EDITORIAL

Risk Management, Clinical Guidelines, Clinical Pathways and Health Law

Risk management – especially in hospitals – is a “movement” to reduce medical errors, to augment cost efficiency, to implement patient rights and to increase the preventive effects of medical malpractice law.

Recently the subject of “Safe Health Care”\textsuperscript{1} or “Patient Safety”\textsuperscript{2} has been intensively discussed in Anglo-American health policy and health law policy. The debate was initiated by empirical studies on the incidence of errors in medical treatment by Brennan (1991) and Thomas (1999), which show adverse reactions in 3-4% of the treated population. One of the most interesting results of QuIC is the finding that medical errors are to a greater extent institutional and systemic rather than individual errors and that systemic efforts might significantly contribute to their avoidance.\textsuperscript{3} Errors are defined as follows:\textsuperscript{4}

“An error is defined as the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim. Errors can include problems in practice, products, procedures, and systems.”

The reduction of errors is increasingly becoming a medical, organisational and economic objective, strongly justified by the desirable increase of patient safety. “To Err is Human” and “Every Error is a Treasure” combine a set of measures for “Building a Safer Health System”. The following activities are recommended as groups of measures for error identification and prevention:\textsuperscript{5}

- Establish a national focus to create leadership, research, tools, and protocols to enhance the knowledge base about safety.
- Identify and learn from medical errors through both mandatory and voluntary reporting systems.
- Raise standards and expectations for improvements in safety through the actions of oversight organisations, group purchasers, and professional groups.
- Implement safe practices at the delivery level.”

Error identification (information about risks) is the prerequisite for error estimation (risk estimates), assessment (risk assessment) and avoidance (risk prevention). Effective and efficient risk management in the field of medical errors must organise these elements in such a manner that the safety of medical treatment is guaranteed
individually and systemically and institutionalise corresponding procedures for their implementation.

If it is true that the character of medical errors is to a greater degree an institutional and organisational one, error prevention also requires to concentrate legally on these types of errors, to supplement the procedures of quality assurance by risk management procedures in health insurance or health service law, to emphasise the preventive effects of medical malpractice law and to stress patient rights in individual and contractual physician-patient relations. In the past, medical errors used to be regarded as individual failures of physicians in health law, but now we have to stress the importance of risk reduction by organising treatment procedures in hospitals or physician networks. It seems necessary to introduce a look-back-study of medical malpractice law to analyse the context of malpractice and to define new “groups” of errors. The objective of such a legal study is to identify the institutional reasons for medical errors e. g. in court rulings and to increase error prevention by creating procedural remedies which are capable of identifying especially “near misses”. “Near misses” are the treasury of error prevention.

Ideally one may differentiate between two types of risk management:

- risk management based on medical malpractice law and
- qualified risk management as a procedure to report, to estimate, to assess and then to manage and to learn from medical risks – including near misses – at the different levels of the health system.

According to experiences in aviation, the second type of identification and communication of risks will only work under the guaranty of confidence and anonymity. The first type of risk management is on the way to general practice e. g. in Germany. The second type is proposed in the USA; but this type involves one serious problem: the disclosure of risks or more commonly unexpected outcomes by the risk-producing institution, in particular under the aspects of patient rights and patient information. The New Patient Safety Standards from JCAHO (Joint Commission on Accreditation of Health Care Organizations in the USA) require the disclosure of unexpected outcomes by hospitals.

One consequence of the IOM-recommendations of 1999 in the USA was a heated debate about the desirable protection of the reported and collected risk data against public utilisation e. g. in medical malpractice procedures. On the one side (= protection) stood the American Medical Association (AMA) and the American Hospital Association (AHA), on the other (= disclosure) the health care organisations, their commissions on accreditation (JCAHO), patient organisations, but, interestingly, also the American Society for Health Care Risk Management. The debate takes place against a background of increasing or decreasing risks of liability proceedings.