

PATIENTS' RIGHTS DIRECTIVE (2011/24)

Assessing the Implementation of EU Directive on Patient Rights to Cross-border Healthcare and its Impact on Nations Healthcare system: A comparative study of United Kingdom, Germany and The Netherlands

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ABSTRACT

BACKGROUND: The movement of patients and health professionals has triggered calls for better coordination of health systems and policies in the European Union (EU). Cross-border healthcare progress at the EU level have been difficult, laborious, including years of rulings by the European Court of Justice (ECJ) and years of consultations between Member States (MS), the Commission and the European Parliaments. The patients' right directive (2011/24/EU) objective was to establish a framework to facilitate access to safe and quality healthcare across the border and reimbursement for healthcare received from other EU/EEC Member States (MS). The directive brought with it new opportunities to patients and challenges to member states. On the part of the state, the need to adequately provide and develop an adequate policy to meet the stipulations of the directive, recognizing both the interests of the patients (home and from other MS) and the need to put systems in place to work on infrastructures like language, information centers, safety, and reimbursement.

OBJECTIVE: The objective of this study is to analyze the implementation of the EU Patients' right directive, its impacts on health systems of UK, Germany and the Netherlands and provide knowledge on the implication of EU rules on cross-border care for national health systems.

METHOD: This thesis is based on a review of journals and research on Patients' right directive and its implementation in member states. This was done to identify contributions made in the area of EU healthcare policies. A case study of UK, Germany and the Netherlands.

RESULTS: The study illustrated how Europeanization of health systems is happening through a central penetration of national systems of governance. It provided an insight into the implementation of the directive by MS and how it could lead to a degree of convergence and divergence. Having analyzed the directive and its implementation in UK, Germany, the Netherlands, one cannot categorically say there is Europeanization of healthcare in the EU or in these countries under study. In addition, one cannot say there is a move by the EU to standardize healthcare in all MS. It is however clear that EU is trying to safe guard the internal market regulation. By providing citizens the right to travel from one MS to another and getting the healthcare they need. MSs are still in charge of their healthcare since they have to decide on prior authorization and determine the amount to be reimbursed.

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List of Abbreviations

AWBZ	Exceptional Medical Expenses Act
BMA	British Medical Association
BAK	German Medical Association
CB	Cross-border
CCG	Clinical Commissioning Group
CEC	Commission of the European Communities
CVZ	College Voor Zorgverzekeringen
DOH	Department of Health
DVKA	The German Liaison Office for Sickness Insurance-Abroad
EC	European Commission

ECSC	European Coal and Steel Community
EEA	Economic Economic Area
EEC	European Economic Community
EHIC	European Health Insurance Card
EP	European Parliament
EU	European Union,
ECJ	European Union Court of Justice
ET	European Team
FTs	Foundation Trusts
GDP	Gross Domestic Product
GP	General Practitioner
HIC	Health Insurance Card
IGZ	Inspectie Gezondheidszorg
KBV	Federal Association for Statutory Health Insurance Physicians
PRG	Patients' Right Law
MOH	Ministry of Health
MS/MSs	Member State, Member States and Member States'
NCP	National Contact Point, National Contact Points
NHI	National Health Insurance
NHS	National Health Service

NIC	National Insurance Contribution, Nation Insurance Contributions
NICE	National Institute for Health AND Care Excellence
OECD	Organization for Economic Cooperation and Development
ONS	Office for National Statistics
PbR	Payment by Results
PCTs	Primary Care Trust
PHI	Private Health Insurance
PMI	Private Medical Insurance
SHI	Social Health Insurance
SHIs	Stuatory Helath Insurance Scheme
SKGZ	Health Care Insurance Complaints and Disputes Foundation
SVG	Code of Social Law
TEC	Treaty Establishing the European Community
TFEU	Treaty on the Functioning of the European Union
UK	United Kingdom
VHI	Complementary Voluntary Health Insurance
VROM	VROM-Inspectie
VWA	Voedsel en Waren Autoriteit
VWS	Ministry of Health, Welfare and Sport
WHO	World Health Organisation

ZFM	Ziekenfondswet
ZVM	Health Insurance Care Act

Chapter 1

Introduction

The movement of patients and health professionals across Member States (MS) has triggered calls for better coordination of health systems and policies in the European Union (EU). The work on developing cross-border healthcare in the EU has been difficult and laborious. It included years of rulings by the European Court of Justice (ECJ) and years of consultations between Member States (MS), the European Commission and European Parliament which indicated the extent to which the conflict and uncertainty facing MSs and their policy-makers in patients' mobility (Palm et al., 2011). The directive on patients' rights to cross-border healthcare (2011/24/EU) objective was to rectify the difficulties and to ensure that the citizens receive reimbursement for healthcare received from other EU/EEC MS. The directive brought with it new opportunities to patients and challenges to MS. On the part of the state, there has risen the need to adequately provide and develop an adequate policy to meet the stipulations of the directive, recognizing both the interests of the patients (home and from other MS) and the need to put systems in place to work on infrastructures such as language, information centers, safety, and reimbursement. Equally, on the part of citizens/patients, the directive brought into being the opportunity to travel from one place to the other and getting the healthcare, they needed. Similarly, those on waiting list could find in-time care in another state and be reimbursed. Hence, this study will seek to get a better understanding of directive 2011/24/EU after two years of full implementation in the United Kingdom (UK), Germany and Netherlands and to investigate the possible impacts on the three different health systems. The choice of three countries is to broaden the scope of the study.

1.1 Background

The EU was formed to nurture cooperation among MSs, ensure peaceful co-existence and adherence to democratic values, respect for human rights, equality, rule of law, and the wellbeing of Europeans (Börzel and Risse 2002). In 1957, the European Economic Community (EEC) was established under the Rome Treaty with the goal of ensuring free trade among MS, establish a common external tariff at its borders, prohibit practices that prevent or distort free competition, and to promote free movement of goods, persons, services and capital (Nugent 2010). The only health related subject in the treaty was occupational

health and workplace health policy and safety (Geyer, 2011). This can be found in EEC Treaty's Title III: Social Policy, including Chapter 1 on Social Provisions and Chapter 2 on The European Social Fund. Thus, health policy remained a MS responsibility and no basis for EEC harmonization of health policy systems was included in the treaty (Geyer, 2011).

In July 2008, the EU proposed a draft directive on the application of patients' right to cross-border healthcare. This draft caused a huge debate among MS, since healthcare policies always have been seen as MS's responsibility (Sauter 2009). Prior to that, an effort by the EU in 2004 to codify patients' mobility in a directive called "Service Directive" was not successful, so the EU had to withdraw it and come out with the patients' right directive (2011/24/EU). As Sauter (2009) highlights, the July 2008 initiative by the EU was necessary as the MSs' healthcare systems vary broadly in relations to key variables such as accessibility, quality and affordability in roles played by both the public and the private sector.

Article 168 EC (ex articles 152 and 129) was enacted by the EC to protect "*citizen Europe*" in the areas of environment, health and consumer rights (Amsterdam 1997). Through this article, the EU can adopt measures aimed at ensuring better quality and safe public health for "*citizen Europe*". Health care issues have always been in the hands of MS with the EU playing a subsidiary role of supporting the efforts of MS and helping them formulate and implement coordinated objectives and strategies. Similarly, the Court of Justice has recognized the rights of MS, to decide individually, the scope and suitability of their social security benefits. However, some rulings by the same court admonish MS to respect the EU's Treaties and Regulations (Van Der Mei 2003). Examples are the case of Decker and Kohll and the Dutch system of social health insurance (SHI), and the case of Geraets-Smit and Peerbooms. These cases and others have imposed restrictions on the power of MS, from regulating cross border healthcare issues (Van Der Mei 2003), thereby modifying the principle that healthcare should be in the hands of the MS. Other cases include IKA verses Loannidis, Vander Duin and Van Wegberg-Van Brederode and Muller-Faure and Van Rier (Case references at the reference and bibliography section).

Hence, this thesis aims at studying how the directive has been implemented and compare the implementation in the United Kingdom (UK), Germany and Netherlands. The study would also highlight similarities and differences in the three health systems, and identify some of the implications of the directive on these different health systems. These three countries have been chosen in order to broaden the scope of the study and encompass the three health care

models. It is also to ensure a diverse approach (since the three countries have different healthcare policies) that would help broaden the scope of the study. In addition to the availability of information, the different experiences of these countries also played a part in choosing them. For instance, United Kingdom, with a population of 64.1million comprising of England, Wales, Scotland, and Northern Ireland, was the first to introduce the Beveridge model (National Health Service). One of the things that makes the choice of UK intriguing is the role of the regions that make up UK (England, Wales, Scotland and Northern Ireland). These regions have their own individual health systems. Still, citizens of the four regions can get healthcare from all four regions of the UK. Moreover, the Beveridge healthcare model originated from the UK (Connolly et al 2010).

Germany's inclusion in this study has to do with origination of the Bismarckian healthcare model (Social Insurance). Germany and the Netherlands both have systems that are mainly financed by premiums not dependent on individual risk but on individual income. Germany and the Netherlands health systems are characterize by a mix of primarily public funding and private provision of healthcare services (Greb et al 2001). Germany's health insurance companies are non-profit whilst those in Netherlands are for profit, hence the inclusion of the two countries. The inclusion of Germany and the Netherlands is also to ascertain the influence of the directive on a managed competition system (a system that allows health insurance companies to select providers for their insured). In contrast, UK has a national health system like Norway. This makes it interesting to look at how the EU directive has been implemented in countries having different healthcare systems.

1.2 Research Question

Health systems among MSs in the EU, although different, are based on the notion of solidarity, which is under great stress. The EU's directive on cross-border healthcare has given patients the right to seek healthcare elsewhere both planned and unplanned. This thesis seeks to analyze how the EU directive 2011/24/EU has been implemented in UK, Germany and the Netherlands using available literature and public documents. This study will also look into the similarities and differences in the health systems and aim to identify some core implications of the directive in the different health systems.

The following research questions will be addressed in this thesis:

- How has the EU directive on cross-border healthcare been implemented in the UK, Germany and Netherlands?
- What are its (directive) possible impacts on the three different health systems (insurance based, managed competition and a tax-based system)?
- Have the health systems in the three MS become more similar or more different after the implementation of the Directive?

The last research question will be further outlined under chapter 2.4.

1.3 EU Directive on Patients' Right to Cross-border Healthcare

The rising cost of healthcare has prompted cost control in various forms and at times, giving rise to 'waiting list' across the continent. Greer (2011) pointed out that the stress on solidarity and changes in the sector such as movements from centralized command to decentralized commands promoted efficiency by means of market incentives that is driving healthcare to be based on ability to pay (Greer 2011).

The role of the state in healthcare systems is becoming more similar all over the world and many countries have integrated non system-specific or innovative elements of regulation. Out of these developments emerged hybrid healthcare systems (Schmid et al 2010). This hybridization can be understood as a soft form of convergence because the evolving mix of regulatory instruments entails increasing similarities across systems. (Schmid et al 2010).

The EU directive on patients' right to cross-border healthcare (directive 2011/24/ EU) makes provision for the introduction of a general framework to explain patients' rights regarding access to cross-border healthcare delivery. It also assures the safety, quality and efficiency of the care that the patient will receive in other MS and encourage cooperation among MS on healthcare issues. However, the social security regulation route (regulation 883/2004) will still be in place and will be used alongside the directive route (see page 21 below and fig. 1).

The directive was also introduced to ensure patients' right to reimbursement for health services provided in another EU MS (Sauter 2009). However, the directive did not include cosmetic surgery, long-term care services and vaccination. The EU's MS had to implement the directive by 25th October 2013. Article 20 of the directive demanded for a report to be submitted to the European Parliament (EP) and the Council by October 2015, detailing processes put in place by MS and a comprehensive and detailed description of the implementation (Zucca 2015).

Before the adoption of the directive into national law, healthcare corporations (i.e., clinic or hospital) had established collaborations with healthcare corporations in other MS (Glinos and Baeten, 2014). Examples of such arrangements are: the Finland–Norway arrangement, covering hospitals in Finnmark and Lapland; Belgium–France arrangement, involving the hospital at Dinant and French health care actors; Germany–Denmark arrangement, between the hospital at Flensburg and Danish health authorities; The Netherlands–Germany arrangement, between Maastricht and Aachen University Hospitals; Romania–Bulgaria arrangement, between hospitals in Całã Rași and Silistra; Spain–France arrangement, between Catalan and French health care actors to build Cerdanya Hospital; Austria–Germany arrangement, between hospitals in Braunau and Simbach to mention but a few (Glinos and Baeten, 2014; Lämsä, Keskimäki, and Kokko, 2013).

Other MS have been using the cross-border healthcare as a form of investment. Examples of such investments are Dialysis services for tourists in the Vento Region in Italy, these investments were made in response to the high volume of tourists received (2.5 million in the summer months). The local Health Authority is using the main hospital at Jesolo and in an outpatient center in Bibione for this service from May to September (Bellometri and Bertinato 2011). Others are; cross-border pediatric in UK; crossing borders for orthopedic care in Hungary; cross-border investments in dentistry in Poland; examples can also be found in France, Switzerland, Germany and the Netherlands (Footman et al., 2014).

Some early problems facing cross-border healthcare are that some patients would rather have treatment back in their home country in order to be with their family members. Language barriers, reimbursement, and how long it takes to settle refund among MS and individuals were also problems facing these cross-border initiatives (Fiscella et al 2002).

However, the implementation of the Directive (2011/24) has the potential of benefiting countries with quality standards of healthcare and to enhance effective communication. For example, countries like Germany and Netherlands, with advanced private health providers, can benefit by taking over healthcare needs of a country like Malta. Italy with their climate can use this directive and introduce health tourism. It may thus positively affect tourism/health among MS. Also, the UK being a global leader in health research with a matured research ecosystem comprising world-class universities, institutes, public sector agencies and a language that is spoken by almost everyone in the EU MS and the world over, could benefit much from implementing the directive.

The objective of this study is to analyze the implementation of the EU Patients' right directive, its impact on these three health systems and to provide knowledge about the implication of EU rules on cross-border care on national health systems.

1.4 Structure of the thesis

The thesis is divided into 6 chapters. Chapter 1 contains an introduction of the study, including research aim, objective and research questions. The second chapter discusses methods and data, and the theoretical and analytical approach. Chapter 3 discusses background to the empirical part, whilst chapter 4 will describes and discuss the patients' right directive, the healthcare structure of the three countries under study and how the directive was implemented in the three countries. Chapter 5 includes an analysis of similarities and differences in the implementation of the directive and its impact on the three health systems. Chapter 6 concludes the study.

Chapter 2

Methods and Data; and Analytical Approach

2.1. Methods and Data

In order to identify contributions made in the area of EU healthcare policies, this thesis is based on a review of journals and research on the Patients' right Directive (2011/24/EU) and its implementation in MS, supplemented with ECJ rulings, EU legislation and preparatory documents. The documents on the subject were critically examined. Several websites (European Health for all, Nordic Health Policy, Social Science and Medicine Journal, European Publications Oxford Journals, Journal of Health Service et cetera) were also searched for relevant publications. The search was limited to English articles from January 2000 to date. The analysis focused on documents and literature in terms of their relevance to the thesis topic, to find trends and to assess differences across the countries under study.

According to Yin (2003a), a case study design should be considered when the focus on the study is to answer "how" and "why" questions, and when it is needed to cover contextual conditions because they are likely relevant to the phenomenon under study, and when the boundaries are not clear between the phenomenon and context. The first research question in this study refers to a "how" question: How the countries under study (UK, Germany and the Netherlands) implemented Patients' rights Directive 2011/24. The second research question concerns the impact of implementing the directive on the different health systems in these countries. The phenomenon – implementing the directive – is occurring in a context (countries with different health systems), but the boundaries between the phenomenon and context is not so clear. Case study strategy is also used because it helps to understand a complex real-life process that has developed over time (Hartley, 2004a).

The purpose of this study is to compare implementation of Patients' rights directive between different MS. This calls for a multiple case study that enables to explore differences between cases (Baxter and Jack, 2008). Because comparisons will be made, it is important that the cases be chosen carefully. The three countries were selected because they had similarities concerning development indicators (such as GDP), social development and health resources (based on data from World Bank). Furthermore, it was decided to include countries that had some differences concerning the health system. Two countries having Social Health Insurance

(Germany and the Netherlands), however, these two countries differ concerning non-profit/profit system. The third country – UK – having a national health system like Norway (tax based), differ quite much from the other two countries. This permit a broader exploration of the impact of implementing the directive under various health systems.

Case study represents an in-depth, multi-sided approach, using data from various sources and using different methods. Some common methods of data collection include observation (direct and/or participant), interviews, and documents/archival records. Based on the research questions, observation as method would not be relevant. Interviews with participant in the process could explore the first research question - how has the EU directive on cross-border healthcare had been implemented in the UK, Germany and Netherlands. To identify and interview the relevant informants in the implementation process, such as bureaucrats and politicians, was not possible due to the time and budget of this thesis. Accordingly, this thesis is mainly based on documents.

The journals and documents that are studied were taken through selection criteria and was subjected to quality assessment. The chosen articles were published not earlier than the 2000, and the selected journals were considered for their relevance to the study topic. The assessment was necessary because it helps to explore diverse and informed decisions regarding the suitability of the journal and document (Chalmers et al, 2002), and to help in making recommendation for future research (Tranfield et al 2003). In order to identify relevant articles, a wide range of scientific databases were searched to identify studies on the implementation of EU directive 2011/24 in MS. The electronic search was supplemented with public documents such as treaties and agreements, regulations, directives, EU documents, and ECJ rulings et cetera. Various internet search engines were used to identify relevant journals. This resulted in the identification of a number of relevant studies for the thesis (see bibliographies and references). For the purpose of this thesis, existing EU policies on health and the new directive (2011/24/EU) were reviewed.

Narrative method will be used to compare and discuss similarities and differences in implementation of the health systems in UK, Germany and Netherlands. The narrative method is an interpretive approach in social sciences, which focuses on how individual or people make sense of events and actions in their society. The implementation of the EU directive on patient's right to cross-border healthcare was completed recently (October 2013). Thus, so far there is only a limited amount of studies on implementation available. Hence, in

this thesis, an evaluative study made by the European Commission, literature, and public documents, including court rulings, legislation, websites and preparatory documents, is used to address the research question.

2.1.2 Scope and Limitations.

This review was centered on the implementation of the Patients' right Directive in the UK, Germany and Netherlands. Further analysis of the role of financing healthcare in a tax based and insurance-based systems will be discussed.

Articles on the implementation of the directive were hard to find, especially that of the UK. Irrespective of the limitations, however, it is hoped that this research will pave way for an in-depth study, analysis and critical interpretation of the nature and contribution of implementing EU's directive on patient's right to cross-border healthcare and its implications on MS's healthcare systems.

2.2. Analytical Approach

According to Hartley (2004), documents collection and document analysis are developed in an *iterative* process because it allows for theory formation/development, which deals with realistic evident. Thus, this section will discuss the theoretical/analytical concepts used in analyzing the data. The data will be organized around the topics below; which will illuminate the research questions.

2.2.1 Europeanization

Many scholars argue that the process of Europeanization is relatively new and that it will be hard to identify one single Europeanization concept with one single meaning. It has also been noted that research so far has not identified a significant impact of European integration on the *organizational structure* of nation-states in Europe (Olsen 2002; Ladrech 2012; Bauer et al 1998; Schmitter 2000). Kassim (2000) states that Europeanization has no precise definition due to variations in ideas. Moreover, he argues that Europeanization has no precise definition because the term is so cumbersome that is pointless to use it as an organizing concept. According to Olsen (2002), Europeanization could be less useful as an explanatory concept than as an attention directory device, and as a starting point for further exploration. Börzel and Risse (2000) point to the need for detailed research in order to understand Europeanization processes. Olsen (2002) concluded that research should not be troubled by

contending definitions as long as the meanings or definition chosen fit the *phenomena* in focus.

Ladrech (2014) defines Europeanization as an incremental process of reorienting the direction and shape of politics to the degree that EU political and economic dynamics become part of the organizational logic of national politics and policymaking. An example of this reorienting was the large-scale policy transfer involved in the EU Legislation that MS candidates had to accept before joining the Union (Bauer et al 2007). Börzel and Risse (2000) define Europeanization as an idea that touches on the ways in which MS policies, politics and institution building or institutional change procedure and styles have been affected by policies created at the EU level. This can be seen as a complex process of political change because of the transferring of policies across MSs (Featherstone and Radaelli, 2003). Ladrech (2012), however, defines Europeanization as a concept used to describe the influence of European integration on the politics and policies of its MS in addition to the process of enhancing *European level political institutions*.

Featherstone and Radaelli (2003) on their part define Europeanization as a series of *top-down* and *bottom-up* processes affecting both formal and informal guidelines as well as system, policy models, styles and shared beliefs and norms. Olsen (2002) distinguishes possible uses of the term Europeanization in respect of structural considerations.

However, for the purpose of this thesis, Olsen's (2002) definition of Europeanization as the central penetration of national systems of governance will be used. According to this definition, Europeanization occurs when dividing responsibilities and powers between different levels of governance. When MS's systems of governance need to work out a balance between central coordination and local autonomy to match that of the penetrated EU systems/directives, one can infer that Europeanization is taking place, as well as when MS has to adopt national and subnational systems of governance (MS's) to EU political center and EU wide norms (Olsen 2002). Olsen's definition was chosen because it was most relevant for the present study, which examine implementation processes and the impact of Patients' right directive on the healthcare systems in three MS.

While the definitions above have described the Europeanization of MS as a creation of a more integrated structure, De Smaele (2007) notes that, there are possible disconnections between Europeanization of MS and integrated structures. Börzel and Risse (2000) clarified that

Europeanization could lead to convergence in policy outcomes in MS or could continue to diverge with regard to policy processes and instruments (Börzel and Risse 2000). The development of health-related laws and policies at the EU level can indicate a process of Europeanization taking place in the area of health. However, the actual impact of this development in individual countries is in fact uncertain. Depending on how EU policies and rules are implemented in national health systems, the development can lead to either more similar health systems in Europe (c.f. convergence) or to status quo or more different health systems in Europe (c.f. divergence). Convergence will indicate that Europeanization of health systems is taking place, while divergence will indicate that the national characteristics of national health systems persist. It is thus important to study how implementation takes place and the factors that may affect the outcome of implementation processes.

2.2.2. Convergence and Divergence

Health systems all over the world are changing because of several factors. Some of the factors include technological advancement, aging population, knowledgeable patients, advance medication, diverse specialization, IT, diverse workforce, globalization and people living longer in some cases (Shortell and Kaluzny, 2000). As healthcare is becoming challenging due to external and internal pressures, it has been suggested that health systems are becoming more similar (Hood 1998; Schmid et al, 2010).

