ORDINES
Per un sapere interdisciplinare sulle istituzioni europee

ISSN 2421-0730
NUMERO 1 – GIUGNO 2023

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A Comparative Analysis of Healthcare Facilities in EU Member States Through the Value-Based Geography Model of Care

ABSTRACT - This paper presents a comparative analysis of healthcare facilities in EU member states using the Value-Based Geography Model of Care. The paper begins by discussing the Italian Constitution and the right to health, as well as public spending and constitutional constraints on public debts. It then examines the implementation of the principle of equality in the European Union area, with a focus on patient mobility between states. The paper introduces the Value-Based Geography Model of Care, which aims to optimize patient care by directing patients to the most competent facility. This model represents a possible and effective solution for improving healthcare efficiency and sustainability, particularly in light of the shortage of financial resources and constitutional constraints on budgets. The paper concludes by discussing the potential benefits of this model for transforming healthcare services in a way that is functional to economic sustainability and the integration of actions and skills in the management of the entire patient care process.

KEYWORDS - Value-Based Geography Model of Care - Healthcare facilities - EU member states - Patient mobility - Economic sustainability - Patient care process

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1. *Introduction*

Constant scientific evolution in the health field leads to patient management problems that do not always find immediate answers in the current legal framework[1] . The rule is sometimes 'late' when it has to deal with a new case determined by scientific and technological evolution. Scientific research introduces specificities that do not fit neatly into the existing legal frameworks and, consequently, the legislator is called upon to regulate the changed context. An outdated legal framework may lead to a delay in the arrival of new technical developments or to a stalemate in research. Moreover, a rapid and summary updating process risks not fully grasping the potential of the sector being regulated. An inadequate body of regulations generates uncertainty and, moreover, sudden changes in the regulations of a given sector should lead to unfavourable situations also in terms of investments and markets. Therefore, when approaching the concept of *Value Based Health Care*, one must certainly bear in mind the innovative scope that it could have in our legal system at the organisational level, but the attempts identified to date appear to be an attempt to transpose legal models from other legal systems and mediated by the obvious rigidities of our system.[2] This certainly represents a starting point, but one that will have to be addressed by the legislature in an organic manner, especially in those passages that regulate the relationship between

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** Contributo sottoposto a valutazione anonima.
[1] S. RANCHORDÁS, *Innovation-friendly regulation: the sunset of regulation, the sunrise of innovation*, Jurimetrics, Vol. 55, No. 2/2015.
[2] D. FUSCHI, *La tutela multilivello del diritto alla salute. Istanze convergenti tra necessità sovranazionali e nuovi modelli di governance*, «STALS», 2023/3 (2023), pp. 1-22.

the public healthcare facility and the private supplier of medical devices, drugs and services[3].

Health care is less and less the domain of a single professionalism or medical speciality; therefore it is increasingly necessary to act in multi-specialist and multi-professional contexts in which the central element becomes the coordination and integration of services and professionalism that intervene at diachronic moments of the same pathway or simultaneously on the same patient. For this reason, considering the logistical management of the patient and the layout of health care facilities in the territory is useful as well, to identify what the weak points of a health care system are.

The analysis proposed here makes it possible to describe, on the one hand, the current and existing legal framework for patient mobility, based on the classic concept of reimbursement per service and, on the other hand, a partly theoretical model of geographical optimisation in which the patient is directed to the most competent facility according to a logic of optimisation of care.

2. *The Italian Constitution and the right to health*

Considering the public system of healthcare delivery in Italy, in which healthcare expenditure is financed through taxation and only a minimal part is covered by the patient[4], it is evident how urgent it is, in a context of shortage of financial resources, conditioned by the constitutional constraints placed on the budget, to intervene in order to make healthcare services more efficient; transformation to be configured in such a way that it is functional to economic sustainability and the integration of actions and skills in the management of the entire patient care process. It is precisely in function of the integration of health care and the transformation of services that the principles and concepts of the so-called *Value Based Health Care*

[3] On legal uncertainty profiles see, *ex multis,* G. FEDEL, *Riflessioni sulla crisi delle istituzioni. L'incertezza del diritto* (1980); G. ZACCARIA, *Introduzione. Crisi della fattispecie, crucialità del caso, concetto di legalità*, «Ars interpretandi», 24/1 (2019), pp. 7-14.

[4] F. LONGO - A. RICCI, *'The Italian healthcare system: a balanced system that has learnt the mechanics of innovation, uncertain about the direction of travel,* Observatory on Healthcare Organizations and Policies in Italy, CERGAS, Milano, 2018.

(VBHC)[5] represent a possible and effective solution to guarantee the evolution of the National Health Care System.

Our Constitutional Charter proclaims the right to health in Article 32, which is enshrined as a 'fundamental right of the individual'[6]. It is immediate and easy to understand the value that the Constituents gave to this matter: they do not speak of citizens, Italians, or other categorisations with respect to the person's legal *status*, they refer to the individual in general[7] , an admirably far-sighted notion when compared to what was later regulated in European law and the possibility of requesting health care throughout the Union's territory. This clarification is necessary because, in the final analysis, the parameters are quantifiable, first of all, in relation to the target group of individuals who can directly access the service under consideration[8].

The term 'individual', therefore, highlights how the Italian system is configured in a welfarist manner, as it values the general condition of a human being and not the legal status of the person to whom medical care is to be provided[9]. An aspect, this, that increases the health expenditure chapter[10].

With regard, however, to the term 'fundamental' used in Article 32 of the Constitution, doctrine is not unanimous in its interpretation. One can identify a direction that detects in this term the requisites of essentiality and inviolability; other authors, on the other hand, recognise that the fundamental nature of the right to health is to be grasped above all in cases

[5] For further details please refer to M.E. PORTER – E.O. TEISBERG, *Redefining health care: creating value-based competition on results*, Harvard business press, 2006.

