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## **A difficult encounter: National healthcare models and the European Union**

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### **Abstract**

This paper examines the institutional output and preliminary outcome of the European Union (EU) Patients' Rights Directive in two healthcare models: the Beveridge and Bismarckian models in Denmark and Bulgaria, respectively. The study applies a most dissimilar system design to explain a similar transposition output through three explanatory variables, namely, institutional misfit, salience and administrative resources. We find that Denmark and Bulgaria have transposed the Directive in protectionist and minimalistic ways, thus far leading to a low outcome, i.e., low patient outflow. The encounter between the European Union (EU) and the national healthcare models has not been enthusiastic but has instead been another example of reluctant and restrictive Europeanisation.

### **Introduction**

Transposition as a process and its eventual output and outcome are conditioned by many factors that form a member state's politics, policies and political. As a result, we can expect that similar systems will have analogous transpositions because similar systems are influenced by comparable factors. Accordingly, the greater the variation is among member states' systems, the greater the differentiation of their transposition outputs is likely to be. This paper examines this expectation in the case of the Directive

2011/24/EU on Patients' Rights in Cross-Border Health Care (the Directive) and its transposition to the healthcare systems of Denmark and Bulgaria. Because the two countries differ in almost every aspect, from overall institutional set up, through salience of the Directive, to resources available in the system, we can expect that transposition output and outcome will differ between the two systems. Our findings, however, show that this is not the case. The output is similar, and the preliminary outcome in both member states is low.

We conceptualise our dependent variable, transposition output, as the transposing acts' ability to achieve the goals of the Directive. To assess the quality of transposition and, thus, the transposition output, we examine the transposing acts' provisions on six central articles of the Directive. We seek to determine whether the provisions adopted nationally provide a sufficient legislative basis for fulfilling the goals of the Directive. Thus, our dependent variable is defined as the 'quality of transposition', meaning the adequacy of national transposition measures to fulfil the goals of the Directive. We argue that despite its more evaluative nature, the quality of transposition output is important to examine because it is likely to condition the outcome of EU law. Outcome is defined as the de facto inflow or outflow of EU patients across borders.

Transposition output may differ among *protectionist*, *minimalist* or *opportunistic* typologies. A protectionist transposition output is restrictive. It intends to preserve the institutional status quo of the national setting, thus intending to limit the cross border inflow and outflow of patients. A protectionist output will result in low outcome, i.e., patient mobility. A minimalist transposition output is also restrictive but not because of an active counter-response. Instead, a minimalist output occurs because of neglect or insufficient time and resources vested in transposition. However, this output will also result in low outcome. Finally, transposition output may be opportunistic, intending to benefit from the new opportunities the Directive offers and minimising national control over patient inflow while investing in attracting patient inflow. The outcome of an opportunistic transposition output is likely to be high patient flows.

Our approach in analysing transposition quality distinguishes our study from the majority of publications on transposition in the European Union (EU). While the majority of these publications primarily focus on meeting transposition deadlines and are conducted through quantitative methods (Dimitrova & Toshkov 2009; Sprungk 2013; Steunenbergh & Kaeding 2009), our approach goes further in examining the adequacy of transposition in fulfilling the objectives of a directive. To simply measure transposition timeliness tells

us little concerning subsequent outcomes. Because we examine two vastly different systems, our study provides a deeper understanding of similar transposition outcomes among different systems.

We expect output and outcome to be influenced by three conditioning factors, namely, institutional fit, salience and administrative resources. Our cases vary in all three of these variables, which leads us to expect different transposition outputs and outcomes. The institutional misfit is greater in Denmark than in Bulgaria; therefore, we can expect better transposition in Bulgaria. We could expect that this would also make the Directive more salient in Denmark than in Bulgaria. The general assumption is that where the salience of the Directive is high, transposition is more successful. Thus, on the basis of salience, we should expect transposition to be better in Denmark (following Versluis 2007). Finally, administrative resources are higher in Denmark than in Bulgaria. Generally, the transposition literature finds that better administrative resources lead to better transposition. Thus, we should expect better transposition in Denmark than in Bulgaria.

This study proceeds as follows. First, we introduce the methodology of our study. The paper follows a most dissimilar systems design (MDS). Next, we introduce our three theoretical expectations based on the state of the art within the literature on transposition. Against this background, we proceed to the analysis of transposition in our two different health systems. Finally, we present our findings on both output and preliminary outcome.

