A Report on

" Compliance to informed consent- a cross sectional study"

At

Submitted by "SUMEET KAUR BAJAJ"

Of

Post Graduate Diploma in Hospital & health Management

2012-2014

Institute of Health Management and Research

As a partial fulfilment of the Summer Training requirement

Of PGDHM Program

(8^{th} April – 8^{th} June 2013)

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CERTIFICATE

This is to certify that Dr. Sumeet Kaur Bajaj, Regd. No. IIHMR/PGDHM/2012-14/17-1388, student of Post Graduate Diploma in Hospital and Health Management (PGDHM) from Institute of Health Management Research, Jaipur- 17th Batch has undergone summer training in Fortis Medical Research Institute, Gurgaon and has done the project titled **"COMPLIANCE TOWARDS INFORMED CONSENT"** in Quality Department.

The candidate has successfully carried out the mentioned study assigned to her during the summer training from 8th April 2013 to 7th June 2013 and her approach to study has been sincere, scientific and analytical.

I wish her success in all her future endeavors.

Prof. Vijay Pratap Raghuvanshi
Assistant Professor & Mentor,
IHMR, Jaipur

Dr. Ashok Kaushik
Dean, Academic & Student Affairs
IHMR, Jaipur

ACKNOWLEDGEMENT

"A Great achievement solution dawns with an idea, grows with our effort and attains fulfilment with our will power". In our effort towards the realization of my project work, I have drawn on the guidance of many people for which I'm glad to acknowledge.

I got the opportunity to pursue my summer internship from Fortis Medical Research Institute, Gurgaon. It was an opportunity to work with one of the best health care service providers.

I would like to thank my mentor & guide **Dr. Anita Arora** , Head Quality and Principal Consultant, Microbiology, Fortis Medical Research Institute, Gurgaon for providing an opportunity to carry out the project work and utilizing the facilities available. Without her valuable guidance and consistent support, this project would not have got underway.

I'm thankful to **Ms. Divya Gautam**, Quality Coordinator, Fortis Medical Research Institute, Gurgaon for being my mentor and project guide for the entire period of my internship, for helping me improve the quality of my work and for helping me identify areas where I lack and work upon them.

I also express my gratitude towards the staff of the hospital, which has helped me a lot in successful completion of my project.

I'm grateful to my mentor **Dr. Vijay Pratap Raghvanshi**, Assistant Professor, IHMR, Jaipur & our Dean **Dr. Ashok Kaushik** for their co-operation, help and wholehearted encouragement. Their assistance enabled me to overcome many obstacles during the work of my project study.

I'm also thankful to all those who have directly or indirectly encouraged me to complete this project.

CONTENTS

PART –I: INTERNSHIP

OBJECTIVE

The main objective of my internship is – "To assist the Quality team of Fortis Medical Research Institute, Gurgaon in ensuring that their Medical Quality goals are met."

ORGANIZATION PROFILE: FORTIS HEALTHCARE LIMITED

Fortis Healthcare Limited is a leading, pan Asia-Pacific, integrated healthcare delivery provider.

The healthcare verticals of the company span diagnostics, primary care, day care specialty and hospitals, with an asset base in 11 countries, many of which represent the fastest-growing healthcare delivery markets in the world.

Currently, the company operates its healthcare delivery network in Australia, Canada, Dubai, Hong Kong, India, Mauritius, New Zealand, Singapore, Sri Lanka, Nepal and Vietnam with 76 hospitals, over 12,000 beds, over 600 primary care centres, 191 day care specialty centres, over 230 diagnostic centres and a talent pool of over 23,000 people.

Fortis Healthcare is driven by the vision of becoming a global leader in the integrated healthcare delivery space and the larger purpose of saving and enriching lives through clinical excellence.

The company provides patient services including nuclear medicine and cardiac imaging, labs,scans, cardiology, cardiacpacing,electrophysiology, neurosciences, orthopedics, gyne -cology and obstetrics, pediatrics, maternity services, diagnostic services, paediatric ophthalmology, neurophthalmology, internal medicine, general surgery, urology, nephrology, gastroenterology, mental health and behavioural sciences, rehabilitative services, Pulmonology and IVF etc.

Vision of Fortis Healthcare Limited:

To be a globally respected healthcare organisation known for Clinical Excellence and Distinctive Patient care.

Values of Fortis Healthcare Limited:

Patient Centricity	Commit to 'best outcomes and experience' for our patients. Treat patients and their caregivers with compassion, care and understanding. Our patients' needs will come first
Integrity	Be principled, open and honest. Model and live our 'Values'. Demonstrate moral courage to speak up and do the right things.
Teamwork	Proactively support each other and operate as one team. Respect and value people at all levels with different opinions, experiences and backgrounds. Put organization needs' before department / self interest.
Ownership	Be responsible and take pride in our actions. Take initiative and go beyond the call of duty. Deliver commitment and agreement made.
Innovation	Continuously improve and innovate to exceed expectations. Adopt a 'can-do' attitude. Challenge ourselves to do things differently.

Below listed are the Hospitals of the Fortis Healthcare Limited:

Amritsar	**Amritsar**	**Fortis Escorts Hospital**
Bangalore	**Bannerghatta Road**	**Fortis Hospital**
Bangalore	**Cunningham Road**	**Fortis Hospital**
Bangalore	**Nagarbhavi**	**Fortis Hospital**
Bangalore	**Rajajinagar**	**Fortis Hospital**
Bangalore	**Seshadripuram**	**Fortis Hospital**
Chennai	**Adyar**	**Fortis Malar Hospital**
Dehradun	**Dehradun**	**Fortis Escorts Hospital**
Faridabad	**Faridabad**	**Fortis Escorts Hospital**
Gurgaon	**Gurgaon**	**Fortis Memorial Research Institute**
Jaipur	**Jaipur**	**Fortis Escorts Hospital**
Kangra	**Kangra**	**Fortis Hospital**
Kolkata	**Rash Behari Avenue**	**Fortis Hospital & Kidney**

		Institute
Kolkata	**Anandapur**	**Fortis Hospital**
Mohali	**Mohali**	**Fortis Hospital**
Moradabad	**Moradabad**	**Fortis Vivekanand Hospital**
Mumbai	**Vashi**	**Fortis Hiranandani Hospital**
Mumbai	**Kalyan**	**Fortis Hospital**
Mumbai	**Mulund**	**Fortis Hospital**
Mumbai	**Mahim**	**S.L. Raheja Hospital**
Mysore	**Mysore**	**Fortis Cauvery Heart Hospital**
New Delhi	**Greater Kailash II**	**Fortis La Femme**
New Delhi	**Shalimar Bagh**	**Fortis Hospital**
New Delhi	**Vasant Kunj**	**Fortis Flt. Lt. Rajan Dhall Hospital**
New Delhi	**Okhla Road**	**Fortis Escorts Heart Institute & Research Centre**
Noida	**Noida**	**Fortis Hospital**
Raipur	**Raipur**	**Fortis Escorts Heart Centre**

Fortis Memorial Research Institute, Gurgaon, is a multi-super specialty, quaternary care hospital with an enviable international faculty, reputed clinicians, including super-sub-specialists and speciality nurses, supported by cutting-edge technology. A premium, referral hospital, it endeavours to be the 'Mecca of Healthcare' for Asia Pacific and beyond. Set on a spacious 11-acre campus with 1000 beds, this 'Next Generation Hospital' is built on the foundation of 'Trust' and rests on the four strong pillars Talent, Technology, Infrastructure and Service.

Vision

To be the ultimate healthcare destination - "Mecca of Medicine"

Mission

To provide quaternary care to the community in a compassionate, dignified and distinctive manner

Motto

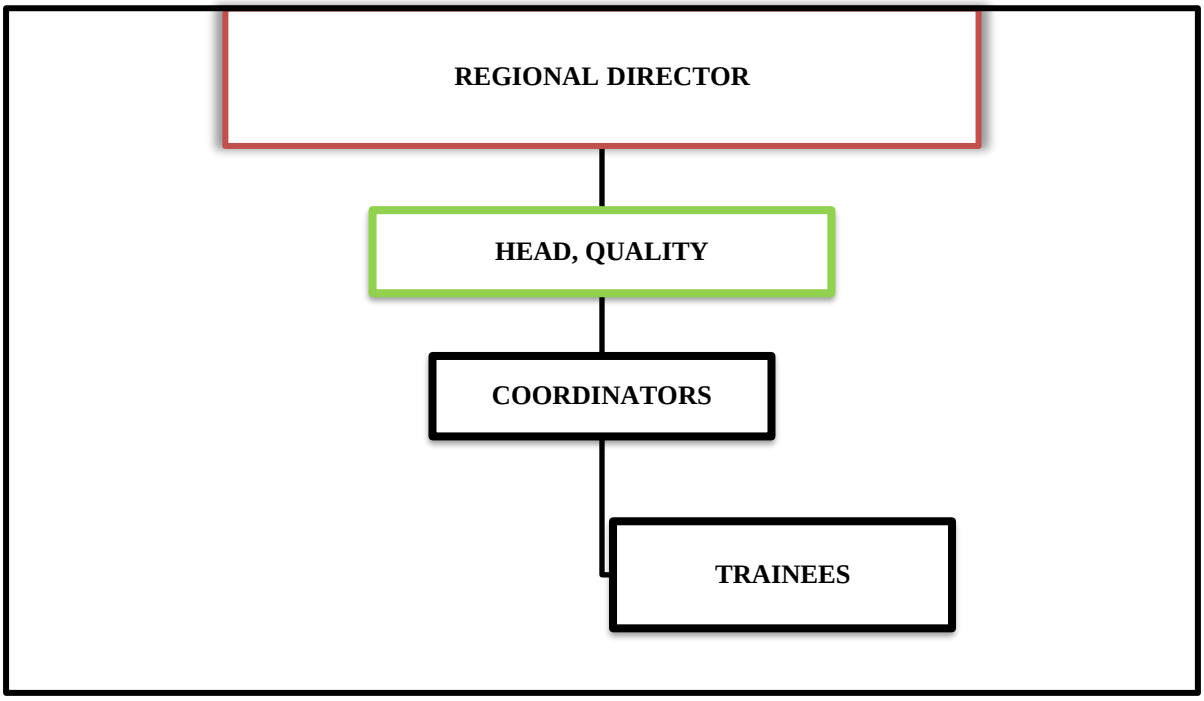
"Best is the Least We Can Do"

