A decade of litigation regarding surgical informed consent in the Netherlands

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A decade of litigation regarding surgical informed consent in the Netherlands

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ABSTRACT

Objective: An inadequate surgical informed consent process (SIC) may result in a medical malpractice claim or medical disciplinary board (MDB) complaint. Aim of this study was to analyse characteristics of a decade of malpractice claims and MDB decisions regarding SIC in the Netherlands.

Methods: A retrospective analysis of malpractice claims and MDB decisions concerning SIC disputes in four major surgical specialties was conducted based on company data from the largest medical malpractice insurance company and two public available online MDB databases.

Results: A total of 11376 malpractice claims and 661 MDB complaints were filed between 2004–2013 and 676(6%) of these claims and 69(10%) of these complaints involved an alleged deficient SIC process. A random sample of 245(37%) claims and all MDB decisions were analysed. Reasons for filing a claim or complaint were insufficient counselling or recording of SIC elements. In 20% of lawsuits and 25% of claims the case resulted in favour of the complainant.

Conclusion: A substantial portion of malpractice claims and MDB decisions is related to a deficient SIC process.

Practice implications: Focusing on crucial SIC elements for patients may improve satisfaction and expectations and result in a lower risk for malpractice claims and MDB complaints.

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1. Introduction

Medical claims and malpractice lawsuits are the final stage of a clinical process where a patient feels aggrieved, maltreated, disappointed, dissatisfied or had expectations that were not lived up to [1–3]. An important reason for patients to file a medical malpractice suit or complaint at a medical disciplinary board (MDB) is an inadequate surgical informed consent (SIC) process [4,5]. Until now the frequency, characteristics, clinical circumstances and legal outcome of malpractice claims and MDB decisions concerning SIC (in the Netherlands) have not been systematically analysed and described.

Informed consent is an evolving concept in history. The oldest document establishing rules for the conduct of medical professionals is the Hippocratic oath, stating that doctors should conceal most information from patients as they could not be trusted with making intelligent health decisions [6]. Only in the 19th century this paternalistic approach shifted towards a patient-centred approach, in which a patient agrees to a health intervention based on an understanding of it [7]. Patients should be educated by their physicians to make informed choices concerning their health. A properly conducted surgical informed consent process (SIC) allows patients to authorize an invasive procedure with full comprehension of relevant information including involved risks and benefits [8]. A sound SIC process consists of three important elements: preconditions, information and consent [6]. Preconditions include a determination of the cognitive competence of a patient to make a voluntary decision about his or her own body [9]. The second element is SIC information consists of seven sub elements [9]. In most common-law countries, patients must be ‘reasonably’ informed on the purpose, possible risks and complications of a

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treatment, alternative treatment options and prognosis, completed with a sound advice from the medical team involved [9]. The last element of SIC is consent [9]. The patient's decision and consent must be registered. Although a written consent in the patient's medical file is highly recommended, in the Netherlands a patient's signature is not legally obliged [10].

An adequate SIC process serves a number of purposes. The patient's autonomy is respected and the patient is protected against potential harm. Better informed patients have more realistic expectations, higher satisfaction rates and become more compliant with their treatment objectives [11–19]. Conversely, SIC violation undermines the patient's right of self-determination and jeopardizes the patient-doctor relationship resulting in an increased risk for disappointed or aggrieved patients filing a malpractice claim or a complaint at an MDB [20–23].

According to annual reports of European, United States and Australian health services the number of malpractice claims and MDB complaints and the associated costs have risen in the past years [24–27]. A substantial number of these claims and complaints is due to omissions during the informed consent process [28–32]. In the Netherlands [6], one in every six surgeons and one in seven orthopaedic or plastic surgeons was faced with an official SIC related complaint in the previous 5 years [33].

The purpose of this study was to describe the frequency, characteristics, clinical circumstances and legal outcome of medical malpractice claims and MDB decisions concerning SIC from a patient's point of view, in order to provide information for future projects to improve the SIC process and to possibly prevent future malpractice litigation.