[6] Art. 32 Const. The Republic protects health as a fundamental right of the individual and an interest of the community, and guarantees free care for the indigent.
No one may be obliged to undergo a given medical treatment except by provision of law. The law may under no circumstances violate the limits imposed by respect for the human person.

[7] G. CORDINI, *Elementi per una teoria giuridica della cittadinanza. Profili di Diritto Pubblico Comparato*, CEDAM, Padova, 1998.

[8] D. FUSCHI, *Il sistema sanitario italiano alla prova delle crisi sistemiche e del mutato concetto di salute*, Rivista Giuridica AmbienteDiritto.it - ISSN 1974 - 9562 - Year XXI - Issue 1/2021 pp. 12.

[9] *Cfr*: C. PICIOCCHI, *Il diritto alla salute nella Costituzione italiana: l'adempimento di una promessa difficile*, «Estudios constitucionales», 20/ESPECIAL (2022), pp. 394-417; A. ROVAGNATI, *La pretesa di ricevere prestazioni sanitarie nell'ordinamento costituzionale repubblicano*, «GRUPPO DI PISA» (2012).

[10] L. VIOLINI, *I confini della sussidiarietà: potestà legislativa" concorrente", leale collaborazione e" strict scrutiny"*, «Le Regioni», 32/2–3 (2004), pp. 587-602;

of contrast with other rights catalogued in the Fundamental Charter. The declaredly 'fundamental' or 'primary' character of the various legal situations that can be attributed to it, far from referring to an alleged 'pre-eminent character' or to a 'rigid hierarchy', imply 'the continuous and reciprocal balancing of principles and fundamental rights'[11]. This concept was affirmed, albeit following a lively doctrinal debate, even after the harshest period of the pandemic, when the right to health was pitted against the right to free movement and economic initiative; therefore, even in extreme cases, the right to health must always be balanced against other fundamental rights[12].

The latter interpretation is, without a doubt, the majority interpretation in jurisprudence. Understood in this way, the term 'fundamental' becomes a necessary tool at the service of the interpreter, scholar and technician to settle disputes in the case of antinomies where the contrast between two constitutionally guaranteed principles is resolved in favour of the one qualified as fundamental[13].

Given that no right can become a tyrant over another right, let us see how the Constitutional Court defined the environment and health as 'primary values' as early as 1993[14] specifying, however, that this does not imply a 'rigid' hierarchy between fundamental rights. The Italian Constitution, like other contemporary democratic and pluralist Constitutions, requires a continuous and reciprocal balancing between principles and fundamental rights, without any claim to absoluteness for

[11] F. MINNI - A. MORRONE, *Il diritto alla salute nella giurisprudenza della Corte costituzionale italiana*, "Rivista della Associazione dei Costituzionalisti Italiani" /3 (2013). A reference is also made to Sentence of the Italian Constitutional Court no. 85/2013, which resolves the "Ilva case" with a decision of unfoundedness, thus settling a complex conflict of constitutional values (health protection, environmental protection, labour protection) connected to the affair of an important national steel plant located in Taranto (closed by the court for reasons of pollution and protection of workers' health and, then, authorised to resume the production cycle by the Government, to guarantee employment levels, through a decree-law then brought to the attention of the Italian Constitutional Court).

[12] F. MASCI, *Il bilanciamento tra diritto alla salute e libertà d'iniziativa economica nell'ordinamento dell'UE, ovvero della nuova gerarchia di valori disegnata dalla CGUE in conformità al Trattato di Lisbona*, «DPCE Online», 52/2 (2022).

[13] *Cfr*: M. CARTABIA, *La giurisprudenza costituzionale relativa all'art. 32, secondo comma, della Costituzione italiana*, «Quaderni costituzionali», 32/2 (2012), pp. 455-468; M. SICLARI, *L'articolo 32, primo comma, della Costituzione italiana nell'interpretazione della Corte costituzionale* (2012); G.U. RESCIGNO, *Dal diritto di rifiutare un determinato trattamento sanitario secondo l'art. 32, co. 2, Cost., al principio di autodeterminazione intorno alla propria vita*, «Diritto pubblico», 14/1 (2008), pp. 85-112.

[14] Constitutional Italian Court Judgment No 365/1993.

any of them[15]. The qualification of certain values as 'primary' therefore means that they cannot be sacrificed to other interests, even where constitutionally protected, but rather a fair balance must be found on a case-by-case basis. The point of balance is not standardised *ex ante* and must be assessed - by the legislator in laying down the rules and by the judge of laws in review - 'according to criteria of proportionality and reasonableness, such as not to permit a sacrifice of their essential core'[16].

All this, of course, does not exclude the right to health from taking precedence over the freedom of economic initiative, as reaffirmed by the amended Article 41 of the Constitution (2c.)[17].

Any prevalence, however, would not be a priori, but limited to the contingent and in any case respectful of the minimum content of the opposing freedom[18].

In the essential lines described herein, the Italian Constitution, while defining certain rights as inviolable, does not identify a hierarchy between them, but entrusts the legislature, judges and the constitutional court with a balancing act that, from time to time, establishes the transitional pre-eminence of one over the non-essential core of the other[19].

3. *Public spending and constitutional constraints to public debts*

On 2 March 2012, the Treaty on Stability, Coordination and

[15] F. MASCI, *Il bilanciamento tra diritto alla salute e libertà d'iniziativa economica nell'ordinamento dell'UE, ovvero della nuova gerarchia di valori disegnata dalla CGUE in conformità al Trattato di Lisbona*, cit.
Constitutional Italian Court Judgment No. 85/2013, see on this point V. ONIDA, *Un conflitto fra poteri sotto la veste di questione di costituzionalità: amministrazione e giurisdizione per la tutela dell'ambiente*, «Giur. cost», 1494 (2013).

