

**ASSESSMENT OF DOCTOR AND
STAFF COMPLIANCE TOWARDS
RECORDING INFORMED
CONSENTS IN CARE HOSPITALS
IP DEPT., BANJARA HILLS,
HYDERABAD DURING APRIL AND
MAY 2022**

DR. SWATI DWIBHASHYAM

Under the guidance of
DR. DHIRENDRA KUMAR

Introduction

BACKGROUND

The term “informed consent” was used for the first time in the case of *Schloendorff v. Society of New York Hospitals* in 1914 in the US, wherein the court had ruled in favour of Mrs. Schloendorff. The case came to light when Mrs. Schloendorff had consented for abdominal examination under anaesthesia but was not made aware of her abdominal tumor and the doctor had removed the tumor without her knowledge of the possible adverse outcome of said procedure(1). Later in 1947, the establishment of Nuremberg Code to lay down strict ethical guidelines in medical practice asserted the right of a patient to have complete disclosure about their condition and the treatment advised- its benefits, adverse effects and alternative treatment options.

For in-patients, since their hospital stay is characterised by various steps taken to treat them, informed consent has to be taken at every crucial step. However, in the view of high patient flow, or complicated cases, compliance of hospitals towards recording these informed consents might have to be assessed.

Introduction

RESEARCH QUESTION

How much is the compliance of doctors and staff towards recording consents in Care Hospital IP Dept, Banjara Hills, Hyderabad during April & May 2022?

OBJECTIVES

- To assess the relevance of types of consent forms and their formats
- To identify the types of consents being recorded
- To assess the completeness, appropriateness, and timeliness of recorded consent forms

Review of Literature

- Existing literature on informed consents mostly addresses patient comprehension, consent form readability and format and overall loopholes in the consent- taking process. Studies on assessing doctor compliance, such as the one by A. Ehteshami, S. Isfahani, S. Saeedbakhsh et al, show the existence of a significant association between doctors' knowledge about the legal aspects of informed consent recording and their compliance towards it, but a weak and reverse correlation(2). This study collected data of ophthalmologists' knowledge about legal aspects of informed consents and checked their compliance via medical records, which showed knowledge of about 78.72%.
- On the contrary, in a review carried out by J. Orkuma, G. Ayia, M. Ikwue et al to assess the compliance to informed consent for blood transfusion in Africa, knowledge gap of healthcare providers was amongst the top constraints to compliance(3).

Review of Literature

- Another study carried out in Nigeria by O. Aisuodionoe-Shadrach et al, aimed at evaluating the process and quality of the consent-recording process. This study looked at the process from the patient's perspective only. In this study, although 90% patients said to have received information about their surgery way before the pre-operative day, only 35% had very sufficient information about their procedure. Amongst the various possible reasons for these results, such as illiteracy or non-comprehension, non-compliance of doctors to provide complete information, remains a very real possibility(4).

Review of Literature

- Similar lack of provision of information about complications and post-operative care was seen in a study undertaken in 60 knee arthroplasty patients at a public hospital in Australia by I. McGaughey(5).
- Lack of competency to provide complete knowledge of a surgery to patients was also one of the critical results in a review carried out by W. Leclercq, Bram, J. Keulers et al, in which meta-analysis was carried out on 71 articles. It proposed an interactive computer-based system for recording informed consents(6).
- A common theme of improper or insufficient communication about the procedure to the patient has been noted from the available literature, especially in surgeries. Especially, communicating the risks, complications, alternative options, pre and post-operative care has been low.

