Aansprakelijkheid van artsen : juridische theorie en medische praktijk

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Summary

LIABILITY FOR MEDICAL NEGLIGENCE. LEGAL THEORY AND MEDICAL PRACTICE

Medicine may improve the health of patients but it can harm them too. Mishaps in medicine are far from rare and may be non-accidental in nature. Increasingly, patients litigate against doctors for their errors. Outside the Netherlands claims for medical negligence have exploded and are subsequently both an economical and societal burden. In the United States, the United Kingdom, Ireland and Australia especially, the consequences are immense, resulting in doctors leaving the profession, insurers pulling out of the market, and patients unable to find doctors who will help them, particularly in first aid or obstetrical care. The situation in the Netherlands is less disquieting but lawsuits for medical mishaps are on the rise here too. To avert a similar situation here in the Netherlands, the Dutch government is considering measures such as tort law reform and restriction of access to legal procedures by patients.

Few issues in health care spark as much fury and fear as medical-malpractice litigation. Rationality requires insight and oversight: what do we really know about this problem? If we want to take actions, we first have to analyse the problems in depth.

This study analyses medical malpractice from a meta-juridical perspective and observes its functioning as a system. What are the goals of the system? What are its effects? Where does is falter and why? Should we reform or overhaul it? A major goal of the legal system is that verdicts will motivate health care professionals to act more reasonably and responsibly but is it really effective?

Chapter 1. Law is a normative science. It scrutinizes human conduct; it regulates it and judges it. So, legal norms are applied in two separate ways: *ex ante* as rules of desired conduct or *ex post* trialling past behaviour when settling a dispute. The key functions of tort law in general and medical litigation in particular are compensation and prevention. How well does medical litigation perform these functions? To answer this question, we have to look at it from a systems perspective examining its total input, throughput and output. Such a societal system has both a physical and organizational structure and is influenced by the context in which it is embedded. We can analyse the system descriptively and prescriptively: how does it work and how should it work?

The aim of this thesis is a critical enquiry of medical litigation at systems level. Is tort law able to adequately compensate injured patients? Do the outcomes of litigation influence the behaviour of doctors and if so, in what way? How does tort law relate to other mechanisms of controlling human conduct?

Chapter 2. When examining the system of medical litigation, we will need different frames of reference. Why does this arrangement exist (rationality) and how does it fulfil its functions (functionality)? A philosophically oriented inquiry can be done from three different but interrelated levels: fundamental, conceptual and operational.

The fundamental aspects of medical litigation comprise its foundations and its functions. The primary legal obligation of prudence governs the conduct of persons. Failure to act in this way may result in indemnity: torts as wrongs. Compensation of material and immaterial damages is a prime function. But what is actually compensated, why and how? The verdict in a case should deter doctors from making the same mistake in similar cases in the future. This is another key function: prevention. But is this merely theoretical or is it reality? Is a defensive response more likely then a preventive one? Liability can be controlled using two fundamentally different approaches: fault liability or strict liability.

The conceptual aspects encompass definitions of key concepts: responsibility, duty of care, obligation of information, fault and risk, negligence, damage, causality and relativity. The normative content of each characterization may be either legal or social in nature. Norms come in two different ways: the ideal or aspirational norm and the realistic or reasonable norm. The reasonable person is the conceptual standard used in tort law. A main obstacle is to put legal concepts into practice.

The operational aspects include ways to settle disputes. The dictum "do not go to law" encourages seeking ways of resolving arguments without formal legal procedures. However, whichever formal or informal legal way is chosen, the procedure and the result should be fair. When judging human behaviour, care should be taken to avoid cognitive errors such as hindsight bias.

The problem of doing a systems analysis of medical litigation is that the legal profession is primarily case and not population orientated. It therefore lacks a tradition and an infrastructure for doing empirical studies on a series of cases and to summarize outcomes in general conclusions.

Chapter 3. In this chapter, all the successive components of the system are examined. How many potential litigants are 'produced' amid all patients medically treated? How many do actually take legal action and why? What are the motives of law firms to accept medical clients and do they act as a high-quality filtering system to select only those cases really deserving normative review? How many claims pass? How are they resolved and was that

settlement in, or outside the court? How often do claimants and/or defendants proceed to a court of appeal? Did the system accomplish its goals? All these questions have to be answered, but very few empirical studies have actually done so.