QUALITY DEAPARTMENT

The objectives of the department are as follows:

a. Satisfying patient needs
b. Enhancement of quality systems
c. Effective performance measurement & compliance systems
d. Continuous Improvement loop
e. Engage every employee in quality drive

ORGANIZATION STRUCTURE – QUALITY



PART – II: SUMMER INTERNSHIP PROJECT

Compliance to informed consent- a cross sectional study

EXECUTIVE SUMMARY

Patient Rights & Education and quality of care are and have always been the foundation and core mission tenets of all health care providers and professionals; however, healthcare providers cannot just communicate their dedication to quality and patient education. An environment and culture of quality, safety and education must be created, fostered, and improved within each healthcare setting.

In order to check the level of Compliance of Patient Rights & Education and Safety practices this audit was undertaken as a part of summer training program required for the PGDHM course curriculum of Institute of Health Management and Research, Jaipur during April-June 2013. It was conducted by Ms. Sumeet Kaur Bajaj, student of IHMR-Jaipur, 2012-2014 batch under the mentorship of **Dr. Anita Arora**, Head Quality and Principal Consultant, Microbiology, FMRI, Gurgaon; **Ms. Divya Gautam**, Quality Coordinaor, FMRI, Gurgaon and **Dr. Vijay Pratap Raghuvanshi**, Assistant Professor, IHMR Jaipur.

It was a checklist based audit. The checklist was prepared with reference to Consent SOPs –F.M.R.I, Gurgaon, to check the percent compliance of it. The below listed parameters were selected for the audit of Informed consents forms:

1. Language Assessment
2. Diagnosis Compliance
3. Awareness of Complications
4. Person Performing the Procedure
5. Compliance of Patient Declaration
6. Compliance of Patient Representative Declaration
7. Compliance of Interpreter's Declaration
8. Compliance of Doctor's Declaration
9. Compliance of Witness' Declaration
10. Awareness of Procedure / Technique
11. Rendering of Post –test Counseling
12. Availability of Valid Consent

NOTE: The checklist used for the audit doesn't represent the complete Policies. The policies only form the basis of the checklist.

This Audit was carried out in various subheads & departments of Fortis Medical Research Institute, Gurgaon :

- Consent for Operation Procedure
- Consent for Anaesthesia
- Consent for Chemotherapy
- Consent for HIV testing
- Consent for Receiving Transfusion of Blood
- Consent for Haemodialysis
- General Consent for Admissions
- Nuclear Medicine Generic Consent
- Consent for Discharge Against Medical Advice
- High risk consent
- Radiation therapy consent

INTRODUCTION

OBJECTIVE

The objective of the audit was to check the percentage compliance with guidelines and S.O.P of Fortis Medical Research Institute, Gurgaon with respect to Informed Consent as a part of the Continuous Quality Improvement & to achieve the target improvement in compliance.

Informed consent is the process of communication between a patient and physician that results in the patient's authorization or agreement to undergo a specific medical intervention (AMA 1998). All patients/individuals undergoing/desirous of undergoing treatment in a hospital; have the right to autonomy and self determination. For both ethical and legal reasons, patients must be given enough information to be fully informed before deciding to undergo a major treatment, and this informed consent must be documented in writing. Although informed consent is not just a form and this physician patient communication involves much more than that, it serves as a tool to document that the necessary information has been conveyed to and understood by the patient/patient representative and that s/he is willing to undergo the said procedure/test/intervention. Informed consent is the legal embodiment of the concept that each individual has the right to make decisions affecting his/ her well being.

The key potential benefits of improving informed consent that must be conveyed include:

- Greater patient safety and satisfaction
- Attainment of higher ethical standards and organizational morale
- Closer adherence to legal requirements and reduced risks of litigation
- Increased levels of institutional quality (e.g., compliance with accreditation standards)
- Potential time and money savings owing to reduced litigation.

Patient Right & Education is the cornerstone of high-quality health care. It provides a method that selects high priority processes for improvement and shows you how to establish process performance measurements and implement process improvements to maximize quality, safety & efficiency.

Auditing is defined as a systematic and independent examination of data, statements, records, operations and performances (financial or otherwise) of an enterprise for a stated purpose. In any auditing the auditor perceives and recognizes the propositions before him for examination, collects evidence, evaluates the same and on this basis formulates his judgment which is communicated through his audit report.

Historically, the word 'auditing' has been derived from Latin word "audire" which means "to hear". According to Dicksee, traditionally auditing can be understood as an examination of accounting records undertaken with a view to establishing whether they completely reflect the transactions correctly for the related purpose. In addition the auditor also expresses his opinion on the character of the statements of accounts prepared from the accounting records so examined as to whether they portray a true and fair picture.

Quality audits are performed to verify conformance to standards through review of objective evidence. A system of quality audits may verify the effectiveness of a quality management system. This is part of certifications such as NABH, JCI, etc. Quality audits are essential to verify the existence of objective evidence showing conformance to required processes, to assess how successfully processes have been implemented, for judging the effectiveness of achieving any defined target levels, providing evidence concerning reduction and elimination of problem areas and are a hands-on management tool for achieving continual improvement in an organization.

To benefit the organization, quality auditing should not only report non-conformance and corrective actions but also highlight areas of good practice and provide evidence of conformance. In this way, other departments may share information and amend their working practices as a result, also enhancing continual improvement.

With reference to the above stated importance of patient right, education & safety, this Audit on Informed Consent was a part of Continuous Quality improvement initiative was taken up during the summer internship period. The below stated audit parameters were selected from the guidelines of the Hospital. Some of the key points from those Policies were taken up for preparing the audit checklist.

The Parameters selected for the audit are as stated below:

1. **Language Compliance :** The patient should be explained in a language which he understands. For this purpose, he mentions the language understood by him in the consent form. There are Hindi & English forms available; but in case patient mentions a language other than English & Hindi, an interpreter is made available to him.

2. **Diagnosis Compliance:** Doctor should write the name of the disease or ailment the patient is suffering from.

3. **Awareness of Complications:** Patient's consent is considered informed only when he is aware of the potential major complications of the procedure.

4. **Person Performing the procedure:** According to consent SOPs, name of the person who will perform the procedure for which consent is being obtained is mandate to be mentioned.

5. **Compliance of Patient Declaration:** Name, Signature/thumb impression, Date & Time of the person providing the consent has to be present.

6. **Compliance of Patient Representative Declaration:** When the patient/individual cannot give informed consent, the Surrogate consent from the patient representative is obtained in which relationship with the patient and reason of patient not providing the consent has to be mentioned additionally.

7. **Compliance of Interpreter's Declaration:** Complete interpreter's declaration includes name, signatures, date & time of the interpreter (if applicable).

8. **Compliance of Doctor's Declaration:** Name, signatures, date & time of person explaining the procedure and obtaining consent.

9. **Compliance of Witness' Declaration:** Name, signatures, date & time of person witnessing the consent (not applicable for HIV testing and some other consents).

10. **Awareness of Procedure / Technique:** Name of procedure/treatment/operation/test for which consent is being obtained.

11. **Rendering of Post –test Counselling:** In cases like HIV testing.

12. **Availability of Valid Consent:** A single informed consent suffices for procedures carried out frequently or regularly on the same patient (e.g. Dialysis) within the hospital for a period of 30 days provided a verbal consent is obtained each time the procedure is performed. A fresh written consent is obtained whenever fresh information is provided or once every 30 days whichever is earlier.

The Audit was carried out in the following subheads that came under the scope of the Audit in each various departments:

- Consent for Operation Procedure
- Consent for Anaesthesia
- Consent for Chemotherapy
- Consent for HIV testing
- Consent for Receiving Transfusion of Blood
- Consent for Haemodialysis
- General Consent for Admissions
- Nuclear Medicine Generic Consent
- Consent for Discharge Against Medical Advice
- High risk consent
- Radiation therapy consent