[17] Art. 41 c.2 of the Constitution: [Economic initiative is private and free.] It may not be carried out in conflict with social utility or in such a way as to harm health, the environment, security, liberty or human dignity.

[18] S. LAFORGIA, *Diritto al lavoro versus diritto alla salute? Il lavoro è sicuro o non è. Note a proposito della sentenza della Corte costituzionale n. 58 del 2018 sulla questione "Ilva", nota a Corte cost. 23 marzo 2018, n. 58*, «RIVISTA GIURIDICA DEL LAVORO E DELLA PREVIDENZA SOCIALE» 1 (2019), pp. 133-145.

[19] M. CARTABIA, *I principi di ragionevolezza e proporzionalità nella giurisprudenza costituzionale italiana*, (2013).

Governance[20] (TSCG) was signed by the EU Member States[21].

The Treaty, which was initially joined by twenty-five member states (all except the United Kingdom and the Czech Republic), posed a real turning point in economic governance between the different levels of government.

It reaffirms the principle of the reduction of 1/20th of the debt-to-GDP ratio for the part exceeding the 60 per cent set in Maastricht. With the Treaty on Stability, Coordination and Governance, the Member States record budgetary provisions at both constitutional and ordinary law level.

In the case at hand, reference must be made to the contrast arising between the spending constraint dictated by the new Article 81 of the Constitution, which has conveyed the dictates of the TFEU[22] (Treaty on the Functioning of the European Union) in our Constitution, and the aforementioned Article 32 of the Constitution. The Constitutional Court has affirmed several times over the years the need to carry out the balancing of constitutional values, in this case 'the right to health treatments necessary for the protection of health is guaranteed to every person as a right constitutionally conditioned by the implementation that the legislature gives it through the balancing with other constitutionally protected interests'[23]; it has always pointed out, however, that this operation requires the careful weighing of the constitutional relevance of the values in the field and, with specific reference always to the right to health, it is not permissible for the outcome of the balancing act to be an impairment of the fundamental prerogatives deriving from the right we hold. It is possible to identify an 'essential core' of the right to health that includes those aspects of which one cannot, under any circumstances, be deprived, on pain of violating the constitutional dictate, which is sanctioned by the illegitimacy of the rules that conflict with it (*ex plurimis,* Constitutional Court sentences n. 309/1999, n. 252/2001, n. 354/2008).

The evolutionary direction of patient management is therefore directed towards a model that does not strictly fall within what is considered the 'essential core' of the right to health. In fact, 'health is no longer considered simply as the absence of disease or infirmity, but is

[20] D. FUSCHI, *Le costituzioni alla prova delle crisi finanziarie: una comparazione tra ordinamenti: Stati Uniti, Italia, Germania, Spagna e Francia*, «CISR: CENTRO ITALIANO PER LO SVILUPPO DELLA RICERCA», 76 (2023).

[21] European Council. 2 March 2012. Retrieved 17 August 2012.

[22] Title XIV, Art. 168(2) TFEU.

[23] Constitutional Italian Court Judgment No. 509/2000.

defined as a state of total physical, mental and social well-being, strictly dependent on interaction in different contexts'[24].

A broader concept of well-being than that linked to strict survival can therefore be pursued through the identification of models for implementing health services that differ from those that respond to the logic of payment for a single service and are not aimed at considering the patient as a *unicum*[25].

Therefore, in the analysis proposed here, reference is also made to a different model of mobility of those in need of care than the traditional one.

While the modelling of national health care systems is based on the concept of so-called mutuals, whether based on a public insurance system or on direct reimbursement, the basis of this form of care is the reimbursement of benefits.

Following this logic, it follows that the legally relevant moment for the paying institution and for the institution that is to be reimbursed for the service provided is the access to the healthcare system; therefore, if the same patient requires several treatments provided by different facilities, these will not come into contact in order to prepare a treatment plan based on the medium term, but each access (i.e. outpatient visits) will become an event that will give rise to a payment and reimbursement. This generates more expenditure and less clinical planning and, in addition, the patient often interrupts the *course of treatment* because he or she has to book the new visit and go to the facility himself or herself, a situation often aggravated by long waiting lists. Interruption of the course of treatment dictated by personal wishes or long waiting lists reduces life expectancy[26].

According to this approach, which is linked to models developed in more limited scientific contexts than today, the *rationale behind the* construction of the system was to provide as much low-specialisation care as possible in a territorial context. In fact, even in small centres we find hospitals with low specialisation intensity that can hardly cope with the health needs demanded by the population today. The concept of territoriality made a *comeback* during the Covid-19 Pandemic, however, the

[24] V. ANTONELLI, *Livelli essenziali, materie trasversali e altri fattori uniformianti,* in L. VANDELLI - F. BASSANINI (ed.), *Il federalismo alla prova: regole, politiche, diritti nelle regioni*, Bologna, 2012, pp. 385 ff.

[25] R. FERRARA, *The Right to Health: Constitutional Principles,* in R. FERRARA (ed.), *Health, op. cit.*, pp. 3 ff.

[26] M. BONETTO - N. MAGGI - D. FUSCHI - A. VENTURI - L. BROGONZOLI - R. IARDINO - M. GIACOMINI, *Healthcare Insights: Evaluating the Access to the Italian Healthcare System*, 'Studies in Health Technology and Informatics', 294 (2022), pp. 709-710.

two concepts must not be confused here. An initial territorial hub is certainly necessary for optimal patient triage, but it must be configured in the logic of directing the patient to the most appropriate facility for the case and not, as in the traditional approach of the healthcare system, to make an initial attempt to resolve the problem.