Chapter 4. This section deals with methodological aspects when analytically examining medical litigation. The prime topic is the definition of medical adverse events and of medical negligence. A harmful outcome is not necessarily at all times the result from negligent medical conduct. Both the process of care and its outcome are needed to properly define medical negligence.

We are in need of a taxonomy to classify medical errors. The basic mechanism, e.g. mistaken medication, incorrect diagnosis, wrong site or side operation, hospital acquired infection, communication error etcetera, may be used for classification of error type.

From a preventive viewpoint, the anatomy of an error is of particular interest: why and how do doctors err? A conceptual framework is whether the mishap was the result of underuse, overuse or misuse of a medical intervention. From an organizational point of view it is important to see where exactly the system faltered: was it at the level of the organization, the group, or the individual? And why did this happen?

Particularly important is the epidemiology of error. How often do doctors err and how good are the tests for detection of medical errors? Which factors are largely responsible for the commitment of errors? How must we interpret the results from such studies and which actions have to be taken in response?

Finally, general legal concepts have to be made practical for medical malpractice. These are: the contractual relationship, damages, attribution, causality, the relationship between attribution and causality, legal and scientific proof. Since legal science is basically conceptual in nature, to put these concepts into practice in medical negligence depends on close cooperation between jurists and doctors.

Chapter 5. Here the communication between patient and doctor is reviewed. This interaction is important for two different reasons. First, the patient has to be informed about his or her situation and to consent to subsequent medical interventions which may be risky: it is the model of informed consent. Second, when things go awry during treatment, openness and honesty from the caretakers is expected.

The legal concept informed consent is highly idealistic in nature. Transfer of information between doctors and patients is complex and ill understood. Adequate risk communication is central to this problem. The patient, when told of benefits and risks of an intervention, has to decide if he or she is willing to take the risk or to choose otherwise. But how far should this information on risk extend? Recent jurisprudence on materialized risks on which the patient was not informed make doctors uncertain as to what to tell and what not to

tell. Subsequently, even if doctors try to communicate a particular jeopardy is it fully understood by the patient? Not all patients want to decide for themselves but instead leave this decision to their physician.

When things go wrong, poor communication often is the basis for liability actions by the ill-treated patient. Honesty is the best policy, but liability insurers often restrict what doctors may tell in fear that such statements may induce legal actions. More clarity is needed what can be said and how, without breaching the insurers contract.

Both problems illustrate the necessity to address the problem of good communication between doctors and patients and the basic elements of such an interaction are described.

Chapter 6. A normative judgment on medical conduct requires a clear point of reference. As described in chapter 4, we have to look at both the process and the following outcome of medical care. Exploration of the process of care is predominantly qualitative in nature, whereas the results from medical interventions are to be examined quantitatively.

Practice guidelines intend to describe how the process of care should be performed. They are being developed more and more on the basis of methodologically sound comparative research and consequently may serve as a standard to prove that good care was given. But guidelines have also been discovered by lawyers to blame doctors for not doing what they were supposed to do. Therefore, guidelines may serve two functions: as a shield or as a sword. They are also designated as the *soft law* of medical litigation. The position of practice guidelines in medical litigation has yet to be established. Much depends on the quality of guidelines and the procedures within the medical community for developing and implementing them.

Outcome examination is primarily quantitative in nature and performance indicators are used for this purpose. They may indicate that medical care was given with a higher rate of adverse events than considered to be acceptable, but we will need both the observational data for ascertainment and a quantitative norm to provide the evidence of increased risk. For many, if not most, medical problems such quantitative information is still deficient.

It is up to the medical profession to formulate qualitative and quantitative norms of reasonable medical practice, this is not a task for the legal profession.

Chapter 7. Most claims of medical negligence require the involvement of a medical expert. The legal concepts of medical liability must be put into practice by the expert doctor, a complicated task. The medical expert must have knowledge of legal concepts, but the jurist has to face several practical problems. Which qualities really qualify a physician as an expert for legal purposes? What are the essential legal questions to be answered? Is the report sensible from legal perspective? Was the method used by the expert scientifically founded and well accepted by the medical community?