METHODOLOGY

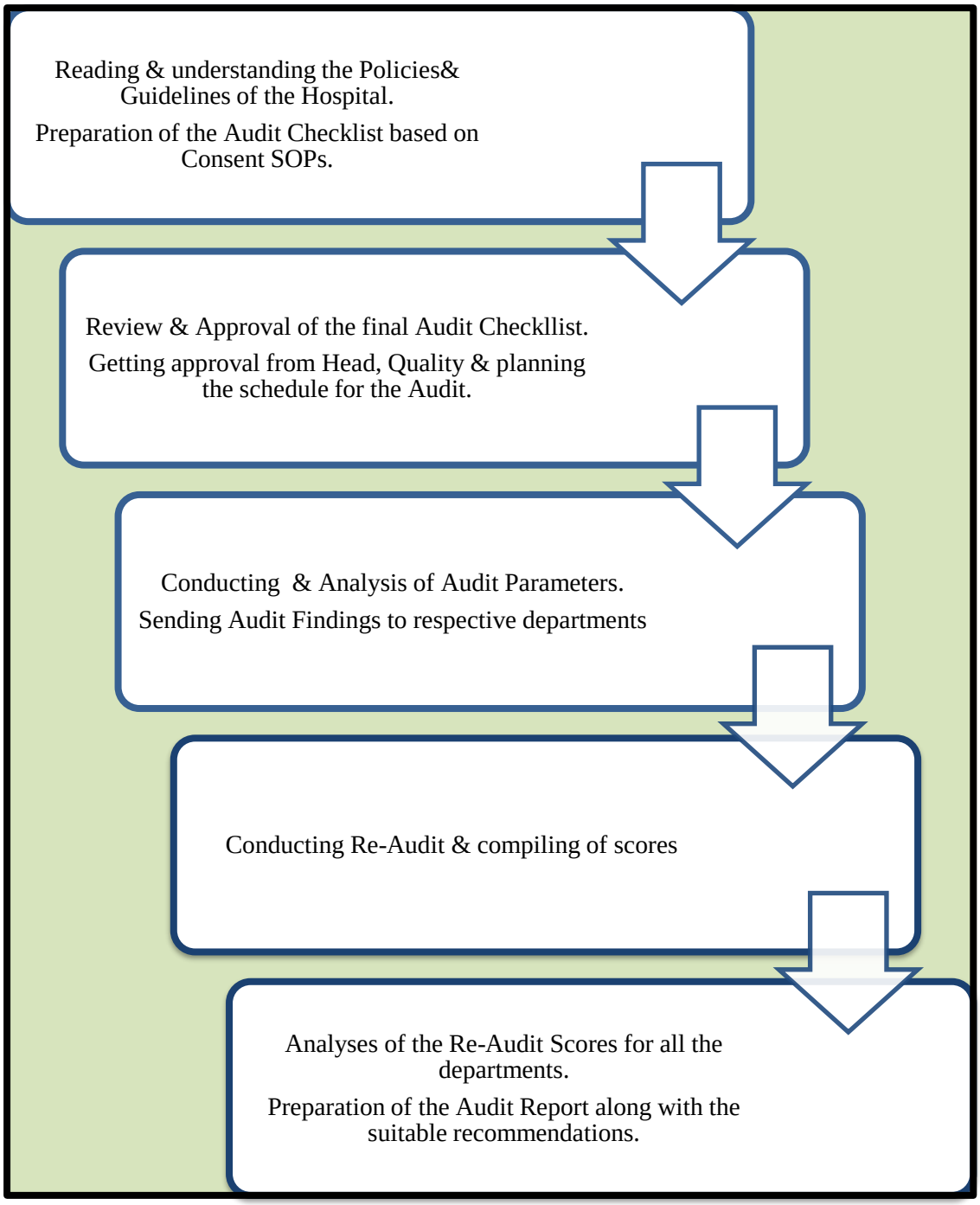
Study design: It is a cross sectional study done on the active files of patients present in the wards.

Data Collection: Primary data was collected for which different checklists were prepared for different types of informed consent forms based both on the consent forms and the consent SOPs.

Sampling: Random sampling done. Different sample size for different departments was selected.

The following section describes in detail the process followed for the Audit.

PROCESS FLOW



Calculation

All the calculations were done with the help of Ms Excel.

- Equal weight-age was given to all Parameters.

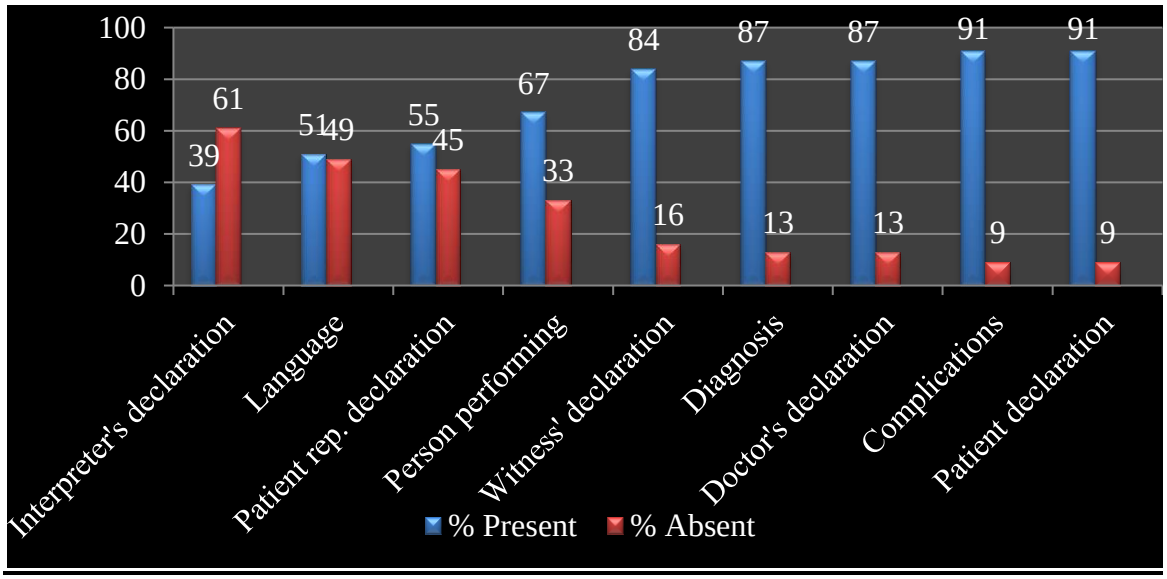
- In case of compliance (presence) - ‘P’ mentioned in Ms Excel and in case of non compliance (absence) – ‘A’ mentioned in Ms Excel.
- For each of the Parameter the total sum of the scores was calculated for each of the departments.
- The not applicable areas were removed from the checklist.

DEPARTMENTAL ANALYSIS & GRAPHICAL REPRESENTATION

Consent for operation/procedure

- Area covered-
    - Nightingale ward
    - Day care
    - 3rd floor
    - 4th floor
- Sample size- 55
- Specialty
    - Neurosurgery- 14
    - Obs/Gyn- 10
    - GI, Minimal access & Bariatric- 8
    - Orthopaedics- 7
    - Paediatric (Surgery+ Ortho)- 5
    - Endoscopy-3
    - Oncology- 2
    - Internal medicine- 2
    - CTVS- 2
    - IVF- 1
    - ENT-1

Percentage compliance in consent for operation/procedure



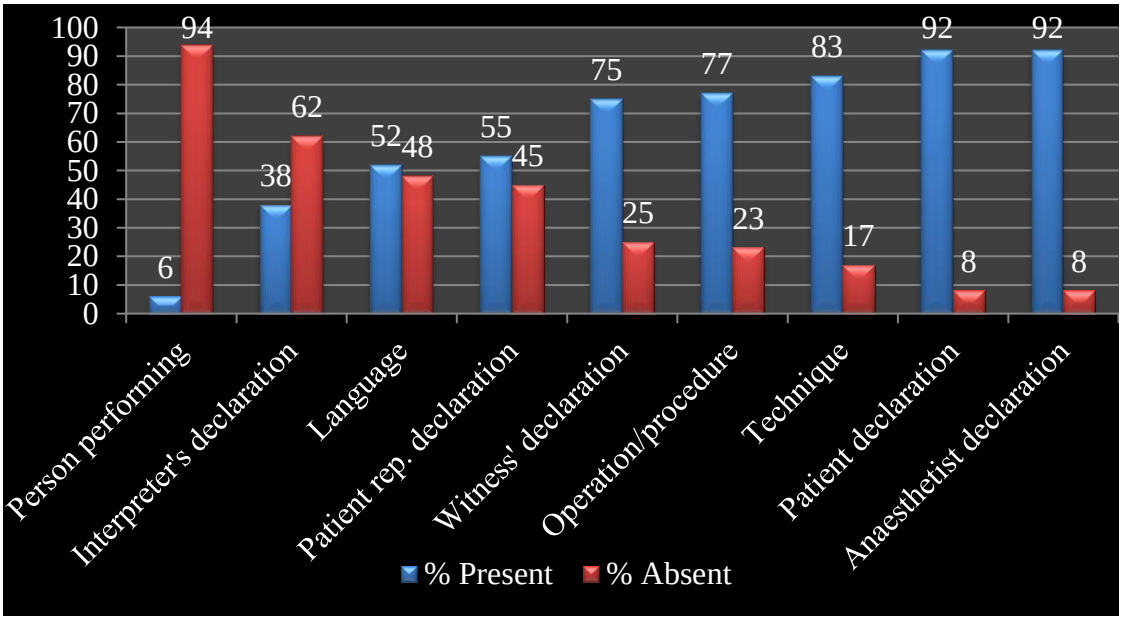
Interpretation:

- The major factor causing non compliance is interpreter's declaration. Out of 61% non compliance, in 22%- interpreter was required but absent. In 35% cases, language was not mentioned so we don't know if interpreter was required or not. And in rest 4%, declaration was present but was incomplete i.e. date and time was absent.
- Language understood by the patient was mentioned only in 51% cases. Out of 49% non compliance, in 22% language was not mentioned and in 27% inappropriate consent was taken as language mentioned by the patient was Hindi whereas form used was English.
- Complete authorisation by patient representative was present only in 55% of the applicable cases.
    - ✓ Reason absent-9%
    - ✓ Relationship absent- 27%
    - ✓ Signatures absent- 9%
    - ✓ Date absent- 9%
    - ✓ Time absent- 27%
- Name of person performing the procedure was absent in 33% of the cases.

