

**“Evaluating Consent Form Compliance Practices to Enhance Legal and
Ethical Standards in a
Multispecialty Healthcare Institution”**

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Introduction

- Consent is the willingness of a party to undergo examination / procedure / treatment by healthcare provider. It may be implied (ie; patient registering in OPD) or expressed (which may be written or verbal). As a legal document, it is one of the most important part of communication in medical field. In many of the medico legal cases, court decisions are with the remark “no proper consent”. Consent means understanding treatment options and making the right decisions on the information provided. Legally the patient is required to agree to the procedure or treatment suggested by the doctor for the medical condition.
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- Incomplete information about the patient diagnosis, therapeutic plan etc. is a commission rather than an omission. Unfortunately, due to many reasons this part is underestimated and missed by the treating doctors. Hence the consent form compliance becomes a very powerful tool to ensure higher degree of indemnity for the concerned hospital. This is the reason why I chose to do my project on Consent form Compliance.
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- My project work would help in assessing the current situation pertaining to practices and process involved in ensuring the required compliance for consent forms. It would also throw light on the shortcomings if any and also to identify areas of improvement. My project work was at a multispecialty hospital near Pune Station. The hospital has 600 beds and over 1500 paramedical staff in employment.
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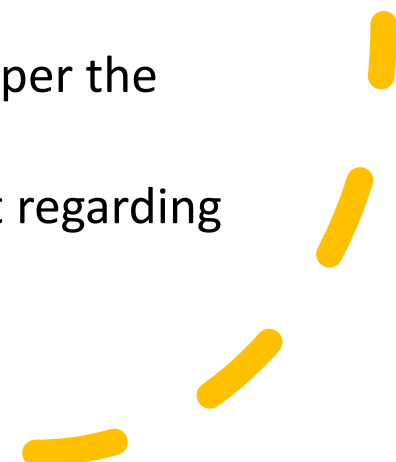


AIM & OBJECTIVES

Aim

- To study the compliance rate of consent policies in a multispecialty hospital and recommend improvements.

Objectives

- To study the types of consent forms and understand the consent policies.
 - To study the rate of compliance as per the hospital policies.
 - To study the areas of improvement regarding compliance of consent policies.
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RESEARCH METHODOLOGY

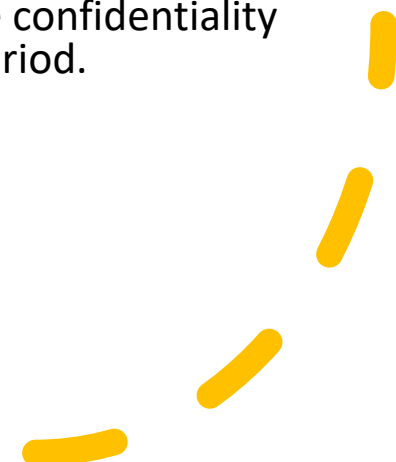
Research Location:

- Multispecialty Hospital
- Dhole Patil road,
- Pune, Maharashtra.

Research Period and Sample Size:

- Research term/Period: From 10th March to 31st May 2025 .
- Sample size: Total 100 consent forms covering different departments.
- Sampling technique: Simple random sampling
- While surveying ethical considerations like confidentiality has been prioritized throughout the study period.

Data Collection Tool's

- Consent completion checklist
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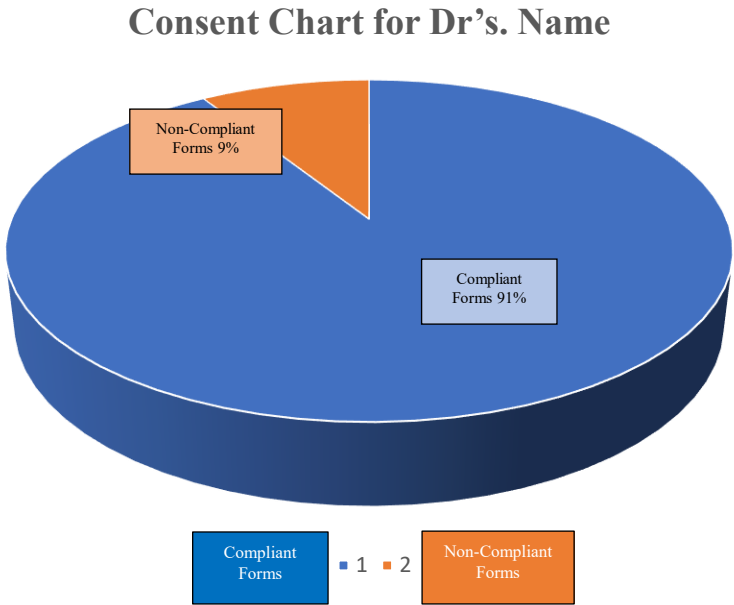


OBSERVATIONS & RESULTS

Table no: 01
Consent Data for DR's Name Entries

	DR's NAME
Applicable forms	100
Compliance	91
Compliance Rate %	91%
Non-Compliance Rate%	9%

