



# Informed consent in plastic surgery, evaluation of its effectiveness for mutual satisfaction of patient and doctor: Comparison of methods

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## KEYWORDS

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Medical litigation

**Summary Background:** The acquisition of signed informed consent is not always enough to ensure adequate medical protection. Particularly, in plastic surgery, improving the doctor-patient relationship by understanding the patient's emotions and expectations becomes a determining factor when choosing the best therapeutic strategy for the subject in question, which may also include nonsurgical eligibility.

**Methods:** Ninety patients with various plastic surgery disabilities were recruited and randomly divided into three groups: Patients in the first group underwent the "traditional" clinical interview, those in the second underwent the clinical approach called Shared Decision Making (SDM), and those in the third group received both the SDM and a questionnaire evaluating patient expectations (Expectation Questionnaire-Pgm).

At the end of each interview, a specialist physician in Plastic, Reconstructive and Aesthetic Surgery was asked to fill in a questionnaire regarding his/her satisfaction with the method used. Likewise, the patient filled in a questionnaire on his/her satisfaction with the interview.

**Results:** For the doctors, the third method was superior in investigating patient expectations, emotions, and personal preferences. For the patients, the third method scored significantly higher than the first one for overall satisfaction and ability to evaluate personal preferences and needs and higher than the first and second methods in assessing expectations.

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**Conclusions:** For doctors, the SDM coupled with the Expectation Questionnaire-Pgm proved to be the most useful tool to understand patient expectations and emotions and thus improve the medical-patient relationship through shared decision-making. The third method therefore aims for better patient coverage and improved informed consent, thereby reducing the likelihood of litigation and better assessing nonfitness for operation.

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## Introduction

Informed consent is voluntary acceptance by a patient of the treatment proposed to him by a doctor. The essential assumption for consent is that the patient be adequately informed by the doctor.

Patients who sign the informed consent declare they have been informed about their pathology, the treatment proposed, the risks and benefits of that treatment/intervention, and any complications.

The problem arises when relational difficulties, related to the different types of patients (to whom the doctor must adapt at a communicative level), arise between the two subjects and prevent complete understanding by the patient, despite his/her signature.

In total, 43.8% of the verdicts against the doctor’s work center on the inadequacy of informed consent. There is a clear need for transparency and adequate information to strengthen the patient-doctor relationship to avoid legal medical disputes.<sup>1</sup>

An effective doctor-patient relationship is also essential from a decision-making point of view in the therapeutic field.

In fact, in plastic surgery, improving the patient-medical relationship by understanding the patient’s emotions and expectations leads to better therapeutic strategy, which may also include nonsuitability for surgery.

In-depth study of the patient is important because no plastic surgery operation is limited to restoring function to a part of the body but always acts on an introspective subjective plane.

This is known as Plastic Surgery Eumorphics, which is defined as “the plastic surgery that operates transformations getting ‘good form’ of the body and ‘good form’ of the mind. It is a surgery that has psychotherapeutic and psychosomatic abilities entering the deep person.”<sup>2</sup>

Moreover, building an adequate patient-medical relationship, it’s easier to discover a pathological condition known as “Body Dysmorphic Disorder”, one of the most common psychosomatic dysmorphopathological conditions in plastic surgery and one of the most complex conditions to identify.

## Materials and methods

For this study, 90 patients were recruited on their first visit to the Plastic Surgery Clinic of the Sant’Orsola-Malpighi Hospital in Bologna.

The patients recruited in the study had a mean age of 46.6±14.2 years, with males having a mean age of 54.5±17.1 years and females of 41.4±9.2 years; all

**Table 1** Schema of the research procedure.

Method 1	Informed consent	Classic interview	
Method 2	Informed consent	Shared decision making	
Method 3	Informed consent	Shared decision making	Expectation-Pgm questionnaire

patients presented pathologies related to the field of Plastic Surgery, such as outcomes of post-oncological mastectomy, outcomes of labiopalatoschisis, outcomes of trauma, giganotomastia, and outcomes of postbariatric interventions.

