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The impact of the EU Directive on patients' rights and cross border health care in Malta[☆]

Natasha Azzopardi-Muscat^{a,b,*}, Christoph Aluttis^a, Kristine Sorensen^a,
Roderick Pace^c, Helmut Brand^a

^a Department of International Health, CAPHRI School for Public Health and Primary Care, Maastricht University, 30 Duboisdomein, Maastricht, The Netherlands

^b Department of Health Services Management, Faculty of Health Sciences, University of Malta c/o MSD 2090 Msida, Malta

^c Institute for European Studies, University of Malta Tal-Qroqq, MSD 2090 Msida, Malta

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ABSTRACT

The patients' rights and cross-border health care directive was implemented in Malta in 2013. Malta's transposition of the directive used the discretionary elements allowable to retain national control on cross-border care to the fullest extent. This paper seeks to analyse the underlying dynamics of this directive on the Maltese health care system through the lens of key health system stakeholders. Thirty-three interviews were conducted. Qualitative content analysis of the interviews reveals six key themes: fear from the potential impact of increased patient mobility, strategies employed for damage control, opportunities exploited for health system reform, moderate enhancement of patients' rights, negligible additional patient mobility and unforeseen health system reforms. The findings indicate that local stakeholders expected the directive to have significant negative effects and adopted measures to minimise these effects. In practice the directive has not affected patient mobility in Malta in the first months following its implementation. Government appears to have instrumentalised the implementation of the directive to implement certain reforms including legislation on patients' rights, a health benefits package and compulsory indemnity insurance. Whilst the Maltese geo-demographic situation precludes automatic generalisation of the conclusions from this case study to other Member States, the findings serve to advance our understanding of the mechanisms through which European legislation on health services is influencing health systems, particularly in small EU Member States.

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Introduction

The patients' rights and cross-border health care directive [1] is a landmark [2] in European health care politics, yet its potential to lead to a widespread impact upon Member States' (MS) health care systems is open to debate [3–6]. The directive deals with people seeking to go abroad for health care on their own initiative as distinct from care that becomes necessary during a temporary visit, care sought by retirees in other countries, care sought across borders in border regions or people sent abroad for care organised by their home systems [7].

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* Corresponding author at: Department of Health Services Management, Faculty of Health Sciences, University of Malta c/o Mater Dei Hospital, MSD 2090 Msida, Malta. Tel.: +356 23401576/79438886.

E-mail addresses: Natasha.azzopardi-muscat@um.edu.mt (N. Azzopardi-Muscat), Christoph.aluttis@maastrichtuniversity.nl (C. Aluttis), Kristine.sorensen@maastrichtuniversity.nl (K. Sorensen), Roderick.pace@um.edu.mt (R. Pace), Helmut.brand@maastrichtuniversity.nl (H. Brand).

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Early non-exhaustive reviews of the implementation of the cross-border directive reveal mixed results [8]. MS with systems that fit less well with EU legislation may be expected to experience larger adaptations [9,10]. MS with national health service type systems would have to undergo more significant changes in order to align their health care systems with the requirements of the cross-border care directive [11–13]. The impact assessment of the Commission's proposal for a directive had highlighted the fact that small MS are [8] likely to face a greater financial impact as a result of cross-border care [14].

In Malta cross-border patient care is mainly based on structured cooperation agreements with the United Kingdom [15], and specific Italian regions [16]. In 2013, 423 patients received organised care overseas, approximately 0.1% of the population [17]. Studies of patient experiences in the national overseas highly specialised care programme have overall revealed a high level of satisfaction [18,19] and the need for an additional type of patient mobility may therefore not feature highly in the Maltese population.

The paper seeks to illustrate how Europeanisation of health care is taking place in a small island EU Member State using the example of the patients' rights and cross border health care directive. Malta's smallness, its 'national health service' type system and long-standing organised cross-border care provides an interesting case study on how the cross-border directive has impacted on its health system. Such case studies are useful for studying European policy processes [20,21] and are applicable in the field of Europeanisation [22]. A brief description of the Maltese health system situates the empirical findings in the appropriate context (see Box 1).

Box 1: Key facts about the Maltese health care system.