- Non compliance in witness's declaration was found in 16% cases. Out of these, it was completely absent in 4% cases and was present but incomplete in 12%.
- Name of the disease/ailment (diagnosis) from which he patient was suffering was absent in 13% of cases.
- Incomplete doctor's declaration was found to be present in 13% cases (Date and time of consent absent)
- Complications of the operation/procedure were not mentioned in 9% cases.
- Incomplete declaration by patients found in 9% cases (date and time of giving the consent absent).
- In 16% of cases, person signing the consent was different from the name mentioned (under doctor's declaration). So the point of concern is whether the person was from the team performing the procedure & capable of explaining the details of the consent or not.

Percentage compliance in consent for anaesthesia

Sample size- 48

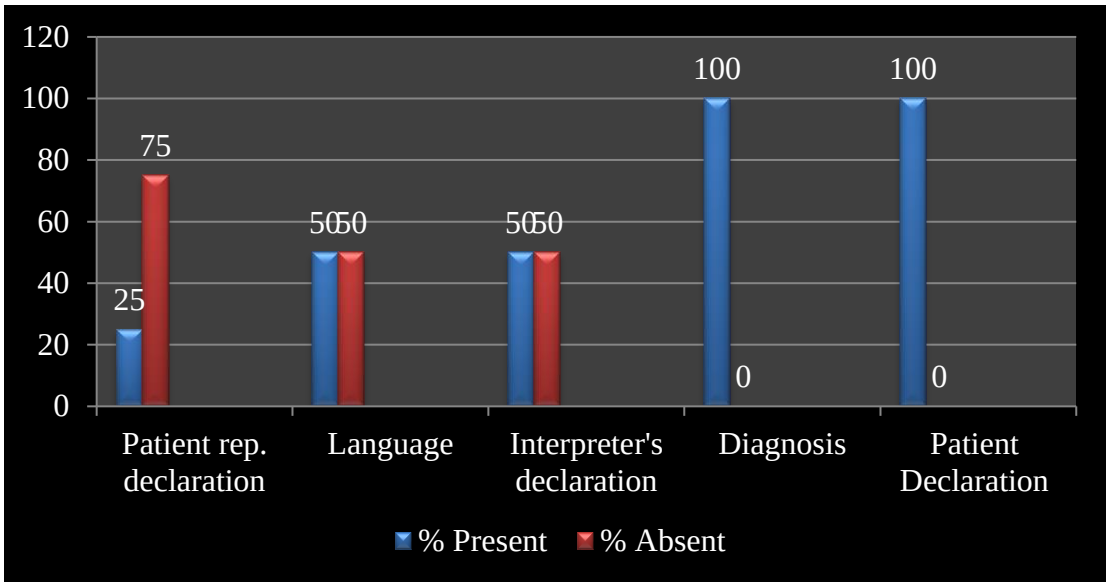


Interpretation:

- The major factor causing non compliance in consent for anaesthesia is that the name of the person performing the anaesthesia was absent in 94% of the cases.
- In interpreter's declaration, out of 62% non compliance, in 8%, interpreter was required but absent. In 54% cases, language was not mentioned so we don't know if interpreter was required or not.
- Language understood by the patient was mentioned only in 52% cases. Out of 48% non compliance, in 33% language was not mentioned and in 15% inappropriate consent was taken as language mentioned by the patient was Hindi whereas form used was English.
- Complete authorisation by patient representative was present only in 55% of the applicable cases.
    - ✓ Reason absent-36%
    - ✓ Relationship absent- 27%
    - ✓ Name & Signatures absent- 9%
    - ✓ Date absent- 18%
    - ✓ Time absent- 27%
- Non compliance in witness's declaration was found in 25% cases. Out of these, it was completely absent in 10% cases and was present but incomplete in 15%.
- Name of the operation/procedure absent in 23% cases.
- Technique of the anaesthesia not mentioned in 17% cases.
- Non compliance in patient's declaration in 8% (Date & Time absent)
- Incomplete anaesthetist's declaration in 8% cases (Time absent)
- One patient underwent hysteroscopy, but no consent for operation/procedure was taken. Only the consent for anaesthesia was present.
- In one case of international patient, interpreter signed in place of patient representative. No patient's and interpreter's signatures present otherwise.

Percentage compliance in consent for chemotherapy

Sample size- 8

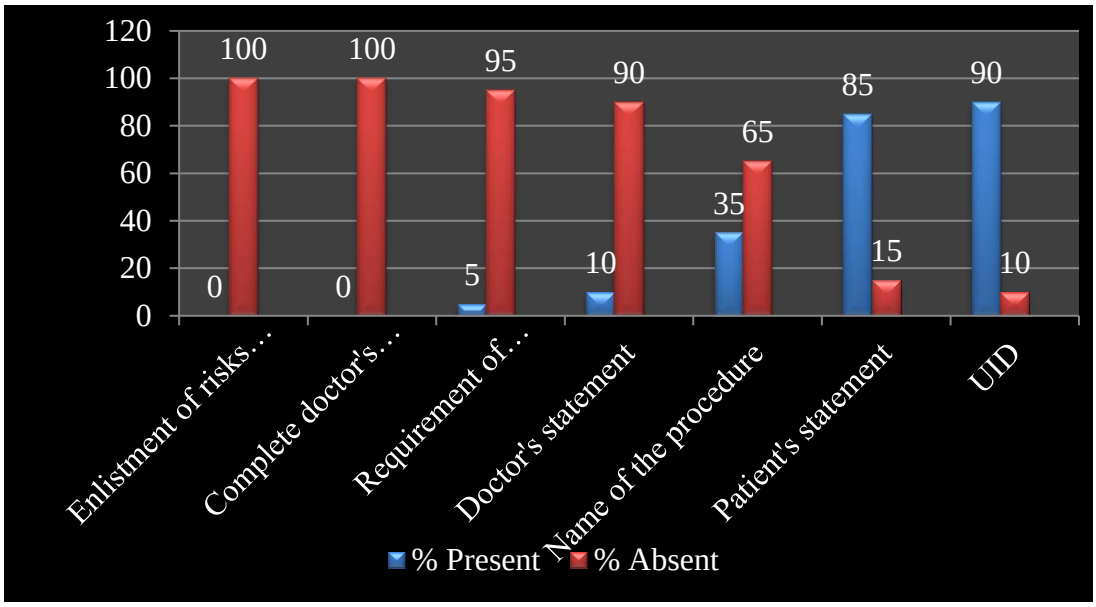


Interpretation:

- In authorization by patient representative, reason and relationship absent- 75%
- Language understood by the patient was mentioned only in 50% cases. Out of 50% non compliance, in 17% language was not mentioned and in 33% inappropriate consent was taken as language mentioned by the patient was Hindi whereas form used was English.
- In interpreter's declaration, out of 50% non compliance, language was not mentioned so we don't know if interpreter was required or not.
- In one case, patient was minor (17 years) but signed the consent himself.
- In two cases, no consent was taken during any of the inpatient episodes.
- In another case, no consent taken during first 3 episodes. 4th & 5th episodes were for supportive care. Consent finally taken during 6th episode.
- All consents taken by resident doctors.

Percentage compliance in nuclear medicine generic consent

Sample size- 20

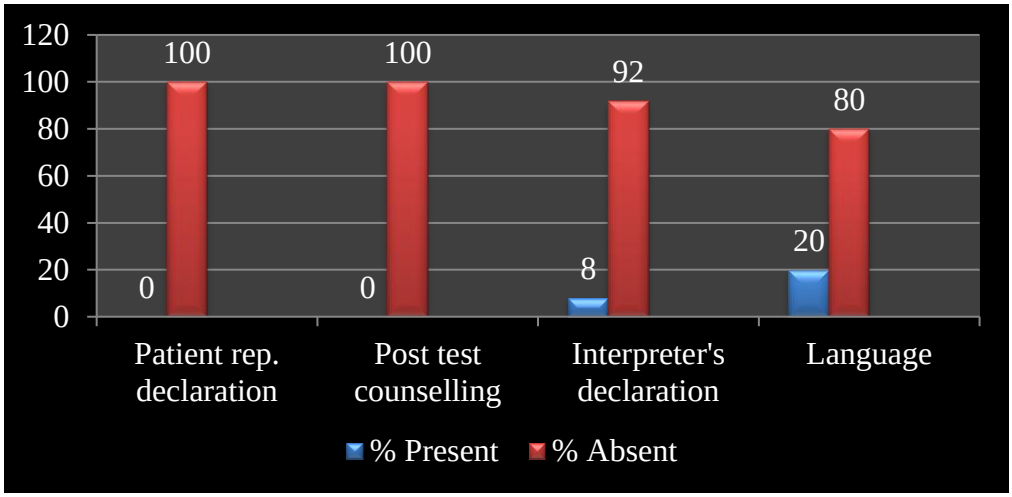


Interpretation:

- In no case (out of 20), risks involved were enlisted.
- Non compliance in doctor's declaration was found in 100%. It was entirely absent in 90% cases while in rest 10%, it was incomplete (Date & Time absent).
- Interpreter:
  - ✓ 5%- Requirement mentioned & present.
  - ✓ 95%- Requirement not mentioned. So it is not known whether interpreter was required or not.
- Name of the procedure not mentioned in 65% cases.
- Non compliance in patient statement found in 15%.
- UID not mentioned - 2 cases (10%)
- In one case, patient underwent PET but apart from the patient's name, nothing was mentioned (not even the UID & patient's signatures).
- Total number of complete & appropriate forms- 0

