Chapter 1

INTRODUCTION AND AIM OF THE STUDY

1 Introduction

On May the third 1999 a 73 year old patient visited the dentist for a routine check-up. During this visit it was decided to extract one of his teeth because the patient complained of being in pain. It turned out that the adjacent tooth was loose, so that tooth was extracted too. The dentist did not consult the patient's cardiologist or the haematology unit for thrombotic patients before the extraction, even though the dentist knew that the patient was using an anti-coagulant. After the extraction, the wound was sutured and, after the bleeding had stopped, the patient returned home. The patient was unaware of the possible complications of the extraction and did not know what to do should excessive bleeding subsequently occur.

In the night of May the fifth the patient became unwell. The family doctor visited him in the early morning and found that his blood pressure was low and his heartbeat too fast. Furthermore, he demonstrated symptoms of shock. The family doctor arranged immediate admission into a hospital, but the man died later on the same day. Post-mortem examination revealed that he had died because of cardiac arrest, caused by massive blood loss after teeth extraction.

This tragic incident raises a number of questions. First of all, did the dentist inform this patient about the possible complications of the extractions? Was the dentist aware of the risks? Or could it be that the dentist did not want to bother the patient with such a small change of complications? The second question has to do with the behavior of the patient. The man died two days after visiting the dentist. What happened in the meantime? And why did he not ask the dentist about the risks of the treatment, knowing that he was taking an anti-coagulant? Unfortunately, with regard to this dramatic case these questions will remain unanswered. However, they do illustrate the relevance of two major themes of the

\footnote{Casus from the Dutch Disciplinary Court. 8 12 2000}
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Medical Treatment Contract Act: informing patients about the treatment and patients' assumed wish for self-determination. This act, which came into effect on the first of April 1995, and in particular these two aspects of it, will be the topic of the present thesis.

2 Background

The Medical Treatment Contract Act can be seen as the result of a long struggle to improve the legal position of the patient in The Netherlands (Sluyters & Biesaart, 1995). The aim of the act is to strengthen and clarify the position of the patient, taking into account the independent responsibility of the health care practitioner. It establishes the mutual rights and duties of both patients and health care practitioners, thereby enhancing the autonomy of patients and their corresponding legal right to self-determination. From this right, the principle that a patient may not be treated without his informed consent has been developed (Sfikas, 1998).

The Medical Treatment Contract Act is not even a decade old. However, ideas about patients' right to self-determination and how disclosure of information and consent should be implemented in medicine can be traced back to the beginning of the twentieth century. To understand more fully the concept of patient autonomy and the way this concept evolved into the legal doctrine of informed consent, it is necessary to briefly describe some legal history. Readers interested in a more thorough discussion on this subject are referred to Faden and Beauchamp (1986).

Almost hundred years ago the term 'self-determination' was first used in the United States of America in the famous Schloendorff v. Society of New York Hospitals case (1914). In this case, the physician removed a fibroid tumor, while the patient had consented to an abdominal examination under anesthesia, but specifically requested no operation. Justice Benjamin Cardozo's much cited words read as follows: 'Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable in damages.' (Cited from Faden & Beauchamp, 1986). Thus, for the first time in legal sentencing a concern for the patient's self-determination is explicitly expressed. However, it is important to state that this case confined itself solely to the patient's consent, without addressing the issue of adequate information provision.

2 Explanatory memory, 29 5 1990
It was not until the second half of the twentieth century that the court said anything about the information requirements of the patient in order to give an intelligent consent (Faden & Beauchamp, 1986). In the Salgo v. Leland Stanford Jr. University Board of Trustees case (1957), the requirement of merely obtaining consent evolved into a duty to inform the patient and then obtain his consent. In this case, Martin Salgo sued his physicians for negligence in performance and in failing to warn him of the risks of the treatment, after suffering permanent paralysis as a result of translumbar aortography. The court decided that the physicians had the duty to disclose any facts that are necessary to form the basis of an intelligent consent by the patient to the proposed treatment (cited from Faden & Beauchamp, 1986). Thus, for the first time in legal sentencing patient consent was directly linked to the obligation to inform the patient.

