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The emerging EU quality of care policy: From sharing information to enforcement

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ABSTRACT

Despite the fact that Member States and many citizens of the EU like to keep healthcare a foremost national competence and the EU treaties state that Member States remain primarily responsible for the organization and delivery of health care services, the European Union (EU) has expanded its involvement in healthcare policy over the last twenty years. Based on interviews and document and literature analysis we show that the scope of EU involvement has widened from public health and access to care, to quality of care. In this paper we concentrate on the latter. Focusing on the recent EU initiatives regarding the quality systems of the Member States and the quality of services, this paper shows how the depth of EU interference has increased from sharing information to standardization and even to the first signs of enforcement. We argue that at this stage, reflection on the feasibility and desirability of the EU's involvement is clearly needed, also considering the differences in quality of care policies between and within EU Member States. Both arguments in favour and against further EU involvement are discussed in this paper.

1. Introduction

A sizeable majority of citizens in the European Union (EU) consistently prefer national decision-making on healthcare over joint decision-making by national governments and the EU [1]. In accordance with these feelings their governments like to keep healthcare foremost a national competence. They have enshrined in the EU treaties that the EU has only a complementary role in public health, emphasizing that "[t]he Union should respect the responsibilities of the Member States for the definition of their health policy and for the organization and delivery of health services and medical care" (article 168 of the Treaty on the Functioning of the European Union). This suggests only limited EU involvement in health care. However, national healthcare systems have been increasingly affected by the creation of a single European market, in which also health professionals, medical devices, pharmaceuticals, health services, and capital should move freely [2–5]. In fact, even the core of health care policy, the quality of healthcare services, is currently on the EU agenda. In this article we describe how the EU has become involved in health care with a specific focus on quality of care. We also reflect on the desirability thereof, which is of particular relevance considering the growing Eurosceptic protest against EU interference within EU Member States.

Quality of care is a multifaceted if not indistinct concept [6,7]. This analysis therefore starts examining the evolution of the EU quality of care policy in terms of scope, i.e. the range of subject areas that are dealt with, as this illustrates the understanding of quality of care within the

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EU setting. In addition, it discusses the EU involvement in quality of care in terms of depth, reflecting the level of regulatory interference. The regulatory strategies used by the EU in this case are, in order of the level of interference; sharing information, developing and diffusing standards voluntarily, and enforcement [8]. The first two can be seen as instances of soft law, which, in contrast to hard law (enforcement), is not formally binding. It concerns standards to which Member States abide through, among other things, peer pressure, socialization, or learning [9].

Our results show a broadening of the scope of EU policy both in general healthcare policy and within the quality of care policy. Secondly, concerning the depth of involvement we can discern a move from a focus on sharing information towards standardization and even the first signs of enforcement. In the discussion section we will discuss the advantages and disadvantages of growing EU involvement in quality of care policies.

2. Methods

EU health policy is of a rather fragmented and diverse nature, touching upon a variety of issues [9]. The empirical focus of this article lies on policies directly related to the provision of healthcare services rather than issues such as the EU working times directive or the health of the workforce. A good understanding of EU involvement concerning quality of care requires a variety of sources and research methods. Therefore, we firstly relied on the growing scholarly literature on EU policies concerning issues such as public health and cross-border care to present an overview of the developments at the EU level. Secondly, we examined policy documents from EU institutions related specifically to healthcare quality, such as resolutions and recommendations adopted by the Council of the EU (in which the ministers of the EU Member States collectively discuss and decide on EU legislation), the EU directive on the application of patients' rights in cross-border healthcare (hereafter patients' rights directive) adopted by the Council and the European Parliament after years of discussions on how to legislate cross-border care in the EU, communications by the European Commission (the EU's administration), the EU's public health programmes run by DG SANCO (the Commission's directorate-general for health and consumers affairs), and minutes of the working group on patient safety and quality (in which civil servants from EU Member States and EU bodies, and stakeholders in the healthcare field participate). Thirdly, we relied on 33 interviews with representatives of key actors in the field conducted in two rounds (2003 and 2012). This complemented our picture of the evolution of the EU's quality of care policy in terms of scope and depth of involvement. These key actors include those involved in European policy-making on quality of care and closely related issues such as cross-border healthcare (e.g., DG SANCO, OECD, the European Hospital and healthcare federation HOPE, the European Health Management Association EHMA, the Dutch Association of Hospitals NVZ, health insurance companies, Ministries of Health), as well as research institutes or researchers active in projects focusing on healthcare and particularly quality of care in the EU (e.g., the European Social Observatory OSE, Nivel, the Danish Society for Patient Safety, and the Dutch Institute of healthcare improvement CBO). This combination of research methods provided a sufficient basis to discern the fundamental trends in the emerging quality of care policy.

