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The role of the 2011 patients' rights in cross-border health care directive in shaping seven national health systems: Looking beyond patient mobility☆

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ABSTRACT

Reports on the implementation of the Directive on the application of Patients' Rights in Cross-border Healthcare indicate that it had little impact on the numbers of patients seeking care abroad. We set out to explore the effects of this directive on health systems in seven EU Member States. Key informants in Belgium, Estonia, Finland, Germany, Malta, Poland and The Netherlands filled out a structured questionnaire. Findings indicate that the impact of the directive varied between countries and was smaller in countries where a large degree of adaptation had already taken place in response to the European Court of Justice Rulings. The main reforms reported include a heightened emphasis on patient rights and the adoption of explicit benefits packages and tariffs. Countries may be facing increased pressure to treat patients within a medically justifiable time limit. The implementation of professional liability insurance, in countries where this did not previously exist, may also bring benefits for patients. Lowering of reimbursement tariffs to dissuade patients from seeking treatment abroad has been reported in Poland. The issue of discrimination against non-contracted domestic private providers in Estonia, Finland, Malta and The Netherlands remains largely unresolved. We conclude that evidence showing that patients using domestic health systems have actually benefitted from the directive remains scarce and further monitoring over a longer period of time is recommended.

1. Introduction

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 (hereafter referred to as the directive) entered into force on 24 April 2011 and had to be transposed into national law until 25 October 2013 [1]. At the time of its development and adoption, the directive was considered contentious since it is the first legislative foray by the European Commission specifically drafted for the area of health services. The directive had been originally triggered by a series of rulings of the Court of Justice of the European Union since 1998 and the thwarted efforts to respond to these through the so called 'Bolkestein' services directive, which aimed to treat health services as a 'normal' service [2],[3]. From the start of the original court rulings in 1998 until the adoption of the directive and its transposition into national law, fifteen years had elapsed. During this period the European Union underwent important transformations and the context within which the directive

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was being implemented was that of a Europe in the midst of a severe economic recession with many Member States implementing harsh austerity programmes including health sector budgetary cuts. [4] In addition, the financial sustainability of several Member States' health systems came under scrutiny of the European Semester process and Country Specific Recommendations. [5] The directive was therefore implemented in an environment that was somewhat hostile and sceptical to the possibility of external European pressures impacting significantly on health care budgets. Reports documenting minimalist approaches to transposition [6–10] as well as the large number of infringement procedures initiated by the European Commission provide evidence of this effect. A report issued by the European Commission in 2015 [11] as well as a Eurobarometer survey in the same year both point towards the directive having made little impact on increasing patient mobility in the European Union [12]. It seems that cultural, language and financial barriers are simply too high to turn patient mobility into a larger phenomenon [13]. One may therefore pose the question, to what extent did the directive actually provide benefits for European patients?

Some have argued that the intrinsic value of this directive may have far more to do with the indirect 'Europeanising' effects that the directive may have on the domestic health systems [14], [15] Whilst it is not the scope of this paper to delve into the detail of the theory of Europeanisation, [16] the promotion of patients' rights has been described as a common European health system value [17] and the changes in domestic legislation, policies and institutions to further promote the concept of patients' rights can therefore be considered as a 'Europeanising' effect [18]. In this paper we therefore choose to focus on an analysis of the effects of the directive on patients who make use of health services in their domestic health system. Specifically we seek to document whether any changes in terms of access or quality improvement measures linked to patients' rights, have been observed in association with the implementation of the Directive.

2. Methods

A structured questionnaire was filled out by key informants in Belgium, Estonia, Finland, Germany, Malta, Poland and The Netherlands during 2015. The countries were selected to reflect the diversity of EU health systems in terms of size, geography, economic development, type of health system and degree of support or resistance to adoption of the directive at voting stage in the Council of the European Union. Key informants were identified from the Observatory on Health Systems and Policies' network of experts, including its Health Systems and Policy Monitor network (www.hspm.org). There were 1–2 experts per country, who worked together in completing the questionnaire. Experts were chosen on having a deep insight into the policy process in their country through involvement in research and policy development and a track record in the field of cross-border care. Data collection took place between June and October 2016 and comprehensive responses were received from each of the five countries. For Malta and Germany, the coordinating authors filled in the questionnaire. Experts were asked to provide information about legislation adopted, new institutions created and other unforeseen effects that may have arisen within the domestic health systems as a result of the implementation of the directive. Experts were given a checklist of areas comprising elements that feature in the directive to enhance comparability of the ensuring analysis (see Box 1).

