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Patients' rights relating to patient safety

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1. Introduction[1]

During the past decade the attention given in health care to patient safety had increased considerably. Patient safety relates to the reduction of risk and is defined as "freedom from accidental injury due to medical care, or medical errors".[2] Patient safety is about managing this risk, using a wide variety of policies and instruments, including –but not limited to– building a safety culture, the development of clinical guidelines, reporting and analyzing adverse events, training doctors and other health professionals in the management of quality and safety and, last but not least, patient empowerment. Patient safety is a global issue. Both at the national and the international level numerous initiatives have been taken to develop sound patient safety infrastructures, which are aimed at reducing the number of patients who are unintentionally harmed when undergoing medical care.[3] On the basis of data gathered from studies performed in

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[1] This paper is an updated and expanded version of: J. Legemaate. Patients' rights and patient safety, in: D Delnoij, V Hafner (eds), Exploring patient participation on reducing health--care-related safety risks. Copenhagen: WHO/Regional Office for Europe, 2013, p. 11-32.

[2] LT Kohn, JM Corrigan, LS Donaldson. To err is human – Building a safer health system. Institute of Medicine, 2000.

[3] See http://www.euro.who.int/__data/assets/pdf_file/0015/111507/E93833.pdf.

the United States, Australia and a number of Western European Countries it is estimated that between 8 % and 12 % of patients admitted to hospital suffer from adverse events whilst receiving healthcare.[4] In actual practice this number may even be higher, due to the significant and widespread under-reporting of adverse events.

This paper describes and analyses the regulatory aspects of patient safety and more specifically the relationship between patient safety developments and patients' rights. The aim of this paper is to explore the legal context of patient safety, with a focus on obligations and possibilities to increase patient involvement and patient participation in the area of safety and quality of care. Patients' rights applicable in this area should not only try to achieve the intrinsic goal of protecting patients against unwarranted interventions (the traditional legal role) but should also try to promote the patient's well-being as well as the realization of equal access of all citizens to patient-centered care that is safe and of good quality. The key issue is to empower and inform citizens and patients: involving patient organizations in policy making, informing patients about standards, safety measures, remaining risks and complaints procedures, and developing core competencies in patient safety for patients.[5]

2. Normative guidelines from international bodies

In recent years international bodies and organizations like the Council of Europe, the OECD, European Union and WHO/WHA (World Health Organization/World Health Assembly) have undertaken many activities in the area of patient safety, ranging from defining principles and standards to developing down-to-earth approaches and tools regarding specific and concrete areas of patient safety. This paper is not the place to present a complete overview of all these activities.[6] However, it is important to assess the normative view of these organizations on the key-aspects of patient safety in relation to patients' rights. These key-

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[4] Technical report 'Improving Patient Safety in the EU' prepared for the European Commission, published 2008 by the RAND Cooperation.

[5] Recommendation of the Council of the European Union of 9 June 2009 on patient safety EU website http://ec.europa.eu/health/patient_safety/docs/council_2009_en.pdf.

[6] See for a more extensive overview: http://www.euro.who.int/__data/assets/pdf_file/0015/111507/E93833.pdf.

-aspects can be deduced from a number of leading documents, the most important of which, in this context, are:

- WHA55.18 Resolution 'Quality of care: patient safety' of 2002, in connection with the Draft guidelines for adverse event reporting and learning systems, as published by the World Health Organization in 2005;
- The Luxemburg Declaration on Patient Safety of April 2005 (under the auspices of the European Union);
- Recommendation 2006/7 of the Council of Europe on the management of patient safety and prevention of adverse events in health care;[7]
- The Recommendation of the Council of the European Union of 9 June 2009 on patient safety, including the prevention and control of healthcare associated infections;
- The Directive of the European Union on the application of patients' rights in cross-border healthcare of 9 March 2011;
- The case law of the European Court of Human Rights.