The demand for health has come to a point where demand has exceeded available resources. Thus, countries are beginning to change the ways their health services are financed and organized. According to Lian (2003), these changes have led to a degree of convergence in healthcare policies in the EU and Western world. Moreover, the role of the state in healthcare is becoming more similar all over the world and many states have integrated non system-specific or innovative elements of regulations to meet and curb rises in cost of healthcare (Schmid et al 2010). Out of these developments emerged hybrid healthcare systems. This hybridization can be understood as a soft form of convergence because the evolving mix of regulatory instruments entails increasing similarities across systems (Schmid et al 2010).

According to Inkeles (1981), convergence is related to development over time and implies a global trend in the formation of health policies. Inkeles (1981) also notes that convergence is moving from different positions toward some common points. The pressures from the EU

can be equated to Mechanic's (1975) theory of convergence. He stated that pressures are producing convergence in the objectives and activities of health systems (Europeanized) and thus the systems will become similar with time (Mechanic and Rochefort 1996). For the purpose of this thesis, the term "convergence" means that health systems are becoming more similar. Some of the forces of convergence in this case are the legal pressures from both individuals/patients and MS, ECJ court rulings, migrations of health workers and patients' pattern, and informed patients with their associated demands and needs (c.f. ECJ rulings). Hence, one can infer that Europeanization is occurring in MS's health systems.

On the other side, the systems could also be diverged (Inkeles 1981). Divergence means that health systems are moving apart (and thus not Europeanized). The divergence view maintains that although the MSs could be moving towards one system (as a result of say the directive), cultural diversity could persist or even be reinforced by the rejection of superficial harmony, thus leading further apart or increasing differences. Forces of divergence could be liken to the directive from the EU, MS discretion in transposing the directive through national cultures and traditions, national institutions through which the directive went through during the transposition period and the outcome/how correct or incorrect the implementation was. Under such circumstances, it could be said that Europeanisation did not take place.

2.2.3. Implementation of EU rules

Primary and Secondary legislation: The legal framework of the EU consists of primary and secondary legislation. Treaties constitute the EU's primary legislation that can be seen or compared to MS constitutional law. Primary legislations consists of the fundamental features of the Union and its responsibilities (EU website, 2016). Examples of EU treaties are the European Coal and Steel Treaty; The European Atomic Energy Treaty and the European Economic Treaty amended together with Annexes and Protocols. They are the primary sources of EU law (EUR-Lex, 2016). The treaties get amended and supplemented on numerous occasions to add or substrate legislatures that are needed or not needed at that juncture. There are also Accession Treaties; Treaty of Stability; Coordination and Governance in the Economic and Monetary Union. The primary legislation of the EU presently lies on the Treaty on the Functioning of the EU. EU treaties consist of basic provisions concerning EU's objectives, rules and principles, and they define the framework for the operation of the EU and how it is administered by the EU institutions (Barnard, Hervey and McHale, 2004; EU website)

Secondary legislation refers to laws by the EU institutions in exercising the powers conferred on the EU by the treaties. The secondary laws consists of binding legal instruments and non-binding instruments, which are described in the Treaty on the Functioning of the EU (TFEU) Article 288. This includes Regulations, Directives, Decision, Recommendations and Opinions (Non-binding instruments) (Hervey and McHale, 2004; EU website). In accordance with the provision in Article 249 ex 189 (treaty establishing the European Community); for the EU (European Parliament, European Council, and the European Commission) to carry out their task , they shall make regulations, issue directive, take decisions, make recommendations or deliver opinions (Luca-Samuel et al 2015).

Directive: The EU website defines a **directive** as a secondary legislative act *that sets a goal that all EU countries must achieve*. However, *it is up to the individual countries to decide* its own laws on how to implement the directive at an exact date. It is a legislative instrument that joins the two objectives of securing the required *uniformity* of *community* law and valuing the diversity of national ethnicities and structures of each other. Directives are only legally effective after implementation has taken place. Thus, legality only starts after the implementation date has expired. In the EU, each directive has a deadline in which MS must assume national transposition measure to integrate the requirements of the directive into national law (EU website).

Directives, unlike regulations, are not immediately applicable and allows each MS, with the use of legislative instruments, time to interpret and adopt the directives. The rationale behind the transposition period in directives is because MS differ in economy, culture and uses different methods in dealing with issues. Thus, when EU directives set out a result to be achieved, MS are given a set time to transpose in their own way and make sure they achieve the goal of the directive. Usually, EU uses regulation to make sure the legislative is directly applicable and appropriate and avoid leaving room for different implementation by MS (Barnard, 2010; EU website). Barrett (2004) identified implementation as the process of translating policy into action. This includes the process where EU directives are interpreted and transposed into MS respective national law. Without proper transposition, the directive/policy will not be fully integrated into MS national legislation and the problem of fragmented and incorrect implementation will arise (Steunenberg and Rhinard, 2010).

Regulations on the other hand are *binding legislative acts*, which must be *applied in its entirety across the EU*. Regulations is different from directive as it has *general application*

and are directly binding for the MS. Once regulations are issued by the EU, they are directly and automatically enshrined in MS legislative because MS have given EU the power to pass laws on their behalf.

Decision on the other hand when taken by the EU shall be *binding in its entirety* upon the MS, organizations or persons to whom they are addressed. While **recommendations** and **opinions** from the EU are non-binding, a MS can decide to work with it or not (Lucas-Samuel et al 2015: Giandomenico 2007: EU website).

Regulations aim to further harmonize the rules and decision made by streamlining the authorization process at the MS level. An advantage of regulations over directives is that they can easily bridge the gap needed to solve problems in time. However, political accountability cannot be ensured in regulations since variety of substantive and procedural controls among different judicial reviews may not be taken in to consideration, as it is in the case of directives. Thus, executive oversights and co-ordination may be improved by using new tools of regulatory clearinghouse (Lucas-Samuel et al 2015: Giandomenico 2007).

Implementation refers to the process and period where EU rules are being interpreted and transposed into MS's national law. When transposition is over, a process of applying the EU directive begins. 25th October 2013 was the deadline for implementation of EU directive on patient's right to cross-border healthcare in MS. The implementation of the directive in MSs began a new period for cross-border healthcare. Although the directive sets out the obligations by which MS must adhere to, MS had the choice of which form or method to follow in order to achieve the set goal by the EU. This unrestricted power opens up for different solutions depending on the MS healthcare system.

2.3. Health System Models

MS in the EU have different healthcare models, with some MS using a mixture of one or two models. Implementation of the directive in MS has tried to open up for a standardized health system. Irrespective of still different healthcare models, they are based on MS's solidarity.

The different healthcare models in the European countries include:

- The Bismarck model;
- The Beveridge model;
- The National health insurance model.

Most MS use a mixture of two or more of these different models.

2.3.1 The Bismarck Model

The Bismarck model was enacted in 1873. The model was named after Chancellor Otto Von Bismarck, a Prussian who developed the welfare state in his bid to unify the Germans in the 19th century (Krtzin et al 2009). The model uses social legislation that insures workers against serious injury and illness through a social insurance model or non-profit sickness fund. Although there is significant variation in terms of organization, the model is based on social solidarity and characterized by universal coverage health insurance within a framework of social security.

It is financed by a combination of employer and individual contributions through non-profit insurance funds. In most cases in this model, the funds are regulated and subsidized by the state (Blank & Burau, 2014). The model covers everyone irrespective of pre-existing conditions. However, the provision of services can be based on private services, sometimes on a fee-for-service terms. Some advantages of this model are less waiting time, improved quality care, relatively low cost, simplified administration, and insurance claims paid without much delay.

The hospitals and doctors are private compared to the Beveridge model where the government employs most of the doctors. This model is highly ranked in World Health Organization's overall ranking. Irrespective of the health care system, the individual states share greater cost. This model was founded in Germany and practiced in Germany, France, Belgium, The Netherlands (mixed with NHI system), and Switzerland.

2.3.2. The Beveridge model:

This model was named after the social reformer and economist Lord William Beveridge. Through his report titled "Social Insurance and Allied Services" to The British Parliament in 1942, he suggested that people of working age should contribute weekly through their wages to a national insurance contributions and in turn, benefit will be paid to people that are sick (Kutzin et al, 2009). The model is characterized by universal coverage, funded on general taxes. Citizens have open-ended free access to all the health care services they need (Blank & Burau, 2014).

In this model healthcare is delivered, administrated, and funded by the government through tax payments (a single payer national health service). The central government own most hospitals and surgeries (clinics), and the government or local authorities employ doctors and other health personnel (Delamothe 2008). This model is believed to have low cost per capita, since the central government is the sole owner and can control and leverage what the doctors and policy makers can charge. The Beveridge model is used in UK, Norway, Italy, Spain and other countries (Blank & Burau, 2014).

2.3.3. The National Health Insurance Model

This system has the elements of both Beveridge and Bismarck. It is characterized by universal coverage, funded by general taxation and public ownership. Although the use of private-sector providers, payments come from the central government's owned insurance program into which employers and individuals pay their contributions. It is a single payer (the government) national health insurance (Blank & Burau, 2014).

There is no competition in this universal insurance and is non-profit, hence, individuals are not denied claims or treatment (Blank & Burau, 2014; box 1.3). This model is cheaper and easier to administer than the profit-based insurance model. The state has the power to discuss for fair/lower prices on treatment and cost of medicine. The policy makers tend to set limits on cost by limiting or prolonging medical services that need to be conducted by putting patients on waiting list (Cheng, 2003). This system is practiced in Canada, Taiwan, and Ghana.

European countries that practice this model do mix it with either the Beveridge model or the Bismarck model. Examples of some European countries that practice the NHI model in conjunction with either the Bismarck or Beveridge model are The Netherlands, France, Denmark and others.

2.3.4 Health Models Summary

Apart from the three models above, the citizens of the countries under study have the opportunity to purchase voluntary health insurances. The Beveridge model (National Health Service) has been practiced in the UK since 1946, hence the description on the model. The system is tax based. Germany and the Netherlands use the Bismarck Model (SHI) that is a universal health system, and is insurance based. However, the two countries differ in the

implementation of the system: Germany has a non-profit approach to the insurance system whilst the Netherlands has a profit-based and market competitive logic to its approach, hence the choice of the three countries.

The foregoing discussion of the health models was to help diversify the study since the UK system is tax based, the German system insurance based while the Netherlands uses insurance and some element of market (managed) competition.

2.4. Assumptions and propositions

This thesis studies the implementation of directive 2011/24/EU and its impact on different health systems. Regulations given by the EU to MS does not allow for discretion in implementation. Directives on the other hand, opens up for discretion in implementation. Hence, one can infer that regulations enhance Europeanization more than directives. Different systems and cultures have impact on the implementation process. One assumption could be that the implementation of the Patients' rights directive has converged the three different health systems to become more similar (Europeanization). An alternative assumption is that implementation of the directive has led to divergence, that is, that the systems in the three countries have become more different than they were previously.

This thesis will investigate the alternative assumptions (the first sentence in [1] and [2] represents propositions) in Chapter 5.2:

[1] Implementation of the Patients' rights directive has led to convergence. National health systems that previously were different have become more similar. This could be due to EU legal pressures, EU normative pressures, and high degree of national responsiveness to EU pressure.

[2] Implementation of the Patients' rights directive has led to divergence. That is, the national health systems in the three countries have become more different than they were previously. Possible explanations for such a divergence effect could be specific national institutions and cultures, and/or that one or more of the countries have filtered the EU rules, which could lead to local adaptations of the directive.

Chapter Summary

This chapter focuses on methods, data and analytical approach of the study, scope and limitation of the study and the concept of Europeanization. It also discussed the EU's primary

and secondary legislature, directives and its implementation. The different health models in the EU was also discussed. Convergence and divergence of health systems was also presented and the issue of convergence leading to the assumption of either Europeanization of health systems in EU or divergence leading to non-Europeanisation ended up in two alternative propositions. The next chapter will focus on the background to the patients' rights directive and highlight topics that will help in answering the research question.

Chapter 3

Background to the Study

This chapter focuses on the background of the Patients' Rights Directive. The chapter would also highlight some of the concepts and topics required to answer the research question. The following topics were reviewed and made focal points of this chapter: EU and MS Autonomy; The Social Security Coordinated Regulation; Judicial Decisions; ECJ Ruling Implications and Patient Mobility.

3.1 The EU and Member State Autonomy

In 1952, before the European Coal and Steel Community (ECSC) Treaty was enacted; Robert Schumann (1952) made a speech where he said:

The free countries of Europe must not only demonstrate concern for the maintenance of peace, security and the good organization of their economy; there is another concern we have no right to ignore – human beings. If there is one area where we must act generously, it is in the area of health. If there is one area that seems to lend itself to unification, it is in the struggle against disease (cited in De La Rosa 2012, pp.1 paragraph 2).

This quote after sixty years has been realized in the patient' rights directives. He pledged in this speech his wish for an EU that is not only safe but an EU with healthcare for all irrespective of one's country (MS). One could say with the implementation of directive 2011/24/EU in 25th October 2015, his pledge has been realized. Thus, unifying EU in both peace and security.

The 1957 Rome Treaty established the EC and introduced the aims, goals, objectives and the values of the EU. Article three of the treaty sets out the role the EU will play and the purpose of the formation of the Union. The revision of the 1957 Rome Treaty into the *Single European Act* (SEA 1987) with the goal of establishing the internal market by 31 December 1992 (Nugent 2010), included steps to be taken to prepare MS for the realization of internal market, enhancing European integration, and increasing the emphasis on European level of public health concerns. The Maastricht Treaty (1st November 1993) is best known for the establishment of the EU, and initiated the process towards an Economic and Monetary Union

(EMU). Part of the Maastricht Treaty included public health policy for the first time. Art 3(o) of the EC affirmed that ‘*contribution to the attainment of a high level of health protection*’ was to be included in all Community activities (Official Journal of the European Communities 1992; Barnard, 2010; Harvey et al., 2004).

The EU treaties are the powers of the EU to issue legislature in the form of regulations, directives, recommendations et cetera to MS. EU institutions cannot modify, create, change, or adopt any new regulation or policy that surpasses the powers or authority given to them by MS. However, the authority to adopt certain aspects of the MS’s internal law involves three areas as stipulated in Article 3, 4 and 6 of the Lisbon Treaty. The authority to change must come from the EU level (the European Parliament and the Council of the European Union) not its institutions (committees under EU). The Council and Parliament alone is capable of regulating and adopting binding acts while the MS’s role is restricted to applying these acts. The MS can adopt certain acts once granted by the EU. The EU can only act in order to support, coordinate or complement the actions of MS through education and protection (Sigurdardottir, 2011). EU does not have jurisdiction to MS health policy or its health regulation. However, EU’s authority in conjunction with MS’s is in the area of internal market, social policy, public health and consumer protection.

The ‘health paragraph’ *Article 100, paragraph 3* “*The Commission, in its proposals envisaged in paragraph 1 concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection*”, was included in the Single European Market program to establish a platform for further development of health related policies in the EU (Greer, 2006). Greer 2006 added that the addition of paragraph 3 of article 100a did not concern MS since it was a voluntary coordination, where each MS can decide whether to accept the proposal or not. He suggested that healthcare (the treatment of illnesses) should be MS’s problem while public health (management of collective health threats) be EU’s problem and be managed by EU.

Even though the European Commission does not have a say in MS health policy, recent actions by the EU in matters of healthcare and in the insurance sector respectively have stated otherwise, especially concerning patients’ right to cross-border healthcare (Van Der Mei, 2003). The EU has also assumed responsibility for public health issues, and this is echoed in the “public health provision” of the EU which is included in the Maastricht Treaty of 1992;

this has had several revisions that ended with Article 168 in the Lisbon Treaty of 2007 (Veggeland and Time, 2015).

Article 168² (ex. Article 129 and ex. Article 152):

A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.

Union action, which shall complement national policies, shall be directed towards improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education, and monitoring, early warning of and combating serious cross-border threats to health.

The Union shall complement the Member States' action in reducing drugs-related health damage, including information and prevention.

Article 168 paragraph 7. *Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organization and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them. The measures referred to in paragraph 4(a) shall not affect national provisions on the donation or medical use of organs and blood.* According to this paragraph (7), even though the governing of health systems and formation of basic health policies is run by the MSs, the EU is playing an active role in health governance in terms of health protection and promotion of good health on a collective basis (prevention) (Mossialos et al. 2010; Mossialos and Lear 2012).

3.2. The Social Security Coordinated Regulation

Social security coordinated regulations were established to ensure the right to social security for workers and their family (Palm and Glinos 2010). To implement this, the EU mapped out social security measures that will prevent EU citizens and their families, refugees/stateless people and non-EU nationals living legally in the EU working in another MS from losing their social security rights. Hence, regulations 1408/71/EEC and implementation regulation 574/72/EEC (now regulation 883/2004) were introduced in the 1970s and became the legal basis for the institution of the 'safety net' (European Commission Communication, 2008).

The regulation was designed to establish social security entitlements to EEC citizens moving to another EEC country and their families, citizens living in multiple MS (for instance pensioners) and stateless persons or refugee seekers (Palm and Glinos 2010). Thus, Article 48 TEC (Treaty Establishing the European Community) ex Article 42 TEC of the principle of the free movement of persons, made it possible for EEC citizens/their families working in another EEC country to receive healthcare from the host country and according to host country conditions (Veggeland and Time 2015).

Article 22 and 22b of regulation 1408/71/EEC addresses people on a short visit and encouraged MS to have cross-border healthcare developments with each other. Although before the regulations (Article 22 and 22b), there were cases of mutual health collaboration among countries. Examples of collaborations are the ones among Norway, Sweden, and Finland at their borders (Lämsä et al, 2013), and collaborations between the Netherlands, Germany and Belgium (Van Thiel and Lugtenberg, 1999).

For someone to qualify for the *social security coordination mechanism*, his/her medical needs must have happened during a short stay with a family member or on a holiday in the said MS or as a worker at the said MS. For planned health needs, citizens must come with prior authorization from their home country (Palm and Glinos 2010).

Article 22

- *Stay outside the competent State – Return to or transfer of residence to another Member State during sickness or maternity – need to go to another Member State in order to receive appropriate treatment.*
- *A worker who satisfies the conditions of the legislation of the competent State for entitlement to benefits, taking account where appropriate of the provisions of Article 18, and:*
- *Whose condition necessitates immediate benefits during a stay in the territory of another Member State, or*
- *Who, having become entitled to benefits chargeable to the competent institution, is authorized by that institution to return to the territory of the Member State where he resides, or to transfer his residence to the territory of another Member State or..*

In September 2009, regulation 987/2009 laid down the procedure for the implementation of regulation 883/2004 on the coordination of social security and was adopted to replace regulation 574/72. The provision does not replace nor harmonize national social security systems, but instead the regulation seeks to provide coordination.

MS have the power to decide on the following:

- Who is to be insured under their legislation
- What benefit to grant and conditions for granting them.
- How benefit is to be calculated and what contributions should be paid (ILO report, 2010).

The difference between the social security coordinated regulation in the 70s and that of the new millennium (2000s) is related to the EU court of justice decisions (which is discussed in the next paragraph) and the additions of stateless individuals in the regulation. Other differences are the organizational methods that have been added to make rights of individuals effective and pleasant to MS citizens and those living in the MS.

3.3 The EU Court of Justice Decisions

Member States (MS) health systems do not allow insured person to go outside MS for medical care and expect a refund from the State unless the medical treatment is approved by the MS. Patients' rights directive was not EU's plan until the cases of patient's rights to medical treatments under the social security coordinated regulation became an issue in the 1990s and early 2000s and worried MS governments (Veggeland and Time, 2015). The EU Court of Justice's (ECJ) ruling in the cases of Kohll and Decker, Geraets-Smits and Peerbooms contributed to the facilitation of the free movement of patients and health services. Moreover, MS's room of maneuver to organize their healthcare systems was also affected (Hervey and Jean 2004). ECJ ruling withheld MS from regulating patient's access to cross-border healthcare in another MS and be reimbursed.

One example of an ECJ case that triggered change in MS health policies was the Kohll and Decker case (1998). The case was about two citizens of Luxembourg who were covered by the Luxembourg social healthcare system (Greer, 2011; Wismar et al, 2011). The system in Luxembourg allows citizens to receive their health care coverage through the social health insurer. Kohll and Decker wanted a service that is covered by their social health insurer, but did not want to have the service in their own country. Mr. Kohll went to Belgium for his service while Mr. Decker went to Germany for his daughter's service. Neither of the two men took prior authorization from their healthcare provider before going to another MS for treatment, however, both men were refused reimbursement on their return (Martinsen and Vrangbæk 2008). The Luxembourg Sickness Fund used the stipulation on Regulation 1408/71/EEC to refuse reimbursement. Both men challenged the decision by the Sickness Fund by maintaining that the decision not to refund them violates the principle of free

movement in Article 28 and 49-50 of the EC Treaty (Martinsen, 2011). The ECJ ruled that the Luxembourg Sickness Fund argument of the case resting on community law and not on social security, the regulation could not be used to violate the EC law.

The courts' consistent view that "Community law does not detract from the powers of the Member States to organize their social security systems" by no means implies that the social security sector constitutes an island beyond the reach of Community law and that, as a consequence, all national rules relating to social security fall outside its scope" (European Court Report 19981-01831)

The ruling meant to an extent that MS had power to organize their health systems but this power is confined (Case C-158/96 Kohll (1998) ECR I 19981-01831). These rulings and others have enacted restraints on the authority of MS and their health policies, in the form of citizens getting access to healthcare outside their country (Van Dei Mei, 2003).

Another case involved Geraets-Smits and Vanbraeket (Van Der Mei, 2002) and focused on the cross-border healthcare rights of pensioners under Regulation 1408/71/EEC on the social security schemes. The Cases of Muller-Faure and Van Riet focused on the application of Article 49 EC on the free movement of services to healthcare. The case of IKA versus Ioannidis centered on Article 22(1) c of Regulation 1408/71/EEC. This regulation deals with people qualified to receive treatment in their home country, who become ill in another MS and received treatment while on short visit in that MS. The ECJ in this case, left the issue to the national court to see if the treatment was planned or not, and in which case Article 22 will not apply. The final ruling on this case was based on Article 31, which is applicable to the right to treatment of persons who become ill during a stay in another MS. In the ruling, the court observed that Article 31 unlike Article 22(1)a of the Regulation does not limit the right to treatment to cases of emergency but also includes persons with chronic illness who know they might be ill during their visit to family members in another MS (Van Der Mei, 2003; Steyger, 2002).

The cases of Van der Duin and Van Wegberg-Van Brederode on the other hand, was about two pensioners, both Dutch citizens, living in France and Spain respectively. Both men returned to the Netherlands for medical treatment. They were refused treatment and asked to go back to France and Spain for treatment (Van Der Mei, 2002). The Dutch health system based their refusal to treat them on the fact that their illnesses were not medical emergence as stipulated in Article 22(1) a of regulation 1408/71/EEC. ECJ ruled that as far as the pensioners and their family members are registered with the country of residence France and

Spain, as stipulated in Article 29 of Regulation 574/72/EEC, they are entitled to medical treatment based on Article 28 of Regulation 1408/71/EEC (Van Der Mei, 2003).