3. Results

In this section we will first show that EU policy concerning health and healthcare has broadened over the years and now includes public health, access to health care as well as quality of care. Subsequently, we will focus on the development of the EU quality of care policy by looking at the scope and depth thereof.

3.1. EU health policy: from health promotion and access to quality of care

The evolution of EU health policy can be described as an accumulation of tasks to be performed by EU institutions and Member States. The Maastricht Treaty (1991) constituted a major step in the EU's role in taking *health promotion* measures to ensure citizens' health. It defined the task to maintain a high level of health protection in all its policies and activities, even though EU level competences remained fairly limited [2]. In later EU treaty revisions, competencies were somewhat extended and strengthened in response to health crises and threats such as BSE, SARS, contaminated blood, and bioterrorism [3,10]. As part of its campaign against cancer, for which it could partly rely on international medical networks [11], the EU took standardizing measures, amongst others by issuing guidelines for quality assurance in screening of cervical cancer, mammography and colorectal cancer and by adopting legislation on tobacco control [12,13]. Furthermore, it set up regulatory agencies, expert networks and working committees related to public health, for instance on drug prevention, communicable diseases, health risks, and medication safety[1] [3,14]. In addition, it focused on providing health information and monitoring the health of EU citizens, partly through EU-funded research projects [2]. As is also reflected in its multi-annual health programmes (2003–2007; 2008–2013; 2014–2020), the EU's emphasis has thus initially been on preventing people from becoming sick and unhealthy, and protecting them from certain health threats.

The EU has also taken measures enhancing *access* to care. Since 1958, European regulations have coordinated the access to public healthcare systems for employees working abroad in the EU's internal market. By now, these regulations include everyone in public healthcare (insurance) systems, covering almost all legally residing people in the EU. The accompanying European Health Insurance Card to facilitate obtaining emergency care abroad has also been launched as a symbolic contribution to European citizenship [15]. In a range of high-profile cases since 1998,

[1] In case of medication safety this policy was not only aimed to ensure a high level of health protection but also to facilitate the internal market of pharmaceuticals in the EU.

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the Court of Justice of the European Union (CJEU) indicated that patients can also access health care across the EU based on the general principle of free movement of goods and services in the EU's internal market, albeit under certain conditions such as the protection of public health and the maintenance of high-quality national healthcare systems. The "holes in the fence" created by the CJEU raised serious concerns among authorities, health care providers and health insurance companies. These concerns were about efficient planning of health facilities when patients can move freely around the EU, as well as about the perceived lack of quality of care received abroad and problems of continuity of care [16,17]. In 2004, the European Commission proposed to include health services into the more general services directive as a legislative follow-up to the CJEU case law. This met fierce resistance in the Council and the European Parliament. Particularly left-wing parties in the European Parliament argued that health services deserved sector-specific legislation to enhance rights of patients going abroad, particularly those with rare diseases, and to guarantee quality of care across the EU [18,19]. In their view, the solidarity underpinning healthcare systems should not be undermined by free choice and competition, for better educated and affluent citizens could benefit more from patient mobility than others [20,21]. In 2011, after years of negotiations, the European Parliament and the Council eventually agreed on the patients' right directive in response to the CJEU's case law. The directive enshrines the right of reimbursement of cross-border care under certain conditions and requires Member States to facilitate access to cross-border healthcare (with the exclusion of long-term care, organ transplantation and vaccination programmes) by providing information to (future) patients on prior authorization, level of reimbursement, quality and prices of health care, and redress mechanisms.

