

Effect of communication skills training for obtaining written Informed consent: an Indian experience

Abhijeet Madhukar Patil^{1,*}, Ajit Subhash Patil²

¹Assistant Professor, ²Associate Professor, Dr. Vasanttrao Pawar Medical College, Hospital & Research Centre, Nashik, Maharashtra

***Corresponding Author:**

Email: drabhi17@rediffmail.com

Abstract

Objectives: The primary objective of the study was to evaluate whether formal communications skills training improves the quality of written informed consent.

The secondary objective was to evaluate the patient satisfaction index.

Methods: Group 1 was subjected to communication for written informed consent by untrained Post-graduate residents. The session evaluated by Objective Structured Clinical Examination (OSCE).

The post graduate residents were then given a communications skills training. Pre-test and post-test were obtained for the educational intervention.

Group 2 was subjected to a communication skills training for the purpose of written informed consent by the same post-graduate residents after communication skills training and evaluated by Objective structured clinical examination.

The data was analyzed by Paired 'T' test and Student 'T' test.

Result: OSCE data of group 1 was 4.05 as compared to 8.85 of group 2, $t = -15.46$ the P value < 0.0001 was highly significant.

Communications skills (group 1) training post-test (9.33) was highly significant with $t = -13.61$, $p < 0.0001$.

The patient satisfaction levels showed an increase from (group 1) 7.95 to 9.25 (group 2). The t value = -4.57 and $p < 0.0001$ was found to be highly significant.

Conclusions: The communications skills training received a very good post test score and confirmed our belief in the use of role-play. The OSCE evaluation of both study groups revealed that the scores were improved significantly in group 2 and that a structured training definitely improved the quality of written informed consent. It also led to an increased patient satisfaction index in our hospital.

Keywords: Communications skills, Written informed consent, Objective structured clinical examination (OSCE), Patient satisfaction index.

Introduction

Indian practice of medicine has hinged on the paternalistic model for a very long time now, where the patient trusted the doctor to decide what was best for them. After 2007 the consumer protection act was expanded to include the medical community as well. Most of the litigations⁽¹⁾ arise from miscommunication or being treated as non-persons.⁽²⁾ It also showed that there are a lot of dissatisfied patients.

In 2011 the Maharashtra university of health sciences⁽³⁾ recognized this issue and decided to integrate communications skills as a part of its curriculum as it was not a part of the course. Whereas it is a central component of skills in the western countries.⁽⁴⁾

Doctors however are not trained formally in communication skills and do falter at times. Few doctors are good at interpersonal communications but all are not as good. A formal curriculum will solve the problem. Communication skills are the most important interpersonal skill in a doctor patient relationship leading to patient satisfaction and less malpractice suits.^(5,6) The doctor patient relationship hinges on this skill.⁽⁷⁾

Another important aspect of the doctor patient communication is obtaining the written informed

consent for the purpose of surgery/ procedure.⁽⁸⁾ It is a patients right to be aware of the illness they suffer from, the various treatment options available, the benefits and risks of the treatment/surgery and the risks of not receiving treatment at all,^(8,9) as pointed out in Royal College Of Obstetricians & Gynecologists guidelines for obtaining informed consent.⁽¹⁰⁾

Developing and maintaining a good rapport with the patient and explaining the patient/ relatives the diagnosis, procedure/ surgery, risks involved and prognosis is important for building this rapport and relationship and thus patient satisfaction. The time has now come to shift from paternalistic (doctor centered) model to patient centered approach in our clinical communications. The use of communication skills for the purpose of obtaining informed consent for surgery and the use of role-play for learning this skill seems to be the way forward.⁽¹¹⁻¹³⁾

This study will try to find out that, does training post graduate residents in communications skills by using role-plays lead to better informed consent and patient satisfaction.

Objectives

The primary objective of the study was to evaluate if a formal communications skills training (intervention) improves the quality of written informed consent in patients about to undergo surgery.

The secondary objective was to evaluate the patient satisfaction index before and after the communications skills training.

Methods

Institutional ethics committee approval is waived in India for research in medical education and hence was not sought.⁽¹⁴⁾ The permission from the Dean of the medical college was taken.

Study design: A prospective, Non- randomized controlled study was carried out.

Study setting: The department of Obstetrics and gynecology at a medical college hospital.

Participants: Post-graduate residents and Post-operative patients were the participants.

Sampling method: The sample was a non-randomized convenient sample of 20 patients in each group

All patients undergoing major operative interventions such as lower segment caesarean section, total abdominal hysterectomy and vaginal hysterectomy were included in the study.

They were separated into 2 groups first 20 in group 1 and next 20 in group 2.