2.1. The World Health Organization

The WHO document most relevant to the legal aspects of patient safety and patient participation is the draft guideline on adverse event reporting and learning systems. This document was published in 2005 by the World Alliance for Patient Safety and can be seen as a one of the means to implement WHA55.18 Resolution 'Quality of care: patient safety' of 2002.[8] The 2005 document focuses specifically on the role of reporting adverse events in enhancing patient safety: "In seeking to improve safety, one of the most frustrating aspects for patients and professionals alike is the apparent failure of health-care systems to learn from their mistakes. Too often neither health-care providers nor health-care organizations advise others when a mishap occurs, nor do they share what they have learned when an investigation has been carried out. As a consequence, the same mistakes occur repeatedly in many settings and patients continue to be harmed by preventable errors. One solution to this problem is reporting: by the doctor, nurse, or other provider

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[7] https://wcd.coe.int/wcd/ViewDoc.jsp?id=1005439&Site=CM.

[8] See http://apps.who.int/gb/archive/pdf_files/WHA55/ewha5518.pdf.

within the hospital or health-care organization, and by the organization to a broader audience through a system-wide, regional, or national reporting system. Some believe that an effective reporting system is the cornerstone of safe practice and, within a hospital or other health-care organization, a measure of progress towards achieving a safety culture. At a minimum, reporting can help identify hazards and risks, and provide information as to where the system is breaking down. This can help target improvement efforts and systems changes to reduce the likelihood of injury to future patients".[9] It is important to note that reporting incidents is not a panacea. Different reporting systems exist, and the effectiveness and efficiency of these reporting system may vary, depending upon the structure, the scope and level (institutional, regional, national) of the reporting system. However, there are strong indications that well-considered reporting systems may have great value.

The draft guidelines of WHO do not explicitly deal with the issues of patients' rights, but the underlying message is clear: patient safety reporting systems play such a fundamental role that if such systems are not in place it will be difficult if not impossible to realize the patient's right to good care.

2.2. The European Union

EU policies are aimed at providing citizens with a high level of health protection. Seen from this perspective it is not surprising that the Luxemburg Declaration on Patient Safety of 2005, created under the auspices of the European Commission, recommends that "Patient Safety" needs to have a significant place high on the political agenda of the EU, nationally in the EU Member States and locally in the health care sector.[10] The European Union is engaging with a range of areas that can facilitate the improvement of patient safety.[11] Over the years the EU has been regulating the safety of blood, tissues and cells. More recently the

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[9] http://www.who.int/patientsafety/events/05/Reporting_Guidelines.pdf.

[10] HDC Roscam Abbing. Patients' right to quality of healthcare: how satisfactory are the European Union's regulatory policies? European Journal of Health Law 2012; 19: 415-422.

[11] JV McHale. Regulating patient safety in the European Union: realistic aspiration or unattainable goal? In: J Tingle, P. Bark (eds), Patient safety, law policy and practice. London: Routledge, 2011, 150-164.

right to free movement of patient and health professionals has generated patient safety concerns at the EU level. In its 2009 Recommendation on patient safety (including the prevention and control of healthcare associated infections) the Council of the European Union expresses a more general view on patient safety in the EU context.[12] The EU Recommendation focuses on empowering and informing citizens and patients by:

(a) involving patient organizations and representatives in the development of policies and programmes on patient safety at all appropriate levels;
(b) disseminating information to patients on: (i) patient safety standards which are in place; (ii) safety measures which are in place to reduce or prevent errors and harm, including best practices, and the right to informed consent to treatment, to facilitate patient choice and decision-making; (iii) complaints procedures and available remedies and redress and the terms and conditions applicable;
(c) considering the possibilities of development of core competencies in patient safety namely, the core knowledge, attitudes and skills required to achieve safer care, for patients.

In addition, the European Union Directive on patients' rights in cross border healthcare of 2011 underlines the importance of helping patients to make an informed choice when they seek to receive healthcare in another Member State. Healthcare providers should provide relevant information to help individual patients to make an informed choice on the availability, quality and safety of the available healthcare services. In general, the Directive clearly stipulates the right of access to safe and high-quality cross-border healthcare.[13] It is one of the examples of the increasing expansion of EU power in the area of health law and policy.[14]

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[12] See http://ec.europa.eu/health/patient_safety/docs/council_2009_en.pdf.