## **Methodology**

Our cases are selected based on their fundamentally different systems. Therefore, our case selection prompts the use of the MDS approach. MDS has been widely discussed in the literature on social inquiry and the methods of case studies (Anckar 2008; Kinget al. 1994; Lijphart 1971; Rihoux 2006) since its introduction in 1970 by Przewoski and Teune (Przeworski & Teune 1970). The basic logic of the approach involves a comparison of systems that share as many dissimilarities as possible yet show the same outcome. This logic allows the researchers to control for every variable that differs between the systems and to exclude the variable as a possible explanation. If the cases demonstrate divergence on all possible variables, then these variables could not possibly explain a convergent result. If, in contrast, the cases share a common factor(s), these commonalities constitute an explanation for similar outcomes. Rihoux describes the strength of the method by stating that it considers many potential explanatory

variables or conditions that are systematically grouped in categories, producing a reduction in complexity (Rihoux 2006: 686).

The examination of transposition in two selected member states has applied the process-tracing method to conduct an in-depth analysis of a process of change as it unfolded. Thus, this paper is a qualitative, comparative study of two cases. The qualitative case study method is useful to examine *how* and *to what extent* different healthcare models are challenged and change as a result of an EU cause. The case study method is well-equipped to uncover complex inter-institutional dynamics because it provides a better opportunity to obtain detailed knowledge of the phenomenon under investigation (Collier et al. 2004: 87). The deficit of the method is often the small-n, whereas the advantages are that the method enables the researcher to examine the details and causal factors of a single unit – and compare it with others (Gerring 2004: 348). The case study constitutes a method capable of addressing the causal complexity often found when European policies are created in areas of high political salience, when such policies evolve and when they impact nationally in a diverse and complex manner such as the present case of national healthcare models and the EU (George & Bennett 2005: 19-22). Process tracing identifies the causal chain between an independent variable (X) and a dependent variable (Y) and thus identifies the explanatory factors assumed to connect X and Y (George and Bennett 2005: 206-207). The method is therefore particularly useful when one addresses causal interference in qualitative research (Beach & Pedersen 2013: 2).

The empirical data for this study were collected as part of a larger comparative research project examining the current dynamics of EU social policy, including healthcare and its subsequent implementation. This study consists of two main data sources. 1) The first data source is documents covering both the EU legislative process and the transposition in the selected member states. These documents include newspaper articles, position papers, national laws, decrees and contributions to the hearings. 2) The second data source is a large collection of qualitative interviews that were held with key respondents in the two member states as well as representatives from the Commission, the Council and the European Parliament during negotiations over the Directive. The key respondents in the member states were civil servants in charge of the transposition from the relevant ministries, regional politicians and civil servants, representatives from patient organisations, boards for patient complaints, and representatives from the involved healthcare agencies, among others. A total of 54 semi-structured interviews were conducted for the present study from December 2009 to October 2014.

## Theoretical propositions

Institutionally, the two systems have developed differently. Denmark is structured along the Beveridgian, tax-funded, universalist model and is a National Health Service system (NHS), whereas Bulgaria has a Bismarckian, mixed social-insurance and tax-funded corporatist model and is a Social Health Insurance (SHI) system. This considerable institutional variation between the two cases means that the systems' *fit* with the Directive also varies. The misfit hypothesis has held a prominent position in Europeanisation studies since the late 1990s, when it was introduced by Duina. The misfit hypothesis's underlying logic emphasises the comparability between EU rules and the national institutions they target. When a directive demands major transformations in these institutions, implementation suffers (Duina 1997: 157). Since the late 1990s, the misfit hypothesis has been prolifically used in studies regarding national compliance with European legislation (Cowlesset al. 2001; Duina 1997; Hérítier 1995; Steunenbergr & Toshkov 2009). From this basic premise, we expect transposition in Denmark to be more restrictive (protectionist or minimalist) because of the greater misfit between the Directive and the Danish healthcare system.

This observation is made by both Obermaier and Kostera who examine Denmark's compliance with the Court of Justice of the European Union (CJEU)'s decisions on patient mobility compared with Bismarckian healthcare systems in Europe. Obermaier compares Denmark in a broader European context and concludes that, in general, NHS systems seem to be far worse regarding compliance with the patient mobility principles stipulated by the CJEU (Obermaier 2009: 84). A comparable conclusion is reached by Kostera in a direct comparison between Denmark and the prototypical Bismarckian system in Germany. Kostera finds that the institutional misfit between Denmark's system and CJEU decisions precluded a simple absorption of European obligations and that Denmark experienced a much higher adaptive pressure (Kostera 2008: 28).

