IIHMR DELHI

"A retrospective assessment of Compliance of appropriateness, Timeliness, Legibility, of informed consents taken during Surgery at Care Hospitals"

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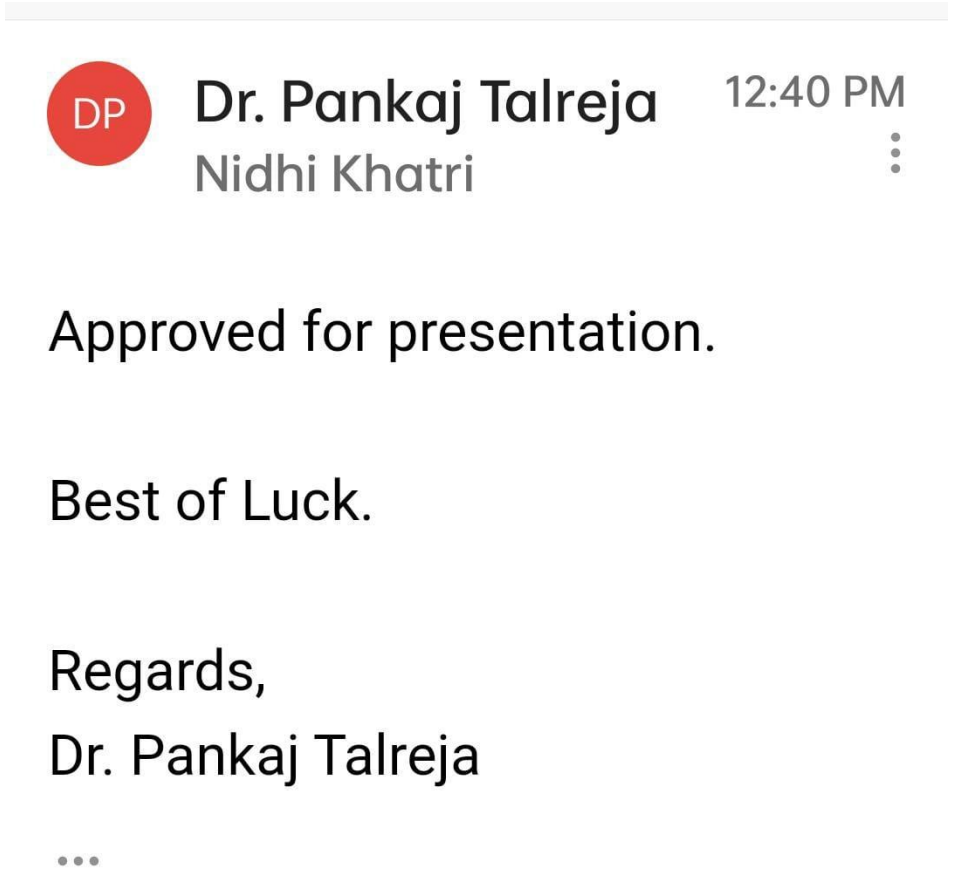
IIHMR Delhi

Screenshot of Approval



Introduction

- Informed consent is a process with respect of which the patient learns
  - about an actual procedure of the medical and surgical intervention

- Informed consent is the main responsibility of the doctors
  - To provide the required information to the patient and make sure that the information is correct to the point and this information should be provide in simple words without creating hectic words.

1. **When two or more persons agree upon the same thing in the same sense, they are said to consent**
2. **The implications are that only a person equal to or above 18 years of age can give a legally valid consent for any procedure that includes risk to life.**
3. **Person above 12 years capable of giving of giving consents.**

Information included in consents:-

- Exact position of patient
- Treatment procedure
- Benefits, risk, alternative , Consequences

- Type of informed consents:-
- Responsibility of the patients:-
- Why consent is necessary?
- Legal Scenario of Informed Consent
  - Right to Refusal-
  - Minor's consent-
  - Medical termination of Pregnancy

Objectives of Your Study

- To measure compliance with standards in available guidelines for informed consent for during surgery.
- To make recommendations to improve the timeliness, and Legibility of process of consenting in surgery.