Chart no: 01

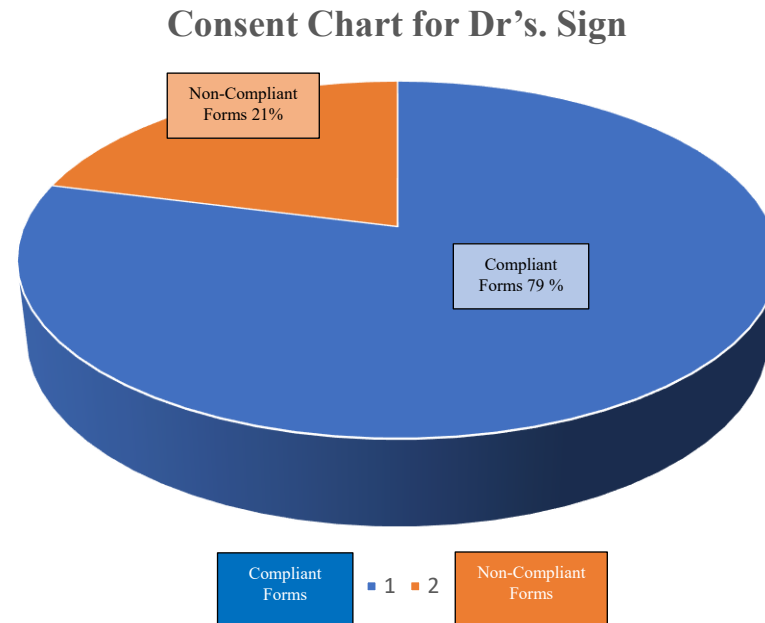


91 % of the forms had Doctor's name compliance
9 % of the forms were non-compliant as Doctor's name was not mentioned

Table no: 02
Consent Data for Dr's Signature

	DR'S SIGN
Applicable forms	100
Compliance	79
Compliance Rate %	79%
Non-Compliance Rate%	21%

Chart no: 02



9 % of the forms had Doctor's sign compliance

21 % of the forms were non-compliant as Doctor's sign was missing.

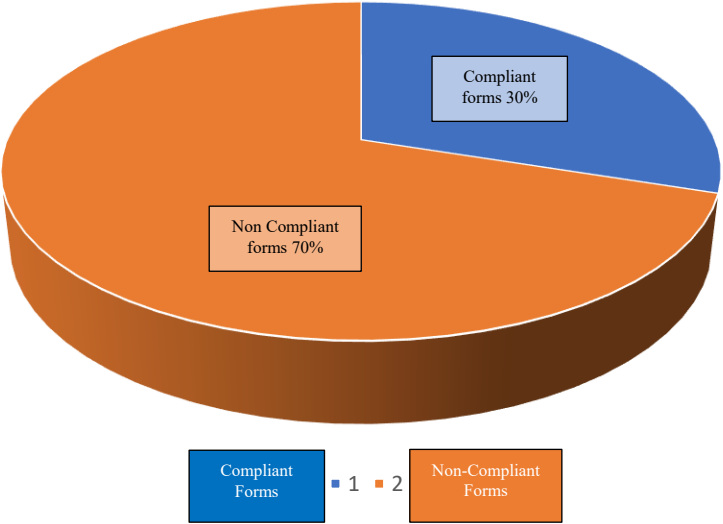
Table no: 03:

Consent Data for Witness Name Entries

	WITNESS NAME
Applicable forms	84
Compliance	25
Compliance Rate %	30%
Non-Compliance Rate%	70%

Chart no: 03

Consent Chart for Witness Name



30% of the forms had witness name compliance

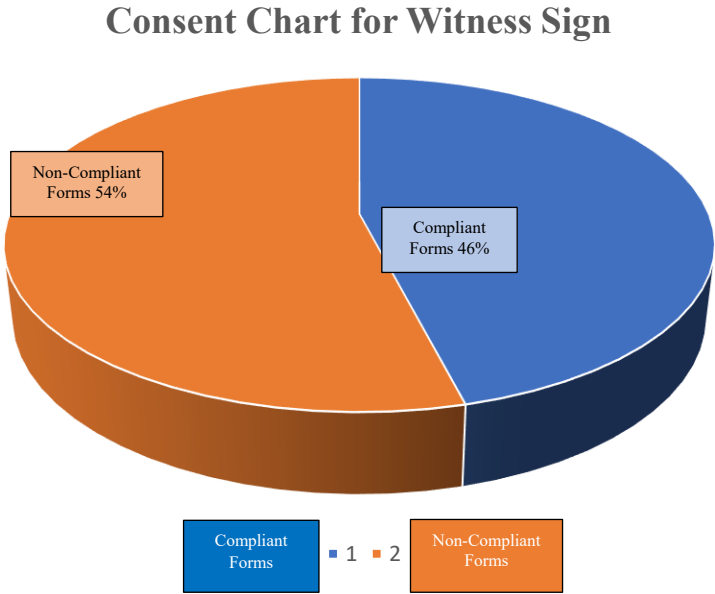
70% of the forms were non-compliant as witness name was not there

Table no: 04

Consent Data for Witness Signature

	WITNESS SIGN
Applicable forms	84
Compliance	39
Compliance Rate %	46%
Non-Compliance Rate%	54%

Chart no: 04



46% of the consent forms had witness sign compliance

54 % of the consent forms were non-compliant as witness sign was missing

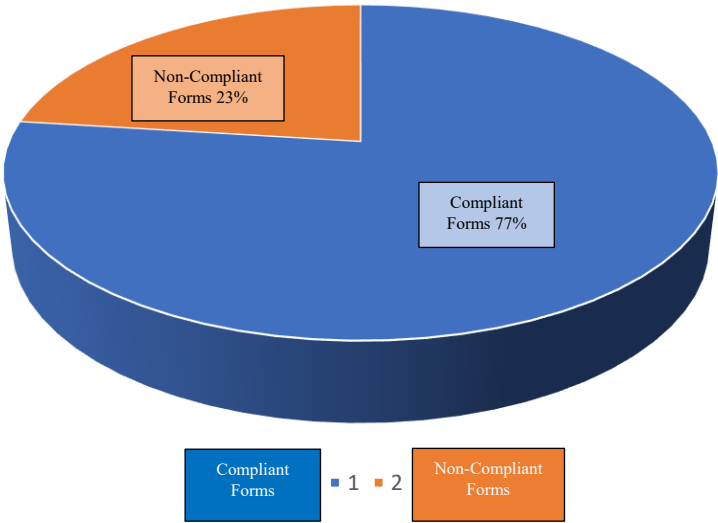
Table no: 05

Consent Data for Patient Name Entries

	PATIENT NAME
Applicable forms	48
Compliance	37
Compliance Rate %	77%
Non-Compliance Rate%	23%