Malta acceded to the EU in 2004. It is the smallest MS in the EU with a population of 417,432 and a total land area of 315 km². The publicly funded health care system is the key provider of health services. The private sector complements provision in particular in the area of primary care and ambulatory specialist care. The Ministry is responsible for setting policy and standards, for regulation of public and private health services as well as for funding and direct organisation and delivery of health care. The public health system is funded by general tax revenues. Total health expenditure was 8.7% of Malta's GDP in 2012 of which public spending was only 5.6% of GDP. Sustainability of the health system has become identified as a key challenge and the Maltese health system has come under the scrutiny of the European Semester process. In 2013 and 2014 Malta has received Country Specific Recommendations (CSRs) calling for a comprehensive reform of the health system to improve the efficiency and sustainable use of available resources.

Source – Health Systems in Transition Vol. 16 No. 1 2014; Malta Health System Review available at https://www.ecoi.net/file_upload/1930.1421314107-hit-malta.pdf accessed on 08/03/2015.

Prior to 2013, Government had not implemented the European Court of Justice Rulings on patient mobility and

was found to be in breach of Law by the domestic judicial system [23]. The Health Act [24] and the accompanying regulations on cross-border health care came into force on the 25 October 2013 [25]. The directive presumes the existence of a clear benefits entitlement package as well as a system to determine exactly who is entitled to access cross-border care. The Health Act provides for a formal and transparent mechanism for the establishment of the benefits package as well as a publicly accessible register of treatments and services offered by the public health system. This can be considered as a response to a national Court Case regarding Government's failure to approve public funding of overseas treatment for a joint kidney-pancreas transplant which Government lost case due to the lack of a publicly available health care benefits package [23]. The Health Act also introduces an explicit legal reference to patients' rights for the first time in Malta.

The detailed implementation of the directive occurs through the regulations on cross-border health care [25]. These regulations primarily establish the role and responsibility of the National Contact Point. Domestic private providers are categorically excluded from the scope of the regulations as is the reimbursement of travel and ancillary costs. Emphasis on the obligation to fulfil all clinical and administrative formalities that are used to establish access to services within the Maltese health care system is evident, such as the use of clinical protocols and the need to be referred through the general practitioner gatekeeping system. The regulations also stipulate the ability of the competent authority to limit access to cross-border care in circumstances where the continued provision of high quality domestic care without waste of resources could be threatened. All the provisions in the directive that are listed as possible justifications for a prior authorisation system appear in the Maltese cross-border regulations.

The obligation for all health professionals to have appropriate indemnity insurance appears for the first time in Maltese legislation in the Indemnity Insurance Regulations [26]. The implementation of obligatory indemnity insurance was considered to be an important and sensitive issue [27,28]. Previously, health care professionals were not required to have any form of indemnity insurance in the private sector and therefore this new provision introduced an additional cost for professionals which could be passed on to the patient. In a health care system where 35% of total expenditure takes place primarily through out of pocket payment in the private sector [29], upward pressure on tariffs particularly in primary care may have an important impact. Whilst Government employees were implicitly de facto covered, there was no official legal reference to such cover and the lack of legal certainty was an issue that had been previous raised by trade unions in the health sector.

Methods

The theoretical framework adopted for this study is that of "Europeanisation" and the classic definition by Radaelli [30] of Europeanisation as '*a series of top-down and bottom-up processes affecting both formal and informal rules as well as procedures, policy paradigms, styles and shared beliefs and norms*' is applied.

Table 1

List of interviewees by primary role.

Role	Number of interviewees
Academic	3
Public health civil servant	13
Politician	5
Clinician	3
European Affairs civil servant	4
Industry	1
Civil Society	4
Total	33

Content analysis of verbatim interview transcripts, obtained from thirty-three face-to-face interviews in July and August 2014, was undertaken. A maximal purposeful sampling approach was adopted [21] in order to obtain the viewpoint of diverse health system stakeholders. The sample consisted of senior leaders from public health, civil servants from the Ministries of Health and European Affairs, politicians, senior clinicians and leaders in civil society. The key inclusion criterion was that participants were either in a leadership position in the health care system or European affairs practitioners for several years. Participants were selected on the basis of the role they currently or previously held e.g. Minister, Director, Secretary of Trade Union. Table 1 provides a description of the interviewees' professional background and primary role description. No gender and age disaggregation is given to reduce the risk of identification of the respondents given the small numbers of stakeholders who occupy key positions in the Maltese health care system.

