
The Current Practice and Medico Legal Aspects of Informed Consent in Obstetrics and Gynaecology in a Tertiary Care Hospital, Can We Improve?: An Interventional Study

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Abstract

The Informed Consent plays major role in both Patients and the Doctors to carry out various aspects in the surgical procedures. 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. This study results will give importance on documenting the Informed Consent day to day life practice.

Keywords: Informed Consent, Documenting, Analysing and Intervention

Introduction

Informed Consent suggests that an agreement, compliance or permission given voluntarily with none compulsion.¹ It may be outlined as "the voluntary and revocable agreement of competent individual to participate during a therapeutic or analysis procedure, supported an adequate understanding of its nature, purpose and implications".² consent is currently accepted because the cornerstone of practice.^{3,4} All medical procedures, as well as examinations, diagnostic procedures and medical analysis on patients within the absence of consent represent

assault (IPC 351) that he's liable in damages.⁵ Consent plays monumental role in way of life of a Doctor. it's necessary to simply accept that seeking consent for surgical intervention goes on the far side getting a signed and completed consent form: it's the method of providing the knowledge that permits the patient to form a choice to endure a selected treatment.⁶ Patients should perceive the character of the wellness, edges of surgery, Risk of surgery, different treatments, sort of physiological condition, Complications of surgery and consequences of surgery. The most aim of our audit was to judge the method of consent within the

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surgical procedures within the busy regional medical specialty and 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 was published with the checklist of the preliminary variables prepared from the informed consent form. 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 analysed. 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.

Checklist with variables prepared from informed consent form

Category B : Procedure Variables

1. Nature of the disease
2. Benefits of surgery
3. Risks of surgery
4. Alternative treatments
5. Type of anaesthesia
6. Complications of surgery
7. Consequences of surgery

Results

Procedure variables of pre-interventional (n=345) and post-interventional (n=345)

List of procedure variables	n (%) pre-interventional	n (100%) post-interventional
Nature of the disease	0%	100%
Benefits of operation	0%	100%
Risk of the operation	0%	100%
Alternative course of treatment	0%	100%
Type of anaesthesia	0%	100%
Complication of surgery	0%	100%
Post- surgical consequences	0%	100%

The study results showed that, on analysing the 345 informed consent forms obtained during the pre-interventional period under category B variables (Preliminary variables) almost all the variables been documented completely. Procedural variables in the pre - interventional informed consent forms used for the patients who underwent major and minor elective surgeries didn't have the printed information about the details of the procedural variables like Nature of the disease, Benefits of surgery, Risk of surgery, Alternative treatments, Type of anaesthesia, Complications of surgery and consequences of surgery but it was asked orally by the check list prepared.

Pre-Interventional

Table 1: Patients details regarding operated procedure information Yes response (n=345)

Serial number	Questions	n (%)
1.	Type of surgery / operation informed	295(85.51%)
2.	Benefits of surgery / operation informed	238(68.99%)
3.	Type of anaesthesia informed	276(80.00%)
4.	Complication of surgery / procedure informed	220(63.77%)
5.	Relative chances of success or failure informed	285(82.61%)
6.	Informed about the risk of surgery / procedure	301(87.25%)
7.	Details of alternative courses of treatment that are available were informed	253(73.33%)

Later during the intervention workshop, post graduate was assigned the role of developing customized informed consent forms including the details of the procedural variables for the commonly done major and minor surgeries in their department, under the guidance of the faculty members. Later during post - intervention analysis of the informed consent the results were analysed.

Post - Interventional

Table 2: Patients details regarding operated procedure information Yes response (n=345)

Serial number	Questions	n (%)
1.	Type of surgery / operation informed	335(97.10%)
2.	Benefits of surgery / operation informed	290 (84.06%)
3.	Type of anaesthesia informed	329 (95.36%)
4.	Complication of surgery / procedure informed	319 (92.46%)
5.	Relative chances of success or failure informed	300 (86.96%)
6.	Informed about the risk of surgery / procedure	337 (97.68%)
7.	Details of alternative courses of treatment that are available were informed	315 (91.30%)

Discussion

In this study, consent forms were associate degree analysed within the pre and post intervention amount with an intervention mode, however there was a study done by O.C Osime et. al., titled "Current practices and medico-legal aspects of pre-operative consent" at University of Republic of Benin teaching hospital, Benin city, wherever they need done analysis of 133 educated and consent forms and additionally interviewed all the patients with any intervention and post intervention analysis. A study conducted by Catherine Leng and Kavita sharma, titled "associate degree audit cycle of consent kind completion: A useful gizmo to boost junior doctor coaching, out of seventy four consent forms ninety one of forms had edges of the procedure documented within the year of 2013 and once the intervention 100 percent within the year of 2014. whereas in our study total 345 consent forms in this 238(68.99%) educated regarding the Benefits of the operation, once the intervention 290 (84.06%) were educated by the doctors. The quality of consent obtained is another

aspect of informed consent.⁷ A study conducted by O.C Osime et al, titled "Current practices and medico-legal aspects of pre-operative consent" at University of Republic of Benin teaching hospital, Benin city, wherever they need done analysis of 133 educated and consent forms, in this only 92 patients (69.2%) were told the benefits when compared our study total 345 consent forms in this 238 educated regarding the Benefits of the operation, once the intervention 290 (84.06%) were educated by the doctors.

The importance of correct documentation of the consent method has been highlighted by in a very review by Bhattacharyya et. al. on the medico-legal aspects of consent in orthopaedic surgery. They found that measures, together with correct documentation and filling of consent in patients notes, were related to a reduced indemnity risk.⁸

When it involves documentation of complications of the surgery, during this study it had been found that in the pre and post interventional amount, 0% and 92.46% severally, was the proportion of documentation, however in comparison study done by Jennifer Isherwood, titled "Documenting informed consent in elective hip replacement surgery: a simple change in practice", the proportion of documenting the procedure specific complication was eight six out of one hundred consent forms analyses.⁹

Conclusion

The study have recorded and analysed the existing standards of documenting informed consent forms and the deficiencies were shared during the intervention workshop, which increased the awareness of the faculties on proper documentation, as evident from the post intervention. The study has improved the consent practices related to surgical procedures in Department of Obstetrics and Gynaecology of our institute by developing a structured informed consent form considering the national and international guidelines in both English and Tamil languages, which was later approved

and implemented in our institute. Such studies have to be done in other specialties also with regular awareness programs and analysis of the consent form documentation, which in- turn benefits the patient by making them aware on the surgery details and the doctors by acting as a better defence against negligence suits.

Ethical Clearance: Sri Manakula Vinayagar Medical College and Hospital, after obtaining approval from Institutional Ethics Committee (IEC No: 98/2016)

Conflict of Interest: Nil

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