भारतीय गुणवत्ता परिषद्
QUALITY COUNCIL OF INDIA
Creating an Ecosystem for Quality

राष्ट्रीय अस्पताल और स्वास्थ्यचर्या-प्रदाता प्रत्यायन बोर्ड
National Accreditation Board For Hospitals and Healthcare Providers

2nd EDITION
EFFECTIVE 1ST JAN 2026

GUIDEBOOK TO NABH ENTRY LEVEL CERTIFICATION STANDARDS FOR HOSPITALS

National Accreditation Board
for Hospitals and Healthcare Providers (NABH)

QUALITY : SAFETY : WELLNESS

Guidebook to NABH Certification Standards for Entry Level Hospital 2nd Edition

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ISQuaEEA | International Society for Quality in Health Care External Evaluation Association

National Accreditation Board for Hospitals & Healthcare Providers (NABH)

Awarded by ISQua EEA
following an independent assessment
against the
Guidelines and Standards for
External Evaluation Organisations,
5th Edition

The period of Accreditation for this Organisation
is from **June 2022** until **June 2026**

Prof Jeffrey Braithwaite, President

Ms Elaine O'Connor, Head of Operations

FOREWORD

17 September 2025

National Accreditation Board for Hospitals and Healthcare Providers (NABH), is in its 20th year of creating an ecosystem of quality in healthcare in India. NABH standards focus on patient safety and quality of the delivery of services by the hospitals in the changing healthcare environment. Without being prescriptive, the objective elements remain informative and guide the organisation in conducting its operations with a focus on patient safety.

Over the years, successive NABH standards have brought about not only paradigm shifts in the hospitals' approach towards delivering the healthcare services to the patients but have equally sensitised the healthcare workers and patients towards their rights and responsibilities.

It is my privilege and pride to release and dedicate this 2nd Edition of Entry level Certification Standards for Hospitals of NABH to all healthcare workers. This edition is unique in its approach and has been presented based entirely on the suggestions made by various stakeholders. It is a merger of earlier two certification standards i.e. Entry level Hospitals and Entry level SHCO.

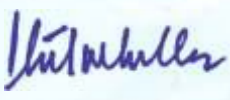
The NABH hallmark methodology of ten Standards Chapters approach has been retained; There are a total of 189 objective elements and 46 standards.

The chapter on Continuous Quality Improvement is now replaced with Patient Safety and Quality Improvement to increase the focus on this critical aspect of healthcare and chapter on Hospital Infection Control is changed to Infection Prevention and Control. Each chapter now has a bibliography for reference, and this will provide organisations with a resource for taking quality beyond the requirements of the objective elements.

These standards along with the key Performance Indicator and Guidance on Monitoring Medication Errors as Annexures have been made available free of charge as a downloadable document on NABH website. I sincerely hope that all healthcare organisations will certainly benefit from the collective efforts of Technical committee of NABH and practical suggestions of thousands of Quality Champions from India and abroad.

NABH remains committed to its mission of taking Quality Safety and Wellness to the last man in the line.

Jai Hind



Dr. Atul Mohan Kochhar
CEO, NABH

ACKNOWLEDGEMENTS

17 September 2025

I acknowledge the contributions of the following in preparing this 2nd Edition of Entry level Certification Standards for Hospitals of NABH.

I would place my heartfelt thanks and deepest gratitude to Shri Jaxay Shah, Chairman Quality Council of India for his vision to take quality to the grassroots and permeate the idea of quality in the DNA of each and every citizen in every part of India.

Mr. Rizwan Koita, Chairman NABH, has been the guiding light throughout the development of this Second Edition of Entry level hospital standards. I thank him for his active participation, support and invaluable suggestions despite of his busy schedule.

I sincerely thank Mr. Chakravarthy T. Kannan, Secretary General of Quality Council of India for his guidance and continuous support by making adequate resources available for this process.

I thank all board members of NABH in giving significant suggestions for betterment of the standards and the guidebook.

The Technical Committee of NABH worked relentlessly and meticulously to accommodate the best practices in patient safety and healthcare quality, referred to innumerable academic references and incorporated suggestions made by all of the stakeholders in bringing this standard to reality. It was, indeed, a mammoth task. I profoundly thank all the members for playing a pivotal role in the development of this edition.

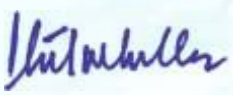
I thank all our passionate assessors, management of the hospitals, quality managers, clinicians, nurses and paramedics who gave us extensive feedback to improve upon the standards and their exhaustive interpretation.

I thank the officers at NABH Secretariat for working round the clock, to complete the work within time.

It is entirely due to the overwhelming participation, dedication, and diligence of all concerned that we could present this guidebook in the current detail and format.

To all of you a sincere, heartfelt and, profound - Thank you.

Jai Hind



Dr. Atul Mohan Kochhar
CEO, NABH

CONTENTS

About NABH

National Accreditation Board for Hospitals and Healthcare Providers (NABH) is a constituent board of the Quality Council of India (QCI), set up to establish and operate accreditation programs for healthcare organisations. NABH has been established with the objective of enhancing the health system & promoting continuous quality improvement and patient safety. The board, while being supported by all stakeholders, including industry, consumers, government, has full functional autonomy in its operation.

NABH provides accreditation to hospitals in a non-discriminatory manner regardless of their ownership, size, and degree of independence.

International Society for Quality in Healthcare (ISQua) has accredited NABH.

Vision: To be apex national healthcare accreditation and quality improvement body, functioning at par with global benchmarks.

Mission: To operate accreditation and allied programs in collaboration with stakeholders focusing on patient safety and quality of healthcare based upon national/international standards, through process of self and external evaluation.

NABH Activities

NABH Accreditation Programmes: NABH offers accreditation to Hospitals, Small Healthcare Organisations, Digital Health, Blood Banks, Eye Care hospitals/clinics, Care Homes, Ayush (Ayurveda, Homeopathy, Unani, Siddha and Yoga and Naturopathy) hospitals, Medical Imaging Services, Dental Healthcare Service Providers, Allopathic Clinics, Ethics Committees and Panchkarma Clinics.

NABH Certification Programmes: NABH offers certification to Entry Level Hospitals, Entry Level Small Healthcare Organisations, Medical Laboratory, Digital Health, Nursing Excellence, Emergency Department, Stroke Center, Entry Level Dental Clinics, Entry Level Ayush Hospitals and Entry Level Ayush Centres and HIS/EMR standards.

NABH Empanelment: NABH offers empanelment program for CGHS, ECHS and Medical Value Travel Facilitator (MVTF)

NABH International: NABH has started its operations overseas under NABH International (NABH I). It offers all accreditation programs as being offered in India. The program is unique as in addition to the accreditation standards it requires compliance with local regulatory requirements

Training & Education: NABH conducts Education/Interactive Workshops, Awareness Programmes, and Programme on Implementation (POI).

Scope and Purpose of the Standards

Scope of the Standards

These standards are applicable for health care organisation willing for Entry level certification program provided that health care organisation fulfils the following requirements:

- The health care organization is currently in operation as a healthcare provider.
- The organisation commits to comply with NABH standards and applicable legal/statutory/regulatory requirements.

These standards are to be used by the whole organisation and not for a specific service within the organisation. Organisations may have different services and it is equally applicable to all services and both public and private hospitals.

Purpose of the Standards

The aim of the standards is to achieve an acceptable level of performance with a view to:

- Improve public trust and community confidence that the organisation is concerned for patient safety and the quality of care;
- Ensure that they listen to patients and their families, respect their rights, and involve them in the care process as partners;
- Ensure that they provide a safe and efficient work environment that contributes to staff satisfaction and improves overall professional development;
- Provide an objective system of empanelment by insurance companies and other third parties;

In addition, these standards can also be used to:

- Guide the efficient and effective management of Entry level Hospitals;
- Guide the organisation in the delivery of patient care services and in their efforts to improve the quality and efficiency of those services;
- Review the important functions of an Entry level Hospitals;
- Provide an opportunity to explore compliance expectations of standards and the additional requirements related to safety and regulation.

How to read the standard?

The standard focuses on the key points required for providing patient-centred, safe, high-quality care. The interests of various stakeholders have been incorporated into the standard. They provide a framework for quality assurance and quality improvement. The focus is on patient safety and quality of patient care. It sets forth the basic standards that organisations must achieve to improve the quality of care. The requirements have been divided into ten chapters. The first five chapters are “patient centric” and the last five chapters are “organization centric”. The ten chapters are:

1. Access, Assessment and Continuity of Care (AAC)
2. Care of Patients (COP)
3. Management of Medication (MOM)
4. Patient Rights and Education (PRE)
5. Infection Prevention and Control (IPC)
6. Patient Safety and Quality Improvement (PSQ)
7. Responsibility of Management (ROM)
8. Facility Management and Safety (FMS)
9. Human Resource Management (HRM)
10. Information Management System (IMS)

Every chapter begins with an 'intent'. The intent states the broad requirements of what the organisation needs to put in place and implement to improve the quality of care. This is followed by the 'summary of standards' which lists all the standards of that chapter. The standards and objective elements are explained after the summary. A list of references is provided at the end of all chapters.

What is a standard?

A standard is a statement of expectation that defines the structures and processes that must be substantially in place in an organisation to enhance the quality of care. The standards are numbered serially, and a uniform system is followed for numbering. The first three letters reflect the name of the chapter and the number following this reflects the order of the standard in the chapter. For example, AAC.1. would mean that it is the first standard of the chapter titled 'Access, Assessment and Continuity of Care’.

What is an Objective Element?

It is that component of standard which can be measured objectively on a rating scale. Acceptable compliance with objective elements determines the overall compliance with a standard. The objective element is scored during assessments to arrive at the compliance. The objective element is numbered alphabetically in a serial order. For example, AAC.1.c. would mean that it is the third objective element of the first standard of the chapter titled 'Access, Assessment and Continuity of Care'.

What is an Interpretation?

The interpretation provides guidance on what the organisation needs to do to ensure that the requirement(s) of the objective element is met. Where applicable, it provides references and suggests a specific methodology that the organisation needs to adhere to. The word 'shall/should' or 'will/would' is used to reflect a mandatory requirement. The interpretation also lists out desirable aspects for the organisation to implement, and the word 'can/could' is used to reflect this. During scoring, the desirable aspects are not considered, and they are only used to reflect on the overall achievement of the standard, which is reflected in the assessment report. At places, the interpretation would not be specific and would have used the words like 'adequate/appropriate'. This has been done keeping in mind the diverse nature of healthcare delivery and adhering to the intent of this standard which is to improve the quality of healthcare and at the same time, be feasible. The expectation is that whenever such a phrase has been used in the interpretation/objective element, the organisation shall base its practice on evidence-based/best practice. In some places, the interpretation has listed out examples. The examples are only illustrative in nature, and the organisation has the liberty to decide what/how to implement. However, the requirement of the objective element would have to be adhered.

The NABH Entry Level Standards 1st Edition was featuring two separate sets of standards based on bed strength:

- One for hospitals with 1–50 beds (Entry Level Standards for Small Healthcare Organisations), and
- Another for hospitals with 51 beds and above (Entry Level Standards for Healthcare Organisations).

These have now been revised and merged into a single, unified standard under the 2nd Edition, offering a more comprehensive and holistic approach to quality and patient safety.

In the 2nd Edition, the objective elements are categorized into three levels:

1. Core
2. Commitment
3. Excellence

The implementation roadmap is as follows:

- Hospitals with 1–50 beds:
  - First cycle: Required to meet only the Core criteria objective.
  - Second cycle: Along with the Core criteria, must additionally fulfill the Commitment criteria objective elements.
  - Third cycle onward: Expected to meet the Excellence criteria along with Excellence criteria objective elements

- Hospitals with 51 beds and above:
    - First cycle: Must comply with both Core and Commitment criteria.
    - Second cycle onward: Required to fulfill the Excellence criteria.

This phased approach ensures a gradual, structured progression in quality improvement, tailored to the hospital's size and capacity.

Other Sections Included in the Standard Book

- About NABH
- Scope and purpose of the standards
- Overview of the NABH accreditation process
- System Documentation
- Abbreviations
- Glossary
- Index

In the book, certain objective elements require mandatory system documentation. The same have been identified by the * (asterisk) mark. A detailed guide on documentation is provided in the next section.

System Documentation

Introduction

Documentation for systems is complicated and best left to specialists in this line, is a perception that is wrongly carried by even the organisations which have well established, functioning, and externally assessed quality systems. It is a notion that is far removed from the truth. An attempt is made here to clear the concepts of documentation and make it simple enough to be carried out by the staff who is responsible for executing various tasks in the organisation without depending on anyone else. This will keep the documentation closer to reality and flexible in the hands of the organisation and will also reduce the dependence on external sources for creating documents that are many times far removed from reality.

Why do we need documentation?

The fundamental purpose of documentation is the standardisation of actions across various departments and functional units in the organisation. Documentation is required for clarity on actions, continuity of systems, and information on the established system that is common to all levels of staff. Therefore, the documentation has various components:

- **Operation System Documentation:** It defines the procedures and processes that are required to be carried out in a standardised manner.
- **Quality system documentation:** The actions that are specifically required for activities that are related to the quality system and are not covered under operation system documentation
- **Specialised documents:** Safety System Documentation, business continuity documentation.

Type of documents

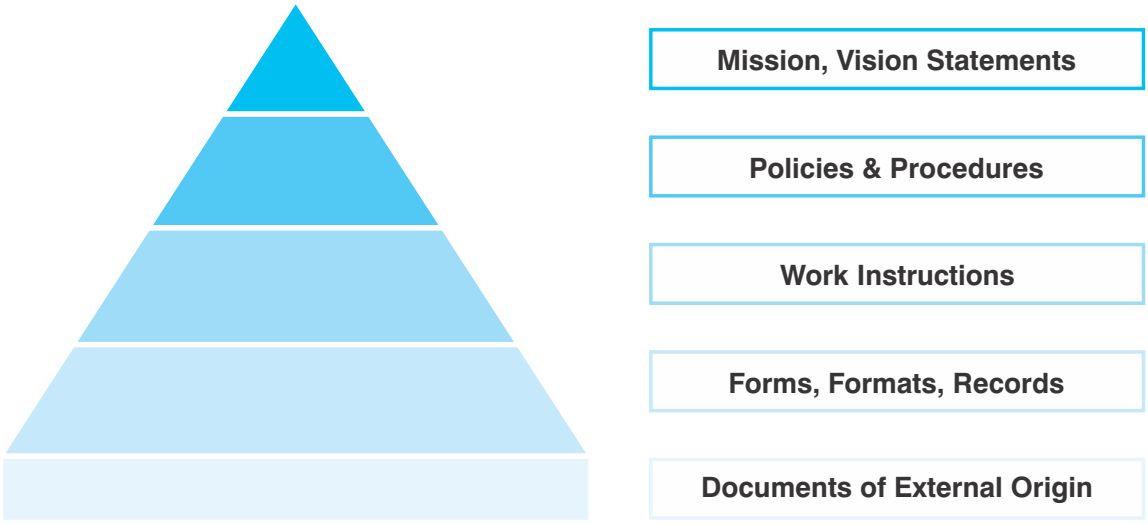
From the top level of planning to the level of maintaining records of activities, the documentation follows a general principle as below::

1. **Policy Documents:** Mission Statement, Vision Statement, Strategic plans, Policies which transcend time and act as guidance in the changing scenarios of the operational, legal, technologically changing environment in which the organisation conducts its activities. They are the principles on which planning is based while adapting to the changes
2. **System Documentation:** Operational and quality system documentation to carry out the activities in conformance with the mission and vision statement. This includes what is commonly known as Standard Operating Procedures or SOPs.
3. **Work Instructions:** These are instructions in a detailed manner for executing tasks, including the physical steps to be carried out.

4. **Forms and Formats:** These are various forms and formats to capture information as a record of the execution of various activities. The records are filled forms. The forms, formats, and records can be in a physical or electronic form. These can be entries as numerical, text, image, sound, etc.

Many organisations add a fifth category to this as Externally Acquired documents such as licenses, statutory clearances, Legal contracts and Memoranda of Understanding, etc.

The documentation structure, if visualised as a pyramid, appears as below:



Vision Statement: Vision statement defines the direction that the organisation wants to chart.

Mission Statement: Mission statement defines the purpose of the existence of the organisation.

Policies: These are statements that transcend time to decide on the way the activities of the organisation will be executed. These statements connect mission and vision statements with the processes and procedures of the organisation. These may change over a relatively moderate time frame of a few years. Whenever these are developed or altered, the focus of this activity will always be guided by the mission and value statements forming a link between the mission and value statements and the actions on the ground which are documented through the Standard Operating Procedures.

Standard Operating Procedures: These documents define the steps that will be carried out to complete tasks or parts of tasks. These are also known as Operations Documentation or Operations Manual. These can be multiple manuals specific to departments, a group of related tasks and will have documentation for the processes and procedures related to the concerned department, a section or activity. The term standard refers to its being standardised for the time being and does not mean that it cannot be altered. Most of the organisations with actively followed systems will address review of these documents for correctness and adaptation at least once a year and sometimes even twice a year. It is essential that these documents are kept relevant to the requirements of alteration to processes and procedures that are necessary from time to time due to the improvements, change in technology, and changes to statutory norms, etc. The term standard, therefore, refers to its current relevance rather than its permanent nature and everlasting non-alterability. This is important to understand because many organisations have the reluctance to alter these documentations mistaking the word standard for unalterable, sometimes even after the processes have changed.

Forms and formats: For the capture of information in a complete and relevant manner, this must be done in a standardised manner. This is achieved through various forms and formats to maintain the records of activities. The forms can be a single page, multipage or a register in which the entries are made. The purposes can be from just capturing whether an activity was carried out, to a very elaborate capture of values related to many parameters related to the activity. Example of the former being tick marking when some action was carried out and the example of the latter being an elaborate record of the initial assessment of the patient on arrival to the wards. Records are filled forms and formats. Forms and formats can be altered through the set alteration process, but records cannot be altered. Forms, formats, and registers are also a part of the system of controlled documents and must have their identity. It is not always necessary to number each form, and this will depend on whether the organisation wants to assign a separate identity to each filled form. Such is rarely required.

Documents of External Origin: For the sake of making the documentation system inclusive, some organisation include documents of external origin. These are licenses, statutory documents, Memoranda of Understanding with various organisations, etc. These are not alterable.

Temporary Documents: Many notes, documents, records in an informal manner get created during the execution of processes. These help in reducing errors or are intermediaries to further calculations. These are not necessarily maintained in a set format and can be rough entries on notepads, diaries, etc. They need not be preserved if the information content does not have lasting importance and the final entry is anyway going to be made in a set format. Such documents do not form a part of the formal documentation system

Documentation related to processes and procedures

The documentation related to processes and procedures deals with operating procedures, quality system procedures, safety procedures, etc. This is the documentation that is commonly known as Standard Operating procedures or SOPs. This can be documented as steps which are numbered or bulleted or in the format of flow charts. Flowcharts use a method of commonly recognised symbols, such as a circle or ellipse for start or end of the process, rectangle for activity, diamond for decision making step, picture of rolled partially document for the steps where documentation is necessary, etc. Most word processing software applications have these symbols inbuilt for use.

Which processes should be documented?

The organisations sometimes fall into a dilemma about the extent of documentation that should be followed. There are some guidelines which can help. Though the list is not exhaustive, the following processes and procedures require documentation:

- Procedures which are required to be followed uniformly at various locations across the organisation
- Procedures which are required to be followed uniformly across time
- Procedures which, if not followed uniformly and correctly will increase the risk to patients, staff or visitors
- Procedures which, if not followed uniformly, can lead to serious consequences concerning the loss of material, time, physical damage, equipment, etc.
- Procedures which are complicated leading to either missing of some steps or risk of variation in their execution

- Procedures which are required to be followed uniformly in spite of high turnover of human resources
- Procedures which are specific to the organisation as against procedures which are universally accepted or that are part of standard curricula of those professionals who carry out these procedures.

How to develop documentation that is easy to follow?

The following steps can help in developing documentation that is easy to follow:

- Providing a clear plan of documentation architecture. This can be as a print map or in electronic form
- Using the uniform format for the visual appearance of the documents to cover their appearance, fonts, symbols, page layout, etc.
- Adding colour codes, font changes for different documents
- Participation of the staff that is involved in carrying out the activities in the development process for documentation
- Using the same language and form of the structure of language as per the users
- Using a direct form of speech (active) than the indirect form (passive)
- Providing Chapter Index or Index of words
- Sequencing activities as per their actual sequence of execution in time
- If necessary replicate the documentation related to specific processes and procedures within all relevant documentation with a clear reference to the original document
- Making relevant documents available at the location of use
- Keeping relevant documents available all days of the year and all times of day and night as per the requirements of execution of the activities.
- Removing obsolete documents from all locations, other than those retained for archiving

Controlled Documents

As mentioned before, the documents bring uniformity and clarity for the execution of activities in the organisation. It is, therefore, imperative that they are not altered without the knowledge of the creator or the staff who is specifically authorised for this. Such documents are known as Controlled Documents. All types of documents described above come under this category, except for the temporary document.

Characteristics of controlled documents:

- Each document is named
- The purpose of the document is defined
- There is a date of creation of the document
- There is a date of approval of the document
- There is a date of review of the document
- There may be a date of expiry of the document
- Signatory for creation is defined.
- Signatory for approval is defined.
- The signatory for alterations is defined. This may be the same or different from the creator.

- Each page is numbered.
- The document may have a number assigned to it.

This information about the identity of the document may be contained in the form of a box at the top of the document. If put in this way, such a box is known as Control Box. It may be put at the top of the document without any box format. It is just that this form is an integral part of each Controlled Document. The staff designation signing the document with the corresponding signature is maintained at the bottom of the page. The dates related to the document may be mentioned at the beginning page of the document and may not be there on each page, though most organisations put it on each page. The alphanumeric identity, if assigned to such document must form a system that may include department, a section of the department, purpose or activity referred in the document, version number of the document, page number. The purpose of this exercise is to create a unique identity for each page of the controlled document. It is not mandatory to have an expiry date for the document.

An example of the control box is given below:

Name of Organisation	Document Code	Date of Issue	Date of next revision / validity

A similar box appears at the bottom of the page for the signatory, an example of which is given below:

Authorised by: Designation	Issue No./Version No./	Issued by: Designation
Signature		Signature

Body of Document

There are many formats for the documentation of the contents. One of them is given below:

Name of Organisation	Document Code	Date of Issue	Date of next revision / validity
Dept. Name/Process			

- Name of the Document:
- Purpose of the Process that is documented
- Start point
- End Point
- Procedure:
  Step 1: XXXXXXXXXXXXX
  Step 2: XXXXXXXXXXXXX
  Step 3: XXXXXXXXXXXXX
  Step n: XXXXXXXXXXXXX
- Related Records
- Related documents

Related documents Authorised by: Designation	Issue No./Version No./	Issued by: Designation
Signature		Signature

MANUALS

One category of controlled documents is manuals. Manuals are documents that are used by various departments as against the SOPs which pertain to a particular department. Some of the examples of manuals are which deal with various specific functions such as infection control, safety, quality, etc. If the departmental SOPs are vertical and restricted to a particular department, then the manuals are horizontal and are used across many departments. The format of the manual is similar to the SOPs but has reference or duplication of departmental SOPs that have relevance to the subject of the manual and are required to be duplicated for coherence and completeness.

Summary of Chapters, Standards and Objective Elements

Chapter	Standard	Objective Element	Core	Commitment	Excellence
AAC	7	29	20	2	7
COP	10	44	24	9	11
MOM	7	28	20	5	3
PRE	2	17	14	1	2
IPC	2	12	7	3	2
PSQ	2	8	4	2	2
ROM	4	12	4	4	4
FMS	4	13	12	1	0
HRM	5	15	9	6	0
IMS	3	11	8	2	1
Grand Total	**46**	**189**	**124**	**36**	**29**

Summary of Changes

Chapter 1 : Access Assessment and Continuity of Care (AAC)

2nd edition Entry Level Hospital	1st Edition Entry level HCO	1st Edition Entry level SHCO	Remarks
AAC1	AAC1	AAC1	Minor modifications in the language
AAC1a	AAC1a	AAC1a	No change, Interpretation added for better clarity
AAC1b	AAC1b	AAC1b	No change, Interpretation added
AAC1c			New Objective element
	AAC1c	AAC1c	Deleted
AAC 2	AAC 2	AAC2	Minor modifications in the language
AAC2a	AAC 2a	AAC2a	Minor modifications in the language, Interpretation added for better clarity
AAC2b			New Objective element
AAC2c	AAC 2b	AAC2b	Minor modifications in the language, Interpretation added
AAC 3	AAC3	AAC3	No change
AAC3a	AAC 3a AAC 3b AAC 3c AAC 3d	AAC 3a AAC 3b AAC 3c	Merged with modification in language, Interpretation added for better clarity
AAC3b			New Objective element
AAC4	AAC 4	AAC4	No change
AAC4a	AAC4a	AAc4a	Minor modifications in the language, Interpretation added
AAC4b	AAC4b AAC4d	AAC4b AAC4d	Merged with modification in language, Interpretation added for better clarity
AAC4c			New Objective element;Interpretation added for better clarity
AAC4d			New Objective element
	AAC3c	AAC3c	Deleted

2nd edition Entry Level Hospital	1st Edition Entry level HCO	1st Edition Entry level SHCO	Remarks
AAC5	AAc5a	AAC5a	No change
AAC5a	AAC5a	AAC5a	Modifications in the language, Interpretation added
AAC5b	AAC5b	AAC5b	Modifications in the language, Interpretation added
AAC5c	AAC5c	AAC5c	Modifications in the language, Interpretation added
AAC5d	AAC5e	AAC5d	Modifications in the language, Interpretation added
AAC5e			New Objective element
AAC5f	AAC5f		Modifications in the language, Interpretation added
	AAC5d		Deleted
AAC 6	AAC6	AAC6	No change
AAC6a		AAC6a	Modifications in the language, Interpretation added
AAC6b	AAC6b	AAC6a	Modifications in the language, Interpretation added
AAC6c	AAC6c	AAC6c	Modifications in the language, Interpretation added
AAC6d	AAC6d	AAC6d	Modifications in the language, Interpretation added
AAC6e			New Objective element
AAC6f			New Objective element
AAC7	AAC7	AAC7	Change in language
AAC7a	AAC7a	AAC7a	Modifications in the language, Interpretation added for better clarity
AAC7b	AAC7c	AAC7c	Modifications in the language, Interpretation added for better clarity
AAC7c	AAC7d	AAC7d	Modifications in the language, Interpretation added for better clarity
AAC7d	AAC7e	AAC7e	Modifications in the language, Interpretation added
AAC7e	AAC7f	AAC7f	Modifications in the language, Interpretation added for better clarity
	AAC7b	AAC7b	Deleted

Chapter 2: Care of Patients (COP)

2nd edition Entry Level Hospital	1st Edition Entry level HCO	1st Edition Entry level SHCO	Remarks
COP1			New standard
COP1a			New Objective element
COP1b			New Objective element
COP1c			New Objective element
COP1d			New Objective element;
COP1e	COP3 COP3b COP3c COP3e	COP3 COP3a COP3c	Modifications in the language, Objective element merged Interpretation added
COP 1f	COP 3a		New Objective element; Interpretation added for better clarity.
COP 1g	COP 3d	COP 3b	New Objective element; Interpretation added for better clarity.
	COP 1	COP 1	Deleted
	COP 1a	COP 1a	Deleted
	COP 1b	COP 1b	Deleted
COP 2	COP 2	COP 2	Change in language
COP 2a			New Objective element;
COP 2b	COP2a	COP2a	Modifications in the language, Interpretation added
COP 2c			New Objective element;
COP 2d			New Objective element
COP 2e			New Objective element;
COP 2f	COP2c	COP2c	Modifications in the language, Interpretation added
COP 2g			New Objective element
COP 2h	COP2d COP2e		Modifications in the language, Objective element merged Interpretation added
COP 2i			New Objective element

2nd edition Entry Level Hospital	1st Edition Entry level HCO	1st Edition Entry level SHCO	Remarks
	COP 2b	COP 2b	Deleted
COP 3	COP 4	COP4	Change in language
COP3a	COP4a	COP4a	Modifications in the language, Interpretation added
COP3b			New Objective element
COP3c			New Objective element;
COP3d			New Objective element
	COP4b	COP4b	Deleted
COP4	COP 5	COP 5	Change in language
COP4a	COP5a	COP5a	Modifications in the language Interpretation added for better clarity
COP4b	COP5b	COP5b	Modifications in the language, Interpretation added for better clarity
COP4c	COP5c	COP5c	Modifications in the language, Interpretation added
COP5	COP6	COP6	Change in language
COP5a	COP6a COP6b	COP6a COP6b	Modifications in the language, Objective element merged Interpretation added
COP5b	COP6c COP6e	COP6c COP6e	Modifications in the language, Objective element merged Interpretation added for better clarity
COP5c	COP6d	COP6d	Modifications in the language, Interpretation added
COP6			New standard
COP6a			New Objective element
COP6b			New Objective element;
COP7	COP7	COP7	Change in language
COP7a	COP7a COP7e	COP7a COP7e	Modifications in the language, Objective element merged Interpretation added

2nd edition Entry Level Hospital	1st Edition Entry level HCO	1st Edition Entry level SHCO	Remarks
COP7b	COP7b COP7c COP7d	COP7b COP7c COP7d	Modifications in the language, Interpretation added
COP7c	COP7f	COP7f	Modifications in the language, Interpretation added
COP7d	COP7g COP 7h	COP7g	Modifications in the language, Interpretation added for better clarity
COP7e	COP7i		Modifications in the language, Interpretation added
COP8	COP8	COP8	Change in language
COP8a			New Objective element
COP8b	COP8a	COP8a	Modifications in the language, Interpretation added
COP8c	COP8b	COP8b	Modifications in the language, Interpretation added
COP8d	COP8c	COP8c	Modifications in the language, Interpretation added
COP8e	COP8e	COP8e	Modifications in the language, Interpretation added for better clarity
	COP8d	COP8d	Deleted
	COP8f	COP8f	Deleted
	COP8g		Deleted
COP9			New standard
COP9a			New Objective element;
COP9b			New Objective element;
COP 10			New standard
COP10a			New Objective element
COP10b			New Objective element
COP10c			New Objective element
COP10d			New Objective element

Chapter 3 Management of Medication (MOM)

2nd edition Entry Level Hospital	1st Edition Entry level HCO	1st Edition Entry level SHCO	Remarks
MOM1			New standard
MOM1a			New Objective element
MOM1b			New Objective element
	MOM1a	MOM1a	Deleted
	MOM1b	MOM1e	Deleted
		MOM1b	Deleted
MOM2	MOM2		New standard
MOM2a	MOM2b		New Objective element
MOM2b	MOM2c	MOM1c	Modifications in the language, v
MOM2c	MOM2d	MOM1d	Modifications in the language, Interpretation added
MOM2d	MOM2e		Modifications in the language for better clarity
	MOM2a		Deleted
MOM3	MOM3	MOM2	Change in language
MOM3a	MOM3a MOM3b MOM3c	MOM2a MOM2b MOM2c	Modifications in the language, Objective element merged Interpretation added
MOM3b			New Objective element;Interpretation added for better clarity
MOM3c			New Objective element
MOM3d			New Objective element;;
MOM3e			New Objective element
MOM3f			New Objective element;
MOM4	MOM4	MOM3	Change in language
MOM4a	MOM3d MOM4b	MOM2d MOM3b	Modifications in the language, Objective element merged Interpretation added
MOM4b	MOM4a	MOM3a	Modifications in the language, Interpretation added

2nd edition Entry Level Hospital	1st Edition Entry level HCO	1st Edition Entry level SHCO	Remarks
MOM5	MOM5		Change in language
MOM5a	MOM5a	MOM4a	Modifications in the language, Interpretation added
MOM5b	MOM5b	MOM4b	Modifications in the language, Interpretation added
MOM5c	MOM5c	MOM4c	Modifications in the language, Interpretation added
MOM5d			New Objective Element
MOM5e	MOM5d	MOM4d	Modifications in the language,
MOM5f			New Objective element;
MOM5g	MOM6a MOM6b	MOM5a MOM5b	Modifications in the language, Objective element merged Interpretation added
MOM6			New standard
MOM6a	MOM7a MOM7b MOM5e	MOM4e	Modifications in the language, Objective element merged Interpretation added
MOM6b	MOM7b		
MOM6c			New Objective Element
MOM6d	MOM5e	MOM 4e	Modifications in the language, Interpretation added for better clarity
MOM7			New standard
MOM7a			New Objective element
MOM7b			New Objective element;
MOM7c			New Objective element

Chapter 4: Patient Rights and Education (PRE)

2nd edition Entry Level Hospital	1st Edition Entry level HCO	1st Edition Entry level SHCO	Remarks
PRE1	PRE1	PRE1	Change in language

2nd edition Entry Level Hospital	1st Edition Entry level HCO	1st Edition Entry level SHCO	Remarks
PRE1a			New Objective element
PRE1b			New Objective element
PRE1c	PRE1a	PRE1a	Modifications in the language, Interpretation added
PRE1d	PRE1b	PRE1b	Modifications in the language, Interpretation added
PRE1e	PRE1c	PRE1c	Modifications in the language, Interpretation added
PRE1f			New Objective element
PRE1g	PRE1d	PRE1d	Modifications in the language, Interpretation added
PRE1h	PRE1e	PRE1e	Modifications in the language, Interpretation added
PRE1i	PRE1f	PRE1f	Modifications in the language, Interpretation added
PRE1j	PRE1g	PRE1g	Modifications in the language, Interpretation added
PRE1k			New Objective element
PRE 2	PRE2	PRE2	Change in language
PRE2a	PRE2a	PRE2a	Modifications in the language, Interpretation added
PRE2b			New Objective element
PRE2c			New Objective element
PRE2d	PRE 2a	PRE 2a	Modifications in the language, Interpretation added for better clarity New Objective element
PRE2e	PRE2b	PRE2b	Modifications in the language, Interpretation added for better clarity
PRE2f			New Objective element

