Patient Medical Documentation as Means to Enhance Patient Safety in a Multi Specialty Hospital

(02 Feb-30 April 2015)

Internship and Dissertation Report Submitted in Partial Fulfillment of the Requirements

for the Award of

Post-Graduate Diploma in Health and Hospital Management

Batch 'F' (2013-15)

By

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(On study leave)

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2015

TO WHOMSOEVER IT MAY CONCERN

1. This is to certify that **Col Ravi Sharma** student of Post Graduate Diploma in Hospital and Health Management (PGDHM) from International Institute of Health Management Research, New Delhi has undergone internship training at **Saket City Hospital** from **02 Feb** to **30 Apr 2015.**

2. The Candidate has successfully carried out the study, **"Patient Medical Documentation as Means to Enhance Patient Safety in a Multi Specialty Hospital"**, which was designated to him during the internship training and his approach to the study has been sincere, scientific and analytical.

3. The Internship is in fulfilment of the course requirements.

4. I wish him all success in all his future endeavours.

Dr. A.K. Agarwal
Dean, Academics and Student Affairs
IIHMR, New Delhi

Dr Preetha G S,
Associate Dean
(Research),
IIHMR, New Delhi.

CERTIFICATE OF APPROVAL

The following dissertation titled **"Patient Medical Documentation as Means to Enhance Patient Safety in a Multi Specialty Hospital"** at **"Saket City Hospital"** is hereby approved as a certified study in management carried out and presented in a manner satisfactorily to warrant its acceptance as a prerequisite for the award of **Post Graduate Diploma in Health and Hospital Management** for which it has been submitted. It is understood that by this approval the undersigned do not necessarily endorse or approve any statement made, opinion expressed or conclusion drawn therein but approve the dissertation only for the purpose it is submitted.

Dissertation Examination Committee for evaluation of dissertation.

Name	Signature
Dr Pooram Rajput	
Dr Preetha KS	
DIVYA AGGARWAL	

CERTIFICATE FROM DISSERTATION ADVISORY COMMITTEE

This is to certify that **Col Ravi Sharma,** a graduate student of the **Post- Graduate Diploma in Health and Hospital Management** has worked under our guidance and supervision. He is submitting this dissertation titled "**Patient Medical Documentation as Means to Enhance Patient Safety in a Multi Specialty Hospital**" at **IIHMR, Delhi**, in partial fulfilment of the requirements for the award of the **Post- Graduate Diploma in Health and Hospital Management.**

This dissertation has the requisite standard and to the best of our knowledge no part of it has been reproduced from any other dissertation, monograph, report or book.

Dr Preetha G S,
Associate Dean (Research),
IIHMR, New Delhi.

SAKET CITY HOSPITAL
You First

Date: 15-May-2015

To whomsoever it may concern

This is to certify that **Col. Ravi Sharma** has successfully completed internship training in the department of **Quality** from **02-February-2015** to **30-April-2015**.

During the tenure of his association with the organisation, we found him actively participating in hospital activities and keen to learn different aspects of Quality Department in Healthcare industry.

We have found him Sincere, Hardworking & Focused towards the assignments given to him.

We wish him all the very best for future endeavours.

For Saket City Hospital

Nikhil Sagar
Senior Manager – Human Resources

SAKET CITY HOSPITAL
You First

TO WHOMSOEVER IT MAY CONCERN

Date: 15th May 2015

This is to certify that, **Col Ravi Sharma** has satisfactorily completed his Internship & Disseration in the Department of Quality at Saket City Hospital from 2nd February to 30th April 2015.

During his tenure, he has successfully completed the project on the topic "Patient Medical Documentation as means to enhance Patient Safety in a Multi Specialty Hospital

Throughout the training he has been a regular and keen learner. His performance during the training period was excellent.

SAKET CITY HOSPITAL New Delhi

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FEEDBACK FORM

Name of the Student: Col Ravi Sharma

Dissertation Organisation: Saket City Hospital

Area of Dissertation: Medical Documentation Practices

Attendance: 100%.

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Suggestions for Improvement: Computer Skills

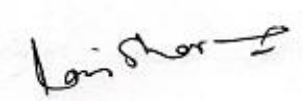
Signature of the Officer-in-Charge/ Organisation Mentor (Dissertation)

SAKET CITY HOSPITAL Saket New Delhi

Date: 15th May 2015
Place: New Delhi

CERTIFICATE BY SCHOLAR

This is to certify that the dissertation titled **Patient Medical Documentation as Means to Enhance Patient Safety in a Multi Specialty Hospital** and submitted by Col Ravi Sharma, Enrollment No. PGDHM/2013/052 under the supervision of **Dr Preetha G S**, for the award of Postgraduate Diploma in Hospital and Health Management of the Institute carried out during the period from **02 February to 30 April 2015** embodies my original work and has not formed the basis for the award of any degree, diploma associate ship, fellowship, titles in this or any other Institute or other similar institution of higher learning.



(Col Ravi Sharma)

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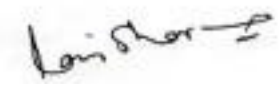
ACKNOWLEDGEMENT

I express my gratitude and sincere thanks to Dr Preetha G S, Professor, at International Institute of Health Management and Research, New Delhi, for her valuable guidance and co-operation in my endeavour.

I am thankful to the management of Saket City Super Speciality Hospital at Saket, New Delhi, for giving me the opportunity to carry-out Internship-cum-Dissertation in their esteemed hospital. I would also like to express my gratitude to the functionaries and the staff of all medical and non-medical administrative departments of the hospital who were extremely helpful in elucidating in detail, the nuances of the tasks and duties performed by them. Their kind cooperation assisted me to have a holistic view of various departments and their linkages, thereby, providing me with an on-the-job insight into the functioning of a modern and technologically advanced Hospital.

I would be failing in my duty if I don't express my sincere gratitude to Dr Manju Mani, Director Quality, Saket City Hospital, for her foresight and generous support, without which I wouldn't have been able to set my objectives for my Dissertation. My heartfelt thanks to the complete women staff of Quality Department, Saket City Hospital for professional guidance at all stages. My sincere thanks to Dr Bindu Sharma, Senior Quality Manager, whose mentoring and guidance during the Internship provided me with an opportunity wherein I improved my understanding of Quality Department of a hospital. During the three months training, I was given opportunity to be part of audit of Patient Medical Documentation which helped me in observing the functioning of various wards. The training schedule ensured that there was adequate in-build flexibility provided to me to understand finer aspects of patient safety. Thus the Internship-cum-Dissertation training has equipped me with an expertise which will ensure my appropriate employability as hospital administrators within the Army.

My special thanks to Mr Shailendra Kumar, Ms Radhika Govil, Ms Divya Sharma and Ms Ekta Sharma, for being there to answer all my queries, even the very basic ones at times, pertaining to the hospital.



Col Ravi Sharma
(on study leave)

LIST OF FIGURES

LIST OF APPENDICES

ACRONYMS / ABBREVIATIONS

1. IPD- In Patient Department
2. NABH- National Accreditation Board for Hospitals & Healthcare Providers
3. NABL- National Accreditation Board for Testing and Calibration Laboratories
4. MAS-Marker Assisted Selection
5. ENT- Ear Nose Throat
6. ICU-Intensive Care Unit
7. CCU- Critical Care Unit
8. CTVS- Cardio Thoracic Vascular Surgery
9. IT-Information Technology
10. OPD-Out Patient Department
11. NHS- National Health Scheme
12. IOM- Institute of Medicine
13. HAI- Hospital Acquired Infection
14. FHL- Functional Health Literacy
15. Doc's IA- Doctor's Initial Assessment
16. Nursing IA- Nursing Initial Assessment
17. NA-Not Applicable
18. Doc's CP- Doctor's Care Plan
19. Nursing CP- Nursing Care Plan
20. BOO- Board of Officers

SECTION 1: INTERNSHIP REPORT

SECTION 1: INTERNSHIP REPORT

(02 Feb-30 Apr 2015)

Introduction

1. Saket City Hospital (SCH) is a 214 bedded multi-super-specialty tertiary care hospital which has started functioning in the present form since 2013. It is located at Saket in South Delhi. Driven by the credo, 'YOU FIRST', the fast emerging Healthcare Centre, promises to provide the highest level of quality amidst technology that is truly world-class and futuristic. Saket City Hospital is a very well laid out hospital which is spread over 12.5 acres of sprawling campus and must be one of the most spacious hospitals in otherwise generally congested hospitals in the heart of Delhi with ample parking and open spaces.

2. SCH is accredited by the National Accreditation Board for Hospitals & Healthcare Providers (NABH), accreditation programme for healthcare organizations. It also aims to obtain accreditation from National Accreditation Board for Testing and Calibration Laboratories (NABL) as well as international bodies.

Mission

3. We ensure that every action and deed is determined by putting You First.

Vision

4. The hospital is working to achieve the following vision of its pioneers:

   (a) To be a world-class center of excellence and innovation in healthcare delivery and patient care experience.

   (b) To support the education of future healthcare practitioners by providing the best in class training and guidance.

   (c) To be the ideal employer, providing a growth oriented environment for our employees

Values

5. Saket City Hospital values define who they are as an organization, what they stand for, and how they continue the work of helping others. These values are:

Y YEARN FOR EXCELLENCE

O OWNERSHIP

U UNDERSTANDING

F FACILITATE

I INTEGRITY

R RESPECT

S SERVICE EXCELLENCE

T TRUST

Organization Profile

6. Saket City Hospital provides Centre of Excellence in following Departments:

(a) Cardiac Sciences.

(b) Orthopedics and Joint Replacement.

(c) Neurosciences.

(d) Pulmonology.

(e) Critical Care.

(f) Urology Sciences.

(g) Clinical Nutrition.

(h) Cosmetic and Reconstructive Surgery.

(j) Dentistry.

(k) MAS & Bariatric Endocrinology.

(l) ENT.

(m) Internal Medicine.

(n) Ophthalmology.

(o) Psychiatry.

(p) Obstetrics & Gynecology.

(q) Physiotherapy.

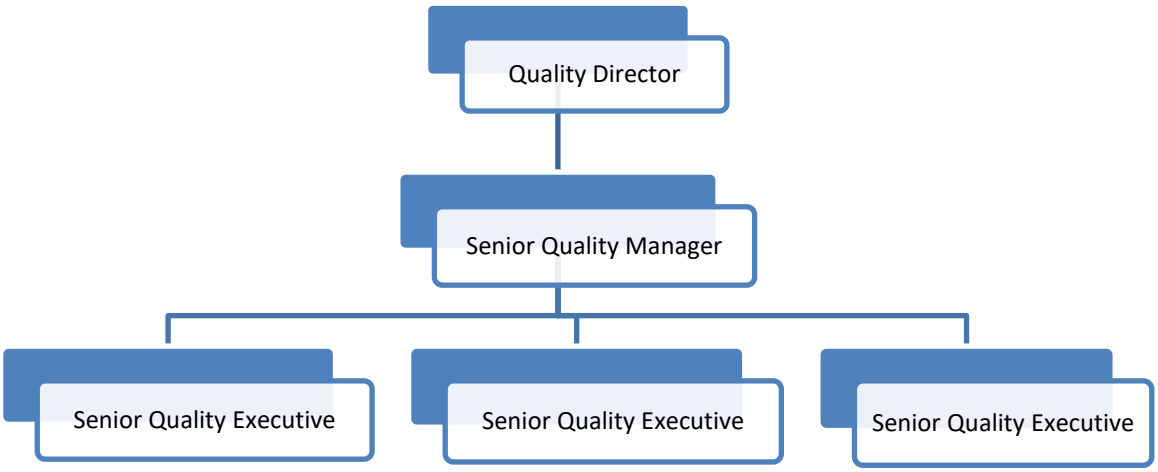
(r) Health Check.

The Continuum: Smart Health City

7. Smart Health City is an ambitious, futuristic project of Dr B K Modi led Smart Global. It will be a complete healthcare destination with services like Smart Living, Multi-Specialty Hospitals, Medical Office Buildings, Medical Rehabilitation Centres, International Patients Centre, Medical Education and Training, Clinical Research, on Campus Staff Residences and a Research and Technology Centre. Spread over 15 acres and located at Saket, the heart of Delhi, India; it is expected to be completed in a phased manner by FY 2016/2017. Jones Lang La Salle has been appointed as the infrastructure partner for Smart Health City.

Quality Department

8. During the Internship period I was attached with the Quality Department of the Saket City Hospital. The organization of Quality Department of Saket City Hospital is as under:



Organisation Chart: Quality Department

9. While being with the Quality Department of the Saket City Hospital I was provided with the opportunity to be part of audit of the Patient Medical Documents. For the audit, I had to go to the IPDs and ICUs of the hospital where the Patient Medical Documents were inspected. Audit as such is the evaluation of data, documents and resources to check performance of systems so that they meet the specified standards. Audit in the wider sense is simply a tool to find out what is being done now; this often is to be compared with what has been done in the past, or what is the intention to achieve in the future. The details of Patient Medical Documentation Audit are as under:

(a) Patient Medical Audit Format. The standard format (Appendix 'A') is being used for the audit of the Patient Medical Documentation.

(b) The total number of Patient Medical Documentation folders audited was 308 (three hundred and eight) as per details in Appendix 'B'.

10. The floor-wise assessment of the data is as per the details given below:

	Name of Ward	**Appendix**
(a)	IPD-1st floor	'C'
(b)	IPD-2nd floor	'D'
(c)	IPD-3rd floor	'E'
(d)	IPD-4th floor	'F'
(e)	ICU-1/CCU	'G'
(f)	ICU-1/CTVS	'H'
(g)	ICU-2	'I'
(h)	ICU-3	'J'
(j)	ICU-4	'K'
(k)	ICU-5	'L'

Recommendations

11. The recommendations based on the general analysis of data and observations during the visits to various departments which can go a long way in improving the Patient Medical Documentation:

(a) Training-Case Studies. There is a tendency to make clerical mistakes during the documentation of a formatted document. Also at times the entries are made just for audit purposes thereby not giving right picture of the quality of treatment. Hence to highlight the importance of correct and appropriate documentation the senior staff might share incidents during their career which might be used for teaching the importance of Patient Medical Documentation.