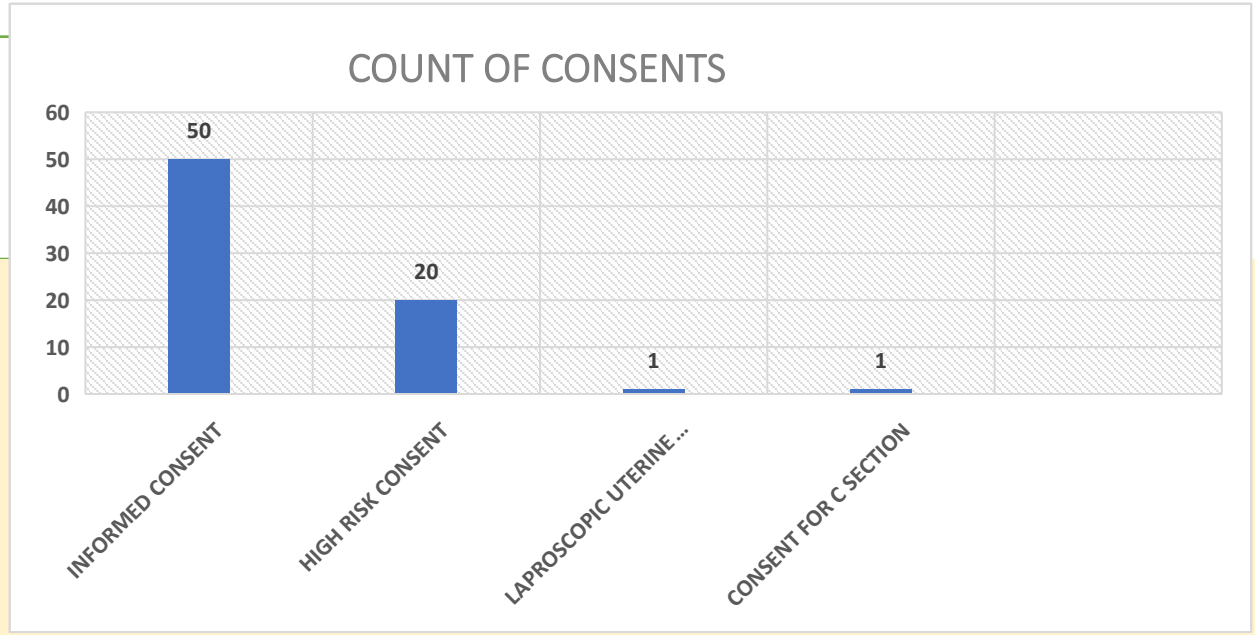
Literature Review

- A Journal Length of time a signed informed consent is valid by Byron Burlin game RN,BSN,MS,CNOR (AORN JOURNAL 2007-2017).
  - This journal says that the time frame for the signed informed consent should be decided by the health care organization's policies and is governed by each state otherwise their are no national standards that are specific for the length of time a signed informed consent is valid.
  - While creating the informed consent policies, first consultation should be taken from state department of health and health care organization's risk management, medical record departments and quality improvement.
  - Every health care organization should determine the length of time that a consent is valid. This decision is based on state rules, especially pertaining to Medicaid recipients (must be U.S. citizens or qualified non-citizens, and may include low-income adults, their children, and people with certain disabilities)

- Junior-doctor Experience and challenge in Obtaining Surgical informed Consent: A qualitative systematic review and meta-ethnography by Josephine DE Costa BA, LLB, MD, M Med, Mandy Shircore BSc, LLB, LLM and Alan de Costa FRACS 2021 .
  - Recommend that additional educational interventions are implemented for all staff, including junior doctors, to improve skills and knowledge around surgical informed consents. Junior doctors in all of the polls have a poor comprehension of the surgical informed consents legal criteria, particularly when it comes to assessing competence and defining material risk.
  - It may be advantageous for all medical schools – including vocational surgical programme – to include mandatory lectures as part of pre - internship training. (simulations or case studies, are also beneficial and may be easier to integrate into structured medical student and junior doctor education).
  - Medical educators and policy-makers should be aware of the issues faced by junior doctors who are Post graduate students and lacking in adequate training and education about the legal aspects when creating policies impacting surgical informed consents, and when designing surgical education programs because the junior doctors are likely to obtain a significant portion of surgical informed consent.

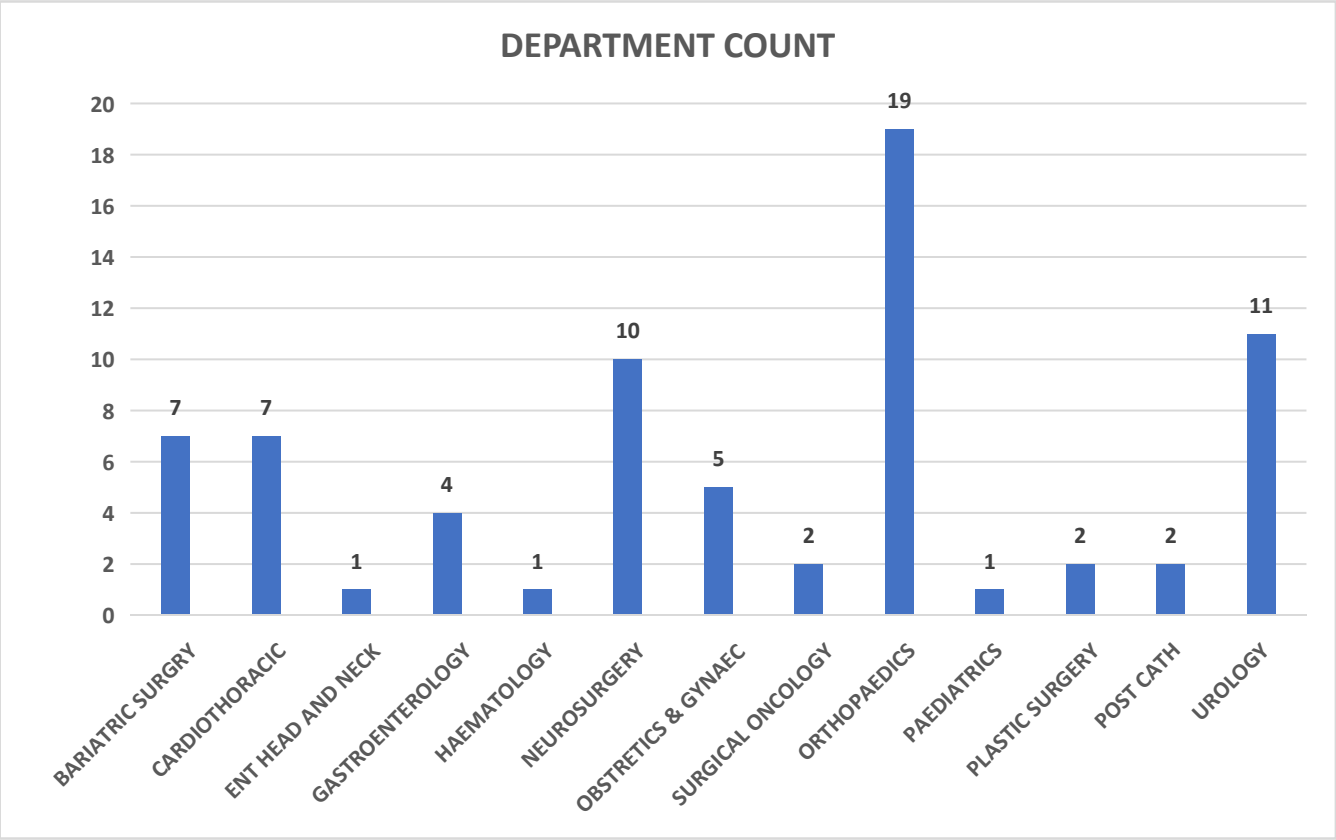
- Are patients truly informed ? A retrospective chart review the documentation of informed consent sin laparoscopy cholecystectomy 2021.
  - Context-- Examination is done on whether the documents are complete or not for all elements of informed consents for laparoscopic cholecystectomy (LC): its alternatives to laparoscopic cholecystectomy, potential complications, and details of the procedure.
  - Objective-- To examine the rate of successful documentation of all elements of informed consents for Laparoscopic cholecystectomy in both the elective and emergent settings.
  - Conclusion:- The documentation of informed consents for Laparoscopic Cholecystectomy was poor; informed consents elements was missing in most cases. The most frequently documented IC element was IC complications; documenting of discussion of alternatives to LC and details of the operation was frequently absent. Although it is crucial to address problems in research aimed at enhancing IC documentation, it is also necessary to discuss options to surgical care, process specifics, and efforts to guarantee patient understanding.