3.4 Implications of the ECJ Rulings

The European Council meeting held in Barcelona in March 2002 replaced the previously used paper form (E Form) with European Health Insurance Card (HIC). Reformers saw this as a way to simplify the complications/issues arising from the co-ordination rules (Regulations 1408/71 and 574/72). This card is to be used by persons from MS on short visit to another MS who become ill and needed medical help (Kostera, 2008).

Another implication of the ECJ rulings was that MS's right to organize their healthcare or social security to an extent had been diminished, and a move towards Europeanized healthcare. In addition, MS and their health system (tax or insurance based) would have to take into consideration the European free market regulation before deciding on measures or methods to finance its healthcare. Both private and public providers require objectivity and transparency in relation to the free market regulation when drawing up insurance packages for healthcare within and outside their country.

Even though the ECJ judgements offered potentials for justifying the restriction of certain types of care, MS viewpoint to some extent are still relevant to all healthcare, since MS could decide delaying reimbursement or even using unrealistic caps on reimbursement. MS could also decide not to provide enough information on the possibility of being reimbursed from healthcare in another MS.

According to Van Der Mei (2003), the above rulings by ECJ presented new prospects to patients and new challenges to MS healthcare systems that were under pressure due to increased healthcare costs. Balancing health care needs through accessibility, quality, financial sustainability and equity are some of the difficulties and challenges facing management and administration of health in the MS (Wismar et al, 2011).

3.5 Patient Mobility

Patient mobility has become a more obvious sensation in the EU (Wismar et al, 2011). Patient mobility rules were decided by policy makers at the EU to create social security mechanism to aid with the free movement of people and services within the EEC (Palm and Glinos 2010: 509; Greer 2011b). This involves that people may cross borders to receive

health care (Legido-Quigley et al. 2012). In principle, patient mobility refers to patients seeking planned healthcare with prior authorization from their country to another MS (Rosenmoller, McKee and Baeten, 2006) or unplanned treatment outside their country of residence (Glinos et al 2010). Workers in another MS including temporary visitors to family members or tourists in another MS, especially pensioners, can access healthcare in another MS. This treatment is facilitated with the EU HIC described above, which entitles holders access to medical benefits and reimbursement of costs from the social security system of their country of origin. People with pre-existing conditions are also entitled (Patterson 2006). Similarly, people retiring to another MS can maintain their pension and have access to care in the new MS (Legido-Quigley: La-Para 2007). People in border regions can also access medical care in a nearby healthcare facility of another MS, for example the Scandinavian region comprising Norway, Finland and Sweden (Glinos 2010).

Health ministers from MS had a seminar on cross-border healthcare in Malaga. At the seminar, it was established that patients generally might prefer to be treated at their home countries because of language barrier. The location of the healthcare facility, travel cost, closeness to the border, income, continuation of care, uncertainties of going into another system, and re-payment of cost might reduce the barrier. The ministers also agreed that there were cases where treatment in another country might be the answer (Van Der Mei, 2003). They went on to highlight the importance and cases that could require such intervention (patient mobility) from another MS. Such cases were:

- *Highly specialized reference centers;*
- *The sharing of spare capacity with patients on waiting lists from other country;*
- *Cross-border care in border region; and*
- *Medical care for persons who set up residence for long periods in another country, while maintaining the financial sustainability of the national health care systems (Van Der Mei, 2003).*

On the revision of Regulation 1408/71, the health ministers emphasized the importance of sharing information and the inclusion of bilateral cross-border agreements among MS. The ministers also agreed to have a reflective group (the Association International de la Mutualite, the standing Committee of European Doctors, the standing Committee of Hospitals in the EU and the European Health Management Association), which would provide an internal medium for discussion and that could contribute to the development of an authentic and

comprehensive European Policy for Patient Mobility. The group whose role was to provide an internal medium of discussion and develop an EU policy on Patient Mobility met in the year 2003 and agreed that:

- *European co-operation to enable better use of resources;*
- *Information requirement for patients, professional and policy-makers;*
- *Access to and quality of care; and*
- *Reconciling national health policy with European obligations* (Van Der Mei, 2011).

A communique released by the Commission of the European Communities (2006) regarding community service actions on health services, stated that there are insufficiencies in the functioning of the internal market, especially in the area of health services due to the legal uncertainties surrounding patient mobility, thereby preventing citizens from benefiting from the free-movement of services (cited in Wismar et al 2011).

The Main areas of uncertainty according to the Commission's Communication were:

- *Shared values and principles for health services on which citizens should be able to rely throughout the EU;*
- *Minimum (practical) information and (legal) clarification requirements to enable cross-border health care;*
- *Identification of competent authorities and related responsibilities in various fields (quality, safety, redress, compensation);*
- *Safeguards for Member States receiving patients to be able to ensure a balanced medical and hospital service accessible to all;*
- *The impact of cross-border care on accessibility, choice, quality and financial sustainability;*
- *Leverage of Member States to regulate and plan their health systems without creating unjustified barriers to free movement; and*
- *Definition of health services and the link with related services (social services and long-term care).*

(Commission of the European Communities, 2006 cited in Wismar et al, 2011)

After the main areas of uncertainty were discovered, and after the ECJ rulings, the Commission started preparing for drafting a directive on Patients' right which was aimed at clarifying EU regulation of cross-border patient mobility (Greer 2013 and Veggeland and Time, 2015). After debates and discussions, the Commission presented a draft of the directive in 2008. However, after further debates and amendments, the EU directive on

Patients' right to cross-border healthcare was adopted in 2011 with implementation effective from 25th October 2013 (Veggeland and Time 2015).

Summary

The topics above illustrate how healthcare issues were introduced at the EU level. It also illustrates that regulations, ECJ rulings and policies on healthcare, though helpful, did not help patient mobility (Zanon 2011). Thus, there are much to be done at the EU level with regards to legislation since the national health systems differ in the EU. Regulation 1408/71/EEC and 574/72/EEC, regulations 883/2004 and 987/2009 can no longer be expected to bailout on issues that arises from cross-border care. This thesis will now analyze the implementation of Directive 2011/24/EU and its impacts in the three countries under study.

Chapter 4

The Implementation of Directive 2011/24/EU on Patients' Right in Cross-Border Healthcare in UK, Germany and the Netherlands

This chapter focuses on patients' rights directive. The chapter will also discuss implementation of patients' rights directive in the three countries under study. A brief historical background of the three countries will also be presented.

4.1 Directive 2011/24/EU on Patient's Rights in Cross-border healthcare

In March 2011, directive 2011/24/EU (legislative act) was adopted by the European Parliament (EP) and the Council. The Directive became a law in April of the same year, when it was listed in the Official Journal of the EU. Directive 2011-24-EU clarifies the guidelines on access to healthcare in another MS and reimbursement. The patients' right directive is aimed at clarifying EU regulation on cross-border healthcare (Zanon, 2011).

Article 168 (TFEU) became one of the legal basis for patients' rights directive which involves the protection of human health and cooperation between MS in health related areas. EU actions will aim at providing collaboration between MS and the EU, while the implementation of the policies must ensure a high level of health protection for its citizens. *A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities* (Article 168 paragraph 1).

Another legal basis of the directive is Article 114 TFEU (ex article 95 TEC). This article empowers EU to adopt legal channels to co-ordinate/protect the functioning of the internal market. Paragraph 3 of the treaty states that *the Commission, in its proposals envisaged in paragraph 1 concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection, taking account in particular of any new development based on scientific facts. Within their respective powers, the European Parliament and the Council will also seek to achieve this objective* (Article 114 paragraph 1). The treaty gives the EU the legal basis to introduce any measure that will help in the functioning/promotion of free movement. Thus, the directive aimed at promoting/developing the free movement within the EU, this free movement involves people/patients; hence, the need to safeguard patient's health has been addressed in the directive and its implementation (Panteli et al, 2015). It is also clear from the treaty that both EU and MS shall collaborate in

the area of common safety in healthcare. The EU will have the competence of supporting and coordinating the actions of the MS in health related areas.

The health of MS citizen is the responsibility of the MS. However, the introduction of free movement of services, directive on service in the internal market regulation, and the ECJ rulings (discussed in chapter 3) have somehow taken this responsibility from the MS, as a result of the need for EU coordination (by introducing the directive). The ECJ rulings on Geraets-Smits and Peerbooms; Kohll and others (discussed in chapter 3) confirmed EU's responsibility in the healthcare of MS and it also confirmed the free movement of services (including patients), by ensuring MS work together in the interest of its citizens (both outside and inside the country).

In addition to addressing patients' right to cross-border healthcare and services, the directive is also clearing up years of legal ambiguity and creating the balance between preserving the sustainability of health systems while protecting patients' rights to seek treatment outside their home country. It also provides for a clear policy/regulations/rule to accessing the quality of care and services (Den Exter et al, 2014).

Reimbursement has always been the cause of disagreement to patient mobility. Thus, the directive on patients' right to cross-border healthcare specified that MS health system would reimburse for the cross-border treatment. The reimbursement would depend on how much that service would be charged had the procedure been done in that MS. Additionally, the reimbursement in some cases could be limited due to certain reasons of general interest to the MS, or higher in some other cases.

The directive does not apply to long-term care, cosmetic surgeries, and unconventional therapies including experimental treatments as seen in the case of UK's Ashya King - a five years old boy with brain cancer (tumor). His parents and doctors did not agree about his treatment. His parents wanted that he should be taken to Prague in Czech Republic for an experimental treatment, while his doctors thought he would be better with conventional and tested radiotherapy. His parents took him to Prague for the treatment and he became better (O'Brien, 2014). The dispute here is that parents were refused to go for the treatment because experimental treatment was not in the directive.

Medical (medication) expenses are also reimbursed under the directive, but only medication used during the treatment (Jakel, 2015). Some writers are advocating for a unified 'cap'

concerning reimbursement policies, and to set up reasonable caps within the financial and economic balance of the MS in question (Santor et al, 2014; Azzopardi-Muscat et al, 2015).

One objective of the directive (2011/24) is to help citizens/patients to have cross-border care while ensuring high level of health protection among Europeans. The directive shall ensure that expenses are reimbursed to the extent that the citizen is entitled to in his/her own country. It is believed that the directive will lead to the setting up of expertise and specialized centers among MS and that MS will cooperate with each other in promoting and sharing such expertise and specialties (Panteli et al, 2015).

Similarly, article 8.1 and 8.2 of the directive give MS the option to introduce prior authorization before a patient can access cross-border healthcare. MS are required to set up a National Contact Point (NCP). This NCP is to enable patients' access clear and reliable information on cross-border care, access, reimbursement, medication, and quality of care in another MS. The NCP should meet the citizens' expectations by giving them the proper health care information including healthcare quality and patients' safety to help them make an informed decision before travelling to the other country (Jakel, 2015).

In addition to clarifying patients' rights in cross-border healthcare, the directive supports cooperation among MS. The directive affirms the quality of the cross-border care by eHealth in the form of electronic transmission of medical information. This offers opportunities for improving continuity of care in a cross-border healthcare setting (Doering et al 2013a). One challenge involving eHealth, however, is that data can fall into the wrong hands, hence the need for strong political priority to advance eHealth (Kierkegaard 2011). Similarly, telemedicine across border can also help in the quality of care in cross-border healthcare. Telemedicine is the delivery of healthcare service at a distance using information and communication technology. This is a new trend gaining popularity and could help to reduce the cost of medical expenses. It can be used to link patients with healthcare providers in other countries; for example, two health professionals in two different MS can use telemedicine to operate on a patient. Some challenges of telemedicine include the lack of *interoperability* between IT systems, difference in regulatory, financial and legislative policies across MS systems (Saliba et al 2012).

Prescription of medication is another issue that can impact cross-border healthcare because of lack of clear guidelines to follow, such as the format of EU prescriptions and their validity

period, who to contact when presented with some foreign prescriptions, what source to consult for information on product composition and prescriber credentials. Clarifying these issues can help to improve presentation of medication to a citizen from another MS (San-Miguel et al 2013). It is also worth mentioning that there are some medication/supplements that are endorsed in one MS and not in others. The prescription issue, however, was rectified in another directive (Directive 52/2014/EU).

Also, the quality of discharge summaries (documents), which describes what treatment have been given and what needs to be given in case of emergency, is key to primary and secondary care giver information. This will also help deal with any unforeseen challenges and will give sufficient information as to where the problem is coming from (Glonti et al 2014; Hesselink et al 2012). A robust quality of discharge documents can help with effectiveness of care and avoid duplication. According to Kiasuwa et al (2014), there are no standards of discharge summaries for follow-ups, hence the need for standardization of documents to enhance the continuity of care (should patient have need of care after discharge from another MS hospital) which happened to be the weakest in cross-border healthcare (Groene et al 2009).

The quality of information has, however, neither added quality to cross-border healthcare nor amount of care received because receiving hospitals look for information in their 'own way', not willing to cooperate with each other. This has made the provision of complete discharge summaries a low priority by medical personnel (Hesselink et al 2012a: 2013). The compatibility of approaches to disease management among MS is vital to in order to reduce the problems associated with incomplete care of cross border care, as this creates problems when it comes to reimbursement (Legido-Quigeley et al 2011b).

In summary, the directive clarifies the rights of patients to seek reimbursement for healthcare received in another MS. It focuses on reimbursement as well as the level of reimbursement. The idea that if a citizen qualifies for a service in their own country, they also qualify for same service in another MS is important to note in this directive. MS are given the discretion of either asking for prior authorization or not.

The directive requests for the establishment of National contact points for information and inquiry for potential patients, healthcare providers, and tourists. It also mandated the recognition of prescription from another MS. The directive is motivating better cooperation between healthcare regulators, providers and purchasers in different MS. Patients' rights

directive clearly identifies cross-border provision of healthcare potential and the most efficient way of organizing health services for increasingly mobile European populations (Glonti et al, 2014).

4.2. Implementation of Directive 2011/24/EU on Patients' Rights in Cross-Border Healthcare: United Kingdom, Germany and the Netherlands: Introduction

The EU regulations on the coordination of social security systems (regulation 883/2004; ex 1408/71) already provide certain levels of healthcare cover to EEA citizens (Palm and Glinos, 2010). It was applicable to tourists requiring care during a short visit to another MS, people working and living in another MS with their families, or patients on a planned healthcare visit with prior authorization from their country. Additionally, the regulation covers pensioners because social security provisions are transferable from one MS to another at state pension age. However, because of ECJ cases and rulings on issues that arose from the regulation, patients' rights directive was introduced.

The patients' rights directive harmonizes regulation 883/2004, hence, the stronger emphasis on the implementation phase is required to closely understand, analyze and improve the functioning of the directives (Treib 2003). The directive provides avenue for accessing safe and quality cross-border healthcare and promote cooperation on healthcare issues among MS. Articles 4 to 8 of the directive highlighted the requirement and responsibilities of MS. It also highlights what needs to be transposed by MS. Article 6 of patients' rights directive asked MS to open a national contact points (NCP) where information on essential aspects of the cross-border healthcare will be given to potential patients. It will facilitate exchange of information between MS NCP. Voluntary information should be given in the official language of the MS in which the NCP is located (for instance in Norway, Norwegian and English). Furthermore, Article 6 of the directive asked the MS to use their own discretions on the number of NCP they will have in their country. The NCP can be incorporated in any existing information center. However it should be given the name NCP (pls. see. <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:EN:PDF>)

Based on Article 6, the NCP should be transparent and efficient and should be in consultation and cooperation with patient organizations, healthcare insurers and healthcare providers both within and out the MS. Opening NCP should not stop MS from opening other links at local level in accordance to their healthcare system. MS are also expected to accelerate cooperation

between healthcare providers, purchasers and regulators of other MS in order to ensure *safe, high quality and efficient* cross-border healthcare for their citizens.

Article 7 highlights the principles of reimbursement of costs. This should be reimbursed by MS of affiliation. The cost that would be reimbursed would be the same had the service been provided in the MS of affiliation. The MS of affiliation may decide to reimburse other costs. A transparent mechanism to calculate cost of healthcare received from another MS should be put in place. According to Article 8, prior authorization is voluntary but the directive allows for prior authorization under certain specified conditions involving hospital care, specialized and cost-intensive care. Prior authorization should also be given within a reasonable time. The MS should inform the citizenry treatments and services that need prior authorization. Article 9 dealt with administrative procedures regarding the cross-border healthcare between MS, and advised that it should be objective and non-discriminatory.

Article 10 advocates cooperation among MS on healthcare issues while article 11 asks for recognition of prescription among MS, hence, the subsequent directive on recognition of prescription in 2014 (Directive 52/2014/EU). Article 12 states that EU will support MS in the opening and developing a common European Reference Network (ERN) between healthcare providers and centers of expertise among MS. The EU also supports MS in cooperating in new developments and new treatment of rare diseases. Article 14 and 15 state that the EU will also support eHealth among MS and cooperation on health technology.

Article 16 dealt with representatives of a Committee that will assist the Commission. This committee will consist of representatives of MS; the chairperson will be a representative of the Commission. Articles 17 to 19 deal with the exercise of the delegate, its revocation and objections to delegated acts. Article 20 concludes the stipulations of the directive on reports to be submitted by the Commission by 25th October 2015 and subsequent ones every three years.

The EU hopes that this Directive will end the court cases (like that of Kohll 1998; Geraets-Smits and Peerbooms 2001) associated with cross-border healthcare that has reshaped EU health law. However, Greer (2013) argues that it will rather produce more judicial challenges. He stated that the idea of patient mobility is good but it has unclear definitions and divergent implementation. Similarly, Vollaard and Martinsen (2014) stated that the transposition process of the directive and the conflicts that arose have been a continuation of the conflicts

regarding EU's interference in the management, organisation and financing of MS healthcare. Glonti et al (2014) add that there is no information prepared specifically for healthcare providers by the European Commission and the extent to which governments take on this role (information to providers) is unclear. Below follows a brief history of the three studied countries, and how they implemented the directive.

4.3. The United Kingdom

The United Kingdom (UK) consists of England, Northern Ireland, Wales, and Scotland and has a population of 64.1 million (Office for national statistics, 2015), with a GDP and GDP per head in 2009 of 1.1 trillion and 19,333 pounds respectively. There are also a number of dependent areas under the UK, these are Anguilla, Bermuda, British Indian Ocean Territory, British Virgin Islands, Cayman Islands, Falkland Islands, Gibraltar, Guernsey, Jersey, Isle of Man, Montserrat, Pitcairn Islands, Saint Helena, South Georgia and South Sandwich Islands, and the Turks and Caicos Islands (Boyle 2011). For the purpose of this thesis UK, consist of England, Northern Ireland, Wales and Scotland.

The UK has a constitutional monarchy governed by a parliament comprised of two houses. Democratically elected MPs represent 650 local constituencies (House of Commons). The head of state is a hereditary monarch, Queen Elizabeth II (since 1952) while the head of government, the Prime Minister, is the leader of the party that can command a majority in the House of Commons (Boyle, 2011).

The unemployment rate in 2004 and 2010 were 4.7% and 7.8% (recession) respectively. Based on a measure of poverty (proportion of individuals living in households whose incomes are below 60% of the contemporary median income), 18% of UK, compared with an EU average of 15% (based on the EU15, the 15 Member States prior to May 2004), 11% in Finland, 12% in France and 15% in Germany (Eurostat, 2007; Boyle, 2011). By 2008–2009, the UK percentage was unchanged at 18% (Department for Work and Pensions, 2010a; Boyle, 2011). In 2009, 20% of UK white live in low-income housing while 60% of Pakistani/Bangladesh and 48% of Black Non-Caribbean households (Department for Work and Pensions, 2010a; Boyle, 2011).

The National Health Service (NHS), established in 1948, is mostly free at the point of use. It is highly centralized when it comes to funding and is mainly financed by government through general taxation and National Insurance Contributions (NICs). Other funding is through

private sources, such as local hospitals, Private medical Insurance (PMI), NHS user charges and direct payment for private care also help raise some funds. There have been some aspects of decentralization in the NHS system with the introduction of internal market by conservative governments since 1991. The role of the internal market was to allow health authorities, GP fund holders and other health organizations to purchase care from trust (hospitals and healthcare providers with Trust status). The role of the internal market has changed the role of the DOH (Department of Health) to that of setting strategy and policy directions that will be taken forward by the semi-independent local bodies created after the introduction of the internal market. In 2006/7, consolidated fund and NHS contributions represented 76.2% with 18.4% from other source of financing (source: DOH 2006; Boyle 2011).

Since 1997, UK NHS system has witnessed a series of organizational changes that have resulted in a shift responsibility away from the department of Health to the local levels. Part of the change included the creation of Primary Care Trust (PCTs) with responsibilities of commissioning health services for geographically defined populations; introduction of new types of NHS providers, Foundation Trusts (FTs), with greater financial and managerial autonomy; and the greater use of private-sector capacity to deliver publicly funded health care.

NHS Payment: Before 2003, hospitals were paid using a system of block contracts based on agreed sum per amount of activity. Under the Payment by Results (PbR) system (introduced in 2003/4), prices were negotiated locally and providers paid a fixed amount irrespective of the work performed. However, the PbR system did not include mental health services, critical care, community health services, ambulance services, and other acute hospital settings (Boyle, 2011). Most healthcare expenses are provided by government and funds allocated to PCTs (third party payers) with responsibility of commissioning healthcare in their localities and providing the services themselves, in some cases. Department of health (DOH) allocates about 80% of the NHS budget to PCTs to commission services in their locations including contracting for PMs, primary dental services, pharmaceutical services, and many others (Boyle, 2011).

The NHS provides preventive medicine, primary care and hospital services to ordinary residents in the UK. About 13% of the population are covered by voluntary health insurance, which is referred to as PMI in UK. The role of the DOH is to set policy on the NHS, public

health, adult social care and other related areas. A range of government and independent bodies, called "arm's length" bodies assist the DOH in setting and monitoring standards at a national level. The role of the Treasury is to set the national budget for publicly funded health care with the Permanent Secretary, providing leadership and direction. NHS Chief Executive provides strategic leadership for NHS and social care, and together with a permanent secretary in the DOH, run the NHS system (Boyle, 2011).

According to the OECD health statistic 2014 report, the total health spending in the UK accounted to 8.5% of GDP in 2012, slightly down from a high of 8.8% recorded in the 2009. Total health expenditure for UK in 2013 was £150.6 billion, an increase of 2.7% between 2012 and 2013. In 2013, health spending was 8.5% of GDP (Lewis and Cooper 2015) with an annual average growth rate of 2% from 2009 to 2013. Health spending in UK surprisingly fell in 2010 and 2011 for the first time since the 1970s (OECD report 2013).

