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Ethical assessment of the EU health policy under the Directive 2011/24/EU: approaching patients' rights and cross-border healthcare

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Abstract

Purpose: The purpose of the present article is to discuss the ethical challenges of the European Union (EU) health legislation framing the patients' rights and the cross-border healthcare (CBHC). *Background*: The paper reviews the EU main legislation in the field, namely the Directive 2011/24/EU (CBHC Directive) of the European Parliament and of the Council of 9 March 2011, on the application of patients' rights in CBHC. *Content*: The aim of the study is to analyze the patients' rights and the CBHC, enhancing the healthcare support and coordination under this regulatory framework. An exploratory and descriptive analysis will be conducted based on these legal provisions by focusing the ethical choices, the ethical duty, the ethical reasons and the patients' rights. An introductory literature overview will be provided and an analysis of the recent data reports published by the European Commission (EC) on the application of the CBHC Directive will be detailed. Therefore, six main themes emerged: (*i*) the protection of the patients' rights; (*ii*) the examination of the ethical challenges to address the EU public health issues; (*iii*) the monitoring of the data reports on the operation of the CBHC Directive; (*iv*) the reimbursement of costs of CBHC; (*v*) the European reference networks (ERNs); (*vi*) the eHealth network and the health technology assessment (HTA). *Conclusions*: The paper reviews the existing legal framework aimed to support the Member States (MS) in achieving a harmonized implementation of the CBHC Directive. Hence, particular ethical issues will be developed under this regulatory framework.

Keywords: patients' rights, cross-border healthcare, reimbursement of costs, eHealth network, European Union.

Introduction

The Directive 2011/24/EU [cross-border healthcare (CBHC) Directive] of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in CBHC [1], adopted in 2011 entered into force by 25 October 2013. The application of the patients' rights in CBHC is a main component of the European Union's (EU) "high level of social protection" based on the legal provisions of the Article 114 and Article 168 (1) of the Treaty of the Functioning of the EU [2]. This study identifies a few legal and ethical comments regarding the patients' rights and the CBHC involving: (*i*) the relationship between the CBHC Directive with the EU existing framework; (*ii*) the data reports on the operation of the CBHC Directive, health and patients' rights; (*iii*) the overview of the main definitions of the CBHC Directive; (*iv*) the regulatory framework of the reimbursement of costs of CBHC; (*v*) the benefits of the European reference networks (ERNs); (*vi*) the cooperation within the eHealth network, the health technology assessment (HTA) and the exchange of information.

Background

The present study aims at presenting an exploratory and descriptive analysis conducted and based on the legal provisions of the CBHC Directive. Furthermore, it examines and focuses the key components emphasizing both the health systems and the social protection as base of the social cohesion (Recital 3 CBHC Directive). Moreover, the purpose of the present article is: (*1*) to analyze the structural and institutional rules facilitating the high-quality in the area of the CBHC and health protection and covering other Union legal settings [Article 2 CBHC Directive]; (*2*) to emphasize the main responsibilities of the Member State of treatment (MST) [Article 4 Responsibilities of the Member State of treatment] and the Member State of affiliation (MSA) [Article 5 Responsibilities of the Member State of affiliation]; (*3*) to examine and focus the main definitions of the directive [Article 3 CBHC Directive]; (*4*) to evaluate the ethical challenges in the field of the patients' rights in relation to the issues of: (*i*) the information on the patients' rights, complaints, procedures and mechanisms for seeking remedies [Article 6(3) CBHC Directive]; (*ii*) the role of the National Contact Points (NCP) in the MSA [Article 6(4) CBHC Directive]; (*iii*) the cooperation in healthcare with focus on the mutual assistance and cooperation [Article 10 CBHC Directive]; (*iv*) the recognition of prescriptions issued in another Member State [Article 11 CBHC Directive]; (*v*) the support of the ERNs [Article 12 CBHC Directive]; (*vi*) the assistance and cooperation "in the development of diagnosis and treatment capacity" [Article 13 CBHC Directive]; (*vii*) the specific conditions for the funding of healthcare under the legal provisions and possibilities offered by the Regulation (EC) No. 883/2004 [3] "for referral of patients with rare diseases to other Member States even for diagnosis and treatments which are not available in the Member State of affiliation" [Article 13 CBHC Directive]; (*viii*) the cooperation and information support with regard to