Methodology

STUDY DESIGN: Retrospective observational study

SETTING: CARE Hospitals in Banjara Hills, Hyderabad was established in the year 2000. The multispecialty hospital has 435 beds, with an annual inflow of 1,80,000 outpatients and 16,000 in-patients

STUDY POPULATION:

- **Inclusion criteria:** Case files of patients who have been admitted and discharged within the months of April & May 2022
- **Exclusion criteria:** Case files of patients admitted before April 2022 or being discharged after May 2022
- **Study tools:** Microsoft Excel

Methodology

DURATION OF STUDY: 4th April 2022 to 31st May 2022

SAMPLE SIZE: 253

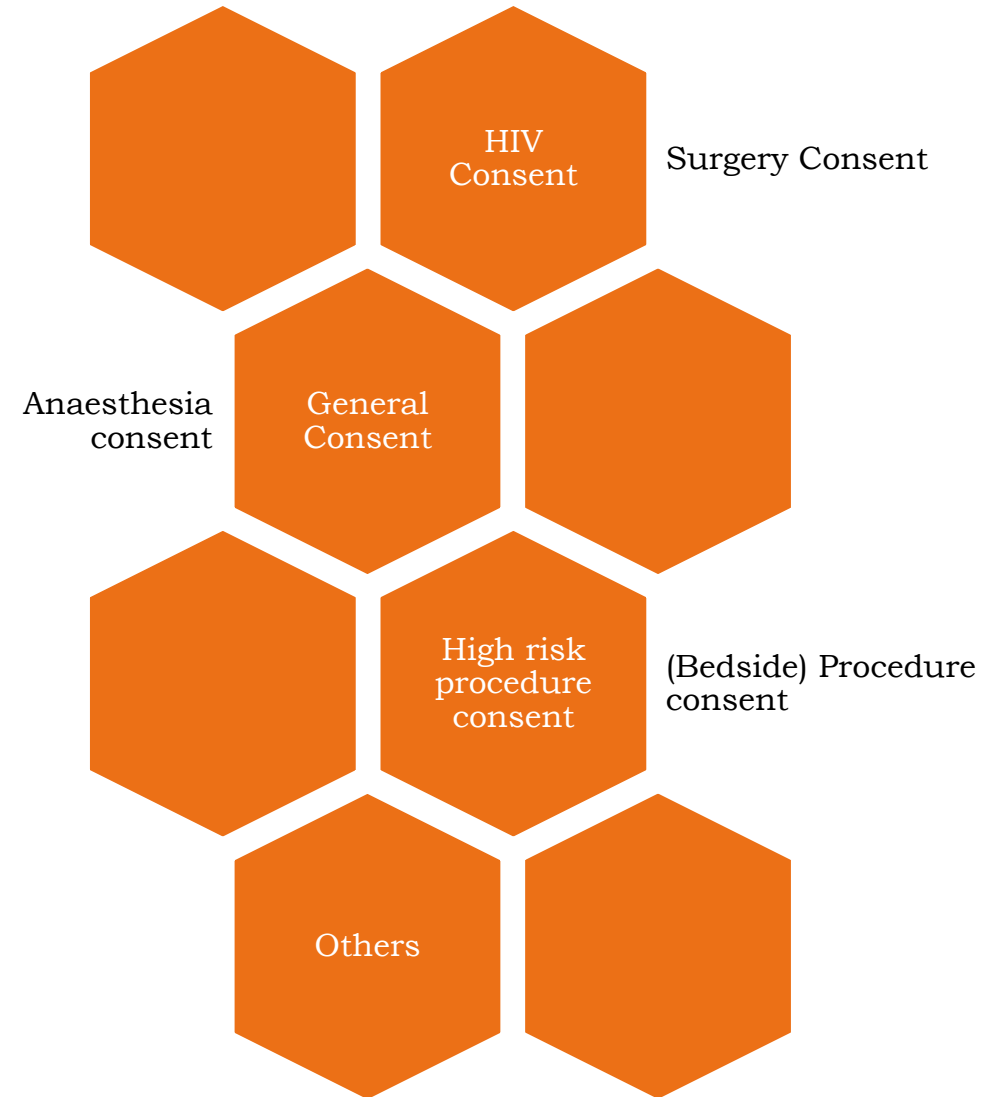
SAMPLING TECHNIQUE: Simple Random Sampling

DATA COLLECTION PROCEDURE: Case files from the Medical Records Department are picked at random and data regarding documentation, completeness and appropriateness of relevant consent forms is recorded in Microsoft Excel.