Given this premise, it is useful to retrace the regulatory pathway of the Union that has given patients the freedom to choose where they seek treatment within the EU space. However, it is also interesting to analyse that kind of patient mobility organised upstream by the healthcare system, which is necessary to optimise care and reduce costs.

Several studies prove the thesis that increased investment in healthcare does not necessarily lead to increased quality if one remains anchored in a vision of patient treatment based on the acute event and not on the medium term. In fact, on an empirical basis, it is analysed how, by reducing costs by cutting waste, by reinvesting these resources in higher quality medical equipment and, finally, by applying a medium-term screening approach, costs decrease in return for better results in terms of quality and life expectancy[27].

The linear cuts to which the Italian health service has been continually subjected over the last ten years, therefore, generate the immediate effects desired by the administrations (e.g. reduction of expenditure in the short term) but this does not reflect the optimal combination of the necessary economic resources and the efficiency of the health service. Further proof of this thesis can also be seen in the average mortality figure. In fact, by comparing different time periods and then relating these values to the investment in the health sector, statistical studies show that as the investment decreases, the average mortality rate increases[28].

It is evident, therefore, that a rethinking of healthcare governance is necessary to optimise the efficiency of the system. The geographic optimisation model is interesting because it combines excellent results in terms of patient satisfaction with substantial savings at the same time.

There is statistical evidence in the literature showing that collaboration between hospitals and gatekeeping facilities, in terms of

[27] For a more detailed discussion please refer to M. MCCLELLAN, *Reforming payments to healthcare providers: The key to slowing healthcare cost growth while improving quality?*, 'Journal of Economic Perspectives', 25/2 (2011), pp. 69-92.

[28] D. GOLINELLI - F. TOSCANO - A. BUCCI - J. LENZI - M. P. FANTINI - N. NANTE - G. MESSINA, *Health expenditure and all-cause mortality in the 'Galaxy' of Italian regional healthcare systems: a 15-year panel data analysis*, 'Applied health economics and health policy', 15/6 (2017), pp. 773-783.

placing patients in the most suitable facility, leads to improvements in the quality of healthcare provision. A study in Michigan showed that, all things being equal, collaboration between vascular surgery units in one region of the state led to a reduction of 2,500 post-operative complications with a saving of $20m[29].

4. *The implementation of the principle of equality in the European Union area: the mobility of patients between States*

The number of European citizens who deliberately decide to seek treatment in a Member State other than their home country is relatively low. Usually, people prefer to be treated as close to home as possible, with practitioners who speak their language, surrounded by relatives and in a system familiar to them.[30] However, seeking care in an EU Member State is possible, and this is especially the case in border areas where the language barrier is not so pronounced and certain care is available in hospitals that, although in a foreign state, are closer to the patient than the equivalent facility in the state of residence. An even less frequent but nonetheless existing case is identified in those cases in which the manifest superiority of a facility in the international field attracts patients from several States.[31] A further hypothesis of access to treatment in a foreign state is found in those cases dictated by the search for a higher standard, whereby the patient seeks treatment abroad to escape the perceived characteristics and shortcomings of the domestic health system, such as long waiting lists, prohibited types of treatment (e.g. certain fertility treatments) or perceived low quality.

When national benefit packages cover treatment only partially or not at all (e.g., dental treatment or cosmetic surgery), patients may seek cheaper alternatives abroad.

Some states that do not have a particularly advanced national healthcare system, or with regard to certain sparsely populated areas, may enter into agreements with other states in order to offer healthcare coverage

[29] E.V.A. KLINE-ROGERS, D. SHARE, D. BONDIE, B. ROGERS, D. KARAVITE, S. KANTEN, S.S. WRIGHT, *Development of a multicenter interventional cardiology database: the Blue Cross Blue Shield of Michigan Cardiovascular Consortium (BMC2) experience*, Journal of interventional cardiology, 15(5), 2002.
[30] R. BAETEN, *Cross-border patient mobility in the European Union: in search of benefits from the new legal framework*, 'Journal of Health Services Research & Policy', 19/4 (2014), pp. 195-197.
[31] I. A. GLINOS - R. BAETEN - M. HELBLE - H. MAARSE, *A typology of cross-border patient mobility*, 'Health & Place', 16/6 (11/2010), pp. 1145-1155.

in line with European standards that can be used without additional bureaucracy for those citizens covered by the agreement. This is especially the case in very small states such as Malta or Luxembourg.

Since 1971, with Regulation 1480/1971[32] the EU has provided specific instruments on the coordination of social security systems and established a legal framework under which patients wishing to receive scheduled treatment in another EU Member State can do so, provided they obtain prior authorisation from their own country's health care institution, e.g., a social insurance fund. Payment is settled between the legal purchasers of the countries concerned. This system is still in force today.

The European Council of Ministers, the legislative body of the Community (later joined by the European Parliament), unanimously voted to take the necessary measures in the field of social security to improve the free movement of persons. The Council of Ministers did this as one of the first measures ever taken by the European Economic Community; already on 1 January 1959, Regulations 3 and 4 on social security for migrant workers were passed.

On 1 October 1972, these Regulations were completely revised and replaced by Regulation 1408/71 and its implementing Regulation 574/72. Since 1971, these Regulations have undergone numerous amendments to adapt to trends in national legislation and progress resulting from Court of Justice rulings.

On 1 May 2010, Regulation 883/2004 and its implementing Regulation 987/2009 entered into force. Without radically changing it, the new regulations modernise and, in some cases, simplify the EU framework for social security coordination.