(b) Dietary. The issue of unsatisfactory Nutritional Assessment of the patient has been highlighted by the audit. There is a requirement of carrying out the Root Cause Analysis of this shortcoming by Head Dietician to arrive at the solution.

(c) Use of IT. In the ICU-5, the Doctor's Initial assessment was done directly on the computer. There is legal requirement of keeping hard copies of the medical document; however, the feasibility of increasing the usage of IT throughout the hospital should be encouraged without compromising on the legal requirement of keeping hard copy of medical documentation.

(d) Training of the medical staff in the legal implication of the correct documentation should be done regularly. The aspect of vicarious responsibility should also be highlighted to stress on the proper signatures on the patient medical documents.

(e) Formation of Quality Circles. Quality Circles should be formed among Resident Doctors, Nursing Staff, House-Keeping, etc so that the experience available amongst the people working on ground is shared amongst themselves for overall benefit of all stake holders.

(f) Allocation of Helpers in each Department for ensuring the completion of documents so that the documentation remains focussed towards patient safety.

(g) Increase the pre-induction training period of the new staff and regular structured refresher training for the complete staff.

(h) Involving of functional staff in the Audit of all departments as first step in the Audit of documentation. For that the staff from both medical and non medical departments can be detailed for carrying out audits on the monthly basis. This can help in the self assessment by the staff and bring in behavioural changes.

SECTION 2: DISSERTATION

PATIENT MEDICAL DOCUMENTATION AS MEANS TO ENHANCE PATIENT SAFETY IN A MULTI SPECIALTY HOSPITAL

CHAPTER 1: INTRODUCTION

Introduction

1. Although Hippocrates said “first, do no harm” over 2000 years ago and many hospitals have long hosted conference to discuss errors (Morbidity and Mortality, or “M&M,” conferences), until recently medical errors were considered an inevitable by-product of modern medicine or the unfortunate detritus of bad provider[1]. Inherent in this aspect of no harm to the patient is the aspect of all efforts taken for curing the patient and to take measures to prevent hospital acquired infections and adverse events.

2. Modern Hospitals have become complex organizations. They are not only providing 24X7 multi-specialty medical care but also a host of other hospitality based services to the patient. This has increased the number of people involved in looking after a patient during the period of healthcare. Hence, any patient entering a hospital may have to undergo following stages or places wherein there will be interaction various services both medical and non-medical:[2]

(a) Reception

(b) OPD of various specialties

(c) IPD

(d) Laboratory

(e) Radiology

(f) Emergency

(g) ICU

(h) Pharmacy

3. While being in these areas, a patient may be exposed to various risks which can affect their safety due to the medical treatment itself or otherwise. The reason for the risk to the patient can be the human error, faulty procedure or malfunction of equipment/facility. Hence the total concept of healthcare has undergone paradigm change to cater for all aspects which affects the patient care. This has led to emergence of standardization in the processes for the safety of a patient.

4. The treatment *per se* depends on the subjective assessment of the doctors but from the perspective of a Hospital Administrator also one can influence patient

safety by being involved in the development of the ways by understanding as to how patient safety works (e.g., high- reliability design, use of safety sciences, methods for causing change, including cultural change)[3] and one of the simplest meeting ground for achievement of the Patient Safety Goals can be through the maintenance of Patient Medical Documentation based on standardization.

5. The process of evolution of the medical documentation in any hospital used to be based on the past experience of the healthcare organizations. However, these days this uncertain and uneven process of self learning has been replaced by taking the assistance of the Accreditation processes which have evolved in the developed countries. In the developed West the accreditation in healthcare started in 1990's[3] whereas in our country this was set in motion by establishment of NABH in 2006[25]. There is a process followed for the accreditation which leads to the development of various check lists which are standardized. These check-lists form the back-bone for establishing standardized processes in a healthcare organization for ensuring patient safety. The accreditation leaves enough scope for adjustments which can be made with regards to the requirements of Patient Safety as per the facilities existing in an organization. These adjustments can be made by matching of the existing facilities with the vision/mission statements of the healthcare organization and the laying down of a suitable patient safety definition and the patient safety goals.

6. There has to be mechanism developed to continuously assess the patient safety parameters, however, in an upcoming accredited healthcare setup, the criteria for comparison may not be available. The past data required may not provide adequate inputs for evaluation which can assist in arriving at logical conclusions regarding the Patient Safety. In such cases, a lot of supervision is required over the processes which are being established so that a professional culture evolves in the outfit. As such, if the healthcare organization is accredited then the processes are followed as per the documented Standard Operating Procedures and every aspect is required to be documented. Hence, if proper Patient Medical Documentation is maintained in an accredited hospital, then its audit itself can act as one of the indicators for the management to assess continued maintenance of the standards of patient safety.

7. The objective of the Medical documents can be different to various stake holders even though the safety of the patient should remain the pivot of the whole exercise. The possible objectives of the creation of the Medical Record in a healthcare organization is to have sufficient data written in sequence of events to justify the diagnosis, treatment and end result of all patients treated in a hospital, keep them under safe custody and make them readily available as and when required for the following[4]**:**

(a) **Patient**. For Patient, the medical record;

(i) Serves to document the clinical history and activities of patient treatment.

(ii) Serves to avoid omission or repetition of diagnostic and therapeutic measures.

(iii) Assists in continuity of Care even in future illness whether it requires attention in or out of the Hospital.

(iv) Serves as an evidence in Medico-legal Cases.

(v) Give necessary certification for employment purposes.

(b) **The Doctor**. For The Doctor, it

(i) Assures quality and adequacy of diagnostic and therapeutic measures undertaken.

(ii) Serves as an assurance of continuity of medical care.

(iii) Evaluates Medical Practices.

(iv) Protection in litigation.

(c) **Hospital Administrators**. For Hospital Administrator

(i) To document the type and quantity of work undertaken and accomplished.

(ii) To evaluate proficiency of Medical Staff for administrative and clinical purposes.

(iii) To evaluate the services of the hospital in terms of accepted norms and standards.

(iv) To serve as an Administrative record and Performance.

(v) To assist in futures Programmers for Planning and developments of hospital.

(d) **Medico Legal Purposes**. For Medico Legal Purposes, it serves

(i) As a documentary evidence

(ii) To dispose claims of the Insurances.

(iii) For Patient's WILL to indicate if the patient was of normal mental state or not.

(iv) Malpractice Suits.

(v) Authorization for operation etc. signed document for consent for operation will prove that the Patient / Relative have allowed the performance of such Procedure.

(vi) Criminal cases – as a Potential Document.

(e) **External Reporting**. Development of Hospital Performance Statistics, Statistical and epidemiological Data are needed to implement and manage medical care planning and to obtain Health Indicators to monitor and evaluate their effectiveness for Hospital Management as follows:

(i) Bed Occupancy Rate.

(ii) Average No. of Out Patients.

(iii) Average No. of Admissions.

(iv) Sex wise Admissions.

(v) Average Length of Stay of Patients.

(vi) Gross and Net Death Rate.

(vii) Number of Types of Operations performed (Major & Minor).

(viii) Number of X-ray / CT Scan, Ultra Sound etc.

(ix) Laboratory Tests.

(x) Information about Institution Deaths (Deaths occurring over 48 hrs).

(xi) Non Institution Deaths (Deaths occurring under 48 hrs).

(xii) Total Number of Babies born in a hospital. (Sex-wise distribution /sex ratio /Still Births).

(xiii) Daily Census of the Hospital.

8. The management of the present day hospitals is heterogeneous mix of people from medical and non-medical fields. The workers from non-medical fields too have assumed significant importance in healthcare and compliment the treatment of the patient. As such there is an obvious feeling of superiority amongst the doctors over the non-medical people in the hospitals set-ups and they consider themselves to be above scrutiny. Therefore, the healthcare set-up should evolve procedures where in the over-all functioning provides an integrated and holistic approach to patient care to ensure that the patient safety remains central to all activities.

9. In Indian context, the basic issue in general is the indifferent attitude towards the basic patient safety which is rooted in the culture and upbringing of those

involved in the healthcare sector. Historically, as a civilization we are not known to be good record-keepers and feast on the mythology. We tend to mystify and glorify the curative powers. Our country missed out on the revolutions through the scientific and technological advancement which is evident in the medical field too. It becomes more prominent in the medical field wherein cultural background coupled with efforts of medical professionals to dominate has led to evolution of standards which leads to shifting of focus from patient safety to the evasion of the likely legal tangles arising out of the errors during the course of treatment. The basic focus of the medical care should always be Patient Safety and if the approach to Patient Medical Documentation is only covering up legally then it will lead to lengthy and clerical documentation. Hence, during the initial medical qualification study stage itself there should be efforts to inculcate an approach which is patient centric and efforts should be to hone up skills including maintenance of documents which are oriented towards patient safety. In fact, “specific training and supervision in prescription should be emphasized during undergraduate and postgraduate teaching to minimize related (medical) errors. (Since) these prescription errors may lead to adverse drug events”.[5] Hence there is requirement of evolving procedures which are followed as drills and are developed as second nature among all stakeholders to improve Patient Safety keeping pace with the present times.

10. All organizations should have mechanisms to introspect to be able to improve continuously. For that to happen, there should be a hindrance-free flow of information both laterally and vertically. The basic parameter, in case of healthcare set-up, is the interest of the patients; however, to maintain the correct reporting in all circumstances from the people directly dealing with the patient, it is important that the information is not used against them. These practices have been followed in other fields and have paid good dividends in terms of improved quality in the long-run. It should be comparable to an individual improving his looks by standing in front of mirror. Quality Department can directly and positively influence patient safety by coordinating amongst both medical and non-medical departments an internal audit mechanism which can actively effect the improvement of overall medication and patient safety. This can be in addition to the audit by Medical Records Department (MRD) which primarily focuses on completing them legally as per the standards being followed.

CHAPTER 2: REVIEW OF LITERATURE

PATIENT SAFETY

11. The developed nations realized in the 1990s that despite all the known power of modern medicine to cure and ameliorate illness, hospitals were not safe places for healing. Instead, they were the places which could harm the patients with Hospital Acquired Infections (HAI), accidents, sentinel events, medication errors etc. The most important response to this realization was the growth of interest of all stake-holders in patient safety which led to it developing into a discipline, complete with an integrated body of knowledge and expertise.

12. The authentic and reliable data regarding the parameters indicating the Patient Safety norms pertaining to India are not available. However, such data in the developed countries are maintained and are available for interpretation. “For instance research carried in United Kingdom suggests that 1 in 10 patients admitted to hospital suffer an adverse event. Now, some adverse events will be inevitable complications of treatment. But at least half of these events were thought to be preventable adverse event. And the research suggests that 8% of these 1 in 20 patients will die as a consequence. It means that there are about 8.5 million hospital admissions each year in National Health Scheme (NHS) in UK. Based on the evidence of 1 in 20 patients experiencing a preventable adverse event, and an 8% mortality one could be looking at over 400,000 events in NHS each year that leave over 34,000 patients dead”.[3]

13 Although the Institute of Medicine (IOM) defined safety as “freedom from accidental injury,” patient safety as a discipline or field of inquiry and action has not been fully defined to date in the major consensus statements of the organizations that have propelled its existence. It is a subject within health care quality. However, its methods come largely from disciplines outside medicine, particularly from cognitive psychology, human factors engineering, and organizational management science. That, however, is also true of the biomedical sciences that propelled medicine forward to its current extraordinary capacity to cure illnesses. Their methods came from biology, chemistry, physics, and mathematics, among others. Applying safety sciences to health care requires inclusion of experts with new source disciplines, such as engineering, but without any divergence from the goals or inherent nature of the medical profession.[1]

14. Patient safety is now recognized in the developing countries like India also with the help of global awareness fostered by the World Health Organization’s World Alliance for Patient Safety. And yet there are significant challenges in implementing patient safety policies and practices. One fundamental requirement to be adopted by a healthcare organization is to articulate a new approach which has a clear evaluation of its resources and its impact on the patient safety outcomes. A lot of components of patient safety have been expressed and implemented by established

leaders, and their model can be taken as reference points. The accreditation also provides various standardized expectations for the patient safety but even that is subjective[6]. Within an organization the evolution of the Patient Safety Goals for a hospital should be first derived from the vision and mission statements given by the leader of the organization. Then these parameters should act like the backbone for reaching the desired standards for Patient Safety after considering all factors.

15. Patient Safety as a topic is largely absent from even the basic building block of the health-care i.e. education, demonstrating the low priority given to safe patient care. Safe care for patients can only be optimized if health-care workers receive the right training and are helped to keep up-to-date with knowledge. This situation represents a deeper system failure which has two main components. Firstly, there is a failure to address patient safety education in training, and secondly, failure repeats itself to ensure the competence of health-care workers through regular and up-to-date training and assessment. In a developing country like ours, a most pragmatic approach by a healthcare organization would be to focus on the second aspect and make efforts to put in place mechanisms for institutionalized on-the-job learning.

16. To achieve the goals of patient safety the healthcare organizations should understand "why people make errors that lead to adverse events shifted from a single cause, legalistic framework to a systems engineering design framework"[6], and in so doing, it must learn from the experiences of developed world without just adopting the accreditation. One must learn from the evolution of the process of patient safety and bring in the conviction of following the norms set in by the standardization. It will be akin to upgrading equipment along with the transfer of technology. Hence, to arrive at the very basics of patient safety, the following stages[2] can be identified from the evolution process of patient safety in the developed countries:

(a) Limiting Blame. The traditional approach assumed that well-trained, conscientious practitioners do not make errors and equated error with incompetence and regarded punishment as both appropriate and effective in motivating individuals to be more careful. This led to practitioners rarely revealing mistakes, and patients and supervisors were frequently kept in the dark. Low reporting made learning from errors nearly impossible, and legal counsel often supported and encouraged this approach in order to minimize the risk of malpractice litigation. Thinking began to change in the 1990s in response to several kinds of new information.