Results

1. Types of informed consents recorded

On thorough examination of the medical records, it was observed that consents recorded were mainly of 7 types-



2. Relevance of types of consent forms and their formats

- The general consent is placed within the admission form itself. However, it doesn't have a section to seek the patient's signature and only seeks relative's or witness's signature.
- The HIV consent form is rather in-detail, mentioning the necessary information and seeking separate approvals for confidentiality, performing and test and giving the test results.
- The Anaesthesia consent form is also a comprehensive document mentioning the benefits and downsides of each form of sedation and having separate sections for patient, witness and doctor approvals if the patient is capable of giving consent and if not, for their representative.

- There isn't one standard template for surgery consent form. Few departments such as Cardiology and OB GYN have special consent forms for surgeries like CAG, LCS, Laproscopic procedures, etc. Other departments usually use the informed consent template which is commonly used for surgeries and bedside procedures. The common format fails to explain in-depth about the procedure that the patient is undergoing.
- High Risk Consent form also has a standardized template, explaining why the certain procedure poses said risk. Few departments such as Cardiothoracic surgery and Neurosurgery have customised forms as well.
- Procedure consent form is the common informed consent template itself.
- Miscellaneous types of consent forms have specific formats each explaining more about the procedure.

Results

3. Assessment of the completeness, and documentation of recorded consent forms

Amongst the 253 random medical record samples examined, following results were obtained-

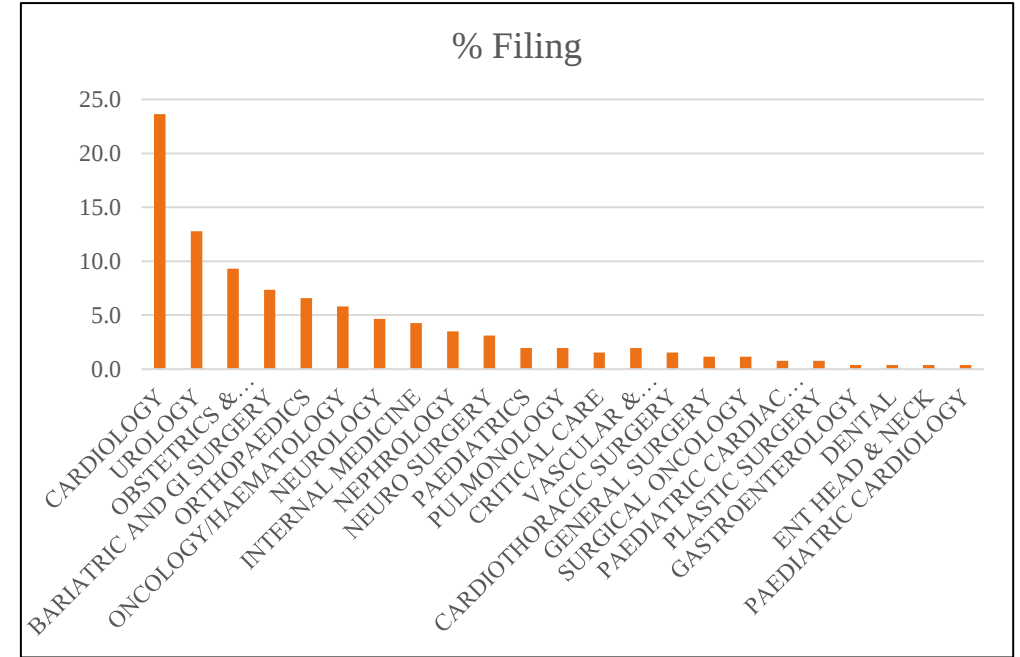
It was seen that one-fourth of the samples were from Cardiology, followed by close to one-tenth of the samples being from Urology and OB GYN, each. The proportions of rest of the 21 departments were below 10% each.

