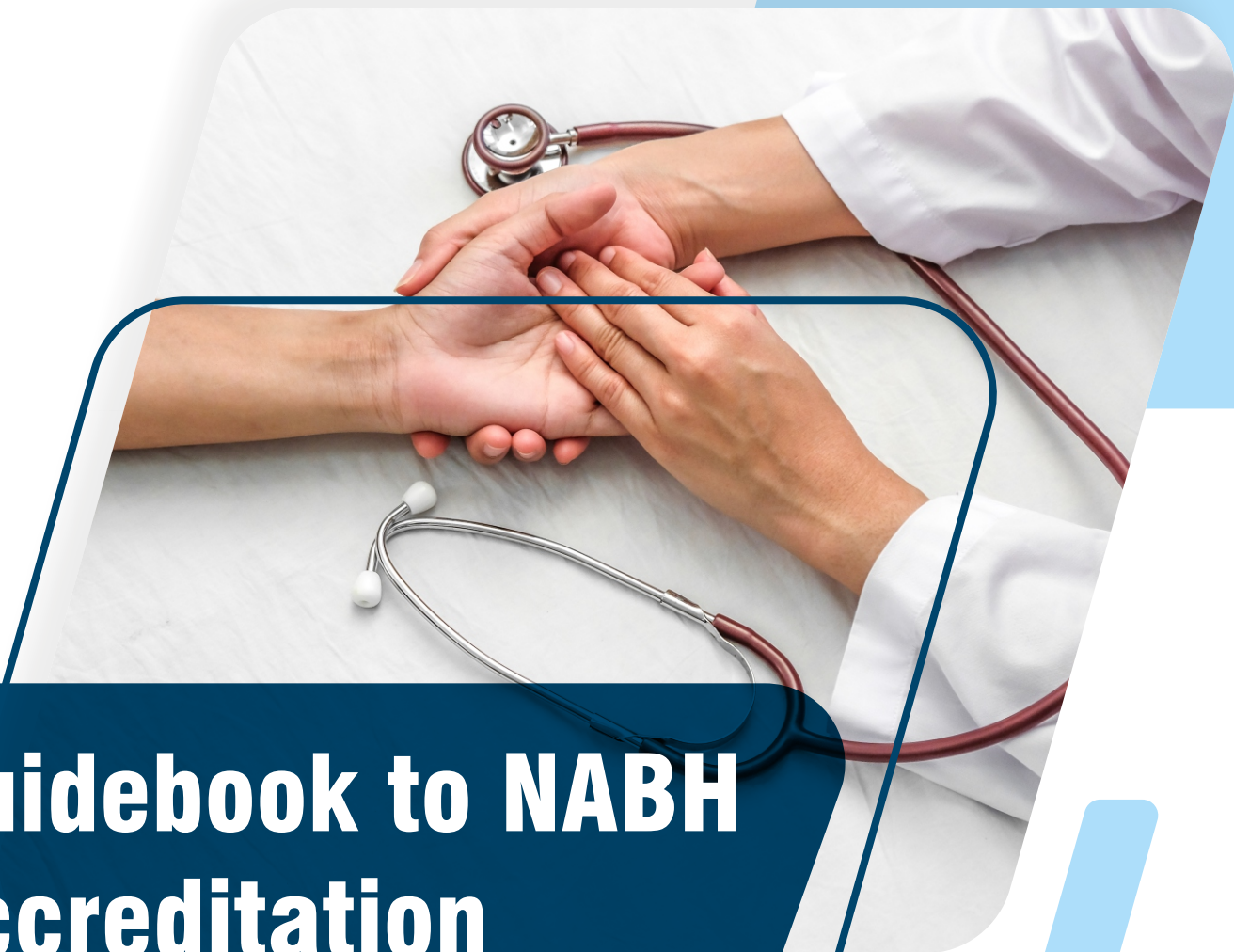


NATIONAL ACCREDITATION BOARD FOR  
HOSPITALS AND HEALTHCARE PROVIDERS (NABH)



# **Guidebook to NABH Accreditation standards for Allopathic Clinics**

**2<sup>nd</sup>  
EDITION**  
JUNE 2023



# **National Accreditation Board For Hospitals and Healthcare Providers (NABH)**

ISBN 978-81-959-6767-4



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2<sup>nd</sup> Edition June 2023

# Foreword

National Accreditation Board for Hospitals and Healthcare Providers (NABH), is in its 18th year of creating an ecosystem for quality in healthcare in India. NABH standards focus on safety and quality of the delivery of services by the organizations in the changing healthcare environment.

The Allopathic Clinics standards were first released in the year January 2011 with an aim to mainly cater the small clinics having only OPD facilities and no inpatients. With the feedback from stakeholders and the need of existing healthcare industry in India, the second edition has been made comprehensive including the emerging facilities of Day care, standalone facilities of Dermatology and Dialysis centres.

The second edition standards focus on achieving patient safety for both smaller & large set ups in the country, thus designing the objective elements as Core, Commitment, Achievement and Excellence.

The 10 chapters approach, as for accreditation standards, has been introduced, (from the earlier 8 chapters) with a total of 174 objective elements out of which 52 are in Core category which will be mandatorily assessed during each assessment, 107 are in Commitment category which will be assessed during the Final Assessment, 13 are in Achievement category to be assessed during Surveillance Assessment and 02 are in Excellence category which will be assessed during re-accreditation.

This objective methodology will aid any clinic (Small / Medium / Large) in a stepwise progression to mature quality system over the full accreditation cycle. The scoring methodology is in a graded scheme to help recognise every progressive effort by the organisation in the implementation of the standards. The accreditation will be a four-year cycle with a midterm Surveillance Assessment at 21-24 months of accreditation.

I sincerely hope that clinics will certainly benefit from the collective efforts of Technical Committee of NABH and practical suggestions of stakeholders involved in formulating the standards.

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

I acknowledge the contributions of the following in preparing 2nd Edition of Allopathic Clinics accreditation standards of NABH.

Mr. Jaxay Shah, Chairman QCI, whose idea to provide quality healthcare to the last mile has encouraged NABH to have standards which are easy to comprehend and understand. I thank him for his active support and encouragement inspite of his busy schedule.

I express my gratitude to Prof (Dr) Mahesh Verma, Chairman NABH for his constant guidance and recommendations for betterment of the services. I also convey sincere thanks to Dr Ravi P Singh, Secretary General of Quality Council of India for his continuous support by making adequate resources available. I thank all Board Members of NABH in giving significant suggestions for betterment of the standards and the respective guidebook.

The Expert group of NABH, Technical Committee of NABH worked relentlessly and meticulously to accommodate the best practices in clinics, referred to innumerable references and incorporated suggestions made by all of the stakeholders in bringing this standard to reality. I profoundly thank all the members for playing a pivotal role in the development of the 2nd edition of Allopathic Clinics accreditation standards.

I thank industry experts who have spared time and given their suggestions in making the standards easy to understand and comprehend. The contributions of IADVL members in streamlining Dermatology standards is worth mentioning who as clinicians have a drive for quality and accreditation. I also thank the members of NATHEALTH- Healthcare Federation of India, Dialysis Service Providers Association of India (DSPAI) who have helped the standards having a practical approach and given their valuable suggestions as and when required. Thank you to the industry for being the driving force behind the formation of the standards.

I thank all our passionate assessors, management of the clinics, 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 these standards in the current detail and format.

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



**Dr Atul Mohan Kochhar**  
CEO, NABH

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# 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/Nursing Homes, Blood Banks, Eye Care hospitals/clinics, Oral Substitution Therapy Centres, Community Health Centres/Primary Health Centres, Ayush (Ayurveda, Homeopathy, Unani, Siddha and Yoga and Naturopathy) hospitals, Medical Imaging Services, Dental Centres, Allopathic Clinics, Ethics Committees and Panchkarma Clinics.

**NABH Certification Programmes:** NABH offers certification to Medical Laboratory, Nursing Excellence, Emergency Department, Entry Level for Hospitals, Entry Level Ayush Hospitals and Entry Level Ayush Centres.

**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 and Education :** NABH conducts Education/Interactive Workshops, Awareness Programmes, and Programme on Implementation (POI) on a regular basis.



# Introduction

## DEFINITION OF CLINIC:

**A healthcare facility that provides patient care services** by Doctors registered with Medical Council of India/National Medical Council or State Medical Council (practicing Allopathic medicine).

The Clinic may be located in the community or in the premises of an organization, such as school, factory, etc. and includes healthcare facilities:

S.no.	Healthcare facility	Definition
1.	Clinic	A Single Doctor running healthcare facility (other than OPD of a hospital) providing patient care services
2.	Polyclinic	A Clinic where multiple doctors either from same speciality or different speciality provide patient care services
3.	Dispensary	A Clinic, where along with consultation for patients, medicine is dispensed.
4.	Day Care Clinic*	Day Care clinic is the facility that has admitting beds for limited time period for providing patient care services (barring overnight stay).

\* The services include treatments such as ambulatory surgical procedures, dialysis, chemotherapy etc.

## In addition, a “clinic” may have add on services as follows:

Diagnostic services such as:

- Clinico-diagnostic examination (e.g. Endoscopy)
- Procedures
- Laboratory-pathology, imaging etc

Therapeutic services such as:

- Intervention
- Pharmacy etc.

Support services such as:

- Physiotherapy
- Occupational therapy
- Nutrition
- Counseling Services (e.g. Psychology Counseling)

**In the Standard, the Clinic/Poly Clinic/Dispensary/Day care Clinic hereinafter will be referred to as “Clinic”**

These Standards are NOT APPLICABLE for non-allopathic systems of medicine such as Ayurvedic, AYUSH, homeopathic, wellness centres Alternative medicine streams etc

**Exclusions:**

1. Molecular Pathology/Biology Laboratory
2. Genetic Counseling
3. Immuno-histochemistry Lab
4. Flow-cytometry
5. MRI
6. Eye Clinic
7. PET Scan
8. Nuclear Scan

**Note :** The document contains allopathic standards along with specific Dermatology and Dialysis care standards.

In case the clinic is providing Dermatology services, Dermatology specific standards requirements are to be adhered to, which is provided in chapter Management of Dermatology services along with the Allopathic clinic standard requirements.

In case the clinic is providing Dialysis services, Dialysis specific standards requirements are to be adhered to, which is provided in chapter Management of Dialysis Care along with the Allopathic clinic

# Scope and Purpose of the Standards

## SCOPE OF THE STANDARDS

These standards are applicable for health care organization willing for Allopathic clinic accreditation program provided that health care organization 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.

Organisations may have different services and it is equally applicable to all services and both public and private hospitals.

## PURPOSE OF THE STANDARDS

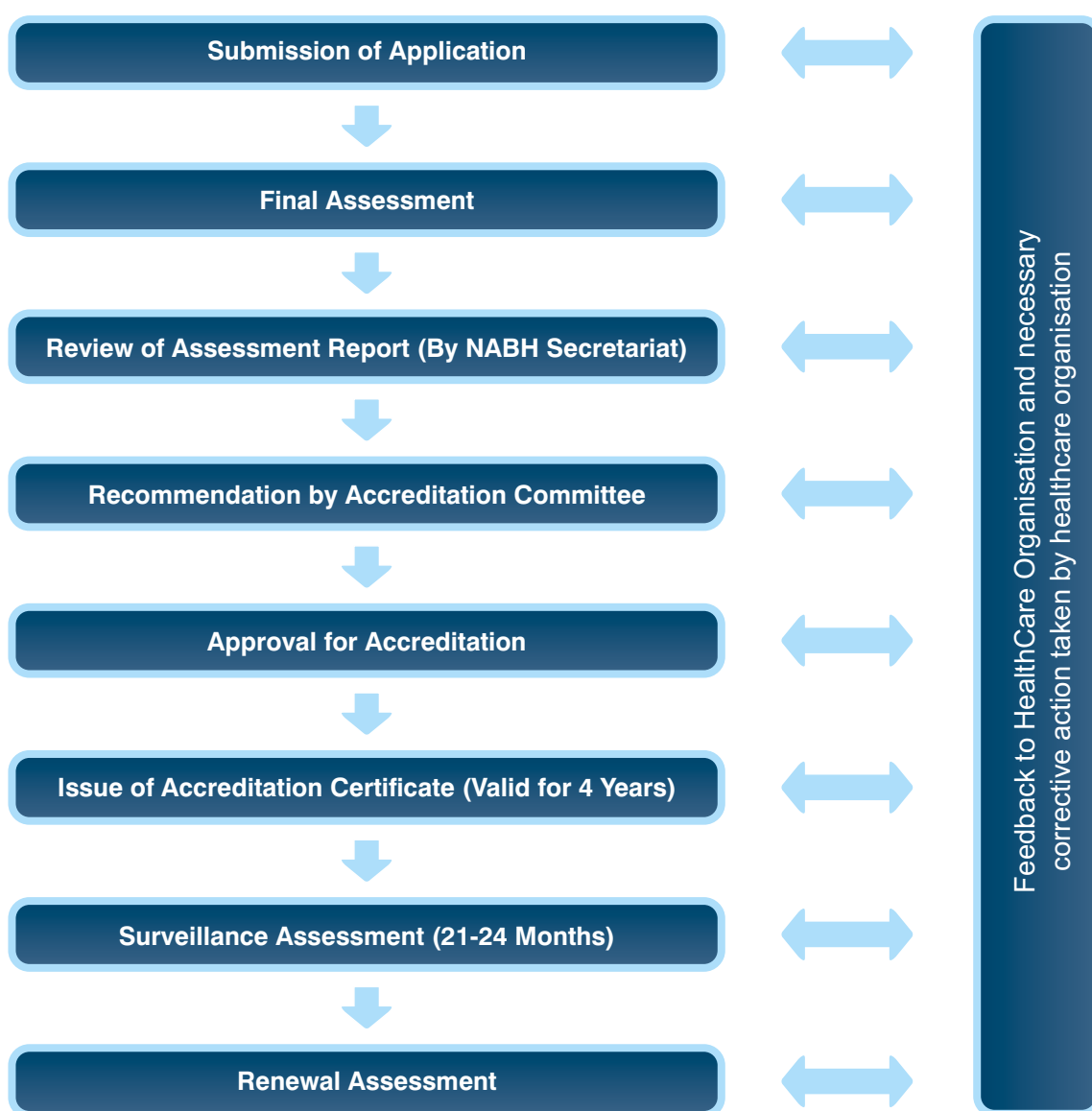
The aim of the standards is to achieve an acceptable level of performance with a view to:

- Improve public trust and community confidence that the organization 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 a Allopathic clinics;
- 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 Allopathic clinics;
- Provide an opportunity to explore compliance expectations of standards and the additional requirements related to safety and regulation.

# Overview of the NABH Accreditation Process



\*For Renewal Assessment, the accredited clinic must apply six months prior to the expiry of the validity of accreditation

# 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 (AAC)'.

## 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.b. would mean that it is the second 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 to.

## CORE OBJECTIVE ELEMENT

Certain standards in the standard have been designated as Core Standard. These are standards that the organisation should have in place to ensure the quality of care or the safety of people within the organisation. CORE has been used to identify such standards.

## LEVELS

The rest of the standards have been divided into three levels, namely commitment, achievement, and excellence. This has been done keeping in mind the fact that quality is a journey and that accredited organisations need to improve constantly. Most of the objective elements would be at the commitment level, and these would form the basis for accreditation at the end of the final assessment. The level of compliance with the standards placed at the achievement and excellence level would also count towards continued accreditation.

## OTHER SECTIONS INCLUDED IN THE STANDARD BOOK

- About NABH
- Scope and purpose of the standards
- Overview of the NABH accreditation process
- Scoring
- Accreditation decision and maintenance of same
- 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 etc.

## 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:

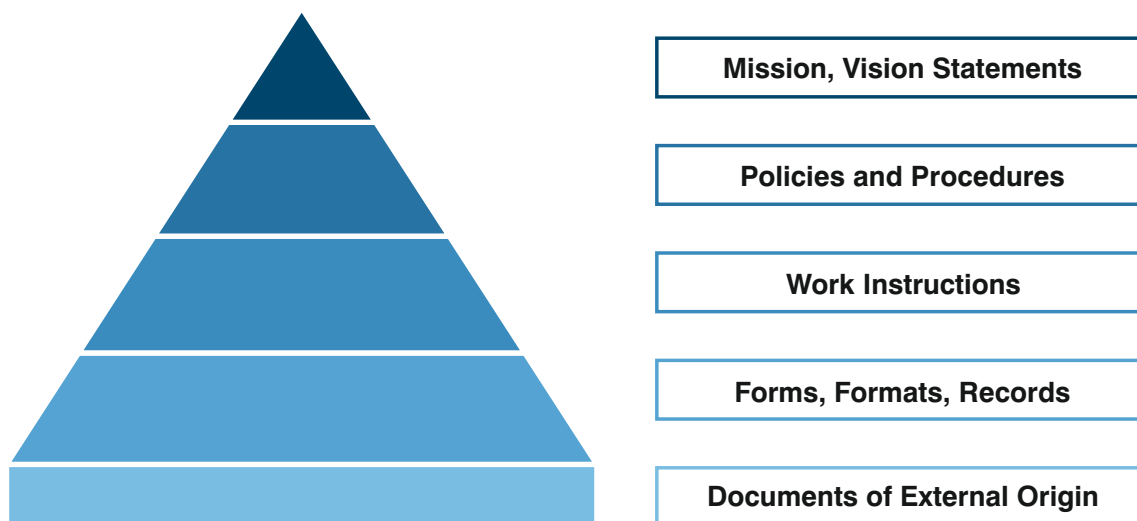
1. **Policy Documents:** Mission statement, vision statement, strategic plans and policies which transcend time and act as guidance in the changing scenarios of the operational, legal, technologically changing environment in which the organisation conducts its activities are policy documents. They are the principles on which planning is based while adapting to changes.



2. **System Documentation:** Operational and quality system documentation to carry out 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. 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 for which the organisation exists.

**Policies:** These are statements that transcend time to decide on the way the activities of the organisation shall 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, they 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. They can be in the form of multiple manuals specific to departments, or 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 organisations which 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 are reluctant to alter these documentations mistaking the word standard for unalterable, sometimes even after their processes have changed.

**Forms and formats:** Capture of information in a complete and relevant manner 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 entries are made. The purpose 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. An example of the former is tick marking when some action was carried out and an example of the latter being an elaborate record of the initial assessment of a patient on arrival to the ward. 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 which is rarely required.

**Documents of external Origin:** For the sake of making the documentation system inclusive, some organisations include documents of external origin in their documentation system. These are licenses, statutory documents, memoranda of understanding with various organisations, etc. and are not alterable.

**Temporary Document:** Many notes, documents, records get created in an informal manner 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. These documents are 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 a 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?**

Organisations sometimes fall into a dilemma about the extent of documentation that should be followed.. 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 a uniform format to ensure uniformity in visual appearance of documents to cover their appearance, fonts, symbols, page layout, etc.
- Adding colour codes, font changes for different documents.
- Participation of staff that is involved in carrying out the activities in the development process for documentation.
- Using the same language and structure 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 real time.
- If necessary replicate the documentation related to specific processes and procedures within all relevant documents 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 above, documents bring uniformity and clarity for 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 purpose. Such documents are known as controlled documents. All types of documents described above come under this category, except for temporary documents.

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 (control box) or otherwise at the top of the document. This information is an integral part of each controlled document. The designation of authorised staff for preparation/review/release or issue of 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 these documents 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 the Document:

Purpose of the Process that is documented

Start point

End Point

Procedure:

Step 1: XXXXXXXXXXXXXXXX

Step 2: XXXXXXXXXXXXXXXX

Step 3: XXXXXXXXXXXXXXXX

Step n: XXXXXXXXXXXXXXXX

Related Records

## 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 a manual is similar to the SOPs but has reference to or duplication of departmental SOPs that have relevance to the subject of the manual, and are required to be duplicated for coherence and completeness.

# Scoring

The objective elements stated in the standards are scored during the assessment. The same should also be used for scoring during the self-assessment. This scoring is to be done using a five-point scale. When applying a score, the following rationale to determine the level of compliance shall be used.

Score	Rationale
1	<b>No compliance</b> <ul style="list-style-type: none"><li>• No systems in place and there is no evidence of working towards implementation</li><li>• None or little (<math>\leq 20\%</math>) of the samples meet the requirement(s) of the objective element</li><li>• Non-conformity exists</li></ul>
2	<b>Poor compliance</b> <ul style="list-style-type: none"><li>• Elementary (limited) systems in place and there is some evidence of working towards implementation</li><li>• Minimal (between 21-40%) of the samples meet requirement(s) of the objective element</li><li>• Non-conformity exists</li></ul>
3	<b>Partial compliance</b> <ul style="list-style-type: none"><li>• Systems are partially in place, and there is evidence of working towards implementation</li><li>• Some (between 41-60%) of the samples meet the requirement(s) of the objective element</li><li>• Non-conformity exists</li></ul>
4	<b>Good compliance</b> <ul style="list-style-type: none"><li>• Systems are in place, and there is evidence of working towards implementation</li><li>• The majority (between 61-80%) of the samples meet the requirement(s) of the objective element</li><li>• Non-conformity could exist</li></ul>
5	<b>Full compliance</b> <ul style="list-style-type: none"><li>• Systems are in place, and there is evidence of implementation across the organisation</li><li>• Almost all (between 81-100%) of the samples meet the requirement(s) of the objective element</li><li>• No Non-conformity</li></ul>

The basis for scoring shall be implementation. However, if there is inadequate/inappropriate system documentation, the score could be downgraded by one.

## **NOT APPLICABLE (NA) CRITERIA**

There could be a few standards/objective elements that may not be applicable to some organisations. A standard/objective element may be described as not applicable when the statement/content of the element would never occur in the organisation. The organisation has to identify such standard/objective element before the assessment and inform the NABH secretariat of the same. During the assessment, the assessment team shall discuss the same with the organisation and a final list shall be arrived at.

# Accreditation Decision and Maintenance of same

After the completion of the final assessment, the assessment team submits the report and the score sheet to the National Accreditation Board for Hospitals and Healthcare Providers (NABH). The organisation is expected to submit an action plan with timelines for rectifying the identified non-conformities. The action plan is reviewed by the assessment team, and a comment is placed indicating acceptance or non-acceptance.

The accreditation committee reviews the assessment report, the score sheet and the submitted corrective actions, Manpower and the assessment team's comments regarding the same. Following the review, a decision is taken.

## ACCREDITATION DECISION CRITERIA FOLLOWING THE FINAL ASSESSMENT

For an organisation to be accredited by NABH, an overall compliance rate of at least 80% must be achieved, and the following rules must be met:

1. The score for every core objective element must not be less than 4.
2. No individual standard should have more than one objective element scored as 2 or less.
3. The average score for individual standards must not be less than 4.
4. The average score for an individual chapter must not be less than 4.
5. Every objective element with a score of 3 or below should have an accepted action plan with timelines.

**Note:** The cumulative score obtained for all objective elements is considered for calculating the overall compliance. At the end of the Final assessment, only the objective elements marked as 'core and commitment' level are considered for scoring. Hence, the overall compliance of 80% corresponds to a score of numerator (135x4) and denominator (135x5) i.e.  $540/675 = 80\%$ . In case of the not applicable objective element(s), the scoring is modified accordingly by excluding them from the numerator and denominator.

## AWARD

If the organisation meets the criteria listed above, the organisation will be awarded accreditation status for four years with effect from the date of the Accreditation Committee meeting when the result is formally approved.

## MAINTAINING THE AWARD

The standards are designed to measure and support the continual improvement of an organization's operation. Continuing accreditation status will be subject to the outcome of the surveillance assessment and the re-accreditation assessment. The criteria for maintaining accreditation following these assessments are listed below.



## ACCREDITATION DECISION CRITERIA FOLLOWING THE SURVEILLANCE ASSESSMENT

For an organisation to continue to be accredited by NABH, an overall compliance rate of at least 80% must be achieved, and the following rules must be met:

1. Overall compliance rate of at least 80% for objective elements at 'commitment' level.
2. Overall compliance rate of at least 80% for objective elements at 'achievement' level.
3. Overall compliance rate of at least 80% for objective elements at 'excellence' level.
4. Improvement in the score of objective elements from the previous assessment, which were scored as 2 or less.
5. The score for every core objective element must not be less than 4.
6. No individual standard should have any objective element scored as 2 or less.
7. The average score for individual standards must not be less than 4.
8. The average score for an individual chapter must not be less than 4.
9. Every objective element with a score of 3 or below should have an accepted action plan with timelines.