(i) First, medical injury was acknowledged as occurring far more often than heretofore realized, with most of these injuries deemed preventable.

(ii) Second was the idea that "active" errors at the "sharp end" — where practitioners interact with patients or equipment—result from

"latent" errors. Latent errors are upstream defects in the design of systems, organizations, management, training, and equipment ("blunt end") that lead individuals at the sharp end to make mistakes. To punish individuals for such mistakes seemed to make little sense, since errors are bound to continue until underlying causes are remedied.

(b) Systems Thinking. The leaders in health care considered that errors could be reduced by redesigning systems and processes using human factors principles. These could reduce mistakes through design features, including standardization, simplification, and the use of constraints. Another corollary quantum leap to view health care as a system took place as people applied engineering design concepts to health care. Some of these systems changes were related to tools and technology. Others were related to organizations and people, such as training doctors and nurses to work better in teams or including a pharmacist in the team during rounds.

(c) Transparency and Learning. The idea that adverse events could yield information was applied in health care. The notion that sharing information about medical errors was essential for effective patient safety outcomes became urgent. Commentators asserted that the more error-related information was shared, the better lessons could be implemented industry-wide[7].

(d) Culture and Professionalism. Clinicians, governing boards, executive leaders, and middle managers of health care delivery organizations were being increasingly encouraged to think in terms of building high-reliability organizations. This required a culture change to one that refrained from assigning "sharp-end" blame for mistakes; that incentivized learning by fully disclosing information about mistakes, failure, and near misses; that trained and provided support to clinicians involved in inherently risky work; and that disclosed all relevant facts to injured parties.

(e) Accountability for Delivering Effective, Safe Care. As modern concepts of negligence developed, emphasizing litigation to deter substandard behaviour and individual accountability for procedures and actions causally linked to adverse outcomes became embedded in both medicine and law of torts.

(f) In an important parallel development, as treatments became increasingly effective, the medical field began to establish methods for accountability, and the profession's credibility in society rose. The scientific method was essential in that development, and with good reason, medicine has adhered to it. The three-phase approach to establishing the efficacy and safety of new medical therapies—

(i) Phase 1, clinical trials to assess safety;

(ii) Phase 2, clinical trials to ascertain efficacy;

(iii) and Phase 3, trials to compare it with another standard intervention—was essential, too.

(g) With the development of safer and more effective surgery, medical care delivery systems began focusing on hospitals; standards for these delivery systems were understood to be necessary. Certification of hospitals and other health care delivery systems followed often with professional groups, such as the Accreditation Council for Graduate Medical Education (ACGME) and the Joint Commission, serving quasi-government oversight and public protection roles.

(h) The nascent realization that health care, including the clinician and other components, also needed to be accountable for learning from error was harder to grapple with. Faltering moves were made toward tort reform and institutional accountability for safety practices. A model for accountability of clinicians that included accountability for continuous learning set the stage for, but stopped short of, a full rendition of what accountability for understanding and optimally designing safe health care systems required.

17. As the healthcare systems evolved in the west, a number of mechanisms got incorporated as part of evolution and involved following to achieve patient safety[6]:

(a) High-Reliability Design. The fundamental mechanism by which patient safety can be achieved is high-reliability design, which includes many components. Thus, the irreducible unit of patient safety delivery is multifaceted; all components of health care delivery must be integrated into a system that is as reliable as possible under complex conditions.

(b) The concept of a multilayered system, which includes the institution and its organization, the professional team and the individuals it includes, and the technology in use.

(c) Error traps (i.e., unpredictable situations in which error is highly likely) are another vivid concept on which safety sciences focus.

(d) For instance, patient safety designs can be thought of as falling into two types: those that are for types of routine care that varies little and can best be managed with protocols allowing for little deviation, and those that are for unique situations where on-the-spot innovation and significant deviation from protocol are required.

18. Invariably the main reason responsible for the failure of any system is the Human Factors. The field of human factors concerns the interaction between humans and the system in which they work. Additional training in non-technical skills has been shown to be vital to reduce errors in the other industries. However,

although human factor training exists within medicine, it is not seen as core part of daily work. Topics such as task management, multidisciplinary team working, risk perception, decision making and recognition of personal and technological limitations all contribute to a deeper understanding of error and have been shown to prevent error. Nevertheless, these concepts are still not taught with the same rigour as more traditional educational topics. Medical education has traditionally taken the form of an apprenticeship. Students are often encouraged to learn based on the principle of see one, do one, teach one. This is rarely an appropriate method of ensuring safe health care. It also reinforces a culture in which training is not prioritised. Poorly trained health-care workers can be a major contributing factor leading to adverse events. Staff may not be well placed to judge their own level of competence; they may also be overconfident as a consequence of their own limited experience.[8] Healthcare organisations cannot do much about the basic training of its staff, however, it can adopt various means to update and upgrade its staff so as to proactively address the issue of Patient Safety. In present day multi-specialty hospitals presence of personnel from varied fields also provide expertise from other fields which may provide readymade insight into training methodology being followed in those fields.

ROLE OF COMMUNICATION IN PATIENT SAFETY

19. Effective communication is the key to patient safety. A review of root cause analyses suggests that in over 60% of errors, poor communication was an important causal factor. Effective communication is also crucial to managing an incident once it has occurred. Communication in the health-care setting may be divided into two types: those between one health-care worker and another, and those between the patient (and/or family member) and a health-care worker. Each has different elements that can contribute to medical errors[8].

Communication Between Patients and Health-Care Workers

20. The patient/ health-care worker interaction is complex and only beginning to be understood. Part of the complexity is due to changing expectations. Fifty years ago, patients were accustomed to a health-care worker being dogmatic and paternalistic. Today, patients usually look to their health-care worker to help them navigate through a complicated system and expect communication to be based on shared decision-making. However, neither model is correct all of the time. The type of communication model that is needed depends very much on the specific situation.

21. During an interaction between a patient and a health-care worker, various forms of communication[8] may be used:

(a) Non-verbal communication. The clues that patients pick up from their health-care worker's body language have been shown to be crucial in the way the patients interpret the information they are given.

(b) Verbal Communication. The studies have shown differences between how health-care workers think they are communicating and how patients perceive the transfer of information. One of the most important factors that contribute to communication is the ability of patients and health-care workers to communicate in the same language. Studies have shown that providing interpreters is not only better for patients but also cost-effective. What is not clear is how best to provide such interpretation. All are agreed that professional interpreters are the most accurate. However, they are not always available and are costly. Patients prefer family members as a second best, whereas health-care workers seem to prefer using telephone interpreting.

(c) Written Information. The final method that may be used to communicate between patients and health- care workers is written information. This too has pitfalls. Many patients find understanding written health-related information difficult. Studies show that the ability to understand this sort of material – also known as Functional Health Literacy (FHL) – is not correlated to other forms of literacy. Furthermore, the average FHL appears to be much lower than the FHL required to read the material generally produced. In addition, novel techniques like patient support material on the internet require literacy skills to navigate the sites that not everyone possesses.

Communication Between Health-Care Workers

22. Research has identified that communication among health-care workers plays a significant role in the development of errors: incomplete handovers, illegible handwriting and unclear instructions are a few examples. Health care is also very hierarchical and juniors rarely feel confident to speak out about concerns they may have. Many of these problems are not unique to health care, and we can learn from external examples.

23. Crew Resource Management is a technique borrowed from the aviation industry and designed specifically to try to break down hierarchy. Through team-building exercises, professionals are empowered to speak out. This is crucial in identifying errors before they occur. This technique has been used in anesthesia, emergency medicine and obstetrics.

Communication and the Management of Incidents

24. When an incident does occur, communication is fundamental to managing the adverse event. Apologizing and explaining to the patient and their family is morally necessary, albeit difficult. Receiving an apology is one of the main objectives of patients when campaigning for increased error disclosure, and lack of information and apology are key reasons for patients taking legal action. Apologising has even been shown to be cost- effective. Patients and their families want to know that the lessons learned in one place will be communicated more widely.

25. Communicating with the health-care team after an error has occurred is also vitally important. Health-care workers may be personally affected after involvement in care which has resulted in error. Understanding this and providing support to health-care workers is challenging, but vitally important.

26. Communication plays a significant role in all aspects of error. Firstly, improving the quality of communication among health-care workers and between patients and health-care workers can help prevent errors. Secondly, good communication is imperative when dealing with errors once they have occurred.

PATIENT MEDICAL RECORD AND AUDIT

Patient Medical Record

27. Before looking at specific role of medical documentation with respect to patient safety, we need to discuss about the medical record, what it is, how it develops and why it is so important. The medical record is an important compilation of facts about a patient's life and health. It includes documented data on past and present illnesses and treatment written by health care professionals caring for the patient. The medical record

> "must contain sufficient data to identify the patient, support the diagnosis or reason for attendance at the health care facility, justify the treatment and accurately document the results of that treatment" (Huffman, 1990).[7]

28. The main purpose[7] of the medical record is:

(a) To record the facts about a patient's health with emphasis on events affecting the patient during the current admission or attendance at the health care facility, and

(b) For the continuing care of the patient when they require health care in the future.

29. A patient's medical record should provide accurate information on:

(a) Who the patient is and who provided health care;

(b) What, when, why and how services were provided; and

(c) The outcome of care and treatment.

30. The medical record has four major sections:

(a) Administrative, which includes demographic and socioeconomic data such as the name of the patient (identification), sex, date of birth, place of birth, patient's permanent address, and medical record number;

(b) Legal data including a signed consent for treatment by appointed doctors and authorization for the release of information;

(c) Financial data relating to the payment of fees for medical services and hospital accommodation; and

(d) Clinical data on the patient whether admitted to the hospital or treated as an outpatient or an emergency patient.[7]

31. It is important to note at this time that accurate, timely and accessible health care data plays a vital role in the planning, development and maintenance of health care services. The quality of data in the medical record and its availability is essential if health care authorities wish to maintain health care at optimal level.

32. The medical record is made up of a number of forms, which are all used for a specific purpose. The basic set of forms in the inpatient medical record includes[9]:

(a) Front sheet or identification and summary sheet, which covers identification, final diagnoses, disease and operation codes, and the attending doctor's signature;

(b) Consent for treatment is often on the back of the Front Sheet and must be signed by the patient at the time of admission. There are two parts to this form. The first half of the form is a general consent for treatment and the bottom half is consent to release information to authorized persons;

(c) Correspondence and legal documents received about the patient, e.g., referral letter, requests for information, etc.;

(d) Discharge summary, if required by the hospital/health authority;

(e) Admission notes, including the patient's family medical history, the patient's past medical history, presenting symptoms, results of a physical examination, provisional diagnosis (the reason the patient came or was brought to hospital), proposed tests and care;

(f) Clinical progress notes recording the patient's daily treatment and reaction to that treatment written by the attending doctor and other health care professionals;

(g) Nurses' progress notes recording daily nursing care including temperature, pulse and respiration charts, blood pressure charts etc.;

(h) Operation report if an operation or operations are performed;

(j) Other health care professional notes, e.g., physiotherapy, Social Workers, etc.;

(k) Pathology reports including hematology, histology, microbiology, etc.;

(l) Other reports – X-ray, etc.;

(m) Orders for treatment and medication forms listing daily medications ordered and given with signatures of the doctor prescribing the treatment and the nurse administering it; and

(n) Special nursing forms for observation of head injuries etc.

Record v/s Documentation

33. Documents are created by planning what needs to be done and records are created when something is done. **Documents can change and records don't change.** Documents need to be reviewed, approved, legible, up-to-date, communicated, and readily available. Records need to be identifiable, stored, protected, retrievable, retained, but disposed of when obsolete.[10]

(a) **Record Definition.**[10]

"Evidence about a past event"

A record is generated in the "do" phase. Records consist of any data you collect during the operation of your business. Records are facts and should not change. If new facts arise that contradict the old facts (an error), then you should strike through the old fact and record the new fact.

(b) **Documentation Definition.**[11]

"The term documentation is generally used for the gathering and recording of information, especially to establish or provide evidence of facts or testimony."

To record (documentation) means to capture information relevant to understanding the physical configuration, evolution and condition of monuments, groups of buildings or sites at known points in time, and the basis of decisions made to alter or care for them.

34. In writing proper Assessments, Care and Discharge plans entails in- depth professional judgment and reflection. Having to prepare proper documentation serves an important role of helping to ensure quality care by making medical staff think about their patients, as well as review and reflect on their interventions. With periodic reviews based on information systematically gathered from patient records, management staff could objectively consider the effectiveness of their services. Findings from evidence-based research could also lead to new perspectives and innovative approaches and programmes. Achievements could be celebrated and distinguished by seeking accreditation to demonstrate a hallmark of quality to clients and other stakeholders. Thus, rather than viewing documentation as tedious and time-consuming, professionals should view it in the light of it being an essential element of professional practice to deliver successful outcomes for clients.[12]

Common Standard of Documentation[13]

35. Medical record standards at a minimum, compliance to these standards must be reviewed:

(a) Each record must contain identifying information on the enrollee, including name, enrollee identification number (Medicaid #), date of birth and sex; and legal guardianship.

(b) Each record must be legible and maintained in detail.

(c) Each record must contain a summary of significant surgical procedures, past and current diagnosis or problems, allergies, untoward reactions to drugs and current medications.

(d) All entries in each record must be dated and signed by the appropriate party.

(e) All entries in each record must indicate the chief complaint or purpose of the visit, the objective findings of practitioner, diagnosis, or medical impression.

(f) All entries in each record must indicate studies ordered, for example: lab, x-ray, EKG, and referral reports.

(g) All entries in each record must indicate therapies administered and prescribed.

(h) All entries in each record must include the name and profession of practitioner rendering services, for example: MD, DO, and OD, including signature or initials of practitioner.

(j) All entries in each record must include the disposition, recommendations, instructions to the patient, evidence of whether there was follow-up, and outcome of services.

(k) Each record must contain an immunization history. Each record must contain information on smoking/ETOH (ethyl alcohol)/substance abuse.

(l) Each record must contain a record of emergency services and care and hospital discharges with appropriate medically indicated follow up.