[13] See the various contributions in the special issue of the European Journal of Health Law on the EU Cross-border Care Directive (EJHL 2014; 21: 1-96).

[14] A de Ruijter. A Silent revolution: the expansion of EU power in the field of human health – A rights-based analysis of the UE health law and policy. Amsterdam: University of Amsterdam, 2015 (PhD thesis).

2.3. The Council of Europe

Recommendation 2006/7 of the Council of Europe outlines a comprehensive policy to improve patient safety[15] and departs from the viewpoint that access to safe health care is the basic right of every citizen in all member states of the Council. Furthermore the Recommendation considers that patients should participate in decisions about their health care, and recognizes that those working in health-care systems should provide patients with adequate and clear information about potential risks and their consequences, in order to obtain their informed consent to treatment. The Recommendation is accompanied by an extensive Appendix which provides a full technical and scientific background and justification of the Recommendation. The Recommendation of the Council of Europe strongly emphasizes the importance of protecting patients' rights. The Recommendation promotes a comprehensive approach, including not only an adverse event reporting system but, in addition, a fair and open complaints system, a just and adequate compensation system and an efficient and reliable supervisory system.

2.4. The case law of the European Court on Human Rights

Patient safety is an issue at the level of the European Court on Human Rights as well. In the 2004 case of Selisto versus Finland the Court stated that patient safety was an important aspect of health care and raised serious issues affecting the public interest. In the 2009 case of Codarcea v. Romania the Court pointed out that under the European Convention of Human Rights States have an obligation to introduce regulations compelling both public and private hospitals to adopt appropriate measures for the physical integrity of their patients.[16] It also stressed that any patient should be informed of the consequences of a medical operation and be able to give or withhold their consent in full knowledge thereof. In more recent cases the Court emphasized that the Convention also requires an effective independent judicial system to be set up so that the harm caused to patients in the care of the medical profession, whether in

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[15] Th Perneger. The Council of Europe recommendation Rec(2006)7 on management of patient safety and prevention of adverse events in health care. International Journal for Quality in Health Care 2008; 20: 305–307.

[16] European Court of Human Rights (ECHR) 2 June 2009, nr. 31675/05 (Codarcea v. Romania).

the public or the private sector, can be determined and those responsible held accountable. According to the Court this can for instance be done by granting patients full access to civil proceedings or to disciplinary proceedings which may lead to liability for medical negligence. Furthermore, the Court emphasized that in case of harm done to patients claims for compensation should be dealt with speedily.[17]

3. Patients' rights in the area of patient safety

In general terms, the relationship between legal rights and patient safety was clearly summarized in a draft report on 'Human rights, the right to health and patient rights', prepared by WHO Europe in 2009: "The fulfillment of the right to health (a human and patient right) involves all health care actors: patients/consumers, governments and health care providers/stakeholders in rendering it concrete. All binding and non--binding international documents revised emphasize that international frameworks and policy instruments should be used to protect the fundamental human rights including patients' rights. In the quest towards strengthening political commitment of member states, the WHO Declaration on the promotion of patients' rights in Europe and the European Charter of patients' rights, seek to render the right to health concrete, applicable and appropriate to the current transitory situation in health services across the region. Work towards a common European framework for action and international instruments for realizing national policies in the field of patients' rights recorded substantial progress according to reported data. Most of the European member states have national dedicated policies and charters addressing patient rights. The implementation of local instruments as juridical legislation or extra juridical organisms (e.g. national or regional ombudsman) have to be encouraged and promoted to render effective the patient/ consumer protection. The right to safety is a key point in the implementation of the right to health. Promoting patient safety is strictly connected with the development of consumer empowerment, and involvement in the process of health promotion and care, including participation in the policy making process. It is expec-