Chart no: 05

Consent Chart for Patient Name Entries



77 % of the forms had Patient name compliance

23 % of the forms were non-compliant as patient name was not there

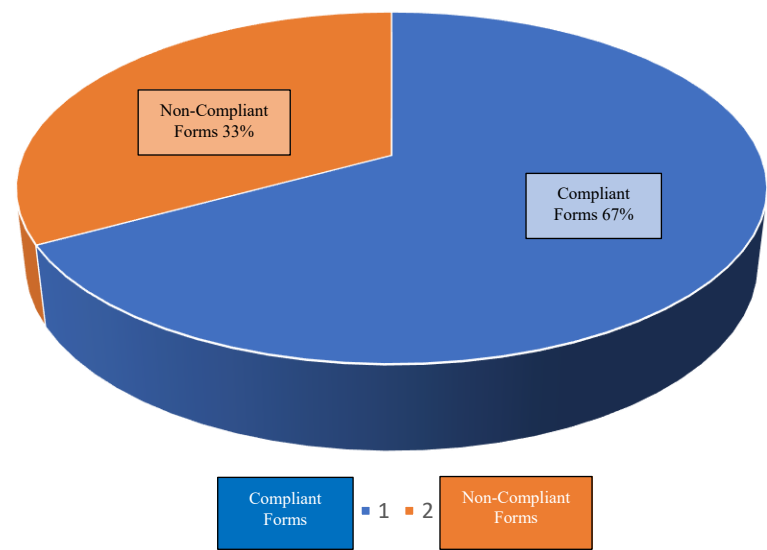
Table no: 06

Consent Data for Patient Signature

	PATIENT SIGN
Applicable forms	48
Compliance	32
Compliance Rate %	67%
Non-Compliance Rate%	33%

Chart no: 06

Consent Chart for Patient Sign on form



67 % of the forms had Patient’s sign compliance

33 % of the forms were non-compliant due to missing patient’s sign

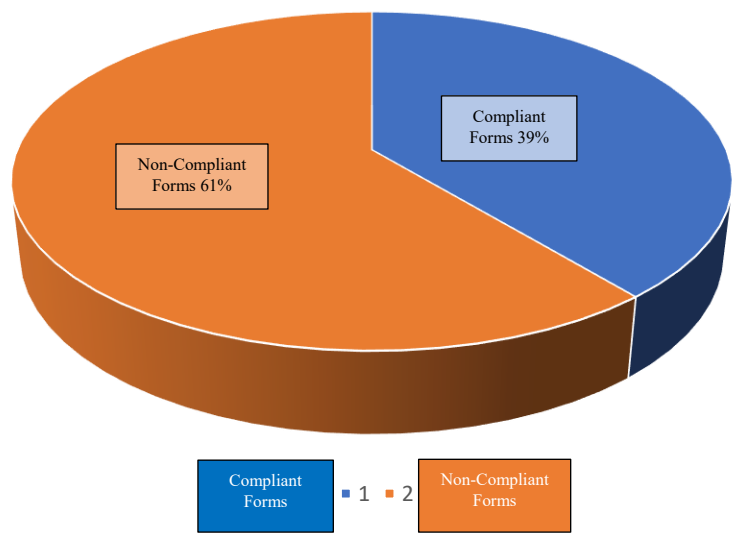
Table no: 07

Consent Data for Relative’s Name

	RELATIVE'S NAME
Applicable forms	59
Compliance	23
Compliance Rate %	39%
Non-Compliance Rate%	61%

Chart no: 07

Consent Chart for Relative's Name



39% of the forms had Relative’s name compliance

61 % of the forms was non-compliant as Relative’s name was missing

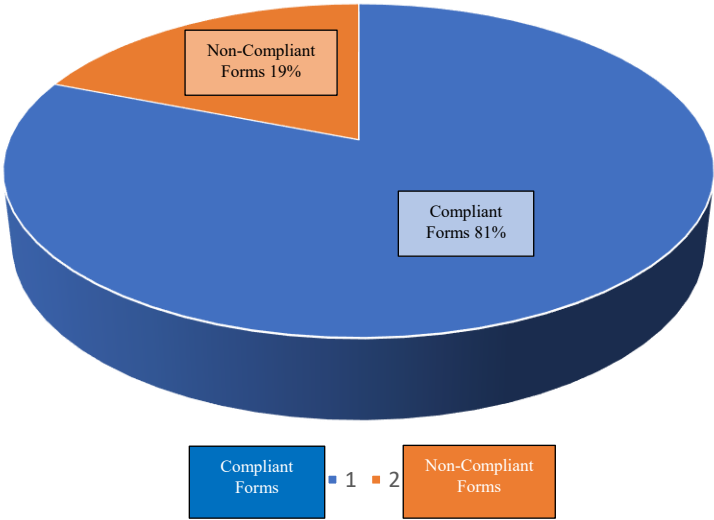
Table no: 08

Consent Data for Relative’s Signature

	RELATIVE'S SIGN
Applicable forms	59
Compliance	48
Compliance Rate %	81%
Non-Compliance Rate%	19%

