Applying a Sociolinguistic Model to the Analysis of Informed Consent Documents

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Nurs Ethics 2009 16: 797
DOI: 10.1177/0969733009341908

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Key words: decision-making preferences; informed consent; professional development; Spain; surgery; surgical nursing care

Information on the risks and benefits related to surgical procedures is essential for patients in order to obtain their informed consent. Some disciplines, such as sociolinguistics, offer insights that are helpful for patient–professional communication in both written and oral consent. Communication difficulties become more acute when patients make decisions through an informed consent document because they may sign this with a lack of understanding and information, and consequently feel deprived of their freedom to make their choice about different treatments or surgery. This article discusses findings from documentary analysis using the sociolinguistic SPEAKING model, which was applied to the general and specific informed consent documents required for laparoscopic surgery of the bile duct at Torrecárdenas Hospital, Almería, Spain. The objective of this procedure was to identify flaws when information was provided, together with its readability, its voluntary basis, and patients' consent. The results suggest potential linguistic communication difficulties, different languages being used, cultural clashes, asymmetry of communication between professionals and patients, assignment of rights on the part of patients, and overprotection of professionals and institutions.

Background

When patients are hospitalized they may experience pain and anguish and, perhaps, feel engaged in a struggle between life and death. The moment of a surgical procedure is, therefore, quite delicate, and autonomous personal decisions should be respected. Before the surgical procedure takes place, and in accordance with Spanish legislation, it is compulsory for informed consent to be obtained in writing. This implies an act of communication prior to signing the informed consent document, by which the patient, a family member or a legal representative accepts the recommended surgical procedure. This process may not fully guarantee either the nature of the relationship or a complete

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understanding, and may end with a lack of information that affects patients' awareness about the crucial points on which to base their decisions.[1]

Section 10.5 of the 14/1986 Ley General de Sanidad[2] (General Health Law), as of 25 April, 1986, mentions two complementary documents used in Spain: (1) the General Informed Consent Document (Appendix 1), which deals with the general considerations and prerequirements of the procedure; and (2) the Specific Informed Consent Document (Appendix 2), which provides information on specific conditions according to the pathology and the surgical procedure to be performed. In Spain, the coming into force of the Council of Europe Convention on Human Rights and Biomedicine[3] had an influence on legislation about patients' right to autonomy. The Convention described the information received by patients as 'adequate' but not 'complete'. The changes required were included in the 41/2002 Act,[4] which is the Basic Law applied in Spanish territory that recognizes patients' autonomy and their right to decide on the surgical procedures that suit them best. Informed consent is a free and voluntary act, thus information adequacy is dependent on objective and subjective criteria and needs to be kept under review.

The participation of people in clinical decisions is advantageous because it brings about negotiation with patients and increases acceptance and compliance[5] with relevant decisions. However, we believe the information given to patients before the performance of surgical procedures is not properly developed, which could have serious repercussions on the decision-making process, a situation that can be aggravated by the complex nature of the concept of 'autonomy' depending on culture and health systems.[6]

Document analysis and tools targeted at patients' participation would open new ways of dialogue among health institutions, professionals, patients and society. Because of our own concerns and aiming to create a suitable process, we analysed two informed consent documents used at Torrecárdenas Hospital: the General Informed Consent Document and the Specific Informed Consent Document for laparoscopic surgery, using the bile duct as an example.

The sociolinguist Dell Hymes[7] developed a method of documentary analysis of discourse and speech within specific cultural contexts, known as the SPEAKING[8] model, the results of which, if applied to clinical documentation, could be sorted into categories. Implementation of this informed consent document analysis model in our hospital would allow comprehensive review of communication acts and reveal the points that should be improved.

No permission or ethical clearance was sought for this study because it did not require patients' participation.

Objectives

- To examine the process of obtaining written informed consent through a socio-linguistic analysis of the support documents used in Torrecárdenas Hospital, part of the Public Andalusian Health System.
- To develop hypotheses about aspects to be improved in already existing informed consent support documentation.

