

Closing Gaps, Stimulating Health Equity: EPHA Report on the Implementation of the Cross-border Healthcare Directive

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Introduction

This report examines the current status of cross-border healthcare in the EU and the implementation of the Directive on patients' rights in cross-border healthcare (Directive 2011/24/EU), which Member States were required to transpose into national law by 25 October 2013. The analysis is based on the findings of the implementation report released by the European Commission's Directorate-General for Health and Food Safety (DG SANTE) in September 2015.¹

The EPHA report serves to highlight aspects where implementation is lacking and/or would need further improvement in order to fulfil the objectives of the law, which includes facilitating access to safe and high quality cross-border healthcare and promoting cooperation on healthcare between Member States (without restricting national health competences). It also explores how current cross-border healthcare provisions could be reshaped in order for the Directive to better support the principles (universality, access to good quality care, equity and solidarity) Member States are meant to take into account in cross-border healthcare.²

The Cross-border Healthcare Directive

In 2011 the EU adopted legislation to clarify the rights of patients to seek reimbursement when travelling abroad for the purpose of receiving healthcare treatments (Directive 2011/24/EU). This legal framework was necessitated by a series of case laws between the late 1990s and mid-2000s in which the Court of Justice of the EU (CJEU) ruled that health was not excluded from the internal market for services and that EU citizens therefore have the right, in certain circumstances, to receive healthcare in another member state covered by insurance provided by their home country.

The Directive makes clear that health treatment falls firmly within the scope of the internal market. The Directive states that patients have the right to reimbursement when receiving care abroad, up to the value which the same care would have cost in their home health system. Crucially, health systems may not require patients to obtain prior authorisation

¹ COM (2015) 421 final

² See DIR 2011/24/EU, Art. 4, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:en:PDF>



before seeking treatment abroad, unless the intended treatment is highly specialised and cost intensive, or involves an overnight stay in hospital. In these cases, authorisation may only be refused if the same treatment can be received at home without 'undue delay' - however, the concept of undue delay is not adequately defined in the legislation.

Likewise, the Directive has no intention of encouraging patients to seek treatment abroad. Instead, it is mainly designed to help avoid long waiting times for specific treatments or to satisfy unmet medical needs (e.g. dental care). Moreover, the Directive complements other cross-border arrangements between Member States (e.g. bilateral or multilateral agreements between countries and border regions) and EU level provisions such as the European Health Insurance Card (for health problems during temporary travel in another MS state).

In addition to enumerating the rights of patients, the Directive aims to improve the provision of information about receiving healthcare abroad, most notably by setting up National Contact Points (NCPs). These provide outgoing patients with information about their rights, entitlements, reimbursement and appeal processes and incoming patients with information about quality, safety, complaints and redress procedures.

Moreover, the Directive establishes the so-called European Reference Networks (ERNs), comprised of healthcare providers and centres of expertise and designed to facilitate the sharing of information and knowledge on specialised care and rare diseases. The first such networks are expected to be approved by the Board of Member States in 2016.

Results of the European Commission Report on the Operation of the Directive

The Commission released its first report on the operation of the Directive in September 2015. According to Article 20(1) of the Directive, it is required to draw up such a report every three years. The first report highlights a number of implementation gaps that seem to suggest that some Member States appear to be deliberately complicating cross-border healthcare processes for patients.

For example, among the demanding obstacles patients need to overcome in order to claim their cross-border healthcare rights feature the requirement of some Member States to demonstrate why it is medically necessary for the intervention to be received abroad, the obligation to receive specialist referral in the country of affiliation (rather than in the country of treatment), and requests to obtain sworn translations of invoices issued by embassies abroad.

In addition, the statutory 'baskets of benefits' patients are entitled to in their home countries more or less determine the range and quality of offers they may receive abroad. This spells a problem for new modes of healthcare delivery such as telemedicine, which, as a sub-category of eHealth, relies on remote service provision and interoperability.

Transposition

Regarding the state of play of the transposition process, on 1 July 2015 four infringement proceedings against Member States remained open, however all countries involved have committed to rectify the problems.



