision and of reducing hospital infrastructure has also been a reform target. In some countries a reduction in hospital infrastructure (numbers, scale and capacity) is in prospect. Denmark centralised hospital services involving closure of hospital (departments) [10] and government plans exist to reduce the number of hospitals further from 35 to 20 in the next ten years [20]. In Greece, some hospitals have been merged and some closed [10]. Latvia converted more than 1100 hospital beds to residential care beds. Furthermore, the number of Latvian hospitals has been reduced from more than 80 in 2008 to about 40 in 2010 including closing regional hospitals [1, 10]. Pressured by the bailout contract, Portugal aims to exploit economies of scale by the re-organisation of hospital and primary care and decrease of hospital beds [10, 21]. The number of hospital beds was reduced by more than 500 in 2009 in Ireland [22] and by

approximately 1500 in Catalonia in 2011 [14]. The centralisation of emergency care and specialised care services has been reported as well for Finland; however this has less to do with the economic crisis and is more a longer-term program. Plans to reduce acute care beds in 2011 existed in the Czech Republic and in Romania (9000 beds) [1]. In the Czech Republic, such beds are envisaged to be used for rehabilitation and long-term care [23].

Second, the move towards non-hospital setting – either independent or combined with other re-organisation measures – has been reported only for Ireland, Greece, the Baltic States, and Slovenia. The stimulation of day care and outpatient services is achieved for example by redirecting funds (Lithuania) or restructuring hospitals in favour of day care clinics and outpatient facilities (Slovenia) [1, 10]. Lastly, the improvement of integration of care providers has been supported for instance in the Netherlands [10], Portugal and Finland [1].

3.3.2 Implications for health system goals

Health policy reforms described above have implications for health systems' goals including among others health status, level of financial protection, efficiency, equity, quality and responsiveness [10]. Some are already reported for only a few countries, others are expected to take effect soon. In Latvia budget cuts and closing of inpatient facilities led to increasing emergency care provision in hospitals, hampering elective provision of care [1]. In Catalonia, hospital emergency service use has dropped by 3% in 2011 and in the first half of 2011 6% fewer surgeries were performed [14]. Discouraged doctors and nurses either emigrate or leave the health sector as reports from Ireland indicate [24]. Increases in waiting lists as an effect of responses to austerity have been reported for Ireland indicating a 9% increase of number of people on waiting lists between 2009 and 2010 [10]. In Catalonia surgical waiting lists increased by 23% (17000 people) within the first half of 2011 [14, 15] and increases in waiting times are reported from parts of Finland without specifying the degree [13]. Higher barriers to access healthcare because of co-payments, waiting times, or closing of hospital facilities were experienced by Italian patients in 2011 [25]. For 2010 an increase in admission to public hospital by 24% and at the same time a reduction in admissions for private hospitals is reported for Greece which is linked a reduce ability to pay for hospital care privately [26, 27].

Moreover, further negative implications are discussed in the literature. This includes the fact that a reduction in the workforce in the absence of a productivity increase implies the risks of deterioration in patient throughput [25], quality and increased workforce volatility. Specific concerns about a fall in quality of care and patient safety have been voiced by nurses in Austria, Croatia, Greece, Ireland, the Netherlands, Poland, Portugal and Slovakia [18]. Hence, it is a delicate balance to push for efficiency and not unwittingly create conditions for risks to patient care to escalate [28].

On the contrary, the Irish case is an example where as well positive effects on efficiency have been reported. Thomson et al. report that while budgets and staff have been reduced, the level of day cases and day surgeries has increased in 2010 and the average length of stay went slightly down [24].

3.4 EU influence on hospitals

The line of demarcation on subsidiarity implies that Member States are wholly responsible for the internal operation of their health systems. However, the EU is strongly promoting and influencing reforms by different means. The macro-economic context in which hospital policies develop is inevitably influenced by the EU [8]. The EU can also exercise other forms of leverage through an increasingly assertive EU healthcare agenda involving support options for hospital policies [29]. EU support comprises expert advice, stimulation of innovations and financial support primarily through its Cohesion Policy and Europe 2020 strategy.

The influence of the former, the EU's economic governance tools to encourage reductions in government debts and to coordinate national policies varies according to the conditions of the Member States' economy and public finances. The economic adjustment programme underpinning bailout packages include specific requirements to ensure public finances are brought under control. The result in some countries will inevitably mean further austerity applied to current and future budgets. The health and hospital system have been specifically targeted in Greece and Portugal as described above [16, 30]. In all Member States stronger EU fiscal and economic surveillance of national public budgets was introduced with the "Fiscal Compact Treaty"² and additional legislation [31] to reinvigorate the Stability and Growth pact (SGP) and its stability targets³. These mechanisms are intended to push Member States towards more budgetary discipline [8]. In addition, in the framework of the European Semester [31] reforms of the healthcare sector towards greater efficiency and sustainability have been addressed [9] and have been reiterated in the Annual Growth Survey 2013 [32]. Using these routes for financial consolidation the EU drives Member States indirectly to reduce public expenses in the hospital sector.

In addition, tighter financial requirements for investors make it more difficult for hospitals to acquire investment through capital markets. EU-based investors have already reduced their project lending during the financial crisis. Moreover, the EU has just adopted new provisions for banks (Basel III/Capital Requirement Directive IV) and is currently in the phase of revising

²Treaty on Stability, Coordination and Governance entering into force January 1st, 2013 (not applicable to UK & Czech Republic)

³ among others general government gross debt lower than 60% and deficit spending lower than 3% of GDP

requirements for insurance (Solvency II Directive) and pension funds (IORP II Directive) involving, among other measures, higher capital buffers. It will lead to more costly and challenging acquirement of investment money especially for long-term investments such as hospital infrastructure projects [33]. Hence, the EU is not only pushing indirectly for cost saving measures in the hospital sector. Perhaps paradoxically, the EU simultaneously limits the ability of hospitals to react to austerity measures by discouraging long-term investments needed for re-organisation of infrastructure and other key attributes required to achieve efficiencies in care provision and administration.

The growing agenda at EU level for health systems change implies the availability of better tools to inform and stimulate hospital reforms in its Member States. This includes, firstly, commissioning of comparative data and overview reports [6, 12, 34]. Second, sources of advice include a newly installed expert panel on health investments linked to health system and hospital reforms⁴ [35, 36] and a reflection process among Member States coordinated by the Commission. The goal of the reflection process is *“to identify effective ways of investing in health, so as to pursue modern, responsive and sustainable health systems”*. The reflection process entails five working groups on the representation of health in the Europe2020 strategy, on the use of EU Structural Funds for health investment, on cost effective use of medicines, on integrated care models and better hospital management, and on measuring and monitoring effectiveness of health investments [37]. Third, EU sources for funding innovations in hospital care services (on a project basis) include EU Structural Funds, the framework programme for research (FP7/Horizon 2020) and the programme for action in the field of health. Hence, the EU’s health system agenda has moved towards providing a more complete reference source for Member States for ideas, guidance and financial support for *“changing healthcare”*.

Despite ostensibly not being in the driver’s seat as regards hospital reforms, the EU now has several instruments at its disposal to prompt, recommend or set economic incentives for national hospital reforms according to the status of Member States’ public finances. Nevertheless, except for the bailout countries, it remains largely at the discretion of the Member State to take up incentives or not. The subsidiarity principle still holds in this sector to a very high degree.

⁴ Initial mandates of work cover (1) integration of care, (2) public-private partnerships for care delivery and (3) health system performance assessment.

3.5 Discussion

The current reform agenda on hospital services highlights several things. First, hospitals have been and continue to be one of several focal points of healthcare reform efforts during the current financial crisis [10]. Wide variances in operational effectiveness create pressure to deliver greater efficiency gains in the hospital sector [5, 8]. Second, so far there has been a tendency towards short-term and quick-fix solutions to contain cost. This involves the reduction in payment for medical goods and staff salaries lowering the operational costs of hospital activity and cuts in hospital infrastructure maintenance and capital investments. Though they have some impact short-term, these measures are not likely to control future growth in spending [2]. Moreover, evidence from previous crises suggests that reductions in expenditure growth have always been only a temporary fix and that health spending growth resumes as soon as economies begin to grow again [38]. If, when, and to which degree future economic growth will be able to alleviate the effects of prior expenditure cuts remains to be seen as the current crisis is deeper and longer than any other crisis since the 1930s. Thirdly, addressing the structural redesign of the hospital sector by changing financial reward systems or integrated care arrangements – beyond project status – is only reported for a few countries. Structural reforms inevitably face resistance at the front line and arguably at political level [39, 40]. Reform of the hospital sector can prove to be high risk for some governments.

The framework on policy responses to the financial crisis [10, 11] has been supportive in clustering the magnitude of hospital reforms and reform plans according to the described domains and helping to understand the potential implications of the reforms on health system goals despite limited reporting in this regard. Applying the framework only to the hospitals setting has raised questions, which reported reform tools to include or not because some are applicable outside the hospital domain as well (e.g. health professions, medical goods, capital investments). Reforms were considered as far as a direct link to the hospitals environment existed.

3.5.1 The risks and politics of short-term reforms

Short-term measures to control costs and increase efficiency involve nevertheless a difficult trade-off between sustaining levels of quality and service provision and potential negative (long-term) health systems outcomes [10, 28]. Immediate reductions in hospital infrastructure (capacity) must go hand in hand with the establishment of alternative provision. If this is not the case, unjustifiable treatment delays or increased emergency care provision (such as in Latvia) can and will occur. Other examples of this difficult trade-off include cost-savings targeting professionals that can aggravate expected personnel shortages in the future because health professionals can migrate into other sectors or countries. Moreover, increasing co-payments can

prevent unnecessary care but may also withhold people from demanding necessary care. Co-payments place a heavier financial burden on poorer parts of the society and may therefore hamper equity goals [41, 42]. It is therefore critical that, potentially detrimental effects on health system goals in the long run should be fully assessed and monitored as part of any major drive towards improving cost efficiency as a short-term goal.

It is fair to say that short-term reforms are sometimes the only way to handle cuts in the budgets. In addition, looking at the politics of healthcare reforms, good reasons exist to favour short-term over long-term reforms. Politically it is more important to have short-term success than to prepare for long-term gains. Structural reforms normally go ahead with creating winners and losers in the system, which is a risk to politicians and creates resistance towards the reform [59, 60]. Hence, small cuts across many different parties might be more desirable and feasible. Nevertheless, the crisis has prompted some contributors [e.g. 2] to stress even more long-term objectives in the policy development of (hospital) reforms.

3.5.2 Organisational and financial requirements to modernise hospitals in the long term

To further the long-term reform agenda towards structural redesign of the health and hospital system there is a need to address both the clinical system and the financial structures. The former involves the advancement of innovative models such as integrated care (pathway) models across parts of the health system, including social care to increase coordination within the chain of providers. Shifts towards coordinated provision in non-hospital settings seem promising and increasingly probable because of technological (e.g. telemedicine, remote diagnosis) and service innovations. Moreover, pathway based care models are promising as a basis for redesigning processes, infrastructure redesign and resource realignment in hospitals. Lastly, in some countries there is room to shift services still performed currently in hospitals towards primary care settings but availability of alternative and more suitable accommodation within the community are not yet in place.

Reforms of hospital financing systems are also critical. On the one hand, payment systems should support organisational changes such as bundled payments in the Netherlands to facilitate integrated care arrangements [43] or GP-led commissioning in the UK to stimulate service provision in community settings [44]. Early evaluations of the innovative financing models suggest that more care is allocated to the primary setting and responsiveness increases but there is no proof so far that cost savings are achieved or provision of hospital services are altered profoundly by these models [44]. However, in general well-established primary care systems are associated with better health outcomes at lower cost [63, 64].

On the other hand, investment models in the hospital sector also need to change and innovate. In addition to the shortage of public money for hospital investments, private finance is getting

tight. Currently, acquiring investment money for hospitals from private investors is quite difficult as the reduction in new start Public-Private Partnerships (PPP) in the UK suggests [45]. New PPP models “bundling” services with infrastructure are regarded as an opportunity to improve PPP performance and leverage reforms in the service provision towards integrated care systems [46]. The experiences so far with PPP in financing hospitals are at best mixed [45]. Lastly, the reported, short-term cuts in capital investments disregard the need for initial extra investments to restructure hospital sector. It follows that a crisis situation is something of a paradox. It creates the need and stimulus for change, but at the same time may create financial disincentives for the investment in capital resources required, as our findings tend to indicate.

3.5.3 What role does the European Union play in the reform of the Member States’ hospital systems?

The EU can have a direct impact through the conditions applying to macro fiscal support in requiring action to get public spending back under control. Global hospital budget cuts of hundreds of millions of Euros as described above is likely to cause severe distortions in the service provision as case reports from Greece or Spain indicate [47, 48]. For all Member States the EU exerts additional pressures for austerity in light of meeting the Maastricht criteria. In contrast, the EU can offer support and resources for hospital reforms to national decision makers. Because they can imply a “buy in” of EU principles into domestic hospital provision, they are not neutral. [29]. Additionally, the EU has at its disposal “European solutions” to improve efficiency in the hospital sector such as cross-border care solutions in terms of sharing of infrastructure and of investment costs or steered patient mobility. The plans for European networks of reference for rare diseases would facilitate quality of care, training and research for diseases across Europe with a low prevalence for which establishing infrastructures on a national scale would be inefficient.

Albeit, Member States remain largely responsible for organising their hospital system as described above; the trigger for Member States to engage in short-term budget cuts and the barriers for investments following from the measures of the EU’s economic governance package is more immediate compared to the various incentives set by the EU’s health agenda for long-term reforms.

3.6 Conclusions

An agenda for a structural redesign of the hospital sector would include moving future operational and financial emphasis for patient care away from a hospital-centred health system. We conclude that, although such an agenda is desirable, it is emerging only slowly across the EU. Currently, Member States are preoccupied with balancing macro financial strategy with manageable austerity in the health sector. This has driven a reliance on quick fix improvements in productivity and efficiency. It can be questioned if these provide a sufficient answer to the challenges of the current crisis. Such steps may not be sufficient to build modern, responsive and sustainable hospital and health systems. Nor may such steps address the growing demands on services resulting from an ageing population and related rise in chronic diseases. At present it stays open how structural hospital reforms will look like in practice. The current financial crisis creates a significant window of opportunity⁵ for health policy reforms in general but also establishes barriers and disincentives to change of the scale required. It has been argued that structural reforms will only occur in the presence of a perception that system deficits are insurmountable and where alternative models of hospital care have gained a critical level of perceived legitimacy among key decision makers [49]. The EU is increasingly attempting to lever both factors. Moving to a redesigned hospital sector in Europe will require embracing what for many will be new and untried models of care in an environment of financial constraints. It follows that current reform plans for hospitals need to assess and take into account changing needs for the future population they serve. Moreover, financial resources and the regulatory flexibility need to be in place to develop further and test new models of organising and financing hospital services as the current evidence remains inconclusive so far. Lastly, beyond the work on concrete tools and technological innovations in the hospital setting a broader discussion on the role and function of hospitals in future health systems has to be initiated because investments and research funding on the national and EU level follow accordingly.

⁵ Policy windows according to Kingdon involve a higher probability that concrete political action is taken. But they may close without practical policies put forward [65].

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Capacities for health governance

at EU level

Chapter 4

DG SANCO 1999-2014: An assessment of its functional capacities

based on

The Directorate-General for Health and Consumers 1999-2014: An assessment of its functional capacities

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Abstract

Capacity assessment has become a popular measure in the health sector to assess the ability of various stakeholders to pursue agreed activities. The European Commission is increasingly dealing with a variety of health issues to coordinate and complement national health policies. This study analyses the functional capacity of the Directorate–General for Health and Consumers (DG SANCO) for policy making regarding its mandate for public health and health systems between 1999 and 2014 following the UNDP Capacity Assessment Framework on the basis of a review of literature, EU policy documents and expert interviews. Our results suggest that DG SANCO has established capacities to engage with stakeholders; to assess various health issues, to define issue-specific health policies and to collect information for evaluative purposes. In contrast, capacities tend to be less established for defining a clear strategy for the overall sector, for setting priorities and for budgeting, managing and implementing policies. We conclude that improvements to the effectiveness of DG SANTE’s (the successor of DG SANCO) policies can be made within the existing mandate. A priority setting exercise may be conducted to limit the number of pursued actions to those with the greatest European added value within DG SANTE’s responsibilities.

4.1 Introduction

The improvement of capacities for public policy in general [1-3] and for health systems in particular [4-6] has become a key approach for effective (health) policy making. By capacity we understand broadly the ability to pursue a certain action in accordance with defined goals or choices [3]. The performance of public policies is deemed to be improved by strengthened capacities because they are regarded as necessary conditions to develop, implement and evaluate policy actions effectively [1, 5]. Capacity entails not only the institutional strengths and competences of a government but also the strategies and skills used to pursue policies [3, 7]. Since the mid-1990s, multiple examples of capacity assessments have been conducted in the health sector using different conceptual models with varying geographical coverage and focal areas of interest [8].

The European Union (EU) has established a mandate for health. As enshrined in Article 168(2) of the Treaty on the Functioning of the EU, the major form of European action in public health is to foster cooperation between Member States (MS) and to support national activities. However, over the last two decades, the EU has increased the applicability of its legal principles to national laws regulating health [9-11]. This has been explained by a series of developments including responses to international public health crises, spill-over effects from internal market law to healthcare as well as a strategic coordination led by the European Commission (EC) [12]. In contrast to the wide scholarly attention that the development of EU competences has received [11, 13], capacities are not frequently discussed at EU level in terms of the Commission services pursuing health policies effectively. The analysis on the effects of EU health policy making on national policies remains incomplete so far [14]. To bridge the gap, the aim of the study is to assess the functional capacities of the Directorate-General for Health and Consumers (DG SANCO) for policy making regarding its mandate for public health and health systems (see Figure 4.1) between 1999 and 2014 by critically reviewing literature including EU official documents and interview data. On the basis hereof, we draw conclusions on potential avenues for more effective EU health policy making.

4.2 Methods

4.2.1 Framework for analysis

We assessed the functional capacities of DG SANCO with the help of the United Nations Development Programme (UNDP) Capacity Assessment Framework [15]. The UNDP framework has so far been applied at national and subnational levels in low to middle income countries. Although the EU combines functions of a state and of an international organisation in health

policy and represents upper-middle-income to high-income countries, the UNDP framework is beneficial to study the European Commission's capacities for health policy making. It identifies a number of functional capacity dimensions necessary to "get things done", these comprise the capacities to:

- a. ***engage stakeholders*** (mobilising stakeholders, creating partnerships, open dialogue, managing different interests)
- b. ***assess a situation and define a vision*** (gathering and analysing data and information, specifying capacity assets and needs, defining a vision)
- c. ***formulate policies and strategies*** (setting objectives, managing priority setting, devising (inter)sectoral policies)
- d. ***budget, manage and implement projects and programmes*** (managing projects and programmes, setting indicators of monitoring)
- e. ***evaluate*** (collecting feedback, establishing lessons learned).

These functional capacities are embedded in a wider framework [15] covering broader institutional and societal arrangements which are described in the background section (see section 4.3.1).

4.2.2 Data collection and analysis

This assessment of capacities uses a qualitative design for the analysis of EU policies based on three data sources: a literature review, an analysis of EU policy documents, and interview data. First, to map the functional capacities, a literature search in Medline via PubMed was performed using the MeSH term combination of "Capacity Building" OR "Health Resources" OR "Health Policy" OR "Legislation" OR "Health Planning" AND "European Union". The search was limited to English publications and human subjects. From a total of 889 retrieved sources, 100 publications have been considered for full text analysis after the screening of titles and abstracts and 28 sources have been used in this review. Publications were included if functional capacities according to the UNDP framework at EU level were assessed, described or commented on. Retrieved research articles, viewpoints and editorials were also screened for additional publications and relevant EU documents in their bibliographies.

The second source, EU official documents, including internal and external evaluations, reports, communications, and strategy documents discussing health policy outputs at European level were analysed. In addition to the hand searching of bibliographies, a pool of EU documents were taken from an earlier study [14] in which experts identified them as potential policy outputs. The selected documents either commented on capacities as in the case of evaluation reports or were regarded as the output of a certain level of capacities like strategy documents.

The third data source comprises twenty semi-structured interviews on the successes, failures and missed opportunities of EU health policy among twenty key informants [14]. Themes identified included perceptions on functional capacities within the EU health sector linked to specific policy areas and the policy process in general. A direct content analysis [16, 17] was used to extract relevant information on DG SANCO and to group information to the predefined capacity dimensions according to the UNDP framework described above. Triangulation of different data sources allowed for cross-checking of findings and helped to ensure credibility [18, 19].

4.3 Results

4.3.1 Background

Overall, the capacities at EU level for policy making on health systems and public health are scattered. First, regulative power is predominantly with Member States on the basis of Article 168 of the Lisbon Treaty [20]. Article 168(7) grants that the responsibilities for the organisation and financing of healthcare systems rest with Member States. The EU is supposed to complement and coordinate Member State actions by establishing guidelines, exchanging best practices, funding research and supporting health monitoring and surveillance (Article 168(1-2)). Only in a limited number of public health domains, such as cross-border threats, substances of human origin, veterinary and phytosanitary measures, medicinal products and medical devices the EU has legislative power (Article 168(4)). The implementation and application of EU legislation in the above described areas remains with Member States like in social policy in general [21].

Second, EU policies for health have developed in other policy areas such as social policy, consumer protection, occupational health protection or environmental policies. Moreover, other non-health policy domains of the EU affect health systems and determinants of health as well, such as internal market policies, competition law or fiscal surveillance of national government budgets [22]. Hence, policy capacities for health at the European Commission exist also in other Directorate Generals (DGs). An overview of various Directorate Generals working on health or related policies is given in Figure 4.1.

Figure 4.1 Responsibilities for health within the European Commission (2014)

Abbreviation: ESIF: European Structural and Investment Funds

Sources: Greer SL, Fahy N, Elliot HA, Wismar M, Jarman H & Palm W. Everything you always wanted to know about European Union health policies but were afraid to ask (2014) Copenhagen, WHO Europe on behalf of the European Observatory on Health Systems and Policies; DG SANCO Organisational Chart 01/09/2013.

Third, DG SANCO was only established in 1999 by augmenting the existing DG on consumer protection. The responsibility for certain health policies were added including food policy, feed and animal health and public health issues from other DGs. On these specific health dossiers DG SANCO is the leading policy actor within the EC. However, DG SANCO's responsibilities have changed over the years – most remarkably the pharmaceutical dossier including the relations with the European Medicines Agency have been added in 2010 – and changed again after the time of writing when the new Juncker Commission took office. From end of 2014 onwards DG

SANCO has been renamed and reorganised to the Directorate General for Health and Food Safety (DG SANTE). A summary over the historic developments regarding the composition of DG SANCO's remit between 1999 and 2014 is provided in Table 4.1.

Fourth, capacities for health at EU level do not only rest within the European Commission but in other EU bodies as well. Three institutions are occupied with the law making at the EU level in general. The European Commission is the executive body. Its role involves, firstly, policy making by laws subject to subsequent Member State implementation then. Secondly the European Commission has the right to initiative. The legislative process of the EU usually starts by a proposal from the Commission. Thirdly, the Commission is tasked to safeguard the compliance with EU legislation in Member States.

The European Parliament, representing EU citizens, and the Council of Ministers, representing national governments, hold jointly the legislative powers in the EU policy making process. More specifically, the Parliament's Committee for Environment, Public Health and Food Safety (ENVI) is tasked to prepare a report (and suggestions for changes) on the Commission's proposal in the area of health. With the Council, the Member State holding the Council Presidency has an important role in setting the agenda and facilitating compromises within the legislative process. The Council can issue also non-binding Recommendations which can be nevertheless influential because they portrait the joint view of all Member States. Moreover, the European Union uses agencies to delegate technical tasks such as scientific assessments outside the Commission spheres [22, 23].