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[17] See ECHR 23 March 2010, nr. 4864/05 (Oyal v. Turkey), ECHR 25 September 2012, nr. 19764/07 (Spyra & Kranczkowksi v. Poland), ECHR 13 November 2012, nr. 41108/10 (Bajic v. Croatia) and ECHR 15 January 2013, nr. 8759/05 (Csoma v. Romania).

ted to support the active partnership needed in the process of improving safety, quality and efficiency of health service delivery".[18]

In this paragraph the focus will be on the specific rights of patients in the area of patient safety. In the past decades the rights of patients have been identified and elaborated in international documents and guidelines, national legislation, case law, deontological codes and so on. A number of these rights are relevant in the area of patient safety.

3.1. The right to health care which is safe and of good quality

Every citizen's right to health care can be found in many international treaties and guidelines as well as in national legislation (either at the level of a Constitution or Charter or 'translated' in to the specific national legislation on health care insurance). Already in 1946, the WHO Constitution stated that "the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being". The right to health care has both collective and individual dimensions. At the collective level this right stipulates that national authorities should strive to realize a health care system that is comprehensive (prevention, cure, care), accessible (both geographically and financially) and of good quality (safe, state of the art). At the individual level the right to health care is embodied in the entitlements of citizen regarding health care as defined in the national legislation. These entitlements may vary from country to country as well as over time, dependent on various factors, including the availability of resources.

The WHO Declaration on the Promotion of Patients' Rights in Europe of 1994, the socalled Amsterdam Declaration, stipulated that patients have the right to a quality of care marked by high technical standards and a humane relationship between the patient and health care providers.[19] The European Charter of Patients' Rights of 2000 mentions that "each individual has the right to be free from harm caused by the poor functioning of health care services, medical malpractice and errors, and the right of access to health services and treatments that meet high standards".

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[18] WHO Europe. Human rights, the right to health and patient rights in the WHO European region. Copenhagen, 2009, p. 39 (draft, internal report).

[19] HDC Roscam Abbing. Twenty years WHO principles of patients' rights in Europe, a common framework: looking back to the future. European Journal of Health Law 2014; 21: 323-337.

The Luxemburg Declaration on Patient Safety of 2005 values the access to high quality care as a key human right. The international recommendations I described earlier in this paper are based on the same assumption. In national legislation several examples can be found of provisions concerning the safety and quality of care that has to be provided. A clear example is Article 2 of the Dutch Quality of Care in Institutions Act of 1996: "The care providers offers appropriate care. Appropriate care implies care of a good level, that is effective, efficient, patient centered and adjusted to the needs of the patient". It is not always common to make an explicit distinction between the quality and safety of health services, but it is important to do so, because quality levels may vary, while safety is a baseline that has to be maintained in all circumstances.

3.2. The right to participate in policymaking

It is broadly acknowledged that patients or their organizations or representatives should take part in the development of health policies, at all levels (national, regional, local). Patient centered care can only be achieved if the views and experiences of patients are used as input for policymaking, next to other relevant sources of information. Recommendation 2 of the European Union Recommendation on Patient Safety of 9 June 2009 stipulates that patient organizations and representatives should be involved "in the development of policies and programmes on patient safety at all appropriate levels".[20] There are many ways to realize this, varying from consulting national patient organizations on policy issues to creating a legislative basis for clients' councils in health care institutions. See in more detail Recommendation No. R (2000)5 of the Committee of Ministers of the Council of Europe on the development of structures for citizen and patient participation in the decision-making process affecting health care.[21]

This right implies that governments and health authorities stimulate and facilitate the establishment of patient groups and organizations and that these groups and organizations are well-informed. At the level of individual patients it is important that they are free to participate in representative bodies and organizations and that they are supported if

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[20] See http://ec.europa.eu/health/patient_safety/docs/council_2009_en.pdf.

[21] See https://wcd.coe.int/wcd/ViewDoc.jsp?id=340437&Site=CM.