Although much discussed, the insufficiency of the goodness of fit hypothesis has generally been noted. Alternative explanatory variables should also be addressed. The political *salience* of an EU directive is likely to condition its output and outcome. Essentially, salience denotes a relatively heightened attention from decision makers dedicated to a specific issue. The amplified considerations can be based, inter alia, on a subject's estimated policy impact, its political sensitivity or the attention it receives from core constituencies (Warntjen 2012: 169). The institutional misfit between the Danish system and the provisions of the Directive are likely to result in greater attention dedicated to the Directive in Denmark.

We thus expect the Directive to be more salient in Denmark compared with Bulgaria because it potentially implies more change of national policies.

In the literature, the central premise of salience has been linked to other concepts, such as political sensitivity (Steunenberg & Kaeding 2009), conflict (König & Luetgert 2009) and controversy (De Wilde 2011). However, all of these concepts denote an increased attention from decision makers and are therefore inextricably connected to the idea of issue salience. The literature has also emphasised the complexity behind measuring salience. Warntjen warns that salience is a fluctuating phenomenon with varying levels across policy fields and political actors, i.e., different issues affect different participants in the political process in different ways (Warntjen 2012: 169). This observation also holds true across political systems. Some issues are important in some countries, whereas they go unnoticed in others (Dimitrova & Toshkov 2009: 4).

Here, the literature does not agree regarding how salience conditions transposition. Knill and Versluis link the lack of salience in legislative proposals with untimely transposition and insufficient implementation. The lack of attention from decision makers is associated here with a lack of incentive for reform (Versluis 2007: 63). Spendzharova and Versluis reach a similar conclusion (Spendzharova & Versluis 2013: 1500). In contrast, Dimitrova and Toshkov find that the lack of salience results in timely transposition (Dimitrova & Toshkov 2009: 11). Because of this discrepancy in the literature, we leave for further examination how the high salience we expect for Denmark conditions output and outcome.

Finally, we consider *resources* a conditioning factor for transposition output. This consideration is another dimension in which our two cases can be distinguished. Denmark is among the richest member states of the European Union, whereas Bulgaria is the poorest. We can therefore expect that the resources allocated in the course of transposition will enable a better transposition in Denmark than in Bulgaria. Table 1 provides a short overview of the considerable differences that exist in the resource base of the two systems.

Table 1 to be inserted here

Obviously, Bulgaria lags considerably behind Denmark in every aspect of resource availability. The importance of resources has been recognised by several studies in the field (Börzel, et al. 2010; Falkner et al. 2008; Vasev & Vrangbæk 2014; Zubek & Staronova 2010). The resource hypothesis is connected to the basic understanding that resources allow for a more prompt, comprehensive and better implementation

of policies because exhaustive implementation of EU policies costs money (Hille & Knill 2006: 539). Resource-strapped administrations, in contrast, are more likely to decline minimalistic transposition because they simply cannot afford a different approach.

### **Aims and instruments of the patient rights directive**

The patient rights directive is not easy to read. It expresses considerable ambiguity because, on the one hand, it intends to consolidate free movement principles in the healthcare sector; on the other hand, it respects the healthcare competences of the member states (Vollaard & Martinsen 2014: 718). The overall idea of the Directive has at least the following three components: 1) to allow free movement of goods, services and persons in cross border healthcare; 2) to establish legal certainty and ensure clarity concerning the rights of European patients in the cross border provisions of healthcare; and 3) to enable patients to make an informed choice regarding the provisions of healthcare in other member states. However, the underlying national concern has also been given considerable weight in the Directive, allowing member states various grounds to deny patients to go abroad for healthcare treatment (Greer 2013: 417).

Several articles are important instruments to realise the European aims of the Directive. Below, the institutional output of six key articles will be examined, and we analyse how they have been transposed in the two member states. During the conducted interviews, these six articles were noted as challenging to the established status quo of national healthcare provisions across the EU, although to different degrees and to varying extent across the member states. Articles 4, 5 and 6 intend to establish adequate and accessible information for patients to make an informed choice regarding cross border healthcare. Article 7 addresses clear pricing. Article 8 establishes when and how prior authorisation is a justifiable means of national control for cross border care. Article 11 requires the mutual recognition of prescriptions, thus allowing patients to purchase medicine in other member states in accordance with the reimbursement policies of their member state of affiliation. Table 2 demonstrates the likely implications of the articles concerning output and outcome.

Table 2 to be inserted here

We now turn to the analyses of the Directive's transposition in Denmark and Bulgaria.

