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The transposition of the Patients' Rights Directive in Finland—Difficulties encountered☆

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ABSTRACT

The Directive on the application on patient rights' in cross-border healthcare (2011/24/EC) was transposed in Finland by the Act on Cross-Border Health Care (1201/2013), which entered into force on 1 January 2014.

A new reimbursement model for cross-border health care costs was designed. The Finnish legislator considered the chosen reimbursement model to correspond both with the aims of the Directive as well as to the functioning of the national health care scheme. The European Commission, however, initiated the first infringement procedure against Finland already in January 2014.

In spring 2015, the Government launched a Regional government, health and social services reform, which would fundamentally transform the organizing, production and financing of health care services in Finland. Consequently a Government bill (HE 68/2017 vp) to change the existing reimbursement model for cross-border health care costs was delivered to the Parliament on 1 June 2017.

In this article, Finland's implementation process of the Directive is reviewed. Special attention is drawn to the argumentation concerning the reimbursements of cross-border health care costs. The differences of views on reimbursements can generally illustrate the conflicting objectives to expand access to cross-border health care services and to ensure financial sustainability of states thereof.

1. Introduction

The European Union (later *EU*) Directive on the application on patients' rights in cross-border health care (2011/24/EC, later *Patients' Rights Directive, PRD* [1]) was aimed to codify the rulings of the Court of Justice of the European Union (later *CJEU*) on reimbursements in situations where a patient has used health care services abroad. According to the PRD, the costs of cross-border health care shall be reimbursed up to the level of costs, had this health care been provided in the territory of the state responsible for the reimbursements. The reimbursement shall not exceed the actual costs of health care received. The transposition of the PRD has faced challenges of various kinds in many European states ([2–6]; see also [7], 377). Kattelus [8] has described Finland's implementation from the viewpoint of the realization of individual patients' rights. She noted that the new reimbursement model for cross-border health care costs could be questionable in light of EU legislation.

The principles of the PRD were not difficult for the Finnish decision makers to accept, as they were principally already endorsed by Finnish legislation. But due to a twofold Finnish health care system, the most difficult provision in the PRD's transposition was the level of reimbursements. The risk of illness is covered by both statutory residence and statutory insurance-based systems. There are universal public health care services available for the permanent residents of a municipality [9], and statutory client fees are collected for the use of these services. The actual costs of public health care vary between municipalities, and these are covered primarily by tax-funds. All residents of Finland are also covered by the statutory health insurance, from which the use of private health care services is reimbursed [10]. The material scope of reimbursements is enacted in the legislation, but the reimbursement levels are low in real value ([11,12], 93–115).

The Parliament of Finland enacted a new Act on Cross-Border Health Care (1201/2013, later *the Act*), which entered into force on 1 January 2014 (Fig. 1). The solution for the cross-border health

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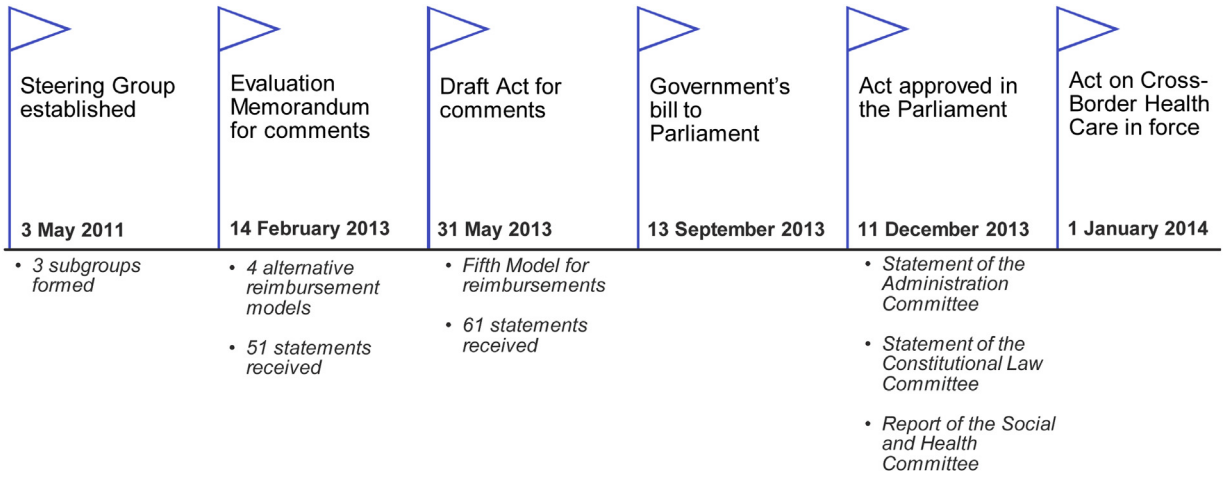