These institutional arrangements and their main developments have been well described in the literature [9-13, 24-26]. In contrast, this assessment will focus on the functional capacities of DG SANCO on public health and health systems from an organisational perspective, because pursuing healthy policy at EU level effectively is regarded as key given the existing scattered responsibilities described above [14, 27].

Table 4.1: Changing health responsibilities within DG SANCO and the European Commission 1999-2014

Year	Developments
Until 2014	<p>Barroso II Commission:</p> <p>DG SANCO Health and Consumers</p> <ul style="list-style-type: none"> • Directorate B Consumer Affairs • Directorate C Public Health (Programme management & Diseases, Health threats, Health information, Health determinants) • Directorate D Health Systems & Products (Strategy & International, Healthcare systems, Medicinal products, Products of human origin, eHealth & Health Technology Assessment) • Directorate E, F & G Food Chain (Safety of the food chain, Food and veterinary affairs) <p>Changes (in 2010)</p> <ul style="list-style-type: none"> • Health technology and pharmaceutical policy (incl. responsibility for EMA) moves from DG Enterprise to DG SANCO • Biotechnology, Pesticides and Health moves from DG Environment to DG SANCO • Consumer Contract and Marketing Law moves from DG SANCO to DG Justice <p>Responsible for</p> <ul style="list-style-type: none"> • Consumers, Health and Food Executive Agency (CHAFEA, est. 2005) • The Community Plant Variety Office (CPVO, est. 1995) • The European Centre for Disease Prevention and Control (ECDC, est. 2005) • The European Food Safety Authority (EFSA, est. 2002) • The European Medicine Agency (EMA, est. 1995)
1999	<p>Prodi Commission:</p> <p>DG XXIV Consumer Protection renamed to DG Health and Consumers (DG SANCO)</p> <p>Changes/Merging responsibilities of</p> <ul style="list-style-type: none"> • DG XXIV on Consumer Protection • Feed and animal policies move from DG Agriculture to DG SANCO • Food policies move from DG Enterprise to DG SANCO • Public Health policies move from DG Employment to DG SANCO [12]
Before	<p>Health responsibilities with the European Commission:</p> <ul style="list-style-type: none"> • DG III Industrial policy responsible for pharmaceutical and foodstuff policies • DG V Employment & Social Affairs responsible for health protection and occupational health and safety • DG VI Agriculture responsible for feed and animal policy • DG XI Environment on consumer protection (later DG XXIV) and environmental health determinants

Sources: European Commission (2009), President Barroso unveils his new team, Press Release 27 Nov 2009 (IP/09/1837) http://europa.eu/rapid/press-release_IP-09-1837_en.htm?locale=fr; DG SANCO Organisational chart 01/09/2013.

4.3.2 DG SANCO: a capacity assessment

In line with the matrix of the UNDP framework, this section provides an analysis of the functional capacities of DG SANCO for policy making regarding its mandate for public health and health systems. By means of a literature and document review augmented by interview data the capacities for policy making regarding DG SANCO's public health and health system dossier have been assessed. An overview of the main findings is provided in Table 4.2.

4.3.2.1 Capacities to engage stakeholders

"Decision makers are obviously facing [...] better worked out set of opinions, because there is DG SANCO and because it has networks and because there's people around it." (Interview 19)

In order to engage stakeholders and create partnerships and networks among various interested parties, DG SANCO uses first and foremost a set of formal structures to engage public and private actors in the policy process. Among these are communications and green papers inviting stakeholders to comment on initial positions, problem framing or questions. Secondly, there are initiatives such as the EU Health Forum, the Inter-service Group on Public Health or the Working Party on Public Health at Senior Level which bring together various actors relevant to health at EU level. Moreover, issue-specific structures to create dialogue with interested parties include inter alia the EU Platform for Action on Diet, Physical Activity and Health or the EU Alcohol and Health Forum. DG SANCO also has a reputation to finance – via the Action Programmes – professional and stakeholder networks to pro-actively engage them in agenda setting and problem definition processes at an early stage [12].

While the organisational capacities in many areas seem to be in place based on the established structures, the extent to which some of them are effective is debated in the literature; the retrieved sources do not touch upon all structures. On the one hand, specific networks have been instrumental to put certain topics prominent on the health agenda in Europe such as cancer [28], health literacy [29], or infectious diseases [30]. On the other hand, the limited scope of the EU Health Policy Forum excluding health responses to EU trade or previously pharmaceutical policy has been regarded as a drawback [31]. Moreover, the capacity to collect opinions could be detrimental to health because of larger industry investments into lobbying [32]. This has also been documented with respect to conducting EU impact assessments with *"less well-resourced [public health] stakeholders [...] either unaware of or unable to fully participate in the consultation processes"* [33, p. 482].

Table 4.2: Main findings of the capacity assessment by data source

Data sources/Main findings			
UNDP framework	Document analysis	Literature review	Interviews
Engage stake-holders	Various fora for engagement of actors have been established	Mixed view on the effectiveness of consultations	Multi-stakeholder approach of DG SANCO is welcomed
			Confirmation of mixed views regarding its effectiveness
Assess a situation	Improvement/ widened scope of data collection activities	Challenges of meaningful comparative data analysis	Data relevant for benchmarking purposes
			A number of blank spots have been identified where comparable data on EU level is still lacking
Define a vision	Strategy document White Paper “Together for Health”	Move from vertical to horizontal approach has been welcomed	White Paper is regarded as important policy output
		Need for a clearer framework for action	Strategic vision is still lacking
Formulate policies	EU policies using hard and soft law regarding the included policy dossiers of DG SANCO	Structural problems of the EU health mandate and scattered health policy responsibilities have been raised	Priority setting is lacking
		Priority setting is lacking	Clearer division of tasks between EU and MS needed
Manage projects	Criticism on the management of EU action programmes for health	Lack of implementation	Importance to devise hard law for effective policy making
		Only effective in raising awareness	
Evaluate	Mechanisms to receive feedback are in place		n. a.
	Adjustment of policies using the received feedback is less clear		

The interview data addressed the collaboration between Member States as a general theme where the EU is held to be an arena for knowledge sharing, for facilitating research consortia and for collaborative work on specific topics such as rare diseases, infectious diseases or cancer. Moreover, DG SANCO is complimented for its multi-stakeholder approach in general (Interview 6, 8, 9, 23, 26). However, engagement of stakeholders from outside the public health sector (Interview 9) has not been without problems. Some interviewees mentioned examples where engagement has improved (WHO, European Innovation Partnership on Active and Healthy Ageing) (Interview 6, 9) while others corroborated the failure of the system by which engagement options are used much more by the industry than by public health advocates (Interview 2, 9, 22).

4.3.2.2 Capacities to assess a situation

“So, policy makers, the fact they now have a peer group of 27 other countries and that the data is now being collected by Eurostat or the OECD or anyone else, that's a powerful mechanism for change.” (Interview 32)

The capacities to gather data and information have gradually increased over time. First, the collection of public health statistics have been formalised by a regulatory framework in 2008 [34] formally requesting Member States to deliver some of the relevant health data on a regular basis. Second, the European Commission is a partner of the European Observatory on Health Systems and Policies which provides in-depth analyses of health systems and their reforms to support evidence informed policy making in Member States and at an EU level [35, 36]. Third, data on specific topics is collected via project funding for example on maternal health, health literacy or via grants to other bodies such as the International Agency for Research on Cancer or the OECD [37, 38]. While continuous grants to other bodies ensure to some extent sustainability in data collection and assessment capacities, project-based data collections only provide a one-time assessment [39]. Fourth, a relatively new form of providing advice to the European Commission is the Expert Panel on effective ways of investing in health [40] and the reflection processes on chronic diseases and resilient healthcare systems in which Member States cooperate to compile evidence and experiences with certain health system tools or interventions [41, 42]. Fifth, more data on specific health areas is collected within the mandate of several health agencies such as the European Centre for Disease Prevention and Control (ECDC), the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) or the European Agency for Safety and Health at Work (EU-OSHA). In doing so, the European Commission is committed to synthesise data in a comparative manner and to strengthen national data collection infrastructures in these areas.

Despite the upgrade of capacities for data collection over the last two decades, the European Commission acknowledged that the “[g]athering [of] information on the comparative effectiveness of health systems is still at an early stage” [43, p. 4]. Meaningful data for policy making is produced for certain areas regarding health systems but does not cover all areas systematically [44]. Certain areas such as rare diseases [45] or health system performance assessment – despite the efforts and investments by inter alia DG SANCO – still lack comprehensive and comparative data sets due to lacking or incomparable data at Member State level [44].

Overall, the interview partners reflect the mixed discussion on assessment capacities. On the one hand, the ability to compile data at a central level and perform benchmarks – albeit on a limited scale – is regarded to be in place and to be a catalyst for change and mutual learning in some areas (Interview 3, 6, 32). On the other hand, interviewees mentioned several areas where data is still missing or not comparable such as morbidity data, behavioural risk factors (Interview 6), performance indicators for obesity and tobacco policy (Interview 30) or healthcare quality indicators (Interview 3).

4.3.2.3 Define an overall strategy for the public health field

“European health policy has never been the object of an overall master plan or strategy. Health policy is located within many different Commission Directorates with differencing priorities and tasks, with health often not being the central one.” [46, p. 143]

The major EU document as an output of the DG SANCO’s capacity to contour an overall strategy for its actions is the 2007 White Paper “Together for Health” which outlined a new overall vision for the health sector for the period 2008-2013 [47]. The White Paper embraced four underlying principles: I) Shared health values, II) Health is the greatest wealth, III) Health in all Policies and IV) EU’s voice in global health. In order to implement the principles and objectives laid out in the Strategy, the Commission established the Second Programme of Community Action in the Field of Health 2008-2013. At the time of writing (December 2014) it remains unclear how the expired EU Health Strategy will be followed up.

The White Paper has been prepared by an extensive consultation process over several years. At the start, a communication on a health strategy has been launched in 2000 [48]. This has been followed by a reflection process on enabling good health for all initiated in 2004 by Commissioner Byrne [49]. Finally a discussion document was launched in 2006 to retrieve comments for the plans of an overall health strategy [50]. The White Paper has devised actions for public health that go beyond the remit of DG SANCO as such (and thereby the scope of this

analysis) by including strategies to address wider determinants of health by seeking collaboration with other sectors and partners inside and outside the European Commission.

According to the literature, the inclusion of the principles of “Health in all Policies” and “Health is wealth” by DG SANCO has been welcomed in the White Paper as an attempt towards more inter-sectoral strategies and collaboration. However, given the limited resources linked to its implementation by means of the Action programmes administered by DG SANCO with the help of the Executive Agency, doubts have been raised on whether the strategy would be designed to accomplish the aligning of health policies at EU level across other policy streams [51]. Moreover, the White Paper has been assessed as very broad in nature and not able to address areas of action where EU level coordination could bring added value. In fact, the Mid-term evaluation of the 2nd Action programme suggested that a “*clearer framework for action*” is needed [52, p. 207f].

The White Paper [47] has been rated as important policy output by a majority of the interview partners [14]. Moreover, a few interview partners share the perception that a common vision is lacking (Interview 12, 25, 29). One interviewee relates this to a current absence of individual visionary leaders within DG SANCO compared to the 1990s and early 2000s (Interview 25).

4.3.2.4 Capacities to formulate policies and strategies

“Europe works best on public health when it gets a specific point and a specific network of people that it can mobilise. That Europe works best when the data is meaningful.”
(Interview 09)

DG SANCO has proven its capacities to develop sectoral policies and strategies on some specific issues of health policy. Next to the few policy areas where DG SANCO has been leading to come to hard law output namely on blood safety, tobacco, cross-border healthcare, or infectious diseases, in many other areas DG SANCO pursues soft law measures due to the limited scope for legislation in the Treaty. An array of “new governance” tools is used such as recommendations, conclusions, communications, action plans, programmes, green and white papers, platforms or coordination tools. The policy areas subject to new governance tools applied by DG SANCO that are discussed in the retrieved literature and interviews include eHealth [53, 54], organ donation [55], alcohol [56, 57], mental health [58, 59], rare diseases [45], cancer [28], patient safety [60, 61] and quality of care [62]. However, EU policies affecting considerably public health and health systems are made by other DG’s as well (see section 4.3.1 and Figure 4.1). Examples include the regulation of cancer causing agents led by DG Environment, licensing of health professionals by DG MARKT or the safety regulations of medical devices by DG Enterprise.

The capacities to formulate cross-sectoral public health and health system policies are less positively rated in the literature and by interview partners. Issues like health promotion, health inequalities, or Health in all Policies are seen as less effective because of the interference with other EU priorities and policy sectors on dossiers such as alcohol or nutrition [63, 64]. The interview data adds that the respective EU infrastructure – the set-up and mandate of DG SANCO – is not designed to support the cross-sectoral nature of these policies (Interview 29). In addition, it is acknowledged that these policies on average need more time to evolve (Interview 01).

“...if one looks what is happening currently at EU level in the area of health. There is nothing which is not dealt with. [...] albeit in many areas European action is unnecessary. In this respect, this is a suggestion to reduce and focus on concrete things.” (Interview 12, author’s translation)

The capacity to formulate policy entails the element of priority setting [65] – the ability to determine which policies and its respective goals should be focused on by DG SANCO. Within its portfolio, firstly, DG SANCO has moved from managing specific vertical programmes to set out wider public health topics of health promotion, health protection, health inequalities and health in all policies in its action programmes [66-68]. Secondly, DG SANCO is adding healthcare systems challenges to its portfolio such as cross-border care, quality of care, patient safety or performance of health systems since the start of the new millennium. However, critics have been raised regarding the mismatch between the abundance of objectives and resources in the 1st Action Programme [69] and the EU Health Strategy [64].

4.3.2.5 Capacities to budget, manage and implement

“The health programme has never seriously got traction and we have been fighting, since it was created, in 2002 people have been saying it’s underfunded. And you know what: we haven’t money to increase it, in fact it’s even less than it was.” (Interview 32)

The main implementing tool of DG SANCO’s health policies is the Action Programme for Health which provides finances and more explicit and practical formulation of established policies. The Action Programme has been administered by the Executive Agency for Health and Consumers (EAHC) (now Consumers Health and Food Executive Agency, CHAFEA) since 2005. Nevertheless, the capacities to budget, manage and implement health policies are perceived as weak so far.

First, DG SANCO's budget is rated to be very small with respect to three issues. The budget is only a small fraction compared to what Member States spend on health [44]. Moreover, the budget operated is small in terms of what other DGs spend on health such as for example DG Research and Innovation (RTD). Additionally, the budget is limited when taking into consideration the large number of topics it is expected to support (see section 4.3.2.4 above on priority setting).

Second, while there has been severe criticism on the management and implementation of the 1st Action Programme [70, 71], the situation may have improved as regards the 2nd Action Programme. The establishment of the Executive Agency provided opportunities for enhanced guidance for beneficiaries and for comprehensive selection and management procedures. However, the mid-term evaluation calls for improved support and guidance during the design and dissemination phase by CHAFAEA but at the same time raises concerns about the feasibility of such enhanced support as the work load of project officers was estimated to be already high [72]. Moreover, difficulties in disseminating projects' results have not only been a concern for the Action Programme's projects but also for health related projects funded under the EU FP5 and FP7, too [73-75]. Meanwhile to support dissemination, CHAFAEA has started to organise Regional conferences and Media Cluster meetings on specific issues such as rare diseases, HIV/AIDS, patient safety and quality of care or transplantation and blood diffusion. Results of multiple projects funded by the Action Programme in the dedicated areas are presented for information and exchange to public health experts, journalists, national public authorities and policy makers [74].

Third, the assessment regarding the capacities for implementation varies. On the one hand, the reliance on project structure for financing actions seems to be counter-effective for implementation which often needs sustained commitment to be successful as has been pointed out for cancer [76] or health monitoring [77]. Since the majority of health policy areas are implemented via soft law measures, DG SANCO is largely reliant on Member State action to translate its policy goals into concrete actions [78]. As a potential solution to implementation difficulties, DG SANCO is increasingly reliant on Joint Action financing. Joint Actions focus on sustained implementation by involving national competent authorities as partners, and ensuring commitment by higher percentages of co-financing by the Member States [72].

Interview data on the theme of implementation stresses the relevance of the ability to enact hard law for effective policy making (Interview 6, 8, 15, 18) despite the limited scope of the health mandate. Several interviewees acknowledged that soft law tools for implementation have impacts but they are less obvious (Interview 2, 32). Others corroborated that the capacity to implement is constrained by a lack of priorities (Interview 12). In this regard, according to an interview partner, the fragmented application of the Health Strategy is exacerbating the lack of

capacities for implementation (Interview 3). Finally, concerns by McHale [58] with regard to EU mental health policy might be valid for other policy initiatives in so far that *“the EU initiatives [...] may have helped to raise awareness but there is the risk that many of these initiatives simply work at a rhetorical level”* [p. 618].

4.3.2.6 Capacities to evaluate

DG SANCO has achieved mechanisms and procedures to receive feedback on the progress of its health policies. Examples include mid- and end-term evaluations of policy actions, status, progress and implementation reports or (Eurobarometer) surveys after defined time periods laid down in policy documents. Often, data collection and the measuring of results are tendered to external providers, commissioned and financed through the Action Programmes. Alternatively, reports may be based on data provided by Member States to DG SANCO and produced by DG SANCO staff itself. In addition, the various platforms, fora, expert or working groups in the specific areas of health policy are a potential source of feedback to the EU [79]. All these sources for feedback could serve as the foundation of evaluation.

The degree to which DG SANCO is capable of codifying the feedback into lessons learned – into the adjustment of policies – remains less clear from the examples in this review. On the one hand, severe criticism on the management of the 1st Action Programme [71] has led to the development of the Executive Agency. Moreover, evaluations of previous Action Programmes have informed the design and management of the new 3rd Action Programme. On the other hand, when it comes to health policies it seems that recommendations are sometimes not taken into account in the development of follow-up policies. In fact, a number of cases, strategies or action plans come to an end without a (immediate) successor (Health Strategy; Mental Health Pact). There are also instances when reports conclude it would be too early for a sound analysis and recommend another moment of review eventually procrastinating actions to be taken up from the evaluation.

4.4 Discussion

Previous work has strongly focused on the development of competences for EU health policy making elucidating the drivers for increased relevance and scope of EU activities in the field of health [12, 24]. In this study, the UNDP Capacity Assessment Framework has been applied to analyse the current state-of-the-art concerning different functional capacities of DG SANCO regarding its mandate for public health and health systems that may be used to better understand its policy making. This capacity assessment of DG SANCO has been based on a

review of literature and EU policy documents, complemented and advanced by an interview study with European health experts.

Overall, the DG SANCO has gradually improved its capacities for public health and health systems policies linked to additional institutional capacities. From an organisational perspective, DG SANCO has: (1) established capacities to engage with stakeholders; (2) developed different capacities to assess various health issues of which some still lack a sustainable basis; (3) not defined a clear strategy providing direction for its actions; (4) demonstrated the capacity to formulate policies and strategies in some areas of its policy making; (5) needs to improve priority setting capabilities, (6) established limited capacity to budget, manage and implement policies and (7) capacities to collect information potentially useful for evaluating its own progress. In light of the policy cycle process, results suggest that DG SANCO's capacities to assess a situation, set the agenda and decide on a concrete policy are to some extent established, whereas, the capacities for implementation and evaluation are perceived as less developed.

In light of these findings, two observations are worth mentioning. First, difficulties in the setting of priorities and defining inter-sectoral actions are also common in national political arenas. Various forms of priority setting activities for example establishing principle frameworks for priority-setting [80] or health targets [81], despite being institutionalised in selected European countries, had meagre influence on the practice of national health policy making. Similarly, inter-sectoral policy making for health at national level had little success because of "administrative silos" [82, p. 336]. DG SANCO has committed to clearer priorities for its action in the design of the new 3rd EU Action programme for Health which is claimed to be more targeted and with clearer indicators towards its priorities [83]. However, results need to be awaited because the political realities may require taking on new responsibilities and the impact of new financing mechanism such as Joint Actions on the level of implementation in Member States are not clear yet.

Second, limited implementation capacities of DG SANCO need to be balanced against the institutional constraints at EU level described above in section 4.3.1. The Treaty mandate in Article 168 gives only delineated legislative powers to the EC. Moreover, DG SANCO is supposed to pursue coordination among Member States by means of soft-laws and incentive measures, while the European Commission in general predominantly pursues regulatory policies [21, 84]. DG REGIO's cohesion policy is an exception here because the Structural Funds' direct health sector investments have co-funded considerably health infrastructures in various central European countries [85]. This implies that DG SANCO's policies in the area of public health and health systems are largely contingent to the discretion of Member States for implementation and application at national level [78] in the multi-level governance structure of the EU [86].

Despite these constraints, our findings propose that improvements in the effectiveness of DG SANCO's (now DG SANTE) policies can be achieved in the existing institutional framework. Prioritising a set of specific policies – within DG SANTE remit – with the greatest EU added value is likely to yield concrete results. The use of limited EU resources has shown to be capable of redirecting existing national infrastructures, funding and policies to be in line with, for example, EU social policy goals [87], cancer [28] or infectious diseases policy [30]. This might ultimately halt the ongoing addition of new topics to the Commission's health policy portfolio which are not reflected in its resource allocation. The EU health policy field has been so far an uncompleted area with "blank spots" where the EU's added value is marginal [24]. And a "patch work" of responsibilities exists at the European Commission with other DGs leading on certain health policies [10]. The reputation of DG SANTE should not be defined by the number of health topics that they are dealing with but whether they can make a difference to existing national activities on selected health issues.

This research provides an initial assessment of DG SANCO's functional capacities rather than an in-depth analysis to devise a comprehensive capacity development response. In order to be able to develop needed capacities, future work would have to collect information from inside DG SANTE to better understand the processes and structure in place to produce certain outcomes. Moreover, a follow-up analysis could cover other institutions with capacities for health policy making at EU level taking into account the spreading of health responsibilities across EU institutions and additional capacities at other international organisations. This would help to understand better how institutions can match each other's resources, responsibilities and expertise in potential future co-operations as called for above.

4.5 Conclusions

Since the inclusion of the health mandate in the Maastricht Treaty, much attention has been devoted to how the mandate can be enlarge, concretise and empowered. Notwithstanding a strong health mandate is crucial for the development of capacities, in the current Euro-sceptic mood this seems not very likely [75]. This study has focused on a number of functional capacities within DG SANCO. Results suggest that some capacities seem to be rather well established while others need to be strengthened. Our results indicate that improvements are possible in the given institutional arrangements; more concentration should be devoted to develop capacities at EU level for more effective policy making for health. This is a point of attention for DG SANTE to continue to work on, not only in light of the European Commission's "Better Regulation" agenda but as well to contribute to a healthier place for European citizens.

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**Implementation and compliance
with EU law and new governance tools
at national level**

Chapter 5

Implementation of National Contact Points for cross-border healthcare

based on

Information for patients and health system cooperation by means of the National Contact Points for cross-border healthcare

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5.1 Introduction

The establishment of National Contact Points for cross-border healthcare (hereafter NCPs) is the most tangible outcome Directive 2011/24/EU (hereafter the Directive) has produced in Member States. The Directive requested Member States to designate an institution to fulfil the tasks assigned to the NCP in the Directive. They are basically twofold: NCPs need to provide patients with information on their rights and entitlements to receive cross-border healthcare (Article 6) and NCPs are deemed to be key for mutual assistance and collaboration among Member States (Article 10) in the areas described in Chapter IV of the Directive¹. By setting up NCP offices and websites the Directive goes beyond requesting the transpositions of EU law into national legislation (“the law in books”) but includes an instance of practical policy formulation (“the law in action”)². The established or designated NCP offices are institutions that citizens can phone, email and sometimes even go to. On NCP websites people can look for information and get answers on their questions regarding cross-border care. Via the NCPs stakeholders and decision makers in Member States of treatment and Member States of affiliation, are supposed to exchange information and cooperate to facilitate cross-border care. In this regard, NCPs are institutions that require staffing, resources, intelligence systems and networks to fulfil their tasks. All this needs to be facilitated and budgeted by domestic policy makers. Because NCPs are very practical creations of the Directive and by its mission for information and collaboration they are a vehicle to put the Directive into practice and at the same time a gauge how well the legal provisions have been transposed into practice.