Department	Cases (%)
CARDIOLOGY	25.30
UROLOGY	13.44
OBSTETRICS & GYNAECOLOGY	9.49
BARIATRIC AND GI SURGERY	7.51
ORTHOPAEDICS	7.11
ONCOLOGY/HAEMATOLOGY	5.93
NEUROLOGY	4.74
INTERNAL MEDICINE	4.35
NEPHROLOGY	3.56
NEURO SURGERY	3.16
PAEDIATRICS	2.37
PULMONOLOGY	1.98
CRITICAL CARE	1.98
VASCULAR & ENDOVASCULAR SURGERY	1.98
CARDIOTHORACIC SURGERY	1.58
GENERAL SURGERY	1.19
SURGICAL ONCOLOGY	1.19
PAEDIATRIC CARDIAC SURGERY	0.79
PLASTIC SURGERY	0.79
GASTROENTEROLOGY	0.40
DENTAL	0.40
ENT HEAD & NECK	0.40
PAEDIATRIC CARDIOLOGY	0.40

Results

General Consent

It was seen that general consent wasn't filed in 3% samples indicating these samples did not have admission forms itself. The percentage filing of the general consent across departments was in correspondence with the proportions of each department within the sample. The major fields within the general consent which were found to show less compliance were staff signature and patient/ guardian signature. Only half of the samples had signature of the consent-taking staff and one-fifth of the samples did not have guardian signature. It was also observed that doctor's signature wasn't being taken despite there being a separate field for it within the form. The absence of staff signature was seen maximum in OB GYN, Neurology and Internal Medicine case records.