The general aim of these regulations is to create coordination between the various social security systems in the EU and not to harmonise the different national regulations - which would mean creating a common European social security system - these regulations create bridges between national social security systems; the national systems are interlinked, so that people who move within the EU do not lose their social security rights as a result of their movement.

These regulations therefore leave intact the competences of the member states in determining the principles and rules of their national social security systems. This means that the different national legislators

[32] Council Regulation (EEC) No 1408/71 on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community.

remain competent to determine who is insured or entitled to care in the relevant healthcare system, what benefits are provided and under what conditions, how the benefits are calculated and for how long they are provided, provided that there is no discrimination between EU citizens. This means that national rules cannot, in principle, be superseded by European rules in these areas. For example, the level of pensions, retirement age and the determination of invalidity remain within the competence of the national legislator.

These coordination instruments only apply in situations where there is a cross-border element. Coordination aims to ensure, *first and foremost*, that those who want to go to work in another Member State do not lose their social security rights due to provisions in other social security systems.

Furthermore, its aim is to prevent migrant workers from being treated unfairly in the field of social security compared to people who have worked all their lives in the same Member State.

Given the primary objective of the rule, in line with the founding principles of the European Community regarding the free market and the free movement of goods, from which derives a careful regulation for the protection of workers, the above is extended, obligatorily, to all European citizens and, given the degree of evolution of society and the ever-increasing attention to the issue of health and quality of care, the phenomenon of patient mobility between the various EU states is better understood[33].

Given the regulatory framework that allows for patient mobility within the European space without generating inequality or additional burdens for the person receiving care, it is useful to analyse how compensation between the healthcare system providing the care and the healthcare system of the patient's home country takes place.

With the entry into force of Directive 2011/24/EU, a new parameter for the reimbursement of healthcare services was introduced.

Previously, reimbursement could take place under EU Reg. 883/2004, through cross-border agreements signed between two states (such as the above-mentioned case of Malta and Luxembourg), directly by the patient or, where there was one, through the patient's private insurance.

According to Directive 2011/24, patients are entitled to reimbursement of treatment up to the level that would be financed for the same treatment in the country of origin. Member States may decide to subject the requested

[33] I.A. GLINOS - R. BAETEN - M. HELBLE - H. MAARSE, *A typology of cross-border patient mobility*, cit.

treatment to prior authorisation when it involves a hospital stay, even if only for one night, or requires the use of highly specialised and expensive medical facilities and equipment. Authorisation may be refused if the treatment can be provided at home within a reasonable waiting time.

The case introduced by Directive 2011/24/EU presents some interesting profiles for patient mobility opportunities.

First, patients have the possibility of being reimbursed for most outpatient care received abroad without prior authorisation from the financing institution. This could meet the needs of those patients who feel that care in their chosen foreign country is better. Secondly, the directive offers more choice to patients who, in principle, can receive reimbursement for care abroad from any healthcare provider, whereas under EU Reg. 883/2004 only care received in certain facilities, usually public ones, were reimbursable.

Secondly, the directive may allow patients, especially those living in border areas, to receive the desired outpatient and inpatient service in the facility with the shortest waiting time; since in the case of outpatient treatment, no authorisation is required, whereas in the case of services involving a stay in a hospital facility, prior authorisation may not be denied if the service cannot be provided in the patient's home country in a suitable time frame so as not to aggravate the patient's state of health. From a financial point of view, the directive is the least advantageous since it reimburses up to the cost of the equivalent service in the country of origin, whereas the regulation always guarantees the patient the most advantageous reimbursement rate, be it that of the country where the treatment is carried out or that of the country where the patient is covered by healthcare.

From an organisational point of view, the patient must, in principle, pay for treatment abroad in advance and only receives reimbursement on his or her return home. It is the patient who is responsible for ensuring that the care abroad complies with the conditions and eligibility criteria that apply to care at home and for submitting accurate invoices to prove correct treatment. Patients treated abroad on the basis of the regulation or cross-border contracts have no such burden. In fact, under the regulation, they are treated according to the regime that applies to persons covered for healthcare in the country of treatment; healthcare facilities abroad will, in principle, be paid through the same mechanism as domestic providers.

In summary, the directive improves access to care and patient choice in a relatively limited number of circumstances, particularly for outpatient

care. However, the potential burden on patients is considerable and the risk of not being reimbursed is real.

So why do we need new reimbursement rules and what is the added value of the amended legal framework? The directive is the result of 15 years of searching for policy responses to a series of EU Court of Justice rulings that emphasise the need for clear rules that allow patients to freely decide where to seek the most appropriate medical treatment in the event of problems in their home country (see the Petru case[34]), and the case law also highlights the need to apply the fundamental principles of free movement of the EU Treaty to health services and products under the existing general legal framework.[35] The Directive seeks to resolve the uncertainties that may arise from a case-by-case jurisprudential assessment and represents a valid attempt to preserve the governance role of the health authorities of each country in the context of the deregulation dynamic influenced, in part, by the free movement principles of the EU Treaty.

Finally, the directive may increase legal certainty and direct national authorities to address the weaknesses of their national systems, in particular with regard to waiting times. This could be due to the fact that they want to reduce patient mobility so that they do not have to reimburse services to foreign states that, in relation to the different level of the economic system, as highlighted by the Petru case, could be very costly for the patient's home state.[36]

The framework briefly described here traces the specifics of the right of each citizen to move freely within the EU space, also in order to identify the best facilities in which to be treated.[37] What is described below, on the other hand, refers to a model of optimisation of patient management

[34] In the Petru judgment of 9 October 2014, the Court of Justice held that it is not possible, and contrary to the principle of free movement of citizens of the Union, to deny the prior authorisation necessary to obtain reimbursement of medical expenses incurred in another State, when medical treatment - and related expenses - cannot be obtained in one's own Member State of residence within a reasonable time, where the delay is due to a lack of medicines, medical equipment, specific equipment or expertise. The ruling resulted from a reference for a preliminary ruling concerning the interpretation of Article 22 of Regulation 1408/71.

