Original Study

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Informed Consent: How much information is enough? In a Obstetrics and Gynaecology Department in Tertiary Care Hospital – An Interventional Study

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ABSTRACT

Permission granted in full knowledge of the possible consequences, typically that which is given by a patient to a doctor for treatment with knowledge of the possible risks and benefits.A process in which patients are given important information, including possible risks and benefits, about a medical procedure or treatment, genetic testing, or a clinical trial.This paper was an interventional study it was conducted in the Department of Forensic Medicine and Toxicology,Sri Manakula Vinayaga Medical College and Hospital, Madagadipet, Puducherry to audit and to improve it was conducted in the Department of Obstetrics and Gynaecology. The deficiencies were identified and it was analysed. The results of both pre-interventional and post-interventional were recorded, which showed the significant improvement in the consent form of the major and minor procedures. It is essential that this information be discussed in simple terminology that can be easily readily understood and help the patient togive proper consent for the procedures.

Keywords: Informed Consent,Documenting, Analysing & Intervention.

INTRODUCTION

Informed consent it can be defined as "the voluntary and revocable agreement of a competent individual to participate in a therapeutic or research procedure, based on an adequate understanding of its nature, purpose and implications".[1] An Ethical debate persist on the informed consent process on four basic elements for discussion.[2]

a. Decision-making capacity is a requirement.
b. The Physician should disclose sufficient details to the decision-maker to produce an informed consent.
c. Decision-maker should show her agreement of the disclosed information.
d. Decision-making should freely pass the handling plan.[4]

In current clinical practice, these four components are translated into five elements which are included in a discussion seeking to obtain informed consent.

a. Diagnosis.
b. Proposed treatment.
c. Risk and benefits of the surgery.
d. Alternative treatment and their risk and benefits of the procedure.[2]

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The most aim of our audit was to judge the method of consent within the surgical procedures within the busy regional medical Specialty and the medical Specialty unit. It absolutely was aimed to judge post interventional observe of consent for surgery.

MATERIALS AND METHODS

This study was done at Department of Forensic Medicine and Toxicology, Sri Manakula Vinayaga Medical College and Hospital, after obtaining approval from Institutional Ethics Committee (IEC No: 98/2016). It was a hospital based Interventional study conducted in the period of 24 months from October 2016 to October 2018. The informed consent form of the major and minor cases was taken in the Department of Obstetrics and Gynaecology. It was divided in to three category of A, B & C. Already the category of A and B category was published with the checklist of the preliminary variables prepared from the informed consent form were published. Now the category of B the Procedure variables of Nature of the disease, Benefits of surgery, Risk of surgery, Alternative treatments, Type of anaesthesia, Complications of surgery and consequences of surgery were also analysed and it got published.Now category C like.

Category C : Procedure Variables

1. Details of alternative treatment available were informed
2. Need of blood / blood products during / after surgery informed
3. Given opportunity to ask questions and clarify doubts
4. Patient satisfied with the information provided
5. Consent signed by the patients

Sampling method was by using systemized random sampling method. The total sample was 690 consent forms using "Epi info Software Version 7.2 2.6", taking in to the account the improvement in practice of documenting Informed Consent form 34% based on previous study with 95% confidence interval and 90% power. 690 consent forms were taken and it is analysed in which 345 consent forms were analysed in Pre – Interventional and 345 in Post – Interventional.

A check list Proforma of the informed consent form contains 18 variables which was prepared after going through the guidelines of MCI, Royal college of Obstetricians and Gynaecologist of London. The 18 variables were securitized and validated by the Department of Forensic Medicine and Toxicology, in these it was divided in to 3 categories. In which categories B (Procedural variables) 345 consent form analysed in the period of pre – intervention. After identifying the deficiencies we kept the interventional workshop for the faculty of Department of Obstetrics and Gynaecology aiming is to emphasise the importance of documenting the informed consent forms. Post – interventional of checklist of 345 consent forms were again analysed, "Student T test" was used to compare the data obtained from the Pre and Post – interventional period. This is to find the effect of documentation of the Informed Consent forms.

RESULTS

PRE-INTERVENTIONAL

The table 1 shows details of surgical treatment explained and doubt clarified (category C). Details of alternative treatment available were explained to 253 (73.33%) of patients. Need of blood / blood products during / after surgery was informed to 233 (67.54%) patients. Given the opportunity to ask questions and clarify doubts to 296 (85.80%) patients. Patients were satisfied with the information given by doctor 326 (94.49%) patients. The consent forms were voluntarily signed by 344 (97.71%) patients.