## **Keeping the gates: Transposing cross border health care in Denmark**

The Danish healthcare model belongs to the Beveridge NHS family, is primarily tax-financed and provides universal public healthcare for all residents. Providing healthcare is a shared responsibility among the state, the five regions and the 98 municipalities (Martinsen & Vrangbaek 2008: 173). Denmark has a long tradition of decentralisation of the healthcare sector. However, over the last decade, a considerable centralisation has been noticeable because of structural reforms and the introduction of performance management principles to the sector. Regional autonomy to prioritise and plan capacity have been primarily reduced by the following two patient rights granted by the state (Vrangbæk 1999): 1) the introduction of choice, which allows patients to access treatment in other regions; and 2) waiting time guarantees, creating a free choice of hospitals outside one's own region (see further details below). Other elements of planning and controlling capacity remain an integral part of the Danish system. The 'family doctor', i.e., the General Practitioner (GP), is an important gatekeeper for healthcare treatment and has been regarded as important to the quality of care by bridging patients' demands and system supply. The GP thus has an important control function in the Danish system, including access to pharmaceuticals through prescriptions, referring patients to specialist treatment and hospital care, ensuring the continuity of care, and providing information on care, among other factors. In performing these tasks, the GP has an equally important function in the system: controlling healthcare expenditures. The GP refers patients to specialised care and hospital care. A patient, once referred by the GP, has an extended free choice of hospital care if s/he cannot be treated within one month in his/her own region. In this case, the patient can choose healthcare at a public hospital in another region or at a private or foreign healthcare provider with which the Danish regions have established a previous agreement. The waiting time for hospital care is currently short because of this extended free choice.

### *Transposing the patient rights Directive in Denmark*

In Denmark, the Ministry of Health was responsible for the transposition of the Directive, whereas the regions and healthcare providers were responsible for the practical implementation of it. The regions expressed frustration at not being closely involved in the transposition process, which mainly involved few civil servants in the Ministry of Health (Interviews, November 2012). The preparation of the law to

transpose the Directive was delayed several times, but the proposed law was finally presented in late June 2013 and proposed to the Parliament in October 2013. The Danish law entered into force on 1 January 2014, meaning that Denmark did not meet the transposition deadline of 25<sup>th</sup> October 2013.

Danish transposition of the Directive has generally intended to limit its outcome. This domestic objective has produced a largely protectionist output demonstrated by the way the six key articles have been transposed. Currently, Danish patients can access considerable *information* regarding the quality of care and waiting times. However, this information is developed in a Danish context and is not immediately comparable across borders. Thus, the amount of information will not enable Danish patients to make an informed cross border choice. Concerning the inflow of foreign patients, there are linguistic limitations. For the relevant dissemination of information, the role of the *contact points* is considered crucial but unclear (Interviews, November 2012, July 2013, August 2013). Contact points with a high level of services are likely to cause an enhanced inflow of foreign patients, whereas lower service quality is likely to limit de facto patient flow and simultaneously increase uncertainty. The transposing law requires each region to establish a contact point. However, these contact points were created by using the already existing patient supervisor offices in the regions instead of establishing new institutions. In addition, a coordinating function of the five contact points is placed in the National Agency for Patients' Rights and Complaints, or 'patientombudet' in Danish (Danish law proposal, L 33 as adopted 20. December 2013).

Currently, the public sector is not sufficiently prepared for incoming patients (Interviews, July 2013, August 2013). Healthcare providers do not fulfil their obligation to provide adequate information concerning their services. Healthcare providers are required not to discriminate against foreign patients. However, the webpage on the main Danish hospital – Rigshospitalet – simply states that

“Regrettably Rigshospitalet does not have the necessary capacity to offer treatment to private and/or foreign patients, even if they are willing to pay for their treatment themselves” (see <http://www.rigshospitalet.dk/RHenglish/Menu/Diseases+and+Conditions/Private+patients/>, accessed January 2014).

In contrast, regional authorities are required to make healthcare providers comply with their EU obligations, but they are unsure how to perform this monitoring function (Interviews, October 2014). Therefore, although Denmark is regarded as potentially attractive to foreign patients with low waiting times and a perception of relatively high-quality healthcare, a considerable patient inflow should not be

expected as an outcome. Furthermore, inflow is impeded by the lack of market logic in the public sector. 'Clear pricing' is not straightforward for the Danish model. The Ministry of Health has decided to use DRG prices as tariffs, thus turning to existing solutions (Interviews, August and November 2012). However, representatives from the regions have noted that the DRG is an abstract means of price setting, which neither disaggregates the different components of a healthcare service nor specifies when a healthcare treatment begins and ends (Ibid.). DRG prices may function in a national setting where regions and national healthcare providers have learned to trust this price mechanism. However, in an internal market, DRG prices scarcely constitute transparent or full prices (ibid.).