Methodology



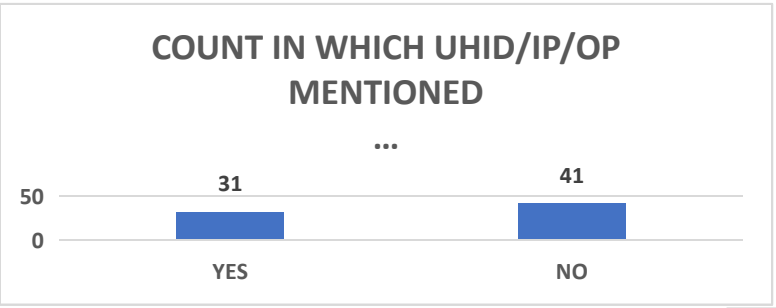
- Research Design:- Retrospective Study
- Data Type:- Secondary Data
- Data collection Method:- Purposive sampling from MRD at CAREHOSPITALS.
- Sample size:- 72
- Data Sources:- Published articles, New Articles, Journals.
- A retrospective study was conducted from for 3 months. The data was collected by using MRD records of passive patients who had under gone surgeries. Administered structured questionnaire will be created based on the standard criteria and will be analyzed in Excel.

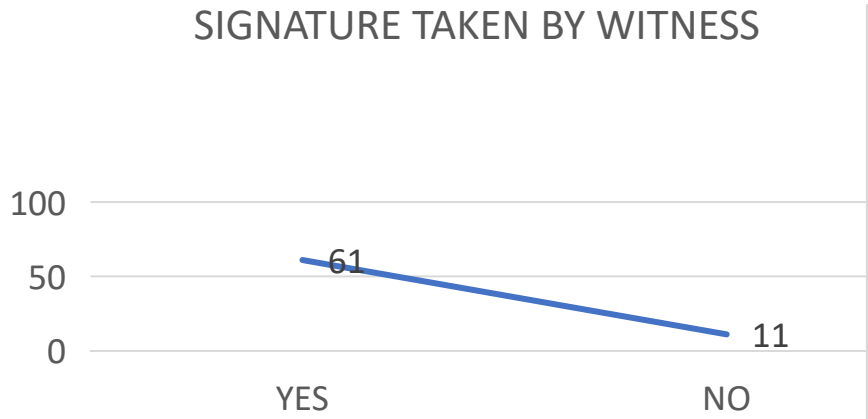
Methodology

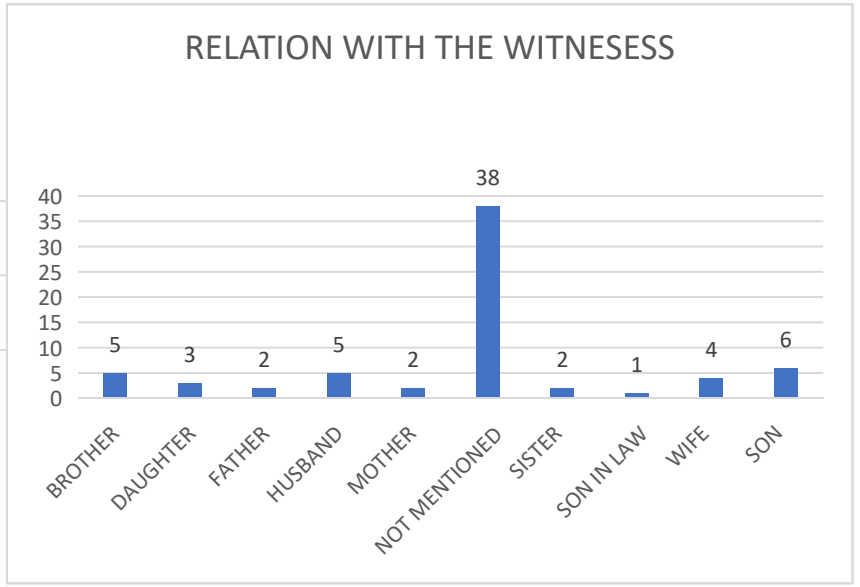


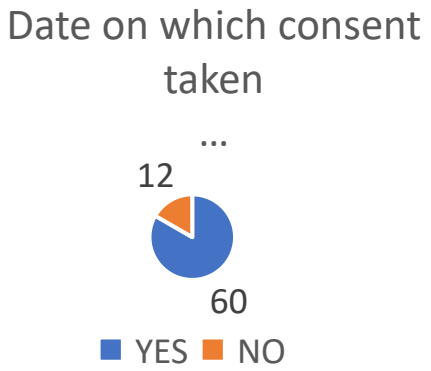
Department	General
PATIENT UHID	L/A
NAME OF CONSENT	Spinal
IP/OP NO/UHID	Epidural
DATE OF CONSENT TAKEN BY PATIENT /WITNESS	Caudal
Signature done by Patient	Brachial plexus
Signature of witness	Regional block
Realtion with witness	Timing of consent
Address of witness	Signed by staff
Signature Taken by staff	Missing Consent
Proposed Procedure	No. of extra consent signed by patient or staff
Date of procedure	Demographics
Benifits of procedure	Witness
Alternative treatmet	Thumb impression/ Not capable to sign
Disposal of any tissue or part to be removed during the procedure	General risk procedure marked (yes /no)
Expected Risk	Specific risk procedure marked
Appropriate language used for patient understanding(English/Telgu)	Name of Staff mentioned
Type of anaesthesia given	Address of patient
	Consent signed by
	Surgery Name

