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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☆

Natasha Azzopardi-Muscat[a,*], Rita Baeten[b], Timo Clemens[c], Triin Habicht[d], Ilmo Keskimäki[e,f], Iwona Kowalska-Bobko[g], Anna Sagan[h], Ewout van Ginneken[i]

[a] Department of Health Services Management, Faculty of Health Science University of Malta, Department of International Health, CAPHRI School for Public Health and Primary Care, Maastricht University, Maastricht, The Netherlands
[b] European Social Observatory (OSE), Belgium
[c] Department of International Health, CAPHRI School for Public Health and Primary Care, Maastricht University, Maastricht, The Netherlands
[d] Ministry of Social Affairs, Tallinn, Estonia
[e] National Institute for Health and Welfare (THL), Department of Health and Social Care Systems, Helsinki, Finland
[f] University of Tampere, Faculty of Social Sciences, Finland
[g] Jagiellonian University, Medical College, Faculty of Health Science, Kraków, Poland
[h] European Observatory on Health Systems and Policies, London School of Economics and Political Science (LSE), UK
[i] European Observatory on Health Systems and Policies, Berlin University of Technology, Germany

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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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* Corresponding author at: Department of Health Services Management, Faculty of Health Sciences, University of Malta, Tal-Qroqq MSD, Msida, 2080, Malta.
E-mail address: Natasha.azzopardi-muscat@um.edu.mt (N. Azzopardi-Muscat).

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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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