Percentage compliance in consent for HIV testing

Sample size- 15

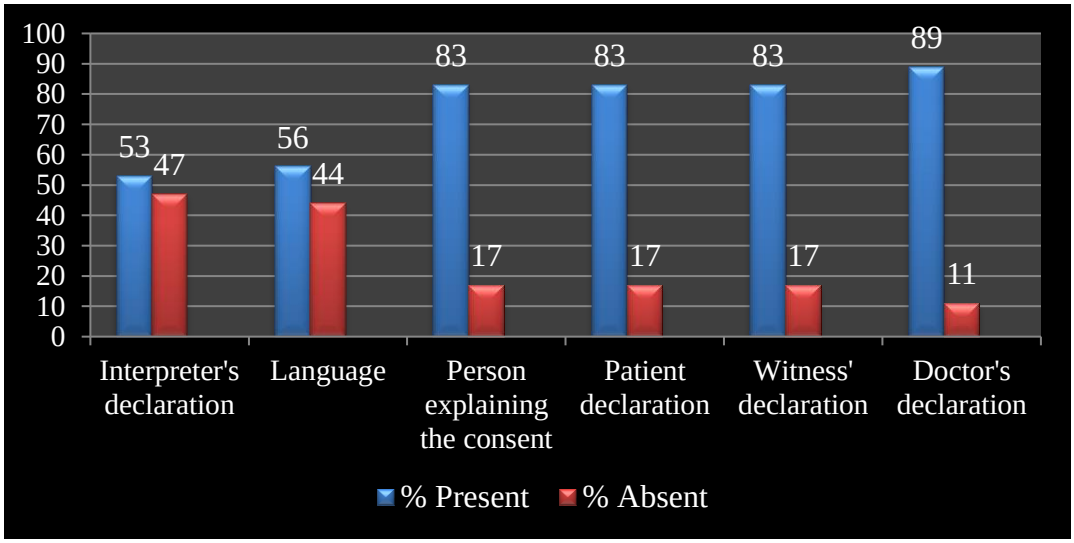


Interpretation:

- In none of the cases, patient representative declaration was complete i.e. 100% non compliance.
    - ✓ Reason absent- 25%
    - ✓ Relationship absent- 75%
    - ✓ Time absent- 62.5%
- Post test counselling was either not done or not documented in 100% of the cases.
- In interpreter's declaration, out of 92% non compliance, in 58%- interpreter was required but absent. In 34% cases, language was not mentioned so we don't know if interpreter was required or not.
- Language understood by the patient was mentioned only in 20% cases. Out of 80% non compliance, in 67% language was not mentioned and in 13% inappropriate consent was taken as language mentioned by the patient was Hindi whereas form used was English.
- 11/15 consent obtained by resident doctors.

Percentage compliance in Radiation therapy consent

Sample size- 18

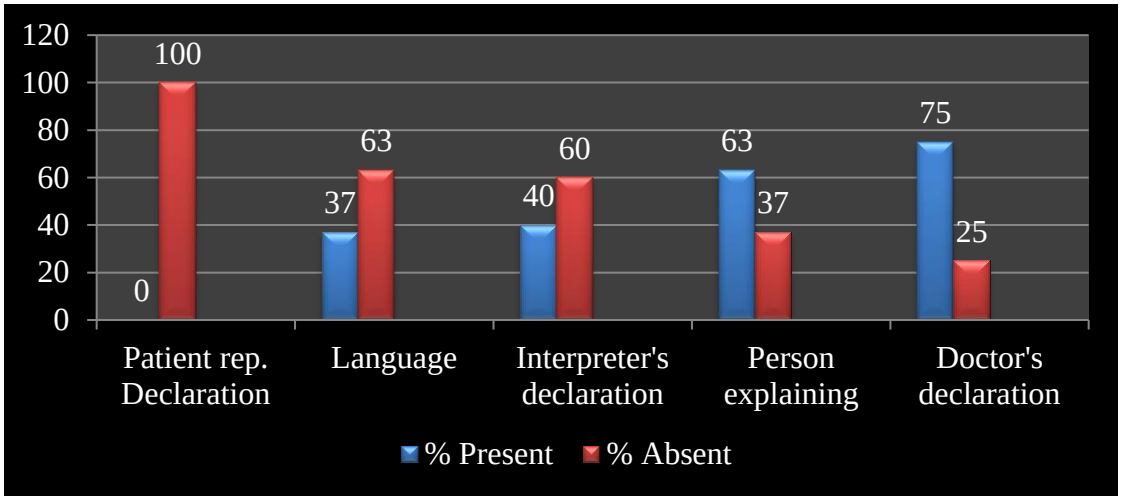


Interpretation:

- Non compliance in interpreter's declaration was found in 47% as language understood by the patient was not mentioned. So it is not known whether the interpreter was required or not.
- Language understood by the patient was not mentioned in 44% of the cases.
- Name of the person explaining the consent was not written in 17% cases.
- Witness' declaration was completely absent in 1 file while it was incomplete in 2 cases accounting to non compliance of 17%
- Incomplete doctor's declaration in 11% (Time not mentioned).

Percentage compliance in consent for receiving transfusion of blood

Sample size- 8

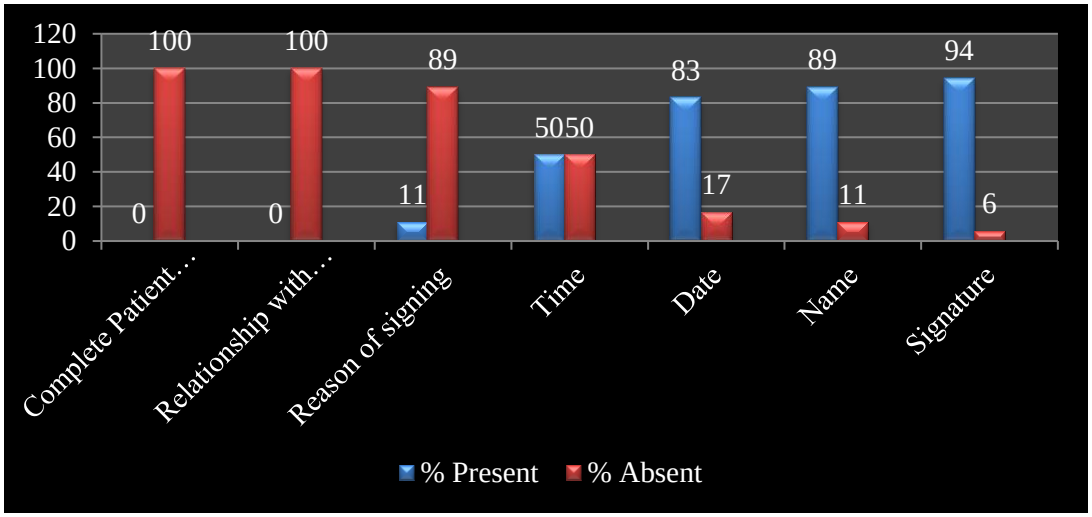


Interpretation:

- Non compliance in patient representative declaration found in 100%
    - ✓ Reason absent-50%
    - ✓ Relationship absent- 100%
- Language understood by the patient was mentioned only in 37% cases. Out of 63% non compliance; in 25% language was not mentioned and in 38% inappropriate consent was taken as language mentioned by the patient was Hindi whereas form used was English.
- In interpreter's declaration, out of 60% non compliance, interpreter was required but absent in 20%, in 20%-language was not mentioned so we do not know whether interpreter was required or not and in rest 20% declaration was incomplete.
- Name of the person explaining the consent absent in 37%.
- Doctor's declaration was incomplete in 25% cases (Time not mentioned).
- All the consents were taken by resident doctors
- In one case, patient was minor (16 years) but signed the consent himself.

Percentage compliance in general consent for admission

Sample size- 18

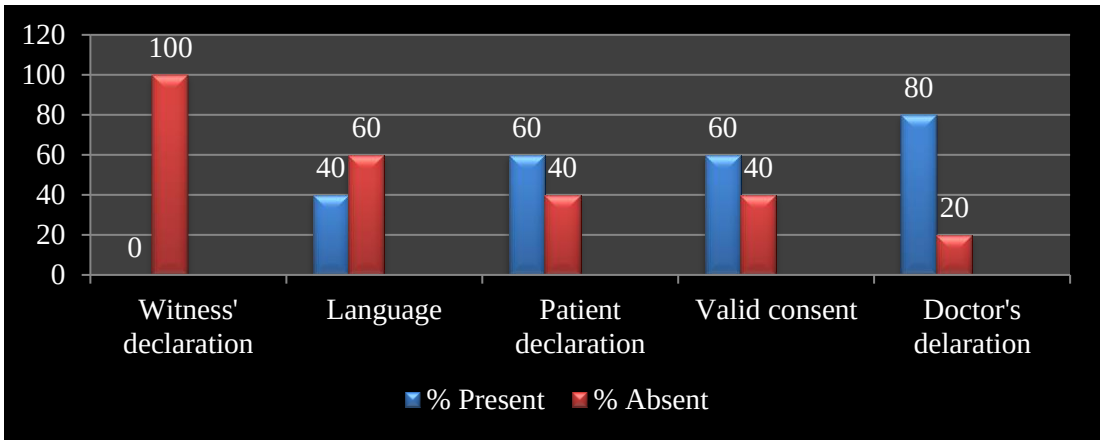


Interpretation:

- Complete patient representative declaration was absent in -100% cases.
    - ✓ Relationship absent – 100%
    - ✓ Reason – 89%
    - ✓ Time- 50%
    - ✓ Date- 17%
    - ✓ Name- 11%
    - ✓ Signatures- 6%