The two objectives of NCP for information and collaboration can be seen in a broader context of developments in European health systems. Firstly, providing information to patients as to make decisions about various aspects of their healthcare has gained attention since the 1990s. In many European countries comparative information on the features of care providers, the quality of services offered or patient experiences has been published increasingly³. In some European countries these developments towards “consumer” rights have even been codified into a patient right for information, second opinion or quality of care⁴. However, the quality of information and its usefulness for patients to base treatment decisions on is still discussed⁵. This is the context in

¹ Directive 2011/24/EU of 9 March 2011 on the application of patients’ rights in cross-border healthcare [2011] OJ L88/45

² I have borrowed these terms from Esther Versluis, “Even rules, uneven practices: Opening the ‘black box’ of EU law in action” (2007) 30 *West European Politics* 50

³ Karsten Vrangbaek and others, “Choice policies in Northern European health systems” (2012) 7 *Health Economics, Policy and Law* 47; Bernd Rechel and others, “Public reporting on quality, waiting times and patient experience in 11 high-income countries” (2016) 120 *Health Policy* 377

⁴ Pre-Max consortium, *Patients’ Rights in the European Union – Mapping eXercise – Final Report* (European Commission, forthcoming)

⁵ Olga C Damman and others, “An International Comparison of Web-based Reporting About Health Care Quality: Content Analysis” (2010) 12 *Journal of Medical Internet Research* e8

which the Directive requires Member States to provide information to patients on the financial and non-financial aspects of cross-border care⁶. For this, NCPs tap into the available information resources and aligned expert networks in their domestic healthcare systems.

Secondly, EU cooperation among Member States on aspects of (cross-border) healthcare already existed before. The European Court of Justice's (ECJ) Kohl⁷ and Decker⁸ rulings and subsequent cases⁹ made clear that under certain conditions patients can enjoy access to health services in other EU member states and that likewise services providers can deliver their services to patients across borders¹⁰. Initially, between 2002 and 2004 a High level Process of Reflection on Patient Mobility and Healthcare Developments in the European Union has been established. Its recommendations called for a more stable structure to EU level cooperation regarding health systems, the High Level Group in Health Services and Medical Care. The High Level Group has been a forum for discussion between 2004 and 2006 and shortly relaunched activities in 2008¹¹. Although the plenary meetings of the High level group have ended, some of the working groups are still active today such as the Working group on Quality of Care and Patient Safety or on the European Workforce for Health. Likewise, the new Cross-border Healthcare Expert Group has been set up by referring to the High level group¹².

Not only patient mobility has been covered by EU level cooperation but also professional mobility. The right to free movement and establishment of healthcare providers is codified in the Professional Qualification Directive¹³, which has required cooperation inter alia on exchange of information on disciplinary measures for health professionals, recognition of qualifications and experiences or health workforce planning.

⁶ Willy Palm and others, "Towards a renewed community frame-work for safe, high quality and efficient cross-border healthcare within the European Union" in Matthias Wismar and others (eds), *Cross-Border Healthcare: Mapping and Analysing Health Systems Diversity* (World Health Organization on behalf of the European Observatory on Health Systems and Policies 2011)

⁷ Case C- 158/96 Kohl v Union des Caisses de Maladie [1998] ECR I-1931

⁸ Case C- 120/95b Decker v Caisse maladie des employes prives [1998] ECR I-1831

⁹ Including Joined Cases C-157/99. *Geraets-Smits v Stichting Ziekenfonds VGZ and Peerbooms v Stichting CZ Groep Zorgverzekeringen* [2001] ECR I-5473, Case C-372/05 *Watts* [2006] ECR I-4325, Joined Cases C-385/99 *Mueller-Faure v Onderlinge Waarborgmaatschappij OZ Zorgverzekeringen UA* and *van Riet v Onderlinge Waarborgmaatschappij ZAO Zorgverzekeringen* [2003] ECR I-4509; Case C-368/98 *Vanbraekel v Alliance nationale des Mutalites Chretiennes (ANMC)* [2001] ECR I-5363; Case C-56/01 *Inizan v Caisse primaire d'assurance maladie des Hauts-de-Seine* [2006] ECR I-12403; Case C-173/09 *Elchinov v Natsionalna zdravnoosiguritelna kasa* [2011] ECR I-8889; Case C-268/13 *Petru v Casa Județeană de Asigurări de Sănătate Sibiu* [2015] PTSR 139

¹⁰ Tamara K Hervey and Jane V McHale, *Health Law and the European Union* (Cambridge University Press 2004)

¹¹ Mossialos E and others (eds), *Health Systems Governance in Europe - The Role of European Union Law and Policy* (Cambridge University Press 2010)

¹² European Commission, *Rules of procedure of the cross-border healthcare expert group. Ref.Ares(2017)414436-26/01/2017* (European Commission 2017)

¹³ Directive 2005/36/EC of 7 September 2005 on the recognition of professional qualifications [2005] OJ L255/22

Next to the cooperation at EU level, multiple cooperation initiatives for steered cross-border care have occurred throughout the European Union. This involves in many cases arrangements in border regions where healthcare infrastructures across the border are made available to patients in another Member State, healthcare professionals practice at both sides of the border or joint infrastructures are set up¹⁴. In other cases, cross-border arrangements occur along historically routed ties with other, not geographically close Member States¹⁵. Cross-border care occurs where patients' needs are not met, since they are not available in a country or region, and covers collaboration on emergency care, general hospital care but as well highly specialised treatments such as reproductive medicine, cancer treatment or complex surgical interventions¹⁶.

It became clear in the preparation of the Directive in order to facilitate cross-border care for patients, not only reimbursement questions needed to be addressed but also the availability of information about other non-financial issues surrounding the enjoyment of care in another Member State needed to be improved. On these grounds, cooperation became integral to the design of the Directive to addressing “flanking measures” to create trust for patients and also among professionals engaging in cross-border care in the other Member States' healthcare systems. These additional conditions cover various aspects of relevant information, transparency about quality and safety standards, facilitation of continuity of care, and knowledge about mechanisms for redress and compensation in the case of harm¹⁷.

In the following, an analysis will be provided of what kind of information NCP websites provide and how cooperation of NCPs started. To study the information available to patients a content analysis of NCP websites was conducted in early 2014 and combined with an analysis of data derived from evaluative studies commissioned by the European Commission for which data was collected in 2014, 2015 and 2016¹⁸. Furthermore, the analysis on how NCPs collaborate is based on data of the same evaluative studies combined with the documents of the NCP coordinators meetings that have taken place so far. The analysis in this chapter will evolve in four steps. Firstly, the legislative requirements set out by the Directive for NCPs regarding information provisions and collaboration are described. Secondly, an overview about how NCPs are

¹⁴ Magdalena Rosenmöller, Martin McKee and Rita Baeten (eds), *Patient Mobility in the European Union: learning from experience* (World Health Organization on behalf of the Europe 4 Patients project and the European Observatory on Health Systems and Policies 2006); Irene Glinos and Matthias Wismar (eds), *Hospitals and borders. Seven case studies on cross-border collaboration and health system interactions* (World Health Organization acting as the host organization for, and secretariat of, the European Observatory on Health Systems and Policies 2013)

¹⁵ Natasha Azzopardi-Muscat and others, *Health care systems in transition – Malta* (WHO Regional office for Europe 2015)

¹⁶ Rosenmöller (n 14)

¹⁷ Palm (n 6)

¹⁸ Giulio Zucca and others, *Evaluative study on the cross-border healthcare Directive (2011/24/EU) -Final Report* (European Union 2015); European Commission, *Member State Data on cross-border healthcare following Directive 2011/24/EU – Year 2015* (European Commission 2015); Grega Strban G (ed.) and others, *Access to healthcare in cross-border situations - Analytical Report 2016* (European Union 2017)

configured in the national health systems is provided. Thirdly, an assessment of the information they provide is given. And fourthly, the ways NCPs collaborate and the current and future issues for collaboration are analysed. The chapter will end by way of a concluding section.

5.2 Responsibilities of Member States

The provisions in Directive 2011/24/EU on NCPs set out responsibilities for Member States in three domains: (1) on the setup and establishment of NCPs, (2) on information to be provided, specified for Member States of treatment and Member States of affiliation, and (3) for cooperation with relevant stakeholders and among NCPs themselves. Article 6 is the main reference in the Directive regarding the establishment of NCPs, its design and functions.

5.2.1 *The structure and setup of the National Contact Points*

First of all, Member States are supposed to “*designate one or more NCPs*” in their country according to Article 6(1) of the Directive, leaving open to whether set up a new one or mandate an existing “*information centre*” to take up the role of the NCP (Recital 49). Moreover, no specification of what kind of institution or legal format the NCPs should have is provided. Recital 49 reiterates that “*form and number*” of NCPs is up to Member States and they are free to establish other linked contact points at regional or local level. Moreover, NCPs should be established in “*an efficient and transparent way*” but “*should have the appropriate facilities*” for providing information.

The approach by the EU to obligate Member States to designate a NCP acknowledges the situation that very different national institutions across and within Member States are providing information to patients on features of treatment and patients’ rights in general and on cross-border care specifically. The designation of NCPs differs from the approach the EU has used under the coordination of social security scheme¹⁹ where the involved authorities, institutions and persons were called to directly communicate, mutually inform and cooperate with each other.

5.2.2 *Responsibilities for information provision*

The Directive predominantly addresses *what kind of information* should be provided discerning the responsibilities of a Member State of treatment and of a Member State of affiliation. In this

¹⁹ Regulation (EC) No 883/2004 of 29 April 2004 on the coordination of social security systems [2004] OJ L166/1, Article 76; Regulation (EC) No 987/2009 laying down the procedure for implementing Regulation (EC) No 883/2004 of 16 September 2009 on the coordination of social security systems [2009] OJ L284/1, Article 22(1)

regard, Recital 48 indicates that a compulsory set of information “*should be specified*” and that NCPs “*may provide more voluntarily*”.

Providing information via NCPs includes for *Member State of treatment* the following aspects:

- on standards and guidelines on quality and safety laid down by Member State of treatment
- on the supervision and assessment of healthcare providers
- on which healthcare providers are subject to these standards and guidelines
- on accessibility of hospitals for persons with disability (Article 4(2)a).

Member State of affiliation’s responsibilities cover, according to Article 5(b), provision of information:

- on their rights and entitlements in that Member State relating to cross-border healthcare
- on the terms and conditions for reimbursement of costs
- on procedures for accessing and determining those entitlements
- and for appeal and redress in case patients consider that their rights have not been respected
- on the rights patients have by virtue of this Directive and rights from Regulation (EC) No 883/2004.

Furthermore, the Implementing Directive 2012/52/EU requires NCPs in Article 4 to “*inform patients about the elements to be included [...] in prescriptions issued in a Member State other than the Member State where it is dispensed*”²⁰.

Hence, the Directive does not require Member States to ensure harmonised patients’ rights across the EU – something that has been described by Member States as a red line not to be crossed during the political discussion in establishing the Directive – but only to provide information on existing relevant rights, standards and guidelines in countries²¹.

Secondly, *the way how information* should be provided is addressed to a lesser extent by the Directive. NCPs are obligated to provide information:

- easily accessible [...] by electronic means and in formats to people with disabilities,... [Article 6(5)]

²⁰ Commission Implementing Directive 2012/52/EU of 20 December 2012 laying down measures to facilitate the recognition of medical prescriptions issued in another Member State [2012] OJ L356/68

²¹ Willy Palm and Rita Baeten, “The quality and safety paradox in the patients’ rights Directive” (2011) 21 The European Journal of Public Health 272

- in any of the official languages [...]. Information may be provided in any other language (Recital 48).

The Directive invites Member States to rely on existing information sources (Recital 49) and is prescribing which information regarding patients' rights to be provided to patients, but it does not – and most likely cannot so far – determine how information should be edited to be “*easily accessible*” for patients²².

5.2.3 Responsibilities for cooperation

As Article 6 sets out, the main obligations of NCPs' cooperation tasks are specified to involve

- to consult with patient organisations, healthcare providers and healthcare insurers
- to cooperate closely with each other and with the Commission
- to provide patients on request with contact details of NCPs in other Member States.

Additionally, Article 10 on *Mutual assistance and cooperation* further highlights the NCP's role in exchanging of information among each other including on the supervision of providers and content of invoices.

Member States in general are obliged in Recitals 49 “*to work together [with the Commission] to facilitate cooperation among NCP*”. They are encouraged to “*facilitate cooperation between healthcare providers, purchasers and regulators of different Member States to ensure safe, high quality and efficient cross border care*” (Recital 50). Furthermore, Recital 51 reiterates that the “*Commission should facilitate cooperation in the areas set out in Chapter IV by identifying obstacles, recommendations and disseminating information and best practices*”. As such, Article 10 sets out a number of areas where Member States should cooperate, including

- cooperation on standards and guidelines on quality and safety and the exchange of information (Article 10(1))
- to facilitate cooperation in cross-border healthcare provision at regional and local level as well through ICT and other forms (Article 10(2))
- to cooperate in cross-border healthcare in border regions (Article 10(3))
- [to] ensure that information on the right to practice of health professionals [...] is made available to the authorities of other Member States [...] via the Internal Market Information System (IMI) (Article 10(4)).

²² Ibid, Palm and Baeten

Beyond these areas for cooperation described above, to achieve the immediate aims of the Directive, cooperation is foreseen on a number of “*flanking measures*” for cross-border care²³ including recognition of prescriptions (Article 11), European Reference Networks (Article 12), Rare Diseases (Article 13), eHealth (Article 14) and health technology assessment (Article 15) in Chapter IV of the Directive. The totality of provisions on cooperation has been described as to establish a “massive European cooperation structure”²⁴. Outside the cooperation in the framework of the Directive 2011/24/EU and the Regulation 883/2004, a number of cooperation agreements for cross-border healthcare exists on a bilateral basis involving neighbouring countries such as Belgium, the Netherlands, Germany, Luxembourg and France, but also non bordering countries such as the Malta–UK agreement²⁵.

5.3 Structures of National Contact Points

On the basis of the provisions set out by the Directive, largely Member States have chosen for a unified approach how to set up their NCP within their healthcare systems. Some differences in the establishment can be attributed to the flexibility given to Member States in the Directive and the attempt for an efficient way of setting up the NCP given the domestic healthcare system structures. A vast majority of Member States have chosen to simply mandate existing general patient information centres for the general public or institutes with cross-border care expertise, to take on the role of the NCP; only very few Member States have chosen for a more innovative way across existing institutions to set up the NCP. Largely, the NCP is linked to a governmental or public body such as the Ministry of Health or a linked agency (see Table 5.1).

The great majority of Member States chose to establish a single NCP. The UK and Denmark designated NCP tasks to multiple regional entities reflecting the decentralised character of their health systems. Hungary, Lithuania and Sweden kept the structures for information provision for own citizens wishing to seek care abroad and EU citizens interested to be treatment in their healthcare systems apart. An overview of the NCP’s affiliations and setup is shown in Table 5.1.

²³ Wolf Wolf Sauter, *Harmonisation in healthcare: the EU patients' rights Directive*. TILEC Discussion Paper No 2011-030. (Seminar on social Protection and Social Inclusion in the EU: interactions between law and policy, 2011) Sauter, *Harmonisation in healthcare: the EU patients' rights Directive*. TILEC Discussion Paper No 2011-030. (Seminar on social Protection and Social Inclusion in the EU: interactions between law and policy 2011)

²⁴ Miek Peeters, “Free Movement of Patients: Directive 2011/24 on the Application of Patients' Rights in Cross-Border Healthcare” (2012) 19 European Journal of Health Law 2

²⁵ Pacolet J and De Wispelaere F, Planned cross-border healthcare – PD S2 Questionnaire, Report prepared in the framework of Network Statistics FMSSFE, 2014, p 16; Strban (n 18)

Table 5.1 National Contact Points' structures

Country	URL NCP Webpage	Host institution	No offices /www
Austria	www.gesundheit.gv.at	private/MoH	1/1
Belgium	www.crossborderhealthcare.be	MoH	1/1
Bulgaria	www.nhif.bg	NHIF	1/1
Croatia	www.hzzo.hr	NHIF	1/1
Cyprus	www.moh.gov.cy/cbh	MoH	1/1
Czech Republic	www.cmu.cz	9 insurers	1/1
Denmark	www.patientombudet.dk/	Gov. Agency	4/1
Estonia	www.kontaktpunkt.sm.ee	MoSocAff	1/1
Finland	www.kela.fi/yhteyspiste	SHI institute	1/1
France	www.sante.gouv.fr/point-de-contact-national-pour-la-france.html	MoH	1/1
Germany	www.eu-patienten.de	HI associations	1/1
Greece	www.eopyv.gov.gr	NHS	1/1
Hungary	www.eubetegjog.hu www.patientrights.hu	Gov. Agency	1/2
Ireland	www.hse.ie/eng/services/list/1/schemes/cbd/CBD.html	NHS	1/1
Italy	www.salute.gov.it/	MoH	1/1
Latvia	www.vmnvd.gov.lv/ www.lncp.lt/ www.vaspvt.gov.lt/en www.vlk.lt/vlk/en/	MoH & Gov. Agency	1/1
Lithuania	www.vlk.lt/vlk/en/	NHIF & Gov. Agency	2/1
Luxembourg	www.cns.lu	MoH	1/1
Malta	www.gov.mt/en/Pages/gov.mt%20homepage.aspx	MoH	1/1
Netherlands	www.cbhc.nl	Gov. Agency	1/1
Poland	www.nfz.gov.pl/new/index.php	NHIF	1/1
Portugal	http://diretiva.min-saude.pt/home-2/	NHS PT	1/1
Romania	www.cnas-pnc.ro	NHIF	1/1

Table 5.1 National Contact Points' structures (continued)

Country	URL NCP Webpage	Host institution	No offices /www
Slovakia	www.udzs-sk.sk	MoH & HI	1/1
Slovenia	www.nkt-z.si/wps/portal/nktz/home	NHI institute	1/1
Spain	www.msssi.gob.es/	MoH	1/1
Sweden	www.socialstyrelsen.se www.forsakringskassan.se	Gov. Agency	2/2
UK ¹	www.nhs.uk/nationalcontactpoint	NHS UK	5/1

¹ Information presented retrieved from NCP England. Characteristics and information can differ on the other regional webpages.

Legend

MoH	Ministry of Health
NHIF	National Health Insurance Fund
MoSocAff	Ministry of Social Affairs
(S)HI	(Social) Health Insurance
NHS	National Health Service
Gov. Agency	Governmental Agency

5.4 Information provision

For the purposes of the analysis the information requirements defined in Article 4(2a) for Member States of affiliation and Article 5(b) regarding Member States of treatment have been grouped into five domains: information on (1) quality and patients safety standards; (2) provider rights; (3) patients' rights; (4) dispute procedures and (5) entitlements for cross-border care. The analysis of web content has checked for the extent to which Member States complied with these information obligations. Domains were deemed satisfactory if respective information was presented either on the website of the NCP itself or by a referral to another page using a link.

Many NCP websites provided only short overviews containing incomplete information but frequently links were used to refer to existing additional web content. Some NCP websites would only give a web-link as the single source of information outside the NCP website. Linked web content often was deemed very technical and less accessible from the perspective of patients. These linked websites were often only available in the official language of the respective country as these were institutions, laws or pre-existing web content dealing with respective information. Moreover, web content of a certain information domain differed between national NCP websites and often provided only parts of the rights or regulation regime. In this regard, it reflects the strive of many Member States to organise the NCP in an efficient

way – relying on what is already existing elsewhere rather than aiming at a well-established informative “single stop shop” for patients seeking cross-border care²⁶. The object of an efficient organisation of NCPs should be seen as well in the light of the number of information requests NCPs receive. Estimations²⁷ of information requests from 2015 indicate that the majority of NCPs receives only a couple of hundreds requests per year²⁸. Likewise, data from 2014 indicated that the most of the NCPs (7/9) on average received less than 100 requests per month²⁹.

5.4.1 What kind of information is provided?

Information on quality and patient safety provision was available on three-quarter (18/24) of the NCP websites where frequently links to web content of institutions, laws and other sources dealing with quality and patient safety was given. Information on provider rights was present on approximately half (13/24) of the NCP websites referring predominantly to the web content of professional or medical associations. When it came to the domain of patients’ rights, many NCP websites (20/24) varied in what kind of patients’ rights issues they addressed. These issues covered access to medical records, patients’ right to information, informed consent or data protection regulations but a comprehensive overview was often lacking. Also, web content on dispute settlement procedures (18/24) appeared to be incomplete referring often only to a selection of complaint procedures such as an ombudsman, civil and criminal law procedures, the medical code of practice, or via medical associations. On many NCP websites (23/24) we found good, understandable information on the entitlements involving the rights and procedures for cross-border healthcare including an explanation of the differences between the Directive 2011/24/EU and Regulation 883/2004³⁰. A few NCP websites contrasted the advantages and disadvantages of using the different regulations or provided the required forms to apply for authorisation directly on the websites.

²⁶ Andre den Exter, Alceste Santuari and Tomislav Sokol, “One Year after the EU Patient Mobility Directive: A Three-Country Analysis” (2015) 40 European Law Review 279

²⁷ Quality of data is contested given different national registration systems for requests and overlaps with information requests for other tasks of institutions hosting the NCP

²⁸ European Commission, Member State Data (n 18)

²⁹ European Commission, Evaluative study (n 18)

³⁰ Regulation (EC) No 883/2004 (n 19)

Table 5.2 Information available at National Contact Points' webpages (spring 2014)

Country	Quality and Safety standards	Provider rights	Patients' rights	Dispute procedures	Cross-border care
Austria	X	X	X	X	X
Belgium	X	o	X	X	X
Bulgaria	o	o	X	X	X
Croatia	X	o	X	X	X
Cyprus	X	o	X	X	X
Czech Republic	o	X	X	X	X
Denmark	X	X	X	X	X
Estonia	X	o	X	X	X
Finland	X	X	X	o	X
France	X	X	X	X	X
Germany	X	X	X	X	X
Greece ¹	-	-	-	-	-
Hungary	X	X	X	X	X
Ireland	X	o	o	o	X
Italy ¹	-	-	-	-	-
Latvia	X	X	X	o	X
Lithuania	X	X	X	X	X
Luxembourg	o	o	o	o	X
Malta	X	o	X	X	X
Netherlands ²	o	o	o	o	o
Poland	o	o	X	X	X
Portugal ¹	-	-	-	-	-
Romania ¹	-	-	-	-	-
Slovakia	X	X	X	X	X
Slovenia	X	X	X	X	X
Spain	X	X	X	X	X
Sweden	X	X	X	X	X
UK (England) ³	o	o	o	o	X
SUM	18/24	13/24	20/24	18/24	23/24

¹ website at initial data collection not operational in spring 2014

² website was operational, but content under construction

³ Information presented has been retrieved from NCP England

An initial analysis of users of NCP websites indicates that patients considering the cross-border route are mostly interested to find answers to administrative questions rather than on the question which provider to choose³¹. Regarding administration of cross-border care, patients were looking for information on coverage, reimbursement and administrative procedures such as prior authorisation³². A similar priority of information needs has been detected among German patients treated in other European countries³³. Patients seeking information for determining the choice for a certain cross-border provider including quality and safety information rather rely on the advice of their domestic healthcare provider (e.g. GP or medical specialist) or the experiences of other patients, friends or family than on web-based information as provided by NCPs³⁴. However, information on quality and patient safety aspects of care is only emerging in European countries³⁵ and the effectiveness of different formats to inform patients' choices is largely not understood yet³⁶.