(m) Documentation of referral services in the enrollee's medical records.

(n) All services provided by providers must be documented. These services must include, but are not limited to, family planning services, preventive services, and services for treatment of sexually transmitted diseases.

(o) All records must reflect the primary language spoken by the enrollee and translation needs of the enrollee.

(p) All records must identify enrollees needing communication assistance in the delivery of health care services.

(q) All records must contain documentation that the enrollee was provided written information concerning the enrollee's rights regarding advanced directives (written instructions for living will or power of attorney), and whether or not the enrollee has executed an advanced directive.[13]

Audit

36. An audit is a planned and documented activity performed by qualified personnel to determine by investigation, examination, or evaluation of objective evidence, the adequacy and compliance with established procedures, or applicable documents, and the effectiveness of implementation. Evaluation of data, documents and resources to check performance of systems meets specific standards. Audit in the wider sense is simply a tool to find out what you do now; this often to be compared with what you have done in the past, or what you think you may wish to do in the future[14]. Generally in healthcare organizations Audit refers to Clinical Audit, Audit by MRD, Audit by Accreditation Agencies, External Audit etc.

37. The audit is a cyclical process which can be outlined in five stages[15]:

(a) Stage 1-Planning for audit

(b) Stage 2-Standard/criteria selection

(c) Stage 3-Measuring performance

(d) Stage 4-Making improvements

(e) Stage 5-Sustaining improvements

38. **Selecting and Developing Appropriate Performance Levels**[15]. Audit criteria should consist of measurable statements of what should be happening with explicit and quantifiable performance levels. These performance levels or targets may be expressed as percentages. There are a number of ways to set targets for compliance, including discussion and development of a consensus opinion among audit team members and relevant stakeholders and benchmarking against national rates. Three factors should be taken into account and assessed when setting targets. These factors are clinical importance, practicability and acceptability. The expected level of performance or target can range from 0% (the criterion is something that must never be done) to 100% (the criterion is something that must always be adhered to).[8] For the audit to be carried out for non-medical aspects the criteria of 100% adherence needs to be followed. The documents at the sharp-end can be broadly classified as:

(a) Initial assessment

(b) Plan of Care.

(c) Progress Notes.

(d) Findings and Reports.

(e) Discharge Summary.

Initial Assessment

39. Initial assessment of a patient is done for finding out the medical state of patient and to give broad direction to the treatment and the nursing care. Being the foundation of the subsequent treatment it should bring out the details of the ailment based on existing facts and symptoms and suggest the best possible future course of action. It is important that this is documented and validated since it lays down the starting time of the medical-care of the patient in a hospital. It also is the medium to give a brief insight into the courses of events leading to the condition of patient and the first medical judgment in the hospital.

Plan of Care

40. A care plan outlines the medical and nursing care to be provided to an individual / family / community. It is a set of actions the doctors and nurses will implement to resolve / support diagnoses identified by Doctor's and Nursing Initial Assessment. The creation of the plan is an intermediate stage of the medical-care process. It guides in the ongoing provision of care and assists in the evaluation of that care.

(a) Its focus is holistic, and is based on the clinical judgment of the medical staff, using assessment data collected from medical framework.

(b) It is based upon identifiable medical diagnoses (actual, risk or health promotion).

(c) It focuses on client-specific outcomes that are realistic for the care recipient.

(d) It includes medical interventions which are focused on the risk factors of the identified diagnosis.

Progress Notes

41. Progress Notes are the part of a medical record where healthcare professionals record details to document a patent's clinical status or achievements during the course of hospitalization or over the course of outpatient care. Reassessment data may be recorded in the Progress Notes, Master Treatment Plan (MTP) and / or MTP review. Progress notes are written in the variety of formats and

details, depending on the clinical situation at hand and the information clinician wishes to record.

(a) One example is the SOAP note, where the note is organized into Subjective, Objective, Assessment, and Plan sections.

(b) Another example is the DART system, organized into Description, Assessment, Response, and Treatment.

42. Progress notes are written by both physicians and nurses to document patient care on a regular interval during a patient's hospitalization. Physicians are generally required to generate at least one progress note for each patient encounter. Nurses are required to generate progress notes on a more frequent basis, depending on the level of care and may be required anywhere from several times an hour to several times a day.

Findings and Reports

43. There are thousands of medical tests used on patients to diagnose, measure progression of a disease or condition, or measure the effectiveness of the treatment. There are two basic types of medical tests results:

(a) Tests that give yes or no answer (usually used for diagnostic purposes.)

(b) Tests that gives relative results , as in measuring something to be higher or lower , bigger or smaller than before , or inside or outside a "normal" range.

Discharge Summary

44. Discharge summary means a clinical report prepared by a physician or other health professionals at the conclusion of a hospital stay or series of treatments. It outlines the patient's chief complaint, the diagnostic findings, the therapy administered and the patient's response to it, and recommendation on discharge. In another words a document prepared by the attending physician of a hospitalized patient that summarizes the admitting diagnosis, diagnostic procedures performed, therapy received while hospitalized, clinical course during hospitalization, prognosis, and plan of action upon the patient's discharge with stated time to follow up.

Medication Safety

45. In the past, safety issues surrounding medication have centered on adverse drug reactions due to the side-effects of correct medication. Medication safety is a broader term that encompasses errors which are not side-effects of the intended drug, but, for example, the result of the wrong drug being administered in error or the right drug being given in the wrong dose or via the wrong route. These are termed adverse drug events.[1]

46. Harm from adverse drug events occurs across the world. Some studies suggest that they account for a quarter of all medical errors. In the United States, Australia and France, adverse drug events occur in approximately 4% of hospital admissions and death results from these errors 5-10% of the time. In the United Kingdom, over 1000 people died from adverse drug events in 2001 alone. It has been suggested that 75% of these errors are preventable[8]. There is no such statistics available in our country, however, in all probability it is likely to be more alarming and hence need to be audited so as to prevent adverse drug events.

47. In a multi-specialty hospital, written medical notes are the only means health-care workers have of communicating with each other. Medical records need to be clear and unambiguous. They need to provide an accurate way of conveying important information. This is especially important when the written information concerns drug, dosages, route, delivery timings and changes to the current regime. All too often, medical notes are not kept up-to-date, and in addition to illegibility, transcription is problematic. These contributing factors have been shown to be at the root cause of many adverse drug events.

Nutritional Assessment

48. The health care organisations requires to ensure that patients have a choice of food that is prepared safely and provides a balanced diet; and that 'individual nutritional, personal and clinical dietary requirements are met, including any necessary help with feeding and access to food 24 hours a day' (NHS, 2004). The National Patient Safety Agency reported that up to 40 per cent of all hospital patients are undernourished. This percentage increases once patients have been in hospital for one week. This highlighted the need to be monitoring what people were eating and drinking. [16]

49. The main barriers to compliance with nutritional screening within the first 24 hours of admission were identified as:

(a) Lack of equipment – weighing scales and height measures.

(b) Lack of leadership.

(c) Lack of clarity relating to screening and assessment.

(d) Dependency of patients.

(e) Credibility and usability of available screening tools.

(f) Lack of education and training for medical and nursing staff.

(g) Nutritional screening not mandatory.

Accountability

50. With clarity over objectives, stakeholders, and outcomes, you than need to define the key accountability arrangements within your organization. Who is responsible to whom, and for what? Include any committees or other groups with responsibility for specific issues. Start with the board and work down. Produce an organization chart that clearly shows the accountability arrangements.[3]

51. Then set down the capability required to meet your objectives. Capability can be expressed in many ways- leadership is crucial, but also important are financial and human resources, physical resources such as buildings and equipment, staff attributes such as specific knowledge, competence, skills and expertise, so on.

52. Now define the arrangements you have to have in place for management, including the board, to monitor and review all aspects of the system of internal control- to learn from identified weaknesses, and improve the system where necessary.[3]

53. Monitoring and review processes will also look at the work carried out by those individuals, functions and organizations providing aspects of internal or external independent assurance. Within an organization, this might include internal audit and clinical audit, specialist risk and safety personnel who are in a position to provide truly independent assurances, and so on. Externally, this might include external auditors, professional colleges, the Commission for Health Improvement, Accreditation bodies, and various regulatory bodies. Write them down and make sure their reports and any other communications with the healthcare organization are properly taken into account as part of monitoring and reviewing ones system of internal control.[15]

54. Finally set down organization's arrangements in place for communication and consultation with both internal and external stakeholders.

CHAPTER 3: AIM AND OBJECTIVES

Aim

55. To Audit the Patient Medical Documentation in In-patient wards and ICUs for contributing towards Patient Safety in a multi-specialty hospital.

Objectives of Study

56. The objectives of this study are to analyze the following from the perspective of an administrator:

(a) To establish the role of documentation in the patient safety.

(b) To identify the likely non-medical errors by doctors and nurses in Patient Medical Documentation having direct bearing on safety of patient.

(c) To utilize internal audit of the Patient Medical Documentation as a possible means to Patient Safety in a new accredited hospital.

(d) To recommend a broad mechanism of internal audit so as to bring behavioral changes in the approach to documentation as means to improve patient safety in a hospital.

CHAPTER 4: METHODOLOGY

57. **Methodology of Data Collection.**

(a) **Study Area**. The study was carried-out in a Multi Specialty Tertiary Care Hospital.

(b) **Study Design**. Cross sectional Descriptive study design.

(c) **Study Period**. 2nd Feb to 30th Apr 2015.

(d) **Study Population**. Patient Medical Documentation in In-patient wards and ICUs.

(e) **Sample Size**. A sample of 308 (Three Hundred and Eight) Patient Medical Documentation folders in the In-patient wards and ICUs was audited for the study (Appendix 'B').

S No	Wards	Number of Folders Audited
1.	IPD x 4	197
2.	ICU x 6	111
	TOTAL	**308**

(f) **Study Tool**. Existing Patient Medical Documentation Audit form (Appendix 'A') was utilized.

(g) **Sampling technique**. Non-Probability Convenience Sampling Technique was used. Intention was to not disturb the process of medical care and hence the patient safety.

58. **Procedure**. To have an initial understanding about the Patient Medical Documentation a checklist was prepared after going through the NABH Guidelines. It was analysed for the medical and non-medical aspects. Being a management study, the non-medical aspects were excluded and then matched with the Performa (Appendix 'A') of the existing Audit of Patient Medication Documentation of the hospital. Since the in-patient departments are the most complete part of any hospital which requires maintenance of all types of Patient Medical Documentation, the data was collected from four IPD's and six ICUs of the hospital. The departments selected

were basically the ones where a patient is admitted in the hospital and wherein the documentation covers the complete array of medical and non-medical documentation. All the selected in-patient departments were visited and their Patient Medical Documentation was scrutinized for meeting the Patient Safety requirements and simultaneously understanding how the Quality standards are maintained through Continuous Service Evaluation Methodology.

59. For initial 168 folders the data was collected and forwarded to Quality Department. For the balance of the documents audited the data was compiled as daily report along with the photographs of the documents where there was any observation and forwarded to Quality Department. This data was shared with the doctors and nurses to be able to reflect upon the areas of improvement with respect to documentation. Simultaneously, the data was compiled in excel-sheet for collective analysis of the data.

60. **Terms of Reference**. The terms of reference for the audit were to assess the Patient Medical Documents from the perspective of contributing to patient safety by the management as per the existing format without commenting on the medical aspects. The focus of the audit was to scrutinize the “HOW” and “WHEN” the ‘sharp end’ forms were filled in the Patient Medical Documentation without getting into “why” and “what” of the whole process.

61. The Patient Medical Documents were scrutinized for the following parameters:

(a) Doctor’s Initial Assessment.

(b) Nursing Initial Assessment.

(c) Doctors’ Care Plan.

(d) Nursing Care Plan.

(e) Nutritional Assessment Done within 24 hrs.

CHAPTER 5: OBSERVATIONS AND ANALYSIS

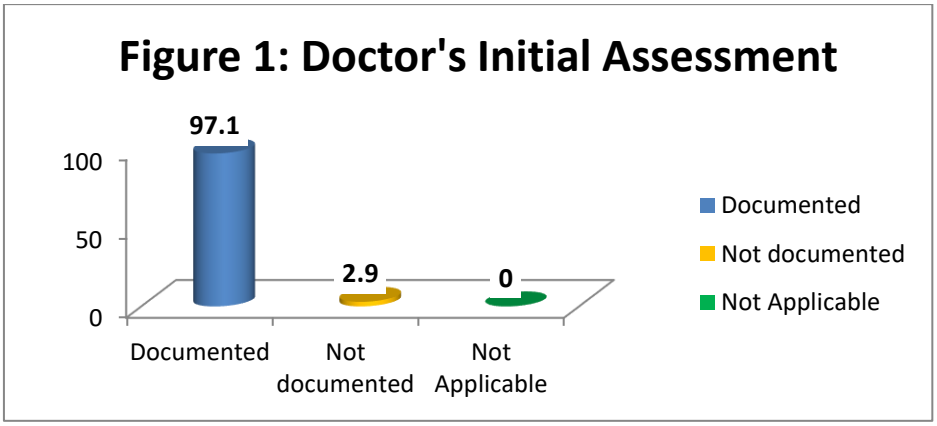
62. **Doctor's Initial Assessment (IA).** 98.8% of the Doc's IA were documented **(Figure 1)** and 95.8% of the documents have been validated **(Figure 2).** The Doc's IA is responsible for the plan of treatment and needs to be done as per the documented procedure and should be completed. Even though, the Doc's IA seemed to be complete as per the format evolved as per the NABH guidelines, there were general shortcomings noted in the documentation which are given as under:

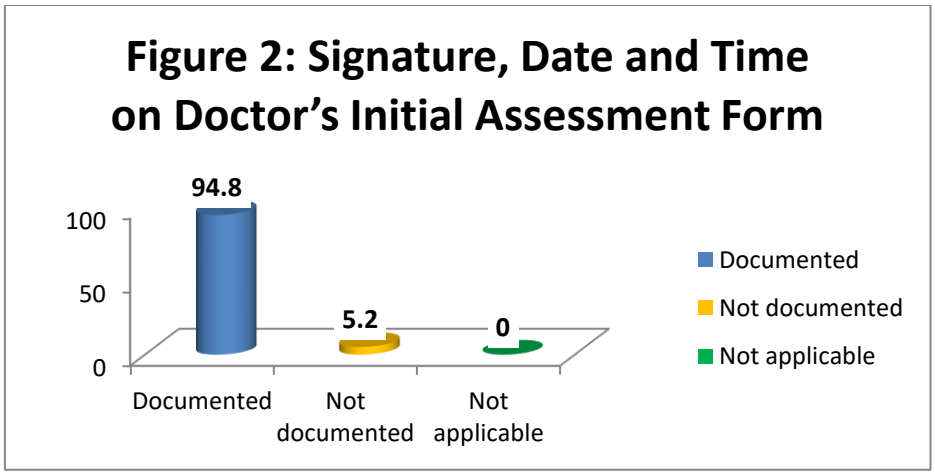
(a) The time for DIA has not been endorsed in certain documents.