Considering article 8 regarding *prior authorisation*, the government, in strong support of the regions, has not liberally permitted the outflow of Danish patients – but maintains the prior authorisation policy. For hospital care and 'highly specialized and high cost care' not requiring hospitalisation, authorisation must be issued (Danish law proposal, L 33 as adopted 20. December 2013; § 89). The law requires the Danish Health and Medicines Authority to issue a list that establishes which treatments require prior authorisation. The issued list determines that all treatments requiring at least one night of hospitalisation and all treatments listed in the 'plan for specialization' ('specialeplanen') require authorisation. The list simply links to the 'plan for specialization' where a somewhat overwhelming range of treatments appear, including several requiring minor specialisation.<sup>1</sup> There is no further justification for why this entire range of treatments require authorisation. In addition, the government has refused to issue a positive list of what treatments can be accessed directly without prior certification from the Danish health authorities (see the Minister of Health's response to question 27, additional report from the Health Committee of the Danish Parliament, 18 December 2013). To date, the practice of issuing prior authorisation has been clearly restrictive, estimated to be only approximately 10 each year across the country from 2011-2012 (Interviews, April 2012, November 2012, August 2013).

Article 11, which establishes the *mutual recognition of prescription*, may have the highest impact on Danish healthcare. Medicine can now be purchased in other member states and reimbursed at the same level as if it had been purchased in Denmark. Because medicine is relatively expensive in Denmark, Danish patients are incentivised to buy pharmaceuticals across the borders or through the internet. In addition, it will be increasingly difficult for the GP to control access to medicine because it can be prescribed by GPs in other member states.

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<sup>1</sup> See <https://sundhedsstyrelsen.dk/da/sundhed/planlaegning-og-beredskab/specialeplanlaegning/specialeplan-2010>, accessed January 2014.

Despite its *salience*, there was no extensive public discussion of the proposal and no major political disagreements on how to transpose. However, the liberal parties 'Venstre' and 'Liberal Alliance' criticised the Social Democratic government for not addressing the market opportunities that the Directive could offer the Danish healthcare sector and for adopting overly restrictive control measures through prior authorisation (Additional report from the Health committee of the Danish Parliament, 18 December 2013). However, these criticisms did not prevent the two parties from voting for the proposal. All parties, except for the left wing party 'Enhedslisten', voted for the proposal, and the law was adopted on 20 December 2013. Even the Danish People's Party, the EU's sceptical right-wing party, which generally argues strongly against EU cross border welfare, warning against 'welfare tourism', voted for the proposal. Thus, contrary to our expectation that the salience of the Directive should be high in Denmark because of considerable misfit, salience was low. There was no major opposition to the transposition of the Directive, no important parliamentary or public debate, and the government enjoyed considerable autonomy in how to transpose. De facto, the salience of the Directive was low.

Concerning '*resources*' expected to cause different transposition output in Denmark and Bulgaria, our analysis on the Danish transposition demonstrates a need to distinguish between 'available resources' and 'allocated resources'. Available resources are relatively high in Denmark, whereas the resources allocated to transposition were low. No extra manpower and only limited resources were allocated to the regional contact points for performing the new functions. In contrast, the regions note that although there may be a limited number of inquiries from patients, all inquiries are complex and demanding. The Directive is complex to counsel on, and all patient situations differ (Interviews, October 2014). No routines or general practices have been established. Administering the new rules in practice are considered highly resource demanding (Ibid.). Against this background, allocated resources have been criticised as inadequate and can be viewed as a minimalist approach to the functions that the institutions must perform (Interview, August 2013; hearing response by the Danish Regions as of 16 August 2013). With a low level of allocated resources, the regions have less ability to fulfil the goals of the Directive.

Denmark has transposed with caution and in a protectionist manner, thus preventing significant outcomes of the Directive. The outcomes in the long term depend on how the Commission will respond to and monitor Danish implementation and how patients, interest organisations and private providers drive the application of the rules. Currently, Danish transposition does not meet the threefold goals of the Directive, namely, to allow free movement within the healthcare sector, establish legal certainty or enable patients to make an informed, cross border choice. A high degree of institutional *misfit* explains in part the

restrictive Danish transposition, but the two other causal mechanisms can also explain the Danish output because both *saliency* and allocated *resources* are low in Denmark, despite our theoretical expectations.