5.4.2 How is information presented

Based on the provisions set out in Article 6(5) of the Directive web formats supporting people with disabilities were identified and grouped if available. Moreover, language versions and general communication channels with the NCP were covered as well. Only half of the NCPs' websites did provide any format to support the access of web-content for people with disabilities at the start of 2014. Formats included the change of letter size, a high contrast view, voice reader and easy content view.

The Italian, Irish and English NCP websites remained with the minimum requirement of one official language version (Recital 49). Although, the English NCP website offers a built-in Google translate function. Many NCP websites provided information in between one and three different language versions. English was the preferred second choice of a non-domestic language. Although the website analysis did not systematically compare web content between different language versions, a number of raters reported that non-domestic language versions, such as in many countries English, do not provide the same level of information. This difference in the level of information has been corroborated by the Analytic Report 2016³⁷. Next to retrieving information from NCP websites, NCP offices in all Member States could be approached for

³¹ European Commission, Evaluative study (n 18)

³² Ibid

³³ Demitra Panteli and others, "Know before you go": information-seeking behaviour of German patients receiving health services abroad in light of the provisions of Directive 2011/24/EU" (2015) 3 Journal of Health Services Research & Policy 154

³⁴ Ibid; European Commission, Evaluative study (n 18)

³⁵ Vrangbaek (n 3)

³⁶ Vrangbaek (n 3); Damman (n 5); Mads S Nybo and Jane Skov, "Patient knowledge of anticoagulant treatment does not correlate with treatment quality" (2016) 141 Public Health 17

³⁷ Strban (n 18)

individual questions or request for information by either via email or a contact form. In some countries, NCP offices offered to send written requests via the post. NCP offices in Austria, France, the Netherlands and Italy did not provide a telephone line, but relied on written routes of contacts only. Moreover, a number of NCPs have arranged office hours to allow citizens to personally present a request.

Based on the website analysis and additional consulted analytic studies, the picture emerges that the establishment of NCPs as a source of information to patients is very welcomed but that information provided by NCPs is often too general, sometimes incomplete and not well accessible due to technical language, being scattered or language barriers in order to make an informed decision about whether or not using the cross-border route. It has been called for a harmonisation of web contents provided by the NCPs, although this goes certainly beyond the current provisions in the Directive. However, (1) continued exchange and cooperation along the lines described in the next section, (2) the development of a toolbox and training material³⁸ and (3) the idea of an umbrella EU contact point for cross-border healthcare complementing NCPs³⁹ may all serve towards such a harmonising effect.

5.5 Cooperation

5.5.1 Cooperation with relevant stakeholders

Cooperation between the NCP and relevant stakeholders such as health insurers, healthcare providers and patient organisations was encouraged by the Directive to ensure cross-border care (Recital 50). In the majority of Member States health insurer, the national health insurance fund, the Ministry of Health or a related agency are involved as the (joint) host institution operating the NCPs which provide immediate and strong links for cooperation among those stakeholders and the NCP (see Table 5.1). Patient organisations seem to be rather a new stakeholder in many countries with whom cooperation is encouraged by the Directive; only half of NCPs sought cooperation with them initially. This pattern of cooperation along pre-existing links is confirmed by the European Commission's evaluation with a subset of eight NCPs at a later point in 2014. However, while it was held that cooperation with relevant stakeholders improved, cooperation was often sought on an ad-hoc basis to fix individual patient requests rather than to establish general procedures⁴⁰.

³⁸ European Commission, *Cross-Border Healthcare Expert Group, Meeting of National Contact Points for Cross-Border Healthcare, Agenda* 5 May 2017 (European Commission 2017)

³⁹ Strban (n 18)

⁴⁰ Zucca (n 18)

Given the ties with patient organisations were not well established, NCPs organised seminars, consultations or questionnaires, to receive their feedback or input. In this regard cooperation with patient organisations served different goals. Some NCP sought cooperation with patient organisations during the actual transposition process into national law and the establishment of the NCP. Some NCPs cooperated with them for information provision and other NCPs for evaluating the website content because they represent patients' views.

5.5.2 Cooperation among National Contact Points

In 2014, only a few NCPs had established formal contacts with NCPs in other countries themselves initially; most often, when arrangements for cross-border cooperation existed, already previously. Many other NCPs reported some informal contacts or pointed to the first NCP coordinators meeting organised by the European Commission in February 2014 to use for cooperation and networking. Data from the European Commission's evaluative study suggested that cooperation among NCPs has intensified throughout 2014 since from the subsample all eight NCPs indicated to have frequent contacts (>8 per year) with other NCPs⁴¹.

In order to support cooperation among NCPs the Commission itself organised a number of meetings for NCP coordinators from 2014 onwards. Overall, the meetings were used to exchange information (1) on the status of implementation of the Directive, (2) on linked data collection exercise using NCPs, (3) on project results in relevant areas such as patients' rights or payment of cross-border care and (4) discuss ways and areas for cooperation of NCPs. Regarding the latter, the first meeting in February 2014 focused on an exchange of experiences regarding the design and content of NCP websites and exchange of invoices between providers and payers in different Member States⁴². The Internal Market Information System (IMI) was presented as a possible tool to collaborate and clarify the status of healthcare providers across border⁴³. In addition, future areas of cooperation were discussed. While the European Commission stressed the obligation to cooperate on safety and quality standards and guidelines, the meeting concluded by intending to work further together on invoices and how to communicate best towards citizens.

A subsequent coordination meeting of NCP representatives in December 2015⁴⁴ followed up on the intention to collaborate regarding information provision towards patients. Participants wished to work together to establish a common Frequently Asked Questions for NCP websites

⁴¹ Zucca (n 18)

⁴² European Commission, *Coordination Meeting of National Contact Points (NCPs) - Agenda* (European Commission 2014)

⁴³ European Commission, *Summary record of the 1st meeting of the National Contact Points Coordinators* (European Commission 2014)

⁴⁴ European Commission, *Coordination Meeting of Representatives of National Contact Points 2 December 2015 Agenda* (European Commission 2015)

while additional areas for cooperation on informational texts and documents were suggested. An extended use of the IMI system was proposed to cover exchanges regarding questions on patients' rights in different Member States as well⁴⁵. The next meeting of the Cross-border Healthcare expert group⁴⁶ in March 2016 proposed, as a new measure, a feedback exercise on the NCP system towards provision of patient information which was welcomed by participants. During a conference on the Directive in October 2016, where 18 representatives of NCPs participated, it was emphasised (1) that the number of applications to NCP offices are comparatively few, (2) that NCPs are still occupied to update and improve information material and communication and (3) that the Commission was encouraged to facilitate the exchange between NCPs even further⁴⁷. During the Cross-Border Healthcare Expert Group Meeting on the same day the results of the data collection exercise for 2015 were discussed in the context of the status of implementation of the Directive⁴⁸. The meeting in May 2017 addressed the findings and work plans of a number of Commission financed studies regarding cross-border cooperation that are connected to the work of the NCPs. These studies focus on "enhancing information provision to patients" in cross-border care inter alia by developing training material and a toolbox aimed at NCP staff; an analysis of "access to healthcare in cross-border situations" addressing flows, form, means and content of information⁴⁹ as well as mapping "existing initiatives for cooperation in cross-border regions". Moreover, the possibility to inform about treatment for rare diseases via NCP websites was discussed in the context of the launched European Reference Networks (ERNs)⁵⁰.

Beyond those immediate areas for cooperation, addressed in the meetings, new areas for cooperation among NCP are likely to emerge. The Directive has endorsed cooperation on the recognition of prescriptions (Article 11), European Reference Networks (ERNs, Article 12), Rare Diseases (Article 13), eHealth (Article 14) and health technology assessment (EUnetHTA, Article 15) in Chapter IV. In these areas NCPs offices and website will likely play a role in communicating to citizens and cooperating with professionals. For example, low recognition (56% overall) of foreign medical prescriptions in five Member States indicates that pharmacies are an important stakeholder in ensuring cross-border treatments⁵¹, NCPs should reach out to. In addition,

⁴⁵ European Commission, *Minutes of Meeting - Coordination Meeting of Representatives of National Contact Points 2 December 2015* (European Commission 2015)

⁴⁶ The meeting of representatives of NCPs is a sub-group to the Cross-border Healthcare expert group.

⁴⁷ European Commission, *Report of the Conference "Towards amplified awareness of EU rights to cross-border care"*, 24 October 2016 Brussels (European Commission 2016)

⁴⁸ European Commission, *Cross-Border Healthcare Expert Group Meeting, Draft Agenda (Version 2)* 24 October 2016 (European Commission 2016)

⁴⁹ Strban (n 18)

⁵⁰ European Commission (n 38)

⁵¹ Lorena San Miguel and others, "Obstacles to the recognition of medical prescriptions issued in one EU country and presented in another" (2013) 23 *European Journal of Public Health* 972

discharge summaries seem to be another important vehicle to ensure continuity of care⁵². NCPs can play a role in providing insights into practical obstacles and useful information that prescriptions and discharge summaries should contain. Likewise, in the course of establishing European Reference Networks on highly specialised treatments, NCPs will need to have an understanding how ERNs and national models and systems of highly specialised care are organised to be able to reach out to national centres for excellence and provide respective information on their websites and on individual request. This will include aligning information provision between NCPs and the Orphanet website⁵³ in the area of rare diseases. Thus, cooperation among NCPs is likely to intensify to contribute to the smooth operation of cross-border care – not without challenges – and the collaboration of domestic health systems in the EU.

5.6 Conclusions

At first sight, NCPs are designed to be the information portal for own citizens and patients from other Member States seeking care abroad – benefiting comparably few people. However, NCPs could potentially benefit domestic patients in general as well by pooling and presenting information in an understandable way about patients' rights in the home country's health system. This information is currently scattered and most often not presented in a patient friendly way. Moving beyond the function of an information portal to patients, NCPs could act as the communication hub for professionals and decision makers to provide detailed insights into national practices across the border. Better communication and cooperation could benefit the smooth operation of cross-border care and domestic health systems in the EU in general. However, the current rather minimalistic implementation of the NCPs in many countries is not facilitating purposes beyond cross-border care.

Finally, law and new governance modes are linked in the implementation of the Directive to help enlarging the health system agenda of the EU, as well⁵⁴. The contour of this agenda is not legally prescribed, but the Directive instigates an array of objectives and principles in which these rules are to be developed between national and EU officials, experts and other stakeholders⁵⁵. The Commission – invited by means of technical support and expertise – will keep alive, and

⁵² Ketivan Glonti and others, "European health professionals' experience of cross-border care through the lens of three common conditions" (2015) 7 *European Journal of Integrative Medicine* 29

⁵³ ORPHANET – The portal for rare diseases and orphan drugs www.orpha.net

⁵⁴ Tamara K Hervey and Bart Vanhercke, "Health care and the EU: the law and policy patchwork" in Mossialos and others (eds), *Health Systems Governance in Europe - The Role of European Union Law and Policy* (Cambridge University Press 2010)

⁵⁵ Charles F Sabel and Jonathan Zeitlin, "Learning from Difference: The New Architecture of Experimentalist Governance in the EU" (2008) 14 *European Law Journal* 271

potentially advance, cooperation as the examples of Commission actions in this analysis indicate. It may lead to a further “formalisation of [...] cooperation”⁵⁶ at EU level in areas relevant to cross-border care and health systems in general.

⁵⁶ Sauter (n 23)

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Chapter 6

Influence of EU law and new governance tools on domestic hospitals and hospital policy in Belgium, the Netherlands and Germany

based on

Influence of EU law and new governance tools on domestic hospitals and hospital policy in Belgium, the Netherlands and Germany

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Abstract

Assessing the impact of EU law and new governance tools upon hospitals in Belgium, the Netherlands and Germany, this study reveals that EU hard law is regarded to increase requirements for running national hospitals albeit in non-salient areas. Moreover, domestic hospital reforms can be influenced by EU's new governance tools. National decision makers perceive their decision latitude being reduced and see increasingly a need to monitor relevant EU activities.

6.1 Introduction

The design of domestic healthcare policy and national laws regulating hospitals are subject to the European Union's (EU) law principles and EU-level discussions on health systems [1,2]. The EU's influence is likely to increase towards a joint responsibility of the EU and its Member States (MS) to control certain aspects of health systems [3]. This holds, despite a clear Treaty provision in Article 168(7), that the organisation and financing of healthcare system is the sole responsibility of Member States [4]. However, the practical consequences of greater EU involvement for healthcare reforms and provision of healthcare at the national and regional levels remain unclear [5]. Few studies thus far have focused upon the actual effects of EU influences on the domestic healthcare policy and provision of services taking place. Existing contributions deal exclusively with binding European legislation such as the Patients' Rights Directive (Dir. 2011/24/EU, PRD) [6], European Working Time Directive (Dir. 2003/88/EC, EWTD) [7], Professional Qualification Directive (Dir. 2005/36/EC, EPQD) [8] or competition law [9].

In addition, new modes of EU governance have emerged in the health sector since the late 1990s implying an "increasingly assertive EU healthcare agenda" [10]. New modes of governance are characterised by a *non-coercive*, *collaborative* and *decentralised* style of policy making. In addition, policy issues are discussed in *coordinated* (i.e. acknowledging diverse views as source for learning) and *integrative* (i.e. including other policy sectors or arenas) ways [11]. Thereby, the "EU now has several instruments at its disposal to prompt, recommend or set incentives for national healthcare reforms" [10]. The domestic impact of these new governance forms is subject to diverging opinions [12, 13] and the ways, conditions and reasons why and how they matter are understudied [14].

Hospitals were chosen as point of focus because, first, they are an important player in European health systems in terms of the financial resources. Second, they remain the central node in the pathways of patient care despite calls for "moving away from hospitals-centred systems" [15]. Third, because of the diverse functions and roles hospitals fulfil, there are multiple contact points between EU policies and hospital activity. Interview data was collected from key informants from the Netherlands, Belgium and Germany – countries with longstanding EU membership and their hospitals frequently subject to cross-border care – to gather the perceptions of "experts" being aware of the national context in which EU hard law and new governance tools impact upon hospital policy. Our research question was: What is the impact of EU hard law and new governance tools on domestic hospitals and hospital policy?

6.2 Methods

18 interviews were conducted with 22 interview partners. Initially five experts with different functions were purposely selected to ensure heterogeneity. In addition, snowball sampling was applied until data saturation was reached. Out of 24 persons contacted, 18 participated in the study, four declined participation due to time constraints and two did not respond to the invitation. In four cases the approached expert invited a colleague to join the interview. The composition of the study sample can be found in Table 6.1.

Table 6.1 Characteristics of interviewees

Function/ country	NL	DE	BE	N
Civil servants	1	1	2	4
Academics	3	0	0	3
Policy advisers	0	2	3	5
Hospital managers	2	2	6	10
N	6	5	11	22

Legend
Countries where interview partners are based
Civil servants in national Ministries of Health or regional health authorities
Policy advisers working at interest groups, umbrella organisations, or consultancies
Hospital managers include board members or members of relevant staff units in hospitals

Interviews were conducted in the period between January and March, 2014. All interviews were audio-recorded, transcribed verbatim and anonymised. The interviews were performed using a specifically designed semi-structured interview guide. The guiding themes were based on insights from Europeanisation [16] and EU compliance research [17]. The interviews were analysed by the two principal investigators (TC, KR) using the five stages “framework” approach [18]. A directed content analysis approach was applied whereby initially (1) *familiarisation* with the data was ensured by an initial coding of five interviews. On the basis hereof, a retreat session was organised to (2) *develop the thematic framework*. After (3) *indexing* of all interview transcripts to the framework, themes were (4) *charted* according to the initial research questions and finally, concepts were defined and associations and potential explanations established during the (5) *mapping and interpretation* phase.

The study received ethical approval by the Medical Ethical Committee of the University Hospital Maastricht and University Maastricht (METC 13-05-075). All participants provided consent to be interviewed and for the interview to be recorded.

6.3 Results

The assessment results on the impact of EU hard law and new governance tools on domestic hospitals and hospital policy are presented in three steps. First, examples of EU governance tools are illustrated. Second, the context and conditions these tools unfold in is analysed. Finally, the perceived impact upon various stakeholder groups is shown.

EU hard law on hospitals – the unnoticed impact on non-salient issues

With regard to the operational level of hospitals interviewees commonly agreed that predominantly EU hard laws (e.g. Directives, Regulations) are of relevance and they require adaptations or change of procedures in hospitals to comply with EU provisions. Although EU legislation covers a variety of hospital activities, it was believed that EU hard law does not directly concern hospitals' core business of patient care.

“It is not always about very important things. It can be very trivial things like paying for intellectual property rights of authors when playing music on wards. That does not have obviously a very big impact on the organisation of hospitals.” [Interview P4]

For a detailed overview of issues addressed by EU law and their impacts perceived by the interviewees see Table 6.2. Moreover, despite a considerable number of EU laws applicable to hospitals the EU influence is hardly taken notice of. Three potential explanations arose from the interviews. First, EU laws are not viewed as European but rather national laws due to the transposition process into national laws (in case of EU Directives). Second, the discussion during the EU agenda setting and EU decision making are often not linked to hospitals or health policy, because the laws originate from non-health mandates of the EU and therefore are discussed in non-health-related policy settings at EU level. Third, EU laws are not regarded as important because they do not concern the core business of hospitals.

“In order to be recognised by hospitals it needs legal implications. [EU] Regulations are directly applicable. You recognise that in a hospital. Directives are recognised when transposed into the national legal order. But if you ask a hospital practitioner what role the EU plays for him, you generally get a thin or no answer, because this is generally not identifiable as EU law.” [Interview P5, author's translation]

Table 6.2: EU legislation with relevance for hospitals

	Dossier/Title of the EU legislation	Perceived impact or outcome of EU legislation on hospitals
1	2011/EU/EU Directive on the application of patients' rights in the cross-border healthcare	<ul style="list-style-type: none"> - pressure to establish an international interoperable electronic patient file (1, 2) - pressure to comply with criteria so that receipts for medicines [e-prescriptions] are accepted across borders & recognise by yourself (2) - establishing a list what is regarded as inpatient and out-patient care (2) - pressure to establish translation services in order to inform XBC patients sufficiently (2) - pressure to increase the provided level of information towards patients (1, 2, 8, 10) - requirement to ensure continuity of care for XBC patients (2) - requirement to have or extend liability insurance for medical professions towards XBC patients (1, 2, 5) - criteria are high to participate in European Reference Centres (ERNCs) => perception that only academic hospitals will be able to join, excluding other providers with expertise (5, 8) - extending ways for conflict resolution (15) - requirement to apply the same domestic tariffs for cross-border patients (8, 13) - the additional efforts for hospitals are not corresponding with the number of patients using cross-border care (5) - dealing with a lot of topics quite vaguely (1) - push to provide information on accessibility, quality and prices, however, many will not have the tools to provide that information(1) - system of quality assurance at European level failed to get into the Directive (1) - new requirements regarding the signing of the informed consent form (10)
2	European Working Time Directive (EWTD) 2003/88/EC	<ul style="list-style-type: none"> - inactive time during on-call duties is working time (5, 15) - maximum average weekly working hours are set (5, 9, 18) - push to contract (self-employed) doctors (1, 15) - new ways of organizing working shifts (1, 18) - re-structuring educational schemes for doctors (1, 18) - need to hire additional medical and technical staff (5) - massive cost increases (5, 15)

Table 6.2: EU legislation with relevance for hospitals

Dossier/ Title of the EU legislation	Perceived impact or outcome of EU legislation on hospitals
3 Directive 2013/55/EU amending Directive 2005/36/EC on the recognition of professional qualifications	<ul style="list-style-type: none"> - discussion to increase the minimum of school education for nurses from 10 to 12 years (1, 5) [not passed in Dir. 2013/55/EU] - (potential) problem to recruit nursing trainees (5) - discussion to move towards nursing as an academic training (15) - (potential) increase of salaries, increase of costs (15) - facilitates the hiring of foreign professionals (2) - helps to ease shortness of certain medical specialists (2) - only recognises training/professional qualifications across borders but does not provide a licence to practice [national responsibility] and criteria differ between and within countries (10, 16) - ease the recognition of foreign qualifications (2) - regulates only requirements on minimum training periods, partly on content of the training (2) - allows for exchanging information in case of de-licensing/misconduct of professionals (17)
4 Public Procurement Directive 2014/24/EU on public procurement and repealing Directive 2004/18/EC on the coordination of procedures for the award of public works contracts, public supply contracts and public service contracts (to be enforced in 2016 only)	<ul style="list-style-type: none"> - specific countries underestimated the scope of rules with regard to hospitals (1) - increase of transparency (1, 7) - insecurity around applicable criteria for the award of public contracts in the hospital sector (7) - reducing the freedom/flexibility of hospitals to award contracts (4, 18) - procedures have become formalistic with a high administrative burden (4) and are slow (18) - duty to respect time frames and to publish tender offers (4) - need to hire (extra) personnel with expertise to comply with rules (4) - can be bad for the domestic health economy (4) - no specific impact mentioned/aware of (10)
5a Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) (1990) Council Directive 93/42/EEC on Medical Devices (MDD) (1993) Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDMD) (1998)	<ul style="list-style-type: none"> - re-design of the sterilisation plant including new validated equipment (9) - systematic documentation (9) => increase of transparency (9) => switch from multi to single use products (e.g. scissors) because of cost reasons (9) - higher requirements for the qualification of personnel in the sterilization department (9) - additional requirement for the built infrastructure and technical equipment (9)

Table 6.2: EU legislation with relevance for hospitals

Dossier/ Title of the EU legislation	Perceived impact or outcome of EU legislation on hospitals
5b A proposal for a Regulation on medical devices AND for a Regulation on <i>in vitro</i> diagnostic medical devices	<ul style="list-style-type: none"> - (potentially) limiting reprocessing of single-use equipment (1, 5) => increase of costs (5) => increase of patient safety (6) - (potentially) extending the procedure for tracking (via product ID) to many more medical devices (5) => increase of administrative burden (5) => improves the backtracking of medical devices (5) - extending oversight of quality of medical devices (17) - Directives mentioned, impact not clear yet (4)
6 State Aid rules for Services of General Economic Interest (incl. Almunia package)	<ul style="list-style-type: none"> - EU's surveillance on state aids in the hospital sector increases (4) - insecurities on the application to the hospital sector remain (4, 5); impact not clear yet (4) - Almunia package more specific regarding hospital sector (4) - acts of entrustments in the hospital sector are more and more checked => if applied on a larger scale, public hospitals are expected to be pushed to operate more efficient (7) - covering deficits of hospitals by public authority is subject to EU state aid conditions (5) - increases transparency regarding contracting and state aids (5) - supporting (fairer) competition between public and private hospitals (5, 7)
7 Blood, Tissues and Cells, Organs Directives Directive 2002/98/EC, Directive 2004/23/EC, Directive 2010/45/	<ul style="list-style-type: none"> - in many accession countries [2004/07] [the Directives] changed important parts of the system (1) => improved the "products" patients are using (1) - Directives mentioned, impact not clear (4)
8 Food Labelling Regulation (EU) No 1169/2011 on the provision of food information to consumers	<ul style="list-style-type: none"> - requirement to provide detailed information (1) about allergens (4) in served food - not clear what precise information needs to be on the label (1) => administrative burden increases (although patients are asked generally about food intolerances at admission to the hospital) (4)
9 Directive 2011/77/EU on combating late payment in commercial transactions	<ul style="list-style-type: none"> - 30 days limit regarded as not feasible for hospitals (1, 4) => derogation for public entities providing healthcare (1, 4) [Art. 4 (4)b of the Directive]
10 Radiation DIRECTIVE 2013/35/EU on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields)	<ul style="list-style-type: none"> - lower limits would have meant that MRI could not operate anymore in hospitals => derogation for MRIs (5) [Article 10 of the Directive]

Table 6.2: EU legislation with relevance for hospitals

	Dossier/ Title of the EU legislation	Perceived impact or outcome of EU legislation on hospitals
11	EU Emission Trading System (EU ETS)	<ul style="list-style-type: none"> - tightening of the system in 2009 would have made ETS applicable to large hospitals with own power plants (5) => need to buy certificates & increase of costs (5) - opt-out for hospitals (5)
12	Food waste processing	<ul style="list-style-type: none"> - food waste can only be used as animal feed after thermal processing => increase of costs by 10% (5)
13	Safety at the workplace & Workers rights	<ul style="list-style-type: none"> - Regulations mentioned, but impact not clear (4)
14	Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC	<ul style="list-style-type: none"> - impact on researching hospitals (perception of engaging in many trials) (4) => not clear what the precise consequences will be (4) [Regulation applicable in 2016]
15	F-Gas in air conditioning Regulation (EU) No 517/2014 on fluorinated greenhouse gases and repealing Regulation (EC) No 842/2006	<ul style="list-style-type: none"> - not clear what the precise consequences will be (1) => likely adaptation of equipment (1) [checks for leakage and recovery of F-Gas (at the end of product life) in existing air conditioning systems => increase of costs]
16	Intellectual property rights	<ul style="list-style-type: none"> - need to pay for author rights when music is played publicly on wards (4)
17	Needle stick injuries Council Directive 2010/32/EU implementing the Framework Agreement on prevention from sharp injuries in the hospital and healthcare sector concluded by HOSPEEM and EPSU	<ul style="list-style-type: none"> - not clear what the precise consequences are (4)
18	Water Directive	<ul style="list-style-type: none"> - need to comply for hospitals, impact not specified (6)
19	VAT Directive Council Directive 2006/112/EC on the common system of value added tax	<ul style="list-style-type: none"> - duty to pay VAT on specific medical services (6) [see for exemptions Art. 132 VAT Directive; see for services not exempted ECJ cases D Case C-384/98, Kugler Case C-141/00, Unterperinger Case C-212/01.
Legend		
Number in bracket at the end (X) indicates then number interview partner(s) bringing up the impact		
Information in brackets [...] are authors' additions		

EU new governance tools – even frameworks, uneven triggers for policy shifts

Interview partners felt that *soft-law documents* such as EU Council Conclusions or Recommendations have an impact at the level of national hospital policy making rather than at the level of individual hospitals. However, the influence was described as unclear and only taking clear form over the long-term. Moreover, EU influence is perceived as being subject to the specific political and policy context in each Member States (see next section). Interviewees agreed that it is difficult to trace the actual impact of such documents on the policy making in Member States. Conducive to an EU influence are existing parallel reform developments or discussions in countries or individual persons. Then, the EU can be an additional trigger or complementary dynamic for reform.