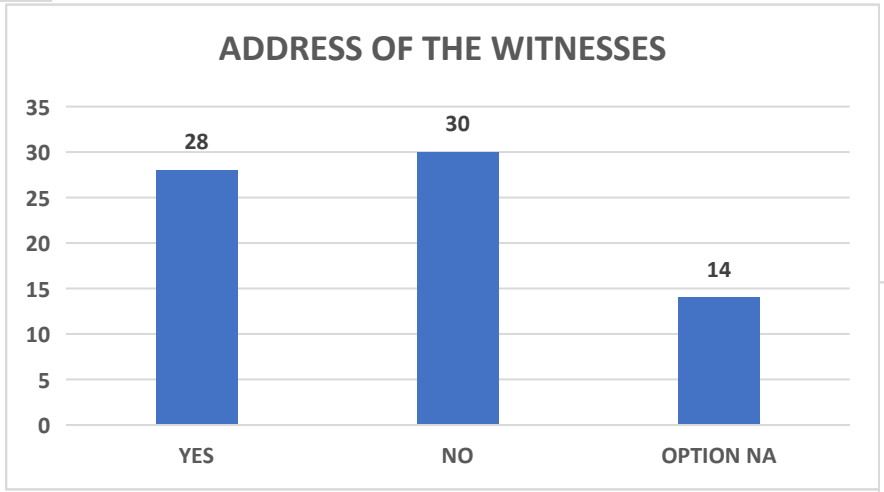
Results

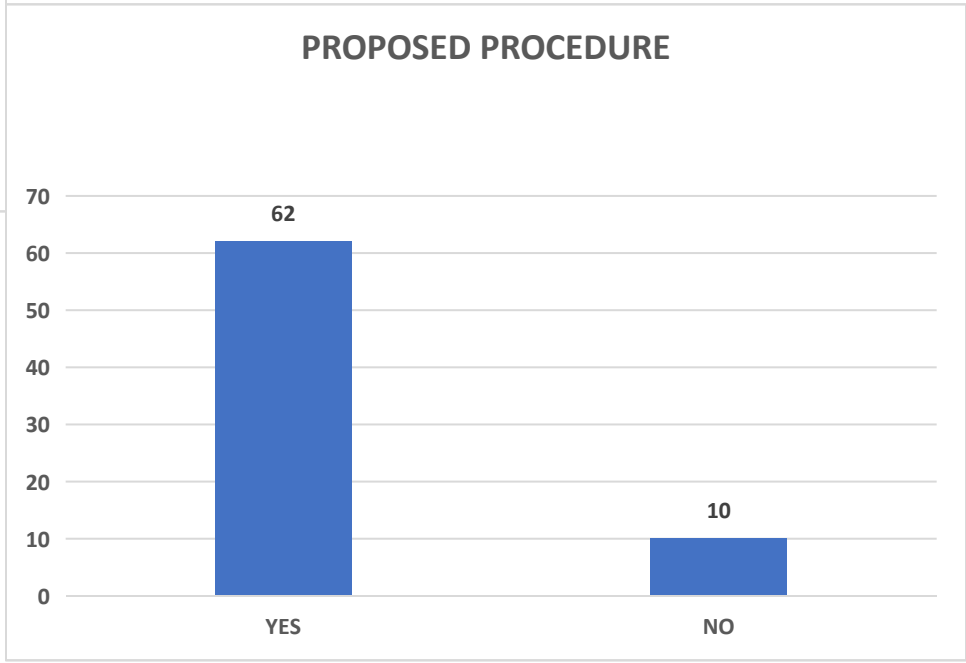

COUNT IN WHICH UHID/IP/OP MENTIONED
...
50
0
31
41
YES
NO

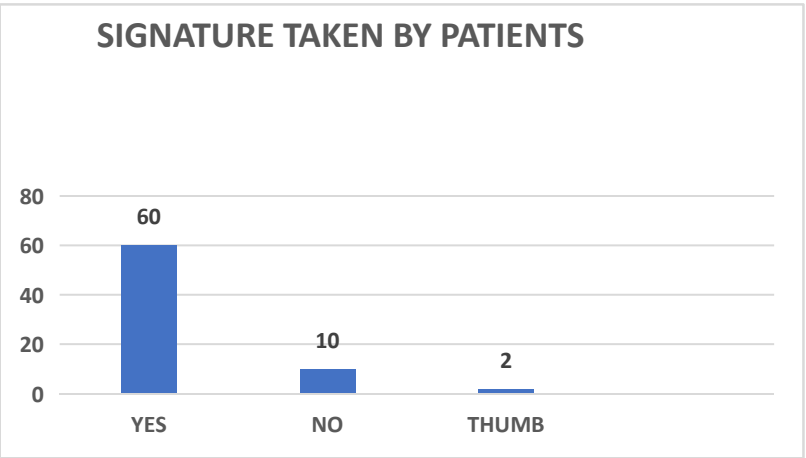

SIGNATURE TAKEN BY WITNESS
100
50
0
61
11
YES
NO


RELATION WITH THE WITNESESS
40
35
30
25
20
15
10
5
0
5
3
2
5
2
38
2
1
4
6
BROTHER
DAUGHTER
FATHER
HUSBAND
MOTHER
NOT MENTIONED
SISTER
SON IN LAW
WIFE
SON