Chart no: 08

Consent Chart for Relative's Sign



81% of the forms had Relative’s Sign compliance

19 % of the forms were non-compliant as there was no sign of Relative

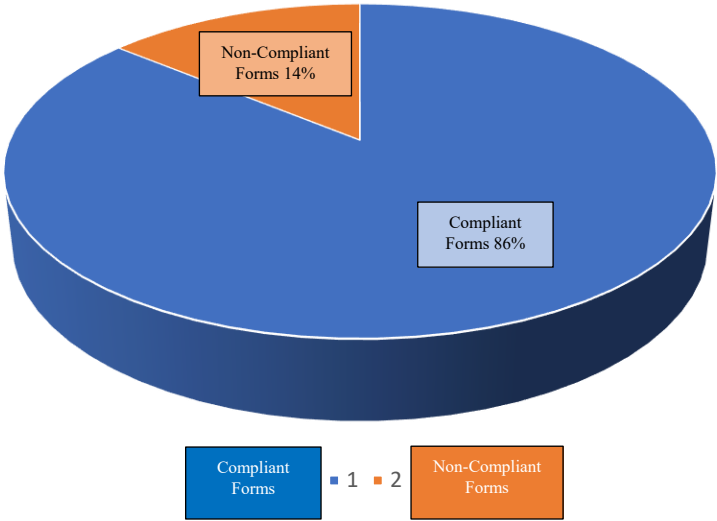
Table no: 09

Consent Data for Date Entries

	DATE
Applicable forms	100
Compliance	86
Compliance Rate %	86%
Non-Compliance Rate%	14%

Chart no: 09

Consent Chart for Date entries



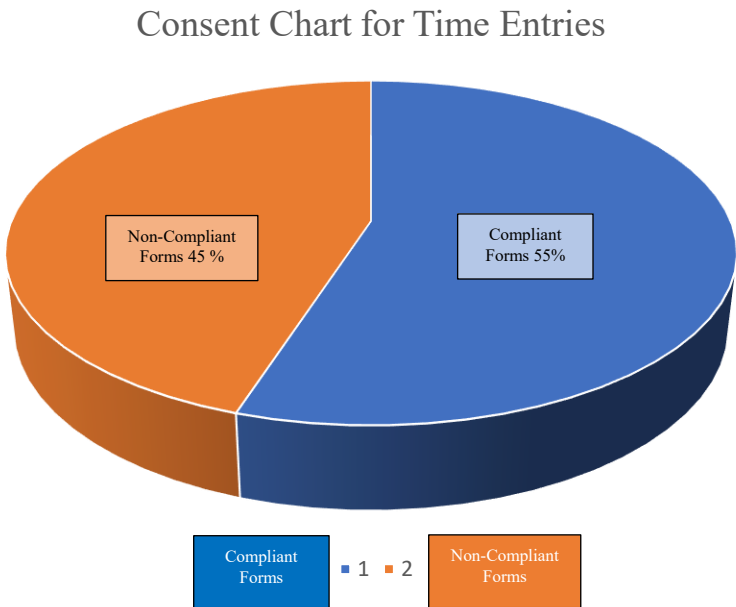
86 % of the forms has Date entry compliance

14 % of the forms were non-compliant due to missing Date on form

Table no: 10
Consent Data for Time Entries

	TIME
Applicable forms	100
Compliance	55
Compliance Rate %	55%
Non-Compliance Rate%	45%

Chart no: 10



55 % of the forms were compliant for Time entry

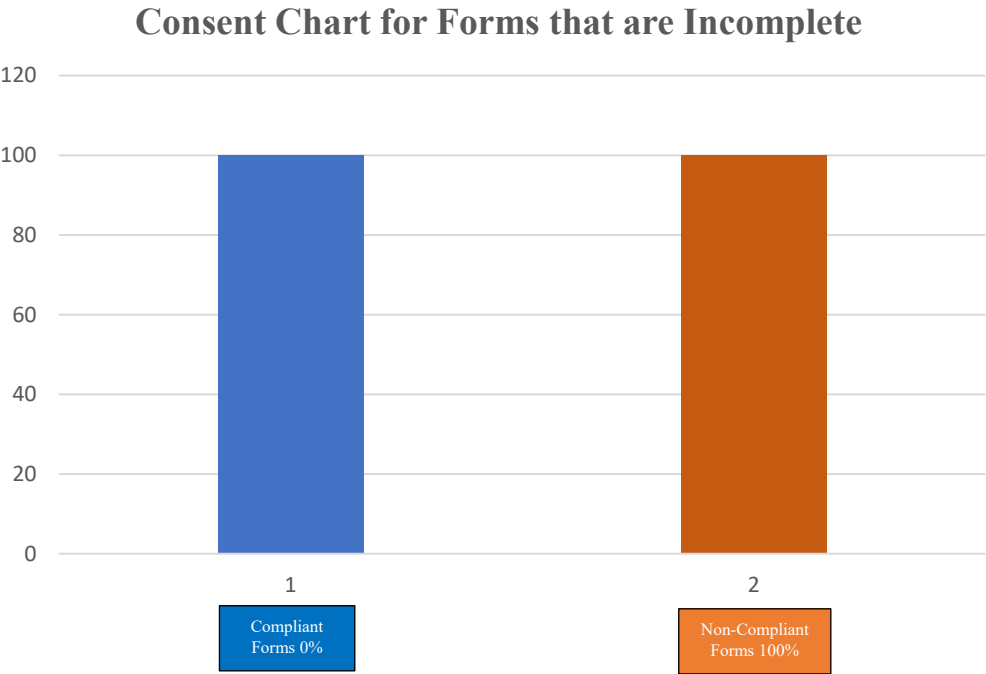
45 % of the forms were non-compliant for Time entry

Table no: 11

Consent Data for Incomplete Areas in the form

	INCOMPLETE AREAS
Applicable forms	100
Compliance	100
Compliance Rate %	0%
Non-Compliance Rate%	100%

