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

Authors:
Gillie Gabay (gillie.gabay@gmail.com)
Yaarit Bokek-Cohen (ybokek@gmail.com)

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Author’s response to reviews:

Dear Editor,

Thank you for your time and the consideration you are giving to our manuscript “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”, in BMC Medical Ethics [METH-D-18-00064R2].

As requested, please find below a point-by-point response letter accompanying our revised manuscript. We provide a detailed response to each point raised and describe what amendments we made to the manuscript text and where these can be found. Your comments will appear in Yellow and our response follows in Blue.

1. In the Ethics approval and consent to participate section, please be sure to also include the full name of the Ethics committee.

The ethics committee that granted a written approval for this research is a body of the research authority at the College of Management Academic Studies.

These details were added to the manuscript both in the Methods section and as a declaration at the end of the manuscript. (Page 8, lines 173-174; Botton of page 27, respectively).

2. Please confirm whether the consent was written or verbal, in the Ethics approval and consent to participate section. If verbal, please confirm that your ethics committee formally approved this
consent and how the verbal consent was documented. For more information regarding our ethics policy, please go to: https://www.biomedcentral.com/getpublished/editorial-policies#ethics+and+consent

Participants signed a written informed-consent form, that the ethics committee approved, which related to both participation and potential publication. This information now appears in the Methods section (Page 10, lines 205-206).

From the revised manuscript:

“Participants were asked to sign a written statement of IC regarding participation and publication.”

3. Please only include one copy of figure 1, in the file inventory. If you intended to include two figures, please be sure to include the appropriate files and references in the main text of the manuscript.

Figure 1 was omitted from the manuscript and was loaded as a separate submitted file.

4. We note that the current submission contains some textual overlap with other previously published works, in particular:

"Patient Self-worth and Communication Barriers to Trust of Israeli Patients in Acute-Care Physicians at Public General Hospitals"

https://journals.sagepub.com/doi/10.1177/1049732319844999

"Perceived control over health, communication and patient–physician trust"


"A Nonheroic Cancer Narrative: Body Deterioration, Grief, Disenfranchised Grief, and Growth"


"https://en.wikipedia.org/wiki/Objectification"

This overlap mainly exists in the Background, Methods and Discussion sections.

While we understand that you may wish to express some of the same ideas contained in these publications, please be aware that we cannot condone the use of text from previously published
work. We would therefore be grateful if you could reformulate in your own words the overlap between your manuscript and other sources.

We apologize for the unintended overlap of text from another published work written by the first author.

We reformulated the ideas using different wordings so there is now no overlap. Below is the text from the INTRODUCTION section in the revised manuscript: (Page 6 line 118 to page 8, line 157).

"Patient trust is essential in determining the level of recuperation, the level of medication adherence and number of readmissions [24-33]. Trust, however, has not been applied to the context of surgical IC. The concept of patient trust includes inter alia, compatibility between the patient's prior expectations and the behaviors acted upon, a risk evaluation, and the willingness to become dependent on another person [34]. This conceptualization of Hupcey, Penrod, and Morse [35] suggests that the patient may have her own expectations for receiving care and she agrees to be involved in a relationship that may elevate her vulnerability owing to her reliance upon the physician [36-37].

Extensive studies have examined communication that promotes patient trust in physicians. It was found that trust was higher when technical competence and listening skills, as well as honesty and confidentiality, were characteristics displayed by the physician [38-41]. Physicians' communication styles were a pivotal prerequisite for the patient to become more involved in the recovery process [42-44]. When patients were involved in decision making to a lesser degree than they would have liked, the effect on trust was more detrimental than if the opposite situation occurred and they felt they had been involved too much [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]. Patient satisfaction with clinical outcomes improved patient trust in the physician [48]. Perceptions and interpretations of patients regarding their encounters with their physicians affected patient satisfaction [47]. Patient empowerment through physicians' explanations in acute-care units built patient trust and resulted in improved outcomes and in greater well-being, post-discharge [49].

Patient-physician interactions that created doubt, irritation, anxiety, fear, or similar negative feelings developed into distrust [50]. Distrust in physicians was associated with a patient's feeling of objectification, failure to preserve a patient's self-value, a physician's lack of a bedside manner, and lack of cultural competency [49, 51]. Patient distrust has been found to be correlated with more incidences of psychopathology and with lower life satisfaction [52].

Meeting patient expectations was a pivotal theme that combined all categories of trust [35]. Patients evaluated their encounters with their physicians in reference to their prior expectations [34]. Unmet expectations have been found to be correlated with low satisfaction [53-55] and may, therefore, diminish 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 patient's expectations are met or even exceeded, then trust in physician is established. However, if the patient is disappointed, because her expectations are not met, distrust is formed. Despite the fact that surgical IC dialogues are intended to promote the patient’s best interest and have much potency in creating surgeon-patient trust, they lack the component of an interpersonal interaction between the surgeon and the patient [6]).

