

# ERNs Multi-Stakeholder Forum to Enhance Patients' Rights and to Enhance Cooperation on Cross-border Healthcare

Mariano Votta <sup>1\*</sup> , Daniela Quaggia <sup>2</sup>, Michaela Papavero <sup>3</sup>

<sup>1</sup> Director Active Citizenship Network, c/o Cittadinanzattiva APS, Via Cereate 6, 00183 Rome, Italy

<sup>2</sup> Senior Project Manager Active Citizenship Network, c/o Cittadinanzattiva APS, Via Cereate 6, 00183 Rome, Italy

<sup>3</sup> Community & Fellowship Assistant at Active Citizenship Network, c/o Cittadinanzattiva APS, Via Cereate 6, 00183 Rome, Italy

\* Corresponding author: Mariano Votta, Director Active Citizenship Network, c/o Cittadinanzattiva APS, Via Cereate 6, 00183 Rome, Italy. Phone: +3906367181; Fax: +3906 36718333; E-mail: [m.votta@cittadinanzattiva.it](mailto:m.votta@cittadinanzattiva.it)

Submitted: 04.19.2021

Accepted: 05.10.2021

## Keywords:

Patient Rights  
Cross-border Healthcare  
Health Disparities  
European Health Union  
PAGs  
Civic Participation

Copyright © 2021, The Author(s). This is an open-access journal under the CC BY-NC license (<https://creativecommons.org/licenses/by-nc/4.0/>)

## Abstract

Directive 2011/24/EU established a comprehensive set of patients' rights regarding access to health services in the EU. However, reports from both public actors (including the European Parliament and the European Court of Auditors) and private entities agree that the overall impact of such legislation on patients is still too limited. Until today, in the EU only 2% of citizens have planned treatment abroad. However, if properly adopted, the Directive can help reduce health inequalities not only among the Member States but within each country, benefitting the remaining 98% of the EU population.

Against this background, the new EU4Health 2021-2027 program aims to boost the EU's preparedness for major cross-border health threats and, among other things, will try to expand successful initiatives like the European Reference Networks for rare diseases and continue to pursue international cooperation on global health threats and challenges. This will necessarily require a broader involvement of the actors engaged in cross-border healthcare. Given that the Directive's success depends highly on citizens being aware of their rights, it will be necessary to put citizens at the heart of decision-making by complementing the existing channels of engagement.

Consequently, Active Citizenship Network, the EU branch of the Italian NGO Cittadinanzattiva – a civic organization engaged in the protection of citizens' rights and the promotion of civic participation in public policy since 1978 – makes the ensuing proposals: on one side, it proposes an integration of different European policies (which may end up being also a cost-effective and cost-efficient strategy); on the other side, the establishment of a multi-stakeholder forum for each European Reference Network (ERN). These proposals are under close examination of the European Commission that closed the public consultation "Cross-border healthcare – evaluation of patients' rights" on February 11th, 2021.

## INTRODUCTION

Directive 2011/24/EU on patients' rights in cross-border healthcare [1] has been regarded by many as a major achievement of the "patient empowerment" policy promoted by patient organizations as well as European institutions, granting European citizens the right to access healthcare services in a different Member State. Designed to address the obstacles deriving from the diversity of healthcare systems, such as reimbursement rules and the delivery of healthcare services, the Cross-Border Healthcare Directive [2] has established a general legal framework aimed at maintaining the sustainability of health systems while protecting patients' right to seek treatment outside their home country [3].

On the one hand, according to the World Health Organization's report "Cross-Border Healthcare in Europe" [4], the volume of patient mobility within the European Union remains relatively low as people are frequently unwilling to travel to other countries for care. Moreover, more recent reports both from public actors (including the European Parliament [5] and the European Court of Auditors [6]) and private entities (including Active Citizenship Network multi-annual activities carried out in 24 Member States [7]) (Fig.1) concluded that the overall impact of such legislation on patients is still too limited.

On the other hand, where patient mobility exists, it has raised

issues related to its impact on patients, health professionals, and health systems.

The commitment of Cittadinanzattiva/Active Citizenship Network to implement patients' rights in cross-border healthcare (CBHC) started several years ago [8], supporting first the drafting, and then the implementation, of Directive 2011/24/EU. For the first time, the "patients' rights" perspective was included in the title of an EU Directive. Since 2014, Cittadinanzattiva/Active Citizenship Network has promoted the MEPs Interest Group "European Patients' Rights & Cross Border Healthcare" [9], a political initiative within the EU Parliament. The initiative is now active for its second mandate and represents our main achievement in the field (Fig.2).