Chapter 5: Infection Prevention and Control (IPC)

2nd edition Entry Level Hospital	1st Edition Entry level HCO	1st Edition Entry level SHCO	Remarks
IPC1			New standard
IPC 1a			New Objective element
IPC 1b	HIC2a	HIC2a	Modifications in the language, Interpretation added
IPC 1c			New Objective element
IPC 1d			New Objective element
IPC 1e	HIC2c	HIC2c	Modifications in the language, Interpretation added
IPC 1f			New Objective element
	HIC1a		Deleted
	HIC1b		Deleted
IPC 2			New standard
IPC 2a	HIC3a	HIC3a	Modifications in the language, Interpretation added for better clarity
IPC 2b			New Objective element
IPC 2c	HIC1c	HIC1c	Modifications in the language, Interpretation added
IPC 2d	HIC1d	HIC1d	Modifications in the language, Interpretation added for better clarity
IPC 2e	HIC1e	HIC1e	Modifications in the language, Interpretation added
IPC 2f			New Objective element
	HIC2b	HIC2b	Deleted
	HIC3b	HIC3b	Deleted
	HIC3c	HIC3c	Deleted
	HIC3d	HIC3d	Deleted
	HIC3e	HIC3e	Deleted

Chapter 6: Patient safety and Quality Improvement (PSQ)

2nd edition Entry Level Hospital	1st Edition Entry level HCO	1st Edition Entry level SHCO	Remarks
PSQ1	CQI1	CQI1	Change in language
PSQ1a			New Objective element
PSQ1b			New Objective element
PSQ1c			New Objective element
PSQ 1d	CQI 1a	CQI 1a	Modifications in the language, Interpretation added for better clarity
	CQI1b	CQI1b	Deleted
	CQI1c	CQI1c	Deleted
PSQ2	CQI2	CQI2	No change
PSQ2a PSQ2b PSQ2c	CQI2a CQI2b	CQI2a CQI2b	Modifications in the language, Objective element merged Interpretation added
PSQ2d			New Objective element

Chapter 7: Responsibilities of Management (ROM)

2nd edition Entry Level Hospital	1st Edition Entry level HCO	1st Edition Entry level SHCO	Remarks
ROM1	ROM1	ROM1	Change in language
ROM1a			New Objective element
ROM1b	ROM1b	ROM1b	Modifications in the language, Interpretation added
	ROM1a	ROM1a	Deleted
ROM2	ROM2	ROM2	No change
ROM2a	ROM2a	ROM2a	Interpretation added; Interpretation added for better clarity
ROM2b	ROM2b	ROM2b	Interpretation added

2nd edition Entry Level Hospital	1st Edition Entry level HCO	1st Edition Entry level SHCO	Remarks
ROM2c	ROM2d	ROM2d	Interpretation added
	ROM2c	ROM2c	Deleted
ROM3	ROM3		New standard
ROM3a	ROM3a ROM3b		Modifications in the language, Objective element merged Interpretation added
ROM3b			New Objective element
ROM3c			New Objective element
ROM 4			New Standard
ROM 4a			New Objective element
ROM 4b			New Objective element
ROM 4c			New Objective element

Chapter 8: Facility Management and Safety (FMS)

2nd edition Entry Level Hospital	1st Edition Entry level HCO	1st Edition Entry level SHCO	Remarks
FMS1	FMS1	FMS1	No change
FMS1a			New Objective element
FMS1b			New Objective element
FMS1c			New Objective element
FMS1d	FMS1a	FMS1a	Modifications in the language, Interpretation added
FMS1e			New Objective element
	FMS1b		Deleted
	FMS1c		Deleted
	FMS1d		Deleted
	FMS1e		Deleted

2nd edition Entry Level Hospital	1st Edition Entry level HCO	1st Edition Entry level SHCO	Remarks
FMS2	FMS2	FMS2	Change in language
FMS2a	FMS2a	FMS2a	Modifications in the language, Interpretation modified for better clarity
FMS2b			New Objective element
FMS3	FMS3	FMS3	No change
FMS3a	FMS3a	FMS3a	Interpretation modified for better clarity
FMS3b	FMS 3c	FMS 3c	Modifications in the language, Interpretation modified for better clarity
	FMS3b	FMS3b	Deleted
FMS4	FMS4	FMS4	No change
FMS4a	FMS4a	FMS4a	Modifications in the language, Interpretation modified for better clarity
FMS4b			New Objective element
FMS4c	FMS4b	FMS4b	Modifications in the language, Interpretation added
FMS4d	FMS4d	FMS4d	Modifications in the language, Interpretation added
	FMS4c	FMS4c	Deleted

Chapter 9: Human Resource Management (HRM)

2nd edition Entry Level Hospital	1st Edition Entry level HCO	1st Edition Entry level SHCO	Remarks
HRM1	HRM1		Change in language
HRIM1a	HRM1a		Modifications in the language, Interpretation added
HRM1b			New Objective element
HRM1c			New Objective element;

2nd edition Entry Level Hospital	1st Edition Entry level HCO	1st Edition Entry level SHCO	Remarks
	HRM1b		Deleted
HRM2	HRM2	HRM 1	Change in language
HRM2a			New Objective element
HRM2b			New Objective element
HRM2c	HRM2c	HRM 1c	Modifications in the language, Interpretation added
HRM2d	HRM2a	HRM1a	Modifications in the language, Interpretation added
HRM2e			New Objective element
	HRM2b	HRM1b	Deleted
HRM3	HRM3	HRM2	Change in language
HRM3a			New Objective element
HRM3b	HRM3a HRM3b HRM3c	HRM2a HRM2b HRM2c	Modifications in the language, Objective element merged Interpretation added
HRM4	HRM4	HRM3	Change in language
HRM4a	HRM4a HRM4b	HRM3a HRM3b	Modifications in the language, Objective element merged Interpretation added
HRM4b			New Objective element
HRM5	HRM5	HRM4	No change
HRM5a	HRM5a	HRM4a	Modifications in the language, Interpretation added
HRM5b			New Objective element
HRM5c	HRM5b	HRM4b	Modifications in the language Interpretation modified for better clarity
HRM 5d			New Objective Element

Chapter 10: Information Management System (IMS)

2nd edition Entry Level Hospital	1st Edition Entry level HCO	1st Edition Entry level SHCO	Remarks
IMS1			New standard
IMS1a			New Objective element)
IMS1b			New Objective element
IMS 1c			New Objective Element
IMS2	IMS1	IMS1	No change
IMS2a	IMS1a	IMS1a	Interpretation modified for better clarity
IMS2b	IMS2a IMS2b IMS2c IMS2d IMS2e	IMS2a IMS2b IMS2c IMS2d IMS2e	Modifications in the language, Objective element merged Interpretation modified for better clarity
IMS2c	IMS1b IMS1c IMS1d	IMS1b IMS1c IMS1d	Modifications in the language, Objective element merged Interpretation modified for better clarity
IMS2d	IMS 1e	IMS 1e	Modifications in the language Interpretation modified for better clarity
	IMS2f	IMS2f	Deleted
IMS3	IMS3	IMS3	Change in language
IMS3a	IMS3a	IMS3a	Modifications in the language Interpretation modified for better clarity
IMS3b	IMS3b	IMS3b	Modifications in the language, Interpretation modified for better clarity
IMS3c	IMS4a IMS4b IMS4c	IMS4a IMS4b IMS4c	Modifications in the language, Objective element merged Interpretation modified for better clarity
IMS3c			New Objective Element
IMS 3d	IMS4a IMS4b IMS4c	IMS4a IMS4b IMS4c	Modifications in the language, Objective element merged Interpretation modified for better clarity

ABBREVIATIONS

ACLS	:	Advanced Cardiac Life Support
AERB	:	Atomic Energy Regulatory Board
AHRQ	:	Agency for Healthcare Research and Quality
AHU	:	Air Handling Unit
ALARA	:	As Low As Reasonably Achievable
BLS	:	Basic Life Support
BMW	:	Bio-Medical Waste
BP	:	Blood Pressure
CAPD	:	Continuous Ambulatory Peritoneal Dialysis
CCTV	:	Closed-Circuit Television
CDC	:	Centers for Disease Control and Prevention
CPR	:	Cardio-Pulmonary Resuscitation
CSSD	:	Central Sterile Services Department
CT	:	Computerised Tomography
DG	:	Diesel Generator
ECG	:	Electrocardiogram
EMR	:	Electronic Medical Record
EPR	:	Electronic Patient Record
EQA	:	External Quality Assurance
ETO	:	Ethylene Oxide
ETP	:	Effluent Treatment Plant
FCU	:	Fan Coil Unit
FDA	:	Federal Drug Authority

FMEA	:	Failure Modes and Effects Analysis
GNM	:	General Nursing and Midwifery
HAI	:	Healthcare-Associated Infection
HAZMAT	:	Hazardous Material
HDU	:	High Dependency Unit
HIRA	:	Hazard Identification and Risk Analysis
HIS	:	Hospital Information System
HISI	:	Hospital Infection Society-India
HIV	:	Human Immunodeficiency Virus
HT	:	High Tension
HTM	:	Health Technical Memorandum
HVAC	:	Heating Ventilation and Air Conditioning
HvPI	:	Haemo Vigilance Programme of India
ICD	:	International Classification of Diseases
ICN	:	Infection Control Nurse
ICO	:	Infection Control Officer
ICU	:	Intensive Care Unit
ID	:	Identification Data
IP	:	In-Patient
IPD	:	In-Patient Department
IPHS	:	Indian Public Health Standards
ISMP	:	Institute for Safe Medication Practices
ISO	:	International Organisation for Standardization
IT	:	Information Technology
IV	:	Intravenous

LAMA	:	Leaving Against Medical Advice
LASA	:	Look-Alike Sound-Alike
LIS	:	Laboratory Information System
LPG	:	Liquefied Petroleum Gas
LT	:	Low Tension
MBBS	:	Bachelor of Medicine and Bachelor of Surgery
MCI	:	Medical Council of India
MDRO	:	Multi-Drug Resistant Organisms
MLC	:	Medico-Legal Case
MoU	:	Memorandum of Understanding
MRD	:	Medical Records Department
MRI	:	Magnetic Resonance Imaging
MRSA	:	Methicillin-Resistant Staphylococcus aureus
MSDS	:	Material Safety Data Sheet
MTP	:	Medical Termination of Pregnancy
MvPI	:	Materio-Vigilance Programme Of India
NACO	:	National AIDS Control Organisation
NALS	:	Neonatal Advanced Life Support
NDMA	:	National Disaster Management Authority
NFPA	:	National Fire Protection Association
NICU	:	Neonatal Intensive Care Unit
OP	:	Out-Patient
OPD	:	Out-Patient Department
OT	:	Operation Theatre
PALS	:	Paediatric Advanced Life Support

PC-PNDT	:	Pre-Conception and Pre-Natal Diagnostic Testing
PDSA	:	Plan Do Study Act
PICU	:	Paediatric Intensive Care Unit
PPE	:	Personal Protective Equipment
PROM	:	Patient Reported Outcome Measures
PvPI	:	Pharmaco-Vigilance Programme of India
RIS	:	Radiological Information System
RO	:	Reverse Osmosis
RTI	:	Right To Information
SBAR	:	Situation, Background, Assessment, Recommendation
SHEA	:	Society for Healthcare Epidemiology of America
SOP	:	Standard Operating Procedure
STG	:	Standard Treatment Guideline
STP	:	Sewage Treatment Plant
TLD	:	Thermo Luminescent Dosimeter
TPR	:	Temperature, Pulse and Respiratory Rate
UPS	:	Uninterrupted Power Supply
VRE	:	Vancomycin-Resistant Enterococci
WHO	:	World Health Organisation

CHAPTER 1

Access, Assessment and Continuity of Care (AAC)

Intent of the chapter

The organisation defines its scope of service provision and provides information to patients about the services available. This will facilitate appropriately matching patients with the organisation's resources. Once the patient is in the organisation, the patient is registered and assessed, whether in OPD, IPD or Emergency. The laboratory and imaging services are provided by competent staff in a safe environment for both patients and staff.

A standardized approach is used for referring or transferring patients in case the services they need do not match with the services available at the organisation. Further, the chapter lays down key safety and process elements that the organisation should meet, in the continuum of the patient care within the hospital and till discharge.

SUMMARY OF STANDARDS

AAC.1.	**The organization defines and displays the healthcare services that it provides.**
AAC.2.	**The organization has a well-defined registration, admission and transfer process.**
AAC.3.	**Patients cared for by the organization undergo an established initial assessment.**
AAC.4.	**Patient care is continuous and all patients cared for by the organization undergo a regular reassessment.**
AAC.5.	**Laboratory services are provided as per the scope of the hospital's services and laboratory safety requirements.**
AAC.6.	**Imaging services are provided as per the scope of the hospital's services and established radiation safety programme.**
AAC.7.	**The organization has an established discharge process.**

Standards and Objective Elements

Standard

AAC. 1 — **The organization defines and displays the healthcare services that it provides.**

Objective Elements

CORE **a. The healthcare services being provided are defined.**

Interpretation: The services provided are clearly defined. Each department's (Broad speciality, Super speciality and diagnostic services) scope is defined. The scope could be by inclusion or exclusion in relation to the services practiced in the department. All clinical and diagnostic outsourced services shall be documented and information of the same shall be known to all the staff.

The staff handling admission and registration needs to be aware of the services that the organisation can provide. It is also advisable to have a system wherein the staff is aware as to whom to contact if they need any clarification.

CORE **b. The defined services are prominently displayed.**

Interpretation: Display should state the names of clinical and diagnostic departments of the organisation. The healthcare services so defined should be displayed prominently in an area visible to all patients and visitors. The display could be in the form of boards, citizen's charter, etc. They should be permanent. Electronic displays could be used by the organisation. The display should be at least bilingual (state language / language spoken by most people in that area and English).

CORE **c. Each defined healthcare service should have outpatient, Inpatient and emergency covered by qualified medical staff to take care of the patient's needs.**

Interpretation: The organisation shall ensure that each defined healthcare service has suitably qualified medical and nursing staff to take care of the patient's clinical needs. The said service shall have outpatient and inpatient services and the consultant(s) shall provide emergency cover.

Standard

AAC. 2 — **The organization has a well-defined registration, admission and transfer process.**

Objective Elements

CORE

a. The written guidance governs the process that addresses registering and admitting out-patients day care, in-patients and emergency patients*.

Interpretation: Organisation shall have written guidance for registration and admission of patients which should also include unidentified patients. All patients who are assessed in the hospital shall be registered. The organisation could consider mechanisms to verify the identity of the patient during registration. All admissions must be authorised by a doctor.

Patients with a clinical problem which warrant an earlier response are identified and prioritized in emergency settings. All the staff handling these activities should be oriented to the applicable guidelines.

The procedures address out-patients, day-care, in-patients and emergency patients.

General Consent for treatment is obtained when the patient enters the organisation and its scope is explained. The organisation defines what is the scope of the general consent and the same shall be communicated to the patient and /or his family members in his/her own language. This cannot include consent for Invasive procedures and other surgery specific procedures for which a specific consent is required as per this standard.

CORE

b. A unique identification number is generated at the end of the registration.

Interpretation: The organisation shall ensure that every patient gets a unique number which is generated at the end of registration of the first interaction that the patient has with the organisation. This number shall be used for identification of the patient across the organisation and to ensure continuity of care. All hospital records of the patient shall have this number.

"Unique" implies that this is a one-time affair. A particular patient can have only one unique number. However, in case of multiple visits (OP/IP) a different number could be generated additionally, which shall be linked to the unique number to ensure continuity of care.

Commitment

c. There is an appropriate mechanism for transfer (in and out) or referral of patients*.

Interpretation: This shall address both planned and unplanned transfers.

Patients needing transfer-out include those who have come to the emergency but need to be transferred to another organisation or those already admitted, but who now require care in another organisation. It also includes patients being shifted for diagnostic tests.

The staff accompanying shall be appropriately trained to manage medical emergencies during the transfer process. A doctor should accompany an unstable admitted patient who is being transferred out of being shifted for diagnostic purpose.

The organisation gives a transfer notes/summary to all patients who are being transferred from the emergency ward /or patients being transferred for diagnostic and therapeutic purposes mentioning the significant findings and treatment given.

Standard

AAC. 3 **Patients cared for by the organization undergo an established initial assessment.**

Objective Elements

CORE **a. The initial assessment of the out-patients, day-care, in-patients and emergency patients is done in a standardised manner.**

Interpretation: The organisation shall have a format for initial assessment of patients done in the OPD, day-care, emergency and in-patients. It shall be designed to ensure that the laid down parameters are captured. It could be standardized across the hospital or modified depending on the need of the department. However, it shall be the same in that particular area.

In the emergency department, this shall include recording the vital parameters.

Abridged documentation may be used for day-care as appropriate. This includes patient coming for dialysis.

The organisation shall define and implement the time frame within which the initial assessment is to be completed. The maximum time within which the initial assessment is completed for an in-patient is 24 hours. In case of emergency, the time frame shall be from the time that the patient arrives at the emergency department until the initial assessment is completed.

Excellence **b. The initial assessment for in patients results in a documented care plan.**

Interpretation: The care plan is prepared and documented based on initial assessment and result of diagnostic tests if available for inpatients and day-care patients. The care plan shall be documented by the treating doctor or by a doctor member of the treating team in the patient record. It should include a provisional diagnosis / differential diagnosis, relevant diagnostic investigations when required, initial treatment suggested and specific instructions if any.

Standard

AAC. 4 **Patient care is continuous and all patients cared for by the organization undergo a regular reassessment.**

Objective Elements

CORE **a. During all phases of care, there is a qualified individual identified as responsible for the patient's care who coordinates the care in all the settings within the organisation.**

Interpretation: For all patients cared for by the organisation, there is a qualified doctor identified as responsible for care. Although care may be provided by a team, the hospital record shall identify a doctor as being responsible for patient care.

CORE **b. Patients are reassessed at appropriate intervals to determine their response to treatment and to plan further treatment or discharge.**

Interpretation: After the initial assessment, the patient is reassessed periodically, at least once a day, by doctors and nursing staff, and is documented in the case sheet. The frequency may be different for different areas based on the setting and the patient's condition, e.g. patients in ICU need to be reassessed more frequently. Reassessments shall also be done in response to significant changes in the patient's condition. Reassessments shall be done for day-care patients (before discharging) or patients awaiting admission / bed.

Actions taken under reassessment are documented.

Care givers, including physiotherapists and dietitians, where necessary, perform reassessment within their scope of practice, registration and applicable laws and regulations.

Excellence **c. The organisation lays down the guidelines and implement process to identify early warning signs of change or deterioration in clinical conditions for initiating prompt intervention*.**

Interpretation: Defined physiological parameters are used to identify clinical deterioration. These may include assessment of vital parameters, airway, circulation, neurological status, and any other concerns felt by the staff or patient /patient family. The parameters may be tailored to suit the needs of the specialty and the age-group. There is a mechanism whereby this information reaches appropriate medical personnel to initiate prompt and appropriate actions. The effectiveness of early warning system shall be monitored.

Excellence

d. **The organisation implements standardized hand over communication during each staffing shift, between shifts and during transfers between units/departments.**

Interpretation: Change of shift and change of unit handover by doctors, nurses and other staff involved in direct patient care should be standardised and documented. Information shared should consist of the patient's current condition, recent changes in condition, ongoing treatment and possible changes or complications.

Information sharing could be done through entries either in the case sheets or in electronic medical records (EMR). The patient's records are available to the authorised care providers to facilitate the exchange of information.

Referral could be for opinion, co-management and takeover. The referral note should mention the reason for referral. All referrals shall be based on clinical significance and for a better outcome. All referrals shall be seen in a defined time frame.

Standard

AAC. 5 **Laboratory services are provided as per the scope of the hospital's services and laboratory safety requirements.**

Objective Elements

CORE

a. **Scope of the laboratory services is commensurate to the services provided by the organisation through appropriate infrastructure (physical, equipment and manpower).**

Interpretation: The organisation should ensure availability of laboratory services commensurate with the healthcare services offered by it. The organisation shall ensure that these services are available round the clock and patient care is not disrupted.

The results are reported in the standardized manner.

Laboratory shall have adequate space and equipment to meet its defined scope of services. The layout of the laboratory prevents cross contamination.

The number of laboratory personnel should be commensurate with the workload with sufficient staff for each shift and emergencies.

In case the laboratory services are outsourced, there shall be a valid MOU for the same.

CORE

b. **Requisition for the tests, collection of specimens, identification, handling, safe transportation, processing and disposal of specimens is performed as per written guidance*.**

Interpretation: The organisation has documented written guidance for requisition,

collection, identification, handling, safe transportation, processing, and disposal of the specimen, to ensure safety of the specimen till the tests and retests (if required) are completed (observing standard and special precautions). The organisation shall ensure that the unique identification number is used for identification of the patient. The disposal of waste shall be as per the current statutory requirements (Bio-medical waste management and handling rules.)

CORE

c. Laboratory reports are available in standardized manner within a defined time frame and critical results are intimated immediately to the concerned personnel*.

Interpretation: The laboratory reports should be in standardized manner. At a minimum, the report shall include the name of the organisation (or in case of outsourced laboratory, the name of the same), the patient's name, the unique identification number, reference range of the test (where applicable) and name and signature of the person reporting the test results. All reports from the outsourced laboratory shall incorporate these features, and the organisation shall not alter/modify anything in the report. In the case of the outsourced test results, the same shall be either on the outsourced laboratory's letter head or on the organisation's letter head. If it is done on the organisation's letter head, it should at least include name of the outsourced laboratory, date and reference number of the report given by the outsourced laboratory.

The organisation shall define the turnaround time for all tests. The turnaround time could be different for different tests and could be decided based on the nature of the test, criticality of the test and the urgency of the test result (as desired by the treating doctor).

The laboratory shall document critical limits for tests which require immediate attention for patient management. Critical results of outsourced investigations are also included.

The critical test results shall be communicated to the person from the treating team (treating doctor / doctor member of the treating team / ward nurse) at the earliest, but not later than one hour after completion of test / report being ready. The intimation includes documentation of the name of the patient; unique ID; date and time of intimation; the person who has communicated the value; and the identity of the recipient; read-back and date and time of acknowledgement.

In case of electronic health systems, system generated critical result reporting can supplement the physical reporting of critical results.

CORE

d. There is established laboratory safety program with laboratory personnel trained in safe practices and are provided with appropriate safety equipment/ devices.

Interpretation: Laboratory safety manual is available in the laboratory. This takes care of the safety of the workforce as well as the equipment available in the laboratory. It shall be in consonance with the risks and hazards identified. The manual should incorporate the appropriate Material Safety and Data Sheet (MSDS). All the laboratory staff undergo training regarding safe practices in the laboratory, as well as in the relevant MSDS.

Adequate safety measures are available in the lab, e.g. PPE, eye wash facilities, dressing materials, disinfectants, fire extinguishers etc. All laboratory personnel shall adhere to standard precautions and shall be appropriately immunized.

Excellence **e. There is established laboratory quality assurance program*.**

Interpretation: The organisation has a documented quality assurance programme. Quality assurance includes internal quality control (IQAs), external quality assurance (EQAs)/proficiency testing. The laboratory shall participate in external quality assurance programme when available. When such programmes are not available, the laboratory may exchange samples with another laboratory for purposes of peer comparison. Corrective and preventive actions are taken to address the deviations.

The frequency of calibration and maintenance shall be as per the equipment manufacturer's / professional bodies recommendation.

Committment **f. Laboratory tests not available in the organisation are outsourced to an organisation based on its quality assurance system*.**

Interpretation: The organisation shall have a Memorandum of Understanding (MOU) / agreement for the same, which incorporates quality assurance. The organisation should have laid down guidelines for list of tests outsourced, their safe packaging and timely transport of specimens with requisite details to the outsourced laboratory. In the case of outsourced test results, the same shall be either on the outsourced laboratory's letterhead or on the organisation letterhead.

Standard

AAC. 6 **Imaging services are provided as per the scope of the hospital's services and established radiation safety programme.**

Objective Elements

CORE **a. Imaging services comply with legal and other regulatory requirements.**

Interpretation: The organisation is aware of the legal and other requirements of imaging services. It maintains and updates its compliance status of legal and other

requirements in a regular manner. All the statutory requirements are met with, such as Atomic Energy Regulatory Board (AERB) clearance, dosimeters, lead shields, lead aprons, signage, display as per Pre-conception and Pre-natal Diagnostics Techniques (PC-PNDT) Act, reports to competent authority, etc. The organisation shall have a Radiation Safety Officer (of appropriate level). Imaging signages are prominently displayed in all appropriate locations.

Commitment **b. Scope of the imaging services is commensurate to the services provided by the organisation through appropriate infrastructure (physical, equipment and manpower).**

Interpretation: The organisation should ensure availability of imaging services commensurate with the healthcare services offered by it.

Imaging services may be provided within the organisation, outsourced to another organisation or both. The organisation shall ensure that these services are available round the clock, and patient care is not disrupted. Imaging modalities required for emergency management could preferably be available within its premises.

Reports should not get delayed due to lack of adequate equipment or human resources.

Qualified and trained personnel perform, supervise and interpret the investigations.

CORE **c. Imaging reports are available in standardised manner within a defined time frame and critical results are intimated immediately to the concerned personnel*.**

Interpretation: At a minimum, the report shall include name of the organisation (or in case of an outsourced imaging center, the name of the center), the patient's name, unique identification number, the name and signature of the person reporting the results. In case of teleradiology, there shall be the name of the reporting doctor and a remark to that effect. It should also include the name of the reporting organisation if outsourced to the organisation. All reports from the outsourced imaging center shall incorporate these features, and hospital shall not alter/modify anything in the report. The report should be in the prevailing context, taking into account the clinical details and results of any previous imaging.

The organisation shall document turnaround time of imaging results for all modalities. The defined timeframes could be different for a different type of tests and could be decided based on the nature of the test, modality, criticality of the test and the urgency of the test result (as required by the treating doctor).

The organisation shall define and document the critical results which require immediate attention for patient management and the same shall be documented, e.g. ectopic pregnancy. The critical results must be documented for each modality of imaging. Critical results of outsourced investigations shall also be intimated.

The critical test results shall be communicated to the person from the treating team (treating doctor / doctor member of the treating team / ward nurse) at the earliest, but not later than one hour of completion of test / report being ready. The intimation includes documentation of the name of the patient; unique ID; date and time of intimation, the person who has communicated the value; and the identity of the recipient; read-back and date and time of acknowledgement. In case of electronic health systems, system generated critical result reporting can supplement the physical reporting of critical results.

CORE **d. There is an established imaging safety program with imaging personnel trained in safe practices and are provided with appropriate safety equipment/ devices.**

Interpretation: Shielding of body parts of staff, patients, and attendants shall be adhered to using appropriate aprons and shields. The number of such devices shall be adequate to ensure that all workers have proper protection. Staff directly working with radiation sources shall possess and use Thermo Luminescent Dosimeters (TLD) badges.

Radiation-safety and monitoring devices are periodically tested and results are documented. TLD badges must be replaced by the fresh badges supplied by accredited laboratories according to the frequency recommended by AERB.

Radiation safety measures refer to the steps taken to protect the patient and staff from unwanted radiation.

Patients in the child bearing age group who need to be exposed to radiations should be screened for pregnancy. Patients undergoing MRI should be screened for any magnetic substance. This shall also apply to attenders accompanying the patient/child into the imaging area. Informed consent should be taken for contrast injection, moderate-deep sedation, interventional procedures, and whenever the higher risk due to imaging is found on risk screening.

Excellence **e. There is established imaging services quality assurance program.**

Interpretation: The quality assurance should be a comprehensive programme addressing equipment, protocols, surveillance and safety. Also, statutory (AERB) requirements will have to be met. Quality assurance programme includes tests for imaging equipment, such as congruence of optical and radiation field, focal spot size, output consistency, leakage rate, magnetic field homogeneity, slice position accuracy, phantom checks, etc. The tests as applicable shall be performed. Quality Assurance, including calibration and maintenance of all equipment, will be performed as per AERB guidelines, as well as the manufacturer's recommendations.

The peer review shall be done. The peer review system is in place to review the imaging results of CT and MRI.

The peer review shall be done in a structured manner, and the sample size, periodicity

for each modality shall be defined by the organisation. However, at a minimum, it shall be 1 percent. Corrective and preventive actions are taken on the discrepancies in the reports.

Excellence

f. Services not available at the organisation are outsourced to an organisation based on its quality assurance system

Interpretation: The organisation shall have a Memorandum of Understanding (MOU) / agreement for the same, which incorporates quality assurance. There shall be written guidance for outsourcing tests for which it has no facilities. This shall include list of tests outsourced, identification of personnel in the outsourced facilities to ensure the safe transportation of the patients and completing the imaging results.

Standard

AAC. 7 **The organization has an established discharge process.**

Objective Elements

CORE

a. The organisation has a process for discharge of all patients including Medico-legal cases.

Interpretation: The discharge summary shall be signed by the treating doctor or a doctor member of the treating team. Patient / family acknowledges the receipt of the same.

The organisation hands over the discharge summary and reports to the patient/attendant in all cases, and a copy is retained in the medical record. In LAMA cases, the patient's right to refuse treatment and his/her request to leave the organisation is respected. The declaration of the patient/attendant is to be recorded on a proper format and a discharge summary and all reports are handed over as usual. For medico-legal cases (MLC) the organisation shall ensure that the police is informed.

CORE

b. The discharge summary contains the patient's name, unique identification number, name of treating doctor, date of admission, date of discharge, the reasons for admission, Medication Administered, significant findings, investigation results, diagnosis, procedure performed (if any), any other treatment given and the patient's condition at the time of discharge.

Interpretation: The discharge summary shall have the above details. In addition to the name of the treating doctor, it could also have the names of the other consultants involved in the treatment.

CORE

c. Discharge summary contains follow up advice, medication and other instructions in an understandable manner.

Interpretation: The discharge summary shall have the above details. This shall also incorporate preventive aspects, where appropriate. The organisation ensures that the follow-up advice, medication and other instructions are explained to the patient / relatives in a language and manner that they understand. Medical terms like BD, TDS, QID should not be used.

CORE

d. Discharge summary incorporates instructions about when and how to obtain urgent care.

Interpretation: The discharge summary should contain information on 'when' the patient should seek urgent care. This information shall be specific to the patient's diagnosis and clinical condition at the time of discharge. For example, development of fever, bleeding/discharge from site. The advice could be in the form of what medicines to take, when to consult a doctor or how to seek medical help and contact number of the hospital/doctor. The organisation ensures that instructions about when and how to obtain urgent care are explained to the patient and or relatives in a language and manner that they understand.

CORE

e. In case of death the summary of the case also includes the cause of death.

Interpretation: In case, the cause of death is not clear and a post mortem is performed (For example MLC), the same shall be documented.

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CHAPTER 2

Care of Patients (COP)

Intent of the chapter

The standards in this chapter aim to guide and encourage patient safety as the overall principle for providing care to patients.

Specific services such as Intensive Care, Surgery, Blood Transfusion, Emergency, Anesthesia, Obstetrics and Pediatric are addressed, where patient care is guided by policies and procedures.

The organization is also encouraged to identify and adapt clinical guidelines, so as to bring about uniformity in patient care.

SUMMARY OF STANDARDS

COP. 1	**Written Guidance is used to provide uniform care across the organization.**
COP. 2	**Emergency services, including ambulance are provided in accordance with written guidance, applicable laws and regulations.**
COP. 3	**The organization provides care in intensive care and high dependency units in a systematic manner.**
COP. 4	**Organization provides safe obstetric care.**
COP. 5	**Organization provides safe paediatric and neonatal services.**
COP. 6	**Procedural sedation is provided in a consistent and safe manner.**
COP. 7	**Anaesthesia services are provided in a consistent and safe manner.**
COP. 8	**Clinical procedures, as well as procedures in the operation theatre are performed in a safe and consistent manner.**
COP. 9	**The organization identifies and manages patients who are at higher risk of morbidity and mortality.**
COP. 10	**Pain management, rehabilitation services and nutritional therapy are provided to the patients in a safe, collaborative and consistent manner.**

Standards and Objective Elements

Standard

COP. 1 — **Written Guidance is used to provide uniform care across the organization.**

Objective Elements

CORE **a. Care shall be provided in consonance with applicable laws & regulations**

Interpretation: The organisation shall adhere to the norms laid down by the government through relevant legislations like the Clinical Establishment Act, Pre-conception and Pre-natal Diagnostic Techniques (PC-PNDT) Act, the Transplantation of Human Organs Act, Medical Termination of Pregnancy (MTP) ACT or any such similar legislation. For example, consent before surgery, providing first aid to emergency patients and police intimation in medico-legal cases.

Commitment **b. The care and treatment is provided following written guidance.**

Interpretation: Clinical practice guidelines brought out by national and international professional organisations may be used. Standard treatment guidelines (STGs) brought out by the Government of India, are a good starting point. In the absence of evidence based clinical practice guidelines, sound clinical practices shall guide the delivery of care.

