

STUDY ON INFORMED CONSENT PROCESS IN SHARED DECISION-MAKING AMONG PATIENTS SCHEDULED FOR VARIOUS KIND OF SURGERIES AT A MEDICAL SCHOOL OF NORTHERN INDIA

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ABSTRACT

Objective: The objective of this study was to study perceptions of specialists and patients with respect to the informed consent process in shared decision-making.

Methods: A cross-sectional study was done among doctors of various departments carrying various kinds of surgeries at a medical school of northern India. One hundred and twenty-five specialists and 250 patients finished an organized survey on the informed consent process.

Results: Out of total specialists, 81 (64.8%) were men and 44 (35.2%) were women; 98 (78.4%) were trained professionals/super subject matter experts and 27 (21.6%) were occupants. Practically, all patients (94.8%) detailed that they had picked the treatment strategy proposed by specialist. Not exactly 50% of doctors 52 (41.6%) announced being completely familiar with the educated assent process, critical disparity was enlisted between the responses from patients and doctors to every one of the inquiries contrasting their encounters in regards to the strategy of getting educated agree to treatment ($p < 0.001$).

Conclusion: There exists a gap among doctors and patients concerning both comprehension and information on the informed consent process. The distinction in discernment and halfway information on the lawful ramifications of informed assent shows that consenting in its ongoing structure is not educated and ought to be rethought to accomplish patient independence, which is a definitive objective of informed consent.

Keywords: Patient rights, Informed consent, Patients.

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INTRODUCTION

Informed consent is the most common way of consenting to partake in a review in light of admittance to all important and effectively edible data about what support implies specifically, with regard to harm and benefits [1]. Sufficient information is essential to give informed consent before conducting any surgical procedure. Data ought to incorporate a depiction of the advantages, dangers, and confusions of the expected technique as well as elective therapy options [2,3]. It ought not be a un-interactive process, in which a clinical or careful choice is surrendered to the doctor just; however, an interactive process by which patients inclinations with respect to clinical or careful choices are considered [4-6].

It is undeniably true that few patients will generally see written consent as a regulatory hindrance may pointless feel restless and compelled by giving consent and report that they do not peruse or comprehend the consent form [7]. In spite of the fact that, there has been an examination on patient's comprehension to what has been clarified for them and their understanding about it after the counsel when consent is obtained [8,9]. Till date, we are not clear about patients' information and understanding of the consent process.

It is fundamental for medical care and medico general set of laws to be familiar with reasons of existing patient-doctor communication gap, so understanding and doctor can come to a common conclusion about their clients. This study was conducted to study the informed consent process in shared decision-making among patients scheduled for various kinds of surgeries at a medical school of northern India.

METHODS

This study was done among doctors planning to perform various surgeries in different departments at a medical school located at northern India. Before commencement of the study, patients were well informed about the reason regarding the study and that cooperation was voluntary. The study pro forma was passed out to 182 specialist doctors performing surgical procedures in various departments such as orthopedics, ophthalmology, general surgery, otorhinolaryngology, and gynecology.

The patients going through surgical procedures during the study time frame were likewise mentioned to take part in the study during preanesthetic visit before the procedure. Of the 300 eligible patients, 250 consented to an organized meeting with a the anesthesiologist questions and recorded their responses. There were 159 patients talked with at the division of general medicine procedure, 11 at the orthopedics, 34 at the ophthalmology, 19 at otorhinolaryngology, and remaining at the department of gynecology.

Data were gathered utilizing a study tool. The inquiries were connected with the informed consent, for example, arrangement of data to patients, regarding patient independence, information on guidelines, and understanding toward the course of informed consent. The polls were already pilot-tried among 25 subjects and changed in like manner. The majority of the inquiries on the doctor and patient surveys were comparative; nonetheless, the inquiries were reworded to pose to about encounters intended for either doctors or patients. Patients were carefully guided to allude to the informed consent for method that they

are as of now ready for, while doctors were mentioned to allude to their last gotten informed consent process.

