Author’s response to reviews

Title: Infringement of the right to surgical informed consent: Negligent disclosure and its impact on patient trust in surgeons at public general hospitals - The voice of the patient

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Author’s response to reviews:

We thank the editor and our reviewers for their time, efforts and suggestions to improve this manuscript. For each comment, reviewers’ comments are marked in Yellow and our responses are marked in Blue. References we used for this response appear by their order in the revised references.

Editorial Comments

Guidelines regarding participants’ attributes

Age was modified to age range (30s instead of 34) and number of children was deleted.

Declarations

All declarations were added

Ethics information was disclosed.

Addition to the manuscript:

“Following ethics approval by the ethics committee of the COLLMAN’S research authority (#099)”
Reviewers’ comments

Comment: Although the authors try to study surgical IC-related problems, this work includes several problems. Overall, since study background is not succinctly summarized, it is difficult to understand the research background and evaluate what findings are unique and new. To improve the quality of the manuscript, I think the following points need to be addressed.

Comment: (1) Literature review seems to be incomplete. For example, authors say that "Empirical research based on patient perception of IC is scant [7]" (p4, line 48), I want to know findings in the neighboring field such as patient-physician communication.

Thank you for this comment. We broadened the literature on patient-physician communication regarding patient satisfaction ad trust. The following section was added to the revised manuscript:

“Extensive studies examined communication that promotes patient trust in physicians. Trust was higher when the physician demonstrated: Technical competence, listening abilities, confidentiality, honesty, an impartial concern for the wellbeing of patients, compassion, and reliability [38-41]. Physicians' communication style was pivotal in facilitating patient involvement [42-44]. When patients were involved in decision making to a lesser degree than they preferred, the effect on trust was more detrimental than when patients were involved in decision making to a greater degree than they preferred [45-46]. Both physicians and patients perceived the amount of explanations provided by the physician as a measure of the quality of the physician-patient communication [47]. Satisfaction with clinical outcomes also nurtured trust [48]. Patients' perceptions and interpretations of their encounters with physicians impacted patient satisfaction [47]. Patient empowerment by physicians' explanations in acute-care units built patient trust and resulted in improved outcomes and in higher well-being, post-discharge [49].

Interactions that created anxiety, fear, doubt, irritation, or other negative feelings developed into distrust [50]. Patient distrust was related to physician's lack of a bedside manner, lack of cultural competency, patient's experience of objectification, and failure to preserve patient's self-worthiness [49, 51]. Patient distrust was related to a higher degree of psychopathology and to lower general life satisfaction [52].
Meeting patient expectations was a theoretical core that linked all categories of trust [35]. In critical medical situations, as in life-saving surgeries, the vulnerability of patients is high and their need to trust the physician is overwhelming [34]. Patients evaluated their medical encounters in reference to their expectations for care. Unmet expectations were predictive of low satisfaction [53-55] and may, therefore, decrease trust. While physicians perceived their explanations as sufficient to meet patient expectations, thinking there were no more important issues to discuss, patients often thought differently about the explanations and were accordingly unsatisfied with the level of explanations [56]. If expectations are met or exceeded, trust is formed. If the patient’s experience falls short of meeting expectations, distrust is formed. Although surgical IC discussions aim at promoting the patient’s best interest and may create surgeon-patient trust, they lack a constructive notion of the surgeon–patient interaction [6].”

(2) In addition, the authors need to identify regional boundaries where the patient IC-related problem is raised. You are talking about the problem in Israel or in other countries?

The informed-consent problem is valid to any surgeon-patient relationship, as our literature review indicates from 15 studies that we cited. Previous studies that we cited suggest that informed consent is deficient in the dialogue, the extent of content, and the manner in which the disclosure was conducted in health systems around the globe. We added references indicating that the surgical IC is problematic in other countries as well.

Addition from the revised manuscript:

Previous studies and meta-analyses indicate that, in different countries, the content of surgical IC failed to meet acceptable standards, thereby reducing the quality of the surgical IC process and resulting in patients' inadequate understanding, and consequently, their inability to participate in decision-making [7-12].”

(3) Only 12 Israeli patients recruited by snowballing were studied. Why did you decided 12 patients? Please justify the sample size (n=12). Why snowballing was adopted as a sampling strategy?

Thank you for this comment.
The sample size was determined by the principle of "information saturation", as participants described the informed consent process and deficient communication the same way, despite the variances in the type of surgery or the hospital size and location [58-61]. Despite the size of the sample, participants fulfill Lincoln and Guba's (1985) requirement [62] for a wide range of attributes (gender, age, disease, hospital).