### **From a healthcare periphery: Transposing cross border healthcare in Bulgaria**

In contrast to its Danish counterpart, the Bulgarian system is a Social Health Insurance (SHI) system. Traditionally, the coverage in these systems reflects the level of the patients' employment, but currently, SHI systems offer almost universal coverage to their patients because participation in the system is obligatory. In the Bulgarian system, there is a reciprocal concentration of power compared with the Danish system. Although the healthcare provision infrastructure comprises 28 Regional Health Insurance Funds (RHIF), they exercise little autonomy and are almost entirely subject to the National Health Insurance Fund (NHIF), the exclusive health insurance fund in the country. Since its introduction in 1999, the NHIF has been responsible for collecting health insurance contributions, contracting hospitals and covering patients' expenses in the contracted healthcare providers. Between the NHIF and the Ministry of Health, which is centrally involved in the preparation of legislation and the budget of the NHIF, the Bulgarian health system is characterised by a minimal number of healthcare actors, and the majority of the power is concentrated between the Ministry and the NHIF.

In Bulgaria, the prices of the treatments are listed in an annually negotiated National Framework Contract (NFC). Prices for treatments included in the basic benefit package are listed in the National Framework Contract. When providers are contracted by the NHIF, their contract determines what treatment they must offer to insured patients (Dimova et al. 2012: 19). The NFC is mostly determined by the Ministry and the NHIF. However, the prices in the NFC do not reflect the market evaluation. This discrepancy is connected to decreased purchasing power in the country. Ultimately, the costs are assumed by the healthcare providers and patients. For patients, their high participation in covering some of the treatments is reflected in the high shares of Out of Pocket Payment (OPP). For health providers, this obligation results in considerable indebtedness. The deficiency of funds means that the majority of Bulgarian healthcare is characterised by a decreased quality of services. Although low prices may appear conducive to an inflow of foreign patients, low quality standards are prohibitive. Similar to the Danish system, the general practitioner plays a central role. The GP has controlling functions because a referral from him or her is required to access an outpatient specialist. After the patient visits a specialist, the

specialist can issue an additional referral for hospitalisation if needed. Thus, the GPs control access to the system because a referral is required to see a specialist and/or obtain hospitalisation.

### *Transposing the patient rights directive in Bulgaria*

In Bulgaria, the transposition failed in meeting its deadline because of the political instabilities preceding the adoption of the Directive. From February 2013, the country experienced instability when the incumbent government was forced to resign, an interim government assumed control, and finally, a new government was elected. This disorder was accompanied by continuous popular protests demanding the resignation of the government. These protests put the focus on national legislation and side lined transposition procedures. Therefore, the political environment prior to the adoption of the Directive was relatively unstable, and this ultimately resulted in a delay in the transposition. The adverse effect of the protests was emphasised by the fact that there was effectively no political opposition to the Directive's adoption in parliament. Only two members of parliament abstained in the vote, and there were no votes against it. The transposition of the Directive in Bulgaria mirrors the situation in Denmark. The parliamentary discussion proceeded without contestation, and there were no public debates concerning the Directive. Media attention was also limited. Similar to Denmark, *salience* became low.

The new law was adopted on the 19<sup>th</sup> of December 2013 and was officially published as a law on December 27. In late March 2014, the Ministry of Health published an ordinance that contains provisions for the detailed implementation of the Directive. The new laws designate the NHIF as the single *National Contact Point* that relies on the existing structures of the NHIF without creating a new institution. At the time of this writing, no information concerning the NHIF's new obligations has appeared on the website of the Fund. The rest of the information on the NHIF's website is detailed, offering *information* on not only patients' rights but also the NFC and other central elements of the health system. However, this information was available prior to the transposition, and the Directive has contributed little to influence its availability. It is also likely that information will be only in Bulgarian because the English version of the site is currently parsimonious. Thus, information provided by the NHIF has scarcely been influenced by the Directive. This limited information will impede patient flows.

For the NHIF, the greatest challenge in the establishment of the contact point is the shortage of human and technical *resources* (Interview, February 2014). Neither the new law nor the Ministry ordinance

designates any extra resources for the establishment of the new structures necessary for the proper functioning of the National Contact Point. This deficiency reflects the low amount of allocated resources for the establishment of the new institution. This low amount of allocated *resources* will cause difficulties if the inflow of foreign or the outflow of Bulgarian patients increases.