In addition to hard law on patients' rights to reimbursement of *cross-border* care, a general right of access has been underlined by the Charter of the Fundamental Rights of Workers (1989), a Council Recommendation on the convergence of social protection objectives and policies (1992), the Council Conclusions on Common values and principles in European Union Health Systems (2006), and particularly by the Lisbon Treaty (in force since 2009) through a reference to the binding Charter of Fundamental Rights of the European Union, stating that "everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices" [22]. Specific reference to "the principles of universality, [and] access to good quality care" in the binding patients' rights directive has enhanced the legal weight of these principles [23]. Access to health care has not just been a legal issue. From its modest budget, the European Commission has also provided funding to facilitate efficient use of healthcare facilities in border regions [16]. Furthermore, (candidate) Member States have received financial support and recommendations to undo their social-economic weaknesses by strengthening their health infrastructure [24,25]. A variety of e-health applications also received subsidies from the European Commission to ease access to health care within and between Member States, although inter-operability has remained a major obstacle as, for instance, the case of the European Health Insurance Card shows [26]. Access to health care has also gradually appeared on the EU agenda in the last twenty years due to concerns about the social nature of Europe and the growing financial burden on healthcare systems because of ageing in particular. Even though national governments continued to emphasize their responsibilities regarding the organization and financing of their healthcare systems, they asked the European Commission to foster mutual learning and to share best practices on how to avoid the negative effects of the burgeoning healthcare costs while enhancing social inclusion through health improving policies [27–29]. In this way, a general right of access has become also part of soft law arrangements.

The third task the EU has taken up concerns the provision of healthcare itself by trying to influence the multi-faceted issue of *quality of care*. First the relevant EU institutions adopted legislation to ensure the quality and safety of pharmaceuticals, blood, human tissues, human organs and medical devices [3,30]. In addition, to guarantee a certain level of quality of health professionals seeking registration elsewhere in the EU, legislation on the mutual recognition of diplomas sets minimum standards regarding professionals' education and training. The EU's role has not been restricted to goods and persons however, but also regards the quality and safety of healthcare *services*, the specific subject of interest in this article. Since the early 1990s, the issue of quality of care has gradually appeared on the EU agenda. This is partly due to the growing attention to the issue within the EU Member States and in international organizations with partly overlapping membership such as the World Health Organization (WHO), the Organization of Economic Cooperation and Development (OECD) and the Council of Europe (an intergovernmental organization focusing on democracy and human rights), resulting in definitions and indicators facilitating international comparison and assessment of quality of care in all its facets [31]. In the 1990s the European Commission and the Council started referring to the value of high-quality health care, while continuously emphasizing Member States' prerogatives in this regard in non-binding communications and recommendations, respectively [2,9,32]. The depth and scope of the EU's quality of care policy has yet expanded in recent years, it is this evolution of EU policy that we will now turn to.

3.2. Sharing information on quality

Sharing information started with collecting data on quality policies within the EU Member States with the purpose to learn from each other. In the 1990s, the European Commission started to fund some research on quality assurance and improvement from its EU Framework Programmes for Research and Technological Development, managed by DG Research [2]. Meeting informally under the Austrian EU presidency 1998, the Ministers of Health of the EU Member States also decided to collaborate more closely to exchange information on quality of care [2,31]. As a result, since 2000 EU health programmes paid more and more attention to this subject. Particularly in recent years, there have been large EU-funded research projects

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(funded from the Framework Programmes) on quality and safety, such as Simpatie and Marquis [30,33]. They aimed to gain insight into national safety and quality strategies. An important conclusion of this research was that there is much variation between and within Member States and that therefore there is a large potential to learn from each other.

An institutional infrastructure to share information has been set up, largely facilitated by DG SANCO. In response to the CJEU's case law on cross-border health care, the EU Council of ministers for health hesitantly and reluctantly agreed in 2002 to start rather informal yet regular meetings of health officials to discuss and monitor the impact of EU market law on their health systems. It resulted in the establishment of the so-called high level group on health services and medical care in 2004, involving senior health officials from the Member States and the Commission reporting to the EU Council [34,35]. In 2005, this group set up a working group specifically addressing patient safety. This working group consists of representatives of Member States, EU bodies and international organizations such as the WHO. It meets two to three times a year to share information, discuss the results of research projects, and reflect on possible actions for the future [36]. According to our interviewees involved in the working group, patient safety was tackled first, since there was quite some agreement on the definition of the subject. Safety can be seen as being part of quality of care, but the latter is a much broader subject consisting of many more aspects than just patient safety.