Method

We conducted a survey from naturalistic, qualitative and constructionist perspectives, emphasizing the social nature of health sciences together with the importance of private experience when dealing with various situations. According to Hymes, speaking a language properly is not only linked to grammar but also to a cultural context in which words are used. This is real communication competence,[9] a set of skills and knowledge that allows community members to understand each other and use language depending on a specific situation. This theory turns the 'act of speaking' into a minimal social unit provided with communicative intention, 'a unit of analysis', which is assessed by means of several operational factors within the community where it is developed.[10] This is the reference guide of the SPEAKING model,[8] which we used for the informed consent document analysis, and in which each letter of the acronym matches one of eight rules of social interaction and gives answers to eight questions:

1) *S: Setting and scene.* This answers the question of 'where and when' and refers to the setting and scene of the communication act, describing it in terms of place and time.
2) *P: Participants.* This answers the question of 'who and whom' and includes participants or those having an influence on the communication act.
3) *E: End.* This answers the question of 'what for' and concerns the speaker's objectives, aims and intentions, together with the results expected as a response to what he or she says.
4) *A: Act Sequence.* This answers the question of 'what about' by analysing the message content as well its type and style.
5) *K: Key.* This answers the question of 'how' and relates to the way in which the communication act takes place.
6) *I: Instrumentalities.* This answers the question of 'which method' and refers to linguistic resources used in the communication act, how this is done and the connection of words, sentences and paragraphs.
7) *N: Norms.* This answers the question of 'which standards' and includes interaction patterns (when to speak, when to interrupt, how long a person can speak, etc.) together with interpretation rules (shared reference frames or patterns that allow us to interpret what is said/written and what is not).
8) *G: Genre.* This answers the question of 'which type of discourse' and refers to the category of analysing the symmetry of participants, discourse patterns and texts.

The model described by Hymes in 1972[11] aims to bring sociocultural aspects to the surface by the analysis of any communication act. Although there is little research relating to the accurate implementation of this model, as Duranti[12] states, workers in various fields have used it for reference. Our literature search shows it has been used in quite disparate studies, for example, in discourse analysis of the mass media when dealing with natural catastrophes,[13] in studies undertaken on artificial intelligence[14] and, to a lesser extent, in health sciences such as informed consent document content analysis in assisted reproduction clinics[15] and clinical interviews.[16]

Despite not being a standard method, our choice of the model is based on its many aspects, especially those related to the circumstances involved in obtaining informed consent documentation. However, we have taken into account, at least for descriptive purposes, accuracy issues by complying with the following procedures:

1) The three researchers simultaneously conducted a lexical, syntactical and semantic analysis of the documents examined.
2) All researchers separately drew their own conclusions on possible linguistic functions and meanings, and matched significant segments of the text to the eight elements of the SPEAKING model.
3) A preliminary accuracy assessment was carried out for each of the identified units using an accuracy percentage ≥ 0.539 (which corresponded to the observed variance < 0.333, equivalent to 66% consensus of the researchers).[17]
4) The authors drew up the interpretation rules associating the categories with clinical contexts.

Results

The results of analysing the general and specific informed consent documents using the SPEAKING model are presented below.

Situation (setting and scene)

Informed consent in the context studied is an institutional and specialized communication whereby patients are provided with information about the suitability of a surgical procedure. Both documents are written in the first person by an alleged patient, who states that he or she agrees with the indicated surgical procedure, and acknowledges that, prior to signing the documents, he or she has been informed both verbally and in writing by the surgeon. Signing of the documents, except in cases of emergency, occurs well before the operation, after receiving a diagnosis and studying the different therapeutic options. This allows patients to read carefully, understand and reflect on this issue before signing with the aim of obtaining their understanding, involvement and collaboration. The professional role is represented by a healthy person talking to another who is ill, and expressions such as: 'Don't worry, everything is going to be all right' are used. Linguistic barriers may arise because at the root of every such act of communication there is sad news, but also, because of the different languages spoken and the strict western perspective of bioethics that is not linked to the social or cultural contexts that should be present when informed consent is given.[18] Patients' pathological conditions may hinder the capacity of their understanding even more: dysarthria, respiratory distress, therapeutic equipment (e.g. oxygen masks), lowered consciousness or sensory disorder owing to intoxication, poisoning, drug addiction or other irreversible chronic pathology. During social interaction discourse, each society follows its own cultural scripts; adjustments are not made by a society towards cultural differences, which is well reflected in standard informed consent documents.