For definitions of "evidence based medicine" and "clinical practice guidelines", refer to glossary

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Commitment **c. Care delivery is uniform for a given clinical condition when similar case is provided in more than one setting.**

Interpretation: When similar treatment / care is provided in various settings such as out-patients, in-patients, and different categories of wards, the organisation shall ensure that patients with the same clinical condition and care needs, receive the same quality of healthcare throughout the organisation. Care delivery shall be applicable irrespective of the setting and category of the ward, and whether the patient is paying or non-paying, and / or is supported from a government / private insurance scheme or not. For example, the decision to offer any form of intervention or medication, frequency of consultant visit, nature of support care, decision to discharge is not influenced by the class or category of the patient, but is decided by the clinical needs of the patient. Further, in case the organisation has separate OPDs for different categories of patients, the methodology of care delivery shall be uniform in all OPDs.

Excellence

d. Nursing care and procedures are performed in consonance with the established protocols.

Interpretation: Care shall be provided as per the established protocols for nursing. Uniformity and continuity of care should be practised.

Components of nursing care could include:

- Assessment
- Plan of care
- Implementation of care
- Evaluation
- Modification of plan of care as may be required.

The documentation includes all nursing-related care and not just monitoring of vitals and documentation of medication administration. The nursing progress shall be documented in a timely manner for the individual patient.

There shall be an adequate number of sphygmomanometers, thermometers, weighing scale(s), and other basic equipment/ gadgets necessary for functioning in the designated area. Further, the equipment shall be appropriate for the area. For example, the BP cuffs in the Paediatric area should be of appropriate size.

CORE

e. Transfusion services are provided as per the scope of services of the organisation, safely and are governed by the applicable laws and regulations.

Interpretation: The organisation should have blood / blood components available from either an in-house or outsourced licensed blood centre, if applicable. In case the organisation uses an outsourced blood bank, it shall have an MOU and ensure that patient care does not suffer for want of blood / blood components. The blood shall be transported from the external blood centre safely and appropriately. A good reference guide is the NABH standards for blood banks. The organisation shall define as to what constitutes "use in an emergency situation" and accordingly develop procedures to ensure the availability of blood / blood components. The organisation should define the time frame within which blood shall be available for use in an emergency situation. Use in emergency includes both for actual and anticipated need. The objective element is applicable even if the organisation doesn't have the blood bank facility in-house.The organisation shall ensure that any transfusion reaction is reported. These are then analysed (by individual/ committee as decided by the organisation) and appropriate corrective/ preventive action is taken. The organisation shall maintain a record of transfusion reactions.

For "transfusion reactions" refer to the glossary.

CORE **f. Transfusion of blood and blood components is managed by written guidance.**

Interpretation: The written guidance shall at a minimum include how the orders are written including pre-medications if any, where appropriate the rate of transfusion (rate needs to be mentioned for paediatric patients), safe storage as per guidelines and transport of blood, how the blood/blood product is verified prior to transfusion, how the patient is identified and how the patient is monitored. Verification, transportation, cold chain and delivery at the right source should be taken care of.

Blood and blood component usage should be based on the standard practice guidelines / sound clinical practices brought out by the national and international professional organisations.

CORE **g. Informed consent should be taken for transfusion of blood and blood products when there is a requirement for transfusion (actual or anticipated) for transfusion.**

Interpretation: The consent should include risks (including those of transfusion-related infections in spite of the best possible screening to ensure infection free blood / blood components), benefits and possible complications of multiple transfusions.

Patient and family education about the donation should be evidenced. Information could be in the form of a booklet/leaflet, and has to be given along with the consent form.

The same consent may be valid for multiple transfusions of blood/ components in a given admission (in-patient), which has a definite validity period. In case of patients who are transfusion dependent (e.g. haemophilia, thalassemia etc.) the consent can be taken at the first instance and once in six months. Such consent shall have a defined validity period but not more than 6 months. The patient/competent relative or guardian endorses the consent at each repeat transfusion.

COP. 2 Emergency services, including ambulance are provided in accordance with written guidance, applicable laws and regulations.

Objective Elements

CORE **a There shall be an identified area in the organisation, which is easily accessible to receive and manage emergency patients, with adequate and appropriate resources.**

Interpretation: The identified area to treat emergency patients should be easily accessible for initiation of care. There should be signage and directions in an

understandable manner leading to the emergency area. The organisation shall also specify the minimum number of beds based on its scope of services. Emergency services should have adequate and appropriate equipment and human resources to receive and initiate care of emergency patients. At a minimum, basic resuscitation equipment, equipment for monitoring vital parameters, appropriate consumables and life saving and emergency care drugs shall be available.

CORE

b. The organisation manages medico-legal cases and provides emergency care in consonance with statutory requirements and in accordance with written guidance. *

Interpretation: Written guidance could include guidelines/ SOPs/ protocols to provide general emergency care as well as management of specific conditions, e.g. poisoning, road traffic accidents, patients with coronary disease, etc. It shall address both adult and paediatric patients.

In case, emergency services are out of the scope of the organisation, or the organisation does not have facilities for appropriate emergency care of a given clinical condition, at a minimum, such patients shall be provided with first aid before transferring them to another centre. A process should be in place to ensure patients safety.

The care provided, especially the documentation and intimation to appropriate authorities, shall be in accordance with statutory requirements. The organisation shall also define what constitutes an MLC (by statutory guidelines).

CORE

c. Cardio-pulmonary resuscitation services are provided uniformly across the organisation.

Interpretation: This shall be in consonance with accepted practices. The organisation shall ensure that medical equipment for resuscitation and medications for basic and advanced life support are provided in standardized manner, as appropriate. Basic life support should be initiated as soon as a condition requiring CPR is identified. This is implemented in all areas of the organisation. The protocols could be displayed prominently in all critical areas such as emergency, ICU, OT, etc.

The team members have a clear understanding of their roles and responsibilities during the resuscitation to effectively function as a team. In the actual event of a cardiopulmonary resuscitation, or a mock drill of the same, all the activities along with the personnel attended should be recorded. At the minimum, it will include timeliness of response, availability of human resources, equipment, drugs, and barriers if any. The recording could be done using the pre-defined procedural checklist and by monitoring whether the prescribed activity has been performed properly and in the right sequence.

The equipment and medications for use during CPR are available in various areas of organisation. Other equipment like defibrillators should be easily accessible to ensure that there is no delay in cardiopulmonary resuscitation. It is preferable that the minimum emergency medication is standardised across the organisation.

The post-event analysis of all CPR shall be done. The analysis shall focus on the initiation of CPR, time of arrival of the team, availability of suitable resources, recording of the sequence of events during CPR (including technique) and the overall coordination. The organisation shall also monitor the outcomes. The analysis should be completed within a defined time frame.

Corrective and preventive measures should be completed preferably within a defined time frame.

Commitment **d. Initiation of appropriate care is guided by a system of triage.***

Interpretation: Triage shall be done only by qualified/trained individuals. The triage should be part of the routine day-to-day functioning of the emergency department and not from the perspective of managing a large number of patients during a disaster. If several patients are waiting to be triaged, a visual triage assessment may be conducted.

For "triage" refer to the glossary.

Commitment **e. All patients in emergency are reassessed as appropriate for the change of status.**

Interpretation: A patient's condition may worsen or improve, and so a reassessment is needed for early identification of deterioration or improvement, and modification of care accordingly. The findings of reassessment shall be documented in the patients' medical record.

CORE **f. Admission or discharge to home / transfer to another organisation is documented and discharge/transfer note shall be given to the patients.**

Interpretation: The organisation shall maintain documentation to indicate if a patient who came to the emergency was sent home after providing initial care / was admitted in an emergency for a short stay and then discharged / transferred to another organisation. The staff should have a clear understanding of the scope of activities of the organisation and the procedure of referral and transfer to an appropriate another centre, of patients who cannot be cared for in-house, after administering the due first-aid/ emergency care.

The discharge /transfer note shall contain salient clinical findings, investigations done, treatment given, and condition at discharge / transfer. The basis / reasons for discharge or transfer should be documented.

Commitment **g. The organisation has system in place for the management of patients found dead on arrival and patients who die within few minutes of arrival.**

Interpretation: There is written guidance for managing situations where a patient is either found dead on arrival or dies within a few minutes of arrival (after a failed attempt at resuscitation). The written guidance should conform to the relevant local laws.

In case of a patient found dead on arrival (brought dead), the following should be addressed and the staff should be aware of the same:

a) Maintaining a log book of found dead on arrival.

b) The decision on whether to perform a post-mortem.

c) The decision regarding the issue of a medical certificate of cause of death.

d) The temporary storage of the body in appropriate conditions.

e) What to do in case of unclaimed/unaccompanied bodies.

In case of death within a few minutes of arrival (after a failed attempt at resuscitation), the following should be addressed and the staff should be aware of the same:

a) Process of registration of such patients and recording the entire resuscitation events.

b) The decision on whether to perform a post-mortem.

c) The temporary storage of the body in appropriate conditions.

d) Issue of Medical certificate of cause of death certificate and handing over of the body.

Commitment **h. Appropriately manned and equipped ambulance is available and checked daily.**

Interpretation: Commensurate to its scope of services the organisation may provide in-house or use outsourced ambulance service for safe patient transport with appropriate care.

The vehicle used as an ambulance shall adhere to statutory requirements, e.g. registration as an ambulance under the Motor Vehicle Act, valid fitness certificate, pollution control certificate, and insurance of the vehicle.

The ambulance should be operated by a driver with a valid licence. Additionally, technician/nurse and/or doctor depending on the situation and the scope of the ambulance, shall accompany. Personnel in the ambulance shall have training in basic life support, and be trained in basic cardiopulmonary resuscitation. Ambulance shall be equipped with basic life support or advanced life support as per organisation's scope of the services.

Equipment is checked daily using a checklist

Emergency medications are available in the ambulance during patient transport. Based on a check list, a daily check is done to ensure availability and expiry dates of emergency medications, and documented.

Excellence **I. The organisation plans and implements mechanisms for the care of patients during community emergencies, epidemics and other disasters.**

Interpretation: The organisation identifies potential community emergencies, epidemics and other disasters. The disaster plan must incorporate essential elements of alert code, information and communication, action cards for each of the staff, availability and earmarking of resources including adequacy of medical supplies, equipment, materials, trained personnel, establishment of command nucleus, training and mock drills, managing clinical activities during the event.

It should also include aspects like activating and deactivating plan; receive identify and triage casualties; defined areas for reception and treatment for casualties; transportation aids; communication aids; manage visitors, and control the movement of individuals vehicles, relocate / discharge admitted patients wherever needed.

The plan should conform to the relevant local laws and national plans on disaster management. The plan is tested twice at least twice a year with mock drills, one of which, instead, could be a table top exercise. This shall test all the components of the plan and not just awareness. In case of mock drill, simulated patients (not real) shall be used.

Standard

COP. 3 **The organization provides care in intensive care and high dependency units in a systematic manner.**

Objective Elements

CORE **a. The care of patient in intensive care units and high dependency units is in consonance with written guidance by adequately available staff and equipment.**

Interpretation: The organisation should develop criteria for admission / transfer-in / discharge / transfer-out of patients to ICU / HDU based on physiological parameters and / or diagnostic parameters, and adhere to the same.

As and when there are no vacant beds in the ICU and there is a requirement of such a bed, a detailed policy and procedure should be in place to address the situation.

The written guidance shall be based on standard treatment guidelines/sound clinical practices regarding intensive/critical care. The ICU/HDU should be equipped with all necessary life saving and monitoring equipment as well as suitable handled by trained

staff. The exact requirements shall be decided by the organisation based on the scope and complexity of its services. Staff working ICU /HDU shall be competent based on their qualification and training.

Excellence **b. The organisation shall implement a quality-assurance programme for its intensive care / high dependency units*.**

Interpretation: The written guidance for quality assurance could be developed individually or it could be a part of the organisation's overall quality-improvement programme. The quality assurance programme should involve all aspects of the functioning in the intensive care unit. The organisation shall monitor care outcomes, like mortality rate, infection rates, readmission rates, re-intubation rates, etc.

Commitment **c. The organisation has a mechanism to counsel the patient and / or family periodically.**

Interpretation: Patients and families are counselled by a doctor of the treating team, at periodic intervals (at-least once a day) and when there is a significant change in the patient's condition. Significant events since the last counselling session, expected outcomes, and queries related to the changing condition of the patient, could be addressed.

Excellence **d. End of life care is provided in compassionate and considerate manner.**

Interpretation: The organisation develops written guidance for implementation of End-of-Life Care based on good practices (National and International) and in accordance with the law of the land.

This shall include:

i. providing appropriate pain and palliative care according to the wishes of the family and patient;

ii. sensitively addressing such issues as autopsy and organ donation;

iii. respecting the patient's values, religion, and cultural preferences;

iv. involving the patient and family in all aspects of care; and

v. responding to the psychological, emotional, spiritual, and cultural concerns of the patient and family (where possible).

Standard

COP. 4 — **Organization provides safe obstetric care.**

Objective Elements

CORE **a** **Obstetric services are organized and provided safely as per defined scope of services.**

Interpretation: At a minimum, this shall include assessment of these patients including nutrition, immunisations and education; and ante-natal, perinatal and post-natal care guidelines.

The organisation shall define in its written guidance whether care for high risk obstetric cases is provided or not. The organisation shall define as to what constitutes a high risk obstetric case in consonance with best clinical practices.

CORE **b.** **Obstetric care includes ante -natal check ups, maternal nutrition assessment, peri-natal monitoring and post-natal monitoring based on written guidance.**

Interpretation: Antenatal examination(s) should guide the early identification of high risk obstetric cases. High risk obstetric cases have more frequent ante-natal check-ups, where appropriate. In case, care of high-risk obstetric cases is not in the scope of the organisation's obstetric services, there should be a pro-active referral to the appropriate organisation.

The organisation caring for high risk obstetric cases has trained workforce and facilities to take care of such mothers and neonates. Persons caring for high risk obstetric cases are competent. This shall not just be doctors, but shall include nursing staff also. The competency shall be based on qualification and / or experience and / or training

The maternal assessment shall, at a minimum include assessment, immunisation, diet counselling and frequency of visits. There shall be an ante-natal card (or equivalent) for every such patient. The antenatal card shall be complete with medical and obstetric history of the expectant mother.

In the context of maternal and foetal monitoring, at a minimum, this shall include monitoring of foetal heart rate during labour, the progression of labour and post-natal monitoring of post-partum haemorrhage. Safety tools like WHO "safe birth check list" can be used to improve maternal and child safety.

CORE **c.** **The organisation caring for obstetric cases has the facility to take care of neonates of such cases.**

Interpretation: The organisation shall have an NICU (level I, II or III) with appropriate equipment and staff, including competent paediatrician / neonatologist and nurses (based on qualification and training)

Standard

COP. 5 **Organization provides safe paediatric and neonatal services.**

Objective Elements

CORE **a. Paediatric and neonatal services are organized and provided safely by doctors and nurses having age-specific competencies.**

Interpretation: The scope of paediatric and neonatal services may include various paediatric subspecialties and special clinics. For example, well baby clinic, different levels of NICUs, PICU, etc.

Sound clinical practices govern the organisation and delivery of safe neonatal and paediatric care. At a minimum this shall include assessment of these patients, organisation of care and addressing special needs. The hospital shall actively promote breastfeeding practice.

Doctors and nurses shall have age specific competency. The competency shall be based on qualification, and / or experience and / or training.

Adequate amenities for the care of infants and children shall be available in the hospital.

CORE **b. Paediatric assessment includes growth, developmental, nutritional and immunization assessment.**

Interpretation: The growth, developmental and immunisation assessment is performed using appropriate tools (preferably validated) and documented. The growth charts and immunisation records are maintained and updated as applicable.

The education should be in the language that the family understands. This could be done using educational material. The education on nutrition should address the importance of breastfeeding, weaning and various aspects of malnutrition that includes protein-energy malnutrition and childhood obesity.

CORE **c. The organisation has measures in place to prevent child/ neonate abduction, swapping and abuse.**

Interpretation: The organisation shall ensure that there is an adequate

security/surveillance to prevent such happenings. For example, the installation of CCTV cameras. There is a defined process for rapid response in case of an eventuality. The defined process shall be tested at pre-defined intervals, either through table-top exercise or mock drill. Staff are trained in prevention and rapid response. Staff are aware of how to handle and escalate such incidence if any.

Standard

COP. 6 **Procedural sedation is provided in a consistent and safe manner.**

Objective Elements

Excellence **a. Procedural sedation is provided in a consistent manner and is administered as per written guidance.**

Interpretation: Written guidance based on standard treatment guidelines/sound clinical practices governs the administration of procedural sedation. At a minimum, this shall include identification of procedures where this is required, the mechanism for writing orders, the pre-procedure assessment, monitoring during and after the procedure and the discharge/transfer out criteria after the procedure.

Equipment and workforce are available to manage patients who have gone into a deeper level of sedation than initially intended

Excellence **b. Competent and trained persons perform and monitor sedation after informed consent.**

Interpretation: The informed consent shall be taken by the person administering the sedation or a doctor member of the team administering the sedation. The person monitoring sedation is different from the person performing the procedure, and should be trained in the detection of abnormalities of the monitoring parameters and also in recognition of apnoea and airway obstruction. Whenever a parenteral route is used this may be administered by a doctor or a nurse under supervision of a doctor. The technician shall not administer sedation.

Intra-procedure monitoring includes at a minimum the heart rate, cardiac rhythm, respiratory rate, blood pressure, oxygen saturation, and level of sedation. The monitored parameters should be documented. The cardiac rhythm may be monitored on a monitor during the procedure and the same need not be documented. However, in case of rhythm abnormalities the same shall be documented.

Post procedure, patient vitals shall be monitored and documented at regular intervals till he/she recovers completely from the sedation. At a minimum, the heart rate, respiratory rate, blood pressure, oxygen saturation and level of sedation are

monitored. The level of sedation can be monitored by using a checklist which incorporates the various components of levels of sedation (mild, moderate and deep).

The discharge/transfer criteria shall be developed and documented by the organisation in consonance with physiologic parameters and sound clinical practices, to determine appropriateness of discharge from the observation /recovery area. A qualified individual shall apply the criteria, and the same is documented.

Standard

COP. 7 **Anaesthesia services are provided in a consistent and safe manner.**

Objective Elements

CORE **a. There is a written guidance for administration of anaesthesia.**

Interpretation: Written guidance based on standard treatment guidelines/sound clinical practices governs anaesthesia services across the organisation. The organisation shall document the indications, the type of anaesthesia and procedure for the same.

The informed consent shall be taken by the person administering anaesthesia or a doctor member of the team administering anaesthesia. Patient and/or, family are educated on the risks, benefits, and alternatives of anaesthesia by the anaesthesiologist.

This shall be separate from the surgery consent.

CORE **b. The pre-anaesthesia assessment results in the formulation of an anaesthesia plan which is documented.**

Interpretation: Patients for anaesthesia have a pre-anaesthesia assessment by a qualified anaesthesiologist. This shall be done before the patient is wheeled into the OT complex. It shall be applicable for both routine and emergency cases. It is preferable to assess using a standardised format. The pre-anaesthesia assessment may even be carried out prior to admission in case of elective surgeries. This could be done up to 30 days in advance.

The plan should mention the pre-medications, type of anaesthesia, special requirements and anticipated post-anaesthesia care where appropriate. The anaesthesiologist would review the medication the patient is currently taking.

A pre-induction assessment shall be done by an anaesthesiologist. Any changes to the anaesthesia plan shall be documented. When anaesthesia needs to be provided on an urgent basis, the pre-anaesthesia assessment and pre-induction assessment may

be performed one after another, or simultaneously, but should be documented separately.

CORE

c. Patients are monitored while under anaesthesia.

Interpretation: The parameters including temperature, heart rate, cardiac rhythm, respiratory rate, blood pressure, oxygen saturation and end tidal carbon dioxide, should be monitored and documented. In case of regional anaesthesia, instead of end-tidal carbon dioxide, the adequacy of ventilation shall be evaluated by continual observation of qualitative clinical signs. Anaesthesiologist shall be present throughout the procedure, when the patient is under anaesthesia.

The cardiac rhythm may be monitored on a monitor during the procedure, and the same need not be documented. However, in case of rhythm abnormalities, the same shall be documented.

The type of anaesthesia and anaesthetic medications used are documented in the patient record.

The anaesthesia notes/records shall include the name of the anaesthesiologist who performed the procedure. The documentation shall have name, date, time and signature, and the author of the entry can be identified.

CORE

d. Post anaesthesia monitoring is documented, and patients are discharged from the recovery area based on objective criteria.

Interpretation: Post anaesthesia monitoring shall be done in the recovery area/OT and at least include monitoring of vitals till the patient recovers completely from anaesthesia and shall be done by an anaesthesiologist. If the patient's condition is unstable and he/she requires ICU care, the same shall be monitored there. When the patient is transferred directly from the OT to ICU, monitoring and documentation shall be the same as would be required in the recovery room.

Criteria shall be developed and documented by the organisation in consonance with physiologic parameters and sound clinical practices, to determine appropriateness of discharge from the observation /recovery area. The anaesthesiologist shall apply the criteria, and the same is documented.

Commitment

e. Intraoperative adverse anaesthesia events are recorded and analyzed

Interpretation: Intra-operative adverse anaesthesia events are documented and analysed for the purpose of taking corrective and preventive action. The organisation shall define the various intra-operative adverse anaesthesia events, following the administration of anaesthesia. The hospital may have a mechanism to ensure that all adverse events are captured. It could do the same by incorporating in the anaesthesia record a heading for the same.

Standard

COP. 8 — **Clinical procedures, as well as procedures in the operation theatre are performed in a safe and consistent manner.**

Objective Elements

Commitment

a. Clinical procedures as well as procedures done in operation theatres are done in a consistent and safe manner as per written guidance.

Interpretation: The decision to perform a procedure shall be based on the clinical needs of the patient, in consonance with standard treatment guidelines and / or sound clinical practice for the given condition / procedure. A qualified medical practitioner decides if the procedure is indicated. Qualified personnel order, plan, perform and assist in performing procedures. It is preferable that a brief assessment is done prior to performing a clinical procedure.

There shall be written guidance available on who will perform which procedure. This shall include the list of procedures (including surgical procedures) as well as competency level for performing these procedures.

The operation theatre is monitored for infection control practices. The components of standard precautions include hand hygiene, appropriate use of PPE, cleaning and disinfection of equipment, and needle-stick and sharp injury prevention. Appropriate preparation of body parts, and the use of disinfected / sterilised instruments is ensured.

The layout / practices of the operation theatre should be such that the mix of sterile and unsterile patients does not happen or if it is not possible, the mix is reduced to the bare minimum.

Surveillance activities of the operation theatre environment include the daily monitoring of humidity, pressure differential and temperature; and at least six monthly monitoring of the air quality. Also, the efficacy of OT cleaning and disinfection processes shall be monitored.

The organisation shall ensure that the operating theatre complex has facilities for pre-op holding, changing rooms, hand-washing, operating rooms, waiting area for relatives, storage area, collection area for waste and linen and recovery room (where applicable). In addition to the equipment required for anaesthesia and surgery, there shall be equipment for resuscitation, radiation protection (where applicable) etc. Instruments shall be in working condition. The supplies to the OT are commensurate to the scope and complexities of the surgery.

CORE

b. Surgical patients have a preoperative assessment, a documented pre-operative diagnosis, and pre-operative instructions are provided before surgery and documented.

Interpretation: Patients undergoing surgery are assessed pre-operatively, a pre-operative diagnosis is made, and pre-operative instructions documented. This shall apply to all elective cases and wherever possible to emergency cases. This shall be done by the operating surgeon or a doctor member of the operating team.

CORE

c. An informed consent is obtained by a surgeon from the operating team or the doctor performing the procedure prior to the surgery/ clinical procedure.

Interpretation: The informed consent for procedures/surgeries shall be taken by the person performing the procedure or a doctor of his/her team. In case the procedure is being done by a person in training, it shall specify the same. All such procedures shall be supervised by the treating doctor.

In case there is a change in clinical status / expected outcomes after the consent, but before the surgery, the same is explained to the patient / family and is documented. In case, a new and / or additional procedure that was not planned or for which an explicit consent had been taken before the surgery, a fresh consent needs to be taken for the same.

CORE

d. Care is taken to prevent adverse events like wrong site, wrong patient and wrong procedure/surgery and documented*.

Interpretation: Written guidance should be available for preventing adverse events like wrong site, wrong patient, wrong surgery by a suitable mechanism. The organisation shall use a documented check-list to prevent adverse events like a wrong site, wrong patient and wrong procedure. This check-list could be based on the "WHO safe surgery saves lives" check list or its modification. At least two identifiers should be used to identify the patient out of which one shall be the unique identification number. The organisation should be able to demonstrate methods to prevent these events, e.g. identification tags, badges, cross-checks, time-outs etc.

There is consistency in marking surgical sites across the organisation. The mark should be visible in the procedural field when draping is complete.

Responsibility for ensuring the correct site (including side where applicable)/patient/procedure verification rests with all team members. However, the person performing the procedure carries ultimate responsibility.

In emergencies, all attempts should still be made to identify the correct site (including side where applicable)/patient/procedure, according to the laid down guidance, although it may not be possible or appropriate to complete all the checks.

CORE

e. Procedures / operation notes, post procedure monitoring and post-operative care plan are documented accurately in the patient record.

Interpretation: This note provides information about the procedure performed,

postoperative diagnosis and the status of the patient before shifting from recovery, and shall be documented by the surgeon/doctor member of the operating team. If it is documented by a person other than the chief operating surgeon, the same shall be countersigned by the chief surgeon. At a minimum, it shall include the surgery performed, name of the surgeon (s), name of anaesthesiologist(s), salient steps of the procedure and the key findings intra-operative findings.

Patients are appropriately monitored during and after the procedure. At a minimum, for invasive procedures, this shall include pulse, blood pressure and respiratory rate and other parameters as clinically required. The extent and duration of monitoring may be tailored to the need based on the complexity of the procedure and the co-morbidities of the patient.

Post-operative care plan should address, as required advice on IV fluids, medication, care of wound, nursing care, observing for any complications, etc. This plan should be documented by the operating surgeon or member of the operating team.

Standard

COP. 9 — **The organization identifies and manages patients who are at higher risk of morbidity and mortality.**

Objective Elements

CORE **a. The organisation identifies and manages vulnerable patients. ***

Interpretation: Written guidance for identification and management of vulnerable patients is developed in consonance with statutory requirements, national and international guidelines. Vulnerable patients should include, (but not limited to) elderly, children, differently-abled and / or mentally challenged, mentally ill, comatose, critically ill, patients under sedation and anaesthesia, pregnant women, patients on dialysis, patients receiving chemotherapy, etc. The Person is responsible for identifying these patients, risk management in these patients and monitoring of these patients (at least twice a day) should be explicit in the guidance.

The guidance should include how informed consent is obtained from a vulnerable patient, and from the family or legal representative of a patient incapable of making an independent decision.

Refer to the glossary for a definition of "vulnerable patient".

The organisation shall provide a proper and safe environment considering the requirement of the vulnerable patient.

Excellence **b. The organisation identifies and manages patients who are at risk of fall, developing / worsening of pressure ulcers, deep vein thrombosis and patients on restraint*.**

Interpretation: The organisation identifies and manages patients who are at risk of fall. A validated tool shall be used for the assessment of the risk of fall. Patients found at a risk of a fall shall be managed according to written guidance.

A validated tool shall be used for the assessment of the risk of pressure sores. For example, the Braden scale, European Pressure Ulcer Advisory Panel (EPUAP) and National Pressure Ulcer Advisory Panel (NPUAP) scale for categorising or grading pressure ulcers (EPUAP-NPUAP, 2009) to look for worsening of pressure ulcers. Patients found at risk of pressure ulcers shall be managed according to written guidance.

A validated tool shall be used for the assessment of the risk of development of deep vein thrombosis. Patients found at a risk of deep vein thrombosis shall be managed according to written guidance.

When restraints are used, the following shall be documented in the medical record: the reason for using restraints, monitoring for complications and the time frame during which restraints are used.

Standard

COP. 10 **Pain management, rehabilitation services and nutritional therapy are provided to the patients in a safe, collaborative and consistent manner.**

Objective Elements

Commitment **a. Patients in pain are effectively managed ***

Interpretation: Sound clinical practices govern the care of patients in pain. It shall include as to how patients are screened for pain, the mechanism to ensure that a detailed pain assessment is done (when necessary), pain mitigation techniques and monitoring. All patients entering the hospital shall be screened for pain.

A detailed pain assessment is done when pain is the predominant (or one of the main) symptoms. The pain assessment shall include intensity of pain (can be done using a pain rating scale), pain character, frequency, location, duration and referral and/or radiation. It shall be done for all post-operative patients. The assessment should be done in an objective manner so that it facilitates regular reassessment. Based on the assessment of pain, and underlying conditions, pain alleviation methods or medication are initiated for the patient. Pain management includes medical, surgical and anaesthetic techniques. Subsequently the patient is monitored for response to pain alleviation methods. Based on the response, measures and medication are duly

titrated. In case the hospital does not have facilities for further pain management, it could refer such patients to centres specialising in pain management.

Excellence

b. Scope of rehabilitation services at a minimum is commensurate to the services provided by the organisation.*

Interpretation: Rehabilitation services include physiotherapy, occupational therapy, speech therapy, clinical psychology, etc. The organisation should ensure the availability of rehabilitation services (at least basic) commensurate with its scope of services. For example, an organisation providing neurological services should have a neuro-rehab service. In case the organisation does not have a facility for advanced rehabilitation, it could refer its patients to a centre with a relevant facility.

Care providers collaboratively plan rehabilitation services. Care providers include treating doctors, a rehabilitation therapist, and other professional experts.

CORE

c. Patients admitted to the organisation are screened for nutritional risk. *

Interpretation: Nutritional screening is done by the caregiver (doctor or nurse).

Excellence

d. Nutritional assessment shall be done by a dietician for all patients found at risk during nutritional screening.

Interpretation: The assessment shall include at a minimum, planning, preparation and distribution of diet.

The therapeutic diet is planned and provided collaboratively. The nutritional assessment should result in the formulation of a therapeutic diet. The dietician shall ensure that this is planned in consultation with the treating doctor and the patient/patient's relative after taking into regard the patient's food allergies, food habits (veg/non-veg) and likes and dislikes. The process ensures that the patient receives food as per the diet order.

The dietician/nurse shall ensure education to patient and family during diet planning and its implementation. When a family provides food, the dietitian shall monitor compliance with the prescribed diet.

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CHAPTER 3

Management of Medication (MOM)

Intent of the chapter

The organisation has a safe and organised medication process. The process includes policies and procedures that guide the availability, safe storage, prescription, dispensing and administration of medications.

The availability of emergency medication is stressed upon. The organisation should have a mechanism to ensure that the emergency medications are standardised throughout the organisation, readily available and replenished in a timely manner. There should be a monitoring mechanism to ensure that the required medications are always stocked and well within expiry dates.

The process also includes monitoring of patients after administration and procedures for reporting and analysing adverse drug events, which include errors and events.

Special emphasis is laid on use of radioactive drugs.

Medications also include blood, implants and devices.

SUMMARY OF STANDARDS

MOM. 1	**Pharmacy services and usage of medication is done safely.**
MOM. 2	**Medications are stored appropriately and are available where required.**
MOM. 3	**There is written guidance for safe and rational prescription of medications.**
MOM. 4	**There is written guidance for the safe dispensing of medications.**
MOM. 5	**Medications are administered safely.**
MOM. 6	**Narcotic drugs and psychotropic substances, chemotherapeutic agents and radioactive agents are used in safe manner.**
MOM. 7	**Implantable prosthesis and medical devises are used in accordance with laid down criteria.**

Standards and Objective Elements

Standard

MOM. 1 **Pharmacy services and usage of medication is done safely.**

Objective Elements

CORE **a. Pharmacy services and safe medication usage are implemented following written guidance.**

Interpretation: A written guidance is available for the formulation and implementation of pharmacy services and medication usage.

It is preferable that the organisation has a 24-hour pharmacy, otherwise there should be a process to procure the drugs when the pharmacy is closed.

CORE **b. The organisation shall review and update the hospital formulary as per scope of its clinical services.**

Interpretation: The formulary shall be reviewed and updated at least annually. The formulary must be available for the physicians to refer.

Standard

MOM. 2 **Medications are stored appropriately and are available where required.**

Objective Elements

Commitment **a. Medications are stored in a clean, safe and secure environment; and incorporating the manufacturer's recommendation(s).**

Interpretation: The medication storage space shall be clean, safe and secure. The organisation shall adhere to the storage requirements of the drug as specified by the manufacturer. In the absence of manufacturer's instructions, the organisation shall develop and implement storage requirements. Storage requirements shall apply to all areas where medications are stored, including wards.

Medications shall be protected from loss or theft. Some of the ways of ensuring this is to limit access to medication storage areas to authorised team members, locking medication carts and never leaving them unattended, or storing medications in an area

that is continuously staffed. It is preferable that the medication storage area is organised. Overall cleanliness of the storage area shall be maintained.

Where appropriate, temperature monitoring of the room, the cold storage area/refrigerator shall be done at least once a day. In case of areas which are not open all days, it shall be done on all working days.

To check for loss or theft, the organisation could conduct audits at regular intervals (as defined by the organisation) to verify the stock and detect instances of loss or theft.

CORE

b. Written guidance exists for storage of high risk medications including look alike and sound alike medications *

Interpretation: The organisation shall define and update its list of high risk medications periodically. High risk/high alert medications carry a heightened risk for adverse outcomes and catastrophic harm whenever there is an error. High-risk medications/high alert medications include low therapeutic window, controlled substances, psychotherapeutic medications, look-alike and sound-alike medications, and concentrated electrolytes. The list shall be available in the pharmacy and all clinical areas where high risk medications are stored.