The framework from the "Europeanisation" theory regarding *goodness of fit* was applied to describe the findings that emerged [19], [20]. This framework predicts that depending on the degree of *misfit* between the proposed EU legislation and the situation in the Member State, Member States will respond accordingly. A low degree of misfit is expected to lead to minimal upheaval with adoption and adaptation taking place. A high degree of misfit on the contrary is expected to generate one of two scenarios. Member States may *use* the opportunity afforded by the need to transpose EU legislation in order to bring about transforming effects into their domestic system, by changing legislation, institutions and policies to fully assimilate the EU directive and additionally implement desired changes that may even go beyond the minimum directive requirements. Alternatively, the high degree of misfit may be viewed as being too costly to adapt to and Member States engage in policy behaviour that has been described as 'inertia' or 'retrenchment' [19].

3. Results

This section will first discuss the implementation of the directive. We then highlight those areas where actual changes occurred in the domestic health systems across countries and that were reported to be related to the implementation of the directive. The impact on patients' rights is presented. Lastly, we look at individual countries, the dominant changes and policy debate and seek to situate these findings within the 'goodness of fit' framework [19].

3.1. Implementation of the directive

Implementation of the directive appears to have generally followed the patterns predicted by the *goodness of fit* theory. In Member States such as Belgium, Estonia, Germany, and the Netherlands, generally speaking minimal impacts of the directive have been reported since these countries had been early adopters of the ECJ case law on patient mobility. Germany and the Netherlands for example, already brought national legislation in line with case law in 2004. Moreover, Belgium, Germany, and the Netherlands operate multiple payer health insurance systems, which mean that they already had rather explicitly defined benefit packages, reimbursement amounts and rules [3]. Estonia, which operates a single payer insurance system, also reportedly had a relatively smooth implementation of the directive since the benefits package and reimbursement rules were already in place.

On the other hand, Member States such as Poland, Malta and to a lesser extent, Finland appear to have had to implement larger health system adaptations. These countries had not taken significant steps to implement ECJ rulings prior to the transposition of the directive. With the exception of Poland, they are National Health Service type health systems, which historically have not had explicitly defined benefit packages and reimbursement rules, and therefore had a greater degree of misfit with the proposals in the directive [21]. The Polish and Maltese authorities also feared that long domestic waiting times could provide another motivation to seek care abroad. Furthermore, the authorities in Estonia and Poland, both countries with relatively low spending and pricing levels feared that the directive would encourage patients to seek expensive care abroad. An upsurge in patients seeking care abroad would imply an outflow of public funding that could threaten the financial sustainability of the domestic system. These reasons combined greatly affected the attitude taken in the transposition of the directive. A summary of the effects on key dimensions pertaining to patients' rights is presented in Table 1.[1]

[1] This table uses a framework from work carried out on patients rights which is in the process of being published. Appropriate citation will be provided shortly.

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Table 1
Overview of findings on the implementation of the directive in relation to patients' rights.

Patients' rights	Belgium	Estonia	Finland	Germany	Malta	Netherlands	Poland
Access to health care	legal framework with regard to prior authorisation for care abroad was revised. Monitoring waiting times		adoption of an explicit benefits package setting up of the Council for Choices in Health Care		adoption of an explicit benefits package newly established Advisory Committee on Health Benefits 18 months waiting time adopted		Attempts to lower waiting times for oncology patients reduce access for cataract surgery by reduced reimbursement and higher severity levels
Choice		access to domestic private providers (discussed)	access to domestic private providers (discussed)		access to domestic private providers (discussed)	access to domestic private providers (discussed)	access to domestic private providers (discussed)
Information	lay information on patients' rights a law providing transparency on the applied tariffs for care and the reimbursable amount was enacted. Flemish Indicators project comparing quality aspects amongst hospitals			improve transparency about quality and cost (parallel development)			
Redress		mandatory professional liability insurance (expected)		existing liability insurance adapted	mandatory professional liability insurance implemented		mandatory professional liability insurance implemented
Self-determination							
Confidentiality							

3.2. Changes and trends across health systems

Turning specifically to the situation of *patients' rights* within the domestic health system the following developments have been reported. Malta reports that specific reference was made to Patients' Rights in a new legislative act for the first time [22]. In addition, Finland and Malta report the adoption of an explicit benefits package. In Finland this entailed the setting up of the Council for Choices in Health Care whose mandate went beyond the requirement of the directive and includes the task of priority setting. In Malta, responsibility for determination of the benefits package was given to the newly established Advisory Committee on Health Benefits whose remit also includes prioritisation and use of health technology assessment. Whilst patients can benefit from this increased transparency, the issue of explicit treatment rationing can also be an alternative consideration in this situation.

The introduction of mandatory professional liability insurance in Malta and in Poland (in 2012) can also be viewed as an example of a patient rights and empowerment mechanism as patients are in a stronger position to claim compensation and redress. In Estonia, while mandatory professional liability insurance has not yet been introduced, it is expected to be implemented during coming years and the directive has reportedly played an important role to foster this process. In Germany, existing liability insurance had to be adapted and incorporated that physicians who do not have sufficient liability coverage can be suspended.