“So slow, but we have an influence. Yeah you can take into account the recommendation on patient safety [Rec. 2009/C151/01]. It’s difficult if it has really huge influence in all countries [...], there is this document that has pushed some countries to at least increase the pressure on the healthcare system to provide information on adverse events and so on.” [Interview P1]

EU funded projects were regarded to have no immediate influence on the hospital practice but were acknowledged to have a potential long-term impact on hospital policy by generating new ideas or changes in policy actions. The advantage of EU funded research was seen as residing in opportunities for innovations in hospital practice and policy to reap the benefits of (often) comparative analysis with other Member States. However, two interview partners indicated that the EU project funding is sometimes used to argue for EU level action despite the limited legal basis in the Treaty.

To induce policy change, *comparisons* among hospitals and across Member States need to be robust and drastic. Moreover, to be a potential trigger for change the compared issue needs to be perceived as a policy problem in the domestic setting.

[regarding international comparisons] “...hence, the evidence needs to be hard and in a certain way shocking. And then you always see a reflex. [...] Yes, it is not one thing. You have a number of indicators, you have a number of issues, that are relevant at a certain point in time and these come together.” [Interview P3, author’s translation]

The domestic policy and political context: reciprocity between EU and national level

Interview partners stressed the differences in how healthcare systems are organised in Germany, the Netherlands and Belgium. These differences create the context for different national problems arising from the same EU legislation. The most evident examples included public procurement in Belgian hospitals or potential new requirements for entering nursing

training in Germany arising from the revised EPQD. Different contexts ask for different handling/transposition of the same EU requirements.

However, the most important current reform projects mentioned by the interview partners in the three countries are very similar. The top reform priorities include changes to hospital financing, improvement to service quality (accreditation, publication of quality data, pay-for-performance) and initiation of various forms of cooperation between independent (public) hospitals.

EU actions resonate with national practices in three ways according to interview partners. First, EU initiatives reflect developments in Member States that are “taken up” or “uploaded” to the EU level. The eHealth agenda is one example which Member States have initiated in domestic spheres and where policy makers are now seeking agreements at European level. Another example is the EU PRD which mirrors trends in Member States to strengthen transparency, choice and patient empowerment in healthcare systems. This does not imply that certain provisions of EU hard law do not require a change of national practices as shown above.

“The European directive mirrors earlier developments in different Member States. [...] This has not been invented by Europe of course. Europe has taken it into its own hands, but the trend was ongoing before.” [Interview P4, author’s translation]

Second, especially for EU new governance tools such as recommendations, comparisons, project funding, a “conductive” national context is described as a prerequisite to such measures taking effect. Either Member States have already initiated similar developments in the national policy landscape, or there is a sense of a problem or urgency which will help EU initiatives/discussion to be an amplifier in the agenda setting or policy formulation phases towards a decision on a reform.

“You don’t need always hard law to influence or stimulate a dynamic slightly. Because there are by now so many issues that they have set up specific working groups for that one can create thereby a dynamic as well, ...” [Interview P16B, author’s translation]

Third, EU actions can stimulate both ideas and actions in national arenas. EU hard law can be a trigger for national political action because of national actions called for in the legal text. For example, Chapter IV of the PRD calls for interoperable patient files and prescriptions, as well as cooperation regarding HTA to be established among Member States. Many other laws have provisions on reporting; a report to be delivered to the EU regarding the implementation status of a certain EU policy which requires Member States to collect data and information and to consult stakeholders to compile the report. More indirectly, because of a transposition of EU laws, a Member State may use the window of opportunity to address other complementary

issues not directly linked to EU provisions as such. The example raised by an interviewee concerned the EU legal regime for blood, tissue and organs [19] which led to national action not only on the quality and safety of blood but in addition stimulated actions on prudent use of blood products in hospitals.

Outcomes of EU influences: increase of requirements

This section describes what kind of changes or implications the involvement of the EU in domestic hospitals has for various professionals.

For *citizens* especially the clarification of rights with regard to patient mobility and the provision of care services have been stressed in the context of the PRD. More generally, some interviewees believed that the EU role from a consumer protection angle has been central by ensuring safe products and services.

“This is a typical topic of patient safety. This stems from the rationale how to safeguard as much as possible the patient from harm. [...] Basically it is the rationale how to ensure that EU citizens can live a safe life.” [Interview P6, author’s translation]

For *clinicians* the EU implies a need to adhere to EU social protection and occupational safety regulation such as the provisions related to the EWTD. Moreover, the EPQD was held to have eased movement of clinicians within the EU by recognition of diplomas despite varying licensing practices in Member States. And finally, the European Guidelines for quality assurance in cervical, breast and colorectal cancer screening and diagnosis – although not laws but “agreements among peers” – have changed practices clinicians need to adhere to.

Hospital managers need to cope with an increased administrative burden – procedures that are perceived to be alien to existing practices or over-regulatory – and increased requirements for educational standards, infrastructure and transparency. In many cases this has led to higher immediate costs. Examples of more stringent standards for processes and standards subject to EU laws include the handling of blood and blood products, procurements for product purchase or service delivery, and sterilisation of medical devices (see Table 6.2). In addition to increasing the hospitals’ operational costs EU laws are regarded as reducing managers’ flexibility in the hospitals organisation.

“This is all EU law and it impacts immediately on hospitals’ activities. In case I cannot run my sterilizing plant anymore, because it is not in line with the legislative provisions anymore, it costs money. I need to change my procedures in the hospital; I need to designate new personnel and train it to be fit and they need to have the respective certificates for qualification. All of this is meanwhile common practice...” [Interview P6, author’s translation]

A loss of flexibility or independence in political decision making is described as well as an outcome for *national decision makers*. In the political and administrative spheres there is growing recognition that Europe is governing hospital policy and a necessity to take this into account when making decisions. Some interviewees see a change of reference frameworks due to structural EU interference; others would not go that far.

“... earlier we were able to develop our own activities, but the impact of what Europe demands is that we are pushed to more and more take Europe into account. This is not evident, because it works in a different way. We are asked to use different reference frames than the existing ones. [...] We at the operational level find this more difficult.”
[Interview P16B, author’s translation]

However, on a practical basis, decision makers still seem to have difficulties in acknowledging the need to systematically take Europe into account when making hospital policies or reforms. The subsidiarity principle and provisions of Treaty Article 168 (7) are advanced as reasons for this behaviour to deny the EU as an additional reference point.

“It is more like this: Europe does things, and it happens to us. And subsequently stakeholders think “But they [the EU] should not be concerned with this.” And then we are searching for pragmatic solutions” [Interview P3, author’s translation]

6.4 Discussion

This study analysed the impact of EU hard law and EU new governance tools on domestic hospitals and policy by means of qualitative interviews with hospital managers and decision makers, hospital advocates and academics. EU hard law matters on the operational level in individual hospitals when transposed via national laws. Although EU directives and regulations do not concern the core business of hospitals – the financing and provision of patient care – they do increase the requirements for documentation, transparency, higher demands for infrastructure, education, procedures which in many cases is described to increase the costs for hospitals. However, the EU’s influence at the individual hospital is perceived to be low. EU’s new governance tools such as comparisons, involvement in projects, recommendations, can be a trigger for change in the definition of domestic hospital policy if related developments or discussions have started in national fora in parallel. The impact of new governance tools is described as undetermined and likely to become clear over the long-term. Altogether EU governance tools are of a structural nature for domestic hospital policy. They limit the flexibility and independence of national decision makers. However, national reactions to EU influences remain more on an *ad hoc* basis than systematic and proactive.

There are a number of limitations to this study. First, our sample of cases was restricted to the Netherlands, Belgium and Germany. We are confident the selected cases have been rich sources due to the countries' longstanding EU membership and their hospitals are frequently subject to cross-border care and travel. However, limiting the sample in this way may have excluded implications of hospitals and hospital policy in NHS type systems and hospitals in new Member States where European Structural and Investment Fund (ESIF) support may have had a stronger impact on hospitals as in old Member States [20]. Second, our inventory of EU laws and its impact in Member States is certainly not comprehensive regarding the EU legislation applicable to hospitals and certainly regarding the impacts on Member States. However, many of the topics raised resemble earlier analysis of EU impacts on health provisions in Member States [2, 5].

This study suggests that the EU has become a structural feature of national hospital policy making despite not touching upon the core activities of the sector. Nevertheless, domestic policy makers feel that it is difficult to adapt to EU influences and the corresponding need to search for pragmatic solutions. A more proactive attitude towards the EU's involvement could be of added value. However, it would mean, at the same time, a further legitimisation of EU involvement in practical hospital issues which many stakeholders seem to fear.

In terms of its mode, EU new governance regarding hospital policy should be aimed at sharing of tasks in a way that the definition of broader policy frameworks and the monitoring thereof is left to the EU. It is the role of Member States to flesh out the frameworks practically with a wide discretion of the employed tools and mechanism to accomplish those goals [21]. The EU's approach *"to achieve greater effectiveness, accessibility and resilience of their [Member States] health systems"* by developing the respective methods and tools [22] may be too narrow for experimentalism of Member States.

European hospital policy is not only pressured to reform by epidemiological and technical changes. As well, hospitals in Europe must continually grapple with a highly complex system of governance between European and national arenas which now impacts how they operate from day to day and year to year.

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Chapter 7

General discussion

This thesis aimed to assess how health system governance is developing between the EU and its Member States. Applying insights from governance theory to the object of hospitals, the aim has been to get better insights how a growing health system agenda at EU level – moving from insular issues towards a more comprehensive approach – has influenced hospitals and hospital policy in its Member States. Hospitals have been chosen as the case of interest because, firstly, they still fulfil multiple roles in the wider health systems they are integrated in. Secondly, hospitals still consume a large share of health system resources and, therefore, are frequently an object of health system reform efforts. Thirdly, the governance of hospital is supposed to be the sole responsibility of Member States despite multiple instances where EU law and activities are applicable to hospitals. The analysis has evolved in three steps according to the output criteria for legitimising EU governance (Baldwin, Cave, & Lodge, 2012; Knill & Lenschow, 2003) looking at:

- (1) the needs and problem-solving capacities at EU level and Member State level to reveal which objectives of healthcare systems (chapter 2) and hospitals in particular (chapter 3) are addressed and how they are framed,
- (2) the capacities for decision making of the Directorate General for Health and Consumers (DG SANCO)¹ have been assessed to understand the degree to which the European Commission has the resources and functional structures to formulate policies in the area of public health and health systems (chapter 4),
- (3) the level of implementation and compliance with EU hard law and new governance tools have been analysed
 - a. in all Member States with regard to the Directive 2011/24/EU with a special focus on the National Contact Points for cross-border healthcare, its structures, information provision and support for cooperation (chapter 5)
 - b. in Belgium, Germany and the Netherlands for an array of EU hard law and new governance tools influencing hospitals and hospital policy (chapter 6).

The work on this thesis has taken place in the context of external events affecting the object of interest, hospitals and national healthcare systems. First, the Financial and Sovereign Debt Crisis caused a downturn of European economies and by this a decrease of revenues – to a varying degree – for national health systems in Europe (Mladovsky et al., 2012). In the aftermath, interlinked questions of health system performance, efficiency, sustainability, health system governance and implementation of reforms have come to the front. This has particularly covered hospitals as a high cost and high resource demanding setting. Second, after lengthy

¹ Here, I refer to DG SANCO in connection with the analysis in chapter 4, which has assessed the period from 1999 to 2014. With the Juncker Commission taking office in November 2014 the Directorate General responsible for health has been renamed to DG SANTE, DG Health and Food Safety. I refer to DG SANTE in the wider discussion within this chapter.

discussions, the Directive 2011/24/EU on the application of patients' rights in the cross-border healthcare² setting was agreed upon in 2011 and transposed in autumn 2013. The Directive has not been – as expected – a game changer to the levels of patient mobility in Europe and, thereby, not affected the provision of care in domestic hospitals directly. Nevertheless, the Directive has propelled the existing work to use eHealth applications such as e-prescriptions in the cross-border setting and paved the way for cooperation among hospitals regarding rare diseases in the European Reference Networks (ERNs). More broadly, the Directive has facilitated national developments to substantiate patients' rights, to increase the level of available information to patients and to improve transparency around quality and patient safety measures (Palm & Baeten, 2011; PRE-MAX Consortium, 2017, forthcoming).

In this chapter the main findings per chapter and per research question are summarised, then the implications for European Union governance regarding hospitals and health systems from a EU and from Member State perspective are discussed including broader reflections on how the “European healthcare union” may likely unfold in the future based on different scenarios, the methodological approach and its limitations are addressed in subsequent step and, finally, the implications of the findings for research, policy and practice are presented.

7.1 Summarising the main findings

Chapter 2 dealt with problem solving capacities at EU level more broadly for healthcare systems in light of the financial crisis. This study *assessed – from a EU health policies perspective – potentially supportive EU actions for national health systems in light of the crisis by reviewing policy documents and scientific literature*. The assessment offered an alternative account to the prevailing negative impact of the EU on healthcare systems by its support for national retrenchment policies and tighter EU fiscal governance (cf. Kentikelenis & Papanicolas, 2012; Mladovsky et al., 2012).

Assessing the areas of (1) patient and professional mobility, (2) the (revised) objectives of the EU structural funds policy, of the 3rd Action Programme for Health for the period 2014-2020, and of the European Investment Partnership of Active and Healthy Ageing (EIP-AHA) and (3) the work regarding health systems and in particular the initiated reflection processes within the Working Party Public Health at Senior Level. The chapter reveals that the EU has enlarged its health system agenda during the crisis. The EU's healthcare system goals exhibit a stronger link between health system endpoints and economic targets. While health systems previously have

² Directive 2011/24/EU of 9 March 2011 on the application of patients' rights in cross-border healthcare [2011] OJ L 88/45

been regarded as a pre-condition for economic growth in the framework of the Lisbon Strategy (EU European Council, 2000), they are more and more approached as a means where economic growth can be realised. As such, the chapter concludes that the analysed tools used by the European Commission to support cooperation and innovation to alleviate crisis effects in national health system “are not neutral”. Moreover, in how far those tools can effectively support problem solving in Member States, has been questioned given the strong subsidiarity principle in place for health systems and the predominant financial consolidation rationale at EU level (Azzopardi-Muscat, Clemens, Stoner, & Brand, 2015; Baeten & Vanhercke, 2017).

Figure 7.1 Summary of the main findings

Chapter 3 zoomed in on the objectives of hospital policy during times of crisis both, at national and European level, by analysing *how EU Member States align short-term and long-term pressures for hospital reforms and how the EU is influencing the context of these national reforms*. Using a literature review and document analysis, hospitals’ reform strategies were identified in EU Member States and the associated policies at EU level. The assessment used the WHO Observatory framework to chart the policy responses according to level of expenditures,

policy tools and the effects on health system goals (Mladovsky et al., 2012). Overall, Member States were focusing on short-term reforms to contain the operational costs of hospitals which have been described as the *long-hanging fruits* (Bengoa and Repullo, 2013 in World Health Organization, 2015). On the contrary, structural reforms of the hospital sector that go beyond project status, involving changes to financial reward systems or integrated care arrangements, were reported only for a few countries. Against the background of these national reforms the European Commission is recommending and setting financial incentives using several instruments. However, the uptake is largely depending on the discretion of Member States; only the bailout countries are more pressured to take up EU reform ideas. Political and financing disincentives exist for structural reforms explaining why the crisis as a window of opportunity may close without structural hospital reforms taking place. The chapter concludes that a European agenda to move away from the hospital centred healthcare system and turn to efficient, accessible and resilient health systems is only slowly emerging. So far, in many Member States the perception is lacking that, first, the current system in place has overwhelming deficits to address current and future patients' needs and that, second, new models have proven to be effective.

Moving to the criterion of decision making capacities **chapter 4** has assessed the capacities of the European Commission, Directorate-General for Health and Consumers (DG SANCO), to take decisions regarding the area of public health and health systems. The United Nations Development Programme (UNDP) Capacity Assessment Framework was used (United Nations Development Programme, 2008) to assess functional capacities of DG SANCO necessary "to get things done" in the period 1999-2014. The focus has been explicitly on the functional capacities within the broad UNDP framework, because the institutional and societal arrangements of the EU health mandate as such – identifying drivers for increased relevance and scope of EU activities despite the limited Treaty provisions – were described extensively before (Greer, 2006; Hervey & McHale, 2004; Mossialos, Permanand, Baeten, & Hervey, 2010). The analysis combined a literature review, document analysis and interview data.

The capacity assessment shows that, overall, DG SANCO has gradually extended its remit for health system policies; an own Directorate within DG SANCO is dealing with health system dossiers including the important pharmaceutical dossier which has been moved in 2010 from DG ENTERPRISE; linked to additional institutional capacities. From an organisational perspective, DG SANCO has: (1) established capacities to engage with stakeholders; (2) developed different capacities to assess various health issues of which some still lack a sustainable basis; (3) not defined a clear strategy providing direction for its actions; (4) demonstrated the capacity to formulate policies and strategies in some areas of its policy making; (5) needs to improve priority setting capabilities, (6) established limited capacity to budget, manage and implement policies

and (7) capacities to collect information potentially useful for evaluating its own progress. In light of the policy cycle process, results suggest that DG SANCO's capacities to assess a situation, set the agenda and decide on a concrete policy, are to some extent established, whereas, the capacities for implementation and evaluation are perceived as less developed.

While some efforts for priority setting and clearer targets have been identified in the formulation of DG SANCO's health system policies (e.g. Joint Actions, 3rd Action programme) there is room for improvement towards more effective policy making for health systems. The chapter concludes that DG SANCO's reputation maybe better defined by the added value it can deliver to existing national activities rather than the number of health topics it is dealing with.

Turning to implementation and compliance with EU provisions as the last criteria of legitimisation for EU governance, the study described in **chapter 5** aimed to assess the practical implementation of National Contact Points (NCP) for cross-border healthcare requested under Directive 2011/24/EU³. National Contact Points are tasked to provide information to patients on their rights and entitlements to receive cross-border healthcare (Article 6) and to facilitate assistance and collaboration among Member States (Article 10) in the areas described in Chapter IV of the Directive. A content analysis of National Contact Points' websites in all EU Member States and of relevant EU legal and policy documents was used to determine the requirements regarding National Contact Points, set out by the Directive, and the respective compliance in Member States.

While there were signs of minimalistic implementation in many countries with regard to the amount of and way of presentation of relevant information, there is a large degree of uniformity regarding the set-up of the National Contact Points and the kind of information they provide. Some national variation of National Contact Points reflects differences in the organisation and priorities of the domestic health system they are integrated in; a degree of flexibility that has been accounted for in the design of the Directive. The cooperation activities have only started slowly and cover so far a limited number of issues relevant for National Contact Points and the smooth facilitation of cross-border care. So far they have not reached out to broader goals of health system cooperation described in Chapter IV and beyond. The chapter concludes that, based on the requirements set out in Chapter IV, and the started cooperation activities supported by the Commission; health system cooperation is likely to advance.

Chapter 6 focused on the implementation and compliance with EU law and new governance tools regarding the hospital sector. Based on an interview study with key informants (civil servants, hospital managers, hospital advocates) *the impact of EU hard law and new governance tools on domestic hospitals and hospital policy was analysed*. Implementation of EU hard law

³ Ibid, Directive 2011/24/EU (n 2)

leads to an increase of requirements for documentation, infrastructure, education and procedures on the operational level of hospitals. In many cases this increases the operational costs for hospitals. However, the core hospital business of patient care is not or only in distant fashion affected by those EU laws so far. The EU's new governance tools are regarded as not immediate relevant for the hospitals as such, but can trigger change in domestic hospital policy under certain conditions. These conditions include (1) an existing problem pressure or ongoing similar activities in the domestic policy arena where the EU actions can act as additional triggers or amplifier in the policy process and (2) providing new tested ideas and innovations or raising awareness of problems as a starting point for discussions. However, the impact seems less clear, only emerging in the long term and may vary between different countries. National decision makers in the countries under study perceive their decision latitude being reduced by the EU policies and legal influence and see increasingly a need to monitor relevant EU activities. Nevertheless, national compliance to EU influences remains *ad hoc* so far rather than being systematic and proactive.

Overall, this thesis has demonstrated that – based on an increasingly comprehensive EU healthcare agenda – the way hospitals are governed domestically has been impacted by

- (1) the **problem solving** capacity of the EU that is stimulating structural hospital reforms in Member States by providing evidence of the current and future pressures, testing potential solutions via project funding and providing financial incentives to take on reforms. Thereby, the EU has added the economic rationale to the discussion of health systems. However, Member states have turned to quick-fix solutions to lower operational cost in the context of the crisis. The macro-economic and political conditions in Member States – and partly favoured by the EU – have largely not been conducive for structural reforms;
- (2) DG SANCO's enlarged remit for health systems despite the **decision making capacities**, from a health policy perspective, still being limited due to the structural conditions (Article 168, TFEU, constitutional asymmetry, patch work of health responsibilities within the European Commission). DG SANCO has proven to be able to steer the agenda, assess a situation and taking decisions. But whether DG SANTE can deliver on implementation via clearer targets and stronger tools is still to be seen;
- (3) EU hard laws that are **complied** with in national hospitals and new governance tools that take effect in Member States' health policy under certain conditions (chapter 5 & 6). Nevertheless, EU Member States largely govern their hospital systems themselves (chapter 3).