Fig. 1. The implementation process in Finland, 2011–2013.

care reimbursements was twofold. The key of the new model was, to clarify the circumstances of a patient's use of health care services abroad, and then to conduct the reimbursements as if the patient had used either public or private health care services in Finland. Hence, in different situations, the patient would receive a reimbursement either up to the cost level of equivalent medical care in Finnish public health care or a health insurance reimbursement ([13], 54–56).

Due to the reimbursement model, the European Commission (later *Commission*) has indicated doubts towards Finland's implementation. The Commission has initiated infringement procedures. It considers that patients treated abroad should, in all cases, be reimbursed according to the costs of Finland's public health care scheme (Fig. 2).

2. Implementation process

The Finnish Government raised already in 2008 the question on cross-border health care reimbursements, when it informed the Parliament of Finland on the PRD proposal: "*. . . the question to be solved nationally, which authority will reimburse the care obtained in another EU country according to the Directive. . . . nationally a solution should be chosen that would be most advantageous to the patient. In practice this would mean a reimbursement level corresponding to the health care services organized by a municipality. . . .*" ([14]; see also [15,16]). The Grand Committee of the Parliament, however, expressed differing views. It examined reimbursements from the viewpoint of the Finnish health care and health insurance system. The Committee considered it very problematic, if the Directive were to be interpreted to mean that patients should not carry more cost responsibility for health care costs incurred abroad compared to the use of municipal health care services at home [17,18].

In May 2011 a steering group, which consisted of authorities, organisers and providers of health services as well non-governmental organisations, was established to prepare the transposition of the PRD [19]. The provisions that concerned patient rights, judicial proceedings, insurance against treatment injury, recognition and use of foreign prescriptions as well as foreign patients' access to Finnish health services were not seen as problematic. But questions on how to define publicly financed health services and how to reimburse the costs of planned medical care, were from an early stage recognized as the most difficult questions to be resolved ([8], 32; [20], 72–75, 84). The puzzle was how to execute the implementation respecting both the EU rules and the national twofold statutory health care system.

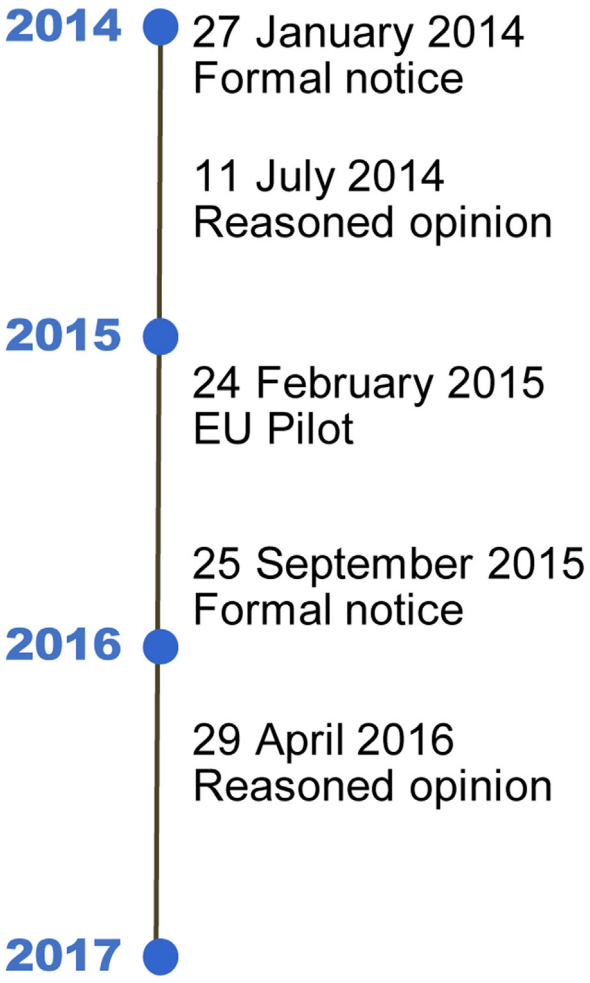

Fig. 2. Infringement and other procedures by the European Commission [29,53,36].