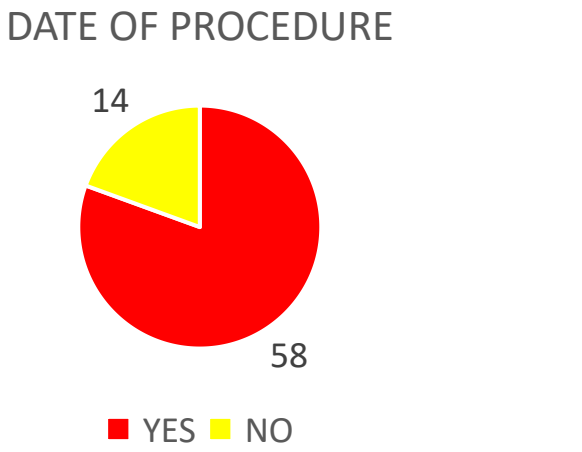

Date on which consent taken
...
12
60
YES
NO

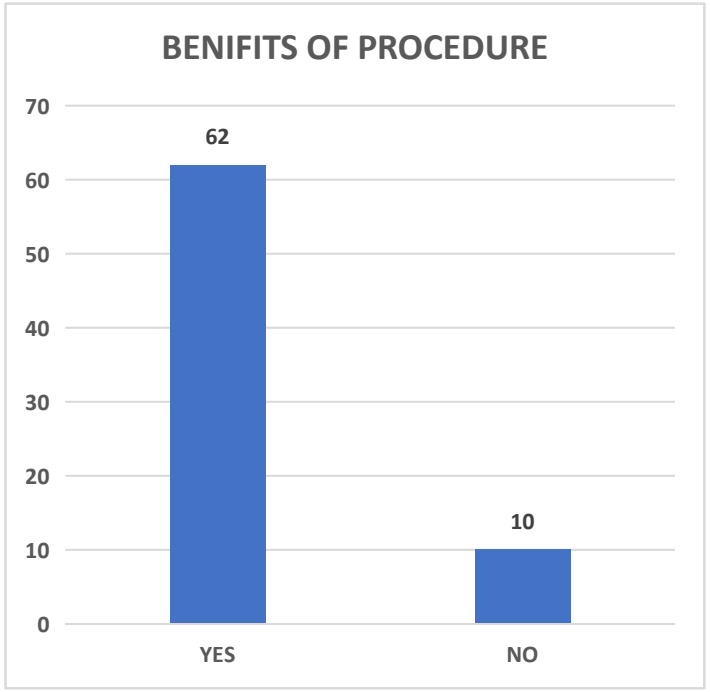

ADDRESS OF THE WITNESSES
35
30
25
20
15
10
5
0
28
30
14
YES
NO
OPTION NA

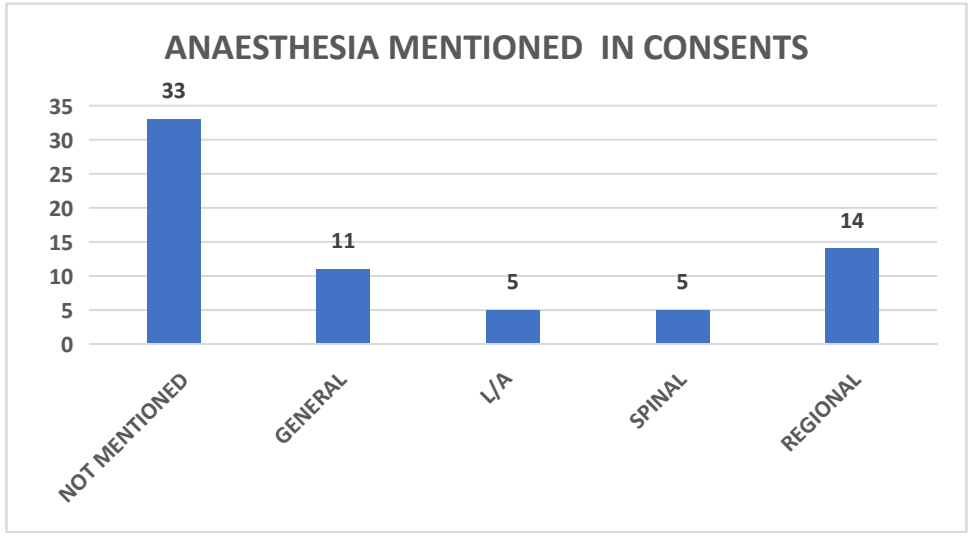

PROPOSED PROCEDURE
70
60
50
40
30
20
10
0
62
10
YES
NO

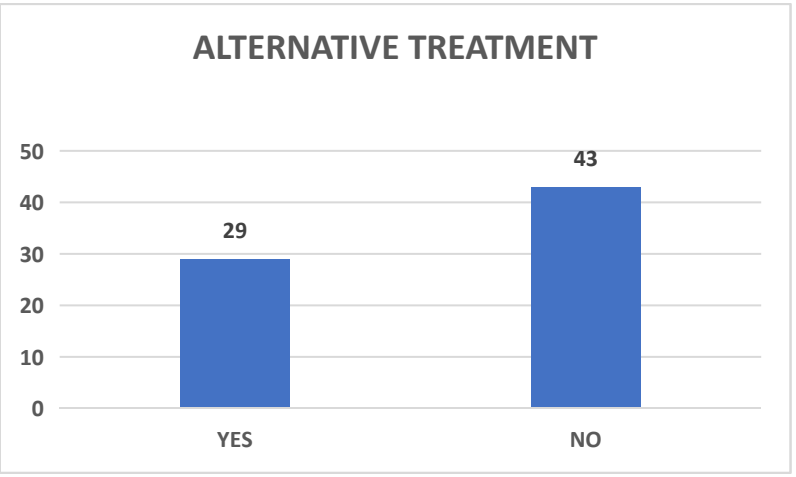

SIGNATURE TAKEN BY PATIENTS
80
60
40
20
0
60
10
2
YES
NO
THUMB

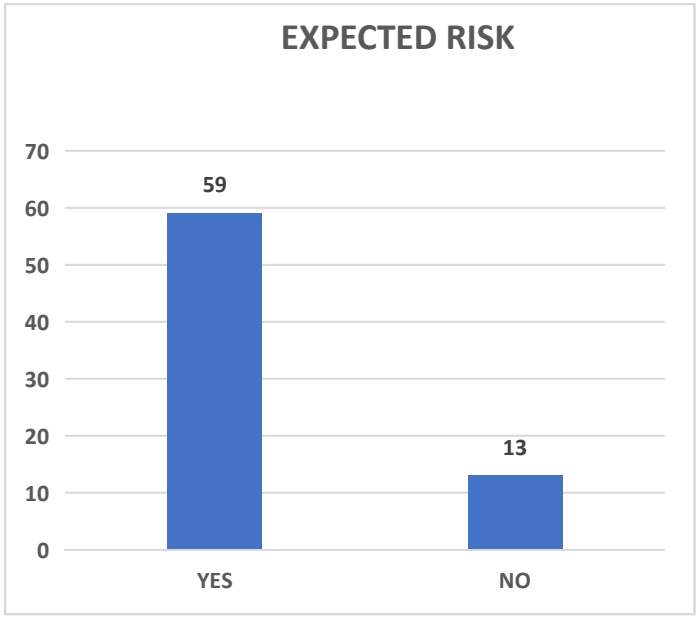
Results

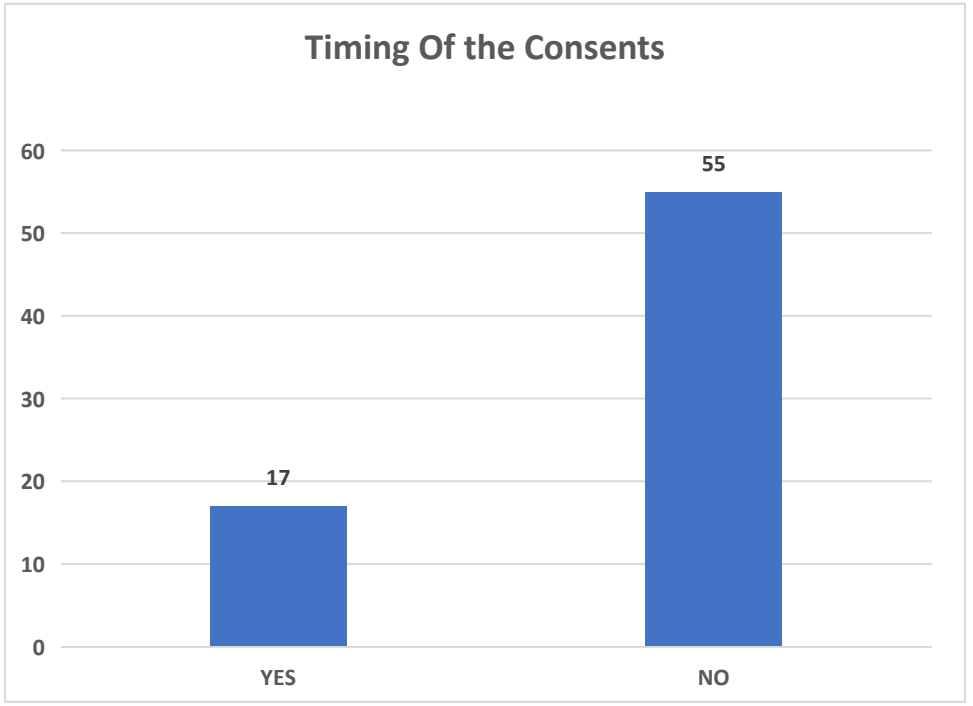