Healthcare policy and decisions are the responsibility of each region's respective government/regional leaders (autonomous). However, healthcare policies and decisions for England is the responsibility of the UK central government, this is because 84% of the UK population live in England. Meanwhile, all the 4 regions had its own NHS structure and organization, not so different from each other.

4.3.1 Implementation of the Directive in the UK.

Even though England, Scotland, Wales and Northern Ireland make up the UK, the four regions had separate consultations on the implementation of the directive because they all have their own health systems. The UK started their implementation process in April 2013, after a report group called the 'European group' set up from the NHS submitted their report (DOH 2013). The report submitted by the 'European group' gave the UK government perspective on how the directive could be transposed. After deliberations and debates, on 9th September 2013, Regulation 2013 No. 2269 NHS (UK Cross-Border Healthcare Regulation) was made and laid before Parliament on 13th September 2013. After debates by stakeholders and Parliament, the regulation came into force 25th October 2013 (Statutory Instruments, 2013). The Parliament agreed to dissolve the PCTs and allow NHS to take over responsibilities that deal with patient mobility (DOH, 2013). PCTs responsibility of making decisions on prior authorization and reimbursing the costs of healthcare under the social security coordination regulation was replaced by 6A and 6B (of the NHS Act). When

implementing the directive, the government has also set out to the NHS's constitution a number of additional rights for NHS patients. These include:

- *To access drugs and treatments that have been recommended by National Institute for Health and Care Excellence (NIHC) for use in the NHS, if your doctor says they are clinically appropriate for you.*
- *To expect local decisions on funding of other drugs and treatments to be made rationally following a proper consideration of the evidence. If the local NHS decides not to fund a drug or treatment that you and your doctor feel would be right for you, they will explain that decision to you (Jackson, 2013).*

Implementation in Wales, England and Scotland came into force on 25th October 2013 while Northern Ireland implemented the directive on 27th December 2013. The aim was to clarify and simplify the rules and procedures applicable to patients' access to cross-border healthcare. It is also aimed to comply with EU directive on providing EU citizens with better information on their rights (BMA, 2014). This was to ensure that cross-border healthcare is safe and of high quality and finally to promote cooperation among MS. The principle was based on the logic: 'if you are entitled to it here, then you can get it there'. However, it depended on the service being same as or equivalent to the service that would have been provided to the patient within NHS in the same circumstances (DOH, 2012).

England, Wales, Scotland and Northern Ireland set up NCPs in accordance with the stipulations in the directive's implementation process (Article 6 of the Directive). The general role of the NCPs was to inform citizens of treatment they can have overseas and those that can be on the directive route or S2 route (regulation 883/2004 ex 1408/71) (see fig 1 in appendix).

The NCP is also responsible for receiving patient application for authorization under the directive and under regulation 883/2004 and reimbursement under the directive 2011/24/EU. It also involves informing the public about the rights to entitlements and reimbursement principle including which services that patients will be reimbursed, and services that are not refundable. NCP has also the responsibility for calculating the reimbursement levels and informing potential patients about it, considering application for prior authorization, dealing with appeals, reviews and data collection. NCPs was opened in all the four regions of the

UK, however, there are reports of inconclusive information by the NCP (EU Commission Report 2015).

4.3.2. Prior Authorization and Reimbursement in the UK

Unlike Norway, where there is no prior authorization for both planned and unplanned cross-border healthcare, the patients need prior authorization according to the UK's implementation. This is in agreement with the stipulation of article 8 of the directive where MS has the discretion of either having prior authorization or not. The European Team (ET) prepared a list of illnesses that needed prior authorization (see appendix 2), that give potential patients an idea about the reimbursement of the treatment.

There are five steps for a patient to get prior authorization, and be reimbursed. First, potential patients apply for funding and in the application; patients would have to add evidence of clinical need and proof that they can pay for the treatment before reimbursement. The ET will then look into the application, after which patients are informed of the outcome, and if successful, will be reimbursed (see fig. 1).

The UK made it clear that even with prior authorization, there is no reimbursement of travel or accommodation expenses unless patients are entitled to the travel and accommodation assistance had the service been given in the UK.

There are a number of reasons for a patient to be granted authorization under the NHS implemented directive. These include undue delay; in this case, patients are to provide documentations that prove the need for urgency and the effect of the delay, this they do by submitting their medical history, evidence of pain and discomfort of the illness to their daily activities et cetera. In addition, patients are to submit to NHS proof that this treatment abroad (another MS) can alleviate the said problems before the patient is treated at home (UK) (Regulation 7 of NHS and regulation 2013 S.I 2013/261).

However, according to the EU commission report to the European parliament, 36% of the UK citizens know there is reimbursement to cross-border healthcare (EU commission 2015). NHS makes sure that patients know NHS is not liable for any failure they might encounter whilst having treatment outside its territories (NCP, 2013).

Patients from another MS to UK for healthcare must put into consideration UK's different systems although all four are NHS. Wales, Scotland, England and Northern Ireland have

different healthcare procedures. There are some differences in seeking care in the UK. For instance, if the patient (from another MS) is seeking care in UK (England, Northern Ireland, Scotland or Wales) and the treatment/service is to take place in a public healthcare facility in England, the patient will pay consultation fees (if patient is working and is not a mother). Nevertheless, in Wales, Scotland and Northern Ireland, consultation and medication are free for both home patients and patient from another MS.

However, if the treatment is in a private facility (in England, Wales, Scotland and Northern Ireland), the patient will pay for both consultation and medication and is entitled to reimbursement as stipulated in the directive 2011/24 in their home county. The advantage of using private facilities is that they can have quick available time. However, both the private and public facilities treat patients based on first-come- first-serve basis, irrespective of where you are coming from (UK citizen or another MS citizen), unless in the case of an emergency or life threatening situation (NHS Website).

Unlike the directive route, the S2 route (regulation 882/2004 EU) relates to how state-provided treatment and cost of treatment is dealt with between MSs, with the S2 acting as a form of payment guarantee. Patients in most cases are not required to pay anything by themselves but they need prior authorization. However, with the directive route (2011/24/EU), patients who want to seek health care in another MS can seek reimbursement (Article 7 stipulation) if the costs provided by the service is the same and the right to claim is only what the NHS would have spent had the treatment occurred back home. In addition, patients in the directive route may have the treatment and ask for reimbursement later. However, patients are advised to ask for authorization to be sure there is reimbursement for the service before taking the treatment.

Healthcare providers in the UK providing treatment to visiting patients under the provision of the directive need to observe some key requirements. These include:

- *Afford patients relevant information on treatment options, quality of care and safety;*
- *Clarify invoices and price information;*
- *Apply fees in non-discriminatory manner (same price for UK and MS patients);*
- *Have transparent complains procedure and also redress process; apply adequate system of professional liability insurance or similar process;*
- *Respect privacy in the handling of personal information;*

- *Supply patient with a copy of their medical treatment for continuation of treatment if need be* (BMA site).

The patients' right directive did not stipulate that MS must accept all patients from another MS although it is required for MSs to do so. This means MS are using their discretion to give available, safe and reliable services to patients from another MS and their citizens. Patients are allowed to come into the UK for cross-border healthcare. The ET department however, advise visiting patient to contact health providers first before coming to avoid undue delay (BMA site).

In summary, the UK according to stipulation in Article 6 opened NCP in all four regions of the UK. In addition, according to the stipulation of Article 7 on reimbursement, the UK implemented it. Patients are entitled to reimbursement if they have prior authorization. Article 8 stipulation of prior authorization was also implemented; the UK decided to use the option of prior authorization.

4.4. Germany

Germany, with a population of about 81.1million, is the biggest economy in the EU (OECD, 2013a, cited in Busse and Blumel 2014; Destatis, Statistisches Bundesamt, 2015). Germany has a federal and constitutional system of government with 16 autonomous states. One thing that contributed to the choice of Germany in this study was the fact that it shares borders with many countries (Denmark, Poland, the Czech Republic, Austria, Switzerland, France, Luxembourg, Belgium and the Netherlands) and its diversity in terms of population and religion. For instance, 33% of inhabitants are citizens of another EU MS (Busse and Blumel, 2014). Germany is also seen as the first country to introduce a national system of social and health insurance 1883, during the chancellorship of Otto von Bismarck. Some of the core values of this system centered on solidarity and non-risk related contributions kept separate from general taxes (Busse and Blumel, 2014).

This system (Social Health Insurance) and the shift from cash payments to benefits in kind corresponded with growth in healthcare professionals in Germany. Fixed co-payment per prescription and an additional co-payment for ambulatory care consultations were introduced in 1930 because of high unemployment and rising expenditures in health care (Busse and Blumel, 2014). With the unification of Germany, the challenges to the health system increased and required immediate reforms. The reforms from 1988 through mid-1990 show

more government intervention as health expenditures went up. The addition of new benefits to better suit the needs of the people, and pro-competition regulations among payers and in hospital sectors were introduced. In addition, access to long-term care was expanded with the introduction of a statutory long-term care insurance scheme as one of the pillars to the German social insurance system. By 1996/78, reform act with emphasis on revenue generation by raising out of pocket payment and reducing preventive and rehabilitation benefits, in addition to the removal of dental implant services for people born after 1978, was passed. In 1998, a new reform with more focus on stricter cost containment and sustainability in all sectors was introduced and some of the earlier reforms were revoked consequently. With the grand coalition government in power, since 2013, the major focus is now on new initiatives with emphasis on improving the quality of care (Busse and Blumel, 2014).

A lot of the German SHI transformation and reforms depended on which political party was in charge. Some of the parties included; Social Democratic/Green Coalition Government, Christian Democratic Union/ Social Democratic Party, and the Christian Democratic Liberal government (Deutscher Bundestag, 2014; Busse and Blumel, 2014).

The German SHI focuses more on efficiency and effectiveness of the care as well as social reforms and development in areas outside the health sector. The stakeholders involved in the SHI systems are more simplified. The Federal assembly, Council and Ministry of Health (with six departments) are the major players in the health care system. Health responsibility is combined with labor and social affairs (Busse and Blumel, 2014). The German SHI uses a Sickness Fund that have many responsibilities. Some of the responsibilities include; collecting contributions from members, negotiating prices, quantities and quality assurance measures with providers, and others. A good portion of Germany's wealth is spent on its healthcare system. In 2012, the total health expenditure was 300 billion Euros, representing 11.4% of GDP. When you consider health expense as a percentage of GDP in Europe, Germany ranked fifth behind the Netherlands, France, Republic of Moldova, and Denmark. The public share of the total health expenditure in Germany has decreased from 81.7% to 75.9% from 1995 to 2011 (WHO data).

SHI or sickness fund is the major source of healthcare financing in Germany, representing 85% of the population in 2012. The other 15% was covered by Private Health Insurance (PHI) (11%) and sector-specific governmental schemes such as military and social welfare (4%). Even though SHI accounts for 85% of the population, its actual overall health

expenditure was 57.4%. The top four main sources of finance as a percentage of total health expenditure in 2012 were Statutory Health Insurance (57%); OOPs/NGOs (14%); Statutory Long term Care Insurance (8%); and PHI (9%).

There was a rise of almost 1% from 2008 to 2009, and a drop in 2010 and further 0.3% downward trend which continued from 2011 to 2014 (0.2%). Like the UK, there is the need for further research into this steady decline in health expenditure as a share of GDP. Either the downward trend could be because of the new directive or because of MS actions toward healthcare reduction through their own policies (see fig. 4).

4.4.1 Implementation Process in Germany

According to Kifmann and Wagner (2015), Germany has since 2004 implemented most of the transposition requirements even before the directive and its implementation dates. This is because Germany was one of the countries that were affected by the ECJ rulings. Germany's implementation process, unlike the UK was different. The Germans introduced Statutory Health Insurance Modernization Act of 2004 (GMG). In this Act, Germany implemented provisions regarding reimbursement and prior authorization. The stipulation highlighted in Article 7 that is the principle of reimbursement has been in place since 2004. In addition, the stipulation of prior authorization highlighted in Article 8 was also taken care of in 2004 with the introduction of GMG. The only aspect of the directive that needed to be transposed was on Article 6, which is on the setting up of national contact points (NCP). The Ministry did not see the need for a debate as it had already implemented most aspects of the directive unlike the UK (Goscinska 2014). The *minimal* transposition was added to the Patients Right Law (PRG). This addition had to do with information on diagnosis and treatments, treatment options and cost. This information was not in the initial change done in 2004. Other information includes availability of treatment, quality of care, registration, insurance coverage and issuance of invoices. This aspect, were however, the responsibility of the German Lander, hence no need for public debate or legislature at the federal level unlike the UK.

Germany added NCP by the modification of the application group and it was published in November 2012 (Austausch-anderungsantrag Zu AA no.7). There were problems with the addition of this legislature because not all stakeholders were able to review the amendment (Goscinska 2014). Like the UK, it was suggested that comprehensive information should be made available to patients, not only to policy makers.

The German Medical Association (BAK) and the Federal Association for Statutory Health Insurance Physicians refused to give information about costs (Goscinska 2014). This is because the allocation of costs is not done by them unlike the UK, where the doctors are government 'gate keepers' and have been given the job of determining the costs and who is eligible to a service. The implementation legislature that now stipulates that doctors should give out all information on costs did not go down well with the BAK. Because doctors in the UK are government workers and the institutions are owned by the government, unlike Germany where the Sickness Fund and the PHI own the establishment.

EU-Patienten.de (non-competitive platform) NCP is a department added to the already functioning DVKA (The German Liaison Office for Sickness Insurance-Abroad) since 2004, it had the responsibility to see to the provision (establishment of NCP) of directive 2011/24 since 2013. The platform is to offer information to insured German citizens, citizens from other MS and EEA and Switzerland citizens wanting to have cross-border care. The department is also available to answer questions about healthcare outside Germany and inside Germany for both outsiders and insiders. The department works in liaison with other NCPs (MS) to help receive information on possible treatment in other MS. It acts as the intermediary for potential patients to another MS and provide an interpreter in language situations.

Like the UK, the German NCP provides information to insured and legitimate potential patients from another MS on specific treatment in Germany. List of healthcare providers and their addresses are available to patients from other MS. The NCP is also available to deal with patients directly or through their NCP contact. Germany has mutual agreements and collaborations with countries in and outside the EU.

4.4.2 Prior Authorization and Reimbursement in Germany

There are two types of health insurance in Germany: statutory insurance and private insurance. For hospital treatments or highly specialized treatment, patients need prior authorization and usually patients are given the regulation route (s2 route). Prior authorization is not needed or necessary for planned or unplanned ambulatory care in the Directive route. As this is a care that takes place at outpatient medical facilities, the cost however will be reimbursed depending on the rates of the patients' insurance fund. Like the

UK, the Germans advise patients to check with their health insurance or sickness fund to find out if the specific illness is reimbursed and the amount that will be reimbursed.

If patient has statutory insurance and wants to have planned treatment in another MS, he/she needs to have prior authorization from their health insurance fund. When the person passes the process of applying for prior authorization, the person will then be issued with form S2 like the UK. This enables patients to have treatment that would be reimbursed by their health insurance fund (S2). Form E112 (the directive provision), patients do not need prior authorization. Patients receive treatment like someone with PHI (where you pay for the treatment and be reimbursed later). Like the UK, the two routes differ (see appendix 2). Patients do not pay with S2 (regulation 883/2004) form. However, patients with the E112 form can pay and be reimbursed later.

The patients with PHI need to contact their insurance organization, to find out if they are covered for the service and how much will be reimbursed, before going for the treatment in another MS. Also before going for authorization, patients have to gather most of the information themselves like UK.

Germany's NCP, like the UK, has information for patients from other MS too. They also have addresses of healthcare providers. The policy is 'if you are qualified for healthcare in your country, you are also qualified in Germany'.

The benefit entitlement in the framework has been largely regulated in Germany since 2004 in section 13 sub. 4 to 6 of book V of Social Code (SGB V). The information also includes benefit for drug prescription (EU directive No. 52/2014).

In summary, the Germans through the introduction of the GMG implemented one out of the three stipulations of the Directive to MS. Patients do not need prior authorization in Germany since 2004. Patients are reimbursed of the cost incurred from healthcare in another MS since 2004. However, the Germans put in place NCPs, where patients will receive information about cross-border healthcare. The NCP is also used to give information to patients from other MS and to healthcare providers both in and out of Germany.

4.5 The Netherlands

The Netherlands has a population of 16.9 million (Statistics Netherlands 2015) and covers an area of 41,543km². According to Statistics Netherlands (2009) report, 80% of the population

are native Dutch. Even though the Netherlands has a relatively small size and small population, its economy is among the world's top 20 in terms of total GDP and top 10 when one considers only export volume. The Dutch economy, with relatively lower unemployment rate compared to other European countries, is known for its advanced transport infrastructure, financial and commercial services, and agricultural sector (The Ministry of Foreign Affairs [Ministerie Van Buitenlandse Zaken] 2009).

Since 1970, the Netherlands has witnessed decreasing annual population growth. The country is known to have had an ageing population with percentage of children under 14 years decreasing since 1970 whilst those of the elderly has steadily been increasing. The most affected is the rural population, which has dropped more than 50% from 38.3% to 18.7%, as a percent of total population since 1970 (World Bank 2009).

Additionally, Netherlands has seen a decline of mortality rate and an increase of life expectancy from 73.6 years to 77 years between 1970 and 2006. The life expectancy rate for women is higher than that of men (World Bank 2009). In 2009, the life expectancy compared to the other European Countries has declined from a top ranking to an average that prompted the Ministry of health, Welfare and Sport (Ministerie Van Volksgezondheid, Welzijn en Sport, VWS) to make reversing this trend, a priority. The major cause of death is cancer. Smoking and obesity are two of the major risk factors affecting the Dutch health status. As at 2007, for instance, the percentage of Dutch daily smokers was 29.1% compared to European average of 27% (WHO Regional Office for Europe 2009). According to a self-reported data on obesity, about 50% of the population seems overweight as at 2007 (statistics Netherlands 2009).

Irrespective of the above health problem faced by the Netherlands, a key measure of health status improvement in Netherlands is the National Vaccination Program. Immunization levels for measles is well above the EU's 27 average and in 2009, national level update rates for vaccination coverage in all immunization categories in this program was well above the lower limit of 90% (Van Lier et al 2009).

Government became more involved in social security in the beginning of the 20th century in issues related to illness. The 1901 Accident Act was the first government move towards a more social insurance system (De Swan 1989; Veraghtert and Widdershoven 2002).

Government interference in the health insurance sector began with the sickness act that was

adopted in 1913 (Ziektewet) but implemented in 1930. The Act excluded medical expenses and only covered sickness benefits until the German occupiers in 1941, forced the establishment of the Sickness Fund Decree with compulsory insurance for employees and their relatives earning less than a certain income threshold and with uniform and broader benefits that included ambulatory and inpatient specialist care. The 1941 decree increased health care coverage from 45% to 60% (Kappelhof 2005; Veraghtert and Widdershoven 2002). The next act by government was in 1964 where it passed the Sickness Fund Act or the compulsory Health Insurance Act (Ziekenfondswet, ZFM). The Act was enforced in 1966 and included a Compulsory Social Insurance Scheme with income-related contributions for severe medical risks for the entire nation (Schåfer et al 2010). Government's role was initially limited with majority played by non-profit providers, insurers, and self-employed practitioners. A social insurance scheme replaced subsidies to mental health, inpatient long-term care, and disability services in 1967. Major focus from 1970 to 2006 centered on cost containment, by introducing hospital budget-caps, measures to resolve the uneven service provisions and attempts to abolish the dual system of social and PHI (Schåfer et al 2010).

The Dutch healthcare system is categorized by the governance mechanism of regulated competition (Heldermann et al, 2005). A 2006 healthcare reform seen as a by-product of the "Bismarckian" system, introduced a single compulsory insurance scheme that allows multiple private health insurers to compete for insured persons and make profit in the process. This reform has changed the roles of health insurers and patients. The citizen are asked to choose their own health insurer, which encourage competition among insurance companies. The Dutch Ministry of Health determines the basic costs of insurance packages on annual basis. The system's management has been delegated from government to independent bodies with each municipality responsible for social support (Schåfer et al 2010; Hamilton, 2013; Enthoven and Van de Ven 2007).

Prior to 2006, the health insurance in the Netherlands was a mixture of mandatory public insurance (greater than 60%) and voluntary private insurance (less than 40%). From 2006 (Health Insurance Act) to date it has been mandatory private insurance (100%), mandatory for everyone in the country to buy individual health insurance from a private insurer, a standard benefits package. Individuals have the choice of both insurer and insurance contract and it is mandatory for everyone in the Netherlands to buy individual health insurance. The Netherlands new system allows private health insurers to compete for insured persons and

make profit in the process has changed the roles of health insurers and patients. Since patients are allowed to choose their own health insurer, this allows for competition among insurance companies (Schâfer et al 2010; Hamilton, 2013; Enthoven and Van de Ven 2007).

Sixty six percent (66%) of the Dutch Health care sector was mainly financed by contributions and premiums in 2007. The breakdown was as follows: Health Insurance Care Act (ZVM) accounted for 36% while Exceptional Medical Expenses Act (AWBZ) accounted for 31%. Private expenditure contributed 14% of which 10% was out-of-pocket payments and 4% for complementary Voluntary health Insurance (VHI), whilst government contributes 14% (Schâfer et al 2010).

Healthcare expenditure grew by 38% from 1998 to 2007 and represented 8.9% of GDP in 2007 (OECD 2008). In 2012, health expenditure accounted for 11.8% of its GDP (OECD 2014) and similar to the other countries, 86% of health expenditure in the Netherlands comes from the government or through social insurance. This figure has increased in recent years and is well above the average of 72% in the OECD countries for 2012. Despite the economic crisis, the health expenditures in the Netherlands continues to grow with an average yearly growth rate of over 3% between 2006 and 2012. The growth rate on the other hand, slowed down to 1.2% in 2011 but picked up in 2012 at 3.5% (OECD, 2014) (see fig. 5).

Unlike the UK and Germany, the healthcare expenditures for the Netherlands have been increasing from 2008 to date. However, it has been steady from 2012 to 2014. The Netherlands unlike Germany and UK has had an element of market logic to its health system since 2006, and as such, one cannot be certain that it is the Directive that has caused this increase or created the stability seen from 2012 to 2014. A further research need be done to find the reason for this trend.

The Netherlands' healthcare system is divided into three parts:

1. **Compulsory SHIs** scheme for long-term care for the provision of care to patients with chronic and continuous care need. It is regulated in the Exceptional Medical Expenses Act (AWBZ) and financed through income-dependent contributions.
2. **SHIs** system that covers the entire population for basic health insurance and regulated by the Health Insurance Care Act (ZVM). It is made up 59% contribution-financed health care in the Netherlands. People insured will pay a flat rate premium to their

health insurer or an income dependent employer contribution through payroll and paid into the Health Insurance Fund.