Participants: status and documents

Communication asymmetry occurs because physicians have the advantage of professional knowledge in addition to knowing about health on a personal level. Patients thus feel themselves to be inferior owing to their lack of knowledge and confidence. They know that the physician has explained to them how appropriate it is to perform the proposed treatment, but they do not have the necessary tools to refute or contrast its

suitability. In general, negotiable terms are totally absent and patients even authorize other treatment if serious complications arise: 'I am aware that in cases where it is impossible to bring surgery to a successful completion in this way, due to technical or intra-operative reasons, the regular incision will be performed (laparotomy)' (Specific Informed Consent Document). Not only do patients authorize a different technique, but also other surgical procedures: 'In some events, there may be related surgery to the liver, duodenum or pancreas' (Specific Informed Consent Document).

End

Patients should receive available information on the suitability and complications of, or alternatives to, the indicated surgical treatment so that they can make a decision based on their own autonomy. However, despite the documents being well structured, the main aim is focused on obtaining their consent. Patients sign a document that is imprecise regarding the advantages and disadvantages of the technique and in which the benefits and risks are not quantified and are preceded by qualitatively defined ambiguous terms relating to various possibilities such as 'the risk is reduced', 'is less intense', 'we could attempt to', 'it is usually', 'there might be', 'which are usually resolved', etc. (Specific Informed Consent Document).

Act sequence

An explanation, which comes before the informed consent, using understandable words and written by the physician, is given to patients or their relatives or representatives about the diagnosis, alternatives, risks and complications that may arise during the surgical procedure. Before surgery, patients will be given the informed consent documents during an outpatient visit or while hospitalized. This event is included in doctors' practice protocol and is under a lot of pressure owing to an overloaded health system, which turns it into a simple administrative measure instead of a communication act that is a part of patients' basic rights. A nurse will also be present to witness this act and to make sure the documents are included in patients' files.

Key

The level of formality in the text is quite high and the relationship between participants is distant. This is a powerful text, which, theoretically, grants patients the capacity to choose freely whether to accept or reject the treatment; nevertheless, it is the professional who handles, selects and manages the information, and its alternatives and possibilities. The text includes only a mere pattern of authorization for instructional purposes: 'I have been informed of the possibility of using my surgical procedure for research or instructional purposes without carrying any additional risks' (Specific Informed Consent Document). We consider that this should be included in a different document.

Instrumentalities

Lexical resources aim to be adequate for patients' comprehension, although some terms are used more specifically in a surgical context: 'incision, hernia, blood products, trocar,

subcutaneous incision, gas embolism, pneumothorax, etc.' (Specific Informed Consent Document). They become very difficult to understand for general users because the text is full of technical language. In addition, terms referring only to the male sex are quite frequent in the General Informed Consent Document (regardless of its ambivalent use) whereas the Specific Informed Consent Document uses terms for both sexes: Mr/Ms. We can also observe certain sociolectic/ethnolectic traits deriving from terms linked to the western understanding of health, its technology and society, and, even though there are no metaphoric elements in the Specific Informed Consent Document, there is specific phraseology (e.g. use of the first person in the Statement).

Likewise, the text is full of euphemisms to allow indirect explanation of the procedure: '... trocar introduction by means of small incisions ...' (Specific Informed Consent Document). As far as syntactic resources are concerned, we should highlight many incomplete sentences in which the physician may introduce specific elements referring to the benefits of, or alternatives to, the indicated surgical procedure: 'It is common practice to leave drainage systems in the surgery area or within the bile duct ...' (Specific Informed Consent Document).