In 2008, the European Commission published the *Communication on patient safety, including the prevention and control of healthcare-associated infections* [37]. In it, facilitating the dissemination of best practices on patient safety was one of the few concrete measures. Together with a consultation of stakeholders (in 2008) and an EU-wide survey on patient safety and quality of care (in 2009), the Communication rather aimed at raising awareness of the issue in the EU [37,38]. Supported by the public health programme of the European Commission, the European Union Network for Patient Safety (EUNetPaS) was set up in 2008 to increase collaboration on patient safety among its Member States [39]. Furthermore, in 2009 the EU Council agreed upon a non-binding *Recommendation on Patient Safety including the prevention and control of healthcare-associated infections*, aiming among other things to share knowledge, experience and best practices [40]. Dissemination of information should not only be targeted at national and international health bodies and providers, but also at (future) patients. The Commission published in 2012 a first report on the implementation of the Recommendation by the Member States which the Commission also linked with its existing "Action plan against the rising threats from antimicrobial resistance." The original idea was to include quality in the Communication and Recommendation, but this proved too controversial and technically too complicated according to our interviewees (see also [41]). There is less agreement on what quality of care actually is, due to its widely diverging (cultural) understandings and applications between and within the EU member states [32,42]. This makes it much more difficult to reach agreement on the subject and for the EU to take measures. In 2008, however, the working group on patient safety changed its name into working group on patient safety and quality of care, reflecting a broadening of its scope [43].

The broadening of the scope from safety to quality can also be seen in the Joint Action on patient safety and quality of care, launched in 2012. This Joint Action is a collaboration mechanism between the Commission, OECD, European health organizations such as HOPE, the 27 Member States and Norway and Croatia and is funded by the Commission's health programme. The overall objectives of the Joint Action are to support the implementation of the Council Recommendation on patient safety and to strengthen the cooperation between Member States on rather practical issues related to quality of health care, including patient safety and patient involvement [44]. The Joint Action focuses on sharing information; identifying best practices in quality and patient safety also at clinical level, learning from each other and reaching an understanding on what quality of care actually is [45]. Regarding the Joint Action's work on safety and quality of care, a respondent closely involved indicated that the aim is to learn how better quality can be achieved and also how to make healthcare systems more effective in times of economic crisis. Part of the Joint Action is the establishment of national contact points on patient safety and quality in each Member State within the so-called European Union network for patient safety and quality of care to ensure that this collaboration will continue in the future.

3.3. Standardization

The EU's interference in quality of care also involves the development and diffusion of standards. Standardization structures the attention to a certain understanding of quality of care, leading to informal norms and yardsticks to assess the level of quality of care. First of all, the process of standardization includes a common understanding emerging from the increased exchange of information in international networks of professionals and experts [46]. Effective comparisons within and between Member States require collection of data in a similar way. For this reason, the European Commission has made the OECD's Health care quality indicators project, in which EU Member States also take part, a matter of priority in its public health programmes [47]. Quality indicators of the OECD include indicators on avoidable hospital admissions for certain conditions, in-hospital mortality following certain conditions, patient safety (such as data on complications) and screening, survival and mortality for certain types of cancer [48]. The aim of the Communication and Recommendation on Patient Safety was also to "classify and measure patient safety" according to common definitions and terminology. The Recommendation also provided common definitions of a number of key concepts such as "harm" and "patient safety". Reflecting its contested understanding, the core concept of quality of care is often left undefined, even though the EU institutions refer to high-quality of care as a "key human right" [49]. According to the Communication, quality of care at least includes patient safety and patient-centeredness. A preliminary definition seems to emerge in descriptions of several EU-funded studies also referring

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to patient safety and patient-centeredness in addition to clinical effectiveness [50,51].

In addition to common definitions and indicators concerning quality of care, standardization at EU level involves the non-binding prescription of how to diagnose or treat certain diseases, such as the quality guidelines regarding cancer screening and surgery, and drugs prevention. In addition, the EU stimulates the development of voluntary standards of products and services, also in the field of e-Health [45,52]. Recent studies funded from the EU framework programmes also aim to offer more general guidance on the implementation of quality improvement. For example, the Simpatie and Marquis studies provide toolboxes and recommendations to work on safety and quality [30,53]. Currently, other EU-funded projects such as Duque and Quaser aim to provide guides for hospitals and payers (governments, insurers) in EU Member States to work on quality and safety [50,51]. These projects also provide a meeting point for researchers and policy-makers through which a common understanding of effective quality of care policies in hospitals may emerge across Europe.

Further steps towards standardization are to be expected soon. The draft version of the multi-annual health programme for the period 2014–2020, includes a proposal to enhance collaboration, exchange best practices and develop tools and guidelines to improve health care quality and patient safety across the EU [54]. A Recommendation on health care quality and the development of common quality standards, either indicative or mandatory, have been contemplated before [55]. The latter reflects the possibility towards a deeper level of EU involvement, enforcement.