Altogether, five different alternative proposals for the implementation were designed (Table 1). The proposals differed primarily relative to reimbursements: the reimbursement rates, the gatekeeper mechanisms, responsibility of reimbursement costs and the use of prior authorisation ([13], 43–58).

In winter 2013, an evaluation memorandum [21], consisting of models 1–4, was delivered for consultation to multiple stakeholders, such as municipalities, hospital districts, state authorities,

Table 1
Alternative proposals for the PRD's transposition in 2013.

	Model 1	Model 2	Model 3	Model 4	Model 5
Reimbursements					
(i) on the basis of municipal public health care costs	x		x	x	x
(ii) health insurance reimbursements as when used private health care in Finland		x	x	x	x
Use of Directive's prior authorisation				x	
Responsibility for reimbursement costs					
municipality	x		x	x	x
health insurance fund		x	x	x	x
state	x	x	x	x	x

private health care providers, patients' organisations and unions. The proposals' main differences consisted of the reimbursement levels, the utilization of the PRD's prior authorisation and cost-responsibility. A wide number of the 51 respondents expressed concerns on all four models and demanded further discussions. It was noted that the proposals could be evaluated and discussed from multiple viewpoints, such as equality, patients' share of costs, cost-responsibility as well as industrial, social and health policy, but there was no obvious majority on behalf of any of the models [19].

In spring 2013 the discussions continued and a new proposal, the so-called *Fifth Model*, was designed. The key of the *Fifth Model* was not to bind reimbursements to the status of the health care service provider, but to provide reimbursements based on a patient's reason to use services abroad. According to this proposal, reimbursements would be carried out based on a consideration whether the patient would have used public or private health care services in Finland. Firstly, if the patient had fallen acutely ill abroad or had received a prior authorisation on the basis of EC Regulation 883/2004 [22] on coordination of social security systems, the administrative mechanisms of this regulation should apply. Had the patient paid actual costs, the patient would be entitled to a reimbursement equivalent to the costs of the corresponding medical care provided by Finland's public health care sector. Secondly, if the patients freely and on their own initiative chose not to use the Finnish public health care services, but favoured another health care service provider in Finland or abroad, health insurance reimbursements were administered [13].

A draft Government bill [23] was delivered for consultation in May 2013 to multiple stakeholders. The respondents provided altogether 61 statements. The *Fifth Model* was extensively supported. Cost containment and equal treatment of health care service providers in Finland and abroad were seen by the majority of respondents as the advantages of this model. The model would also increase the reimbursement levels for urgent medical care. The relatively low level of planned medical care reimbursements and the laborious administrative handling process of reimbursement applications, however, were described problematic. The majority of respondents recognised also the model's inability to increase patients' freedom of choice and equal opportunity of access in cross-border health care. The reimbursement model was, nevertheless, considered by the respondents' extensive majority an acceptable compromise in reforming and adapting the national health care system [19].

The Government delivered a proposal for the Act [13] to the Parliament of Finland on 13 September 2013 on the basis of the *Fifth Model*. It regarded the proposed reimbursement model to best correspond to Finland's statutory residence and insurance-based health care schemes, as well as, with some reservations, to EU rules. In the bill, however, the Government highlighted the judicial questions on free movement of patients and services that should be examined in the light of EU rules. The Government also recommended that a statement of the Constitutional Law Committee of the Parliament was requested [13].