Norms

Interaction

The introduction contains the aims of consent and patients' affiliated personal information The central part gives a detailed account of the process of consent, which ends with an explanation about the way it was obtained (on the reverse side of the document) and details on the option of withdrawal (General Informed Consent Document).

Interpretation: This refers to the reference frames used to understand adequately what was previously presented. Both are direct texts full of circumlocutory phrases, where politeness and empathy are hardly present. There is very little chance for dialogue, consensus or issues related to the sociocultural diversity of patients as individuals.

Relevance

The shared cognitive context is completely different with reference to specific knowledge, cultural level and health status. Patients' wish to receive information is even questioned because it seems they are trying to avoid giving it: 'I wish to be informed about my disease and the surgical procedure to be performed: Yes/No' (General Informed Consent Document). What appears relevant to the writer of the text is that suitability, complications and perspectives of the surgical process are expressed simply. What appears relevant to the recipients of the text is that its terms and general meaning are clearly understood so that it will be easier for them to exercise their rights when making their decision.

Redundance

The client's personal information, an explanation of the technique to be used and its possible complications, the expression of consent, signature and withdrawal are all central points of interest. As for how the text addresses the participants, this is

as follows: 'the surgeon, the patient, the representative' (Specific Informed Consent Document).

Interpretation: The text assumes implicitly that patients fully understand the complicated technique to be used, and it exonerates the health professional and the institution from any complications or failures, which are clearly expressed but hardly justified: 'I understand that, despite having adequately chosen the technique and despite having implemented it correctly, some undesired effects may appear, be they the usual ones derived from regular surgery affecting every organ and system or those specifically derived from the process, which can be serious and less frequent ...' (Specific Informed Consent Document).

Genre of the communication act

The text presents a clear asymmetrical relationship between the participants in the communication act when obtaining informed consent, including the potential recording of the surgical procedure or tissue removal. These details are easy to miss when the document is read quickly before signing it: 'The surgical procedure may be recorded for scientific and instructional purposes unless otherwise stated' (Specific Informed Consent Document); 'Parts of the tissues removed may be used on scientific terms, not commercial, unless otherwise stated' (Specific Informed Consent Document). Neither of these standardized documents come with non-verbal elements such as diagrams or images that would make them easier to understand.

Discussion

Surgical ethics models relating to informed consent have generally been framed in broad terms and lack reference to specific issues such as the severity of treatment and, most of all, proximity to and presence as virtues.[19] The majority of claims or complaints submitted to health institutions are not due to scientific or technical problems relating to medical, surgical or nursing professionals, but to humanitarian factors that are either not implemented or are wrongly performed.[20] Communicative competence between health professionals and patients is complicated, involving social, psychological, cultural and contextual factors that converge on communication analysis. Furthermore, this problem becomes even worse when we note the reported low level of readability concerning forms used to obtain informed consent.[21]

This is why sociolinguistic research is so helpful for analysing the use of verbal and written language in professional contexts, and aims to improve comprehension. Likewise, informed consent becomes a right that interferes with the quality of the relationship among the participants, which will determine not only its obtention but also patients' satisfaction, participation and commitment, which will improve greatly when decisions are made clearly and not from a position of paternalism and defensive medicine. Research shows that patients have an incorrect understanding of the information given about their diagnosis and the different healing alternatives, palliative treatments, improvement in symptoms or quality of life. Mostly, they blame this on deficiencies in the process of obtaining their informed consent.[22] It is not surprising that a large number of patients sign an informed consent document without reading

it beforehand. Others have difficulty in understanding it[23] (mostly older people[24]) and some cannot identify the advantages and disadvantages in surgical procedures of short duration.[25]