Many drugs in ampoules, vials or tablets may look-alike or sound-alike. These are identified periodically, and the Look-alike Sound-alike medications (LASA) list shall be made available in all units where drugs are stored. Different concentrations of the same drug need to be identified. The list shall be developed from the hospital formulary. The list will have to be revised at regular intervals depending on the changes in the formulary and changes in the packaging (in case of look-alike).

High risk medications including look alike and sound alike medications are stored physically apart from each other.This is in addition to regular storage practices. In addition to the pharmacy, these storage practices should be followed in patient care areas.

CORE

c. Beyond expiry date medications are not stored/used.

Interpretation: Beyond expiry date drugs (before disposal), shall be stored separately and away from drugs which are intended for patient use.

CORE

d. List of emergency medicines is defined, stored, and available all the time.

Interpretation: The list of emergency medications shall be prepared in consonance with sound clinical practices and documented. The List of drugs could be modified according to the needs of the clinical department for example ICU, Physiotherapy, emergency, cath lab etc. A crash cart would help the organisation to store these medications in a standardised manner, i.e. the rows and drawers have defined medicines.

No other drug shall be kept stored with emergency medications.

Adequate quantity of emergency medicines should be stocked at all times. An inventory check shall be done at least daily to ensure this. In case the organisation follows a system of sealing the emergency cart, then the check shall be carried out after each use of the cart/once every month.

Standard

MOM. 3 **There is written guidance for safe and rational prescription of medications.**

Objective Elements

CORE

a. The organisation ensures that only authorized personnel can write prescription/ medication orders in a uniform manner as per good practices/guidelines which are legible, dated, timed and signed.

Interpretation: The medication shall be prescribed by only those authorised by law to do so. The medication shall be prescribed by Registered Medical Practitioners with minimum MBBS qualifications. In case there is any other category of staff authorised to write medication orders, the same shall be backed by a legislation or government order. This should address both out-patient and in-patient prescriptions. The medication order card in the IP shall have the orders written by a doctor, even if it is the case of transcribing orders of the treating consultant from an OP record or an admission note. In facilities which use Electronic Medical Record (EMR), the doctor shall directly enter the prescription in the Hospital Information System (HIS) using his or her unique login. In case the HIS entry is made by an assistant, the same shall be verified and authorised by the doctor.

All the orders for medicines are recorded on a uniform location of the medical record. Only medications written in this location shall be administered to the patient. It is imperative that medication orders that are written in any other location of the medical record be transcribed to this location. Electronic orders, when typed, shall again follow the same principles. It is preferable that the prescription and the administration record is on the same sheet. This would help minimise medication errors. A drug 'Kardex' could be used for this purpose. The treatment orders are written daily or authorised daily in a 'Kardex' like format. Phrases like "CST"/"continue same treatment"/"repeat all"/"repeat 1,4,5,8" should not be accepted.

Whenever there is a modification in the medication order in the existing order for a particular drug, a fresh order will have to be written for that drug. e.g. Tab. Paracetamol 500 mg QID changed to Tab. Paracetamol 500 mg BD - this shall warrant the first order

to be discontinued and a fresh medication order to be written. A strike-through or over-writing the previous order is not acceptable.

CORE

b. The organisation adheres to the determined minimum requirements of a prescription.

Interpretation: Prescriptions generated within the organisation (IPD, OPD and emergency) shall adhere to national/international guidelines and regulatory bodies. At a minimum, the prescription shall have the name of the patient; unique hospital number; name of the drug (generic composition is mandatory except in the case of combinations of vitamins and/or minerals), strength, dosage instruction, duration and total quantity of the medicine; name, signature and registration number of the prescribing doctor. Error-prone abbreviations shall not be used. A good reference is the Institution for Safe Medication Practices guidelines. It is preferable to use digital prescription system to reduce error.

Prescription errors or illegible prescriptions will be initialled after single strikethrough and rewritten.

CORE

c. Drug allergies and previous adverse drug reactions are ascertained before prescribing.

Interpretation: The drug allergy and previous adverse drug reaction shall be ascertained during the initial consultation or at any point in time during care. It is a good practice to document drug allergies prominently in the medical record, both in OP and IP.

CORE

d. Medication orders are clear, legible, dated and signed and include name of medicine, strength along with the route and frequency/time of administration.

Interpretation: In case abbreviations are used, a list of approved standardised abbreviations for medication orders shall be used throughout the organisation.

The identity of the person who has written the medication order should be traceable. This could be done by either writing the name against every order or by having a 'master signature list' in the medical record which has the name of the person against the signature or by stating the employee code number against every medication order.

There should be a mechanism for taking action when medications orders are incomplete with respect to any of the above parameters.

The written guidance shall mention who can give verbal orders, when can it be given and how these orders will be authenticated. Verbal orders should be limited to urgent situations where immediate written or electronic communication is not practical. To the

extent possible, their usage should be limited. The organisation should have approved list of formulary drugs which can be ordered verbally. This list can be defined either by inclusion or exclusion.

It shall ensure that the procedure incorporates good practices like "repeat back/read back".

Verbal orders shall be counter-signed by the doctor who ordered it within 24 hours of ordering.

For the definition of 'verbal order', refer to the glossary.

Excellence **e. Reconciliation of medications occurs at transition points of patient care.**

Interpretation: The purpose of medication reconciliation is to ensure that the list of medication that a patient is to receive is complete and up-to-date with past clinical conditions and present care plan. The prescribed medications shall be checked for accuracy at the transition points, such as the time of admission, transfer of the patient from one ward setting/department to another, or at the time of discharge. It is preferable that medication reconciliation also occurs after cross-consultation. Medication reconciliation should be documented. There is a system for effective communication during handover regarding the reconciliation of medications.

Excellence **f. Audit of medication orders /prescription is carried out to check for safe and rational prescription of medication. Appropriate Corrective and /or preventive actions(s) is taken based on the audit.**

Interpretation: The scope of the audit shall include:

- Legibility, use of capitals in written orders;
- the appropriateness of the drug, dose, frequency, and route of administration;
- the presence of therapeutic duplication;
- the possibility of drug interaction and measures taken to avoid the same;
- the possibility of food-drug interaction and measures taken to avoid the same.
- This shall be done at least once a month using a representative sample size.

The records of the same have to be maintained. It is preferable that corrective and/or preventive action(s) is taken based on the root-cause analysis. The record of the same shall be maintained.

Standard

MOM. 4 **There is written guidance for the safe dispensing of medications.**

Objective Elements

CORE **a. The organisation defines a list of high-risk medication and process to prescribe them.**

Interpretation: High risk/high alert medications carry a heightened risk for adverse outcomes and catastrophic harm whenever there is an error. High-risk medications/high alert medications include low therapeutic window, controlled substances, psychotherapeutic medications, look-alike and sound-alike medications, and concentrated electrolytes. Legal requirements governing prescription of Narcotic Drugs and Psychotropic Substances shall be met.

High-risk medications shall be given only after written orders, and they should be verified by the staff before dispensing. This shall adhere to statutory requirements where applicable.

CORE **b. Dispensed medications are labelled*.**

Interpretation: At a minimum, the label must include the dosage instruction in a manner that the patient understands. Labelling is applicable only for out-patients. In instances when medicines are dispensed either as cut strips or from bulk containers, the label must include the drug name, strength, dosage instruction (in a manner that the patient understands) and expiry date. This shall be applicable for both in-patients and out-patients. Dispensing medications for outpatients are labelled in a manner that patient understands. It shall also be applicable where drugs are reconstituted, e.g. Chemotherapy.

Standard

MOM. 5 **Medications are administered safely.**

Objective Elements

CORE **a. Medications are administered by those who are permitted by law to do so.**

Interpretation: Only a registered nurse or doctor with a minimum of MBBS

qualification shall administer medication. In case there is any other category of staff authorised to administer medication, a legislation or government order shall back the same.

CORE **b. Prior to administration, medication orders including patient, dosage, route and timing are verified.**

Interpretation: At a minimum, two identifiers shall be used for patient identification with one of them being the unique identification number (e.g. hospital number/IP number, etc.) and name.

Staff administering medications should verify the medication order and ensure that medications are administered appropriately. It is required to check the general appearance of the medication (e.g. melting, clumping, etc.) and the expiry dates before administration. If any of the parameters concerning an order, namely name, strength, route or frequency/time are missing/incomplete, the medication administration shall be deferred pending early verification by the treating team. In case the confirmation is got verbally, it shall be considered a verbal order and the procedure for verbal orders shall be adhered.

In the case of high-risk medication(s), the verification shall be done by at least two staff (nurse-nurse or nurse-doctor) independently and documented.

The nurses are knowledgeable regarding high-risk medications and are empowered to highlight prescription errors noted while verifying the orders.

Before administration, the person administering the drug shall verify the strength from the medication order. In case of discrepancy, medication administration shall be deferred. Where applicable, the site of administration shall also be verified.

CORE **c. Prepared medication is labelled before preparation of a second drug.**

Interpretation: Labelling is required when more than one drug is prepared and loaded. Examples of these are anaesthetic drug preparation in OTs, chemotherapy drugs.

Excellence **d. Measures to avoid catheter and tubing mis-connections during medication administration are implemented*.**

Interpretation: The organisation ensures that inadvertent administration of a drug through a wrong route is avoided. This could be done by using design features that prevent misconnections and prompt the user to take the correct action. Intravenous (IV) extension tubes should not be used for epidurals, irrigation, drains, and central lines or to extend enteric feeding tubes. Care shall be taken to position functionally dissimilar tubes used in patient care away from one another. Staff administering

medications could trace all lines from their origin to the connection port to verify attachments before making any connections or reconnections, or administering medications, solutions, or other products.

CORE **e. Medication administration is documented.**

Interpretation: The organisation shall ensure that documentation of medication administration is done in a uniform location. It shall include the name of the medication, strength, route of administration, timing and the name/employee ID number and signature of the person who has administered the medication. Medicines administered are documented each time for each dose of the same medication separately. In the case of infusions, it shall capture the start time, the rate of infusion and end time. The records shall reflect the actual administration. For example, if brand Y was given in place of brand X (same generically), the documentation shall be of brand Y. Similarly, if the order was for a tablet of 250 mg, but the administration was ½ a tablet of 500 mg, the latter shall be documented. In case a patient refuses to take a medication, the same shall be documented.

Commitment **f. Patients are monitored after medication administration. ***

Interpretation: Relevant monitoring is done collaboratively to verify that medicine is having its intended effect. It could also include monitoring the effects of medications through laboratory results (beneficial or adverse). Besides, this should help identify near misses, medication errors and adverse drug reactions.

The organisation defines those situations where more frequent monitoring is required. For example, administration of high-risk medicines. The effect of medication in high risk patients like those on dialysis, in the ICU and elderly group shall be monitored on a regular basis.

CORE **g. Near miss, medication errors and adverse drug events are defined, documented, reported and analysed within a specified time frame.**

Interpretation: The organisation shall define the timeframe for reporting once any of this has occurred and adhere to the same. Details of the near miss, medication errors and adverse drug reaction incidents are collected and analysed. The analysis shall be completed in a defined time frame. It is preferable that a clinical pharmacologist/ clinical pharmacist is a part of this exercise.

Where appropriate, corrective and/or preventive action are taken. The records of the same have to be maintained. It is preferable that corrective and/or preventive action(s) is taken based on the root-cause analysis.

Standard

MOM. 6 **Narcotic drugs and psychotropic substances, chemotherapeutic agents and radio-pharmaceuticals are used in safe manner.**

Objective Elements

CORE

a. Narcotic drugs and psychotropic substances, chemotherapeutic agents and radioactive agents are used safely. *

Interpretation: Written guidance developed in consonance with local and national regulations/guidelines are implemented. The written guidance could address all the objective elements of this standard. Examples of regulations/guidelines are Narcotic Drugs and Psychotropic Substances Act and AERB guidelines.

Chemotherapy is prescribed by those who have the knowledge to monitor and treat the adverse effect of chemotherapy. This is preferably a medical oncologist or a doctor who has been trained and has achieved competency in the same.

Radiopharmaceuticals are only prescribed the caregiver authorised by the statutory body.

CORE

b. Narcotic drugs and psychotropic substances, chemotherapeutic agents and radio-pharmaceuticals drugs are stored safely.

Interpretation: Narcotic drugs shall be stored safely in consonance with statutory requirements. The security measures should ensure that these medications are not diverted and abused.

Chemotherapeutic agents shall be accessible only to authorised personnel.

Radio-pharmaceuticals shall be stored as per AERB guidelines.

It is preferable that these medications are stored separately from other medications.

CORE

c. Chemotherapy and radio-pharmaceuticals are prepared properly and safely and administered by qualified personnel.

Interpretation: It is required that qualified personnel has received special training in the preparation and administration of chemotherapeutic drugs. Staff are also trained.

A bio-safety cabinet of class II (preferably IIA) with appropriate personal protective equipment shall be used for preparing/mixing chemotherapeutic drugs.

Radio-pharmaceuticals shall be prepared and administered by the caregiver authorised by the statutory body.

CORE **d. A proper record shall be kept of the usage, administration and disposal of narcotic drugs and psychotropic substances, chemotherapeutic agents and radio-pharmaceuticals .**

Interpretation: A strict inventory control shall be kept for narcotic drugs and psychotropic substances, chemotherapeutic agents and radio-pharmaceuticals . Record of usage, administration, wastage and disposal of narcotic drugs shall be kept following statutory requirements. These shall be disposed of according to existing statutory requirements (including Narcotic Drugs and Psychotropic Substances Act, AERB rules and Biomedical waste management rules) and the manufacturer's recommendation (where applicable).

Standard

MOM. 7 **Implantable prosthesis and medical Devices are used in accordance with laid down criteria.**

Objective Elements

CORE **a. Written guidance address procurement and usage of implantable prostheses**

Interpretation: The organisation shall ensure that relevant and sufficient scientific data are available before selection. It shall also look for international (e.g.US-FDA) or national notification (Drugs and Cosmetics Act notification October 2005) for approval of the particular product.

The organisation has written guidance to direct procurement, storage/stocking, issuance and usage of the implantable prosthesis and medical devices. Infection prevention and control requirement related to use of prosthesis and medical devices is implemented. This should address statutory regulations/guidelines and manufacturer's recommendation(s).

Commitment **b. Patient and his/her family are counselled for the usage of the implantable prosthesis and medical devises including precautions if any.**

Interpretation: Precautions could include non-usage of specific drugs and reporting to the hospital if a particular symptom occurs. The organisation shall document the details of counselling provided to the patient /his or her family in informed consent.

Commitment **c. The batch and the serial number of the implantable prosthesis and medical devices are recorded in the patients' medical records, the master logbook and the discharge summary.**

Interpretation: In case where implantable prosthesis do not have pre-labelled stickers, the organisation shall have suitable mechanisms in place for identifying the implant (manufacturer, type, size, batch number, serial number) and any other important detail.

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CHAPTER 4

Patient Rights and Education (PRE)

Intent of the chapter

The HCO defines the patient and family rights and responsibilities. The staff is aware of these and is trained to protect patient rights. Patients are informed of their rights and educated about their responsibilities at the time of admission. The costs are explained in a clear manner to patient and/or family. The patients are educated about the mechanisms available for addressing grievances.

A documented process for obtaining patient and/or families consent exists for informed decision making about their care.

Patient and families have a right to information and education about their healthcare needs in a language and manner that is understood by them.

SUMMARY OF STANDARDS

PRE. 1	**Patient rights are documented displayed and support individual beliefs and values.**
PRE. 2	**The patient and/or family are educated to make informed decisions and are involved in the care planning and delivery process.**

Standards and Objective Elements

Standard

PRE. 1 **Patient rights are documented displayed and support individual beliefs and values.**

Objective Elements

CORE **a. Patient and family rights and responsibilities are displayed and they are made aware of the same.**

Interpretation: Organisation should document the patient's rights and inform them of their responsibilities. These shall be documented in consonance with Charter of Patients' Rights laid down by the statutory body. The rights and responsibilities of the patients should be displayed in the hospital where it is prominently visible to patients, families and visitors. Information, education and communication material should at least be bilingual.

CORE **b. Patients and family rights include respecting beliefs and values.**

Interpretation: This could include how they wish to be addressed, dietary preferences and worship requirements. This may also include any specific requirement following death.

CORE **c. Patient and family rights include respect for personal dignity and privacy during examination, procedures and treatment.**

Interpretation: During all stages of patient care, be it in the examination or carrying out a procedure, hospital staff shall ensure that the patient's privacy and dignity are maintained. The organisation shall develop the necessary guidelines for the same. During procedures, the organisation shall ensure that the patient is exposed just before the actual procedure. With regards to photographs/recording procedures, the organisation shall ensure that explicit informed consent is taken and that the patient's identity is not revealed.

CORE **d. Patients and family rights include protection from neglect or abuse.**

Interpretation: Examples of this include falling from the bed/trolley due to negligence, assault, repeated internal examinations (unwarranted), manhandling, etc. Special precautions shall be taken, especially concerning vulnerable patients, e.g. elderly, neonates, physically and mentally challenged patients, comatose patients, patients under anaesthesia etc.

CORE

e. Patients and family rights include treating patient information as confidential.

Interpretation: The organisation and the treating team shall take effective measures to maintain the confidentiality of all patient-related information. Staff shall avoid having patient-related discussions in public places. Statutory requirements regarding privileged communication shall be followed at all times (refer the glossary for a definition of privileged communication). Confidential information, including HIV status, shall not be revealed without the patient's permission. It shall not be explicitly written/pasted on the cover of the medical record, nor shall it be displayed in a manner that is easily understandable by the public at large.

The organisation needs to evolve a mechanism to provide sensitive and/or confidential information to the patient and the next of kin if desired by the patient. In the case of minors, it will be provided to at least one of the parents/ guardian.

CORE

f. Patient and family rights include the refusal of treatment and right to seek additional opinion regarding clinical care.

Interpretation: The treating doctor shall discuss all the available options and allow the patient to make an informed choice. In case of refusal, the treating doctor shall explain the consequences of the refusal of treatment and document the same. After explanation of consequences, if the patient still refuses treatment, the same must be respected.

There is a mechanism for patient and family to seek a second opinion if they wish, from within or outside the organisation. The organisation shall respect the decision of the patient and family and facilitate access to all relevant information or clinical evaluation. Request for additional information on a particular physician in terms of qualifications and experience may be provided.

CORE

g. Patient and family rights include informed consent before the transfusion of blood and blood components, anesthesia, surgery, initiation of any research protocol and any other invasive/high-risk procedures/treatment.

Interpretation: Informed consent shall be obtained by the treating doctor or a doctor member of the treating team. During the consenting process, patient and/or family are screened (informally) for their understanding abilities and language requirements. The consent shall be taken in the language which patient understands. In case the patient is unable to read the consent, the consent shall be taken in the language in which the patient has been explained during the consenting process. In latter cases, the signature of a witness and his/her details must be affixed on the consent form.

CORE

h. Patient and family right include a right to complain and information on how to voice a complaint.

Interpretation: The displayed patient rights should include the right to make a

complaint and also mention the methodology to voice the same. The complaint mechanism must be accessible, and redressal of complaint must be fair and transparent.

CORE

i. Patient and family right include information on the expected cost of the treatment.

Interpretation: Patients and families are explained about the expected costs of treatment in a transparent manner. This includes consultations, procedures and investigations. It may involve giving written estimates or making the concerned tariff available.

The patient and/or family members are made aware of the pricing policy in different settings (out-patient, emergency, ICU and in-patient). The key components of pricing, namely consultation charges, bed charges, nursing charges, security deposit, are displayed near registration and/or admission desk.

The organisation shall ensure that there is an updated tariff list and that the relevant tariff is available for review to patients when required. The organisation shall charge as per the tariff list. The tariff rates should be uniform (in a given setting) and transparent.

CORE

j. Patient and family rights include access to their clinical records.

Interpretation: The organisation shall ensure that every patient has access to his/her record. This shall be in consonance with the Code of Medical Ethics laid down by the National Medical Council and statutory requirements.

Excellence

k. Patient and family right include information on the name of the treating doctor, care plan, progress and information on their health care needs.

Interpretation: Information on the name of the treating doctor, care plan, the progress of the patient and the healthcare needs are discussed with patient and family. The proposed care, including referral to internal and/or external services, is discussed by the attending doctor with the patient and/or family members. This should be done in a language the patient/attendant can understand. The above information could be documented and signed by the doctor concerned. The patients and/or family members are explained in detail by the treating physician or his/her team about the expected outcomes of such treatment at periodic intervals. Possible complications of the treatment, if any, are clearly communicated to the patient and/or family members. During the preparation of the care plan, the patient and/or family members are explained about the various treatment options, risks and benefits. The care plan, where possible, incorporates patient and/or family concerns and requests. The religious, cultural and spiritual views of the patient and/or family shall be considered during the process of care delivery. Incorporating patient and/or family requests shall be limited by the statutory requirements.

Standard

PRE. 2 **The patient and/or family are educated to make informed decisions and are involved in the care planning and delivery process.**

Objective Elements

CORE **a. The patient and/or family members are explained about the proposed care, including the risks, alternatives and benefits.**

Interpretation: The proposed care, including referral to internal and/or external services, is discussed by the attending doctor with the patient and/or family members. This should be done in a language the patient/attendant can understand. The above information could be documented and signed by the doctor concerned.

CORE **b. The organisation obtains informed consent from the patient and or family for the situations where informed consent is required.**

Interpretation: A list of procedures should be made for which informed consent is required. This shall be prepared to keep in mind the requirements of this standard and statutory requirement. For example, some statutory requirements are MTP Act, PC-PNDT Act and The Transplantation of Human Organs Act. The policy for HIV testing should follow HIV and AIDS (Prevention and Control) act 2017 and the national policy on HIV testing laid down by National AIDS Control Organisation (NACO). The organisation shall have written guidance explaining the various steps involved in the informed consent process and the person responsible. The staff are aware of the same.

CORE **c. Informed consent process adheres to statutory norms.**

Interpretation: This includes (but is not limited to):

1. Taking consent before the procedure;
2. At least one witness signing the consent form.

The witness shall be a person who was present for the entire duration of the communication between the doctor and the patient.

In case the patient has to undergo a procedure repeatedly for a long time (e.g. dialysis), informed consent is taken at the first instance. Such consent shall have a defined validity period but not more than six months. The patient endorses the consent at each repeat treatment. However, if there is a change in the treatment modality or an addition of another modality, then fresh consent shall be obtained.

The consent form shall at a minimum be bilingual. When consent is taken in a language other than what the patient understands, there should be clear documentation detailing the language in which the patient has been counselled and if any interpreter has been used.

The consent shall have the name of the doctor performing the procedure. In case a procedure requires more than one doctor from different specialities, then the same will have to be explained to the patient and consent shall include the name of the principal surgeon from each speciality who is performing the procedure. Each doctor will have to explain his role and address all aspects required for informed consent, e.g. if the surgery involves the requirement of a neurosurgeon, ENT surgeon and an Ophthalmologist, the consent should reflect the same. It should have the names of the principal surgeons of the three specialities. It is the responsibility of each of the surgeons/team to explain their role and the benefits/risks and alternatives of the procedures they are performing on the patient.

Informed consent is taken by the person performing the procedure. A doctor member of the team can take consent on behalf of the person performing the procedure. Also, refer to COP 3.d. (procedure), COP 4.d.(blood transfusion), COP.8.b. (procedural sedation), COP 9.d. (anaesthesia) and COP 10b (surgery).

If it is a "doctor under training" the same shall be specified. However, the name of the qualified doctor supervising the procedure shall also be mentioned.

The person performing shall be responsible for the entire consent process, including providing explanation and taking the signature. For example, it is not acceptable if the person performing the procedure only explains, and the written consent is taken by the nurse.

It is preferable to have the risks, benefits and alternatives of the procedure as a part of the documentation. The focus is on informed consent as a process of effective communication between a doctor and patient and not a signature on a form.

Commitment

d. Patients and families are educated on plan of care, preventive aspects, possible complications, medications, and the expected results.

Interpretation: The patients and/or family members are explained in detail by the treating physician or his/her team about the expected outcomes of such treatment at periodic intervals.

Possible complications of the treatment, if any, are clearly communicated to the patient and/or family members.

The results of all diagnostic tests are explained at least in broad terms to patient and family members and their implication on progress and treatment.

The patient and/or family members are explained about any change in the patient's condition in a timely manner. The counselling includes improvement, deterioration or

occurrence of complications. Withholding of resuscitation requests from relatives and family could be discussed within ethical and legal parameters.

Excellence **e. Communication with patients and or family is done effectively.***

Interpretation: Communication is considered to be effective if it serves the purpose. The principles of effective communication are complied. For example, the seven C's namely clear, correct, complete, concrete, concise, considerate and courteous.

The organisation has plans to identify and overcome potential communication barriers. For example, the language barrier could be overcome by having interpreters.

The organisation could adopt any model of effective communication.

CORE **f. The organisation has a mechanism to capture patient`s feedback and to redress complaints.***

Interpretation: The feedback could be captured either physically or electronically. It is preferable that separate data is obtained from out-patients and in-patients.

The written guidance shall incorporate the mechanism for lodging complaints (including verbal or telephonic complaints), method of compiling them, analysing complaints including the time frame, the person(s) responsible and documenting the action taken. It is for the organisation to decide if it wants to give credence to anonymous complaints.

Patient complaints include those against healthcare workers.

Patient and or family are made aware of the procedure for giving feedback and/pr lodging complaints. The awareness shall be either by display or providing written information. The organisation must create an environment of trust wherein the patients would be comfortable to air their views.

Feedback and complaints are reviewed and/or analysed within a defined time frame. The entire process shall be documented. Where appropriate, the patient and/or family could be involved in the discussions and also informed regarding the outcome.

Corrective and/or preventive action (s) are taken based on the analysis where appropriate. The analysis identifies opportunities for improvement and the same are carried out.

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CHAPTER 5

Infection Prevention and Control (IPC)

Intent of the chapter

The standards guide the provision of an effective infection prevention and control programme in the organisation. The programme is documented and aims at reducing/eliminating infection risks to patients, visitors and providers of care.

The organisation proactively monitors adherence to infection control practices such as standard precautions, cleaning disinfection and sterilization. Adequate facilities for the protection of staff are available. Antimicrobial use is rational. Biomedical Waste is managed as per policies and procedures.

SUMMARY OF STANDARDS

IPC. 1	**The hospital has an established infection prevention and control programme with adequate resources.**
IPC. 2	**The organization implements the infection prevention and control programme in support services.**

Standards and Objective Elements

Standard

IPC. 1 — **The hospital has an established infection prevention and control programme with adequate resources.**

Objective Elements

CORE

a. The Infection prevention and control programme is documented and is periodically updated.

Interpretation: The written guidance shall be directed at prevention and control of infection in all areas of the hospital and include its monitoring.

The organisation shall have Infection prevention and control manual (IPC manual) that shall incorporate the structure of the programme, overall aims and objectives, all processes, activities and surveillance procedures related to the programme.

The manual shall be reviewed and updated at least once a year. This shall be based on organisational priorities, current scientific knowledge, guidelines from national/international professional bodies and statutory requirements where applicable.

The responsibilities could include surveillance of healthcare associated infections and healthcare associated organisms, compliance monitoring (hand hygiene, transmission-based precautions, isolation, infection specific prevention bundles, disinfection and sterilisation procedures, and prevention checklists), education, working on outbreaks and documentation.

The organization has a multidisciplinary committee/team which co-ordinates all infection prevention and control activities.

The infection control committee/team shall lay down the written guidance for implementation. The composition, frequency of meetings, the minimum quorum required and the minutes of the meeting shall be documented.

CORE

b. The organisation adheres to hand hygiene, standard precautions and transmission-based precautions at all times.

Interpretation: The organisation provides at least one easily accessible washbasin with running water in every patient care area. Where such handwash basin is not feasible, hand rubs are available at all times. The instrument washing areas and hand washing areas should not be same. The organisation shall adhere to international/national guidelines on hand hygiene. The organisation could display the necessary instructions near every hand-washing area.

Adherence to standard precautions is one of the fundamental tenets of infection prevention and control. In every area of the organisation, standard precautions shall be adhered. Refer to the glossary for "standard precautions". The organisation provides adequate resources to its staff for infection prevention and control. The organisation ensures that health care providers use appropriate personnel protective equipment and adheres to standard precautions to prevent blood and body fluid exposures.

Transmission based precautions shall cover airborne, droplet and contact modes of transmission.

CORE **c. The organisation adheres to safe injection and infusion practices*.**

Interpretation: This shall include "One needle, One syringe, Only one time" as recommended by CDC.

Commitment **d. The organisation establishes and implements the antimicrobial usage policy.**

Interpretation: The organisation shall identify clinical conditions in which antimicrobial agents (antimicrobials, anti-fungal agents, anti-viral agents and anti-parasite agents) shall be used. A good reference guide to develop antimicrobials policy is 'Step-by-step approach for development and implementation of hospital antimicrobials and standard treatment guidelines' by WHO-2011. The antimicrobial usage policy must aim to guide efforts to improve appropriate and necessary antimicrobials use. The policy should identify a list of restricted antimicrobial agents if any and ensure adherence to the same.

The hospital antimicrobials policy should include pre surgical prophylaxis and post-surgical antimicrobials guidelines. The implementation of the same should be monitored on regular basis.

CORE **e. Appropriate pre and post exposure prophylaxis is provided to all concerned staff members.**

Interpretation: The organisation shall have a pre-employment health screening programme to capture immunisation status and exposures to various pathogens. The relevant vaccination is provided as per the risk from time to time and in accordance with applicable statutory requirements.

The organisation provides post-exposure prophylaxis for hepatitis B and HIV exposure. This shall align with NACO guidelines. The organisation maintains documentation of pre-exposure screening and post-exposure prophylaxis record (for example, PEP for needle stick injury).

Excellence

f. **The organisation performs surveillance to capture and monitor infection prevention and control data.**

Interpretation: The scope of surveillance incorporates tracking and analysing of infection risks, rates, trends and high-risk activities. The organisation could lay down the data that needs to be captured, periodicity of carrying out the surveillance and the process for reporting. Verification of data shall be done by the infection control team.

The organisation must be able to provide evidence of conducting periodic surveillance directed towards its identified high-risk activities and indwelling devices as per standard definitions.

Surveillance includes monitoring compliance with hand -hygiene guidelines.

The monitoring shall be done at a minimum once every month.

Monitoring of the effectiveness of housekeeping services shall be done regularly at a defined periodicity. The routine use of microbiological cultures and swab tests are not recommended

Standard

IPC. 2 — **The organization implements the infection prevention and control programme in support services.**

Objective Elements

CORE

a. **Biomedical waste (BMW) is handled appropriately and safely.**

Interpretation: Proper segregation and collection of biomedical waste from patient-care areas of the hospital are implemented. Waste is segregated and collected in different colour-coded bags and containers as per statutory provisions. Monitoring shall be done by members of the infection control committee/team. Biomedical waste shall be handled in the proper manner using appropriate personal protective equipment.

The organisation ensures that biomedical waste is stored in accordance with statutory provisions. Biomedical waste is handed over to the authorised vendor for transport to the site of treatment and disposal. Monitoring of biomedical waste management program shall be done as per statutory requirements.

Commitment

b. **The organisation has appropriate engineering controls to prevent infections as per written guidance.**

Interpretation: This shall include the design of patient care areas (optimum spacing between beds is one-two metres), operating rooms, air quality and water supply.

Issues such as air-conditioning plant and equipment maintenance, cleaning of air-conditioning ducts/filters, air handling units, cleaning/replacement of filters, prevention of fungal colonisation should be included. Water-supply sources and system of supply, testing for water quality must be included.

Facility construction/renovation could ensure that when new facilities are built, infection prevention and control is considered from the design stage onwards. Any renovation work in the hospital should be planned with the infection control team concerning architectural segregation, traffic flow, use of materials, etc.

CORE

c. Cleaning and disinfection practices are defined and monitored as appropriate.

Interpretation: Written guidance is available for equipment cleaning /disinfection after use and surface cleaning.

Housekeeping shall be addressed at all levels of the organisation, e.g. ward, OT, public areas including toilets, corridors. Regular cleaning to remove visible dirt and dust is mandatory. This includes the furnishings, equipment, etc., as applicable.

The common disinfectants used are identified, dilution protocols are established, and its usage in the appropriate situation is complied with. It shall also include procedures for terminal cleaning, blood and body fluid cleanup and isolation rooms. Dry brooming in the clinical areas should be avoided.

CORE

d. Instruments/devices cleaning, disinfection and sterilization practices are implemented and monitored as per written guidance.

Interpretation: The organisation provides adequate space and appropriate zoning for sterilisation activities. Adequacy of space refers to the central sterile services department (CSSD/ Sterilization area), which should have a suitable location, proper layout (unidirectional flow, zoning) and separation of clean and dirty areas. Sufficient space shall be available to ensure that the activities can be performed properly. It is preferable to have separate areas for receiving, washing and disinfection, cleaning, packing, sterilisation, sterile storage and issue of supplies.

Cleaning, packing, disinfection and/or sterilisation, storing and the issue of items is done as per the written guidance.

The sterilised/disinfected instruments/devices shall be stored appropriately across the organisation and not just in CSSD/ sterilization area. The expiry date of sterilised instruments shall be guided by the packing material used and the mode of sterilisation.

Regular validation tests for sterilization are carried out and documented. This shall be done by accepted methods. Physical/chemical tests shall be done daily, and biological tests at least weekly. Engineering validations like Bowie-Dick tape test and leak rate test need to be carried out.

Each load should have a unique number and content description. Where applicable, temperature, pressure and time-record chart shall be maintained. The organisation could have a batch processing system with date and machine number for effective recall. The processes could be verified through a mock drill.