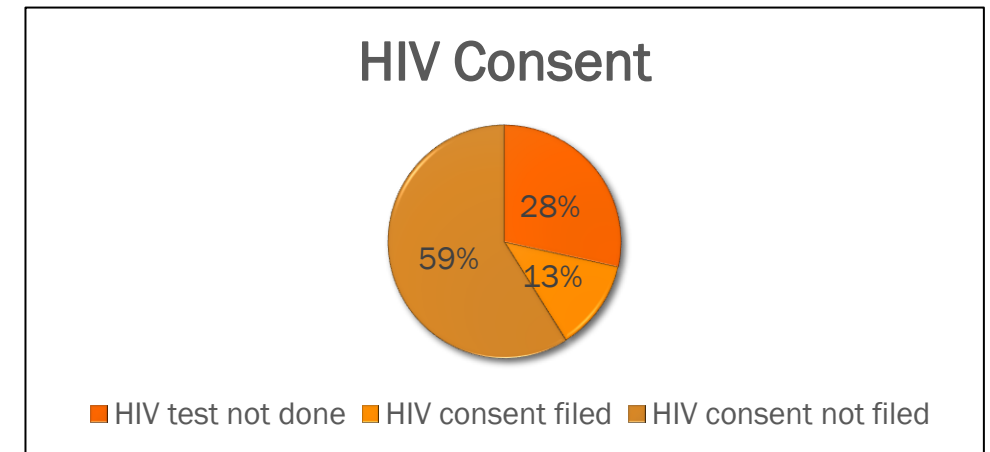


Department-wise percentage of general consent documentation

Results

HIV Consent

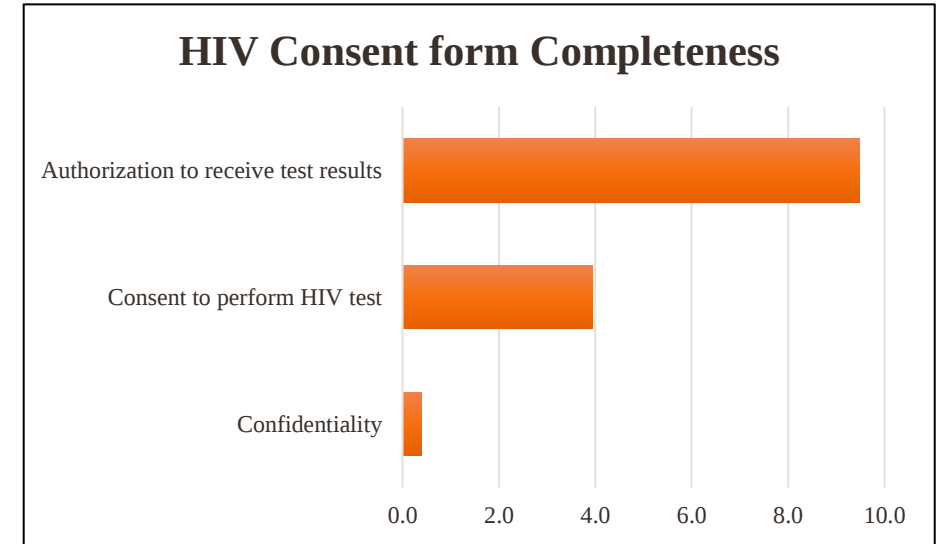
The primary drawback in judging if the HIV consent was applicable in a case or not, was the absence of any documentation to show if the patient needed an HIV test. And if yes, has the HIV test been done at this hospital or not. For the purpose of this study, this judgement has been made based on documentation in the Pre-Anaesthesia Checklist, which directly mentions if the patient is HIV positive or negative. If such documentation was observed, it was by default considered that the HIV test has been conducted in the hospital and that the test was needed.



Proportion of HIV tests not done to Consents filed and not filed

Results

It was observed that HIV test was done in 72% cases but consents were filed for only 13% of them. Amongst the 253 samples, a fully completed HIV consent was not seen in any of the samples. The confidentiality section was seen to be filled in one case, only 4% cases had the patient's authorization to conduct the HIV test and about 9.5% cases had filled the authorization to receive test results, partly or fully. It was seen that in departments like Urology, OB GYN, Internal medicine which contain more proportion patients in which HIV test was done, no HIV consents were filed.