the eHealth as a "voluntary networking" connecting the national authorities responsible in this field [Article 14 CBHC Directive]; (*ix*) the support for the HTA designed at the Member States level [Article 15 CBHC Directive]; (*5*) an in-depth analysis and a comparative interpretation in the light of the ethical choices, the ethical duty, the ethical reasons and patients' rights. In addition to the legal provisions of the Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in CBHC, the present article also contains additional provisions that specifically address the ethical challenges of the EU public health legislation: (*i*) the protection of the principles of the medical ethics; (*ii*) the examination of the ethical challenges to address the EU public health issues; (*iii*) the good clinical practice and the patients' rights [Article 2(g) CBHC Directive].

Literature overview of the CBHC Directive

However, much of the literature discussing the health policies, the ethical governance of the medical research and the main elements of the CBHC Directive on the application of patients' rights in CBHC focuses seven developments in the policy making process: (*1*) the procedural mechanisms in accordance with the healthcare quality control guaranteeing the patients' rights [4]; (*2*) the ethical implications of the CBHC Directive in the field of the patient mobility and CBHC [5]; (*3*) the role of the exchange of information with the aim of informing patients concerning the legal documentation at the European level [6]; (*4*) the importance of the ethical governance of the medical research within the EU regulatory framework [7–8]; (*5*) the analysis mapping a convergence between the "information-seeking behaviour", the "types and sources of information", the information accessibility and availability and the structured approach to the information provisions at the Member State level [9]; (*6*) the comparison of the European hospitals focusing the information on the health-care services, the factors of an informed choice and several elements indicating the types of the public access to data [10]; (*7*) the linkage between the prior authorization of healthcare, the coordination of the national healthcare systems, the reimbursement of costs and other structural and information mechanisms at the level of the MST and also the MSA [11].

Nonetheless, other studies display the analysis of the CBHC framework focusing the nexus between the voluntary basis and the cooperation mechanisms within the ERNs. Furthermore, the path to law harmonization identifies other important factors, such as the new communication technologies and the "adoption of the digitized and networked information society" [12]. The authors have also discussed the role played of the ERNs analyzing: (*1*) the legal settings mapping information and knowledge and indicating "a systematic knowledge use and knowledge generation plan" [12]; (*2*) the challenges of the interoperability structures with the aim to facilitate the cross-border health data use and exchange under the CBHC Directive [13].

It must be acknowledged that alternative studies have examined the role of the cross-border collaboration and health systems coordination pointing: (*i*) the role of the border-region projects and the initiatives namely: encouraging the cooperation in the field of health cross-border, supporting the ERNs at the level of the healthcare providers and the centers of expertise and analyzing the role of the institutional actors "in pushing (or not) for cross-border collaboration" [14]; (*ii*) the additional focus on the linkage between the role of the health professionals, the patients and the development of the industry in the funding of the ERNs with the aim to foster "the development of clinical practice guidelines" [15]. It the view of the above debates, it is useful to focus also the relationship of the CBHC Directive with the EU existing framework.