Thirty-five participants were approached through an e-mail by the principal investigator. Two persons declined to participate stating that they did not feel they had the required expertise. Written informed consent for audio recording was obtained prior to the interviews.

The questions were open-ended and asked about the interviewee's beliefs, attitudes and experience regarding their experience of the impact of Malta's EU membership upon the health care system. Further probing was used to gain additional insights on specific topics that respondents mentioned during the interview, including the implementation of the cross-border care directive. The interviews were audio recorded and transcribed in full.

Each interview was coded in parallel by two persons following an inductive approach supported through QSR Nvivo 10. Codes were compared and discussed among the members of the research team while allowance was made for the continued creation of new codes. The stakeholders' perceptions regarding the patients' rights and cross-border directive and its impact on the domestic health system were explored through qualitative content analysis. Thick descriptions of the emerging themes including "cross-border" and "patients' rights" were developed. Key word searches in the transcripts for "cross-border" and "patients' rights" ensured that all relevant statements were identified. Discussion between the research team was carried out until consensus on the themes and their inter-relationships was reached. Permission to carry out this study was sought and obtained from the University Research Ethics Committee (UREC) at the University of Malta.

Results

Seventy-nine "cross-border" and 103 "patients' rights" references were identified in the transcripts. Fig. 1 depicts the results of the study showing how the mechanism of Europeanisation in the form of implementing a directive led to three main impacts according to the interviewees: moderate enhancement of patients' rights, negligible additional patient mobility and unforeseen reform in the domestic health care system. Furthermore, it was possible to identify three main streams of perceptions of emotions and behaviours: fear of the potential impact of increased patient mobility, strategies employed for damage control and the exploitation of opportunities for domestic health system reform. These themes are presented in two main groups as the reported perceptions and behaviour triggered by the directive and the actual early impact of the directive as perceived by the interviewees.

Perceptions and behaviour triggered by the directive

Fear from the potential impact of increased patient mobility

All stakeholders groups, with the exception of civil society representatives, expressed fears about the financial implications associated with the possibility of the directive leading many patients to seek cross-border care. Lengthy waiting lists for cataracts and orthopaedic surgery were the main factors cited for the expected patient exodus.

"The fear was that with our waiting lists – especially in things like cataracts and orthopaedic surgery, we might be facing an exodus of patients trying to make use of the Cross-Border Healthcare." (P17 health civil servant)

Other factors mentioned included the perceived better quality of care in larger Member States and the propensity of Maltese patients to seek care overseas. However several respondents readily equally acknowledged that this much-feared threat had actually not yet materialised and referred to it as a future challenge as exemplified below.

"I think we felt that this (the cross-border directive) could have been very challenging to us because we thought that it might lead to an increase in expenditure which would be difficult to cover given that the Maltese are very keen on going abroad, more than other EU citizens. This has not yet materialised but it was looked at with trepidation" (P4 clinician)

Fear regarding the outward mobility of health care professionals and the potential loss of patients manifesting specific diseases since the decrease in patient volume could have a subsequent negative impact on clinical expertise, was an important theme mentioned in the small country context.

"I think the big risk, in my opinion, is the outward mobility of expertise and loss of pathology" (P5 health civil servant)

On the other hand the potential influx of patients into the domestic health system was mentioned as a key concern by a minority of respondents.