From Active Citizenship Network, which is deeply involved in the protection of patients' rights (we are the promoters of the European Charter of Patients' Rights [10] and the European Patients' Rights Day [11]) (Fig.3), the development and full implementation of the Cross-border Healthcare Directive is crucial for the reduction of health inequalities across Europe and the development of a European Health Union. We believe that not only the Directive can become a tool to find medical assistance in another country, but we also expect that, if properly implemented across Europe, the principles set in the Directive will allow every patient to enjoy equal rights in terms of access to care, information and free choice, innovation, quality and safety of care, and forwarding complaints in every country, region or local health care place.

## METHODS

### Identification of the problems and the key issues addressed

The report on the state of play of the Cross-border Healthcare Directive, published by the European Commission in the second half of 2015 [12], reported that less than two in 10 EU citizens were informed about their rights in this area, and only one in ten knew the role and responsibilities of National Contact Points. Five years later, the situation has not changed. In this regard, civic and patient organizations indicate the following key issues and obstacles:

Lack of information: low awareness of the Cross-Border Healthcare Directive and patients' rights.

Language is one of the main stumbling blocks when reading/understanding medical prescriptions as the Directive lacks specific rules for the Member States.

Disparities amongst NCPs in the way they operate and not only in the information they provide. National Contact Points (NCPs) work very differently in the Member States, and cooperation among them is largely lacking. To overcome this problem, there is a need for enhanced information and real guidance.

In theory, the information on cross-border healthcare should be easily available: NCPs should have an essential role to play, providing information and raising awareness of patients' rights, and responding to information needs. In reality, in-depth information on patients' rights is generally lacking on NCPs' websites, including insights into what to do in case of undue delay.



Figure 1: Communication materials produced by Active Citizenship Network in the framework of the multi-annual EU project "Patients' rights have no borders"



Figure 2: Event at the European Parliament "Cross-border healthcare and centers of excellence to enhance patients' rights: access, information and innovation", 27 February 2018, Brussels



Figure 3: European Charter of Patients' Rights promoted at the European Parliament



**Figure 4:** Event at the European Parliament “Exploring Areas and Benefits of Cooperation in Cross-Border Healthcare to Protect Patients’ Rights”, 1st March 2017, Brussels

Information on complaint procedures and settlement of disputes is also scarce, as well as information on the time required to process reimbursements and prior authorization requests. Information varies also on which treatments are reimbursed.

Lack of homogeneous information and assistance: a complicated system of prior authorization, different from the Member States to Member State; little or denied reimbursements; long or complicated administrative procedures. The result is a series of common obstacles in the patient’s journey, including delays in and/or denial of authorization and difficulties in obtaining reimbursements.

Legal complexity and lack of transparency: every Member State should make available to the public the list of exceptions and all relevant information concerning prior authorization. The restrictive interpretation of prior authorization from social security services: in some border regions, it seems that prior authorization is used to control patient flow, even if a service cannot be adequately provided or provided at all. Coexistence of the Directive 2011/24 con Social Security Regulations 883/04 and 987/09 with scarce knowledge on the related application fields.

Lack of economic resources provided by EU Institutions and the Member States to increase awareness of the role and potential of National Contact Points.

Broader cooperation among stakeholders is still missing: to date, article n.6 of the Cross-border Healthcare Directive is still not fully implemented: “[...] Member States shall ensure that the National Contact Points consult with patient organizations, healthcare providers and healthcare insurers”. In particular, the involvement of organizations is still not considered a priority and a way of ordinary governance of the National Public Health System.

### **Proposals to empower citizens to benefit from cross-border healthcare opportunities**

Given the topic’s significant broadness and complexity, in this article, we’ll concentrate only on the need to better empower citizens to benefit from Cross-Border Healthcare opportunities. In this regard, Cittadinanzattiva/Active Citizenship Network advances the following recommendations to the Institutions and relevant stakeholders:

1. To make the directive work, appropriate information is

needed for both citizens and doctors, hospitals, and social security services alike. A vulgarization of the very technical information is desperately needed: simple language should be used.