Relationship with the EU existing framework

The CBHC Directive was built with the objective to provide "rules for facilitating the access to safe and high quality cross-border healthcare in the Union" "achieved at Union level" (Recital 64 CBHC Directive). Moreover, the new legal framework has been introduced to focus also the cooperation in the field of healthcare between the MS in accordance with the national requirements concerning the healthcare sector [Article 1(1) CBHC Directive]. Further questions address: (*i*) the coordination of the social security systems namely: the information on the "coordination rules" [Recital 13 of the Regulation (EC) No. 883/2004]; the "social security rights" [Recital 16 the Regulation (EC) No. 883/2004]; the cooperation concerning the measures and mechanisms of implementation, but also the changes in the national legislation [Article 76(1) the Regulation (EC) No. 883/2004]; (*ii*) the application of the provisions regarding the prices of medicinal products for human use (Council Directive 89/105/EEC of 21 December 1988 [16]); (*iii*) the legislation regarding the implantable medical devices and the *in vitro* diagnostic medical devices (Council Directive 90/385/EEC of 20 June 1990 [17] and Council Directive 93/42/EEC of 14 June 1993 [18] concerning medical devices and Directive 98/79/EC [19]); (*iv*) the discussions concerning the processing of personal data and protection of privacy using the electronic system (Directive 95/46/EC [20] and Directive 2002/58/EC [21]). Subsequently, the legal provisions of the Article 1(4) of the CBHC Directive indicate the respect of the structural and financial functioning of the national healthcare systems "in situations not related to cross-border healthcare". Therefore, the CBHC Directive examines the arguments for efficiency and responsibility assurance considering the reimbursement policy if the healthcare providers do not participate in the social security system or the national public health system [Article 1(4) CBHC Directive].

Data reports on the operation of the CBHC Directive

A report published in June 2018 and entitled "Study on cross-border health services: enhancing information provision to patients" points: (*i*) the needs of the patients; (*ii*) the legal requirements for the NCP (of the MST and of the MSA); (*iii*) the information provisions under the CBHC Directive; (*iv*) the regulatory framework concerning the patient mobility and the "procedural barriers" in the context of CBHC; (*v*) the information provided by the

NCP considering three criteria: the type of request, the type of institutions and the type of service [22].

Moreover, the report entitled "Commission Report on the operation of the CBHC Directive on the application of patient's rights in cross-border healthcare" published by the EC in September 2018 outlines the need to enable the "information about healthcare, the healthcare provided, the reimbursements made and the reasons", the functioning of the NCP and the ERNs focusing on: (*i*) "the state of play of transposition" in accordance with the two discussed phases: the completeness check and the compliance check; (*ii*) the information on patient mobility according to the Article 20 of the CBHC Directive mapping seven developments: (*1*) the situation of the patient mobility with prior authorization; (*2*) the situation of the patient mobility not subject to prior authorization; (*3*) the financial implications of the patient mobility; (*4*) the information to patients focusing the data provided by the MS based on the requests received by NCP and pointing the importance of the cooperation between the MS health systems; (*5*) the data provided for the eHealth and eHealth Digital Service Infrastructure; (*6*) the analysis of the thematic ERNs; (*7*) the recognition of prescriptions enabling the regional and cross-border cooperation [23]. The analysis is aimed to ensure the "access to care for patients" and to provide the required legal information relating the implemented mechanisms, the information provision, the information on patients' rights and the accurate information in health system [23]. Additionally, in terms of the evaluative studies, the same Report presents an overview of the "Evaluative study on the cross-border healthcare Directive (2011/24/EU)" published in March 2015 [24] outlining: (*i*) the reimbursement of CBHC services and (*ii*) the processes and strategies guaranteeing quality and safety for the patients. Data collections on the CBHC were assessed to overview the web analysis of the NCP websites, the online survey to NCP, the pseudo patient investigation and the stakeholders' interviews [24].