3. **Complimentary Voluntary Health Insurance (VHI)**, which may cover health services, not included in the first two schemes. The SHI and VHI does not handle prevention and social support.

Since 2006, GPs are paid through a combination of capitation fees and fee-for-service. Diagnosis and Treatment Combinations system is used instead of hospitals and mental care. Long-term care providers are, however paid according to care intensity packages (GreB et al 2001; Schäfer et al 2010; Schut and Van De Ven 2011).

The introduction of the Health Insurance Act in 2006 (Zorgverzekeringswet), the Netherlands government's role in regulation has been to safeguard the process from a distance instead of direct involvement with emphasis placed on quality, accessibility and affordability of healthcare. Providers, patents and insurers shoulder a bulk of the responsibilities. A new watchdog was established to avoid any undesired market effects in the new system (Schafer et al 2010).

4.5.1. Implementation Process in Netherlands

The ECJ rulings on the cases of Geraets-Smit, Peerbooms, Muller-Faure and Van Riet who were all citizens of the Netherlands put the Netherlands ahead of other MS in the implementation of the directive (Vollaard 2004). The case and the rulings dealt with The Netherlands' non-conformity with cross-border healthcare regulations and EU treaties (Bongers and Townend, 2014). As such, the Netherlands have had more experience with cross-border healthcare issues including the directive. The Dutch have been making efforts to comply with EU Regulations since the ECJ rulings. The rulings unearthed questions on the *sustainability* of the Dutch system in the face of the free movement of goods and services and regulations/directives coming from it (Vollaard 2004).

The Netherlands' health system has a market concept unlike the UK and to some extent different from Germany. The introduction of the Health Insurance Act of 2006 (Zvw) stopped the system of prior authorizations for basic healthcare that was practiced in the National Exceptional Medical Expenses Act (AWBZ). AWBZ was *universal and obligatory* and income-dependent insurance established in 1968. Clients receive a benefit-in-kind from

contracted providers and needed prior authorization before having healthcare outside the Dutch system (Vollaard and Martinsen 2014).

The Netherlands' parliament deliberated and implemented the directive immediately because according to them, the 2006 Health Insurance Act (Zvw) was in conformity with the directive stipulations (Bongers and Townend 2014). The transposition was therefore related to the establishment of the NCP. Like the Germans, the Netherlands has implemented stipulations in Article 7 and 8, which highlighted to MS the principle of Reimbursement of healthcare cost from another MS by MS's citizens. Article 8 gave MS the option of asking citizens to get prior authorization. The Dutch opted for no prior authorization. The two stipulations (Articles 7 and 8) were taken care of in the 2006 Zvw. Hence, the Dutch only had to implement Article 6 (establishing NCPs). They used, however, the opportunity during the transposition of the directive to implement directive 2012/52/EU on mutual recognition of medical prescription. The directive on mutual recognition of medical prescription among MS introduced a year after the Patients' right directive was for MS to recognize prescription from one another and to enhance the Patients' right directive effectiveness (Vollaard and Martinsen 2014).

The Dutch did not implement the directive on time like the UK and Germany. The mutual recognition of prescriptions and NCP establishment by the CVZ (Health Insurance Board) were not incorporated into legislation before the deadline of the directive (25th October 2013). The Dutch implementation unlike that of the UK and Germany was confronted with controversies, which lead to its late implementation. Some of the controversies were indecisiveness of personnel. This is because the Dutch health system has an element of market logic; they were not sure which personnel to use and what position would the personnel hold to avoid personal interest. There were also conflicts concerning which stakeholder should be responsible for what. This took some time. Additionally, the implementation of the directive was late because the Dutch believed that they had already implemented the directive through the introduction of the Zvw.

Division of responsibilities was unclear, because some of the stakeholders were profit organizations while others such as the government were non-profit organizations. Conflict of interest arose when insurers with profit as objective were given the responsibilities of patients information on cross-border healthcare, and deciding if their 'customers' were entitled to go abroad for healthcare, since most of these insurers had negotiated (low cost)

with domestic hospitals, clinics and pharmaceutical on the cost of treatment, diagnosis and medication.

According to Vollaard and Martinsen (2014), the Dutch government's attempts to use the Health Insurance Act of 2006 as fulfillment of the directive's stipulation was also some of the reasons for the failure. According to them, it shows how *policy-entrepreneur can exploit a certain solution to combat a different problem than planned* (Vollaard and Martinsen 2014). The Dutch thought that because the Zvw had an element of market mechanism, it could be equal to the Directive's stipulation.

The Ministry of Health, Welfare and Sport (VWS) set up the NCP. The NCP provide information for patients from the Netherlands trying to get treatment in another MS and citizen of another MS wanting to have health treatment in Netherlands. NCP is also set up to consult with patients; organizations; healthcare providers; and health insurers within Netherlands and MS on the provisions of the directive.

In summary, the Netherlands implemented the directive. However, due to some administrative problems, the implementation of the directive was late.

4.5.2 Prior Authorization and Reimbursement in the Netherlands

For planned treatment, citizens in the Netherlands, in line with the UK and Germany, need to have prior authorization under the S2 route. Unlike the UK and to some extent Germany (Health insurer non-profit), patients are to contact their health insurer (for profit) for referral (which could be seen as form of prior authorization, coming from organizations that are in business for profit). The health insurer will advise them on the treatment that their insurance cover can provide for them. The insurer would let the patient be aware if the company has a provider who can provide the same treatment in another MS. The insurer will also determine if the treatment he/she need will be better using the directive route (E112) or the regulation route (S2). If you are travelling on the regulation route (S2), you need your insurers' prior authorization. However, on the Directive route, one do not need prior authorization.

Like the UK and Germany, the Netherlands has S2 form (social security regulations) and E112 form (the patients' rights directive). Under S2, the patients do not need prior authorization, but they should find out from their providers if the treatment is reimbursable. Similar to the UK and Germany on the directive route, citizens' pays for services and are

reimbursed later. With the social security regulations route, patients are not required to pay during the treatment; instead, their S2 form is a payment guarantee for the service.

In the Netherlands, most of the process, negotiation and information on patients' right to cross-border healthcare are with the insurer (insurance provider), as well as power of access. This raises the question of conflict of interest because unlike UK and German systems, the insurers that are supposed to give out the information are in business for profit. Nevertheless, if the decision by your insurer is not to your satisfaction you can complain to Health Care Insurance Complaints and Disputes Foundation (SKGZ).

For patients from another MS to the Netherlands, and if the treatment is based on the directive route, the qualification for the treatment will be based on those of the patients' country insurance. Under the directive route, if the patients do not need prior authorization in their home country, then they do not need it in the Netherlands. If they need to have prior authorization in their home country, they will also need it in the Netherlands.

In summary, the Netherlands implemented the directive by adding NCP establishment into legislature. This is because the Netherlands with the introduction of Zvw, implemented prior authorization and reimbursement stipulation highlighted in the directive.

4.6 How the Implementation is working in the Three Studied MS.

MS healthcare systems are under increasing pressure owing to demographic changes, increase in chronic diseases, and declining budgets. Thus, increasing emphasis on patients' right directive calls for better integration on the above activities across MS (Marschang and Bernardo, 2014).

The UK, Germany and the Netherlands have all implemented the directive. However, awareness of the directive is very low in these MS (EU Commission Report 2015). It has been noted that unavailability of information about the Directive and lack of awareness of entitlement (reimbursement) to cross-border services/treatment have limited the use of the Directive. The issue of prior authorization in these countries is a bit confusing. In their legislature, Germany and the Netherlands stated that patients do not need prior authorization. In practice, however, patients are asked to go to their health insurers for further information on prior authorization. One might infer that these countries (Germany and the Netherlands) expect patients to get prior authorizations before going for cross-border healthcare even

though their national laws do not require this. One may also conclude that MSs are regularizing patients' rights directive by asking potential patients to go back to their GPs, then back to NHS in the case of the UK, and insurers (Germany and the Netherlands) for information. This echoes what the EU Commission reports, that some of the ways of implementation by MS are deemed limiting and the processes of prior authorization and information dissemination are restraining (EU Commission report, 2015).

UK, Germany and the Netherlands' NCPs were not collaborating with a range of stakeholders inside their countries (Goscinska 2014). In the case of the UK, only the department of health and the NHS were involved in the distribution of information. Information about the Directive was sent out to stakeholders (BMA, Private sector, intuitions of health research, pharmacist, patients etc.) after implementation. However, the information was not always addressed to the right stakeholder. For instance, pharmacist should receive information on medication while doctors receive information on patients' healthcare.

The make-up of the German Liaison Office for Sickness Insurance-Abroad (DVKA) did not include patient's organizations, health professionals and third-party players (Panteli et al 2015a). The DVKA was not dynamic in monitoring cross-border movement, which can assist in determining the range, medium and language of relevant information to the health sector. The Netherlands handed over jobs like referrals and prior authorization to insurance companies with stakes in the healthcare sector. Enquiries at the three NCPs (countries under study) were not consistent. Information to stakeholders (within the MS under study and other MS) was also not consistent (Panteli et al 2015a).

The implementation of the Directive has significant implications for doctors (deciding on patients' cross-border healthcare requirement, writing reports in addition to their job specifications), patients, funding and other providers in numerous areas relating to the quality, safety and continuity of care.

Some of the Directive's stipulations were practiced in the Netherlands after the ECJ rulings that led to the introduction of the Health Insurance Act of 2006. The Dutch health care system was already based on market logics and the Directive has affected their system (Vollaard and Martinsen 2014). This is because the health insurance companies were already negotiating with hospitals, pharmaceuticals both in and outside the country on ways to reduce cost and undue delays, which are one of the major reasons for patients seeking cross-border

healthcare. The introduction of the Directive would imply costs since negotiations takes time. The implementation of the Directive has affected the German sickness fund with a number of challenges; some of these challenges include caring for patients with complications after having healthcare abroad. In addition, they had to carry the burden of other MS patients coming for dentistry care (Kifmann and Wagner 2015).

In summary, the implementation, planned treatments by patients from Germany and the Netherlands to other MS have mainly been successful and have a low rate of follow-ups, compared to unplanned treatment (Kifmann et al 2015). Continuity of care after treatment abroad raised the most concerns among the treated patients (Kifmann et al 2015). There are not so many planned treatment abroad by patients from the UK, however, the UK have had mostly unplanned treatment as a result of people getting sick whilst on holidays.

Information on continuity of care is not present in the implementation of the Directive in the three countries, though, it was not stipulated in the Directive that this was necessary. Most Germans who had cross-border healthcare did so because of trust in the information gathered from a given provider, and from referral from friends and family members (Kifmann and Wagner, 2015). In Germany for instance, out of the 45,169 (2012) patients treated under the provision of the directive, 8% had complication that needed follow-up, which were done in Germany. Twelve percent (12%) of the reported patients, who had been treated, reported problems with medication and prescription. These include unknown products and prescription, and medication reimbursement problems (Kifmann and Wagner, 2015).

The Directive urged MS to cooperate with each other. However, there is no forum or information procurement between providers across the MS. Rather, the information is only available at the NCPs (Panteli et al 2015b). Most information has mostly to be conveyed by the patients themselves. Patients document rights and document requirement information should be endorsed at the EU levels and not by the MS or at the provider's level (Panteli et al 2015b). This will provide treating health personnel, available health records that are understandable and comprehensive, since some of the records received by health personnel are sometimes incomprehensible.

Chapter 5

Discussion

The aim of this study is to analyze the implementation of the EU's Patients' rights Directive and its possible impact on three healthcare systems. One of the basic logic of the Directive is to safeguard the internal market regulation. The Netherlands has elements of market logic in their health system, since the health insurance companies are profit organizations and promote competition among each other. What happens to other systems without market competition like the UK? Hence, this chapter will discuss the impact of the implementation of the Directive on a universal tax based system, an insurance based and a managed/regulated competition based system. Based on a comparison of similarities and difference between the UK, Germany and Netherlands, this chapter will also analyze whether the implementation has led to convergence or divergence between the various health systems.

5.1. Implementation of the EU directive: an introduction

There are relatively few studies on EU's health policy implementation. Directive 2011/24/EU is the first EU legislation (health policy), which explicitly is aimed at the governance of national healthcare sectors. However, there are EU implementation studies on other policies. In these other implementation studies, there is better grip of the size, scope and dimension of compliance problem in implementing EU directives. Nonetheless, the complete account of the observed patterns of implementation of EU directives in general remain open (Steunenberg and Toshkov 2009). Based on implementation studies, there often seems to be shortcomings in the timing and correctness in the compliance of EU directives (Börzel 2001). According to Versluis (2007), practical implementation often follows formal incorporation of the EU rules in the MS legal orders. Thus, unlike regulations which are legislative acts that needs to be applied in its entirety, the directive have an implementation period that gives the MS time to interpret and adopt the directives in their own way and arrive at the desired outcome. This echoes Steunenberg and Toshkov (2009) statement that most of the exploratory studies on the implementation process show the influence of national institutional factors. Constitutional/legislative restraints on decision-making and the closely related *concept of veto players* are assumed to have an impact on transposition and implementation performance (Steunenberg and Toshkov 2009).

Vollaard and Martinsen (2014) argue that the implementation of the directive is likely to be hindered by economic and legitimacy crises and these crises could affect the durability of the cross-border *social sharing* in the EU. Based on the arguments above, the implementation process may vary in the MS; both because of differences in interpretation and adoption, and macro-economic conditions may differ between countries.

5.1.1 Similarities in Implementation

EU citizens receive healthcare in their country through the health system, where they are covered or insured. However, under the EU regulation on the coordination of social systems (regulation 883/2004; ex 1408/71), patients may have planned care in other MS or receive unplanned care while in another MS. Based on the above regulation, there were court cases at the EU court, hence the introduction of Directive 2011/24/EU, which offers a common legal background for all MS and urges development of co-operation and partnership among MS. The Directive seeks to clarify the ECJ ruling and enhance the implementation of cross-border care and services, thereby respecting the fundamental and ethical choices of citizens (Santor et al, 2014).

UK, Germany and the Netherlands are members of the EU and as such, they are bound by the treaties of the EU to adhere to EU directives. Accordingly, the countries were bound to implement the Directive. Although the Netherlands was late in implementing (as explained above), the directive was implemented into UK, Germany and the Netherlands respective constitutions.

The three countries under study implemented Article 6 stipulations on establishment of NCPs. The NCPs had no forum and information processing between providers across the MSs, all information was through the national NCPs (Panteli et al 2015b). Most information has to be processed mainly by the patients themselves in all the three countries. The information process is cumbersome which can make it difficult for people with low educational background. Kifmann and Wagner (2015) state that the Directive implementation is benefiting the rich and educated citizens. According to them rich people can afford to spend and later be reimbursed as the stipulation of the directive states ‘pay and be reimbursed later’. According to their research, most of the people who have had cross-border healthcare in the past year in Germany were educated and rich citizens (Kifmann and Wagner, 2015). Thus, one can infer that the directive has moderately affected MS citizens, since mainly the rich and

educated citizens have enjoyed the directive. The three countries implemented the setting up of NCP similarly. This is similar because the NCPs in these countries was established in accordance to the stipulation of the Directive and it provides the information that is required of an NCP. Additionally, it is in the languages that both citizens of home country and other MS can understand.

Article 7 of the directive highlighted the principles of reimbursement of cost. The three countries implemented reimbursement. Patients are entitled to reimbursement of cost incurred up to the amount if the treatment was taken in their MS of affiliation. However, the three countries did not implement it at the same time, the Netherlands and Germany already started implementing theirs before the directive (see Germany and the Netherlands implementation in chapter 4). The UK started theirs after the directive implementation. These similarities in reimbursing patients cost incurred from treatment abroad though similar, it has been asked for a uniformed “cap” in reimbursement. They want this cap to come from the EU. The need for this cap is because most people are not equal financially, and that the MS economies are not the same. Thus, asking MS to pay according to what they would have paid will deprive some patients from accessing cross-border healthcare.

Article 8 also asked for healthcare that is subject to prior authorization. In this case, the MS could use their discretion of whether to ask for prior authorization or not. The UK asked the patients to get prior authorization and went on to publish illnesses that may be subject to prior authorization (see appendix 3). In the case of Germany and the Netherlands, patients do not need prior authorization. However, the patients are advised to contact their health insurers to find out what reimbursement they are entitled to before travelling. This brings out the issue of transparency and conflict of interest in the case of the Netherlands.

The number of patients that are travelling under the directive in the three countries has not increased. However, researchers on this subject agreed that it is too early to infer that there will be no increase in the number of patients travelling for healthcare under the Directive. (Kifmann and Wagner, 2015; Zanon 2011). To get an early treatment is one of the reasons why several patients use the cross-border care. If waiting-time keep increasing, more patients may consider cross-border healthcare (Kifmann and Wagner, 2015; Zanon 2011). Undue delay is likely to be an important reason why people in the three countries use the cross-border care.

The three countries established NCPs. The NCPs provide information to potential patients, but it seems that they have not succeeded in doing this. According to the Commissions' report (EU Commission, 2015) most citizens do not know of the existence of an NCP. Inadequate information from NCPs can affect the use of the directive, because most people will not have the adequate information to access healthcare outside their MS of affiliation. This will then defeat the purpose of the Directive.

Incomplete information could imply that the patients will not have the quality and safety care according to the Directive and that relatively few citizens (rich/educated) will benefit from the Directive. Furthermore, the healthcare systems that are subject to prior authorization implemented by the three MSs are considered as not being transparent and in some cases, the issue of conflicts of interest arises. In addition, there is the need for a universal cap on reimbursement in MS.

Similarities in implementation could promote that different health systems become more similar, thereby standardizing the EU MS health systems and promoting convergence. However, as outlined below, there have been differences in implementation between the three countries.

5.1.2 Differences in Implementation

In implementing the Directive, the three countries went into national adjustments of their healthcare systems and its regulations. This is because they had to transpose the Directive into their respective national laws by forming new legislature to accommodate the Directive and its stipulations. The implementation process in the three countries went without controversies. For example, the Netherlands saw the Directive and its implementation as EU's continuous interference in the organization and financing of national healthcare (Vollaard and Martinsen 2014). The Germany had a favorable attitude and voted for the Directive quickly (Goscinska 2014). The UK on its part had to go through firm procedures of setting up a group called European Team (ET) that went through the Directive, after which it was sent to the Parliament before the implementation was legalized. According to Goscinska (2014), differences in the implementation of the directive in MS show how different EU MS health systems are, hence the controversies encountered during the transposition period at MS and the EU level respectively.

Financing of healthcare in the EU is made up of a mixture of public and private spending. For instance, eighty percent (80%) of all spending in the UK both regional and local government is on health (OECD, 2014). In Germany and the Netherlands, sickness fund is the dominant financing scheme, funding 70% or more in both countries health expenditure. Germany's PHI finance 10%. In Germany and the Netherlands, one out of every five euro spent is on health (OECD 2014). Out of pocket in Netherlands represents 6% and 9% for the UK (OECD/European Union, 2014). Thus, the implementation of the Directive may affect the financing of health care through the following: the financing of NCPs; new employees to take care of the NCPs; those on waiting-time could decide to go elsewhere for treatment and still be reimbursed before time. This may lead to additional funds spent on health and lead to break down of government procedures (waiting-time procedures). The implementation of the directive in these countries seems to have promoted divergence rather than convergence/Europeanization of the health systems.

The establishment of NCPs gave the patients information but did not include clinical guidelines. UK, Germany and the Netherlands have an established national, regional and local clinical guideline programs (Legido-Quigley et al 2012b). However, these guidelines are meant for an individual country, which will make it difficult for patients/providers in another MS to understand or interpret. It is so decentralized at times (within the MS). According to Legido-Quigley (et al 2012b), even the MS find it difficult to understand. The differences in developing and implementing clinical guidelines across MS reflect the different stages that the countries are currently at, in developing quality assurance mechanism for health systems. Thus implementing the Directive (NCP) without clinical guidelines of other MS's clinical guidelines could lead to unsatisfactory treatment abroad. Lack of such guidelines may promote further differences in the health systems of MS, thus divergence and not Europeanization of health systems, since MSs are still in charge of their clinical guidelines and development of their quality assurance mechanism.

One of the purpose of the Directive was to ensure safe and quality cross-border healthcare. However, care pathway, which is defined as complex intervention for the mutual decision-making and organization of care for a well-defined group of patients during a well-defined period (Deneckere et al 2012), is lacking in both the Directive and its implementation in the three countries. The lack of care pathway or different care pathways in the three countries' implementation means that there will be problems in improving the quality of organisation

and consistency of care in the use of evidence-based guidelines, and could lead to incomplete care, and inconsistency in caring for patients from another MS. Hence, incomplete care pathways challenge the evaluation of the effectiveness of the care patient had or will have in another MS. This can reduce the Directive's secured and safety healthcare across the MS, and may promote more diverge healthcare. Which echoes Glonti et al (2014) statement that there are substantial differences in definitions, regulations and laws, and professional backgrounds of healthcare providers in MS. These differences continue and give credence to the impression that Europeanization of health systems is not happening in the EU.

In summary, UK, Germany and the Netherlands have different implementation with regard to provision of adequate information and differences on healthcare that may be subject to prior authorization. These differences have more to do with their different health systems, the UK with their NHS, the Netherlands SHI with market logic or managed care and Germany's SHI. The different systems include differences in the financing system. The implementation was influenced by the previous health systems in the countries; they did not converge to an Europeanized health system. Rather, it seems that the health systems in the three countries have diverged.

5.2. Impact of Implementing the Directive in the UK, Germany and the Netherlands

5.2.1. The Issue of Convergence

In recent years, the rising cost of healthcare has prompted cost control in various forms like health reforms, strategic behaviours like waiting lists et cetera across the EU. Greer (2011) pointed out that the stress on solidarity and changes in the health sector such as movements from centralized command to decentralized command promoted efficiency by means of market incentives that is driving healthcare to be based on ability to pay. In recent years, several theories of convergence of healthcare systems have been presented (Blank and Burau, 2006). However, according to Blank and Burau (2006), there are co-existing processes of convergence and divergence, which could lead to similarities (convergence) or differences in direction (divergence). They went on to state that despite this sign of co-existing, policy content and the ideal policy mechanisms for implementing such policies continues to vary widely across countries (Blank and Burau, 2006)

In the EU, one can infer that health systems have been converging (becoming similar) towards a standardized system since the introduction of free movement of workers. This is

because, free movement of workers lead to introduction of social coordination mechanism regulation (regulation 883/2004). The regulation then raised legal issues, which consequently lead to the ECJ court rulings. Such mechanism could have forced health systems in the MS to be driving towards a similar health system. If MS health systems adapted both national and subnational into conformity with EU's political center, there would be an Europeanization (Olsen, 2002) of the health systems. For instance, if the UK with its tax based system, Germany and the Netherlands insurance based systems with a market twist in that of the Netherlands were converged, they had to agree on using the same financial basis.