Percentage compliance in consent for haemodialysis

Sample size- 5

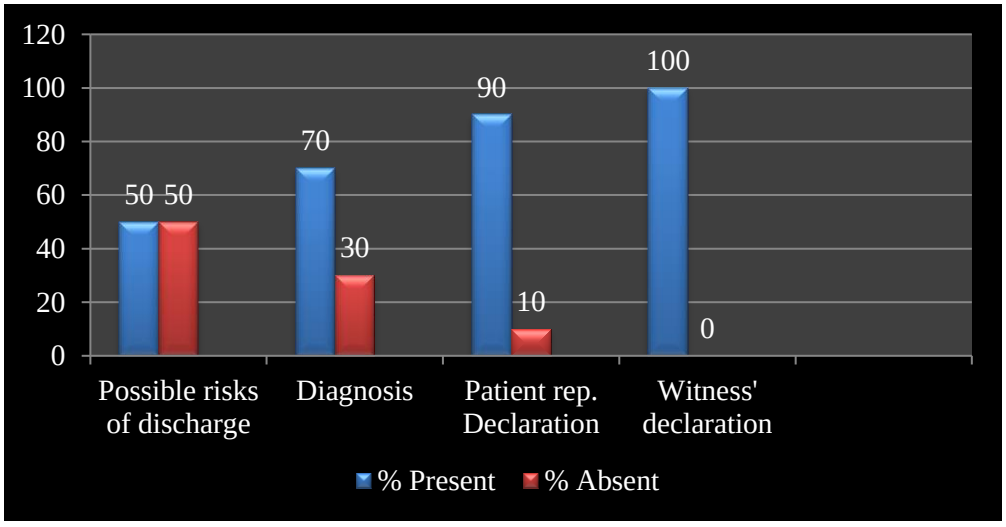


Interpretation:

- Witness's declaration absent in 100% of the files audited.
- Language understood by the patient was mentioned only in 40% cases. Out of 60% non compliance, in 40% language was not mentioned and in 20% inappropriate consent was taken as language mentioned by the patient was Hindi whereas form used was English.
- Patient declaration incomplete in 40% cases.
- Consent not valid in 40% cases (initial consent older than 30 days and fresh consent was not taken).
- Doctor's declaration incomplete in 20%

Percentage compliance in Discharge Against Medical Advice

Sample size- 10

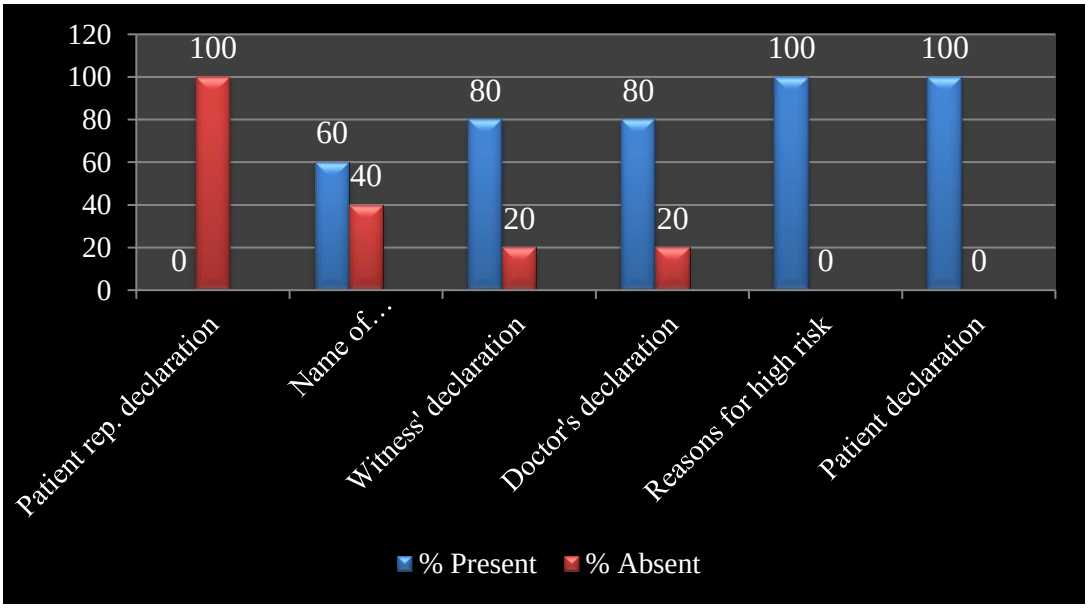


Interpretation:

- Possible risks of discharge not documented in 50% of the cases.
- Patient's diagnosis not mentioned in 30%
- Incomplete declaration by patient representative in 10% cases.
- Compliance in witness' declaration- 100%

Percentage compliance in high risk consent

Sample size- 5



Interpretation:

- Incomplete authorisation by patient representative found in 100% cases.
- Name of surgery/anaesthesia/operation not mentioned in 40% cases.
- Incomplete witness' declaration found in 20% (Time not mentioned)
- Incomplete doctor's declaration found in 20% (Time not mentioned)

For the purpose of extracting the main reason of non compliance in all types of informed consent forms, division of all the parameters of the checklist into various stakeholders has been done who are directly or indirectly responsible for appropriate obtainment of consent.

Various stakeholders with inclusive parameters are:

1. Doctors

    - ✓ Diagnosis
    - ✓ Name of operation/procedure
    - ✓ Enlistment of complications
    - ✓ Name of person explaining the consent
    - ✓ Name of person performing the procedure
    - ✓ Doctor's/anaesthetist's declaration
    - ✓ Post test counselling (In HIV testing)
    - ✓ Language understood by the patient

2. Nurses

    - ✓ Ensuring that forms used are Hindi when language understood by the patient is Hindi or by placing copies of consent forms in both English & Hindi
    - ✓ Ensuring that fresh or valid consent is taken (eg. In case of haemodialysis consent not older than 30 days should be used)

3. Patients

    - ✓ Language understood
    - ✓ Patient's declaration
    - ✓ Patient representative declaration

4. Interpreters

    - ✓ Interpreter's declaration

Number of errors due to various stakeholders (in total sample of 210)

1. Due to doctors

a) Errors related to diagnosis- 10 (71 maximum errors possible)
b) Errors related to name of operation/procedure- 28 (out of 128 possible errors)
c) Errors related to enlistment of complications- 30 (80)
d) Errors related to name of person explaining the consent- 7 (81)
e) Errors related to Name of person performing the procedure – 63 (103)
f) Errors related to Doctor's/anaesthetist's declaration- 102 (684)
g) Errors related to post test counselling- 15 (15)
h) Errors related to Language understood by the patient- 70 (175)

Total errors committees by doctors- 325 (Out of maximum1337 probable errors)

2. Due to Nurses

a) Errors related to form in English and language in Hindi – 30 (137)
b) Errors related to validity of consent- 2 (5)

3. Due to patients

Errors related to patients and patients representative declaration – 117 (912)

4. Due to interpreter

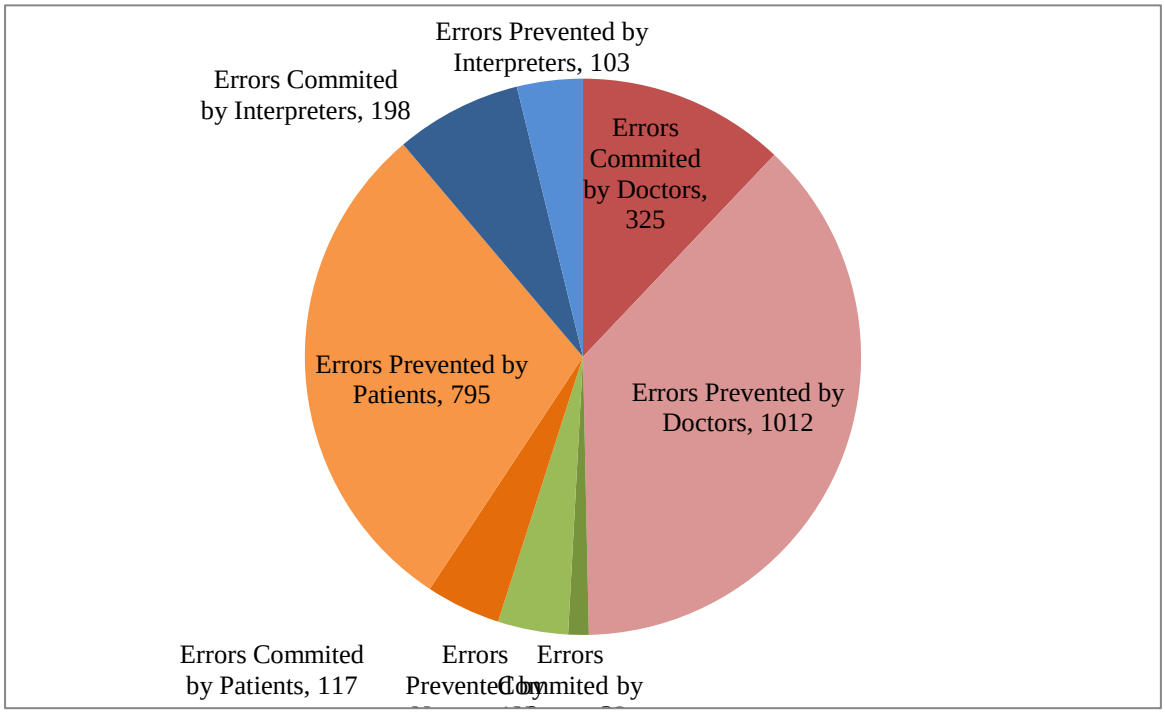
Errors related to interpreter's declaration- 198 (301)

Total number of errors = 672

Total number of maximum possible errors= 2692

Comparing the non compliance amongst stakeholders

	Errors committed	Maximum possible errors	Probability of non compliance
By Doctors	325	1337	0.243
By Nurses	32	142	0.225
By Patients	117	912	0.128
By interpreters	198	301	0.658



From the findings, it can be seen that interpreters are committing maximum errors. The probability of interpreter committing an error is approximately 66%, while that by the patients is minimum i.e. 13%. So even if the stakeholders from the hospital's side are aimed at, we can have a considerable increase in the compliance percentage in the informed consent.