Health and patients' rights

The CBHC Directive is also aimed at providing the patient mobility, the mutual cooperation and the healthcare services within the EU framework. However, there are five main areas clarifying the linkage health–patients' rights–health systems in the CBHC Directive: (*i*) the "health protection" (Recitals 1, 2, 5, 11, 12, 56 of the CBHC Directive); (*ii*) the "health systems" (Recital 3, 5, 21, 44, 50, 58 of the CBHC Directive); (*iii*) the "cooperation in healthcare" (Chapter IV "Cooperation in Healthcare of the CBHC Directive"); (*iv*) the "patients' health" (Recital 25) and (*v*) the "patients' rights" [Article 6(3) and Article 1(1) of the CBHC Directive]. These provisions enable the legal framework for the mutual assistance and cooperation ensuring compliance with the "guidelines on quality and safety and the exchange of information" [Article 10(1) of the CBHC Directive]. Moreover, one of mentioned and discussed principles is the principle of equal treatment considering the legal settings of the Council Directive 2000/43/EC [25] by focusing the equal treatment between persons irrespective of racial or ethnic origin. Moreover, other two legal provisions examine a special focus on the patients' rights and the health systems coordination namely: (*i*) the protection of the patients' rights and the framework of the public healthcare scheme, as follows: the "Member States should continue to be able to specify in their national legislation who is considered as an insured person for the purposes of their public healthcare scheme and social security legislation as long as the patients' rights set out in this Directive are secured" (Recital 18 CBHC Directive); (*ii*) the focus on the principle of the coordination of the social security systems as follows: "This Directive also aims at clarifying its relationship with the existing framework on the coordination of social security systems, Regulation (EC) No. 883/2004 with a view to application of patients' rights" [Article 1(1) CBHC Directive].

Main definitions of the CBHC Directive

The main definitions grounding the CBHC Directive can be conveniently organized into two perspectives: (*1*) the legal accounts regarding the healthcare services, healthcare providers and CBHC and (*2*) the legal accounts regarding the patients, insured persons and the medical records. One should note that the definitions for the "healthcare" and "cross-border healthcare" highlight the role of the health professionals "to assess, maintain or restore their state of health, including the prescription, dispensation and provision of medicinal products and medical devices" [Article 3(a) CBHC Directive] and the legal requirements concerning the CBHC. Furthermore, Article 3(e) of the Directive defines the "cross-border healthcare" by engaging the healthcare services "provided or prescribed in a Member State other than the Member State of affiliation" [Article 3(e) CBHC Directive]. Moreover, the Directive's purposes are: (*i*) to define and assess the "Member State of treatment" [Article 3(d) CBHC Directive]; (*ii*) to set out the legal status of the "insured person" [Article 3(b) CBHC Directive]; (*iii*) to focus in accordance with the Article 3(f) CBHC Directive the "health professional" as "doctor of medicine, a nurse responsible for general care, a dental practitioner, a midwife or a pharmacist" taking into consideration the legal settings of the Directive 2005/36/EC [26] and the "healthcare provider" referring to "any natural or legal person or any other entity legally providing healthcare on the territory of a Member State" [Article 3(g) CBHC Directive]. In addition, the Directive fosters a better understanding of the definition of the "patient" as a "natural person who seeks to receive or receives healthcare in a Member State" [Article 3(h) CBHC Directive]. It should also be noted also that the Article 3(l) and Article 3(m) seek to identify the legal extent to which the "health technology" and the "medical records" are defined and reflected. Thus, the point of departure for the definition of the "medical records" are all documents "containing data, assessments and information of any kind" regarding the situation of a patient and the "clinical development throughout the care process" [Article 3(m) CBHC Directive]. Moreover, as regards the "prescription", the Article 3(k) of the CBHC Directive reflects the "prescription for a medicinal product or for a medical device issued by a member of a regulated health profession" under the provisions of the Article 3(1)(a) of the Directive 2005/36/EC regarding the "regulated profession" [26].