2. Communication campaign with dissemination activities & study visit aiming at informing and raising awareness among European patients on ERNs, with the direct involvement of civic organizations & PAGs already active on the topic.

3. Integration of different European policies (which may end up being also a cost-effective and cost-efficient strategy): introduction of rules on mediation, ODR/ADR (Online Dispute Resolution/Alternative Dispute Resolution). If we consider cross-border disputes and the rules on mediation/alternative dispute resolution promoted in several sectors by the European Commission, we feel that these issues should be introduced also in the framework of cross-border healthcare to increase the protection of the patients’ rights.

4. Work for better coordination of the EU agencies and structures (Solvit, Your Europe Advice, National Contact Points, Europe Direct, European Consumers’ Centers-Network) which help and inform citizens, so that they can cooperate more, and more efficiently, keeping one another informed on their role and activities.

5. Integration of the principles of the Directive in the context of the EU mobility policy, considering the enormous work that is being done at the European level on the issue of mobility and the protection of passengers. The Directive can increase a new category of passengers, which is that of citizens with their specific needs as patients and as users of transportation. Hence, to promote knowledge amongst citizens, it would be useful to integrate the principles of the cross-border Directive in the context of the EU mobility policy. On the other hand, the means of transportation should also adapt to the needs of the mobility of those who travel not for business or pleasure, but for healthcare reasons (multiple languages, specific comfort facilities, prices, etc.).

6. To explore the feasibility to integrate the function of the existing European Consumer Centres Network (ECC-Net) - a network supported both by the European Commission and the Member States with consumer organizations for the management of cross-border disputes in consumer policies [13] - also in healthcare issues, or to establish a European Patient Centres Network (EPC-Net) to improve citizens’ protection & empowerment in the framework of cross-border health issues, with the direct involvement of civic & patient organizations. It could be a great example to put the respect of citizens’ needs and the protection of their rights at the center of the EU policy and to avoid any silos approach. The EPC-Net could boost health confidence across the EU, in line with the hope of creating a European Health Union.

We are aware that the lack of economic resources does not encourage the Institutions to undertake this solution, but they should explain to EU citizens why cross-border consumer issues can be managed while patients’ issues cannot. We are also aware that the EU Commission is directly accountable for consumers’ issues in the European Union, while each Member State is responsible for its health system. Of course, we are not suggesting changing EU treaties, but finding a common solution for common problems. Why protecting a consumer who buys a product abroad more than a patient who uses and buys a healthcare service? This proposal is under examination of the European Commission, after being promoted by Active

Citizenship Network as a constructive contribution on the occasion of the recent public consultation on the proposal for a Regulation on “Serious cross-border health threats – stronger, more comprehensive rules” (opened 8 December 2020 and closed 2 February 2021) [14].

## RESULTS

The Conclusions of the Council of the European Union in June 2017 [15] have recognized that European Reference Networks (ERNs), when fully developed, will represent an opportunity for the dissemination of knowledge and innovative practices in the provision of specialized health services in the field of rare diseases. The Council has invited the Member States and the European Commission to encourage the European Reference Networks, thus, to attain their intended objectives of providing better access for patients requiring highly specialized healthcare.

This will be possible thanks to the new EU4Health 2021-2027 promoted by the European Commission to strengthen the 24 European reference networks existing today, but also thanks to greater involvement of all actors - including private bodies and the civil society - interested in strengthening care options at European level.

## DISCUSSION

### The leading role of the ERNs

European Reference Networks (ERNs) are not meant to operate in isolation: their impact should be much broader, as they mark a new chapter in the European healthcare sector. ERNs could serve as a platform for the development of e-Health tools and could foster greater cooperation on more common chronic diseases too, in addition to the rare ones. They are a clear example of how it is possible to work together, creating an added value for the citizens. Indeed, they represent a concrete opportunity to speak together about shared challenges in healthcare and to think beyond the borders. In the context of ERNs, what is in place at this stage is excellent. The actors already involved are the ones who had to be there since the first step of the process. But, talking about the following steps of their development, this is probably not enough: indeed, the model of ERNs should be opened also to non-rare diseases and, to achieve this goal, the involvement of a broader multi-stakeholder group is needed. That’s why the governance of ERNs needs to be updated.

