

THE TRANSPOSITION OF THE PATIENTS' RIGHTS DIRECTIVE IN VARIOUS MEMBER STATES

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Abstract

This paper aims to research the transposition process of the Patients' Rights Directive in the EU member states Germany, Poland, the Netherlands, and Denmark, to test whether additional costs for the healthcare systems and preferences of key actors caused a delayed or incorrect transposition. The respective transpositions of the directive among the cases will be analyzed on the basis of the misfit and actor-centered approach which will be applied within the framework of the Process Tracing Theory. The scope of the analysis will specifically focus on cost factors regarding the misfit approach, whilst a broader range of potential key actors will be considered for the actor-centered approach.

The outcomes of the analysis suggest that an interplay of both aspects significant impacted the timeliness and degree of the respective transposition in the analyzed cases. In conclusion, several explanatory factors could be identified which contributed on the basis of misfit and actor-centered preferences to an either (in-)correct and/or timely transposition.

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List of Abbreviations

Abbreviation	Expansion	Translation
AOK Bundesverband	Bundesverband der Allgemeinen Ortskrankenkassen	Federal Association of the Local General Sickness Funds
AWBZ	Algemene Wet Bijzondere Ziektekosten	National Exceptional Medical Expense Act
BÄK	Bundesärztekammer	German Medical Association
BZÄK	Bundeszahnärztekammer	German Dental Association
BGB	Bürgerliches Gesetzbuch	German Civil Code
CJEU	Court of Justice of the European Union	
CVZ	College voor Zorgverzekering	Health Insurance Board
DKG	Deutsche Krankenhausgesellschaft	German Hospital Federation
DVKA	Deutsche Verbindungsstelle Krankenversicherung-Ausland	German Liaison Office for Sickness Insurance-Abroad
EKD	Diakonisches Werk der Evangelischen Kirche in Deutschland	Diaconal Agency of the Evangelical Church in Germany
GKV-Spitzenverband	Spitzenverband Bund der Krankenkassen	National Association of Statutory Health Insurance Funds
IGeL	Individuelle Gesundheitsleistungen	Individual Medical Benefits
KBV	Kassenärztliche Bundesvereinigung	Federal Association for Statutory Health Insurance Physicians
KZBV	Kassenärztliche Bundesvereinigung	German Federal Association of Sick Fund Dentists
MDS	Medizinischer Dienst Bundesspitzenverband	Federal Association of the Medical Services of the Health Care Funds
NCP	National Contact Point	
NIL	Naczelna Izba Lekarska	The Chamber of Physicians and Dentists
NFZ	Narodowy Fundusz Zdrowia	Polish National Health Fund
PKV-Verband	Verband der Privaten Krankenversicherung	Association of Private Health Insurances
P1C	Porozumienie 1 czerwca	The 1st June Agreement
PRG	Patientenrechtegesetz	Patients' Rights Law
PT	Process Tracing Theory	

vdek	Verband der Ersatzkassen e.V.	Association of Substitute Insurance Funds
STOMOZ	Stowarzyszenie Menedżerów Opieki Zdrowotnej	Association of Healthcare Managers
TFEU	Treaty on the Functioning of the European Union	
Zvw	Zorgverzekeringswet	The Health Insurance Act

1. Introduction

This chapter outlines the background and policy related considerations of the patients' rights directive¹ and its transposition process. On this basis, the research problem will be identified which in turn will subsequently lead to the formulation of the research question. In addition, the theoretical application will be presented to address the societal relevance of the presented context, whilst guiding the structure of this paper.

1.1. The Patients' Rights Directive

The EU Directive 2011/24/EU on patients' rights aims to guarantee the mobility and transparent provision of healthcare services for patients among all member states of the European Union and the European Economic Area. Prior to the introduction of the Patients' Rights Directive, the Coordination Regulations (EC) Nos. 883/2004² and 987/2009³ entitled individuals who were insured in the European Economic Area, to seek healthcare treatments abroad according to guidelines which applied in relation to their country of affiliation (Cleiss, n.d.). The Patients' Rights Directive was subsequently introduced to fulfill the Article 114 TFEU, and "improve the functioning of the internal market and the free movement of goods, persons and services" (OJ L 88, 2011(2), p. 2).

The directive grants each member state the independent authority to organize and provide healthcare services, while facilitating the access to safe and high-quality cross-border healthcare. At the same time, the transposition and application of the directive should not result in patients being encouraged to receive treatments outside their member state of affiliation (OJ L 88, 2011(4)). In its wording, the directive refers to 'individual patients'⁴ since all citizen of the European Union as well as insured residents of third countries are covered by the directive if they meet specific qualifying criteria⁵. According to the proceedings of the CJEU, the

¹ Parliament and Council Directive 2011/24/EU of 9 March 2011 on the application of patients' rights in cross-border healthcare OJ L 88/45 (Patients' Rights Directive)

² "Regulation 883/2004 lays down the rules protecting social security rights of European citizens, and occasionally also the rights of third persons, when moving within Europe. The regulation covers various branches of social security [...]" (Remac, 2017, p. 2), and in the same time prevents the overlapping of benefits for compulsory insurances in the same period (Remac, 2017).

³ "This implementing regulation adopts coordination measures in order to guarantee the effective exercise of the free movement of persons. It contains provisions concerning the cooperation and the exchange of data between the Member States' institutions and the persons concerned" (Remac, 2017, p. 3), to regulate the application of the Regulation 883/2004, to determine which member state's legislation is applicable (Remac, 2017).

⁴ Patients' Rights Directive, art. 4(2)(b)

⁵ Applied to the EEA member states (Iceland, Liechtenstein, and Norway), the directive does not cover citizens of third countries (Cleiss, n.d.).

freedom to provide healthcare services does not discriminate on its special nature or the way in which it is organized or financed, which translates to the provision that healthcare services are subject to reimbursement, no matter whether they are provided by public or private practitioners.⁶ However, the directive also states that “the Member State of affiliation may choose to limit the reimbursement of cross-border healthcare for reasons to the quality and safety of the healthcare provided, where this can be justified by overriding reasons of general interest relating to public health” (OJ L 88, 2011(11), p.2). The rulings of the CJEU⁷ extend the interpretation of overriding reasons of general interest to measures of member states which aim to ensure a sufficient and permanent access to a balanced range of high-quality treatments on their own territory, to control healthcare spending and avoid as far as possible any waste of resources.⁸ Hence, the provision ensures that member states may prioritize the maintenance of their treatment capacities and medical competences on their national territory, over the obligation to provide their citizen with the freedom to attain medical and hospital services abroad.⁹ Thus, a tradeoff between the right to seek healthcare abroad and sustainable financing of the national healthcare provision is excluded. Furthermore, “the obligation to reimburse the costs of cross-border healthcare should be limited to healthcare to which the insured person is entitled according to the legislation of the Member State of affiliation” (OJ L 88, 2011(13), p. 2). So, if the healthcare provisions of the member state in which the patient seeks his or her treatment is more extensive, the reimbursements of the healthcare basket is only subject to treatments which are provided in the scheme of the member state of affiliation.¹⁰ However, the directive also allows member states to organize their healthcare and social security system in such a manner which may even explicitly extend the reimbursement of healthcare benefits and reimbursements for patients who deliberately seek treatments abroad.¹¹ This aspect might allow member states to relieve or channel the demand on their domestic healthcare systems by encouraging patients to seek their treatment abroad and by doing so, outsourcing their potential structural shortcomings of the healthcare sector. This constellation has, in particular, the potential to pay off, in the case of border regions¹² by avoiding double structures.

⁶ Id. art. 1(2)

⁷ See Case C-512/08, *European Commission v French Republic*, EU:C:2010:579

⁸ Patients’ Rights Directive, art. 4(3)

⁹ The concept of ‘overriding reasons of general interest’ of the directive has been developed by the Court of Justice in its case-law in relation to Article 49 and 56 TFEU and may continue to evolve (OJ L 88, 2011, p. 2).

¹⁰ Id. art. 7(1)

¹¹ Id. art. 7(3)

¹² Id. art. 10(3)

Furthermore, several measures are taken into force to narrow the information asymmetry between healthcare providers, the administration bodies and patients, to enable the latter to make an informed choice when they seek healthcare in another member state. The directive states that each member state is supposed to ensure that specifically patients from abroad who seek treatment on their territory, are on request provided with sufficient information about safety and quality standards. Also, each member state is supposed to obligate its healthcare providers to extend the respective national information obligation to patients from abroad, if they demand specific aspects considering healthcare services.¹³ The directive does not obligate healthcare providers to provide patients from other member states with more extensive information compared to domestic residents, but it allows each member state in turn to take further measures to ensure a sufficient provision of information about healthcare services on its territory which might also involve other actors such as public authorities.¹⁴ In particular, the directive recognizes that the organization of the healthcare systems varies among the member states and thus allows that different entities, regardless of their statutory or private structure, can be considered for the fulfillment of the duties on cross-border healthcare.¹⁵

In order to enable patients to exercise their new rights in practice, they need to be provided with appropriate information on the various aspects of cross-border healthcare. This is why all member states are required to establish National Contact Points (NCP), to provide patients with compulsory information.¹⁶ Whereas the directive states that the NCPs should be able to maintain consultations with patient organizations, healthcare insurers and providers, it also leaves it to the member states to decide on the structure and number of their NCPs and how to establish them in an efficient and transparent way.¹⁷ The NCPs can be incorporated in, or build on structures of already existing information centers of the national level, whilst the European Commission is supposed to facilitate a sufficient cooperation across borders with all member states and NCPs.¹⁸

Several measures are included in the directive to prevent potential hazardous effects which might occur as a result to the extended free movement of patients across borders. In exceptional cases such as if the inflow of patients creates a demand for a given treatment which cannot be

¹³ Id. art. 4(2)(b)

¹⁴ Id. art. 4(5)

¹⁵ Id. art. 5(b)

¹⁶ Id. art. 6(1)

¹⁷ Id. art. 6(1)

¹⁸ Id. art. 6(2)

met by the healthcare facilities of a member state, it may (temporarily) suspend the planned treatment of patients from other abroad.¹⁹

A significant aspect of the directive is the way in which it highlights the principal to protect the general public interest. It allows all member states to introduce a system of prior authorization before granting a reimbursement to patients who seek their treatment abroad, to ensure that they can fulfill their responsibility to maintain their established high quality and safety standards as well as the sufficient capabilities of their healthcare systems.²⁰ However, if a member state decides to introduce a prior authorization mechanism, it has to be in alignment with the criteria that are defined in the directive which require to provide patients a publicly available, sufficient and transparent access to predetermined healthcare treatments that are subject to prior authorization.²¹ The CJEU aimed to establish with the possibility to introduce a prior authorization mechanism, a balance between the freedom of movement for patients and the responsibility of the member states in the light to fulfill the overriding reasons of general interest.²² Furthermore, the CJEU identified several potential threats which might undermine the member states responsibility to ensure a sufficient and permanent access to a balanced range of high quality treatments.²³ Therefore, member states may introduce measures the control costs and avoid as far as possible any waste of financial, technical and human resources which might affect the financial balance of their social security systems. On the other hand, these protective measures are also supposed to contribute to the safety of the patients. Since the medical sector is well known for its information asymmetries, prior authorization mechanisms shall not only ensure the maintenance of the general capacity and competence of the member states' public health systems, but also contribute to the safety of the patients by providing them with adequate procedural information.²⁴ However, the directive conversely states that the refusal to grant prior authorization may not be based on the consideration of waiting lists of national healthcare practitioners which is why national authorities who determine the conditions for their prior authorization mechanism, may not consider to plan and manage the demand for their domestic healthcare providers as an criterion for prior authorization.²⁵ Moreover, general clinical

¹⁹ A suspension of the obligations can be initiated in accordance with Articles 52 and 62 TFEU (OJ L 88, 2011(21)).

²⁰ Id. art. 8(2)(a)

²¹ Id. art. 8(7)

²² See Case C-169/07, *Hartlauer Handelsgesellschaft mbH v Wiener Landesregierung and Oberösterreichische Landesregierung*, EU:C:2009:141

²³ *Id.*

²⁴ Patients' Rights Directive, art. 8(2)(c)

²⁵ Id. art. 7(11)

priorities may not lead to the refusal to grant prior authorization, without carrying out an objective medical assessment.²⁶ Nevertheless, a member state can predetermine specific healthcare treatments which are subject to a prior authorization regulation, since certain (costly) treatments of highly specialized nature might easily affect the general interest²⁷, whilst more routine treatments bear the potential to improve the distribution of resources. Thus, member states may set different criteria for different regions and relevant administrative criteria or even specific treatments, as long as the system is transparent, easily accessible and is made public in advance (OJ L 88, 2011(44)). This aspect does not diminish the bureaucratic drawback in the practice that patients will still need to pay the healthcare treatments in advance and file afterwards for a reimbursement.²⁸

Furthermore, the directive states that all member states are responsible to implement certain mechanism and structures for the protection of patients which also allow them to seek remedies in the event of an adverse event.²⁹ Even though, this aspect goes beyond the clear definition of the provision to introduce an obligatory liability insurance for healthcare providers, it leaves the determination of the nature and modalities of such a mechanism to the responsibility of the member states.³⁰

Explicitly excluded from the scope of the directive are home-based long-term care, organ donations, and public vaccination programs³¹, since the CJEU discriminates between the risk of reliance on care and sickness benefits in respect of medical treatments³². The court's current jurisprudence does not consider the former as applicable to Article 114 TFEU (Strban, 2018).

Accordingly, to the case-law rulings and recommendations of the CJEU³³, the Council of the EU recognized the significant differences of the healthcare systems among the member states, acknowledging that there cannot be a single solution to overcome the various obstacles which every country is facing (OJ L 88, 2011(5)), whilst both opening their internal healthcare market for patients from abroad, and enabling their own citizen to claim healthcare in other member states. Therefore, it recommended that each national context need to be addressed separately,

²⁶ Id. art. 8(5)

²⁷ Id. art. 7(9)

²⁸ Id. art. 7(1)

²⁹ Id. art. 6(3)

³⁰ Id. art. 4(2)(b)

³¹ Id. art. 1(3)

³² See Case C-562/10, *European Commission v Federal Republic of Germany*, EU:C:2012:442

³³ *European Commission*, EU:C:2010:579

in particular considering the domestic healthcare basket to which their citizens are entitled to and the market mechanisms which are involved in financing and delivering that healthcare (OJ L 88, 2011(5)).

After all, the implementation of the Patients' Rights Directive was carried out in different means and extents among the member states. Some established mechanisms which promote the opportunity for patients to seek treatments abroad, whereas others rather followed a restrictive approach by creating altogether burdens and disincentives. The consideration of the perspective and aims of the member states are essential to comprehend the outcomes, since "the EU does not have its own administrative machinery to implement its legislation, but has to rely on the member states to fulfill this task" (Treib, 2003, p. 2).