DATE OF PROCEDURE
14
58
YES
NO


BENIFITS OF PROCEDURE
70
60
50
40
30
20
10
0
62
10
YES
NO


ANAESTHESIA MENTIONED IN CONSENTS
35
30
25
20
15
10
5
0
33
11
5
5
14
NOT MENTIONED
GENERAL
L/A
SPINAL
REGIONAL


ALTERNATIVE TREATMENT
50
40
30
20
10
0
29
43
YES
NO


EXPECTED RISK
70
60
50
40
30
20
10
0
59
13
YES
NO


Timing Of the Consents
60
50
40
30
20
10
0
17
55
YES
NO

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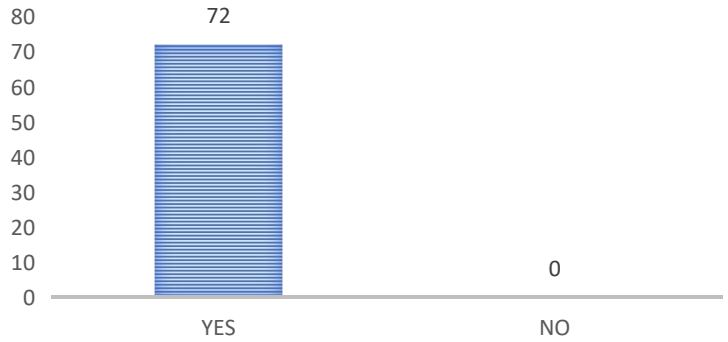
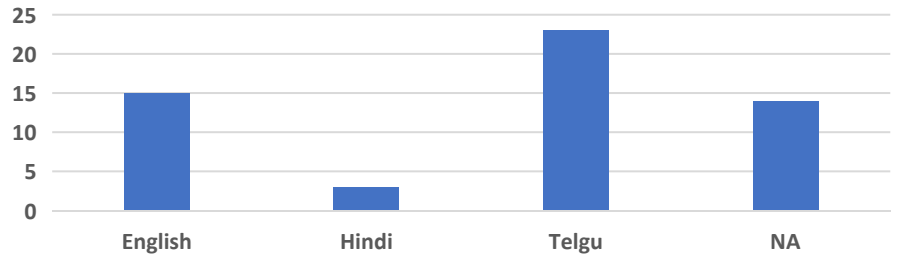
Results