The 90 patients were randomly divided into 3 different groups; each group was then assigned to one of three different methods of approach to the patient (Table 1):

- Group I patients underwent Method 1, which consists in routine request for informed consent by the doctor, supported by a common clinical interview.
- Group II patients underwent Method 2, which includes administration of informed consent to the patient combined with a clinical interview based on the principles of Shared Decision Making (SDM) to reach a shared decision.
- Group III patients underwent Method 3, which consists in the patient compiling a questionnaire designed to assess his/her expectations (Questionnaire Expectations-Pgm), and the doctor reading and analyzing the aforementioned questionnaire, followed by administration of

- STEP 1 - *Choice talk* refers to the step of making sure that patients know that reasonable options are available.
- STEP 2 - *Option talk* refers to providing more detailed information about options.
- STEP 3 - *Decision talk* refers to supporting the work of considering preferences and deciding what is best.

**Figure 1** Diagram of the phases of the Glyn Elwyn model.



- 5) How do you rate your self-esteem?  
minimum \_\_\_\_\_ maximum
- 6) Are you satisfied with your body image?  
minimum \_\_\_\_\_ maximum
- 7) Are you satisfied with your work environment?  
minimum \_\_\_\_\_ maximum
- 8) Are you satisfied with your family life?  
minimum \_\_\_\_\_ maximum
- 9) Are you satisfied with your emotional life?  
minimum \_\_\_\_\_ maximum

**Please, answer the following questions. Write down your sentence.**

- 10) What, in particular, made you decide to have surgery?
- 11) In the past, when an important project in your life did not succeed as expected, how did you react?
- 12) If you were dissatisfied with this therapy, what would your reaction be?
- 13) What type of expectation do you have?
- 14) How will surgery change your life ?

**Figure 3** Expectation-Pgm questionnaire - Pag.2.

*best available evidence. Patients are encouraged to think about the available screening, treatment, or management options and the likely benefits and harms of each so that they can communicate their preferences and help select the best course of action for them. Shared decision making respects patient autonomy and promotes patient engagement.”<sup>3</sup>*

The Glyn Elwyn model is characterized by three steps (Figure 1):

- Step 1: Introduction to choices (Choice Talk), where the doctor informs the patient that he/she will be shown different options. At this stage, it is essential to explain to the patient that each option has different

**DATABASE - DOCTORS**

Please indicate which of the following methods was used in the **NEWLY COMPLETED INTERVIEW**:

- Method 1: Informed Consent
- Method 2: Informed Consent + Shared Decision Making
- Method 3: Informed Consent + Shared Decision Making + "Expectation-Pgm Questionnaire"

Answer the following questions by marking a vertical bar (|) on the horizontal line, where the left extremity corresponds to the minimum possible and the right end to the maximum possible, choosing the position on the line that best expresses your opinions.

1) How much was the method used with this **SPECIFIC PATIENT** easy to apply?

Not at all  Very much

2) How much was the method used useful to understand the **needs** of **THIS SPECIFIC PATIENT**?

Not at all  Very much

3) How far was the method used effective in evaluating the expectations of surgery for **THIS SPECIFIC PATIENT**?

Not at all  Very much

The following questions relate to **IDENTIFICATION OF PATIENT ELIGIBILITY FOR SURGERY**.

1) How important was the **patient's personal preference** determining his fitness / ineligibility for surgery?

Not at all  Very much

2) How important were the **patient's expectations** of surgery in determining his/her suitability?

Not at all  Very much

3) How effective was the method used in determining the patient's eligibility for surgery?:

Not at all  Very much

COMMENTS: \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

Figure 4 Medical satisfaction questionnaire.

characteristics, especially regarding the risk/benefit ratio and that, for this reason, it is important to discuss it beforehand.

- Step 2: List of options and availability for discussion (Option Talk), where the doctor provides a list and description of the various therapeutic options, focusing on the pros and cons. It is necessary to reassure the patient, reminding him/her that for any information about treatments, any doubts, or perplexities, one is only too willing to talk about it and discuss it together.
- Step 3: Moment of the shared decision (Decision Talk) where the doctor will ask what is the patient's point of

view regarding the proposed options and which one is considered the most interesting option and why.

Method 3 first consists of the patient receiving and completing the "Expectation-Pgm Questionnaire," which will be given to the doctor before he/she even meets the patient.