As for the sampling method, snowball sampling typically refers to sampling where existing participants provide the researcher with contact information of prospective participants. In this study, participants provided contact information about prospective participants from among their acquaintances (i.e., either people they met at the hospital or people whom they heard had just been discharged from a lengthy hospitalization). This method was used since it was difficult to recruit participants upon their discharge from a long hospitalization in acute-care and to interview them when they were in a relatively poor physical and emotional state. Despite the size of the sample, participants fulfill Lincoln and Guba's (1985) wide range of attributes (gender, age, disease, hospital).

To clarify for the readership of BMC medical ethics, we added the following to the revised manuscript:

"The sample size was determined by the principle of "information saturation", as participants described the informed consent process and deficient communication the same way, despite the variances in the type of surgery or the hospital size and location [58-61]. Despite the size of the sample, participants fulfill Lincoln and Guba's (1985) requirement [62] for a wide range of attributes (gender, age, disease, hospital).”

Also-

A snowball sampling was used to find Informants in their initial recovery phase upon discharge from a public general hospital. Participants provided contact information about prospective participants from among their acquaintances (i.e., either people they met at the hospital or people whom they heard had just been discharged from a lengthy hospitalization). “This method was used since it was difficult to recruit participants upon their discharge from a lengthy hospitalization in acute care and to interview them when they were in a relatively poor physical and emotional state. We focused on participants who underwent major surgeries to emphasize the fact that although their clinical outcomes improved and their lives were saved, they vividly remembered the informed-consent process and were deeply troubled by it.”
(4) Please clearly state the external validity of the present finding. Is the finding is applicable to other patients experiencing surgery in Israel? Is the study finding is applicable to patients in other countries, such as European countries, US or Canada? If so, why? If not applicable, why?

Qualitative research methods help deepen our understanding of a phenomenon, in this case, patient experience with informed consent. As this is a global rather than a regional phenomenon, it is applicable to any patient-surgeon communication or patient-anesthesiologist communication. Although qualitative and quantitative strategies are complementary, procedures for textual interpretation in qualitative methods differ from those of statistical analysis due to the different type of data used (narratives) and the research questions. Thus, external validity in qualitative methods is assessed by the following criteria: relevance, validity of interpretation, transferability, shared assumptions of interpretation and reflexivity.

Please see pages 8-11 in the manuscript from the title "Research Quality Criteria" through "Analytic Strategy" for quality standard criteria.

(5) Please explain the reason why patients with minor diseases were not studied?

As noted in the methods section, this study focused on experiences of patients in lengthy hospitalizations (three weeks versus the average of three days) for cardiac disease, neurological diseases, cancer, and life-threatening accidents. Participants were in mortal danger and underwent life-saving surgeries due to chronic diseases that became acute. Inclusion of participants with major surgeries highlights the importance of our claims. It stresses that although the clinical outcomes of participants improved and their lives were saved, they vividly remembered the informed-consent process and were deeply troubled by it. In all interviews regarding the hospitalization experience, the deficient informed-consent process took up much of their narratives and was engraved in their memory.

Since this is an important clarification for the readership of BMC medical ethics, the following was added to the revised manuscript:
“We focused on participants who underwent major surgeries to emphasize the fact that although their clinical outcomes improved and their lives were saved, they vividly remembered the informed-consent process and were deeply troubled by it. In all interviews regarding their hospitalization experience, the deficient informed-consent process took up much space in their narratives and left a serious imprint on their recollections.”

(6) If you want to elucidate valid findings based on this qualitative methodology, how many more patients are necessary?

Thank you for this question.

There are several debates in the literature concerning the right sample size. By the principle of "Information saturation" [58-61]. Saturation is defined as the point at which the data collection process no longer offers any new or relevant data [61]. Conceptual categories in a research project are considered saturated “when gathering fresh data no longer sparks new theoretical insights, nor reveals new properties of the core theoretical categories” [58, p. 113]. Since most scholars argue that the concept of saturation is the most important factor to think about when mulling over sample size decisions in qualitative research [61], at the 12th participants, it was clear to us that we reached the point of information saturation.

(7). We want to know what new material the authors are trying to report in addition to the previous findings.

This study is the first to link experiences of patients with surgical IC and patient trust in surgeons. The research question is: Does patient experience of surgical IC accord with the principles of IC that surgeons are instructed to implement? A related question is: How does the conduct of the surgical IC process shape patient trust in surgeons?