Articles 6, 7, 8 of the directive stipulates that MS open NCP, provide medical condition that needs prior authorization and reimburse cost of treatment from abroad, witnesses that MS systems conformed with EU's health policy. Thus, the patients' rights directive and its implementation in MS is seen as a way of standardizing health systems of MS thereby Europeanizing MS health systems and affecting their systems.

Since the ECJ rulings in the health care cases, it is clear that MS health system and health services operation cannot work in isolation from the other MS (Busse et al., 2011).

Differences in health benefit packages and MS health tariffs could significantly increase the acceleration of the Directive. This is because health systems differ among MS and health benefits differ alone MS systems (NHS, or SHI). For example, SHI health benefits relate to specification of entitlements of the insured person, whilst in NHS, it is specifically the duties and obligations of the local NHS to balance equity to all in sundry (Busse et al., 2011). With these differences in health tariffs and health benefit packages, a Directive that spelt out the same measure could promote health systems to be converged and thus affect those different health systems.

In an insurance-based system, premiums are income related and collected separately from taxes. Employees and their families are members of sickness funds. Insurance contributions are paid into funds organized by occupation or region. In Germany, these funds contract with what is usually a mixture of public and private providers of inpatient care and with independent physicians paid according to the service, they provide (Freeman 2000). The impact of implementation of the Directive in Germany has been minimal compared to the UK (Goscinska, 2014). The impact is minimal in Germany, probably because the country has been adapting the EU recommendations after the ECJ rulings, and have been developing policy preferences to the EU level to avoid further adaptive pressures. It is still an

interference in their health system, the reason being that policy makers in Germany had to again adopt new recommendations from the EU. UK on the other hand, had to start from the beginning and implement all the stipulations of the Directive at the same time, thereby, converging the Germany health system and that of the UK towards similar health systems, hence, its impact on the UK health system. This echoes Baetem, (2012) point, that with all the changes and challenges in financing and organizing healthcare among MS, it was surprising that the EU is trying to “Europeanize” (converge) the health care policy, management and organization in MS with the adoption and implementation of directive 2011/24/EU - Patients' rights to cross-border healthcare (Baetem, 2012).

According to Kostera (2008), to what degree a process of institutional adaptation will take place depends on the pace and the scale of implementation of EU legislation to domestic legislation, subject to its fits to existing domestic institutions. This is true in Germany's institutional set-up and their social insurance system, which showed a lower degree of institutional misfit than the UK's NHS. Germany had been putting institutional set-up in place since the ECJ rulings to accommodate EU rules. The Netherlands' on the other hand with the introduction of the Health Insurance Act aimed to control the risk rating and the risk selection that was activities of PHI toward cost control and conformity to EU stipulations (GreB et al 2001). This affected the health systems of these MS because they had to plan their health systems in conformity to the EU regulation and not to their national regulations in some instance. The above notwithstanding, does not mean Europeanization of health systems occur, since the MSs institutional set-ups still differ.

UK, Germany and the Netherlands having transposed the directive, are now obliged to treat patients' rights, and obligations of every patient in their state irrespective of their MS of affiliation. Thus, one can infer that the Directive and its implementation has rearranged most of UK, Germany and the Netherlands into a state for a cross-border patient treatment. Thereby, indicating that the Directive is Europeanizing healthcare systems in the EU.

5.2.2. The Issue of Divergence

Factors influencing care delivery include cost, accountability, specialized health personnel, media, well-informed and empowered patients, and new policies from both within the country and outside the country that has resulted in increased pressure in the leadership and governance of the health care institutions in the EU (Shortell and Kaluzny, 2000).

“Divergence” means in this context that health systems are moving further apart. It can be inferred that health systems in MS are continuing to be different irrespective of the Directive and its implementation. This is because as mentioned before, the Directive gives MS the discretion of interpreting the content and adopting it to fit their system if the interpretation arrives at the desired result. The Directive also allows traditional, cultural and national institutions to play a part in the transposition process.

Since the Directive is not a Regulation, which must be *applied in its entirety*, implementation of the directive in MSs cannot be said to be the Europeanization of health systems or converging health systems. Some stipulations in the Directive are an indication that the Directive is not converging the MS health systems; rather it is diverging MS health systems. An example is the stipulation that gives MS the option of introducing prior authorization (Article 8) for patients seeking care abroad. The UK for example published a list of healthcare that may be subject to prior authorization. Furthermore, the UK patient needs prior authorization to access cross-border healthcare. In Germany and the Netherlands, however, patients do not need prior authorization, but are advised to contact their health insurers (Germany insurers are non-profit; the Netherlands insurers are for profit). These examples show that it is the MS who decide what healthcare that is available to its citizens irrespective of where the treatment is taken, home or abroad, they also decide whether a patient need prior authorization or not. Thus, health systems are not Europeanized, they are rather diverged.

The general principle for reimbursement of cost to patients (Article 7) should according to the Directive be equivalent to what is required to be paid had the treatment been provided back home (patient’s MS of affiliation) and also the need for transparency. The stipulation of reimbursing cost is not equivalent across the MS. Patients from ‘richer’ countries can afford to go to ‘poorer’ countries at any time for treatments and get complete reimbursement, while those from ‘poorer’ countries will receive less reimbursed than the cost incurred of the treatment abroad. The issue of paying for the cost of care and be reimbursed afterward may favor the more wealthy people. Similarly, reimbursement amounting to what MS could pay indicates that the directive only recognizes MS government’s values and principles but not patients’ rights in the real sense of the word. Thus, one can infer that Europeanization of health systems did not occur. Furthermore, the cost of travelling, accommodation and time spent outside while having the treatment are not catered for by the Directive, and in its implementation in the three countries. According to Panteli et al (2015b), this will limit

patients from assessing healthcare abroad in particular for poor people. Since healthcare still is in the hands of the respective MS, the Directive may produce increased differences between people in a MS and between countries, which indicate greater divergence.

Additionally, the Directive and its implementation has diverged patients' right to cross-border healthcare further apart. This is because of the process patients have to go through before accessing cross-border care. For instance, the process of prior authorization in UK, and patient in Germany and Netherlands having to go to their insurers to find out what can be reimbursed and what cannot be reimbursed, shows that the patients have limited rights. Rather, MS are in charge of their health systems. These positions agrees with Azzopardi-Muscat et al.'s (2015) findings that the Directive has moderately enhanced patients' rights. It also agrees with De la Rosa (2012) statement that the Directive did not to an extent, protect patients' fundamental rights, as patients' right ought to be. Because patients in most cases have to take the initiative of getting documentations for their treatments abroad.

Similarly, in the UK for instance, patients according to NHS are liable for their safety and legal uncertainties during their treatment in another MS. This statement from NHS may infer that patients are not safe sourcing healthcare outside their country, hence, deterring patients from accessing healthcare abroad. On the part of Germany, the Parliament passed a legislative on the Directive during the implementation process without consulting stakeholders. This agrees with Goscinska, (2014) statement that it illustrates how MS are still in control of their health system and may include who they want treatment for in their policy adoptions. The UK's numerous rigid processes during the implementation phase and their not sharing information to all stakeholders' after implementation implies that MS are in charge of their health systems. Although, the Directive was also to harmonize issues of non-transparency in MS health systems as illustrated in some of ECJ rulings (bureaucracy, non-inclusion of stakeholders) et cetera Europeanization is not taking place because MS are still deciding on who to include or not, and the kind of information that should be given.

Furthermore, the implementation of the Directive has different consequences in different health models. Instead of bringing the different health systems together, the Directive is rather moving the different health systems further apart. For instance, the Netherlands reformed their health system in 2006 by introducing managed competition. The aim was to achieve healthcare for all and to address some of the ECJ rulings. This reform made it possible for insurance companies to compete for patients and make profit in the process. The

insurance companies are given the mandate of deciding if a patient needs prior authorization or not and how much the patients is to be reimbursed. Allowing the insurance companies the access or power to prior authorization and reimbursement after patient's treatment in another MS could infer conflict of interest. In addition, the insurers, medical providers and regulators are all part of the health system and since there is competition among the insurance companies and providers, there is no cooperation between them and information among them could be unclear. The dependency on each of these actors on each other will not help the application of the Directive. Thus moving the health systems further apart, since MS and their policy makers are still in charge of their health system, Europeanization has not taken place.

The UK's NHS is a tax-based system and is a health system that has universal coverage. The healthcare facilities are owned by the state and the government pays medical professionals (Freeman 2000) Tax based models place high priority on the goal of equal supply of services. The system creates entitlement to health services based on patients' needs and not their ability to pay. However, such a system may lead to moral hazard from both users and suppliers. Especially in a country like UK where patients do not pay co-payment like Norway, the NHS can be exposed to moral hazards from the users. Since it is financed through general taxes, the use of funds goes through political processes. In order to lower costs, budgetary allocations may be insufficient, thus leading to underfunding which gives rise to waiting lists, aging infrastructure and sometimes-old technology. Waiting lists may also be used as a check and balances strategies. Implementation of the Directive in a system that is almost free at the point of care could affect strategies and diverges a health system. Thus, the impact of implementation of the Directive could drive the taxed-based system further apart from other systems (like Insurance-based system) because it could intensify the insufficient fund issue, if people on waiting list decide to take EU offer.

The implementation of the Directive in the UK's (tax-based) institutional set-ups showed a high degree of institutional misfit - unlike Germany and Netherlands (Kostera, 2008). This is because Germany and the Netherlands have been implementing the Directive since the ECJ rulings. Thus, the impact on their institutional set-up was low because most of these set-ups have been on going in these countries for some time. The impact on UK institutional set-up was high because the system (healthcare) services are deemed as free of charge. Thus, the directive implementation is seen as having high degree of institutional misfit. Since the

system is still different from that of others, it implies that the Directive is not promoting convergence rather it is diverging.

Insurance-based systems have in some cases limited the possibility for patients to choose their physicians unlike the tax-based system. The system introduced cost sharing between sickness funds and patients. The politics and regulation of the system are in the hands of organizations such as insurance companies, private health service providers, and pharmaceutical companies. The implementation of the Directive could affect the policies and strategies of the mentioned stakeholders because they have already put in place strategies that work. The Directive was also to safeguard the Internal Market Regulation. In this instance, it could affect an already established internal market. The German SHI uses a Sickness Fund that has many responsibilities, which include collecting contributions from members, negotiating prices, quantities and quality assurance measures with providers, and others (Busse and Blumel, 2014). This could indicate that healthcare is more technical than political, echoing what Freeman (2000) pointed out that “health policy problems are problems of and for the state”. The implementation of the Directive can influence the mentioned arrangements.

The Netherlands’ Health Insurance Act on the other hand, allows for competition among insurance companies, and the citizens are mandated to purchase individual health insurance from a private insurer within a standard benefit package (Wynand et al, 2009). Mandatory Health Insurance is a system that pays the costs of healthcare for those who are enrolled and in which enrolments is required for all members of a population (World Bank 2008). The insurers are in the business to make profit unlike that of Germany. Government does not interfere, they have a say as to how much premiums citizens should pay and they have set up regulatory machinery to intervene and protect citizens’ interest. There is competition among the health insurance companies and competition among providers of care. This is because the insurance companies selectively contract with providers for their insured (Wynand et al, 2009). The goal of the Health Insurance Act of 2006 was not to increase the efficiency of providing health insurance, but to encourage health insurance companies to increase the efficiency of the health care provision by becoming prudent buyers of health services on behalf of their customers. The implementation of the directive could affect this arrangement because patients could look for another MS for on time treatment rather than wait for their insurance companies to negotiate with providers on their behalf. Since it takes time for companies to negotiate outside their immediate environment, patients will look elsewhere,

and be reimbursed for it. The Netherlands added this market logic in order to comply with some of the ECJ ruling. However, this market logic could play into other MS hands instead of within as the Dutch taught, and could affect an already diverged health system.

In summary, one can infer that as long as decisions on financing, organizing and service delivery are in the hands of MS, there is scarce Europeanization of health systems or standardization of healthcare in the EU. After the implementation, the impact of the Directive has been small, because cross-border healthcare accounts for 1% of public healthcare expenditure in the MS (Panteli et al., 2015b). However, it is believed that it could account for more expenditure in the future for those at the border regions and for smaller MS like Malta (Azzopardi-Muscat et al 2015). Planned treatment has been successful since the implementation in the countries under study and has low rate of follow-up compared to unplanned treatment (Panteli et al (2015c).

The EU commission's report on the operation of the Directive has accused MS of deliberately complicating cross-border healthcare processes for patients. Each MS should provide patients with far greater clarity as to which services/treatment it does and does not reimburse. If the information on entitlements are not published (on a reliable platform), patients will not be able to know their rights. According to Glonti (et al 2014), there are substantial differences in definitions, regulations/laws, professional backgrounds of providers and in reimbursements among the MS. Glonti et al (2014) stated also that there is no information prepared specifically for healthcare providers by the European Commission and that the extent of government's role is unclear.

From the above, it can be concluded that Europeanization of health systems is not taking place in the EU. Rather, the health systems have become more different from before.

Chapter 6

Conclusion

The Patients' Rights Directive was supposed to be implemented by the MS within the deadline in MS 25th of October, 2013. Before the implementation, there were legislative acts taken by MS in order to transpose the Directive into national law. This thesis has studied the implementation processes in the UK, Germany and the Netherlands. It showed both similarities and differences in implementation in the three countries under study. It also answered the question of how it has affected the three different health systems.

The study illustrated how the MS under study established NCPs centers in their respective countries and how inadequate/incomplete information has been provided by the NCPs. This inadequacy of information demonstrates the challenges that the MS are going through in implementing the Directive. Some of the challenges includes; recognizing both the interests of the patients from another MS coming for treatment, and that of its citizens going to another MS for cross-border healthcare. Based on the three countries in this study, this study's conclusion is that the MS have not succeeded in developing/providing an adequate policy on healthcare outside its border. This conclusion was reach due to the inadequacies at the NCPs.

The studied MS also adhered to the stipulation of reimbursement. However, the reimbursement procedure are cumbersome. One of the aims of the Directive was to achieve equal health access to all. However, there will not be health equalities unless there is transparent reimbursement information, improvement in the administration of NCPs and better data collection methods. Additionally, payment for treatment before being reimbursed will be a barrier to poor patients. One may say this could lead to health inequalities rather than health equality to all. This is because not all patients can afford to travel and pay for travel costs and healthcare cost before being reimbursed. Patients also have to pay for translation of invoices in some cases. Furthermore, it is feared that cost could become a huge factor because of the economic status of some MS compared to others. It seems that the Directive mainly has been used because of undue delay. We are likely to see an increase in patients seeking cross-border healthcare unless the undue delay issue is addressed.

The study illustrated how the Directive could positively drive competition among major hospitals and private providers and lead to improved performance among healthcare

providers, by fewer mistakes and reducing cost associated with healthcare in MS. The study showed also the differences and similarities in implementation and the way forward for the EU to improve on their coordination efforts. It also illustrated the need for the EU to address some issue such as information processing, unified cap for reimbursement, continuity of care, medical records, and if possible list of diseases/illness that can be used under the Directive.

The study also showed how the three studied MS have complied with prior authorization issue of using their discretion in either allowing patients to go for cross-border healthcare with prior authorization or not. In Germany and the Netherlands, the patients do not need prior authorization; however, in the UK the patients need prior authorization. When such authorization has been accepted, health tourism may increase among MSs since people will feel safer to travel to a place they can get better healthcare and be reimbursed for it. It may also increase health cooperation among MS.

The study has illustrated how Europeanization is happening through a central penetration of national systems of governance since the introduction of free movement of people, services and goods in the EU. By providing an insight into the implementation of the Directive in MS, the study has discussed how it could lead to convergence, as well as divergence in some cases. In addition, how Europeanization of health systems in EU could lead to country specifics being adopting in some areas, and how it cannot adopt in some areas, which could lead to further divergence in health systems.

Having analysed the Directive and its implementation in the UK, Germany, the Netherlands, one can say that there is a degree of Europeanization of health systems in the EU. However, there is the question of how much of national health systems in practise that have been Europeanized. In some cases, the MS have had different adaptation of the Directive, which leads to divergence, while for other cases there have been similar adaptation that leads to convergence. The MS are still in charge of their healthcare. The overall conclusion is that the Directive has not promoted convergence.

After the ECJ cases and rulings, it became apparent that for free movement of people, services and goods to function better, it was necessary for the Directive to be introduced and implemented. Since this was a Directive and not a Regulation, one cannot say that there is a move by the EU to standardize healthcare in all MS. It is however clear that EU is trying to safeguard the internal market regulation, by providing citizens the right to travel from one MS

to another and getting the healthcare, they need. Those on waiting lists could find in-time care in another MS/country and be reimbursed for it. Additionally, avoiding waiting time, the cost of waiting time (by both MS and citizen), and having the care when needed are some of the reasons for the Directive and its implementation. However, the impact of implementing the Directive with respect to providing healthcare abroad seems so far to be limited

The EU is confronted with several challenges, such as refugee crises and UK withdrawing from the EU. The refugee crisis will increase the demand for health care services in the MS. Since a large number of the refugees will be settled in another MS than where they first arrived, this will increase the need for coordination of the health care services between the MS. The impact of Brexit is difficult to forecast. Leaving the EU will result in the end of the free movement of migrant workers, including healthcare professionals between the MS and the UK. Neither the Directive nor the other EU Regulations will be valid for the UK after the Brexit. It is likely that the UK's government will need to negotiate with the EU as to how UK citizens and citizens from elsewhere in the EU will access health care services in the future. For the MS, the Brexit will reduce the funding of the EU, including the Directive. Vote Leave campaign argued that membership of the EU was costing the UK £ 350 million a week. Less financial resources may have consequences for how the MS will prioritize health treatment of own citizens versus citizens from other MS.

The limitations of this study are as follows. First, only three MS have been analysed. The process of implementing the Directive may have been different in the other MS than in those studied here. Accordingly, how the directive has been implemented and how it has worked cannot be generalized to the other MS. Second, this study is mainly based on historical documents and research reports. By using multiple methods of data collection – method triangulation – the validity of the present study may have increased. Personal interviews would be a relevant method, however, time and budget restrictions excluded use of this method.

References and Bibliography:

- Anderson V. (2004), 'Research Management in Human Resource Management', London: CIPD.
- Axelrod R., (1967), 'Conflict of Interest: An Axiomatic Approach', *the Journal of Conflict Resolution*, Vol. 11, No. 1, pp. 87-99.
- Azzopardi-Muscat N, Alultis C., Sorensen K, et al., (2015), the Impact of the EU Directive on Patient Rights and Cross Border Health care in Malta; *Health* www.elsevier.com/locate/healthpol.
- Baetem R., (2012), 'Europeanisation of National Health Systems, National Impact and EU Codification of the Patient Mobility Case Law', *European Social Observatory/European Federation of Public Service Union*, July 2012 Report.
- Baringhausen T., and Sauerborn R., (2003), 'One Hundred and Eighteen Years if the German Health Insurance System: Are there any Lessons for Middle and Low-Income Countries?', *Social Science and Medicine* 54: 1559-87.
- Barnard C., (2010), 'The Substantive Law of the EU, the Four Freedoms', 3rd Ed. Oxford University press, Oxford.
- Barrett S. M., (2004), 'Implementation Studies: Time for a Revival? Personal Reflections on 20 Years of Implementation Studies' (<https://perguntasapo.files.wordpress.com/2014/06/s-barrett-implementacao.pdf> accessed on 30th May 2016).
- Bauer T. N., Morrison E. W., and Callister R. R., (1998), 'Organisational Socialization: A Review and Directions for Future Research'. *Research in Personnel and Human Resource management*, Vol. 16, pp149-214).
- Baxter, P., and Jack, S., (2008), 'Qualitative Case Study Methodology: Study Design and Implementation for Novice Researchers.' *The Qualitative Report*, Vol. 13, No. 4, pp. 544-559.
- Bell J., (2005), 'Doing your Research Project: A Guide for First Time Researchers in Education, Health and Social Science', 4th ed. Maidenhead: Open University Press.
- Bennett C. J., (1991), 'What is Policy Convergence and What Causes it?', *British Journal of Political Science*, Vol. 21, pp.215-233.
- Bettany-Saltikov J., (2010), 'Leaning how to Undertake a Systematic Review: Part 2' *Nursing Standard*, Vol. 24. No. 51. pp 47-56.
- Blank R. H., and Burau V., (2006), 'Setting Health Priorities Across Nations: More Convergence than Divergence?', *Journal of Public Health Policy*, Vol. 27. No. 3., pp. 265-281.
- Blank R. H., and Burau V., (2014), 'comparative Health Policy'; *Palgrave MacMillan NY*.

- Bongers L. M. H., and Townend D. M. R., (2014), 'The Implementation of the Directive on the Application of Patients' Right in Cross-border Healthcare in the Netherlands', *European Journal of Health Law*, Vol. 21, Issues 1, pp. 65-78.
- Boyle S., (2011), 'United Kingdom Health system Review', Health System in Transition, *European Observatory on Health Systems and Policy*.
- British Medical Association (BMA), Cross-border Healthcare, EU Directive on Cross-border Healthcare, (<http://bma.org.uk/support-at-work/gp-practices/service-provision/cross-border-healthcare> accessed 7th November, 2015).
- Budgen D., and Brereton P., (2006), 'Performing Systematic literature Reviews in Software Engineering' ICSE 06, pp 1051-1052, New York, ACM, ISBN 1-59593-375-1. doi: 10.1145/1134285.1134500.
- Busse R., and Blumel M., (2014), 'Germany Health System Review', *European Observatory on Health Systems and Policy*.
- Börzel T. A. and Risse T., (2000), 'When Europe Hits Home: Europeanization and Domestic Change', *European Integration Online Papers*, vol.4 No.15. (<file:///C:/Users/Gloria/Downloads/SSRN-id302768.pdf> accessed 3rd November 2015).
- Börzel T., (2001), 'Non-Compliance in the European union. Pathology or Statistical Artefact?', *Journal of European Public Policy*, Vol.8. No., 5., pp. 803-824.
- Börzel T. A. and Risse T., (2002), 'Public-Private Partnerships: Effective and Legitimate tools of International Governance?', (http://userpage.fu-berlin.de/~atasp/texte/021015_ppp_risse_boerzel.pdf accessed 18th February, 2016)
- Börzel T., Risse T., Featherstone K., et al., (2003), 'Conceptualizing the Domestic Impact of Europe, in The Politics of Europeanization', Oxford University Press, pp 57-80.
- Chalmers I., Hedges L. V., and Cooper H., (2002), 'A Brief History of Research Synthesis' *Evaluation and the Health Professions*, 25(1), 12/37.
- Charter of Fundamental Rights of the European Union (2010/C 83/02), Official Journal of the European Union (<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2010:083:0389:0403:en:PDF> accessed 17th October 2015)
- Cheng T.M. (2003), 'Taiwan's New National Health Insurance Program: Genesis and Experience So Far', *Health Affairs* 22.61-76.
- Connolly S., Bevan G and Nicholas M., (2010), 'Funding and Performance of Healthcare Systems in the Four Countries of the UK before and after devolution'. *The Nuffield Trust*, London.
- Cousins M., (2007), 'Patient Mobility and National Health Systems'. *Legal Issues of Economic Integration*, 34(2); 183-193.
- De La Rosa S., (2012), 'The Directive on cross-Border Healthcare or the Art of Codifying Complex Case Law', *Common Market Law Review*, Vol.49, No.1, pp. 34-38

Delamothe T., (2008), 'NHS at 60: founding principles', *BMJ*, 336:1216-8 doi: 10.1136/bmj.39582.501192.94.