The questionnaire Expectation-Pgm is born of the need to have a quick and effective method for assessing the patient expectations and reasons for wanting to undergo surgery.<sup>4</sup>

It divides into two parts (Figures 2 and 3): a first part consisting of questions on a VAS inquiring into the patient's motivation for undergoing surgery, his/her feelings

**DATABASE PLASTIC SURGERY CLINIC**

**INSTRUCTIONS:** Please answer the following questions regarding the interaction with your doctor during the newly completed visit, marking with a cross the number that indicates the answer that best describes your experience:

	Not at all 0	A bit 1	Rather 2	A lot 3	Very Much 4
<b>ABOUT THE VISIT NEWLY COMPLETED:</b>					
<b>1</b>	Was it difficult for you to ask questions?				0 1 2 3 4
<b>2</b>	Was the doctor respectful to you?				0 1 2 3 4
<b>3</b>	Did you feel comforted in talking to your doctor?				0 1 2 3 4
<b>4</b>	Did any information you received about the possible surgery operation seem understandable and clear to you?				0 1 2 3 4
<b>5</b>	Did the doctor give you an opportunity to speak and examine aspects of surgery in depth?				0 1 2 3 4
<b>6</b>	Did you believe in your doctor's skills?				0 1 2 3 4
<b>7</b>	Did the information you received from your doctor about your surgery seem incomplete and not very detailed?				0 1 2 3 4
<b>8</b>	Are you satisfied with the relationship with the doctor during the interview?				0 1 2 3 4
<b>9</b>	Did the information you received from your doctor seem to match the truth?				0 1 2 3 4
<b>10</b>	Did the doctor listen to you during the interview?				0 1 2 3 4
<b>11</b>	Are you satisfied with the information received about forms of surgery?				0 1 2 3 4
<b>12</b>	Did you manage to express your concerns to your doctor?				0 1 2 3 4
<b>13</b>	How helpful was your doctor's attitude?				0 1 2 3 4
<b>14</b>	Did the doctor dedicate you all the time you needed?				0 1 2 3 4
<b>15</b>	Did the Doctor give you the chance to tell all you had in mind?				0 1 2 3 4

Figure 5 COSM-PLAS form - Pag.1.

about possible failure of the surgery, and his/her current satisfaction with body image, emotional, and family life.

The second part of the questionnaire presents open questions, which are very similar to the questions already posed in the first part for content and aspects investigated but, this time, allowing the patient to express him/herself freely and not only on a set scale of values.

Once the doctor has read the Pgm-questionnaire, (s)he meets the patient and proceeds with the examination and clinical interview based on SDM. The informed consent form to be signed is then given to the patient.

The doctors participating in the study are all specialists in Plastic Reconstructive and Aesthetic Surgery.

To evaluate the effectiveness of the three different methods, a satisfaction questionnaire had been devised for the doctor, to be delivered and completed at the end of each interview.

All the doctors, at the end of each interview, regardless of the method used, filled out a questionnaire about their satisfaction with the method just used ("Medical Satisfaction Questionnaire").

The "Medical Satisfaction Questionnaire" (Figure 4) consists of 6 different questions evaluated on a VAS (from "not at all" to "very much") as to the ease of applying the method used and how effectively it enabled the needs of the patient and expectations to be understood.

The last three questions concerned: weight of the patient's personal preferences, his/her expectations in determining the suitability of the patient for surgery or not, and the effectiveness of the method used in determining the patient's suitability for surgery.

At the same time, a questionnaire was sent to all patients regarding their satisfaction about the interview just ended (COSM-PLAS Questionnaire).

Answer the following questions by marking a vertical bar (|) on the horizontal line, where the left extremity corresponds to the minimum possible and the right end to the maximum possible, choosing the position on the line that best expresses your opinions.

1) During the interview were you provided with **INFORMATION USEFUL** in making a decision about your surgery?

Not at all \_\_\_\_\_ Very much

2) During the interview, were you provided with your **PERSONAL PREFERENCES** about surgery?

Not at all \_\_\_\_\_ Very much

3) During your visit, were your **EXPECTATIONS OF SURGERY** analyzed?

Not at all \_\_\_\_\_ Very much

Gender:		Age: _____
<input type="checkbox"/> Male	<input type="checkbox"/> Female	
Qualification:		
<input type="checkbox"/> None <input type="checkbox"/> Primary School Certificate <input type="checkbox"/> Secondary School Certificate <input type="checkbox"/> High School Diploma <input type="checkbox"/> University Degree <input type="checkbox"/> Second Cycle Degree		

Figure 6 COSM-PLAS form - Pag.2.