**Note:** The cumulative score obtained for all objective elements is considered for calculating the overall compliance. At the end of the surveillance assessment, only the objective elements marked at 'core', 'commitment' and 'achievement' level are considered for scoring. The compliance of 80% of the 'core' and 'commitment' corresponds to a score of numerator (135x4) and denominator (135x5) i.e.  $540/675=80\%$ . In addition to the 'core' and 'commitment', the compliance of 80% of the achievement level corresponds to the score of numerator (16x4) and denominator (16x5) i.e.  $64/80=80\%$ . Hence, the cumulative score for 'core', 'commitment' and 'achievement' for surveillance assessment corresponds to the numerator (151x4) and denominator (151x5) i.e.  $604/755=80\%$ . In case of the not applicable objective element(s), the scoring is modified accordingly by excluding them from the numerator and denominator.

## ACCREDITATION DECISION CRITERIA FOLLOWING THE RE-ASSESSMENT

For an organisation to continue to be accredited by NABH, an overall compliance rate of at least 80% must be achieved, and the following rules must be met:

1. Overall compliance rate of at least 80% for objective elements at 'commitment' level.
2. Overall compliance rate of at least 80% for objective elements at 'achievement' level.
3. Overall compliance rate of at least 80% for objective elements at 'excellence' level.
4. Improvement in the score of objective elements from the previous assessment, which were scored as 2 or less.
5. The score for every core objective element must not be less than 4.
6. No individual standard should have any objective element scored as 2 or less.
7. The average score for individual standards must not be less than 4.
8. The average score for an individual chapter must not be less than 4.

9. Every objective element with a score of 3 or below should have an accepted action plan with timelines.

**Note:** The cumulative score obtained for all objective elements is considered for calculating the overall compliance. At the end of there-accreditation assessment, all the objective elements marked at 'core', 'commitment', 'achievement' and 'excellence' level are considered for scoring. The compliance of 80% of the 'core' and 'commitment' corresponds to a score of (135x4) and denominator (135x5) i.e. 540/675=80%. In addition to the 'core' and 'commitment', the compliance of 80% of the achievement level corresponds to the score of numerator (16x4) and denominator (16x5) i.e. 64/80 = 80% and compliance of 80% of the excellence level, corresponds to score of numerator (2x4) and denominator (2x5) i.e. 08/10 = 80%. Hence, the cumulative score for 'core', 'commitment', 'achievement' and 'excellence' for re-accreditation assessment corresponds to the numerator (153x4) and denominator (153x5) i.e. 612/765=80%. In case of then applicable objective element(s), the scoring is modified accordingly by excluding them from the numerator and denominator.

The table below summarises the accreditation decision criteria.

	Final	Surveillance	Re-accreditation
Overall compliance (cumulative score)	≥80%	≥80%	≥80%
Commitment (cumulative score)	≥80%	≥80%	≥80%
Achievement (cumulative score)	NA	≥80%	≥80%
Excellence (cumulative score)	NA	NA	≥80%
Core Objective (individual OE score)	≥ 4	≥ 4	≥ 4
Average score for individual standard	≥ 4	≥ 4	≥ 4
Average score for individual chapter	≥ 4	≥ 4	≥ 4
Improvement in the score of OEs that have been scored ≤ 2 in the previous assessment	NA	Required	Required
Individual standard with OEs < 2 (number)	1	1	1
Closure for OEs with a score of ≤ 3	Required	Required	Required

NA = Not Applicable

# Summary of Chapters, Standards and Objective Elements

	Standard	Objective Elements	Core	Commitment	Achievement	Excellence
AAC	06	25	5	15	5	0
COP	04	10	2	7	1	0
MOM	07	38	11	22	3	2
PRE	05	23	7	15	1	0
IPC	02	09	6	3	0	0
PSQ	02	05	1	4	0	0
ROM	03	10	5	4	1	0
FMS	03	11	4	6	1	0
HRM	03	11	2	9	0	0
IMS	03	11	1	9	1	0
<b>Total</b>	<b>38</b>	<b>153</b>	<b>44</b>	<b>94</b>	<b>13</b>	<b>2</b>
MDS	1	9	3	6	0	0
MDC	1	12	5	7	0	0

# SUMMARY OF CHANGES

2 Edition Allopathic Clinic	1st Edition Allopathic Clinic	Remarks
AAC.1.	AAC.1.	No Change
AAC.1.a.	AAC.1.a.	Change in the language
AAC.1.b.	AAC.1.c.	Change in the language
	AAC.1.b.	Deleted
AAC.2.	AAC.2.	No change
AAC.2.a.	AAC.2.a.	Change in the language
AAC.2.b.	AAC.2.b. AAC.2.c.	Change in the language
AAC.2.c		New Objective element
AAC.3.	AAC.3.	No change
AAC.3.a.	AAC.3.a.	Change in the language
AAC.3.b.		New objective element
AAC.3.c.	AAC.3.b. AAC.3.c.	Change in the language
AAC.3.d.	AAC.3.d. AAC.4.a.	Change in the language
AAC.3.e.		New Objective
AAC.3.f.		New Objective
	AAC.3.e.	Deleted
	AAC.3.f.	Deleted
	AAC.3.g.	Deleted
AAC.3.g.	AAC.5.a. AAC.5.b. AAC.5.c.	Change in the language
AAC.4.	AAC.6.	Modification in language
AAC.4.a.	AAC.6.a. AAC.6.c.	Modification in language
AAC.4.b.	AAC.6.d.	Modification in language
AAC.4.c. AAC.4.d.	AAC.6.b.	Modification in language
AAC.4.e.	AAC.6.g.	Modification in language

2 Edition Allopathic Clinic	1st Edition Allopathic Clinic	Remarks
	AAC.6.e.	Deleted
	AAC.6.f.	Deleted
AAC.5.	AAC.7.	Modification in language
AAC.5.a.	AAC.7.a. AAC.7.c.	Modification in language
AAC.5.b. AAC.5.c.	AAC.7.b.	Modification in language
AAC.5.d.	AAC.7.g.	Modification in language
	AAC.7.d.	Deleted
	AAC.7.e.	Deleted
	AAC7.f.	Deleted
AAC.6.		New Objective
AAC.6.a.		New Objective
AAC.6.b.		New Objective
AAC.6.c.		New Objective
AAC.6.d.		New Objective
COP1.	COP1.	Modification in Language
COP1.a.	COP1.a.	Modification in Language
COP1.b.		New Objective
COP1.c.		New Objective
COP2.		New Standard
COP2.a.	COP1.c.	Modification in Language
COP2.b.		New Objective
COP3.	COP2.	Modification in Language
COP3.a.	COP2.a. COP2.b.	Modification in Language
COP3.b.	COP2.d.	Modification in Language
COP3.c.	COP2.h.	Modification in Language
COP4.		New Standard
COP4.a.		New Objective

2 Edition Allopathic Clinic	1st Edition Allopathic Clinic	Remarks
COP4.b.		New Objective
	COP2.b.	Deleted
	COP2.c.	Deleted
	COP2.e.	Deleted
	COP2.f.	Deleted
	COP2.g.	Deleted
	COP2.i.	Deleted
	COP3.	Deleted
	COP3.a.	Deleted
	COP3.b.	Deleted
	COP3.c.	Deleted
	COP3.d.	Deleted
	COP4.	Deleted
	COP4.b.	Deleted
	COP4.c.	Deleted
	COP4.d.	Deleted
	COP5.	Deleted
	COP5.a.	Deleted
	COP5.c.	Deleted
	COP6.	Deleted
	COP6.a.	Deleted
	COP6.b.	Deleted
MOM.1.		New Standard
MOM.1.a.		New Objective
MOM.1.b.		New Objective
MOM.1.c.		New Objective
MOM.1.d.		New Objective
MOM.1.e.		New Objective
MOM.2.		New Standard

2 Edition Allopathic Clinic	1st Edition Allopathic Clinic	Remarks
MOM.2.a.		New objective
MOM.2.b.		New objective
MOM.2.c.		New objective
MOM.2.d.		New objective
MOM.2.e.		New objective
MOM.2.f.		New objective
MOM.2.g.		New objective
MOM.3.		New Standard
MOM.3.a.		New objective
MOM.3.b.		New objective
MOM.3.c.		New objective
MOM.3.d.		New objective
MOM.3.e.		New objective
MOM.3.f.		New objective
MOM.3.g.		New objective
MOM.3.h.		New objective
MOM.4.		New Standard
MOM.4.a.	COP.4.a	Modification in language
MOM.4.b.		New objective
MOM.5.		New Standard
MOM.5.a.		New objective
MOM.5.b.		New objective
MOM.5.c.		New objective
MOM.5.d.		New objective
MOM.5.e.		New objective
MOM.6.		New Standard
MOM.6.a.	COP.4.a	Modification in language
MOM.6.b.		New objective
MOM.6.c.		New objective

2 Edition Allopathic Clinic	1st Edition Allopathic Clinic	Remarks
MOM.6.d.		New objective
MOM.6.e.		New objective
MOM.7.		New Standard
MOM.7.a.		New objective
MOM.7.b.		New objective
MOM.7.c.	COP5.b.	Modification in language
MOM.7.d.		New objective
MOM.7.e.		New objective
MOM.7.f	COP5.d	Modification in language
PRE.1.	PRE.1.	Modification in language
PRE.1.a.	PRE.1.a. PRE.1.b.	Modification in language
PRE.1.b.	PRE.1.e.	Modification in language
PRE.2.	PRE.2.	Modification in language
PRE.2.a.	PRE.2.b.	Modification in language
PRE.2.b.	PRE.2.c.	Modification in language
PRE.2.c.	PRE.2.d.	Modification in language
PRE.2.d.	PRE.2.e.	Modification in language
PRE.2.e.		New objective
PRE.2.f.		New objective
PRE.2.g.	PRE.2.h.	Modification in language
PRE.2.h.		New objective
PRE.2.i.	PRE.2.i.	Modification in language
PRE.3.		New standard
PRE.3.a.		New objective
PRE.3.b.		New objective
PRE.3.c.		New objective
PRE.4.	PRE.4.	Modification in language
PRE.4.a. PRE.4.b.	PRE.4.a.	Modification in language



2 Edition Allopathic Clinic	1st Edition Allopathic Clinic	Remarks
PRE.4.c.	PRE.4.b.	Modification in language
PRE.4.d.	PRE.4.c.	Modification in language
PRE.4.e.	PRE.4.d.	Modification in language
PRE.4.f.		New objective
PRE.4.f.		New objective
PRE.5.	PRE.5.	Modification in language
PRE.5.a.	PRE.5.a.	Modification in language
PRE.5.b.	PRE.5.b. PRE.5.d.	Modification in language
	PRE.1.c.	Deleted
	PRE.1.d.	Deleted
	PRE.2.a.	Deleted
	PRE.4.d.	Deleted
	PRE.5.c.	Deleted
IPC.1.	I.C.	Modification in language
IPC.1.a.	IC.1.a.	Modification in language
IPC.1.b.	IC.1.b.	Modification in language
IPC.1.c.	IC.1.c.	Modification in language
IPC.1.d.		New Objective
IPC.2.		New Standard
IPC.2.a.		New Objective
IPC.2.b.	IC.2.a.	Modification in language
IPC.2.c.	IC.1.d.	Modification in language
IPC.2.d.		New Objective
	IC.1.e.	Deleted
PSQ.1		New Standard
PSQ.1.a.		New Objective
PSQ.1.b.		New Objective
PSQ.1.c.		New Objective

2 Edition Allopathic Clinic	1st Edition Allopathic Clinic	Remarks
PSQ.2.	CQI.1.	Modification in language
PSQ.2.a.	CQI.1.a. CQI.2.a.	Modification in language
PSQ.2.b.	CQI.1.d.	Modification in language
	COI.2.b.	Deleted
	CQI.2.c.	Deleted
	CQI.1.b.	Deleted
	CQI.1.c.	Deleted
ROM.1.	ROM.1.	Modification in language
ROM.1.a.	ROM.1.a.	Modification in language
ROM.1.b.	ROM.1.b.	Modification in language
ROM.1.c.	ROM.1.c.	Modification in language
ROM.1.d.	ROM.1.d.	Modification in language
ROM.1.e.	CPI.1.e.	Modification in language
ROM.2.	ROM.2.	Modification in language
ROM.2.a.	ROM.2.a.	Modification in language
ROM.2.b.	ROM.2.c.	Modification in language
ROM.2.c.	ROM.2.d.	Modification in language
	ROM.2.b.	Deleted
ROM.3.	CPI.1.	Modification in language
ROM.3.a.	CPI.1.a.	Modification in language
ROM.3.b.	CPI.1.d.	Modification in language
	CPI.1.b.	Deleted
	CPI.1.c.	Deleted
	ROM.1.e.	Deleted
	ROM.3.d.	Deleted
	ROM.4.d.	Deleted
	ROM4.f.	Deleted
FMS.1.	FMS.1.	Modification in language

2 Edition Allopathic Clinic	1st Edition Allopathic Clinic	Remarks
FMS.1.a.	FMS.1.a.	Modification in language
FMS.1.b.	FMS.1.b.	Modification in language
FMS.1.c.	FMS.1.c.	Modification in language
FMS.1.d.		New Objective
FMS.2.	FMS.2.	Modification in language
FMS.2.a.	FMS.2.a.	Modification in language
FMS.2.b.		New Objective
FMS.2.c.	FMS.2.b. FMS.2.c. FMS.2.d.	Modification in language
FMS.2.d.	FMS.2.e.	Modification in language
FMS.3.	FMS.3.	Modification in language
FMS.3.a.	FMS.3.a.	Modification in language
FMS.3.b.	FM3.b.	Modification in language
FMS.3.c.	FMS.3.c.	Modification in language
HRM.1.	ROM.4.	Modification in language
HRM.1.a.	ROM.4.a.	Modification in language
HRM.1.b.		New Objective
HRM.1.c.		New objective
HRM.1.d.		New Objective
HRM.1.e.		New Objective
HRM.2.		New Standard
HRM.2.a.		New Objective
HRM.2.b.	ROM.4.c. ROM.4.e.	Modification in language
HRM.3.	ROM.4.g.	Modification in language
HRM.3.a.	ROM.4.g.	Modification in language
HRM.3.b.		New Objective
HRM.3.c.	IC.1.d.	Modification in language
IMS.1.	ROM.3.	Modification in language

2 Edition Allopathic Clinic	1st Edition Allopathic Clinic	Remarks
IMS.1.a.	ROM.3.a. ROM.3.b.	Modification in language
IMS.1.b.	ROM.3.b.	Modification in language
IMS.1.c.		New Objective
IMS.1.d.		New Objective
IMS.1.e.	ROM.3.c.	Modification in language
IMS.2.		New Standard
IMS.2.a.		New Objective
IMS.2.b.		New Objective
IMS.2.c.		New Objective
IMS.3.		New Standard
IMS.3.a.		New Objective
IMS.3.b.		New Objective
IMS.3.c.		New Objective

# ABBREVIATIONS

<b>ACLS</b>	Advanced Cardiac Life Support
<b>AERB</b>	Atomic Energy Regulatory Board
<b>AHRQ</b>	Agency for Healthcare Research and Quality
<b>AHU</b>	Air Handling Unit
<b>ALARA</b>	As Low As Reasonably Achievable
<b>BLS</b>	Basic Life Support
<b>BMW</b>	Bio-Medical Waste
<b>BP</b>	Blood Pressure
<b>CAPD</b>	Continuous Ambulatory Peritoneal Dialysis
<b>CCTV</b>	Closed-Circuit Television
<b>CDC</b>	Centres for Disease Control and Prevention
<b>CPR</b>	Cardio-Pulmonary Resuscitation
<b>CSSD</b>	Central Sterile Services Department
<b>CT</b>	Computerised Tomography
<b>DG</b>	Diesel Generator
<b>ECG</b>	Electrocardiogram
<b>EMR</b>	Electronic Medical Record
<b>EPR</b>	Electronic Patient Record
<b>EQA</b>	External Quality Assurance
<b>ETO</b>	Ethylene Oxide
<b>ETP</b>	Effluent Treatment Plant
<b>FCU</b>	Fan Coil Unit
<b>FDA</b>	Federal Drug Authority
<b>FMEA</b>	Failure Modes and Effects Analysis
<b>GNM</b>	General Nursing and Midwifery
<b>HAI</b>	Healthcare-Associated Infection
<b>HAZMAT</b>	Hazardous Material
<b>HDU</b>	High Dependency Unit
<b>HIRA</b>	Hazard Identification and Risk Analysis
<b>HIS</b>	Hospital Information System
<b>HISI</b>	Hospital Infection Society-India
<b>HIV</b>	Human Immunodeficiency Virus
<b>HT</b>	High Tension
<b>HTM</b>	Health Technical Memorandum
<b>HVAC</b>	Heating Ventilation and Air Conditioning

<b>HvPI</b>	Haemo Vigilance Programme of India
<b>ICD</b>	International Classification of Diseases
<b>ICN</b>	Infection Control Nurse
<b>ICO</b>	Infection Control Officer
<b>ICU</b>	Intensive Care Unit
<b>ID</b>	Identification Data
<b>IP</b>	In-Patient
<b>IPD</b>	In-Patient Department
<b>IPHS</b>	Indian Public Health Standards
<b>ISMP</b>	Institute for Safe Medication Practices
<b>ISO</b>	International Organisation for Standardization
<b>IT</b>	Information Technology
<b>IV</b>	Intravenous
<b>LAMA</b>	Leaving Against Medical Advice
<b>LASA</b>	Look-Alike Sound-Alike
<b>LIS</b>	Laboratory Information System
<b>LPG</b>	Liquefied Petroleum Gas
<b>LT</b>	Low Tension
<b>MBBS</b>	Bachelor of Medicine and Bachelor of Surgery
<b>MCI</b>	Medical Council of India
<b>MDRO</b>	Multi-Drug Resistant Organisms
<b>MLC</b>	Medico-Legal Case
<b>MoU</b>	Memorandum of Understanding
<b>MRD</b>	Medical Records Department
<b>MRI</b>	Magnetic Resonance Imaging
<b>MRSA</b>	Methicillin-Resistant Staphylococcus aureus
<b>MSDS</b>	Material Safety Data Sheet
<b>MTP</b>	Medical Termination of Pregnancy
<b>MvPI</b>	Materio-Vigilance Programme Of India
<b>NACO</b>	National AIDS Control Organisation
<b>NALS</b>	Neonatal Advanced Life Support
<b>NDMA</b>	National Disaster Management Authority
<b>NFPA</b>	National Fire Protection Association
<b>NICU</b>	Neonatal Intensive Care Unit
<b>OP</b>	Out-Patient
<b>OPD</b>	Out-Patient Department

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

# Chapter 1

## Access, Assessment and Continuity of Care (AAC)

**Intent of the chapter:** The clinic defines the scope of its services and provides information to patients about the services available. This will facilitate appropriately matching patients with the clinic's resources. Once the patient is at the clinic, the patient is registered and assessed in OPD. 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 clinic. Further, the chapter lays down key safety and process elements that the organization should meet, in the continuum of the patient care within the clinic and till discharge.

### SUMMARY OF STANDARDS

<b>AAC.1.</b>	The clinic defines and displays the services that it can provide.
<b>AAC.2.</b>	The clinic has a well-defined patient registration process and appropriate mechanism for referral of patients who do not match its resources.
<b>AAC.3.</b>	Patient's initial and continuing healthcare needs are identified through an established assessment process.
<b>AAC.4.</b>	Laboratory services, if provided, are as per the scope of the services at the clinic.
<b>AAC.5.</b>	Imaging services, if provided, are as per the scope of services of the clinic.
<b>AAC.6.</b>	The day care clinic has an established discharge process and defines contents of discharge summary.

Objective Element	AAC.1.	AAC.2.	AAC.3.	AAC.4.	AAC.5.	AAC.6.
a.	Commitment	Core	Core	Core	Core	Commitment
b.	Commitment	Commitment	Commitment	Commitment	Commitment	Commitment
c.		Commitment	Achievement	Commitment	Commitment	Achievement
d.			Commitment	Commitment	Achievement	Commitment
e.			Core	Achievement		
f.			Commitment			
g.			Achievement			



## Standard

### AAC.1.

**The clinic defines and displays the services that it can provide.**

## Objective Elements

### Commitment

#### a. The clinic defines the services it can provide.

**Interpretation:** The scope could be by inclusion or exclusion in relation to the services practiced in the Clinic. For example, in a Dialysis clinic both haemodialysis and Continuous ambulatory peritoneal dialysis (CAPD) could be done.

The needs of the community could be captured through various feed-back mechanisms. Expertise for the defined service shall be available.

### Commitment

#### b. The services provided are prominently displayed.

**Interpretation:** The services so defined should be displayed prominently in a permanent manner in an area visible to all patients entering the clinic. The display could be in the form of boards, citizen's charter, scrolling messages etc. Care should be taken to ensure that these are displayed in a language(s) the patient understands. Display in the form of brochures only is NOT acceptable. Display should be at least bi-lingual.

## Standard

### AAC.2.

**The clinic has a well-defined patient registration process and appropriate mechanism for referral of patients who do not match its resources.**

## Objective Elements

### CORE

#### a. Written guidance governs the patient registration process.\*

**Interpretation:** The clinic shall prepare a document(s) detailing the process for registration of patients which shall also address day care patients / emergency patients and unidentified patients.

### Commitment

#### b. Patients are accepted only if the clinic can provide the required services.

**Interpretation:** The staff handling registration needs to be aware of the services that the Clinic can provide. The Clinic establishes criteria for guiding decisions for acceptance and/or referral of patients. The registration process shall also include admission of day care patients. In case of emergency, life-saving treatments shall be initiated before any decision is taken regarding registration/ referral.

If the patient's needs do not match the clinic's resources, the clinic will guide the patient in identifying appropriate sources of care.

## Commitment

### c. The patients are prioritized as per clinic needs.

**Interpretation:** The patient registration and assessment process is designed to give priority to those with urgent needs.

## Standard

### AAC.3.

**Patient's initial and continuing healthcare needs are identified through an established assessment process.**

## Objective Elements

### CORE

### a. Written guidance governs the content of the initial assessments.\*

**Interpretation:** Content of initial assessment are defined and implemented.

At the minimum, it shall include the vital signs, presenting complaints and working diagnosis leading to documented plan of care or referral.

The initial assessment shall have additional elements as per the scope of services.

For example, in a paediatric OPD anthropometry shall be a part of the initial assessment apart from other contents of initial assessment.

Assessments shall be performed within its scope of practice, and applicable national / international laws, and regulations.

The clinic can have different assessment criteria for the first visit and for subsequent visits.

The clinic shall define who can do what assessment as per their qualification, experience and training based on applicable laws and regulations.

For day care admitted patients the assessment findings are documented in a uniform manner and uniform location in a patient's record and the patient's record is readily available to those responsible for the patient's care. The care plan shall be documented by a doctor.

The care plan is prepared and documented based on initial assessment and results of diagnostic tests, if available.

## Commitment

### b. Initial assessment is completed in a defined time frame.

**Interpretation:** Written guideline defines the timeframe within which the initial assessment shall be completed and also identify timeliness of assessment process for those patients who do not meet the criteria for treatment and care and require referral to another clinic/facility.

## Achievement

### c. The clinic identifies special needs of the patient.

**Interpretation:** The assessment process for the special needs patients is appropriately modified to reflect their needs and risks.

Some patients like, pregnant diabetic women may require medicine/ endocrinology opinion. ,

A patient for paediatric surgery may require referral to the paediatrician for the immunisation, malnutrition etc,

A patient being treated by general practitioner may require cardiology opinion.

## Commitment

### d. Written guidance governs the process for integrated patient care.\*

**Interpretation:** The patient assessment process may include the relevant findings through outside assessments and investigations (referral source, laboratory, radiology etc.).

Written guidance shall address:

- Process of obtaining and using outside assessment findings.
- Outside assessments requiring review and verification.
- Situations when outside assessments are not available

The laboratory / imaging reports are accepted only if duly signed by qualified / authorized personnel.

## CORE

### e. Patients are reassessed to determine their response to treatment and to plan further treatment or discharge.

**Interpretation:** After the initial assessment the patients are reassessed periodically and the same is documented. The frequency may be different for different conditions.

The care plan shall be subject to modifications or changes at reassessments.

Every patient in day-care clinic shall be reassessed at least once after admission and once before discharging and in between if patient condition suddenly changes.

Reassessment shall be done by the treating doctor or doctor member of the team.

Caregivers perform reassessment within their scope of practice, registration and applicable laws and regulation.

## Commitment

### f. Patients are informed of their next follow-up, where appropriate.

**Interpretation:** The information could be either in terms of specific date or after a certain period (weeks/months) and shall be documented in out Patient consultation sheet or in discharge record of day-care patients.

This may not be applicable in cases where the patient has come for just an opinion or the patient's condition does not warrant a repeat visit.

## Achievement

### g. The clinic has a process to identify the transportation needs of the patients and facilitate the same, as applicable.\*

**Interpretation:** The clinic shall identify conditions in which patients need to be transported for investigation/ an emergency situation to another facility. The centre

shall have a tie up with ambulance providers/ referral centers, preferably multi-specialty HCO in its vicinity, based on its scope of services.