Deloitte, (2016), '2016 Global Health Care Sector Outlook', <http://www2.deloitte.com/global/en/pages/life-sciences-and-healthcare/articles/global-health-care-sector-outlook.html> accessed 21st January, 2016).

Den Exter, A., Santuari A., and Sokol T., (2015), 'One year After the EU Patient Directive; A Three-country Analysis', (<https://www.pravo.unizg.hr/images/50005049/EU%20Patient%20Mobility%20Directive%20-%20A%20Three-Country%20Analysis.pdf> accessed 17th October, 2015)

Deneckere s., Euwema M., Lodewijckx C., et al., (2012), 'The European Quality of Care Pathways (EQCP) Study on the Impact of Care Pathways on Interprofessional Teamwork in an Acute Hospital Setting: Study Protocol: for a Cluster Randomised controlled Trial and Evaluation of Implementation Process', *Implement Sci*, Vol.18, 7:47

Department of Health UK (2012), 'EU Directive on Patient's Right in Cross-border healthcare' *IA No*: 6013 (http://www.legislation.gov.uk/ukia/2012/42/pdfs/ukia_20120042_en.pdf accessed 7th November, 2015).

Department of Health (2013), Cross Border healthcare and Patient Mobility in Europe, Information to Accompany the Implementation of Directive 2011/24/EU – On Patients' Right in Cross-Border healthcare, (https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/252940/Cross_Border_Healthcare_Information.pdf) accessed 20th January, 2016).

Department for Work and Pensions (2010a). Households below average income: an analysis of the income distribution 1994/95-2008/09. London, Department for Works and Pensions (http://statistics.dwp.gov.uk/asd/hbai/hbai_2009/pdf_files/full_hbai.Pdf, accessed 12th January 2011).

Department of Health (DH) Consultation Group (2013), 'Cross Border Healthcare & Patient Mobility – Consultation on UK implementation of Directive 2011/24 EU', UK. (https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/181168/Cross_Border_Healthcare_and_Patient_Mobility.pdf accessed 15th January 2016)

De-Swaan A., (1989), 'Zorg en de Staat' ('In care of the State'), *Amsterdam*, Bert Bakker.

Deutscher Bundestag, (2014), Sitzverteilung des 18. Deutschen Bundestages. Stand: 03.03.2014. Berlin, Deutscher Bundestag (<http://www.bundestag.de/bundestag/plenum/sitzverteilung18.html>, accessed 21st May, 2014).

Dickman R., (2013), 'International Division Malta Health Network' (<http://www.owenwebhosting.com/OWD/mhn/docs/RD%20Presentation%20to%20Malta%20Health%20Network%20-%20June%202013.pdf> accessed 15th January 2016).

Doering N., Doupi P., and Glonti K., (2013), 'Is Current European EHR Policy and Practice Conducive to Harmonizing Hospital Discharge Summaries Across Europe?', *international Journal of Care Coordination*, Health Policy and Technology.

Doscinska D., (2014), 'Transposition of the Patients' Right Directive: A discourse Analysis in Germany, Poland and Austria', *Working Papers in Health Policy and Management*, Vol. 8, Universitätsverlag der TU Berlin, ([/books.google.no/books?id=HosOBAAQBAJ&pg=PA39&dq=what+is+the+Article+that+a+sk+for+implementation+of+directive+2011/24/ec&hl=en&sa=X&redir_esc=y#v=onepage&q&f=false](https://books.google.no/books?id=HosOBAAQBAJ&pg=PA39&dq=what+is+the+Article+that+a+sk+for+implementation+of+directive+2011/24/ec&hl=en&sa=X&redir_esc=y#v=onepage&q&f=false) accessed 15th January).

Easterby-Smith M., Thorpe R., and Jackson P., (2008), 'Management Research', *3rd edition*. London: Sage.

Enthoven. A. C., and Van De Ven, W. P. M. M., (2007), 'Going Dutch – Managed-Competition Health Insurance in the Netherlands', *The New England Journal of Medicine*, 357(24):2421-2423.

EUR-Lex (2016), (<http://eur-lex.europa.eu/collection/eu-law/treaties-overview.html> accessed 29th May, 2016)

European Commission Communication, A Community Framework on the Application of Patients' Right in Cross-border healthcare, COM, (2008) 415 final of 2 July 2008, (http://ec.europa.eu/health/index_en.htm accessed 7th January, 2016).

European Union (2005), Directive 2005/36/EC of the European Parliament and of the Council on the Recognition of Professional Qualifications, Stat. 2005/36/EC, (2005/36/EU).

European Union, EU Law (http://europa.eu/eu-law/decision-making/legal-acts/index_en.htm accessed 4th November, 2015)

European Union, Public health (2015), 'Cross-border care' *European Union DG health and Food Safety*, (http://ec.europa.eu/health/cross_border_care/policy/index_en.htm accessed 18th October 2015).

European Union Website (2016), (<http://www.eui.eu/Research/Library/ResearchGuides/EuropeanInformation/EULegislation.aspx> accessed 29th May, 2016).

Eurostat, (2007), 'Europe in figures: Eurostat yearbook 2006-07', *Luxembourg, European Commission* (http://epp.eurostat.ec.europa.eu/cache/ITY_OFFPUB/KS-CD-06-001_EN.PDF, accessed 10 January 2011).

Fiscella K., Franks P., Doescher M.P., and Saver B. G., (2002); 'Disparities in healthcare by Race, ethnicity, and language. Among the insured: findings from a National Sample', *medical care*: Volume 40 Issue 1 pp 52-59.

Footman K., Knai C., Baeteb R., Glonti K., and McKee M., (2014), 'Cross-border Health Care in Europe', *European Observatory on Health Systems and Policies*, 14, ISSN 2077-1584.

Form W., 'Comparative Industrial Coviology and the Convergence Hypothesis', *Annual Review of Sociology*, Vol. 5, pp. 1 -25.

- Freeman R., (2000), 'The Politics of Health in Europe', *Manchester and New York*, Manchester University Press.
- Frischhut M., and Levaggi R., (2015); 'Patient Mobility in the Context of Austerity and Enlarged EU- The European Court of Justice Ruling in the Petru Case'; *Health Policy* www.eleview.com/locate/healthpol.
- Giandomenico M., (2007). 'The Rise of the Regulatory State in Europe', *West European Politics*, DOI> 10.1080./01402389408425031, pp 77-101
- Gill J. (2002) 'Research Management for Managers', 3rd ed. London: Sage.
- Glinos I. A., Baeten R., Helble M., et al., (2010), 'A Typology of Cross-border Patient Mobility', *Health & Place*, 16(6): 1145-55.
- Glinos I. A., and Baeten R., (2014), 'Dream Vs. Reality: Seven Case-Studies on the Desirability and Feasibility of Cross-border Hospital Collaboration in Europe', *Social Science & Medicine*, Vol. 117, pp. 18/24.
- Glonti K., Doering N., Kiasuwa R., et al., (2014), 'An Exploratory analysis of Hospital Discharge Summaries Across Europe', *Journal of Health Services Research & Policy*, (Mimeo).
- Glonti K., Hawkesworth S., Footman K., et al., (2014), 'European Health Professional' Experience of Cross-border Care Through the Lens of Three Common Conditions', *European Journal of Integrative Medicine*, www.sciencedirect.com.
- Goscinska D., (2014), 'Transposition of the Patients' Right Directive 2011/24/EU: A Discourse Analysis in Germany, Poland and Austria',
- Government of the United Kingdom,
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/252940/Cross-Border_Healthcare_Information.pdf accessed 6th November 2015).
- GreB S., Okma K., and Hessel F., (2001), 'Managed Competition in Health Care in The Netherlands and Germany - Theoretical Foundation, Empirical Findings and policy Conclusions', *Diskussionspapier 04/2001 Institute of Health Care Management*, University of Greifswald, Germany.
- Greer S., (2006), 'Uninvited Europeanization: Neofunctionalism and the EU in Health Policy', *Journal of European Public Policy*, Vol. 13(1): 134-152).
- Greer S., (2011a), 'The Politics of EU Health Policy and the Case of Direct-to-Consumer Advertising for Prescription Drugs', *The British Journal of Politics and International Relations*, Vol. 13:586-602.
- Greer S., (2011b), 'The Weakness of Strong Policies and the Strength of Weak Policies': Law, experimentalist Governance, and Supporting Coalitions in European Union Health Care Policy, *Regulation and Governance*, Vol. 5: 187-203.
- Greer S., (2013), 'Avoiding Another Directive: The Unstable Politics of European Union Cross-border Health Care Law', *Health Economics and Law*, 8(4), 415-21.

- Hartley J., (2004a), 'Case Studies in Organizational Research'. In *Catherine Cassell and Gillian Symon (Eds), Qualitative Methods in Organizational Research, a Practical guide*, pp. 208 – 229. London: Sage
- Hartley J., (2004b), 'Case Studies Research'. In *Catherine Cassell and Gillian Symon (Eds), Essential Guide to Qualitative Methods in Organizational Research*, pp. 323 – 333. London: Sage
- Hervey T.K., and McHale J. V., (2004), 'Health Law and the European Union', Cambridge University Press, Cambridge.
- Hervey T.K., McHale J. V., and Spaventa E., (2005), 'Health Law and the European Union', Cambridge University Press, Cambridge.
- Hesselink G., Flink M., Olsson M., et al., (2012), 'Are Patients Discharged with Care? A Qualitative Study of Perceptions and Experiences of Patients, Family Members and Care Provider', *BMJ Quality & Safety*, 21, 139-49.
- Hesselink G., Vernooji-Dassen M., Pijnenborg L., et al (2013), 'Organisational Culture: An Important Context for Addressing and Improving Hospital to Community Patients Discharge' *Medical Care*, 51 (1):90-8.
- Hood C., (1998), 'The Art of the State: Culture, Rhetoric, and Public Management', *Clarendon Press*, Oxford.
- How to Germany, (2015), Health Insurance Options in Germany, <http://www.howtogermaany.com/pages/healthinsurance.html#container> accessed 16th Novemeber, 2015).
- Inkeles A., (1981), 'convergence and Divergence in Industrial Societies' *West Press*, pp. 3-38.
- International Labour Organisation, (2010), 'Coordination of Social Security Systems in the European Union, An Explanatory report on EC Regulation No 883/2004 and its Implementing Regulation No. 987/2009, (http://www.ilo.org/wcmsp5/groups/public/---europe/---ro-geneva/--sro-budapest/documents/publication/wcms_166995.pdf accessed 7th January, 2016).
- Jackson E., (2013), 'Medical Law, Text, Cases and Materials', *Oxford University Press*, UK.
- Jakel C., (2015), 'Cross-border Healthcare in the European Member State- An Exploratory Study on the adaption of the Directive 2011/24/EU.
- Jakubowski E. and Busse R., (1998); 'Healthcare Systems in the EU; A Comparative Study, European Parliament Directorate General for Research'; *Working Paper. Public Health and consumer Protection Series*; SACO 101 EN 11-1998.
- Kappelhof T., (2005), *Onderzoeksgids Zorgverzekeraars 1870-1968*, Research paper on health insurers 1870-1968. The Hague, Instituut Voor Nederlandse Geschiedenis (http://www.inghist.nl/pdf/zorgverzekeraars/inleiding_Volledige_versie.pdf, accessed 19th January 2009).
- Kelner P., (2013), 'The EU Referendum Paradox' *YouGov. As of 31 March 2014 and 16 January 2016*, (<http://yougov.co.uk/news/2013/05/07/eu-referendum-paradox/> accessed 16th January 2016).

- Kiasuwa R., Baeten R., McKee M., et al., (2014), 'Crossing the Border to Give Birth: A Qualitative Study', *Facts, Views & Vision in ObGyn*.
- Kifmann M., and Wagner C., (2015), 'Implications of the EU Patients' Right Directive in Cross-border Healthcare on the German Sickness Funds System', *Dev. Health Econ. Public Policy*, 12: 49-66.
- Kierkegaard P., (2011), 'Electronic Health Record: Wiring Europe's Healthcare', *Computer Law & Security Review*, 27(5); 503-15.
- Knai C., Brusamento S., Legido-Quigley H., et al., (2012), 'Systematic Review of the Methodological Quality of Clinical Guideline Development for the Management of Chronic Disease in Europe', *Health Policy*, Vol. 107, Issues 2-3, pp. 157-167.
- Kutzin J., Ibraimova A., Melitta J. and O'Dougherty S., (2009). 'Bismarck meets Beveridge on the Silk Road: Coordinating Funding Sources to Create a Universal Health Financing System in Kyrgyzstan'; *Bull World Health Organ* 87-549-554, doi: 10.2471/BLT.07.049544.
- Ladrech R., (1994), 'Europeanization of Domestic Politics and Institutions: The Case of France. *Journal of Common Market Studies*, 32(1): 69-88
- Ladrech R., (2002), 'Europeanization and Political Parties: Towards a Framework of Analysis', *Patty Politics*, 8 (4) 389-403.
- Legido-Quigley H., and La Parra Casado D., (2007), 'The Health Care Needs of UK Pensioners Living in Spain: An Agenda for Research', *Eurohealth*, 13:14-18
- Legido-Quigley H., Passarani I., Knai C., et al (2011), 'Cross-border Healthcare in Europe: Clarifying Patients' Right, Analysis of Health Systems Perspectives', *BMJ*, 342(7793):364-7.
- Legido-Quigley H., Glinos I. A., Baeten R et al (2012a), 'Analysing Arrangements for Cross-border Mobility of Patients in the European Union: A Proposal for a Framework', *Health Policy*, 108:27-36.
- Legido-Quigley H., Panteli D., Brusamento S., (2012b), 'Clinical Guidelines in the European Union: Mapping the Regulatory Basis, Development, Quality Control, Implementation and Evaluation Across Member State', *Health Policy*, 107:146-56.
- Lewis H., and Cooper J., (2015), 'Office for National Statistics, Expenditure on Healthcare in the UK, 2013', (http://www.ons.gov.uk/ons/dcp171766_399822.pdf accessed 20th January, 2016).
- Lian O. S., (2003), 'Convergence or Divergence? Reforming Primary Care in Norway and Britain', *Milbank Q. Journal of Population health and Health Policy*, Vol. 81. No. 2, pp.305-330.
- Lucas-Samuel S., Ferry N., and Trouvin J. H., (2015), 'Overview of the Regulatory Oversight Implemented by the French Regulatory Authorities for the Clinical Investigation of Gene therapy and Cell Therapy Products', *American Society of Gene and Cell Therapy*, Vol. 871, pp. 73-85, (http://link.springer.com/chapter/10.1007/978-3-319-18618-4_4#page-2 accessed 7th January, 2016).

- Lämsä R., Keskimäki I., and Kokko S, (2013), Official Projects, Grass-roots Solutions: the Sami People using Cross-border Health Services in the Teno River valley (Finland–Norway), <http://www.euro.who.int/en/publications/abstracts/hospitals-and-borders.-seven-case-studies-on-cross-border-collaboration-and-health-system-interactions> 15th November, 2015.
- Marschang S., and Bernado G., (2014), ‘Prevention and Control of healthcare-associated infection in Europe: A Review of Patients’ perspectives and Existing Differences’, *Journal of Hospital Infection*, Vol. 89, Issues 4, pp. 357-362.
- Martinsen D. S., (2011), ‘Judicial Policy and Europeanization: The Proportionality of National Control and Administrative Discretion’, *Journal of European Public Policy*, 18(7): 944-961.
- Martinsen D. S., and Vrangbæk K., (2008), ‘The Europeanization of Health Care Governance: Implementing the Market Imperatives of Europe’. *Public Administration* 86(1): 169-184.
- Mechanic D., ‘The Comparative Medical Systems’, *Annual review of Sociology*, Vol. 1, pp. 43 -65.
- Mechanic D., and Rochefort D. A., ‘Comparative Medical Systems’, *Annual review of Sociology*, Vol. 22, pp. 239 - 270.
- Ministry of Foreign Affairs, (2009), (Web site), *Economy, The Hague, Ministry of Foreign Affairs*. General Information, The Hague, Ministry of Foreign Affairs.
- Moher D., Liberati A., Tetzlaff J., and Altman D. G., (2009), ‘Preferred Reporting Items for Systematic Reviews and Meta-Analysis, *The Prisma Statement, Annals of Internal Medicine*, Vol. 151, No. 4. pp. 264-269.
- Mossialos E and Lear R., (2012), ‘Balancing Economic Freedom Against Social Policy Principles: EC Competition Law and National Health Systems’, *Health Policy*, Vol. 106:127-137.
- Mossialos E., Permanand G., Bæeten R., and Hervey T., (2010), ‘Health Systems Governance in Europe: The Role of European Union Law and Policy’, Chapter 1, *Health Systems Governance in Europe; The Tole of European Union Law and Policy*, Cambridge University Press.
- National Contact Point, DVKA, Germany. ‘Regional Sources of Information’ (http://www.eu-patienten.de/en/behandlung_ausland/regionale_informationstraeger/regionale_informationstraeger_uebersicht.jsp accessed 8th Novemeber, 2015).
- National Contact Point DVKA, Germany, ‘Homepage’, <http://www.eu-patienten.de/en/startseite/startseite.jsp> accessed 8th Novemeber, 2015).
- National Contact Point, DVKA, ‘Treatment in Another EU Country’, (http://www.eu-patienten.de/en/behandlung_ausland/behandlung_im_eu_ausland.jsp accessed 8th Novemeber, 2015)

- Nugent N., (2010), *The Government and Politics of the European Union 7th ED*., Basingstoke, Palgrave Macmillan.
- O'Brien A., (2014), 'Lessons from the Ashya King Case', *BMJ*, 349, g5563, (<http://www.bmj.com/content/349/bmj.g5563> accessed 7th March, 2016)
- OECD, (2008), 'The looming Crises in the health Workforce: How can OECD Countries Respond, Paris, Organisation for Economic Co-operation and Development.
- OECD, (2013), Health Data 2011, 2012, 2013. Paris, Organisation for Economic Co-operation and Development (<http://www.oecd.org/els/health-systems/health-data.htm>, accessed 21st May, 2014).
- OECD, (2014), OECD Health Statistics 2014: How does the Netherlands Compare? (<http://www.oecd.org/els/health-systems/Briefing-Note-NETHERLANDS-2014.pdf>. Accessed 11th October 2015).
- OECD/European Union (2014), 'Financing of Health Care', *Health at a Glance, Europe 2014*, OECD Publishing, Paris.
- OECD., Stat (2015), 'Health Expenditure and finance' (http://stats.oecd.org/index.aspx?DataSetCode=HEALTH_STAT# accessed 20th January, 2016).
- Office for national statistics, (2015) Part of Population Estimates for UK, England and Wales, Scotland and Northern Ireland. Mid-2014 release (<http://www.ons.gov.uk/ons/rel/pop-estimate/population-estimates-for-uk--england-and-wales--scotland-and-northern-ireland/mid-2014/sty---overview-of-the-uk-population> accessed 17th September 2015).
- Official Journal of the European Union, Brussels (2011), 'Directive 2011/24/EU of the European Parliament and of the Council, *European Union*, (<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:EN:PDF> accessed 18th October, 2015).
- Olsen P. J., (2002), 'The Many Faces of Europeanization', *Journal of Common Market Studies*, 40(5): 921/52
- ONS, (2010d), 'Mortality Statistics: Deaths Registered in 2009', Newport, *Office for National Statistics*. (<http://www.statistics.gov.uk/downloads/theme-health/dr2009/dr-09.pdf>, accessed 12 January 2011).
- Oxford Dictionary (<http://www.oxforddictionaries.com/definition/english/directive> accessed 4th November 2015).
- Palm W., and Glinos I. A., (2010), 'Enabling Patient Mobility in the EU: Between Free Movement and Coordinating', Chapter 12, Mossialos et al (Eds), *Health Systems Governance in Europe: The Role of European Union Law and Policy*' Cambridge University Press.
- Palm W., Wismar M., Van Ginneken E., Busse K. E., and Figueras J., (2011), 'Towards a Renewed Community Framework for Safe, High-quality and Efficient Cross-Border Health

Care within the European Union', *European Observatory on Health Systems and Policies*, http://www.euro.who.int/_data/assets/pdf_file/0004/135994/e94875.pdf accessed 16th April, 2016.

Panteli D., Wagner C., Verheyen F., and Busse R., (2015a), 'Know Before You go': Information-seeking German Patients Receiving Health Service Abroad in Light of the Provision of Directive 2011/24/EU', *Journal Health Serv Re Policy*, 1355819615580003.

Panteli D., Wagner C., Verheyen F., and Busse R., (2015b), 'Continuity of Care in the Cross-border Context: Insights from a Survey of German Patients treated abroad', *European Journal of Public Health*, 10.1093/eurpub/cku251.

Panteli D., Augustin U., Rottger J., et al., (2015c), 'Informed Consumer or unlucky Visitor? A Profile of German Patient Who Received Dental Services Abroad', *Community Dentistry and Oral Epidemiology*, Vol. 43, Issue 5, pp 415-423.

Paolucci F., Den Exter A., and Van De Ven, W. P., (2006), 'Solidarity in Competitive Health Insurance Markets: Analysing the relevant EC Legal Framework', *Health Economics, Policy and Law*, 1: 107-126.

Patterson I., (2006), 'Growing Older: Tourism and Leisure Behaviour of Older Adults', *Wallingford, CABI*.

Payne C. S., (2013), 'Expenditure on healthcare in the UK, 2011', *Office for National Statistics*, (http://www.ons.gov.uk/ons/dcp171766_308689.pdf accessed 20th January 2016).

Peeters M., McKee M., and Merkur S., (2010), 'EU Law and Health Professionals', Chapter 14, Mossialos et al (Eds), *Health Systems Governance in Europe: The Role of European Union Law and Policy* Cambridge University Press.