Commitment **e. The organisation adheres to laundry and linen management processes.**

Interpretation: The laundry can be in-house or outsourced. The organisation shall have written guidance for the change of linen. The organisation shall implement its defined process of handling linen in patient care units, during transport to and from the laundry (either in-house or outsourced) and inside the laundry. Process for storage and distribution of clean linen within the organisation should be complied. The separation of clean linen from dirty linen should be maintained at all times. If outsourced, the organisation shall ensure that it establishes adequate control measures for infection prevention and control.

Excellence **f. The organisation adheres to kitchen sanitation and food handling issues.**

Interpretation: This shall be applicable even if this activity is outsourced. The organisation shall adhere to all statutory requirements, including screening of kitchen workers and food handlers. It is preferable that they also adhere to national and international guidelines while addressing this issue. Kitchen sanitation measures are implemented to prevent the risk of cross-contamination.

Food is prepared, handled, stored and distributed safely. The dietary services shall be designed in a manner that there is no criss-cross of traffic. All the activities should fall in a sequence. The organisation shall ensure that hygienic conditions are followed throughout.

Other indicative points are:

- Dedicated food storage/refrigeration areas exist to ensure food preservation;
- Food storage areas/refrigerators are maintained appropriately;
- All food products are stored off the floor;
- Cleaning supplies stored in a separate location away from food;
- Separate dedicated food preparation areas exit;
- Measures are in place to ensure that flies and insects do not come in contact with prepared /stored food;
- Food distribution to patient occurs, where possible, in temperature appropriate food services trolleys (hot food kept hot and cold food kept cold).

All food samples must be stored at appropriate temperature and for appropriate time as per guidelines for their ready availability in case of suspected food poisoning outbreak.

All kitchen workers should be screened for food borne infections and are provided with appropriate immunizations as per guidelines.

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CHAPTER 6

Patient Safety and Quality Improvement (PSQ)

Intent of the chapter

The standards introduce the subject of continual quality improvement and patient safety. The quality and safety programme should be documented and involve all areas of the organisation and all staff members. The organisation should identify and collect data on structures, processes and outcomes, the collected data should be collated, analysed and used for further improvements.

SUMMARY OF STANDARDS

PSQ. 1	**The organization implements patient safety and quality improvement program.**
PSQ. 2	**The organization identifies key indicators to monitor the structures, processes and outcomes which are used as tools for continual improvement.**

Standards and Objective Elements

Standard

PSQ. 1 — **The organization implements patient safety and quality improvement program.**

Objective Elements

CORE **a. A comprehensive quality improvement and patient safety programme(s) is/are developed, implemented and maintained.**

Interpretation: The quality improvement and patient safety programme shall be developed, implemented and maintained in a structured manner.

It shall be integrated across the organisation and provide a framework for risk management, ongoing monitoring and performing improvements based on reviews.

A multi-disciplinary committee co-ordinates quality and patient safety issues.

The roles and responsibilities of the quality improvement and patient safety committee are defined, and it shall have representation from management, various clinical and support departments of the organisation. This committee shall receive inputs on significant deliberations from other committees in the organisation. The committee may be called as the core committee, Quality Improvement and Patient Safety Committee.

The organisation ensures that the quality improvement and patient safety committee meets every month to coordinate development, implementation and monitoring of the safety plans and policies to provide a safe and secure facility and environment. The committee shall ensure that patients are protected from harm either from the environment or from lack of appropriate care or lack of safety measures.

The quality improvement and patient-safety programme is documented as a manual. The manual shall incorporate all the requirements of this standard. This should be documented, keeping in mind the requirements of other objective elements in the standard.

The quality improvement and patient-safety programme identifies opportunities for improvement based on review of facility inspection rounds, patient safety incidents, internal audits, mock drills, and risk management analysis and key quality and safety indicators at pre - defined intervals.

The quality improvement and patient safety program covers incidents ranging from no harm to sentinel events. The organisation shall define and monitor Sentinel events, After due analysis, an incident could be termed as a near miss or adverse event or

sentinel event. Based on the nature of the near miss or adverse event or sentinel event. The sentinel events relating to system or process deficiencies that are relevant and important to the organisation must be clearly defined. The list of the identified and relevant sentinel events shall be documented.

Refer to glossary for definition of sentinel events.

Commitment **b. The organisations adapts and implements Patient Safety Goals.**

Interpretation: At a minimum, the organisation shall adhere to the current National Patient-Safety Framework, NABH safety Goals or WHO patient-safety solutions and International Patient Safety Goals. NABH Patient safety goals are

1. Identify patients correctly
2. Improve effective communication
3. Improve the safety of high alert medications
4. Ensure safe surgery
5. Reduce the risk of healthcare associated infections
6. Reduce the risk of patient harm resulting from falls

Excellence **c. There is an established process in the organisation to monitor and improve quality of nursing care.**

Interpretation: Monitoring could be done through nursing audits. This could also be in the form of a competency evaluation by written questionnaire or witnessed demonstration for key nursing procedures such as medication administration, peripheral, intravenous cannula placement, tracheostomy care etc. The organisation could identify key performance indicators that reflect excellence in nursing care. This shall be integrated with quality improvement programme of the organisation.

CORE **d. The organisation has a designated individual(s) to oversee the hospital wide quality and patient safety programme.**

Interpretation: There is/are designated individual(s) for coordinating and implementing the quality improvement and patient safety programme(s).The designated individual should preferably be having a good knowledge of accreditation standards, statutory requirements, hospital quality improvement principles and evaluation methodologies, hospital functioning, patient safety and operations.

The designated individual shall report directly to the Top Management. The role and responsibilities of the designated individual shall be defined.

Standard

PSQ. 2 **The organization identifies key indicators to monitor the structures, processes and outcomes which are used as tools for continual improvement.**

Objective Elements

CORE **a. The organisation identifies and monitors the key indicators to oversee infection control activities**

Interpretation: The organisation shall identify and monitor appropriate key performance indicators suitable to it. Indicators mandated by the Government of India/State Government shall be monitored.

Some of the indicators that could be monitored include the rate of Catheter Associated Urinary Tract Infection (CAUTI), Central Line Associated Bloodstream Infection (CLABSI), Surgical Site Infection (SSI) and Ventilator Associated Pneumonia (VAP).

These indicators are based on available literature or created in accordance with good practice. Every indicator shall have a defined numerator, denominator and multiplier. Where appropriate, the definition of terms should be provided. In the case of healthcare associated infections, the current surveillance definitions provided by the CDC's National Healthcare Safety Network definitions shall be used.

CORE **b. The organisation identifies and monitors key indicators to oversee patient safety activities**

Interpretation: The organisation shall identify and monitor appropriate key performance indicators suitable to it. Indicators mandated by the Government of India /State Government and the National Accreditation Board for Hospitals and Healthcare Providers (NABH) shall be monitored.

Some of the indicators that could be monitored pertain to patient safety goals.

These indicators are based on available literature or created in accordance with good practice. Every indicator shall have a defined numerator, denominator and multiplier. Where appropriate, the definition of terms should be provided.

Commitment **c. The organisation identifies and monitors key indicators to oversee the clinical & managerial structures, processes and outcomes.**

Interpretation: The organisation identifies and monitors priority clinical and managerial activities in the organisation. Indicators mandated by the Government of India/State Government shall be monitored.

Some of the indicators that could be monitored pertain to medication procurement,

utilisation rates, patient and staff satisfaction, waiting time for consultation and diagnostics, and availability and content of medical records.

These indicators are based on available literature or created in accordance with good practice. Every indicator shall have a defined numerator, denominator and multiplier. Where appropriate, the definition of terms should be provided.

Excellence **d. Clinical audits are performed to improve the quality of patient care with the involvement of doctors and nursing staff.**

Interpretation: The organisation should use clinical audits as a quality improvement tool to improve the quality of patient care. The clinical audit could be retrospective/prospective in nature. The topic for audit could be disease-based, cost-based, community-based or based on morbidity (length of stay). The organisation needs to take care to differentiate clinical audit from research projects.

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CHAPTER 7

Responsibilities of Management (ROM)

Intent of the chapter

The standards encourage the governance of the organisation in a professional and ethical manner. The responsibilities of the management are defined. The services provided by each department are documented.

Leaders ensure that patient-safety and risk-management issues are an integral part of patient care and hospital management.

SUMMARY OF STANDARDS

ROM. 1	**The responsibilities of the governance are defined.**
ROM. 2	**The organization is managed by the leaders in an ethical manner.**
ROM. 3	**Patient safety, Quality management are an integral part of patient care.**
ROM. 4	**Those responsible for governance ensure sustainability in hospitals by addressing environmental, social and economic factors from long term well-being of healthcare system and community**

Standards and Objective Elements

Standard

ROM. 1 The responsibilities of the governance are defined.

Objective Elements

Commitment

a. Those responsible for governance are identified and their roles and responsibilities are defined and documented.

Interpretation: Those responsible for management are accountable for the quality of care and help the healthcare organisation achieve its goals. The terms of reference, by-laws and membership of those responsible for management is documented. Those responsible for management meet at regular intervals and minutes of the meeting are maintained.

The organisation shall have a well-defined organisation structure/chart and this shall clearly document the hierarchy, line of control, along with the functions at various levels. Organogram is transparent and is disseminated to all stakeholders.

The organogram shall also incorporate various committees

The management allocates adequate budget for Infection prevention and Control , Quality improvement and Patient Safety activities.

CORE

b. The organisation is registered with appropriate authorities and complies with the applicable statutory requirements.

Interpretation: The leader is conversant with the different statutory requirements as per the scope of services and takes measures to adhere to the same. The organisation conducts its functioning as a duly permitted legal entity under the relevant registering authority(s). The leader could develop a mechanism which ensures implementation of various requirements stated in the laws and regulations. There should be a mechanism to regularly update any amendments in the prevailing laws of the land. A tracker sheet could be developed for this purpose.

Applications to update statutory documents must be made in accordance with the timelines set out in the relevant laws/registration authority requirements to ensure continuity of statutory compliances.

Research, including clinical trials, shall be conducted in accordance with statutory norms.

Standard

ROM. 2 The organization is managed by the leaders in an ethical manner.

Objective Elements

CORE **a. The management makes public the mission statement of the organisation.**

Interpretation: The organisation shall enunciate its vision, mission and values through an authorised document. These shall be developed and reviewed by those responsible for governance in consultation with the organisation's leaders. Further, inputs could be from external stakeholders, including patients and families. The vision, mission and values of the organisation should be displayed prominently. Only a display on its website would not be appropriate. The same could be translated and displayed in the local language also.

For the definition of "mission", "vision" and "values" refer to the glossary.

CORE **b. The leaders/management guide the organisation to function in an ethical manner.**

Interpretation: This includes the ethical management framework, resolving ethical issues and addressing conflicts of interest. It also includes support for the ethical conduct of research.

The organisation honestly portrays its affiliations and accreditations. It implies that the organisation convey is affiliations, accreditations for specific departments or whole hospital in an honest manner, wherever such exist.

It also discloses its ownership. The ownership of the hospital, e.g. trust, private, public with the name of the ownership has to be disclosed. The disclosure could be in the registration certificate.

Commitment **c. The organisation's billing process is accurate and ethical.**

Interpretation: The patient and/or family members are made aware of the pricing policy in different settings (outpatient, emergency, ICU and in- patient). The patient and/or family members are explained about the expected costs and are informed about the financial implications when there is a change in the patient condition or treatment setting.

Standard

ROM. 3 — **Patient safety, Quality management are an integral part of patient care.**

Objective Elements

CORE

a. Designated committees oversee Infection prevention and control, Quality improvement and Patient Safety .

Interpretation: The organization establishes multi-disciplinary committees to oversee specific areas of Infection prevention and Control , Quality improvement and Patient Safety. This committees have representation from management, various clinical and support departments (administrators, engineers, doctors, nurses, housekeeping staff and maintenance staff)

Committees include Quality improvement and Patient Safety committee, Infection Control committee, Pharmacy and Therapeutics committee, Blood Transfusion committee, Medical Records committee, Internal complaints committee, Grievance redressal committee, Cardio Pulmonary Resuscitation committee etc.

There shall be defined committee members with identified terms of reference. The frequency and minimum quorum of the committees should be defined and meetings are held accordingly. The agenda of the meetings along with minutes of meeting are documented. Follow up meetings shall include level of implementation decided by the committee during the previous meeting. The plans decided during the meeting are implemented and reviewed by the committee.

The functioning of the committees is reviewed for their effectiveness by the management.

Commitment

b. Management ensures that it has a documented agreement for all outsourced services & monitors the quality of outsourced services.

Interpretation: The agreement shall specify the service parameters and validity period. Examples of service parameters include quality, numbers, reports and timelines. The agreement should include agreed dispute resolution mechanisms. Even if a group/affiliate concern is providing services, there shall be an agreement with that unit.

The frequency of monitoring shall be determined by the organisation but shall not be less than once a year. This shall be done keeping in mind the criticality of that service towards providing patient care. It is preferable that the monitoring is done as per the service standards laid down by the organisation. Based on the results of the monitoring, the organisation should work with the vendor to try and ensure that the agreed service parameters are met.

In instances where the outsourcing has been done based on prescribed statutory norms/regulations, it is not mandatory to monitor the quality of the outsourced services.

Commitment **c. The organisation has a mechanism to report a violation of patient and family rights and such violations are monitored, analysed and corrective/preventive action taken within defined time frame.**

Interpretation: The organisation may develop a list of such instances which could be considered as infringements of the patients and families' rights and trained the staff accordingly. For Example, compromising the privacy breaching confidentiality, disrespect to the religious and cultural needs, not providing the medical records within the stipulated time etc. Violation of patients and family rights is reported to top management. The report should provide the details of how the right was violated and where applicable, by whom. Also, there should be a mechanism for the patient and/or family to report the violation of their rights. The patient feedback form (by incorporating patient rights worded appropriately) could be used as a tool to capture violation of patient right.

Standard

ROM. 4 **Those responsible for governance ensure sustainability in hospitals by addressing environmental, social and economic factors from long term well-being of healthcare system and community**

Objective Elements

Excellence **a. Those responsible for governance address the organisation's sustainability programme in terms of environment social and governance (ESG) responsibility.**

Interpretation: Environmental sustainability includes energy usage and efficiency, climate change strategy, waste reduction, biodiversity loss, greenhouse gas emissions and carbon footprint reduction.

Social Sustainability includes fair pay and living wages, equal employment opportunity. Employee benefits, workplace health and safety, community engagement, responsible supply chain partnerships. Adhering to labour laws.

Governance Sustainability includes corporate governance, risk management compliance, ethical business practices, avoiding conflicts of interest, accounting integrity and transparency.

Excellence **b. The organisation takes initiatives towards an energy efficient and environmentally friendly hospital*.**

Interpretation: This includes using the concepts of reduce, recycle and reuse in promoting the basic concepts of the green hospital. Energy-efficient lighting, rainwater harvesting, increase usage of solar power, wind energy, use of battery operated vehicles, recycling of STP /ETP water for gardening and flush water, reduction of plastic usage where possible, use of green materials in construction, use of volatile organic compounds free paints are some of the examples. The organisation shall take measures to create awareness among staff and patients regarding saving electricity and water.

Excellence **c. Those responsible for governance address the organisations social responsibility.**

Interpretation: The board of governance and leaders shall develop social responsibility policy and implement it. Free camps, outreach programs for below poverty line population are some of the examples. At a minimum all regulatory requirement like corporate social responsibility shall be met.

Excellence **d. Staff well-being is promoted.**

Interpretation: Organisation takes proactive steps to ensure staff well-being.

Examples of these include promoting healthy lifestyle programmes, having defined work hours and workload monitoring, providing scheduled breaks, stress management, access to dining facilities, rewards and recognition, staff engagement activities.

Tracking absenteeism or over-time could help organisations to monitor stress and fatigue indirectly. The staff satisfaction survey is another tool to capture this data.

The organisation shall have facilities for staff to seek support and advice when necessary.

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CHAPTER 8

Facility Management and Safety (FMS)

Intent of the chapter

The standards guide the provision of a safe and secure environment for patients, their families, staff and visitors. To ensure this, the organisation conducts regular facility inspection rounds and takes the appropriate action to ensure safety.

The organisation provides for equipment management, safe water, electricity, medical gases and vacuum systems.

The organisation manages its hazardous materials safely.

The organisation plans for fire and non fire emergencies within the facility.

SUMMARY OF STANDARDS

FMS. 1	**The organization's environment and facilities operate in a manner to ensure safety of patients, their families, staff and visitors.**
FMS. 2	**The organization has a program for facility, engineering ,support services and Medical equipment management.**
FMS. 3	**The organization has provisions for safe water, electricity, medical gas and vacuum systems.**
FMS. 4	**The organization has plans for fire and non-fire emergencies within the facilities.**

Standards and Objective Elements

Standard

FMS. 1

The organization's environment and facilities operate in a manner to ensure safety of patients, their families, staff and visitors.

Objective Elements

CORE

a. The organisation has appropriate infrastructure for patient safety and is inspected periodically.

Interpretation: Patient safety devices are installed across the organisation and inspected periodically.

Patient safety devices and infrastructure are installed across the organisation. For example, grab bars, bed rails, signposting, safety belts on stretchers and wheelchairs, alarms both visual and auditory where applicable, warning signs like radiation or biohazard, call bells, fire-safety devices, etc. Provisions are made for differently-abled persons like the physically challenged, the visually impaired and mentally impaired person. At a minimum, this shall be as per regulatory requirement. For example, wheelchair accessible entrance. They are maintained and inspected periodically.

Patient safety aspects in terms of structural safety of hospitals, especially of critical areas, are considered. Vertical transportation in terms of lifts/ramp for patients is available. In the absence of lifts/ramps the organisation shall demonstrate safe transport of critical patients.

CORE

b. Facility inspection rounds to ensure safety are conducted at least once a month.

Interpretation: Potential safety risks are identified during the rounds using a checklist. The potential security risk areas and restricted areas are identified and are monitored.

Inspection reports of facility rounds are documented, and corrective and preventive measures are undertaken.

Maintenance staff is contactable round the clock for emergency repairs..

Commitment

c. Organisation identifies areas which need additional security and access control to staff, Visitors and patients.

Interpretation: The planning process shall begin by identifying various categories of people in a hospital. At a minimum, this shall include staff, patients and visitors, in the hospital. The hospital shall define access to different areas in the hospital for the

defined categories as per the operational security plan. The process should give details of access to OT, ICU(s) including NICU, labour room, and emergency room. Vulnerable areas like dark areas, long corridors, entrances to critical areas need to be identified,and appropriate security is in place such as CCTV coverage.

CORE

d. Internal and External Signage shall be displayed in a language understood by the patients, families and community.

Interpretation: The signages should be in a language that patient, families and community understand. They can be pictorial where appropriate. The signages should be bilingual and should comply with statutory norms.

CORE

e. Hazardous materials are identified and used safely within the organisation.

Interpretation: The organisation shall identify and document the hazardous materials and has a documented procedure for their sorting, storage, handling, transportation and disposal. In addition to chemicals, biological materials like blood, body fluids and microbiological cultures, mercury, nuclear isotopes, medical gases, LPG gas, steam, ETO, etc. are some of the other common hazardous materials.

The organisation could develop its procedures based on Material Safety Data Sheets (MSDS). Applicable statutory requirements shall be complied.

The plan for managing spills of hazardous materials is implemented. The plan shall be developed based on information provided in MSDS. The key elements shall be summarised in a manner that is easy to understand (if necessary, translated in local language) and available for staff to refer to wherever such materials are stored. Personnel who handle such material are accordingly trained. The organisation has a HAZMAT kit(s) for handling spills of hazardous materials. staff should be able to practically demonstrate actions like taking care of blood spills, handling hazardous materials etc.

Standard

FMS. 2 — **The organization has a program for facility, engineering support services and Medical equipment management.**

Objective Elements

CORE

a. The operational and maintenance (preventive and breakdown) plan for engineering support services and utility systems are implemented based on written guidance.

Interpretation: Preventive maintenance and breakdown maintenance plans are available for all utility equipment, engineering equipment, electrical systems, water management, HVAC, facility and furniture. The maintenance plan should consider the manufacturer's recommendations, risk level and past maintenance history. There shall be a planned preventive maintenance tracker for utility equipment, facility items and furniture items.

Electrical maintenance plans shall incorporate statutory requirements where applicable. Transformers, LT and/or HT panel maintenance shall also be included. All lifts shall be included in this maintenance plan.

Water maintenance plans shall include cleaning of water storage tanks at regular intervals and treating of water, where appropriate. It shall also include the RO unit and STP, in case it is available in the organisation.

HVAC maintenance plans shall include chiller unit, AHU, FCU and various air-conditioners. This shall adhere to the manufacturer's recommendations and good infection-control practice requirement. This includes timely cleaning and/or replacement of filters.

Facility and furniture maintenance plans shall include civil work as a wall, floor and roof, etc., fixed furniture like nurse station, shoe racks, etc., loose furniture like emergency cart, chairs and trolleys. This shall adhere to the manufacturer's recommendations, good infection-control practice requirement, etc.

This includes regular inspections, timely repair of civil structure like walls, servicing of furniture etc.

The maintenance plan includes periodic checks, execution of timely preventive maintenance, and response to any breakdown issues including at night and weekends. There shall be a planned preventive maintenance tracker.

CORE

b. The operational and maintenance (preventive and breakdown) plan for medical equipment are implemented based on written guidance. Critical equipment are identified and their down time is monitored.

Interpretation: The operational plan of medical equipment includes evaluation of safe usage of equipment like validation with respect to the instruction manual, user training on equipment, operational check of equipment and verification of set parameter. The maintenance plan includes periodic checks, execution of timely preventive maintenance, and response to any breakdown issues including at night and weekends. There shall be a planned preventive maintenance tracker.

The operator is trained in handling the medical equipment. The operational plan must assist the operator in operating the medical equipment daily. The original equipment manual is a good source for this. In case this is not available, the organisation shall develop the operational plan for the concerned equipment. The Maintenance plan includes periodic checks, execution of timely preventive maintenance and response to

any breakdown issues including at night and weekends. There shall be a planned preventive maintenance tracker.

Medical equipment is periodically inspected and calibrated for their proper functioning.

The organisation shall identify critical medical equipment. At a minimum, this shall include ventilators, X-ray, MRI, Cath lab, CT scan, anaesthesia machines, monitors, laboratory, ultrasound etc. These are the equipment for which there is no alternate is available and in case of failure of such equipment clinical care or physician decision making capacity suffer.

A complaint log is to be maintained (physical or electronic) to indicate the date and time of receipt of the complaint, allotment of job and completion of the job. Completion of the job should always be ratified by the user department. The start of downtime shall be the time when the complaint was lodged, and the end of the downtime shall be the time at which completion of the job was ratified by the user department.

Standard

FMS. 3 **The organization has provisions for safe water, electricity, medical gas and vacuum systems.**

Objective Elements

CORE **a. Potable water and electricity, are available round the clock.**

Interpretation: The organisation shall make arrangements for the supply of adequate potable water and electricity. Alternate sources for water and electricity shall be made available all the times.

Potable water quality is monitored and documented. Water testing includes bio-chemical (once in three months) and microbiological analysis (once in a month). Water shall be collected at the user end (tap). For water quality, refer to the current version IS 10500. In case of an RO plant of the dialysis unit, the water from the inlet port of dialysis machine shall be tested for endotoxin levels every month to ensure that levels should conform to national and/or international guidelines. Alternate source of water can be bore/open well, supply through water tanker or extra storage tanks.

The electric load shall be appropriate to the requirements of the organisation and adhere to the regulatory requirements.

Alternate electric supply could be from DG sets, solar energy, UPS and any other suitable source. In case of electrical supply through alternate sources (Diesel generator or uninterrupted power supply), the capacity and longevity of power availability based on usage are considered.

The organisation identifies and mitigates the risk of critical areas/services during electrical supply failure, or when water is contaminated or interrupted.

CORE

b. Medical gases and vacuum systems are handled safely and are available round the clock.

Interpretation: Medical gases are handled, stored, distributed and used in a safe manner.

This shall apply to all gases used in the organisation. It shall also address the issue of statutory requirements and approvals wherever applicable. It shall follow a uniform colour coding system. Proper signage is kept for full and empty cylinders. The organisation shall adhere to statutory requirements under the provisions of the Indian Explosives Act, Gas Cylinder rules and Static and Mobile Pressure Vessel (unfired) rules

The procedures for medical gases address the safety issues at all levels. This shall include from the point of storage/source area, gas supply lines and the end-user area. Appropriate safety measures shall be developed and implemented for all levels. This shall include alarm units and valve boxes installation at various locations. The alternate sources for medical gases, vacuum and compressed air are available in case of failure. In case of air compressor and vacuum pump, it could be the stand by unit. For medical gases it could be stand by gas manifold/ bulk cylinders.

Standard

FMS. 4 — **The organization has plans for fire and non-fire emergencies within the facilities.**

Objective Elements

CORE

a. The organisation has plans and provisions for identification, early detection, abatement and containment of fire and non-fire emergencies*.

Interpretation: The organisation shall have a fire plan covering fire arising out of burning of inflammable items, explosion, electric short-circuiting or acts of negligence or due to the incompetence of the staff on duty;

The organization shall:

i. deploy adequate and qualified personnel for this;

i. follow NABH minimum fire safety guidelines;

ii. have safety measures in place to minimise the effect of smoke during the fire;

iii. have adequate training plans;

iv. have schedules for the conduct of mock fire drills;

v. maintain mock drill records;

vi. display exit plans prominently;

vii. have a dedicated emergency illumination system, which comes into effect in case of fire.

The organisation shall take care of non-fire emergencies by identifying them and by deciding the appropriate course of action such as terrorist attack, invasion of swarms of insects and pest, earthquake, flood, mob violence, toxic gas and chemical leaks, building or structural collapse, sudden failure of supply of electricity, gas, vacuum, bursting of boilers and/or autoclaves etc. The organisation shall establish liaison with civil and police authorities and fire brigade as required by law for enlisting their help and support in case of an emergency. Guidelines of NDMA/SDMA/DDMA shall be referred to.

CORE

b. There is a maintenance plan for fire related equipment and infrastructure.

Interpretation: The plan should address inspection, testing, preventive and breakdown maintenance. This shall adhere to manufacturers and/or statutory recommendations.

CORE

c. The organisation has a documented and displayed safe exit plan in case of fire and non-fire emergencies.

Interpretation: Exit plan shall be displayed on each floor, particularly close to the lifts and inside all enclosed areas like individual rooms and laboratories. Exit doors should remain open or have push bars on them. Fire signage should follow the norms laid down by respective statutory body (for example, fire service) and/or National Building Code. Signage and maintenance of refuge area as applicable should be done.

CORE

d. Mock drills are held at least twice in a year.

Interpretation: Testing twice a year is only the minimum frequency, and this may be increased. This includes fire and important non-fire emergencies (as identified by the organisation).

The plan can be tested using a table-top exercise, or a mock drill. At a minimum, at least one mock drill should be held once in 12 months. This shall test all the components of the plan and not just awareness/demonstration of practices. In the case of a mock drill, simulated patients (not real) shall be used. After every table-top exercise/mock drill, the variations are identified, the reason for the same is analysed, debriefing conducted and where appropriate the necessary corrective and/or preventive actions are taken.

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CHAPTER 9

Human Resource Management (HRM)

Intent of the chapter

The most important resource of a hospital and healthcare system is the human resource. Human resources are an asset for effective and efficient functioning of a hospital. Without an equally effective human resource management system, all other inputs like technology, infrastructure and finances come to naught. Human resource management is concerned with the "people" dimension in management.

The goal of human resource management is to acquire, provide, retain and maintain competent people in right numbers to meet the needs of the patients and community served by the organisation. This is based on the organisation's mission, objectives, goals and scope of services. Effective human resource management involves the following processes and activities:-

(a) Acquisition of Human Resources which involves human resource planning, recruiting and socialization of the new employees.

(b) Training and development relates to the performance in the present and future anticipated jobs. The employees are provided with opportunities to advance personally as well as professionally.

(c) Motivation relates to job design, performance appraisal and discipline.

(d) Maintenance relates to safety and health of the employees.

The term "employee" refers to all salaried personnel working in the organisation. The term "staff" refers to all personnel working in the organisation including employees, "fee for service" medical professionals, part-time workers, contractual personnel and volunteers.

SUMMARY OF STANDARDS

HRM. 1	**The organization has staffing commensurate with patient care needs.**
HRM. 2	**There is induction training and an on-going programme for professional training and development of the staff.**
HRM. 3	**The organization has a well-documented appraisal system, disciplinary and grievance handling procedure.**
HRM. 4	**The organization promotes and addresses their health and safety needs of the staff.**
HRM. 5	**There is documented personal record for each staff member.**

Standards and Objective Elements

Standard

HRM. 1 **The organization has staffing commensurate with patient care needs.**

Objective Elements

Commitment **a. The mix of staff is commensurate with the volume and scope of services.**

Interpretation: The staff should be commensurate with the workload and the clinical requirement of the patients. Staffing norms for nurses shall be as per published guidelines. Staffing requirements at minimum shall be based on peak occupancy rates for various areas in last one year. Whenever there is a shortfall of staff, contingency plans to meet the workforce shortage exists. This includes support staff too.

The contingency plans could manage long- and short-term workforce shortages, including unplanned shortages. At various times, the mix of skills required for the organisation to function at peak efficiency may not be immediately available due to workforce shortages, which can occur on a shift-by-shift, short-term or long-term basis. Existing staff crises can be managed using a contingency plan, which may include strategies such as re-prioritising tasks, allocating tasks to different staff members, and relying on a pool of filler staff, which may consist predominantly of previous employees and casual staff sourced from agencies

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Commitment **b. The job specification and job description are defined for each category of staff.**

Interpretation: The content of each job should be defined. The qualifications, skills and experience required for performing the job should be laid down. The job description should be commensurate with the qualification.

For a job which requires the skills of a doctor or a nurse, the minimum qualification shall be an MBBS and GNM degree respectively. The exception would be in cases where exemption has been granted by government/statutory body.

Refer to the glossary for a definition of "job description" and "job specification".

CORE **c. The organisation defines and implements a code of conduct for its staff.**

Interpretation: The code of conduct should outline the do's and don'ts for staff

behaviour at the workplace. It should be aligned with the organisation's values and ethics framework. It shall include protection of patient confidentiality. It is preferable that the staff sign the code of conduct at the time of joining.

Standard

HRM. 2 **There is induction training and an on-going programme for professional training and development of the staff.**

Objective Elements

Commitment **a. Written guidance governs training and development policy for the staff.**

Interpretation: A training manual incorporating the procedure for identification of training needs, the training methodology, documentation of training, training assessment, and impact of training should be prepared. There should be a training calendar.

The training shall be for all categories of staff including doctors and outsourced staff (wherever applicable).

The Human Resources department shall maintain a record of all trainings provided. At a minimum, it shall include the title of the training, the trainer(s), list of trainees (with signatures). Where possible, the contents of the training may also be captured. Training records could be in digital format.

Evaluation of training effectiveness is done by the organisation. The evaluation should focus on knowledge, skills and attitude. Based on the evaluation, where appropriate, re-training has to be provided.

The organisation supports continuing professional development and learning.

CORE **b. Staff are provided with induction training.**

Interpretation: The organisation shall determine as to when induction training shall be conducted. It should at a minimum include vision, mission and values of the organisation, staff and patients' rights and responsibilities, various aspects of safety and codes, cardio-pulmonary resuscitation, Infection prevention and control program, service standards and administrative policies and procedures of the organisation as well as the department / service /programme.

The training shall incorporate aspects of patient, visitor and staff safety.

The contents of this training could be provided to every staff in the form of a booklet. There can be a separate induction training at the organisational level and for the respective departments. The records of the training shall be maintained.

CORE

c. Staff are regularly trained on patient care activities based on their specific job description.

Interpretation: Relevant staff involved in blood transfusion services (doctors, nurses, technicians and staff involved in the transport of blood from the blood bank/ blood storage unit) are trained in the handling of blood and blood products. Training shall be on various aspects of transfusion services such as safe transport of blood, obtaining informed consent, various documents to be maintained, identification of transfusion reactions, process of handling transfusion reactions and educating patient and family on donation.

Staff shall be trained in identifying and rendering care to vulnerable patients as per written guidance. The training shall also be on stating who is responsible for identifying these patients, and on how an informed consent is obtained. The training shall, in addition, include risk management in these patients and monitoring of these patients.

Relevant staff shall be trained in the appropriate use of control and restraint techniques. Training shall include identifying patients who need restraints and providing care to them, the frequency of monitoring these patients and the validity of restraint orders.

The staff shall be trained on good practices in health care communication, and also on how to handle challenging situations. The training needs for communication skills can also be identified by analyzing patient complaints, incident reports, appraisals and employee feedback.

Training also occurs when job responsibilities change/ new equipment is introduced.

CORE

d. Staff are regularly trained in safety and quality related aspects.

Interpretation: Staff are trained on identified aspects of safety including patient safety in the organisation. This could be done through a regular training programme or printed materials. Staff working in laboratory and imaging services are trained in their respective safety programmes.

They are provided training in the detection, handling, minimisation and elimination of identified risks within the organisation's environment. These risks could be physical (poor lighting, slippery floors, blind corners, open electrical points, naked wires, etc), chemical (improper handling, spills, aerosolization, etc), environmental (noise, smoke, dampness, heat, etc), or process related (needle-stick injury, blood and body fluid chemicals, cytotoxic drugs, spills, soiled linen, etc). Further, staff should be able to practically demonstrate actions like taking care of blood spills, handling hazardous materials, etc.

The staff should be able to intimate the sequence of events that they will undertake in the eventuality of occurrence of any incident.