Group 1 patients were the controls and the process of obtaining written informed consent by obstetrics and gynecology residents for the above mention surgeries will be according to current practices. The communications session was evaluated with an Objective structured clinical examination (OSCE). During the post-operative period patient feedback form was used to evaluate patient satisfaction levels. The

feedback form was rated from very poor (0) to very good (>8)

Intervention: One day training workshop was conducted on effective communications skill using role play and teacher as simulated patients, for the purpose of obtaining written informed consent for post-graduate residents. A pre-test and post-test was administered to evaluate the training.

Group 2 cases (post intervention) were the study group and written informed consent was taken for the above mentioned surgery using effective communication skills. The evaluation of communications skills was done by Objective structured clinical examination (OSCE) and patient feedback.

The data obtained by evaluation of OSCE and patient feedback questionnaire (Ordinal data) were quantitative. Statistical analysis was done with Paired 'T' test and Student 't' test was applied as test for significance. The level of significance was fixed at $P < 0.05$.

Patient satisfaction index was assessed with the patient feedback forms and use of role play as an effective training method was assessed by using Pre-test and Post-test results.

Result

The process of conducting a communication session for obtaining written informed consent was observed and evaluated by an OSCE for 40 patients (20 pre interventional and 20 post-intervention). There was an improvement in the patient's involvement in her health issues notwithstanding educational statuses.

The evaluation of OSCE scores for pre and post educational innovational intervention showed promising results.

Table 1: OSCE scores for communication during obtaining written informed Consent

OSCE	N	Mean	Median	Standard deviation	Standard error of Mean	T value	P value	Result
Group 1	20	4.05	4	1.050	0.235	- 15.46	<0.0001	Highly Significant
Group 2	20	8.85	9	0.973	.218			

N= sample size.

On analysis of data there was a statistically significant improvement in the mean scores of OSCE, in group 1 (pre-intervention) was 4.05 as compared to (post-intervention) group 2 score of 8.85 as shown in Table 1. The median scores were increased from 4 to 9 after the educational intervention. On applying test of significance (the paired T test) the t value was -15.46 the p value < 0.0001 was highly significant. Not only did the post-graduate students benefit from the intervention but also passed on the benefit to the patients.

The intervention was a one day (6 hours) communications skills training with emphasis on obtaining voluntary written informed consent. Role play and simulated patients were conducted and evaluated. Pre-test and post-test questionnaires were administered.

Table 2: The pre-test and post-test scores of communication skills training

Pre/post test	N	Mean	Median	Standard Deviation	Standard error of Mean	T value	P value	Result
Group 1	12	5.17	5	0.937	0.937	-13.61	<0.0001	Highly Significant
Group 2	12	9.93	9	0.492	0.142			

N= sample size.

The intervention (i.e. use of role-play and simulated patient for 1 day training) for the purpose of communications skills training for obtaining written informed consent in Post Graduate residents showed an increase in mean scores in post-test (5.17 to 9.33) in group 2. The paired t test was highly significant with $t = -13.61$, < 0.0001 . Statistically significant results were seen in the ability to take written informed consent in group 2 (post interventional).

The results of patient satisfaction obtained by patient feedback are tabulated below. The student's t test was applied as the test for significance.

Table 3: Patient satisfaction index

Patient feedback	N	Mean	Median	Standard deviation	Standard error of Mean	T value	P value	Result
Group 1	20	7.95	8	1.050	0.235	-4.57	<0.0001	Highly Significant
Group 2	20	9.25	9	0.716	0.160			

N= Sample size.

The patient satisfaction levels ascertained by patient feedback showed an increase in mean scores from (group 1) 7.95 to 9.25 (group 2) the student's t test was applied as test for significance) $t = -4.57$ and $p < 0.0001$ was found to be highly significant.

The patient satisfaction index increased to 92.5% from 79.5% after the intervention.

Discussion

Rosenbaum et al⁽¹⁵⁾ Adult learning is best facilitated through instruction that is interactive and learner-centered, draws on previous experience and knowledge, is relevant to the learner's practice, allows the learner to apply what is being learned in a timely manner, and includes the opportunity for feedback and reflection.

Abdelkhayek et al⁽¹⁶⁾ reported that their study encouraged their program to increase the use of faculty as simulated patients for formative and summative assessment of students. It also allowed the teachers to identify weaknesses in the students and how to improve them through modification in training.

Manzoor et al⁽¹³⁾ state that role play is a powerful intervention which can be used to enhance cognition, psychomotor skills and affective domains in learners. The power of role play to engage emotions is its power as a teaching aid.

D Nestel et al⁽¹²⁾ found "Role-play was reported to be an effective means of learning communications skills

The value of a proper written informed consent in avoiding complaints and litigation in the future has been stressed by E Daniels et al.⁽⁸⁾

Thompson et al⁽¹⁷⁾ also agree that communications skills training improved surgery residents' ability to discuss and document informed consent.