Table 1; Information regarding surgical treatment and their clarifying doubts YES Response

	Informations	n (%)
1.	Details of alternative treatment available were informed	253 (73.33%)
2.	Need of blood / blood products during / after surgery informed	233 (67.54%)
3.	Given opportunity to ask questions and clarify doubts	296 (85.80%)
4.	Patient satisfied with the information provided	326 (94.49%)
5.	Consent signed by the patients	344 (97.71%)

POST – INTERVENTIONAL

The table 2 shows details of surgical treatment explained and doubt clarified (category C). Details of alternative treatment available were explained to 315 (91.30%) of patients. Need of blood / blood products during / after surgery was informed to 317 (91.88%) patients. Given opportunity to ask questions and clarify doubts to 345 (100%) patients. Patient were satisfied with the information given by doctor to 344 (99.71%) patients. The consent form was voluntarily signed by 345 (100%) patients.

DISCUSSION

In the present study, during pre-interventional interview of the patients, 342 patients (99.13 %) were informed about the patient present condition before the surgery and an audit study done by Temidayo O Ogundiran et al, titled "Surgeons opinion and practice of informed consent in Nigeria" at College of Medicine, University of Ibadan, Ibadan, Nigeria, the results showed that (61.8 %) were not informed about the patient present condition before the surgery.[7]

Table 2:Information regarding surgical treatment and their clarifying doubts YES Response

S. No.	Questions	n (%)
1.	Details of alternative treatment available were informed	315 (91.30%)
2.	Need of blood / blood products during / after surgery informed	317 (91.88%)
3.	Given opportunity to ask questions and clarify doubts	345 (100%)
4.	Patient satisfied with the information provided	344 (99.71%)
5.	Consent signed by the patients	345 (100%)

Pre-interventional interview of the patients, 300 patients (86.96 %) were informed about the relative chances of success or failure of the procedure, but in a study conducted by Pragnesh Parmar et al, titled "Consent in medical practice - Perceptions of patients towards legal aspects of informed consent" at GMERS Medical college, Valsad, Gujarat, the results showed that 91 % of the patients informed about the relative chances of success or failure of the procedure.[6,9]

In the present study, during pre-interventional interview of the patients, 315 patients (91.30 %) were informed about the details of the alternative treatment available, whereas in a study conducted by Amina T. Ghulam et al, titled "Patients satisfaction with the preoperative informed consent procedure: A multicentre questionnaire survey in Switzerland" at University hospital Zurich, Zurich, Switzerland, it was observed that out of 885 patients, 375 patients got excellent information about the alternative treatment available, 423 patients were well informed about the details of the alternative treatment available, 70 patients were neutral about the

Table 3: Comparison of pre-interventional and post-interventional variables of category C

S. No.	Variables of patient questionnaire	Pre –interventional n (%)	Post-interventional n (%)	p value
1.	Details of alternative treatment available were informed	253 (73.33%)	315 (91.30%)	0.003
2.	Need of blood / blood products during / after surgery informed	233(67.54%)	317 (91.88%)	0.005
3.	Given opportunity to ask questions and clarify doubts informed	296(85.80%)	345 (100%)	0.003
4.	Patient satisfied with the information provided	326 (94.49%)	344 (99.71%)	0.005
5.	Consent signed by the patient	344 (97.71%)	345 (100%)	0.004

details of the information provided about the details of the alternative treatment available, 14 patient got poor information about the details of the alternative treatment available, and 3 patients got very poor information about the details of the alternative treatment available.[3,6,1]

In the present study, during pre-interventional interview of the patients, 315 patients (91.30 %) were informed about the details of the alternative treatment available, whereas in a study conducted by Pragnesh Parmar et al**,** titled "Consent in medical practice - Perceptions of patients towards legal aspects of informed consent" at GMERS Medical college, Valsad, Gujarat, it was observed that, out of 121 patients, 91 patients were informed about the alternative course of treatment available and in an another study conducted by M Jawaid et al, titled "Preoperative informed consent: Is it truly informed?" at Dow University of Health Sciences, Karachi, Pakistan, the results showed that out of 345 patients, 11 patients were informed about the alternative course of the treatment available and in an another study conducted by Mikayla MC keague et al, titled, "Patients perception of the adequacy of informed consent: a pilot study of elective general surgical patients in Auckland" at Auckland Hospital, the results showed that out of 79 patients, 8 patients were informed about the alternative course of treatment available.[5,6, and 10]

Ethical Clearance: Sri ManakulaVinayagar Medical College and Hospital, after obtaining approval fromInstitutional Ethics Committee (IEC No: 98/2016)

Conflict of Interest: Nil

Source of Funding: Nil

CONCLUSION

The study have recorded and analysed the existing standards of documenting informed consent form and the defencies were analyzed during the intervention workshop, which increased knowledge of faculties of appropriate literature determined by post-intervention analysis, knowledge of faculties of appropriate literature determined by post-intervention analysis.This will improve patient comprehension, satisfaction and expectations. The exercise of consent is an important process for transmitting information to the patient and should be accompanied by meticulous and accurate documentation.Documentation is an essential final step. It records the process that is vital for proper patient care and can be the only evidence that a discussion took place. Legal advice provides little detail on what constitutes adequate documentation.

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