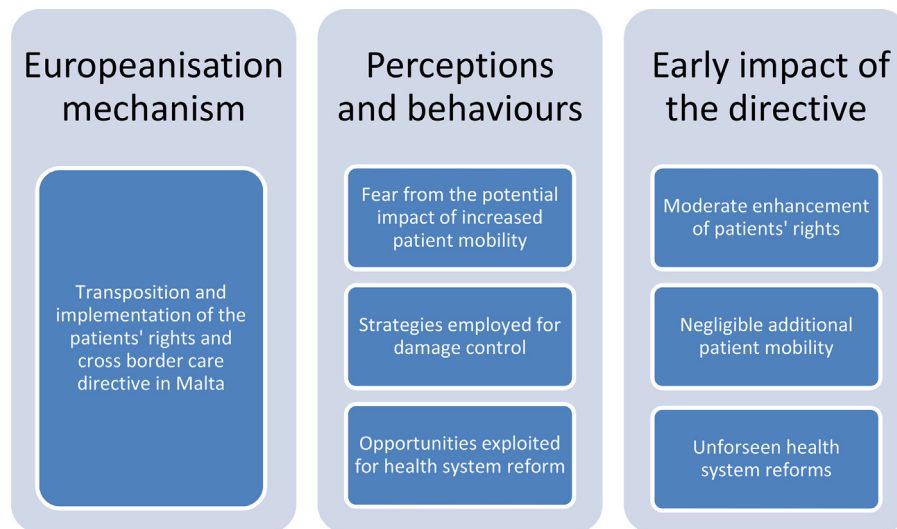


Fig. 1. The impact of the patients' rights and cross border care directive on the Maltese health care system.

"From a service provision side perspective, there is a possibility of seeing a surge of the patients who may use our healthcare system because it is reputed to be quite a good healthcare system." (P24 health civil servant)

Strategies employed for damage control

Civil servants dominantly contributed to the theme of "damage control" which appears to have prevailed as an established approach from the early days of lobbying efforts. Reportedly, attempts were made to modify the Commission's proposal for the directive, by for example, ensuring that prior authorisation, not initially included in the proposal, was eventually inserted in the text.

"The way in which the cross border directive itself was starting to move, for example, first prior authorisation was not included and then eventually it did get into the text." (P13 health civil servant)

This "damage control" behavioural approach to counteract the expected patient outflows is believed to have prevailed during the transposition and implementation process. Civil servants attribute the application of such restrictions to the observation that no sudden patient outflows were actually experienced.

"I think the way it was transposed, the way it was applied locally – ensured that till now the expected exodus didn't happen. ...we have not been able to exploit cross-border health care but we have been more focussed on the damage control agenda at this point." (P17 MoH civil servant)

Several civil society representatives report that Government carried out a minimalist, correct implementation without actively encouraging patients to make use of their rights as exemplified by the two excerpts below.

"The Government is trying to act according to the policy but actually not enforcing it, not encouraging them to seek cross border care and the public is not that fully aware to go search for these things" (P16 civil society)

"Hopefully we will soon have a full transposition in practice, because in theory, we have it, but in practice we have to see" (P19 politician)

Opportunities exploited for health system reform

All stakeholder groups generally perceive the directive as a turning point because Governments came under pressure from the EU to provide their citizens with good health care.

"The Cross Border Directive has basically got us to look into the way we provide health services." (P21 European affairs practitioner)

Some civil servants and clinicians viewed the directive as an attempt by the European Commission to introduce a minimum level or standard of health care in all MS.

"Now, in the name of having the same standards everywhere, they (the European Commission) could introduce a minimum level or standard in all Member States." (P7 health civil servant)

For several stakeholders the directive was perceived to be instrumental in introducing legislation which had been repeatedly postponed.

"I think it is the Health Bill. We have just seen it happen. It had been for I don't know how long for, but it was a Parliament point on their agenda, which had been postponed, but as soon as the Cross Border Healthcare Directive came into force, the bill was implemented." (P28 civil society representative)

A public health civil servant also contended that the directive served as an impetus to enact legislation on the organisation and governance of the departments within the Ministry for Health.

"The healthcare act wouldn't have been implemented if it were not for the cross-border directive. However not all the reforms in the Health Act were directly related to the

Directive. I'd say that part of the content of the Health Act, is purely related to national matters for example, the organisational structure is not imposed by the EU. So the Health Act was pushed because of the EU Directive deadline but we managed to include strictly national issues" (P5 health civil servant)

Perceived impact of the implementation of the patients' rights and cross border health directive

Unforeseen health system reforms

Generally civil society representatives felt that the cross-border directive raised awareness on the manner in which the EU can impact the health system.

"Civil society organisations think that the EU will never influence the way we think and give advice because of the famous myth that has been amplified and disseminated, that is, EU accession will not affect our national health system. But we know that due to the directive, policies, legislation, even guidelines—we will be affected. Now we have been feeling and living it especially after the implementation of the cross-border directive" (P28 civil society)

Amongst civil servants the reform of the entitlement system and the introduction of a health care package are mentioned as important indirect outcomes of the directive's implementation. Entitlement became important for fear of having to refund someone for costly treatment overseas when that person was not even entitled to coverage under the Maltese health system.