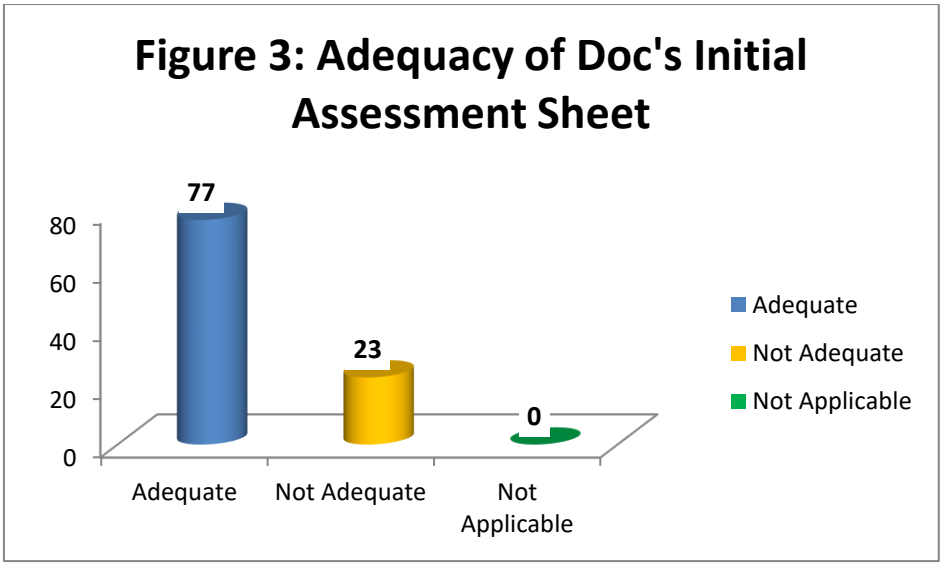
(b) The names of doctor's and consultants were not legible in most of the places. This despite the fact that all doctors were issued with personalized rubber stamps and none of the Doc's IA had stamp of the doctor.

(c) The plan of care was not marked in certain cases.

(d) These shortcomings reduced the adequacy of the documents substantially to 77% as depicted in **Figure 3** from seemingly better looking statistics of **Figure 1 &2**.





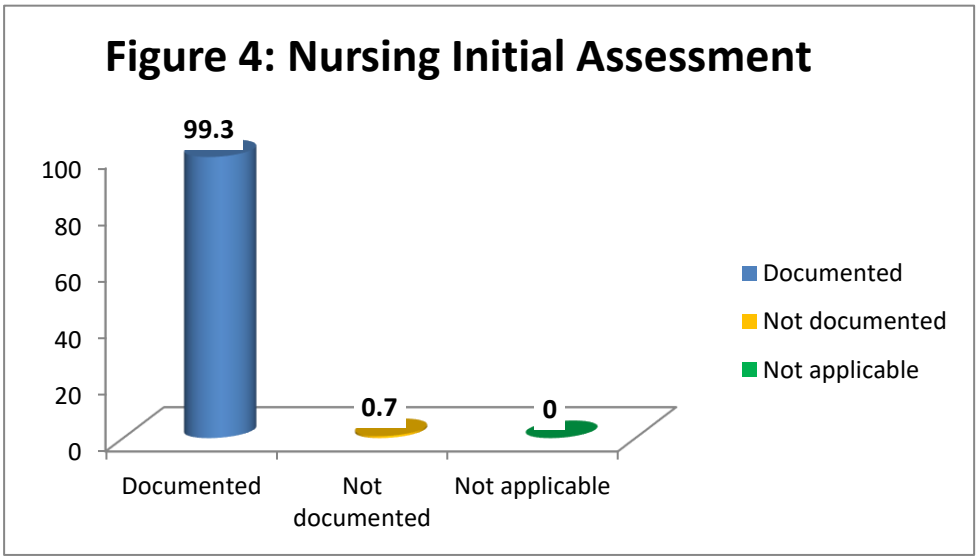


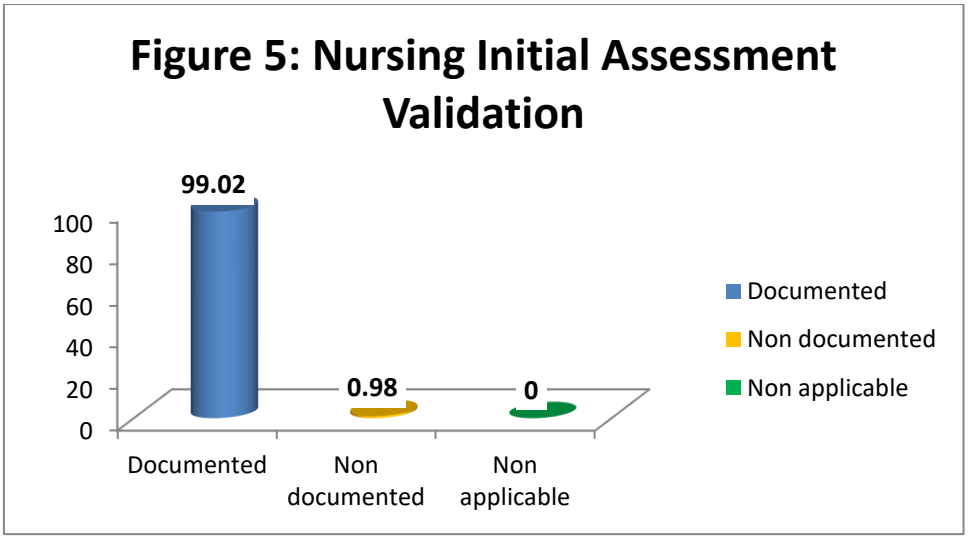
63. **<u>Nursing Initial Assessment (Nursing IA)</u>.** 98.8% of the Nursing IA are documented **(Figure 4)** and 98.2% of the documents have been validated **(Figure 5).** The general documenting deficiencies noticed in the documentation are as follows:

(a) The column of 'Handed Over To' has not been signed in certain documents.

(b) The date and timings were not written clearly.

(c) The entries which are not relevant should be scored out or endorsed with a remark 'NA' and not left blank as was done in a few documents.

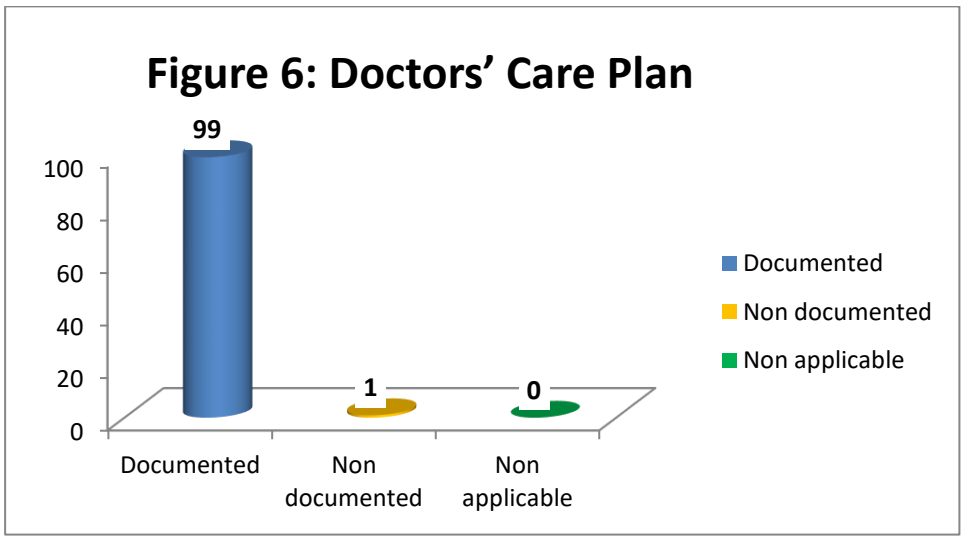


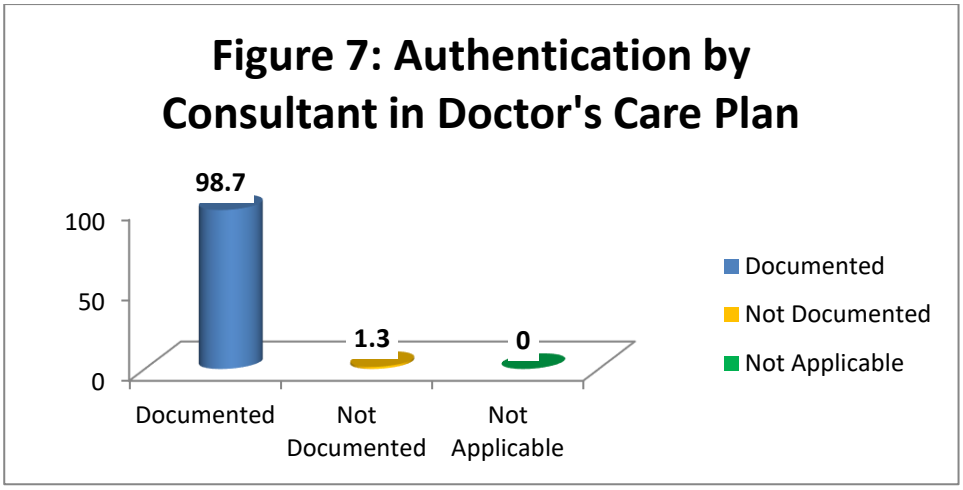


64. **<u>Doctors' Care Plan (Doc's CP)</u>.** The Doc's CP was complete in all documents (99 %) **(Figure 6),** however, in a few cases the signature of the doctor was not endorsed (Documented-98.7%) **(Figure-7).** It was difficult to ascertain the signature of the consultant in the documents especially where patient was attended to by doctors from various specialties. There were certain places were the resident doctors had signed on the behalf of the consultant. As per NABH requirements too, following needs to be followed:

(a) The endorsement by the Consultant at least once in a day.

(b) The use of personal stamp of the doctor along with the signatures.



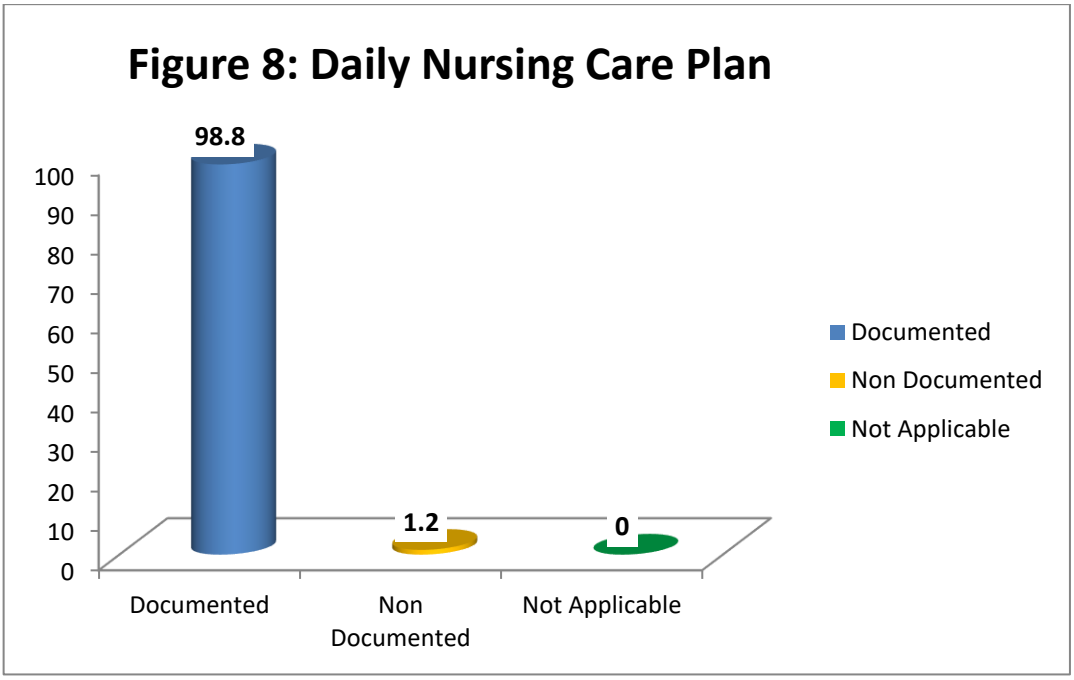


65. **Nursing Care Plan (NCP)**. The NCP is quite exhaustive in details and contains a lot of documented procedures and readings which are relevant for the treatment of patients. It was found that 98.8% of the NCP were complete **(Figure 8)** and same percentages of document were authenticated too. The major shortcomings in the documentation of the NCP were:

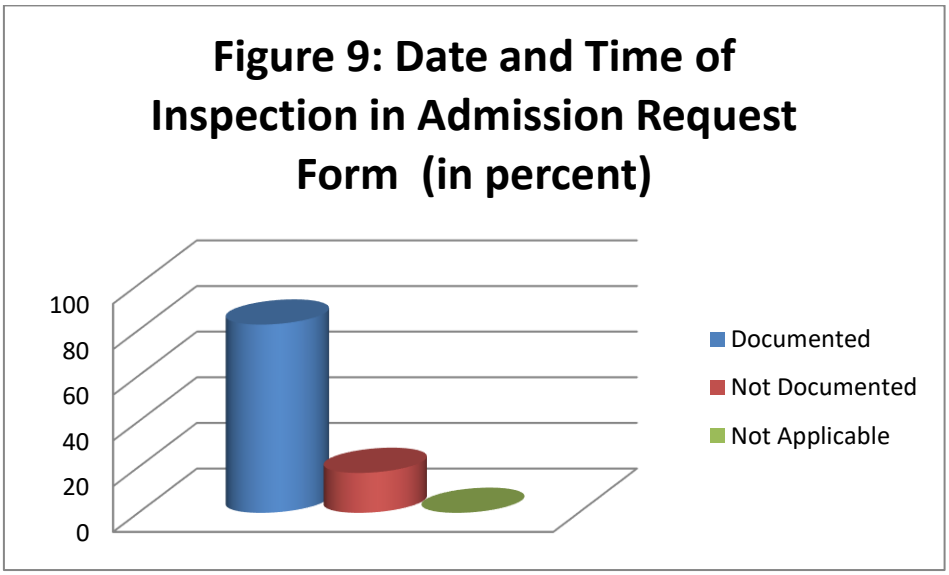
(a) Entries in the NCP were left blank at certain places.