Graph no: 11



All 100 consent forms were found to be non-compliant due to incomplete entries

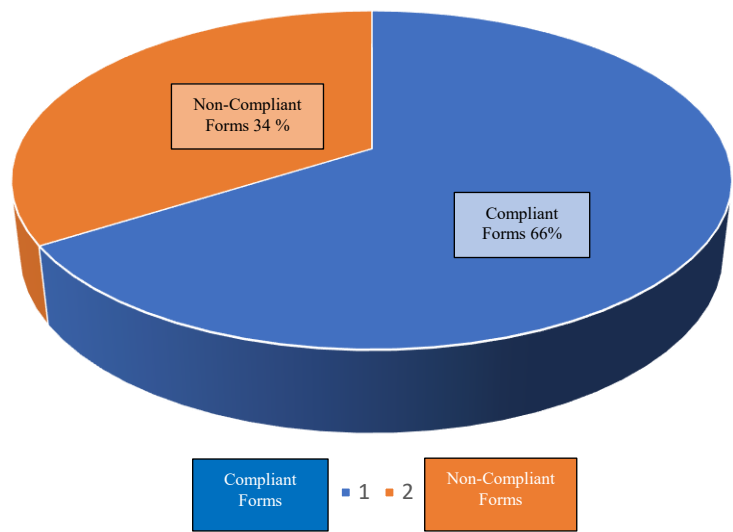
Table no: 12

Consent Data for Entries in Improper Areas

	IMPROPER AREAS
Applicable forms	100
Compliance	66
Compliance Rate %	66%
Non-Compliance Rate%	34%

Chart no: 12

Consent Chart for Improper Entries



34 % of the forms were having Improper entry compliance,
66 % of the consent forms were found to be non-compliant due to entries in improper areas / spaces

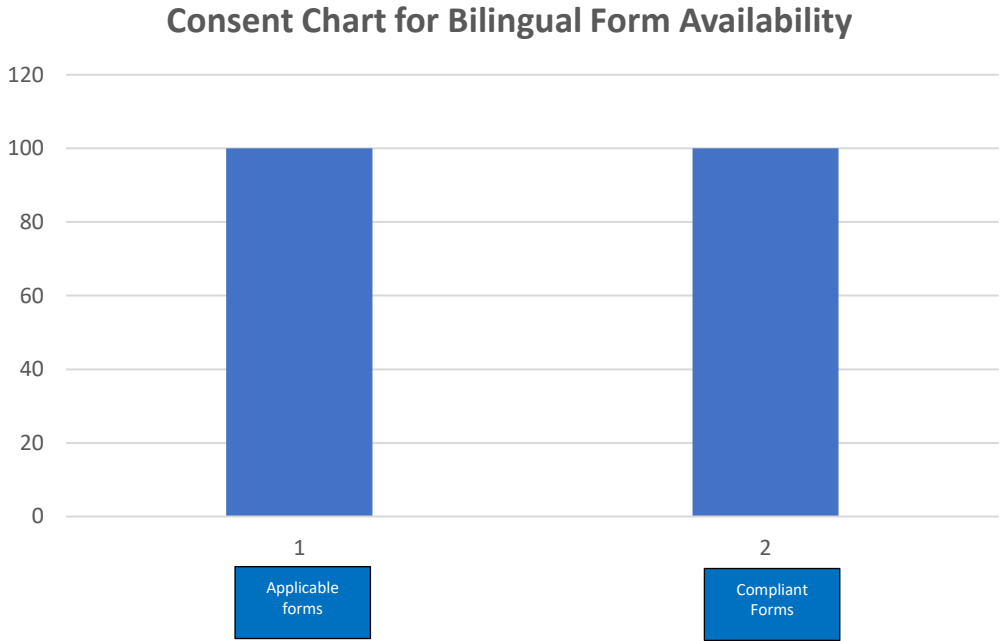
Table no: 13

Data for Consent Form availability

In Bilingual format

	BILINGUAL FORMAT
Applicable forms	100
Compliance	100
Compliance Rate %	100%

Graph no: 13



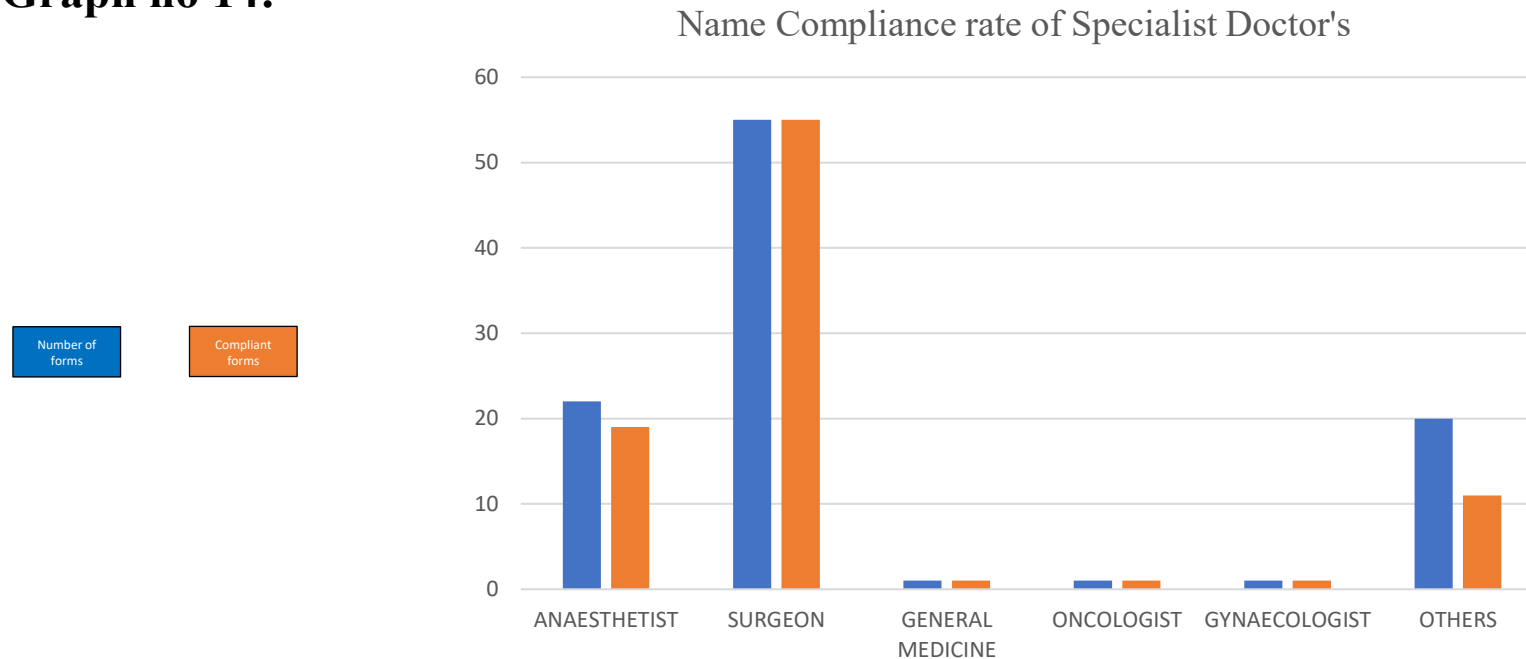
All the Consent forms were in Bilingual format having English and Marathi versions.