The issue of access to domestic private providers that are not contracted by the public system was mentioned by Estonia, Malta, Finland, the Netherlands and Poland. Different approaches to this issue were reported in the different Member States. Although the Directive does not require opening up funding to domestic private providers operating in the private market, these providers argue that they would be discriminated if the directive gives patients access to foreign private providers but not to non-contracted domestic private providers. This phenomenon, is commonly referred to in European law as reverse discrimination. This arises when nationals/service providers of a Member State are disadvantaged because they are subject to a national measure, while foreign (EU) nationals/service providers are protected from that national measure by virtue of EU law [23]. However, to date, none of the Member States studied has allowed open access to domestic providers on an equal basis as non-contracted health care providers in another country due to indirect pressure that emerged as a response to the Directive.

The issue of waiting times has played an important role in ECJ case law on patient mobility [24]. The directive incorporates this aspect such that if health care cannot be provided domestically within a medically justifiable time limit, which depends on a person's condition, an authorisation cannot be refused. In the countries studied we have found no establishment of maximum waiting times as a result of the directive. Estonia, Finland and the Netherlands already operate such systems, while German authorities view this as unnecessary. In Poland however attempts have been made to lower waiting times for oncology patients (without much effect) by increasing funding. In Malta a maximum 18 month waiting time was adopted in the Patients Charter in late 2016. The need felt by the government to specifically establish a maximum waiting time has been linked to the implementation of the directive [25].

3.3. Country specific debates and changes

Although Belgium was not required to make major changes to its health system to implement the provisions of the direc-

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tive, domestic patients benefitted from provisions clarifying their rights. For example, patient-friendly lay information on patients' rights was for the first time presented in a systematic manner, through the website of the national contact point. Furthermore, a law providing transparency on the applied tariffs for care and the reimbursable amount was enacted. The latter enables patients to compare out of pocket payments between providers and thus has the potential to improve access to care. Some quality improving initiatives were facilitated by the directive, such as the Flemish Indicators project where hospitals can compare specific quality aspects amongst themselves. A working group has been officially tasked with the elaboration of a system to monitor patients waiting times. Furthermore, another aspect of quality is the concentration of treatments of rare cancers to a limited number of centres of reference that comply with certain quality standards. This proposal, which is expected to be implemented as part of a major hospital reform, was justified by making reference to the provisions concerning quality and centres of reference found in the EU Directive.

In Estonia, the issue of opening up access to non-contracted domestic hospital providers through the provision of cash benefits, which would amount to the domestic tariff of the particular service, has been included in legislation. This was primarily due to pressure from private providers rather than from patient groups and sought to address the existence of reverse discrimination. To date, however, the authorities have not taken steps to implement this measure in practice due to three sets of concerns. It is feared that this new benefit [1] may undermine equity and widen existing inequalities because it is paid only retrospectively, [2] may draw capacity away from contracted providers and lead to waiting lists for those who rely on benefits in kind, and [3] may make it difficult for the Estonian Health Insurance Fund to control quality and overall expenditure. Thus in Estonia the phenomenon of discrimination against domestic private providers persists.

In Finland, a two-tier system for reimbursement of care from public providers and non-contracted private domestic providers exists. The domestic social insurance level is applied if the patient decides to go abroad to use health services and does not have a prior authorisation. If the use is due to an urgent need for care when otherwise travelling in another EU/EEA country or the patient has authorisation, the costs are covered according to the public sector tariff in the country of treatment. In order not to disadvantage domestic private providers, in its transposition of the directive Finland chose to reimburse overseas providers on the same level as its domestic private providers so as not to create a situation of reverse discrimination. This was not deemed to be in conformity with the directive by the European Commission. The Finnish Government is preparing a health and social care and local/regional government reform. The planned reform includes the abolishment of the health insurance reimbursement for the use of private services. Since the overseas reimbursement tariff has been linked to the domestic private reimbursement rate, it remains to be seen what wider effects this reform could have. Therefore with respect to the position of access to domestic non-contracted private providers, the directive has not had an effect on opening up access for patients in their home health care systems to date.

Germany, was not required to implement major changes to its health system as an early adopter of relevant case law, other than to set up a national contact point and centralize certain information that was before mostly available from individual sickness funds and regional authorities. German authorities had no concerns regarding increased mobility from and to Germany and potential negative effects for domestic patients in terms of accessibility. In addition, waiting times never formed a pressing issue due to the broad range of well accessible services available while initiatives to improve transparency about quality and cost were already underway. This together perhaps explains why it was implemented without much public and political debate. Small adaptations were however necessary in state level liability insurance regulations, not because they were currently insufficient, but because the directive focused on personal liability insurance, while in Germany there are other mechanisms, e.g. reserves held at the hospitals, to cover liability. Leaving current state regulations untouched could have led to suspension of physicians although de facto enough liability coverage was available.