3.4. Enforcement

First steps have been made to deepen EU interference concerning quality of care in terms of enforcement. This means that EU policies can be enforced by hard law, which most often takes place by the inclusion or transposition of EU law into national legislation. This already applies to goods such as medical devices and pharmaceuticals. The EU sought to codify CJEU case law concerning cross-border healthcare services in the patients' right directive, which has to be transposed into national legislation by October 2013. Certain definitions of quality of care include access to healthcare, timeliness, and continuity of care [32]. If so, this directive as well as the much older Regulation coordinating access to public healthcare systems are already a significant instance of deepening EU involvement in quality of cross-border care, since it requires Member States to give authorization to patients seeking health care abroad when they face undue delay, while they have to ensure that patients receive a record of their treatment at their request.

EU involvement in quality of care proved to be highly controversial in the development process of the directive according to our interviewees. Member States did not disagree on the value of high-quality care in their respective systems, even though quality systems are still in its infancy in various Member States [32]. However, the Commission included an article specifically on health care quality in a draft version of the directive but this found very little support [56]. It was stipulated that Member States should define clear quality and safety standards and put mechanisms in place to ensure that providers are able to meet such standards. Moreover, it obliged Member States to regularly monitor the application of these standards and to take corrective action when needed. The Commission would also be given power to develop guidelines in cooperation with the Member States to facilitate the implementation of such standards, albeit under certain conditions. However, this article enabling standardization and enforcement on quality did not make it to the final draft. According to our interviewees, especially the fact that the Commission would be allowed to develop guidelines proved very contentious (see also [57]). Yet, with the removal of the article in question, the subject of quality did not vanish from the directive completely.

Recital 22 states that "systematic and continuous efforts should be made to ensure that quality and safety standards are improved", whereas article 10 calls upon the Member States to cooperate on standards and guidelines on quality and safety to allow for the implementation of the directive. More importantly, the directive requires Member States to provide foreign patients with relevant information on the standards and guidelines on quality and safety through national contact points (article 4.2a). In addition, health care providers have to provide information to foreign patients on the quality and safety of the care they provide to the same extent as domestic patients (article 4.2b). It has been argued that for some Member States requests for information by foreign patients may exert pressure to provide relevant quality and safety information to domestic patients also [58]. Other articles relate to quality as well, such as the establishment of European Reference Networks, consisting of healthcare providers and centres of expertise, which among other things are aimed at providing highly specialized care or developing quality and safety benchmarks. So the directive touches upon the issue of quality and safety in a number of ways, and presupposes a relatively well defined and shared understanding of quality. However, the legal grounds for EU interference are not as far reaching as the earlier draft of the directive proposed; the Commission cannot prescribe guidelines on quality of care. Furthermore, as in other EU documents, high-quality care is not further defined, leaving it largely to the Member States to decide on the standards of quality of care [41]. Hard law allowing the EU institutions to enforce quality of care in the Member States thus faces sheer limits at this point in time.

4. Discussion

Even though a large majority of EU citizens and their national governments want to keep healthcare by and large a national competence, we can clearly discern a trend towards more EU involvement. Through its policies on public health and access to cross-border care, quality of care is now gaining ground on the EU agenda. The EU policy on quality of care has expanded in scope from patient safety towards the broader concept of quality. In contrast to issues such as pharmaceuticals or organ donation, quality of healthcare services is still largely a subject of soft

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law. Nevertheless, deepening EU interference from sharing information to standardization to the first signs of enforcement can be identified. As EU's health policy in general, the policy on quality is the result of a fragmented and incremental process in which health crises, the Commission's agenda-setting activities, and market pressures have been the most important push factors [3]. This is partly due to Member States 'dragging their feet' not willing to cede much power on healthcare to the EU [9]. Nevertheless, EU involvement in healthcare has been growing. Although we cannot speak of a full-fledged EU competence concerning healthcare or quality of care in particular yet, it is important to reflect on the desirability of the evolution of such a competence, also since this can easily go unnoticed due to the fragmented and technical nature of EU health policy.

A first argument for EU involvement is that it offers a forum for Member States to learn from each other on the subject of quality of care. A large share of EU involvement in quality of care concerns sharing of information. Sharing information to learn from best practices across borders is not new to healthcare. Medical decisions are increasingly made on the basis of the scientific evidence available in the international literature. It would be a logical step to apply this to quality and safety policies that hospitals use to develop and control quality and safety as well. Especially less affluent countries which do not have quality systems can benefit from learning about the experiences in other countries without having to finance research themselves. The EU has funded research and created several platforms in order to stimulate this sharing of information. Member states would thus have the opportunity to learn from each other.