Hence the compliance for Bilingual form requirement is 100 %

Table no: 14

<u>Specialist Doctor's Name Compliance on consent form</u> <u>(Out of total 100 forms)</u>			
<u>SPECIALISATION</u>	<u>NO OF FORMS</u>	<u>Name Compliant</u>	<u>Name Compliance Rate</u>
ANAESTHETIST	22	19	86%
SURGEON	55	55	100%
GEN. MEDICINE	1	1	100%
ONCOLOGIST	1	1	100%
GYNAECOLOGIST	1	1	100%
OTHERS	20	11	55%
TOTAL FORMS	100		

Graph no 14:



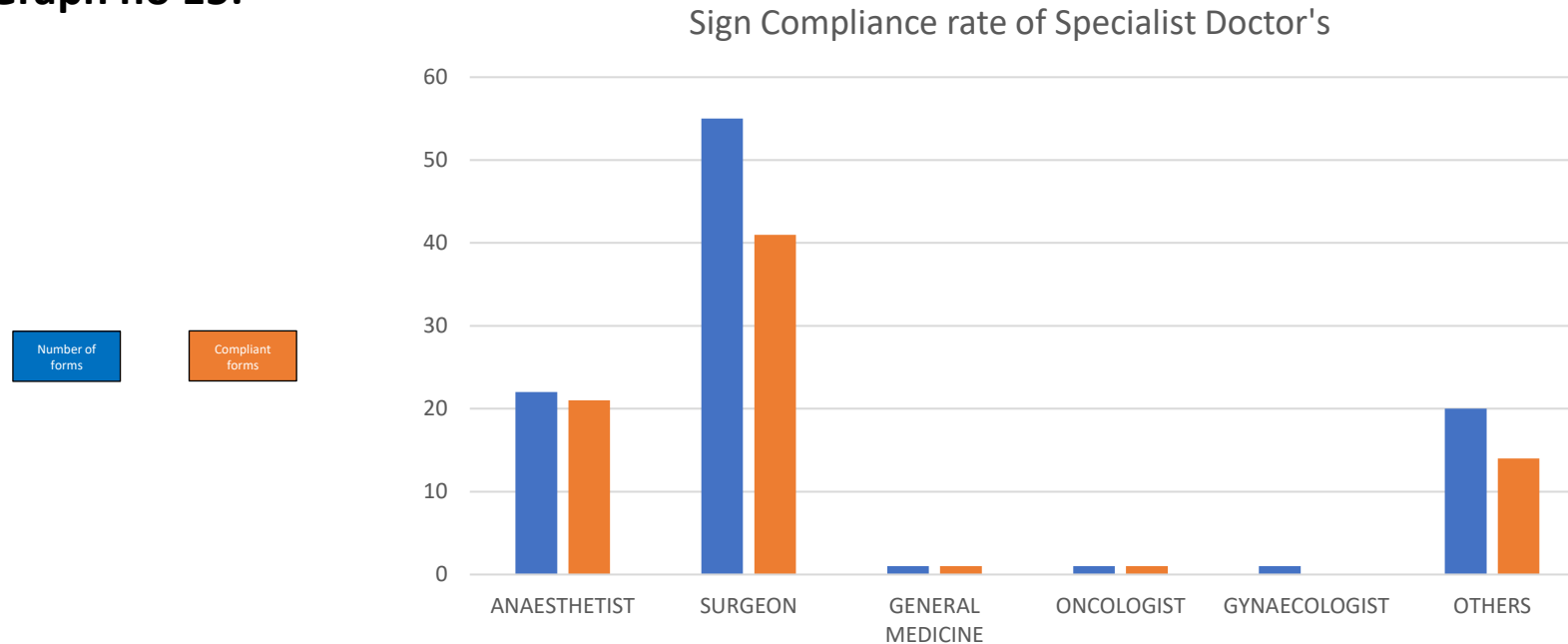
In the analysis of Name Compliance of Specialist Doctor's in the consent form

- Anesthetists had 19 forms out of 22 as compliant, this is 86 % Compliance rate
- Surgeons had 100 % compliance with all 55 forms having names
- General medicine Practitioners had a Name compliance rate of 100 %
- Oncologists had 100 % Name compliance
- Gynecologists had 100% Name compliance
- Other Doctor's Category had 11 out of 20 forms having Name compliance resulting in 55 % Name compliance rate