Ethical choices, ethical duty and ethical reasons

An important contextual issue of the CBHC Directive regards the ethical challenges in the field of the patients' rights. In this circumstance, the ethical approach reinforces the legal requirements for: (*1*) the information on patients' rights, complaints, procedures and mechanisms for seeking remedies [Article 6(3) CBHC Directive]; (*2*) the role of the NCP in the MSA [Article 6(4) CBHC Directive]; (*3*) the cooperation in healthcare and mutual assistance; (*4*) the recognition of prescriptions issued in another Member State [Article 11 CBHC Directive]; (*5*) the support of the ERNs [Article 12 CBHC Directive]; (*6*) the assistance in the case of rare diseases [Article 13 CBHC Directive]; (*7*) the situation of the patients with rare diseases pointing the diagnosis and treatments not available in the MSA; (*8*) the eHealth network founded as a "voluntary network" connecting the national authorities responsible for the eHealth [Article 14(1) CBHC Directive]; (*9*) the cooperation on the HTA [Article 15 CBHC Directive]; (*10*) the reimbursement of costs of CBHC [Articles 7 CBHC Directive].

The analysis on CBHC and the patients' rights also provides clear legal settings about the ethical choices, the ethical duty and the ethical reasons. Under the provisions of the Recital 7, the CBHC Directive focuses that no legal provision of this Directive "should be interpreted in such a way as to undermine the fundamental ethical choices of Member States". Another distinctive trait of the CBHC Directive is that the "fundamental ethical choices", the "ethical duty" and the "ethical reasons" are detailed by providing a particular perspective where certain legal developments are examined and highlighted together with other fundamental rights, such as the protection of personal data (Recital 7, Recital 25, and Recital 53 of the CBHC Directive). In essence, the ethical choices are analyzed arguing that the "Directive respects and is without prejudice to the freedom of each Member State" to decide the type of healthcare provided (Recital 7 CBHC Directive). This means that the Directive offers a specific interpretation with regard to the "respect" and "without prejudice to the freedom of each Member State" addressing "the type of healthcare" provided by each Member State (Recital 7 CBHC Directive).

In the following, the CBHC Directive relies on the "ethical duty" according to the Recital 5 by enabling the recognition of prescriptions. As stipulated in the same Recital, this recognition should not affect "any professional or ethical duty that would require pharmacists to refuse to dispense the prescription" (Recital 5 CBHC Directive). One other reason for the recognition of prescriptions "should also be without prejudice to the decision of the Member State of affiliation" concerning the inclusion of these medicinal products "among the benefits covered by the social security system" (Recital 53 CBHC Directive).

One of the central aspects of the "ethical reasons" refers to the recognition of prescriptions and the pharmacist's right to refuse, for "ethical reasons", "by virtue of national rules" "to dispense a product" prescribed in another Member State [Article 11(1)(b) CBHC Directive]. Further, the dominant themes of the Article 11 of the CBHC Directive are assessed through an account of: (*i*) the authorization of the medicinal product to be marketed in another Member State according to the legal settings of the Directive 2001/83/EC on the Community code relating to medicinal products for human use [27] or the Regulation (EC) No. 726/2004 regarding the Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency [28]; (*ii*) the national rules in the field of "prescribing and dispensing" [Article 11(1) CBHC Directive]; (*iii*) the protection of the "human health" [Recital 1, Recital 2, Recital 53 and Article 11(1) CBHC Directive]; (*iv*) the compatibility of the prescription with the EU law and the measures taken for the MSA "to ensure the continuity of treatment" [Article 11(1) of the CBHC Directive].

As a result, in order to facilitate the implementation of the legal provisions of the CBHC Directive, it is relevant to focus apart from the "recognition of prescriptions issued in another Member State" [Article 11 CBHC Directive] and the "application of patients' rights" [Article 1(1) CBHC Directive], other necessary measures referring to: (*i*) the verification of the authenticity of the prescription by a health professional [Article 11(2)(a) CBHC Directive]; (*ii*) the guidelines enabling the interoperability of the ePrescriptions [Article 11(2)(b) CBHC Directive; (*iii*) the measures enabling the "correct identification of medical products or medical devices prescribed in one Member State and dispensed in another" here including the measures focusing the patient safety concerning "their substitution in cross-border healthcare" (for the cases where the national rules enable the case of substitution) [Article 11(2)(c) CBHC Directive].