The organisation shall identify the areas with potential occupational hazards. Staff are

made aware of the possible risks involved and the preventive actions to avoid risks. For example, needle stick injury and blood/ body fluid exposure, radiation exposure, LASER exposure, medical gases, chemotherapy exposure, noise in utility areas.

Staff are trained in the organisation's quality improvement programme. They are made aware of the structure of the quality improvement programme of the organisation and also of their roles in contributing to it. Staff working in the laboratory and imaging services, are trained on their respective quality assurance programmes.

CORE **e. Staff are trained in handling disaster, fire and non-fire emergencies.**

Interpretation: In case of fire, training shall include the various classes of fires, information and demonstration on how to use fire extinguishers, evacuation plans and other procedures to be followed in case of fire. Staff in the organisation shall be trained on identified non-fire emergencies. They are also trained on their specific role in such emergencies. The training shall include the various elements of the disaster management plan, they are also trained in their specific role during management of external /internal disaster.

Standard

HRM. 3 **The organization has a well-documented appraisal system, disciplinary and grievance handling procedure.**

Objective Elements

Commitment **a. Performance appraisal is done for staff within the organisation at defined intervals based on predetermined criteria.**

Interpretation: Performance appraisal shall be done for all categories of employees starting from the person heading the organisation and all, including doctors. Where appropriate, the performance appraisal should include competency assessment. The staff are made aware of the system of appraisal at the time of induction Performance is evaluated based on the pre-determined criteria.

In the case of outsourced staff, the performance appraisal could be done by the contractor.

Performance appraisal is carried out at defined intervals and is documented. It shall be done at least once a year.

For definition of "performance appraisal" refer to glossary.

CORE **b. Process for disciplinary and grievance handling is defined and implemented.**

Interpretation: The disciplinary policy and procedure is based on the principles of natural justice, which implies that both parties (employee and employer) are given an opportunity to present their case and decision is taken accordingly. All staff should be aware of the disciplinary procedure and the process to be followed in case they feel aggrieved.

Grievances should include workplace issues like bullying and harassment. The redress procedure addresses the grievance. Actions that are taken shall be documented and communicated to the aggrieved staff.

The organisation shall designate an appellate authority to consider appeals in disciplinary cases. The appellate authority should be higher than the disciplinary authority. The organisation shall follow statutory norms for prevention of sexual harassment at workplace.

For definition of "disciplinary procedure" and "grievance handling" refer to glossary.

Standard

HRM. 4 **The organization promotes addresses their health and safety needs of the staff**

Objective Elements

CORE **a. Health problems of the staff, including occupational health hazards, are taken care of in accordance with the organisation's policy.**

Interpretation: The organisation has a written guidance on staff health and safety programme that addresses staff physical and mental health and safe working conditions. The organisation shall make appropriate arrangements for safety of health care workers at workplace during all shifts. The organisation's policy shall be in consonance with the law of the land and good work practices.

The organisation develops and implements a staff vaccination and immunization program.

Appropriate personal protective equipment is provided to the staff concerned, and they are educated on how to use them.

The organisation shall support the staff (second victim) involved in unanticipated adverse events, medical error or patients related injury. For the definition of "occupational health hazard" and "second victim" refer to the glossary.

Commitment

b. The organisation has measure in place for prevention and handling workplace injuries and violence.

Interpretation: Examples of workplace related injuries are needlestick injuries, back injuries sustained during patient transport, hearing impairments due to noise levels, etc.

An integrative and participative approach is used to address this. Key aspects include workplace risk assessment, including identifying situations at special risk, workplace interventions including information and communication, environmental interventions including signage, security and restricted access and individual interventions like training.

The organisation shall have a mechanism in place to handle these situations, including liaison with law enforcement agencies where applicable and provision of counselling to affected staff.

The organisation provides treatment to staff who sustain work-place related injuries. Treatment also includes counselling where appropriate. Injuries due to workplace violence are included.

Refer to glossary for a definition of "workplace violence."

Standard

HRM. 5 **There is documented personal record for each staff member**

Objective Elements

CORE

a. Personal files are maintained in respect of all staff .

Interpretation: Each file must be current and updated. The organisation maintains confidentiality and access to personal files is restricted. The personal files contain personal information regarding the employee's qualification, registration, disciplinary actions and health status. The personal files contain personal information regarding the staff's qualification, job description, verification of credentials, and health status.

CORE

b. Credentialing records are maintained in personal files.

Interpretation: the education, registration, training and experience of the identified medical professionals is documented and updated periodically. Update is done after acquisition of new skills and/or qualification. All credentials required by organisation are documented and maintained for each medical staff member in his or her personal file.

All such information pertaining to the medical and nursing professionals, is appropriately verified when possible. The credentials are verified from the organisation which has awarded the qualification/training. Records of in-service training and education are also included. In case of internal trainings the organisation could file a summary of all trainings attended by the employee on an annual basis. However, there shall be a supporting document to verify that the employee has actually attended the training. In case the organisation maintains training records elsewhere, traceability shall be provided in the personal file, to ensure that the intent of the objective element is addressed. Electronic training records are Acceptable.

Personal files contain results of all evaluations and remarks. Evaluations would include performance appraisals, training assessment and outcome of health checks. The personal files would include records of achievement / appreciation / complaint / warning / memo etc.

Commitment **c. Medical and nursing professionals are granted privileges to admit and care for patients in consonance with their qualification, training, experience and registration and records are kept in the personal files.**

Interpretation: The organisation shall identify clinical services which each medical and nursing professional is authorised to do. This shall be done based on qualification, experience and any additional training received. For example, radiotherapy can only be given by a radiation oncologist, an infection prevention and control nurse shall have requisite in-house and external training and experience and the aptitude and knowledge to perform the tasks required of him/her. Privileges shall be reviewed every year and where necessary revised.

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CHAPTER 10

Information Management System (IMS)

Intent of the chapter

This chapter emphasizes the requirements of a medical record in the hospital. As we know, the medical record is an important aspect of continuity of care and communication between the various care providers. The medical record is also an important legal document as it provides evidence of care provided. The organisation will lay down policies and procedures to guide the contents, storage, security, issue and retention of medical records.

SUMMARY OF STANDARDS

IMS. 1	**Information needs of the patients, visitors, staff, management and external agencies are met.**
IMS. 2	**The organization has a complete and accurate medical record for every patient.**
IMS. 3	**The organisation maintains confidentiality, integrity and security of records, data and information.**

Standards and Objective Elements

Standard

IMS. 1 — **Information needs of the patients, visitors, staff, management and external agencies are met.**

Objective Elements

Commitment

a. The organisation identifies captures and disseminate the information needs of the patients, visitors, staff, management, external agencies and community*.

Interpretation: Information needs of the various stakeholders are identified by the organisation through a systematic process. For example,

- For the patient, it could be information on OPD timings, availability of services, etc.
- For the visitors, it could be visiting hours, the age restriction for visitors, etc.
- For the staff, it would include information on leave policy, standard operating procedures, etc.
- For the management, daily census report, utilization rates, etc.
- For the external agencies, it could be data of vital statistics, notifiable diseases, etc.
- For the community, it could be information on the addition of new service, induction of new medical staff, etc.

A written guidance is available for capture and / or dissemination, and the same is implemented. The written guidance shall also specify the frequency of data collection and the person(s) responsible.

The mechanism for dissemination of patient/ visitor/ staff information needs could be through a website, intranet, information booklets, display and signage.

The information needs of the management could be captured through manual and/ or electronic hospital information system and/ or management information system.

Timely and accurate information is given to relevant stakeholders. The organisation could decide on what needs to be shared with whom and the modalities (memos, circulars, webpage, etc.) for the dissemination of such information.

The organisation contributes to the external databases in accordance with the law and regulations. The organisation shall send relevant information at set frequency and format to the concerned authorities as per statutory norms. For example, sending birth and death statistics, notifiable diseases etc (Refer to the glossary for "notifiable diseases). The organisation shall identify all notifiable diseases after taking into consideration the local/state/national laws, rules, regulations and notifications thereof.

Excellence

b. **Use of Telemedicine is as per applicable guidelines.**

Interpretation: The Organisation is aware of the legal and other requirements of Telemedicine facilities and the same are documented. The organisation maintains and updates its compliance status of safety and security of Telemedicine services as per current guidelines. The organisation shall have a mechanism for appropriate data storage and retrieval.

When electronic communication, such as mobile-devices or patient-facing portals issued for Telemedicine, the organisation ensures quality of patient care, security and confidentiality of information The organisation shall implement protection of the patient's identity and confidentiality. The organisation shall ensure quality patient care as per current clinical guidelines. The organisation will preferably also care about transmission quality of the consultation given to the patients.

Whenever the telemedicine facility is provided to community services or outreach organisation, there should be a written guidance in consonance with prevailing laws and guidelines. Limitations of information and communication technologies shall be explicitly addressed.

The organisation should have an MoU for its telemedicine services, as applicable.

Commitment

c. **The organisation shall make efforts to use digital health technology to improve operational efficiency, patient safety and patient experience.**

Interpretation: The organisation shall make efforts to use digital health technology to improve operational efficiency and patient safety through the use of software for different functions such as registration, billing, pharmacy, laboratory, Imaging, In-patient and outpatient case records etc.

Standard

IMS. 2 — **The organization has a complete and accurate medical record for every patient.**

Objective Elements

Core

a. **Every medical record has a unique identifier.**

Interpretation: The medical record shall have a unique identifier number. Every sheet in the medical record shall have this unique identifier. This shall also apply to records on digital media. In case of electronic records, all entries for one unique identifier shall be available in one place and/or traceable to the number.

CORE

b. The medical record provides a complete, up-to-date and chronological account of patient care.

Interpretation: The organisation identifies the documents that are part of the medical record and implements the same. For example, admission orders, face sheet, IP sheet, discharge summary, doctor's order sheet, TPR chart, consent form, nursing assessment, nursing care plans, dietary assessments and plans, physiotherapy assessments etc. The contents of the medical record can be hand written, typed, printed or in electronic form. There can be a mix of these, but appropriate linkages must be available

The medical record has all the identified sheets filed in sequential order. Entries in the components of the record are filed in chronological order. It shall ensure that all medico-legal case records have mandatory information. In case a sheet is missing note to that effect would be put in the medical record. It is preferable that the pages in the medical record are numbered.

When patient is transferred to another hospital, the medical record contains the details of the transfer. The medical record should contain the date of transfer, the reason for transfer and the name of the receiving organisation. It is mandatory to mention the clinical condition of the patient before the transfer. If the patient has been transferred at his/her request, a note may be added to that effect. In such instances, the name of the receiving hospital could be the name the patient desires to go to. In such instances, the name of the receiving organisation could be recorded accordingly. All available details of the transfer are documented.

The medical record contains a copy of the discharge summary or death summary and death certificate, as applicable. The discharge summary or death summary should be signed by appropriate and qualified personnel.

In case of death, the death summary shall mention the cause, date and time of death. The organisation provides the death certificate as per the International Form of Medical Certificate of Cause of Death (WHO). Cardiac and respiratory arrest is an event and not the cause of death.

CORE

c. Every medical record entry is signed, named dated and timed by those authorized to make entries in medical record.

Interpretation: Organisation shall have written guidance authorising who can make entries and the content of entries. This could be a different category of staff for different entries, but it shall be uniform across the organisation. For example, medication orders by the doctor, medication administration chart by the nurse and nutritional assessment by the dietician.

All entries should be documented immediately but no later than one hour of completion of the assessment/procedure. For records on electronic media,it is preferable that the date and time are automatically generated by the system.

CORE **d. Medical records are reviewed periodically.**

Interpretation: The contents of medical record are identified and documented. The organisation shall define the periodicity of review. A checklist can be used for this purpose, the review shall be carried out for physical and /or electronic medical records.

The organisation defines the periodicity for reviewing the medical records. The review of records is based on identified parameters. At a minimum, the review should include timeliness, legibility and completeness of the medical records. Other parameters which could be included are the completeness of consent forms, missing a final diagnosis, availability of operation / procedure notes, etc.

The review points out and documents any deficiencies in records, for example final diagnosis not mentioned, incomplete OT notes in an operated patient, incomplete consents, missing signature, name date and time for all entries etc.

An adequate mix of both active and discharged patients should be used. The organisation shall define the principles on which sampling is based.

Based on the deficiencies recorded, appropriate corrections are carried out in a defined time,and the same is documented. The preventive actions are disseminated to the relevant staff.

Standard

IMS. 3 **The organisation maintains confidentiality, integrity and security of records, data and information.**

Objective Elements

CORE **a. The organisation maintains confidentiality, integrity and security of information including electronic medical records.**

Interpretation: Confidentiality implies that only authorised persons have access to the contents of the record. This shall align with the applicable laws.

The organisation shall control the accessibility to the medical records department and its Hospital Information System. In electronic systems, the access should be different for different types of personnel and specific for that user.

Integrity implies that the entries are not tampered. Any corrections shall be done in accordance with the organisation's defined written guidance. This shall also address how entries in the patient record are corrected or overwritten. The organisation should have a system to keep track of changes made in the records or data.

Security refers to the protection of the record, data and information against loss and destruction.

Wherever electronic storage is done, the organisation shall ensure that there are adequate safeguards for protection of data, including protection against virus/ trojans. A proper backup procedure should be implemented. For physical records, the organisation shall ensure that there are adequate pest and rodent control measures. There must be a provision to store in fire-safe cabinets, or there must be adequate (and appropriate) fire-fighting equipment.

CORE

b. The organisation discloses privileged health information as authorized by the patient /physicians and/or as required by law.

Interpretation: The authorisation from the patient shall be obtained in writing. Special care should be taken in medico-legal cases and other special situations identified by the Government and the organisation.

Request for access to information in the medical records by patients/physicians and other public agencies are addressed in accordance with the written guidance. In the case of patients, the release of information is in accordance with the Code of Medical Ethics 2002. Grievances concerning RTI shall be addressed by the government and other applicable bodies, as per the written guidance. Denial of information is permitted only if in the opinion of a licensed healthcare professional, the release of the information would endanger the life or safety of the patients and others.

Request from physicians for access to medical records of patients treated by him/her shall be addressed in accordance with the written guidance.

CORE

c. Written guidance is available for document control.

Interpretation: The organisation ensures that all documents including forms, formats, policies and procedures in use are current and relevant. They are created, reviewed for adequacy, authorised and released by designated individuals. Documents are reviewed for updating them as per a planned schedule. All approved documents are identifiable. Obsolete documents are removed from use and archived as per a planned retention period based on the organisation's policy

Only the current valid versions of the documents are available for use.

Refer to "System documentation"

Required policies, procedures and plans are available and the staff understands how to access those documents which are relevant to their work.

CORE

d. Written guidance is available for retention and destruction of the patient's clinical records, data and information. *

Interpretation: The organisation retains patients clinical records, data and information according to its requirements.

The organisation shall define the retention period for each category of medical records: out-patient, in-patient and MLC. The retention period shall be in consonance with rules laid down by NMC and respective state authority. It shall also do the same for various data and the formats (e.g. registers and forms) that have been used for capturing this data.

The retention process provides expected confidentiality and security applicable for both manual and electronic systems.

The destruction of medical records, data and information is in accordance with the laid down procedure and relevant guidelines.

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Glossary

The commonly-used terminologies in the NABH standards are briefly described and explained herein to remove any ambiguity regarding their comprehension. The definitions narrated have been taken from various authentic sources as stated, wherever possible. Notwithstanding the accuracy of the explanations given, in the event of any discrepancy with a legal requirement enshrined in the law of the land, the provisions of the latter shall apply.

Term	Definition
Accreditation	Accreditation is self-assessment and external peer review process used by health care organisations to accurately assess their level of performance in relation to established standards and to implement ways to improve the health care system continuously.
Accreditation assessment	The evaluation process for assessing the compliance of an organisation with the applicable standards for determining its accreditation status.
Advance life support	Emergency medical care for sustaining life, including defibrillation, airway management, and drugs and medications.
Adverse drug reaction	A response to a drug which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease or for the modification of physiologic function.
Adverse event	An injury related to medical management, in contrast to complications of the disease. Medical management includes all aspects of care, including diagnosis and treatment, failure to diagnose or treat, and the systems and equipment used to deliver care. Adverse events may be preventable or non-preventable. (WHO Draft Guidelines for Adverse Event Reporting and Learning Systems)
Anaesthesia Death	It is defined as death occurring within 24 hours of administration of anaesthesia due to cases related to anaesthesia. However, death may occur even afterwards due to the complications.
Assessment	All activities including history taking, physical examination, laboratory investigations that contribute towards determining the prevailing clinical status of the patient.
Barrier nursing	The nursing of patients with infectious diseases in isolation to prevent the spread of infection. As the name implies, the aim is to erect a barrier to the passage of infectious pathogenic organisms between the contagious patient and other patients and staff in the hospital, and thence to the outside world. The nurses wear gowns, masks, and gloves, and they observe strict rules that minimise the risk of passing on infectious agents.

Term	Definition
Basic life support	Basic life support (BLS) is the level of medical care which is used for patients with life-threatening illnesses or injuries until the patient can be given full medical care.
Breakdown maintenance	Activities which are associated with the repair and servicing of site infrastructure, buildings, plant or equipment within the site's agreed building capacity allocation which have become inoperable or unusable because of the failure of component parts.
Byelaws	A rule governing the internal management of an organisation. It can supplement or complement the government law but cannot countermand it, e.g. municipal by-laws for construction of hospitals/nursing homes, for disposal of hazardous and/or infectious waste
Calibration	Set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realised by standards.
Care Plan	A plan that identifies patient care needs, lists the strategy to meet those needs, documents treatment goals and objectives, outlines the criteria for ending interventions, and documents the individual's progress in meeting specified goals and objectives. The format of the plan may be guided by specific policies and procedures, protocols, practice guidelines or a combination of these. It includes preventive, promotive, curative and rehabilitative aspects of care.
Citizen's charter	Citizen's Charter is a document which represents a systematic effort to focus on the commitment of the organisation towards its citizens in respects of standard of services, information, choice and consultation, non-discrimination and accessibility, grievance redress, courtesy and value for money. (Reference: https://goicharters.nic.in/faq.htm)
Clinical audit	A quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change. (Reference: Principles for Best Practice in Clinical Audit 2002, NICE/CHI)
Clinical autopsy	It is a surgical procedure that consists of an examination of a corpse by dissection to identify the cause, mode and manner of death or to evaluate any disease or injury that may be present for research or educational purposes.
Clinical care pathway	Clinical care pathways are standardised evidence-based, multidisciplinary management plans. They identify an appropriate sequence of clinical interventions, timeframes, milestones and expected outcomes for a homogenous patient group.

Term	Definition
Clinical practice guidelines	Clinical practice guidelines are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.
Competence	Demonstrated ability to apply knowledge and skills (para 3.9.2 of ISO 9000: 2015). Knowledge is the understanding of facts and procedures. Skill is the ability to perform a specific action.
Confidentiality	Restricted access to information to individuals who have a need, a reason and permission for such access. It also includes an individual's right to personal privacy as well as the privacy of information related to his/her healthcare records.
Consent	1. The willingness of a party to undergo examination/procedure/ treatment by a healthcare provider. It may be implied (e.g. patient registering in OPD), expressed which may be written or verbal. Informed consent is a type of consent in which the healthcare provider has a duty to inform his/her patient about the procedure, its potential risk and benefits, alternative procedure with their risk and benefits so as to enable the patient to make an informed decision of his/her health care. 2. In law, it means active acquiescence or silent compliance by a person legally capable of consenting. In India, the legal age of consent is 18 years. It may be evidenced by words or acts or by silence when silence implies concurrence. Actual or implied consent is necessarily an element in every contract and every agreement.
Control Charts	The statistical tool used in quality control to (1) analyse and understand process variables, (2) determine process capabilities, and to (3) monitor effects of the variables on the difference between target and actual performance. Control charts indicate upper and lower control limits, and often include a central (average) line, to help detect the trend of plotted values. If all data points are within the control limits, variations in the values may be due to a common cause and process is said to be 'in control'. If data points fall outside the control limits, variations may be due to a special cause, and the process is said to be out of control.
Correction	Action to eliminate the detected non-conformity (Reference: ISO 9000:2015)
Corrective action	Action to eliminate the cause of a non-conformity and to prevent recurrence. (Reference: ISO 9000:2015)
Credentialing	The process of obtaining, verifying and assessing the qualification of a healthcare provider.
Data	Data is a record of the event.
Discharge summary	A part of a patient record that summarises the reasons for admission, significant clinical findings, procedures performed, treatment rendered, patient's condition on discharge and any specific instructions given to the patient or family (for example follow-up medications).

Term	Definition
Disciplinary procedure	A sequence of activities to be carried out when staff does not conform to the laid-down norms, rules and regulations of the healthcare organisation.
Drug dispensing	The preparation, packaging, labelling, record keeping, and transfer of a prescription drug to a patient or an intermediary, who is responsible for the administration of the drug. (Reference: Mosby's Medical Dictionary, 9th edition, 2009, Elsevier.)
Drug Administration	The giving of a therapeutic agent to a patient, e.g. by infusion, inhalation, injection, paste, pessary, suppository or tablet.
Effective communication	Effective Communication is a communication between two or more persons wherein the intended message is successfully delivered, received and understood. The effective communication also includes several other skills such as non-verbal communication, engaged listening, ability to speak assertively, etc.
Employees	All members of the healthcare organisation who are employed full time and are paid suitable remuneration for their services as per the laid-down policy.
End-of-life Care	Helps all those with an advanced, progressive, incurable illness to live as well as possible until they die. It enables the supportive and palliative care needs of both patient and family to be identified and met throughout the last phase of life and into bereavement. It includes management of pain and other symptoms and provision of psychological, social, spiritual and practical support.
Enhanced communication	Enhanced communication is using the methods of communication to ensure meaning and understanding through the recognition of the limitations of others. The intent is to ensure purposeful, timely and reliable communication. The communication must be sensitive, empathetic and inclusive.
Ethics	Moral principles that govern a person's or group's behaviour.
Evidence-based medicine	Evidence-based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients.
Family	The person(s) with a significant role in the patient's life. It mainly includes spouse, children and parents. It may also include a person not legally related to the patient but can make healthcare decisions for a patient if the patient loses decision-making ability.
Failure Mode and Effect Analysis (FMEA)	A method used to prospectively identify error risks within a particular process.
Formulary	An approved list of drugs. Drugs contained in the formulary are generally those that are determined to be cost-effective and medically effective.

Term	Definition
Goal	A broad statement describing a desired future condition or achievement without being specific about how much and when. (Reference: American Society for Quality) The term "goals" refers to a future condition or performance level that one intends to attain. Goals can be both short- and longer-term. Goals are ends that guide actions. (Reference: Malcolm Baldridge National Quality Award)
Grievance-handling procedures	The sequence of activities carried out to address the grievances of patients, visitors, relatives and staff.
Hazardous materials	Substances dangerous to human and other living organisms. They include radioactive or chemical materials.
Hazardous waste	Waste materials dangerous to living organisms. Such materials require special precautions for disposal. They include the biologic waste that can transmit disease (for example, blood, tissues) radioactive materials, and toxic chemicals. Other examples are infectious waste such as used needles, used bandages and fluid soaked items.
Healthcare-associated infection	Healthcare-associated infection (HAI), also referred to as "nosocomial" or "hospital" infection, is an infection occurring in a patient during the process of care in a hospital or other health care facility which was not present or incubating at the time of admission. (Reference: World Health Organization)
Healthcare organisation	The generic term is used to describe the various types of organisation that provide healthcare services. This includes ambulatory care centres, hospitals, laboratories, etc.
High-dependency unit	A high-dependency unit (HDU) is an area for patients who require more intensive observation, treatment and nursing care than are usually provided for in a ward. It is a standard of care between the ward and full intensive care.
High Risk/High Alert Medications	High-risk/high-alert medications are medications involved in a high percentage of medication errors or sentinel events and medications that carry a high risk for abuse, error, or other adverse outcomes. Examples include medications with a low therapeutic index, controlled substances, psychotherapeutic medications, and look-alike and sound-alike medications.
Incident reporting	It is defined as written or verbal reporting of any event in the process of patient care, that is inconsistent with the deserved patient outcome or routine operations of the healthcare facility.

Term	Definition
In-service education/ training	Organised education/training usually provided in the workplace for enhancing the skills of staff members or for teaching them new skills relevant to their jobs/tasks.
Indicator	A statistical measure of the performance of functions, systems or processes over time. For example, hospital acquired infection rate, mortality rate, caesarean section rate, absence rate, etc.
Information	Processed data which lends meaning to the raw data.
Intent	A brief explanation of the rationale, meaning and significance of the standards laid down in a particular chapter.
Inventory control	The method of supervising the intake, use and disposal of various goods in hands. It relates to supervision of the supply, storage and accessibility of items in order to ensure an adequate supply without stock-outs/excessive storage. It is also the process of balancing ordering costs against carrying costs of the inventory so as to minimise total costs.
Isolation	Separation of an ill person who has a communicable disease (e.g.,measles, chickenpox, mumps, SARS) from those who are healthy. Isolation prevents transmission of infection to others and also allows the focused delivery of specialised health care to ill patients. The period of isolation varies from disease-to-disease. Isolation facilities can also be extended to patients for fulfilling their individual, unique needs.
Job description	1. It entails an explanation pertaining to duties, responsibilities and conditions required to perform a job. 2. A summary of the most important features of a job, including the general nature of the work performed (duties and responsibilities) and level (i.e., skill, effort, responsibility and working conditions) of the work performed. It typically includes **job specifications** that include employee characteristics required for competent performance of the job. A job description should describe and focus on the job itself and not on any specific individual who might fill the job.
Job specification	1. The qualifications/physical requirements, experience and skills required to perform a particular job/task. 2. A statement of the minimum acceptable qualifications that an incumbent must possess to perform a given job successfully.
Maintenance	The combination of all technical and administrative actions, including supervision actions, intended to retain an item in, or restore it to, a state in which it can perform a required function. (Reference: British Standard 3811:1993)

Term	Definition
Medical equipment	Any fixed or portable non-drug item or apparatus used for diagnosis, treatment, monitoring and direct care of a patient.
Medication error	A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labelling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use. (Reference: The National Coordinating Council for Medication Error Reporting and Prevention)
Medication Order	A written order by a physician, dentist, or other designated health professionals for a medication to be dispensed by a pharmacy for administration to a patient. (Reference: Mosby's Medical Dictionary, 10th edition, Elsevier)
Mission	An organisation's purpose. This refers to the overall function of an organisation. The mission answers the question, “What is this organisation attempting to accomplish?” The mission might define patients, stakeholders, or markets served, distinctive or core competencies or technologies used.
Monitoring	The performance and analysis of routine measurements aimed at identifying and detecting changes in the health status or the environment, e.g. monitoring of growth and nutritional status, air quality in operation theatre. It requires careful planning and use of standardised procedures and methods of data collection.
Multidisciplinary	A generic term which includes representatives from various disciplines, professions or service areas.
Near-miss	A near-miss is an unplanned event that did not result in injury, illness, or damage--but had the potential to do so. Errors that did not result in patient harm, but could have, can be categorised as near-misses.
No harm	This is used synonymously with a near miss. However, some authors draw a distinction between these two phrases. A near-miss is defined when an error is realised just in the nick of time, and abortive action is instituted to cut short its translation. In no harm scenario, the error is not recognised, and the deed is done, but fortunately for the healthcare professional, the expected adverse event does not occur. The distinction between the two is important and is best exemplified by reactions to administered drugs in allergic patients. A prophylactic injection of cephalosporin may be stopped in time because it suddenly transpires that the patient is known to be allergic to penicillin (near-miss). If this vital piece of information is overlooked, and the cephalosporin administered, the patient may fortunately not develop an anaphylactic reaction (no harm event).

Term	Definition
Notifiable disease	Certain specified diseases, which are required by law to be notified to the public health authorities. Under the international health regulation (WHO's International Health Regulations 2005), the following diseases are always notifiable to WHO: (a) Smallpox (b) Poliomyelitis due to wild-type poliovirus (c) Human influenza caused by a new subtype (d) Severe acute respiratory syndrome (SARS). In India, the following is an indicative list of diseases which are also notifiable, but may vary from state to state: (a) Polio (b) Influenza (c) Malaria (d) Rabies (e) HIV/AIDS (f) Louse-borne typhus (g) Tuberculosis (h) Leprosy (i) Leptospirosis (j) Viral hepatitis (k) Dengue fever
Nursing empowerment	Empowerment for nurses may consist of three components: a workplace that has the requisite structures to promote empowerment; a psychological belief in one's ability to be empowered; and acknowledgement that there is power in the relationships and caring that nurses provide. It could include structural empowerment and psychological empowerment. Structural empowerment refers to the presence or absence of empowering conditions in the workplace. Kanter's (1993) theory of structural empowerment includes a discussion of organisational behaviour and empowerment. According to this theory, empowerment is promoted in work environments that provide employees with access to information, resources, support, and the opportunity to learn and develop. Psychological empowerment is related to a sense of motivation towards the organisational environment, based on the dimensions of meaning, competence, self-determination, and impact Evidence of nursing empowerment include initiating and carrying out CPR even in the absences of physicians, implementing standard protocols in the ICU such as weaning a patient off ventilator, tapering or titrating inotropic as per standard policies, nurse-led discussions during patient rounds, preparing nursing budgets, decisions to procure equipment that aid and ease nursing care, empowered to correct, stop non-compliance to protocols defined by the hospital.
Objective	A specific statement of a desired short-term condition or achievement includes measurable end-results to be accomplished by specific teams or individuals within time limits. (Reference: American Society for Quality)

Term	Definition
Objective element	It is that component of standard which can be measured objectively on a rating scale. Acceptable compliance with the measurable elements will determine the overall compliance with the standard.
Occupational health hazard	The hazards to which an individual is exposed during the course of the performance of his job. These include physical, chemical, biological, mechanical and psychosocial hazards.
Operational plan	The operational plan is the part of your strategic plan. It defines how you will operate in practice to implement your action and monitoring plans - what your capacity needs are, how you will engage resources, how you will deal with risks, and how you will ensure the sustainability of the organisation's achievements.
Organogram	A graphic representation of the reporting relationship in an organisation.
Outsourcing	Hiring of services and facilities from other organisation based upon one's own requirement in areas where such facilities are either not available or else are not cost-effective. For example, outsourcing of house-keeping, security, laboratory/certain special diagnostic facilities. When an activity is outsourced to other institutions, there should be a memorandum of understanding that clearly lays down the obligations of both organisations: the one which is outsourcing and the one who is providing the outsourced facility. It also addresses the quality-related aspects.
Patient-care setting	The location where a patient is provided health care as per his needs, e.g. ICU, speciality ward, private ward and general ward.
Patient record/ medical record/ clinical record	A document which contains the chronological sequence of events that a patient undergoes during his stay in the healthcare organisation. It includes demographic data of the patient, assessment findings, diagnosis, consultations, procedures undergone, progress notes and discharge summary.
Patient-reported experience measures (PREMs)	Patient-reported experience measures are questionnaires measuring the patients' perceptions of their experience whilst receiving care.
Patient-reported outcome measures (PROMs)	Patient-reported outcome measures are questionnaires measuring the patients' views of their health status.
Patient Satisfaction and	Patient satisfaction is a measure of the extent to which a patient is content with the health care which they received from their health care provider. Patient satisfaction is thus a proxy but a very effective indicator to measure the success of Health care providers.

Term	Definition
Patient Experience	Patient Experience is the sum of all interactions, shaped by an organisation's culture, that influence patient perceptions across the continuum of care. It is a holistic perception that the patient forms about the healthcare provider based on the overall interactions/ care touchpoints.
Performance appraisal	It is the process of evaluating the performance of staff during a defined period of time with the aim of ascertaining their suitability for the job, the potential for growth as well as determining training needs.
Point of care equipment	Medical Equipment that is used to deliver care/intervene at or near the site of patient care. These are primarily Point-of-care testing (POCT), or bedside testing equipment that helps in reducing turn-around times. POCT Machine examples; Glucometer, ABG Analyser, Stat Lab at ICU/ER, portable USG etc.
Policies	They are the guidelines for decision-making,e.g. admission, discharge policies, antimicrobials policy,etc.
Preventive action	Action to eliminate the cause of a potential non-conformity. (Reference ISO 9000:2015)
Preventive maintenance	It is a set of activities that are performed on plant equipment, machinery, and systems before the occurrence of a failure in order to protect them and to prevent or eliminate any degradation in their operating conditions. The maintenance carried out at predetermined intervals or according to prescribed criteria and intended to reduce the probability of failure or the degradation of the functioning of an item.
Prescription	A prescription is a document given by a physician or other healthcare practitioner in the form of instructions that govern the care plan for an individual patient. Legally, it is a written directive, for compounding or dispensing and administration of drugs, or for other service to a particular patient. (Reference: Miller-Keane Encyclopedia and Dictionary of Medicine, Nursing, and Allied Health, Seventh Edition, Saunders)
Privileging	It is the process for authorising all medical professionals to admit and treat patients and provide other clinical services commensurate with their qualifications and skills.
Privileged communication	Confidential information furnished (to facilitate diagnosis and treatment) by the patient to a professional authorised by law to provide care and treatment.