Table no: 15

<u>Compliance of the Specialist Dr's Sign Compliance on consent form</u> <u>(Out of total 100 forms)</u>			
<u>SPECIALISATION</u>	<u>NO OF FORMS</u>	<u>SIGN COMPLIANT</u>	<u>SIGN COMPLIANCE RATE</u>
ANAESTHETIST	22	21	95%
SURGEON	55	41	75%
GEN. MEDICINE	1	1	100%
ONCOLOGIST	1	1	100%
GYNAECOLOGIST	1	0	0%
OTHERS	20	14	70%
TOTAL FORMS	100		

Graph no 15:



In the analysis of Sign compliance of Specialist Doctor's in the consent form.

- Anesthetists had 21 forms out of 22 as Sign compliant, this resulted in 95% Sign compliance.
- Surgeons had 41 out of 55 forms as Sign compliant, resulting in 75% Sign Compliance
- General Medicine practitioners had 100% Sign compliance
- Oncologists had 100% Sign compliance
- Gynecologists had 0 % sign compliance as the form had no sign
- Other Doctor's category had 14 out of 20 forms as compliant resulting in 70% compliance rate.

ANALYSIS & DISCUSSION

- The sampling and analysis of consent form compliance in Hospital was done with the objective of understanding the degree of compliance while filling the consent forms, keeping in mind the legal validity and significance of compliant consent forms and the practices involved towards this compliance in the hospital.
- 100 consent forms sampling was done covering 5 specialties including Anesthesia, Surgery, High Risk Consents.
- It was found that from the legal perspective all the 100 samples of the consent forms were non-compliant.
- In the analysis of the Project, following were the notable points
 - From the technical side, the anomaly involving Doctor's Name and Sign on the consent forms which were entered in wrong space in the form or it was missing from the form. This makes the consent form invalid.
 - On the administrative side anomalies concerning entry of date and time, patient name and sign, relative name and sign, witness name and sign where applicable, incomplete areas and entries in improper areas / Spaces renders the consent forms invalid as a legal document.
 - In cases where signatures have been done in Marathi, the consent forms should have been filled on the Marathi version of the consent forms, else this might be seen as a situation where the patient or relative signing the form might not have been able to read and understand the form. To better indemnify the hospital, this can be rectified easily.
 - There have been some consent forms where critical information like "benefits of the surgery", "alternatives to the surgery", "specific risks related to anesthesia" etc., has not been explained to the patient / relative.
 - One of the flaws which can be easily and immediately corrected is the entry of "name and sign" in its appropriate space. It was found that 36 forms were having entries in the wrong space which rendered the forms non-compliant.
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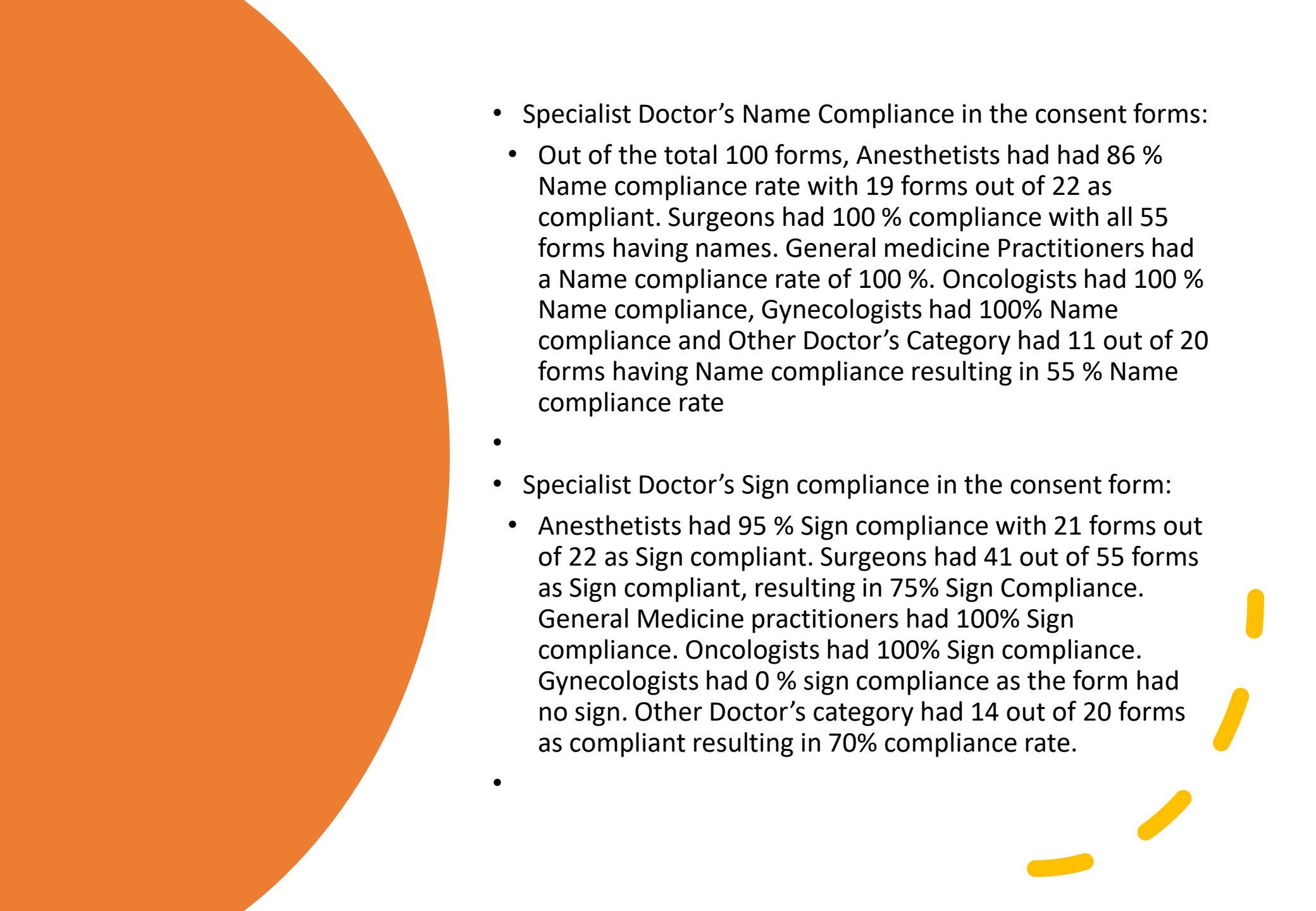