2. Methods

This study involves a retrospective analysis of malpractice claims and MDB decisions concerning SIC disputes. Definitions and information on Dutch law are established in Table 1.

Medical malpractice claims were obtained from the company database of Medirisk, the Netherlands' largest provider of medical indemnity insurance. Medirisk, a non-profit organization, covers almost 70% of the country's registered general hospitals. MDB decisions were obtained from two online legal databases: www.tuchtrecht.nl and www.tuchtcollege-gezondheidszorg.nl. These databases comprise all medical MDB decisions in the Netherlands. (Table 1)

2.1. Case identification

The flowchart of our study sample is shown in Fig. 1. All claims and MDB decisions concerning SIC, filed between 1 January 2004

Fig. 1. Flowchart of our study sample.

and 31 December 2013 were included for analyses. Cases closed more than 10 years or still in progress at time of this study were excluded. Claims and lawsuits were labelled according to their main subject. Claims with an 'informed consent' label and lawsuits with an 'information' label were selected. Subsequently all cases within surgical specialties were selected and read completely. Cases in which the patient had a complaint about his or her IC procedure were included. A second reviewer re-reviewed some of the files to reduce the risk of bias. A random sample of claims and a total of MDB decisions concerning SIC were to be included for analysis. The study focused on four major surgical disciplines: general surgery, orthopaedic surgery, plastic surgery and gynaecology.

Table 1
Definitions in.

Medical malpractice: Professional negligence by act or omission by a health care provider in which the treatment provided falls below the accepted standard of medical practice and causes injury or death to the patient.

In case of medical malpractice patients can file a medical claim to an insurance company and/or they can file a complaint at a medical disciplinary board (MDB). There is a significant difference between a medical claim and an MDB complaint. A medical claim does not involve the court system, whereas an MDB complaint is a court decision.

Medical claim

If monetary compensation is sought in professional negligence, patients can file a claim to a medical insurance company (Medirisk). The insurance company then researches that claim. The insurer will consult the accused doctor and ask for a reaction. A medical advisor (who is in the same field as the accused doctor) will analyze the case and give an expert opinion. Finally a lawyer of the insurance company will choose to pay all, some or nothing of the claim.

MDB complaint

If a patient is not satisfied with the settlement of a malpractice claim or wants to take legal action, a complaint with the MDB can be filed. The MDB consists of fellow professionals of the subject of the complaint. The MDB does not decide on any damages. The board can issue a caution or reprimand or impose a fine. Professionals may also be barred temporarily or permanently from practicing their profession. In the Netherlands, legal complaints are dealt with by regional MDBs primarily. If the patient or accused doctor disagrees with the verdict, an appeal can be made to the national MDB, which makes the final decision.

Because our study was based on retrospective analysis of existing databases, the rules laid down in the Medical Research Involving Human Subjects Act do not apply to this study.

2.2. Data, variables and study instrument

All data were anonymized. Of all claims and MDB decisions, the following data were extracted: patient and doctor characteristics, the patient's allegations and the legal outcome of claims and MDB decisions (Table 2). The patient's allegations were coded into 9 pre-defined categories based on the description of informed consent in the Dutch law [8]. The reasonableness or legitimacy of the patient's allegations was not evaluated in this study. The judicial outcome of claims was not specifically focused on SIC, therefore statistics were only performed on cases in which the lack of informed consent was the main issue ($n = 95$)

In case of a MDB decision, two different sentences were imposed in our study: a caution or a reprimand. We analysed how often the accused doctors recognized the patient's complaint about SIC in comparison to medical advisors, lawyers of Medirisk or the MDB.

2.3. Statistical analysis

Due to a limited time frame to access the Medirisk database a random sample was taken of the medical claims about surgical informed consent. In order to have a balanced sample over the total time frame a random sample per year was taken. An employee of Medirisk who was not involved in the research, did this randomization with a computer. Analyses were descriptive and outcomes depicted as whole numbers and percentages. Continuous variables for group comparison were tested using Student's T-tests or Mann Whitney U tests. Significance of categorical variables and proportions were analysed using a two-sided Fisher's exact test. The sign test, which can be used to identify differences between paired observations on an ordinal scale, was used to identify differences between the judgment of the doctor, the medical advisor, the lawyer or the medical court [14]. P-values (two-tailed) of <0.05 were considered as statistically significant. Data analysis was performed using SPSS statistics data 22.