The gathered information was placed in Microsoft Succeed. Coding of the factors was finished. SPSS version 22 was utilized for examination. Understanding of the gathered information was finished by utilizing suitable techniques such as rate and extents. Chi-square test was applied to test for significance if any.

RESULTS

Out of aggregate, 137 specialists returned surveys giving a reaction pace of 78.3%. One hundred and twenty-five surveys (71.4%) were completely finished and remembered for the investigation. Among the specialists who returned the completely finished survey, 81 (64.8%) were men and 44 (35.2%) were ladies; 98 (78.4%) were subject matter experts/super trained professionals and 27 (21.6%) were occupants. The middle period of specialists was 45 years (range 28–65 years).

Dissimilarity was seen in the responses to the inquiries on how much data that were given or gotten about understanding’s ailment, impending clinical techniques, and on the potential entanglements of impending operations (p<0.001). Practically, all patients (94.8%) announced that they had picked the treatment technique proposed by specialist (Table 1).

Huge disparity was enrolled between the responses from patients and doctors to every one of the inquiries contrasting their encounters with respect to the method of getting educated agree to treatment (p<0.001). Conflict was the most conspicuous in the inquiry on how much the data introduced to the patients before they needed to go with their choice on the approaching methodology. In the occasion that patients could not settle on their own choice with respect to treatment, a large portion of them would pass on the choice to doctors (Table 2).

Not exactly 50% of doctors 52 (41.6%) revealed being completely familiar with the educated assent process, though 73 (58.4%) detailed

having incomplete or no information. Most patients (174; 69.6%) detailed having incomplete information on the educated assent process. A sum of 112 (89.4%) doctors detailed that they totally or somewhat illuminated their patients about their freedoms, although just 37 (14.8%) patients revealed that they felt that they were completely educated about their privileges (p<0.001) (Table 3).

DISCUSSION

The main objective of informed assent is that the patient ought to have a potential chance to be an educated member in their medical services choices, so it goes about as a shield to guarantee the safeguarding of individual freedoms and to achieve this objective that there should be strong doctor patient interaction [10]. As of late, a review has distinguished various issues, for example, regulation, morals, information, data, underlying medical services issues, and financing issues as significant areas of significance inside a specific doctor patient interaction [11].

The discoveries of present review have shown huge contrasts in the information and impression of these places of interests characterizing patient-specialist cooperation between two review gatherings. Doctors needed mindfulness about their expert, lawful, and moral commitments to give patients data concerning their ailment and impending analytic and remedial techniques. Then again, a lot of patients detailed getting just restricted or fragmented data, or at times no data got by any means. Comparative perceptions were additionally made by one more review from Israel [12].

We saw in present review that the degree of data trade was a restricted during the doctor patient counsel. This might happen in light of the fact that doctors frequently feel in a hurry. It tends to be a potential clarification for the equivalent. This comes conversely, with the discoveries of another review which saw that the patients frequently do not wish to be completely educated regarding the dangers and potential inconveniences of the impending surgery [13].

Table 1: Responses of participants as per their mindfulness and understanding toward informed consent

Variable	No. of participants (%)		p-value
	Doctors (n=125)	Patients (n=250)	
I inform patients about their condition and treatment modalities/I was informed about my condition			
In detail	39 (31.2)	25 (10.0)	<0.001
As much as necessary	68 (54.4)	174 (69.6)	
Only as much as needed (for a patient) to make a decision	18 (14.4)	51 (20.4)	
I answered whatever patients want to know/Doctor answered my questions			
In detail	32 (25.6)	46 (18.4)	<0.001
Clearly and briefly	87 (69.6)	145 (58.0)	
By providing only the most necessary information	6 (4.80)	59 (47.2)	
I provide/received information on risks and possible complications of treatment			
In detail	34 (27.2)	21 (8.4)	<0.001
As much as necessary	61 (48.8)	108 (43.2)	
Only on most common risks and complications	29 (23.2)	80 (32)	
No (to avoid upsetting the patient)	01 (0.8)	41 (16.4)	
Patients/I usually make decision about the treatment method			
Suggested by a clinician	100 (80.0)	237 (94.8)	<0.001
Suggested by friends	04 (3.20)	02 (0.80)	
I don't know	21 (16.8)	11 (4.4)	
I provide/received information on possible alternative methods of treatment			
On more than one method (if existing)	96 (76.8)	134 (53.6)	<0.001
I do not talk about other methods in order not to confuse the patient/No, clinician did not mention other methods	14 (11.2)	87 (34.8)	
Patients themselves can find information/I myself found information	15 (12.0)	29 (11.6)	
How long does/did the conversation with the patient/clinician last?			
<5 min	39 (31.2)	59 (23.6)	<0.001
10–15 min	82 (65.6)	181 (72.4)	
>15 min	04 (3.2)	10 (4.0)	
Do you inform patients about their length of hospital stay?/Were you informed about the length of your hospital stay?			
Yes	99 (79.2)	197 (78.8)	<0.001
No	24 (19.2)	53 (21.2)	