In Malta, a Parliamentary motion calling to open up the health system to private providers in cases of undue delay was defeated in 2014. In 2016, the Ministry for Health adopted a Patient Charter which includes the provision that persons waiting for longer than 18 months will be able to access the domestic private sector under similar terms and conditions as those provided for access to overseas non-contracted providers under the directive. This is the first time an explicit waiting time target has been introduced. The political commitment to introduce maximum waiting times was a government electoral programme initiative. It is difficult to ascertain to what extent the implementation of the directive played a role in influencing the implementation of this policy measure.

Similarly to the situation in Germany, the directive did not necessitate large changes in the Netherlands. However, attempts were made by Government to scale back the existing rights to access care from non-contracted providers and be reimbursed 75–80% of the cost. These were met by strong opposition fearing that it would give too much power to insurers to decide what care is good enough as well as concern that they would not be in line with the Directive. Finally, the status quo position was preserved [26]. In this sense, the Directive indirectly helped to safeguard that patients in the Dutch health care system continue to exercise the wide choice they were previously accustomed to.

In Poland, patients may actually have been negatively affected by the directive when using domestic health services [27]. Reimbursement tariffs for cataract operations were reduced and the threshold to qualify for cataract surgery, which is described in terms of severity of impairment, was heightened. It is believed that this measure was implemented as a safeguard to dissuade patients from seeking care for this condition outside Poland. The large difference between the cost abroad and the actual reimbursement tariff would be of such magnitude that patients may prefer to wait to access care within their own system rather than face the extra cost of the non-reimbursed portion of care. The revision of the threshold for access to surgery was an indirect method to curb demand, hence reducing waiting times, but does little to solve a real and existing health need in the country.

4. Discussion

Further to the implementation of the directive, European patients may benefit from a more explicit and thus transparent description of benefits packages where this was hitherto not the case. This increases access to comparability of benefits packages thereby equipping patient groups with information to advocate for introduction of additional benefits, indirectly setting normative benchmarks for health services. The introduction of professional indemnity insurance where this was previously unavailable also facilitates right of redress and compensation. Moreover, although we do not find direct evidence that countries have defined maximum waiting times as a direct result of the directive, the directive *does* put a certain pressure on European health systems to not run up waiting times beyond a medically justifiable time limit. Although this is generally benefiting to patients, countries could also respond by heightening the indication thresholds to shorten waiting times, as was visible in the Polish cataract case, or to remove certain procedures from the benefit basket altogether.

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The topic of access to domestic private providers is a complex one. It is recognised that in certain countries the directive has created a situation where domestic non-contracted providers are discriminated as patients are able to access services from non-contracted providers abroad and claim reimbursement but are unable to do so within their domestic health system. Quality, equity and sustainability considerations have arisen and as a result Governments have been reluctant to change the nature of their health systems where domestic non-contracted providers are to date excluded. The Polish case stands out as an example where patients may have been negatively affected by the directive and access to certain services is impeded. It seems that strict monitoring of such cases is needed.

This study has attempted to document the domestic impacts that implementation of the cross-border directive has had on seven EU health systems. It is limited to experts providing country reports based mostly on grey literature and national data sources and therefore the findings must be interpreted within these caveats.

5. Conclusion

The overall picture obtained from the reports on implementation of the patients' rights and cross-border care directive in the seven Member States studied is one in which the directive has not had some major transformative effect on domestic health systems. In The Netherlands, Germany and Belgium the domestic health systems already had the required systems in place and as predicted by the goodness of fit framework minimal domestic changes were by and large easily accommodated. Estonia, Finland, Malta and Poland had to introduce certain changes to meet the cross-border care directive requirements, but there is no evidence of leveraging the directive to bring about major changes in the domestic health systems. Indeed the behaviours adopted can better be described in terms of policy inertia and retrenchment.

The introduction of patients' rights legislation, a larger emphasis on transparency and the issue of access to non-contracted domestic providers could all potentially serve to change policies around access to domestic health services in the long run. Some efforts to improve quality in health systems can also be linked to specific initiatives listed in the Directive, e.g. centres of reference and e-health.

We conclude that whilst the directive has triggered the implementation of some measures related to patients' rights, waiting times and quality of care that may intuitively lead to benefits for patients seeking health care in their domestic health systems, to date, evidence showing that patients have actually benefitted from such measures remains scarce and further monitoring over a longer period of time is recommended. In that light, the EU's increased interest in monitoring waiting times across Europe is a good initiative but it could perhaps also be extended to include changes in benefit baskets, tariffs and coverage.

Conflict of interest statement

None.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at https://doi.org/10.1016/j.healthpol.2017.12.010.

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