ORIGINAL ARTICLE

Is informed consent practice in a general surgery unit adequate? An audit report

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Abstract:
Objective: To obtain an informed consent is essential part of surgical practice. It not only ensures patients rights but also decreases the chances of legal proceedings against surgeons in case of any issue from procedure. The objective of this study is to evaluate the prevailing practices of getting informed consent and documentation in case of general surgical patients.
Material and Methods: This cross sectional (audit) study was carried out in department of Surgery District Head Quarter (DHQ), Abbottabad from December 2020 till February 2021 in general surgical unit. 132- patients chosen randomly were included. Both cases of elective as well as emergency cases were included. Patient operated on General and spinal anesthesia were interviewed according to questionnaire relating to informed surgical practices. Data of interviewed patients were analysed using spss 17.
Results: 132 patients were included in study. Mean age was 34.98±16.1 years. Study comprised of 70 female(53%) and 62(47%) male. 117(88.6%) consent were taken by house officers while 15(11.4%) consent were taken by operating surgeon. 84(63.6%) consent were signed by patients themselves while 48(36.4%) were signed by relatives. All 132(100%) consent were written consent.
Conclusion: The quality of obtaining consent is below optimal and needs improvement. Education amongst health care workers is required so that they realize the importance of patients right's so they make their own independent decision in the light of knowledge given. Also knowing that to have a complete and upto mark consent is beneficial for clinician in case of legal issues.

Keywords: Audit, informed consent, surgical practice.

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Introduction:

The essence of safe surgical procedure lies in accurately and timely taken informed consent. There are many parts of informed consent and neglecting, missing or complete absence of those essential steps might lead to errors in surgery. Consent can be taken as part of safety process, the purpose of which is to provide safest and best type of surgical care for patients. Every where there are national guidelines as well as set standards relating to getting consent for surgical procedures.[1,2] The process of consent is not merely about getting a signed and complete consent form rather it has more purposes. It also provides information to patient regarding specific treatment so that he or she can decide for themselves. However, a well taken and signed consent is the documentary evidence that guarantees that all the pre-requisites were done properly. The job of surgical team is to make sure that consent has been taken properly. Patient should have adequate knowledge of their disease along with the treatment options available and the reason of opting a specific intervention. Along with this the hazards and complications relating to the procedure should be known to patient.

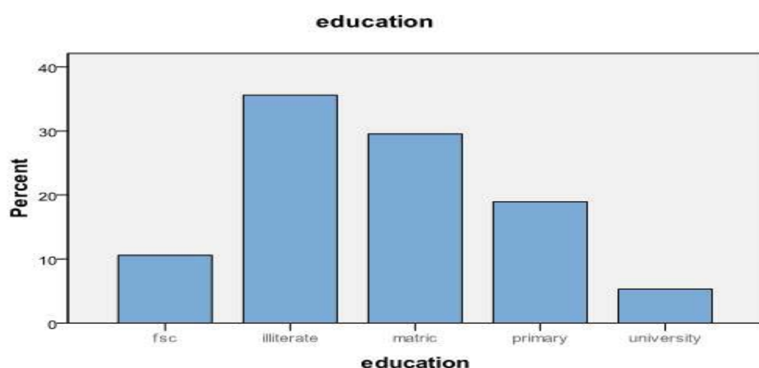

Figure I: Educational status

Table 2: Questionnare and answers: n(132)

Questions	Yes (number and percentage)	No(number and percentage)
Did you understand the consent fully	125(94.7%)	7(5.3%)
Was detail of disease explained	131(99.2%)	1(0.8%)
Details of surgical procedure explained	128(97%)	4(3%)
Were other treatment options discussed	101(76.5)	31(23.5%)
Type of anesthesia discussed	106(80.3%)	26(19.7%)
Possible complications of surgery explained	52(39.4%)	80(60.6%)
Was consent obtained by operating surgeon	15(11.4%)	117(88.6%)
Risk associated with anesthesia discussed	52(39.4%)	80(60.6%)