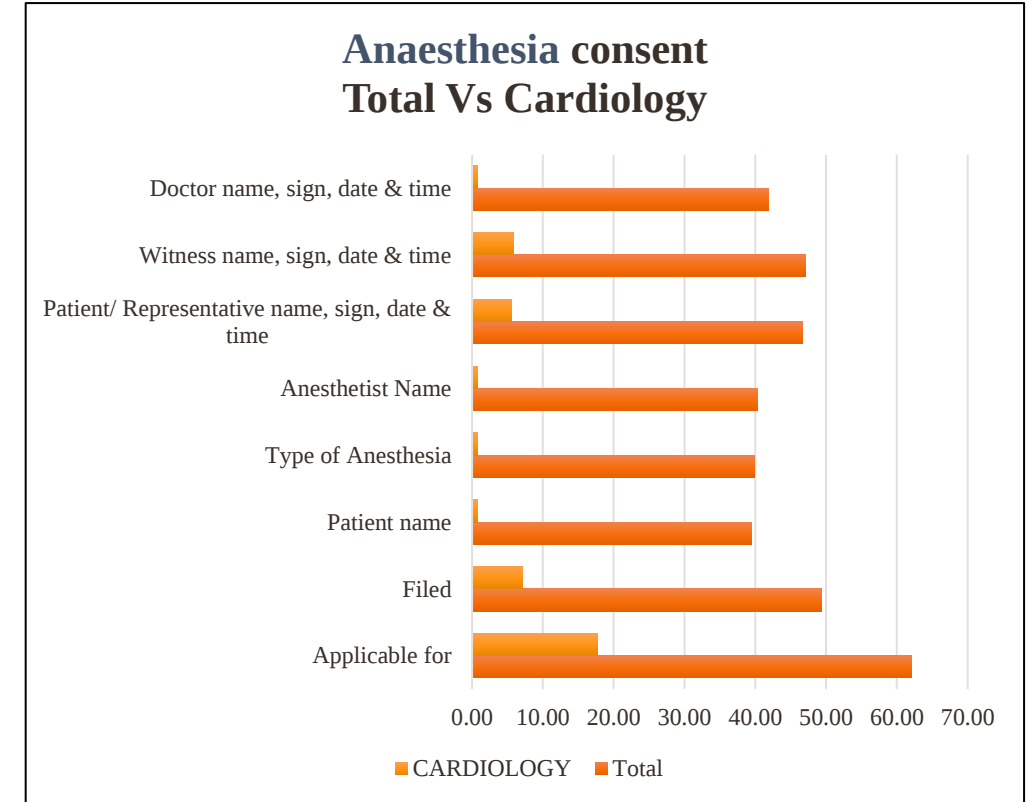


Section-wise completeness of the documented HIV consent forms

Results

Anaesthesia Consent

It was observed that only 40% samples had the patient's name and type of anaesthesia mentioned. The doctor's name and signature were missing in 40% and 42% cases, respectively. It was seen that Cardiology department showed the least compliance towards filing anaesthesia consents, which was just one-third of the cardiology cases which needed anaesthesia. Even in the ones filed, almost none of the cases had patient name, type of anaesthesia, anesthetist name and signature.

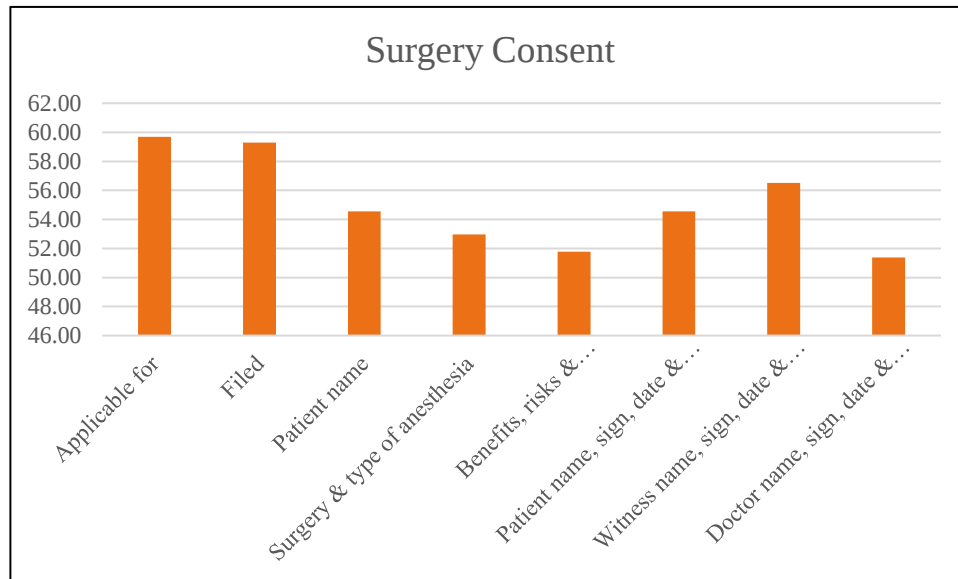


*Field-wise comparison of anaesthesia consent form completeness
(Total vs Cardiology cases)*