[35] I.A. GLINOS - R. BAETEN - M. HELBLE - H. MAARSE, *A typology of cross-border patient mobility*, cit.

[36] R. BAETEN, *Cross-border patient mobility in the European Union: in search of benefits from the new legal framework*, cit.

[37] R. BAETEN - E. JELFS, *Simulation on the EU cross-border care directive*, 'Eurohealth', 18/3 (2012), pp. 18-20.

operated through a precise scientific assessment that leads the patient to interface with a network of facilities and not only with a single reality.

Moreover, the arrangement of these networks in a strategic manner across the territory makes it possible to optimise expenditure chapters in such a way that homogeneous clinical cases are channelled to networks specialised in those cases, thus avoiding the necessary expenditure for replicating medical teams and investment in technical equipment in different facilities that do not make the best use of capital due to low patient flow[38].

5. *The Value-Based Geography Model of Care*

The geography of care - the place where healthcare is delivered - has the potential to be one of the most important levers for improving the *value* of healthcare. Care providers can create competitive differentiation if they systematically optimise key variables in space and time, i.e. if they focus patient care where multidisciplinary and highly qualified teams can reliably and efficiently meet these needs.[39] However, using geographic leverage is not so simple; in fact, creating healthcare facilities that are optimised, in a theoretical model, to perform a specific procedure for all patients at a single site is a model for maximising the healthcare facility's revenue and not the value and quality of care for patients.

The strategic use of the model based on geographic optimisation of care should enable a group of healthcare facilities to deliver what is currently an ideal service, namely to provide care wherever it can be delivered with excellent results, lower costs, and greater convenience for the patient, even if this means using different sites for different parts of the care cycle, so that in the perspective of mobility, under conditions that naturally have to be configured in accordance with the canons of safety, the patient can be moved from one facility to another according to the treatment needed in order to pursue the best attainable outcome. The model to aspire to is that of complex structures in which to direct the patient according to the clinical picture and not that of efficient structures in which one tries to cope with any clinical picture. This is why geographic reorganisation is

[38] R. BAETEN - B. VANHERCKE - M. COUCHEIR, *The Europeanisation of National Health Care Systems: Creative Adaptation in the Shadow of Patient Mobility Case Law* (1/2010).

[39] M. E. PORTER - T. H. LEE - A. C. MURRAY, *The value-based geography model of care*, 'NEJM Catalyst Innovations in Care Delivery', 1/2 (2020).

crucial: the goal to strive for, therefore, is to create hubs that serve a wider territory than the current distribution of hospitals; to refer patients to these centres even if they are far from their homes, so as to provide the best possible care that takes into account the entire care process.

The creation of such systems is complex and, when dropped into our healthcare system, disruptive in some ways.

The type of facility providing care is decisive insofar as it affects the public budget; for example, university hospitals cost on average 30% more than community hospitals for the same service.[40] Another cost-saving situation is found in those services that can be provided on an outpatient basis; the same care provided in a hospital costs about 40% more. We see, therefore, how maintaining general facilities leads, first of all, to poor resource optimisation[41].

The concentration of patient volume is also a decisive factor in terms of resource optimisation. This is especially the case for those chronic diseases that require a prolonged relationship between patient and healthcare facility, as the high volume generates high staff specialisation and lower costs in terms of reduction of adverse cases and time optimisation[42].

The territorial optimisation of facilities, therefore, is a powerful tool for increasing value in three dimensions: the right organisation of teams of healthcare professionals, working in technologically appropriate facilities, and integration over time (i.e. the overall patient care cycle and not management limited to the acute case). The model does not merely aim to triage patients to the most specialised facility in order to contain costs, as if it were a mere logistical exercise; the ultimate goal is to create complex structures in which individual departments are connected and evaluate the entire cycle of care. Some of the major healthcare organisations in the United States of America are moving with increasing speed in this direction, but the changes can sometimes be seen as disruptive and difficult to

[40] J.K. IGLEHART, *Rapid Changes for Academic Medical Centers*, 'New England Journal of Medicine', 331/20 (17/11/1994), pp. 1391-1395.

[41] CENTERS FOR DISEASE CONTROL AND PREVENTION, NATIONAL CENTER FOR HEALTH STATISTICS, *Table 90. Community hospital beds and average annual percent change, by state: United States, selected years 1980-2015* (2017), pp. 2.

[42] M.E. PORTER - T.H. LEE - A.C. MURRAY, *The value-based geography model of care*, cit.

implement due to traditional legacies relating to the organisation of care on the ground[43].

An illustrative example, relating to the hospitalisation to which President Eisenhower was subjected after he suffered a myocardial infarction in 1955, although referring to an outdated scientific context, highlights the geographical limitations of the traditional system of care.

The President was forced to remain bedridden for several days and his hospitalisation at the Fitzsimons Army Hospital in Aurora lasted six weeks, a typical duration for the treatment of this condition at the time as there was no cardiopulmonary resuscitation, DC defibrillation or coronary care unit. Bed rest until nature would take its course, one way or another, was the prevailing model of care for this diagnosis for even the most prominent patient in America. This example does not serve to emphasise how much care has progressed and how the approach to the patient in the clinical field has changed, it is necessary to emphasise how the construction of most healthcare facilities was designed, planned, and built at a time when the approach to care was, even for the most important and protected person in the United States of America, very low-tech and based on the principle of proximity to the patient.

