

NATIONAL ACCREDITATION BOARD FOR
HOSPITALS AND HEALTHCARE PROVIDERS (NABH)



NABH Accreditation standards for Allopathic Clinics

**2nd
EDITION**
JUNE 2023



National Accreditation Board For Hospitals and Healthcare Providers (NABH)

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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, 104 are in Commitment category which will be assessed during the Final Assessment, 16 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.

In order to broaden the reach of quality and to strengthen the healthcare in nation, NABH is offering a significant inaugural discount to the applications received till 31st Dec'2024 under Dermatology & Dialysis Services.

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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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)

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 (METF)

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.

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 of Diagnostic Services are:

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

In case the clinic is a providing Dialysis services, Dialysis specific standards requirements are to be adhered to, which is a 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

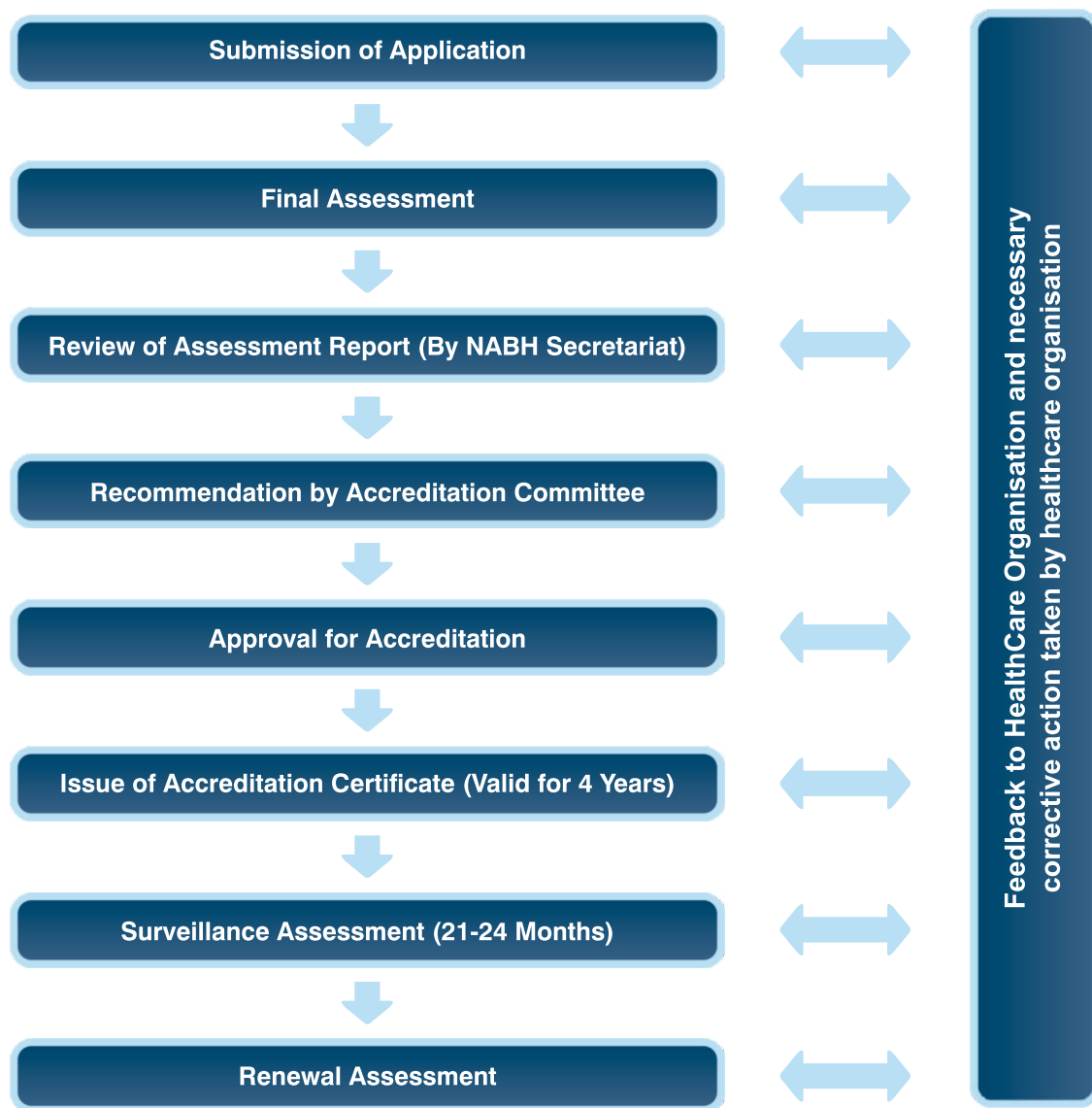
The aim of the standards is to achieve an acceptable level of performance with a view to:

- 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'.

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.

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.