For such services, the MoU shall include the description of validity, service levels (e.g. BLS/ALS ambulance, availability of nurse, etc.) and who will be responsible for care during transport etc.

Clinically unstable patients need to be accompanied by a doctor while transferring to another facility.

Written guideline shall guide the maintenance, readiness and availability of patient transport vehicle. There should be adequate space for parking at the clinic. Ambulance(s) is appropriately equipped. The ambulance is manned by the trained staff. The equipment/medicines in the ambulance are checked daily using a checklist. There is a proper communication system between ambulance and clinic. Licensing of drivers, pollution-control, registration of vehicle etc. should be available

All staff shall be trained at least in Basic Life Support.

## Standard

**AAC.4.**

**Laboratory services, if provided, are as per the scope of the services at the clinic.**

## Objective Elements

### CORE

- a. Lab services, if provided on site, are commensurate with the scope of services and comply with applicable local/ and national standards, laws and regulations.**

**Interpretation:** The scope of the laboratory services whether provided by the in-house or by outsourced/referral centre is clearly defined. If the lab is outsourced or has a collection centre, the relationship between the lab services and the clinic is defined in terms of :-

1. Ownership
2. Working relationship
3. Person responsible for safety of patient.
4. Service standard for example turnaround time, critical alerts, etc.

In case of in-house services, adequately qualified and trained personnel perform and supervise the investigations and report the results.

### Commitment

- b. Written guidelines govern collection, identification, handling, safe transportation, processing and disposal of specimens.\*.**

**Interpretation:** The clinic has documented procedures for collection, identification, handling, safe transportation, processing and disposal of specimens, to ensure safety of the specimen till the tests and retests (if required) are completed.

## Commitment

### c. The Laboratory services, if provided on site, will have a quality assurance programme.\*

**Interpretation:** The laboratory quality assurance programme:

- Is documented.
- Quality assurance is implemented in terms of Internal Quality Control, External Quality Assurance Program and test standardization.
- Addresses verification of test methods.
- Includes periodic calibration and maintenance of all equipment's.
- Critical results are intimated to the person concerned at the earliest.\*
- Laboratory results are available within a defined time frame.\*Includes the documentation of corrective and preventive actions.

## Commitment

### d. Laboratory services if provided on site will have a laboratory safety programme.\*

**Interpretation:** The laboratory safety programme:

- Is documented.
- Addresses handling and disposal of infectious and hazardous materials and protective equipment.
- Training of staff on laboratory safety
- Laboratory personnel are provided with adequate safety measures

## Achievement

### e. Laboratory tests if outsourced are based on quality assurance.\*

**Interpretation:** For assurance of the performance of the outsourced Imaging centre a handy method could be refer to/tie up with a NABH accredited Imaging centre.

## Standard

AAC.5.

Imaging services, if provided, are as per scope of services of the clinic.

## Objective Elements

### CORE

#### a. Imaging services if provided on site are restricted to support primarily the scope of clinical services and comply with legal and other requirements.

**Interpretation:** The Clinic may have availability of Imaging services commensurate with the health care services offered by it, either by providing the same in house or by outsourcing/referral.

The Clinic shall comply with the legal and other requirements of imaging services and the same are documented for information and compliance by all concerned in the Clinic. The Clinic maintains and updates its compliance status of legal and other requirements in a regular manner.

Qualified and trained personnel perform, supervise and interpret the investigations.  
AERB guidance could be used as a reference document.

## Commitment

### b. Quality assurance programme for imaging services is implemented.

**Interpretation:** The Imaging quality assurance programme:

- Is documented.
- Addresses quality of imaging services.
- Includes periodic calibration and maintenance of all equipment's.
- Imaging results are available within a defined time frame.
- Critical results are intimated immediately to the concerned personnel.
- Include the documentation of corrective and preventive actions.

## Commitment

### c. Radiation safety programme for imaging services is implemented.

**Interpretation:** The radiation safety programme:

- Is documented.
- Addresses patient and staff safety
- Ensures that imaging signages are prominently displayed in appropriate locations
- Imaging personnel are provided with appropriate radiation safety devices
- Imaging personnel and patients use appropriate radiation safety and monitoring devices where applicable. Shielding of body parts of staff and patients, attendants shall be adhered to using appropriate aprons, shields and TLD badges. The numbers of such devices shall be adequate.
- Training of staff in Imaging safety practices and radiation–safety measures.

## Achievement

### d. Imaging services, if not available in the clinic, are outsourced to meet patient needs.

**Interpretation:** For assurance of the performance of the outsourced Imaging centre a handy method could be refer to/tie up with a NABH accredited Imaging centre.

## Standard

AAC.6.

The day care clinic has an established discharge process and defines contents of discharge summary.

## Objective Elements

Commitment	<p>a. <b>The patient's discharge process is planned in consultation with the patient and/or family.</b></p> <p><b>Interpretation:</b> The patient's treating doctor determines the discharge process in day-care clinic in discussion with the patient and family.</p>
Commitment	<p>b. <b>A discharge summary is given to all the patients leaving the organization (including patients leaving against medical advice and on request).</b></p> <p><b>Interpretation:</b> A discharge summary is provided to the patients at the time of discharge.</p> <p>The treating doctor should explain the consequences of this action to the patient/attendant.</p> <p>The discharge summary shall be signed by the treating doctor or doctor-member of the treating team. Patient/family shall acknowledge the receipt of the same.</p> <p>The clinic hands over the discharge summary and investigation reports to the patient/attendant in all cases, including LAMA, and a copy is retained in the clinic's record.</p>
Achievement	<p>c. <b>Discharge summary contains follow-up advice, medication, other instructions and when and how to obtain urgent care in an understandable manner.</b></p> <p><b>Interpretation:</b> The Clinic ensures that the follow up advice, medication and other instructions are explained to the patient/ relative in a language and manner that they understand.</p> <p>Medical terms like BD, TDS, QID should not be used.</p>
Commitment	<p>d. <b>In case of death of a patient, the summary of the case also includes the cause of death.</b></p> <p><b>Interpretation:</b> Statutory and regulatory aspects will be kept in view while dealing with death in the clinic and the death summary will be provided which shall include the cause of death.</p>

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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.

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

### SUMMARY OF STANDARDS

<b>COP. 1</b>	Care and treatment is provided in a uniform manner
<b>COP. 2</b>	The clinic provides treatment and care as per established guidelines.
<b>COP. 3</b>	Written guideline governs the care and treatment of patients with special identified needs.
<b>COP. 4</b>	Identification of early warning signs and cardiopulmonary resuscitation services are provided uniformly across the clinic.

Objective Element	COP.1.	COP.2.	COP.3.	COP.4.
a.	Commitment	Achievement	Commitment	Commitment
b.	Core	Commitment	Core	Commitment
c.	Commitment		Commitment	

## Standard

### COP.1.

### Care and treatment is provided in a uniform manner.

## Objective Elements

### Commitment

#### a. Uniform care is provided following written guidance.\*

**Interpretation:** Care delivery shall be guided by clinical needs of the patient and not by the class or the category of the patient.

Uniform care delivery shall be applicable irrespective of setting/ category, and whether the patient is paying or non-paying or is supported by government or private insurance schemes or not. For example, the decision to offer any form of intervention or medication, frequency of patient/ doctor 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 patients. Further, in case the clinic has separate OPD timings for different category of patients, the methodology for care delivery shall be uniform in all OPDs.

### CORE

#### b. During all phases of care, there is a qualified individual available for the patient's care.

**Interpretation:** The clinic shall ensure that the care of patients is always given appropriately by qualified medical personnel. (E.g. - National/State council registered doctors, nurses).

Although care may be provided by a team, the clinic's record shall identify a doctor as being responsible for patient care.

### Commitment

#### c. The care and treatment orders are signed, named, timed and dated by the concerned doctor.

**Interpretation:** All care and treatment orders shall bear concerned doctor's signature, name, time and date in a legible manner.

This shall also be applicable in situations like hand over on the phone of particular patient, or transfer in or transfer out of the patient to and from the clinic.

## Standard

### COP.2.

### The clinic provides treatment and care as per established guidelines.

## Objective Elements

### Achievement

#### a. The clinic adapts evidence-based clinical practice guidelines.

**Interpretation:** Clinical practice will be guided by national and international guidelines and evidence-based medicine.

Standard treatment guidelines (STGs) brought out by GOI is good starting point.

## Commitment

### b. Nursing care is provided to day care patients in accordance with written guidance, as per the scope of services \*

**Interpretation:** Written guidance could be in the form of a nursing manual incorporating all nursing procedures. The document shall be guided by nursing clinical practice guidelines based on best clinical practices, reviewed annually at the minimum, and revised as appropriate.

Examples of nursing clinical practice guidelines include bed-side nursing procedures, for example, - wound care, naso-gastric feed, prevention of fall, deep venous thrombosis, risk assessment and prevention etc.

## Standard

COP3.

Written guidance governs the care and treatment of patients with special identified needs.

## Objective Elements

## Commitment

### a. The Clinic identifies patients who are at high risk of morbidity and mortality and manages them as per the scope of services available.

**Interpretation:** The clinic identifies vulnerable patients. High risk and vulnerable patients should include, (but not be 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. The management of these patients shall be in consonance with statutory requirements, national and international guidelines. The guidance shall include who is responsible for identifying and managing these patients.

**CORE**

### b. Written guidance addresses handling of medico-legal cases.\*

**Interpretation:** The care provided and the documentation and intimation process to appropriate authority is in accordance with statutory requirements. The clinic shall have a method to ensure preservation of medico-legal documents in accordance with statutory requirements.

## Commitment

### c. Written guidance governs the management of pain.\*

**Interpretation:** Pain management shall include screening for pain, pain assessment and pain mitigation techniques and monitoring, when necessary. A detailed pain assessment and re-assessment is done when pain is the predominant symptom. Pain alleviation measures or medications are initiated and titrated according to patient's needs and response.

## Standard

### COP.4.

**Identification of early warning signs and Cardiopulmonary resuscitation services are provided uniformly across the clinic.**

## Objective Elements

### Commitment

- a. **There is a written guidance for prioritization in OPD, based on early warning signs of change or deterioration in clinical conditions for initiating prompt intervention\***

**Interpretation:** Sensitization to approach of easing access to the healthcare services on priority, based on clinical condition shall be done in OPD and diagnostic area.

Early warning signs shall be monitored to detect earliest possible deterioration of an impending untoward event, including day care patients. The clinic uses defined physiological parameters 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 shall suit the needs of the specialty and the age group.

The clinic shall have a mechanism whereby the information is escalated to appropriate medical personnel to trigger prompt and appropriate action.

All the staff handling these activities should be oriented to give priority care to patients with complaints of giddiness, pain, fever, palpitation, shortness of breath and restlessness.

Vulnerable patients are prioritised.

### Commitment

- b. **Resuscitation services are available to all patients, at all times when required.**

**Interpretation:** The clinic shall ensure availability of adequate resources based on written guidance at all times across the clinic in consonance with accepted practice.

Basic life support shall be initiated as soon as possible when the patient's condition requires cardiopulmonary resuscitation.

Prominent display of protocols to guide the uniform use of resuscitation throughout the clinic shall be done. Where appropriate, the written guidance and practice shall address paediatric and neonatal patients.

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# Chapter 3

## Management of Medication (MOM)

**Intent of the chapter:** The clinic has a safe and organized medication process. The process includes policies and procedures that guide the availability, safe storage, prescription, dispensing and administration of medications.

The availability of medication is stressed upon. The clinic should have a mechanism to ensure that the medications are standardized throughout the clinic, 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.

There are processes to ensure monitoring of patients after medication administration and procedures for reporting and analysing adverse drug events, which include errors and events.

### SUMMARY OF STANDARDS

<b>MOM. 1.</b>	The clinic develops, updates and implements a formulary.
<b>MOM. 2.</b>	Medications are stored appropriately and are available where required.
<b>MOM. 3.</b>	Medications are prescribed safely and rationally.
<b>MOM. 4.</b>	Medications orders are written in a uniform manner.
<b>MOM. 5.</b>	Medications are dispensed in a safe manner wherever applicable.
<b>MOM. 6.</b>	Medications are administered safely.
<b>MOM. 7.</b>	Patients are monitored after medication administration.

Objective Element	MOM.1.	MOM.2.	MOM.3.	MOM.4.	MOM.5.	MOM.6.	MOM.7.
a.	Core	Core	Commitment	Commitment	Commitment	Commitment	Commitment
b.	Commitment	Commitment	Core	Commitment	Commitment	Commitment	Commitment
c.	Excellence	Core	Commitment		Commitment	Commitment	Core
d.	Commitment	Achievement	Excellence		Core	Core	Commitment
e.	Commitment	Core	Core		Core	Commitment	Commitment
f.		Commitment	Achievement				Commitment
g.		Commitment	Achievement				
h.			Core				

Core



Commitment



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Achievement



Excellence





## Standard

### MOM.1.

### The clinic develops, updates and implements a formulary.

## Objective Elements

### CORE

- a. **A list of medications appropriate for patients as per the scope of the clinical services is developed collaboratively by a multi-disciplinary committee.**

**Interpretation:** A multidisciplinary committee, with defined roles and responsibilities, shall prepare the clinic formulary.

Some of the responsibilities of the committee include developing medication management processes; developing and revising the clinic's formulary, evaluating medication and material use and patient safety incidents involving medications.

For clinic, at a minimum, a clinician should be a part of the committee.

The formulary shall include medications necessary to meet the Clinic's mission, patient needs and scope of services. The formulary could be prepared keeping in mind the "National List of Essential Medicines" and "WHO Model List of Essential Medicines". The list of medications could be based on national or international standards like WHO/ANSI/ADA/ISO/CE. The clinic shall look at the possibility of having system-wise/speciality wise formulary.

At a minimum, the formulary should include the name of the molecule, formulation and strength(s). The clinic should endeavour to limit the number of drug concentrations of a particular drug in the formulary.

Implants and devices also come under drugs.

### Commitment

- b. **The current formulary is available for clinicians to refer to.**

**Interpretation:** The current formulary shall be made available to all treating clinicians. The clinic needs to ensure that clinicians have access to the current version of the formulary. The formulary could be made available in either physical or electronic form.

### Excellence

- c. **Clinicians adhere to the current formulary.**

**Interpretation:** The clinic shall ensure that the prescriptions are as per the formulary. It shall monitor the frequency of prescriptions being rejected/ or which local purchase is done because it contained non-formulary drugs.

### Commitment

- d. **The clinic adheres to the written guidance for acquisition of formulary medications. \***

**Interpretation:** The written guidance should address the issues of vendor selection, vendor evaluation, reorder levels, indenting process, generation of the purchase order, and receipt of goods. The guidance also addresses managing stock-outs due to various reasons.

## Commitment

- e. **The clinic adheres to the procedure to obtain medications not listed in the formulary. \***

**Interpretation:** Written guidance shall be used to obtain medications not listed in the formulary. Whenever there is a local purchase of medication that is not listed in the formulary, the clinic has a process of evaluation, authorisation and ratification and to decide on its subsequent inclusion in formulary if necessary. Local purchase/hotline, which takes care of the immediate requirement are examples of the procedure to obtain medications not listed in the formulary.

## Standard

**MOM.2.**

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

## Objective Elements

### CORE

- 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 clinic shall adhere to the storage requirements of the drug as specified by the manufacturer. In the absence of manufacturer's instructions, the clinic shall develop and implement storage requirements. Storage requirements shall apply to all areas where medications are stored, including wards and in house labs respectively. Beyond expiry date drugs (before disposal), shall be stored separately and away from drugs/ material which are intended for patient use.

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 on all days, it shall be done on all working days.

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

## Commitment

- b. **Sound inventory control practices guide storage of the medications.**

**Interpretation:** Clinic shall follow sound inventory control practices like ABC, VED, FSN, First Expiry First Out, Lead Time Analysis, etc. or a combination of these. Medicines are available at all times and are replenished promptly when used. Adequate quantity of medications should be stocked at all times. An inventory check shall be done at least daily/weekly to ensure the same. Medicines can be stored in an alphabetical order of their generic names. The clinic also has a mechanism for handling medications which are not a part of the regular inventory. For example, a physician's sample medications.

## CORE

### c. The clinic defines a list of high-risk medication(s). \*

**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 medicines with a low therapeutic window, controlled substances, psychotherapeutic medications, look-alike and sound-alike medications, and concentrated electrolytes.

## Achievement

### d. High-risk medications are stored in areas of the clinic where it is clinically necessary.

**Interpretation:** High-risk medications are stored in pre-determined areas of the clinic. Clinical needs shall determine the availability of these drugs in such areas. In all such areas, safeguards shall be in place to prevent inadvertent administration.

## CORE

### e. High-risk medications including look-alike, sound-alike medications and different concentrations of the same medication are stored physically apart from each other. \*

**Interpretation:** Many drugs in ampoules, vials or tablets may appear similar (look-alike) or have similarly sounding names (sound-alike). These drugs and material 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 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). A good practice is to store the two identified look-alike/sound-alike drugs or different concentrations of the same drugs as far apart physically as possible, say at opposite ends of the room. This is in addition to regular storage practices.

## Commitment

### f. The list of emergency medications is defined and is stored uniformly. \*

**Interpretation:** The list of emergency medications shall be prepared in consonance with sound clinical practices and documented. A crash cart would help the clinic 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.

## Commitment

### g. Emergency medications are available at all times and are replenished promptly when used.

**Interpretation:** Adequate quantity of emergency medicines should be stocked at all times. An inventory check shall be done at least daily to ensure this.

## Standard

### MOM.3.

### Medications are prescribed safely and rationally.

## Objective Elements

### Commitment

- a. **Medication prescription is in consonance with good practices/guidelines for the rational prescription of medications.**

**Interpretation:** This should address both out-patient and daycare prescription. The clinic shall ensure that the doctors are trained/sensitised on the rational prescription of medications. WHO states: "Rational use of medicines requires that patients receive medications appropriate to their 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."

Refer to the glossary for a definition of "prescription".

### CORE

- b. **The clinic adheres to the determined minimum requirements of a prescription. \***

**Interpretation:** Prescriptions generated within the clinic (day care and OPD) shall adhere to national/international guidelines and those of regulatory bodies. At a minimum, the prescription shall have the name of the patient; unique 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. Only the designated medical officer(s) who is permitted by the relevant regulatory authority shall prescribe narcotics. Error-prone abbreviations shall not be used. A good reference is the Institution for Safe Medication Practices guidelines. All prescriptions shall be written in capital letters. Prescription errors or illegible prescriptions will be initialled after single strikethrough and rewritten. A good reference is the Drugs and Cosmetics Act and the Code of Medical Ethics.

### Commitment

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

**Interpretation:** 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 day care.

### Excellence

- d. **The clinic has a mechanism to assist the clinician in prescribing appropriate medication.**

**Interpretation:** The clinic needs to provide its doctors with a mechanism(s) to help identify drug interactions, food-drug interactions, therapeutic duplication, dose adjustments etc. This could either be in electronic or physical form.

## CORE

### e. Written guidance governs implementation of verbal orders and ensures safe medication management practices. \*

**Interpretation:** The clinic shall ensure safe medication management practices for verbal orders through written guidance and implementation of the same. The written guidance shall mention who can give verbal orders, when can they 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 clinic should have an 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”.

A verbal order shall be counter-signed by the doctor who ordered it within 24 hours of ordering.

## Achievement

### f. Audit of medication orders/prescription is carried out to check for safe and rational prescription of medications.

**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.
- The requirements of this standard (MOM.3.b. to h.).

This shall be done at least once a month using a representative sample size.

It could preferably be done by a clinical pharmacologist/clinical pharmacist. In case there is no clinical pharmacologist/clinical pharmacist, it shall be done by the multidisciplinary committee.

## Achievement

### g. Corrective and/or preventive action(s) is taken based on the audit, where appropriate.

**Interpretation:** 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.

## CORE

### h. Reconciliation of medications occurs at transition points patient care

**Interpretation:** The purpose of reconciliation of medication is to ensure that the list of medication that a patient has 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 entry in the clinic. It is preferable that medication reconciliation also occurs after cross-consultation. Medication reconciliation should be documented.

## Standard

### MOM.4.

### Medications orders are written in a uniform manner.

## Objective Elements

### Commitment

#### a. The clinic ensures that only authorised personnel write orders. \*

**Interpretation:** Medication orders shall be written by a doctor who at a minimum, holds a MBBS qualification. 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. In facilities which use Electronic Medical Record (EMR), the doctor shall directly enter the prescription 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.

### Commitment

#### b. Orders for medicines are written in a uniform location in the medical records, which also reflects the patient's name and unique identification number.

**Interpretation:** Medication orders shall be written in capital letters. In case abbreviations are used, a list of approved standardised abbreviations for medication orders shall be used throughout the clinic. Error-prone abbreviations shall not be used. A good reference is the Institution for Safe Medication Practices guidelines. Medication orders contain the name of the medicine, route of administration, strength to be administered and frequency/time of administration.

## Standard

### MOM.5.

### Medications are dispensed in a safe manner wherever applicable.

## Objective Elements

### Commitment

#### a. Dispensing of medications is done safely. \*

**Interpretation:** Written guidance is laid down for the dispensing of medications. Medications should be dispensed only against a valid prescription or medication order (except for over-the-counter drugs). The medication should be checked before dispensing. This should include a check of the generic composition, formulation, expiry date, and where applicable the strength. This shall include both bulk and retail pharmacy.

Physicians' samples shall not be sold.

### Commitment

#### b. Medication recalls are handled effectively. \*

**Interpretation:** Recall may be based on communication from regulatory authorities, manufacturers or internal feedback. Recall procedure in response to internal feedback also includes providing information to the appropriate regulatory authority.

## Commitment

### c. Near-expiry medications are handled effectively. \*

**Interpretation:** The clinic could define as to what constitutes “near expiry”, for example, three months before the expiry date. The clinic's mechanism shall ensure that near expiry drugs are withdrawn and that no beyond expiry date medication is available.

## CORE

### d. 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 day care and out-patients.

## CORE

### e. High-risk medication orders are verified before dispensing.

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

## Standard

### MOM.6.

### Medications are administered safely.

## Objective Elements

## Commitment

### 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.

## Commitment

### b. Prepared medication is labelled prior to 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.

## Commitment

### c. The patient is identified prior to administration.

**Interpretation:** At a minimum, two identifiers shall be used for identification with one of them being the unique identification number and name.

## CORE

### d. Medication is verified from the prescription and physically inspected before administration.

**Interpretation:** 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 or incomplete, administration of medication shall be deferred pending early verification by the treating team. In case the confirmation is obtained verbally, it shall be considered a verbal order and the procedure for verbal orders shall be adhered to.

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.

## Commitment

### e. Strength, route and timing is verified from the order and medication administration is documented.

**Interpretation:** 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.

The organisation shall ensure that the 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.

## Standard

### MOM.7.

### Patients are monitored after medication administration.

## Objective Elements

## Commitment

### a. Patients are monitored after medication administration

**Interpretation:** Relevant monitoring is done collaboratively to verify that medicine is having its intended effect. Medication administration is documented. Besides, this should help identify near misses, medication errors and adverse drug reactions.

## Commitment

### b. Medications are changed where appropriate based on the monitoring.

**Interpretation:** Medication changes are based on clinical response and adverse drug reactions if any.



## CORE

### c. The clinic captures near miss, medication error and adverse drug reaction. \*

**Interpretation:** Near miss, medication error and adverse drug reaction are defined. This shall be in consonance with best practices. The clinic shall have written guidance to direct the implementation of identifying, documenting, reporting, analysing and acting in response to a near miss, medication error and adverse drug reaction.

Refer to the glossary for “near miss”, “medication error” and “adverse drug reaction”.

#### Commitment

#### d. Near misses, medication error and adverse drug reaction are reported within a specified time frame. \*

**Interpretation:** The clinic shall define the timeframe for reporting once any of this has occurred and adhere to the same.

#### Commitment

#### e. Near misses, medication errors and adverse drug reactions are collected and analysed.

**Interpretation:** Details of near miss, medication error and adverse drug reaction incidents are collected and analysed by a multidisciplinary team, which includes the clinicians. The analysis shall be completed in a defined time frame.

#### Commitment

#### f. Corrective and/or preventive action(s) are taken based on the analysis.

**Interpretation:** 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.

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# Chapter 4

## Patient Rights and Education (PRE)

**Intent of the chapter:** The clinic defines 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

<b>PRE. 1</b>	The clinic protects patient and family rights and informs them about their responsibilities during care.
<b>PRE. 2</b>	Patient and family rights support individual beliefs, values and involve the patient and family in decision making processes.
<b>PRE. 3</b>	A documented process for obtaining patient's and/or family's consent exists for informed decision making about their care.
<b>PRE. 4</b>	Patient and families have a right to information and education about their healthcare needs.
<b>PRE. 5</b>	Patient and families have a right to information on expected costs.

