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Original article

Proof of patient information: Analysis of 201 judicial decisions

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ABSTRACT

Introduction: The ruling by the French Court of Cassation dated February 25, 1997 obliged doctors to provide proof of the information given to patients, reversing more than half a century of case law. In October 1997, it was specified that such evidence could be provided by "all means", including presumption. No hierarchy in respect of means of proof has been defined by case law or legislation. The present study analyzed judicial decisions with a view to determining the means of proof liable to carry the most weight in a suit for failure to provide due patient information.

Material and method: A retrospective qualitative study was conducted for the period from January 2010 to December 2015, by a search on the LexisNexis® JurisClasseur website. Two hundred and one judicial decisions relating to failure to provide due patient information were selected and analyzed to study the characteristics of the practitioners involved, the content of the information at issue and the means of proof provided. The resulting cohort of practitioners was compared with the medical demographic atlas of the French Order of Medicine, considered as exhaustive.

Results: Two hundred and one practitioners were investigated for failure to provide information: 45 medical practitioners (22 ± 3%), and 156 surgeons (78 ± 3%) including 45 orthopedic surgeons (29 ± 3.6% of surgeons). Hundred and ninety-three were private sector (96 ± 1.3%) and 8 public sector (4 ± 1.3%). Hundred and one surgeons (65 ± 3.8% of surgeons), and 26 medical practitioners (58 ± 7.4%) were convicted. Twenty-five of the 45 orthopedic surgeons were convicted (55 ± 7.5%). There was no significant difference in conviction rates between surgeons and medical practitioners: odds ratio, 1.339916; 95% CI [0.6393982; 2.7753764] (Chi^2 test: $p = 0.49$). Ninety-two practitioners based their defense on a single means of proof, and 74 of these were convicted (80 ± 4.2%). Forty practitioners based their defense on several means of proof, and 16 of these were convicted (40 ± 7.8%). There was a significant difference in conviction rate according to reliance on single or multiple evidence of delivery of information: odds ratio, 0.165; 95% CI [0.07; 0.4] (Chi^2 test: $p = 1.1 \times 10^{-5}$).

Discussion: This study shows that surgeons, and orthopedic surgeons in particular, are more at risk of being investigated for failure to provide due patient information (D = –0.65 [–0.7; –0.6]). They are not, however, more at risk of conviction ($p = 0.49$). Being in private practice also appeared to be a risk factor for conviction of failure to provide due information. Offering several rather than a single means of proof of delivery of information significantly reduces the risk of conviction ($p = 1.1 \times 10^{-5}$).

Level of evidence: Level IV: Retrospective study.

1. Introduction

The duty for a physician to inform the patient on his or her state of health and the proposed treatments and examinations is a long-standing obligation, going back to the Code of medical ethics, as seen in articles 35, 34 and 41 of the French Medical Deontology Code [1].

Legislation and jurisprudence, however, have greatly modified all aspects of this duty.

Traditionally, the French Court of Cassation (Final Appeals Court) considered that when a patient felt that he or she had not received due information, it was up to the patient to provide proof. On February 25, 1997, however, the Court went back on previous case law in a major ruling making the health professional

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responsible for providing evidence of delivery of patient information (so-called "*Hédreul*" ruling) [2].

Three years later, in the so-called "*Telle*" ruling, the Council of State (*Conseil d'État*) handed down the same decision [3].

Shortly thereafter, on October 14, 1997, the Court of Cassation further developed its jurisprudence, confirming that the burden of proof lies on the physician, but agreeing that this could be provided by "all means" [4]. It was, indeed, laid down that evidence could be provided by "presumption" of facts which, as in article 1382 of the French Civil Code are "left up to the understanding and prudence of the magistrate, who should accept only serious, precise and concordant presumptions".

This progress in jurisprudence was given a legislative foundation in Act No. 2002-303 of March 4, 2002, "concerning patients' rights and the quality of the health system".

However, despite such legislative clarification, the question of the best means for a physician to provide such proof remains a matter of concern.

Numerous guidelines have been published in the specialist literature in an attempt to answer this question, testifying to the medical community's worries about judicialization of the doctor-patient relationship.

Many of these guidelines recommended formalizing information in writing [5–9].