Most patients prefer being informed verbally by the surgeon before surgery is performed[26] because at that time they and their relatives are expected to formulate all the questions they need to ask about the risks, benefits and alternatives and can thus make an autonomous decision. Difficulties arise when all these issues are embodied in a written standardized document that is not easy to understand. This procedure is altogether valid, yet it does not mean that the informed consent always attains its goals. Research studies such as those conducted by Larobina *et al*.[27] stress the low level of comprehension patients attain from informed consent regarding their illness, the surgical intervention and its complications. Surveys such as those performed by Masood *et al*.[28] conclude that additional written consents do not improve the understanding of patients about the nature of a surgical procedure, its risks and complications because the information is understood but quickly forgotten. Ghulam *et al*.[29] point out the adequacy of combining previous written and oral information as the most suitable way of meeting the desires of patients,[30] a positive element when recalling the main complications of surgery, and shown obviously by a reduction of claims based on this deficit.[31] Even in cases of urgent abdominal surgery, studies such as that by Kay and Siriwardena[32] have found that some patients are able to participate in discussion on written informed consent in these situations.

In contrast to those with physicians, nurse–patient relationships are less vertical. Accessibility and a 24-hour presence make nurses' contribution to information dissemination both pertinent and indispensable in surgical units where time dedicated to providing information and to listening can lead to positive experiences.[33] This is a significant contribution to the increase in informed consent document efficiency regarding collaboration:[34] to improve patients' comprehension, to ask them to translate what they understand into their own words, to demand translation services, to assess their level of autonomy and possible family pressure, to refer questions to the surgeon, and to make sure deadlines are met.

Nevertheless, this concept does not yet seem to be internalized as part of the nursing role.[35] According to Killen,[36] only 27% of preoperative nurses admitted to being in care situations in which ethical dilemmas occurred, instead turning to their personal background to sort out problems. We agree with Aveyard,[37] who discusses the difficulty raised in identifying nurses' tasks when the need for informed consent is compulsory, especially in Spain, where nurses perform very different roles depending on the hospital in which they work. A change, therefore, should be considered in the way informed consent is obtained. Likewise, Leino-Kilpi *et al*.[38] found differences between Spain and other European countries in how patients and professionals understand autonomy, privacy and informed consent.

Many nurses implement procedures without ever obtaining informed consent. This, together with variation in their consideration of its necessity, is already generating research evidence.[39] For example, patients are still required to confirm they fully understand the information before treatment or nursing care begins.[40]

Regardless of reference to treatments or care procedures, patients' right to autonomy is the main point since they want this to be guaranteed. To this end, both verbal and written information should be clear, complete, understandable and adjustable to

specific circumstances. Within this context, the use of tools such as the SPEAKING model can be useful for informed consent document analysis including formal and contextual elements.

Our work was limited by the lack of literature relating to the use of documentary analysis techniques. An analysis of the use of a single informed consent document, such as for laparoscopic surgery of the bile duct, emphasizes a deficiency with regard to specific informed consent documents on nursing procedures. It is our opinion that this is an issue that requires attention.

Conclusion

Informed consent is important because it promotes individual autonomy and offers security that patients will not be forced or misled into making decisions. It must therefore be designed to allow patients to have control over most of the information received and the chance to withdraw their own previous consent.[41]

In surgical patients' care, ethnographic analysis[42] such as the SPEAKING model provides a useful source of information on the role of the social context in surgical procedures, together with their implementation. Analysing institutional documents such as those for informed consent may identify some problems that could easily be solved by health institutions and provide data for review by ethics committees, such as: the linguistic correction of some terms that are difficult to understand; being more specific about the risks that may arise; to separate consent for surgery from the authorization of recording for scientific purposes; and promoting improvement and quality suggestions.

We suggest that this analysis could encourage nurses to take up a collaborative role in obtaining informed consent for surgical procedures. A cultural change is urged, which would require review of the Specific Informed Consent Document and consideration of the way in which informed consent is obtained.

The SPEAKING model has proved to be very helpful despite not being a validated tool. We recommend that further studies should be conducted to validate the model in clinical documentation analysis.

Conflict of interest statement

The authors declare that there is no conflict of interest.