Hence, in contrast to Lamping and Steffen (2009) the findings support that EU hospital policy is not anymore “*issue-specific, fragmented and [...] patchy*” (Lamping & Steffen, 2009, p. 1375) but has moved towards a comprehensive and relevant EU agenda for national decision makers. This is in line with a recent legal analysis that a new field of European Union Health law has emerged:

“EU law (those based on its public health competence and those based on other competences, but with health as their central concern) have, over time, sufficiently coalesced to become a sufficiently coherent entity...” (Hervey & McHale, 2015, p. 70)

Based on the summary of the main findings the discussion moves now to the implications for European Union governance regarding hospitals. In the following, first, reflections from an EU perspective will be presented in section 7.2 before the Member State perspective is outlined in section 7.3. Both sections unfold avenues for EU governance for healthcare systems and hospitals in the future based on different scenarios.

7.2 Revisiting European Union governance regarding hospitals

This section addresses different ways and loci of the impact of EU governance for hospitals, reflects on the interplay of the EU and Member States beyond the national federal level from a Multi-level Governance perspective and sketches a number of health system implications based on Juncker’s Future of Europe scenarios.

Modes of EU influence

Despite the emergence of a comprehensive and relevant EU agenda for national decision makers regarding hospitals it should be reiterated – as described in the introduction – that the EU has stronger (law-making) powers and direct and indirect influences in areas of hospital policies linked with the EU internal market than in many other areas where the EU has shared competences with Member States fulfilling a coordinating function. EU coordination involves less stringent policy tools using funding, facilitating voluntary cooperation or providing policy guidance by recommendations (Greer et al., 2014). This is due to the delineated Treaty mandate in Article 168, TFEU and the constitutional asymmetry of the EU favouring economic over social goals.

Regarding the former EU powers, this affects especially input variables to hospital systems linked to the free movement principles of the EU internal market (pharmaceuticals, medical devices, training standards of health professionals, working time, occupational health and safety, public procurement, state aid, merger control) or issues that have proven to have a cross-border

dimension (quality and safety standards for blood, tissues and organs, infectious disease control, consumer protection, patient mobility and coordination of social security systems).

In the latter areas of EU involvement with a coordinating nature – addressing predominantly process and outcome variables of hospital care – the EU acts as a spin doctor, knowledge broker and financier for pilot projects with the EU affecting the context in which national hospital policy being made (see as well chapter 6). Examples include skill mix of health professionals, quality of care and patient safety, integrated care arrangements, payment and organisation of hospital and aligned health and social services and financing structures and planning for hospitals. Moreover, the European Commission is funding health research and investment in hospital infrastructure via the Horizon 2020 and the European Structural and Investment Funds (ESIF) schemes respectively.

Multi-level Governance

Acknowledging that the EU is addressing hospitals more comprehensively raises the question what the implications for various actors within a multi-level governance structure between the EU, national governments and various other domestic stakeholders are. Multi-level governance (MLG) is defined as authority “*slipp[ing] away from central states both up to supranational level and down to the subnational level*” (Marks, Hooghe, & Blamk, 1996, p. 167) and refers moreover to how “*levels connect, interact and, most notably overlap*” (Zürn, Wälti, & Enderlein, 2010, p. 4). Nevertheless, multi-level governance acknowledges that states are still regarded as important and powerful actors in the decision making process (Marks et al., 1996, p. 167).

The enforcement of EU law is primarily a role of public authorities of Member States (Jans, de Lange, Prechal, & Widdershoven, 2007) which has been the primary interaction studied in this thesis. However, structural health systems arrangements, such as corporatism and federalism, and health system developments towards decentralisation and the implementation of new public management principles embarking on the provision by third parties have included increasingly additional governmental (regions, communities) and non-governmental stakeholders (insurances, hospital associations, medical representations) to be involved in the governance of health systems and hospitals. Hence, problem solving capacities and compliance and implementation with EU laws rest with other stakeholders outside the national government *vis-a-vis* the EU and may touch upon issues of interest representation towards the EU as well.

Obviously, the EU allows for various positions to be heard in their consultations and to interact at various fora during the phase of agenda setting. A number of European regions and interest groups of health system stakeholders have opened up own offices in Brussels or are represented by their European associations. For example, the European Hospital and Healthcare Federation (HOPE, est. 1966) and the European Association of Hospital Managers (EAHM, est. 1970) are two

umbrella organisations at EU level representing the views of respective national member organisations in case EU activities concern hospitals. Moreover, in various expert groups advising the European Commission (e.g. EUnetHTA, expert group on patient safety or workforce) not only national governmental representatives but regional and non-state actors are involved as well (European Commission, n.d.). Nevertheless, domestic health system stakeholders outside the governmental sphere may not be adequately heard in Brussels, for example, in case their position may profoundly differ from the position of their own national government. Lacking resources or channels for hospital associations or limited interest representation within national spheres might be other reasons why differences in the possibility to engage with EU policy exist.

Moreover, the EU itself has allowed non-governmental institutions to be involved in the enforcement and implementation of EU law. In chapter 5, Member States have assigned non-state actors or regional authorities as the National Contact Points for cross-border care⁴. Other examples constitute the use of Notified Bodies for the certification of medical devices⁵ or the competent authorities under the Professional Qualification Directive⁶ where medical or professional chambers or regional authorities can be tasked to evaluate and recognise foreign diploma and training schemes. This resembles broadly governance arrangements in corporatist organised social health insurance systems.

The future of Europe

Outlining the implications of a coherent EU healthcare entity for the governance of health systems as described above, assumes that the general EU architecture will remain or develop further in a path-dependent way. However, in March 2017 the European Commission presented the White Paper on the “Future of Europe” outlining five scenarios for the shape of the EU as a union by 2025 (European Commission, 2017b). Four out of the five scenarios sketch a considerably different EU by 2025. The outlined scenarios addressed more specifically the policy issues of (1) *Capacity to deliver*, (2) *EU budget*, (3) *Foreign policy and Defence*, (4) *Schengen, migration and security*, (5) *Economic & Monetary Union* and (6) *Single Market & Trade* but do not touch on health systems specifically.

The White Paper has been followed up in April 2017 by a Reflection Paper on the Social Dimension of Europe (European Commission, 2017a). The Reflection Paper continues the debate

⁴ Ibid, Directive 2011/24/EU (n 2)

⁵ Directive 2007/47/EC amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices [2007] OJ L247/21

⁶ Directive 2005/36/EC on the recognition of professional qualifications [2005] OJ L 255/22; Directive 2013/55/EU amending Directive 2005/36/EC on the recognition of professional qualifications and Regulation (EU) No 1024/2012 on administrative cooperation through the Internal Market Information System [2013] OJ L354/132

by first mapping the challenges and trends that European societies are likely to face in the future and then focuses on potential implications for citizens and social policies in the EU.

Implications for health systems are not explicitly addressed in the White Paper, although the linked “Illustrative snapshots” do address implications for the social policies in general (European Commission, 2017b). The Reflection Paper addresses indeed some health system snapshots. The directly and indirectly relevant snapshots are presented in Box 7.1.

Box 7.1: Snapshots concerning health systems

Future of Europe scenarios and related snapshots

Scenario 2 Nothing but the single market

- *“Finding a job abroad is also harder and the transfer of pension rights to another Member State is not guaranteed. Those falling ill abroad face expensive medical bills”* (White Paper, p. 19)
- *“Free Movement of workers is not guaranteed”* (Reflection Paper, p. 23)
- *“Patients can still get treatment in another Member State, but there is no European action plan to fight the increase of antibiotic-resistant bacteria”*
- *“There is no coordination and preparedness in response to common health threats, ...”* (Reflection Paper, p. 27)

Scenario 3 Those who want more do more

- *“Workers in 21 countries can access additional and increasingly similar labour rights and social protection regardless of their nationality or place of residence.”* (White Paper, p. 21)
- *“A person’s diploma is automatically recognised in some Member States, but not in others.”*
- *“A group of countries agree on the common pricing of medicines and vaccines. ...”*
- *“A group of countries agree on joint planning of their health workforce, including the number of doctors and nurses they will train collectively.”* (Reflection Paper, p. 29)

Scenario 4 Doing less more efficiently

- *“Salaries, social legislation and taxation levels continue to vary significantly across Europe.”* (White Paper, p. 23)
 - *“Every European has a single social security number to identify himself/herself. Claims, checks and payments are made online, seamlessly from one country to another.”*
 - *“People retire at the same age across Europe in line with trends in life expectancy. [...]”*
 - *“There are EU resources to respond to cross-border health threats. [...]”*
 - *“There are mandatory benchmarks to improve public health intervention, for example on fat and sugar content in food.”*
 - *“Citizens can transfer their medical information electronically when receiving treatment in another Member State and use e-prescriptions to get their medication dispensed.”* (Reflection Paper, p. 31)
-

In the following the five scenarios are reviewed for “reflections” – important potential changes – on health systems in order to propose how the scenarios may change the rationale for the governance of health systems within a changed EU. In order to do so, the objectives of the 3rd Action Programme for Health⁷ are taken to apply the scenarios to selected and important EU health policy dossiers. In addition, a fifth dimension regarding the general infrastructures for health research and policy at EU level has been added. Thereby, the snapshots describe, based on the application of the White Paper’s scenarios, either general developments and rationales that may become institutionalised within the health sector in the future or specific outcomes hereof. This exercise is meant to raise awareness that the EU most likely will change in the future and that external events such as spill-over effects from other integrated EU policy areas or crisis may alter the rationale for EU health policy in the future as they have done in the past. Finally, such periods of “critical junctures” or “branching points”⁸ (Capoccia & Kelemen, 2007; Krasner, 1984; Pierson, 2004) may offer the possibility for public health stakeholders to actively shape the EU and its policies regarding health systems.

⁷ Regulation (EU) 282/2014 of 11 March 2014 on the establishment of a third Programme for the Union's action in the field of health (2014-2020) and repealing Decision No 1350/2007/EC [2014] OJ L86/1, Annex I Thematic Priorities

⁸ More, recent contributions to Historical Institutionalism (Clemens & Cook, 1999; Hacker, 2004; Pierson, 2004; Thelen, 2004) have paid attention to institutional changes outside critical junctures. Central to this recent school of thought are incremental change mechanism like layering, conversion (Thelen, 2004) and policy drift (Hacker, 2004) which still cause considerable institutional alterations.

Table 7.1 Health reflections on the Future of Europe scenarios

	Carrying on	Nothing but the single market	Those who want more do more	Doing less more efficiently	Doing much more together
	<div> <div> </div> <div> Capacity to deliver Schengen, Migration & Security </div> </div>				<div> <div> </div> <div> Foreign policy & defence Single Market & Trade </div> </div>
	<div> <div> Economic & Monetary Union </div> <div> EU budget </div> </div>				
Priority 1: Promote health, prevent diseases and foster supportive environments	<p>The EU seeks a voluntary agreement to reduce the sugar content in food</p> <p>The EU continues to prevent a double burden for MSS and continues to tender more and more health data from OECD and WHO Europe</p>	<p>The Tobacco Advertising Directive is annulled and regulation is left to MSS</p> <p>EUROSTAT stops to collect health data from MSS</p>	<p>European Guidelines for Quality Assurance in Cancer Screening and Diagnostics are issued for additional cancers by various combinations of MSS</p>	<p>The current logic for financing health promotion activities is replaced by clear and reduced priorities informed by an established Health System Performance Assessment framework</p>	<p>A European health data architecture has been established for research and practice.</p> <p>The EU White Paper on a "One Health Strategy for the EU 2025-2035" is setting quantifiable targets for disease prevention and healthy environments in an intersectoral manner</p>
Priority 2: Protect citizens from serious cross-border health threats	<p>ECDCs mandate remains untouched</p> <p>The Joint Procurement Initiative is only barely used by MSS</p>	<p>ECDC is dissolved including the coordination and preparedness of common health threats</p>	<p>Some MSS have moved on in joint risk management of CDs and assessment of NCDs, e.g. the Mediterranean MSS cooperate to monitor vector-borne diseases</p>	<p>ECDC mandate is reduced to host the coordination and preparedness of common health threats</p>	<p>ECDC mandate has been extended to non-communicable diseases and is now called the European Institute for Public Health</p>

Table 7.1 Health reflections on the Future of Europe scenarios

	Carrying on	Nothing but the single market	Those who want more do more	Doing less more efficiently	Doing much more together
Capacity to deliver				
	Economic & Monetary Union				
	Foreign policy & defence				
	Single Market & Trade
Priority 3: Contribute to innovative, efficient and sustainable health systems				
	Ongoing efforts and investments in the eHealth agenda European Semester process continues without much direct implications for national health system reforms A scheme for long term investment in health is emerging A follow-up to the 1 st ERA-NET on sustainable and resilient health systems is proposed	eHealth cooperation is reduced to technical standards Country Specific Recommendations on health are not issued any longer Mobility of health professionals is not guaranteed	Low population density MSs and rural regions cooperate for telemedicine applications to provide health services at the patient's home Those MSs seeking advice form the Expert Panel or WHO Observatory will get financial support to their reform efforts The ERA-NET on sustainable and resilient health systems is sustained and enhanced by half of MSs	The eHealth agenda is woven into the Digital Public Service and Smart Cities programmes of the EU Compliance with Country Specific Recommendations on health and National Reform Plans within European Semester process is enforced and linked to eligibility for EU funds	A common European IT standard for eHealth has been agreed and implemented widely EMA negotiates pharmaceutical prices for the entire EU

Table 7.1 Health reflections on the Future of Europe scenarios

	Carrying on	Nothing but the single market	Those who want more do more	Doing less more efficiently	Doing much more together
	Capacity to deliver			Foreign policy & defence	
	Schengen, Migration & Security			Single Market & Trade	
	Economic & Monetary Union				
Priority 4: Facilitate access to better and safer healthcare	State aid rules do not touch on support for public hospitals in MSS The logic for collaboration across borders persist and only takes place when there is a strong need at one side of the border	Market driven cross-border cooperation in procurement procedures by some hospital chains Mobility of patients is restricted again European Reference Networks are terminated The fight to combat antimicrobial resistance is left to MSS	The Joint Procurement Initiative is widely used and extended to various goods and services in the health sector by various combinations of MSS Transnational hospitals chains and health insurances have started to operate in certain regions such as the Baltics, BeNeLux or on the Iberian peninsula	Certification and controls of medical devices is integrated into the EMA mandate The Working Time Directive is fully enforced in hospitals (no opt-out)	A minimum basket for health services has been agreed and backed up by EU financial resources A European health insurance has started to offer services to all EU citizens
General infrastructures for health research and policy at EU level	DG SANTE keeps on promoting other funding sources to finance health related activities at EU level	The Action programme for Health is terminated DG SANTE and CHAFAEA are dissolved	Joint Actions are established and coordinated in a bottom up fashion by MSS	The resources for the Action programme for health are integrated in the FP9 for Research and its original themes and objectives are further reduced Following the snapshots above a number of units with DG SANTE are closed	Strengthening research cooperation by among others twinning small and huge MSS The dossiers on environmental and occupational health are integrated in the remit of DG SANTE to support the One Health Strategy

7.3 The Member States perspective

In this section the perspective is changed from a focus on the EU to a Member State perspective. Based on the main findings of this thesis, on how the governance of hospitals has evolved between the EU and Member States, in the following potential effects for the domestic steering of systems (cf. Greer, 2009) are outlined. These questions have been raised already at the very beginning of the thesis when the dynamic between the EU and Member States regarding the governance of health and hospitals was sketched. It has been stated that it was undecided whether in the future the EU will

- influence directly Member States in their decisions for organising (parts of) healthcare services, or
- define some of the framework conditions of healthcare systems, or
- be the arena where national decision makers seek information and collaborations to shape developments regarding healthcare systems.

In the following each of the scenarios will be revisited more closely.

Scenario 1 The EU influences directly Member States in their decisions for organising (parts of) healthcare services

The findings of this thesis made clear that Member States are still in charge of their healthcare system with regard to health system reforms (chapter 3) and the impact of EU law rather not touching upon the hospital's core business (chapter 6). However, Member States in need of financial assistance are an exemption to this rule given the request for health system reforms in the Memoranda of Understanding as outlined in chapter 3. In the current political mood it does not seem likely that the EU will get more directly involved in health systems organisation, in the short term, on two grounds.

Firstly, the European Commission itself seems to be hesitant to get further stakes in domestic health systems. The Juncker Commission made clear when coming into office that, with the prioritisation of tasks in a way that the European Commission to “*be bigger and more ambitious on big things, and smaller and more modest on small things*”, health policy was regarded as a small thing (European Commission, 2014b). The focus is on the health sector potentially contributing to the economic growth and focusing on “*modernizing or simplifying the existing legislation*” rather than advancing the health agenda (Juncker, 2014, p. 4). After the transposition of the Patients' Rights Directive⁹ there is no entirely new specific health related dossier on the way to be molded into EU law in the coming years. Moreover, other contested

⁹ Directive 2011/24/EU (n 2)

political actions of the European Commission seem to be apparently, currently, on hold. For example, a new course on patient safety and quality of care is awaited since the 2nd Implementation report on the Recommendation on Patient Safety¹⁰ was published in 2014. Another example concerns the impact of health professional mobility and the brain drain it causes for sending EU Member States. The brain drain may require stronger legislative actions by the Commission than the current approach of an action plan¹¹. Due to the implications for patient care and safety a similar sectoral legislation as the Patients' Rights Directive may be needed (Glinos, 2012; Hervey & McHale, 2015). Finally, the dossier on the potential enlargement of the European Centre for Disease Prevention and Control (ECDC) mandate towards the surveillance of non-communicable diseases, possible under the establishing regulation¹², seems not to have the priority of DG SANTE and neither of parts of Member States currently.

Secondly, traditionally there is a strong resistance among Member States to pool authority for health system organisation and financing at EU level (cf. Article 168 (7), see also chapter 1). With the rise of Eurosceptic and populist parties in the EU Parliament as well as in a number of EU Member States any substantive additions to the EU's mandate for health seem unlikely. On the contrary, in the EU referendum the *Vote Leave* campaign used arguments that the UK needs to halt the excessive use of scarce NHS services by immigrants and that the UK's transfers to the EU budget could be spent better on the NHS (Vote Leave Campaign, n.d.)

However, one potential driver for more direct impact of the EU on the organisation of Member States is the emerging importance of the EU's fiscal governance framework as a new narrative for EU's health system policy. In the context of the crisis this has been only shortly addressed in chapter 3 for hospitals. From early on it was regarded as likely that health systems could not escape the fiscal scrutiny of the European Semester given the considerable amount of government budget it consumes (Fahy, 2012; Helderma, 2014). Further analysis revealed that the finance actors were favoured by the governance structures of the European Semester process rather than health actors (Greer et al., 2014). Moreover, Country Specific Recommendations (CSRs) on health – an output of the European Semester process – were framed predominantly with a fiscal sustainability narrative. Access and quality issues being less frequently addressed (Azzopardi-Muscat et al., 2015). Lately, an analysis of how the CSRs come into being reveals that economic perspectives and actors are dominating the process (Baeten & Vanhercke, 2017). It will remain open, so far, how national reform programmes informed by the CSRs will be taken up by Member States and how it will change the health system reform agendas given CSRs are developed in collaboration with Member States from early onwards.

¹⁰ Council Recommendation 2009/C 151/01 on patient safety, including the prevention and control of healthcare associated infections [2009] OJ 2009/C 151/01

¹¹ Commission Staff Working Document on an Action Plan for the EU Health Workforce SWD(2012) 93 final

¹² Regulation 853/2004 establishing a European centre for disease prevention and control [2004] OJ L142

Nevertheless, it could be a foot in the door for the European Commission to directly influence national health systems in the future.

Scenario 2 The EU defines some of the framework conditions for health systems

Evidence throughout this thesis suggests that the EU is framing the conditions for domestic health systems in terms of a structural health system and hospital reform agenda in Europe (chapter 3 & 4), requests for transparency and information on various aspects of patients' rights to support choice (chapter 5), training schemes and working conditions of health professionals (chapter 2 & 6) as well as requirements for transparent and fair procedures especially with regard to hospitals' economic activities (chapter 6). Other areas of EU action that set the broader conditions for health system activities include the EU's funding of research (Horizon 2020), market authorisation of drugs, regulation of medical devices, financial support to healthcare infrastructures especially in new Member States via European Structural and Investment Funds (ESIF) or EU competition law and state aid provisions. Those have only been touched upon in chapter 2 and 6 (see Table 6.2) of this thesis.

As of now, there is wide discretion for Member States for the implementation of EU actions in the area of health as this thesis and evidence beyond has shown:

- Member States are often concerned with short-term reforms rather than preparing long term structural reforms in the context of the crisis (chapter 2);
- Member States provide information on National Contact Points' websites that is readily available already without making considerable efforts to increase level of transparency and information (chapter 5);
- Compliance with the European Working Time Directive especially in hospitals has been delayed (Pärgmäe, Martins, Rodríguez, Christopoulos, & Werner, 2011);
- The goals of ESIF funding are largely set by Member States;
- Member States are responsible for the reimbursement of medicines albeit in a transparent manner¹³.

The scenario is supported by the findings from chapter 6 that especially new governance tools rely on the conditions in Member States to unfold such as existing problem pressure or ongoing similar reform efforts. On the one hand, the use of flexible governance tools allows Member States to experiment with different ways how to achieve the broad goals set by the EU, for example towards integrative healthcare system (Sabel & Zeitlin, 2008). On the other hand, the strive of the European Commission for more effective implementation and compliance requires

¹³ Council Directive 89/105/EEC relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems [1989] OJ L42/8

to use more specific tools allowing for less flexibility and discretion of Member States. Given the impact of new governance tools is expected to unfold only in the long-term it remains to be seen whether they will remain framing policies as alternatives to law or will finally unfold more stronger – fulfilling a *para law* function (Senden, 2005).

Scenario 3 The EU is an arena where national decision makers seek information and collaborations to shape developments in their health systems

On the basis of the findings the EU has developed the remit and partly capacities to become such an arena. However, so far the European Commission is the active agent to develop such an arena rather than Member States themselves. Activities of the Commission to offer information and intelligence to Member States include “*preparation of infrastructure by networks and the organisation of data collection and maintenance of the information base*” (Rosenkötter, 2017, p. 151f) to advance an EU health information system. Cooperation in the area of health system information includes joint work with the WHO (financial support to the WHO European Observatory for Health Systems and Policy) and the OECD (OECD, 2010, 2012, 2014). Efforts to provide relevant data and information include the State of the Health in the EU process (OECD/EU, 2016) to collect international available expertise, to tailor it to the needs of Member States and to, finally, support evidence based health policy making. In addition, the Expert Panel on Effective Ways of Investing in Health provides scientific advice how to invest for modern, responsive and sustainable health systems. However, so far opinions by the Expert Panel have been predominantly issued by the Commission itself rather than by Member States. And, anecdotal evidence suggests that EU Member States rather seek advice on specific health system reform plans from WHO Europe experts rather than from the EU. Moreover, the European Commission has issued a number of influential reports (European Commission, 2009; European Commission & European Policy Committee, 2010, 2016) to map the policy challenges ahead for European health systems and hosts a number of expert groups for exchange between Member States. Experts groups include issues such as workforce, quality of care and patient safety, cross-border healthcare (see chapter 6) and Health System Performance Assessment (HSPA).