Objective Element	PRE.1.	PRE.2.	PRE.3.	PRE.4.	PRE.5.
a.	Core	Commitment	Core	Core	Commitment
b.	Core	Commitment	Commitment	Commitment	Achievement
c.		Core	Commitment	Commitment	
d.		Commitment		Commitment	
e.		Commitment		Commitment	
f.		Core		Commitment	
g.		Commitment		Commitment	
h.		Core			
i.		Commitment			

## Standard

PRE.1.

The clinic protects patient and family rights and informs them about their responsibilities during care.

### Objective Elements

**CORE**

- a. **Patients and families are informed of their rights and responsibilities in a format and language that they can understand.\***

**Interpretation:** The rights and responsibilities of the patients should be displayed bilingually in a permanent manner at strategic locations like the entrance/lobby, registration, billing, outpatient areas etc. where it is prominently visible to patients, families and visitors.

The display could be in the form of boards, scrolling messages etc.

**CORE**

- b. **Violation of patient rights is reviewed and corrective/preventive measures taken.**

**Interpretation:** Staff is aware of their responsibility in protecting patient's rights. patients' feedback should be regularly monitored. The clinic may define such instances which could be considered as patient's and families rights. For example, compromising privacy, breaching confidentiality, disrespect to the religious and cultural needs. The patient feedback form (by incorporating patient rights worded appropriately) could be used as a tool to capture violation of patient rights.

Violations of patient's rights shall be identified and documented.

CCTV coverage in patient care areas shall be restricted as per local and national regulations.

## Standard

PRE.2.

Patient and family rights support individual beliefs, values and involve the patient and family in decision making processes.

### Objective Elements

**Commitment**

- a. **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 examination or carrying out a procedure, the clinic staff shall ensure that patient 's privacy and dignity is maintained.

During procedures it shall be ensured that the patient is exposed just before the actual procedure is undertaken.

For photographs/recording procedures, an explicit informed consent is taken and it is ensured that the patient's identity is not revealed.

Commitment	<p><b>b. Patient and family rights include protection from neglect or physical abuse.</b></p> <p><b>Interpretation:</b> 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 with respect to vulnerable patients.</p>
CORE	<p><b>c. Patient and family rights include treating patient information as confidential.</b></p> <p><b>Interpretation:</b> The clinic and the treating team shall take effective measures to maintain confidentiality of all patient -related information.</p> <p>Statutory requirements regarding privileged communication shall be followed at all times.</p> <p>Staff shall avoid having patient- related discussions in public places. Confidential information including HIV status shall not be revealed without the patient's permission and shall not be explicitly written / pasted on the cover of the medical record or displayed in a manner that is easily understandable by the public at large.</p>
Commitment	<p><b>d. Patient and family rights include the refusal of treatment.</b></p> <p><b>Interpretation:</b> After being informed of all the available options the patient shall have a right to make an informed choice. In case of refusal, the treating doctor shall explain the consequences of refusal of treatment and document the same.</p>
Commitment	<p><b>e. Patient and family right include right to seek additional opinion regarding clinical care.</b></p> <p><b>Interpretation:</b> There is a mechanism for patient and family to seek a second opinion if they wish, from within or outside the clinic.</p> <p>The clinic shall allow access to all relevant information or clinical evaluation.</p>
CORE	<p><b>f. Patient and family rights include informed consent before any invasive procedure.</b></p> <p><b>Interpretation:</b> Informed consent shall be obtained by treating doctor or a doctor member of the treating team.</p>
Commitment	<p><b>g. Patient and family rights include a right to complain and information on how to voice a complaint.</b></p> <p><b>Interpretation:</b> The displayed patient rights should include the right to make a complaint and also mention the methodology to voice the same. Complaint mechanism must be accessible and redressal of complaint must be fair and transparent.</p>
CORE	<p><b>h. Patient and family rights include information on the expected cost of the treatment.</b></p> <p><b>Interpretation:</b> Patients and families are explained 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.</p>

## Commitment

### i. Patient and family has a right to have an access to his / her clinical records.

**Interpretation:** The clinic shall ensure that every patient has access to his/her record. This shall be in consonance with the Code of Medical Ethics and Statutory requirements.

## Standard

PRE.3.

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

## Objective Elements

### CORE

#### a. The clinic obtains informed consent from the patient or family for situations where informed consent is required. \*

**Interpretation:** A list of procedures should be made for which informed consent should be taken. This shall be prepared keeping in mind the requirements of this standard and statutory requirement.

For example, some statutory requirements are MTP Act and PC-PNDT Act. The policy for HIV testing should follow the national policy laid down by NACO.

## Commitment

### b. Informed consent process adheres to statutory norms and includes information regarding the procedure; it's risks, benefits, alternatives and as to who will perform the requisite procedure, in a language that the patient/family can understand.

**Interpretation:** The consent shall have the name of the doctor(s) performing the procedure.

Consent form shall be in the language that the patient understands.

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.

At least one witness shall sign the consent form.

In case the patient has to undergo a procedure repeatedly for a long time (e.g. dialysis) an informed consent is taken at the first instance. Such consent shall have a defined validity period but not more than 6 months unless there is a change in the treatment modality or an addition of another modality.

The patient endorses the consent at each repeat treatment.

Each doctor will have to explain his role and address all aspects required for informed consent, for example, if a surgery involves requirement of multiple specialties, the consent should reflect the same. It should have names of the involved surgeons from different specialties.

## Commitment

- c. **The clinic describes who can give consent when patient is incapable of independent decision making.\***

**Interpretation:** The consent shall be taken from the patient in all cases when the patient is capable of giving consent and above the legal age for giving consent.

The clinic shall take into consideration the statutory norms when the patient is incapable of independent decision making. This would include next of kin/legal guardian.

For life threatening situations when a patient is incapable and next of kin is not available, in the interest of time the treating doctor and another clinician can take a decision to safeguard the patient's life.

The order of preference of next of kin is legal guardian is spouse/ son /daughter / parents / brothers /sister.

## Standard

PRE.4.

**Patient and families have a right to information and education about their healthcare needs.**

## Objective Elements

### CORE

- a. **Patient and/or families are educated in a language and format that they can understand.**

**Interpretation:** During the patient's treatment, patient and or/family are screened(informally) for their understanding abilities and language requirements. The patients and or family members are educated through counselling/use of printed material/audio-visual aids etc.

## Commitment

- b. **Patient and/or families are educated about the safe and effective use of medication and the potential side effects of the medication, when appropriate.**

**Interpretation:** The clinic shall make a list of such drugs and accordingly educate, for example Digoxin. This could also include education regarding the importance of taking a drug at a specific time.

## Commitment

- c. **Patient and families are educated about food-drug interaction and diet and nutrition.**

**Interpretation:** The clinic shall make a list of such drugs and accordingly the patient and family should be educated about their diet during medication, for example no alcohol when taking Metronidazole.

The education could include the relationships between various foods or supplements and specific health conditions. Where ever there are specific dietary requirements or restrictions, the patient shall be educated regarding the same.

## Commitment

- d. **Patient and families are educated about immunizations.**

**Interpretation:** In adults it could be for Influenza, Streptococcus pneumonia, Typhoid, Hepatitis B, Neisseria meningitides, etc.



<b>Commitment</b>	<p><b>e. Patient and families are educated about their specific disease process, prognosis, complications and prevention strategies.</b></p> <p><b>Interpretation:</b> The education shall include information on lifestyle modifications (stress management, physical exercise, cessation of smoking and substance abuse), diet changes and immunizations, where appropriate.</p> <p>Information, Education and Communication(IEC) tools shall be used to educate patients with chronic diseases, for example, diabetes, hypertension, joint disorders, coronary artery disease, chronic renal or liver disorders etc. The education shall also include topics like healthy eating habits, lifestyles, tobacco-free living, etc.</p> <p>IEC can be in form of individual counselling, workshops, educational material, appropriate signages etc.</p> <p>The IEC materials shall be culturally appropriate and will also be in local languages and use symbols where appropriate.</p>
<b>Commitment</b>	<p><b>f. Patient and families are educated about preventing healthcare associated infections.</b></p> <p><b>Interpretation:</b> For example, hand washing and avoiding overcrowding and masking.</p>
<b>Commitment</b>	<p><b>g. Patient and/or family are educated on various pain management techniques, when appropriate.</b></p> <p><b>Interpretation:</b> The education on pain management techniques could be done only for patients who are likely to have long-term pain because of the underlying condition not being treatable. This should be done within the framework of their personal, cultural and religious beliefs.</p>

## Standard

<b>PRE.5.</b>	<b>Patient and families have a right to information on expected costs.</b>
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## Objective Elements

<b>Commitment</b>	<p><b>a. The tariff list is available to patients.</b></p> <p><b>Interpretation:</b> The clinic shall ensure that there is an updated tariff list and that the relevant tariff is available for reviewing to patients when required.</p> <p>The clinic shall charge as per the tariff list. The tariff rates should be uniform (in a given setting) and transparent.</p>
<b>Achievement</b>	<p><b>b. Patients are educated about the expected cost of treatment.</b></p> <p><b>Interpretation:</b> Patients should be given an estimate of the expenses on account of the treatment preferably in a written form. This estimate shall be prepared on the basis of the treatment plan. It could be prepared by the OPD/ registration/admission staff in consultation with the treating doctor.</p> <p>Patients are informed about the revised costs when there is a change in the patient condition or treatment setting.</p>

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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 clinic. The programme is documented and aims at reducing/eliminating infection risks to patients, visitors and providers of care.

The clinic 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

<b>IPC. 1</b>	The clinic has an Infection Prevention and Control programme.
<b>IPC. 2</b>	The clinic implements the infection prevention and control program for support services.

Objective Element	IPC.1.	IPC.2.
a.	Core	Commitment
b.	Core	Core
c.	Core	Commitment
d.	Core	Commitment
e.	Core	

## Standard

### IPC.1.

The clinic has an Infection Prevention and Control programme and is implemented.

### Objective Elements

#### CORE

#### a. Written guidance for infection prevention and control is available. \*

**Interpretation:** The written guidance shall be directed at Infection Prevention and Control (IPC) for all activities at the clinic. The guidance shall be reviewed at least annually based on newer literature.

#### CORE

#### b. The clinic adheres to standard precautions at all times.

**Interpretation:** Adherence to standard precautions is one of the fundamental tenets of infection prevention and control. In every area of clinic, standard precautions shall be adhered.

Clinic adheres to transmission-based precautions. This shall cover airborne, droplet and contact mode of transmission. PPE use is done appropriately. This shall be applicable across the clinic.

Hand washing/hand disinfecting facilities in all patient care areas are accessible to health care providers, visitors and patients.

Adequate gloves, masks, soaps, and disinfectants are available and used correctly.

#### CORE

#### c. Cleaning, packing, disinfection of surfaces, equipment cleaning and sterilization practices including reprocessing of instruments / single use devices is done as per written guidance

**Interpretation:** Cleaning, packing, disinfection of surfaces, equipment cleaning and sterilization practices including reprocessing of instruments / single use devices is done as per standard national and international guidelines. A good reference is CDC guideline for disinfection and sterilization in healthcare facilities, 2008, as applicable to the scope of clinic and services. Regular validation test for sterilization is carried out and documented. Single use instruments and devices which are meant for re-use are identified. The number of re-uses are defined and monitored for integrity and functionality of the device and frequency of use. The patient is informed about the same.

This shall be based on standard guidelines. For reprocessing of dialyzer a good reference may be Indian Society of Nephrology (ISN) guidelines.

#### CORE

#### d. Antibiotic use is guided by standard guidelines. \*

**Interpretation:** The clinic should implement the rational use of antibiotics.

A good reference is Standard Treatment Guidelines (STG) and Antibiotic treatment guidelines released by NCDC, ICMR.

**CORE**

**e. The clinic adheres to safe injection and infusion practices.\***

**Interpretation:** This shall include “One needle and One syringe only in one time”. A good reference is CDC and WHO guidelines

Standard

IPC.2.

**The clinic implements the infection prevention and control programme for support services.**

Objective Elements

Commitment

**a. The clinic adheres to housekeeping services guidelines.**

**Interpretation:** Housekeeping shall be addressed at all levels of the clinic for example, reception areas including toilets, corridors, doctor's chambers, furniture and equipment etc.

A good reference is “Swachhta Guideline for public health facility.

**CORE**

**b. Biomedical waste (BMW) complies with national/state regulations and is handled appropriately and safely.**

**Interpretation:** Proper segregation, collection and storage of biomedical waste in the clinic shall be implemented as per current BMW rules.

Commitment

**c. The clinic adheres to laundry and linen management processes.**

**Interpretation:** Safe linen management practices shall be adhered to, for example, segregation of dirty and soiled linen at source, linen disinfection and washing protocols.

Commitment

**d. The clinic adheres to kitchen sanitation and food-handling issues.**

**Interpretation:** The food services in the clinic, if provided, may be available for patient and/or visitor inside the premises. The organization shall ensure that statutory rules are adhered to, even if the food Services are outsourced. The clinic shall implement screening of kitchen workers and food handlers as per national and international 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 clinic and all staff members. The clinic 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 clinic establishes a patient safety programme.
PSQ.2	There is a structured quality improvement and continuous monitoring programme.

Objective Element	PSQ.1.	PSQ.2.
a.	Commitment	Commitment
b.	Commitment	Commitment
c.	Core	

## Standard

PSQ.1.

The clinic establishes a patient safety programme.

### Objective Elements

#### Commitment

- a. **The patient safety programme is implemented as per the scope of services.**

**Interpretation:** The programme should address all elements of safety affecting clinical and support services.

The comprehensive programme shall cover elements of safety in OP areas and procedure rooms. It shall also cover day care wards, dialysis unit, laboratory, radiology, operation theatre, etc.as applicable. The patient safety programme shall be reviewed and updated at least once a year.

#### Commitment

- b. **The programme covers incidents ranging from “NO Harm” to “Sentinel events”. \***

**Interpretation:** The clinic shall clearly define as to what constitutes no harm and sentinel events respectively. There is be a mechanism to identify sentinel events. This can be based on incident reporting system. The documented record of the same shall be reviewed periodically

The reporting system shall be simple (a few steps), clear (what needs to be reported, how to report and to whom), confidential and focused on process improvement.

#### CORE

- c. **The clinic adapts and implements national/international patient safety goals/solutions.**

**Interpretation:** The clinic shall adhere to current national patient safety goals or WHO patient – safety solutions.

For example, correct patient identification, medication safety, enhanced and effective communication, safe surgical procedures etc.

Adequate gloves, masks, soaps, and disinfectants are available and used correctly.

## Standard

PSQ.2.

There is a structured quality improvement and continuous monitoring programme.

### Objective Elements

#### Commitment

- a. **The quality improvement programme is documented. \***

**Interpretation:** Quality improvement programme shall have defined objectives and goal

The clinic shall monitor following quality indicators:

1. Incidence of medication errors
2. Compliance to Hand hygiene practice.
3. Waiting time for OPD
4. Rate of sharp injuries
5. Percentage of cases where the organisation procedure to prevent adverse events like wrong site, wrong patient and wrong procedure have been adhered to.
6. Number of variations observed in mock drills
7. Equipment down time
8. Out patient satisfaction index
9. Incidence of blood body fluid exposures
10. Percentage of incomplete case records

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**Commitment**

- b. The quality improvement programme is reviewed at predefined intervals and opportunities for improvement are identified.**

**Interpretation:** The analysis and review of the quality indicators shall be done and program at least once in a year.

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# Chapter 7

## Responsibilities of Management (ROM)

**Intent of the chapter:** The standards encourage the governance of the clinic 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 clinic management.

### SUMMARY OF STANDARDS

<b>ROM. 1</b>	The responsibilities of the management are defined.
<b>ROM. 2</b>	The clinic is managed by the leaders in an ethical manner.
<b>ROM. 3</b>	The clinic participates in health promotion and disease prevention.

Objective Element	ROM.1.	ROM.2.	ROM.3.
a.	Commitment	Core	Achievement
b.	Commitment	Core	Commitment
c.	Core	Commitment	
d.	Core		
e.	Core		

## Standard

### ROM.1.

### The responsibilities of the management are defined.

#### Objective Elements

##### Commitment

- a. Those responsible for governance define the clinic's vision, mission, and resources\*

**Interpretation:** The clinic shall define and display its vision, mission and values.

##### Commitment

- b. Those responsible for governance establish the clinic's organogram, as applicable. \*

**Interpretation:** 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. The clinic's organogram is transparent and is disseminated to all stakeholders.

The organogram shall also incorporate various committees as applicable.

##### CORE

- c. Administrative written guidance for each section is maintained. \*

**Interpretation:** Written guidance shall enable the operating and functioning of the clinic.

##### CORE

- d. The clinic complies with the laid down, applicable legislations and regulations at all times.

**Interpretation:** The leader of the clinic shall be conversant with different statutory requirements as per scope of services and undertakes the responsibility to adhere to the same.

There could be a tracker sheet to regularly update any amendments in the prevailing laws of land.

Applications to update statutory documents is made in accordance with the timelines set by laws/ registration.

For example, Clinical Establishment Act, consent before surgery, providing first aid to emergency patients and police intimation in cases of medico-legal cases, compliance to PCPNDT, MTP Act.

##### CORE

- e. In cases of notifiable diseases, information (in relevant format) is sent to appropriate authorities.

**Interpretation:** The clinic shall identify all notifiable diseases after taking into consideration the local laws, rules, regulations and notifications, thereof. The clinic shall ensure that this is sent at the specified frequency and in the format as required by statutory authorities.



## Standard

<b>ROM.2.</b>	<b>The clinic is managed by the leaders in an ethical manner.</b>
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### Objective Elements

#### CORE

##### a. The clinic functions in an ethical manner.

**Interpretation:** The clinic shall function ethically. One of the guiding principles shall be transparency. Handling of complaints, clinical care delivery, conflict of interest, breach of confidentiality, ethical behaviour, informed consent, etc. are some of the areas to be addressed.

A good reference guide is "Code of Medical Ethics-2002" published by NMC.

#### CORE

##### b. The clinic honestly portrays its affiliations and accreditation.

**Interpretation:** The clinic shall convey its affiliations, accreditations for specific departments in an honest manner, wherever such exist.

#### Commitment

##### c. The clinic accurately bills for its services based upon a standard billing tariff.

**Interpretation:** This essentially means that the organization does not charge differently from different patients in the same category for the same procedure.

## Standard

<b>ROM.3.</b>	<b>The clinic participates in health promotion and disease prevention.</b>
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### Objective Elements

#### Achievement

##### a. There is a process and mechanism in place to ensure health promotion and disease prevention.

**Interpretation:** The clinic should be aware of the national and local public health programmes and initiatives for health promotion and should support the same based on its scope of services and statutory obligations.

The participation may include health education, counselling, health advice, screening and testing, immunizations etc.

The clinic shall give advice on sanitation, hygiene, safe drinking water (potable), etc.

Social activities are provided by the clinic in cooperation with community organizations and agencies.

## Commitment

- b. **The clinic cooperates and collaborates with the community partners in provision of surveillance, epidemiological investigations, data collection, when required.**

**Interpretation:** The clinic will identify diseases requiring outbreak investigation and prepare a short list of relevant 'warning signals'. The staff are trained to remain alert to these signals and respond rapidly.

This can be used for identification of emerging health problems, threats and preparedness for outbreaks.

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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 clinic conducts regular facility inspection rounds and takes the appropriate action to ensure safety.

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

The clinic manages its hazardous materials safely.

The organization plans for fire and non-fire emergencies within the facilities.

### SUMMARY OF STANDARDS

<b>FMS. 1</b>	The clinic shall operate in an environment which ensures safety of patients, staff and visitors.
<b>FMS. 2</b>	The clinic has a programme for equipment and facility management.
<b>FMS. 3</b>	The clinic has plans for emergencies (fire and non-fire) and hazardous materials within the facility.

Objective Element	FMS.1.	FMS.2.	FMS.3.
a.	Commitment	Commitment	Core
b.	Core	Commitment	Commitment
c.	Commitment	Commitment	Core
d.	Achievement	Core	

## Standard

**FMS.1.**

**The clinic shall operate in an environment which ensures safety of patients, staff and visitors.**

### Objective Elements

#### Commitment

- a. **Updated drawings are maintained with details of site layout, floor plans and fire escape routes.**

**Interpretation:** The drawings should be as per the approved plan, The drawings help in future repair and maintenance.

In addition to fire evacuation plans, it is preferable that separate civil, electrical, plumbing, HVAC and piped medical gas drawings are maintained, as applicable.

#### CORE

- b. **There are internal and external sign posting in the Clinic in a language understood by patient, families and community.**

**Interpretation:** These signages shall guide patients and visitors. Statutory requirements shall be met. It is preferable that signages are bilingual. The signages should be prominently displayed.

Fire signage should follow the norms laid down by National Building Code and/or respective statutory body (for example, fire service). There should be warning signage outside the room with laser equipment, when applicable.

#### Commitment

- c. **Facilities and space provisions are appropriate to the scope of clinic.**

**Interpretation:** The facilities provided shall be as per best practices/ national /international guidelines and commensurate with the scope of the services offered.

Adequate space should be provided keeping patient safety and ease of providing clinical care in mind.

For adequacy of space, the reference could be IPHS standards and various international standards, government directives from agencies like AERB guidelines for radiation equipment, etc.

#### Achievement

- d. **Patient safety devices and infrastructure are installed across the clinic.**

**Interpretation:** The clinic should be easily accessible to receive and manage non-ambulatory patients and differently abled persons.

Patient-safety devices could include grab bars, bed rails, sign posting, 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.

## Standard

### FMS.2.

### The clinic has a programme for equipment and facility management.

#### Objective Elements

##### Commitment

##### a. The clinic plans for equipment in accordance with its services and strategic plan.

**Interpretation:** The plan could also be implemented in a phased manner and shall also take into consideration future requirements. At the minimum it shall include list of equipment available at the clinic, expected life span, equipment serial no, location and maintenance schedule. The future requirement in terms of number of existing equipment and new equipment along with their expected timelines can also be the part of the plan.

Written guidance supports medical equipment replacement and disposal

##### Commitment

##### b. Equipment is periodically inspected and calibrated for their proper functioning.

**Interpretation:** The periodicity for inspection and calibration for each equipment could vary, but shall be defined.

A unique identification is provided to each equipment.

The operator shall be trained in handling the equipment.

The maintenance plan should be considered based on manufacturer's recommendations and past maintenance history.

There shall be a mechanism for addressing the breakdowns along with monitoring of the turnaround time for repairs.

There shall be a planned preventive maintenance tracker. The clinic either calibrates the utility equipment in-house or outsources, maintaining traceability to national or international or manufacturer's guidelines / standards.

Examples could include pressure gauges of steam sterilizer, temperature monitoring devices of refrigerators used for storage of medicine etc.

##### Commitment

##### c. Safe water and uninterrupted electrical supply is available.

**Interpretation:** The organization shall make arrangements for sufficient supply of adequate potable water. The quality of potable water is monitored at last once in six months or more frequently and documented.

For water quality, refer to IS 10500.

In case the clinic has dialysis facility available, monthly testing of RO water for endotoxin levels and other parameters, as per standard guidelines, shall be implemented. A good reference could be Indian Nephrology Association guidelines.

The electric load applied for shall be appropriate to the requirements of the clinic.

In case of a shortfall in water or electricity, alternate sources shall be arranged.

A good reference for estimating the water requirement is the National Building Code. Alternate electric supply could be from DG sets, solar energy, UPS and any other suitable source.

## CORE

### d. Written guidance governs procurement, handling, storage, distribution, usage and replenishment of medical gases.\*

**Interpretation:** The clinic shall adhere to statutory requirements.

It shall follow a uniform colour coding system. Proper signage is kept for used, full and empty cylinders respectively

Appropriate safety measures shall be developed and implemented for all levels, including alarm units and valve boxes installation at various locations, as applicable

Alternate sources for medical gases, vacuum and compressed air are provided for, in case of failure.

There is a maintenance plan for piped medical gas, compressed air and vacuum installation, if applicable

## Standard

FMS.3.

The clinic has plans for emergencies (fire and non-fire) and hazardous materials within the facility.

## Objective Elements

## CORE

### a. The clinic has plans and provisions for early detection, abatement and containment of fire and non-fire emergencies.\*

**Interpretation:** The clinic shall have a fire plan covering fire arising out of burning of inflammable items, explosion, electric short circuiting etc., including deployment of fire-fighting equipment.

Training plan and schedule for conducting mock drills (at least twice a year), shall be available. Outcome of these mock drills with the scope of improvement is documented

Fire-exit plan shall be displayed on each floor of the clinic.