Consequently, following the above-portrayed discourse, the aim of this paper will be dedicated to answer the following research question:

(RQ) How did existing policies of member states in the area of healthcare and healthcare insurance, and the political preferences of relevant actors affect the transposition of the EU Directive 2011/24/EU?

The outcomes would contribute to a better understanding of why different member states introduced the directive in different extents, whilst highlighting the most important cost and actor-centered factor in each case. This in turn could eventually provide the relevant insights to address potential shortcomings of the transposition process and further deepen or adjust the implementation of the directive.

2. Theory

2.1. The Transposition of European Law in EU Member States

One might think that the extensive supranational legislative procedure of the creation and agreement on a directive, would lead to a statute that anticipates broad administrative and political preferences of all member states which in turn allows them a smooth transposition into national law. After all, the decision-making process on the European level enables several stakeholders to gain influence on the legislative procedure, giving them the opportunity, if necessary with several amendments and revisions, to reach not only a common agreement but also to develop a directive which can be transposed with no or little administrative traction into domestic legislation.

In practice however, it is not unusual for the transposition process to take plenty of time and efforts until a new policy instrument gets finally transposed into domestic legislation, even if all member states of the EU agree on a new directive, regardless of extensive deadlines and the strict obligation to comply (Steunenberg & Rhinard, 2010). Proper transposition of a directive is nothing to expect with certainty from a member state, since many factors can affect a timely transposition, causing time lags or even mal transposition which are in the worst case followed by long-lasting shortcomings in the respective domestic policy field (Steunenberg & Rhinard, 2010). The European Commission monitors the performance of the transposition of several directives by the publication of scoreboards and also the member states agreed during the Brussels European Council in 2007, to continuously reduce the number of their outstanding European legislation to under 1 % by 2009, authorizing precursory the Commission to adopt a 'zero tolerance' approach to enforce implementation (Steunenberg & Rhinard, 2010). However, despite these commitments, many member states lack behind these transposition goals including cases which exceeded the mandated deadline by more than two years or resulting in mal transposition with a crucial deviation from the legislative intentions of the Commission (Steunenberg & Rhinard, 2010).

2.2. Contemporary research

Approaches from several branches of public administration and political science offer differing perspectives, on how domestic actors receive and process European policy. The field of transposition studies attracted several scholars who employed in their existing work a variety of research designs and methodology which range from case studies to qualitative comparative analysis, or nested analyses based on mixed methods (Toshkov, 2010). The sheer variety of the research, consists on publications in the field of EU compliance, implementation, transposition and Europeanization studies (Toshkov, M., & Wewerka, 2010) which relate to the formal or legal transposition of European directives to national legislation by a member state, whilst levying the member states to ensure that the EU legislation is effectively put into practice (Versluis, van Keulen, & Stephenson, 2011). The transposition of directives, which are only binding for the member states with regards results that are expected to be achieved, need to be distinguished in this sense from the directly applicable policy instruments of decisions and regulations which are simply absorbed by the member states within their body of laws (Versluis et al., 2011).

Toshkov (2010), compared in his extensive overview several publications on the transposition and implementation of EU law, criticizing that the operationalization and measurement of the

dependent variables are lacking consistency. Research of both transposition and infringement data, only provide a partial perspective on compliance since the former only refers to the formal legal part of the process, and the latter simply relates to a strategic interaction between the Commission and the member states and does not reflect the actual process to pursue the compliance of EU law (Toshkov, 2010). The perspective on both transposition and infringement data need to be considered in the context that compliance constitutes an irreducibly (inter-) subjective rather than an objective concept since its operationalization and measurement are facing biases and insufficient information (Toshkov, 2010). Since “there can be no objective standard of compliance that is applicable to all cases at all times, [...] the shortcomings of transposition and infringement data should not be measured against some ‘perfect’ objective measure because such a measure does not exist” (Toshkov, 2010, p. 13).

Most transposition studies use the CELEX (EURLEX) database as their source of choice which however has been extensively criticized as insufficient and unreliable since it is essentially only a database of transposition notifications (Toshkov, 2010). The researcher has to assume that the notifications present a close representation of the actual state of transpositions to make valid conclusions, however “the database leaves the question whether an absence of notified measures signifies no need for notification (thus, full compliance), failure to notify the transposition measures, or a failure to adopt any transposition measures (thus complete non-compliance)” (Toshkov, 2010, p. 15). This is the reason, why many transposition analyses only use CELEX (EURLEX) as a first step to collect the data and complement it with further national or EU-level databases (Toshkov, 2010; Treib, 2014).

Whereas the operationalization of transposition data focusses on the timeliness and delay of a directive, the analyses of infringement data relies on the number and occurrence of either the ‘Letter of Formal notice and Reasoned Opinion’ on the initial stage or the actual judgments of the ECJ (Toshkov, 2010). However, due to the lack of individual data on infringements, the bulk of the research make use of aggregated data which in turn may entail serious problems to derive proper estimations from the relationship between variables in statistical models due to technical concerns (i.e., auto-correlation from one year to the next) (Toshkov, 2010). The generated data on infringements also raise serious concerns regarding measurement validity and imperfect information, since the Commission is an actor with limited capacities and specific institutional interests (Treib, 2014) which is why infringement procedures rather reflect biased strategic considerations and a distorted picture of compliance within the EU (Toshkov, 2010). These concerns can be addressed with the complementation of the dataset with individual-level

data, along with the consideration of the potentially serious problem of selection bias (Toshkov, 2010).

In conclusion, both quantitative analyses to measure the performance of transposition and infringements require great care in their framing and interpretation of each individual study (Toshkov, 2010) since their operationalization are fraught with major problems of measurement validity (Treib, 2014).

The employment of qualitative techniques can address these shortcomings, due to their immanent measurement of the timeliness and correctness of the transposition, since they are usually gathered from direct sources (e.g., expert interviews, legal documents, NGO reports, and media coverage) (Treib, 2014). This may lead to a high degree of internal validity, but however also brings the cumbersome application of qualitative analyses with the implication that only a small number of cases can be studied (Treib, 2014). The downsides of such a small-N setting could be overcome by the formation of a larger collaborative project, which enables scholars to conduct their research without making compromises in the external validity of their findings (Treib, 2014). The application of such medium-N studies are also suggested to be used in the analyses of the practical implementation of EU policy instruments (Versluis et al., 2011). Thus the measurement of the enforcement and application of EU policies is almost exclusively restricted to qualitative studies (Treib, 2014). Since the published documents on the domestic level are usually written in the language of each member state, the language barrier constitutes an additional obstacle to the external validity of qualitative techniques (Versluis et al., 2011). Thus the collaboration in international research projects could provide a remedy to the geographical and linguistic barriers and ensure the generalizability of the data (Versluis et al., 2011).

A variety of articles on the transposition of EU policy instruments demonstrate the impact and relationship of several independent variables on the transposition process. The categorization in Table 1 illustrates the indication between several independent variables and their relationship to the compliance of the transposition process.

Table 1: *The relationship between explanatory factors and compliance of directives*

	Negative (significant)	Negative	~ Zero	Positive	Positive (significant)
Federalism and regionalism	5	3	0	0	0
Corporatism	0	1	0	2	1
Parliamentary scrutiny	0	0	0	1	2
Veto players	5	1	1	0	0
Administrative efficiency	0	1	1	0	8
Corruption index	3	0	0	0	0
Societal EU attitude	0	1	1	0	1
Government EU position	0	1	0	1	2
Government Left/Right position	0	3	0	1	1
Disagreement with the directive	1	2	2	0	0
EU-level conflict	2	0	0	0	2
Misfit	4	0	0	2	1
Discretion	3	0	0	1	1
Voting rule	1	0	1	1	1

Note: Adapted from (Toshkov, 2010, pp. 25-34)

The only variables that seemingly affect the transposition positively (or at least not negatively) are the efficiency of the administration and parliamentary scrutiny, whereas negative (or at least not positive) influences are defined as federalism/regionalism, corruption levels, veto players, the number of involved ministries and domestic conflict (Toshkov, 2010). The impact of the following variables cannot be affirmed, due to their mixed evidence and inconclusive outcomes: Corporatism, the type of government and number of parties in a government, a countries

disagreement with a directive, EU level conflict, discretion, and the voting rule according to which a directive will be adopted (Toshkov, 2010).

It seems that misfit has repeatedly been found to have a negative impact on transposition, whereas variables related to the actor-centered preferences have shown inconclusive results. A reason behind this might be the selection of the transposition instrument for a directive (e.g., parliamentary legislation, decree, ministerial order, etc.) since it determines the constellation and scope of the actors who are involved into the transposition process (Treib, 2014). Consequently, the selection of the transposition instrument also impacts whether political parties and interests groups enter the scene and potentially politicize the process, or whether a smaller set of actors, like just a ministry as in the case of a ministerial order, are involved to transpose a directive (Treib, 2014).

The impact of actor-centered preferences seem to be case-dependent but still serve all together with the policy misfit as one of the most important explanatory factors. Thus, a study of both approaches and their implications on the transposition of the Patients' Rights Directive suits to deliver promising results for this paper.

3. Methodology

The existing literature discussed the policy misfit and actor/political conflicts extensively as relevant explanatory factors for the transposition of EU directives. The outline and theoretical analysis of this paper will test whether and how these factors play out in the transposition of a directive from the field of healthcare which has not been studied very extensively as yet.

3.1. The misfit approach

The misfit theory views Europeanisation as an EU-induced adaptation process. The central aspects of this approach focus on the misfit between state-centric and EU level parameters during the transposition procedure (Bafail, Beichelt, & Cerami, 2008). The less both spheres are compatible, the smaller the goodness of the fit and the more domestic actors are facing adaptation pressures, who in turn will oppose changes which aim to challenge the current status-quo of the established system (Bafail et al., 2008). On the other hand, a directive is expected to be transposed smoothly, if it is consistent with or strengthening the current status-quo (Duina, 1997).

This approach which focuses on cost factors developed on the basis of the directives and their impact on domestic institutions where parliaments are assumed to act as guardians of the status-

quo by protecting national legal-administrative traditions and interest groups from radical demands that descend from the EU level (Duina, 1997; Mastebroek & Kaeding, 2006). The significance of parliaments is underlying on the unwillingness or incapability of legislators to build the consensus that is necessary to draft a transformative law which is why parliaments only accept those directives that are in consistence with past policies (Duina, 1997; Mastebroek & Kaeding, 2006). At the same time, interest groups merely reinforce the decision of the legislation since strong groups support the state's protection of the status-quo while weak groups generally fail to pressure the state to act otherwise (Duina, 1997; Mastebroek & Kaeding, 2006). Some directives may be in consistence with the whole or parts of existing policy legacies, since naturally not all directives challenge both state policy legacies and the organization of interest groups (Duina, 1997). It might be for instance likely to transpose a directive without actually applying it if it is in consistence with the legal but not the administrative traditions (Duina, 1997). Further cost factors can be specified by examining the enforcement and management of a directive. Speaking from a rationalist perspective, approaches on enforcement assume that states choose to violate European norms because they are not willing to bear the costs of compliance which in turn can only be prevented by increasing the costs for noncompliance (Börzel, Hofmann, Panke, & Sprungk, 2010). The obstinacy of states can be traced to their perceived power to resist the effects of non-compliance since they are less sensitive to the costs which may be imposed by material and ideational sanctions (Börzel et al., 2010). On the other hand, powerful states can also deploy an impact at the EU decision-making stage which in turn allow them to decrease the costs of compliance by shaping European law according to their preferences (Börzel et al., 2010; Mastebroek & Kaeding, 2006). The management approach assumes instead that noncompliance of states is involuntary since a predetermined lack of conditions prevents them from fulfilling the expectations of the EU (Börzel et al., 2010). Sources of such involuntary noncompliance can be insufficient state capacities, ambiguous definitions of norms or inadequate timetables within which compliance needs to be achieved (Börzel et al., 2010). The correct application, as well as the production of new legal acts, require both government capacity and autonomy, whereas a lack of such or a large number of veto players reduces the capacity of a state to bear the costs to challenge the status-quo (Börzel et al., 2010). Thus, the chances for an impact of EU induced policies on national structures increases with the extent to which a domestic policy context is characterized by a contested interest constellation and even distribution of power and resources across opposing actor coalitions (Knill & Lehmkuhl, 2002).

Alternative hypotheses emphasize the importance of further factors such as the degree of how strong national publics identify themselves with the idea of a unified Europe whilst legislators, civil servants and politicians are assumed to feel dependent on the public for electoral support and legitimacy and act accordingly by either supporting or rejecting further European integration (Duina, 1997). The legislative and executive capacities of a member state are another aspect which determines the degree of transposition, since the implementation of European legislations are subject to the same potential (in-)efficiencies as domestic ones, regardless of the interests of political leaders or public sentiments (Duina, 1997). The legitimacy approach employs constructivism as a theoretical basis to explain the of compliance of member states with EU policies (Börzel et al., 2010). In detail, the logic of appropriateness, national actors aim to find an appropriate stance in a given social situation and thus comply on the basis of normative beliefs with EU norms, due to their socialization rather than because it suits their instrumental self-interests (Börzel et al., 2010; Risse, 2009). The successful transposition and compliance of costly EU legislation correlate with a strong domestic culture of law-abidingness and values which goes hand in hand with a strong support for the EU as a rule-setting institution (Börzel et al., 2010; Risse, 2009).

Knill & Lehmkuhl (2002) identified three analytical mechanisms to explain the impact of Europeanization on the domestic arena. *Europeanization by institutional compliance* is pronounced in policies that enable positive integration and aim to replace existing domestic regulatory arrangements by imply to reshape and reform existing domestic provisions (Knill & Lehmkuhl, 2002). *Europeanization by changing domestic opportunity structures* aims to alter the distribution of power and resources between domestic actors by abolishing certain options and hence impact policymaking with the approach of negative integration (Knill & Lehmkuhl, 2002). *Europeanization by framing domestic beliefs*, as a more weaker form neither prescribe concrete institutional requirements nor modify the context for strategic interaction, but aim to alter the beliefs and expectations of domestic actors and induce institutional changes with an indirect cognitive approach to trigger domestic adjustments to EU regulatory objectives (Knill & Lehmkuhl, 2002). However, the framing approach only allows to adopt policies which are vague and more or less symbolic, since the decision making context of the domestic reform consensus still depends on the initial constellation of interests and opportunity structures (e.g., number of veto points or resistance of actors) which are unlikely to overcome for the sake of European objectives (Knill & Lehmkuhl, 2002).