In 2014, there were roughly 40,000 requests for cross-border reimbursements among the 20 countries that reported data. Denmark topped the list with about 30,000 claims, followed by France and Luxembourg, all three wealthy EU countries with generous health and social security systems. In terms of transparency, the incompleteness of data noted in the Commission report raises doubts about Member States' transposition and data collection efforts.

From a health equity perspective, it is worrying that richer Member States cover cross-border treatments more readily than their poorer neighbours. The Commission report also found that three countries are calculating reimbursements based on costs borne by private or non-contracted providers, which reduces payments to patients as their rates are lower than those of public or contracted providers.

Regarding transparency about patients' rights, it is also deplorable that patients themselves have yet to feel or even be aware of the rights and entitlements the Directive could offer them. Fewer than 20% of patients feel they are informed about their cross-border healthcare rights, and the National Contact Points (NCPs) are only known to about 10% across the EU. More worryingly, there are significant divergences when it comes to the performance of the NCPs and the information patients are able to receive on health and safety provisions in other Member States.

Already in March 2015, DG SANTE released an Evaluative Study that found that the number of patients making use of cross-border services under the Directive remains low and that analysed three main aspects of cross-border care: reimbursement, quality and safety, and undue delay.³

In terms of reimbursement, where the NCPs are asked to provide assistance the information available is deemed to be satisfactory and the study identifies no specific problems with reimbursement procedures. However, the burden on insurers and health system administrators remains a point of concern, even though the number of applications for reimbursement is currently low.

As regards quality and safety, the study finds that concerns about standards – either at home or in the intended country of treatment – are not core drivers in patients' decisions to seek care abroad. However, the information provided by NCPs in this area is often not comprehensive and hampered by differing procedures and indicators in the national evaluations of quality and safety upon which it relies.

Finally, the study establishes that the different elements of the health system (e.g., insurers, providers) share a common understanding of 'undue delay' in waiting times – this is easily compared across countries and large discrepancies are found to exist. However, they do not share a common approach to gathering, publishing and utilising waiting time data. Standardised acceptable waiting times are only applied in Denmark and the Netherlands, with other countries assessing on an individual basis.

The study notes that it is too early to draw concrete conclusions about the implementation and impact of the Directive, since Member States are not yet collecting adequate data about patient inflows and outflows. However, on the basis of available information, it finds that knowledge-sharing between NCPs and relevant authorities is

³ http://ec.europa.eu/health/cross_border_care/docs/2015_evaluative_study_frep_en.pdf



improving and that awareness amongst health professionals is rising, though uptake by patients remains low.

Key issues and concerns

There remain a number of concerns about access to cross-border healthcare in practice, as outlined in EPHA's briefing on the Directive.

In particular, its impact upon health inequalities, increased bureaucracy, oversubscription of health systems, continuity of care and increased demand on healthcare professionals was questioned. Though low uptake has limited the potential impact of the legislation, experiences to date have done little to assuage the concerns of patient groups and health advocates. Ongoing cuts to healthcare budgets across many Member States, combined with slowly increasing patient awareness of the possibility to receive care abroad, makes it ever more urgent to tackle these concerns pre-emptively.

Cost, reimbursement and bureaucracy

EU Health Commissioner, Vytenis Andriukaitis has been quoted stating that the different administrative systems, costing frameworks and reimbursement policies employed by Member States were hampering the system.⁴ Some countries have been charging incoming patients at the higher level set for private treatment, whilst others will only reimburse outgoing patients at the lower level set for public care. The procedures and administrative requirements for reimbursement are, in some cases, extremely complex and are putting patients off seeking care abroad. Burdensome administrative requirements are also problematic for hospitals and health system managers and, should awareness and uptake of cross-border services increase, cumbersome bureaucratic procedures may become an even more prominent barrier.

The Directive might prove to have a positive impact in the transparency and comparability of data on health systems. The NCPs gather vital data from national health systems, which might otherwise not have been readily available to patients, and present it in a way which should facilitate comparison. In line with the Commission's work in health system performance assessment (HSPA), this could help to improve the transparency, accountability and sharing of knowledge in Europe's health systems.