3. Enactment and deliberation in 2013–2016

The Administration Committee of the Parliament acknowledged the Government's considerations on both public and private health care in the design of the proposed law. The Committee considered the proposed reimbursement model just for the private health care service providers in Finland. Due the low level of health insurance reimbursements it thus considered that the model could be partially problematic in terms of patient mobility [24]. The Constitutional Law Committee stated that: "*. . .planned medical care costs are reimbursed principally similarly as they are reimbursed domestically. . . . The proposed provisions are neutral in the sense that reimbursements for care and travel costs are calculated on the same basis for all . . . and the reimbursement system is the same as for domestic costs occurred. . . .*" ([25], 3–4). The Social Affairs and Health Committee stressed the importance to develop a national health care system to decrease patients' demand for planned medical care abroad. It also considered the presented reimbursement model the best [26].

The Act was approved on 11 December 2013, and it came into force on 1 January 2014 [27,28]. The Commission sent a letter of formal notice in January 2014 and then a reasoned opinion in July on the partial transposition of the PRD. Finland's full transposition was confirmed only in September 2014, as the legislative process continued longer in the autonomous Åland Islands [29–31].

In February 2015, the Commission approached Finland by using an informal dialogue called the EU Pilot inquiry to receive information on reimbursements. Finland answered in May, highlighting the particularities of the Finnish social security and health care systems, client fees and health insurance reimbursements. The Finnish Government stressed that the enacted reimbursement model followed its national system, which safeguards equal treatment for patients and service providers in both national and in cross-border situations [32,33].

In a letter of formal notice in September 2015, the Commission again viewed Finland's reimbursement model unsatisfactory. According to the Commission, patients treated abroad should be reimbursed according to the costs of the municipal public health care scheme. In its reply in November 2015, Finland denied the Commission's views emphasising that as health care systems are not harmonised in the EU, the implementation should be made in line with the special characteristics of each country [34]. These views were echoed in the Commission's reasoned opinion in April 2016 and in Finland's reply in June 2016 [35,36]. At the time of the writing this article, there has not been closure for these infringement procedures.

4. Proposed national health care reform

The Finnish population is ageing and their health and social care service demands are increasing. Furthermore, socio-economic inequalities in health and wellbeing remain high in Finland [37]. It has been widely recognised that the country's health and social care system requires reforming due to problems of accessing the

Table 2
Alternative proposals for the cross-border health care reimbursements after the reform.

	Model 1	Model 2	Model 3	Model 4
Reimbursements				
(i) on the basis of statutory health services' costs	x		x	x
(ii) up to the level of treatment country		x	x	x
Use of Directive's prior authorisation			x	
Responsibility for reimbursement costs				
county	x	x	x	x
health insurance fund				
state	x	x	x	x

public primary health care services and due to the rising costs of social and health care services. The twofold health care system as well as the inefficiencies and suboptimization caused by the multi-channelled funding are considered as partial root causes for these problems ([38], 18–20).

The current ongoing governmental *Regional government, health and social services reform* aims to establish 18 new counties that would be responsible for organising and financing the services. If the reform is accepted, fundamental changes in the Finnish health care system will materialize. Furthermore, on 5 December 2018 the Finnish Government delivered a bill to abolish the health insurance reimbursements from 1 January 2023 [39]. At the time of writing this article, the Parliament of Finland is yet processing these bills.

In line with the reform proposals, alternative new reimbursement models for cross-border health care were considered. The basis in all models was that (i) the health care in question belonged to the Finnish health care service basket, (ii) the patient was always liable for statutory client-fee costs and (iii) the patient's home county was liable for the reimbursements' costs. Four alternative reimbursement models were considered (Table 2). These models differed again in terms of reimbursement levels, utilization of the PRD's prior authorisation and cost-responsibility.

The Government favoured model 4, the so-called *Gatekeeping Model,* which entitled the patient to receive reimbursements of primary health care services without any additional requirements. For secondary and tertiary health care services, the patient was entitled to reimbursements, if the patient's necessity for medical care was medically assessed *ex ante* or *ex post* by a county's public utility in Finland or by an equivalent medical professional abroad. The amount of reimbursement was always either the cost of equivalent health care provided in the patient's home county or, at maximum, the total cost paid by the patient. The utilization of the PRD's prior authorisation was not endorsed.

In March 2017 a draft bill was delivered for consultation [40], and subsequently a Government's proposal was delivered to the Parliament of Finland on 1 June 2017 [41]. The Parliament commenced a first plenum discussion on 6 June 2017, but at the time of the writing of this article, the proceedings in the Parliament are unfinished.