To avoid confusion, it needs to be noted that Europeanization scholars regard a misfit between EU legislation and the domestic status-quo as a necessary precondition to trigger changes as a

respond to major impacts from the EU (Börzel & Risse, 2003), whereas compliance scholars regard the same as an obstacle to a smooth transposition (Falkner, Treib, Hartlapp, & Leiber, 2005).

In detail, the pressure to which domestic actors are exposed to is regarded as a necessary pre-requirement to initiate the transposition procedure and set the sufficient incentives to reveal the potential for internal transposition and changes (Bafoil et al., 2008). However, this top-down perspective lacks under closer examination of several weaknesses, such as the explanation of the beginning of the Europeanization process, the impact of member states in the initial legislative phase, the impact of actors to the transposition in a later stage, or the explanation of factors which might cause potential opposition to reforms (Bafoil et al., 2008). Treib (2003) concluded in his analysis that the major weakness of the theory is caused by its disregard of the impact of political parties and relevant domestic actors who follow their own logics and interests. Furthermore, Mastebroek & Kaeding (2006) argue that the concept of the goodness of fit lacks empirical strength, since the relationship between the status-quo and the response to EU legislation is spurious, as both variables are contingent upon the preferences of domestic political and administrative actors. The conceptual basis of “the goodness of fit hypothesis is rather intuitively appealing and parsimonious” (Mastebroek & Kaeding, 2006, p. 334) which has been supplemented with auxiliary approaches from various authors who attempt to bring more dynamism into the framework. Cautious to put too much emphasis on the concept, most authors still do not discard the goodness to fit argument completely, claiming that it is a necessary condition that initiates pressure to member states to adjust themselves to differing EU policies (Mastebroek & Kaeding, 2006). The poor empirical performance of the original goodness of fit approach is rooted in its strict deterministic aspect that national governments and parliaments want to maintain the status-quo, yet domestic policy-makers often want to change existing policies and institutions (Mastebroek & Kaeding, 2006). The problem with the approach is that it is an essentially apolitical concept that disregards to explain the domestic politics of compliance (Mastebroek & Kaeding, 2006). It has been proven in practice, that directives were transposed timely and correct, despite an enormous misfit with existing policies and institutions (Mastebroek & Kaeding, 2006). Thus, the importance of domestic politics has been recognized by several advocates of the misfit hypothesis who complemented it with auxiliary variables of political nature, concluding that it is necessary rather than a sufficient condition for a successful transformation (Mastebroek & Kaeding, 2006). Furthermore, several cases demonstrated how domestic policy-makers decide to either over- or under-comply with directives regardless of the goodness of fit, leading to the conclusion to reject the approach

as a whole condition (Mastenbroek & Kaeding, 2006). Even the reported good explanatory results of the modified fit approaches are supposed to be stemmed from explanatory values which suffer from selection bias (Mastenbroek & Kaeding, 2006).

Duina (2007) as the first author who formulated the goodness of fit argument, responds to this criticism by highlighting the motives of the actors who decide whether to accept or reject EU laws. They make their decisions *because* it either fits or challenges the institutional status-quo which is why the fit theory has at least in some cases genuine empirical support and thus cannot be dismissed on the grounds that it has no proven explanatory power (Duina, 2007). Multiple factors might exist which can potentially impact how a conflict in the transposition phase may affect its outcomes (Duina, 2007). Thus a reconciling of both the fit and actors-centered theories is needed to attain the best results from both approaches (Duina, 2007).

3.2. The actor-centered approach

Due to the above-discussed shortcomings of the misfit approach, the theoretical analysis will be complemented with the add-on of the actor-centered approach which supplements the theoretical framework with a bottom-up perspective.

The role of interest groups is in a particular an important supplementary factor of the actor-centered approach with regard to qualitative case studies (Falkner et al., 2005). The ‘pull-and-push model’ which is used to conceptualizes the role of interest groups describes their impact on policymaking as an exercise of domestic pressure for adaptation (pull from below) through various channels to either foster or impede the implementation of EU law (Falkner et al., 2005). Such attempts of domestic mobilization most effective if they are linked up with the European Commission which may (push from above) the implementation of EU policies by opening infringement proceedings against reluctant member states (Börzel, 2000; Falkner et al., 2005).

Interest groups can also facilitate adaptation pressures from above by initiating litigation to impel member states to comply with EU law since the EU’s legal institutions provide them the opportunity to seek enforcement of EU law before national courts (Börzel, 2016; Slepcevic, 2009). Also, the Commission relies heavily on external actors like interest groups when it comes to monitoring the compliance of member states (Börzel, 2016). The Commission encourages interest groups to lodge complaints and litigate before national courts, however interest groups have also the opportunity to lodge petitions and queries to the European Parliament which effectively enables the Commission to open an infringement proceeding before the ECJ, once it believes to have sufficient evidence (Börzel, 2016; Panke, 2007).

Political parties are alongside with interest groups another crucial factor of the actor-centered approach since their capacity to exert pressure on the government can impact the decision-making process (van der Vleuten, 2005). The risk of a legislative deadlock may be triggered when the expectation of far-reaching positive or negative policy changes, especially during election times, potentially compromises the support of a party's grassroots (van der Vleuten, 2005). Furthermore, constituting parties of the acting government can exercise their influence and veto position while they download the EU legislation and adapt it accordingly to the preferences of their electoral clientele (Treib, 2004). Thus, "even relatively minor changes to domestic policies may spur ideologically motivated resistance by government parties and thus may give rise to significant delays" (Falkner, Hartlapp, & Treib, 2007, p. 399) during the transposition process. Also, agreements which were signed by the parties at the EU arena imply a factor of strength and autonomy to push their own priorities and agenda which in turn unfold later a significant impact in the national parliaments (Giuliani, 2003).

Treib (2003) suggests that domestic party politics and partisan composition of governments play a decisive role in the transposition process, while the match and mismatch between European standards and national arrangements only plays a minor role. Thus, "governments do not merely act as guardians of the status quo [...], [while] party political preferences [are] much more important determinants for [governments]" (Treib, 2003). Regardless of the degree of fit or misfit, if a directive contradicts the party-political goals of a government, it will likely cause explicit opposition, leading to potential time lags and incorrect transposition (Treib, 2003). Whereas a directive that harmonizes with the party-political preferences is likely to be actively supported, leading to a swift and correct transposition, or even resulting in an over-implementation (Treib, 2003). These actor-related effects can be observed in both single-party governments and coalitions, where disagreements can, in turn, lead to intra-coalition disputes and the exercise of veto powers (Treib, 2003).

The actor-centered approach mostly reveals its explanatory validity within policy fields with a high degree of political support or opposition, such as social or labour policies (Treib, 2003).

Thus, the misfit approach appears to have an advantage in its explanatory validity within policy fields that are less politicized between left-wing and right-wing parties (i.e., environmental policies) (Treib, 2003).

3.3. Contemporary research

Most of the contemporary transposition research on the Patients' Rights Directive is based on qualitative case studies. Usually, the publications involve the analysis of one to three member

states by examining the transposition process from a top-down perspective whilst applying the misfit approach, or they conduct qualitative interviews with professionals who were involved into the transposition process. Numerous publications examine the transposition of the Patients' Rights Directive and attempt to explain its lacks with either solely administrative shortcomings or a lack of goodness to fit. Goscinska (2014) in contrast, demonstrates in her analyses accordingly to Duina's (2007) suggestion, how the combined application of both the misfit and the actor-centered approach can contribute to the examination of the Patients' Rights Directive.

This paper will aim to modify her approach by including more cases and streamlining the research design by restricting the misfit approach to the cost factors of the respective healthcare systems.

In order to address the research question, the following hypotheses can be deriving on the basis of the previously discussed theories:

(H1) The more the preferences of party politics and interest groups deviate from the aim of the directive, the more transposition delays and/or incorrect implementation occur.

(H2) The more the aim of the directive results in additional costs for the domestic healthcare system, the more transposition delays and/or incorrect implementation occur.

The results of the research will also reveal the validity of both cost and actor-centered factors on a transposition within the field of healthcare policy. Thus, the outcomes should contribute to determine the explanatory strength of both theoretical concepts, if they are expanded to this policy field.

3.4. The research design

As mentioned before, the scope of this paper is deliberately restricted to the application of the Patients' Rights Directive within the policy area of cross-border healthcare and its transposition procedure. The sampling of the analyses will be conducted considering the micro-level perspective on the units (EU member states), since several decisive factors within the context of their healthcare systems suggest to favor a convergent approach over a random sampling, to enable a comparative analysis. Nonetheless, the units already share significant features, regardless of the differing financial and administrative structures of the healthcare systems. For instance, all member states of the EU can be characterized as countries with universal healthcare systems (World Health Organization, 2016).

3.5. Case selection

The case selection will be based on the ‘most different’ approach which assures a prolific insight into the varying transposition process of several member states and enables the comparison of several cases with the covariation of just one independent and dependent variable, whereas other variables may obtain divergent values (Seawright & Gerring, 2008). Thus, a qualitative case study of the four member states Germany, Poland, the Netherlands, and Denmark will constitute the underlying structure for the research design. Consequently, the independent variables in this paper are the ‘the misfit exerted by the costs of the transposition’ and ‘the preferences of key actors (e.g., party politics and interest groups)’, whereas the dependent variable is ‘the extent of the directive’s transposition’. The case selection deliberately intends to ensure the variance in both independent variables, by scattering an ensemble of nordic/central, east/west, and rich/poor variation among the member states. These factors are derived from the units’ welfare state model, the period of becoming a member state of the EU, and their gross domestic product (GDP). Furthermore, the four countries differ substantially in the organization of their healthcare systems which reflect the impact of various factors, such as the priority to limit costs or long-standing healthcare legacies, whilst ensuring the variance of the misfit approach. At the same time, these countries cover a wide range of ideological leanings of governments, interest groups, and actor constellations which contribute to a sufficient variance of actor-centered preferences.

3.6. Method of Data analysis

The examination of the transposition process will be based on the theory testing approach of the Process Tracing Theory (PT) which has proven to be fruitful for the application of qualitative research in the field of political science (Beach & Pedersen, 2011). The theory testing approach of the PT is described as a method that “deduces a theory from the existing literature and then tests whether there is evidence that a hypothesized causal mechanism is actually present in a given case” (Beach & Pedersen, 2011, p. 2). This makes its methodical outline most applicable for the restrictive analysis of this paper. This variation of the PT is used to determine whether a robust empirical correlation between an X and Y exists (Beach & Pedersen, 2011). While the initial indication for a causal mechanism may be found in previous research, the approach consequently carries on to prove whether there is actually a causal mechanism present which links X and Y (Beach & Pedersen, 2011). In detail, the conceptualization in the theory testing approach constitutes a deductive exercise, whilst in practice the theory testing itself has inductive elements, since the conceptualization aims to use logical reasoning to formulate a causal mechanism whereby X supposedly produces Y, whereas

the operationalization aims to draw existing case-specific empirical predictions of what evidence to expect if the theory is valid (Beach & Pedersen, 2011). Or to put it in other words, “the theory comes first, followed by a detailed empirical analysis of single cases where evidence is gathered in a focused manner, aiming at testing whether the evidence predicted by the theorized mechanism is actually present in the case” (Beach & Pedersen, 2011). Each part of a causal mechanism can be described as being individually insufficient but a necessary part of the theory testing, since they have no independent and sufficient relation to produce Y, but merge to an integral model which in turn sufficiently produce Y (Beach & Pedersen, 2011). Thus, the activities that are supposed to produce change need to be conceptualized in order to highlight the causal forces which transmit X to Y, followed by the testing of the outcomes which in turn confirm or reject the existence of a hypothesized causal mechanism (Beach & Pedersen, 2011). After all, this approach should produce strong evidence with the underlying theorized parts of the causal mechanism, leading at the end to a conjunction between X and Y (Beach & Pedersen, 2011).

The first step of the actual ‘tracing’ in the PT theory-testing approach, is the conceptualizing of a causal mechanism between X and Y based upon existing theorization and to test whether a hypothesized causal mechanism is actually present in the case (Beach & Pedersen, 2011). This is followed by the operationalization of theoretical expectations into case-specific predictions which are then subsequently embodied with empirical evidence that can be used to produce the causal interference, in order to finally confirm or reject the initial hypothesized mechanism (Beach & Pedersen, 2011). Empirical analyses are meant to proceed step-wise on testing, to reveal whether evidence indicates that each part of the mechanism is present in the case (Beach & Pedersen, 2011). The advocates of the theory testing approach acknowledge that it does not read like an analytical narrative and that even the produced evidence might differ between the cases which may make them even partly non-comparable with each other (Beach & Pedersen, 2011). This drawback of the approach is considered and counteracted in the analysis of this paper, since to the case selection aims to gather sufficient data from sophisticated resources. Nevertheless, the type, scope, and origin of the publications that are used in the analysis vary between the cases. However, a reflection of the empirical data revealed that an overlap of the necessary and significant factors is present among the cases which in turn allows to conduct a sophisticated comparative analysis.

3.6.1. Operationalization

Consequently, the theoretical causal mechanism of this paper will be based on the misfit theory to evaluate the degree of the respective transposition process among the units. In addition, to the misfit theory, the actor-centered approach will be used to supplement the analytical framework with the notion to include the influence of national governments, administrations and interest groups. The employment of both approaches assures to consider static, as well as dynamic factors for the analysis since in particular significant actors, are known to favor their self-centered preferences over the domestic status-quo when it comes to the adaptation of European policy measures (Treib, 2003).

3.6.2. Data collection

A variety of publications are supposed to provide the empirical resources for the analysis. Despite that the resources applied different approaches of transposition research, they all share aspects of both the misfit and actor-centered approach which in turn assures the internal validity of the analysis. Goscinska (2014) particularly analyzed in her paper the transposition of the Patients' Rights Directive by applying the actor-centered approach, and partly the misfit theory for the member states Germany, Poland, and Austria. Her analytical structure first examines the initial transposition proposal of the member states, followed by a national discourse analysis and subsequently a discourse evaluation. This paper will adapt and build on this structure that allows a stepwise and chronological analysis of the transposition process. The case of Poland caught special attention since it sets a bad example, and thus will be complemented with additional resources. The paper of Vollaard & Martinsen (2014) serves to analyze the cases of the Netherlands and Denmark. They analyze the actor-centered role of various political and administrative actors, and provide insights to the institutional misfit which impacted the transposition process.

4. Analysis

4.1. Germany

4.1.1. Transposition Proposal

The provisions of the Patients' Rights Directive were implemented through the Patients' Right Law (Patientenrechtegesetz – PRG)³⁴ which came into force in February 2013 and included in addition to the legal provisions of the directive, further reforms of the German healthcare system (Goscinska, 2014). The PRG aimed already at the stage of its draft proposal to fulfill the requirements of the directive by highlighting its compatibility with European Law (Goscinska, 2014). Both the PGR and the Patients' Rights Directive imply the duty for medical practitioners to provide all patients with sufficient information and relevant treatment data including the diagnosis, implications for the treatment, follow-up measures and further therapy options (Goscinska, 2014). The information duty also includes an estimation of the potential costs that are not covered by the health insurance fund, given that the medical practitioner has enough evidence to proceed a cost calculation (Goscinska, 2014). A new feature that was added accordingly to the provision of the directive is to provide patients the right to look into their medical records and obtain a copy of such documentation even if they have to bear the costs themselves (Goscinska, 2014).