Exit doors are identified with adequate signages.

There shall be a maintenance plan for fire-related equipment and infrastructure.

The organization conducts electrical safety audit for the clinic periodically.

Non-fire emergencies may include but not be limited to floods, earthquake, anti-social behaviour by patients/relatives, terrorist attacks etc. depending upon the location of the clinic.

## Commitment

### b. The staff is trained for their role in case of such emergencies.

**Interpretation:** In case of fire, the roles of each designated person shall be well defined.

The training shall include various classes of fire, information and demonstration on how to use a fire extinguisher and the procedure to be followed in case of fire emergencies. The process of evacuation for patient and staff shall be an integral part of training.

Staff training also includes non-fire emergencies.



**CORE**

- c. **The clinic has addressed identification, sorting, storage, handling, transportation, disposal mechanism, and method for managing spillages of hazardous materials.**

**Interpretation:** The clinic shall identify, list and document the hazardous materials and has a documented procedure for their sorting, storage, handling, transportations, disposal mechanism, and method for managing spillages and adequate training of the personnel for these jobs.

The clinic shall take all necessary steps to eliminate or reduce hazards and associated risks.

Material Safety Data Sheets (MSDS) for all hazardous materials shall be available and personnel who handle such materials are appropriately trained.

There shall be a plan for managing spills of hazardous materials, including availability of HAZMAT kit(s).

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## Chapter 9

# Human Resource Management (HRM)

**Intent of the chapter:** The most important resource of a clinic and healthcare system is the human resource. Human resources are an asset for effective and efficient functioning of a clinic. 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 clinic. This is based on the clinic's mission, objectives, goals and scope of services. Effective human resource management involves the following processes and activities: -

- Acquisition of Human Resources which involves human resource planning, recruiting and socialization of the new employees.
- Training and development related to the performance in the present and future anticipated jobs. The employees are provided with opportunities to advance personally as well as professionally.
- Motivation related to job design, performance appraisal and discipline.
- Maintenance related to safety and health of the employees.

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

### SUMMARY OF STANDARDS

HRM. 1	The clinic implements human resource plan as per scope of services.
HRM. 2	The clinic establishes a program for professional training of the staff.
HRM. 3	There is a process and mechanism in place to ensure staff health and safety programme.

Objective Element	HRM.1.	HRM.2.	HRM.3.
a.	Core	Core	Commitment
b.	Commitment	Commitment	Commitment
c.	Commitment		Commitment
d.	Commitment		Commitment
e.	Commitment		

## Standard

### HRM.1.

### The clinic implements human resource plan as per scope of services.

#### Objective Elements

#### CORE

- a. **The clinic plans and maintains an adequate number and mix of appropriately qualified and experienced staff.**

**Interpretation:** The staff should be commensurate with the scope of services and patient workload. The clinic shall ensure that the staff has the necessary registration, qualification, skill and experience to perform its work.

#### Commitment

- b. **The clinic 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. The code of conduct shall include protection of patient's rights.

It is preferable that the staff signs the code of conduct at the time of joining.

#### Commitment

- c. **Disciplinary and grievance handling is defined and implemented.**

**Interpretation:** The disciplinary and grievance procedure is in consonance with the prevailing relevant labour laws and CCS (CCA) rules. Internal Complaints Committee should be established to handle complaints of sexual harassment. The disciplinary and grievance handling mechanism is known to all categories of staff.

The disciplinary policy must uphold principles of natural justice.

#### Commitment

- d. **Background verification and pre-employment medical examination is conducted for the staff.**

**Interpretation:** The clinic can have a suitable methodology to verify the antecedent and background of staff.

Pre- employment medical examination is conducted to ensure that the staff is fit to provide safe care to patients.

Diagnostic tests for the same are chosen based on standard guidelines. The clinic shall bear the expenses of such test.

#### Commitment

- e. **Personal record of all clinic staff shall be maintained.**

**Interpretation:** Employee files contain personal information regarding the employee's qualification, registration, experience, training, medical examination, job description, performance appraisal etc.

## Standard

**HRM.2.**

**The clinic establishes a programme for professional training of the staff.**

### Objective Elements

#### **CORE**

**a. Staff are provided induction training at the time of joining.**

**Interpretation:** All staff including doctors, nurses, paramedical and support staff are provided induction training in a structured manner. The clinic shall determine as to when the induction training shall be conducted. However, it shall be within 15 days of staff joining.

The induction training shall include orientation to clinic's vision, mission, values, staff and patients' rights and responsibilities, facility safety, cardio-pulmonary resuscitation, infection prevention and control, etc

#### **Commitment**

**b. There is an ongoing program for professional training and development of the staff.**

**Interpretation:** Ongoing training program shall be held periodically for various safety aspects, for example patient safety, occupational safety, facility safety, communication, skill development, new equipment and services added etc.

The training should include the policies, procedures and practices of infection control and prevention programme.

## Standard

**HRM.3.**

**There is a process and mechanism in place to ensure staff health and safety programme.**

### Objective Elements

#### **Commitment**

**a. The clinic takes care of the health problems of the staff including occupational health hazards.**

**Interpretation:** The clinic shall follow staff health and safety policy. Appropriate PPE is provided to the staff and they are trained to use them.

#### **Commitment**

**b. Health checks of staff are done at least once in a year.**

**Interpretation:** The results of these tests should be documented in personal files.

**Commitment**

- c. **The clinic identifies health care workers with transmissible infections and implements containment measures.**

**Interpretation:** The clinic shall encourage staff to report their illness or exposure and shall not penalize them. The clinic may modify job responsibilities after due counselling of the affected staff.

For example, exposure with Covid positive patient, or smear positive Tuberculosis case, staff affected with blood borne transmissible diseases (HIV, HBV etc.)

**Commitment**

- d. **Appropriate pre- and post-exposure prophylaxis is provided to all concerned staff members.**

**Interpretation:** This includes preventive immunization e.g. Hepatitis B vaccination and post exposure prophylaxis for Hepatitis B and HIV Exposure.

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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 clinic. 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 clinic will lay down policies and procedures to guide the contents, storage, security, issue and retention of medical records.

### SUMMARY OF STANDARDS

IMS. 1	The clinic initiates and maintains a medical record for every patient.
IMS. 2	The clinic meets information needs of patients, staff, management and external agencies.
IMS. 3	Telemedicine services are provided as per regulatory guidelines.

Objective Element	IMS.1.	IMS.2.	IMS.3.
a.	Core	Commitment	Commitment
b.	Commitment	Commitment	Commitment
c.	Commitment	Commitment	Achievement
d.	Commitment		
e.	Commitment		

## Standard

IMS.1.

The clinic initiates and maintains a medical record for every patient.

### Objective Elements

#### CORE

##### a. A unique identifier is assigned to the medical record.

**Interpretation:** Every sheet in the medical record shall have a unique identifier. This also applies to records on digital media. If the clinic maintains electronic records, all entries for one unique identifier shall be available in one place.

The unique identification number should be generated at the end of registration into the Clinic. One of the identifiers for identification of the patient shall be an unique identification number.

#### Commitment

##### b. Medical record provides a complete, up-to-date and chronological account of patient care as applicable.

**Interpretation:** In the case of patients undergoing procedures, the medical record shall have all identified sheets in a sequential order. Entries in the medical records are in a chronological order. All medico- legal case records shall have mandatory information. It is preferable that pages in the medical record are numbered.

#### Commitment

##### c. Every medical record entry is dated, timed and the author of the entry can be identified.

**Interpretation:** The author of the entry can be identified by writing the full name or by mentioning the employee code number, with the help of a stamp etc.

In case of electronic records, authorised e-signature provision, as per statutory requirements must be kept.

Traceability could be done by writing the name against every entry or having a “master signature list” in medical record which has the name of the person against the signature or employee code number against every entry.

For electronic record, it is preferable that the date and time are automatically generated by system.

#### Commitment

##### d. Care providers have access to current and past medical record.

**Interpretation:** The clinic provides access to medical records to designated health care providers (those who are involved in the care of that patient).

For electronic medical record system, identified care providers shall have a user ID and a password.

Provision is made for availability of the patient's record when needed to healthcare providers to ensure continuity of care

## Commitment

- e. **Retention period and process of destruction of medical records is defined as per national and State Laws/Guidelines.**

**Interpretation:** The clinic shall define the retention period for each category of medical records: Out-patient, day care patients and MLC. Retention period shall be in consonance with rules laid down by NMC and respective government authorities. The same shall apply to retention period of various data and the formats (e.g. registers and forms) that have been used for capturing this data.

## Standard

IMS.2.

**The clinic meets information needs of patients, staff, management and external agencies.**

## Objective Elements

### Commitment

- a. **Clinic identifies information needs of patients, visitors, staff, management and external agencies.\***

**Interpretation:** The information needs of various stake holders are identified through a systematic process. The identified information needs shall be documented. For example, the information needs of patients could be met through information on OPD timings, availability of service etc. For the staff, it would include information on leave policy, standard operating procedure etc. For external agencies it could be data of vital statistics, notifiable diseases etc. For the community it could be addition of new services, common symptomatology, or emerging disease.

### Commitment

- b. **Information management and technology acquisitions are commensurate with the identified information needs.**

**Interpretation:** The clinic shall define the needs for software and hardware solutions as per current and future information needs. In case the clinic uses electronic medical records, they could refer to Electronic Medical Record/ Electronic Health Report guidelines published by Ministry of Health and Family Welfare. 2017. The clinic shall ensure that it has the necessary license for the software.

### Commitment

- c. **Clinic develops, maintains, and tests a program for response to planned and unplanned downtime of data systems.**

**Interpretation:** The frequency for upkeep and maintenance of the system shall be defined & monitored. There shall be a defined process for backup of data. A comprehensive mitigation plan for handling various situations of system failure shall be documented. The staff shall be trained on handling the situations of system failure.

## Standard

IMS.3.

Telemedicine services are provided as per regulatory guidelines.

### Objective Elements

#### Commitment

- a. **Telemedicine facility is provided safely and securely based on National/Local Guidelines.\***

**Interpretation:** The clinic is aware of the legal and other requirements of Telemedicine facilities and the same are documented. The clinic maintains and updates its compliance status of safety and security of Telemedicine services as per current Ministry of Health and Family Welfare guidelines. The clinic shall have a mechanism for appropriate data storage and retrieval.

#### Commitment

- b. **The clinic ensures quality of patient care, confidentiality and security of information.**

**Interpretation:** When electronic communication is used, such as mobile-devices or patient-facing portals issued for Telemedicine, the clinic ensures quality of patient care, security and confidentiality of information. The clinic shall implement protection of the patient's identity and confidentiality. The clinic shall ensure the quality of patient care, as per current clinical guidelines. The clinic will preferably also care about transmission quality of the consultation given to the patients.

#### Achievement

- c. **There is a defined process for community linkages and outreach activities through Telemedicine consultation service.**

**Interpretation:** Whenever telemedicine facility is provided to community services or outreach clinics, there should be a written guidance in consonance with prevailing laws and guidelines. Limitations of information and communication technologies shall be explicitly addressed.

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# Management of Dermatology Services (MDS)

**Intent of the chapter:** This chapter emphasizes the special requirements for providing dermatology care at the clinic and/ or dermatology care center. The dermatology care should be provided in safe manner. The assessment and monitoring requirements as per the patient clinical needs based on the dermatology care guidelines are adhered to. The procedure in these patients are performed after informed consent. Nursing care is provided as per the established protocols. The dermatology care is provided with adequate infection prevention activities. The key performance indicators are used to improve the quality of care of the patient's undergoing dermatology at the clinic.

## SUMMARY OF STANDARDS

<b>MDS.1</b>	The Clinic provides safe dermatology services.
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Objective Element	MDS.1.
a.	Core
b.	Commitment
c.	Commitment
d.	Core
e.	Core
f.	Commitment
g.	Commitment
h.	Commitment
i.	Commitment



## Standard

### MDS.1.

### The clinic provides safe dermatology services.

#### Objective Elements

#### CORE

- a. **Scope of procedures being done at the clinic are commensurate with the clinical needs and safety of the patients.**

**Interpretation:** Persons qualified by law shall perform procedures. The scope of procedures carried out at the clinic are based on written guidance.

Care is organized and delivered as per written guidance.

The clinic shall have necessary equipment in consonance with scope of its services as per national / international guidelines.

#### Commitment

- b. **Patients requiring continuous monitoring beyond clinical timings shall be referred to an identified facility.**

**Interpretation:** For patients requiring unanticipated overnight stay, the clinic shall have a MoU with an appropriate facility

#### Commitment

- c. **All patients are assessed before a procedure.**

**Interpretation:** The clinical assessment shall also reaffirm the working diagnosis. The assessment shall also cover history, co-existing disease (e.g. Hypertension, Diabetes mellitus, COPD, seizure etc.) vital signs, documentation of drug allergies, review of the medications the patient is taking currently etc.

The pre procedure instructions shall include but not limited to written instructions about arrival time, place, fasting requirements, post-procedural course, driving limitation, need for responsible accompanying adult etc.

#### CORE

- d. **Informed consent is taken before a procedure.**

**Interpretation:** There shall be separate consent for procedure and sedation/ anaesthesia. Informed consent shall adhere to statutory norms.

Informed consent shall include information regarding the procedure; its risks, benefits, alternatives and as to who will perform the procedure in the language they can understand.

The informed consent shall be taken by the person performing the procedure.

#### CORE

- e. **Care is taken to prevent adverse events like wrong site, wrong patient and wrong procedure.**

**Interpretation:** The organization 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 patient's unique identification number. The organization should be able to

demonstrate methods to prevent these events, for example, identification tags, badges, cross-checks, time-outs etc. Refer to WHO “Safe surgery saves lives” initiative.

Adequate care should be taken during procedures such as UV radiation treatment, laser treatment etc. to ensure staff and patient safety.

## Commitment

### f. Written guidance governs procedural sedation.

**Interpretation:** Written guidance at a minimum shall include identification of procedures and patients which will need sedation, along with the drug and doses.

If sedation is given, intra-procedure monitoring includes at a minimum the heart rate, cardiac rhythm, respiratory rate, blood pressure, oxygen saturation, and level of sedation (for example Ramsay sedation scale). Certain other parameters may be monitored on a case-to-case basis. The competent person shall be appropriately trained in ALS.

The sedation notes shall include pre-procedure assessment, monitoring during and after procedure, discharge / transfer out criteria after the procedure.

The person monitoring sedation is trained in detection of rhythm abnormality / apnoea / airway obstruction and is different from the person performing the procedure. Whenever parenteral route is used the drug may be administered by a doctor or a nurse under supervision of a doctor.

## Commitment

### g. Written guidance governs administration of anaesthesia.

**Interpretation:** Written guidance at a minimum shall include identification of procedures and patients which will need anaesthesia along with plan for anaesthesia.

During anaesthesia, the monitoring shall include regular recording of temperature, heart rate, cardiac rhythm, respiratory rate, blood pressure, oxygen saturation and end tidal carbon dioxide and is documented. During regional anaesthesia, instead of end tidal carbon dioxide, adequacy of ventilation is monitored by continual observation of clinical signs. Certain other parameters may be monitored on a case-to-case basis. An Anaesthesiologist will be present throughout the procedure.

Intraoperative adverse anaesthesia events shall be clearly defined and monitored.

The post operative care plan shall advice on IV fluids , medication , care of wound, nursing care, observing for any complications, etc. The plan could be written by the dermatologist in collaboration with the anaesthesiologist.

When anaesthesia is provided on an urgent basis, the pre-anaesthesia assessment and pre-induction assessment may be performed immediately following one another, or simultaneously, but should be documented separately.

## Commitment

### h. The operative procedure note is documented.

**Interpretation:** The note provides information about the procedure performed, intraoperative findings, if any, status of the patient after the procedure. This shall be documented by the dermatologist.

## Commitment

- i. **The Dermatology clinic develops appropriate key performance indicators suitable to monitor clinical structures, processes and outcomes.**

**Interpretation:** The Dermatology clinic shall at a minimum identify and monitor the following indicators in addition to those mentioned under quality assurance program.

1. Negative biopsy rate.
2. ADR related to steroid applications
3. Adverse events during procedures.

## References:

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# Management of Dialysis Care (MDC)

**Intent of the chapter:** This chapter emphasizes the special requirements for providing dialysis care at a clinic and/ or a dialysis care centre. Dialysis care should be provided in safe manner. The assessment and monitoring requirements are adhered to, based on the dialysis care guidelines and the patient's clinical needs. . The procedure in these patients are performed after informed consent. Nursing care is provided as per established protocols. Dialysis care is provided with adequate infection prevention activities and engineering controls. Key performance indicators are used to improve the quality of care of the patient's who undergo dialysis at the clinic.

## SUMMARY OF STANDARDS

<b>MDC.1</b>	The Centre provides safe dialysis services.
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Objective Element	MDC.1.
a.	Core
b.	Commitment
c.	Core
d.	Core
e.	Core
f.	Commitment
g.	Commitment
h.	Commitment
i.	Core
j	Commitment
k.	Commitment
i.	Commitment

## Standard

### MDC.1.

### The Centre provides safe dialysis services.

#### Objective Elements

#### CORE

- a. **The scope of procedures being done at clinic are commensurate with the clinical needs and safety of the patients.**

**Interpretation:** Persons qualified by law shall perform the procedures. The scope of procedures carried out at centre are based on written guidance.

Care is organised and delivered as per written guidance.

The equipment will be in consonance with scope of the centre as per national / international guidelines.

#### Commitment

- b. **Patients requiring continuous monitoring, beyond the scope of care shall be referred to an identified facility.**

**Interpretation:** For patients requiring unanticipated stay, the centre shall have a MoU with an appropriate facility.

#### CORE

- c. **All patients are assessed before the procedure.**

**Interpretation:** The clinical assessment shall also reaffirm the working diagnosis. The assessment shall also cover history, co-existing disease (e.g. Hypertension, Diabetes mellitus, COPD, seizure etc ) vital signs, documentation of drug allergies, review of the medications the patient is taking currently etc.

The pre-procedure instructions shall include, but not be limited to, written instructions about arrival time, place, fasting requirements, post- procedural course, driving limitation, need for responsible accompanying adult etc.

#### CORE

- d. **Informed consent is taken before the procedure.**

**Interpretation:** There shall be a separate consent for procedure and sedation/ anaesthesia.

Informed consent shall adhere to statutory norms.

Informed consent shall include information regarding the procedure; its risks, benefits, alternatives and as to who will perform the procedure in a language that the patient can understand.

The informed consent shall be taken by the person performing the procedure.

The validity of the informed consents shall be defined and mentioned in the respective consent forms. 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 will not exceed six months. The patient endorses the consent at each repeat procedure. However, if there is a change in the treatment modality or an addition of another modality, then a fresh consent shall be obtained.

## CORE

### e. Care is taken to prevent adverse events like wrong site, wrong patient and wrong procedure.

**Interpretation:** The organization 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 organization should be able to demonstrate methods to prevent these events, for example identification tags, badges, cross-checks, time-outs etc. Refer to WHO “Safe surgery saves lives” initiative.

## Commitment

### f. Written guidance governs procedural sedation.

**Interpretation:** Written guidance at a minimum shall include identification of those procedures and patients who will need sedation, along with the drug and doses.

If sedation is given, intra-procedure monitoring includes at a minimum the heart rate, cardiac rhythm, respiratory rate, blood pressure, oxygen saturation, and level of sedation (for example Ramsay sedation scale). Certain other parameters may be monitored on a case-to-case basis. The competent person shall be appropriately trained in ALS

The sedation notes shall include pre-procedure assessment, monitoring during and after procedure, discharge / transfer out criteria after the procedure.

The person monitoring sedation is trained in detection of rhythm abnormality / apnoea / airway obstruction and is different from the person performing the procedure. Whenever the parenteral route is used the drug may be administered by a doctor or a nurse under supervision of a doctor.

## Commitment

### g. Written guidance governs administration of anaesthesia.

**Interpretation:** Written guidance, at a minimum shall include identification of procedures and patients which will need anaesthesia along with an anaesthesia plan.

During anaesthesia, the monitoring includes regular recording of temperature, heart rate, cardiac rhythm, respiratory rate, blood pressure, oxygen saturation and end tidal carbon dioxide and is documented. During regional anaesthesia, instead of end tidal carbon dioxide, adequacy of ventilation is monitored by continual observation of clinical signs. Certain other parameters may be monitored on a case-to-case basis. An Anaesthesiologist will be present throughout the case.

Intraoperative adverse anaesthesia events shall be clearly defined and monitored.

The post operative care plan shall advice on IV fluids, medication, care of the wound, nursing care, observing for any complications, etc. The plan could be written by the surgeon in collaboration with the anaesthesiologist.

When anaesthesia is provided on an urgent basis, the pre-anaesthesia assessment and pre-induction assessment may be performed immediately following one another, or simultaneously, but should be documented separately.

## Commitment

### h. The operative procedure note is documented.

**Interpretation:** The note provides information about the procedure performed, intraprocedural findings, if any, status of the patient after the procedure. This shall be documented by the doctor performing the procedure.

## CORE

### i. Patients are monitored for adverse events before discharge and the same is documented.

**Interpretation:** Patients at the time of discharge are monitored for

1. Vitals
2. Weight of the patient
3. Bleeding from the site of incision.
4. Any eventful stay to the centre.
5. All above parameters shall be recorded in the discharge summary and patient records.

## Commitment

### j. Nursing care is provided to patients while at the centre, in consonance with clinical protocols.

**Interpretation:** Written guidance governs nursing care before, during and after the procedure.

For example, nursing initial assessment, shall guide the nursing care plan. Nurses are trained in identifying early warning signs and actions to be taken thereof.

Nursing care training shall also include care of vascular access (centreline catheters, fistula, grafts etc).

## Commitment

### k. The written guidance governs equipment and engineering controls.

**Interpretation:** Standard operating procedures for dialysate and equipment maintenance are available. This shall include the following:

- Monthly microbiological analysis of the dialysate collect samples from the inlet to the dialyser.
- Disinfection of each machine out as per manufacturers instructions and recommended infection control practises (CDC guidelines on disinfection and sterilisation) yearly machines servicing and calibration records etc.
- Dialyzers reprocessing protocols shall address at a minimum,
- The number of reuses
- Time for reprocessing
- Storage (dialyzer closed with caps and disinfectant is filled completely; dialyzer and dialyzer storage box marked with Patient Name and ID) and
- Final disposal of dialyzer.
- A record of the same shall be maintained.

Periodic monitoring of RO water as per standard guidelines (for example, daily monitoring of TDS of the RO water, pH; In case of 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 the levels conform to national / or International standards. Such monitoring shall be governed by established standards and the guidance shall be updated from time-to-time.

## Commitment

### I. The dialysis centre develops appropriate key performance indicators which are suitable to monitor clinical structures, processes and outcomes.

**Interpretation:** The dialysis centre shall at a minimum identify and monitor the following indicators in addition to those mentioned under quality assurance programme :

1. Catheter related blood stream infection rates
2. Adverse events during dialysis
3. Percentage of cases where dialysis was interrupted.

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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.

<b>Accreditation</b>	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.
<b>Accreditation assessment</b>	The evaluation process for assessing the compliance of an organisation with the applicable standards for determining its accreditation status.
<b>Advance life support</b>	Emergency medical care for sustaining life, including defibrillation, airway management, and drugs and medications.
<b>Adverse drug reaction</b>	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.
<b>Adverse event</b>	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)
<b>Anaesthesia Death</b>	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.
<b>Assessment</b>	All activities including history taking, physical examination, laboratory investigations that contribute towards determining the prevailing clinical status of the patient.
<b>Barrier nursing</b>	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.
<b>Basic life support</b>	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.
<b>Breakdown maintenance</b>	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.
<b>Byelaws</b>	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
<b>Calibration</b>	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.

<b>Care Plan</b>	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.
<b>Citizen's charter</b>	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: <a href="https://goicharters.nic.in/faq.htm">https://goicharters.nic.in/faq.htm</a> )
<b>Clinical autopsy</b>	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.
<b>Clinical practice guidelines</b>	Clinical practice guidelines are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.
<b>Competence</b>	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.
<b>Confidentiality</b>	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.
<b>Consent</b>	<ol style="list-style-type: none"> <li>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.</li> <li>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.</li> </ol>
<b>Control Charts</b>	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.
<b>Correction</b>	Action to eliminate the detected non-conformity (Reference: ISO 9000:2015)
<b>Corrective action</b>	Action to eliminate the cause of a non-conformity and to prevent recurrence. (Reference: ISO 9000:2015)
<b>Credentialing</b>	The process of obtaining, verifying and assessing the qualification of a healthcare provider.