Term	Definition
Procedural sedation	Procedural sedation is a technique of administering sedatives or dissociative agents with or without analgesics to induce a state that allows the patient to tolerate unpleasant procedures while maintaining cardiorespiratory function. Procedural sedation and analgesia (PSA) is intended to result in a depressed level of consciousness that allows the patient to maintain oxygenation and airway control independently. (Reference: The American College of Emergency Physicians)
Procedure	1. A specified way to carry out an activity or a process (Para 3.4.5 of ISO 9000: 2015). 2. A series of activities for carrying out work which when observed by all help to ensure the maximum use of resources and efforts to achieve the desired output.
Process	A set of interrelated or interacting activities which transforms inputs into outputs (Para 3.4.1 of ISO 9000: 2015).
Programme	A sequence of activities designed to implement policies and accomplish objectives.
Protocol	A plan or a set of steps to be followed in a study, an investigation or an intervention.
Quality	1. Degree to which a set of inherent characteristics fulfil requirements (Para 3.1.1 of ISO 9000: 2015). Characteristics imply a distinguishing feature (Para 3.5.1 of ISO 9000: 2015). Requirements are a need or expectation that is stated, generally implied or obligatory (Para 3.1.2 of ISO 9000:2015). 2. Degree of adherence to pre-established criteria or standards.
Quality assurance	Part of quality management focussed on providing confidence that quality requirements will be fulfilled (Para 3.2.11 of ISO 9000:2015).
Quality improvement	Ongoing response to quality assessment data about a service in ways that improve the process by which services are provided to consumers/patients.
Radiation Safety	**Radiation safety** refers to safety issues and protection from radiation hazards arising from the handling of radioactive materials or chemicals and exposure to Ionizing and Non-Ionizing Radiation. This is implemented by taking steps to ensure that people will not receive excessive doses of radiation and by monitoring all sources of radiation to which they may be exposed.(Reference: McGraw-Hill Dictionary of Scientific & Technical Terms) In a Healthcare setting, this commonly refers to X-ray machines, CT/PET CT Scans, Electron microscopes, Particle accelerators, Cyclotron etc. Radioactive substances and radioactive waste are also potential Hazards. **Imaging Safety** includes safety measures to be taken while performing an MRI, Radiological interventions, Sedation, Anaesthesia, Transfer of patients, Monitoring patients during imaging procedure etc.

Term	Definition
Re-assessment	It implies a continuous and ongoing assessment of the patient, which is recorded in the medical records as progress notes.
Reconciliation of medications	Medication reconciliation is the process of creating the most accurate list possible of all medications a patient is taking — including drug name, dosage, frequency, and route — and comparing that list against the physician's admission, transfer, and/or discharge orders, with the goal of providing correct medications to the patient at all transition points within the hospital. (Reference: Institute for Healthcare Improvement)
Resources	It implies all inputs in terms of men, material, money, machines, minutes (time), methods, metres (space), skills, knowledge and information that are needed for the efficient and effective functioning of an organisation.
Restraints	Devices used to ensure safety by restricting and controlling a person's movement. Many facilities are "restraint-free" or use alternative methods to help modify behaviour. Restraint may be physical or chemical (by use of sedatives).
Risk abatement	Risk abatement means minimising the risk or minimising the impact of that risk.
Risk assessment	Risk assessment is the determination of the quantitative or qualitative value of risk related to a concrete situation and a recognised threat (also called hazard). Risk assessment is a step in a risk management procedure.
Risk management	Clinical and administrative activities to identify, evaluate and reduce the risk of injury.
Risk mitigation	Risk mitigation is a strategy to prepare for and lessen the effects of threats and disasters. Risk mitigation takes steps to reduce the negative effects of threats and disasters.
Risk reduction	The conceptual framework of elements considered with the possibilities to minimise vulnerabilities and disaster risks throughout society to avoid (prevention) or to limit (mitigation and preparedness) the adverse impacts of hazards, within the broad context of sustainable development. It is the decrease in the risk of a healthcare facility, given activity, and treatment process with respect to patient, staff, visitors and community.
Root Cause Analysis (RCA)	Root Cause Analysis (RCA) is a structured process that uncovers the physical, human, and latent causes of any undesirable event in the workplace. Root cause analysis (RCA) is a method of problem-solving that tries to identify the root causes of faults or problems that cause operating events. RCA practice tries to solve problems by attempting to identify and correct the root causes of events, as opposed to simply addressing their symptoms. By focusing correction on root causes, problem recurrence can be prevented. The process involves data collection; cause charting, root cause identification and recommendation generation and implementation.

Term	Definition
Safety	The degree to which the risk of an intervention/procedure, in the care environment is reduced for a patient, visitors and healthcare providers.
Safety programme	A programme focused on patient, staff and visitor safety.
Scope of services	Range of clinical and supportive activities that are provided by a healthcare organisation.
Security	Protection from loss, destruction, tampering, and unauthorised access or use.
Sedation	The administration to an individual, in any setting for any purpose, by any route, moderate or deep sedation. There are three levels of sedation: Minimal sedation (anxiolysis) - A drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are not affected. Moderate sedation/analgesia (conscious sedation) - A drug-induced depression of consciousness during which patients respond purposefully to verbal commands either alone or accompanied by light tactile stimulation. No interventions are needed to maintain a patent airway. Deep sedation/analgesia - A drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully after repeated or painful stimulation. Patients may need help in maintaining a patent airway.
Sentinel events	A relatively infrequent, unexpected incident, related to system or process deficiencies, which leads to death or major and enduring loss of function for a recipient of healthcare services. Major and enduring loss of function refers to sensory, motor, physiological, or psychological impairment not present at the time services were sought or begun. The impairment lasts for a minimum period of two weeks and is not related to an underlying condition.
Social responsibility	A balanced approach for an organisation to address economic, social and environmental issues in a way that aims to benefit people, communities and society,e.g. adoption of villages for providing health care, holding of medical camps and proper disposal of hospital wastes.
Sound clinical practice	Practitioner decisions based on available knowledge, principles and practices for specific clinical situations.
Special Educational needs of the patient	In addition to routine carried by the healthcare professionals, patients and family have special educational needs depending on the situation. For example, a post-surgical patient who has to take care of his wound, nasogastric tube feeding, patient on tracheostomy getting discharged who has to be taken care of by the family etc. The special educational needs are also greatly influenced by the literacy, educational level, language, emotional barriers and physical and cognitive limitations. Hence it is important for the staff to determine the special educational needs and the challenges influencing the effective education.

Term	Definition
Staff	All personnel working in the organisation including employees, “fee-for-service” medical professionals, part-time workers, contractual personnel and volunteers.
Standard precautions	1. A method of infection control in which all human blood and other bodily fluids are considered infectious for HIV, HBV and other blood-borne pathogens, regardless of patient history. It encompasses a variety of practices to prevent occupational exposure, such as the use of personal protective equipment (PPE), disposal of sharps and safe housekeeping 2. A set of guidelines protecting first aiders or healthcare professionals from pathogens. The main message is: "Don't touch or use anything that has the victim's body fluid on it without a barrier." It also assumes that all body fluid of a patient is infectious, and must be treated accordingly. Standard Precautions apply to blood, all body fluids, secretions, and excretions (except sweat) regardless of whether or not they contain visible blood, non-intact skin and mucous membranes
Standards	A statement of expectation that defines the structures and process that must be substantially in place in an organisation to enhance the quality of care.
Sterilisation	It is the process of killing or removing microorganisms including their spores by thermal, chemical or irradiation means.
Strategic plan	Strategic planning is an organisation's process of defining its strategy or direction and making decisions on allocating its resources to pursue this strategy, including its capital and people. Various business analysis techniques can be used in strategic planning, including SWOT analysis (Strengths, Weaknesses, Opportunities and Threats), e.g. Organisation can have a strategic plan to become a market leader in the provision of cardiothoracic and vascular services. The resource allocation will have to follow the pattern to achieve the target. The process by which an organisation envisions its future and develops strategies, goals, objectives and action plans to achieve that future.
Surveillance	The continuous scrutiny of factors that determines the occurrence and distribution of diseases and other conditions of ill health. It implies watching over with great attention, authority and often with suspicion. It requires professional analysis and sophisticated interpretation of data leading to recommendations for control activities.
Table-top exercise	A table-top exercise is an activity in which key personnel assigned emergency management roles and responsibilities are gathered to discuss, in a non-threatening environment, various simulated emergency situations. (Reference: https://uwpd.wisc.edu/content/uploads/2014/01/What_is_a_tabletop_exercise.pdf)

Term	Definition
Traceability	Traceability is the ability to trace the history, application, use and location of an item or its characteristics through recorded identification data. (Reference: ISO 9000:2015)
Transfusion reaction	A transfusion reaction is a problem that occurs after a patient receives a transfusion of blood.
Triage	Triage is a process of prioritising patients based on the severity of their condition so as to treat as many as possible when resources are insufficient for all to be treated immediately.
Turn-around-time	Turnaround Ttime (TAT) means the amount of time taken to complete a process or fulfil a request.
Unstable patient	A patient whose vital parameters need external assistance for their maintenance.
Validated tool	A validated tool refers to a questionnaire/scale that has been developed to be administered among the intended respondents. The validation processes should have been completed using a representative sample, demonstrating adequate reliability (the ability of the instrument to produce consistent results) and validity (the ability of the instrument to produce true results).
Validation	Validation is verification, where the specified requirements are adequate for the intended use.
Values	The fundamental beliefs that drive organisational behaviour and decision-making. This refers to the guiding principles and behaviours that embody how an organisation and its people are expected to operate. Values reflect and reinforce the desired culture of an organisation.
Verbal order	Verbal orders are those orders given by a physician with prescriptive authority to a licensed person who is authorised by the organisation.
Verification	Verification is the provision of objective evidence that a given item fulfils specified requirements.
Vision	An overarching statement of the way an organisation wants to be, an ideal state of being at a future point. This refers to the desired future state of an organisation. The vision describes where the organisation is headed, what it intends to be, or how it wishes to be perceived in the future.
Vulnerable patient	Those patients who are prone to injury and disease by virtue of their age, sex, physical, mental and immunological status,e.g. infants, elderly, physically- and mentally-challenged, semiconscious/unconscious, those on immunosuppressive and/or chemotherapeutic agents.
Workplace violence	Incidents where staff are abused, threatened or assaulted in circumstances related to their work, including commuting to and from work, involving an explicit or implicit challenge to their safety, well-being or health. (Adapted from European Commission)

Annexure
Key Performance Indicators

The concept of performance in health services represents an instrument for bringing quality, eficiency and eficiacy together. Performance represents the extent to which set objectives are accomplished. Performance is a multidimensional one, covering various aspects, such as evidence-based practice (EBP), continuity and integration in healthcare services, health promotion, orientation towards the needs and expectation of patients and family members.

Key Performance Indicators (KPIs) help to systematically monitor, evaluate, and continually improve service performance. By themselves, KPIs cannot improve performance. However, they do provide “signposts” that signal progress toward goals and objectives as well as opportunities for sustainable improvements.

Well-designed KPIs should help the organisation to do a number of things, including:

- Establish baseline information i.e., the current state of performance
- Set performance standards and targets to motivate continual improvement
- Measure and report improvements over time
- Compare performance across geographic locations
- Benchmark performance against regional and international peers or norms
- Allow stakeholders to independently judge health sector performance.

Healthcare organisations (HCO) are encouraged to capture all data which involves clinical and support services. The data needs to be analysed and risks, rates and trends for all the indicators have to be demonstrated for appropriate action.

The intent of the NABH KPIs is to have comprehensive involvement of scope of services for which a HCO has applied for the accreditation program. Standardised definitions for each indicator along with numerator and denominator have been explained. Each HCO can have the data set measure, analyse the aggregated data and appropriate correction, corrective and preventive action can be formulated. Each HCO can also design their own methodology of data collection but a broad guidance note has been given to facilitate organisation's compliance.

Suggested minimum sample size to be taken for various audits and KPIs as applicable has been specified.

NABH Key Performance Indicators

The Key performance indicators expected to be monitored by healthcare organisations:

S. No.	Standard	Indicator	Definition	Formula	Unit	Frequency of data collation/ Monitoring	Remarks
1	PSQ.2.a	Catheter-associated Urinary tract infection rate		(Number of urinary catheter-associated UTIs in a month/ Number of urinary catheter days in that month)*1000	/1000 urinary catheter-days	Monthly	Sampling: No
2	PSQ.2.a	Surgical site infection rate		(Number of surgical site infections in a given month/Number of surgeries performed in that month)*100	/100 procedures	Monthly	Keeping in mind the definition of SSI, the numbers would have to be updated on a continual basis until such time that the monitoring period is over. For example, in January, the data for December would be reported. The denominator would be the number of surgeries performed in December, and that would not change. With respect to the numerator, there would be some data but it would not be complete data. Hence, whatever value the organisation gets at this stage would at best be a preliminary value. The organisation will continue to monitor the patients and by the end of January, will have complete data with respect to procedures which have a 30-day surveillance period. At this point in time, based on the data that the organisation has collated the numerator may change and hence, the SSI rate. However, this again would not be the final data. The organisation will continue to monitor procedures that have a 90-day surveillance period, and if there are new SSIs, it would get added to the numerator and thus the rate would change.

S. No.	Standard	Indicator	Definition	Formula	Unit	Frequency of data collation/ Monitoring	Remarks
							The surveillance period for surgeries which are done in December and have a 90-day surveillance period would end on March 30th (give or take a few days). It is only at this point in time that the organisation can have the final SSI rate for December. Sampling: No
3	PSQ.2.b	Incidence of medication errors	A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer.	(Total number of medication errors/ Number of Patient Days) *1000	Percentage	Monthly	In addition to incident reporting, to detect medication errors the organisation shall either adopt medical record review or direct observation. The sample size for this shall be as per the preceding column. The average occupancy shall be of the preceding 3 months. Medication Error is to be calculated only in IP. OP calculations are beyond the scope. Sampling: Yes Sampling methodology: Stratified random
4	PSQ.2.b	Percentage of surgeries where the organisation's procedure to prevent adverse events like the wrong site, wrong patient, and wrong surgery have been adhered to.		(Number of surgeries where the WHO safe surgery checklist was followed/Number of surgeries that were audited)*100	Percentage	Monthly	This should be done by a prospective audit. The audit shall be done when the surgery is being performed. A person(s) working in the OT complex could be entrusted with this responsibility. It is preferable that the identity of the person auditing is anonymized from the operating team. Sampling: Yes Sampling methodology: Stratified random (distributed across various days and operating surgeons).

S. No.	Standard	Indicator	Definition	Formula	Unit	Frequency of data collation/ Monitoring	Remarks
5	PSQ.2.b	Incidence of patient falls	The US Department of Veteran Affairs National Centre for Patient Safety defines fall as "Loss of upright position that results in landing on the floor ground or an object or furniture or a sudden, uncontrolled, unintentional, non-purposeful, downward displacement of the body to the floor/ground or hitting another object like a chair or stair." It is an event that results in a person coming to rest inadvertently on the ground or floor or other lower level.	(Number of patient falls/Total number of inpatient days)*1000	/1000 patient days	Monthly	Falls may be: at different levels – i.e., from one level to ground level, for example from beds, wheelchairs or downstairs on the same level as a result of slipping, tripping, or stumbling, or from a collision, pushing, or shoving, by or with another person below ground level, i.e. into a hole or other opening in the surface All types of falls are to be included whether they result from physiological reasons (fainting) or environmental reasons. Assisted falls (when another person attempts to minimize the impact of the fall by assisting the patient's descent to the floor) should be included. (NDNQI, 2005). Sampling: No
6	PSQ.2.c	Percentage of safe and rational prescriptions	Rational use of medicines requires that patients receive medications appropriate to their	(Total number of safe and rational prescriptions/Total number of prescriptions audited)*100	Percentage	Monthly	This includes only prescriptions for out-patients. This indicator shall be captured through the prescription audit. The methodology for audit shall be as stated in NABH's document on prescription audit. Sampling: Yes Sampling methodology: Stratified random

S. No.	Standard	Indicator	Definition	Formula	Unit	Frequency of data collation/ Monitoring	Remarks
			clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community				
7	PSQ.2.c	Mortality Rate		(Number of Deaths/Number of Discharges and deaths)*100	Percentage	Monthly	
8	PSQ.2.c	Average Length of stay (ALOS)	Length of stay (LOS) is a term used to measure the duration of a single episode of hospitalization.Inpatient days are calculated by subtracting day of admission from day of discharge. However, persons entering and leaving a hospital on the same day have a length of stay of one	Number of inpatient days in a given month/Number of discharges and deaths in that month	Days	Monthly	Number of inpatient days-It is a sum of daily inpatient census. While calculating the overall length of stay and available number of inpatient beds, emergency, rehabilitation and day care beds should not be considered.

S. No.	Standard	Indicator	Definition	Formula	Unit	Frequency of data collation/ Monitoring	Remarks
9	PSQ.2.c	Percentage of medical records having incomplete and/or improper consent	Informed consent is a type of consent in which the health care provider has a duty to inform his/her patient about the procedure, its potential risk and benefits, alternative procedures with their risk and benefits so as to enable the patient to make an informed decision of his/her health care	(Number of medical records having incomplete or improper consent/Number of discharges and deaths)*100	Percentage	Monthly	If any of the essential elements/requirements of consent is missing, it shall be considered incomplete. If any consent obtained is invalid/void (consent obtained from the wrong person/consent obtained by the wrong person, etc.), it is considered improper. Sampling: No
10	PSQ.2.c	Time taken for discharge	The discharge process is deemed to have started when the consultant formally approves discharge and ends with the patient leaving the clinical unit	Sum of time taken for discharge (in minutes)/Number of patients discharged	Minutes	Monthly	In case patients request additional time to leave the clinical unit that shall not be added. The discharge is deemed to have been completed when the formalities for the same have been completed. Day care patients are not included. Sampling: No
11	PSQ.2.c	Time for initial assessment of indoor patients	The time shall begin from the time that the patient has arrived at the bed of the ward until the time	(Sum of time taken for the assessment (in minutes)/ Total number of admissions)	Minutes	Monthly	This shall be captured either through the HIS or through an audit. In case of an audit, the sample size shall be as specified in the sample size calculation table. Daycare patients are not included.

S. No.	Standard	Indicator	Definition	Formula	Unit	Frequency of data collation/ Monitoring	Remarks
			that the initial assessment has been completed and documented by a doctor.				Sampling: Yes Sampling methodology: Stratified random For data captured through HIS- Sampling: No The system should track the number of records for which the initial assessment time could not be captured due to incomplete data.
12	PSQ.2.c	Waiting time for outpatient consultation	Waiting time is the length of time which one must wait in order for a specific action to occur after that action is requested or mandated. Waiting time for outpatient consultation is the time from which the patient has come to the concerned outpatient department (it may or may not be the same time as registration) till the time that the concerned consultant (not the junior doctor/resident) begins the assessment.	Sum total time (in minutes) for consultation/Total Number of outpatients	Minutes	Monthly	In the case of appointment patients, the time shall begin with the scheduled appointment time and end when the concerned consultant (not the junior doctor/resident) begins the assessment. In cases where the patient has been seen ahead of the appointment time, the waiting time shall be taken as zero minutes. Sampling: No

S. No.	Standard	Indicator	Definition	Formula	Unit	Frequency of data collation/ Monitoring	Remarks
13	PSQ.2.c	Incidence of hospital-associated pressure ulcers after admission	A pressure ulcer is a localized injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with shear and/or friction.	(Number of patients who develop new/worsening of pressure ulcer/Total number of inpatient days)*1000	/1000 patient days	Monthly	The organisation shall use The European and US National Pressure Ulcer Advisory Panels (EPUAP and NPUAP) staging system to look for worsening pressure ulcers. Sampling: No
14	PSQ.2.c	Compliance to hand hygiene practices		(Total number of actions performed/Total number of hand hygiene opportunities)*100	Percentage	Monthly	Observation involves directly watching and recording the hand hygiene behavior of healthcare workers and the physical environment. A good reference is the WHO hand hygiene compliance monitoring tool. Please refer: http://www.who.int/gpsc/5may/tools/en/ http://www.who.int/entity/gpsc/5may/Observation_Form.doc?ua=1 Sampling: Yes Sampling methodology: Stratified random. However, the organisation should try to ensure that all staff relevant categories of staff are covered at least once in a quarter.

Sample size calculation (Monthly)

Solvent formula

n=N/(1+Ne2)

(Where n=Number of samples, N = Total population and e=Error tolerance)

Using 95% confidence interval (margin of error 95%), the values are calculated as follows:

Screening Population#	Sample Size*
50	44
100	79
150	108
200	132
500	217
1000	278
2000	322
5000	357
10000	370
20000	377

Screening population is the 'base' from which the samples would be selected. The 'base' shall be the average of the previous three months. For example, in the case of time for initial assessment of patients, this would be the average number of patients admitted per month in the preceding three months. Assuming that the average is 200, this would constitute the screening population and the organisation would have to sample 132 patients over the entire month.

*It is preferred to take samples on Stratified random basis where indicated to eliminate the bias that can occur due to convenient sampling.

No sampling means that all the occurrence in the numerator shall be recorded irrespective of rate of occurrence.

Guidance on Monitoring Medication Errors

Definition

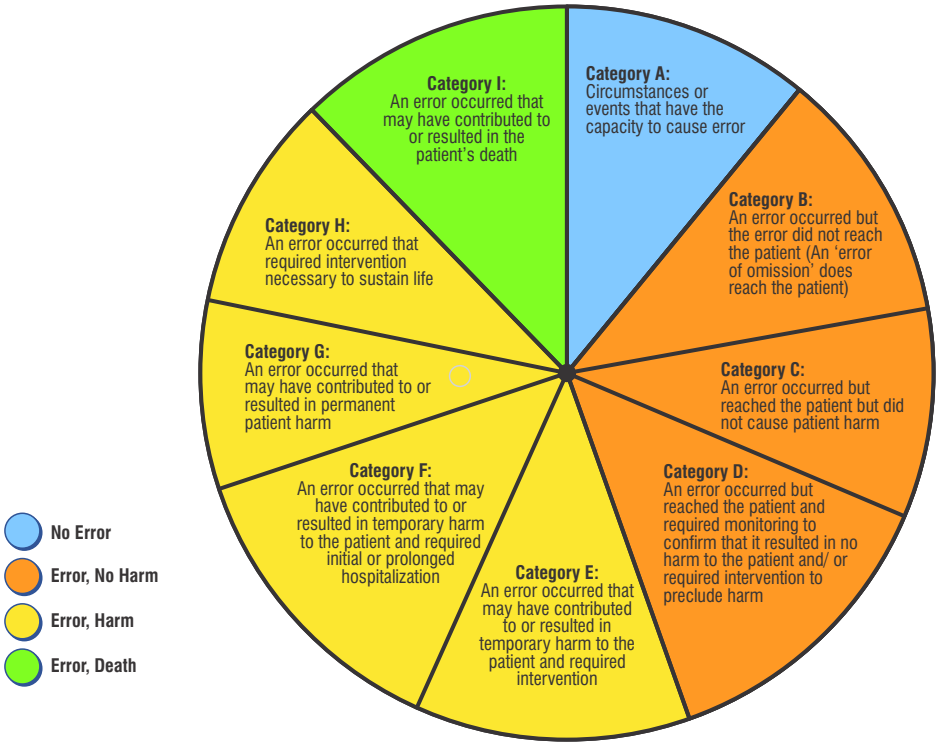
NCC-MERP (National Coordinating Council for Medication Error Reporting and Prevention) defines medication error as

"A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient or consumer. Such events may be related to professional practice, health care products, procedures and systems, including prescribing, order communication, product labelling, packaging and nomenclature, compounding, dispensing, distribution, administration, education, monitoring and use."

Categories of Medication Error

Level of Harm	Category of Error	Explanation of events/ error
NO ERROR	Category A	Circumstances or events that have the capacity to cause error
ERROR, NO HARM	Category B	An error occurred, but the error did not reach the patient (An "error of omission" does reach the patient.)
	Category C	An error occurred that reached the patient but did not cause patient harm.
	Category D	An error occurred that reached the patient and required monitoring to confirm that it resulted in no harm to the patient and/or required intervention to preclude harm
ERROR, HARM	Category E	An error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention
	Category F	An error occurred that may have contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalization
	Category G	An error occurred that may have contributed to or resulted in permanent patient harm
	Category H	An error occurred that required intervention necessary to sustain life
ERROR , DEATH	Category I	An error occurred that may have contributed to or resulted in the patient's death.

NCC MERP Index for Categorizing Medication Errors



Definitions

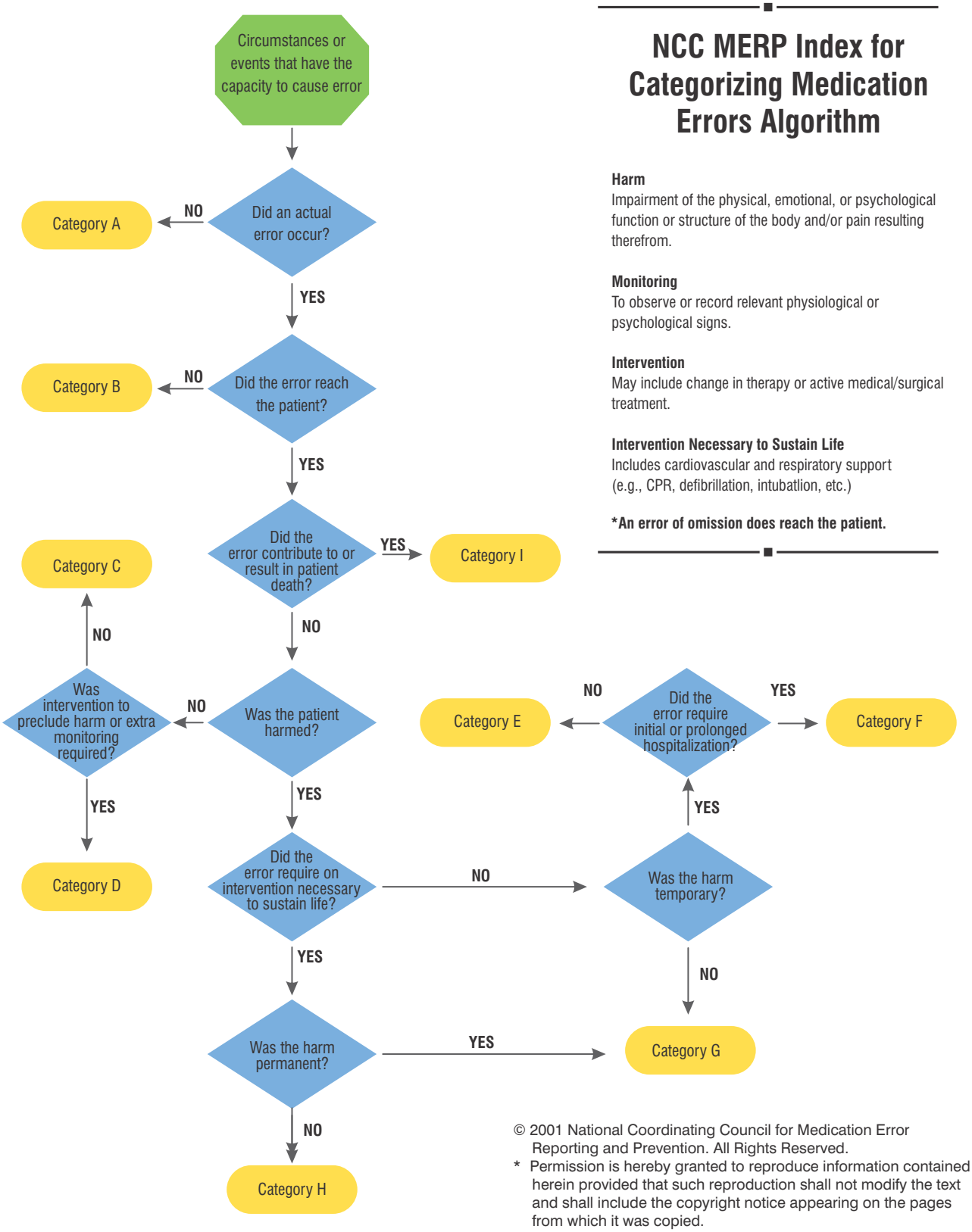
Harm
Impairment of the physical, emotional, or psychological function or structure of the body and/or pain resulting therefrom.

Monitoring
To observe or record relevant physiological or psychological signs.

Intervention
May include change in therapy or active medical/surgical treatment.

Intervention
Necessary to Sustain Life
Includes cardiovascular and respiratory support (e.g., CPR, defibrillation, intubatlion, etc.)

National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) index for categorizing medication errors. © 2001 National Coordinating Council for Medication Error Reporting and Prevention.



NCC MERP Index for Categorizing Medication Errors Algorithm

Harm
Impairment of the physical, emotional, or psychological function or structure of the body and/or pain resulting therefrom.

Monitoring
To observe or record relevant physiological or psychological signs.

Intervention
May include change in therapy or active medical/surgical treatment.

Intervention Necessary to Sustain Life
Includes cardiovascular and respiratory support (e.g., CPR, defibrillation, intubatlion, etc.)

***An error of omission does reach the patient.**

Algorithm developed by the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) for applying the NCC MERP index for categorizing medication errors. © 2001, National Coordinating Council for Medication Error Reporting and Prevention.

Methodology

Chart Review, Audit and Self Reporting of Medication Errors are preferred methods in case medication charts are documented manually in the HCO. Software programmes can be used where prescriptions are generated online.

The format for capturing medication errors by routine chart review is provided in Annexure.

The idea of trying to identify personnel involved in errors is to ensure that the organisation does a proper root cause analysis and takes appropriate corrective and/or preventive action. It is not meant for punitive action. Process improvements are a must to reduce errors.

Formula

Total number of errors identified	X 100
Total number of opportunities	

Note:
Self-reported medication errors, medication errors identified during audits or medication errors identified by any other methodology shall be added to the numerator i.e. the total number of errors identified.

Sample size

Adhere to the formula stated by NABH in its document on indicators for sample size calculation. The 'population' would be calculated from the running average of the previous three months of admissions.

Care needs to be taken to ensure that files from all clinical specialities are included. Stratified sampling will help the organisation achieve this.

Correction

Pending analysis, it is imperative that the organisation do a correction to mitigate the effect(s) of the error. An example of how correction could be done is provided below.

For category A and B	Administer the drug within a reasonable time frame
For Category C and D	Consult the clinician and follow orders accordingly

Analysis

The first step in the analysis is the collation of data. This would help identify

- Categories of error
- Personnel involved in error

The data could be collated as per the table below.

	A	B	C	D	E	F	G	H	I	TOTAL
DOCTORS										
NURSES										
PHARMACISTS										
TOTAL										

The organisation should identify the proper root cause to ensure that effective corrective and/ or preventive action are taken. It is suggested that appropriate tools are used for the same. Some of the possible causes of medications errors are provided in the table below.

People	Environment	Equipment	Process
Casual Attitude	Pharmacy- poor drug storage- poor ventilation, lighting, humidity	Defective syringe pumps	'Ten' rights not observed
Inexperienced/ New staff	Pharmacy space constraint for storage		Wrong stocking
Untrained staff	Pharmacy manpower constraint for dispensing		Wrong labelling
Shift change time/ in a hurry			Inappropriate syringe/ diluent
Emotionally unfit			No cross-checking
Physically unfit			Stock-outs

People	Environment	Equipment	Process
Casual Attitude	Pharmacy- poor drug storage- poor ventilation, lighting, humidity	Defective syringe pumps	'Ten' rights not observed
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Untrained staff	Pharmacy manpower constraint for dispensing		Wrong labelling
Shift change time/ in a hurry			Inappropriate syringe/ diluent
Emotionally unfit			No cross-checking
Physically unfit			Stock-outs
Wrong indent/ receiving			Unauthorized replacement of the drug
Patient identification error			LASA medicine error
Wrong dispensing pharmacy			
Wrong distribution GDA			
Illegible handwriting of doctors			

Some of the common corrective actions include

- Training
- Manpower recruitment
- Pharmacy stock rectification
- Equipment replacement/ rectification

Suggested Reading

1. www.nccmerp.org. National Coordinating Council for Medication Error Reporting and Prevention
2. American Society of Health-System Pharmacists. ASHP guidelines on pre- venting medication errors in hospitals. Am J Health-Syst Pharm. 2018; 75:1493–1517.
3. Nrupal Patel, Mira Desai, Samdih Shah et al. A study of medication errors in a tertiary care hospital. Perspect Clin Res. 2016 Oct-Dec; 7(4): 168–173.
4. Khandelwal AK. Getting it Right. Healthcare Radius 2014; March: 32-34

Annexure:
Medication Chart Review Checklist

Auditor: Date of Audit: Location:
UHID:

Date of Admission: Primary Consultant: Drug allergies documented: Yes/No

	Error Perpetuation (Write Category of error from A to I)# In case of no error, kindly write 0; if a particular parameter is not applicable, kindly write NA (Multiple errors can be there and documented for each row and column)									
	Drug 1	Drug 2	Drug 3	Drug 4	Drug 5	Drug 6	Drug 7	Drug 8	Drug 9	Drug 10
Doctors										
1. Incorrect drug selection										
2. No/wrong dose										
3. No/wrong unit of measurement										
4. No/wrong frequency										
5. No/wrong route										
6. No/wrong concentration										
7. No/wrong rate of administration										
8. Illegible handwriting										
9. Non-approved abbreviations used										
10. Non-usage of capital letters for drug names										
11. Non-usage of generic names										
12. Non-modification of drug dose keeping in mind drug-drug interaction										
13. Non-modification of time of drug administration/ dose/drug keeping in mind food-drug interaction										

	Error Perpetuation (Write Category of error from A to I)# In case of no error, kindly write 0; if a particular parameter is not applicable, kindly write NA (Multiple errors can be there and documented for each row and column)									
	Drug 1	Drug 2	Drug 3	Drug 4	Drug 5	Drug 6	Drug 7	Drug 8	Drug 9	Drug 10
Doctor and/or Nurse										
14. Wrong formulation transcribed/indented										
15. Wrong drug transcribed/indented										
16. Wrong strength transcribed/indented										
Pharmacist										
17. Wrong drug dispensed										
18. Wrong dose dispensed										
19. Wrong formulation dispensed										
20. Expired/Near-expiry drugs dispensed										
21. No/wrong labelling										
22. Delay in dispense > defined time										
23. Generic or class substitute done without consultation with the prescribing doctor										
Nurses										
24. Wrong Patient										
25. Dose Omission										
26. Improper Dose										
27. Wrong Drug										
28. Wrong Formulation Administered										

	Error Perpetuation (Write Category of error from A to I)# In case of no error, kindly write 0; if a particular parameter is not applicable, kindly write NA (Multiple errors can be there and documented for each row and column)									
	Drug 1	Drug 2	Drug 3	Drug 4	Drug 5	Drug 6	Drug 7	Drug 8	Drug 9	Drug 10
29. Wrong Route of Administration										
30. Wrong Rate										
31. Wrong Duration										
32. Wrong Time*										
33. No documentation of drug administration										
34. Incomplete/Improper documentation by nursing staff **										
35. Documentation without administration										
Others										

Number of errors (Number of cells having a value between A to I) =

For example, if drug 1 has an error of category C for doctors and an error of category B for Pharmacists and drug 4 has an error of category C for nurses; numerator will be 3.

