PROTECTION OF THE RIGHTS OF PATIENTS
IN INCIDENTS REPORTING SYSTEMS

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INTRODUCTION.

Patient safety is a new and emerging patient right. An opinion of the European Economic and Social Committee on “Health safety” called patient safety “a collective obligation and a new right”.¹ The patient rights legislations of the Member States of the EU do not yet mention patient safety explicitly a patient right.² There is a growing recognition of the right to safety at an international level. Article 9 of the European Charter of Patients’ Rights approved by the Active Citizen Network in November 2002 stipulates: “Each individual has the right to be free from harm caused by the poor functioning of health services, medical malpractice and errors and the right of access to services and treatments that meet high safety standards”.³ There is also the Luxemburg Declaration on Patient Safety adopted on 5 April 2005.⁴ And article 20 of the Universal Declaration on Bioethics and Human Rights, adopted by UNESCO on 19 October 2005 calls on the Member States to promote “appropriate assessment and adequate management of risks related to medicine, life sciences and associated technologies”.⁵ More recent and important is the proposal for a Directive of the European Parliament and European Commission on the application of patients’ rights in cross border care.⁶ According to article 5 (1) of the proposal the Member States have to define clear quality and safety standards for healthcare provided on their territory.

¹ Opinion of the European Economic and Social Committee on Health Safety : a collective obligation and a new right, Official Journal European Union, 20 May 2005, C 120/47
² See www.europatientsrights.eu
³ www.activecitizenship.net
⁴ www.ec.europa.eu/health
⁵ http://portal.unesco.org
Patient safety calls for a systematic approach: “in the midst of complicated medical procedures one can ask how long can a human being – an individual health care professional – cope with the rising demands of managing the increased risk level? We have come close to the limits”.\(^7\) One of the means to promote patient safety is the reporting of adverse events by health personnel. Such reporting raises a lot of difficult questions such as: Should it be mandatory or voluntary? Based on legislation or self-regulation? Anonymous or not? Related to litigation and accountability or not? And also: Is it possible and how to reconcile safe (“blame free”) reporting by health care professionals with the right of patients to be informed of an adverse event that occurred and to be compensated if any damage occurred.

In this article paper I will deal with these questions from a legal point of view. The starting point of my analysis is the Recommendation 2006 \(^7\) of the Committee of Ministers of the Council of Europe to the member states on management of patient safety and prevention of adverse events in health care.\(^8\) Together with two other documents it will serve as the background for my analysis. Denmark was the first country in Europe to introduce a nationwide reporting system of adverse events in health care: Act No.429 of 10 June 2003 on Patient Safety in the Danish Health Care System or (Danish) Patient Safety Act. In Belgium a bill to amend the Hospitals Act has been prepared by a working group with a view to introduce a reporting system for adverse events in hospitals. It is still an unofficial document.

\(^7\) P.Pennanen, Chair of the Committee of Experts of the Council of Europe on recommendations on patient safety. “Recommendations on patient safety- Committee of experts in the Council of Europe”, 2 www.teo.fi, (entered on 18 October 2005) (not available anymore)

\(^8\) www.coe.int
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1. ENCOURAGING HEALTH CARE PROVIDERS TO REPORT SAFETY INCIDENTS

On 24 May 2006 the Committee of Ministers of the Council of Europe approved Rec (2006) 7 to the member states on management of patient safety and prevention of adverse events in health care. One of the recommendations is that member states should “promote the development of a reporting system for patient-safety incidents in order to enhance patient safety by learning from such incidents” (Recommendation iii). According to Recommendation iii,c) such a reporting system should “be designed in such a way as to encourage health-care providers and health-care personnel to report safety incidents (for instance, where possible, reporting should be voluntary, anonymous and confidential)”. The Appendix to the Recommendation contains more details on how to encourage health care workers to report safety incidents.

1.1. Reporting should preferably be voluntary

A reporting system should “preferably be voluntary in nature (…). A mandatory system for individual health-care personnel could completely demotivate those directly involved in the provision of health care and who are involved in such reporting systems” (Appendix D.1.4 a). With regard to a legal obligation to report, Appendix D.1. 10 notes : “Experience from different countries varies as to whether there is a need to make reporting systems and analysis of patient-safety incidents a legal obligation”. Regrettably, no further information is given regarding the countries involved. P.Pennanen who presided a committee of experts set up by the Council of Europe in order to prepare the Rec (2006)7 stated that “mandatory reporting can turn out to be spurious, because in many cases it is just the professional in question who knows about a near miss or an adverse event. Voluntariness is more
respecting and motivating but needs the support, activity and fair handling by the management of health care units and organizations”.  