<b>Data</b>	Data is a record of the event.
<b>Discharge summary</b>	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).
<b>Disciplinary procedure</b>	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.
<b>Drug dispensing</b>	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.)
<b>Drug Administration</b>	The giving of a therapeutic agent to a patient, e.g. by infusion, inhalation, injection, paste, pessary, suppository or tablet.
<b>Effective communication</b>	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.
<b>Employees</b>	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.
<b>Enhanced communication</b>	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.
<b>Ethics</b>	Moral principles that govern a person's or group's behaviour.
<b>Evidence-based medicine</b>	Evidence-based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients.
<b>Family</b>	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.
<b>Failure Mode and Effect Analysis (FMEA)</b>	A method used to prospectively identify error risks within a particular process.
<b>Formulary</b>	An approved list of drugs. Drugs contained in the formulary are generally those that are determined to be cost-effective and medically effective.
<b>Goal</b>	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 Baldrige National Quality Award)
<b>Grievance- handling procedures</b>	The sequence of activities carried out to address the grievances of patients, visitors, relatives and staff.
<b>Hazardous materials</b>	Substances dangerous to human and other living organisms. They include radioactive or chemical materials.

<b>Hazardous waste</b>	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.
<b>Healthcare- associated infection</b>	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)
<b>Healthcare organisation</b>	The generic term is used to describe the various types of organisation that provide healthcare services. This includes ambulatory care centres, hospitals, laboratories, etc.
<b>High-dependency unit</b>	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.
<b>High Risk/High Alert Medications</b>	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.
<b>Incident reporting</b>	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.
<b>In-service education/training</b>	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.
<b>Indicator</b>	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.
<b>Information</b>	Processed data which lends meaning to the raw data.
<b>Intent</b>	A brief explanation of the rationale, meaning and significance of the standards laid down in a particular chapter.
<b>Inventory control</b>	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.
<b>Isolation</b>	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.

<b>Job description</b>	<ol style="list-style-type: none"> <li>1. It entails an explanation pertaining to duties, responsibilities and conditions required to perform a job.</li> <li>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.</li> </ol>
<b>Job specification</b>	<ol style="list-style-type: none"> <li>1. The qualifications/physical requirements, experience and skills required to perform a particular job/task.</li> <li>2. A statement of the minimum acceptable qualifications that an incumbent must possess to perform a given job successfully.</li> </ol>
<b>Maintenance</b>	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)
<b>Medical equipment</b>	Any fixed or portable non-drug item or apparatus used for diagnosis, treatment, monitoring and direct care of a patient.
<b>Medication error</b>	<p>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.</p> <p>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)</p>
<b>Medication Order</b>	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)
<b>Mission</b>	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.
<b>Monitoring</b>	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.
<b>Multidisciplinary</b>	A generic term which includes representatives from various disciplines, professions or service areas.
<b>Near-miss</b>	<p>A near-miss is an unplanned event that did not result in injury, illness, or damage--but had the potential to do so.</p> <p>Errors that did not result in patient harm, but could have, can be categorised as near-misses.</p>

<b>No harm</b>	<p>This is used synonymously with a near miss. However, some authors draw a distinction between these two phrases.</p> <p>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).</p>
<b>Notifiable disease</b>	<p>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:</p> <ul style="list-style-type: none"> <li>(a) Smallpox</li> <li>(b) Poliomyelitis due to wild-type poliovirus</li> <li>(c) Human influenza caused by a new subtype</li> <li>(d) Severe acute respiratory syndrome (SARS).</li> </ul> <p>In India, the following is an indicative list of diseases which are also notifiable, but may vary from state to state:</p> <ul style="list-style-type: none"> <li>(a) Polio</li> <li>(b) Influenza</li> <li>(c) Malaria</li> <li>(d) Rabies</li> <li>(e) HIV/AIDS</li> <li>(f) Louse-borne typhus</li> <li>(g) Tuberculosis</li> <li>(h) Leprosy</li> <li>(i) Leptospirosis</li> <li>(j) Viral hepatitis</li> <li>(k) Dengue fever</li> </ul>
<b>Objective</b>	<p>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)</p>
<b>Objective element</b>	<p>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.</p>
<b>Occupational health hazard</b>	<p>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.</p>
<b>Operational plan</b>	<p>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.</p>
<b>Organogram</b>	<p>A graphic representation of the reporting relationship in an organisation.</p>



<b>Outsourcing</b>	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.
<b>Patient-care setting</b>	The location where a patient is provided health care as per his needs, e.g. ICU, speciality ward, private ward and general ward.
<b>Patient record/ medical record/ clinical record</b>	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.
<b>Patient Satisfaction</b>	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.
<b>Patient Experience</b>	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.
<b>Performance appraisal</b>	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.
<b>Point of care equipment</b>	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.
<b>Policies</b>	They are the guidelines for decision-making, e.g. admission, discharge policies, antibiotic policy, etc.
<b>Preventive action</b>	Action to eliminate the cause of a potential non-conformity. (Reference ISO 9000:2015)
<b>Preventive maintenance</b>	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.
<b>Prescription</b>	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)

<b>Privileging</b>	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.
<b>Privileged communication</b>	Confidential information furnished (to facilitate diagnosis and treatment) by the patient to a professional authorised by law to provide care and treatment.
<b>Procedural sedation</b>	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)
<b>Procedure</b>	<ol style="list-style-type: none"> <li>1. A specified way to carry out an activity or a process (Para 3.4.5 of ISO 9000: 2015).</li> <li>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.</li> </ol>
<b>Process</b>	A set of interrelated or interacting activities which transforms inputs into outputs (Para 3.4.1 of ISO 9000: 2015).
<b>Programme</b>	A sequence of activities designed to implement policies and accomplish objectives.
<b>Protocol</b>	A plan or a set of steps to be followed in a study, an investigation or an intervention.
<b>Quality</b>	<ol style="list-style-type: none"> <li>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).</li> <li>2. Degree of adherence to pre-established criteria or standards.</li> </ol>
<b>Quality assurance</b>	Part of quality management focussed on providing confidence that quality requirements will be fulfilled (Para 3.2.11 of ISO 9000:2015).
<b>Quality improvement</b>	Ongoing response to quality assessment data about a service in ways that improve the process by which services are provided to consumers/patients.
<b>Radiation Safety</b>	<p>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.</p> <p>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 &amp; Technical Terms)</p> <p>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.</p> <p>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.</p>
<b>Re-assessment</b>	It implies a continuous and ongoing assessment of the patient, which is recorded in the medical records as progress notes.

<b>Reconciliation of medications</b>	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)
<b>Resources</b>	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.
<b>Risk abatement</b>	Risk abatement means minimising the risk or minimising the impact of that risk.
<b>Risk assessment</b>	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.
<b>Risk management</b>	Clinical and administrative activities to identify, evaluate and reduce the risk of injury.
<b>Risk mitigation</b>	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.
<b>Risk reduction</b>	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.
<b>Root Cause Analysis (RCA)</b>	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.
<b>Safety</b>	The degree to which the risk of an intervention/procedure, in the care environment is reduced for a patient, visitors and healthcare providers.
<b>Safety programme</b>	A programme focused on patient, staff and visitor safety.
<b>Scope of services</b>	Range of clinical and supportive activities that are provided by a healthcare organisation.
<b>Security</b>	Protection from loss, destruction, tampering, and unauthorised access or use.

<b>Sedation</b>	<p>The administration to an individual, in any setting for any purpose, by any route, moderate or deep sedation. There are three levels of sedation:</p> <p>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.</p> <p>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.</p> <p>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.</p>
<b>Sentinel events</b>	<p>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.</p>
<b>Social responsibility</b>	<p>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.</p>
<b>Sound clinical practice</b>	<p>Practitioner decisions based on available knowledge, principles and practices for specific clinical situations.</p>
<b>Special Educational needs of the patient</b>	<p>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.</p>
<b>Staff</b>	<p>All personnel working in the organisation including employees, "fee-for-service" medical professionals, part-time workers, contractual personnel and volunteers.</p>
<b>Standard precautions</b>	<ol style="list-style-type: none"> <li>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</li> <li>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.</li> </ol> <p>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</p>
<b>Standards</b>	<p>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.</p>
<b>Sterilisation</b>	<p>It is the process of killing or removing microorganisms including their spores by thermal, chemical or irradiation means.</p>

<b>Strategic plan</b>	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.
<b>Surveillance</b>	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.
<b>Table-top exercise</b>	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: <a href="https://uwpd.wisc.edu/content/uploads/2014/01/What_is_a_tabletop_exercise.pdf">https://uwpd.wisc.edu/content/uploads/2014/01/What_is_a_tabletop_exercise.pdf</a> )
<b>Traceability</b>	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)
<b>Transfusion reaction</b>	A transfusion reaction is a problem that occurs after a patient receives a transfusion of blood.
<b>Triage</b>	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.
<b>Turn-around-time</b>	Turnaround Time (TAT) means the amount of time taken to complete a process or fulfil a request.
<b>Unstable patient</b>	A patient whose vital parameters need external assistance for their maintenance.
<b>Validated tool</b>	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).
<b>Validation</b>	Validation is verification, where the specified requirements are adequate for the intended use.
<b>Values</b>	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.
<b>Verbal order</b>	Verbal orders are those orders given by a physician with prescriptive authority to a licensed person who is authorised by the organisation.
<b>Verification</b>	Verification is the provision of objective evidence that a given item fulfils specified requirements.

<b>Vision</b>	<p>An overarching statement of the way an organisation wants to be, an ideal state of being at a future point.</p> <p>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.</p>
<b>Vulnerable patient</b>	<p>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.</p>
<b>Workplace violence</b>	<p>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)</p>

## CHECK POINTS BEFORE ASSESSMENT

Parameters	Check points before undergoing assessment
Licenses	Compliance to statutory compliance such as Registration, Biomedical Waste Authorization from Pollution Control Board, Fire NOC / 3rd party fire safety audit report, AERB licenses (If applicable), PCPNDT (If applicable), MTP (If applicable), Pharmacy (If applicable)
Infection control	Hand rub disinfectant available at each bedside and hand hygiene opportunities are used
	All staffs are vaccinated against HB-V and Covid
Bio-Medical Waste management	Availability of Biomedical Waste Authorization form Pollution Control Board
	Bio-waste disposed off regularly, as per state guidelines
	Use of appropriate colours bags to dispose waste with segregation of sterile & unsterile items
Emergency Preparedness	Availability of crash cart / list of emergency medicines which are stored separately and not mixed with regular inventory. Written policy guiding use and replenishment of medicines to be known to staffs.
	Centre has adequate quantities of working Oxygen Flow-meters and Cylinders and they have been kept in designated place with proper visible labelling
	Suction Apparatus, Nebulizer Laryngoscope, Defibrillator are all working and all staff know how to use
	Fire extinguishers are in place, checked at defined intervals and all the staff members have been trained in handling Fire emergencies
	All staff members are trained on Basic Life Support (BLS)
Documentation	Written SOPs to be in place as per standards & guidebook wherever (*) is given
	Adverse Events details captured either Manual or Electronically
	Case sheets of patients are complete in all respects (Arrival, chief complaints, course during stay, discharge advice)
	Consent forms have been completed along with all signatures
	Patient files have labels with name, ID, gender and Age
Pharmacy	Availability of Pharmacy license and licensed Pharmacist
	Refrigerator, if present and used has temperature being maintained at 2-8 degrees centigrade and cleaned/defrosted as needed

List of Policies	Policy on Patient Registration
	Policy on Initial Assessment of patients
	Policy on transfer of lab specimens
	Policy on lab safety and Quality Assurance (If applicable)
	Policy on uniformity in care
	Policy on handling Medico Legal Cases
	Policy on High Risk Medicines
	Policy on identification of patient
	Policy on Verbal Orders
	Policy on medication order, dispensing, administration , monitoring
	Policy on Adverse Drug Reaction (ADR)
	Policy on display of patient rights and grievance handling
	Policy on consents
	Policy on Infection Control, Infusion Practices, Antibiotic Uses
	Program on Patient Safety covering incidents from "No Harm" to "Sentinel Events"
	Documented Quality Improvement Program which covers monitoring of indicators as mentioned in PSQ.2
	Policy on Vision, Mission of clinic
	Written guidance on Fire & Non Fire emergencies and hazardous materials
	Policy on Medical Records, retention and discard
	Policy on HR files and record
	Policy on Grievance Redressal
	Policy on acquisition of formulary medications
	Written guidance on procurement, handling, storage, distribution, usage and replenishment of medical gases
	Written programme for equipment and facility management
	Written guidance for equipment and engineering controls in Dialysis unit.
	Written guidance of Dialyzer use, re-use and discard
	Standard Operating Procedures on testing of endotoxins and RO water
	Monitoring of Quality Indicators as mentioned in the guidebook



The Allopathic Clinics having OPD and/or Day Care need to register and submit the required application fee. After submission of application cum annual fee, reference number will be generated. The reference number will be unique and will required to be quoted while mentioning about the application. The clinic will get 30 days time to fill in the application and give their readiness to undergo Final Assessment (FA). The Final Assessment may be on a virtual mode / Onsite. The number of assessors shall depend upon the size and scope of services of Clinic. Clinics with single Speciality will have one assessor for one day whereas Poly clinics (clinics having more than one service) will have 2 assessors visiting the facility to assess the requirements as per Allopathic Clinics standards second edition. To guide the clinics, about requirements of standards, Self Assessment Toolkit has been prepared which is a checklist to have all the required documents ready in the time span after registering till the assessment. The toolkit will serve as a methodology to check the clinics' availability of written guidelines wherever asterisk (\*) mark is given and the implementation of the written guidelines within facility.

## Elements

### Chapter 1: ACCESS, ASSESSMENT AND CONTINUITY OF CARE (AAC)

<b>AAC.1. The Clinic defines and displays the services that it can provide.</b>	
a.	The Clinic defines the services it can provide.
b.	The services provided are prominently displayed.
<b>AAC.2. The Clinic has a well-defined patient registration process and appropriate mechanism for referral of patients who do not match its resources.</b>	
a.	<b>Written guidance governs the patient registration process.*</b>
b.	Patients are accepted only if the clinic can provide the required services.
c.	The Patients are prioritized as per clinic needs.
<b>AAC.3. Patient's initial and continuing healthcare needs are identified through an established assessment process.</b>	
a.	<b>Written guidance governs the content of the initial assessments.*</b>
b.	Initial assessment is completed in defined time frame.
c.	The Clinic identifies special needs of the patient.
d.	<b>Written guidance governs the process for integrated patient care.*</b>
e.	Patients are reassessed to determine their response to treatment and to plan further treatment or discharge.
f.	Patients are informed of their next follow-up, where appropriate.
g.	<b>The Clinic has a process to identify the transportation needs of the patients and facilitate the same as applicable.*</b>

<b>AAC.4. Laboratory services, if provided, are as per the scope of the services at the Clinic.</b>	
a	Lab services, if provided on site are commensurate with the scope of services and comply with applicable local/ and national standards, laws and regulations.
b	<b>Written guidelines guide collection, identification, handling, safe transportation, processing and disposal of specimens.*.</b>
c	<b>The Laboratory services, if provided on site, will have a quality assurance programme.*</b>
d	<b>Laboratory services if provided on site will have a laboratory safety programme.*</b>
e	<b>Laboratory tests if outsourced are based on quality assurance.*</b>

<b>AAC.5. Imaging services if provided are as per scope of services of the Clinic.</b>	
a	Imaging services if provided on site are restricted to support primarily the scope of clinical services and comply with legal and other requirements.
b	Quality assurance programme for imaging services is implemented.
c	Radiation safety programme for imaging services is implemented.
d	Imaging services if not available in the Clinic are outsourced to meet patient needs.

<b>AAC.6. The day care clinic has an established discharge process and defines contents of discharge summary.</b>	
a	The patient's discharge process is planned in consultation with the patient and/or family.
b	A discharge summary is given to all the patients leaving the organization (including patients leaving against medical advice and on request).
c	Discharge summary contains follow-up advice, medication, other instructions and when and how to obtain urgent care in an understandable manner.
d	In case of death of a patient, the summary of the case also includes the cause of death.

## Chapter 2: CARE OF PATIENTS (COP)

<b>COP1. Care and treatment is provided in a uniform manner.</b>	
a	Uniform care is provided following written guidance.*
b	During all phases of care, there is a qualified individual available for the patient's care.
c	The care and treatment orders are signed, named, timed and dated by the concerned doctor.

<b>COP2. The Clinic provides treatment and care as per established guidelines.</b>	
a	Clinic adapts evidence-based clinical practice guidelines.
b	Nursing care is provided to day care patients in accordance with written guidance as per the scope of services *

<b>COP3. Written guideline guides the care &amp; treatment of patients with special identified needs</b>	
a	The Clinic identifies patient who are at high risk of morbidity and mortality and manages them as per the scope of services available.
b	Written guidance addresses handling of medico-legal cases.*
c	Written guidance governs the management of pain.*

<b>COP4. Identification of early warning signs and Cardiopulmonary resuscitation services are provided uniformly across the clinic.</b>	
a	<b>There is a written guidance for prioritisation in OPD, based on early warning signs of change or deterioration in clinical conditions for initiating prompt intervention*</b>
b	Resuscitation services are available to all patients at all times when required.

### Chapter 3: MANAGEMENT OF MEDICATION (MOM)

<b>MOM.1. The clinic develops, updates and implements a formulary.</b>	
a	A list of medications appropriate for patients as per the scope of the clinical services is developed collaboratively by a multi-disciplinary committee.
b	The current formulary is available for clinicians to refer to.
c	Clinicians adhere to the current formulary.
d	<b>The clinic adheres to the written guidance for acquisition of formulary medications. *</b>
e	<b>The clinic adheres to the procedure to obtain medications not listed in the formulary. *</b>

<b>MOM.2. Medications are stored appropriately and are available where required.</b>	
a	Medications are stored in a clean, safe and secure environment; and incorporating the manufacturer's recommendation(s).
b	Sound inventory control practices guide storage of the medications.
c	The clinic defines a list of high-risk medication(s). *
d	High-risk medications are stored in areas of the clinic where it is clinically necessary.
e	High-risk medications including look-alike, sound-alike medications and different concentrations of the same medication are stored physically apart from each other. *
f	The list of emergency medications is defined and is stored uniformly. *
g	Emergency medications are available at all times and are replenished promptly when used.

<b>MOM.3. Medications are prescribed safely and rationally.</b>	
a	Medication prescription is in consonance with good practices/guidelines for the rational prescription of medications.
b	The clinic adheres to the determined minimum requirements of a prescription. *
c	Drug allergies and previous adverse drug reactions are ascertained before prescribing.
d	The clinic has a mechanism to assist the clinician in prescribing appropriate medication.
e	<b>Written guidance governs implementation of verbal orders and ensures safe medication management practices. *</b>
f	Audit of medication orders/prescription is carried out to check for safe and rational prescription of medications.
g	Corrective and/or preventive action(s) is taken based on the audit, where appropriate.
h	Reconciliation of medications occurs at transition points patient care

<b>MOM.4. Medications orders are written in a uniform manner.</b>	
a	The clinic ensures that only authorized personnel write orders. *
b	Orders for medicines are written in a uniform location in the medical records, which also reflects the patient's name and unique identification number.

<b>MOM.5. Medications are dispensed in a safe manner wherever applicable.</b>	
a	Dispensing of medications is done safely. *
b	Medication recalls are handled effectively. *
c	Near-expiry medications are handled effectively. **
d	Dispensed medications are labelled. *
e	High-risk medication orders are verified before dispensing.

<b>MOM.6. Medications are administered safely.</b>	
a	Medications are administered by those who are permitted by law to do so.
b	Prepared medication is labelled prior to preparation of a second drug.
c	The patient is identified prior to administration.
d	Medication is verified from the prescription and physically inspected before administration.
e	Strength, route and timing is verified from the order and medication administration is documented.

<b>MOM.7. Patients are monitored after medication administration.</b>	
a	Patients are monitored after medication administration
b	Medications are changed where appropriate based on the monitoring.
c	<b>The clinic captures near miss, medication error and adverse drug reaction. *</b>
d	<b>Near misses, medication error and adverse drug reaction are reported within a specified time frame. *</b>
e	Near misses, medication errors and adverse drug reactions are collected and analyzed.
f	Corrective and/or preventive action(s) are taken based on the analysis.

## Chapter 4: PATIENT RIGHTS AND EDUCATION (PRE)

<b>PRE.1. The Clinic protects patient and family rights and informs them about their responsibilities during care.</b>	
a	Patients and families are informed of their rights and responsibilities in a format and language that they can understand.*
b	Violation of patient rights is reviewed and corrective/preventive measures taken.

<b>PRE.2. Patient and family rights support individual beliefs, values and involve the patient and family in decision making processes.</b>	
a	Patient and family rights include respect for personal dignity and privacy during examination, procedures and treatment.
b	Patient and family rights include protection from neglect or physical abuse.
c	Patient and family rights include treating patient information as confidential.
d	Patient and family rights include the refusal of treatment.
e	Patient and family right include right to seek additional opinion regarding clinical care.
f	Patient and family rights include informed consent before any invasive procedure.
g	Patient and family rights include a right to complain and information on how to voice a complaint.
h	"Patient and family rights include information on the expected cost of the treatment. "
i	Patient and family has a right to have an access to his / her clinical records.

<b>PRE.3. A documented process for obtaining patient and/or families consent exists for informed decision making about their care.</b>	
a	The clinic obtains informed consent from the patient or family for situations where informed consent is required. *
b	Informed consent process adheres to statutory norms and includes information regarding the procedure; it's risks, benefits, alternatives and as to who will perform the requisite procedure, in a language that the patient/family can understand.
c	The clinic describes who can give consent when patient is incapable of independent decision making.*

<b>PRE.4. Patient and families have a right to information and education about their healthcare needs.</b>	
a	Patient and/or families are educated in a language and format that they can understand.
b	Patient and/or families are educated about the safe and effective use of medication and the potential side effects of the medication, when appropriate.
c	Patient and families are educated about food-drug interaction and diet and nutrition.
d	Patient and families are educated about immunizations.
e	Patient and families are educated about their specific disease process, prognosis, complications and prevention strategies.
f	Patient and families are educated about preventing healthcare associated infections.
g	Patient and/or family are educated on various pain management techniques, when appropriate.
<b>PRE.5. Patient and families have a right to information on expected costs.</b>	
a	The tariff list is available to patients.
b	Patients are educated about the expected cost of treatment.

## Chapter 5: Infection Prevention and Control (IPC)

<b>IPC.1. The clinic has an Infection Prevention and Control programme and is implemented.</b>	
a	Written guidance for infection prevention and control is available. *
b	The clinic adheres to standard precautions at all times.
c	Cleaning, packing, disinfection of surfaces, equipment cleaning and sterilization practices including reprocessing of instruments / single use devices is done as per written guidance
d	Antibiotic use is guided by standard guidelines.*
e	The Clinic adheres to safe injection and infusion practices.*
<b>IPC.2. The Clinic implements the infection prevention and control program for support services.</b>	
a	The Clinic adheres to housekeeping services guidelines
b	Biomedical waste (BMW) complies with national/state regulations and is handled appropriately and safely.
c	The Clinic adheres to laundry and linen management processes.
d	The Clinic adheres to kitchen sanitation and food-handling issues.

## Chapter 6: Patient Safety and Quality Improvement (PSQ)

<b>PSQ.1. The clinic establishes a patient safety programme.</b>	
a	The patient safety programme is implemented as per the scope of services.
b	<b>The programme covers incidents ranging from “NO Harm” to “Sentinel events”.*</b>
c	The Clinic adapts and implements national/international patient safety goals/solutions.
<b>PSQ.2. There is a structured quality improvement and continuous monitoring programme.</b>	
a	The quality improvement programme is documented.*
b	The quality improvement programme is reviewed at predefined intervals and Opportunities for improvement are identified.

## Chapter 7: RESPONSIBILITIES OF MANAGEMENT (ROM)

<b>ROM.1. The responsibilities of the management are defined.</b>	
a	<b>Those responsible for governance define the clinic’s vision, mission, and resources*</b>
b	<b>Those responsible for governance establish the Clinic’s organogram, as applicable. *</b>
c	<b>Administrative written guidance for each section is maintained. *</b>
d	The Clinic complies with the laid down, applicable legislations and Regulations at all times.
e	In cases of notifiable diseases, information (in relevant format) is sent to appropriate authorities.
<b>ROM.2. The Clinic is managed by the leaders in an ethical manner.</b>	
a	The Clinic functions in an ethical manner.
b	The Clinic honestly portrays its affiliations and accreditation
c	The Clinic accurately bills for its services based upon a standard billing tariff.
<b>ROM.3. The Clinic participate in health promotion and disease prevention.</b>	
a	There is a process and mechanism in place to ensure health promotion and disease prevention.
b	The Clinic cooperates and collaborates with the community partners in provision of surveillance, epidemiological investigations, data collection, when required.