(b) The one or more column (morning, evening or night) for the planning of nursing were left blank.

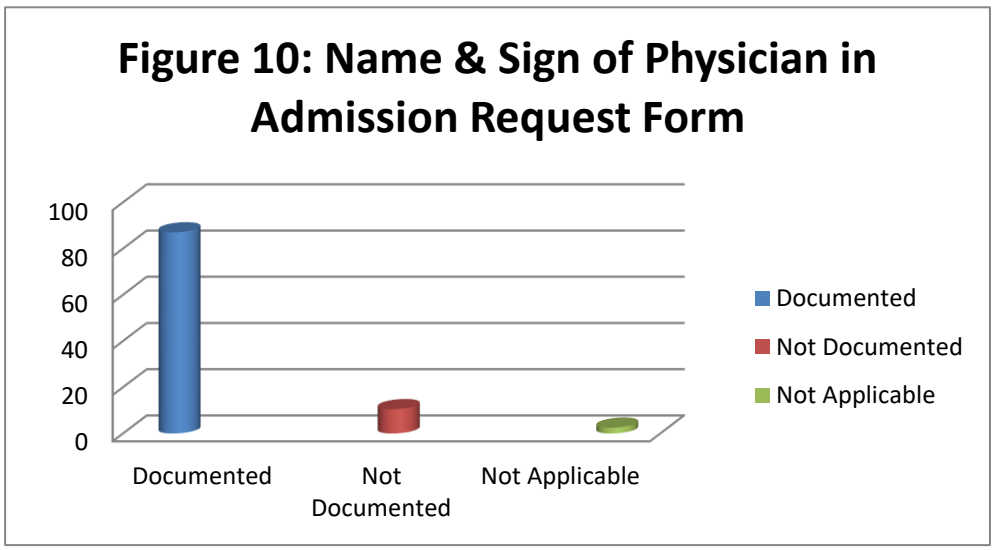
(c) Signature of Floor Managers was missing in some of the documents.



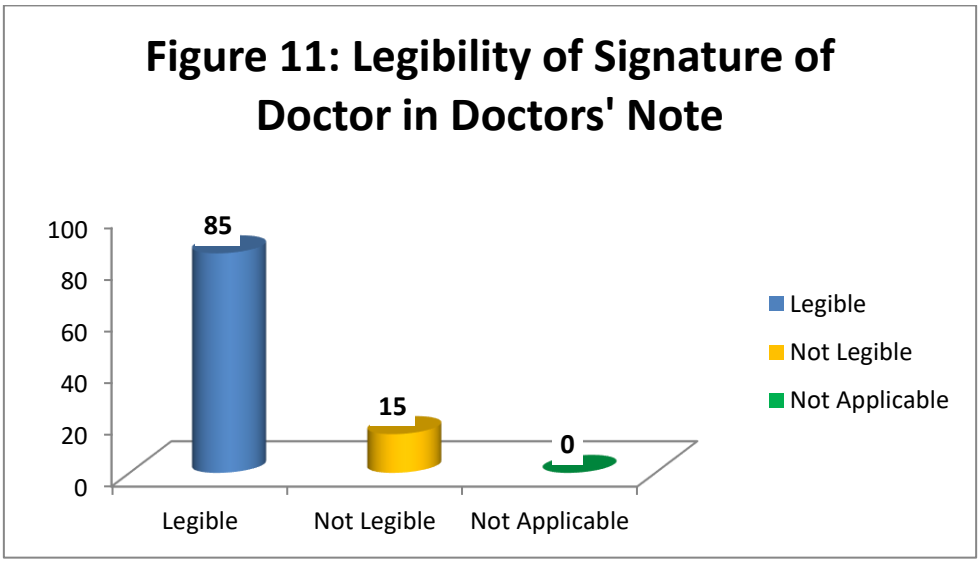
66. **<u>Admission Request Form</u>**. Endorsement of Date and Time of initial inspection in the Admission Request Form by the doctor indicates the actual time taken for the doctors to attend to the patient after admission. It was found that 82.5% of the documents had the necessary endorsement and balance 17.5% didn't have it **(Figure 9)**.

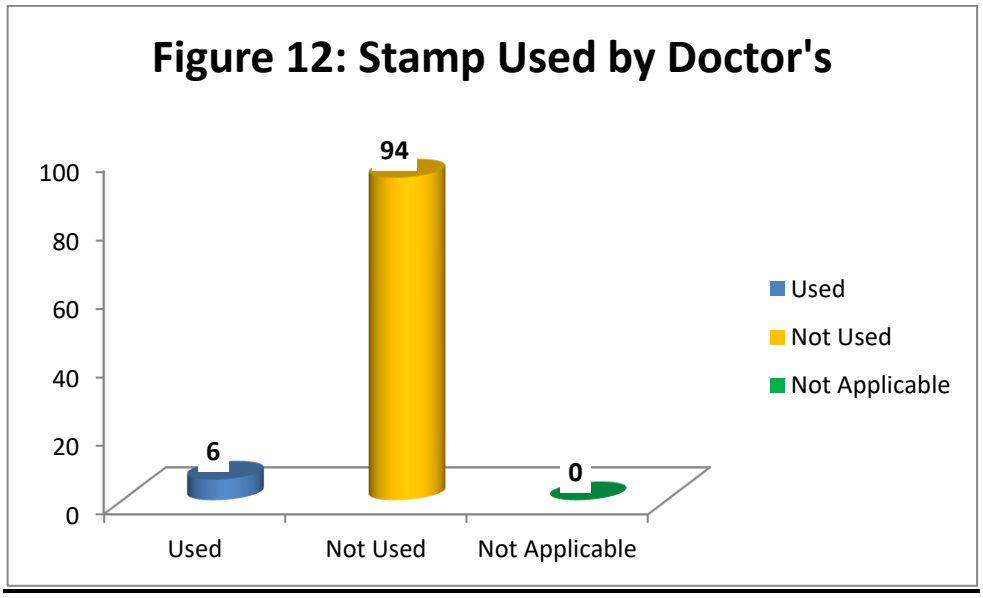


67. Name & Sign of physician was not endorsed in 10.5% of admission request form **(Figure 10)** thereby making the subsequent assessment difficult since in modern medical care where there is involvement of variety of people, a lot is communicated by the knowing the person endorsing on the document.



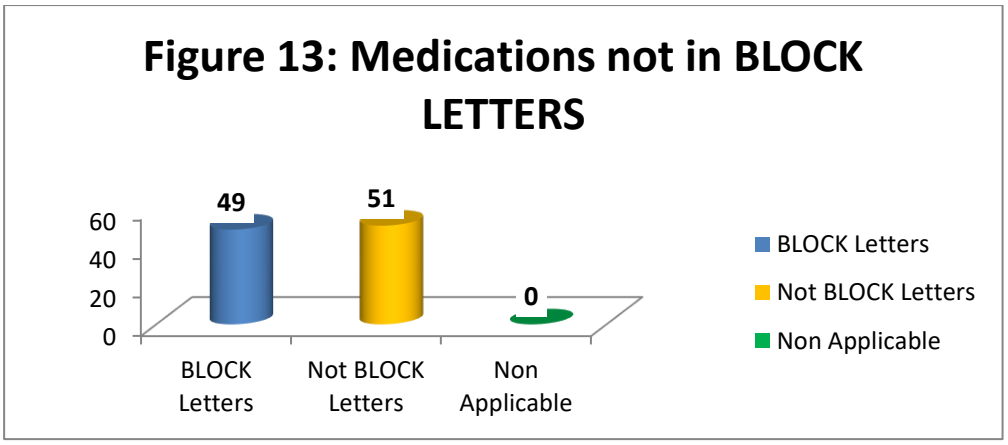
68. 15 % of the signatures of doctor are not legible in Doctors' Note **(Figure 11).** And in the absence of use of stamps by 94 % of the doctor's **(Figure 12)**, in case of emergency, crucial time may be lost in giving feedback to the concerned doctor and thereby delaying in soliciting the urgent medical advice which eventually affects the patient safety.



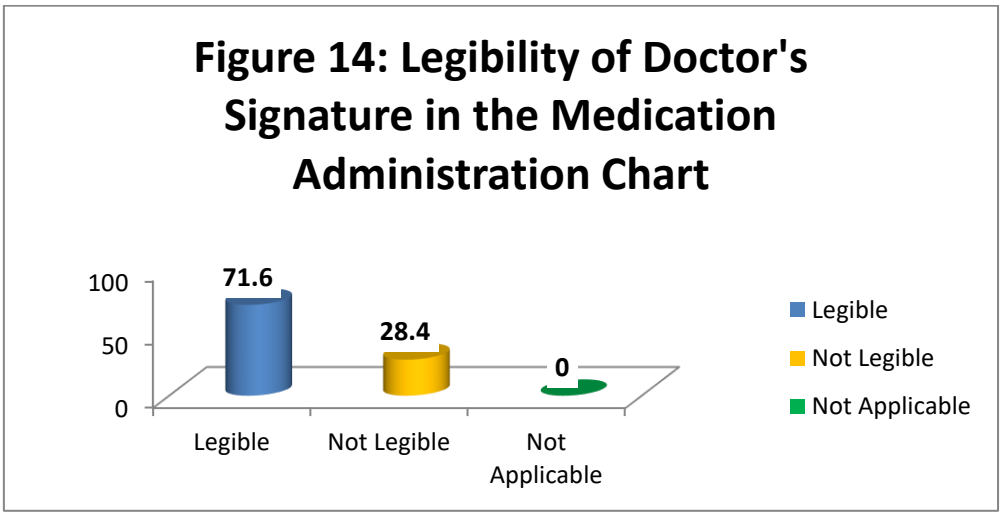


69. **<u>Medication Administration Chart</u>**. The Medication Administration Chart is the record of one of the major intervention by the healthcare professionals. It is made as per NABH standards to root out all the reasons for adverse drug event. The results of the audit are as under:

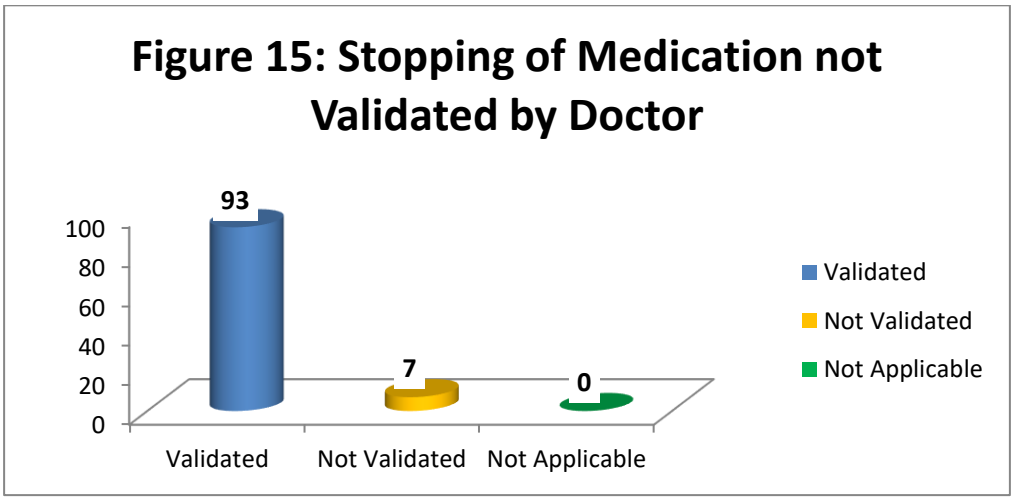
(a) Prescription of Medication in BLOCK LETTERS has not been done in 51 % of Medication Administration Charts **(Figure 13)**.