Section 3 (2) of the Danish Patient Safety Act obliges a health care professional, who becomes aware of an adverse event in connection with a patient’s treatment or stay in a hospital, to report such event to the hospital risk manager who in turn must report to the county councils 10. However, the Patient Safety Act does not provide for sanctions when an adverse event has not been reported. As a result of the evaluation of the Act in 2006 an expansion to the primary health care sector is planned to take place during 2009. After this expansion the reporting system of adverse events will cover all sectors of the health care system 11. The number of reported cases has increased from 5,740 in 2004 to 15,556 in 2006. The increase probably reflects that the reporting system has become known and accepted by the health care professionals, and that a change of safety culture has taken place focusing on the potential of learning from adverse events 12. The evaluation of the system in 2006 also showed that generally the reporting system functions very well at local, regional, and central level. However, less well-functioning aspects were pointed out. The evaluation showed that not all adverse events are reported, and different reasons were mentioned. Some professionals are unsure of the definition of an adverse event and

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11 Ministry of Health and Prevention, Health Care in Denmark, Chapter 6 : Quality improvement and safety www.sum.dk ( entered 23 May 2009)

12 Ministry of Health and Prevention, Health Care in Denmark, Chapter 6 : Quality improvement and safety www.sum.dk ( entered 23 May 2009)
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others pointed at the lack of time and resources.\(^\text{13}\) No reference was made to the possible demotivating effect of mandatory reporting.

While Denmark has opted for a mandatory reporting system, the Belgian proposal of a bill provides that the use of the reporting and learning system is voluntary.

1.2. A reporting system should respect the confidentiality of those who report

Appendix D.2. 5 of Rec (2006)\(^7\) identifies the following barriers to report which should be removed through appropriate policies:

a) fear of blame, resulting from a lack of open and fair culture;

b) fear of the reports being used out of context by the media and others;

c) lack of feedback as to what has changed as a result of the report;

d) lack of time to report;

e) lack of support from the management of the organization;

f) *lack of legal protection against using the information for purposes other than learning* (see 2.3. of this paper)

g) *breaches of confidentiality or anonymity leading to ineffective separation of incident reporting systems from disciplinary and regulatory bodies.*

Appendix J of Rec (2006)\(^7\) relates to the legal framework. The diversity of existing legal traditions and practices in Europe calls for a country-specific approach. Such legal approaches should:

\(^{13}\) Ministry of Health and Prevention, Health Care in Denmark, Chapter 6 : Quality improvement and safety [www.sund.dk](http://www.sund.dk) (entered 23 May 2009)
“comply with professional-secrecy and data protection rules, for example by providing the information in a register in an anonymous form” (Appendix J, 2, a, v);

“ensure the confidentiality of the reporting procedure, that is, ensure the identity of the reporting health-care professional or patient shall not be disclosed to patients or to the public; if the event is to be analyzed and learned from, the names of the personnel involved may need to be known locally (that is, inside the actual institution)” (Appendix J, 2, a, vi);

With regard to confidentiality and anonymity the Danish Patient Safety Act distinguishes different stages in the reporting system.

The first stage is the input of information in the system. Reporting can be done in an anonymous way or not. The Danish Patient Safety Act does not contain a rule in this regard. It is not mandatory for a health care professional to state his/her name or other identifiable information when reporting, but anonymity makes the collection of further information difficult for the analyzing team. Less than 10% of health care professionals choose to be anonymous.\(^{14}\)

In a second stage the county councils that receive reports on adverse events have to transmit this information to the National Board of Health (Section 3.1 of the Danish Act). The National Board of Health establishes a national register of adverse events (Section 4.1). In the reports of adverse events from county councils to the National Board of Health both patient and health care professional are

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anonymous (Section 4.5). The name of the professional related to an adverse event is not of any meaning in the systematic evaluation of patient safety incident data.\textsuperscript{15}

According to Section 5.1 reports on adverse events, which may be attributed to specific individuals, may without the consent of the patient or the involved health care personnel be exchanged within the group of people who locally, within the county council, record and analyze the reported adverse events. According to Section 5.2 the county councils may not disclose information about the reporting health care professional’s identity to anybody except the people who locally, within the county council, record and analyze the reported adverse events.

The Belgian proposal of a bill provides that the reporting system should offer the possibility to report an adverse event anonymously. Personal data in the reporting system may not be kept longer than necessary for the analysis and classification of the adverse event and not longer than during one year.