There are also other issues related to reimbursement as revealed by rulings of the European Court of Justice. For example, a recent ruling in favour of a Romanian patient used the 'timely available treatment' argument, in this case related to the lack of adequate medicines and medical supplies, which forced the patient to seek open heart surgery in Germany.⁵

Financial and mobility barriers

In addition to presenting an administrative barrier to the use of cross-border care, the issues around cost and reimbursement present a financial barrier which aggravates

⁴ <http://www.imtj.com/blog/eu-directive-cross-border-healthcare-update/>

⁵ den Exter, A., 'The patient mobility saga continues', *Croat Med J.* 2014 Oct; 55(5): 441-442, <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4228299/>



health inequalities across the continent. The Directive requires Member States to reimburse citizens to the value that care would have cost at home – an essential provision for protecting the financial sustainability and viability of national health systems – but this immediately disadvantages patients from poorer countries with less-developed health systems. Health services are provided for substantially less money in Croatia, for example, than in Sweden. Thus, a Croatian patient would have to cover the considerable difference in the cost in treatment out of their own pocket, whilst patients from wealthier Member States are free to travel almost anywhere else for their care without contributing to the costs themselves. Another side effect is that wealthier governments are effectively gaining if the treatment is less expensive abroad.

The way in which the Directive functions also favours patients who are mobile (in terms of physical ability, transport and personal budget), with little in the way of facilitating provision for those less able to travel and no direct benefit or value for vulnerable groups, such as Roma communities or the disabled. As such, it might be considered that it benefits only a small proportion of the patient population whilst doing little to improve the overall health of Europeans.

One exception to this is of course patients from smaller countries where many treatments or procedures (e.g. transplants) are not available and for whom the Directive provides a new legal framework and more clarity to seek care abroad.

In addition, the Directive's limited scope of application also means that a number of healthcare access concerns that could benefit from European coordination remain unsolved. These include the following points contributed by Médecins du Monde International Network:⁶

- Non-application of Directive 2011/24 for insured citizens who try to access the public healthcare system under the same conditions as insured nationals with their EHIC, e.g. owing to discrimination on ethnic grounds (e.g. Roma)
- Non-application of Directive 2011/24 in the sense that not all public providers of health insurance across Europe effectively deliver the EHIC. This can result in unreasonable waiting times before a patient can prove health coverage status in his/her country of origin with no access to healthcare during this period (often > 6 months),
- Insured but destitute EU citizens who cannot afford to advance the costs of care in those countries where health insurance only reimburses costs afterwards,
- EU citizens without health insurance or revenues who overstay 3 months of residence and can consequently be considered as irregular in accordance with Directive 2004/38/EC – in most countries this group has no access to healthcare at all.

Prior authorisation systems and ERNs

During the negotiation of the Directive, prior authorisation was a key topic of debate. The CJEU had ruled that Member States may not require blanket prior authorisation for all treatment received abroad, but acknowledged the need for some national control over the amount of money that the health system would have to pay to outgoing patients.

⁶ www.mdmeuroblog.wordpress.com



Thus, care of a specialised, complex or cost-intensive nature requires prior authorisation. The Commission clearly states however that ‘any system of prior authorisation must be necessary and proportionate to the objective to be achieved, and may not constitute a means of arbitrary discrimination or an unjustified obstacle to the free movement of patients’.⁷

But according to a recent article, in most of the small number of applications made for such authorisations to date, they were denied on the basis that such care can be delivered in the home state without ‘undue delay’.⁸ Since terms such as ‘necessary’, ‘proportionate’ and ‘undue delay’ are open to interpretation by the Member States, there are big differences in how systems of prior authorisation are applied – on the other hand, some countries do not use them at all.

For those with rare diseases or complex conditions which require specialist care not available in the home country, authorisation should be more readily granted and treatment in another state reimbursed. However, even if prior authorisation is received, patients are still required to pay up front for cost-intensive care, as well as travel and ancillary expenses, which is a de facto barrier to access. Furthermore, the specialised Reference Network set up by the Directive to better facilitate the sharing of information about rare conditions and the cross-border utilisation of specialist treatment centres is already struggling. ERNs will not receive direct EU funding and are thus reliant upon Member States and health systems for both financing and political momentum. Networks of experts and rare-disease specialists were already in place before the establishment of the ERN in the Directive and cooperation between Member States has been ongoing for many years – the aim of the ERNs is to bring these networks together into one, central European database of expertise, but this requires leadership, resources and incentive.