An argument can also be made for deeper EU involvement. As we have described, its involvement in quality and safety includes a certain measure of standardization. In this respect healthcare is moving in the same direction as consumer goods such as toys or food [32,42,59]. The large variation in how countries ensure quality and safety of care [60] can be considered a stumbling block for cross-border care. However, only few patients seem to use their opportunity of crossing borders to receive care, and a recent study questions whether this number will grow in the future [61]. In border regions and for highly specialized care, standardization may yet allow for efficient use of health care facilities across national borders. However, the overall marginal use of cross border care makes the argument of standardizing quality of care through EU involvement to ensure patients' rights less compelling. But there are other arguments that warrant the EU to proceed with caution.

Firstly, the fact that citizens and national governments want to keep healthcare a national competence should carry some weight, particularly when the EU is increasingly charged of being undemocratic and of undesired meddling with domestic affairs. The field of healthcare is particularly prone to the common critique of being "technocratic" and removed from public and national democratic influence. Healthcare discussions at the EU level are likely to involve highly technical matters, which requires professional expertise that national ministers and parliamentarians are unlikely to possess [9,10,41]. Health professionals are better positioned to enter such debates as they already operate in international knowledge networks. Yet, mutual understandings among health professionals may overlook the desire of national governments and EU citizens to keep healthcare a primarily national competence. The fact that quality of care has been left rather unspecified at EU level, which leaves EU involvement without conceptual bounds, makes this issue especially relevant. Also, the EU has more legal instruments than other international organizations such as the WHO and the Council of Europe which creates the potential for a further expansion of interference in terms of scope and depth. Increased EU interference in national healthcare systems is also reflected in the EU support programmes for Member States facing a debt crisis and could spill over to other Member States as part of the more stringent role of the EU concerning its supervision of national budgets [25]. This involvement impacts the organization and financing of healthcare systems and shows that the EU is becoming increasingly involved in Member States healthcare systems. Reflection on the desirability of such interference in national healthcare systems is therefore clearly needed at this point in time. To put it in terms of EU politics, reflection on the principle of subsidiarity which, simply put, means that the EU should only be involved if it would have additional value (such as in the case of highly specialized care), is essential at the moment EU policies on healthcare are expanding in scope and depth.

Secondly, variation between countries regarding their quality policy on patient care can be considered a problem (see above), but there can also be good reasons for it. Setting common enforceable standards may face both resistance from Member States that perceive these standards too high and therefore too expensive to maintain, and Member States that fear their own high quality standards to be replaced by lower ones. Furthermore, it is also important to realize that soft law has a normative dimension, too. The EU may thus steer and shape a particular understanding of quality of care, despite different quality norms and standards between and within its Member States [5]. Especially considering quality and quality policy there are cultural differences as well as practical and institutional concerns between and within countries which may lead them to, e.g., prefer different combinations of specialized and non-specialized services, different degrees of centralization and de-centralization and different thresholds for medical vs surgical intervention. Apart from the question whether standards may enhance quality of care at all, they may also impose a particular understanding of (quality of) care which would not necessarily suit the needs and desires of individual patients embedded in different national cultural contexts across the EU. A uniform EU quality improvement system would therefore not only be unfeasible, but also undesirable [62,63]. In this respect, the restraint of Member States to give the EU more legal say on matters of quality of care would be rather justified.

5. Conclusion

Although it is continuously emphasized that the organization of healthcare systems is mainly the responsibility of

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its Member States, this article shows an increasing involvement of the EU in healthcare. This influence concerns not only public health and access to care, but also quality of health services. Largely based on its public health and cross-border care policy, the subject of quality is now placed on the EU agenda. The EU broadened the scope of its policy from safety to quality and increased the depth of involvement from a focus on sharing information towards standardization and even a certain measure of enforcement. It is important to realize that the absence of strong EU competences in healthcare does not mean that the EU is without influence [64]. At this stage, reflection on the desirability of the EU's involvement is clearly needed. Both arguments in favour and against further EU involvement have been discussed, drawing attention to the issue of which actor should be allowed to determine the policy of quality of care in a situation where a wide variety of understandings within and between countries exists.

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