To evaluate patient satisfaction, the “COSM-PLAS Form,” an adaptation of the COSM-R questionnaire, was used for multiple sclerosis.<sup>5</sup>

The “COSM-PLAS Form” (Figures 5 and 6) is a questionnaire divided into two distinct parts:

- The first part consisting of 15 items to which the patient can respond with a number from 0 to 4 (which, respectively, represent “Not at all,” “A bit,” “Rather,” “A lot,” and “Very Much”). These items mainly concern two aspects of the interview just ended:
  - quality of the information obtained during the interview with the doctor
  - quality of the relationship established with the doctor during the interview
- The second part consisting of 3 questions on the VAS (starting from “Not at all” to “Very much”) with regard to the usefulness of the information received, the discussion of personal preferences during the interview, and

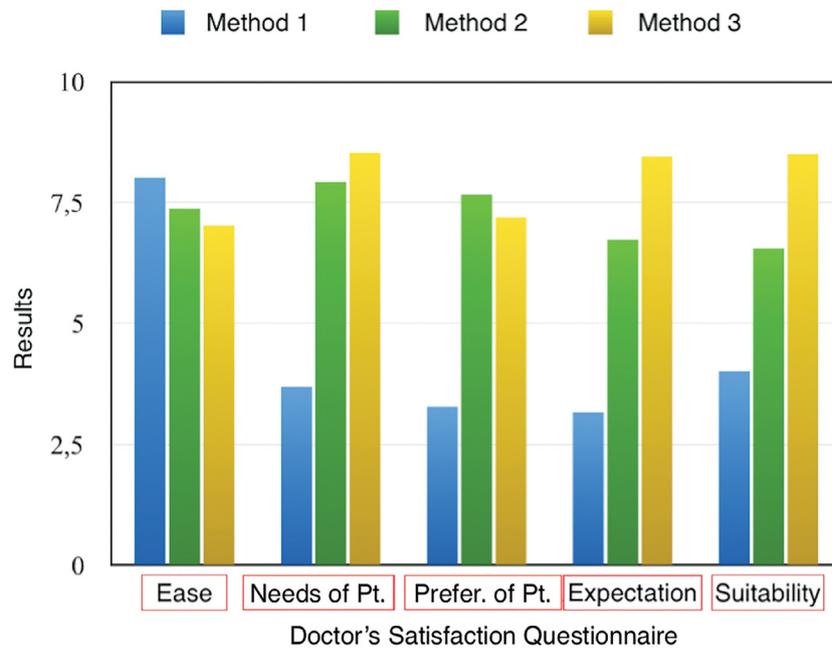
expectations. One part asks for patient’s gender, age, and educational qualification.

## Results

From the descriptive analyses carried out on the 90 patients examined, there was high overall satisfaction, assessed on the first part of the “COSM-PLAS Form,” after adding algebraically the answers from 0 to 4 of the 15 questions and reversing the values for questions 1 and 7. The average total sum of all 90 questionnaires is  $50.93 \pm 7.54$ , compared with maximum total score of 60. This score is a value calculated on all 90 completed questionnaires and therefore does not depend on the method.

However, when correlating the results of the first part of the “COSM-PLAS Form” with the various characteristics of the patient group, the following results were found:

- There are no significant differences between males and females in the answers.



**Figure 7** Chart comparing the three methods as expressed by the doctors through the doctor's satisfaction questionnaire.

- There are no significant differences between patients with different levels of education.
- There are no significant differences between the different ages of the patients and the answers to the questionnaire.

On comparison between the same initial part of the COSM-PLAS Form, unified by sum of score, and the three different methods of approach to the patient, significance was observed between the three aforementioned methods.

The same type of analysis was also performed for the second part of the COSM-PLAS Form regarding patient satisfaction, consisting of the three questions with regard to the usefulness of the information received, the discussion of personal preferences during the interview, and expectations. For this part too, as with the previous one, correlations were found with gender, qualifications, age, and methods.

The results showed that there were no significant differences among methods in terms of gender, educational qualifications, and age. On the other hand, there were significant differences for two questions out of the last three.

Once the significant difference between the methods was established, an ANOVA was performed, as well as post-hoc analysis to determine and investigate what these differences were.

Using the Bonferroni correction<sup>6</sup> as a post hoc analysis for method pairs, the following results were obtained:

- In the first part of the "COSM-PLAS Form," evaluated as the sum of the scores of the 15 questions from 0 to 4, *Method 3 is significantly superior to Method 1*; Method 2 is superior to Method 1 but not significantly.
- At last-but-one question of the "COSM-PLAS Form" concerning the possibility of discussing personal preferences regarding surgery during the interview, it was found that *Method 3 is significantly superior to Method 1*.