## Chapter 8: Facility Management and Safety (FMS)

FMS.1.	The Clinic shall operate in an environment to ensure safety of patients, staff and visitors.
a	Updated drawings are maintained with details of site layout, floor plans and fire escape routes.
b	There is internal and external sign posting in the Clinic in a language understood by patient, families and community.
c	Facilities and space provisions are appropriate to the scope of clinic.
d	Patient safety devices and infrastructure are installed across the clinic.
FMS.2.	The Clinic has a programme for equipment and facility management.
a	The Clinic plans for equipment in accordance with its services and strategic plan
b	Equipment is periodically inspected and calibrated for their proper functioning.
c	Safe water and uninterrupted electrical supply is available.
d	<b>Written guidance governs procurement, handling, storage, distribution, usage and replenishment of medical gases.*</b>
FMS.3.	The Clinic has plans for emergencies (fire and non-fire) and hazardous materials within the facility.
a	The Clinic has plans and provisions for early detection, abatement and containment of fire and non-fire emergencies.*
b	The Staff is trained for their role in case of such emergencies.
c	The clinic has addressed identification, sorting, storage, handling, transportation, disposal mechanism, and method for managing spillages of hazardous materials.

## Chapter 9: Human Resource Management (HRM)

HRM.1.	The Clinic implements human resource plan as per scope of services.
a	The clinic plans and maintains an adequate number and mix of appropriately qualified and experienced staff.
b	The clinic defines and implements a code of conduct for its staff.
c	Disciplinary and grievance handling is defined and implemented
d	Background verification a pre-employment medical examination is conducted on the staff.
e	Personal record of all clinic staff shall be maintained.
HRM.2.	The clinic establishes a program for professional training of the staff.
a	Staff are provided induction training at the time of joining.
b	There is an ongoing program for professional training and development of the staff.



<b>HRM.3.</b>	<b>There is a process and mechanism in place to ensure staff health and safety programme.</b>
a	The clinic takes care of the health problems of the staff including occupational health hazards.
b	Health checks of staff are done at least once in a year.
c	The clinic identifies health care workers with transmissible infections and implements containment measures.
d	Appropriate pre and post exposure prophylaxis is provided to all concerned staff members.

## Chapter 10: Information Management System (IMS)

<b>IMS.1.</b>	<b>The Clinic initiates and maintains a medical record for every patient.</b>
a	The unique identifier is assigned to the medical record.
b	Medical record provides a complete, up-to-date and chronological account of patient care as applicable.
c	Every medical record entry is dated, timed and the author of the entry can be identified.
d	Care providers have access to current and past medical record.
e	Retention period and process of destruction of medical records is defined as per national and State Laws/Guidelines.

<b>IMS.2.</b>	<b>The Clinic meets information needs of patients, staff, management and external agencies.</b>
a	<b>Clinic identifies information needs of patients, visitors, staff, management and external agencies.*</b>
b	Information management and technology acquisitions are commensurate with the identified information needs.
c	Clinic develops, maintains, and tests a program for response to planned and unplanned downtime of data systems.

<b>IMS.3.</b>	<b>Telemedicine services are provided as per regulatory guidelines.</b>
a	Telemedicine facility is provided safely and securely based on National/Local Guidelines.*
b	The Clinic ensures quality of patient care, confidentiality and security of information.
c	There is a defined process for community linkages and outreach activities through Telemedicine consultation service.

## Management of Dermatology Services (MDS)

<b>MDS.1. The clinic provides safe dermatology services.</b>	
a	Scope of procedures being done at the clinic are commensurate with the clinical needs and safety of the patients.
b	Patients requiring continuous monitoring beyond clinical timings shall be referred to an identified facility.
c	All patients are assessed before a procedure.
d	Informed consent is taken before a procedure.
e	Care is taken to prevent adverse events like wrong site, wrong patient and wrong procedure.
f	Written guidance governs procedural sedation.
g	Written guidance governs administration of anesthesia.
h	The operative procedure note is documented.
i	The Dermatology clinic develops appropriate key performance indicators suitable to monitor clinical structures, processes and outcomes.

## Management of Dialysis Care (MDC)

<b>MDC.1. The Centre provides safe dialysis services.</b>	
a	The scope of procedures being done at clinic are commensurate with the clinical needs and safety of the patients.
b	Patients requiring continuous monitoring, beyond the scope of care shall be referred to an identified facility.
c	All patients are assessed before the procedure.
d	Informed consent is taken before the procedure.
e	Care is taken to prevent adverse events like wrong site, wrong patient and wrong procedure.
f	Written guidance governs procedural sedation.
g	Written guidance governs administration of anesthesia.
h	The operative procedure note is documented.
i	Patients are monitored for adverse events before discharge and the same is documented.
j	Nursing care is provided to patients while at the centre, in consonance with clinical protocols.
k	The written guidance governs equipment and engineering controls.
l	The dialysis centre develops appropriate key performance indicators which are suitable to monitor clinical structures, processes and outcomes.

# ANNEXURE 1

## NABH Key Performance Indicators

The concept of performance in health services represents an instrument for bringing quality, efficiency and efficacy 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 organisation:

S. No.	Standards	Indicator	Definition	Formula	Unit	Frequency of Data Collation/ Monitoring		Remarks
1.	PSQ2a	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.	<div>Total number of medication errors</div> <div>Total number of opportunities*</div>	X 100	Percentage	Monthly	<p>The methodology for capture shall be as stated in NABH's document on medication errors. The indicator shall be captured for admitted patients</p> <p>Sampling: Yes</p> <p>Sampling methodology: Stratified random</p> <p>*Total number of opportunities monitored.</p>
2.	PSQ2a	Compliance to Hand hygiene practice.		<div>Total number of actions performed</div> <div>Total number of hand hygiene opportunities</div>	X 100	Percentage	Monthly	<p>Observation involves directly watching and recording the hand hygiene behaviour of health care workers and the physical environment. Good reference is WHO hand hygiene compliance monitoring tool. Please refer:</p> <p><a href="http://www.who.int/gpsc/5may/tools/en/">http://www.who.int/gpsc/5may/tools/en/</a></p> <p><a href="http://www.who.int/entity/gpsc/5may/Observation_Form.doc?ua=1">http://www.who.int/entity/gpsc/5may/Observation_Form.doc?ua=1</a></p> <p>Sampling: Yes</p> <p>Sampling methodology: Stratified random</p>

S. No.	Standards	Indicator	Definition	Formula	Unit	Frequency of Data Collation/ Monitoring		Remarks
3.	PSQ 2a	Waiting time for OPD	Waiting time for OPD is the time from which the patient has come to the OPD (requisition form has been presented to the counter) till the time that the consultation is done.	Sum total time  Number of patients reported in OPD		Minutes	Monthly	Waiting time for OPD is applicable only for out-patients and for laboratory and imaging. In case of appointment patients, the time shall begin with the scheduled appointment time and end when the consultation, diagnostic procedure begins. Sampling: No
4.	PSQ2d	Rate of sharp injuries	Needle stick injury is a penetrating stab wound from a needle (or other sharp object) that may result in exposure to blood or other body fluids. Needle stick injuries are wounds caused by needles that accidentally puncture the skin.  (Canadian Centre for Occupational Health and Safety)	Number needlestick injuries  Number of OPD's	X 100	/100 occupied beds	Monthly on a cumulative basis	Number of occupied beds is the average of the sum of the daily figures for the number of beds occupied by patients. The rate will be monitored on a monthly basis but reported cumulatively i.e. in the form of year to date. For example, in January it would be January data but in February it would be January + February data, in July it would be data from January to July and so on so that by the end of the year the annual rate is obtained. Sampling: No
5.	PSQ2a	Percentage of cases where the organisation procedure to prevent adverse events like wrong site, wrong patient and wrong procedure have been adhered to.		Number of cases where the procedure was followed  Number of procedures performed	X100	Percentage		This could be checked in the post-op/recovery room and documented in a register / system (Includes adherence to Surgical Safety Check List)

S. No.	Standards	Indicator	Definition	Formula	Unit	Frequency of Data Collation/ Monitoring		Remarks
6.	PSQ2a	Number of variations observed in mock drills	Mock drill is a simulation exercise of preparedness for any type of event. It could be event or disaster. This is basically a dry run or preparedness drill. For example, fire mock drill, disaster drill, Code Blue Drill.	Total number of variations in a mock drill			Continuous	To capture the variation it is suggested that every organisation develop a checklist to capture the events during a mock drill
7.	PSQ2a	Equipment down time	The term downtime is used to refer to periods when a system is unavailable. Downtime or outage duration refers to a period of time that a system fails to provide or perform its primary function	Sum of down time for all critical equipment in hours in a month.			Continuous	Critical equipments shall include devices essential for delivering critical care such as ECG machine, monitors anaesthesia machine, steam autoclave, , ABG machine, Pulse oxymeter etc.
8.	PSQ2a	Out patient satisfaction index	Patient Satisfaction is defined in terms of the degree to which the patient's expectations are fulfilled. It is an expression of the gap between the expected and perceived characteristics of a service.	Average Score achieved	X 100		Continuous	
				Maximum possible score Maximum possible score				

S. No.	Standards	Indicator	Definition	Formula	Unit	Frequency of Data Collation/ Monitoring		Remarks
9.	PSQ2a	Incidence of blood body fluid exposures	An exposure is when blood, blood components or other potentially infectious materials come in contact with a staff's eyes, mucous membranes, non- intact skin or mouth. (Adopted from Joan Viteri Memorial Clinic "PEP" Post Exposure Prophylaxis)	Number of blood body fluid exposures	X 1000	Percentage	Monthly	All exposures to blood/body fluids should be assessed on a case-by-case basis.
				Number of Patient visits				
10.	PSQ2a	Percentage of incomplete case records	Documented individualised patient-focused case plan includes case analysis and evaluation, differentiation , choice of remedy and posology for each patient	Number of incomplete case management records	X100	Percentage	Monthly	It will improve the qualitative application of record keeping and documentation
				Total number of case management records				

## SAMPLE SIZE CALCULATION (MONTHLY)

Solvent formula

$$n = N / (1 + Ne^2)$$

(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.



## ANNEXURE 2

# Guidance on Monitoring Medication Errors

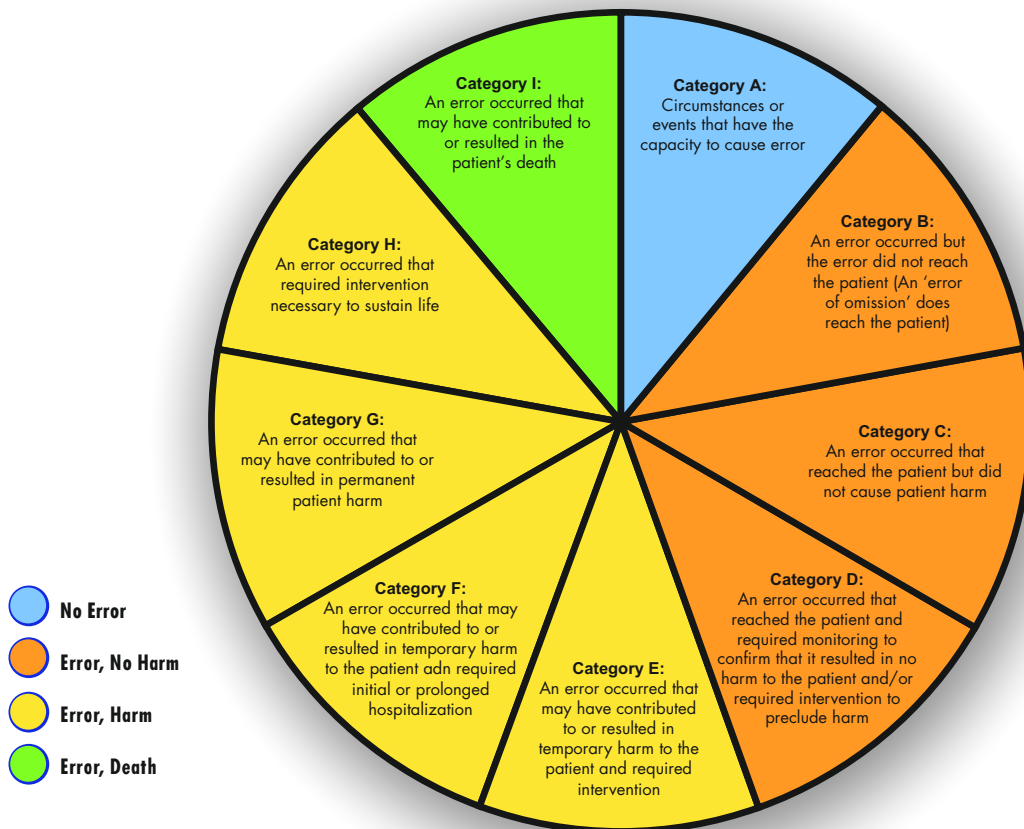
**Definition:** NCC-MERP (National Coordinating Council for Medication Error Reporting and Prevention) defines medication error as

"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.

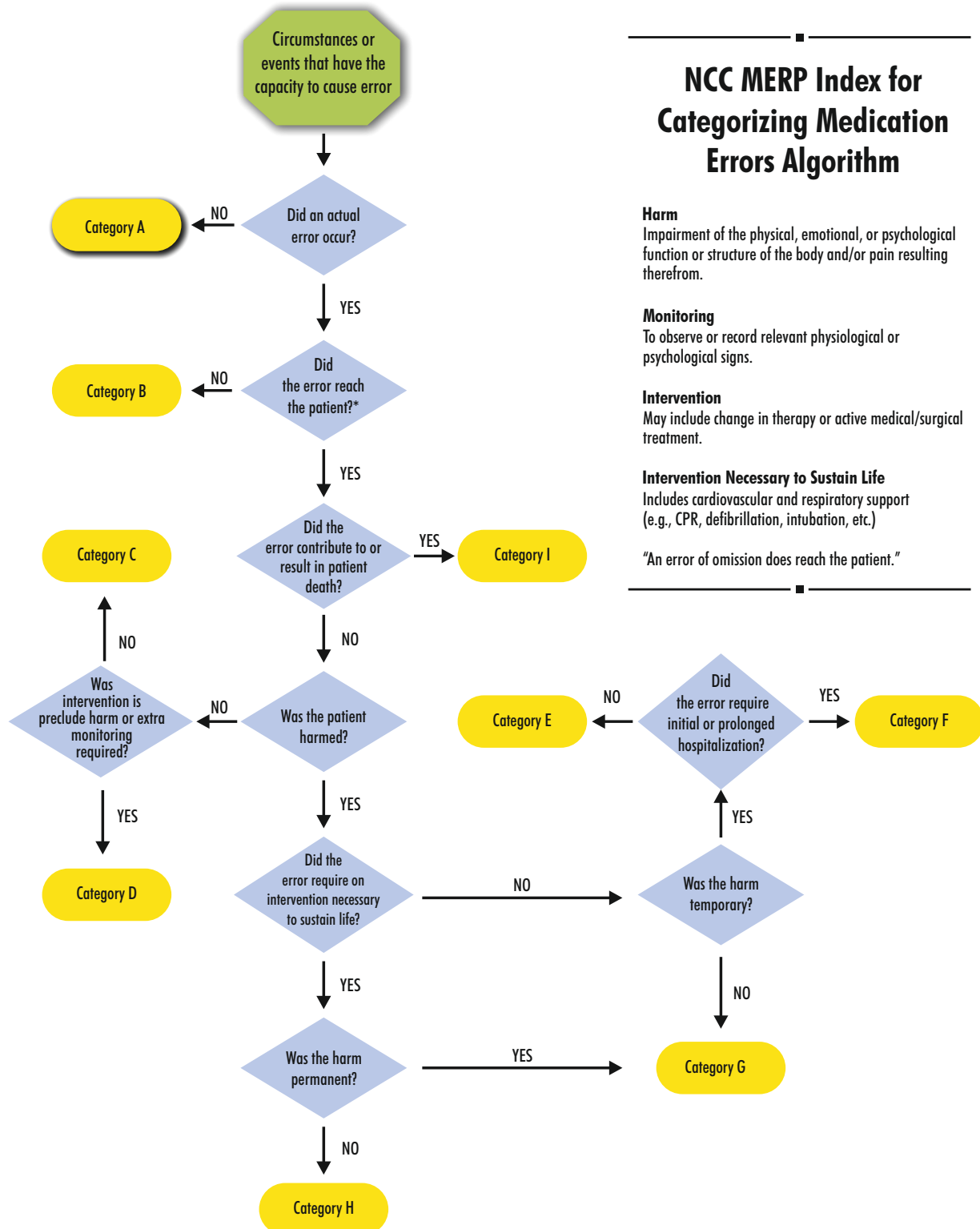
#### Intervention

May include change in therapy or active medical/surgical treatment.

#### Intervention Necessary to Sustain Life

Includes cardiovascular and respiratory support (e.g., CPR, defibrillation, intubation, 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.*



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	X100
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
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](http://www.nccmerp.org). National Coordinating Council for Medication Error Reporting and Prevention
2. American Society of Health-System Pharmacists. ASHP guidelines on preventing medication errors in hospitals. *Am J Health-Syst Pharm*. 2018; 75:1493–1517.
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4. Khandelwal AK. Getting it Right. *Healthcare Radius* 2014; March: 32-34

# Medication Chart Review Checklist

Auditor:

Date of Audit:

Location:

UHID:

Date of Admission:  
documented: Yes/No

Primary Consultant:

Drug allergies

	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										

	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
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										
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										



	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
Nurses										
24. Wrong Patient										
25. Dose Omission										
26. Improper Dose										
27. Wrong Drug										
28. Wrong Formulation Administered										
29. Wrong Route of Administration										
30. Wrong Rate										
31. Wrong Duration										
32. Wrong Time*										
33. No documentation of drug dministration										
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.

**Number of opportunities {Number of cells having a value of either 0 or a value between A to I (excluding NA)} =**

For example, if the case sheet had ten drugs and all the cells had values, then the number would be 350. However, if there were six drugs and there were 24 cells with a value of 'NA' the number of opportunities would be  $186\{(35 \times 6) - 24\}$ .

#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  $\frac{1}{2}$  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.

## ANNEXURE 3

### 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 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.

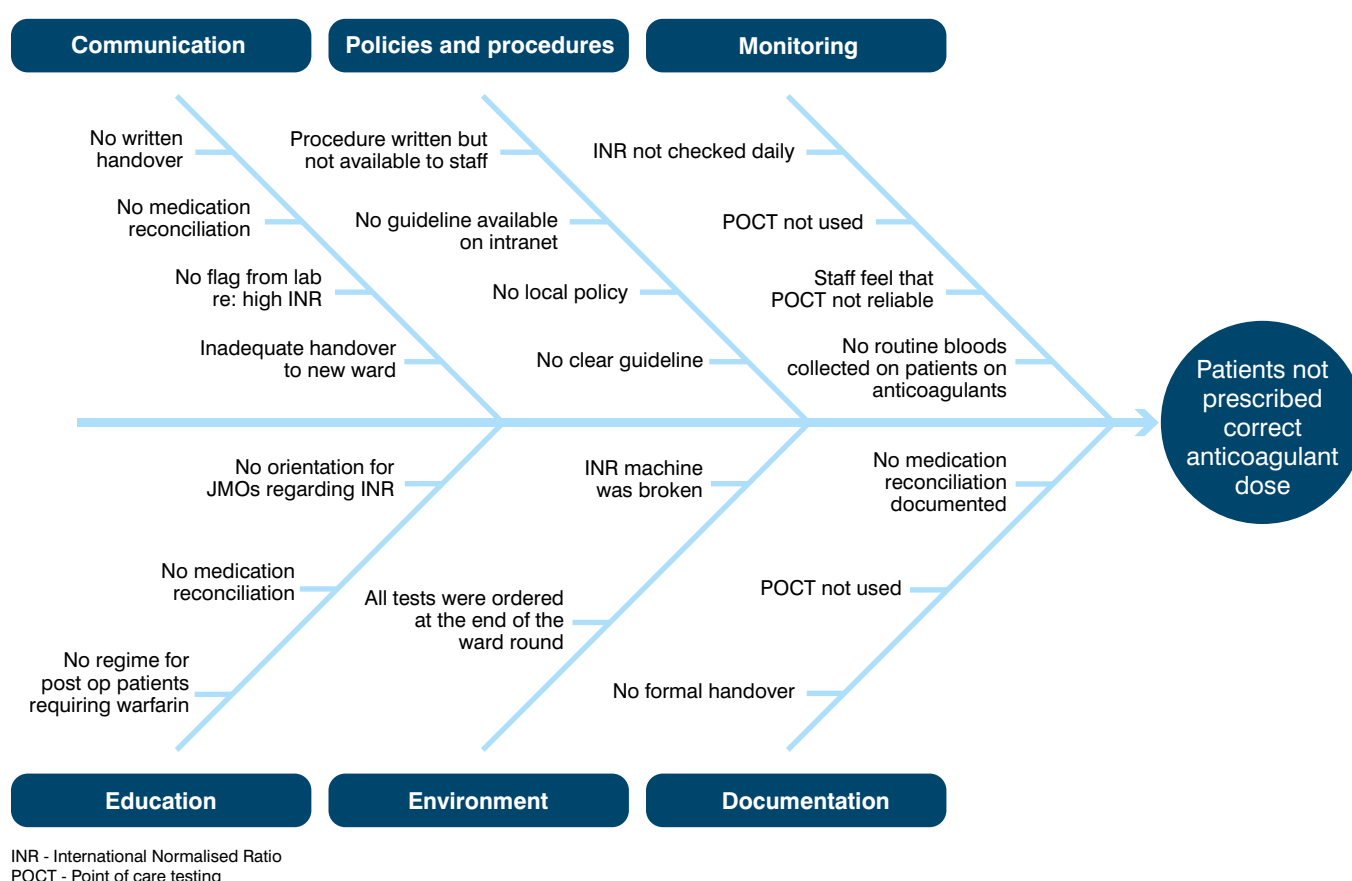


Figure Example of a Cause and Effect Diagram by Clinical Excellence Commission. Reasons why patients are not on a standardised anticoagulation pathway  
(<https://www.cec.health.nsw.gov.au/CEC-Academy/quality-improvement-tools/cause-and-effect-diagrams>)

**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.

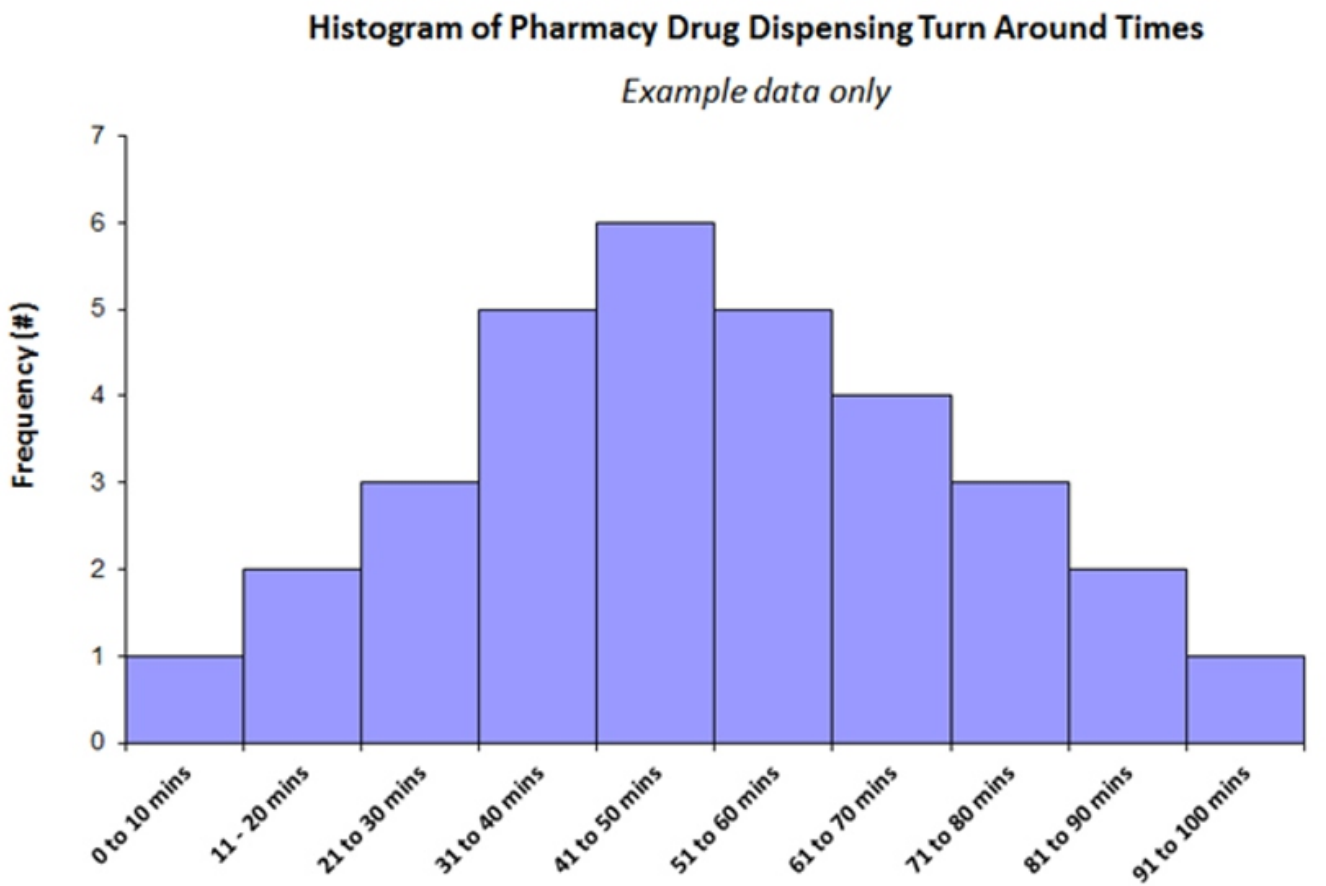


Figure Histogram on turnaround time for dispensing of the drug  
(<https://www.cec.health.nsw.gov.au/CEC-Academy/quality-improvement-tools/histogram> accessed on April 30, 2022)