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Appendix 1

GENERAL INFORMED CONSENT DOCUMENT (GICD)

TORRECÁRDENAS Hospital Complex
HEALTH BOARD

- □ TORRECÁRDENAS HOSPITAL. Paraje de Torrecárdenas, no number. 04009 Almería (Spain). Tel. 00 34 950 016000
- □ PROVINCIAL HOSPITAL. Calle Hospital, no number. 04002 Almería (Spain). Tel. 00 34 950 017600
- □ RED CROSS HOSPITAL. 196, Ctra. Ronda. 04009 Almería (Spain). Tel. 00 34 950 017400
- □ CENTRE OF SPECIALISATION. 226, Ctra. Ronda. 04008 Almería (Spain). Tel. 00 34 950 017200

Surgical procedure_____

Service/Unit _____Medical Record_____

Medical Practitioner_____CNP_____

Patient_____NUSS_____

This document aims to provide evidence that either you or your representative have consented to the surgical procedure mentioned above, which authorizes us to perform surgery according to the terms previously agreed. Before signing this document, you should have been informed both verbally and in writing about the surgical procedure to be carried out.

CONSENT

I state that I agree with the recommended treatment and that I have received and fully understood the information necessary to make my choice. Likewise, I have been informed about patients' right to withhold their consent at any time without unfair repercussions towards them.

I also state I have been told of my right to ask for more information in the event that I require it and that I should not receive any additional treatment, except the treatment I have been informed about and to which I have given my approval, unless it is strictly necessary to save my life or to avoid any irreversible damage to my health.

THE MOST SERIOUS RISKS FOR THE PATIENT ARE AS FOLLOWS:

_____ _____ _____

Patient's signature: Date:	Patient's representative's signature: ID number:..... Date:	Signature of informing doctor: CNP: Date:
Representation on the grounds of:..... ..... □ Wish of the interested party □ Under age □ Disability of the interested party	REVOCATION SIGNATURE Name: ID number: Date:	

NB: Please, read the information printed [below].

INFORMATION PROVIDED

- □ Adequate information provided about the patient's illness and suitability of applying the chosen surgical procedure.
- □ Brief and simple explanation about the objectives of the treatment, what it consists of and how it will be performed.
- □ Information about in which hospital centre the surgery will be performed.
- □ Description of certain consequences arising from the surgery and which are of considerable importance.
- □ Description of typical risks derived from the surgery performed; that is, those that should be expected to occur according to experience and the current state of knowledge. In addition, the patient should receive information on risks that may not be frequent but are not exceptional, being important for their health.
- □ Likely side effects that may result from the surgery and any temporary consequences.
- □ Expected course of the illness in the event of not applying the recommended surgical procedure together with other alternative treatments.
- □ In the event of requiring another person's blood or any other derived substance, the patient should be informed about the typical risks of this procedure.
- □ Information about other complementary procedures that may be necessary to deal with any unexpected situation.
- □ Information on any further enquiry submitted by the patient.
- □ Possibility of an offer of the surgical procedure being performed in another hospital.

Appendix 2

SPECIFIC INFORMED CONSENT DOCUMENT (SICD)

INFORMED CONSENT FOR LAPAROSCOPIC SURGERY OF THE BILE DUCT

PERSONAL INFORMATION

Patient's full name: ……..…… Medical record number: ….....
Representative's full name (where appropriate): ……..

INFORMATION REQUEST

I wish to receive information on my disease and the surgical procedure to be performed: Yes □ No □

SURGICAL PROCEDURE DESCRIPTION

The surgeon has explained to me that, via laparoscopy, an examination of the bile duct will be conducted to confirm the extent of the obstruction and the cause. In addition, my gall bladder may be removed unless removed previously. The choice will depend on the extent and position of the obstruction; the gall bladder will be cleaned, extracted or drained.

A surgical procedure on the liver, duodenum (small intestine) or pancreas may also be performed in some cases. Should the bile duct be removed, it will be reconstructed using part of the duodenum. These surgical procedures are sometimes associated with anastomosis and drainage systems.

Laparoscopy is a surgical procedure in which a fibre-optic instrument is inserted through the abdominal wall to view the organs in the abdomen or permit small-scale surgery. This technique does not differ from the usual one. If this procedure cannot be performed on the grounds of technical aspects or complications arising during the surgery, a laparotomy will be performed.