Below is the modified Methods section in the revised manuscript (Page 10 line 212 to page 13, line 267).

Research quality assurance

"In order to advance the credibility of this study and allow participants to talk freely and refrain from downplaying or over-emphasizing their feelings, the first author endeavored to create a relaxed and empathetic atmosphere during the interview. In order to enhance the transferability of the conclusions, the first author described the research methodology in detail and provided detailed descriptions of participants’ perspectives. Moreover, the preliminary results were triangulated by a qualitative peer debriefing with eight clinicians and three colleagues who specialize in qualitative methodology. Based on their comments, technical medical terms were clarified and data analysis was enhanced.

Procedures

Twenty-four interviews were conducted at the interviewees' homes. The issue of surgical IC appeared to be very emotionally loaded. The first interview with each participant was carried out within the first two days after discharge and the second interview was carried out a month later. In accordance with the method of a narrative interview, participants were asked to answer one question in detail: "Please tell me how you arrived at the hospital and what you experienced there." Interviewees spoke of their experiences from the first appearance of symptoms until the time of discharge from hospital. The first author introduced herself as a person specializing in health psychology, studying the experience of hospitalization and explained the research methodology. Almost all interviewees stressed that, although it was very challenging for them to submit to the interview in their poor physical state so soon after discharge, they nevertheless wanted to share their experience in order to improve the experiences of others. The first author thanked them for their willingness to contribute to the project.
The first author actively listened beginning with the opening question, as guided by the narrative method [63], and did not attempt to ask questions, comment, or judge what interviewees said, in order to allow them to express themselves freely and convey their own subjective interpretations for what they remembered had occurred. All were highly emotional.

Analytic Strategy

Data were interpreted using the narrative method, which is based on the assumption that narratives constitute a main cognitive scheme in human development [63-65]. Cases where there were repeated elements across narratives reflect the authenticity of these narratives. The data analysis was informed by the holistic principle that views narratives as representing whole experiences where parts of a narrative are related to each other. For example, openings of narratives that may be related to their endings with pivots of content are expected to be interrelated; and episodes that may seem unrelated at first sight may later be revealed to be associated to one another [66-67]. The principle of wholeness builds on constructive ontology and epistemology [65].

The data analysis method is based on four analytical phases and is hence suitable for a data-driven analysis and for exploring themes that originate in experiences of participants [68]. In the first phase, the transcription of each interview was read again and again as a whole unit. Initial themes were detected for each participant's experience. Original words, body language and tone, were documented. In the second phase, each transcribed interview was analyzed using six selection mechanisms as described below [65]; these mechanisms are assumed to describe what participants inadvertently chose to tell and not to tell, leading to the 'end-point' of each narrative (i.e., the focal theme). The selection mechanisms that were at work in the interpretation of the narratives: inclusion — meaning the facts and experiences reported by each participant and the common motif amongst them; sharpening — meaning the events which the participants themselves stated as being central; omission — meaning the occurrences that participants thought were irrelevant to the desired end-points; silencing — meaning those occurrences that participants felt to be in conflict with the desired end-point; flattening — meaning the reductionist stance towards occurrences that participants perceived as unimportant for them; and, attribution of appropriate meaning — relating to meaning ascribed to occurrences that participants found to be compatible with the end-points, although these end-points may not necessarily align with their original meaning."

Please be sure to only include the original source/ scientific publications when amending this section of overlap and including the relevant sources.

The following original publications were added to complete the reference list:


49 Gabay G. Patient Self-worth and communication barriers to trust of Israeli patients in acute-care physicians at public general hospitals. Qualitative health research. 2019. 1049732319844999. (Page 34)

88 Gabay, G. and Bokek-Cohen, Y. What do patients want? An enhanced subjective model of informed consent. A manuscript under review.

Additional Comments from BMC’s site:

Please provide a list of abbreviations after the Conclusions section. If abbreviations are used in the text, they should be defined in the text at first use and included in this list.

From the manuscript: (Bottom of page 27).

ABBREVIATIONS

IC – Informed consent

COLLMAN -College of Management Academic Studies

According to the submission guideline, the main text should be structured to the following separate sections: Background; Methods; • Results; Discussion; and Conclusions, which were missing.

The last paragraph was re-defined as conclusions (Page 27, lines 632-637). From the manuscript:
CONCLUSIONS

Having edged back from either soft or hard paternalism, it is now time for a renewed effort to construct a conscious, practical, trust-facilitating process of surgical IC [88]. It is our hope that the model we propose may offer insights which could serve as the cornerstone for such an improved surgical IC process.