Ranjan et⁽¹⁸⁾ all agree that patients level of satisfaction is increased by better level of recognition and understanding of their ailments.

During the time of implementation of the project there was no complaint from patients regarding their management and neither was there any litigation!!!

Conclusion

Communications skills has come up in western medicine as an effective tool for obtaining consent, to developing a good doctor patient relationship, reducing litigation, improving patient satisfaction and the overall quality of healthcare. Communication skills have been a core curriculum since almost 10 – 12 years now.

Structured training for communications skills using role-play has been shown to be highly effective. Also use of faculty as simulated patient for role-play helps faculty evaluate the skills of the trainee during the training. The pre-test and post-test led to very heart-warming results for the educator.

Our study has shown encouraging results in use of communications skills training for the purpose of taking written informed consent and has helped the patient satisfaction index in our hospital.

It is the duty of a doctor to communicate with the patient and obtain a proper informed consent. This communication if done in a structured way goes miles in improving the doctor patient relationship and in the long run reducing medical negligence suits.

More importantly the study has inculcated in our post graduate residents the value of communication skills for interaction with patients and developing a good doctor patient relationship.

Limitations

Small sample size ($n = 40$) was a constraint in the study and larger studies are necessary.

Acknowledgement

To the Dean, for her encouragement and support.

Conflicts of Interest

No conflicts of interest to declare.

References

1. Young O, Parviainen K. Training obstetrics and gynecology residents to be effective communicators in the era of the 80-hour workweek: a pilot study. *BMC Res Notes* [Internet]. 2014;7(1):455. Available from: <http://www.biomedcentral.com/1756-0500/7/455>.
2. Clucas C, St Claire L. Relationship between communication skills training and doctors' perceptions of patient similarity. *Int J Med Educ* [Internet]. 2011 Mar 28 [cited 2015 Aug 16];2:30–5. Available from: <http://www.ijme.net/archive/2/communication-training-and-perceived-patient-similarity/>.
3. Muhs. maharashtra university of health sciences, communication skills and professional ethics circular dated 2011. 2011;17–8.
4. Fragstein M Von, Silverman J, Cushing A, Quilligan S, Salisbury H. communication curricula UK consensus statement on the content of communication curricula in undergraduate medical education. 2008;1100–7.
5. Wofford MM1, Wofford JL, Bothra J, Kendrick SB, Smith A LP. *Acad Med*. 2004. p. Feb;79(2):134–8.
6. Williams S, Sa B, Nunes P, Stevenson K. Communicating with first year medical students to improve Communication Skills teaching in The University of the West Indies. *Int J Med Educ* [Internet]. 2010 Mar 14 [cited 2015 Aug 16];1:5–9. Available from: <http://www.ijme.net/archive/1/communicating-with-first-year-medical-students/>.
7. Ha JF, Hons M, Anat DS, Longnecker N, Charles S, Hospital G. Doctor-Patient Communication: A Review. 2010;38–43.
8. Et ED. Informed consent for clinical treatment. *CMAJ*. 2012;184(5):533–40.
9. General medical council. Consent: patients and doctors making decisions together. general medical council; 2008. Available from: www.gmc-uk.org/guidance.
10. RCOG. RCOG, Clinical Governance Advice no 6, DEC 2008. 2008;(6):1–9.
11. Harnof S, Hadani M, Ziv A, Berkenstadt H. Simulation-Based Interpersonal Communication Skills Training for Neurosurgical Residents. 2013;15(september):557–60.
12. Nestel D, Tierney T. Role-play for medical students learning about communication: guidelines for maximising benefits. *BMC Med Educ* [Internet]. 2007 Jan [cited 2014 Oct 9];7:3. Available from: <http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=1828731&tool=pmcentrez&rendertype=abstract>.
13. Manzoor I, Mukhtar F, Hashmi NR. Medical Students' Perspective About Role-Plays As A Teaching Strategy in Community Medicine. 2012;22(4):222–5.
14. Of I council, Research M. Ethical guidelines for on human participants Indian Council of Medical Research. 2006.
15. Rosenbaum ME, Ferguson KJ, Lobas JG. Teaching Medical Students and Residents Skills for Delivering Bad News: A Review of Strategies. 2004;107–17.
16. Abdelkhalek NM, Hussein AM, Sulaiman N, Hamdy H. Faculty as Simulated Patients (FSPs) in Assessing Medical Students' Clinical Reasoning Skills. 2014;1–7.
17. Thompson BM(1), Sparks RA(2) SJ. Informed consent training improves surgery resident performance in simulated encounters with standardized patients. PMID: 26072190; p. 12.044.
18. Ranjan P, Kumari A Chakrawarty A. How can Doctors Improve their Communication Skills? *JCDR*. 2015;9(3):1–4.