In the years after the Salgo Case, the legal doctrine of informed consent developed further in Anglo-American law. Famous cases, such as the Natanson and Canterbury case followed, in which the duty to disclose information and to obtain the patient's informed consent were further elaborated. Controversy arose around which standard should be used for determining which information should be disclosed: the 'professional doctor standard' or the 'reasonable patient standard'. This area is still under discussion. Some states of America have adopted the standard of what the 'reasonable doctor' would do under the same circumstances, others accepted the view that disclosure should be fit to what the reasonable patient would have wanted disclosed to him (Sfikas, 1998).

Only a few European countries, among which Finland, Denmark and The Netherlands, have developed legislation on patient rights so far (Tiems, 1997). In The Netherlands, the discussion about a statutory regulation of the rights of patients can be traced back to the early nineteen-seventies. Before that time, the dominant view was that legal regulation of the doctor-patient relation was unnecessary, and even undesirable. The relationship between patients and their doctors should be one of trust, instead of one of contract (Legemaate, 1991). Several shifts in society as well as in medicine itself though, stimulated the interest in the creation of legislation of patient rights. Rang's inaugural lecture in 1973, in which he pleaded for the development of more patient-centered legislation, can be seen as an important illustration of this paradigm shift. According to Rang, the first professor in medical law in The Netherlands, not the profession and the qualifications of its practitioners should be the central point in legislation, but instead the needs of patients. In the same period, Sporken (1977) too pointed to the necessity to incorporate the needs of patients in the doctor-patient relation, and defined this relationship as one in which doctor and patient cooperate together to achieve the same goal, namely the preservation or recovery of health.
Dupuis and de Beaufort (1988) have identified several factors that stimulated the shift away from paternalism in medicine towards more autonomy for patients. First of all, the growing assertiveness of patients, resulting from a higher general level of education, more knowledge and the ongoing individualism of our period, has affected the formerly self-evident authority of doctors. Secondly, developments within the field of medicine have contributed to a growing awareness of the necessity to engage patients in medical decision-making. Scientific and technological progress have yielded impressive advances, but at the same time increased medicine's potentiality to encroach deeply on human life and even to harm it. This inevitably has brought the outcomes of medical treatment more into perspective, and has made it more important to involve the norms and values of patients in the decision-making process (Wear, 1993).

In light of the above-mentioned developments, the dependent and unequal position of the patient compared to the position of the doctor has increasingly been criticized. The anti-psychiatry movement of the nineteen-seventies in The Netherlands, which mobilized parts of the population against institutionalization and medicalization, can be seen as a clear example of this criticism (Engberts, 1998). More and more the opinion grew that patients should be protected against the dominant position of the doctor by means of a contractual approach, in which patients would become legally equal parties to doctors under the law.

The Minister of Public Health at the time asked the Central Board for Public Health in 1977 to publish a report on this issue, because of the increasing importance attached to the rights of patients. His request resulted in five reports on the legal relation between the doctor and his patient, in which different aspects of patients' rights are discussed. The topics covered, included the patient's right to information, the duty to obtain consent, protection of privacy and medical experiments. Taken together, the topics described in these reports can be seen as the predecessors of the Medical Treatment Contract Act (Leenen, 1995).

### 3 Medical Treatment Contract Act

More than twenty years after Rang's plea for more patient-centered regulation, the Medical Treatment Contract Act came into effect on the first of April 1995, making legal regulation of patient rights reality at last. Other arrangements with respect to patient rights already existed, such as the agreement between the National Patients Consumers Platform and the Royal Dutch Medical Association as well as the rules of conduct for the health care professions. Within dentistry, the Dutch Dental Association formulated rules of conduct for dentists for the first time in 1987. The content of several of these rules correspond to a great extent with a number of stipulations of the Medical Treatment Contract Act. However,
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whilst these arrangements are not legally enforceable, the Medical Treatment Contract Act is. Formally, the other agreements just form a weighty advice. The Medical Treatment Contract Act on the other hand, is legally binding in nature, which means that one cannot deviate from it to the disadvantage of the patient (Sluyters & Biesaart, 1995; art.468).