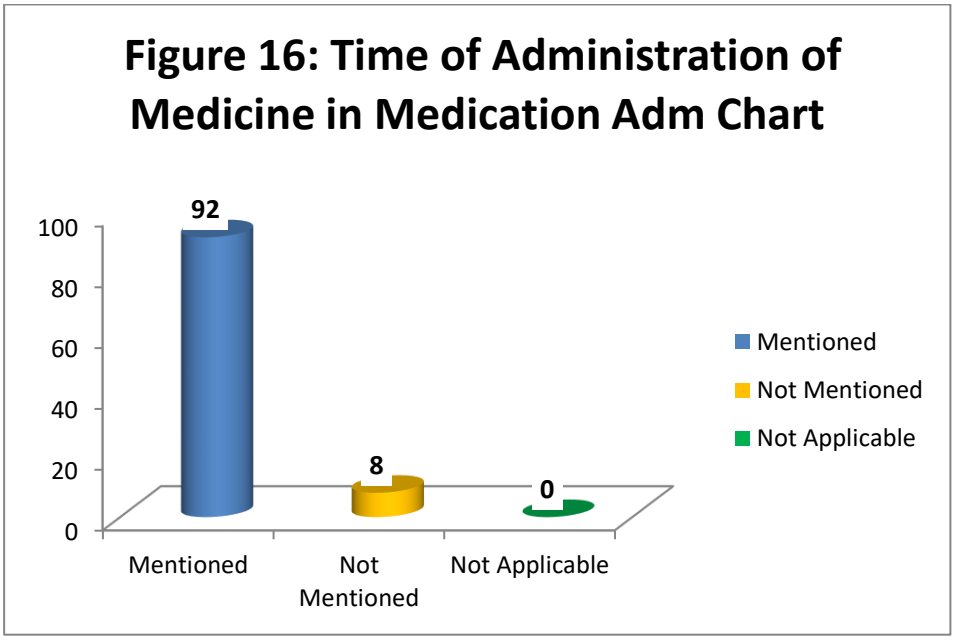
(b) The signature of doctor is not legible in 28.4% of Medication Administration Charts **(Figure 14).**



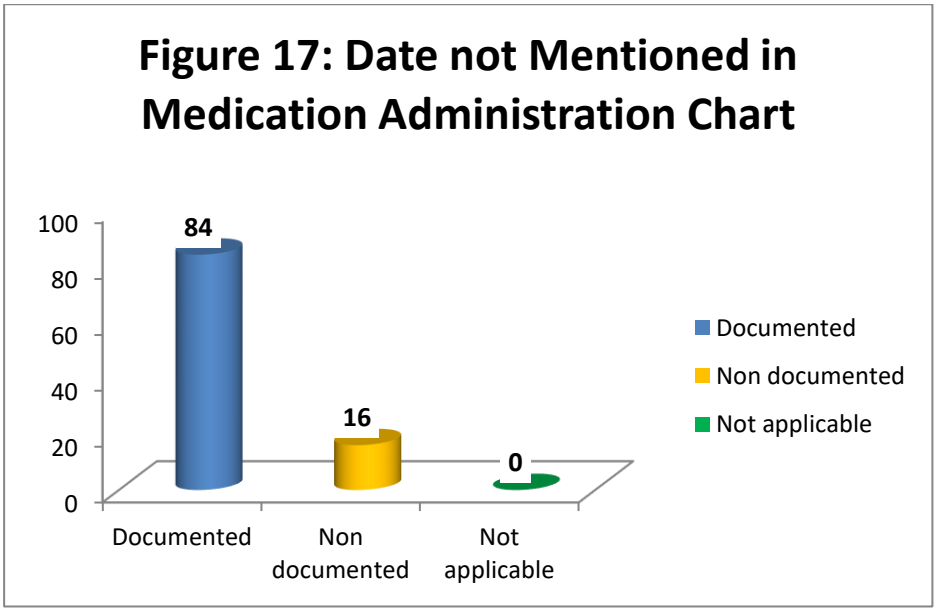
(c) Medications are stopped but not validated by the doctor in 7% of Medication Administration Charts **(Figure 15).**



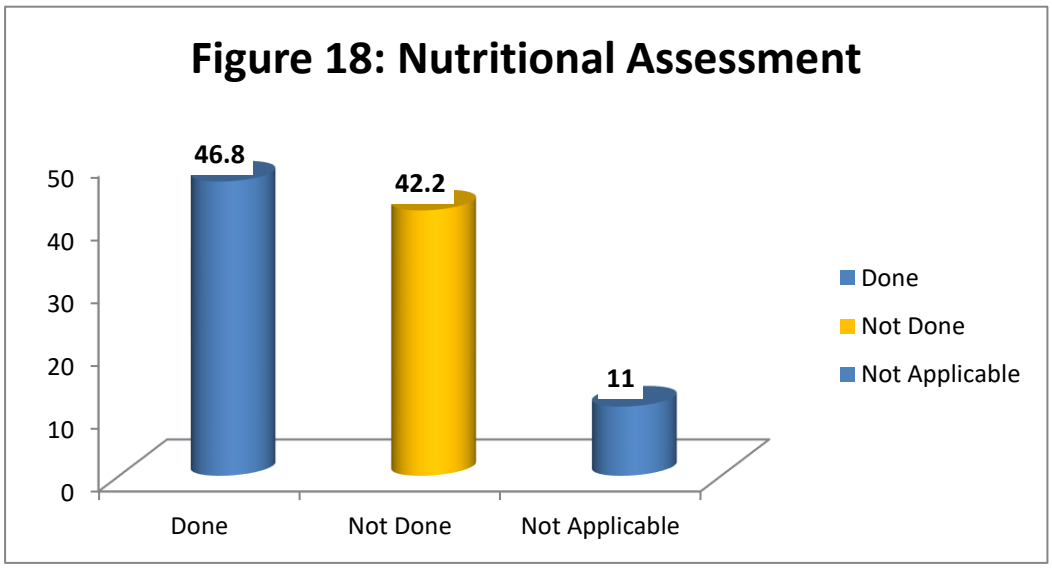
(d) Time of administration of medication is not mentioned in 8% of the Charts **(Figure 16).**



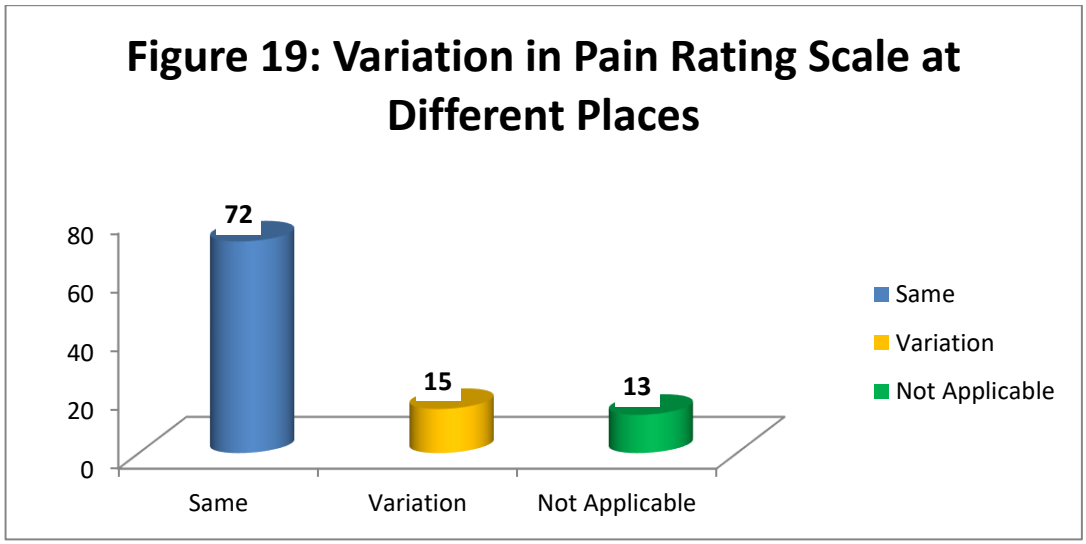
(e) Date of prescription is not mentioned in 16% of Medication Administration Chart **(Figure 17).**



70. **Nutritional Assessment**. Nutritional Assessment of all patients needs to be done within 24 hrs. However, it was found to be the most neglected aspect of the patient care and was not carried-out in 42.2% of cases **(Figure 18).**



71. **Variation in Pain Rating**. The hospitalization of a patient is done with a view to cure the patient and to relieve the pain. The pain scores are reliable indicators to assess the effect of the treatment. However, during the audit it was found that there was variation in the Pain Ratings endorsed at different places for the same duration in 15% of cases **(Figure 19)**.



CHAPTER 6: DISCUSSION

72. The use of audit for assessing the nature of prescription errors and establishing standards may be one viable solution for improving the documentation and contribute towards patient safety. Clinical audit is shown to be beneficial in many developed countries, especially in the UK, where it is commonly utilized[5]. Even though there is a need to improve the Patient Medical Documentation as a means to improve patient safety in India, only one study could be found on the related subject published in Indian J Med Sci, Vol. 62, No. 11, November 2008. In a study done to assess adverse drug events by Bates et al. found 28% of adverse drug events to be preventable in their study and concluded that 56% of those preventable adverse events occurred at the stage of ordering[17]. The data for India in this regards is not available, however, it can be assumed that the results of studies by Bates would be more than relevant.

73. The major findings from the observations and analysis are as under:

(a) **Doctor's Initial Assessment.** The statistics of Doc's IA seems to be satisfactory as per the audit however shortcomings like non-use of stamps, illegible signatures, not mentioning the time and plan of treatment and other deficiencies reduced the adequacy of the Doc's IA substantially to 77% **(Figure 3).** This aspect makes the task of fixing the accountability for any delay in the subsequent treatment and faulty treatment due to error in initial assessment very difficult especially if the event was a near miss and not reported. As such issues like this may not get audited at the MRD stage and hence auditing at the documentation stage may help in identifying the defaulting doctor and undertaking necessary timely measures in terms of training and counseling to bring in behavioural change.

(b) **Doctors' Care Plan (Doc's CP).** The Doc's CP was complete in 99% documents **(Figure 6).** However, it was difficult to verify the signature of the consultant among so many signatures in the Doc's CP. As such NABH standards specify that a consultant should visit the patient at least once a day. The statistics of 15 % of the signatures of doctor being illegible in Doctors' Note **(Figure 11)** and the absence of use of stamps by 94 % of the doctor's **(Figure 12)** indicates something but the benefit of doubt was given to the Doctors initially by the Audit which continued throughout to maintain standard. It has led to the high figure of 98.7% for the Authentication by Consultant in the Doc's CP **(Figure-7).** This aspect if seen in retrospect is reflective of the feeling of supremacy amongst doctors especially the seniors. In case there are many doctors/specialists visiting the patient, each doctor making observation in Doc's CP should be identifiable and putting the stamp along with signature should be the norm to not only maintain the legal sanctity of the record but to contribute to Patient Safety by correct documentation.

(c) **Nursing Documentation.** The Nursing IA (documented 99%) and Nursing Plan seems to give a sense that the nursing is generally close to the standard of 100% however, there is a dichotomy noticed by the Audit in terms of variation in Pain Rating of 15% **(Figure 19).** The high rate of Nursing Documentation indicates that due to the presence of adequate nursing staff in the wards there is a lot of time devoted to Nursing Documentation. However the variation in the pain score of 15% indicates that the events are being documented clerically with a view to fill the column. This aspect brings the other statistics of better documentation also under doubt. The hospitalization of a patient is done with a view to cure the patient and to relieve the pain. The pain scores are reliable indicators to assess the effect of the treatment. It may also suggest that more time is required for the documentation due to the repetitive entries at the cost of patient care. Hence there may be a separate audit carried out to simplify the documents so that the nursing staff to devote more time for the patient care and thus improve patient safety.

(d) **Medication Administration Chart**. The adverse drug events are direct consequence of not being able to ensure 5 Rights: Drug, Route, Time, Dose and Patient[1]**.** The standards for these parameters have to be 100% always and every time, however, the statistics indicates the following:

(i) Prescription of Medication in BLOCK LETTERS has not been done in 51 % of Medication Administration Charts **(Figure 13)**. This is one of the major causes of the adverse event and not resorting to writing the drug in CAPITAL letters can lead to administration of wrong drug. The high rate of defaulting in this regards needs to be addressed urgently by training and counseling.

(ii) The signature of doctor is not legible in 28.4% of Medication Administration Charts **(Figure 14)**. And to read this in conjunction with non use of rubberstamp by 94% doctor **(Figure 12)** can lead to alarming situations. Especially during emergency if the medicine is not written in CAPITALS and signature of the doctor is illegible then crucial time may be wasted in consulting the concerned doctor and administering the appropriate medicine.

(iii) Medications are stopped but not validated by the doctor in 7% of Medication Administration Charts **(Figure 15).** This aspect can be critical to the patient with multiple ailments and being attended to by many doctors. In this case, more than one doctor might want to prescribe a particular medicine and stopping the medicine without validation by one may induce error in judgment of the other.

(iv) Not mentioning the Time of Administration of medication (8% **Figure 16**) may cause over or under-administration of drug and is a threat to patient safety due to the right-drug.

(v) Date of prescription is not mentioned in 16% of Medication Administration Chart **(Figure 17).** This may cause errors in judgment during review. As such date and time of medication sets a starting point for beginning of the treatment and are important at the time of review to assess the treatment. The drugs have side effects too and hence over-dosage due to not knowing the details of beginning of medication is a potential risk to the patient.

(e) **Nutritional Assessment**. Nutritional Assessment of all patients needs to be done within 24 hrs. However, it was found to be the most neglected aspect of the patient care and was not carried-out in 42.21% of cases **(Figure 18)**. Nutritional Assessment is a mandatory requirement as per NABH criteria too. Upto 40% patients are found to be malnourished and these patients stay in hospital longer, are three times as likely to develop complications during surgery, and have a higher mortality rate (Age Concern, 2006; BBC, 2006)[25]**.** Apart from malnutrition a patient may be diabetic, have high/low BP, may be on high protein diet or low fat diet etc and there may be requirement of meeting the nutritional needs differently. This issue required a separate audit to find out specific deficiencies even though the internal audit showed a marked improvement in this parameter.

(f) **Admission Request Form**. Endorsement of Date and Time of initial inspection in the Admission Request Form by the doctor indicates the actual time taken for the doctors to attend to the patient after admission. This time should not be more than 30 minutes. It was found that 17.5% of Admission Request Forms didn't have it **(Figure 9)**. Name & Sign of physician was not endorsed in 10.5% of admission request form **(Figure 10)** thereby making the subsequent assessment difficult since in modern medical care, where there is involvement of variety of people, a lot is communicated about the thought process likely to be taken by a doctor endorsing the document. Absence of authentication in the Admission Request Form denies the subsequent assessment an insight into the vital initial thought process which would itself be based on evidence.