Table 2: Comparing physician's and patient's responses about the procedure of obtaining informed consent

Variable	Number of participants (%)		p-value
	Doctors (n=125)	Patients (n=250)	
In your opinion, do your patients receive sufficient information so that they are able to decide their treatment?/Did you receive sufficient information so that you are able to decide your treatment?			
Yes, complete information	67 (53.6)	30 (12.0)	<0.001
Only the most necessary information	55 (44.0)	189 (75.6)	
Not complete information	03 (2.4)	31 (12.4)	
Your patients/you provided consent to treatment independently, without			
Anyone's help	105 (84.0)	223 (89.3)	<0.001
After consulting with the family	14 (11.2)	20 (8.0)	
After special persuasion by a clinician	06 (4.8)	07 (2.8)	
If patients/you are not able to choose the treatment method, who would you ask for consent?			
(Patient's) family	121 (96.8)	98 (39.2)	<0.001
(Patient's) friends	01 (0.8)	00 (00)	
Colleagues/physician	03 (2.4)	152 (60.8)	

Table 3: Comparing physician's and patient's responses about the knowledge and practice of obtaining informed consent to clinical procedures

Variable	Number of participants (%)		p-value
	Doctors (n=125)	Patients (n=250)	
Are you familiar with the informed consent process?			
Completely	52 (41.6)	65 (26.0)	<0.001
Partly	59 (47.2)	174 (69.6)	
No	14 (11.2)	11 (4.4)	
Do you inform patients about their rights?/Are you informed about your patient rights?			
In detail	48 (38.2)	37 (14.8)	<0.001
Partly	64 (51.2)	150 (60.0)	
No	13 (10.4)	63 (25.2)	
Do patients receive a copy of signed consent form?			
Yes	17 (13.6)	06 (2.4)	<0.001
No	82 (65.6)	169 (67.6)	
I don't know	26 (20.8)	75 (30.0)	
Is the informed consent process legally regulated?			
Yes	50 (40.0)	94 (37.6)	0.584
No	12 (9.60)	21 (8.4)	
I don't know	63 (50.4)	135 (54.0)	

In our review, it was found that most patients detailed giving their assent autonomously and settling on the treatment technique proposed by their PCPs. Another populace-based overview has detailed comparative outcomes to those saw in the present review [14]. In the ongoing time of data and innovation, a lot of wellbeing data is currently open to the overall population including patients. As of late, a review from Bethesda affirmed that patients playing out their own web research are more intuitive with their primary care physicians about the treatment techniques and that the web does not supplant the job of specialists in such scenario [15].

One clear impediment of this study is that the training level of the patient was excluded from the investigation so we could not evaluate what the instructive level of the patient meant for their capacity to comprehend the gave clinical data during the assent cycle. Furthermore, those patients who did not totally comprehended the data gave that was expected to settle on treatment their particular on the educated assent structure is lawfully and morally problematic and assent ought to be gotten from relatives. Furthermore, we talked with just careful patients, though not each of the doctors who finished the survey work in careful strengths.