However, Recital 18 and Article 1(1) outline the protection of the patients' rights. Moreover, the stated provisions of the CBHC Directive include: (*i*) the coordination of the social security systems [Article 1(1) CBHC Directive]; (*ii*) the legal settings concerning the national rules "in organising and delivering healthcare" [Article 1(1) CBHC Directive]; (*iii*) the legal framework establishing who is considered as an "insured person" in the public healthcare structure [Article 3(b) CBHC Directive]. At the same time, with regard to the "fundamental rights" (Recital 25 CBHC Directive), seven key drivers can be identified in the Directive: (*i*) "the fundamental right to privacy" [Article 4(e)] concerning the processing of personal data in accordance with the Directive 95/46/EC [20] and the Directive 2002/58/EC [21]; (*ii*) "the fundamental rights of the individuals" (Recital 25); (*iii*) "the fundamental freedom" regarding the patient's Member State of affiliation (Recital 35); (*iv*) the exercise of rights in the area of the CBHC (Recital 48); (*v*) the "application of patients' rights" [Article 1(1)]; (*vi*) the legal provisions concerning the "rights and entitlements in that Member State relating to receiving cross-border healthcare" [Article 5(b)]; (*vii*) the legal requirements supporting the NCP with regard to the "relation to cross-border healthcare" to provide "information concerning healthcare providers" and the "patients' rights" [Article 6(3) CBHC Directive].

In this study, we therefore choose to point the main legal provisions linking the ethical challenges of the medical research, the patients' rights, the patient mobility

and the particular procedures related to the implementation of the EU provisions reviewing also the conclusions of other studies in the field [29–30].

Reimbursement of costs of CBHC

Throughout the legal provisions of the Chapter III "Reimbursement of costs of cross-border healthcare", the Article 7 explicitly aims to focus the general principles and entitlements namely: (*i*) the reference to the reimbursement of the costs for the CBHC [Article 7(1) CBHC Directive]; (*ii*) the MSA determines "the healthcare for which an insured person is entitled to assumption of costs" [Article 7(3) CBHC Directive]; (*iii*) the legal circumstances under which "the reimbursement for treatment is based on the rate of the treatment state and reimbursement to the patient is determined by the rate of the state of affiliation [31] and the "up to the level of costs" assumed by the state of affiliation [Article 7(4) CBHC Directive]; (*iv*) the guidelines enabling the "same rights" for the patients according to the Treaty of Functioning of the EU [Article 7(5) CBHC Directive]; (*v*) the establishment of "a transparent mechanism of calculation of cross-border healthcare" [Article 7(6) CBHC Directive]; (*vi*) the support for "a balanced range of high-quality treatment" [Article 7(9) CBHC Directive]; (*vii*) the legal conditions concerning a prior authorization [Article 7(10) CBHC Directive].

ERNs in the MS

Situated at the boundary between the development of the social security systems and the funding of the healthcare, the legal framework of the ERNs [Article 12 CBHC Directive] and the rare diseases [Article 13 CBHC Directive] plays an important role in the EU governance of the healthcare services. The concept of the ERNs seeks to identify and design the structure of the cooperation "between healthcare providers and centers of expertise" in the MS here including: (*i*) the mutual assistance and cooperation [Article 10 CBHC Directive]; (*ii*) the recognition of prescriptions issued in another Member State [Article 11 CBHC Directive]; (*iii*) the regulatory framework of the ERNs [Article 12 CBHC Directive]; (*iv*) the correct diagnosis of the rare diseases and the funding conditions of the healthcare for the cases of rare diseases [Article 13 CBHC Directive]; (*v*) the eHealth network and the social developments at the EU level [Article 14 CBHC Directive]; (*vi*) the cooperation on the HTA and the support activities for the MS [Article 15 CBHC Directive].