74. **Effect of Internal Audit**. To assess the effect of Internal Audit of Patient Medical Documentation, the sample data, which was updated in the excel sheet progressively, was divided into five parts. The analysis of the Doc's IA and Nutrition Assessment was found to be distinct and has been elaborated in succeeding paragraphs:

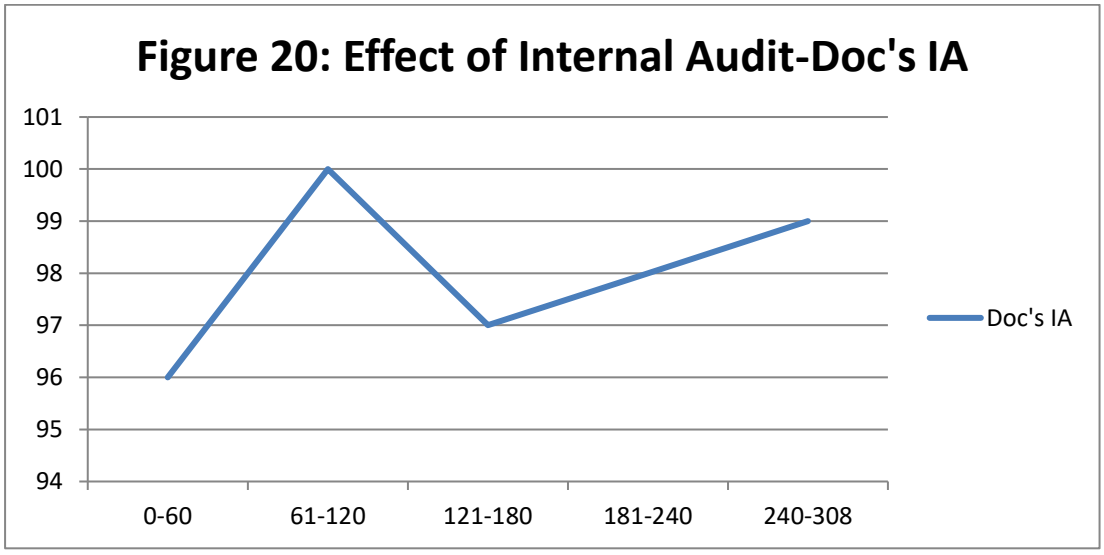
(a) **Progress of Doctor's IA (Figure 20)**.

(i) The average of 96% was achieved for Doc's IA for initial 60 patient medical documentation folders.

(ii) For the next 60 samples, it improved to 100%, probably due to the Hawthorne Effect. The **Hawthorne effect** (also referred to as the observer **effect**) is a type of reactivity in which individuals modify or improve an aspect of their behavior in response to their awareness of being observed.

(iii) For the patient 121-180, it was 97%. The dip was likely to be due to the staff getting used to seeing the audit continuing and becoming complacent. However, the result was better than the first 60 results indicating positive change in the basic behavior.

(iv) For the patient 181-240, Doc's IA improved to 98% and further improvement in the audit of balance of record to 99% shows positive trend in the improvement of the behavior of Doctors carrying out the initial assessment. It thereby indicates that the doctors are adapting to the guidelines and there is improvement in understanding of the perceived non-medical aspects of documentation as per the laid down standards.



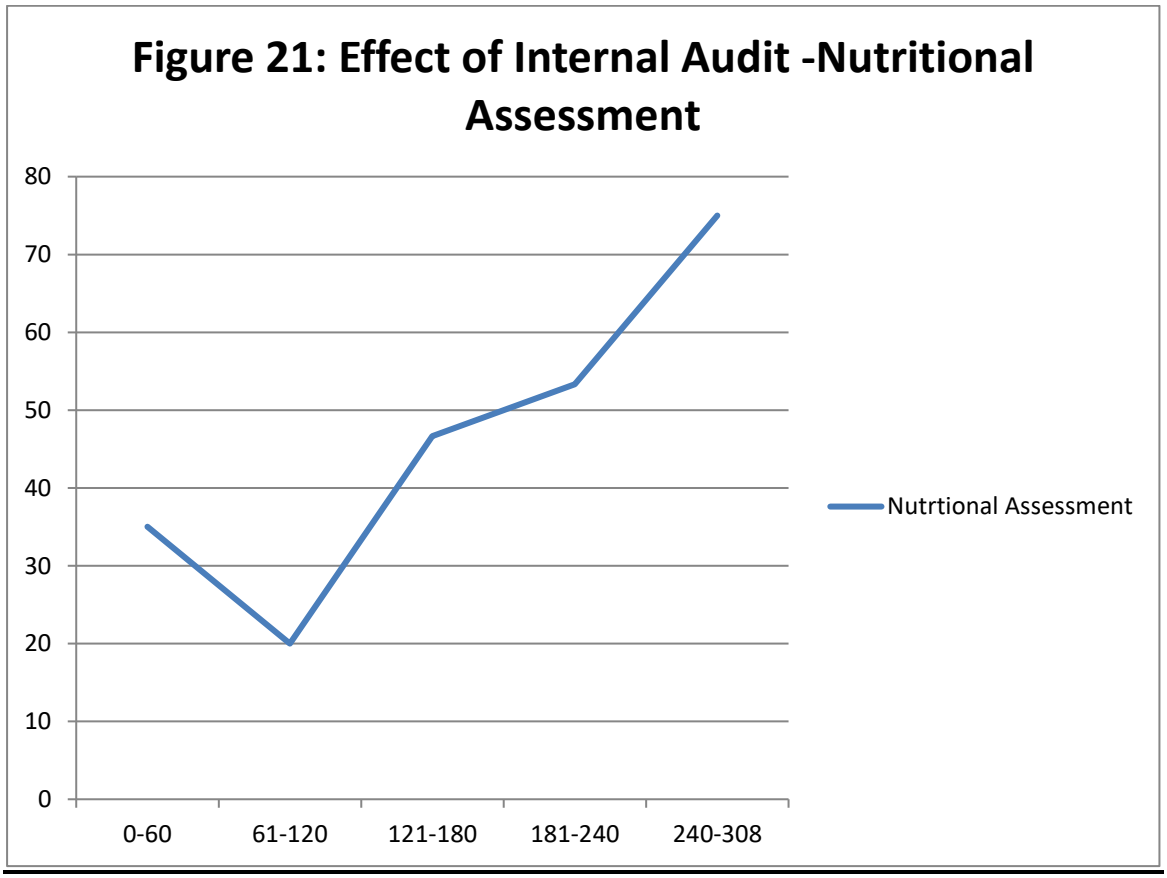
(a) **Progress of Nutritional Assessment (Figure 21)**.

(i) The average of 35% was achieved for Nutritional Assesment for initial 60 patient medical documentation folders.

(ii) For the next 60, it further reduced to 20%, due to the non-availability of the staff due to shortage.

(iii) For the patient 121-180, it was 46.7%. The improvement was likely to be due to improvement in the availability of the staff and awareness that the internal audit is going on.

(iv) For the patient 181-240, Nutritional Assessment improved to 53.3% and further improvement in the audit of balance of record to 75% which shows positive trend in the likely improvement of the behavior of Nutritionists for carrying out the Nutritional Assessment. It thereby indicates that the Nutritionist started adapting to the guidelines and there was an improvement in understanding of the relevance of non-medical aspects of documentation as per the laid down standards.



75. Patient Safety should be the reason of all activity in any hospital and there should be constant endeavour by all to achieve this. The ultimate aim of any healthcare organization should be to have zero tolerance towards patient safety. This is an emerging field even in the developed countries and hence has been talked about in the recent few decades only. In countries like India, following the accreditation process interjects any hospital on the fast road to achievement of patient safety through standardization which is mainly dependent on Patient Documentation. However the hospitals can evolve their own processes keeping the

resources in mind to achieve highest standards of patient safety. The basic deterrent to patient safety in our healthcare and recommended remedies as follows:

(a) No standardization of the training of doctors and nurses at the time of basic educational training. This was observed in the variation in the standards of parameters in different wards (**Appendices 'C' to 'L').** Internal Audit to find gaps and training in the Patient Safety can bring in standardization within a healthcare organization.

(b) The basic medical education does not impart specialized training on patient safety and whatever little is taught is only theoretical. Hence there is a tendency to fill columns in the forms as seen from the statistics of Pain Score variation **(Figure 19)**. Training of nurses will help in improving the awareness on Patient Safety.

(c) The abrupt adaptation of accreditation in our country by healthcare set-ups without being part of evolution of patient safety has brought a gap between thinking and action. The accreditation route through documentation is easiest however there is requirement of developing willing compliance of all since the aim of healthcare should be to achieve 100% patient safety. Compliance above 90% in any parameter may seem to be decent, however, for the patient who falls within the last 10% it may put them in a critical situation. Hence efforts to accept the standard at 100% should be the goal laid down by the management.

76. The issues highlighted by the study regarding our healthcare organizations that were missed out during the process of evolution of patient safety in India as compared to the developed world are:

(a) Our organizations are still in the situation of traditional approach where it is assumed that well-trained, conscientious practitioners do not make errors and equated error with incompetence and regarded punishment as both appropriate and effective in motivating individuals to be more careful. This has led to practitioners rarely revealing mistakes, and patients and supervisors are frequently kept in the dark. This aspect has been highlighted by the non-use of rubber stamp by 94% of the doctors **(figure 12).**

(b) A very few healthcare organizations have now started considering that errors could be reduced by redesigning systems and processes using human factors principles. The audit of Patient Medical Documentation in the present study is an effort to do the same in an accredited hospital.

(c) In an improving system concepts from other established and successful fields are adopted. The internal audits are established norms in the Armed Forces and adoption of this important self improvement tool will definitely improve patient safety.

(d) Due to high quality of education in the developed nations, the route to the reduction of mistakes through document standardization is a viable alternative to achieve patient safety. However, in our context continuous training guided by the deficiencies detected during the audit can provide a workable solution to fill the gaps in the initial medical education. This aspect has been validated by the improvement in the Doc's IA **(Figure 20)** and Nutritional Assessment within 24 hrs **(Figure 21).**

(e) The concept of limiting the blame and avoid finger pointing had brought in the transparency in healthcare organizations and developed team spirit. The present audit limiting to the non-medical aspects seem to have positive effect in the present study and has led to the improvement in the documentation and likely to have positive impact on patient safety.

(f) Culture and Professionalism. There was a collective evolution of culture and professionalism involving Clinicians, governing boards, executive leaders, and middle managers of health care delivery organizations[2]. This assisted in building an overall high-reliability organization. The effort of Patient Medical Documentation Audit was to not blame the medical aspect of treatment thereby reducing the gap between the management and "sharp-end", thereby forging continuity in culture and professionalism. However, to establish seamless integration and overlap of all in the patient safety mechanism there can be a monthly Board of Officers (BOO) detailed by Quality Department which can carry out deeper audit of Patient Medical Documentation to ensure patient safety. This BOO can act as a mirror to "sharp-end" for self correction. To insulate the doctors and nurses from getting blamed and bring in internal transparency, the BOO can include the following:

(i) Presiding Officer- Any Consultant.

(ii) Members:

(aa) One Resident Doctor

(ab) One Nursing Staff

(ac) One member from any of the non-medical staff

(g) The law of torts forced the medical professional to be accountable for safe delivery of patient care. However, due to the poor implementation of law in our context, there is requirement of conscious effort to improve patient safety up to the desired levels. The illegible signatures and non-use of the personal stamp seem to be manifestation of this issue. Even though the better results for filling of the forms shows that awareness amongst the doctors and nurses to be legally recording in the patient medical documentation is there and may be more so in the accredited hospitals the efforts should be undertaken to link the issue to Patient Safety.

(h) The standards and accreditation systems were developed for the hospitals in the developed countries after the development of safer and more effective surgery, medical care delivery systems. However, NABH in our context came up taking inspiration from the advanced countries. So to fill in this void the internal audit mechanism is a good tool as established by positive changes in the study.

CHAPTER 7: CONCLUSION

66. It is recommended to consider the audit process as a method for improving standards of medical care. The audit can be used in prescription practice, as attempted in this study, as well as various other aspects of clinical services (such as clinical examination, indications for investigation, monitoring side-effects of drug). Finally, this report also emphasizes the benefits of focusing on prescription training in the postgraduate curriculum. There is a need to create more awareness in the trainees towards legibility and correctness of spelling of drug as well as review of treatment and stating the name of prescribing doctor[5].

67. The present efforts in our country towards “Make in India” have highlighted the mismatch in the thoughts and the adapted growth, mismanagement of resources, poor implementation of policies, etc. The same is relevant in the medical field too where the mismatch between the basic learning during formative stages and the growing national expectations as per the evolving standards of Developed World has manifested into incoherent advancement. In fact, due to deteriorating education system in our country there is an ever increasing gap between the expectations as per benchmarks, which are taking the Developed World as the reference point, and the ground situation. As part of ‘Make in India’ there is need to start looking inwards in healthcare too by setting our own standards which evolve based on holistic indigenous approach.

68. The shifting of gears in the private healthcare sector in our country to woo business from developed countries has led to abrupt adaptation of the accreditation standards which were evolved in the developed countries after due research. This has led to an accreditation system in healthcare sector in our country which is not evolved indigenously and is largely based on the developed countries. Nevertheless, the accreditation has by and large led to the standardization of medical care in our country also. The way to the accreditation is through following standardized procedures which are implemented by evolving various forms and documents. These documents are subjected to internal and external audit as per accreditation guidelines. However, the purpose of the documentation should be Patient Safety and not be guided by the requirement of accreditation and legal framework only. After the study, it has emerged that the internal audit of the Patient Medical Documentation in wards can assist in positively influencing the behavior of the doctors and nurses towards documentation and hence patient safety in the hospital. This type of internal audit of the Patient Medical Documentation should be strengthened to bring back the focus of a hospital to patient safety which otherwise has shifted to the completion of documents from the point of view of fulfilling the legal requirement only.

69. The present study addressed the issue of Patient Safety through the improvement in the Patient Medical Documentation by trying to influence the behavior of the ‘sharp end’. This aspect require further validation by comparing the

more direct patient safety indicators which may be possible in an older set-up where comparative data of longer duration would be available.

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