Conclusions

An opinion of the Expert Group on Investing in Health, issued in August 2015,⁹ found that ‘cross-border collaboration has, at present, no obvious home at European level, with discussions taking place in many different and often fragmented fora’. This observation confirms that the Directive has not achieved its desired impact so far. The Expert Group recommends further research and better data collection, greater efforts at awareness raising and improvements in the administrative processes around cross-border care.

Overall, EPHA agrees with the conclusions drawn in the DG SANTE Evaluative Study which stipulate that information must be better targeted at patients, that indicators for quality, safety and waiting times must be better standardised, and that the burden for obtaining guidance and information should be shifted further from the patient to the NCPs.

In addition, however, EPHA would like to see the EU Institutions explore how the Directive, and by extension cross-border healthcare provision as such, could be deployed as a solidarity tool to decrease health inequalities. It is not acceptable that, as a result of the current reimbursement rules, the Directive effectively works in favour of patients from economically more powerful Member States - and with high levels of health

⁷ COM(2015) 421 final, p.2

⁸ <http://www.politico.eu/article/patient-journey-health-abroad-crossborder-eu-healthcare/>

⁹ http://ec.europa.eu/health/expert_panel/opinions/docs/009_crossborder_cooperation_en.pdf



literacy - who are empowered to take advantage of more cost-intensive procedures abroad. At the same time, even simple procedures undertaken in another Member State would remain out of the reach of patients from poorer countries with less generous reimbursement options. Moreover, as mentioned above, the governments of richer Member States could benefit since relevant procedures are economical for them if they are carried out in less affluent countries.

The figures about who has filed claims for reimbursement speak for themselves as e.g. Danish patients benefit from higher reimbursements while comparatively high salaries allow them to pay for travel and accommodation out of their own pocket. This is particularly worrying at a time when increasing numbers of patients across Europe are excluded from public healthcare systems as a result of the economic crisis and austerity measures which have resulted, inter alia, in higher co-payments for health services and medicines and in making health insurance coverage dependent on employment and residency status in some EU countries.¹⁰ From a public health point of view, Europe needs to be very careful that cross-border healthcare rules do not contribute to widening the gap between more affluent and poorer Member States, and between well-off and economically vulnerable patients/consumers.

Already there is a noticeable rise in patients travelling abroad for private healthcare offers that may not be available in their home countries (or to shop around for less costly / better quality treatments) and the Directive should not exacerbate this trend by extending private sector rules and conditions to public healthcare systems, thereby creating a new avenue to stimulate health tourism for the few.

For the reasons outlined above, EPHA suggests that the future review process of the Directive should:

- Provide for fair and equal reimbursement rules that apply across Europe
- Clarify responsibilities regarding the provision of information about cross-border healthcare and standardise the operation and scope of activities of the National Contact Points – the same quality of information should be available everywhere. Given the complexity of health-related questions, all NCPs should be contactable in person, by phone and e-mail
 - Introduce harmonised indicators pertaining to quality, safety, and waiting times for transparent comparability and reliability of information provided to patients
 - Ensure full transparency for patients and health professionals about the advantages and opportunities offered under the Directive, e.g. via targeted information campaigns and building up health literacy around this issue – this will require substantial effort and investment, and a long-term vision
- Close existing coverage gaps related to cross-border reimbursement, e.g. parents accompanying their children, travel and accommodation costs
- Consider exploring how cross-border healthcare could go further, e.g. by contributing to the provision of universal access to healthcare, e.g. via a solidarity-based pan-European reimbursement fund that would enable vulnerable individuals unable to receive care in their country of residence to access it in another Member State.

¹⁰ EPHA facts and figures – the impact of the crisis on health

About EPHA

EPHA is a change agent – Europe's leading NGO advocating for better health. We are a dynamic member-led organisation, made up of public health NGOs, patient groups, health professionals, and disease groups working together to improve health and strengthen the voice of public health in Europe. EPHA is a member of, among others, the Social Platform, the Health and Environment Alliance (HEAL), the EU Civil Society Contact Group and the Better Regulation Watchdog.

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