One should also discuss other operative as well as conservative options with the patients. Apart from surgical procedure patient should be aware of the type of anesthesia and adverse effects associated with the use.[3] Informed consent is integral for medico legal purpose. In some cases giving information to patient may relieve stress.[4] The validity of consent does not only depend upon written statement, but its depends on the nature and quality of interaction between patient and surgeon. Signatures and record keeping are part of process. For a consent to be valid patients should be well aware of all the pros and cons of procedure which requires proper delivery of appropriate knowledge in language that patient can understand.[5] In spite of taking meticulous care there are circumstances where patient claim that they were not told the appropriate knowledge which was required for decision making. In western setup patient themselves want to have knowledge about the disease as well as the treatment given along with adverse effects prior to any surgical procedure.[6] Unfortunately, patients and their relatives are given negligible amount of knowledge in most hospital setup. The purpose of this study was to evaluate the practices of taking informed consent in pre-operative emergency as well as elective cases in a District Head Quarter Hospital.

Material and Methods:

This cross sectional (audit) study was carried out in the Department of Surgery, District Head Quarter (DHQ), Abbottabad from December 2020 till February 2021 after Ethical Committee approval. Inclusion criteria included patients above 10 years of age who had undergone elective or emergency surgery in general surgery unit. A total of 132 patients chosen randomly were included in study. Patients were interviewed in the post-operative phase once they recovered fully from anesthesia and were able to answer. They were interviewed according to structured questionnaire. Both cases of general anesthesia as well as spinal were included. Data was collected in Microsoft excel and analysed using SPSS 17. Frequencies and percentages of the variables were determined by descriptive statistics.

Results:

132 patients were included in study. Mean age was 34.98±16.1 years. Study comprised of 70 female(53%) and 62(47%) male. 117(88.6%) consent were taken by house officers while 15(11.4%) consent were taken by operating surgeon. 84(63.6%) consent were signed by patients themselves while 48(36.4%) were signed by relatives. All 132(100%) consent were written consents. Out of which 123(93.18%) consent forms were completely filled, 8(6.06%) consent forms were incomplete, 1(0.76%) consent form was not signed before surgery. 82(62.12%) consent form were signed day before surgery, 49(37.12%) were taken on the day of surgery, 1(0.76%) consent was taken after surgery. 125(94.7%) patients understood the consent fully. Nature and details of the disease was explained to 131(99.2%) patients. Detail of surgical procedure was explained to 128(97%).

Other alternative treatment optioned was discussed with 101(76.5%) patients. Type of anesthesia explained to 106(80.3%) patients. Risk associated and complications with anesthesia discussed with 52(39.4%). Possible complications of proposed surgery were discussed with 52(39.4%) patients. Education level of patients showed that 47(35.6%) of patients were uneducated, 25(18.9%) had primary education, 39(29.5%) had done matriculation, 14(10.6%) had done intermediate education, 7(5.3%) had graduated from University.

Discussion:

Informed consent is essential part of surgical practice and litigations have aroused concerned regarding this.[7] If informed consent is taken in a appropriate way can develop understanding between surgeon and patient and hence the chances of litigations can be decreased.[8,9] Despite the fact that only 17 patients were under 18 years of age still only 84(63.6%) consent were signed by patients themselves 36.4% consent by signed by relatives. Such findings are also noted by other authors that relatives sign the consent form.[10,11] In our study only 11.4% consent were obtained by operating surgeon which was considerably less proportion such findings were also observed in other studies.[5] In most of the developed countries consent is taken by senior surgeons, as in ideal situation the operating surgeon should take informed consent as he/she can answer patient's queries in the best possible way. Unfortunately in most of the cases junior doctors are asked to take consent. In our cases most of the consent form were signed by house officers and many authors believe that house officers provide the minimum possible knowledge to patient regarding nature of disease, risks involved, as well as operative procedure.[12] Another study also showed that house officers taking majority of consent in surgical practice.[13] The timing of taking consent is crucial step as most of the patients expect that knowledge about the disease as well as surgical procedure will not only be given in out patient department setup but also when admitted in ward will be explained in detail regarding the whole course.[14] In our study nearly 62% consent were taken a day before surgery, 37% on the day of surgery but this figure unlike other study is not because of consent being enforced to patient on operating table but is because of emergency nature of procedure as patients were operated on the day of admission. Only in 1-case an emergency surgery was carried out without written consent as was obtained later. In all circumstances whether elective or emergency the patient should be given adequate time to think as consent should not be taken on operative table. In a study it is shown that one third of the patients can change their decision after they had signed consent and they did not even realize this.[12] Success of surgery is dependent on the trust and relationship between patient and surgeon. In technical term surgery is an assault inflicted to patient until patient has given permission for this to happen. Our structured interview was carried out in the post-operative period. In our study most of the patients were adequately informed about the disease and surgical procedure. This is contrast to most of the studies in developing countries where patients are not aware of nature of disease and operative procedure.[15] Even though the knowledge of disease and surgical procedure was given to patients but still adequate knowledge regarding risk of anesthesia and complications associated with the procedure were deficient. In our study 60.6% patient had no information regarding risk with surgery and anesthesia. In some other study no knowledge was given to 69.3% of patients regarding risk associated with surgery and 75% had no idea regarding anesthesia complications.[16] 80.3% patient had knowledge about the type of anesthesia given in our study. Our cases involved general and spinal anesthesia. Such findings were also observed by other authors. Most people think that it is the job of anesthetics to inform patient regarding complications of anesthesia as they are directly involved in this, so anesthesia unit should also take part in consenting process.[17] In our study 35.6% patients were not educated and 18.9% had primary education. Level of education affects the consenting process. All consent were taken on written preformed consent paper printing details in

national language in our case. In cases where people could not sign thumb printed was used as counterpart. Language barrier can not only affect process of consent but also communication between patient and doctor because of lack of understanding the details.[18] In addition to risk associated with disease and operative procedure patient should be given instruction and adequate knowledge about self care after discharge which is a part of information giving process.[19] In certain cases process of consent is affected by nature of the disease for which patient presents to hospital.[20] The process of consent these days is largely affected by novel corona virus disease (COVID-19) and its has increased the risk of requirement for intensive care monitoring in operated patients in certain cases and also has led to increase mortality if a patients contracts disease in immediate post-operative phase.[21] The consent process in our setup lacked this essential part as in case of pandemic hospitals are high risk areas for transmission and this should be discussed with patients prehand.

Conclusion:

The quality of obtaining consent is sub optimal and needs improvement. Education amongst health care workers is required so that they realize the importance of patients right's so they make their own independent decision in the light of knowledge given. Also knowing that to have a complete and upto mark consent is beneficial for clinician in case of legal issues. Apart from this education is vital for society, education for all can not only improve people's own life but will help them in knowing their rights regarding informed consent.

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Role and contribution of authors:

Sameeah Hanif, collected the data, references and did the initial writeup.

Muhammad Nawaz, went through the article critically and made the final changes.

Sumera Naseem collected the references and also helped in discussion writing.