A large part of the stipulations of the Medical Treatment Contract Act concern codification of jurisprudence and the above mentioned regulations for patients. The duty to inform patients for example, being an essential part of this act, can already be found in the rules of conduct for different groups of health care practitioners. There are a few stipulations in the act though, which are modifications of existing regulations, such as the increased autonomy of minors.

As mentioned, one of the most important rights established in the Medical Treatment Contract Act is the patient's right to information. This means that the health care practitioner is obliged to inform his patients about the nature and purpose of the proposed treatment. This includes the consequences and risks of the treatment, alternative treatment options, and state of health. Informing patients is a necessary condition for patients to be able to exert their right to self-determination. They can only make a balanced decision about the proposed treatment if they are well informed about it. A problem that may arise from this obligation though, is that the nature, size and content of the information to be given may not be clear in specific situations. Thus, health care practitioners might be confronted with questions such as 'how much information do I need to give?', 'should I inform the patient about rare complications?', etceteras. The guideline in answering questions like this is that principles as the professional standard and the reasonableness criterion should determine the amount and kind of information (art.448; art.453.) The reasonableness criterion means that information should contain those aspects that a reasonable person in the given circumstances would expect to consider before making a decision (Leenen & Gevers, 1996).

There are a few situations in which the right to information can be circumvented. A health care practitioner has the possibility to appeal to the therapeutic exception, which means that information may be withheld from a patient if the practitioner thinks it will seriously damage the patient. However, use of the therapeutic exception is only justifiably after consultation with a colleague. If the patient does not want to be informed, the patient may waive his right to information. This is also called the patient's right to not knowing (art.448).

Finally, the patient also has a duty to give his health care practitioner the information that is needed to adequately carry out the treatment contract (art.452). This stipulation has only relative meaning though, because it is not
legally enforceable. If inadequate treatment, however, is the result of a lack of information the health care practitioner may not be held liable (Roscam Abbing, 1993).

Closely related to the obligation to inform the patient is the duty of the health care practitioner to obtain the patient's consent to the treatment (art.450). After all, the patient can only give his valid consent to the treatment when he is well-informed. For consent to be valid, it is essential that the patient gives his consent voluntarily and with complete understanding of the information. Therefore, the health care practitioner should avoid medical jargon and inform his patients in a language they can understand (Imber, Glanz, Elkin, Sotsky, Boyer & Leber, 1986). Against the duty to obtain the patient's consent the objection may be raised that the health care practitioner always acts in the interest of his patients. Therefore, he does not need to ask for the patient's consent. However, health care practitioners do not have an autonomous right to treat patients (Roscam Abbing, 1995). More important even, views, norms and values may differ between patients and health care practitioners, as a result of which other than pure medical reasons may become important in the decision making process (Leenen & Gevers, 1996; Wear, 1993). Thus, the health care practitioner has to accept the right of a patient to look after his own interests, even if they are against his medical judgment.

Different forms of consent can be distinguished, among which implicit and explicit consent. It often happens in practice that consent is implicitly given, for example by making an appointment with the doctor, or opening one's mouth at the dentist. Consent may indeed be implicit in case of non-invasive treatment. Invasive treatment, on the other hand, requires the explicit consent of the patient. This simple distinction, however, ignores the fact that in many situations it may not be clear whether a proposed treatment is invasive or non-invasive and how the health care practitioner can know in advance whether the patient will consider the treatment invasive or not (Spreeuwenberg, 1991). In answering questions like this, one can adhere to the guideline that the invasiveness is not just related to the treatment itself, but also to its consequences.