There may be alterations in the surgical procedure arranged in order to provide the most adequate treatment.

This procedure requires an anaesthetic. The patient will be offered information on its potential risks by the anaesthetist. It may also be possible that during or after the surgery blood and/or any blood product may be administered.

Part of the tissues removed can be used on scientific terms, but not commercial, unless otherwise stated.

Also, my surgical procedure can be filmed for scientific or instructional purposes, unless otherwise stated.

BENEFITS OF THE PROCEDURE

The surgeon has told me that this procedure aims to relieve the obstruction or infection I have been suffering in the bile duct.

Not only will the laparoscopy avoid a larger incision, but there will also be less risk of a hernia after surgery because of performing smaller incisions. Furthermore, pain

after surgery is expected to be reduced and intestinal transit recover more quickly, together with a shorter and less painful healing time

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……

ALTERNATIVES TO THIS SURGICAL PROCEDURE

On some occasions, surgeons attempt to remove biliary calculi, place prostheses or dilate the bile duct by means of endoscopy or transhepatic biliary catheterization. Despite this, they have reached the conclusion that surgery is the best option, which could include open surgery

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……

SPECIFIC AND GENERAL RISKS OF THIS PROCEDURE

I am aware that, despite the adequate choice of this procedure and its proper performance, there could be adverse effects, both common effects arising from any surgery, which may affect any organ and body system, and specific effects deriving from the technique itself, such as:

Frequent and not very serious risks: infection or haemorrhage of the surgical wound, acute urinary retention, phlebitis, disorder of intestinal motility. Also, long-lasting pain felt in the surgical area and, if the surgery is conducted by laparoscopy, gas may expand into the subcutaneous tissues or other areas, especially into the shoulders.

Serious and not very frequent risks: biliary fistula, which on most occasions can be relieved by medical treatment (antibiotics, intravenous drips, etc.) although various tests are sometimes required (ERCP and/or bile drainage); haemorrhage or intra-abdominal infection; intestinal obstruction; reduction of the bile duct; cholangitis (inflammation of the bile duct); reoccurrence of the disease; vascular lesions; injury to nearby organs; gas embolism; and pneumothorax.

These complications are usually relieved by means of medical treatment (antibiotics, intravenous drips, etc.) although sometimes an urgent surgical procedure is required and, rarely, the patient might eventually die.

PERSONAL RISKS AND MISCELLANEOUS

……

SURGERY CONSEQUENCES

The gall bladder will be removed, unless this has been carried out beforehand. It is common practice to leave a drainage system in the surgery area or within the bile duct.

WOULD YOU LIKE TO MAKE ANY STATEMENT CONCERNING THIS SURGERY?

……

Statements and signatures:

Mr/Ms …….. ID NUMBER: …….....

- I state I have been previously informed in a satisfactory way on the surgical procedure to be performed **(LAPAROSCOPIC SURGERY OF THE BILE DUCT)** together with its potential risks and complications.
- I know and assume those risks and/or sequelae that may follow this procedure because of the injury position or complications, notwithstanding surgeons will do their best.
- I have read and understood this information and state I am satisfied with it. I asked all the pertinent questions and my doubts have been resolved.
- I have been informed about the possibility of using my surgical procedure for research or instructional purposes without carrying any additional risks.
- I am also aware that I can withdraw this consent at any time and without giving any explanation, just by telling the medical team.

Signature of the practitioner informing: Patient's signature:

Dr ……. Mr/Ms…….
Medical Association Registration number: ……
Date: ……..……

Mr/Ms …….....……. whose ID number is …… as …….....…….. due to ……..…… gives his/her consent to the indicated surgical procedure.

Representative's signature:
Date: …….....……..

CONSENT WITHDRAWAL

Mr/Ms ……...…… whose ID number is …… withdraws the consent previously given of his/her own free will and accepts the consequences resulting from the development of the illness.

Patient's signature: ……....…… Representative's signature: ……....……

Date: ……..