The law as it stands does not clearly set out any hierarchy in the means of delivering patient information. The present study therefore sought to determine the means of proof accepted by the courts as showing that information has been correctly delivered and to specify those most likely to carry weight in a suit for failure to provide due patient information.

In the light of the relevant case law, it was hypothesized that no one means of proof carries more weight than another, notably as concerns signed written information forms.

2. Materials and method

The present retrospective qualitative study of judicial decisions covered the period between January 2010 and December 2015. The inclusion period was based on the year of the ruling, not the year in which the complaint was lodged. The starting date in January 2010 corresponded to the introduction by civil case law of a new prejudice known as "unpreparedness" as a grounds for compensation for lack of patient information.

Rulings were retrieved from the LexisNexis® JurisClasseur website, an exhaustive inventory of Civil and Administrative case law. It also contains Abstracts for each ruling, drawn up by lawyers to elucidate the court's decision.

The search-terms used were "information", "medical" and "patient".

Nine hundred and seventeen documents were retrieved.

All rulings not related to medical responsibility for patient information and all penal sentences were excluded (failure to inform not being a penal charge).

Two hundred and one rulings were studied: 179 by Appeal Courts, 14 by the Court of Cassation, 5 by the Administrative Appeal Court, and 3 by the Council of State (*Conseil d'État*) (Fig. 1).

From each file, the following data were extracted:

- date of ruling;
- content of information claimed to be lacking;
- physician's public or private sector practice;
- physician's specialty;
- type of proof offered in the physician's defense;
- conviction or acquittal;

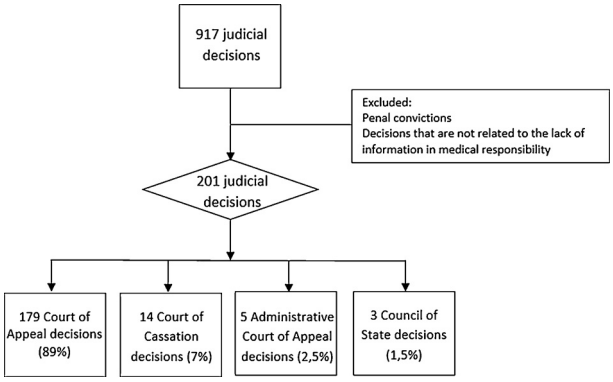

Fig. 1. Flowchart of case selection.

- in case of a single written proof offered in defense, the qualitative content of the proof.

2.1. Statistical analysis

Inter-group comparison of qualitative variables used the Chi^2 test. The significance threshold was set at 0.05.

Standard errors of percentages were calculated as $\sigma = \sqrt{(pq/N - 1)}$.

The medical demographics of the defendants was compared with the 2016 medical demographics atlas of the French Order of Medicine, taken as being exhaustive [10], by percentage comparison with 95% confidence intervals. D values with confidence intervals strictly excluding zero were considered significant.

3. Results

3.1. Convictions per calendar year

Two hundred and one cases resulted in 126 convictions. Conviction rates were independent of year (Fig. 2).

3.2. Content of contested information

In 190 cases ($94 \pm 1.7\%$), the patient complained of not having been informed by the physician of risks inherent to treatment.

In 11 cases ($5.5 \pm 1.6\%$), the patient complained of not having been informed on some other point, such as alternative treatments, choice of treatment, especially when off-label, prognosis associated with the pathology, etc.

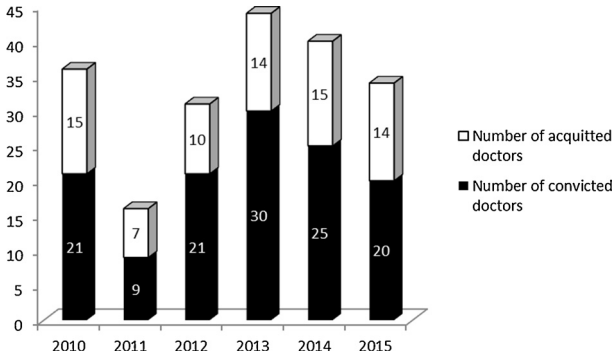

Fig. 2. Convictions per calendar year.

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