The function of the NCP got delegated to the already established German Liaison Office for Sickness Insurance-Abroad (Deutsche Verbindungsstelle Krankenversicherung-Ausland – DVKA), whilst requiring all involved healthcare actors to provide comprehensive information for its new responsibility (Goscinska, 2014). Furthermore, all involved organizations were supposed to share the costs for the NCP accordingly to the specification of the German legislator, unless they decide otherwise (Goscinska, 2014). The involved organizations and interest groups are specifically the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband), the Federal Association for Statutory Health Insurance Physicians (KBV), the German Federal Association of Sick Fund Dentists (KZBV), the Association of the Private Health Insurers (PKV-Verband) and the German Hospital Federation (DKG) (Goscinska, 2014).

4.1.2. National discourse analysis

Only marginal aspects of the directive's provisions were subject to the transposition process in Germany since most requirements were already implemented within the framework of the

³⁴ Gesetz zur Verbesserung der Rechte von Patientinnen und Patienten (PatRechteG) - § 630a ff. BGB; §§ 13, 66, 73b SGB V

preceded introduction of the PRG which involved most importantly the introduction of an extended information duty, and the legal implementation of the NCP (Goscinska, 2014). According to the Ministry of Health, a broad public debate did not take place in Germany, since just a few demands were subject to the transposition and only little controversies evolved among key actors (Goscinska, 2014). The administrative tasks of the German healthcare system are due to the federal structure, delegated to the German Länder which is why neither legislative nor public debates took place on the federal level (Goscinska, 2014). Instead, several actors proposed changes to the government's transposition during the public consultations at the Federal Council of Germany (Bundesrat) which represents the position of the German Länder within the German two-chamber system (Goscinska, 2014). The main proposed changes were of semantic nature concerning the scope of patients' rights as well as the extent of the information duty (Goscinska, 2014).

The extended information duty got conceptualized in the so-called 'Patientenbrief' (Patient letter) as a medical summary that needs to be issued before the treatment, including accurate information (Goscinska, 2014). The Bundesrat and several patient organizations proposed to obligate medical practitioners to include all appropriate treatment information to the letter and issue it as a written memorandum to enable the patient an evaluation of one's own healthcare options (Goscinska, 2014). The German Association of mentally-ill and the GKV-Spitzenverband (The National Association of Statutory Health Insurance Funds) aimed altogether with the Bundesrat to introduce a rigid implementation of the extensive information duty with an exhaustive list for exceptions (Aktion Psychisch Kranke, 2012; Bundesrat, 2012; GKV-Spitzenverband, 2012; Goscinska, 2014). The Federal Association of AOK (AOK-Bundesverband) highlighted the costs aspect of treatments and their provision in the patient letter, arguing that the costs should be coupled to an assessment of the necessity and effectiveness of the respective treatment and the right to withdrawal if the information are uncertain or false (AOK-Bundesverband, 2012; Goscinska, 2014). The Association of Private Health Insurances (PKV-Verband) remarked on the other hand that an excessive information provision about the treatment costs would not affect the privately insured patients since they already provide coverage for additional costs on a contractual basis. Instead, the PKV-Verband suggested to inform the patient in any case about co-payments, if they exceed 300 Euros (Goscinska, 2014; Verband der Privaten Krankenversicherung (PKV-Verband), 2012b).

The German Medical Association (BÄK) and the Federal Association for Statutory Health Insurance Physicians (KBV), who represent the interest organizations of the medical practitioners, argued that the implementation of an extensive information duty of the treatment

costs unnecessarily lead to a legal duplication, since they are already allocated at the health insurance funds (Bundesärztekammer & Kassenärztliche Bundesvereinigung, 2012b; Goscinska, 2014). Moreover, the insurance funds are supposed to have more detailed knowledge about the benefit baskets, than medical practitioners (Bundesärztekammer & Kassenärztliche Bundesvereinigung, 2012b; Goscinska, 2014). Likewise, both dentist chambers BZÄK and KZBV joined in their statements to refuse the proposal of a general cost information duty, arguing that the conjecture of potential uncovered treatments by the health insurance funds cannot be obligated to the duties of dentists in a legal and practical term (Bundesärztekammer & Kassenärztliche Bundesvereinigung, 2012b; Goscinska, 2014). Instead, additional information shall only be provided, if they are explicitly requested by the patient, which also reflects the position of the German Hospital Federation (DKG) that argued that it is impossible to reveal all possible costs of hospital treatments and thus it should not be required by law (Deutsche Krankenhausgesellschaft, 2012; Goscinska, 2014).

Additional treatment costs in the German healthcare system are usually caused by so-called individual health care services (IGeL) that are offered by medical practitioners despite their lack of evidentiary healthcare improvements and exclusion from the basket of the statutory insurance fund (Informed Health Online, 2015). IGeL services constitute an additional income source for medical practitioners and can thus create sometimes a strong incentive to recommend and advertise them in practice (Informed Health Online, 2015), which is why they are seen as a conflict of interest by several social and patient organizations (Goscinska, 2014). They proposed to obligate medical practitioners to provide more detailed and strict information about additional IGeL services, including concrete explanations considering possible health gains, and the option of alternative treatments that are included in the statutory healthcare basket (Goscinska, 2014). Furthermore, the GKV-Spitzenverband and the Federal Association of the Medical Services of the Health Care Funds (MDS) who are in charge to assess the efficacy of medical treatments, as well as civil, charity, and self-help groups demanded a 24-hour retention period for IGeL services that shall enable the patient to evaluate his or her decision to obtain a treatment with a co-payment (GKV-Spitzenverband, 2012; Goscinska, 2014; Medizinischer Dienst des Spitzenverbandes Bund der Krankenkassen e.V., 2012). The Bundesrat proposed to obligate both patients and practitioners to sign a letter of acknowledgement regarding any treatments with additional costs to remind and secure the patient's decision-making, whereas the EKD as a deaconry also proposed to limit the patient's liability to payments, if the costs deviate considerably from earlier estimations (Bundesrat, 2012; Diakonisches Werk der Evangelischen Kirche in Deutschland, 2012; Goscinska, 2014).

After all, the abstract basis of the governmental proposal only stated that treatment-related cost should be provided to the patients in an understandable manner (Goscinska, 2014). However, both dentist chambers refused this proposal, insisting that medical practitioners cannot be obligated with the full responsibility for the comprehensiveness of the cost information and that patients can demand further information on their own stake (Bundeszahnärztekammer & Zahnärztliche Bundesvereinigung, 2012; Goscinska, 2014). Moreover, the requirement of such a mutual conduct between patients and doctors would bring uncertainty in the case of unexpected urgent treatments, when doctors could potentially be prevented to treat due to liability concerns (Bundeszahnärztekammer & Zahnärztliche Bundesvereinigung, 2012; Goscinska, 2014). The application of the information duty for non-German speaking patients would face more challenges according to the position of healthcare providers since the scope of the information that needs to be provided lacks legal clarity (Goscinska, 2014). Thus, to avoid a potential larger information asymmetry for non-German speaking patients, several charity groups proposed to provide an interpreter who shall be financed by the health insurance fund instead by the patients themselves (Goscinska, 2014). Overall, interest groups of healthcare providers, insurers and patients asked the legislator to define and specify the content and extent of the information duty to ensure legal certainty and to adapt it to the practical reality, since even if the doctors who conduct the treatments are the most capable personnel to fulfill the information duty, this task is usually fulfilled by other medical practitioners due to its unpractical procedure (Goscinska, 2014). Moreover, the interest groups of the medical practitioners and hospitals argued, that doctors should be able to judge which information are required since the provision of sufficient information depends on the individual case considering the respective treatment and patient (Bundesärztekammer & Kassenärztliche Bundesvereinigung, 2012b; Deutsche Krankenhausgesellschaft, 2012; Goscinska, 2014). The GKV-Spitzenverband further demanded that the scope of the information duty shall include the provision of potential alternative treatments for the patient, even if those methods are new and unacknowledged or cannot be conducted by the respective medical practitioners (GKV-Spitzenverband, 2012; Goscinska, 2014).

Both BÄK and KBV declared objections against the incorporation of the NCP at the DVKA since it is considered an entity that mainly represents the interests of the compulsory insurance organizations, rather than act as an impartial instance (Bundesärztekammer & Kassenärztliche Bundesvereinigung, 2012a; Goscinska, 2014). Instead, both organizations suggested the Ministry of Health as a more suitable institution for the NCP, which was also supported by the Association for Substitute Insurance Funds (vdek), that highlighted not only a potential conflict

of interest but also a lack of competence, since the DVKA is traditionally regarded as an administrative organization whose focus does not primarily rely on the provision of information on cross-border healthcare (Goscinska, 2014; Verband der Ersatzkrankenkassen e.V., 2012). Thus, the vdek suggested instead to delegate the duties of the NCP to the German Patient's Commissioner (Patientenbeauftragter der Bundesregierung), who could act as an entity on behalf of all German and EU-citizens (Goscinska, 2014; Verband der Ersatzkrankenkassen e.V., 2012). Nevertheless, both BÄK and KBV declared that they will support the NCP by providing relevant information, whereas the KBV strictly refused altogether with the DKG to contribute financially to the NCP, arguing that they will already be performing additional tasks by providing information to the NCP without being compensated, which is why they demanded to burden all additional financial costs to public finances (Bundesärztekammer & Kassenärztliche Bundesvereinigung, 2012a; Deutsche Krankenhausgesellschaft, 2012; Goscinska, 2014). Accordingly to its earlier statements, the PKV-Verband disapproved any involvements with the NCP, since the option to obtain treatments abroad was already introduced to the privately insured on a contractual basis some decades ago, which is why an involvement with the NCP would only bring additional administrative and financial costs to the private insurances as non-statutory entities (Goscinska, 2014; Verband der Privaten Krankenversicherung (PKV-Verband), 2012a). Thus, the PKV-Verband concluded that the NCP could not act as an information body for the privately insured and any financial contribution to it would be unjustified and potentially raise constitutional doubts (Goscinska, 2014; Verband der Privaten Krankenversicherung (PKV-Verband), 2012a).

4.1.3. Actor-centered analysis

The German healthcare system is historically characterized by its corporatist self-administrated structure that reflects the inclusion of diverse key actors to the policy-making process but also entails their engagement in a top-down system that includes the obligation to impose, if necessary, decisions on their own members (Gerlinger & Burkhardt, 2012b). This devotion of interests is also reflected in the distribution of interest groups which are in part organized in both corporatist and pluralist structures (Gerlinger & Burkhardt, 2012a). For instance, from the perspective of actual healthcare practitioners, the former is rather regarded as a biased organization that aims to impose policies on them which are characterized by a partisan relationship to the government, whereas the latter represents their actual interests (Gerlinger & Burkhardt, 2012a). Nevertheless, the corporatist organizations are the ones who are fully involved into the decision-making process (Gerlinger & Burkhardt, 2012b) and thus were

capable to utilize the most significant impact in the transposition process of the Patients' Rights Directive.

The transposition procedure in the German case is rather unique compared to other member states, due to the preceded legislative introduction of the PRG. Most aspects of the directive were already implemented through the national reform, leaving the introduction of the information duty and NCP as the only relevant aspects for further discussions. With regards to the NCP, an obvious cleavage emerged between the interests of healthcare providers on the one side and statutory insurances with patient organizations on the other. The statutory insurances and patient organizations aimed to achieve the implementation of a semantic framework that would obligate healthcare practitioners to burden most of the responsibilities for the information duty and extend its scope regarding its completeness and transparency. On the other side, the healthcare providers aimed to limit those aspects by arguing to provide only extensive information if the patient requests such, or if practitioners may judge when it is necessary. The legislator certainly made a compromise between both positions. Considering all perspectives and representing interest groups, none displayed significant resistance to make compromises which allowed a steady transposition of the information duty accordingly to the intentional aim of the directive without causing significant delays.

Another disputed aspect of the introduction of the NCP between the interest groups of the healthcare providers/practitioners and statutory insurances concerned its organization. The healthcare providers and practitioners agreed to provide further information and also made a compromise by accepting the DVKA as the entity for the establishment of the NCP, but strictly refused to burden a share of the costs. The deviating position of the PKV-Verband can be rather explained by the own provided structures of the private insurance companies who do not depend on the administrative functions of the NCP and therefore aimed to preserve their outstanding position. Despite, the potential for a high conflict regarding the introduction of the NCP, both sides still made compromises and reached an agreement without causing further delays or mal transposition. In detail, even if the information duty and introduction of the NCP were subject to discussions, none of the initial positions of the key actors deviated significantly from the aim of the directive. Thus, conflicting positions could be resolved rather than shifted out by insufficient compromises which enabled a quick transposition of the directive. Thus, the first hypothesis can be approved regarding the transposition procedure in Germany, since there was no enduring resistance from relevant actors which allowed to accomplish a swift and unproblematic transposition.

4.1.4. Misfit analysis

The German legislator did not expect additional costs for the healthcare system or public budget in its initial draft proposal for the transposition of the directive since most provisions were already implemented and judged law. Moreover, the legislator assumed that in an ideal scenario, both patients and healthcare providers would act in an effort-saving way (Goscinska, 2014). This aspect might be even true if the cost calculation is only applied to the framework of the statutory healthcare fund, but the legislators draft did not consider the additional administrative costs like for the NCP. Germany is the only country among the sample where the costs of the NCP are not supposed to be covered by public finances, but instead by a group of key healthcare actors who in turn were in part insistently refusing to bear the additional costs. Furthermore, the extension of the information duty on IGeL services created a controversy between the interest groups of civil organizations and healthcare providers. In both aspects, financial matters played a significant role in the emergence of conflicts. Nevertheless, even if financial matters were the main reason for conflicting positions, their overall financial effect on the healthcare system was marginal or only limited to additional administrative costs. Thus, the second hypothesis can also be approved in the case of Germany, since the aim of the transposition did not significantly affect the financing of the domestic healthcare system, and thus allowed all actors to make compromises which in turn led to a fast and correct transposition.