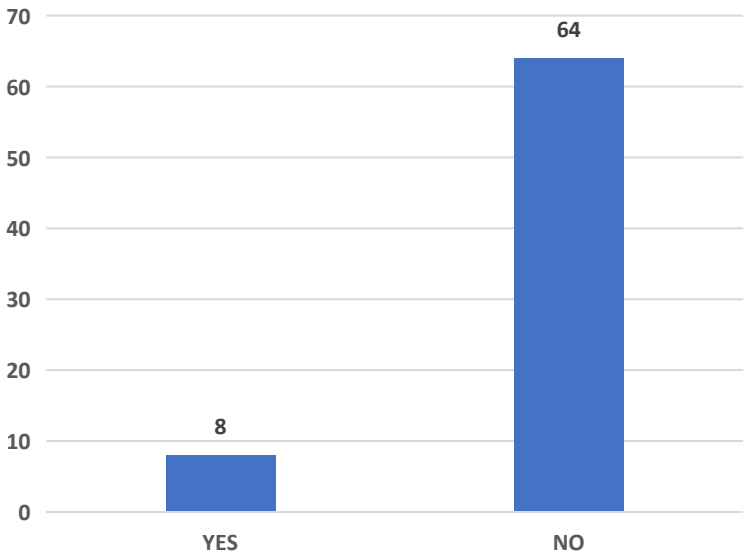
DEMOGRAPHICS



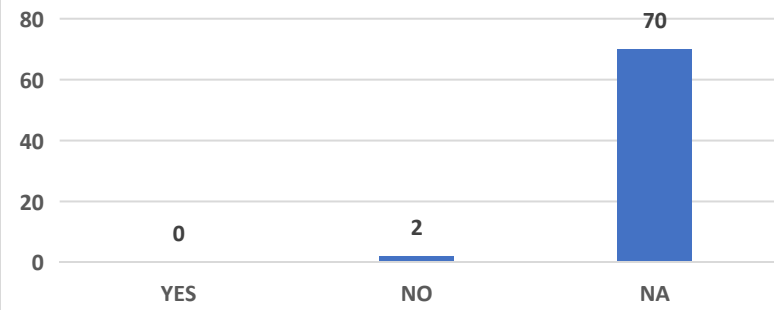
Appropriate language used by the patient



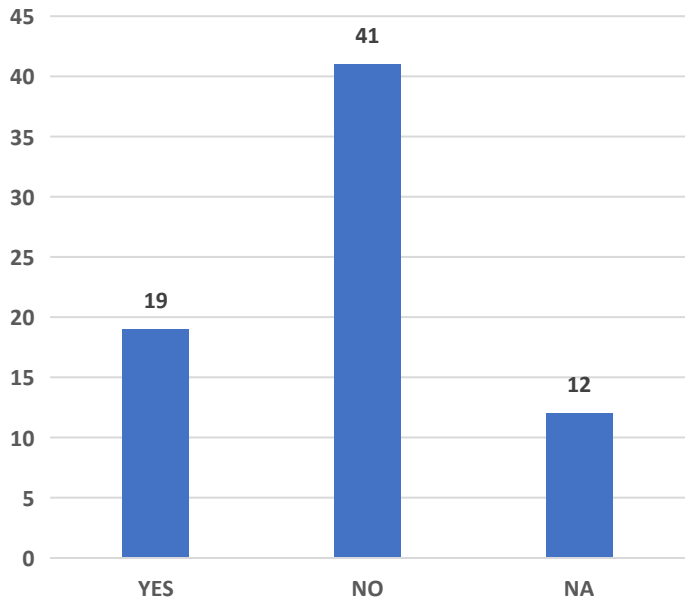
NO OF CONSENT EXTRA SIGNED BY STAFF OR PATIENT



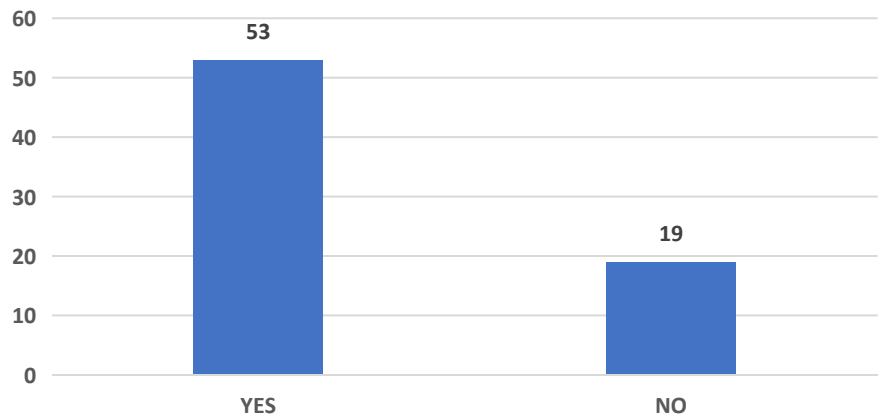
General/Special risk procedure marked (in gynaec and obs consents)