Table 2
Variables of interest.

Patient characteristics	Gender, age, type of surgery
Doctor characteristics	Medical specialty, specialist or trainee status
Lead-time (in days)	Time between the incident and the actual complaint
Informed consent is:	Main complaint / part of the complaint
Association of SIC aspect with	The doctor's behaviour and communication
Patient's allegations	Insufficient documentation in the medical file
	Insufficient information about:
	- Diagnosis
	- Treatment
	- In general
	- Characteristics
	- Aims
	- Risks / complications
	- Alternatives
	- Health status / prognosis
	- No explicit consent was given
Case outcome	Judgment (recognition, settlement, rejection) of SIC complaint by the:
	- Medical advisor
	- Accused doctor
	- Lawyer of Medirisk
	- MDB

SIC = surgical informed consent.

3. Results

A total of 11376 malpractice claims were filed between 1 January 2004 and 31 December 2013 (Fig. 1). 978 (8.6%) of these cases involved allegations of deficiencies in the informed consent process. Nearly 70% (676/978) concerned surgical specialties. 15% of the files were re-reviewed by the second reviewer and conflicting results were discussed until consensus was reached ($\kappa = 0.57$). A random sample of 245 claims (37%) was eligible for analysis. From the online databases 661 MDB decisions were retrieved: 117 concerned surgical specialties of whom 69 MDB decisions met the inclusion criteria and were analysed.

3.1. General characteristics

In more than sixty percent of the malpractice claims and MDB complaints the complainant was female (Table 3). Most claims and complaints were filed against medical specialists. In 39% of claims and 28% of MDB decisions, informed consent was the main subject. Most patients complained about the lack of informed consent in relation to the occurrence of a postsurgical complication. More than 10% of patients were (also) dissatisfied by the doctor's behaviour and communication. In addition to the information complaint, there were often allegations about the insufficient documentation of the SIC process in the medical file.

3.2. Cases per medical specialty

In our study, four surgical specialties accounted for 82% of all claims and lawsuits concerning SIC (Table 4). This was representative for the overall group of 676 malpractice claims in which these specialties accounted for 84%. Relatively, most malpractice claims were against orthopaedic surgeons. Plastic surgeons had the highest rates of informed consent disputes.

3.3. Patient's allegations

In 67% of claims and MDB decisions the primary allegation concerned a particular risk or complication of the treatment that had not been disclosed by the physician (Table 5). The second most common allegation involved insufficient information about the characteristics of the treatment, especially about the medical technical aspects, which doctor performed the procedure or which alternative treatment options were available. In 15% of claims and MDB decisions the treatment was ruled to have been performed without the patient's (full) consent. When a resident was involved in the treatment process, patients claimed significantly more about which doctor performed the treatment ($p < 0.001$).

3.4. Legal outcome of malpractice claims and MDB decisions

An overview of the legal outcome of claims and lawsuits concerning SIC is shown in Tables 6 and 7.

In 25% (24/95) of the malpractice claims and 20% (14/69) of the MDB decisions the patient's allegations were recognized. Our study shows that the accused doctors rarely agree that something went wrong with their SIC procedure. This difference in recognition of the patient's complaint on SIC was significant between doctors and medical advisors ($p = 0.002$) and between doctors and the MDB ($p = 0.013$). In addition, the judgment of the medical advisors often differed from the final judgment of the lawyer of Medirisk ($p = 0.027$). When the patient's allegations involved insufficient documentation of SIC, the complaint on SIC was more often recognized as significant. This applied to both claims ($p = 0.001$) and MDB decisions ($p = 0.005$).

Table 3
Characteristics of SIC claims and MDB decisions (n = 314).