Pohjoisessa R., (2004), 'Työryhmäraportti Suomen ja Norjan välisestä yhteistyöstä pohjoisessa (Without borders in the North. Working group report on the collaboration between Finland and northern Norway)'. *Helsinki, Ministry of the Interior* ([www.poliisi.fi/intermin/biblio.nsf/B9C3CB6C0612E022C2256FA20036E912/\\$file/292004.pdf](http://www.poliisi.fi/intermin/biblio.nsf/B9C3CB6C0612E022C2256FA20036E912/$file/292004.pdf)).

Popay J., Roberts H., Sowden A., et al., (2006), 'Guidance on the Conduct of Narrative Synthesis in Systematic Reviews. (<http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.178.3100&rep=rep1&type=pdf>. Accessed 13th January, 2016)

Risso-Gill I., Panteli D., Kovacs E., et al., (2013a), 'Processes and Regulatory Procedures of Doctors in the European Union', *EuroHealth Euro Observer*, Vol.19, No.4.

Risso-Gill I., Legido-Quigley H., Panteli D., and McKee M., (2013b), 'Assessing the Role of Regulatory Bodies in Assuring Patient Safety and the Quality of Health Care in Europe: An Analysis of Vignettes Medical Errors and Professional Issues', *European Journal of Public Health*, 23.

Rosen-Moller R., Mckee M., Baeten R., (2006), 'Patient Mobility in the European Union: Learning from Experience', *Brussels: European Observatory on health System and Policies*.

Rothgang H., Cacace M., Frisina L., (2008), 'The Changing Public-Private-Mix in OECD Health-care Systems. In Welfare State Transformations', *Comparative Perspectives*, Ed, M. Seeleib-Kaiser, 132 -146, Basingstoke, Palgrave Mackmillan.

Saliba V., Legido-Quigley H., Hallik R., et al., (2012), 'Telemedicine Across Borders: A Systematic Review of Factors that Hinder or Support Implementation', *International Journal of Medical Informatics*, 81(12):793-809.

San-Miguel L., Baeten R., Remmen R., et al., (2013), 'Obstacles to the Recognition of Medical Prescriptions Issued in one EU Country and Presented in Another', *The European Journal of Public Health*.

Saunders M., Lewis P., and Thornhill A., (2007), *Research Methods for Business Students, 4th Edition*, United Kingdom, Pearson Education.

Sauter W., (2009), 'The Proposed Patients' Rights Directive and the Reform of (Cross-Border) Healthcare in the European Union', *Legal Issues of Economic Integration* 36, no. 2, 109-131.

Schafer W., Kroneman M., Boerma W., et al. (2010), 'The Netherlands Health System Review', *Health System in transition vol. 12 no. 1*.

Schmid A., Cacace M., Gotze R., and Rothgang H., (2010), 'Explaining Health Care System Change: Problem Pressure and the Emergence of "Hybrid" Health Care Systems', *Journal of Health Policies, Policy and Law*, Vol. 35, No. 4, DOI 10.1215/03616878-2010-013.

Schmitter P. C., (2000), 'How to Democratize the European Union..... Why Bother?' *Rowman and Littlefield publications*, New York.

Schumann R., (1952), translated from French. The speech, and the documents related to the European Health Community project, are available on the archive site www.enal.lu presently transferring to www.cvce.eu.

Schut F. T., and Van De Ven W. P. M. M., (2011), 'Effect of Purchaser Competition in the Dutch Health System: Is the Glass Half Full or Half Empty' *Health Economics, Policy and Law*, 6, 109-123: doi 10.1017/S1744133110000381.

Schäfer W., Kroneman M, Boerma W., et al., (2010), 'The Netherlands: Health System Review' *Health Systems in Transition*,12(1):1-229.

Shortell S. M., and Kaluzny A. D., (2000). 'Health Care Management', *Organisation Design and Behaviour*; 4th Edition; Albany, NY.

Sigurdardottir L. B., (2011), 'Cross-border Healthcare in the European Union the right to reimbursement under the Directive 2011/24.

Statistics Netherlands (2015), <http://www.cbs.nl/en-GB/menu/home/default.htm>.

Statutory Instruments (2013), http://www.gov.uk/government/uploads/system/uploads/attachment_data/file/252944/NHS_cross_border_regulations_2013.pdf accessed 24th April, 2016).

- Steffen M., Lamping W., and Lehto J., (2005), 'Health Governance in Europe: Issues, Challenges and Theories', *Routledge*, New York.
- Steunenberg B., and Toshkov D., (2009), 'Comparing Transposition in the 27 Member States of the EU: The Impact of Discretion and Legal Fit', *Journal of European Public Policy*, Vol. 16, No. 7, pp951-70.
- Steunenberg B., and Rhinard M., (2010), 'The Transposition of European Law in EU Member States: Between Process and Politics', *European Political Science Review*, Vol. 2 No. 3, pp. 495-520.
- Steyger E., (2002), 'National Health Care System Under Fire (but not too Heavily)', *Legal Issues of Economic Integration*, p.27.
- Struckmann V., Panteli D., Legido-Quigley H., et al., (2015), 'Deciding When Physicians are unfit to practise: An Analysis of Responsibilities, Policy and Practice in 11 European Union Member States', *Clinical Medicine*, Vol. 15, no.4-319-24.
- Tranfield D., Denyer D., and Palminder s., (2003), 'Towards a Methodology for Developing Evidence-Informed Management Knowledge by means of Systematic Review', *British Journal of Management*, Vol. 15. No. 3, pp 207-222. doi:10/1111/1467-8551.00375.
- Treib O., (2003), 'EU Governance, Misfit, and the Partisan Logic of Domestic Adaptation: an Actor-Centered Perspective on the Transposition of EU Directives, Papers Presented at the EUSA 8th International Biennale Conference. Max-Planck Institute. Research Gate, https://www.researchgate.net/publication/29996435_EU_Governance_Misfit_and_the_Partisan_Logic_of_Domestic_Adaptation_An_Actor-Centered_Perspective_on_the_Transposition_of_EU_Directives accessed 15th January, 2016).
- Van Der Mei., (2002), Cross-Border Access to Health Care within European Union: Reflections on Geraets-Smits and Peerbooms and Vandraeket', *Maastricht Journal of European and Comparative Law*, p. 12.1.
- Van Der Mei A. P., (2003), 'Cross-Border Access to Health Care within the European Union: Recent Developments in Law and Policy'. *European Journal of Health Law*, 10: 369-380.
- Van Lier E. A., Oomen, P. J., Oostenbrug, M. W. M., et al., (2009), 'Vaccinatiegraad Rijksvaccinatieprogramma Nederland. Verslagjaar 2009' (Immunization Coverage: National Immunization Program in the Netherlands. 2009 report), Buitgave, *National Institute for Public Health and Environment (RIVM)*.
- Van Theil J., and Lugtenberg (1999), 'Decker and Kohl and the Dutch System of Social Health Insurance', *European Journal of Health Law* 6: 389-395.
- Vasev N., and Vrangbæk K., (2014), 'Transposition and National Level Resources – Introducing the Cross-Border Health Care Directive in Eastern Europe', *West European Politics*, Vol. 37, No., 4, pp. 693-710.
- Veggeland F., and Time M. S., (2015), 'Tales of the Unexpected: The Historical Dynamics of EU's Health Policy and Law, *Sequencing in Public Policy, International Conference on Public Policy*, Milan July, 2015.

Veraghtert K., and Widershoven B., (2002), 'Twee Eeuwen Solidariteit: De Nederlandse, Belgische en Duitse Suckenfondsden Tijden de Negentiende en Twubtugste Eeuw: (Two Centuries of Solidarity: Dutch, Belgian and German Sickness Funds during the 19th and 20th Century). Amsterdam, Aksant.

Versluis E., (2007), 'Even Rules, Uneven Practices: Opening the 'Black Box' of EU Law n Action', *West European Politics*, Vol. 30. No. 50

Vollaard H., (2004), 'Solidarity, Territoriality and Healthcare: Cross-National Policy Learning in Europe', in *Vigoda-Gadot and David Levi-Faur (Eds). 'International Public Policy and Management: Policy Learning beyond Regional, Cultural and Political Boundaries*, New York: Marcel Dekker, 267-96.

Vollaard H, Van De Bovenkamp H.M, and Vrangbæk K., (2013), 'The emerging EU Quality of Care Policies From Sharing Information to enforcement'; *Health Policy* 111; 226-233.

Vollaard H., and Martinsen D.S., (2014), 'Bounded Rationality in Transposition Processes: The Case of the European Patients' Rights Directive', *West European Politics*, Vol. 37, No. 4, pp. 711-731.

White J., (2007), 'Markets and Medical Care: The United States, 1993 – 2005', *Milbank Quarterly*, 85:395-448.

Winkelmann J., Hofmarcher M. M., Kovacs E., et al., (2013), 'Cross-border Dental Care between Austria and Hungary', *Eurohealth*, 19(4) 26-7.

Wismar M., Palm W., Figueras J., et al., (2011), 'Cross-Border Health Care in the European Union, Mapping and Analysing Practices and Policies', *World Health Organisation*, on behalf of the European Observatory on health Systems and Policies.

World Bank (2008), 'Governing Mandatory Health Insurance, Learning from Experience', Washington DC 20433, <http://siteresources.worldbank.org/HEALTHNUTRITIONANDPOPULATION/Resources/Peer-Reviewed-Publications/GovMandatoryHlthIns.pdf> accessed 16th Novemeber, 2015).

World Health Organisation, Regional Office for Europe (2009), European Health for all database (HFA-DB) Copenhagen, WHO Regional Office for Europe (<http://euro.who.int/hfadb>, accessed 12th October 2009).

World Bank, (2009), 'World Development Indicators (online database), *Washington, DC*, World Bank.

Xu K., Evans D. B., Carrin G., and Aguilar-Rivera A. M., (2005), 'Designing Health Financing Systems to Reduce Catastrophic Health Expenditure', *Technical Brief for Policy-Makers*, WHO.

Yin R., (2003a), 'Case Study Research, Design and Methods' 3rd ed., Vol, 5., *Thousand Oaks*: Sage.

Yin R., (2003b), 'Application of Case Study Research', 2nd ed., Vol.34, *Thousand Oaks*: Sage

Zanon E., (2011), 'Health Care Across Borders: Implications of the EU Directive on Cross-border Health Care for the English NHS', *Health Policy Development*, Vol. 17, No. 2-3, pp. 34.

Zucca G., (2015); 'Evaluative Study on the Cross-Border Healthcare Directive' (2011/24/EU); S12.684413; SANCO/2012/02/011-Lot 1.

Appendix

Appendix 1;

Treaties, Articles, Communications, Cases:

- Commission Communication 2 July 2008, Proposal for Directive of the European Parliament and of the council on the application of patients' rights in cross-border healthcare presented by the commission, COM (2008) 414 final.
- Case No. 238/82 Duphar BV et al. v. The Netherlands (1984), ECR 523, para, 16; Joined case nos. C-159/91 and C-160/91 Christian Poucet v. Assurances Generales de France and Casisse Mutuelle Regionale du Languedoc-Roussillon (1993), ECR 1-637, para 6. Cases no. C-70/95 Sodemare SA, Anni Azzurri Holdings SpA and Azzurri Rezzato SrL v. Regione Lombardia (1997), ECR 1-3395, para. 27; and case no. C-158/96 Raymond Kohll v. Union des caisses de maladie (1998), ECR 1-1931, para. 17.
- European Commission, Proposal for a Directive of the European Parliament and of the Council on services in the internal market 2004/0001 (COD) SEC (2004) 21, COM (2004) 2 final/3, 5 March 2004, especially Art. 23 therefore. CF. Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on service in the internal market, OJ 2006 L376/36 (Services Directive), Art. 2 para. 2, subpara. F, and the Preamble, Recital 23.
- Directive 2011/24 of 9 March 2011 of the European Parliament and the Council on the application of patients' rights in cross-border healthcare (OJ L 88, 4 April 2011 p.45)
- Case C-158/96 Kohll (1998) ECR I—1931).
- Case C—157/99 Geraets-Smits and Peerbooms (2001) ECR 1-5473
- Case C-157/99 (2001) ECR I-5473
- Case C-368 (2001) ECR I-5363

Appendix 2; Websites

1. Journal of Health Service Res. Policy 1344819615580003.
2. Journal of hospital Infection
3. Europe publications Oxford journal
4. Community Dentistry & Oral Epidemiology Journal
5. Social Science & Medicine Journal
6. Evaluative Study on the Cross-border Healthcare Directive SANCO/2012/02/011 – Lot 1
7. Nordic Health Policy (NOPSA) journal
8. Developments in Health Economics & Public policy.
9. Social Policy & Administration ISSN journal
10. EU Health Policy (Political Perspectives) journals
11. European Union Web
12. WHO Web.

13. OECD Health data
14. Social Science and Medicine Journal
15. CBS StatLine (Statistics Netherlands StatLine)
16. European Health for all database
17. OECD
18. Nationale Drug Monitor Trimbos
19. World Development Indicators online
20. Common Market Law Review, Kluwer law International
21. RAND Europe

Appendix 3; List of services subject to prior authorisation

Adult ataxia telangiectasia services
 Adult congenital heart disease services
 Adult highly specialist pain management services
 Adult highly specialist respiratory services
 Adult highly specialist rheumatology services
 Adult secure mental health services
 Adult specialist cardiac services
 Adult specialist eating disorder services
 Adult specialist endocrinology services
 Adult specialist intestinal failure services
 Adult specialist neurosciences services
 Adult specialist ophthalmology services
 Adult specialist orthopaedic services
 Adult specialist pulmonary hypertension services
 Adult specialist renal services
 Adult specialist services for patients infected with HIV
 Adult specialist vascular services
 Adult thoracic surgery services
 Alkaptonuria service
 Alström syndrome service
 Ataxia telangiectasia service for children
 Autoimmune paediatric gut syndromes service
 Autologous intestinal reconstruction service for adults
 Bardet-Biedl syndrome service
 Barth syndrome service
 Beckwith-Wiedemann syndrome with macroglossia service
 Behcet's syndrome service
 Bladder exstrophy service
 Blood and marrow transplantation services
 Bone anchored hearing aid services
 Breast radiotherapy injury rehabilitation service
 Child and adolescent mental health services – Tier 4
 Choriocarcinoma service
 Chronic pulmonary aspergillosis service
 Cleft lip and palate services
 Cochlear implantation services
 Complex childhood osteogenesis imperfecta service

Complex Ehlers Danlos syndrome service
Complex neurofibromatosis type 1 service
Complex spinal surgery services
Complex tracheal disease service
Congenital hyperinsulinism service
Craniofacial service
Cryopyrin associated periodic syndrome service
Cystic fibrosis services
Diagnostic service for amyloidosis
Diagnostic service for primary ciliary dyskinesia
Diagnostic service for rare neuromuscular disorders
Encapsulating peritoneal sclerosis treatment service
Epidermolysis bullosa service
Extra corporeal membrane oxygenation service for adults
Extra corporeal membrane oxygenation service for neonates, infants and children with respiratory failure
Ex-vivo partial nephrectomy service
Fetal medicine services
Gender identity development service for children and adolescents
Gender identity disorder services
Heart and lung transplantation service (including bridge to transplant using mechanical circulatory support)
Highly specialist adult urinary and gynecological surgery services
Highly specialist allergy services
Highly specialist colorectal surgery services
Highly specialist dermatology services
Highly specialist metabolic disorder services
Highly specialist pain management services for children and young people
Highly specialist palliative care services for children and young people
Highly specialist services for adults with infectious diseases
Hyperbaric oxygen treatment services
Insulin-resistant diabetes service
Islet transplantation service
Liver transplantation service
Lymphangiomyomatosis service
Lysosomal storage disorder service
Major trauma services
McArdle's disease service
Mental health service for deaf children and adolescents
Middle ear implantable hearing aid services
Neurofibromatosis type 2 service
Neuromyelitis optica service
Neuropsychiatry services
Ocular oncology service
Ophthalmic pathology service
Osteo-odonto-keratoprosthesis service for corneal blindness
Paediatric and perinatal post mortem services
Paediatric cardiac services
Paediatric intestinal pseudo-obstructive disorders service
Pancreas transplantation service

Paroxysmal nocturnal haemoglobinuria service
Positron Emission Tomography – Computed Tomography services
Primary ciliary dyskinesia management service
Primary malignant bone tumours service
Proton beam therapy service
Pseudomyxoma peritonei service
Pulmonary hypertension service for children
Pulmonary thromboendarterectomy service
Radiotherapy services
Rare mitochondrial disorders service
Reconstructive surgery service for adolescents with congenital malformation of the female genital tract
Retinoblastoma service
Secure forensic mental health service for young people
Severe acute porphyria service
Severe combined immunodeficiency and related disorders service
Severe intestinal failure service
Severe obsessive compulsive disorder and body dysmorphic disorder service
Small bowel transplantation service
Specialist burn care services
Specialist cancer services
Specialist cancer services for children and young people
Specialist dentistry services for children and young people
Specialist ear, nose and throat services for children and young people
Specialist endocrinology and diabetes services for children and young people
Specialist gastroenterology, hepatology and nutritional support services for children and young people
Specialist genetic services
Specialist gynaecology services for children and young people
Specialist haematology services for children and young people
Specialist haemoglobinopathy services
Specialist immunology services for patients with deficient immune systems
Specialist mental health services for deaf adults
Specialist morbid obesity services
Specialist neonatal care services
Specialist neuroscience services for children and young people
Specialist ophthalmology services for children and young people
Specialist orthopaedic surgery services for children and young people
Specialist paediatric intensive care services
Specialist paediatric liver disease service
Specialist perinatal mental health services
Specialist plastic surgery services for children and young people
Specialist rehabilitation services for patients with highly complex needs
Specialist renal services for children and young people
Specialist respiratory services for children and young people
Specialist rheumatology services for children and young people
Specialist services for children and young people with infectious diseases
Specialist services for complex liver, biliary and pancreatic diseases in adults
Specialist services for haemophilia and other related bleeding disorders
Specialist services for severe personality disorder in adults

Specialist services to support patients with complex physical disabilities
 Specialist surgery for children and young people
 Specialist urology services for children and young people
 Spinal cord injury services
 Stem cell transplantation service for juvenile idiopathic arthritis and related connective tissue disorders
 Stickler syndrome diagnostic service
 Vein of Galen malformation service
 Veterans' posttraumatic stress disorder programme
 Wolfram syndrome service
 Xeroderma pigmentosum service

Fig. 1 The five steps for prior authorization in UK.

- Step 1. *Patient applies for funding, sending a completed application form, with evidence of clinical need and proof of payment (for retrospective claims) to the European team with the NHS (England, Wales, Scotland and Northern Ireland).*
- Step2. *The European team assesses the application, taking account of the patients' eligibility for NHS services, undue delay, evidence of clinical need and (where appropriate) liaising with the responsible CCG to clarify patient entitlement to the specific treatment.*
- Step 3. *The European team informs the patient of the outcome of their application.*
- Step 4. *If the application has been successful, the European team authorizes the issuing of a reimbursement or an S2 form*
- Step 5. *The European team issues any reimbursement due directly to the patient, and claims the money back from the responsible CCG (where the CCG is the responsible commissioner).*

(Regulation 7 of the NHS and Public Health (functions and miscellaneous provisions)
 Regulation 2013 (S.1. 2013/261).

Fig 2 shows the difference in directive and S2 routes respectively.

Coverage	S2 Route	Directive Route
EU/EEA	Yes	Yes
Switzerland	Yes	No
Requires prior authorization	Yes	Specified treatments only. (see annex 1)
Discretionary (Unless undue delay applies)	Yes	Yes (with due circumstances)
Planned healthcare	Yes	Yes
Unplanned (emergency) healthcare	No	Yes

Treatment in state-run/contracted facilities	Yes	Yes
Treatment in private/non-contracted facilities	No	Yes
Must be granted if undue delay applies	Yes	Yes
Requires payment if undue delay applies	No	Yes
Scope restricted to home entitlements only	No	Yes
Retrospective reimbursement (depending on circumstances)	No	Yes

Source MOH website.

Fig. 3

Healthcare Expenditure as a share of gross domestic product (GDP) UK

Year	2008	2009	2010	2011	2012	2013
GDP (%)	7.9	8.8	8.6	8.5	8.5	8.5
Amount £ Billion	129.0	138.9	140.1	142.8	144.5	150.6

(Source: Lewis and Cooper 2015 and OECD Stat. 2015)

According to OECD health statistic 2014 report, the total health spending in the UK accounted to 8.5% of GDP in 2012, slightly down from a high of 8.8% recorded in the 2009. Total health expenditure for UK in 2013 was £150.6 billion, an increase of 2.7% between 2012 and 2013. In 2013, health spending was 8.5% of GDP (Lewis and Cooper 2015) with an annual average growth rate of 2% from 2009 to 2013. Health spending in UK surprisingly fell in 2010 and 2011 for the first time since the 70s (OECD report 2013). The fall in health expenditure in the UK cannot be attributed to the implementing EU directive. However, the impact on the health expenditure in the UK have remained the same form the inception of the directive to its implementation deadline. (There is no data yet for 2014 and 2015 UK health expenditure), we cannot say the inception and implementation of the directive have been successful for the UK healthcare expenditure however, subsequent reports can be monitored to explain this fall further. The fall or steady GDP could be because of trend in 2010 GDP but the trend could not be repeated for 2008 and 2009, which had almost 1% increase.

Fig. 4

Healthcare Expenditure as a share of gross domestic product (GDP) Germany

The table below shows a rise of almost 1% from 2008 to 2009, and a drop in 2010 and further 0.3% downward trend which continued from 2011 to 2014 (0.2%). Like the UK, there is the need for further research into this steady decline in health expenditure as a share of GDP, it could either be a result of the new directive or the MSs actions toward healthcare reduction through their policies own policies.

Year	2008	2009	2010	2011	2012	2013	2014
GDP (%)	10.2	11.1	11.0	10.7	10.8	11.0	11.1

(Source: OECD Stat. 2015)

Fig. 5

Healthcare Expenditure as a share of gross domestic product (GDP) the Netherlands

Year	2008	2009	2010	2011	2012	2013	2014
GDP (%)	9.6	10.3	10.4	10.5	11.	11.1	11.1

(Source: OECD Stat. 2015)

The table above showed that healthcare expenditure grew by 38% from 1998 to 2007 and represented 8.9% of GDP in 2007 (OECD 2008). In 2012, the health expenditure accounted for 11.8% of its GDP (OECD 2014) and similar to the other countries, 86% of health expenditure in the Netherlands comes from the government or through social insurance. This figure has increased in recent years and is well above the average of 72% in the OECD countries for 2012. Despite the economic crisis, the health expenditures in the Netherlands continues to grow with an average yearly growth rate of over 3% between 2006 and 2012. The growth rate on the other hand, slowed down to 1.2% in 2011 but picked up in 2012 at 3.5% (OECD, 2014)