4.2. Poland

4.2.1. Transposition Proposal

The Polish legislator had to adjust several judicial aspects in its transposition proposal to meet the requirements of the directive and ensure its compatibility with the polish healthcare system. The amendment of the ‘Act on Medical Activity’ obligates healthcare providers to publish necessary information about their services in a public and transparent way (preferably on their websites) to ensure that incoming patients will not be discriminated concerning the respective fees (Goscinska, 2014). Outgoing polish patients who want to exercise their rights on cross-border healthcare, will be reimbursed by the regional National Health Fund (NFZ) that in turn is only supposed to reimburse services which are included in the polish benefit basket, whereas drugs from the State’s medication program are explicitly excluded from reimbursements (Goscinska, 2014). The actual extent of reimbursement for cross-border treatments is based on the regional costs in Poland which however can vary depending on the respective healthcare providers (Goscinska, 2014). Thus, the reimbursement will be based on an average cost calculation of the regional NFZs and their contracts with regional healthcare providers which serve as a reference for the scope of the refunds (Goscinska, 2014). The guidelines for the

application of prior authorizations and reimbursements will be determined by the Health Minister's decree, whilst patients have the right to appeal against a negative prior authorization or reimbursement request at the regional NFZ office, and furthermore to file a complaint against the decision at a regional administrative court (Goscinska, 2014).

In detail, the Polish legislator intended to introduce on a Minister's decree the specification of a list of treatments which are subject to prior authorization and to refuse a request if the needed healthcare can be provided on Polish territory within a timeframe that does not exceed the maximum waiting time (Goscinska, 2014). The latter provisions are justified on the basis of the directive that allows member states to uptake measures to control the costs for cross-border healthcare and ensure the sustainability of the domestic healthcare systems (Goscinska, 2014). The Polish NCP will not be located at a single institution but at the regional headquarters of the respective NFZs which are considered as the entities that are most capable and competent of providing incoming and outgoing patients with all necessary information, in both Polish and English (Goscinska, 2014).

The legislator estimated to entail approximately 200 million zloty in additional costs for the NFZ's reimbursement and administrative purposes (Goscinska, 2014). Nonetheless, except for the budgetary burden of the NFZ and despite the evaluation that about 18% of Polish patients will probably make use of their right to claim cross-border treatments (particularly in the border regions), the legislator does not expect specific additional costs for the public and regional budget (Goscinska, 2014). Instead, the government even expects a financial improvement, due to the expected inflow of foreign patients and at the same time a qualitative improvement among Polish healthcare providers which would be able to utilize their resources in a more efficient way considering the higher demand for their services (Goscinska, 2014). Even the outgoing Polish patients are expected to bring an improvement to the utilization of the national health services since they might slightly reduce domestic waiting times for all patients in Poland (Goscinska, 2014).

4.2.2. National discourse analysis

The main interest group that represented the interests of the healthcare practitioners during the public consultations was the Chamber of Physicians and Dentists (Naczelna Izba Lekarska – NIL) (Goscinska, 2014). NIL criticized that the government's draft did neither clarify a code of conduct for medical records nor does it require the documentation for incoming patients, what might cause interpretative doubts in the practical application of the provisions (Goscinska, 2014). The exemption of drugs from the State's medication program from reimbursements

would also inevitably undermine one of the main goals of the directive by preventing the abolishment of migration barriers within the EU and thus deprive patients of the access to effective healthcare (Goscinska, 2014). The interest group also denounced the verbatim statement of the government that “cost reimbursements shall depend on the principle of economy and purposefulness, which is neither [in this form] anticipated in the Directive nor a transparent criterion for [refunding guidelines]” (Goscinska, 2014, p. 21). Both aspects were also criticized by “the most influential patient organisation named Porozumienie 1 czerwca [eng. 1st June Agreement – P1C] that associates numerous patient groups, civil organizations and individuals” (Goscinska, 2014, p. 21). Both NIL and P1C demanded to introduce the opportunity to file an appeal at common courts and relieve patients from any legal costs, arguing that filing a simple complaint at a regional administrative court does not meet the transparent framework that the directive requires (Goscinska, 2014). Also, both organizations remarked that the refund policy that is supposed to be based on the respective residency of the Polish patients would cause a territorial discrimination since the regional NFZs are independent in their contracting policy and thus in their price-setting for medical services (Goscinska, 2014). This in turn, would lead to different refunds of cross-border treatments depending on the residency of the patients, and violate the aim of the directive to provide a transparent calculation technique (Goscinska, 2014). Instead, P1C proposed to introduce “a nationwide, uniform and periodically evaluated price list to meet the objective criterion in the Directive” (Goscinska, 2014, p. 21), arguing that the draft would otherwise only reflect the budgetary interests of the NFZ (Goscinska, 2014). Another interest group, the Association of Healthcare Managers (STOMOZ) questioned the estimation of the government regarding the number of outgoing Polish patients who are potentially willing to claim healthcare abroad, as well as the additional financial burdens which the NFZ is going to face, since both estimations are based on no practical evidence (Goscinska, 2014). They also criticized that the non-discrimination of public and private healthcare providers for cross-border treatments leaves Polish patients in an ‘absurd situation’, since services from domestic private healthcare providers would still not be reimbursable which in turn could potentially redirect the medical demand of Polish patients to other EU countries (Goscinska, 2014; Helena, 2016). Also, STOMOZ joined the proposal of both NIL and P1C regarding the abolishment of the contracting practice of regional NFZs and suggested instead the introduction of unified tariffs among all healthcare providers, to ensure the sustainable implementation of the directive’s provisions (Goscinska, 2014).

Another aspect of the government’s proposal that was criticized by both NIL and P1C, was the guideline to deny prior authorization if the equivalent treatment can be delivered in Poland

without exceeding a maximum waiting time, since there is no mechanism in place that regulates the actual maximum waiting time for a treatments (Goscinska, 2014). Clear guidelines are missing, which is why this aspect does not only cause a non-transparent regulation but also violates the aim of the directive (OJ L 88, 2011(43)) that specifically denies the application of prior authorization mechanisms considering criteria which are based on waiting lists (Goscinska, 2014). Thus, PIC demanded to abandon or limit the list of treatments which are subject to prior authorization to prevent avoidable administrative burdens to patients, since the prior authorization mechanism is expected to be applied to all treatments in any case, except for basic ambulatory care (Goscinska, 2014). Concluding the public consultations, NIL came to a rather pessimistic outlook for the practical application of the Patients' Rights Directive since the substantial lack of the government's calculations suggests that the Polish legislator does actually not intend to allow (at least hospital) treatments abroad (Goscinska, 2014).

4.2.3. Actor-centered analysis

In contrast to the German case where the conflict lines appeared in a horizontal sense between interest groups on a competitive level playing field, the Polish case involved conflicts in a vertical sense where the government applied a top-down approach towards an alliance of interest groups consisting of healthcare providers and patient groups who were aligned in their positions. The government's restrictive proposal reflects its initial vote against the directive in the Council of the European Union, by incorporating altogether measures which extensively made use of regulatory exemptions (Goscinska, 2014).

The conflict points in the Polish transposition process were characterized by an intrinsic nature and fierce shortcomings in legal and practical matters which caused several burdens for a proper transposition. Furthermore, the interest groups of the civil society and healthcare providers used the transposition process, as a window of opportunity to achieve general improvements of their positions by denouncing general insufficiencies of the Polish healthcare system which were not necessarily related to cross-border healthcare. Approximately, 80% of their arguments are concerned with the access and financing of the healthcare system by accusing the legislator of under-implementation or improper transposition (Goscinska, 2014). The most prevailing arguments against the government's proposal concerned to the limited scope of the reimbursements which reflects according to NIL and PIC the aim of a minimalist approach. General doubts arose on whether the government actually intends to refund cross-border treatments, since the reimbursements will be calculated on the basis of the deviating price-setting of the regional NFZs, or even denied if the treatment can be conducted within an

undefined maximum waiting time in Poland. STOMOZ joined the argumentation of both NIL and P1C, and also opposed the unjustified prevailing discrimination of public and private healthcare providers in Poland, while it will be lifted for cross-border treatments. This is another example of an actor who attempted to achieve a general self-centered improvement that is subject to discussions apart from the scope of the directive.

An important aspect of the transposition process was the insufficient inclusion of actors into the decision-making in general. According to Kowalska-Bobko et al. (2016), the government continuously dominated the decision-making and did not enter into sincere negotiations with key actors. Furthermore, the short timeframe of seven days, which the government foresaw for public consultations, reflected the intentional low influence of the public to the policymaking process (Kowalska-Bobko, Mokrzycka, Sagan, Włodarczyk, & Zabdyr-Jamroz, 2016). The P1C fiercely criticized the lack of civil stakeholder involvement into the decision-making process by referring to the Recommendation of the Council of Europe³⁵, arguing that healthcare policy should be patient-oriented, which requires the involvement of patient organizations and other social groups to the national policy-making process (Goscinska, 2014). The transposition process in Poland got finally completed with a delay of over 12 months after the deadline in October 2014 (Helena, 2016).

After all, how can the first hypothesis be addressed, considering the discussion above? A requirement for a significant key actor in the sense of the actor-centered approach is its respective impact on the policy-making process. The most influential variant of an actor is one that possesses veto powers (Treib, 2003). Nonetheless, the actor-centered approach also acknowledges sector specific stakeholders like the interest groups in the Polish case, by granting them still (but less) influence in the policy-making process (Treib, 2003).

Thus, the first hypothesis can only be addressed in an ambivalent way in the Polish case. Actors who possess veto powers in the Polish healthcare system can be only identified within the government. At the same time, they did not deviate from the government's predominant reluctant position which reflects the ideology of the ruling liberal-conservative party that emphasizes a more self-responsible approach, by aiming for the privatization of the healthcare sector (Harper, 2016; Melck, 2015). Moreover, the short timeframe for public consultations further limited the impact of civil interest groups, who in turn could not utilize their leverage in

³⁵ "Recommendation No. R (2000) 5 of the Committee of Ministers to member states on the development of structures for citizen and patient participation in the decision-making process affecting health care, adopted by the Committee of Ministers on 24 February 2000 at the 699th meeting of the Ministers' Deputies, Council of Europe" (Goscinska, 2014, p. 22)

the negotiations despite their considerable arguments and reasonable doubts against the legislative proposal. Thus, even though several actors aimed to achieve self-centered interests, they cannot be considered as significantly accountable for the delay of the transposition process. Consequently, the actor-centered approach cannot sufficiently address the delay in the Polish case, since the deviating position of key actors did not lead to frictions in the transposition process.

4.2.4. Misfit analysis

Financial matters played a major role in the position of the Polish government which is why it implemented altogether extensive exemptions to ensure the sustainability of the domestic healthcare system. These measures allow the government to regulate or even inhibit its citizen from claiming cross-border healthcare. This restrictive approach gets reflected by such guidelines like to refuse prior authorization, if the respective treatment can be carried out in Poland within a maximum waiting time, without however further defining the actual timeframe. Other controversial aspects of the provision are the exemption of medications from reimbursement which are part of the Polish medical plan, and the refund calculation that is based on the regional price-setting mechanism of the NFZs. These measures indicate the important role of cost factors for the Polish legislator who aimed to limit additional burdens for the domestic healthcare budget with the appraisal that the costs of non-compliance are smaller than full compliance with the directive. Civil interest groups are widely excluded from the implementation of the provisions, i.e., the appointment of the Health Minister as the only authority that determines the scope of the prior authorization mechanism. Instead, the legislator holds on to its top-down approach to prevail its position.

Civil interest groups also noticed that the optimistic evaluation of the government's proposal crucially lacks evidence, particularly regarding financial matters. The Polish Ministry of Health already argued during the negotiations for the directive at the EU level that "unlimited demand for healthcare aboard from Polish patients would provoke uncontrolled outflows of money and would negatively affect the contracts concluded with the national providers and reinforce the problem of waiting lists" (Kowalska-Bobko et al., 2016, p. 1236). Thus, the "fears of high costs of reimbursing cross-border care and of the associated organizational and technical burden were the key reasons for the delay in the directive's implementation" (Kowalska-Bobko et al., 2016, p. 1237).

The strong financial misfit between the domestic healthcare system and the aim of the directive is the main reason for the restrictive approach of the Polish government that prevailed

throughout the transposition process. Consequently, the gains of patient rights in cross-border healthcare were intentionally traded off against the government's aim to reinforce the regulative and financial status-quo of the domestic healthcare system. Thus, the under-implementation of the directive was purposely endorsed, considering the high costs for (full) compliance. The second hypothesis can be approved in the Polish case since the poor financial fit between the domestic healthcare system and the directive led to a time-consuming adaptation process that caused a delay of more than 12 months over the deadline to accomplish the transposition.

4.3. The Netherlands

4.3.1. Transposition Proposal

Two components of the Dutch healthcare system were crucial for the transposition process. The National Exceptional Medical Expense Act (*Algemene Wet Bijzondere Ziektekosten – AWBZ*) is covering long-term and high-cost medical treatments since 1968, as a universal, obligatory and income dependent insurance scheme (Vollaard & Martinsen, 2014). In addition, it has been complemented since 2006 with the Health Insurance Act (*Zorgverzekeringswet – Zvw*) that is financed through direct premium payments to health insurers, income depended contributions, and taxes (Vollaard & Martinsen, 2014). The *Zvw* also regulates the contractual framework between health insurers and their clients, to ensure the provision of a universal and compulsory insurance scheme for basic healthcare (Vollaard & Martinsen, 2014).

Dutch citizen were already entitled to obtain planned cross-border healthcare, even before the implementation of the directive, since the former public health insurance scheme already incorporated a system of prior authorization for healthcare from extraterritorial non-contracted providers (Vollaard & Martinsen, 2014). Facing the increasing salience for waiting lists in the 1990s, health insurance funds were led to facilitate access to Belgian and German healthcare providers, which in turn further incentivized health insurers to constantly expand their contracts with healthcare providers from abroad (Vollaard & Martinsen, 2014). Even today, the *AWBZ* continues to operate a system for cross-border healthcare apart from the provisions of the Patients' Rights Directive to manage in particular treatments with higher costs (Vollaard & Martinsen, 2014). The Dutch government paved the way for cross-border healthcare by responding to CJEU case law and “abolished the distinction between domestic and foreign non-contracted providers, allowed access to non-hospital care without prior authorization, and replaced national with international medical standards to determine the medical necessity of receiving healthcare elsewhere” (Vollaard & Martinsen, 2014, p. 725). Moreover, with the introduction of the *Zvw* in 2006, all requirements for prior authorization have been eventually

abolished in the Netherlands to encourage patients to obtain healthcare abroad, except for some health insurance policies which included a prior authorization on a contractual basis (Vollaard & Martinsen, 2014). This extensive progress towards cross-border healthcare was already achieved only on the basis of preceding domestic reforms in accordance with CJEU case law. Thus, the Dutch legislator was convinced that the Netherlands would already meet the requirements for the Patients' Rights Directive and that the transposition would only require to establish an NCP and the mutual recognition of prescriptions (Vollaard & Martinsen, 2014). The Ministry of Health was assigned to establish the NCP, which in turn designated the Health Insurance Board (college voor Zorgverzekering – CVZ) as the official Dutch NCP that then incorporated a Dutch website accordingly to the guidelines of the European Commission (Vollaard & Martinsen, 2014).