	No (%) Claims (n = 245)	MDB decisions (n = 69)
Patient	158 (64%)	42 (61%)
Female	87 (36%)	27 (39%)
Male		
Doctor	209 (82%)	64 (93%)
Resident	36 (18%)	3 (7%)
Medical specialist		
Role of IC in the complaint	95 (39%)	19 (28%)
Main subject	150 (61%)	50 (72%)
Minor subject		
Role of other aspects in the SIC process	27 (11%)	8 (12%)
Unpleasant attitude of the doctor	38 (15%)	14 (20%)
Insufficient documentation of SIC		
Lead time	614 days ^a	895 days ^a
Mean	22 days	15 days
Minimum	3553 days	3505 days
Maximum		

SIC = surgical informed consent.

^a There is a significant difference (p = 0.003) between the mean leadtime of claims and lawsuits.

4. Discussion

To the best of our knowledge, this is the first study in the Netherlands that analysed the deficiencies in the SIC process in malpractice claims and MDB decisions from a patient's point of view. This analysis might be helpful in future projects enhancing the SIC process.

In the current study most files involved information elements of SIC. Improved understanding of patient's preferences and

expectations regarding preoperative information contributes to a better adjustment of the information and thereby the quality of care [15–17,34]. There is, however, a gap between the information doctors usually share before surgery and the information patients actually want to receive. Surgeons think patients desire more extensive information on the cause, effect and prognosis of the disease, while patients actually wanted more information on the operation characteristics and risk or complication rates of a specific surgery [35]. Our study affirms this, as 67% of the patients felt not properly informed about a particular risk or complication of an operation and 30% felt not adequately informed about the (technical) characteristics of the surgery. The predominance of cases alleging undisclosed risks in SIC is striking. The most accusations in this study involve frequently performed elective or aesthetic surgical procedures. [36,29,37]. This seems plausible, as extensive risk disclosure tends to matter more for patients undergoing elective surgery.

Next to patient's expectations, good communication plays a major role in the perception of care. This is confirmed by the fact that the majority of legal cases is caused by failures in communication, rather than failures in treatment [1,30,38–41]. In our study at least 10% of patients were dissatisfied by the doctor's behaviour and communication. They felt their problems were not taken seriously or the doctor did not have enough time. According to recent studies, Dutch orthopaedic, plastic and general surgeons have poor knowledge and skills regarding SIC [6,32]. If staff is well trained, adequate information provision and consent recording is less at risk.

Our study had some shortcomings. Our results were based upon a random sample of Medirisk cases and our analysis did not include the claims which were not covered by Medirisk. Not all malpractice and MDB cases from this period were fully completed and publicised. This might had some unknown selection bias effects. It was also impossible to specify the lawyer's judgment on SIC. We

Table 4
Top 4 of the most accused specialties, their treatments and alleged unfavourable surgical outcomes.

Total number of claims per specialty	Number of specialists in the Netherlands	Relative number of claims per specialist	Claims concerning Informed Consent	Top 3 most accused treatments per specialty in this study	Top 3 alleged unfavourable surgical outcomes per specialty
1. Surgery n=2777	1289	2,15	235 (8%)	-Varices -Hernia inguinalis repair -Cholecystectomy n=105 12 (11%) 11 (10%) 9 (9%)	-Re-operation -Disability -Nerve damage n=105 38 (36%) 25 (24%) 21 (20%)
2. Orthopedic surgery n=1589	676	2,35	172 (11%)	-Total hip arthroplasty -Knee arthroscopy -Hallux valgus correction n=75 20 (27%) 5 (7%) 4 (5%)	-Disability -Pain -Nerve damage n=75 31 (41%) 28 (37%) 23 (31%)
3. Gynecology n=933	1025	0,91	90 (10%)	-Uterus and adnexa extirpation -Prolaps surgery -Sterilisation n=32 9 (28%) 6 (19%) 5 (16%)	-Re-operation -Psychological damage -Disability n=32 11 (34%) 7 (22%) 5 (16%)
4. Plastic surgery n=393	281	1,40	68 (17%)	-Breast reduction -Breast augmentation -Liposuction n=48 8 (17%) 4 (8%) 4 (8%)	-Disappointing result -Re-operation -Pain n=48 31 (65%) 13 (27%) 9 (19%)

SIC = surgical informed consent.