1.3. A reporting system should offer legal protection to those who report ("blame free" reporting).

The legal protection of the reporting health-care professional can be guaranteed in different ways. The strongest protection is offered by guaranteeing the reporting professional immunity against legal prosecution or sanctions. Such a system exits nowhere. Another form of legal protection is that the reported information may not be used against the reporting professional in legal procedures without his consent. Still another form of protection is that reporting as such may not lead to legal procedures

\textsuperscript{15} P.Pennanen, “Recommendations on patient safety- Committee of experts in the Council of Europe”, www.teo.fi, p.2 (entered on 18 October 2005)
against the reporting physicians. And finally legal protection can be guaranteed by anonymously reporting (see 2.2.).

According to Appendix J, 2 a), vii of Rec (2006) 7, the legal framework of any reporting system should “ensure the legal protection of the reporting health-care professional, that is, ensure that a health-care professional reporting to the system shall not, as a sole result of such reporting, be subjected to disciplinary investigation or measures by the employing authority, or reprisals such as supervision or criminal sanctions by the courts”.

This protection enables sanction free reporting and is crucial for the health care professional’s motivation to report.

Following Section 6 of the Danish Patient Safety Act a health care professional reporting an adverse event may not as a result of such reporting be subjected to disciplinary investigations or measures by the employing authority, supervisory reactions by the National Board of Health or criminal sanctions by the courts. This element is seen as critical to gaining the initial and ongoing support of the health care professionals themselves, and does not appear to have resulted in discontent within the Danish public.16

The similarity between Section 6 of the Danish Act and Appendix J, 2 a) vii of Rec (2006) 7 is striking and is probably no coincidence. Pennanen expressly refers to the Danish Act: “In the Danish Act the reporting health care professional is legally protected so that she/he shall not as a result of reporting according to this act be subjected to disciplinary investigations or measures by the employing authority, supervisory reactions by the National Board of Health or criminal sanctions by the courts. This does

not mean immunity as such, because it only refers to the specific reporting. Health care professionals will always bear personal responsibility for their actions”.17 It is important to keep in mind that in Denmark a health care professional could be subjected to sanctions, even though the adverse event has been reported to the reporting system. For instance, this could happen if a patient submits a complaint to the complaint system. But the complaint system cannot at any time have access to information in the reporting system and use this information for disciplinary purposes. The complaint system, the supervision system and the patient insurance system co-exist with the reporting system but information is not exchanged between the reporting system and the other systems.18

Also the Belgian proposal of a bill offers legal protection to the health care professional who reports an adverse event. Notwithstanding the possibility to deliver proof by using other data, the reporting as such and the reported data may not lead for the person who reported and for the persons mentioned in the report to criminal or civil prosecution, a disciplinary action or measures taken by the employer. Moreover, a reported adverse event cannot be considered as a recognition of criminal, civil or disciplinary liability.

2. “BLAME FREE” REPORTING AND THE RIGHT OF A PATIENT TO BE INFORMED AND TO RECEIVE COMPENSATION

Some have argued that “blame free” reporting by physicians may undermine the relation of trust between the reporting physician and his patient. The Dutch health law professor H.Roscam Abbing is

17 P.Pennanen, “Recommendations on patient safety- Committee of experts in the Council of Europe”, www.teo.fi, p.3 (entered on 18 October 2005)
one of them. She wrote: “Blame free melden onderruigt het vertrouwen” (“blame free reporting undermines trust”). She argues that blame free reporting is violating the right of the patient to be informed about the adverse event.

The Appendix to Rec (2006) 7 has recognized the possible tension between blame free reporting and the right of patients to be informed of adverse events and to receive compensation. Appendix J. 4 states the following: “It may appear difficult to establish a patient-safety reporting system without compromising patients’ rights. However, if the public is ready to accept the presence of a confidential, anonymous, non-punitive reporting system the public must be assured that its legal and financial rights will be protected. The existence of a fair and open complaints system, a just and adequate compensation system and an efficient and reliable supervisory system will certainly make the process easier and politically more acceptable. Promoting a ‘no blame’ culture is not intended to diminish the effective legal protection of patients”.

Appendix J, 3 b) of Rec (2006) 7 states that legal approaches regarding patients’ rights should “ensure that patients are immediately informed of an adverse event and of any events entered into the patient’s medical file” while according to Appendix J, 3 c) such legal approach should “ensure that patients who have been harmed by a patient safety incident are entitled to receive financial compensation”.

The Danish Patient Safety Act does not contain a provision that entitles the patient to be informed of an adverse event. However, Section 4 a) of the Danish Patient Insurance Act 1997 provides that it is incumbent on every authorized healthcare professional who, in the course of his work, becomes

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aware of injuries that may be assumed to entitle the patient to compensation under the Act to inform the injured person thereof.