Regarding the provisions concerning the assurance of adequate *information* on healthcare standards and treatment options, the Bulgarian system is well equipped. The services covered by the NHIF are listed annually in the NFC. In addition, the treatment of patients is regulated through clinical pathways. These pathways resemble the diagnosis related groups (DRG) used in Denmark. Although there have been attempts for years to reform the Bulgarian system to replace the pathways with DRG, clinical pathways remain the standard in Bulgaria, and they provide considerable information on prices and treatment options. Currently, most of the Bulgarian hospitals include this information on their websites, with several hospitals offering the information in English. The transposition law does not impose any requirements on health providers to deliver information in foreign languages.

The Ministry ordinance explicitly prohibits health providers from charging foreign patients different *prices* than Bulgarian patients. This prohibition, however, does not end the issue. Bulgarian healthcare prices are artificially kept low and do not represent the market value of the services (Interview, November 2013). This discrepancy creates more of an issue for Bulgarian patients because under the Directive, the reimbursed costs will reflect a preternaturally low level. Furthermore, if Bulgarian patients find a system where prices are lower than in Bulgaria, the Ministry ordinance precludes a Bulgarian patient receiving more money than he or she paid. Interviews with officials in the Ministry of Health noted this issue as the primary concern for the authorities. Thus, the ordinance prevents any possible 'medical tourism'. However, the ordinance also leaves Bulgarian patients significantly disadvantaged. Due to the artificially low pricing of treatment in Bulgaria, patients will actually incur considerable expenses if they undertake treatment abroad because the difference between foreign prices and Bulgarian coverage can be considerable.

The list of treatments included in the positive list that require *prior authorisation* is remarkably short. The list contains 15 treatments, which are also some of the highest priced treatments in Bulgaria, i.e., cardio-related treatments. Thus, the government has used the provisions in the Directive to restrict mobility for the highest priced treatments. This restriction protects not only the Bulgarian system from financial exposure but also the interests of medical lobbies that control the pricing of these treatments.

The Directive's provisions regarding *mutual recognition of prescriptions*, which allow cross border access to medicine, are also likely to be problematic in the Bulgarian system. Although the Ministry ordinance provides rules for the reimbursement of pharmaceuticals, the reality of the Bulgarian healthcare system creates impediments to the reimbursement of medication. Because of the small size and the low prices of the Bulgarian pharmaceutical market, many pharmaceutical companies have discontinued their supply to it. Because pharmaceutical companies calculate prices for their products with formulae that involve a comparison of prices in all of Europe, Bulgaria's presence in these calculations decreases the prices in other countries. Therefore, companies find it more profitable to exclude Bulgaria from their supply, which leaves Bulgaria with relatively less medications available than in the rest of the EU. In the context of the Directive, this shortage could create a situation where Bulgarian patients return to Bulgaria with recipes for medications that are unavailable in Bulgaria. It is reasonable, therefore, to expect that Bulgarian patients increasingly go to Greece or Romania for pharmaceuticals.

Bulgaria has transposed in a relatively minimalist manner, leading to a restrictive output. Although its Bismarckian healthcare model has a better *fit* from a general, overall perspective than the NHS model in Denmark, Bulgaria has many underlying difficulties in complying with the goals of the Directive. These meso-level incompatibilities are revealed when one examines the quality of transposing individual articles, which was conducted in the analysis above. Similar to Denmark, both *saliency* and allocated *resources* in Bulgaria's transposition were low. In particular, we found low resources to explain the restrictive output and low outcome of the Directive.

## **Conclusions**

The juxtaposition of the Danish and the Bulgarian systems' transposition of the Cross-Border Patients' Rights Directive utilises the benefits of the most different systems design to elucidate analogous outcomes of two dissimilar polities conditioned by comparable factors. The distinctions between the systems and different saliences and resources led us to expect different transposition outputs and outcomes. However, our research has established that low salience and a low level of allocated resources had a comparable impact on both systems.

Saliency in both Denmark and Bulgaria was relatively low. Few actors were involved and engaged in the transposition process. Public debate was absent; therefore, outside input was limited. Although we

expected that the greater misfit between the Directive and the Danish system would result in greater debate, this was not the result. Similar to Bulgaria, the Danish transposition occurred largely without parliamentary debate and notice to society, which enabled decision makers to limit its potential impact by approving a protectionist and restrictive transposition.