The Hill-Burton Act of 1946 helped to finance the construction of local hospitals in US counties that lacked them until then. With many patients hospitalised for long periods, it was desirable for them to be close to home so that family members could easily visit them. During a time when bed rest was often the main service that healthcare could provide, the skills and technologies available at local hospitals were not very different from those at academic medical centres and, therefore, the allocation of spending to different facilities did not differ significantly.

The problem of the low efficiency of some healthcare facilities has arisen since the 1960s, a time when the difference between facilities according to their degree of modernity and specialisation is traced. With the introduction of coronary units, heart valve replacement and cardiac bypass surgery techniques, and the introduction of coronary angiography, there has been a marked evolution of medical care towards complex clinical pictures that require adequate facilities. In this context, existing facilities, located in city centres and not on major thoroughfares, began to decline in efficiency. In order to counter this scenario, smaller facilities specialised in

[43] A.P. CHUNG - M. GAYNOR - S. RICHARDS-SHUBIK, *Subsidies and structure: the lasting impact of the Hill-Burton programme on the hospital industry*, 'Review of Economics and Statistics', 99/5 (2017), pp. 926-943.

high-performance types of surgery, such as vascular surgery, even when their experience in the field was limited and patient volumes were lower than those required to set up a high-performance team that could efficiently optimise patient management capacity, innovation and specialisation of medical personnel in order to achieve maximum profit and the best outcome for patients. The legacy of this approach can be seen in the fact that an index of the efficiency of healthcare facilities, even today, can be referred to the number of beds available in a facility in proportion to the number of inhabitants that that facility serves; a parameter that certainly gives an idea of the size of the facility, which, however, is in contrast with what is the trend in scientific evolution, i.e. that of limiting the length of stay in the healthcare facility and optimising telemedicine.

The capacity for innovation and increased value for the patient found in the traditional system, based on reimbursement of services, is now limited. Market pressures have led to the emergence of a new model that also involves a logistical and territorial assessment in order to arrange healthcare facilities in the territory to produce the best possible results given the limited resources. Responding to these pressures is difficult and takes a long time to achieve appreciable growth margins. Therefore, it is now evident how useful it is to prepare a new model that regulates the relationship between the patient and the healthcare facility, also from the point of view of the best location referable to the subjective condition.

Statistical evidence has shown that 'close' is not necessarily synonymous with patient satisfaction[44].

A possible criticism (and one that has been raised in the literature) is that referring to the limitation of this type of organisation, it is not predictable what the adverse events of each patient are and, above all, one cannot arrive at an absolute standardisation of care delivery processes. These considerations are certainly shareable and tangible, however, considering also the statistical evidence, especially in the management of chronic illnesses[45], the provision of a model, even if not perfect, is a better scenario than no organisation at all.

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[44] G. STEINMANN - K. DANIELS - F. MIERIS - D. DELNOIJ - H. VAN DE BOVENKAMP - P. VAN DER NAT, *Redesigning value-based hospital structures: a qualitative study on value-based health care in the Netherlands*, 'BMC Health Services Research', 22/1 (2022), pp. 1-14.

[45] Cf. E. BUSINK - B. CANAUD - P. SCHRÖDER-BÄCK - A.T. PAULUS - S. M. EVERS - C. APEL - S. K. BOWRY - A. STOPPER, *Chronic kidney disease: exploring value-based healthcare as a potential viable solution*, 'Blood purification', 47/1-3 (2019), pp. 156-165; D. EBBEVI - H.H. FORSBERG - A. ESSÉN - S. ERNESTAM, *Value-based healthcare for chronic care: aligning outcomes measurement with the patient perspective*, 'Quality management in health care', 25/4 (2016), pp. 203; S. AHN

This strategic orientation is certainly at odds with traditional management models, which focus on filling beds or expanding outpatient programmes to maximise high-paying services.

Concentrating care in one team can lead to significant improvements in outcomes and efficiency; however, optimising value does not necessarily mean concentrating the entire care process in one location. Often value can be improved by dispersing care in more than one location: delivering the right care in the right place improves outcomes.

Directing the care process to the appropriate locations optimises team composition and service delivery costs, while improving patient convenience without sacrificing overall provider coordination and integration.

A fundamental condition for the rational implementation of this model is certainly that linked to the measurement and performance of individual professionals and healthcare teams, an aspect that is still little implemented in Italy. In fact, the intrinsic difficulty of any evaluation system, in addition to the effects most frequently related to evaluation, mostly monetary, and cultural resistance to the subject, represents the recurrent alibi that hinders the introduction and consolidation of effective performance evaluation systems[46].

6. *Conclusions*

Deciding where to provide services on the basis of the complexity of the service provided and the complexity of the pathology treated might seem like mere common sense behaviour, however, it is not inherent in the way most healthcare organisations organise themselves. Although many healthcare institutions tend, ideally, to take into account clinical complexity as a function of the facility in which the healthcare service is delivered, in the *real world* many healthcare facilities have limited options at the level of

- R. BASU - M. L. SMITH - L. JIANG - K. LORIG - N. WHITELAW - M. G. ORY, *The impact of chronic disease self-management programs: healthcare savings through a community-based intervention*, 'BMC public health', 13/1 (2013), pp. 1-6; M. E. TINETTI - A. D. NAIK - J. A. DODSON, *Moving from disease-centred to patient goals-directed care for patients with multiple chronic conditions: patient value-based care*, 'JAMA cardiology', 1/1 (2016), pp. 9-10.