Qualitative considerations to six sigma

After the detailed analysis of the data, we can also quote sigma rating for each stakeholder involved to rationalise their standing in the quality parameter of six sigma. The various incomplete, inappropriate and non compliant consent forms were considered as non conformity in comparison with the maximum possible errors that can be committed by each stakeholder.

Name of stakeholder	Sigma rating in accordance with compliance during audit
Doctors	2.699
Nurses	2.302
Patients	2.992
Interpreters	2.356

{2 sigma level = 308537 non compliant consent forms per million consent forms}{3 sigma level = 66807 non compliant consent forms per million consent forms}

SUGGESTIVE MEASURES ADVISED TO BE PRACTICED

It is clear from the findings that out of total 301 possible errors that can be committed by interpreters, only 103 are being prevented. Such high rate can be prevented by:

- Increasing the number of interpreters available.
- Training the interpreters
- Promotional measures
- Ensuring presence of respective interpreters every time the consent is taken/explained (wherever applicable)

Types of languages used commonly	Interpreter available (Internal)	Interpreter available (External)
Arabic	4	0
French	0	5
Pushto	1	1
Farsi	1	1
Congo	0	5

So there is a need of increasing the internal interpreters in the organisation and train the existing ones.

Out of total 1337 possible errors that can be committed by doctors, 1012 are being prevented. So the probability of a doctor committing an error is 24.3%. For this

- Doctors/physicians should be trained regarding all the consent SOPs that the organisation follows.
- Doctor obtaining the consent is actually responsible for ensuring that all the details have to be filled and documented.
- Making doctors aware of the legal complications that can follow due to non-compliance.

The probability of nurses committing error is 22.5%. Out of 142 possible errors, 110 are being prevented by the nurses. 100% errors can be prevented at the nurses' end if they ascertain that there is always a Hindi copy available of all the forms in every patient file so that more number of appropriate consent can be taken according to the language which the patient understands.

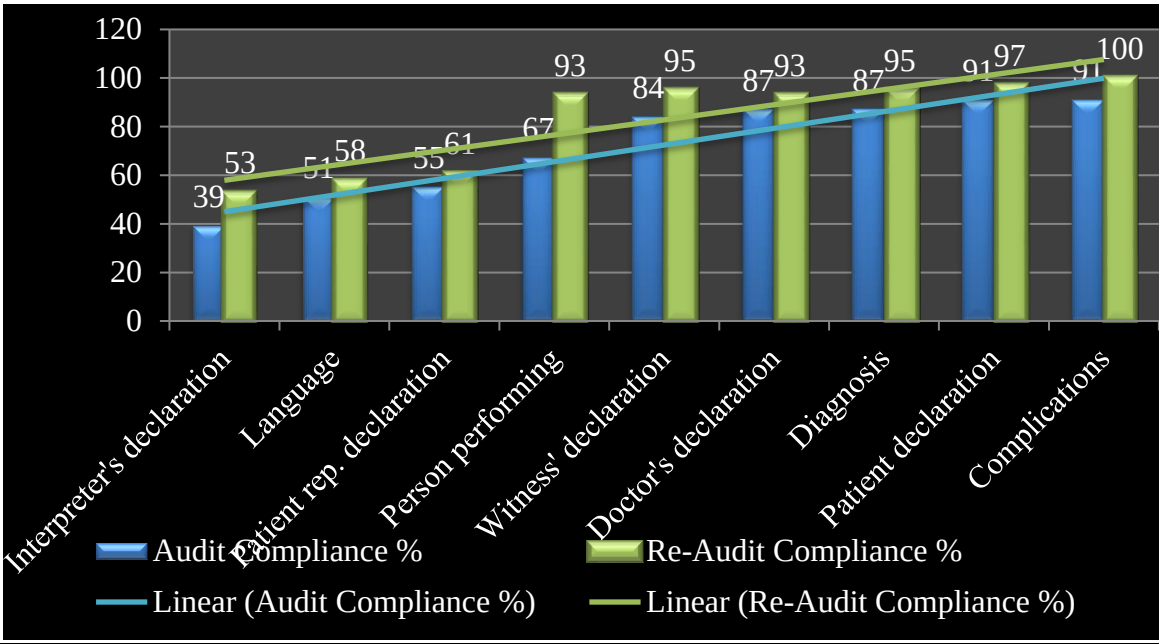
For improvement in compliance at the patient's end, the person (which in most cases is a doctor/physician) obtaining the consent was trained to ensure the appropriate and complete filling of the forms by patients/representatives.

CORRECTIVE MEASURES TAKEN

- The detailed analysis and findings of audit were dispatched to various departments and respective SBU heads
- Various suggestions were welcomed on the basis of root cause analysis by each department.
- Trainings were scheduled for doctors, nurses and interpreters regarding the consent SOPs.
- Copies of all types of consent forms in regional language were ordered to be placed in each respective departments and nursing stations so that inappropriate obtainment of the consent is avoided.

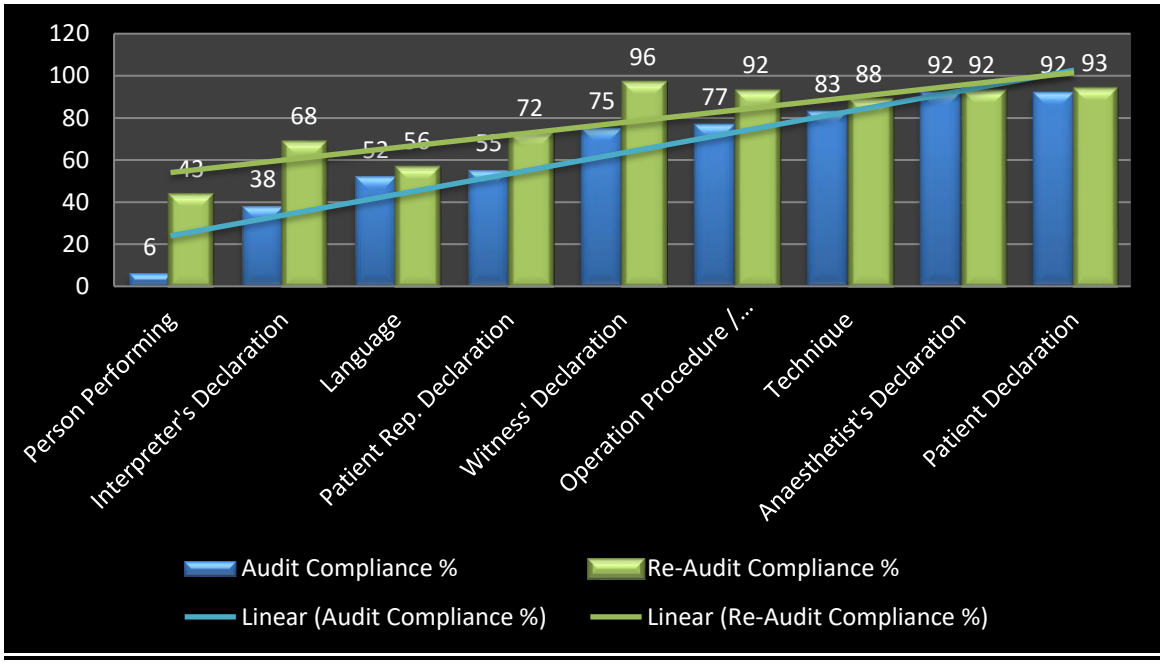
ANALYSIS & GRAPHICAL REPRESENTATION OF RE-AUDIT

Improvement in compliance in consent for operation/procedure



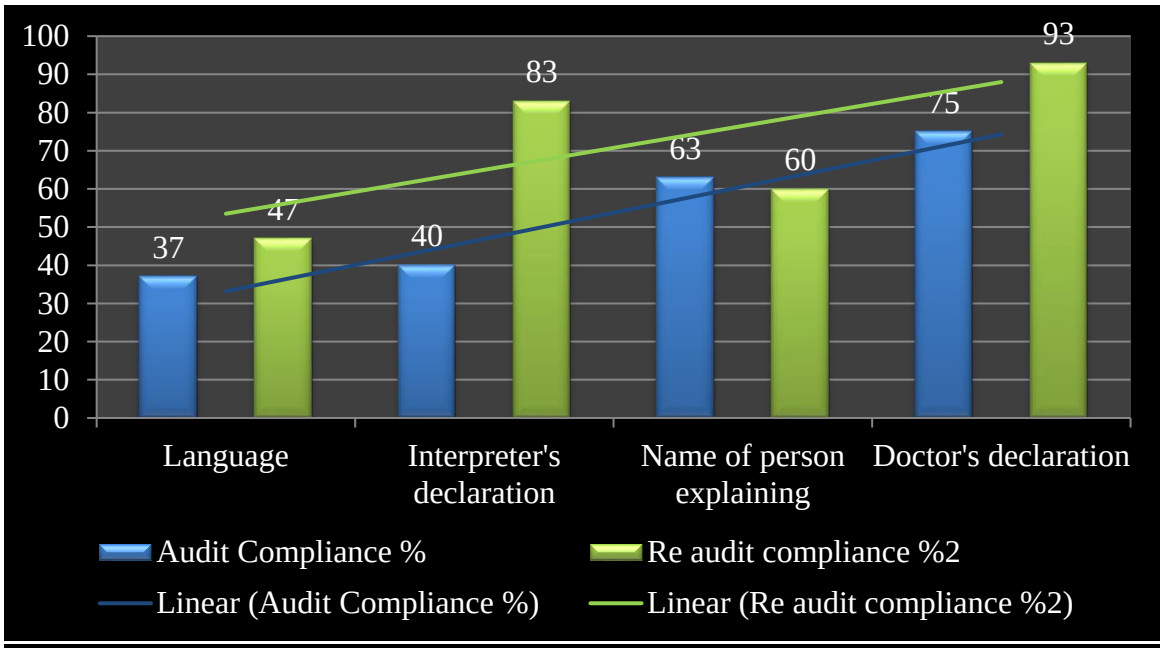
On comparing the compliance level of different parameters during audit and re audit, it can be seen that percentage of compliance is increasing in all the parameters proportionately in re audit.