ADDRESS OF PATIENTS

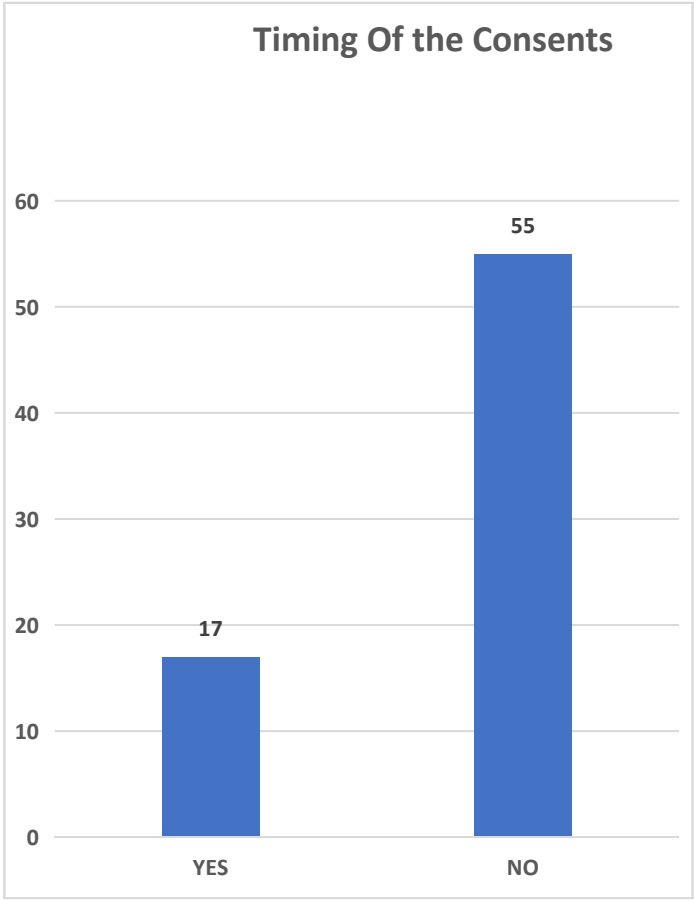


Name of staff mentioned in consents



Discussion

- If we look timing of the consent in this study then only 17 (24%) patient has written the timing on consent.
- Date of the surgery performed and date of the consent taken is same.
- Informed consent in not simply the signing of a consent form by the patient more importantly, it is a process of detailed discussion between doctor and patient.
- This process takes time. However, in the hospitals their is often a trend to hand over the consent form to the patient for signing it or delegate the responsibility to junior doctors.
- In very few consents time of consents was mentioned, relation of the witnesses was not mentioned in more than 35 consents, anaesthesia was not mentioned in most of the consents.



Discussion

- In a research study Saw et al. 54% of patients trust doctors to do the right thing they do not go for the detailed explanation.
- Tay CSK has said better communication between the doctor and his patient with a proper informed consents taking as reviewed above, will avoid claims based on perceived rather than actual negligence on the part of the doctor.
- In this study 10(14%) consent was not signed by the patients. 11(15%) of the consent was not signed by the patients. 30(41%) has incomplete address, 43 (59%) patients no alternative treatment for their surgery. In 14(19%) language used by the patient was not mentioned.

Limitations of the Study

1.Patient under gone Foley's cauterization, Ryles tube has given the informed consent is not been consider.

2.Patient gone under transplants surgery are not included in the study.

Conclusion

- The rights of a person are determined through their human status. The informed consent is an important tool in clinical trials. The responsibilities and importance of this consent must be ethical and genuine for the betterment of the participant.
- It is very important that doctors should perform their duty perfectly, there should not be any lacking point which can raise question on their profession. Health is the most preferred thing for a normal human being and if a doctor shows any point of carelessness towards it, this would be totally wrong. Throughout the whole treatment, a doctor should act as responsible and should work with complete dedication.

References

1.: Jmedsoc.org. 2022. Journal of Medical Society : Free full text articles from J Med Soc. [online] Available at: <https://www.jmedsoc.org/> [Accessed 2 July 2022].

2.India, l., 2022. Legal Service India - Law, Lawyers and Legal Resources. [online] Legalserviceindia.com. Available at: <https://www.legalserviceindia.com/> [Accessed 2 July 2022].

3.Blanchot-Isola, C., 2010. Zoom sur : www. foruminternet. org/, le forum des droits sur l'Internet. La Revue Sage-Femme, 9(3), pp.151-152.

4.de Costa, J., Shircore, M. and de Costa, A., 2022. Junior Doctor Experiences and Challenges in Obtaining Surgical Informed Consent: A Qualitative Systematic Review and Meta-Ethnography.

5.Ncbi.nlm.nih.gov. 2022. National Center for Biotechnology Information. [online] Available at: <https://www.ncbi.nlm.nih.gov/> [Accessed 2 July 2022].

6. Laureano Domínguez, L., 2009. Pericles' "unknown travels": The dimensions of geography in Shakespeare's Pericles. Sederi, (19), pp.73-99.

7. 2022. [online] Available at: <https://aornjournal.onlinelibrary.wiley.com/doi/full/10.1016/j.aorn.2009.08.010> [Accessed 2 July 2022].

Suggestions to the Organization where the Study was Conducted

1.Kindly write the type of anesthesia in c section consents.

2.Timing of the consent taken must been mention in the consents

3.Patient informed about the surgery date and time should be mentioned.

4.Consent Location should be mentioned in the consent so it will help in analyzing the time between transfer of the patient,

5.Translator option should be mentioned in all the consents.

6.Whether the patient was informed about the duration of procedure should be mentioned.

7.Experience of the procedure performing consultant can be mentioned it will help in branding of the hospital.

8.Thumb impression box should be different for illiterate patients.

9.If the signature or name of the patient is written in local language then it should be written on local language consent.

10.In the column of age, gender should also be mentioned.

Dissertation Experiences

What did you learn (skill/ topic)?

- *I have learned about the value of consents and their completness in passive files how much is important for the hospital and for patients too.*

Overall self comments on Dissertation

- My comments on desertation is that their is always a scope of improvement, I should have done more improvement.

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Thank You

Any Questions