[46] M. BARBIERI – L. MICACCHI – F. VIDÈ – G. VALOTTI, *The performance of performance appraisal systems: A theoretical framework for public organizations*, «Review of Public Personnel Administration», 43/1 (2023), pp. 104-129

patient location, and few have built a system capable of reliably delivering this type of care.

Undoubtedly, what is outlined here is not an easy and straightforward model to implement, however, the critical issues outlined at the beginning are a constant problem in healthcare and, therefore, this condition requires *stakeholders to pay* attention to the value of care and, albeit partially, the adoption of these approaches is becoming increasingly common.

A mention on the organisational level of domestic law is necessary. In order to describe the path taken by our country, it is useful to analyse what has emerged from the preliminary work carried out, and currently in progress, for the drafting of a legislative decree amending legislative decree no. 288 of 16 October 2003 on the subject of the regulation of scientific recovery and care institutions. Indeed, it is interesting to see how the principles outlined here are entering into the legal semantics of our legal system.

Given the commitment required of us by the EU in order to utilise the resources introduced by the Next Generation-EU plan through the National Recovery and Resilience Plan (PNRR), and given the fact that we are required to update the National Health System by focusing on aspects relating to changes in relations between the Government and the Regions, progressive diversification of Regional Health Systems, epidemiological transition, the de-hospitalisation process, etc., and the medical, scientific and technological advances (omics sciences, robotics, IoT, personalised medicine, etc.) of the last 15 years, it is clear that changes need to be made to the current structure of the Scientific Hospitalization and Treatment Institutes, as defined by Legislative Decree No. 288 of 2003, in order to enable the IRCCS System to respond to the new challenges of the NHS.

It is now clear, in fact, that 'in order to maintain the high standards of the NHS, it is necessary to ensure that centres of excellence have that *quid pluris* that enables them to compete internationally and guarantee highly complex services to citizens'.[47]

More specifically, the proposed amendment to art. 3, paragraph ter of Legislative Decree no. 288 of 16 October 2003 provides for the regulation of networks between IRCCSs and 'must document the possession of certain requirements such as: a specific research activity with regard to both the number of publications and the number of trials, and in any case no less than 5 per cent of the indicators and evaluation thresholds for scientific

[47] Dossier XIX Legislature, Reorganisation of the discipline of the Institutes for Hospitalization and Care of a Scientific Character (IRCCS), A.G. 4, 14 November 2022.

recognition, a provision of care activities carried out in the network's thematic area, equal to at least 10 per cent of the Institute's overall activity, as well as instrumental resources and platforms to be shared. Possession of the above-mentioned requirements will be subject to validation by the Ministry'[48].

Therefore, we see how the principles set out here are at the heart of the Legislator's semantics in order to identify those concepts deriving from health system optimisation models as indicated by the relevant international literature and the constraints identified by the EU for the purpose of disbursing the PNRR funds. In fact, reading the words of the Legislator we see how clinical data in order to create networks between complex structures, specialisation and the network itself are the fundamental points for pursuing the innovation of networks between IRCCSs.

Finally, we also report the experience launched by the Lombardy Region with resolution XI/6241 of 4 April 2022, which has recently created, within the regional health system, a network of 'pancreas units' characterised by the presence of multidisciplinary clinical staff and by a treatment pathway that sees a 'hub and spoke' approach in a fully VBHC perspective in which the patient is placed at the centre of the treatment pathway[49]. The organisational model proposed by the Lombardy Region presents some of the different organisational challenges outlined here. The results underline the importance of going in the direction of a multidisciplinary approach to care that sees the involvement of even non-traditional players, such as operators from the world of research and industry, and an alliance with a significant exchange of knowledge between the various 'pancreas units'.

Undoubtedly, the critical issues present for an optimisation of the Italian NHS are many. First of all, in view of the management heterogeneity present within the Italian Regions, in fact, although I have not gone into this aspect in depth because it would require an ad hoc discussion, in Italy there are also problems of reimbursability between the different regions when a citizen requests healthcare in a region other than his or her region of

[48] *Ibid.*

[49] P. PREVITALI - F. DAL MAS - S. DENICOLAI - A. VENTURI - S. CAMPOSTRINI - P. COGLIATI - E. COLOMBO - S. CUTTI - M. MEDICI - A. FRIGNANI - M. GIUPPONI - P. IMBROGNO - S. MANFREDI - G. MATOZZO - I. MAZZOLENI - F. MILANI - D. MOTTA - B. NICORA - G. REPOSSI - L. COBIANCHI, *Towards the Lombardy regional pancreas unit network. A possible organisational model analysed through the Delphi method,* 23 (11/2022), pp. 115-129.

residence. In fact, the proposal to amend legislative decree no. 208/2003 also introduces maximum thresholds of out-of-region patients that IRCCSs can accept. This prerogative can be read in two ways: on the one hand, an attempt is made to limit inter-regional mobility in order to lead regional institutions to improve and implement their own system; on the other hand, a constraint is placed on the free movement of patients within the Italian territory, dictated by spending problems; a problem that is logical and rational if placed within the organisational framework of healthcare on a regional basis, for which the reimbursement system is comparable to the process carried out between the EU states as described in this article. Lastly, we have seen how the aspect of patient mobility is closely linked to the financing difficulties of healthcare systems, in fact, the problem lies in the cost that a patient outside a given system generates for the structure and the reference country or region. Therefore, the comparison proposed here between the classic mobility models and the VBHC model is aimed at highlighting how, starting from a proven problem (i.e. problems with the financing of healthcare systems), it is possible to implement an organisational structure that, having set the spending limits, optimises the entire treatment process so as to achieve both a saving in economic resources and a better clinical result for the patient. Even within a legal framework as articulated and evolved as that of the Union, it does not always allow access to care in territories other than one's own without it being burdensome.