Results

Surgery Consent

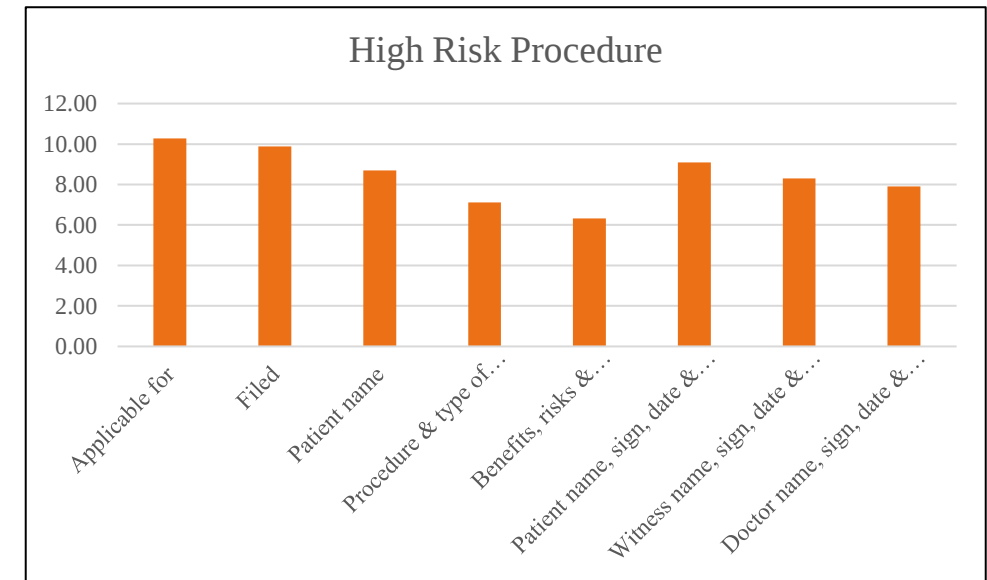
It was seen that amongst the various fields recorded, doctor's signature had the least compliance within the surgery consent.



Field-wise completeness of surgery consent forms

High risk Procedure Consent

It was observed that high risk consent was applicable in only 10% samples, amongst which most of them belonged to Neurosurgery, Endovascular surgery and Cardiothoracic surgery departments. Compliance towards filling the benefits, risks and alternative methods field was the least at 6.3%.