Other examples of duties and rights established in the Medical Treatment Contract Act are the duty to keep patient records, the right to privacy, and several rights concerning specific groups of patients, such as minors and people who are not competent to participate in the decision-making process. There are only a few duties of patients established in the act. The duty of the patient to give the health care practitioner the information that is needed to carry out the treatment contract properly is the most prominent.³

³ The complete Dutch text of the law can be found in the Appendix.
4 Research on informed consent

After the Medical Treatment Contract Act came into effect, many articles appeared in the professional literature, commenting on the consequences of this act for the doctor-patient relationship. The overwhelming consensus was that the act would enhance the doctor-patient relationship – but most articles were written by members of the legal profession. An argument frequently used by them in favor of the Medical Treatment Contract Act was that no major changes were to be expected in the relationship between doctor and patient, as the act mainly is codification of already existing rules and jurisprudence. Moreover, health care practitioners were now stimulated to make the reasons of their actions more explicit to their patients, while at the same time leaving room for their own autonomy (Berkel, 1995; van der Horst, 1995; Leenen, 1995; Legemaate, 1995). Regrettably, most of these articles pursued solely the effects of the intentions of the act, and not how the act actually functions in practice.

Research carried out by the Dutch Institute for Health Care Research has shown that many general practitioners have reservations with respect to certain aspects of information provision to their patients and with granting them access to their records (van Warmenhoven, 1985). Recent studies have also shown that doctors still have mixed feelings about the principle of informed consent (ZorgOnderzoekNederland, 2000; de Haes, de Haan, Willems-Groot, Oosterveld, Spronk, 1998). Fear for commercialization of the doctor-patient relationship seems particularly to be present. Although most doctors endorse the importance of a legal regulation of patient rights, the application of those rights in practice remains, however, problematic (Gevers, 2001). Patients, on the other hand, have indicated that their doctors in general do inform them satisfactorily (see chapter 7 of this thesis). In addition, the knowledge of patients about their rights has increased in the last couple of years (ZorgOnderzoekNederland, 2000). In dentistry, only one study has been undertaken to assess the opinions of Dutch dentists about the Medical Treatment Contract Act – and this was a pilot-study (Eijkman & Goedhart, 1998). The results of this pilot-study showed that most dentists in this study are not well acquainted with the content of the act and see numerous negative consequences for their practice. They mentioned consequences such as a lack of time to inform patients adequately and an increase in administrative activities. Among the positive points mentioned were a higher quality of care and better education of patients.

In conclusion, despite the optimistic views health care lawyers often hold with regard to the implementation of the Medical Treatment Contract Act in medical and dental practice, the results of the empirical studies mentioned above suggest that health care practitioners do have problems with complying with the requirements of this act in practice. The number of empirical studies on the
consequences of this act in dentistry (and medicine) is small and it is uncertain whether results obtained from studies in general medicine can be applied to the dental setting. The evaluation of the Medical Treatment Contract Act in dentistry therefore warrants its independent research. In this thesis, a study on the principle of informed consent in dental practice will be reported – one of the core aspects of the Medical Treatment Contract Act.

5 Aims and structure of this thesis

The overall objective of this thesis is to evaluate the implementation of the Medical Treatment Contract Act, and in particular the dentist's duty to inform his patients as well as his duty to obtain the patient's consent, in dental practice. For implementation of this act to take place, both dentists and patients must be able and willing to meet its requirements. Therefore, the first aim of this study is to examine the knowledge of dentists and patients and their views with regard to this act. The assumption underlying this study aim is that these aspects are necessary conditions for implementation to take place. The second aim of the study is to assess patients' willingness to participate during the dental consultation.

Here is a short summary of the structure of this thesis. In chapter 2 an inventory is given of complaints about dentists with respect to informed consent in the period 1987-2000, dealt with by the disciplinary board of the Dutch Dental Association. Chapter 3 to chapter 5 report on the results of research carried out to measure dentists' knowledge, their attitudes, self-efficacy and self-reported behavior regarding this act. Patients' knowledge, their attitudes, self-efficacy and behavior are assessed too, and these results are described in chapter 6. In chapter 7 the experiences of patients with respect to the information provision by their dentists are examined. In the last three chapters of the study the concept of patient autonomy is studied. In chapter 8, results of research assessing patients' need for information and participation are presented. Chapter 9 deals with the influence of patients' characteristics and dentists' behavior on patient participation during dental consultations. The relationship between dentists' and patients' behavior and their satisfaction with the dental encounter is described in chapter 10. Finally, in chapter 11 the findings of this study are summarized and discussed.
References