**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.

Steps 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)	Actions to Reduce Occurrence of Failure
1								
2								
3								

Figure 4 Institute of Healthcare Improvement's format for Failure Mode Effect Analysis  
(<http://www.ihl.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-

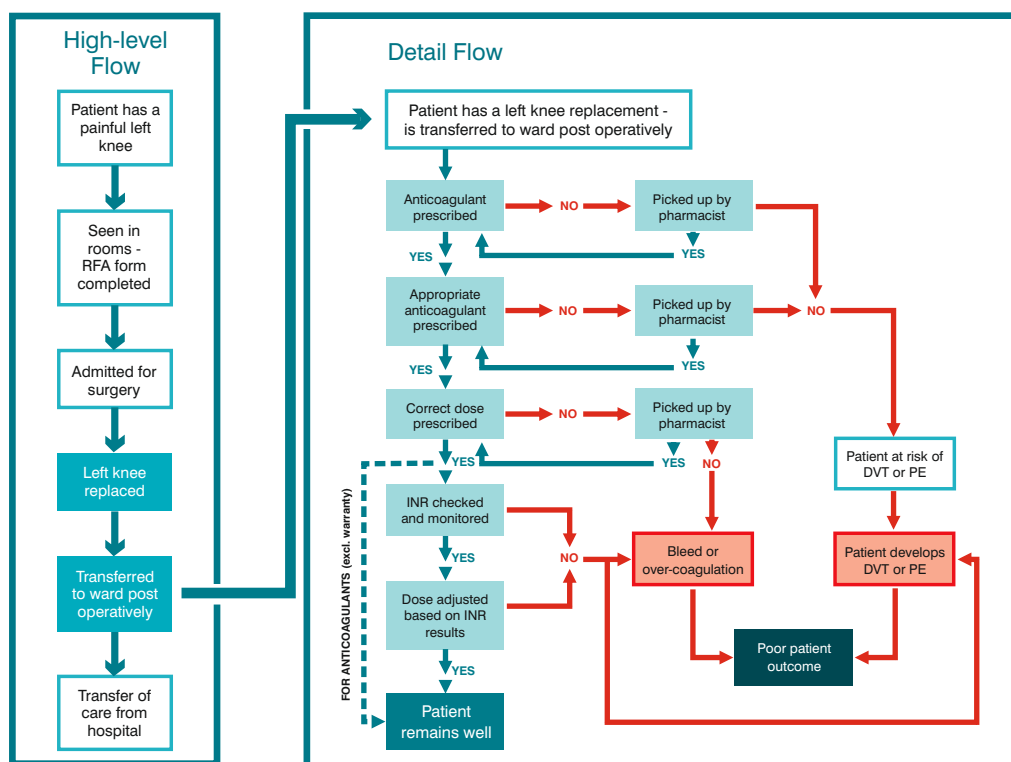


Figure 5 Flow chart of a patient's journey within the hospital  
(<https://www.cec.health.nsw.gov.au/CEC-Academy/quality-improvement-tools/flow-charts> accessed on April 30, 2022)

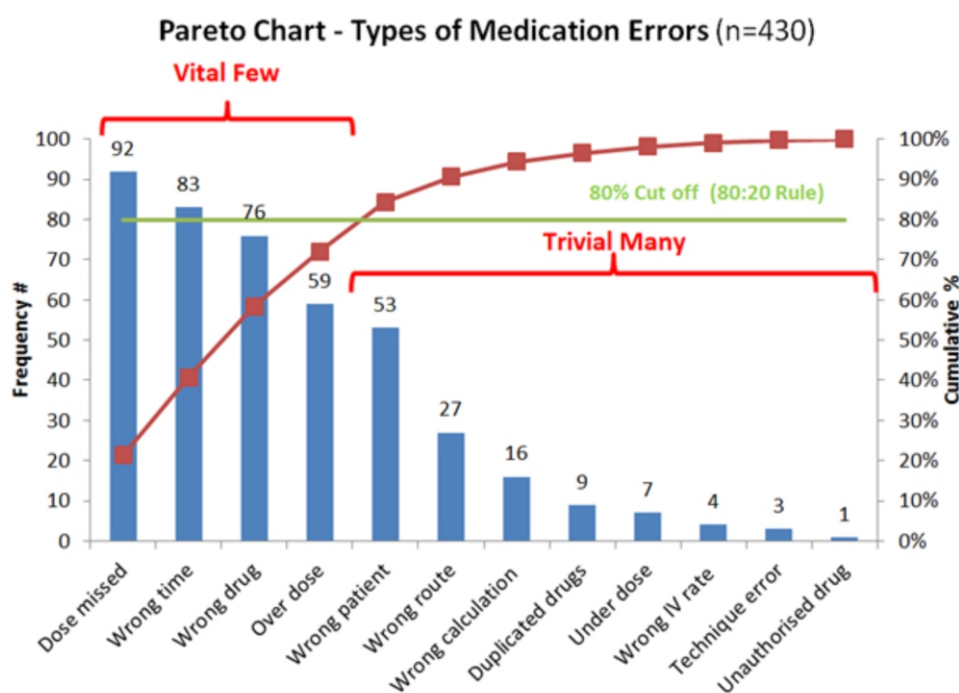
**Pareto Chart:** The “Pareto Principle” is the “80/20 rule” and works on the theory that roughly 80% of the effect comes from 20% (“the vital few”) of the causes. The “vital few” are easily distinguished from the “useful many” by plotting them as a bar diagram. Teams can prioritize and focus improvement 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 brainstorming session by putting together the number of votes cast for the proposed reasons for incidents, adverse trends of indicator data etc.



**Run Chart and 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.



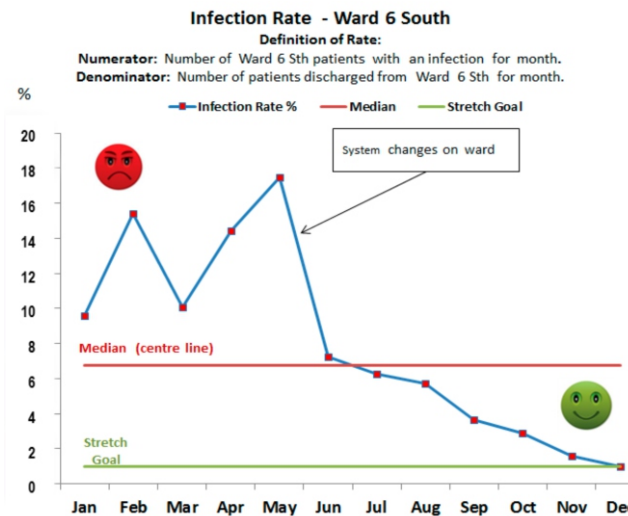


Figure 7. Simple Annotated Run chart with UCL and LCL of an infection rate over time  
(<https://www.cec.health.nsw.gov.au/CEC-Academy/quality-improvement-tools/run-charts> accessed on April 30, 2022)

**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.

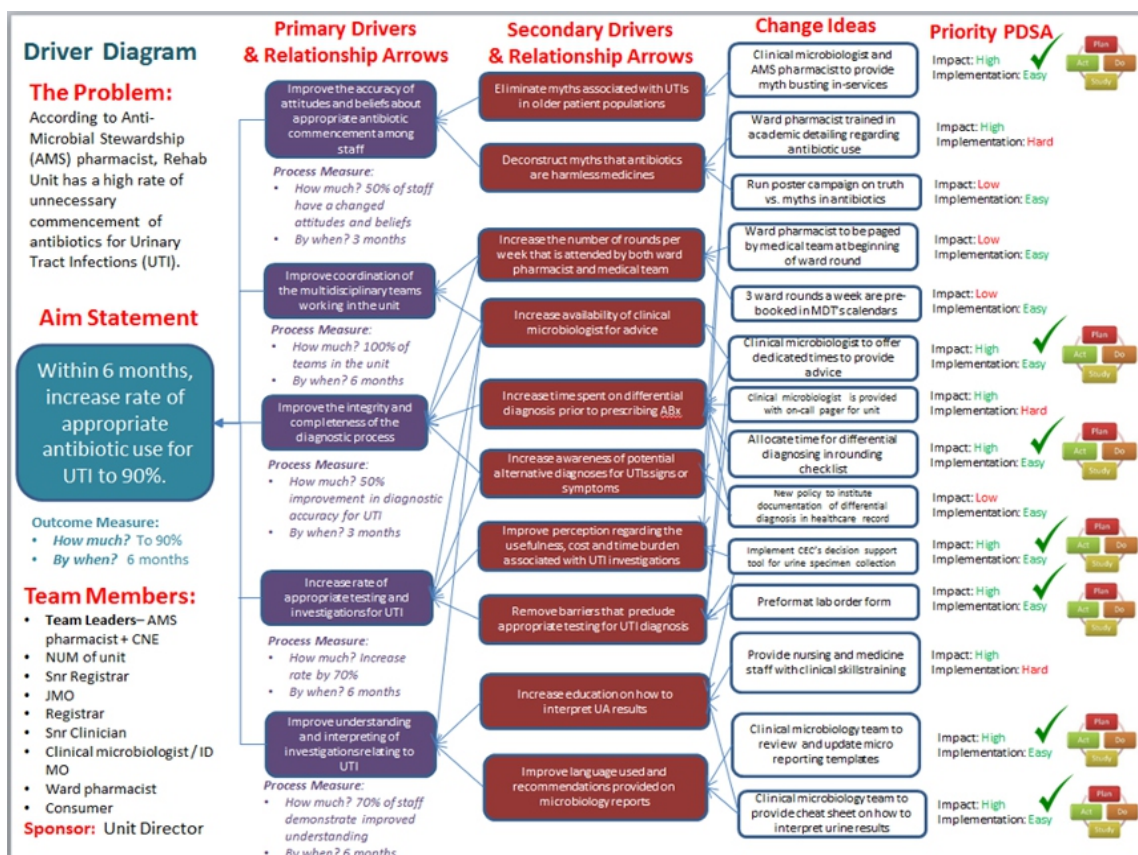


Figure 8 Driver Diagram  
(<https://www.cec.health.nsw.gov.au/CEC-Academy/quality-improvement-tools/driver-diagrams> accessed on April 30, 2022)



**Scatter Diagram/Plot:** Scatter diagrams are used to identify cause-and-effect relationships between two variables. A scatter diagram does not prove causation.

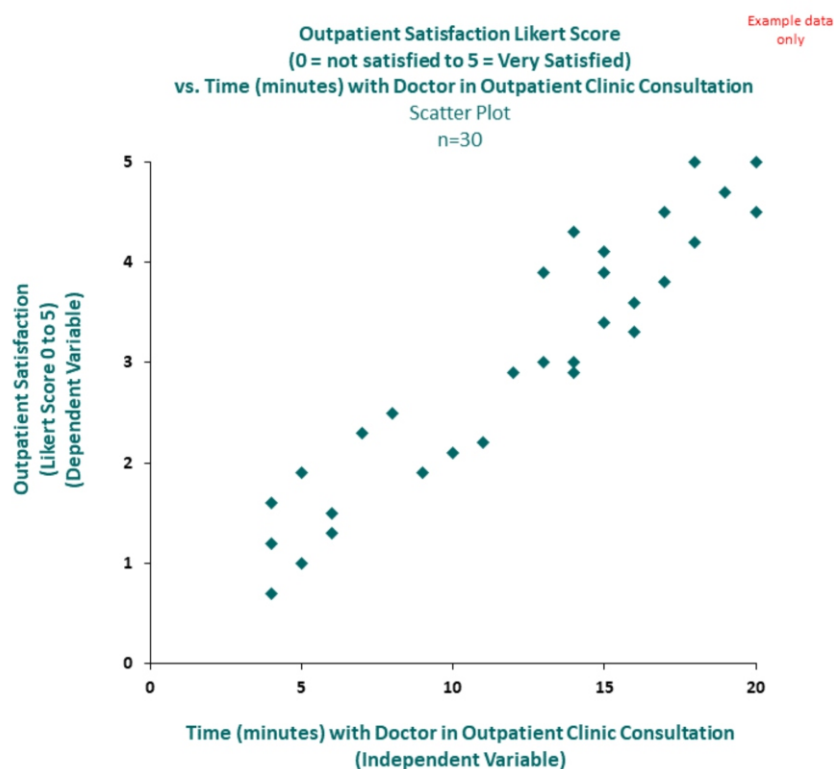


Figure 9 Scatter diagram showing patient satisfaction using likert's score v/s time with doctor consultation  
(<https://www.cec.health.nsw.gov.au/CEC-Academy/quality-improvement-tools/scatter-plot> accessed on April 30, 2022)

**Project Planning Form:** This tool helps teams think systematically about their improvement project. It tracks various elements like Plan-Do-Study-Act (PDSA) cycles.

Table 1. Quality improvement tool applications adapted from Butch S.					
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.

**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.

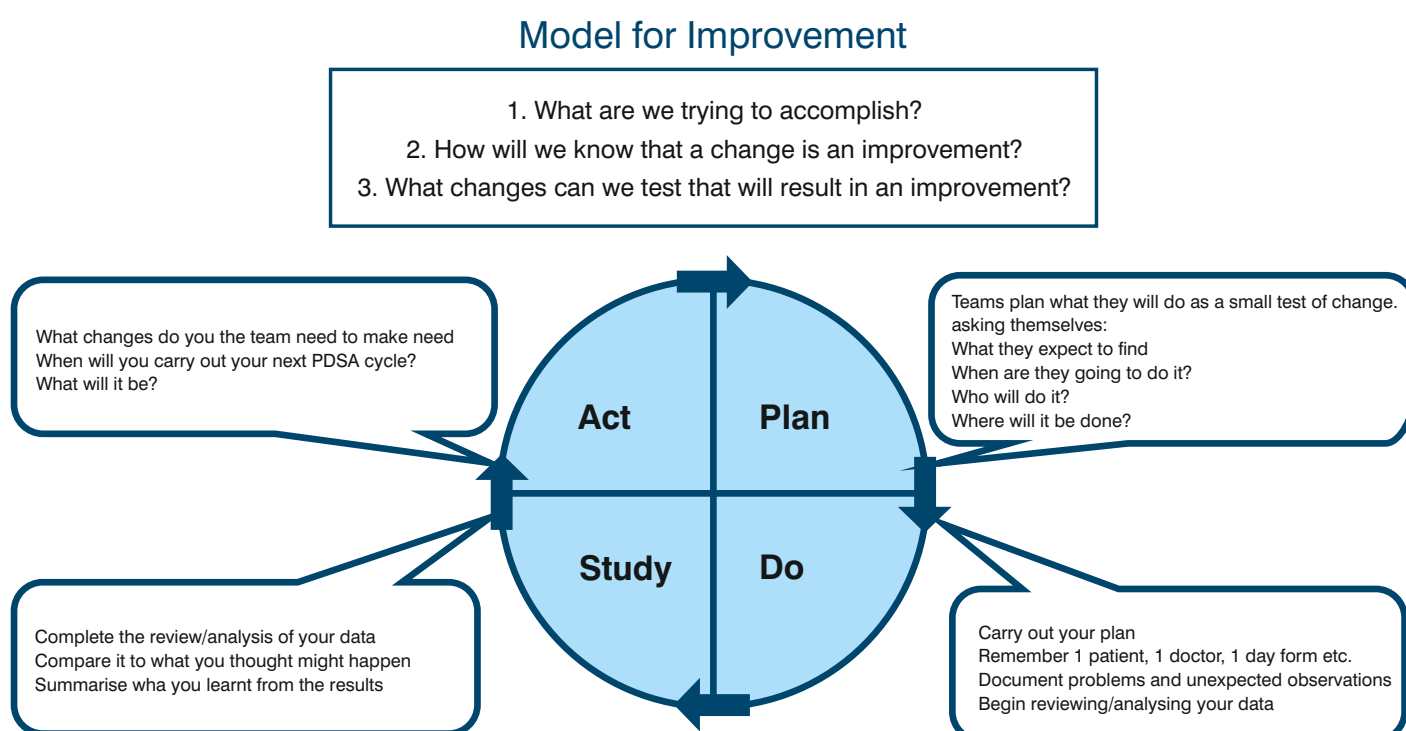


Figure 10: Model for Improvement and PDSA  
(<https://www.cec.health.nsw.gov.au/CEC-Academy/quality-improvement-tools/model-for-improvement-and-pdsa-cycles> accessed on April 30, 2022)

**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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# Annexure-1

## REFERENCE GUIDE ON SENTINEL EVENTS

### Definition:

An unexpected incident, related to system or process deficiencies, which leads to death or major and enduring loss of function\* for a recipient of health care 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.

### Event type description:

#### 1. Surgical events

- Surgery performed on the wrong body part.
- Surgery performed on the wrong patient.
- Wrong surgical procedure performed on the wrong patient.
- Retained instruments in patient discovered after surgery/procedure.
- Patient death during or immediately post surgical procedure.
- Anesthesia related event (anaphylactic shock due to local anesthesia).

#### 2. Device or product events Patient death or serious disability associated with:

- the use of contaminated drugs, devices, products supplied by the Allopathic clinic.
- the use or function of a device in a manner other than the device's intended use.
- the failure or breakdown of a device or medical equipment.
- intravascular air embolism.

#### 3. Patient protection events

- Discharge of an infant to the wrong person.
- Patient death or serious disability associated with elopement from the health care facility.
- Patient suicide, attempted suicide, or deliberate self-harm resulting in serious disability.
- Intentional injury to a patient by a staff member, another patient, visitor, or other.
- Any incident in which a line designated for oxygen or other came to be delivered to a patient and contains the wrong gas or is contaminated by toxic substances.
- Nosocomial infection or disease causing patient death or serious disability.

#### 4. Environmental events

Patient death or serious disability while being cared for in a health care facility associated with:

- a burn incurred from any source.
- a slip, trip, or fall.
- an electric shock.
- the use of restraints or bedrails.

#### 5. Care management events

- Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products.
- Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy.
- Medication error leading to the death or serious disability of patient due to incorrect administration of drugs, for example:
  - omission error.
  - dosage error.
  - dose preparation error.
  - wrong time error.
  - wrong rate of administration error.
  - wrong administrative technique error.
  - wrong patient error.

Patient death or serious disability associated with an avoidable delay in treatment or response to abnormal test results.

#### 6. Criminal events

- Any instance of care ordered by or provided by an individual impersonating a clinical member of staff.
- Abduction of a patient.
- Sexual assault on a patient within or on the grounds of the health care facility.
- Death or significant injury of a patient or staff member resulting from a physical assault or other crime that occurs within or on the grounds of the health care facility.

## Annexure-2

### ESSENTIAL DOCUMENTATION

Like all quality management systems documentation is an essential component of NABH accreditation. NABH standards require documentation. It is suggested that the Allopathic clinic prepare an apex manual (quality manual) incorporating the various standards and objective elements and providing appropriate linkages.

The apex manual could be distributed to all individuals in the first rung of the organogram. It is preferable that procedures and processes (refer to glossary for definition) are not incorporated in the apex manual (only linkages to be provided).

The policies (refer to glossary for definition) for various objective elements could be incorporated in the apex manual. The procedures and processes have to be distributed to all areas where the concerned activities are taking place.

Wherever, the Allopathic clinic feels that only a policy would not suffice it can instead document a procedure.

It is essential that document control be followed during documentation and distribution.

A suggested content is given below.

Introduction of the Allopathic clinic

Management including ownership, vision, mission, ethical management etc.

Quality policy and objectives including service standards

Scope of services provided by the Allopathic clinic and the details of services provided by every department

Composition and role of various committees (in alphabetical order)

- CPR analysis
- Clinical audit
- Ethics
- Infection control
- Pharmacy
- Quality
- Safety

Organogram

Statutory and regulatory requirements

Chapter wise documentation

Annexure (if any)

For example, for AAC 2a which states that “Documented policies and procedures are used for registering and admitting patients” the Allopathic clinic could mention its policy for admission in the apex manual and for procedure in the apex manual just mention as “Refer to AAC/SOP/01”.



**In addition to the apex manual the Allopathic clinic need to have the following manuals:**

Infection Control Manual

Quality Improvement Manual which also incorporates the quality assurance activities of pathological laboratory, imaging, inpatient care and surgical services.

Safety manual which also incorporates pathological lab, safety and radiation safety.

**The Allopathic clinics can have a single manual covering all the above aspect.**

Some sample headings for a documented procedure are given below:

Scope/ Aim/ Objective

Definition

Applicable areas

Responsibility

Contents/ explanations/ detailing or various processes

Monitoring and analysis/Indicators

References

Document control shall be adhered to for all documentation.

## Annexure-3

### LIST OF ACTS, LICENSES AND REGULATIONS APPLICABLE TO ALLOPATHIC CLINIC

This list may be considered just for the reference. The Allopathic clinic may consider whatever is applicable to their organization. In some cases there might be some act or license which may not be listed, but may be applicable as per the local law. The Allopathic clinic should make an effort to be aware of them and follow them.

#### LIST OF LICENSES AND MOUs

##### S.N. Name of License/MOU

1. No objection certificate from the Chief fire Officer
2. Bio-medical Management and handling Rules, 1998
3. Retail and Bulk drug License (Pharmacy)
4. Authorization for operating (Bio Medical Waste)
5. Building permit (from the Municipality) & Map.
6. Income tax PAN Card
7. MOU between Hospital & Out source management.
8. AERB approval wherever applicable.
9. AERB approval for the layout plan wherever applicable.
10. TLD Badges.
11. Registrations of all vehicles under motor vehicles act.
12. Licenses to operate lifts.

#### LIST OF ACT'S

1. Constitution of India. ( Book )
2. Insecticides Act, 1968.
3. Payment of gratuity Act, 1972.
4. Payment of wages Act, 1936.
5. Protection of human right Act, 1993.
6. Central Sales Tax Act, 1956.
7. Indian Nursing council Act, 1947.
8. Employees provident fund Act, 1952.
9. Air (prevention and control of pollution) Act, 1981 and License.
10. Cable Television Networks Act, 1995.
11. Contract Act, 1982.
12. Employment exchange Act, 1969.
13. Equal Remuneration Act, 1976.
14. Explosives Act, 1884.

15. Hire Purchase Act, 1972
16. Registration of births and deaths Act, 1969.
17. The Lepers Act, 1898.
18. The Maternity benefit Act, 1961.
19. The Minimum wages Act, 1948.
20. The Public Provident Fund (PPF) Act, 1968.
21. Repeal of Urban land ceiling & regulation Act, 1976.(ULCRA)
22. The Environment (protection) Act, 1986.
23. The Indian Boilers Act, 1923.
24. The Fatal accidents Act, 1855.
25. The Pharmacy Act, 1948.
26. Central Sales Tax Act, 1956.
27. The Indian Contract Act, 1972.
28. Electricity Act, 1998.
29. Indian penal code.
30. Persons with disability Act, 1995
31. Payment of bonus Act, 1965
32. Consumer Protection Act, 1986. & Rules, 1987.
33. Workers compensation Act, 1923.
34. Indian Copyright Act, 1957.
35. The Drugs and Cosmetics Act, 1940.
36. The Insurance Act, 1938.
37. Arms Act,1950 (if guards have weapons)
38. Copyright Act, 1982.
39. Electricity Rules, 1956.
40. Income Tax Act, 1961.
41. National building code.
42. National holidays under shops Act.
43. Tax deducted at source Act.
44. Sales tax Act.
45. SC and ST Act, 1989.
46. Occupational health act.



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ISBN 978-81-959-6767-4



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