"The entitlement issue became important because you have to determine who is entitled in Malta, and the health care package, where we started to determine what services we can offer clearly to our clients was introduced." (P5 health civil servant)

The introduction of professional indemnity insurance where the directive is believed to have played a determining role in ensuring compulsory indemnity insurance for all health care professionals was mentioned as an important outcome by several stakeholders as captured in the excerpts below.

"The cross-border directive led us to the application of better standards, like the Indemnity issue. We wouldn't have introduced the indemnity issue had there not been the EU directive for sure. . ." (P7 health civil servant)

"We had the success story of the professional indemnity coverage of professionals. We knew that it was a very small paragraph in the cross-border healthcare directive. . . as soon as we saw it we started working on it as an organisation." (P28 civil society)

The directive reportedly created a greater awareness of medico-legal issues and according to a health civil servant acted as a powerful stimulus to provoke changes in practice such as in the prescription and dispensing of medicines where enforcement had been an outstanding problem.

For all stakeholder groups, the directive is considered as a force that will place pressure on the domestic health services and lead to tangible patient benefits, if properly

applied, going farther than the original notion of laying down rules for patient mobility and having future effects on the Maltese health system as stated clearly by a politician.

"My idea of the Cross-Border Directive is not so much the rights that it introduces in terms of people seeking treatment abroad but the inherent pressure on the local authorities to give a better service to Maltese citizens in order to prevent them arriving at the stage when they need to use the Cross-Border Directive. I always looked at EU legislation broadly, including the Cross-Border Directive, as a force that applies pressure on us to change (P18 politician)."

Moderate enhancement of patients' rights

Most interviewees felt that the directive provided the impetus for patients' rights legislation to be enacted and strongly doubted whether this legislation would have been implemented without the need to comply with the EU requirement.

"I don't think this question of patients' rights, for example, would have ever materialised had it not been because we needed to comply with EU legislation." (P26 clinician)

A civil society representative mentioned that Maltese patients are very passive when compared to their European counterparts. The externally-pushed obligation for legislation on patients' rights to be adopted in a system that was not culturally ready seems to have led to a situation where although the legislative framework was adopted, most stakeholders were sceptical since patients still lack empowerment and very little has been done on issues of compensation and redress as strongly voiced by a senior health civil servant.

"We are failing on patients' rights we are not sensitive enough to patients' rights even though we may have them written on paper they are not at all respected in practice." (P13 health civil servant)

Negligible additional patient mobility

Finally there was broad consensus around the fact that the directive to date has not had a real impact on patient mobility with free movement of patients still being 'embryonic' (P24 health civil servant). The lack of information and the gap between patients' expectations and what is possible in practice were mentioned as two key barriers. A health civil servant remarked that patients may have been given the impression that they have a right to every treatment that exists in the European Union countries when in practice there are several restrictions on what is covered and reimbursed.

"I don't think that people understand it very well yet. They think that they can go abroad, get their service and come back. In reality, there are restrictions, it is not so open" (P7 health civil servant)

Furthermore an EU affairs practitioner observed that the EU patient mobility framework could be reformed to make it more patient friendly.

An academic raised the concern that patient mobility is for people who have money and described it as ‘*somewhat of a dream*’ (P1 academic).

The fact that patients only have a right to be reimbursed the local cost of the intervention is considered to be a major barrier by several stakeholders. This is well described by a politician.

“Maltese patients are at a very big disadvantage because they have to pay for their airfare and they only get refunded what the operation costs in Malta. This brings inequity between Maltese patients and patients in other European countries”. (P25 politician)

In conclusion some interviewees, mostly civil servants, believe that the impact will be minimal, particularly if issues such as waiting lists are addressed.

“Personally I do not think it will be a big impact if we take steps to sort out certain health system issues” (P13 health civil servant)

“I think that the Maltese people are very territorial and have a very high opinion of our healthcare services. So only very few would opt, in my opinion, to seek treatment abroad, in those cases where they can’t have it here in Malta (P24 health civil servant)

On the other hand other stakeholders believe that the directive will have a greater impact in future.