CONCLUSIONS - 1

- In the study of 100 sample forms compliance in the hospital all the 100 forms were found to be non-complaint from the legal requirements for a consent form that can be categorized as compliant.
- Compliance for Doctor's "Name & Sign" space:
 - 91% of the forms had the Doctor's name compliance, 9 % did not have Doctor's name on the form's so they were non-compliant.
 - 79% of the forms had Doctor's sign Compliance, 21% did not have the Doctor's sign hence they were non-compliant.
- Compliance of "Date & Time" Space:
 - 86% of the forms had the date compliance, 14 % of the forms did not have the date so they were non-compliant.
 - 55% of the forms had the time compliance, 45% of the forms did not have the time mentioned hence they were non-compliant.

CONCLUSIONS - 2

- Compliance of “Patient, Relative, Witness “Name & Sign”
 - 77% compliance for patient name, 23% patient name non-compliant.
 - 67% Compliance for patient sign, 33% of the forms were found to be non-compliant for patient sign.
 - 39% of the relative’s name entries were as per the required compliance, 61% were found to be non-compliant due to missing entries or due to entries in improper spaces.
 - 81% compliance for Relative’s sign, 19 % non-compliant for relative’s sign.
 - 30% Witness name compliance, 70 % non-compliant.
 - 46% Witness sign compliance, 54% non-compliant.
- Non-Compliance due to entries in improper areas:
 - 66% of the consent forms were invalid due to entries done in improper areas.
- Bilingual forms:
 - 100% of forms were found to be having the option of Bilingual (English & Marathi) thereby making it easy for a non-English speaking person to understand the consent form and sign it based on a clear and well-informed manner.

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- Specialist Doctor's Name Compliance in the consent forms:
 - Out of the total 100 forms, Anesthetists had had 86 % Name compliance rate with 19 forms out of 22 as compliant. Surgeons had 100 % compliance with all 55 forms having names. General medicine Practitioners had a Name compliance rate of 100 %. Oncologists had 100 % Name compliance, Gynecologists had 100% Name compliance and Other Doctor's Category had 11 out of 20 forms having Name compliance resulting in 55 % Name compliance rate
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 - Specialist Doctor's Sign compliance in the consent form:
 - Anesthetists had 95 % Sign compliance with 21 forms out of 22 as Sign compliant. Surgeons had 41 out of 55 forms as Sign compliant, resulting in 75% Sign Compliance. General Medicine practitioners had 100% Sign compliance. Oncologists had 100% Sign compliance. Gynecologists had 0 % sign compliance as the form had no sign. Other Doctor's category had 14 out of 20 forms as compliant resulting in 70% compliance rate.
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RECOMMENDATIONS

- It was concluded after study of 100 samples of consent forms, as per the requirements needed to categorize the consent forms as compliant, all the 100 samples were found to be non-compliant. Following are the recommendations to help rectify the anomalies as mentioned in the conclusion
 - For the doctor's Name & Sign Compliance, the coordinator or admin in charge of the consent form must personally ensure that the doctor's name is entered in the correct space along with the sign
 - Doctor may also take a portion of the responsibility to cross check if the form is filled as per its requirements as the consent form is a legal document.
 - The responsibility for entry of date and time has to be in the hands of the coordinator / admin in charge handling that particular consent form
 - The spaces which require patient name and sign, relative name and sign, witness name and sign, should be ideally guided by the admin in charge or the respective coordinator responsible for that particular form
 - It is recommended to bring about a clause that, only one coordinator/admin in charge/ hospital staff shall be responsible for that particular consent form. This shall fix a clear responsibility and accountability for each consent forms on one responsible staff
 - For all signatures which is in Marathi or in case of thumb print, the Marathi side of the form is filled, and all the relevant entries and signatures are also on the Marathi version of the form
- A valid consent form helps to improve the degree of legal indemnity of the concerned hospital; therefore, it is very important that each consent form must be completed in a legally valid and acceptable manner, thereby ensuring the interests of the hospital. The above recommendations will enable the hospital to ensure its indemnity.

REFERENCES

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- The Quality of Informed Consent Forms – a Systematic Review and Critical Analysis Juhlia Luhnén, Ingrid Mulhauser and Anke Steckelberg, Prof Dr. Phil. Date: 1st June 2018
- Informed Consent for Clinical Treatment – Daniel E. Hall, MD MDiv, Allan V. Prochazka, MD MSC and Aaron S. Fink, MD. (Canadian Medical Association Journal) Date: 20 March 2021
- Transforming Hospital Management & Analysis of NABH Version 5 (3rd Edition May 2023), Page no 172 to 181. Author Dr Anil Jayawant. M.B.B.S., D. Ac, D.C.A., D.Q.M., D.H.M. Consultant-Quality in Healthcare Advisor- Accreditation of Hospitals.

Thank You