

Chronology of the informed consent in France: 1845-2017 (Léonie)

During my internship, I write and adapt cards about some diseases for the patients. These cards inform a patient about his or her disease difficulties, especially when the disease is severe and has huge consequences on the patient's quality of life. This it is necessary to help him or her to be aware and active during the treatment.

At the beginning of my internship, I have been asking myself: : what should be the content of the cards? how much can I write on it ? ? How can I write it ?

From these questions, I started my research with a law perspective. I found an interesting answer to a part of my questions about what should be the content of the card. It was interesting to study the evolution of the informed consent because this evolution illustrates the need of the patient through his or her complaints during the time.

“The old Hippocratic ethic saw the patient as a weak, debilitated, childlike victim, incapable of functioning as a real moral agent...” - Robert Veatch

Three crucial evolutions have been made by the Court of Cassation in France about the implication of doctors in the process of information :

- 1951: the patient must provide evidence that the information that could influence their decision have been forgotten ;
- 1997: the doctor must proof that they gave the information to the patient;
- 1998: the doctor must give all the information about the risks of an intervention, an examination or a treatment;

The doctor Max Simon, in 1845, published the first book about medical ethic¹. In this book, he described the patient as a person **that is too sensible and vulnerable to accept the information**. Thus, information is selected by the doctor to avoid the patient thinking about his or her own death or becoming anxious. Dr Simon said that each physician have to “think about each word to avoid that an imprudent word reveals the serious affliction of the patient”². Moreover, he thought that revealing an information about a serious disease that engages the pronostic of the patient, is going against the duty of the practitioner: “he [doctor] has to respect the last expectancy that attached man to life”³. The royal college of physicians and surgeons of Canada called this approach “paternalism”.

Consent of the patient was a subject of interest since 1889 ⁴, when the surgeon could be incriminated because the patient was not informed about the different existing therapies. In May 20th

¹ *Déontologie médicale de Max. Simon (1845)*, Bernard Hoerni La Revue du Praticien, vol. 64 1474-1477, Décembre 2014

² *Déontologie Médicale ou Des devoirs et des droits des médecins dans l'état actuel de la civilisation*, Docteur Max Simon, 1845, J.B. Baillière, translated from french : “doit peser chacune de ses paroles, dans la crainte qu'un mot imprudent ne révèle au malade l'affection grave dont il est atteint”

³ *Déontologie Médicale ou Des devoirs et des droits des médecins dans l'état actuel de la civilisation*, Docteur Max Simon, 1845, J.B. Baillière, translated from french : “il doit respecter avec la même réserve la dernière espérance qui attache l'homme à la vie. “

1936, the Court of Cassation established as a **contract the nature of the relation patient-physician**⁴. This contract engages the practitioner to get the consent of the patient. A consent required enough information for the patient to decide in all good conscience⁴. Thus, at this point the doctor was already engaged to let the patient have all the information to take his decision. However, the amount of information considered sufficient to take a decision was not yet established and are different depending of the place and the period.

October 7th 1940 was the beginning of the *Conseil de l'Ordre des Médecins* (Council of the Order of Physicians) during the Vichy government. If the creation of this council was thinking before this date, Vichy government used this opportunity to create discriminatory rules against Jewish patients. This institution was completely changed by the new government in 1945. The professor Portes decided to write the *Code de Déontologie Médicale* (Code of Medical Ethics) in 1947 to avoid this situation and have a practice of medicine ethic and moral. This Order was "responsible for the maintenance of morality, probity and devotion crucial for the practice of medicine"⁵.

Professor Louis Portes, in 1950, declared that "emotion or pain dominate his [patient] drive so his will is based on nothing concrete"⁶. Thus, the model patient-physician continue to be "paternalistic" during this period. Actually, this code continues to be used but it is updated according to the evolution of French society.

Simultaneously, a driver was victim of an accident in 1930 and his surgeon decided to practice an osteosynthesis without the informed consent. This operation had catastrophic side-effect for the patient that lost his arm. M. Teyssier, the driver, engaged liability lawsuit against his surgeon because the surgeon had decided the operation for his own interest and without informing the patient about the risks and the possible alternatives of treatments. Teyssier judgment, pronounced January 28th 1942, **forbids the surgeon and confirms the duty for a doctor to let the patient be informed before taking a decision.**⁷

In 1951, M. Birot was amputated after an error of diagnostic. He engaged liability lawsuit and one of the arguments was the lack of information given by the practitioner that caused a non-informed consent for the operation⁸. However, the May 29th 1951, the Court of Cassation decided that : "when [the patient] consents to the operation in a moment of clarity, **he has to report the proof that the surgeon neglects his duty because of a lack of information** about the real implication of the operation"⁸. This decision was contested because it engages the patient to the proof that the doctor

⁴ http://www.univ-reims.fr/gallery_files/site/1/90/1129/1384/1536/1577/1579.pdf

⁵ M Billoux, Health Minister in 1945, translated from French : « *chargé du maintien des principes de moralité, de probité, et de dévouement indispensable à l'exercice de la médecine... et à l'observation des règles dictées par le code de déontologie* »