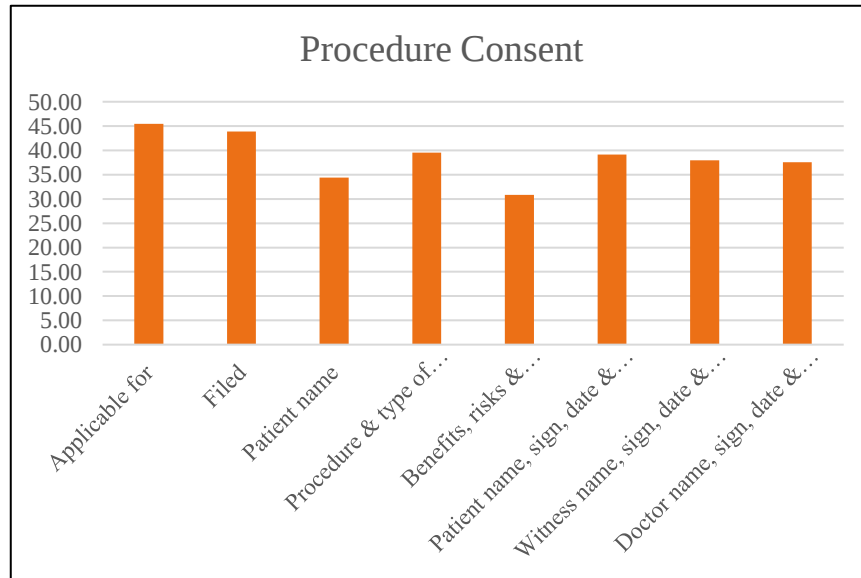


Field-wise completeness of High-risk procedure consent forms

Results

Procedure Consent

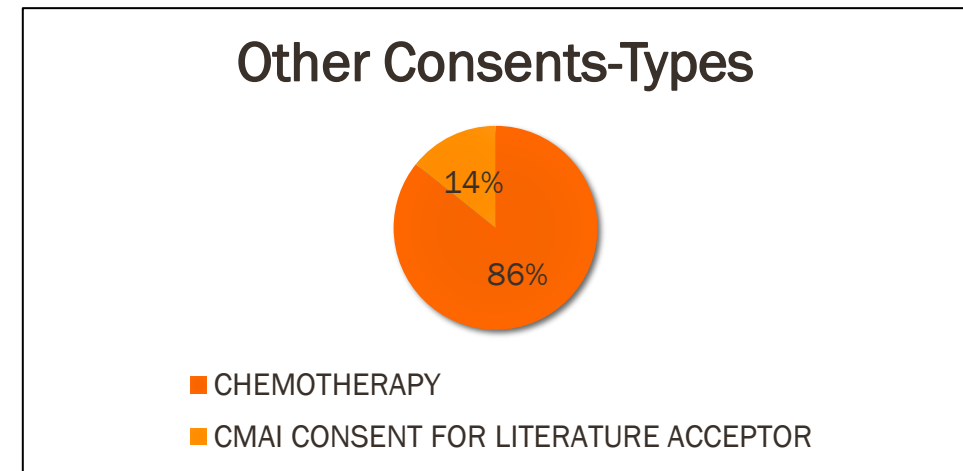
Similar to the high risk procedure consent, the field of benefits, risks and alternative methods showed least compliance compared to others, in all departments.



Field-wise completeness of procedure consent forms

Other Consents

Amongst other type of consents, two types were identified, chemotherapy consent for cancer patients and CMAI consent for literature acceptor for sterilization patients. Completeness of these consents was 100%.



Percentage of other types of consent forms

Limitations

- Applicability of HIV consent in a case was determined based on the documentation in Pre anaesthesia checklist, as the patient being HIV positive or negative. There was no document to determine if the patient underwent the HIV test in the hospital or not.
- In case of multiple consents of a single type being present, only the consent form with least compliance was considered.
- Only informed consents taken using consent forms were considered. Consents taken over progress notes, were not considered for this study.

Conclusion and Recommendations

➤ CONCLUSION

A considerable degree of non-compliance has been noted with respect to documenting consents, especially for HIV tests and completing consents. Completeness of anaesthesia consents and the benefits, risks and alternative methods fields of all consents have been observed to be amongst the primary bottlenecks. Improvisation with regards to these loopholes can markedly enhance the quality of service provided.

Conclusion and Recommendations

➤ RECOMMENDATIONS

- The doctors and staff (consent takers) need to be educated rigorously about the importance of consents.
- Daily active audits to assess daily documentation of consent forms and rectification.
- The format of surgery and procedure consent forms can be modified into different templates, each specific for the most common surgeries and procedures. The benefits and risks section completion must be stressed upon.
- Documentation within the case records about whether the patient needs HIV testing or not, and if the test has been performed.
- Policies to increase compliance amongst departments such as Urology, OB GYN and Cardiology, since maximum patient footfall is received by these departments.

References

1. Kumar N. Informed consent: Past and present. *Perspect Clin Res*. 2013;4(1):21.
2. Ehteshami A, Isfahani SS, Saeedbakhsh S, Isfahani MK. Ophthalmologists' awareness of informed consent and their compliance to its requirements. *Med Arh*. 2013;67(1):31–5.
3. Orkuma JA, Ayia GN, Ikwue MR, Ojobi J, Simji GS. Compliance with the Informed Consent to Blood Transfusion: Constraints and Physic for the Developing Africa. *Asian J Med Heal*. 2021;(October):78–91.
4. Aisuodionoe-Shadrach OI, Ogunlade OS, Amoran OE. An evaluation of the informed consent process for elective surgery at a university hospital. *Niger J Med*. 2006;15(3):281–4.
5. McGaughey I. Informed consent and knee arthroscopies: an evaluation of patient understanding and satisfaction. *Knee*. 2004 Jun 1;11(3):237–42.
6. Leclercq WKG, Bram •, Keulers J, Marc •, Scheltinga RM, Paul •, et al. A Review of Surgical Informed Consent: Past, Present, and Future. *A Quest to Help Patients Make Better Decisions*. 2010;