#Select only one of the medication error categories or subcategories, whichever best fits the error that is being reported. In selecting the patient outcome category, select the highest level severity that applies during the course of the event. For example, if a patient suffers a severe anaphylactic reaction (Category H) and requires treatment (Category F) but eventually recovers completely, the event should be coded as Category H.

* Deviation from the organisation's defined timeframe for the administration of drugs for which the time has not been written. The basis for stating 'wrong time' should be evidence-based. The organisation could adopt/adapt the ISMP Acute Care Guidelines for Timely Administration of Scheduled Medications.

**Incomplete documentation includes the missing date, time, signature. Improper documentation includes writing the wrong dose like instead of stating ½ tablet of 500 mg is administered, stating that 1 tablet of 250 mg was administered (based on how the medication order was written) or not stating the actual brand that was administered in cases of brand substitution.

Quality Tools

Quality Tools: QI data should be analysed using statistical/quality tools to assess compliance with the targets and identify areas for improvement.

Root cause analysis (RCA): RCA a very commonly used tool and is carried out for establishing causality when adverse trends are noted for any parameter or in the case of errors/incidents. RCA is a systematic, extensive and in-depth analysis of a problem with the view to get to the bottom of the problem. RCA is carried out by using either the 5 Why's Tool or the Cause and Effect Diagram.

5 Whys' tool (Taiichi Ohno), helps teams look beyond obvious and initial symptoms by asking "Why?" five times, sequentially in response to the first answer, till one reaches the root cause. As a result the focus(blame) shifts from individuals to the process. There may be multiple root causes of a problem; different people who see different parts of the system may answer the questions differently. The 5 whys has come under criticism for overly simplifying the problem on hand. The cause(s) of a problem and how to address them are likely to be understood more effectively by using multiple 5 Whys in conjunction with a Cause and Effect Diagram.

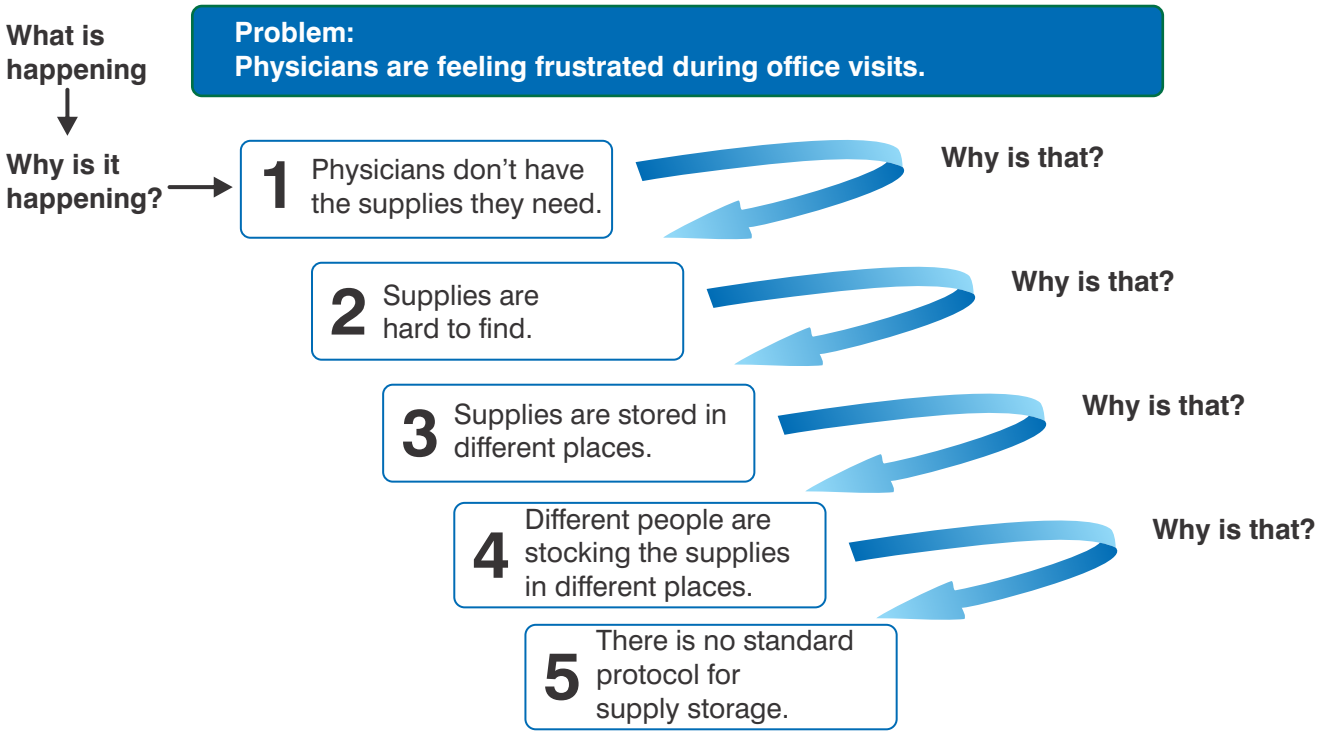

Figure 1: Illustration of 5-Why's Approach for carrying out a root cause analysis. (https://www.aafp.org/fpm/2007/0500/p30.html accessed on April 30, 2022)

Cause and Effect Diagram: Also known as Ishikawa or fishbone diagram, graphically displays the relationship of the many causes to the effect, and to each other; helping teams identify areas for improvement. A line runs horizontally from the tail to the head of the fish, where the effect is written. Causes are grouped under the categories of Materials, Methods, Equipment, Environment, and People or as required.

The tool is used extensively to reach the root cause of deviations from any policy, procedure or protocol and outliers for indicator data and for detailed analysis of incidents and adverse events.

For e.g. Fish bone/cause and effects diagrams can be used to identify the causes of underuse of the electronic health records in a hospital setting by the doctors and nurses.

Affinity Diagram: These diagrams serve the same purpose as the Ishikawa charts but the visual presentation differs..

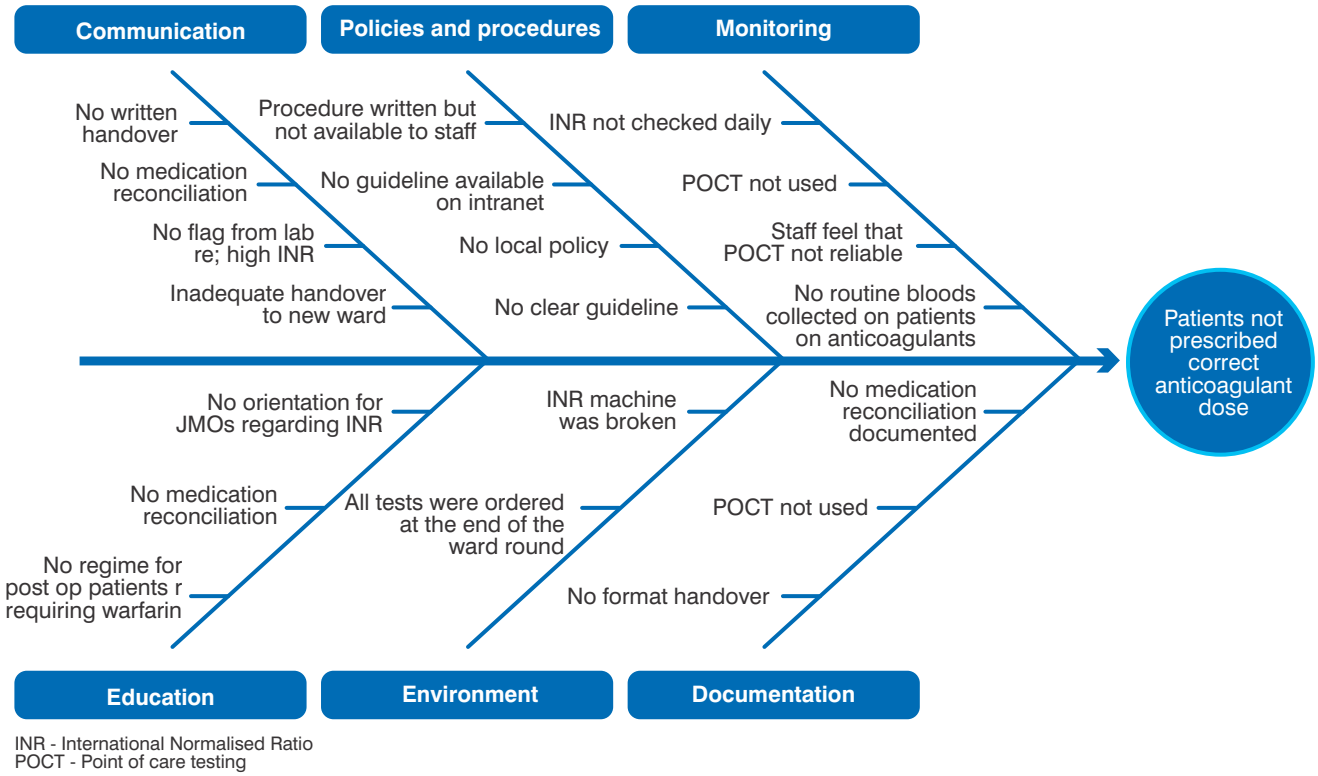

Figure 2 : Example of a Cause & Effect Diagram by Clinical Excellence Commission. Reasons why patients are not on a standardised anticoagulation pathway (https://www.cec.health.nsw.gov.au/CEC-Academy/quality-improvement-tools/cause-and-effect-diagrams)

Histogram: A histogram is a bar chart used to display variation in continuous data like time, weight, size, or temperature. It helps to recognize and analyse patterns not apparent by looking at data tables, or by finding the average or median and will effectively highlight the interval that is most frequently occurring.

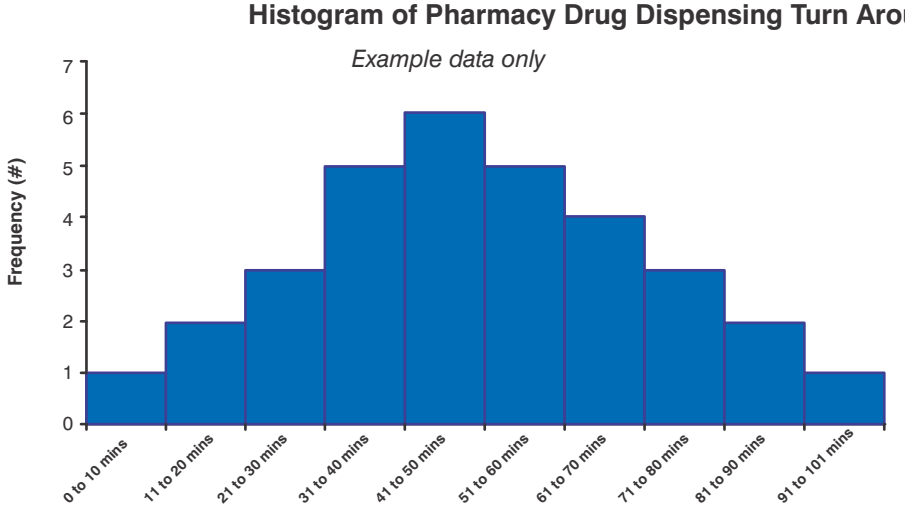

Figure 3: Histogram on Turnaround time for dispensing of the drug (https://www.cec.health.nsw.gov.au/CEC-Academy/quality-improvement-tools/histogram accessed on April 30, 2022)

Failure Modes and Effects Analysis(FMEA): FMEA is a tool for conducting a systematic, proactive analysis of a process in which harm may occur and prevent it by correcting the processes proactively, rather than reacting to adverse events after failures have occurred. The FMEA tool prompts teams to review, evaluate, and record the following:

- Steps in the process
- Failure modes (What could go wrong?)
- Failure causes (Why would the failure happen?)
- Failure effects (What would be the consequences(severity and frequency) of each failure?)
- How can the failure be prevented?

The tool forms the core of risk assessment and risk mitigation. FMEA is particularly useful in

evaluating a new process prior to implementation and in assessing the impact of a proposed change to an existing process.

Step in the process	Failure Mode	Failure Causes	Failure Effects	Likelihood of Occurrence (1-10)	Likelihood of Detection (1-10)	Severity (1-10)	Risk Profile Number (RPN)	Action to Reduce Occurrence of Failure
1								
2								
3								

Figure 4 : Institute of Healthcare Improvement's format for Failure Mode Effect Analysis
(http://www.ihi.org/resources/Pages/Tools/Quality-Improvement-Essentials-Toolkit.aspx accessed on April 30, 2022)

Flowchart (process map): Flow charts help understand a process in depth through visual representation of its steps; and should be prepared in early phase of improvement work. It is a road map of where things are happening, the order in which things happen and the relationships between parts of a process. A Flow Chart is recommended as the first step in almost any study. Often a Flow Chart may reveal that a process does not operate the way management or the operators in the process actually think it does. A high level flow is chart is

prepared first to give a helicopter's view of the process followed by a detailed flow chart. Flow charts help identify gaps in the process, its bottlenecks, wasteful/unnecessary processes, delays, duplication, breakdowns in communication, and also how to improve the process. Improvement work can be focussed on these steps. An example of the same is given below-

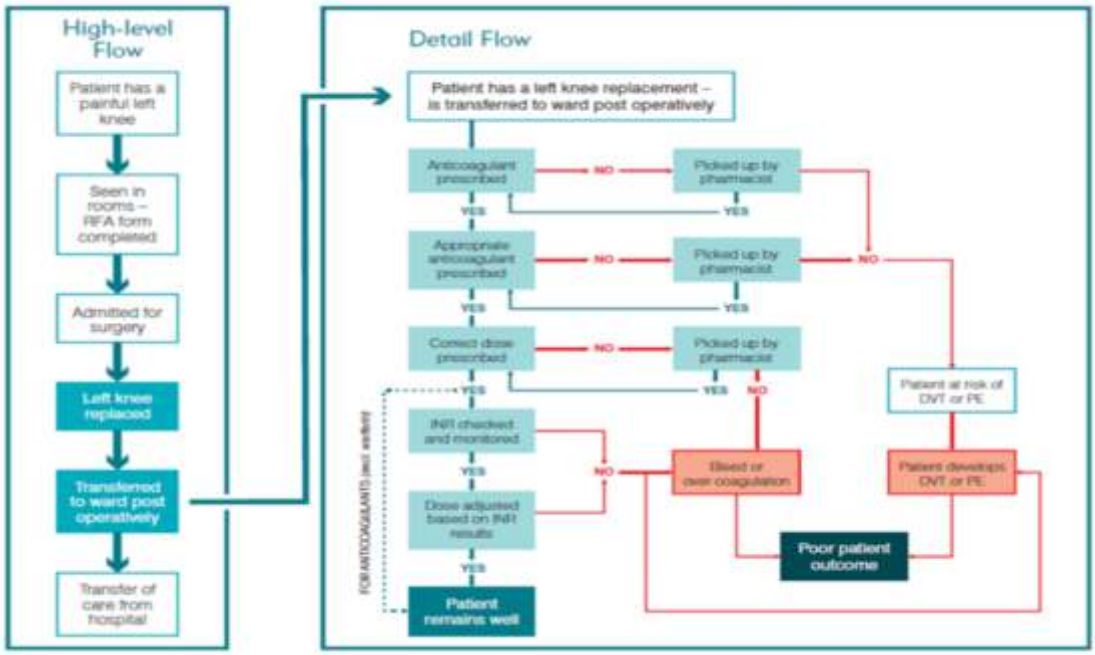

Figure 5: Flow chart of a patient's journey within the hospital
(https://www.cec.health.nsw.gov.au/CEC-Academy/quality-improvement-tools/flow-charts accessed on April 30, 2022)

Pareto Chart: The "Pareto Principle" is the "80/20 rule" and works on the theory that roughly 80% of the effect comes from 20%("the vital few") of the causes. The "vital few" are easily distinguished from the "useful many" by plotting them as a bar diagram. Teams can prioritize and focus improvement efforts on the vital few. The example given below shows a Pareto Chart of types of medication errors. An audit of 430 medication errors was conducted to determine the categories (types) of errors and their frequency. The results were collected initially in a Tally Sheet(a simple sheet which collects data real time and indicates the frequency of occurrence of events) then the data was placed in descending order of frequency in a Pareto Chart Template in Excel. The types of errors that fall under the 80% cut off line indicate the 'vital few' types of medication error that should be addressed as a priority as they contribute most to the problem ie:

- Dose missed
- Wrong time
- Wrong drug
- Over dose

The types of medication errors that fall above the 80% cut off line are known as the 'trivial many' and are generally seen as not a high priority to address when compared to the 'vital few' factors.

A Pareto chart can also be used to study the occurrence of incidents/care management events (medication errors, pressure ulcers, IV complications etc.). Data for a Pareto Chart can also be collected after a braining

storming session by putting together the number of votes cast for the proposed reasons for incidents, adverse trends of indicator data etc.

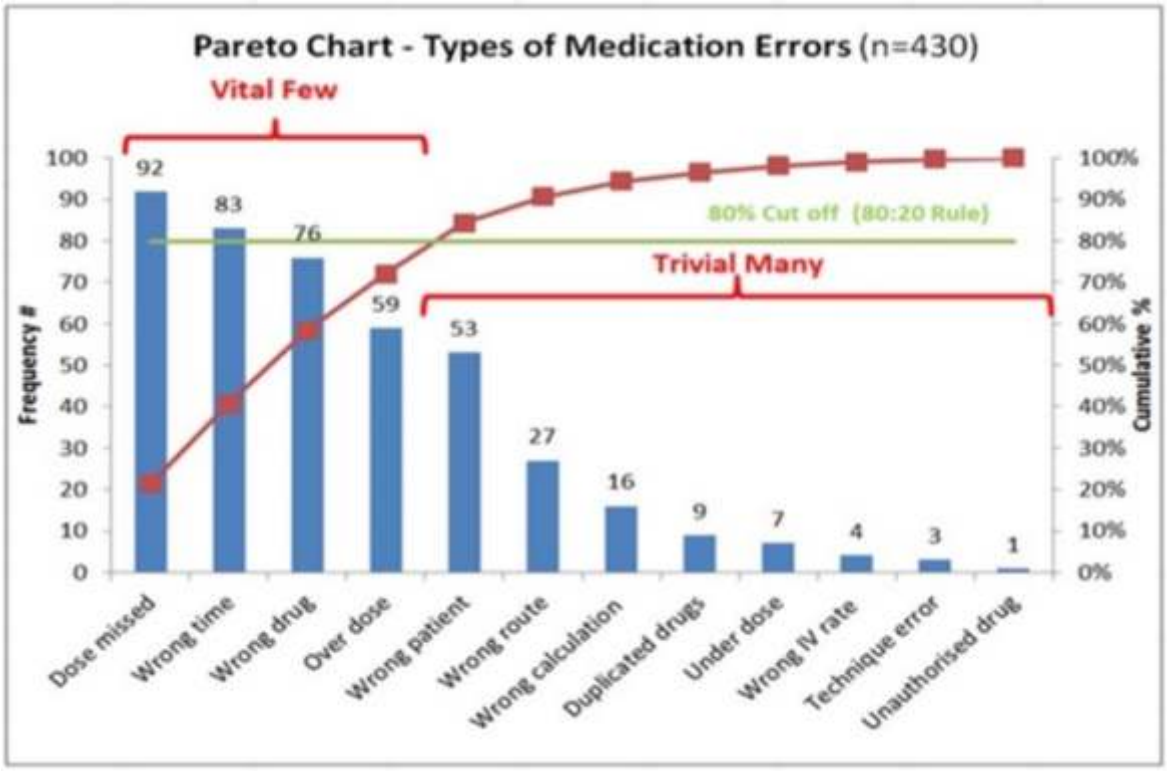

Figure 6: Pareto Analysis of Medication Error in a hospital

Run Chart & Control Chart: A run chart is a graph of data over time and assess variations in performance over a period of time and indicate trends. A control chart, with an upper (UCL) and a lower control limit (LCL), distinguishes between common and special causes of variation within a process.

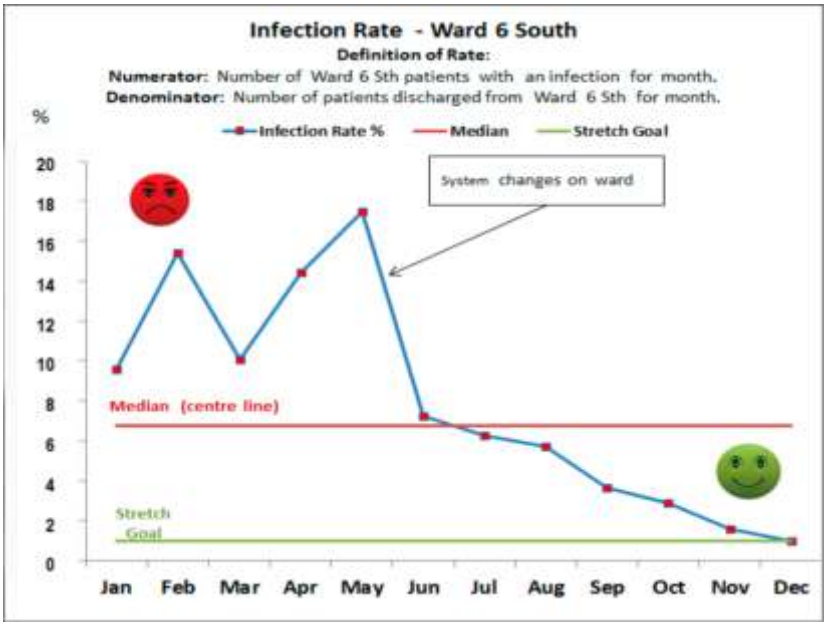

Figure 7: . Simple Annotated Run chart with UCL and LCL of an infection rate over time
(https://www.cec.health.nsw.gov.au/CEC-Academy/quality-improvement-tools/run-charts accessed on April 30, 2022)

Driver Diagram: A driver diagram is a visual display of what "drives," or contributes to, the achievement of a project aim. driver diagram organises information on proposed activities so the relationships between the aim of the improvement project and the changes to be tested and implemented are made clear. The **primary drivers** (sometimes called "key drivers") contribute directly to achieving the aim. The secondary drivers are components of the primary drivers, and **specific change ideas to test** for each secondary driver.

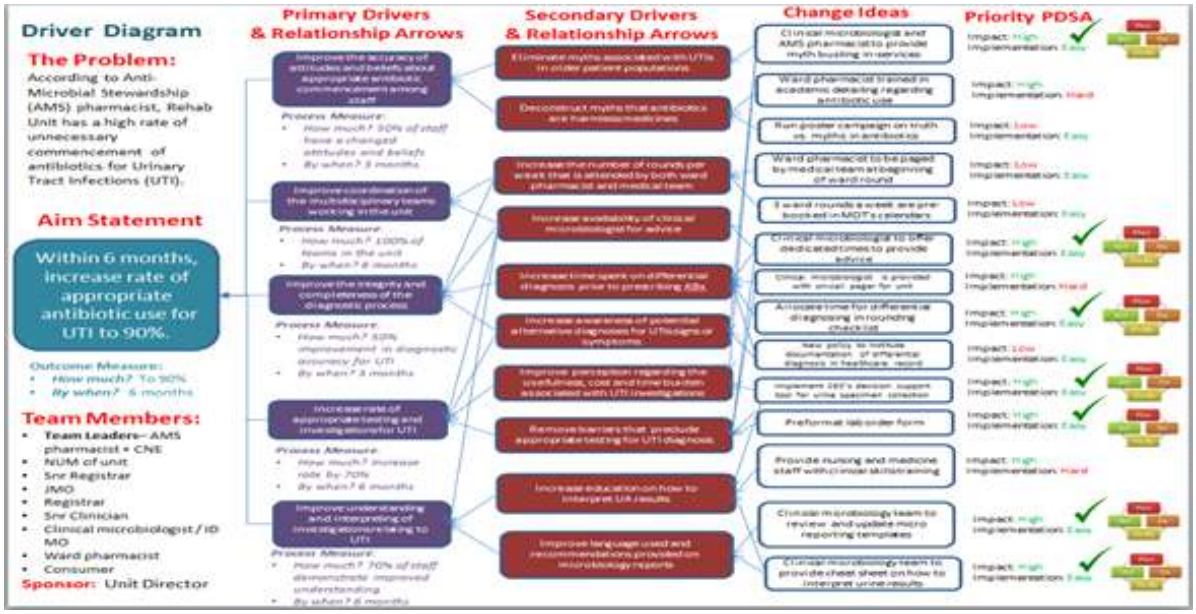

Figure 8: Driver Diagram (https://www.cec.health.nsw.gov.au/CEC-Academy/quality-improvement-tools/driver-diagrams accessed on April 30, 2022)

Scatter Diagram/Plot: Scatter diagrams are used to identify cause-and-effect relationships between two variables. A scatter diagram does not prove causation.

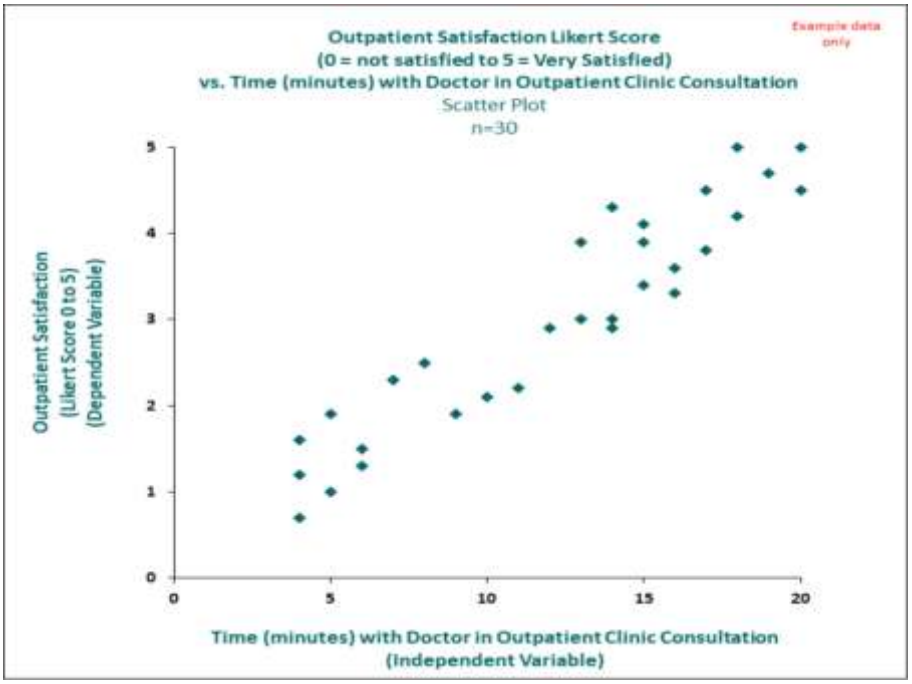

Figure 9: Scatter diagram showing patient satisfaction using likert's score v/s time with doctor consultation (https://www.cec.health.nsw.gov.au/CEC-Academy/quality-improvement-tools/scatter-plot accessed on April 30, 2022)

Project Planning Form: This tool helps teams think systematically about their improvement project. It tracks various elements like Plan-Do-Study-Act (PDSA) cycles.

Quality improvement technique/tool	Decisions	Describe problem	Cause analysis	Develop action plan	Monitor progress
Histogram		Yes		Yes	Yes
Pareto Chart	Yes	Yes		Yes	Yes
Driver Diagram	Yes	Yes		Yes	
Flow chart/					
Process Map		Yes		Yes	
Run chart	Yes				Yes
Scatter Diagram/Plot	Yes	Yes			
Fishbone diagram		Yes	Yes		

Continuous Quality Improvement(CQI): CQI is a progressive incremental improvement of processes, safety, and patient care. Introduced by Shewhart and propagated by Deming, CQI is an analytical decision making tool which allows one to see when a process is working predictably and when it is not.

The Model for Improvement(MFI): The MFI asks three fundamental questions before embarking on a quality improvement project, which can be addressed in any order.

- What are we trying to achieve?
- What changes can we make that will result in an improvement?
- How will know that the change is an improvement?

This is followed by PDSA cycles to test changes in real work settings to determine if the change is an improvement.

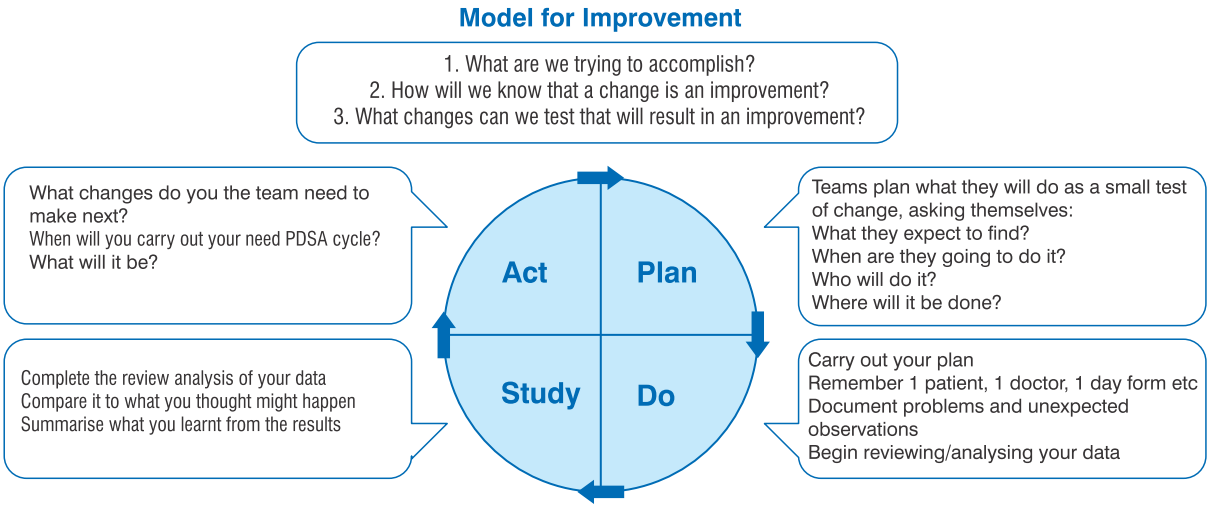

Figure 10: Model for Improvement and PDSA (https://www.cec.health.nsw.gov.au/CEC-Academy/quality-improvement-tools/model-for-improvement-and-pdsa-cycles accessed on April 30, 2022)

Models for CQI : The most common CQI methodologies used in healthcare are the API's Model for improvement(MFI), FOCUS plan-do-study-act (PDSA), Six-Sigma, and Lean strategies. They typically include testing of ideas and redesign of process or technology based on lessons learned. Steps involved in CQI are Plan-Do-Study-Act (PDSA) cycle. The MFI and FOCUS frameworks have been developed to precede the use of **PDSA and PDCA cycles** respectively.

PDSA/PDCA cycle: Involves a sequence of 4 repetitive steps, Plan-Do-Study/Control-Act, eventually leading to exponential improvements 'Plan' phase involves detailing ideas for improvement, 'Do' phase involves implementation and defect prevention. 'Study' phase involves review and analysis of data(Adapt/Adopt/Abandon the change and repeat PDSA). 'Act' phase includes incorporation of lessons learnt into the test cycle. The cycle is repeated again and again as waves of small improvements are considered, tested, evaluated, and incorporated, if effective. This is the most commonly used tool for clinical audits.

FOCUS-PDCA: This model also has two phases. The 'FOCUS' phase focusses attention at the opportunity to improve, and the 'PDCA' phase for pursuit of improvement and assessment of effectiveness of the interventions.

- F = Find what needs to be improved on;
- O = Organize team with good knowledge in the process
- C = Clarify the present knowledge of the process
- U = Understand factors responsible for variations
- S = Select interventions that evidently might improve process

Six-sigma: Six-sigma is a widely used model that is now making steady in-roads into medicine. It seeks to improve performance through identifying causes of process defects/errors and eliminating them. At Six Sigma, error rates should be less than 3.7/million opportunities. Two methods have mainly been employed-DMAIC and DMADV. DMAIC is applicable for existing process improvement; DMADV is used for new design process optimization.

Lean and Lean-Sigma : Originated by Toyota Inc., Japan, this model is essentially geared towards improving process / product / service flow and eliminates waste by identifying and removing non-value added steps Embracing Lean in healthcare, eliminates waste throughout the entire operational system; whilst simplifying and improving the processes, resulting in low cost of production and fast through-put times. A few establishments, have combined Lean and Six Sigma concepts to obtain better quality improvement effects. Such a combination is known as Lean-Sigma.

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