4.3.2. National discourse analysis

The achievements of preceding reforms were also reflected in the transposition process. Only few conflicts emerged between civil and governmental actors, due to the already implemented extensive regulations on cross-border healthcare. Instead, the most serious conflicts circled within the government and its administration. Apart from the directive and CJEU rulings, Dutch authorities also passed by following the recommendation of several studies on cross-border healthcare, various measures to redirect healthcare spendings back to Dutch territory, by, i.e., imposing stricter regulation on the AWBZ in the 1990s. (Vollaard & Martinsen, 2014). Nonetheless, following the verdicts of the CJEU, certain parliamentarians and even Ministers of Health regarded extensive patient rights as an empowering opportunity to provide free choice in healthcare across European countries, and that treatments abroad can be a useful safety valve for waiting lists (Vollaard & Martinsen, 2014). Moreover, the studies which were conducted on behalf of the government did not expect a rapid increase in demand for treatments abroad in the near future (Vollaard & Martinsen, 2014).

However, in the aftermath of the referendum on the European Constitutional Treaty in 2005 and the following Eurosceptic mood, the Dutch government and health sector perceived any further European legal initiative on cross-border healthcare as rather redundant (Vollaard & Martinsen, 2014). The actively involved parliament regarded from then on “the draft Directive as a violation of the principle of subsidiarity, as the organization and financing of healthcare systems is primarily a national competence” (Vollaard & Martinsen, 2014, p. 725). Nevertheless, the government voted in favor of the directive, arguing that no major implementation efforts would be necessary, due to the preceding reforms on cross-border

healthcare in accordance with CJEU case law (Vollaard & Martinsen, 2014). The prevailing Eurosceptic political climate and lack of administrative capacities still impacted the implementation of the directive. For instance, Dutch representatives refused the active involvement in the development of an information exchange system between the member states on the EU level (Vollaard & Martinsen, 2014).

The establishment of the NCP turned out to be a rather challenging task for the Ministry of Health. Dutch health insurers refused to offer information for patients from abroad, and the Ministry was aware that insurers could not serve as an independent entity for their own clients, due to their contracting policy (Vollaard & Martinsen, 2014). Thus, the contracting of an external independent company through a public tender procedure was considered, which then however was dismissed due to its inflexibility and time-consuming administration until eventually the CVZ was delegated to become the official NCP (Vollaard & Martinsen, 2014). The CVZ took over its new duty despite its initial lack of crucial capabilities which were necessary to incorporate a sufficient NCP, which is why the CVZ could only provide a 'slim version' of an NCP in the initial phase (Vollaard & Martinsen, 2014).

However, legal experts raised concerns regarding the potential limitation of reimbursements for non-contracted healthcare providers which are in general all foreign providers, except for those who are contracted specifically by Dutch health insurers (Vollaard & Martinsen, 2014). The criticism focused on two aspects of the governments draft: A potential violation of the directive's principal to free access of services, and the lack of direct judicial enforcement of the provisions in Dutch private-law (Vollaard & Martinsen, 2014). In detail, the Ministry of Health expressed its desire to reform the terms for insurers in granting excess to non-contracted healthcare providers (Vollaard & Martinsen, 2014). Insurers would have been allowed to refuse reimbursements of non-contracted healthcare in general which would limit significantly the choice of patients over their healthcare providers for both domestic and especially cross-border treatments (Vollaard & Martinsen, 2014).

After all, the directive's own exemption that allows member states to implement measures to ensure the sustainability of their domestic healthcare systems, served the Dutch legislator as a pretext to not only maintain control over cross-border mobility, but also to reverse the preceding progressive efforts to conform the Dutch legislation with CJEU case law (Vollaard & Martinsen, 2014). This drastic turnaround was caused by fears which evoked on the basis that an increased demand in cross-border healthcare could potential reverse domestic efforts to contain healthcare costs (Vollaard & Martinsen, 2014). Eventually, the incorporation of these

revoking measures was prevented by the European Commission, as they were regarded as a violation of EU law (Vollaard & Martinsen, 2014).

4.3.3. Actor-centered analysis

Similar as in the Polish transposition process, the actor-centered cleavage in the Dutch case emerged in a vertical sense. Conflicts mainly occurred within the government in a continuous timespan. It is noteworthy to examine the motivations behind the government's reluctant approach towards the transformation of the directive. The initial reluctance was based on the assumption that no major legislative efforts were needed for the transformation, due to the proceeding adaptations in accordance with CJEU verdicts. Moreover, historical legislative initiatives proved to be on a progressive stance to cross-border healthcare, whilst recent surveys showed that new initiatives are supported by the Dutch electorate (Vollaard & Martinsen, 2014). Thus, the Dutch legislator did not expect any administrative or political interferences for the transposition (Vollaard & Martinsen, 2014). The turning point for this progressive attitude was certainly the growing Eurosceptic mood in the Netherlands that emerged in the aftermath of the referendum on the European Constitutional Treaty in 2005, leading to the refusal of further compliance with EU legislation. The impact of this fundamental change of attitude to the transposition could be observed in the government's articulation during open discussions, stating that "our aim is that we don't have to change anything in the Netherlands when we adopt that directive" (Vollaard & Martinsen, 2014, p. 725). Also, parliamentary concerns regarding a potential violation of the principle of subsidiarity revealed the increasing mistrust towards the directive (Vollaard & Martinsen, 2014). The prevailing Eurosceptic political climate led Dutch representatives to refuse to play an active role in the coordination of exchange committees on the EU level, even after the government asserted itself and voted after all in favor for the directive.

The reasons for the fundamental turnaround of the government's position towards the aims of the directive are crucial aspects for the application of the actor-centered analysis. The initial legislative efforts to comply with the CJEU case law aimed to utilize a further facilitation of cross-border healthcare, while enjoying substantial support among the Dutch electorate. Practical arguments like the reduction of waiting times in the domestic healthcare system dominated the debate. However, the same key actors changed their favor to a rather restrained attitude for the directive by following the Eurosceptic swing in the public opinion. Other actors, such as civil organizations or interest groups did not have a significant impact on the transposition process. Moreover, the Ministry of Health refrained to consult the Dutch

healthcare sector for the later implementation process (Vollaard & Martinsen, 2014). Both aspects, the initial progressive attitude towards cross-border healthcare, as well as the reversal of the same can be traced back to the aim of the government to gain the approval and support of the electorate to maximize potential votes.

However, populist ambitions were not the only reason for the reserved attitude towards the directive. As mentioned before, initiatives on cross-border healthcare have a long and progressive history in the Netherlands. The erosion of the same is attributable to the reevaluation and prioritization of budgetary matters over several legislative terms, to contain healthcare costs in general. The flexibility and exemptions of the directive brought the government not only the chance to ensure the sustainability of the domestic healthcare system, but also a window of opportunity to reverse the deep-rooted progress on cross-border healthcare (Vollaard & Martinsen, 2014).

The reason why the transposition process was delayed in the Dutch case is rooted in the self-centered motivations of key actors within the government. Despite the initial confidence for the transposition, key actors in the legislation aimed to utilize the Eurosceptic political momentum to achieve a more restrictive budgetary policy, even if it means to intentionally under-implement the directive. Thus, the actor-centered approach can be approved in the Dutch case, since the delay of over a month to finalize the transposition is a result of self-centered dynamics of key actors with veto-powers who utilize their impact in the transposition process.

4.3.4. Misfit analysis

The Dutch case displayed a high goodness to fit, due to the preceding implementations in cross-border healthcare and progressive stance for further institutional developments. The AWBZ and healthcare insurers already established autonomous mechanisms to address the demand for planned healthcare abroad accordingly to CJEU case law and prior to the transposition of the directive. Thus, the initial confidence of the government to expect a smooth transposition is understandable, considering the previous progress. However, the actual transformation process turned out to be more challenging than expected. In particular, the progress on the financing of cross-border healthcare has been eroded and replaced by more recent and prioritized reforms to limit healthcare expenses. The consequent attempt to reverse the progress on cross-border healthcare caused a significant friction between the Dutch legislator and the European Commission. Disagreements concerning the establishment of the official NCP, jeopardized further the timely transposition of the directive. The eventual selection of the CVZ as the entity for the official NCP was based on a decision that lacked sufficient choice for other options. The

CVZ basically “grope in the dark” (Vollaard & Martinsen, 2014, p. 726) when it attempted to meet the requirements for an NCP. Thus, the designation of the CVZ was certainly not the first choice for the government, but the most appropriate one considering the costs and benefits. Financial matters were the overarching priority for its establishment, and a conflict of interests did not allow to incorporate the NCP at the health insurers. A poor fit of financial matters had a crucial impact on the transposition process. However, this misfit cannot be the reason for the frictions which are rooted in actor-centered dynamics. Thus, the misfit approach does not deliver sufficient, but supplementary reasons for the delayed transposition in the Dutch case.

4.4. Denmark

4.4.1. Transposition Proposal

The Danish healthcare system is decentral organized, tax-funded and operating with a benefits-in-kind principle which allows it to function largely without any additional charges for patients (Vollaard & Martinsen, 2014). The integrated responsibility for the organization and delivery of healthcare services is delegated to the five Danish regions which have a history to maintain a territorially entrenched approach to cross-border healthcare (Vollaard & Martinsen, 2014).

The Danish legislator used to apply a restrictive approach on claims for cross-border healthcare while rarely authorizing reimbursements for outgoing Danish patients and traditionally refusing access for incoming patients from other member states (Vollaard & Martinsen, 2014). This reluctant past was also reflected in the government’s transposition proposal that only foresaw 60 application for prior authorization per year, of which approximately ten were expected to be granted (Vollaard & Martinsen, 2014). Since the benefits-in-kind principle of the Danish healthcare system did not allow hospitals to charge domestic or foreign patients for their services, the so-called Diagnosis Related Group (DRG) was set as the entity to which healthcare providers shall refer to enable a price-setting within the internal market (Vollaard & Martinsen, 2014). Furthermore, the proposal of the government obligated the Danish Health and Medicines Authority to develop a list of treatments which shall be subject to prior authorization for outgoing patients (Vollaard & Martinsen, 2014). The legislator also predetermined in addition to the treatments which are enlisted in the specialeplanen (plan for specialization), that a prior authorization would be required for all treatments that require at least one night of hospitalization (Vollaard & Martinsen, 2014). The responsibilities of the NCP should be delegated the regionally established ‘patient supervisors’, which in turn would be coordinated and supervised by the National Agency for Patients’ Rights and Complaints (Vollaard & Martinsen, 2014). The latter would also serve as the institution to which patients can turn to, in

the case of refused authorizations and complaints (Vollaard & Martinsen, 2014). Moreover, a so-called 'reference group' would be established and coordinated by the Ministry of Health to involve all relevant actors in the transposition process (Vollaard & Martinsen, 2014). The legislator aimed to implement all the provisions of the directive on the foundation of already existing institutions and mechanisms, and thus did not expect any additional costs for the Danish healthcare budget or its administration (Vollaard & Martinsen, 2014).

4.4.2. National discourse analysis

The Danish regions initially aimed to protect the exclusive gatekeeping role of domestic GPs and their referrals to grant access to hospitals but eventually agreed also to accept referrals from doctors of other member states, to comply with the requirements of the directive (Vollaard & Martinsen, 2014). Both regions and municipalities expressed their disappointment about the 'reference group' since the Ministry of Health did not grant them significant influence on the actual transposition process, whereas patient organizations felt to be entirely excluded (Vollaard & Martinsen, 2014). Contrary to the estimation of the government, the regions rather expected a steady increase in demand for the foreseeable future (Vollaard & Martinsen, 2014). The aim to incorporate the directive on the foundation of already existing institutions came to the detriment of a lack in its practical application, while alternative and more practical solutions were neglected (Vollaard & Martinsen, 2014). According to the regions, the functions and resources of the (regional) contact points were not capable of addressing the demands of incoming and outgoing patients, considering the extensive requirements of the directive (Vollaard & Martinsen, 2014). Furthermore, the price-setting mechanism of the DRG is not considered as a sufficient indicator for healthcare services, since it is based on calculations within the internal market and only between the Danish regions (Vollaard & Martinsen, 2014). Thus, the data from the DRG cannot provide a transparent full cost calculation for treatments which is required to charge foreign patients and allow them to claim reimbursements at home (Vollaard & Martinsen, 2014). Doubting that the implementation of the new provisions will not result in additional costs, the regions also demanded additional compensations for the new administrative tasks and liabilities for reimbursements (Vollaard & Martinsen, 2014).

4.4.3. Actor-centered analysis

The actor-centered cleavage in the Danish case emerged in a vertical sense between the government and the Ministry of Health on the one side, and the five regions on the other. Both displayed initially a rather reluctant position and aimed to implement the directive in a defensive and minimalistic sense which reflected their general skepticism towards the opening of the

healthcare sector for foreign patients (Vollaard & Martinsen, 2014). Other actors such as patient organizations were not involved at all, denouncing they had the impression that the transposition was “a very closed process, involving a few servants in the ministry” (Vollaard & Martinsen, 2014, p. 720). Vollaard & Martinsen (2014) even state that the Ministry of Health was largely the only involved actor during the first two years of the implementation process, whereas other actors of the healthcare sector found themselves unsure on how to cope with the challenges and the new more market-based logics (Vollaard & Martinsen, 2014). However, despite the fierce and numerous criticism of the regions and other actors, they barely had any veto powers which left them unable to utilize any significant bargaining powers to influence the decision-making. Consequently, even though the government and the regions had both different decisive aims for the transposition, the former succeeded in continuously overruling the latter. Moreover, the government prevented any further resistance or frictions by the exclusion of other actors, such as patient organizations. Thus, the delay of two months over the deadline in the Danish case, cannot be rooted in actor-centered interests or dynamics.

4.4.4. Misfit analysis

The established structures of the Danish healthcare sector and institutional traditions such as the benefits-in-kind principle and internal market appeared to be major obstacles for the transposition process. Both government and healthcare providers were reluctant and skeptical regarding the required adaptations to fulfill the provisions of the directive. In practice, Danish hospitals did not charge any fees for treatments at all. In contrast, the framework of the directive requires a rather market-based logic with a precise price-setting mechanism to enable a sufficient compensation across borders, and provide patients the certainty about potential co-payments. So far, EU citizen were only able to access the public healthcare system in Denmark through the EU health insurance card in the case of an emergency, or if authorized under the Regulation 883/2004, but not directly on their own private initiative which is the main reason why “the policy fit between the European notion of free movement in healthcare and the Danish healthcare policy was poor” (Vollaard & Martinsen, 2014, p. 720).