Table 5
Patient's allegations concerning SIC.

Patient's allegations	malpractice claims (n = 245)		MDB decisions (n = 69)	
	n	%	n	%
Diagnosis	4	2%	2	3%
Treatment:	245	100%	69	100%
- Insufficient information in general	14	6%	10	28%
- Characteristics of treatment:	78	32%	19	28%
* Medical technical aspects	41	17%	12	17%
* Duration	4	2%	2	3%
* Preparation	2	1%	0	–
* Follow up	18	7%	1	1%
* Time of treatment	1	0,5%	1	1%
* Which doctor performs the treatment	19	8%	7	10%
* Other	4	2%	1	1%
- Aim of treatment	3	1%	0	–
- Risks or complications of treatment	164	67%	46	67%
- Alternative treatment options	33	13%	10	14%
- Current health status or prognosis	9	4%	4	6%
- No explicit permission was given for performing the treatment	43	18%	8	12%
- Other	1	0,5%	0	–

SIC = surgical informed consent.

Table 6
Legal outcome of malpractice claims regarding SIC (n = 95).

Judgment	Doctor	Medical advisor	Judicial outcome
- Recognition	10 (11%)	27 (28%)	24 (25%)
- Settlement	12 (13%)	12 (13%)	8 (8%)
- Rejection	63 (66%)	39 (41%)	54 (57%)
- N/A*	0	4 (4%)	0
- Unknown	10 (11%)	13 (14%)	9 (10%)

SIC = surgical informed consent.

* Not applicable.

Table 7
MDB decisions regarding SIC (n = 69).

Judgment	Doctor	Regional MDB	National MDB
- Recognition	1 (1%)	14 (20%)	3 (4%)
- Settlement	2 (3%)	–	–
- Rejection	61 (88%)	55 (80%)	22 (32%)
- N/A*	–	0	44 (64%)
- Unknown	5 (7%)	0	0

SIC = surgical informed consent.

* Not applicable.

tried to compromise this by only analysing the complaints in which SIC was the main complaint.

Nevertheless this study provides clues to enhance the SIC process. Doctors should discuss all relevant risks, that prioritize patient's preferences [6]. In the Netherlands, 39% of the surgeons claimed that there was no institutional standard operating procedure (SOP) on quality or quantity of preoperative information [6]. It appears useful to standardize the SIC process and specify factual risks for different treatments. Moreover, it is important to enhance patient's understanding, as recall of informed consent information is poor [42–49]. Improving information transfer to patients with currently popular interventions as shared decision making (SDM) and e-health projects might be beneficial and should be further explored in surgical practice.

Good communication requires substantial training and is often offset in practice by lack of consultation time. Improving doctor's skills and knowledge in these specific aspects also appears to be necessary to improve the SIC process and patient care in general.

Modern tools as e-health or multimedia programs could be a useful adjunct to the current SIC process. Different studies

investigated the use of multimedia in informed consent and found significant improvement of patient satisfaction and understanding [21,27,50,51]. Although the patient-doctor relationship remains crucial for the SIC process, multimedia is a promising contribution. Further work is required to establish standardized SIC information within guidelines and determine which type of modern intervention is the best practice in clinical informed consent.

In conclusion, this study presents new information on patient's perspectives of malpractice claims and MDB decisions regarding SIC in the Netherlands between 2004–2013. The majority of SIC related claims and complaints were focused on postoperative complications. Future effort should focus on better transfer of SIC information by improving doctor-patient communication, standardize SIC information within guidelines and use modern tools to enhance shared decision making.

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This study received no funding.

Conflict of interest

All authors do not have any actual or potential conflict of interest including any financial, personal or other relationships with other people or organizations within three years of beginning the submitted work that could inappropriately influence, or be perceived to influence, their work.

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