The decisively higher resources in Denmark should have yielded a better transposition in the system. However, the transposition in Denmark emphasised an important distinction in the significance of resources as a condition for transposition: the Danish case demonstrates the need to distinguish between *available* and *allocated* resources. Although available resources may be high, allocated resources can be limited, which can restrict transposition. In Bulgaria, the limited amount of both available and allocated resources is to be expected. In contrast, in the Danish case, the limited amount of allocated resources is a central cause of a lower quality transposition. Low salience and limited allocated resources result in an essentially protectionist transposition in Denmark and a minimalist transposition in Bulgaria. Transposition output was thus restrictive in both member states, which we determined was likely to produce a low outcome, i.e., inflow and/or outflow of patients. Our preliminary findings concerning outcomes confirm this assumption, as demonstrated in table 3 below.

[Insert table 3 here](#)

Up to October 2014, reimbursement of cross border care for outflowing patients from Denmark and Bulgaria have remained low. Thirty-five patients have been reimbursed from the Danish authorities, and only 4 have been reimbursed in Bulgaria. We have no data on prior authorisation in Bulgaria granted before 2014, but we know that it was approximately 10 per year in Denmark. Although the numbers have increased in Denmark, we still consider this a low outcome of an EU law, designed and negotiated in great detail, negotiated for a long time and intending to facilitate access to cross-border healthcare in the EU. Data on the inflow of patients are not available. According to the respondents, this information will be difficult to obtain because healthcare providers largely control it, without much intervention from national or regional authorities (Interviews, October 2014).

The future implications remain to be seen. Thus far, the encounter between the European Union and the national healthcare models has not been enthusiastic but rather another example of reluctant and restrictive Europeanisation.

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**Table 1: Resources available in the Danish and Bulgarian healthcare sector**

	<b>Denmark</b>	<b>Bulgaria</b>
GDP per capita in USD	56,364	6,977
Health expenditure per capita (current US\$)	6,304	516
Health expenditure, total (% of GDP)	11.2	7.4
Health expenditure, public (% of total health expenditure)	85.5	56.3

(Source: World Bank, 2014)

**Table 2: Six key articles of the Patients' Rights Directive**

Article	Content	Implications
4 & 5	MS are obliged to ensure that information is provided on healthcare standards, treatment options, availability, quality and safety, prices, rights, appeal procedures, etc.	<p><i>Output:</i> MS and healthcare providers must develop accessible info and procedures where they are not available</p> <p><i>Outcome:</i> Accessible info may enable citizens to make an informed choice. Will increase inflow and/or outflow</p>
6	MS to establish contact points	<p><i>Output:</i> Obligation to develop this and ensure sufficient resources so that they can provide relevant information.</p> <p><i>Outcome:</i> Contact points are a venue for information and comparison. Will increase inflow and/or outflow</p>
7	MS required to have transparent mechanisms for the calculation of costs	<p><i>Output:</i> MS must develop prices and tariffs where they do not exist.</p> <p><i>Outcome:</i> Venue for comparing inter-regional prices and question differences. Clear pricing will increase inflow and/or</p>

		outflow.
8	<p>Prior authorisation (PA) justified for hospital care as well as highly specialized and cost-intensive care</p> <ul style="list-style-type: none"> <li>• PA must be issued where treatment cannot be granted within a medically justifiable time limit</li> <li>• MS of affiliation shall make publicly available which healthcare is subject to PA</li> </ul>	<p><i>Output:</i> MS must define and justify which healthcare services require PA. The use of PA must be necessary and proportionate. MS must deliver treatments within a justifiable time-limit, question waiting-time and the ability to prioritize between treatments.</p> <p><i>Outcome:</i> May increase inflow and/or outflow.</p>
11	Mutual recognition of prescriptions	<p><i>Output;</i> procedures must be in place to accept prescriptions from other MS</p> <p><i>Outcome;</i> Possible to access medicine in other MS. Use of medicine more difficult to control</p>

**Table 3: Outflow of patients in Denmark and Bulgaria in accordance with the Patients' Rights Directive between 1/1-2014 and 1/10-2014**

	Denmark	Bulgaria
Inquiries regarding cross-border healthcare since 1/1-2014	900	No data
Applications for reimbursement for treatments that do not require	64	2

prior authorisation since 1/1-2014		
<b>Reimbursement for treatments that do not require prior authorisation since 1/1-2014</b>	<b>21</b>	<b>2</b>
Applications for prior authorisation since 1/1-2014	61	3
<b>Prior authorisation granted since 1/1-2014</b>	<b>14</b>	<b>2</b>