The contribution of our study to the understanding of the surgical Informed- consent process is threefold: first, it is based on narrative interviews, which enable the solicitation of maximal authentic insights into patients' experiences; secondly, our study classifies several distinguishable deficiencies in the disclosure process. Lastly, based on our insights and understandings, we propose practical recommendations and a multi-phase model of informed-consent processes that minimizes the odds for malpractice and promotes trust in surgeons.
(8) In the conclusion of the Abstract, a model for patient-centered surgical informed consent process was proposed. However, this model was not derived from the qualitative analysis. Conclusion would be "an infringement of a patient's right to respect for autonomy". The model should be presented in the discussion on the basis of the results.

Response: Thank you for this important comment.

Based on our data analysis and interpretations, we proposed a multi-phase model aiming at informed-consent processes that fulfill patients' needs in order to prevent patient distrust in surgeons. Following your comment we changed the abstract as follows:

Discussion

Similarity among the distressing experiences of participants led us to contend that the conduct/practice of nullifying/neglecting surgical informed consent does not stem solely from constraints of time and resources but may reflect an underlying paradox that preserves this conduct and leads to objectification of patients and paternalism. We propose a multi-phase data-driven model for informed-consent that attends to patients' needs and facilitates patient trust in surgeons.

Conclusions

Patient experiences attest to the infringement of a patient's right to respect for autonomy. In order to meet the prima facie right of respect for autonomy, moral agency, and dignity, physicians ought to respect patient's needs. It is now time to renew efforts to avoid negligent disclosure practices and implement a patient-centered model of informed consent.

Reviewer 2 (Reviewer 3): PEER REVIEWER ASSESSMENTS:

Thank you for the time and effort you invested in this review.
OBJECTIVE - Full research articles: is there a clear objective that addresses a testable research question(s) (brief or other article types: is there a clear objective)?

Yes - there is a clear objective

DESIGN - Is the current approach (including controls and analysis protocols) appropriate for the objective?

Yes - the approach is appropriate

EXECUTION - Are the experiments and analyses performed with technical rigor to allow confidence in the results?

Yes - experiments and analyses were performed appropriately

STATISTICS - Is the use of statistics in the manuscript appropriate?

Yes - appropriate statistical analyses have been used in the study

INTERPRETATION - Is the current interpretation/discussion of the results reasonable and not overstated?

Yes - the author's interpretation is reasonable

OVERALL MANUSCRIPT POTENTIAL - Is the current version of this work technically sound? If not, can revisions be made to make the work technically sound?

Yes - current version is technically sound

PEER REVIEWER COMMENTS:

GENERAL COMMENTS: This is one of the best papers I have reviewed for a journal. The creative use of a qualitative study methodology yields unique insights into the experiences of patients, surgeons, and issues of informed consent for surgery. The paper is uniformly well-
written, clear, and the authors have covered all their bases. At first I was concerned with the small sample, but given the extensive interviewing involved and the random method by which the sample was chosen, I am convinced that this study results in genuine insight into problematic behavior by surgeons regarding informed consent and its effect on patient trust of surgeons. The authors also admit that the size of their sample is small and invite other studies along this line. Their presuppositions behind the study are made clear as well as its limitations. The focus on the narratives of patients is a promising one -- the authors are correct that human beings understand their lives in terms of stories rather than in terms of abstractions. Only by going beyond the quantitative into the qualitative by listening to patient's stories can a fully-embodied view of patients' experiences with surgeons can be articulated. This paper is clearly worthy of publication and contributes a great deal to the field of informed consent in medical ethics.

Thank you! This is the most touching, empowering review we have ever received.

ADDITIONAL REQUESTS/SUGGESTIONS:

I think this paper is publishable as is; however, there are some minor stylistic points that the authors are free to use or not use as they see fit.

Thank you again for your very thorough reading and your attention to important stylistic points.

On p. 12, around the numbers 12 and 13 on the left side of the page (lines 5-6 in my printout), there is a lack of parallel structure--it may be better to insert "deficiency in" before "implementation of regulatory guidelines."

Thank you! Done.

On the next page, line 2, a comma should be inserted between "discussion" and "and yet it did not take place."

Thank you! Done.
I am not sure that the commas on p. 21, line 1 after "conduct" and line 3 after "manner" should be there.

Thank you! Commas were deleted.

On p. 30, reference #12, there is a "1" after "consent" that I am not sure should be there.

Thank you for saving us this embarrassment! We deleted the digit 1.

On p. 31, reference 20, a period should be inserted after "Methods".

Thank you! Done.