Moreover, the right to receive information regarding one’s state of health is mentioned in Article 16 Section 1 of the Danish Health Act 2005 as part of the right to informed consent. Does the right of a patient to be informed of his state of health also covers the right to be informed of an adverse event in case this event has influenced the state of health? In my opinion the right of a patient to be informed of one’s state of health exists independently of the reason why a change in the state of health occurred or the way the information on the health status has brought to light. Whether the information on the health status results from a diagnostic procedure, a communication by another health care professional or an adverse event should have no consequences for the obligation of the physician to inform his patient. Therefore, the right to be informed of one’s health status encompasses the right to be informed of an adverse event that has influenced the health status. The so called “therapeutic exception” allows a physician not to inform his patient of his health status in exceptional circumstances. However, from the time when the Act on Patient’s Rights came into force in 1998 (this Act has been integrated in the Danish Health Act 2005) it has been illegal in Denmark to withhold information concerning the health status from competent patients, also to protect them against harmful information.

The Belgian proposal of a bill does not contain any provision regarding the right of the patient to be informed of an adverse event. However, article 7 § 1 of the Belgian Act on Patient Rights entitles a patient to receive all information concerning his state of health and its possible evolution. In my opinion, this right also covers the right to be informed of an adverse event that has influenced his state

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21) idem
of health. In exceptional circumstances information on the status of health may be withheld (therapeutic exception).

With regard to the right to receive financial compensation when being harmed by a patient safety incident, the Danish Patient Safety Act does not contain any provision. However, article 2 of the Danish Patient Insurance Act 1997 entitles a patient to compensation in case of an injury that has been, on a preponderance of evidence, caused in one of the following circumstances:

- if it may be assumed that an experienced specialist in the field in question would in the given circumstances have acted differently during examination, treatment or the like, thereby avoiding the injury;

- if the injury is due to the malfunction or failure of technical apparatus, instruments or other equipment used for or in connection with examination, treatment or the like,

- if, on the basis of a subsequent evaluation, the injury might have been avoided using another available treatment technique or treatment method that would have been just as effective in treating the patient's illness from a medical point of view, or

- if injury occurs as the result of examination, including diagnostic procedures, or treatment in the form of infections or other complications that are more extensive than the patient should reasonably have to endure. Account must be taken in this respect of the severity of the injury, the patient’s illness and general state of health, the unusualness of the injury and the general possibility of taking the risk of its occurrence into consideration.

The Belgian proposal of a bill does not contain a right to receive financial compensation when being harmed by a patient safety incident. At the moment of writing, Belgian law concerning medical liability
is being revised. Actually, medical liability is governed by the classic rules of civil liability (“fault” liability). An Act of 15 May 2007 on the compensation of damages caused by health care has introduced a system of compensation according to the Scandinavian type of “no blame” compensation but has never entered into force. This Act will (probably) in the near future be replaced by a system that combines the classic “fault” liability with a system of compensation of severe damage that cannot be attributed to a fault. Such a system has already been introduced in France in 2002.

4. CONCLUDING REMARKS

The right to safety is a new and emerging patient right. One of the means to promote patient safety is the reporting of adverse events by health care professionals. Such reporting however raises difficult questions: Should it be mandatory or voluntary? Based on legislation or self-regulation? Anonymous or not? Related to litigation and accountability or not? And especially: Is it possible and how to reconcile safe (“blame free”) reporting by health care professionals with the right of patients to be informed of an adverse event that occurred and to be compensated if any damage occurred.

Appendix J. 4 of the Rec (2006) 7 of the Council of Europe recognizes that: “It may appear difficult to establish a patient-safety reporting system without compromising patients’ rights”. Although more research on this issue is required, the Danish reporting system seems to have reached a fair balance. The existence of a mandatory reporting system may have contributed to this: “blame free” reporting may be psychologically easier to be accepted by public opinion if reporting is mandatory than purely voluntary. In a voluntary reporting system some professionals may be tempted to report only to protect themselves. But also other elements should be considered: “The Danes are a law-abiding society with acceptance of the need for social order, a strong social security network, and a broad tolerance for diversity. Their innovative approach to patient safety, which incorporates a separation of the pillars of patient compensation, professional discipline, and the reporting of adverse events, is seen as
fundamental to the ‘buy-in’ of health professionals in Denmark. The importance of this factor in the view of all parties interviewed is worth underscoring. Furthermore, it should be noted that patient safety is a ‘hot button’ issue throughout the Danish health care community. One example that was provided is the cover page of a June 2005 arthritis association magazine, with “Patientsikkerhed” (patient safety) as the headline and a picture of diaper pins as background. This is illustrative of the high level of focus on patient safety that is much more of a broad societal movement, not confined to the professional health care sector and to government representatives.”