Several problems are encountered. The expert always has to scrutinize a case in retrospect where there is a real possibility of hindsight bias. If different experts form an opinion on the same case, their judgments often diverge. Sometimes, experts are very creative with *junk science* to 'prove' their conclusions. Therefore, there is an urgent need to develop a scientifically founded standard method for expert review to eliminate hindsight, personal beliefs and even fraud. It should be the method of expert examination which qualifies the report, not the person. Essential elements of such a report are the medical scientific context, the clinical context, procedural examination, (quantitative) outcome analysis, impartial retrospective review (e.g. of radiological examinations, biopsies etc.), organisational context and occasionally personal qualities of the doctor in question.

The choice, the task and the procedural role of the medical expert have to be made more explicit and the legal status of the report from a court appointed expert established. Debiasing techniques have to be developed to guarantee an unbiased examination of the case.

Chapter 8. Medical errors may provide an opportunity for clinical quality improvement and hence doctors must be able to learn from their mistakes. Medical litigation however may obstruct this occasion for learning. Not only is it necessary to be honest to oneself and to the patient, but learning from error in a structured way demands systematic reporting of all errors and of near-misses in a central database where these mishaps can be thoroughly analysed and recommendations formulated for prevention.

A legal procedure encompasses two steps. First, there is the collection of all relevant facts and second a normative verdict pronounced as to whether the doctor was at fault. Recording and reporting of mistakes for learning purposes may provide the litigants with an opportunity of easy data collection. Therefore, some immunity from these investigative actions of errors is fostered: a blamefree reporting of adverse outcomes. But it is a patient's fundamental right to go to court when medical fault is suspected. So, how to reconcile these two opposing opinions? Is medical negligence indeed blocking practice improvement? At this moment we lack empirical evidence confirming or refuting the existence of legal barricades for safe and efficient incident reporting. At the same time we also lack proof that reporting of all errors is actually contributing to safer medical care. It is cooperation, not encounter, between legal and medical professionals which will result in solutions based on scientific evidence and not suppositions.

Chapter 9. Finally, we draw up the balance of this study. Is it feasible to analyse medical litigation as a system? First, such an analysis is hampered by the fact that its goals, compensation and prevention, are rather broad and hence imprecise. Secondly, the true nature of the system is ill conceived: it is a com-

plex system and to study it requires distinctive methods. Any reductionist approach will fail to appreciate its multifaceted character in full.

Thirdly, we lack ample empirical investigations of the system and the impetus for such studies seems to be lacking in legal science. If we want to know how this particular legal system works, we need to analyse aggregated data, not distinct jurisprudence cases. Not only do we lack these observational studies but the process of retrieving relevant published literature is difficult because, contrary to other sciences, a good infrastructure to find articles from large databases is lacking, especially in the Netherlands.

The available data show us that medical mistakes abound but only a minority of these actually result in a claim. Of all complaints levelled against doctors, only a third of these prove to be justified. Those who should claim do not do it and the majority of those who claim should not. Most of the claims, about 95%, are settled outside the legal court.

Going to court means that the conflict becomes truly adversarial in nature with all the psychological consequences of forcing the issue. From a medical perspective, a guilty verdict against doctors is often based more on the destitution of patients than being based on true negligence. This will thwart the preventive goal of medical litigation and stimulate defensive medicine. Therefore, a more rigorous quality control of judicial procedures is needed.

Do we have to radically change tort law and the practice of medicine? As shown, we will first need sound observational and experimental research to answer the many questions brought forward. We do not know how to accurately define negligence and how many mishaps are inevitable in medicine; we are also still unaware of the best practical way to resolve conflicts, and attain the primary goals of justice. We cannot prevent all misfortune in life so we should not demand compensation for every medical calamity, but what we do need is sound information, good analysis and subsequent reflection of matters and wisdom when deciding on change.

Doctors and judges have in common that they must make decisions in situations of uncertainty due to imperfect information and not knowing whether their action will result in a good or a bad outcome. Because of this shared perspective, it is helpful to look at each others professions in terms of these boundaries of practice.