References:

1. Royal Coll. of Surgeons of England, London (United Kingdom);. Good surgical practice. 2002.
2. Department of Health (DoH). Reference guide to consent for examination or treatment.(2001)
3. Leng C, Sharma K. An audit cycle of consent form completion: A useful tool to improve junior doctor training. Indian journal of plastic surgery: official publication of the Association of Plastic Surgeons of India. 2016 Jan;49(1):72.
4. Kitamura T. Stress-reductive effects of information disclosure to medical and psychiatric patients. Psychiatry and clinical neurosciences. 2005 Dec;59(6):627-33.
5. Mudassir H, Zakai SB. An audit of information provided during preoperative informed consent. Pak J Med Sci January-March. 2006;22(1):10-3.
6. Quadrelli S, Colt HG, Lyons G, Cohen D. Respect for autonomy. How much do patients want to know in order to make decisions? Medicina 2008;68(3):198–204.
7. Perlis CS, Campbell RM, Perlis RH, Malik M, Dufresne RG. Incidence of and risk factors for medical malpractice lawsuits among Mohs surgeons. Dermatologic surgery. 2006 Jan;32(1):79-83.
8. Jebbin NJ, Adotey JM. Informed consent: how informed are patients?. Nigerian journal of medicine: journal of the National Association of Resident Doctors of Nigeria. 2004 Apr 1;13(2):148-51.
9. Levinson W, Roter DL, Mullooly JP, Dull VT, Frankel RM. Physician-patient communication: the relationship with malpractice claims among primary care physicians and surgeons. Jama. 1997 Feb 19;277(7):553-9.
10. Shah I, Lahooti RA, Khan MN. Informed consent practices in oral and maxillofacial surgery setups—an audit report. JPMA. The Journal of the Pakistan Medical Association. 2021 Apr 1;71(4):1197-9.
11. Jafarey AM, Farooqui A. Informed consent in the Pakistani milieu: the physician's perspective. Journal of Medical Ethics. 2005 Feb 1;31(2):93-6.
12. Jawaid M, Farhan M, Masood Z, Husnain SM. Preoperative informed consent: is it truly informed?. Iranian journal of public health. 2012;41(9):25.
13. McKeague M, Windsor J. Patients' perception of the adequacy of informed consent: a pilot study of elective general surgical patients in Auckland. N Z Med J. 2003;116(1170):U355.
14. Berry MG, Unwin J, Ross GL, Peacock E, Juma A. A comparison of the views of patients and medical staff in relation to the process of informed consent. Ann R Coll Surg Engl. 2007;89(4):368–73.
15. Amin MF, Jaaid M, Mudassir S, Hina, Zakai SB. An audit of information provided during preoperative informed consent. Pak J Med Sci 2006;22(1):10–3
16. Perez-Moreno JA, Perez-Carceles MD, Osuna E, Luna A. Preoperative information and informed consent in surgically treated patients. Rev Esp Anestesiol Reanim 1998;45(4):130-5
17. Siddiqui FG, Shaikh JM, Memon MM. An audit of informed consent in surgical patients at a university hospital. Journal of Ayub Medical College Abbottabad. 2010 Mar 1;22(1):133-5.
18. Lee JS, Pérez-Stable EJ, Gregorich SE, Crawford MH, Green A, Livaudais-Toman J, Karliner LS. Increased access to professional interpreters in the hospital improves informed consent for patients with limited English proficiency. Journal of general internal medicine. 2017 Aug;32(8):863-70.
19. Agozzino E, Borrelli S, Cancellieri M, Carfora FM, Di Lorenzo T, Attena F. Does written informed consent adequately inform surgical patients? A cross sectional study. BMC medical ethics. 2019 Dec;20(1):1-8.
20. Convie LJ, Carson E, McCusker D, McCain RS, McKinley N, Campbell WJ, Kirk SJ, Clarke M. The patient and clinician experience of informed consent for surgery: a systematic review of the qualitative evidence. BMC medical ethics. 2020 Dec;21(1):1-7.
21. Wainstein AJ, Drummond-Lage AP, Ribeiro R, de Castro Ribeiro HS, Pinheiro RN, Baiocchi G, de Sousa Fernandes PH, Anghinoni M, Laporte GA, Junior MJ, Dall'Inha VN. Risks of COVID-19 for surgical cancer patients: the importance of the informed consent process. Journal of surgical oncology. 2020 Jun 20.