- At the third and last question of the "COSM-PLAS Form" concerning the possibility of discussing expectations of surgery during the clinical interview, it was found that *Method 3 is significantly better than Method 1 and Method 2*.

From analysis of the graph in [Figure 7](#) summarizing responses to the doctor's "Medical Satisfaction Questionnaire," the correlation between this type of questionnaire and the three different methods showed significant differences in 3 questions out of 6.

By means of post hoc comparisons, the extent of the differences between the items was precisely defined:

- On the effectiveness in understanding the patient's needs, Method 3 had a significantly higher score than Method 1.
- On the weight of patient's personal preferences when evaluating suitability for surgery, Method 3 scored significantly higher than Method 1.
- On the patient's expectations as a guide to suitability, Method 3 scored significantly higher than Method 2 and Method 1 ([Figure 7](#)).

## Conclusions

The predetermined goals of this study are as follows:

- improvement of the patient-doctor relationship, trying to reduce as far as possible any misunderstandings due to communication difficulties, which, in legal medical disputes, amount to 43.8% of the total and prevents informed consent from being considered as a valid safeguard for the doctor,
- creation of a valid tool to assess the patient's expectations and emotional level

and seeing the results, it can be said that the third method presents an effective solution.

Method 3 proved to be the most accredited method by patients.

SDM proves to be a method that leaves much more room for understanding the patient than the traditional clinical interview: this is because it involves the patient as a protagonist in the therapeutic choice.

The patient has a chance to understand each option and is empowered in the therapy decision.

Such involvement and accountability was well accepted by patients, as can be seen from the satisfaction results in the "COSM-PLAS Form."

The doctors expressed values on ease of application that were the same for all 3 methods, confirming the simplicity of execution of the clinical approach scheme.

Regarding the "Expectation-Pgm Questionnaire," it was found that for physicians, it represents a simple but effective tool in the surveying expectations. In particular, the tool proved superior to the classic clinical interview, considering that the expectation questionnaire is delivered before the visit.

The doctor thus evaluates the questionnaire him/herself; and the "Expectation-Pgm Questionnaire" presents the following different areas of investigation:

- needs and motivations inclining the patient to want to operate;
- level of expectation of surgery;
- emotions in case of dissatisfaction;
- satisfaction with different aspects of the patient's life;
- influence of success of surgery on the patient's life;

s(he) will then have information before the beginning of the interview and, free from prejudices, will be informed of the emotional state, the relationships with others, and the reaction of the subject toward past unpleasant events that can be compared to failure of a surgical operation.

All these aspects can be clarified and reviewed during the interview and can be strategic toward knowing about and deepening some points not clarified during the interview.

The "Expectation-Pgm Questionnaire" can be a very important tool to exclude patients from eligibility for surgical treatment. It also helps to investigate and recognize in a simple way the presence of a patient with body dysmorphic disorder.

It therefore contributes to careful patient selection, allowing a quick but at the same time very thorough analysis, able to discard patients at risk and thus motivating the possible need for psychotherapy.

The patient's response to the "Expectation-Pgm Questionnaire" was also very positive: the patients showed full willingness to fill out a form that concerned aspects that were personal to them but did not necessarily feel judged or controlled during compilation.

It is important for the doctor to investigate the patient's postoperative satisfaction to be able to compare it with the

analysis of the latter's expectations and to globally evaluate the patient's psychological evolution along the entire path.

A satisfaction assessment method, comparable to the "Expectation-Pgm Questionnaire," does exist and is the "Satisfaction-Pgm Questionnaire," shown in the work by Morselli PG et al.<sup>4</sup>

Method 3, which includes SDM and the "Expectation-Pgm Questionnaire," can have important legal value, as in addition to ensuring a better relationship of trust with the patient (presumably limiting those that may be complaints about misunderstandings), it also represents evidence of tangible and documented investigation into the patient and can be useful to a coroner in documenting the accuracy with which complete informed consent was elicited, based on an improved patient-physician relationship.

Numerous studies, first of all the studies by Lewinson<sup>7</sup> and Hickson,<sup>8</sup> have shown that patients who have a close relationship with their doctor are less likely to take legal proceedings, even in case of error. On the contrary, they are more inclined to take action against doctors who, in their opinion, have neglected to give them due consideration during interviews: it therefore highlights the importance of the patient-doctor relationship as a form of prevention from medical litigation.

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