⁶ *Introduction générale à la bioéthique : histoire, concepts et outils*, Guy Durant, coll. "Fides", 2005, translated from French : "[...] que son affectivité est dominée par l'émotivité ou par la douleur et que sa volonté ne repose sur rien de solide"

⁷ *Arrêt Teyssier de la Cour de Cassation, 28 janvier 1942 : quelques remarques sur une décision "oubliée"*, Bernard Hoerni et J. P. Bouscharain

<http://www.biusante.parisdescartes.fr/sfsm/hsm/HSMx2001x035x003/HSMx2001x035x003x0299.pdf>

⁸ translated from french : "il appartient toutefois à celui-ci lorsqu'il se soumet en pleine lucidité à l'intervention du chirurgien, de rapporter la preuve que ce dernier a manqué à cette obligation contractuelle en ne l'informant pas de la véritable nature de l'opération qui se prépare"

<https://www.pedagogie.ac-aix-marseille.fr/upload/docs/application/forcedownload/2012-06/dgda98en.pdf>

misses an information while he doesn't have the medical knowledge and he is in a position of vulnerability.

Shifting the burden of proof of information occurs in 1997, when the Court of Cassation decides to cancel the judgment from Rennes' Court of Appeal. This judgment rejects the application of a patient victim of a colonoscopy complications. The patient, M Hédreux, defends the non-information of the risk of this examination. The first judgement decided that the patient has no way to prove the lack of information. However, the Court of Cassation, The February 25th 1997, decided that: " the physician is attempt to inform his patient, so he must prove that he fulfils his duty".⁹ Thus, the patient is free from the obligation to demonstrate that he was well informed. **This obligation is now for the doctor.** However, it is important to notice that **nothing indicates what type of proof** the doctor have to give. Or even, the **quality or the quantity** of information was not detailed yet.

If a doctor **does not have to convey** his patient to practice something that the patient doesn't want¹⁰, he must inform his patient about **all the risks** that an operation could cause (except if the patient doesn't want to know or in a case of an emergency)¹¹. In others words, they mean all the **serious risks** that could create an investigation or a treatment. This responsibility is not "excuse just because this risk is exceptional " (Cassation court, judgment established the 07/10/98)¹².

All these laws were established in order to get an **informed consent** from the patient to an operation, an examination or a treatment. They are aligned with the Code de Déontologie Médical, in particular with the articles 35 and 36. The article 35 states that: "The physician owes a **loyal, clear and appropriate** information on his health, the investigations and the care which he proposed to the patient"¹³.

These articles and different laws are supported by the chapter II article 11 of the law n°2002-303 establish the March 4th 2002 about sick's people's rights and system health quality¹⁴. This article is called "**healthcare system users information and expression of their will**"¹⁵. Before a hospitalization, a patient can ask **La charte des personnes hospitalisées** (charter of hospitalized person) which describes all his rights. The two major principles about information are :

- **accessible and loyal information** for the patient (for the investigation, treatment, prevention act, potentiel alternative)¹⁶;

⁹ translated from french : médecin est tenu d'une obligation particulière d'information vis à vis de son patient et qu'il lui incombe de prouver qu'il a exécuté cette obligation
<https://www.lamedicale.fr/documents/201008infomdc.pdf>

¹⁰ <https://www.legifrance.gouv.fr/affichJuriJudi.do?idTexte=JURITEXT000007409555> , *Court of Cassation 18/01/2000*

¹¹ <https://www.legifrance.gouv.fr/affichJuriJudi.do?idTexte=JURITEXT000007038714>, *Court of Cassation 07/10/1998*

¹² *Cass 07/10/1998* translated from french : "il n'est pas dispensé de cette obligation par le seul fait que ces risques ne se réalisent qu'exceptionnellement"

¹³ *code de déontologie médical 2017*

¹⁴ <https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT00000227015&categorieLien=id>, Loi n° 2002-303 du 4 mars 2002 relative aux droits des malades et à la qualité du système de santé (1)

¹⁵ translated from *Loi n° 2002-303 du 4 mars 2002* : "information des usagers du système de santé et expression de leur volonté"

¹⁶ translated from *Charte des personnes hospitalisées* : " L'information donnée au patient doit être accessible et loyale"

- a medical action can't be done without the **free and informed consent**¹⁷;

To conclude, this study depicts the evolution of law on patient's information. During the history, two majors changes have been done: **informing the patient is necessary and doctor have to proof that they have informed their patients before any medical act**. These changes deeply transform the relationship between the patient and the physician. Now, the patient is not approached as a vulnerable child who can't be the actor of his own healthcare but **he is considered as a person capable to evaluate and understand the information in order to take a decision**. However, this relationship is suffering because of the proof and the relativity of some laws. No answer was supplied by law about how communicate the information and when. Some practitioners are afraid to be legally pursued because of a lack of information. **This fear can interfere during the process of information** and harm the quality of the interaction which could be difficult for both patients and practitioners because of the significance and importance of the information to deliver.

¹⁷ translated from *Charte des personnes hospitalisées* : "un acte médical ne peut être pratiqué qu'avec le consentement libre et éclairé du patient"