Civic & patient organizations – together with all the relevant stakeholders across Europe, including the private sector – should play an active role in facilitating access to and sharing information on healthcare, promoting patients’ empowerment, and bridging the gap between patients’ and institutions/providers and thus increasing patients’ treatment options. For this reason, Active Citizenship Network welcomes the intention to scale up networking through the European Reference Networks and extend it to infectious and non-communicable diseases, as established by the new EU4Health program 2021-2027. To do so, ACN advances a concrete proposal that underlines, protects, and promotes patients’ rights in compliance with the European Charter of Patients’ Rights and, in particular, with the rights to access (2<sup>nd</sup>), information (3<sup>rd</sup>), and innovation (10<sup>th</sup>), plus the 3 fundamental rights of

active citizenship, stated in the already-mentioned European Charter of Patients’ Rights [16]: to perform general interest activities, to perform advocacy activities, to participate in policy-making in the area of health. Access, information, innovation, and involvement are also the key features of the European Reference Networks and the scope of the networks themselves (Fig.4).

### Towards the establishment of a multi-stakeholder forum for each European Reference Networks (ERN)

Active Citizenship Network’s proposal aims to encourage the establishment of a multi-stakeholder forum for each European Reference Network [17]. This group should be opened to all actors already involved in the context of cross-border healthcare (CBHC) and the implementation of its Directive, starting but not limited to the unmet needs of patients with severe genetic and rare diseases, potentially interested in the development of personalized medicine and ATMPs (Advanced Therapy Medicinal Products). In fact, to date, due to the complex and individualized manufacturing of the treatments, gene therapies can only be administered in highly specialized centers, several of them included in the ERN. To add to this complexity, the rarity of genetic diseases means that the treatments can only be available in a limited number of countries. Therefore, an effective and efficient CBHC system is critical to ensure reliable and timely access for all European patients regardless of their country of residence.

Several reasons are supporting the proposal sent by Active Citizenship Network to the European Commission on the occasion of the recent evaluation of the Cross-Border Healthcare Directive [18]:

To recognize the principle of fostering the voluntary cooperation between the many actors working in Cross-border healthcare; is what underpins the philosophy of the ERNs. To not waste the existing resources that already play an active role on the topic, as the informal network built by Active Citizenship Network can testify [19];

To encourage the European Reference Networks to be more accountable and open to a broader constituency of stakeholders.

To promote a communication strategy focused mainly on the European Reference Networks as a whole, more than to listen to communication messages focused on a specific center of expertise, as we can find at this stage of the development of the European Reference Networks.

To promote a more cross-cutting approach, based on patients’ rights, assessing and defining best practices of access and hospitalization/follow up (with particular reference to health care humanization of foreign patients).

To promote the application of the ERNs model in European cross-border healthcare cooperation outside the rare diseases area, as already suggested by the Expert Panel on effective ways of investing in health [20], and recently confirmed by the new EU4Health program 2021-2027 [21].

Active Citizenship Network strongly believes that these goals can be reached also thanks to a more active role of the broader constituency of advocacy groups and patients’ associations in terms of raising European citizens’ awareness, facilitating dialogue and exchange of experiences, collection of data & good practices, removing barriers & obstacles. So, it is fun-

damental that the evaluation of the Cross-Border Healthcare Directive promoted by the EU Commission, opened last January 15th, 2021, and closed on February 11th, 2021 [22], leads to a better civic & patient involvement in the Directive implementation, to clearly show EU citizens how powerful the innovative potential expressed by the Directive is.

### ACKNOWLEDGEMENTS

Cittadinanzattiva, through its Active Citizenship Network, thanks to the members of the European Parliament that have decided to support the Interest Group “European Patients’ Rights & Cross-Border Healthcare” during their first mandate 2014-2019 and the second mandate 2019-2024, with special thanks to the co-founders David Borrelli and Gianni Pittella as well as the current co-Chairs Brando Benifei and Tomislav Sokol.

### ETHICAL STATEMENT

Each of the authors confirms that this manuscript has not been previously published and is not currently under consideration by any other journal. Additionally, all of the authors have approved the contents of this paper and have agreed to the Focus on Medical Sciences Journal’s submission policies.

### AUTHORS’ CONTRIBUTION

Each named author has substantially contributed to conducting the underlying research and drafting this manuscript. Additionally, to the best of our knowledge, the named authors have no conflict of interest, financial or otherwise.