In addition to the financial misfit of the healthcare system, the Ministry of Health was subject to major reorganization measures. This included budgetary cuts for its administration which in turn resulted in a lower capacity for the transposition process. In detail, the Ministry experienced a considerable loss of institutional memory during the initial phase of the transposition, since matters on cross-border healthcare were the major responsibility of solely two senior civil servants (Vollaard & Martinsen, 2014). Both servants, who even negotiated the

directive on the EU level and became experts in its regulatory framework, were either fired or relocated which placed the transposition for approximately one year on hold until new civil servants could catch up on the topic (Vollaard & Martinsen, 2014). Other key actors, such as healthcare providers found themselves left by their own, while trying to cope with the ‘very difficult rules’ and the unfamiliar market-based logics (Vollaard & Martinsen, 2014). Rather than being consulted by the government, they operated in sort of a knowledge gap and tried to get ahead by observing how equivalent actors in other member states deal with the transposition (Vollaard & Martinsen, 2014).

The government aimed in general to delegate the new provisions to already existing institutions, even though the regions did not consider this as a sufficient solution. Moreover, commentators accused the government of non-compliance, due to the extensive application of the prior authorization mechanism (Vollaard & Martinsen, 2014). The legislator imposed a large list of treatments which require authorization but omitted to issue a regulation on how to claim healthcare abroad without to consult the Danish authorities beforehand (Vollaard & Martinsen, 2014).

The financial misfit had certainly a significant impact on the transposition process in the Danish case. The legislator aimed to limit the cost factors for the transposition as much as possible. The attempt to incorporate the new provisions on already existing institutions was the main strategy to achieve this goal. However, these existing institutions were historically shaped by the Danish healthcare legacy, which in turn fundamentally deviates in its distributive conception from the directive. Still, the rigid approach in the transposition proposal and fierce criticism from the regions suggest that the government aimed to ‘force the policy fit’ with pre-existing national structures, whilst neglecting the complaints from other key actors. Moreover, further aspects of the misfit approach such as the poor administrative capacity of the Ministry of Health significantly contributed in interaction with the general lack of financial capacities to a delayed transposition. The institutional memory loss, due to the replacement of the civil servants for its own put the transposition process for one year on hold. Thus, the misfit approach can be approved in the Danish case, since unresolved adaptation problems resulted in a delay of two months over the deadline to finalize the transposition process.

5. Conclusion

5.1. Answering the research question

The analysis of the several cases revealed that different factors were impacting the timely transposition of the Patients' Rights Directive. The theoretical approach of this paper tested whether either actor-centered factors and/or a financial misfit of the studied member states affected the timely and correct transposition of the directive. After all, how can these results contribute to address the initial research question:

(RQ) How did existing policies of member states in the area of healthcare and healthcare insurance, and the political preferences of relevant actors affect the transposition of the EU Directive 2011/24/EU?

In order to illustrate both components of the research question, I will first examine the effects of the structural misfits and actor-centered dynamics in an isolated manner. Thereafter, the discussion will be followed by the synergy of both approaches, since the results in Table 2 suggest that the combination of both components contribute even more to the answering of the research question, than a separate evaluation of each concept for its own.

The case studies revealed that the financing of the respective member state's healthcare system significantly impacted to which extent and timely manner the directive was transposed. Thus, a good or poor fit of the member states' healthcare systems and their financing, either contributed to a frictionless transposition process or embodied a major obstacle.

The case of Germany demonstrated how early adaptation efforts through the preceding introduction of the PRG and its compatibility with the directive, created the basis for a timely transposition. The only major remaining disagreement involved the introduction and financing of the NCP, which in turn could be effectively resolved through the willingness of all actors for a compromise. In contrast, the Polish case highlighted how a poor financial fit between the directive's provisions and the domestic healthcare system was capable of inhibiting a proper transposition. The misfit rather motivated the legislator to protect the status-quo, since the costs for non-compliance were smaller than correct transposition. Cost factors and the aim to ensure the control over healthcare expenditures, were also the driving motivation for a reluctant transposition process in the Dutch case. Although a historical legacy of progress in cross-border healthcare laid the foundation for a financial and structural fit in the Netherlands, the overarching objective of the government to cut healthcare expenses led to the reversal of the initial progressive intentions.

Table 2: *Transposition results*

	Transposition timeliness and correctness	Role of costs (misfit)	Role of actor preferences
<i>Germany</i>	<ul style="list-style-type: none"> - Timely transposed - Full and proper compliance - Maximalist approach for the transposition of the provisions - Almost no use of the flexibility of the directive 	<ul style="list-style-type: none"> - Marginal impact of cost aspects - Remaining conflicts of the incorporation of the NCP and information duty could be resolved by compromises <p>→ No impact on the timeliness and correctness of the transposition</p>	<ul style="list-style-type: none"> - Limited impact of actor preferences, due to preceding reforms - Conflicts about the incorporation of the NCP and information duty could be resolved by compromises <p>→ No impact on the timeliness and correctness of the transposition outcomes</p>
<i>Poland</i>	<ul style="list-style-type: none"> - Delayed transposition of >12 months over the deadline - Minimal approach for the transposition of the provisions and exceeding use of the flexibility of the directive <p>Extensive lack of compliance:</p> <ul style="list-style-type: none"> - No code of conduct for medical records - Insufficient reimbursements for drugs - Limited opportunity for appeals and complaints - Non-transparent refund policy - Questionable contracting policy between domestic and foreign healthcare providers - Insufficient and non-transparent prior-authorization mechanism - Shortcomings in both legal and practical matters 	<ul style="list-style-type: none"> - Major impact of cost aspects - Strict aim to control the outflow of patients and potential additional costs - Intentional trade-off between patients' rights and costs in favor to ensure the status-quo of the domestic healthcare system <p>→ Strong impact on the timeliness and correctness of the transposition</p>	<ul style="list-style-type: none"> - Limited impact of actor preferences, due to the exclusion of key actors - Strict top-down approach to enforce the preferences of the legislator - Conflicts of intrinsic nature between civil society/healthcare providers and the government - Aim to address long outstanding reforms from civil society/healthcare providers - The government aimed to achieve a minimalist approach to limit potential costs, whilst accepting an under-implementation <p>→ Strong impact on the correctness, but not timeliness of the transposition</p>

<p><i>The Netherlands</i></p>	<ul style="list-style-type: none"> - Minor delay of one month over the deadline - Sufficient compliance - Turnaround from an initially maximalist to a minimalist approach for the transposition of the provisions and view on cross-border healthcare - Extensive use of the flexibility of the directive 	<ul style="list-style-type: none"> - Crucial impact of cost aspects - High priority of the government to limit healthcare expenses <p>→ Limited impact on the timeliness and correctness of the transposition</p>	<ul style="list-style-type: none"> - Major impact of actor-centered preferences - Eurosceptic mood and budgetary concerns resulted in a turnaround of the initial progressive stance towards cross-border healthcare <p>→ Strong impact on both timeliness and correctness of the transposition</p>
<p><i>Denmark</i></p>	<ul style="list-style-type: none"> - Minor delay of two months over the deadline - Minimalist approach for the transposition of the provisions - Moderate use of the flexibility of the directive <p>Largely sufficient compliance</p> <ul style="list-style-type: none"> - Except for the non-transparent price setting and accounting matters 	<ul style="list-style-type: none"> - Major impact of cost aspects - Clash between the Danish healthcare legacy and provisions of the directive - The government aimed to protect the status-quo - Imperative to limit cost by the government - Insufficient incorporation of the provisions on already established structures - Insufficient capacities in personnel, financing, and administration - Non-transparent price setting and accounting, since the benefits-in-kind principle did not adapt to the directive <p>→ Strong impact on the timeliness and correctness of the transposition</p>	<ul style="list-style-type: none"> - Limited impact of actor preferences, due to the exclusion of key actors - Danish regions aimed to achieve an implementation with more extensive financial and administrative capacities - A strict top-down approach from the government did not allow any interference to the aim to limit costs <p>→ Strong impact on the correctness, but not on the timeliness of the transposition</p>

The strongest misfit among all portrayed cases revealed the Danish case since its healthcare legacy and institutional practices were fundamentally differing from the provisions and framework of the directive. The legislator aimed to enforce the transposition on already established structures and institutions, even though they were not capable of fulfilling the new responsibilities that caused unresolved adaptation pressures.

Throughout all examined cases, it can be stated that the overarching motivations of the policy-makers were determined by the effort to contain potential costs which underlines the explanatory validity of the misfit approach. On the other hand, the Dutch case also revealed the limitations of the same, since the motivations and impact of the respective financial misfit could be only accurately interpreted within the political context. Thus, the misfit approach can be regarded as a supplementing aspect in the Dutch case, whereas it constitutes a conditional burden in the Danish case. Staying for itself, the misfit approach revealed insights on whether already established structures were capable to affect a timely transposition. However, the explanatory limitation of the approach does not allow a sufficient application without a supplementation with further context and actor related information. This drawback corresponds with the objections of Mastebroek & Kaeding (2006), against the sole application of the misfit approach.

The actor-centered approach on the other hand, demonstrated the potential impact of key actors on the transposition process. The case analyses revealed how self-centered interests and dynamics of key actors could significantly impact the timeliness and degree of the transposition, leading eventually to the an under or over-implementation³⁶ of policy measures. The unique case of Germany, in comparison to the other analyzed cases, highlighted that a high degree of corporatism among key actors is seemingly contributing to a timely and correct transposition. The integrated corporatist healthcare legacy in Germany healthcare legacy encouraged all conflicting parties to make compromises within a public discourse, without causing significant time lags. Thus, key actors were able to reach robust agreements, like the financial establishment of the NCP, which complied with the aims of both the directive and government. Nevertheless, it needs to be noted that most conflicting aspects were already alleviated in the German case, due to the preceding extensive integration of the directive in the PRG. In contrast, the Polish highlighted the limitations of the actor-centered approach. Fierce conflicts emerged between the government and civil interest groups which were symptomatic for the structural

³⁶ The case analyses of this paper did not contain any examples of an over-implementation. However, Goscinska (2014) demonstrated in her paper with the case of Austria, a distinctive example of an actor-centred over-implementation in the context of the Patients' Rights Directive.

deficits of the Polish healthcare system and its general need for crucial reforms. The government succeeded to suppress the impact of deviating actors, by the enforcement of a strict top-down approach. Thus, actors which were in conflict with the proposals of the government were effectively excluded from the policy-making, which at the same time prevented any attempts to impede the transposition process. This leads to the conclusion that the government acknowledged the potential impact of actor-centered interests, by responding to any potential frictions with the precautionous exclusion of conflicting actors. This action reveals both the significance and limitations of the actor-centered approach, since a delay took place despite the acknowledgement of the government and its consequent restriction on public consultations. The Dutch case demonstrated the strongest explanatory validity of the actor-centered approach among the analyzed cases. Actor-centered interests within the government led to a reversal of the initially progressive intentions on cross-border healthcare, by utilizing the rising Eurosceptic mood to dissolve the support for cross-border healthcare in favor of outstanding austerity measures on healthcare expenses. This resulted not only in a mal transposition (Vollaard & Martinsen, 2014), but also in a withdrawal from the involvement of further integrative committees on the EU level. Thus, the Dutch case highlighted how actor-centered interests were even capable to counteract with the aims of the directive and deteriorate the rights of patients in cross-border healthcare. The Danish case demonstrated likewise the Polish case, how actor-centered conflicts could be defused by the legislator through the application of a rigid top-down approach. The proposals of the government were meant to be simply absorbed by the regions, whilst integrative measures like the ‘reference group’ which was designated to coordinate the input of the regions, turned out to have a rather symbolic character during the actual transposition phase. The regions could not utilize their deviating positions into an effective bargaining power, due to their lack of veto powers. However, despite this rigid approach for the transposition, the Danish case revealed the limitations of the actor-centered approach, since again a delay took place despite the restricted impact of conflicting actors. After all, the actor-centered approach proved to deliver not sufficient, but necessary explanatory conclusions for a delayed or mal transposition.

The perspective on the case analyses shifts if a combination of both approaches is applied. While staying for themselves, neither the misfit nor the actor-centered approach is capable of delivering sufficient conclusion throughout all analyzed cases, the combined application of both approaches proves to outbalance the shortcomings of each other and thus allows to answer the research question.

The case analyses have demonstrated how actor-centered interests and/or the financial misfit are capable to significantly affect the timely and correct transposition of the Patients' Rights Directive. Either hypotheses can be approved, if the misfit or actor-centered approach can be validated in the respective cases. The legislators in the analyses were well aware of the potential impact of actor-centered dynamics and utilized this in their favor. Actors who were in conflict with the proposals of the governments could only effectively advocate for their interests if they obtained veto powers. This in turn, proved to enable them to take advantage of new policy settings and opportunities. Furthermore, the analyses suggest that corporatism seems to enable and encourage specifically key actors in the healthcare sector, to compete and engage in compromises on a level playing field.

The case analyses also highlighted how financial misfits are not only the roots of conflicts among key actors but define the decisive motivation behind the legislator's proposals. This supports Duina's (2007) argument in defense of the explanatory power of the misfit approach. Further aspects of the approach also proved how a lack of adequate capacities could impact the timeliness of the transposition.

Certainly, the outcomes of the research design are derived from the applied adaptation of the Process Tracing Theory in conjunction with both the actor-centered and misfit approach which entails some limitations for the internal validity of the theoretical concept. As I mentioned before, the theoretical model of the paper is based on a restrictive modification of the theory testing approach of the PT. The analysis aimed to prove a causal relationship on the basis of a deductive approach that is based on the contemporary literature. Thus, the scope of the results and conclusions of this paper can only be specifically limited to the transposition of the Patients' Rights Directive. Nevertheless, despite being delimited from the application in other policy fields, it can be stated that the case analyses of this paper proved a robust inductive causal relationship, whilst ensuring its internal and external validity.

5.2. Discussion and suggestions for further research

The outcomes of this paper showed how the transposition of the Patients' Rights Directive deviated among the analyzed and that the gained patients' rights in the field of cross-border healthcare are far from a harmonized level playing field. On the other hand, the specific aim of the directive does intend the establishment of a level playing field among all member states was not the main intention. The provisions of the directive are based on the concept to improve the functioning of the internal market and free movement of goods, persons, and services. However, its practical application is primarily aimed to codify the case law of the CJEU, whilst promoting

a balanced compromise between the mobility of patients and the concession to allow the member states to ensure the sustainability of their healthcare systems.

This is also the reason why the European Commission takes a rather soft stance on the implementation of the Patients' Rights Directive and does not i.e. include it in the scoreboards of the internal market. Nonetheless, transposition studies on the Patients' Rights Directive revealed significant shortcomings among several member states. Thus, further integrative measures can be expected, following litigations from individuals or NGOs which would enforce the compliance of the short-fallen member states.