The concept and design of the ERNs mainly reflects: (*1*) the "voluntary participation" [Article 12(1) CBHC Directive]; (*2*) the contribution "to the pooling of knowledge regarding the sickness prevention" [Article 12(2)(b) CBHC Directive]. Moreover, the development of diagnosis and treatment capacity in the cases of rare diseases involves: (*1*) the awareness of the tools available at the EU level focusing the *Orphanet* database and the ERNs [Article 13(a) CBHC Directive]; (*2*) the responsibility regarding the funding of healthcare and the possibilities of the Regulation EC No. 883/2004 [Article 13(b)].

In parallel with these approaches, the legal framework of the CBHC Directive resolves the ambiguities regarding the ERNs objectives stating six developments: (*i*) to provide both patients and healthcare systems a "highly specialised healthcare" [Article 12(2)(a) CBHC Directive]; (*ii*) to facilitate the development of innovation in medical research as well as the health technologies [Article 12(2)(a) CBHC Directive]; (*iii*) to focus the linkage between knowledge, research and epidemiological surveillance [Article 12(2)(e) CBHC Directive]; (*iv*) to encourage "quality and safety benchmarks" [Article 12(2)(g) CBHC Directive]; (*v*) to state the "mobility of expertise" and to enable information and good practice [Article 12(2)(f) CBHC Directive]; (*vi*) to support the MS considering the "particular medical condition" [Article 12(2)(h) CBHC Directive]. On the other hand, the Article 12(3) encourages MS to facilitate the implementation of the ERNs viewed by: (*1*) linking healthcare providers and centres of expertise at the national level [Article 12(3)(a) CBHC Directive] and (*2*) facilitating the networking and participation at the ERNs [Article 12(3)(b) CBHC Directive].

eHealth network and HTA

Turning specifically to the eHealth network within the legal framework of the CBHC Directive, the issue of the objectives entails the "sustainable economic and social benefits" and the "interoperable applications" viewed as an empowerment instrument to provide high level of security, continuity and access to high-quality services [Article 14(2)(a) CBHC Directive]. The introduction of "a non-exhaustive list of data that are to be included in patients' summaries and that can be shared between health professionals to enable continuity of care and patient safety across borders" [Article 14(2)(b)(i) CBHC Directive] can also be viewed as an example of a support guideline as the eHealth networks enable the "common identification and authentication measures" allowing the facility of the transferability of data [Article 14(2)(c) CBHC Directive]. Further to the legal provisions of the eHealth network, the evidence of the usage of the medical information increases the benefits framework of the Directive directly involving public health, research and CBHC [Article 14(2)(b)(i) and Article 14(2)(c) CBHC Directive]. In addition, the establishment of other "necessary measures" by the Commission was enacted in the Article 14(3) with the aim to develop the management and the transparency of the eHealth network.

Therefore, with respect to the cooperation and support for the HTA, the relevance of the Article 15 entitled "Cooperation on health technology assessment" creates new entitlements enhancing "a voluntary network connecting national authorities or bodies responsible for health technology assessment designed by the Member States" [Article 15(1)]. However, the objectives of this network enable support and cooperation highlighting the effective links between the national authorities or bodies [Article 15(2)(a–b) CBHC Directive]. Other goals of the HTA are to support the exchange of information and to "avoid the duplication of assessment" [Article 15(2)(c–d)].

Conclusions

The overall framework of the CBHC Directive introduces a larger understanding of the patients' rights and the CBHC. Some legal provisions enable the improvement

of high-quality services in the health systems, focusing the support for cooperation between the MS and the role of the eHealth, ERNs and HTA. The study presents the analysis of the ethical challenges of the CBHC Directive and also the role of the health systems coordination across the EU related to both the exchange of information and voluntary networking. The thematic areas of the study provide guidance for setting the level for the implementation of the EU health policy and development. Both "human health protection" and the patient mobility are key issues to the CBHC. Adding a more individualized relationship with the reimbursement of healthcare at the level of the Member State, the study creates a more accurate analysis of a "wider framework of services of general interest" (Recital 3 of the CBHC Directive).

Conflict of interests

The authors declare that there is no conflict of interests regarding the publication of this paper. All authors read and approved the final manuscript.

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