### FUNDING

The activities promoted over the years by the European network of Cittadinanzattiva, Active Citizenship Network, on the issue of cross-border care have been predominantly self-financed by the association itself. The only contribution dates back to 2016/2017 for the campaign “Patients’ rights have no borders”, promoted to celebrate the 10th Anniversary of the European Patients’ Rights Day, and realized with an unconditional contribution of Novartis.

### CONFLICT OF INTEREST

The authors whose names are listed on the first page declare that they do not have any conflict of interest.

### REFERENCES

1. The European parliament and the council of the European union. 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. Official Journal of the European Union. 2011;88:45–65.
2. European Commission. Cross-border healthcare. Available from: [https://ec.europa.eu/health/cross\\_border\\_care/overview\\_en](https://ec.europa.eu/health/cross_border_care/overview_en).
3. European Health Parliament. Recommendations by the Next Generation 2020. Available from: <https://bit.ly/3dETHQ3>.
4. Footman K, Knai C, Baeten R, Glonti K, McKee M. Cross-border health care in Europe. Policy Summary 14. 2014:1-39.
5. European Parliament. Report on the implementation of the Cross-Border Healthcare Directive (2018/2108(INI)) 2018. Available from: <https://bit.ly/37HSfZb>; <https://bit.ly/2ZLnnm8>.
6. European Court of Auditors. EU actions for cross-border healthcare: significant ambitions but improved management required”, Special Report No 07/2019 2019. Available from: <https://bit.ly/3aJ3ceZ>.
7. Patients’ rights have no borders. Available from: <https://bit.ly/3kinork>.
8. The commitment of Active Citizenship Network on cross-border healthcare. Available from: <https://bit.ly/2MhQQ46>.
9. European Patients’ Rights and Cross-border Healthcare 2020. Available from: [www.interestgroup.activecitizenship.net](http://www.interestgroup.activecitizenship.net).
10. Active Citizenship Network. European Charter of Patients’ Rights 2002. Available from: [https://ec.europa.eu/health/ph\\_overview/co\\_operation/mobility/docs/health\\_services\\_co108\\_en.pdf](https://ec.europa.eu/health/ph_overview/co_operation/mobility/docs/health_services_co108_en.pdf)
11. Active Citizenship Network. European Patients’ Rights Days, what has been done. Available from: <https://bit.ly/2ZLA3JL>.
12. European Commission. Report from the Commission to the European Parliament and the Council “Commission report on the operation of Directive 2011/24/EU on the application of patients’ rights in cross-border healthcare” 2015. Available from: <https://bit.ly/3q-JRSE0>.
13. European Commission. European Consumer Centres Network 2019. Available from: <https://bit.ly/2MoHYKc>.
14. European Commission. Feedback from: Cittadinanzattiva- Active Citizenship Network “Serious cross-border health threats – stronger, more comprehensive rules” 2021. Available from: <https://bit.ly/2ZJG5e4>
15. Council of the European Union. Council conclusions on Encouraging Member States-driven Voluntary Cooperation between Health Systems 2017. Available from: <https://bit.ly/3slaN9t>.
16. Active Citizenship Network. The European Charter of Patients’ Rights. Available from: [www.activecitizenship.net/charter-of-rights.html](http://www.activecitizenship.net/charter-of-rights.html).
17. Active Citizenship Network. Cross-border healthcare and centers of excellence to enhance patients’ rights: access, information and innovation 2018. Available from: <https://bit.ly/3qO01Z8>.
18. European Commission. Feedback from: Cittadinanzattiva- Active Citizenship Network “Cross-border healthcare – evaluation of patients’ rights” 2021. Available from: <https://bit.ly/2ZGAcy3>.
19. Patients’ rights have no borders. A civic perspective. Available from: <https://bit.ly/3aM42I7>.
20. Expert panel on effective ways of investing in health 2018 [22 January 2018]. Available from: <https://bit.ly/3uqUk5C>.
21. European Commission. Funding: EU4Health 2021-2027 – a vision for a healthier European Union. Available from: [https://ec.europa.eu/health/funding/eu4health\\_en](https://ec.europa.eu/health/funding/eu4health_en).
22. European Commission. Cross-Border Healthcare: “Evaluation of the Cross-Border Healthcare Directive”. Available from: [https://ec.europa.eu/health/cross\\_border\\_care/consultations/cbhcdire\\_evaluation\\_en](https://ec.europa.eu/health/cross_border_care/consultations/cbhcdire_evaluation_en)