5. Discussion

Health care systems are not harmonised in the EU, but the PRD nonetheless introduced provisions for transposition touching upon the very foundations of national health care systems, such as access, organising and financing. The Directive enables individuals to use such health services that they have not participated in constructing financially e.g. by paying contributions or taxes. On the other hand, the Directive also obliges the EU states to refund such service costs, whose cost development and pricing are outside their powers. The Commissioner for Health and Consumer Policy in 2011 stated: "*The Directive will benefit patients across Europe by clarifying their rights to access safe and good quality treatment across EU borders, and be reimbursed for it.*" [42]. But it can be debated, whether the Directive achieves these aims on its own right or whether it does it at the expense of others, such as those who pay contributions for the statutory systems and never use cross-border services ([43], 107; see also [44]).

As Vollaard and Sindbejerg Martinsen ([45], 337–351) highlight, the EU was not, before the Maastricht Treaty in 1993, expected to interfere in issues of health care systems, nor did it have the powers to do so. But since then, continuous developments in EU health policy law have taken place. The case law of the ECJ on competition rules, as well as the consumeristic EU rules on health services, are naturally applicable in all EU states, but not entirely without friction (see also [46], 141–142; [43], 172–173, 184–186, 204–210). As Tuori ([47], 376) highlights the EU does not founded on any particular social or health policy, but merely treats these policies as subordinates to competition and internal market rules.

Additionally, the demand to balance public finances has appeared to be high on the agenda of many EU states, also in Finland, and this process thus has implications on the organising and financing of national health care systems ([46], 132; [48], 1–2, 11–12; see also [49], 10–11). Financial savings were not an outspoken aim of the Finnish Government in the PRD's transposition. The Finnish legislator decided to treat health insured persons equally, had they used health care services in Finland or abroad. Cost-containment of public expenses and health expenditure prevailed high on the Finnish political agenda, and thus the economic and commercial impacts of alternative law proposals received conscious evaluation. Consequently, the legislator ensured that private health care service providers in Finland were not disadvantaged. In the aftermaths of the EU's financial crisis and in times of austerity policy, the increase in EU-wide availability of health care services is a challenge to national decision making. The PRD can be perceived also as an illustration of the EU's governance, which expands from common internal market and economic policies to the fiscal policies of EU states ([50], 376, 380–381; [51], 13, 17–22).

Finland's difficulties encountered leads to having to consider the possible incongruity between the PRD's transposition and the TFEU Article 168(7) point 7, which ensures that "*Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care.*". It appears that the implementation of the EU rules on patient mobility trigger changes not only in the delivery of benefits, but also call for compulsive fundamental changes to national social security systems. However, a full recognition shall be ascribed to the CJEU ruling on case C-255/09 [52] where "*the Court has held that Article* [168(7)] *does not exclude the possibility that the Member States may be required under other Treaty provisions, such as Article* [56]*, to make adjustments to their national systems of social security, but that it does not follow that this undermines their sovereign powers in the field.*" Therefore, one prediction is that we will witness an accelerating debate on where the balance between the national decision makers' right to decide upon national social security system remain and what can rightly be assumed as "adjustments".

6. Conclusions

During the past decades the EU's policy on cross-border health care has evolved through various CJEU rulings. Simultaneously the evolutions of the EU's internal market and competition law have considerably impacted EU states' social security systems ([49], 13–16). The Special Eurobarometer data revealed in 2015 that the use of health care services abroad is a rare occasion in Europe, and Europeans are not eager to travel to purchase planned medical care in another country [53]. Continued discussion is therefore important in order to identify, what aims and means are appropriate and desirable for EU's policy on cross-border health care.

Conflict of interest statement

The first author was an Expert Secretary of the Steering Group responsible for the transposition of the Patient Directive in Finland in the years 2011–2013 and was closely involved in the law-drafting process of the national Act on Cross-Border Health Care (1201/2013). At the time she worked in the Finnish Ministry of Social Affairs and Health as well as in the Social Insurance Institution of Finland. At present she holds an office in the Finnish Ministry of Finance.

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