CONCLUSION

This study reveals that there exists a huge conflict between the informed consent made sense of by specialists and saw by patients, affirming presence of patient-doctor communication gap, which make obstacle in shared decision-making. Thus, current consent techniques appear to be

lacking in current situation. The distinction in discernment and halfway information on the lawful ramifications of informed assent shows that consenting in its ongoing structure is not educated and ought to be rethought to accomplish patient independence, which is a definitive objective of informed consent.

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AUTHORS' CONTRIBUTIONS

All the authors have contributed equally.

CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

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REFERENCES

1. Informed Consent in Health and Social Care Research. RCN Guidance for Nurses. 4th ed. London: Royal College of Nursing Research Society; 2021.
2. Department of Health. Reference Guide to Consent for Examination

- or Treatment; 2001. Available from: <https://www.dh.gov.uk/assetroot/04/01/90/79/04019079.pdf> [Last accessed on 2021 Oct 24].
3. Department of Health. Consent Forms. Available from: <https://www.dh.gov.uk/assetroot/04/01/90/34/04019034.pdf> [Last accessed on 2021 Oct 24].
 4. Bates T. Ethics of consent to surgical treatment. *Br J Surg* 2001;88:1283-4. doi: 10.1046/j.0007-1323.2001.01913.x, PMID 11578280
 5. Jefford M, Moore R. Improvement of informed consent and the quality of consent documents. *Lancet Oncol* 2008;9:485-93. doi: 10.1016/S1470-2045(08)70128-1, PMID 18452859
 6. O'Leary KJ, Kulkarni N, Landler MP, Jeon J, Hahn KJ, Englert KM, et al. Hospitalized patients' understanding of their plan of care. *Mayo Clin Proc* 2010;85:47-52. doi: 10.4065/mcp.2009.0232, PMID 20042561
 7. Habiba M, Jackson C, Akkad A, Kenyon S, Dixon-Woods M. Women's accounts of consenting to surgery: Is consent a quality problem? *Qual Saf Health Care* 2004;13:422-7. doi: 10.1136/qhc.13.6.422, PMID 15576703
 8. Mayberry MK, Mayberry JF. Towards better informed consent in endoscopy: A study of information and consent processes in gastroscopy and flexible sigmoidoscopy. *Eur J Gastroenterol Hepatol* 2001;13:1467-76. doi: 10.1097/00042737-200112000-00010, PMID 11742195
 9. Dixon-Woods M. Writing wrongs? An analysis of published discourses about the use of patient information leaflets. *Soc Sci Med* 2001;52:1417-32. doi: 10.1016/s0277-9536(00)00247-1, PMID 11286365
 10. Bhurgri H, Qidwai W. Awareness of the process of informed consent among family practice patients in Karachi. *J Pak Med Assoc* 2004;54:398-401. PMID 15449928
 11. Dieterich A. The modern patient-threat or promise? Physicians' perspectives on patients' changing attributes. *Patient Educ Couns* 2007;67:279-85. doi: 10.1016/j.pec.2007.03.017, PMID 17467948
 12. Brezis M, Israel S, Weinstein-Birenshtock A, Pogoda P, Sharon A, Tauber R. Quality of informed consent for invasive procedures. *Int J Qual Health Care* 2008;20:352-7. doi: 10.1093/intqhc/mzn025, PMID 18625699
 13. Corfield LF. To inform or not to inform: How should the surgeon proceed when the patient refuses to discuss surgical risk? *J Vasc Surg* 2006;44:219-21. doi: 10.1016/j.jvs.2006.04.050
 14. Levinson W, Kao A, Kuby A, Thisted RA. Not all patients want to participate in decision making. A national study of public preferences. *J Gen Intern Med* 2005;20:531-5. doi: 10.1111/j.1525-1497.2005.04101.x, PMID 15987329
 15. Hesse BW, Nelson DE, Kreps GL, Croyle RT, Arora NK, Rimer BK, et al. Trust and sources of health information: The impact of the internet and its implications for health care providers: Findings from the first health information national trends survey. *Arch Intern Med* 2005;165:2618-24. doi: 10.1001/archinte.165.22.2618, PMID 16344419