In terms of facilitating collaboration among Member States the European Commission uses increasingly Joint Actions as financing tools for content work in the 3rd Action programme. Joint Actions require Member States to commit comparatively more financial resource themselves and predominantly governmental stakeholders are joint together rather than universities and research entities. Other areas of cooperation involve the European Reference Networks for rare diseases; 24 EU-wide hospital networks on specific rare diseases have been launched recently. The Joint Procurement initiative for procure medical countermeasures has been set up to allow joint purchasing of medicines. Although 24 Member States have joint the agreement, only one

call for tender has been started in 2016 by five Member States (Azzopardi-Muscat, Schröder-Bäck, & Brand, 2016). Other initiatives have started in a bottom up fashion led by Member States and outside the EU such as Belgium, the Netherlands, Luxemburg and Austria on orphan drugs, the Baltic Partnership Agreement to purchase vaccines and Romania and Bulgaria to buy pharmaceuticals jointly (Espin et al., 2016). Other networks include the eHealth and HTA network. The latter has been funded by the European Commission over the last 15 years using different project funding and there is still hesitation on the side of Member States to move it to a stable infrastructure.

Hence, while a lot of opportunities for information sharing and collaboration have emerged at EU level, there is a hesitant stance by many Member States to engage. Where Member States collaborate across borders a strong need is required to seek partners across the border (Glinos & Wismar, 2013). Other European wide collaborations for information exchange involve the Regions for Health network and the Small Countries initiative under the umbrella of WHO Europe or the Nordic network of the Scandinavian Countries, Finland and Iceland which have long standing traditions of collaboration on various health related domains. Existing examples of collaboration in terms of provision of services include various cross-border initiatives (Glinos & Wismar, 2013). Examples of bi- or multilateral cooperation include the reducing of waiting times by sharing free capacities as it has been practised between the UK, the Netherlands and Belgium on orthopedic surgery (Glinos, Baeten, & Boffin, 2006); steered patient mobility for Maltese cancer patients to Italy or UK (Azzopardi Muscat, Grech, Cachia, & Xuereb, 2006); sharing of highly technical and expensive equipment for diagnostics (e.g. MRIs) between Denmark and Germany (Augustin, Panteli, & Busse, 2013); specialised treatment for burning victims in western Europe, which has been coordinated already several times between Germany, the Netherlands and Belgium, or sharing laboratories capacities in the Mediterranean (Dente et al., 2009).

The mapping of the various initiatives and opportunities for information exchange and collaboration demonstrates that such an EU-level arena is emerging. However, based on the overall perceived reluctance of Member States to engage, it remains open whether the European Union context involving all Member States is always the best approach to collaboration on health systems or if initiatives based on local proximity (e.g. EPIsouth in the Mediterranean, the Nordic Network) or similar characteristics (e.g. WHO Small States initiative, European Regional and Local Health Authorities) may be better suited for fruitful collaboration among European countries. To some degree the EU has accounted for such kind of flexibility and willingness of Member States to participate for example in the Joint Procurement Initiative and the financing of Joint Actions. Finally, at several instances in this thesis and beyond, it has been demonstrated that EU arena is not neutral and that EU involvement has added an economic growth rational to health systems reforms (chapter 2), that domestic policy makers are required

to use “other reference frameworks” in approaching healthcare dossiers with links to EU activities (chapter 6) and that the Country Specific Recommendations have focused much more on sustainability goals than on quality or access (Azzopardi-Muscat et al., 2015). Member States need to understand these non-health policy framings to be able to handle and adapt to their health system policies.

7.4 Limitations

This thesis is rooted on qualitative research methods in order to answer the what, how and why questions with regard to the development of health system governance in EU policies and its influence on Member States. In the following, limitations of qualitative research, the chosen case study method and the criteria for EU governance will be discussed.

Qualitative research

Qualitative research requires the researcher to be reflective about the stance taken, hence his/her own beliefs and positions (Bryman, 2012). This research has predominantly taken a health policy perspective towards the problem solving and decision making capacity of the European Commission in chapter 2, 3 and 4. The analysis covered policy actions regarding health systems and hospitals specifically that could be linked to the European Commission’s Directorate General for Health (DG SANTE). While there is confidence that DG SANTE is a key player for policy making at EU level, it needs to be acknowledged that responsibilities are scattered (Greer et al., 2014). Hence, relevant capacities for problem solving and decision making on health systems and hospitals at the European Commission exists also in other Directorate Generals such as those linked with social or internal market policies. See Figure 4.1 in chapter 4 for a more comprehensive overview.

The selection of interview partners for chapter 4 and 6 is based on a purposive sampling method involving snowball sampling in order to retrieve critical cases which are rich sources of information (Polit & Beck, 2004). This means interviews involved “experts” predominantly actively involved about EU issues and many of them being rather Europhile, although the selected sample in both studies also involved interview partners who were critical about EU actions and the EU’s involvement in healthcare policy. While there is the risk of biases and limited generalisability of the findings inherent to purposive sampling (Polit & Beck, 2004), in both cases we ensured a heterogeneous sample by selecting interview partners based on different functions, backgrounds or countries they were based in. The initial analysis of interview data in both studies was done independently in the first step by two (chapter 6) respectively three investigators (chapter 4) with the help of a deductive analysis framework (Hsieh &

Shannon, 2005; Mayring, 2000; Ritchie & Spencer, 1994) to ensure confirmability. In both studies, a step wise approach analysing interview by interview before moving to a comprehensive analysis across interviews, has been performed jointly by the involved investigators. Moreover, in chapter 4 interview data has been triangulated with findings from a literature search and document analysis. In chapter 6 interview data has been checked against insides from Europeanisation and EU compliance research (Falkner, Treib, Hartlapp, & Leiber, 2005).

Case study research

Within case study research the main occupation is to establish internal consistency, rather than generalisability or transferability, although from a critical realism perspective if one can define the structures or scope conditions a careful inference to other similar cases is possible (Bryman, 2012; Rohlfing, 2012). The case of hospitals is certainly a most-likely case within the health sector given the conditions listed in the introduction. Nevertheless, a careful application of especially the findings regarding problem solving and decision making capacities may be possible to other areas of healthcare such as primary care, mental health services, long-term care, child healthcare or psychiatric care where the EU equally does not have legal competencies. Especially, increasingly EU soft law documents and policy actions concern other than the hospital setting in the move from a hospital centred healthcare systems towards an integrated healthcare system (Council of the European Union, 2011). This includes for example the broadened research setting beyond hospitals of EU funded projects, the latest version of the European Commission Joint Report (European Commission & European Policy Committee, 2016), studies of the Expert Panel on Effective Ways of Investing in Health¹⁴, the reflexion processes of the Working Party on Public Health at Senior level (WPPHSL) (Council of the European Union, 2010, 2011) or the work on mental health (European Commission, n.d.). These EU actions help to elucidate the needs and problems in those non-hospital areas often by means of ongoing comparative analysis.

In contrast, the amount of EU hard law directly applicable to the other mentioned areas is expected to be lower compared to the hospital case. Reasons involve the variety of activities hospitals are involved in, the direct relevance of the newly established European Reference Networks or the financial relevance (see chapter 1 Introduction). Therefore, the overall impact of EU hard law in terms of increased requirements is expected to be lower outside the hospital sector, at least in the short and mid-term perspective.

¹⁴ Commission Decision 2012/C 198/06 of 5 July 2012 on setting up a multisectoral and independent expert panel to provide advice on effective ways of investing in health [2012] OJ C198/7; for the specific studies see http://ec.europa.eu/health/expert_panel/home_en

Moving beyond output criteria of EU governance

This analysis for legitimisation of EU governance on hospitals is based on the output criteria of problem solving, decision making and compliance. It has left aside an in-depth analysis of the input criterion of how democratic a EU healthcare agenda is (Baldwin et al., 2012).

In general, the EU has been accused of a democratic deficit regarding its decision making processes due to limited parliamentary oversights, limited influence on the policy making process in the multilevel structure of the EU and limited possibilities for public participation (Knill & Lenschow, 2003).

With regard to EU's health policy the introduction to this thesis makes clear that the **public mandate** for healthcare is felt to be not with the EU but at the core of national and regional governments and that citizens feel connected to their national political representatives due to healthcare. However, EU Framework Directives and Open Method of Coordination (OMC) like regulation is supposed to be supporting the public mandate given they rely on democratic decision making structures in Member States (Knill, 1998). From a health policy perspective and in view of Article 168(7), TFEU much that has come out of DG SANTE is OMC-style policies relying on national decision making. Moreover, Chapter IV of the Patients' Rights Directive¹⁵ is written in the style of a Framework Directive laying down the areas, general aims and principles for cooperation but the actual implementation is left quite flexible to Member States at first sight (see chapter 5). On the contrary, few interview partners in the hospital study (chapter 6) pointed to the fact that the flexible provisions in the Chapter IV of the Directive may be hardened by the Commission during the enforcement process with the help of implementing acts. Moreover, the development of specific evaluation tools is foreseen in the attempt for effective, accessible and resilient health systems (European Commission, 2014a). Finally, the process and thematic priorities of the health related Country Specific Recommendations neither support the democratic legitimacy of EU health system governance.

Ensuring a **due process** in EU governance of healthcare – the scope of participation of those affected by the implementation of EU law – is demanding given the large-scale delegation of tasks of providing, financing and partly regulating healthcare to non-governmental actors especially in corporatist and social health insurance types of European healthcare systems. In NHS systems the scope may be smaller given the healthcare system is belonging to the governmental sphere; although in many systems private parallel systems of insurance and provision of services have developed meanwhile. Moreover, the dispersed responsibilities at EU and national level may support the picture as suggested in chapter 6; interview partner agree that EU hard law with relevance for the hospital sector is generally not perceived as EU based by

¹⁵ Directive 2011/24/EU (n 2)

hospital managers. Other well-known examples that have come as a “surprise” to national health policy actors are the inclusion of health services in the proposal of the General Service Directive (Bolkestein Directive)¹⁶ and the European Working Time Directive¹⁷. The relevance for healthcare and hospital got only clear when the documents were published and passed respectively.

On the other hand, the EU policy process is deemed to be more open and responsive to stakeholder opinions than policy processes at national level. Interview partners in chapter 4 argued that the space for public participation has been used unproportioned by well-staffed industry representatives rather than public health advocates struggling with limited budgets. However, especially DG SANTE is known to have nurtured own public health advocacy groups via the Action programmes (Lamping & Steffen, 2009) in order to have a balanced input of views on their initiatives. Moreover, the Patients’ Rights Directive has obligated NCPs to cooperate with relevant stakeholders in Member States in order to achieve its objectives. Next to being member of European organisations representing their views in Brussels national provider organisation, insurances or health industries especially from well-staffed countries have their own European affairs representative or office in Brussels.

A prime source for the EU’s democratic deficit was the low level of parliamentary control over EU rule making. **Accountability** has been strengthened by the Lisbon treaty; the EU Parliament has become a full co-legislator in the co-decision procedure and the national chambers becoming the watch dog on the subsidiarity principle. However, national parliaments’ engagement is still selective on salient cases despite “*having arrived in Europe*” (Auel & Christiansen, 2015). The EU parliament is known to have taken multiple times the role of the advocator to safeguard the (healthcare) rights of workers and citizens or ensuring safe living conditions for European citizens. The patients’ rights rulings by the European Court of Justice (ECJ) have been identified by an expert panel as an influential health policy output (Rosenkötter, Clemens, Sørensen, & Brand, 2013). With this series of decisions the ECJ ensured the accountability of national governments regarding the right to free movement as a patient. Moreover, its role to ensure accountability over a due process at EU level has become clear as well by its ruling to annul the first tobacco advertising directive (Boessen & Maarse, 2008; Tridimas & Tridimas, 2002).

¹⁶ Draft Directive of 13 Jan 2004 on services in the Internal Market, COM (2004)

¹⁷ Directive 2003/88/EC of 4 November 2003 concerning certain aspects of the organisation or working time [2003] OJ L 299/9

7.5 Recommendations for research and policy

Further research should seek to analyse how new governance tools – in the EU’s attempt for more effective health policy making by enhancing compliance in Member States – are taking effect in national arenas. In this regard, an assessment is needed, for example of:

- the Joint Actions, a financing tool DG SANTE is increasingly using,
- the National Reform Programmes in response to the Country Specific Recommendations for policy prioritisation, and
- health system performance assessment tools,

in respect of their the problem solving capacity and compliance in Member States. Equally important, a monitoring of their output legitimisation is desirable regarding their democratic quality. Both factors are in so far important as EU new governance should be aimed at sharing of tasks in a way that the definition of broader policy frameworks and the monitoring thereof is left to the EU and Member States are tasked to flesh out the frameworks practically with a wide discretion of the employed tools and mechanism to accomplish those goals (Sabel & Zeitlin, 2008).

Furthermore, there is a need to monitor how changes in the hospital setting require changes in the joint governance of hospital systems. The emergence of private hospital chains or (public) hospital cooperation of very different kinds requires understanding how a larger number of connected hospitals will react to regulatory and financial reforms rather than a single hospital. Besides this, the neat distinction in primary, secondary and tertiary level hospitals is dissolving. On the one hand, there is development towards very specialised hospitals providing a limited set of procedures. On the other hand, hospitals have diverted procedures towards providing ambulatory and rehabilitative treatments or offering supportive services to care providers outside the direct hospital environment (e.g. using eHealth or telemedicine). It remains open if they will react in a uniform and desired fashion to existing regulatory tools aimed at hospitals.

This thesis provides evidence that national health policy makers are aware of the structural relevance of the EU for their decision making regarding health systems and hospitals. It is recommended that the national policy makers develop a pro-active and systematic way to cope with these influences in order to be early able to accommodate EU frameworks into their national agendas and keep disruptive effects at a minimum. Practical solutions to insular EU influences in an ad-hoc fashion seem to have worked in the past but given the structural nature of EU governance this is not likely to stay. It will require ending the hesitation to get involved because of the fear to further legitimise EU action regarding health systems. An increased involvement of national health policy actors at EU level would strengthen the role of health

actors at EU level *vis-a-vis* other players. A stronger voice of health actors is needed especially in the context of the European Semester and the Country Specific Recommendations (Azzopardi-Muscat et al., 2015; Baeten & Vanhercke, 2017).

7.6 Conclusions

This thesis has stated that a comprehensive and relevant EU agenda for national decision makers regarding hospitals is emerging; insular health policy dossiers dealt by the EU have been extended and dovetailed more and more in the last 20 years. However, at the same time there is evidence that Member States are still in the driver's seat for their hospital policies and that core hospital services are only little affected by EU law. Few and insular changes in the organisation of domestic hospitals are directly linked to EU laws (e.g. European Working Time Directive, Patients' Rights Directive) and may depend on the national policy context. More systematically the EU is increasingly influencing the context in which hospital policy is made and built on. EU policies are more and more taken into account when reforms are made – something that was uncommon some years ago. The EU as an arena for genuine hospital policy is providing the intelligence for assessing current hospital structures, acting as spin doctor for innovations and policy directions, providing seed money for testing out practical applications and is a forum for exchange of domestic decision makers. In many instances it is up to the discretion of Member States to take up ideas and initiative. In case they do so, Member States should be aware that the EU role as in hospital policy is not neutral but involving own larger policy rationales of the EU itself.

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Valorisation Addendum

Valorisation

This dissertation was finalised when the EU started to reflect after a period of crises (financial and sovereign debt crisis, migration crisis, Euroscepticism and Brexit) to give contours to the shared future of European societies. In order to pave the way for the next decade and to address the challenges ahead the European Commission has proposed the Future of Europe scenarios (European Commission, 2017a; 2017b). On the one hand, the Europe 2020 agenda and the Juncker Commission have placed economic goals as the sole priority as a reaction to the financial and sovereign debt crisis above social and other end points (European Commission 2014a; Bongardt & Torres, 2010). On the other hand, the Commission continues to aim for the realisation (as well in a self-interested way) of practical benefits of its work to the European citizens. Recently (spring 2017), the end of roaming charges and the establishment of European Reference Networks for Rare Disease treatment have been hailed as such practical successes. We may easily have forgotten that above all red tape produced by the EU, the quality of our drinking water, limits to the exposure to carcinogens and safe medicinal products are regulated by the EU, as well.

At the very start of this dissertation healthcare was sketched as being perceived as a very local phenomenon. The results of the studies provide evidence that this is slightly different regarding the domain of governance to health systems. The results of this dissertation are of relevance to Member States' governments, since it raises the awareness of the role of the EU. Thereby, national governments are encouraged to continue or expand even further the horizon scanning of EU initiatives regarding the impact for hospitals and health systems and to broaden existing lobby activities for hospitals and health system positions. The examples of the amended Professional Qualifications Directive¹ and the exceptions for hospitals to the Radiation Directive² and EU Emission Trading System (EU ETS) demonstrate that it is possible to bargain for the recognition of health system specificities at EU level. At the same time, the results are an invitation to national decision makers to overcome the hesitation and explore the European route – not for the sake of European collaboration – but in order to solve their domestic problems and challenges in a smart way in Brussels when EU involvement is beneficial to sole national actions and European added value can be easily grasped.

For the European Commission the results are of relevance in the design of their health policies towards its goals of effective, accessible and resilient health systems (European Commission, 2014b). The results suggest that the Commission needs to make a delicate compromise between

¹ Directive 2013/55/EU amending Directive 2005/36/EC on the recognition of professional qualifications

² Directive 2013/35/EU on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields)

stronger tools to demonstrate effects of their policies within Member States and returning to only providing the overall policy direction with the practical design and implementation being left largely to Member States. In addition, the findings indicate that the European Commission is using other reference frameworks in the formulation of their health system policies compared to Member States which hampers the level of implementation. Ex-ante evaluation performed by the Commission should place more emphasis on the value or policy context in which new EU legislation is likely to evolve within Member States.

Moreover, the research results of this dissertation are of prime interest to various stakeholders involved in health systems and hospital policy making. One of the published articles included in the dissertation (chapter 3) is co-authored by representatives of relevant advocacy and interest representation organisations based in Brussels. The co-authors are staff members of the European Hospital and Healthcare Federation (HOPE) and the European Centre for Health Assets and Architecture (ECHAA) indicating the relevance for their work and member organisations. The work on this chapter and chapter 2 prepared the ground for an editorial in the British Medical Journal (BMJ) on “Austerity policies in Europe – bad for health”. Departing from an assessment of the immediate health effects in Spain and Greece the editorial argued that “health protection within the EU mandate is more relevant than ever” (Brand, Rosenkötter, Clemens & Michelsen, 2013, p. f3716).

The research on the assessment of National Contact Points of cross-border healthcare (chapter 5) has caught the attention and received the support by European Patients Empowerment for Customised Solutions (EPECS), a network of regional patient organisations. EPECS has provided manpower and logistics to the study as to understand how the patient information portal and support structures are organised in various countries and how collaboration among National Contact Points is emerging. It contributed to EPECS’s aims of empowering patients, to know their rights and actively engage in the clinical decision making process. The results have been further presented at a symposium of the Active Citizenship Network, an Italian Patient organisation in March 2016 and at the master class at the European Institute of Public Administration (EIPA). Furthermore, the research has informed the application for a European Commission funded tender on mapping patients’ rights in 30 countries in Europe which has been granted to the Department of International Health as lead partner. The work on the mapping exercise throughout 2015 added insights to the patients’ rights’ situation in all 28 Member States, Norway and Iceland in regard to basic patients’ rights, consumer-oriented rights and procedural and information rights.

Furthermore, a number of the policy advisors and hospital managers included in the interview study (chapter 6) demonstrated interest in the expected results and requested to receive a copy of the article once published. The European Association of Hospital Managers (EAHM) offered to

include a contribution in their organisation's magazine E-hospital to bring the findings to the attention of their members. The same study has received support by euPrevent, a regional public health actor with the aim of facilitating cross-border collaboration between professionals and organisations in the Euregio Meuse-Rhine, because they regarded the work to support their patient empowerment programme.

With regard to future possibilities for valorisation the following section outlines three practical approaches for developing a better understanding of how health system governance is taking place between the European Union and Member States and how this knowledge could be further disseminated among different users.

A virtual reader on European Public Health

University students often find it difficult to grasp what European Public Health actually is or entails. Parts of the dissertation are intended to be used to establish a (virtual) reader on European Public Health. The reader could follow the logic of the Department of International Health's conceptualisation of European Public Health into Public Health in Europe³, European Public Health⁴ and Global Health Europe⁵ and could cover contributions spanning from public health, healthcare to health policy related topics. Chapters from this dissertation qualify as contributions for either Public Health in Europe or European Public Health, on the topics of the healthcare and health policy. The virtual reader could mainly be offered to Maastricht students by incorporating the material in the curriculum of the Bachelor programme European Public Health and Master programme Governance and Leadership in European Public Health and it could be accessible to other interested educational institutes and persons as well.

Short courses on Health governance in Europe at the UM Brussels campus

University based public health and health management programmes increasingly include and teach the European aspects to the organisation of healthcare. However, not only students should have an understanding of the interplay between the EU and Member States. Especially, civil servants, policy advisors and assistants working in Brussels-based institutions that deal with European health policy making on a day-to-day basis, should have a basic understanding of the rationale, structures and pressures within healthcare systems in Europe and the potential effects EU governance on them. Many policy makers that deal with health are initially trained in public administration, law or European studies where health as domain for policy making is often not considered in the context of the EU because of its incomplete mandate. Based on the research

³ Public Health in Europe describes the different Health Systems in Europe, analyses their performance and tries to find best practice solutions.

⁴ European Public Health concentrates on European solutions of health problems which involve several Member States or are cross cutting issues.

⁵ Global Health Europe looks at Europe as a zone that has to interact with the outside world.

of the dissertation and the education principles of Maastricht University a modular short-course focusing on health policy making could be offered including modules such as

- data sources and use of evidence in medicine and health service planning
- pressures and reform trends in European health systems
- role and function of healthcare actors
- knowledge translation in health and implementation of health innovations
- intersectoral governance for health (at EU level).

This could be offered at the UM Brussels campus in combination with a practical project to apply the acquired knowledge and skills within the participants' organisations.

A European or Euregional Expertise Centre for healthcare

This dissertation has provided evidence that not only patients but also healthcare institutions such as hospitals are not aware of the European influences that play in their daily operations either due to their activities covered by European law or because of cross-border activities. The European or Euregional Expertise Centre for healthcare could act as a contact point for knowledge generation and exchange advising and/or training healthcare institutions and individual persons on cross-border patients and service provision and the application of EU law in practical matters. The Expertise Centre could collaborate with internal and external partners to establish the needed expertise. Within Maastricht University, this could include expertise from the Faculty of Health, Medicine and Life Sciences and the Faculty of Law. External collaboration could involve the National Contact Points for cross-border healthcare, European and domestic healthcare associations, national competent authorities (such as on health professional qualifications) and existing cross-border information points on social security issues.

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Summary

Samenvatting

Zusammenfassung

Summary

Health system governance in Europe: the case of hospitals

European healthcare systems are occupied progressively with questions of governance. Throughout the last decades various reforms have increased the complexity of the systems' structures by inter alia the introduction of integrated care arrangements, healthcare markets or provider networks. Attention and reform efforts have shifted therefore from a health system outcomes perspective towards understanding the processes and capacities in a health system to produce well-designed policies and decisions in terms of health system reforms, crisis responses and implementation of routine tasks.

At the same time, both the applicability of EU law principles to national law governing healthcare and a broader agenda for discussing healthcare system issues at EU level has emerged. This is in contrast to the limited healthcare mandate that the EU has based on Article 168 of the Lisbon Treaty. However, regulations of the internal market on pharmaceuticals, medical devices or health professionals and rules of competition law, have applied in an insular manner to health systems or hospitals for decades. As a consequence, the transposition of EU legislation and the uptake of EU level discussions into national health system policies, are supposed to influence more and more the domestic governance and the design of healthcare systems, as well.