The results of this paper imply a consolidation of both cost factors and actor preferences for further EU compliance and implementation research. The significance of the misfit and actor-centered approach proved their complementing explanatory powers. Thus, I would recommend to employ a (modified) combination of both approaches to achieve the most yielding results, instead to argue in favor of either of them. This is particularly the case for the conduction of research for the transposition of similar directives within the field of social policies since they are prone for politicization and potential implications of exploitative actor-centered preferences, as it was shown in the Dutch case. The misfit approach is only able to ensure sufficient internal validity if such actor-centered preferences are completely absent. This however is rarely the case in the practice. Thus, I would not recommend a sole and unmodified application of the misfit approach for further research, without at least the consideration of actor-centered preferences. On the other hand, I would recommend complementing the actor-centered approach with a misfit aspect, since it is still one of the most important factors in transposition research and significantly contributes to the internal validity of a study.

The choice of the transposition instrument determined not only as expected the inclusion of actors to the policy-making process, but also the depth and extent of the transposition. The extensive use of ministerial decrees to transpose important aspects of the directive led to a disregard of especially civil actors with deviating positions. This violated the Recommendation of the Council of Europe to ensure the involvement of certain civil actors to the decision-making process of healthcare policies. Consequently, the Commission could ensure a deeper transposition of future similar directives as well as the effective involvement of civil actors by narrowing of the flexibility of the provisions. This can be achieved by predetermined transposition instruments or a stricter definition of the provisions in the directive. However, a stricter transposition framework would also entail the problem of the sufficient application of the subsidiarity principle which is even more in question within a Eurosceptic context. Thus,

the Commission needs to consider carefully whether a striker transposition framework can be applied within a certain policy field. If the political context allows it to do so, it should narrow the flexibility of a directive to achieve the most desirable outcomes.

The increased awareness and demand on cross-border healthcare will also bring the necessity to establish a sufficient redress system since liability issues and adverse events are an inevitable aspect to consider with healthcare services (Panagiotou, 2016). The provisions of the Patients' Rights Directive foresaw the establishment of a redress mechanism, to enable patients to claim compensations in the case of adverse events and suffered harm while obtaining cross-border healthcare (OJ L 88, 2011(24)). However, its current implementation among the member states is regarded as not extensive enough to provide a sufficient redress mechanism (Panagiotou, 2016). Thus, the right to redress in the case of an adverse event during cross-border treatments will inevitably constitute a topic for further research.

Furthermore, the inclusion of more cases could extend the scope of the analysis and reveal further explanatory factors which might contribute to a delayed or incorrect transposition. One prominent factor for further research might be the degree of corporatism. It appears to be at least in the field of healthcare an important aspect for the successful involvement of key actors, whilst ensuring a timely and correct transposition through the redistributive delegation of responsibilities.

References

- Aktion Psychisch Kranke. (2012). Stellungnahme zum Gesetzentwurf der Bundesregierung zum Entwurf eines Gesetzes zur Verbesserung der Rechte von Patientinnen und Patienten.
- AOK-Bundesverband. (2012). Stellungnahme des AOK-Bundesverbandes zum Gesetzentwurf der Bundesregierung - Entwurf eines Gesetzes zur Verbesserung der Rechte von Patientinnen und Patienten.
- Bafoil, F., Beichelt, T., & Cerami, A. (2008). *L'européanisation d'Ouest en Est: L'Harmattan*.
- Beach, D., & Pedersen, R. B. (2011). What is Process-Tracing Actually Tracing? The Three Variants of Process Tracing Methods and Their Uses and Limitations. *APSA 2011 Annual Meeting Paper*.
- Börzel, T. A. (2000). Why there is no 'southern problem'. On environmental leaders and laggards in the European Union. *Journal of European Public Policy*, 7(1), 141-162. doi:10.1080/135017600343313
- Börzel, T. A. (2016). Participation Through Law Enforcement. *Comparative Political Studies*, 39(1), 128-152. doi:10.1177/0010414005283220
- Börzel, T. A., Hofmann, T., Panke, D., & Sprungk, C. (2010). Obstinate and Inefficient: Why Member States Do Not Comply With European Law. *Comparative Political Studies*, 43(11), 1363-1390. doi:10.1177/0010414010376910
- Börzel, T. A., & Risse, T. (2003). Conceptualizing the Domestic Impact of Europe *The Politics of Europeanization* (pp. 57-80).
- Bundesärztekammer, & Kassenärztliche Bundesvereinigung. (2012a). Gemeinsame Stellungnahme der Bundesärztekammer und der Kassenärztlichen Bundesvereinigung zu Änderungsantrag 7 der Ausschuss-Drucksache 17 (14)0334 der Fraktionen CDU/CSU und FDP zum Entwurf eines Gesetzes zur Verbesserung der Rechte von Patientinnen und Patienten.
- Bundesärztekammer, & Kassenärztliche Bundesvereinigung. (2012b). Gemeinsame Stellungnahme der Bundesärztekammer und der Kassenärztlichen Bundesvereinigung zum Referentenentwurf des Bundesministeriums der Justiz und des Bundesministeriums für Gesundheit, Entwurf eines Gesetzes zur Verbesserung der Rechte von Patientinnen und Patienten.
- Bundesrat. (2012). Stellungnahme des Bundesrates - Entwurf eines Gesetzes zur Verbesserung der Rechte von Patientinnen und Patienten, Drucksache 312/12.
- Bundeszahnärztekammer, & Zahnärztliche Bundesvereinigung. (2012). Gemeinsame Stellungnahme zum Regierungsentwurf eines Gesetzes zur Verbesserung der Rechte von Patientinnen und Patienten (Patientenrechtegesetz) des Bundesministeriums der Justiz (MNJ) und des Bundesministeriums für Gesundheit (BMG).
- Cleiss. (n.d.). The European directive on patients' rights. Retrieved from http://www.cleiss.fr/docs/directive_en.html
- Deutsche Krankenhausgesellschaft. (2012). Stellungnahme zum Gesetzentwurf der Bundesregierung „Entwurf eines Gesetzes zur Verbesserung der Rechte von Patientinnen und Patienten (Patientenrechtegesetz)“ sowie Änderungsantrag 3 der CDU/CSU und FDP (§ 135a (Absatz 3 neu) SGB V) und zum Änderungsantrag 7 der Fraktionen der CDU/CSU und FDP (§ 219d SGB V).
- Diakonisches Werk der Evangelischen Kirche in Deutschland. (2012). Stellungnahme der EKD Deutschland - Evangelischer Bundesverband zum Regierungsentwurf eines Gesetzes zur Verbesserung der Rechte von Patientinnen und Patienten.
- Duina, F. (1997). Explaining Legal Implementation in the European Union. *International Journal of the Sociology of Law*, 25(2), 155-179. doi:10.1006/ijsl.1997.0039
- Duina, F. (2007). Domestic Actors and Europeanization: Why 'Fit' Still Matters. *Comparative European Politics*, 5(3), 339-341. doi:10.1057/palgrave.cep.6110116
- Falkner, G., Hartlapp, M., & Treib, O. (2007). Worlds of compliance: Why leading approaches to European Union implementation are only ?sometimes-true theories? *European Journal of Political Research*, 46(3), 395-416. doi:10.1111/j.1475-6765.2007.00703.x

- Falkner, G., Treib, O., Hartlapp, M., & Leiber, S. (2005). *Complying with Europe: EU Harmonisation and Soft Law in the Member States*: Cambridge University Press.
- Gerlinger, T., & Burkhardt, W. (2012a). Bismarcks Erbe: Besonderheiten und prägende Merkmale des deutschen Gesundheitswesens. *Gesundheitspolitik*. Retrieved from <http://www.bpb.de/politik/innenpolitik/gesundheitspolitik/72553/deutsche-besonderheiten?p=all>
- Gerlinger, T., & Burkhardt, W. (2012b). Die wichtigsten Akteure im deutschen Gesundheitswesen. Teil 2: Verbände und Körperschaften der gemeinsamen Selbstverwaltung. *Gesundheitspolitik*. Retrieved from <http://www.bpb.de/politik/innenpolitik/gesundheitspolitik/72575/verbaende-und-koerperschaften?p=all>
- Giuliani, M. (2003). Europeanization in Comparative Perspective: Institutional Fit and National Adaptation *The Politics of Europeanization* (pp. 134-156).
- GKV-Spitzenverband. (2012). Stellungnahme des GKV-Spitzenverbandes zur Bundesdrucksache (17/10488) Entwurf eines Gesetzes zur Verbesserung der Rechte von Patientinnen und Patienten.
- Goscinska, D. (2014). Transposition of the Patients' Rights Directive 2011/24/EU - A discourse analysis in Germany, Poland and Austria. Retrieved from doi:<http://dx.doi.org/10.14279/depositonce-3963>
- Harper, J. (2016). Polish right goes left on health. *politico.eu*. Retrieved from <https://www.politico.eu/article/poland-looks-west-on-health-care-revamp-public-hospitals-reform-pis-konstanty-radziwill/>
- Helena, R. (2016). Cross-border healthcare directive: Assessing stakeholders' perspectives in Poland and Portugal. *Health Policy*, 120(4), 369-376. doi:10.1016/j.healthpol.2016.02.009
- Informed Health Online. (2015). Health care in Germany: At the doctor's. Retrieved from <https://www.ncbi.nlm.nih.gov/books/NBK298833/>
- Knill, C., & Lehmkuhl, D. (2002). The national impact of European Union regulatory policy: Three Europeanization mechanisms. *European Journal of Political Research*, 41(2), 255-280. doi:10.1111/1475-6765.00012
- Kowalska-Bobko, I., Mokrzycka, A., Sagan, A., Włodarczyk, W. C., & Zabdyr-Jamroz, M. (2016). Implementation of the cross-border healthcare directive in Poland: How not to encourage patients to seek care abroad? *Health Policy*, 120(11), 1233-1239. doi:10.1016/j.healthpol.2016.07.011
- Mastenbroek, E., & Kaeding, M. (2006). Europeanization Beyond the Goodness of Fit: Domestic Politics in the Forefront. *Comparative European Politics*, 4(4), 331-354. doi:10.1057/palgrave.cep.6110078
- Medizinischer Dienst des Spitzenverbandes Bund der Krankenkassen e.V. (2012). Stellungnahme zur öffentlichen Anhörung zu dem Gesetzentwurf zur Verbesserung der Rechte von Patientinnen und Patienten.
- Melck, B. (2015). Poland's new government – what prospects for healthcare? Retrieved from <https://ihsmarkit.com/research-analysis/polands-new-government-what-prospects-for-healthcare.html>
- Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare, (2011).
- Panagiotou, A. (2016). Medical Liability in Europe at the Dawn of Cross-border Healthcare: Time to Reflect on the Possibility of Harmonising the Policies Regarding Medical Liability? *European Journal of Health Law*, 23(4), 350-372. doi:10.1163/15718093-12341390
- Panke, D. (2007). The European Court of Justice as an agent of Europeanization? Restoring compliance with EU law. *Journal of European Public Policy*, 14(6), 847-866. doi:10.1080/13501760701497709
- Remac, M. (2017). *Coordination of social security systems - Regulation (EC) No 883/2004 on the coordination of social security systems and Regulation (EC) No 987/2009 laying down the*

- procedure for implementing Regulation (EC) No 883/2004*. Brussels: EPRS | European Parliamentary Research Service - Policy Cycle Unit.
- Risse, T. (2009). Social Constructivism and European Integration. In A. Wiener & T. Diez (Eds.), *European Integration Theory*: Oxford University Press.
- Seawright, J., & Gerring, J. (2008). Case Selection Techniques in Case Study Research: A Menu of Qualitative and Quantitative Options. *Political Research Quarterly*, 61(2), 294-308.
- Slepcevic, R. (2009). The judicial enforcement of EU law through national courts: possibilities and limits. *Journal of European Public Policy*, 16(3), 378-394. doi:10.1080/13501760802662847
- Steunenberg, B., & Rhinard, M. (2010). The transposition of European law in EU member states: between process and politics. *European Political Science Review*, 2(3), 495-520. doi:10.1017/s1755773910000196
- Strban, G. (2018). Legal Aspects of Long-Term Care in Slovenia. In U. Becker & H. Reinhard (Eds.), *Long-Term Care in Europe. A Juridical Approach*: Springer International Publishing AG.
- Toshkov, D. (2010). *Taking stock: a review of quantitative studies of transposition and implementation of EU law*. Working Paper No. 01/2010. Institute for European Integration Research.
- Toshkov, D., M., K., & Wewerka, L. (2010). *Connecting the dots: Case studies and EU implementation research*. Institute for European Integration Research.
- Treib, O. (2003). *EU Governance, Misfit and the Partisan Logic - An Actor-Centred Perspective on the Transposition of EU Directives*. Paper presented at the EUSA 8th International Biennial Conference, Nashville, Tennessee.
- Treib, O. (2004). *Die Bedeutung der nationalen Parteipolitik für die Umsetzung europäischer Sozialrichtlinien* (Vol. 1): Campus Verlag.
- Treib, O. (2014). Implementing and complying with EU governance outputs. *Living Reviews in European Governance*, 9(1). doi:10.12942/lreg-2014-1
- van der Vleuten, A. (2005). Pincers and Prestige: Explaining the Implementation of EU Gender Equality Legislation. *Comparative European Politics*, 3(4), 464-488. doi:10.1057/palgrave.cep.6110066
- Verband der Ersatzkrankenkassen e.V. (2012). Stellungnahme des Verbandes der Ersatzkrankenkassen e.V. (vdek) zum Entwurf eines Gesetzes zur Verbesserung der Rechte von Patientinnen und Patienten (Patientenrechtegesetz).
- Verband der Privaten Krankenversicherung (PKV-Verband). (2012a). Stellungnahme zum Änderungsantrag 7 Ausschluss-Drucksache 17(14)0334 zum Entwurf eines Gesetzes zur Verbesserung der Rechte von Patientinnen und Patienten.
- Verband der Privaten Krankenversicherung (PKV-Verband). (2012b). Stellungnahme zum Entwurf eines Gesetzes zur Verbesserung der Rechte von Patientinnen und Patienten.
- Versluis, E., van Keulen, M., & Stephenson, P. (2011). *Analyzing the European Union Policy Process*: Palgrave Macmillan.
- Vollaard, H., & Martinsen, D. S. (2014). Bounded Rationality in Transposition Processes: The Case of the European Patients' Rights Directive. *West European Politics*, 37(4), 711-731. doi:10.1080/01402382.2014.919777
- World Health Organization. (2016). Universal health coverage (UHC) - Fact sheet. Retrieved from <http://www.who.int/mediacentre/factsheets/fs395/en/>