“I mean, it is a bit early but I think in the long run we will start seeing the impact in different areas of health provision (P21 EU affairs practitioner).

“I still believe that it is going to be a challenge but it will not be a challenge just for Malta, it will be a challenge for a lot of European countries. Pleasures yet to come...” (P3 politician)

Discussion

This study has sought to analyse how the implementation of the cross-border directive has impacted upon the Maltese health care system. It has demonstrated how Europeanisation is occurring in health systems through a two-way relationship between EU level instruments and domestic actors embedded in their culture and context. Several key lessons emerge from this case study. Firstly, a high level of anticipated negative impact led to a restrictive approach which was taken to limit patient mobility. This in turn resulted in minimal utilisation of the rights bestowed by the directive with regards to cross-border care. The extensive use of prior authorisation and the decision to exclude private domestic providers from the local legislation are examples of such controls. Secondly, the directive was viewed as having potentially positive implications as a welcome external force for change on issues such as patients’ rights, standards of care, transparency and governance within the health system. Finally, in line with Legido-Quigley et al. [31], it was shown how contextual and cultural issues may greatly influence the legacy that specific directives have.

Despite the fact that the Maltese reported the highest rate of willingness to seek cross-border healthcare services at 78% in 2015 [32], this figure remained relatively stable since 2007, (82%) [33] with the early impact of the patients’ rights and cross-border healthcare directive on the Maltese health system appearing to be limited in terms of patient mobility. The relatively high degree of satisfaction with the local health care system (94%) [34] and the existence of well-established alternative referral channels for care overseas [15,18], may have contributed to this minimal impact. The lack of active information dissemination and the controlling manner in which the directive was implemented were also perceived as being of critical importance in preventing the much-feared patient exodus.

Whilst the implementation of systems and mechanisms to facilitate cross-border care as set out in the directive demonstrate the phenomenon of “downloading” [10] where the MS has to comply with the EU, this study has also illustrated how implementation of the directive could be having a broader effect on domestic health services policy in terms of compliance, opportunism and usage of Europe [5,35,36]. Policy makers appear to have acted as norm entrepreneurs in the case of the legislation on patients’ rights, clarification of entitlement and indemnity insurance with the directive giving them added strength to argue for implementation. The study provides an example of the ‘bounded rationality’ theory [35,37] where policy makers may have not taken a holistic approach to the directive and chose to concentrate on instrumentalising the directive to bring about long-overdue structural reforms in the domestic health system whilst taking steps to mitigate against the anticipated negative financial and public health impact [37]. Similar developments could be observed in other small countries. In Latvia and Luxembourg [38,39] for example, the directive also reportedly provided an opportunity to set up a legal framework for patients’ rights and appears to have provided the opportunity for obligatory professional indemnity insurance to be introduced for health care professionals other than doctors specifically in Luxembourg [39].

The study has certain limitations. Whereas a careful selection took place to ensure a broad range of participants among decision-makers in health, patient representatives were not included. The results derived from the study are closely associated with the Maltese health care system’s unique features including the geo-demographic conditions and long tradition of organised cross-border referrals for highly specialised care. It is therefore acknowledged that the findings may not be easily generalisable to other contexts.

Nonetheless, the dynamics discussed here are ones that could be reasonably expected to be visible in other countries. Hence, comparative analysis of stakeholder perspectives using a Europeanisation perspective from different Member States should be carried out to obtain a picture of the real impact of the directive on the various health systems. Such studies could be important to further elucidate prevailing gaps in service provision and inequalities between the different regions in Europe which the current directive has so far failed to address. Observations

obtained from the grassroots key actors within domestic health systems could lead to useful research that may inform future steps for a genuine European cross-border health policy. This would be grounded in public health needs assessment as opposed to political ideology and legal imperatives. Close monitoring of the unfolding impact of the directive across the EU is warranted.

Conclusion

This study has provided an insight into the implementation of the patients' rights and cross border directive and its early outcomes, as observed through the lens of a small EU Member State with a long-standing tradition of organised cross-border health collaboration. It has illustrated how Europeanisation of health systems through this seminal legislation on health services has occurred through both passive downloading and active utilisation of the EU rules. The indication is that the impact of the Directive in terms of additional patient mobility will be minimal and the Directive is more important in terms of the domestic health system changes it has triggered.

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