Improvement in compliance in consent for anaesthesia



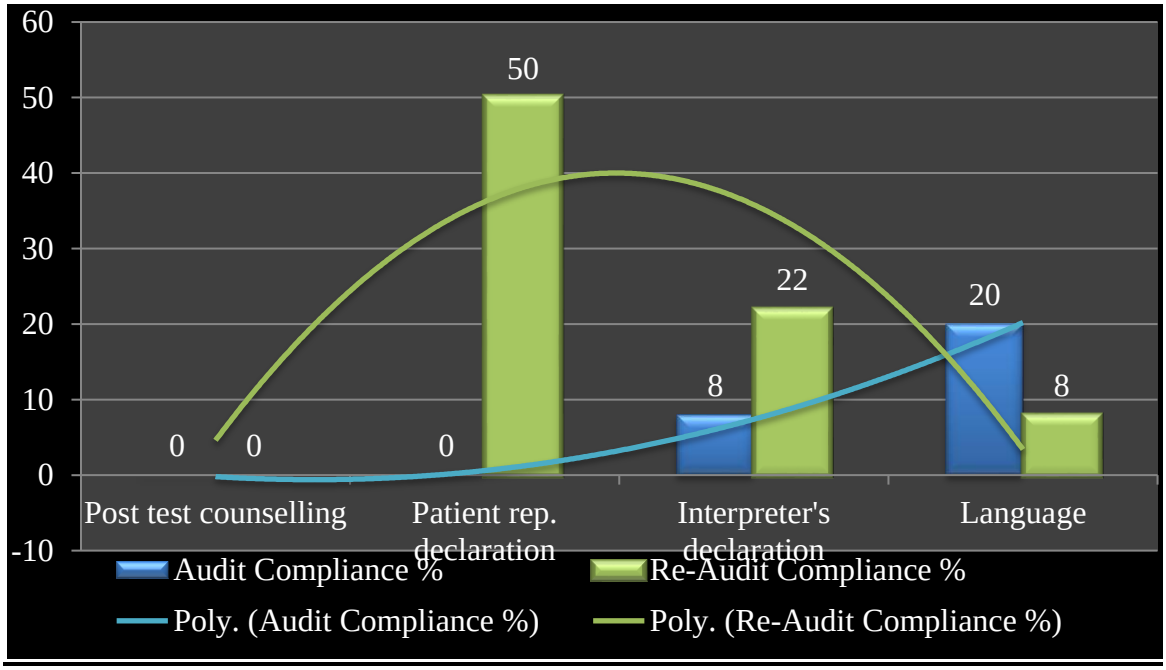
Comparison between parameters during audit and re-audit reveals that compliance has increased greatly in most of the parameters during re-audit except in anaesthetist's and patient's declaration where it remains almost the same.

Improvement in compliance in consent for blood transfusion



Comparison shows the marked improvement in compliance during re-audit.

Improvement in compliance in consent for HIV testing



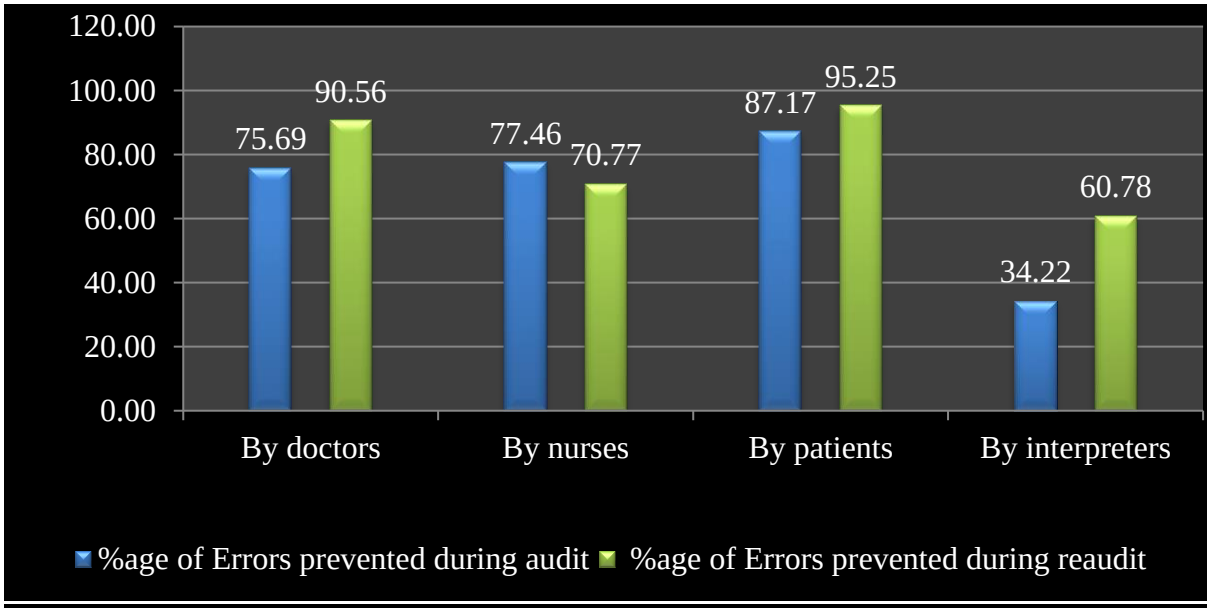
Compliance percentage comparisons shows improvement in the part of patient representative's and interpreter's declaration but compliance in documenting the language has decreased on the contrary during re-audit.

OVERALL FINDINGS OF RE-AUDIT

Gaps prevalent in all respective stakeholders

	Errors committed	Maximum possible errors	Probability of non compliance in re-audit
By Doctors	99	1049	0.0944
By Nurses	38	130	0.293
By Patients	29	610	0.0475
By interpreters	80	204	0.3921

Comparing the number of errors prevented by each stakeholder during the audit & re-audit



It can be seen that there is a increase in the number of possible errors prevented by doctors, patients and interpreters. Maximum increment made by the interpreters. But the preventable errors by nurses have decreased on the contrary signifying more concrete efforts towards the nurses' training.

Qualitative Reconsiderations to six sigma

After the detailed re-analysis of the data, we can also quote sigma rating for each stakeholder involved to rationalise their standing in the quality parameter of six sigma. The various incomplete, inappropriate and non compliant consent forms were considered as non conformity in comparison with the maximum possible errors that can be committed by each stakeholder in re-audit phase.

Name of stakeholder	Sigma rating in accordance with compliance during audit	Sigma rating in accordance with compliance during re-audit
Doctors	2.699	**2.969**
Nurses	2.302	**2.047**
Patients	2.992	**3.738**
Interpreters	2.356	**3.344**

{2 sigma level = 308537 non compliant consent forms per million consent forms}{3 sigma level = 66807 non compliant consent forms per million consent forms}

RECOMMENDATIONS

The following recommendations were suggested in order to achieve the target Compliance level in informed consent:

1. Preparation of effective training material/toolkit for all stakeholders.
2. Planning for a Training schedule & training
3. Various promotional marketing strategies e.g., hoardings, posters, etc can be incorporated to increase the awareness about importance of complete and appropriate documentation of consent forms.
4. Conducting third round of audit in all the departments after certain interval, giving them time for closure of the gaps & a chance of showing improvement.
5. Displaying on the Executive Quality Dashboard of the Department
6. Setting up an online platform for benchmarking practices within FMRI
7. Making regular arrangements for trainers and coordinators with supplemented skill brush up classes for nurses and interpreters.
8. Keeping track of incidents related to informed consent process by using CQI processes to monitor incidents related to informed consent.

LIMITATIONS:

- Interviewing the patients was not permissible.
- Witnessing the process of obtaining the consent actively could not be done considering the patient's confidentiality.
- Less time for intervention period.
- Re-auditing of all the types audited could not be done due to time limitation.

Annex – A:Audit Checklist of Various Forms

1. Checklist for consent for operation/procedureoperation.xlsx
2. Checklist for consent for anesthesia anaesthesia.xlsx
3. Checklist for consent for chemotherapy chemo.xlsx
4. Checklist for consent for receiving transfusion of blood blood transfusion.xlsx
5. Checklist for consent for HIV testing hiv.xlsx
6. Nuclear medicine generic consent nuclear medicine generic consent.xlsx
7. Checklist for Radiation therapy consent Radiation therapy consent.xlsx
8. Checklist for general consent for admission general.xlsx
9. Checklist for discharge against medical advice dama.xlsx
10. Checklist for high risk consent high risk.xlsx
11. Checklist for consent for haemodialysis haemodialysis.xlsx

Annex – B: Re-Audit Checklist of Various Forms

1. Checklist for consent for operation/procedure operation reaudit.xlsx

2. Checklist for consent for anesthesia anaesthesia re audit.xlsx

3. Checklist for consent for chemotherapy re- chemo.xlsx

4. Checklist for consent for receiving transfusion of blood blood transfusion re audit.xlsx

5. Checklist for consent for HIV testing hiv reaudit.xlsx