This dissertation includes a series of separate scholarly papers that all address different aspects of health systems governance at the EU and Member State level. The central research aim has been how health system governance is developing in EU policies and what the effects for domestic hospitals are. The concept of governance is understood as "the general exercise of authority" implying the ways how one can steer or direct. The governance perspective allowed identifying a number of critical factors to evaluate the role of the EU vis-à-vis its Member States. This dissertation is based on qualitative research methods in order to analyse the contextual factors and interactions of laws, policy making and actors at the level of the EU and its Member States.

The case of hospitals has been chosen for three reasons. First, hospitals still play an important role in the domestic healthcare system they operate in. This includes not only the provision of a wide array of services, from basic to highly-specialised ones, but also carrying out health professionals' training and clinical and health services research functions. In addition, hospitals still consume a large share (35-70%) of a country's overall health budget. Secondly, because of the various tasks and roles, applicability of EU laws and activities to the hospital setting is more direct and common. Thirdly, due to societal (demographic change, part-time workers),

technological (eHealth) and health policy developments (reconstruction towards primary care-led systems) the hospitals sector is frequently under pressure to reform.

The studies in this dissertation are grouped in three parts following the output criteria for legitimising EU governance including (1) the problem solving capacities, (2) the capacities for decision making, and (3) the implementation and compliance at national level.

The **problem solving** capacities have been assessed by literature and document reviews focusing on health system objectives at large and on the objectives of hospital reforms in particular during the financial crisis at national and European level. The evidence collected reveals that the EU is stimulating structural hospital reforms by providing evidence of the current and future pressures and by (providing financial support for) testing out potential solutions. At the same time, the EU emphasises the economic rationale for health systems reforms comparatively stronger. In how far EU stimuli can effectively support problem solving in Member States, has been questioned given the strong subsidiarity principle in place for health systems and the predominant financial consolidation rationale at EU level. In fact, during the financial crisis Member States have turned to quick-fix solutions to lower operational cost in hospitals. The macro-economic and political conditions in Member States – and partly favoured by the EU – have largely not been conducive for structural reforms.

The assessment of the DG SANCO's¹ **capacities to take decisions** regarding public health and health systems demonstrated that the health system agenda has been enlarged over the years, but that structural conditions limiting its decision capacities are still in place. The combination of a literature review, document analysis and interview data established that DG SANCO has shown to be able to steer the agenda, assess a situation and take decisions on various dossiers. The evidence was mixed on capacities for implementation and evaluation. It remains to be seen whether DG SANTE is able to deliver better impacts of its policies by means of better priority setting, clearer targets and stronger implementation tools.

The analysis of **implementation and compliance** with EU provisions focused, firstly, on the implementation of Directive 2011/24/EU regarding National Contact Points for cross-border healthcare by means of a website analysis in all Member States. Secondly, the impact of EU hard law and new governance tools on domestic hospitals and hospital policy in Belgium, Germany and the Netherlands has been researched based on an interview study with key informants. The results showed that EU hard laws are complied with in national hospitals, although they do not touch the core of hospitals activities: the care provision to patients. EU hard law is perceived to

¹ Here, I refer to DG SANCO in connection with the analysis in chapter 4, which has assessed the period from 1999 to 2014. With the Juncker Commission taking office in November 2014 the Directorate General responsible for health has been renamed to DG SANTE, DG Health and Food Safety. I refer to DG SANTE regarding the linked recommendations.

have increased the requirements for documentation, infrastructure, education and procedures. In many cases this increases the operational costs for hospitals. New governance tools take effect in Member States' health policy as a starting point for a political discussion or trigger to initiate action, if they match an existing problem pressure or provide new tested ideas and solutions in the domestic policy arena. National decision makers in Belgium, Germany and the Netherlands perceive their decision latitude being reduced by EU law and policies and increasingly monitor relevant EU activities. Nevertheless, national compliance to EU new governance influences remains rather ad hoc, so far.

This dissertation concludes that despite a comprehensive and relevant emerging EU agenda regarding hospitals that Member States are still in the driver's seat for their hospital policies. The EU is increasingly influencing the context in which hospital policy is made by providing the intelligence for assessing current hospital structures, acting as spin doctor for innovations and policy directions, providing seed money for testing out practical applications and is a forum for exchange of domestic decision makers. Nevertheless, in many instances it is up to the discretion of Member States to take up ideas and initiative.

Samenvatting

Bestuur van gezondheidsstelsels in Europa: case study ziekenhuizen

Europese gezondheidszorgstelsels houden zich in toenemende mate bezig met vraagstukken ten aanzien van bestuur. Ten grondslag hieraan ligt de toegenomen complexiteit van systeemstructuren als gevolg van diverse hervormingen in de afgelopen decennia, waaronder o.a. de invoering van geïntegreerde zorgmodellen, marktwerking in de gezondheidszorg en dienstverlenende netwerken. Aandacht en hervormingspogingen zijn verschoven van het louter bereiken van doelen naar het begrijpen van processen en competenties in een gezondheidssysteem. Hiermee kan weldoordacht beleid en besluitvorming voor wat betreft gezondheidshervorming, reactie op crisis en het implementeren van routinematige handelingen, vormgegeven worden.

Tegelijkertijd is toepasbaarheid van EU-regels en –richtlijnen op het nationale recht voor wat betreft gezondheidszorg en een agenda met ruimte voor discussies over gezondheidsstelsels, hieruit voortgekomen. Dit is in contrast met het beperkte gezondheidsmandaat van de EU, gebaseerd op Artikel 168 van het Verdrag van Lissabon. De regulering van de interne markt voor medicijnen, medische producten of gezondheidsprofessionals en regels voor mededingingsrecht is echter decennialang op onsamenhangende wijze toegepast op gezondheidsstelsels of ziekenhuizen. Het gevolg hiervan is dat het omzetten van EU-wetgeving en het overnemen van de op EU-level gevoerde discussies naar nationaal gezondheidsbeleid, ook meer en meer van invloed zouden moeten zijn op bestuur en vormgeving van nationale gezondheidssystemen.

Dit proefschrift omvat een serie afzonderlijke wetenschappelijke teksten die diverse aspecten van het bestuur van gezondheidsstelsels op EU- en lidstaatniveau behandelen. Het centrale doel van dit onderzoek was om te laten zien hoe het bestuur van gezondheidsstelsels zich ontwikkelt binnen EU-beleid en wat de effecten zijn voor ziekenhuizen in de lidstaten. Onder het begrip ‘bestuur’ wordt ‘de algemene uitoefening van gezag’ verstaan: de manier waarop wordt aangestuurd en geleid. Vanuit het begrip bestuur is een aantal kritische factoren geïdentificeerd om de rol van de EU ten opzichte van de lidstaten te beoordelen. Om de contextuele factoren en interacties van wetgeving, het beleidsvormingsproces en spelers op het niveau van de EU en haar lidstaatniveau te kunnen analyseren is dit proefschrift gebaseerd op kwalitatieve onderzoeksmethoden.

De focus op ziekenhuizen is om drie redenen gekozen. Ten eerste spelen ziekenhuizen een belangrijke rol in binnenlandse gezondheidssystemen waarin zij opereren: o.a. (1) in het voorzien in een breed scala van dienstverlening van basis tot hooggespecialiseerde dienstverlening, (2) als zijnde de setting waarin opleiding van een variëteit aan gezondheidsprofessionals en onderzoek

plaatsvindt; en (3) het consumeren van een groot deel (35-70%) van het totale gezondheidsbudget. Ten tweede is de toepasbaarheid van EU-wetgeving en -activiteiten in een ziekenhuissetting steeds meer directer en normaler vanwege de variatie in taken en rollen. Ten derde is de ziekenhuissector vaak gedwongen tot hervorming door de sociale (demografische wijzigingen, deeltijdwerkers) en technologische (eHealth) ontwikkelingen alsmede ontwikkelingen op het gebied van gezondheidsbeleid (verschuiving naar eerstelijns gestuurde zorgsystemen).

Het onderzoek van dit proefschrift bestaat uit drie delen, conform de output criteria voor rechtvaardiging van EU-bestuur, zijnde (1) probleemoplossend vermogen, (2) capaciteiten die leiden tot besluitvorming en (3) de implementatie en naleving op nationaal niveau.

Het **probleemoplossend vermogen** is onderzocht op basis van beoordeling van literatuur en documenten die zich concentreren op de doelen van een gezondheidsstelsel en de doelstellingen van ziekenhuizen voor wat betreft hervorming op nationaal en Europees niveau, gedurende de financiële crisis. Het onderzoek toont aan dat de EU structurele ziekenhuishervormingen stimuleert door te laten zien hoe de huidige en toekomstige problematiek is en door (het geven van financiële ondersteuning voor) het uitproberen van mogelijke oplossingen. Tegelijkertijd benadrukt de EU, verhoudingsgewijs, de economische beweegredenen voor hervormingen van gezondheidsstelsels steeds meer. In hoeverre de EU-stimulans ook echt ondersteuning geeft aan lidstaten voor het oplossen van problemen, is maar de vraag gezien het sterke subsidiariteitsprincipe op het vlak van gezondheidsstelsels en de overheersende principes van financiële consolidatie op EU-niveau. In feite hebben de lidstaten gedurende de financiële crisis gebruik gemaakt van korte termijnoplossingen om de operationele kosten van ziekenhuizen te verlagen. De macro-economische en politieke voorwaarden in lidstaten – gedeeltelijk gevoed door de EU – zijn grotendeels niet bevorderlijk voor structurele hervormingen.

Het onderzoek naar DG SANCO's² capaciteiten die leiden tot besluitvorming inzake volksgezondheid en gezondheidsstelsels, toonde aan dat de gezondheidsagenda door de jaren heen is uitgebreid, maar dat structurele voorwaarden die de besluitvorming beperken nog steeds van kracht zijn. De combinatie van een literatuuronderzoek, documentenanalyse en gegevens uit interviews lieten zien dat DG SANCO heeft bewezen dat ze de agenda dirigeren, een situatie analyseren en politieke beslissingen kunnen nemen met betrekking tot verschillende dossiers. Ten aanzien van de capaciteiten voor implementatie en evaluatie gaf het onderzoek geen eenduidigheid. Het blijft te bezien of DG SANTE in staat is een betere werking van haar

² Ik verwijs hier na DG SANCO met betrekking tot de analyse in hoofdstuk 4, die de periode 1999-2014 onderzocht. Met de ingang van de Commissie Juncker in november 2014, is de naam van het Directoraat-Generaal verantwoordelijk voor gezondheid gewijzigd in DG SANTE, Gezondheid en Voedselkwaliteit. Ik verwijs naar DG SANTE bij de aanbevelingen.

beleid te bewerkstelligen door een betere prioriteitenstelling, duidelijkere doelen en sterkere implementatietools.

De analyse met betrekking tot **implementatie en naleving** van de EU-regelgeving concentreert zich, ten eerste, op het invoeren van Richtlijn 2011/24/EU inzake Nationale Contact Punten voor grensoverschrijdende gezondheidszorg. Het onderzoek vond plaats door middel van een websiteanalyse in alle lidstaten. Ten tweede, is de impact van collectieve EU-wetgeving en nieuwe bestuursmogelijkheden voor nationale ziekenhuizen en ziekenhuisbeleid in België, Duitsland en Nederland onderzocht gebaseerd op een interviewstudie met mensen op sleutelposities. De EU-regelgeving wordt toegepast in nationale ziekenhuizen alhoewel deze niet de kernactiviteit van ziekenhuizen (de zorg voor patiënten) betreft. De EU-regelgeving wordt verbonden met verhoogde eisen voor documentatie, infrastructuur, educatie en procedures. In veel gevallen verhoogt dit de operationele kosten van ziekenhuizen. Nieuwe bestuursinstrumenten laten in het gezondheidsbeleid van lidstaten een startpunt zien voor politieke discussie of brengen nieuwe initiatieven op gang, indien ze passen bij de bestaande problematiek of nieuw geteste ideeën en oplossingen in de nationale beleidsarena bieden. Nationale beleidsmakers in België, Duitsland en in Nederland zien hun besluitvormingsruimte als ingedamd door EU-wetgeving en beleid en houden de EU-activiteiten nauwgezet in de gaten. Desalniettemin blijft het toepassen van de invloeden van de het nieuwe EU-bestuur, tot nu toe, op ad hoc basis.

Dit proefschrift concludeert dat, ondanks het feit dat een brede en relevante EU-agenda voor ziekenhuizen verrijkt, de lidstaten nog steeds aan het roer staan van het ziekenhuisbeleid. In toenemende mate beïnvloedt de EU de context waarin ziekenhuisbeleid is gemaakt door te voorzien in de informatie ter beoordeling van het huidige ziekenhuisstelsel, ideeën aan te dragen voor innovatie en beleidsrichtingen, startkapitaal te bieden voor het testen van praktische applicaties en beschikbaar stellen van een forum voor uitwisseling tussen nationale beleidsmakers. In veel gevallen is het toch aan de lidstaten om ideeën te opperen en initiatieven te nemen.

Zusammenfassung

Gesundheitssystemsteuerung in Europa: eine Fallstudie zu Krankenhäusern

Europäische Gesundheitssysteme sind zunehmend mit Fragen der Steuerung beschäftigt. Während der letzten Jahrzehnte haben verschiedene Reformen die Komplexität von Systemstrukturen erhöht, unter anderem durch die Einführung von Integrierten Versorgungsmodellen, Gesundheitsmärkten oder Dienstleister-Netzwerken. Die Aufmerksamkeit und Reformbemühungen haben sich dabei von der alleinigen Sorge um Ergebniserzielung verschoben, hin zum Verständnis von Prozessen und Kapazitäten in einem Gesundheitssystem, um gut-gestaltete Politiken und Entscheidungen in Bezug auf Gesundheitsreformen, Krisenreaktionen und der Einführung von Routineaufgaben zu entwickeln.

Gleichzeitig, ist die Anwendbarkeit der Prinzipien des EU Gemeinschaftsrechts auf die nationale Regulierung von Gesundheitssystemen sowie eine breitere politische Diskussion über Gesundheitssysteme auf EU Ebene zutage getreten. Dies steht im Gegensatz zu dem eingeschränkten Gesundheitssystemmandat der EU auf der Grundlage von Artikel 168 des Vertrages von Lissabon. Jedoch, besteht die Anwendbarkeit der Regulierungen des EU Binnenmarktes zu Medikamenten, Medizinprodukten oder Gesundheitsberufen sowie den Regeln des Wettbewerbsrechts auf Gesundheitssysteme und Krankenhäuser inselartig schon seit Jahrzehnten. Als Konsequenz wird vermutet, dass die Umsetzung der EU Gesetzgebung und die Übernahme von auf EU-Ebene geführten Diskussionen auch zunehmend die Steuerung und die Ausgestaltung von nationalen Gesundheitssystemen beeinflusst.

Diese Dissertation umfasst eine Reihe von einzelnen wissenschaftlichen Texten, die alle verschiedene Aspekte von Gesundheitssystemsteuerung auf EU- und Mitgliedsstaatenebene behandeln. Das zentrale Forschungsziel war zu ermitteln, inwiefern sich das Thema der Gesundheitssystemsteuerung in EU-Politik entwickelt und welche Auswirkungen für nationale Krankenhäuser entstehen. Das Konzept der Governance als "allgemeine Ausübung von Amtsgewalt" beinhaltet die Art und Weise, wie man steuert und führt. Die Governance Perspektive erlaubte die Identifizierung von einer Anzahl kritischer Faktoren, um die Rolle der EU gegenüber den Mitgliedstaaten zu bewerten. Diese Dissertation basiert auf qualitativen Forschungsmethoden, um die kontextbezogenen Faktoren und Interaktionen von Gesetz, Politikmachen und Akteuren auf EU und Mitgliedsstaatenebene zu untersuchen.

Das Fallbeispiel der Krankenhäuser wurde aufgrund von drei Faktoren gewählt. Erstens nehmen Krankenhäuser noch immer eine wichtige Rolle in den heimischen Gesundheitssystemen ein, in denen sie tätig sind. Dies schließt die Erbringung von einer Vielzahl von einfachen zu hoch-spezialisierten medizinischen und Pflege-Leistungen und den Verbrauch von einem großen Anteil

(35-70%) des allgemeinen Gesundheitsbudgets, ein. Daneben sind Krankenhäuser das Setting, in dem die Ausbildung von verschiedenen Gesundheitsberufen sowie die klinische und Versorgungsforschung stattfindet. Zweitens ist wegen ihrer verschiedenen Aufgaben und Rollen die Anwendbarkeit von EU Gesetzen und Aktivitäten auf den Krankenhausbereich direkter und verbreiteter. Drittens, sieht sich der Krankenhaussektor wegen sozialer (Demografischer Wandel, Teilzeitarbeit), technologischer (E-Health) und gesundheitspolitischen Entwicklungen (Umbau hin zu Primärversorgungs-geführten Systemen) oft zu Reformen genötigt.

Die Forschungsarbeiten in dieser Dissertation sind in drei Bereiche eingeteilt, die den Output-Kriterien zur Legitimierung von EU Governance folgen: (1) Problemlösung-Kapazitäten, (2) Kapazitäten zur Entscheidungsfindung und (3) die Implementierung und Einhaltung auf nationaler Ebene.

Die **Problemlösung-Kapazitäten** wurden durch Literatur- und Dokumentenreviews untersucht, die sich auf Gesundheitssystemziele im allgemeinen und den Zielsetzungen von den Krankenhausreformen im speziellen während der Finanzkrise auf nationaler und EU-Ebene konzentrierten. Die Analyse der verschiedenen Quellen zeigt, dass die EU Strukturreformen im Krankenhausbereich anregt durch die Erbringung von Nachweisen zu den heutigen und zukünftigen Problemlagen und durch (die finanzielle Unterstützung für) das Austesten von potenziellen Lösungen. Gleichzeitig betont die EU vergleichsweise stärker die ökonomischen Gründe für Gesundheitssystemreformen. Inwieweit EU Anreize wirksam Problemlösungen in Mitgliedstaaten unterstützen wurde in Frage gestellt aufgrund des starken Subsidiaritätsprinzips im Bereich der Gesundheitssysteme sowie des vorherrschenden Logik der finanziellen Konsolidierung auf EU Ebene. Tatsächlich haben Mitgliedstaaten sich während der Finanzkrise kurzfristigen Lösungen zugewandt, um die operativen Kosten in Krankenhäusern zu senken. Die makro-ökonomischen und politischen Konditionen in Mitgliedstaaten – teilweise begünstigt durch die EU – waren größtenteils Strukturreformen nicht zuträglich.

Die Untersuchung zu den **Kapazitäten zur Entscheidungsfindung** der Generaldirektion Gesundheit und Verbraucherschutz (GD SANCO)³ in Bezug auf das öffentliche Gesundheitswesen und Gesundheitssysteme zeigte, dass die Gesundheitssystemagenda sich über die Jahre vergrößert hat, aber die strukturellen Konditionen, die die Entscheidungskapazitäten einschränken, immer noch vorhanden sind. Eine Verbindung aus Literaturreview, Dokumentenanalyse und Interviewdaten zeigte das GD SANCO unter Beweis stellt, dass sie eine Agenda steuern, eine Situation analysieren und politische Entscheidungen in verschiedenen Dossiers treffen können. Die Belege waren nicht einheitlich bezüglich Implementierung und

³ Ich verweise hier zu GD SANCO im Zusammenhang mit der Analyse in Kapitel 4, die den Zeitraum 1999-2014 untersuchte. Zu Beginn der Juncker Kommission wurde die Generaldirektion verantwortlich für Gesundheit umbenannt in GD SANTE, Gesundheit und Lebensmittelsicherheit. Ich verweise auf GD SANTE bei den Empfehlungen.

Evaluation. Es muss sich zeigen, ob GD SANTE es schafft, eine bessere Wirkung ihrer Politiken zu erreichen mittels besserer Prioritätensetzung, klareren Zielen und stärkeren Implementierungsinstrumenten.

Die Analyse zur **Implementierung und Einhaltung** der EU Regelungen konzentrierte sich, erstens, auf die Umsetzung von Richtlinie 2011/24/EU in Bezug auf die Nationalen Kontaktstellen für die grenzüberschreitende Gesundheitsversorgung mittels einer Websiteanalyse in allen Mitgliedstaaten. Zweitens, wurde der Einfluss von EU Gemeinschaftsrecht und neuen Governance Instrumenten auf nationale Krankenhäuser und die Krankenhauspolitik in Belgien, den Niederlanden und Deutschland untersucht basierend auf einer Interviewstudie mit Schlüsselinformanten. Die Ergebnisse zeigten, dass EU Gemeinschaftsrecht in nationalen Krankenhäusern eingehalten wird, obwohl diese nicht das Kerngeschäft von Krankenhausaktivitäten, die Krankenversorgung, betreffen. EU Gemeinschaftsrecht wird wahrgenommen als einhergehend mit erhöhten Anforderungen an Dokumentation, Infrastruktur, Ausbildung und Prozessgestaltung. In vielen Fällen führt dies zu Steigerungen der operativen Kosten für Krankenhäuser. Neue Governance Instrumente zeigen eine Wirkung in mitgliedsstaatlicher Gesundheitspolitik beispielsweise als Startpunkt einer politischen Diskussion oder als Auslöser zur Initiierung von Aktivitäten, wenn sie mit den bestehenden Problemlagen zusammenpassen oder neue getestete Ideen und Lösungsansätze für die heimische Politik bieten. Nationale Entscheider in Belgien, Deutschland und den Niederlanden nehmen ihren Entscheidungsspielraum als eingeschränkt wahr durch EU Recht und Politik und beobachten EU Aktivitäten mehr und mehr. Nichtsdestotrotz, bleibt die nationale Befolgung von Einflüssen der EU neuen Governance Instrumenten bisher eher ad hoc.

Diese Dissertation folgert, dass obwohl eine umfassende und relevante EU Agenda zu Krankenhäusern sich abzeichnet, Mitgliedstaaten noch immer das Sagen über ihre Krankenhauspolitik haben. Die EU beeinflusst zunehmend den Kontext in dem Krankenhauspolitik gemacht wird durch Informationen für die Untersuchung von gegenwärtigen Krankenhausstrukturen, Ideen für Innovationen und Politikrichtungen, Startkapital für das Austesten von praktischen Anwendungen und ein Forum für den Austausch zwischen nationalen Entscheidern bereitzustellen. Dennoch ist es in vielen Fällen im Ermessen der Mitgliedstaaten, um Ideen und Initiativen aufzunehmen.

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Dankwoord

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Curriculum Vitae

Curriculum Vitae

Timo Clemens was born on 3 November 1977 in Heinsberg (Rheinland), Germany. He started his professional career by a vocational training as a nurse at the University Hospital Aachen, Germany between 1998 and 2001. He continued to work as a general nurse at the University Hospital in Aachen until 2006. Between 2006 and 2010 he studied European Public Health at a Bachelor and Master level at Maastricht University. He obtained both degrees with distinction ('cum laude').

After completion of the Master, Timo joined the Department of International Health in 2010 to start a PhD trajectory. The focus of his PhD research has been on the governance of health systems between the Member States and the EU. Throughout his PhD track, Timo has taken on various teaching roles in the Bachelor European Public Health and the Master in Governance and Leadership in European Public Health. Since 2013, Timo has been involved as research officer in various EU financed projects, including a mapping of patients' rights in 30 European countries (PRE-MAX), the influence of the European Union on the health systems in small states (SMShealth.eu) or analysing the situation of Rare Disease patients in the Euregio Maas-Rhine (EMRaDi). In 2012 and 2013, Timo was a Young Forum Gastein Scholar, awarded by the International Forum Gastein and the European Commission. He serves as a reviewer for Health Policy, BMC Public Health and BMJ Open.

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