TYPES OF DOCUMENTS

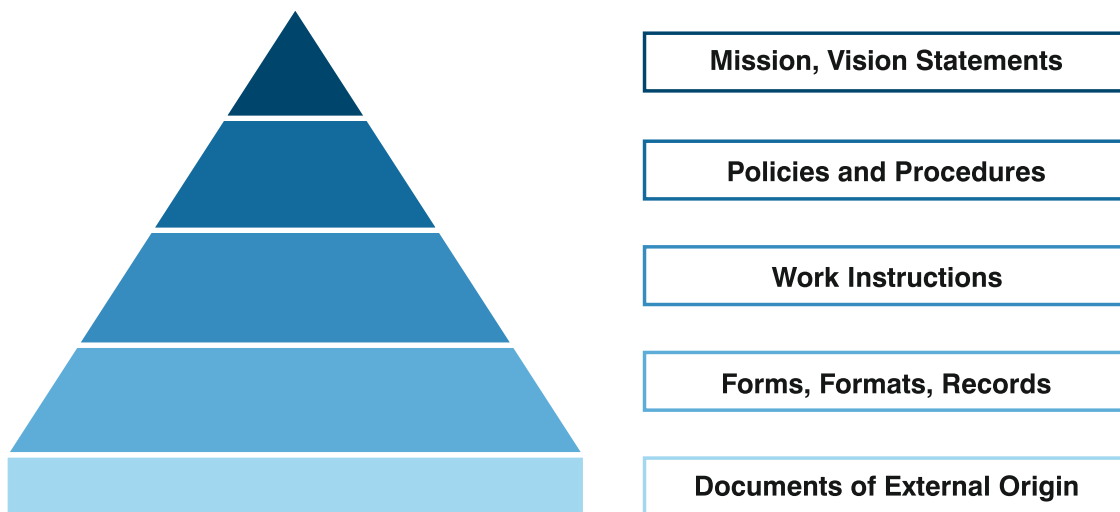
From the top level of planning to the level of maintaining records of activities, the documentation follows a general principle as below:

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: XXXXXXXXXXXXX

Step 2: XXXXXXXXXXXXX

Step 3: XXXXXXXXXXXXX

Step n: XXXXXXXXXXXXX

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

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)	$\geq 80\%$	$\geq 80\%$	$\geq 80\%$
Commitment (cumulative score)	$\geq 80\%$	$\geq 80\%$	$\geq 80\%$
Achievement (cumulative score)	NA	$\geq 80\%$	$\geq 80\%$
Excellence (cumulative score)	NA	NA	$\geq 80\%$
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	12	21	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	4	4	2	0
FMS	03	11	4	5	2	0
HRM	03	11	2	9	0	0
IMS	03	11	1	8	2	0
Total	38	153	44	91	16	2
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

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

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

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

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

Commitment

b. The services provided are prominently displayed.

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.*

Commitment

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

Commitment

c. The patients are prioritized as per clinic 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.*

Commitment

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

Achievement

c. The clinic identifies special needs of the patient.

Commitment

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

CORE

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

Commitment

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

Achievement

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

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.

Commitment

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

Commitment

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

Commitment

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

Commitment

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

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 requirement.

Commitment	b. Quality assurance programme for imaging services is implemented.
Commitment	c. Radiation safety programme for imaging services is implemented.
Achievement	d. Imaging services, if not available in the clinic, are outsourced to meet patient needs.

Standard

AAC.6.

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

Objective Elements

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

References:

1. Agency for Healthcare Research and Quality. Patient Safety Network. (2012, June). Transfer Troubles. Retrieved on May 03 2022, from <https://psnet.ahrq.gov/webmm/case/269>
2. Albrecht, J.S., Gruber-Baldini, A.L., Hirshon, J.M., et al. (2014). Hospital Discharge Instructions: Comprehension and Compliance Among Older Adults. *Journal of General Internal Medicine*, 29(11), 1491-1498. doi:10.1007/s11606-014-2956-0
3. Brady, A.P. (2016). Error and discrepancy in radiology: inevitable or avoidable? *Insights into Imaging*, 8(1), 171-182. doi:10.1007/s13244-016-0534-1
4. Coleman, E.A., Chugh, A., Williams, M.V., et al. (2013). Understanding and Execution of Discharge Instructions. *American Journal of Medical Quality*, 28(5), 383-391. doi:10.1177/1062860612472931
5. Communication During Patient Hand-Overs. (2007). Retrieved on May 03 2022, from [https://cdn.who.int/media/docs/default-source/integrated-health-services-\(ihs\)/psf/patient-safety-solutions/ps-solution3-communication-during-patient-handovers.pdf?sfvrsn=7a54c664_4&ua=1](https://cdn.who.int/media/docs/default-source/integrated-health-services-(ihs)/psf/patient-safety-solutions/ps-solution3-communication-during-patient-handovers.pdf?sfvrsn=7a54c664_4&ua=1)
6. Déry, J., Ruiz, A., Routhier, F., et al. (2019). Patient prioritization tools and their effectiveness in non-emergency healthcare services: a systematic review protocol. *Systematic Reviews*, 8(1). doi:10.1186/s13643-019-0992-x
7. Egan, N. (1999). Managing a bed crisis. *Emergency Medicine Journal*, 16(2), 145-146. doi:10.1136/emj.16.2.145
8. Gail M. Keenan; Elizabeth Yake; Dana Tschannen; (2008). Chapter 49 Documentation and the Nurse Care Planning Process. In *Patient Safety and Quality: An Evidence-Based Handbook for Nurses*.
9. Goldberg-Stein, S., Frigini, L. A., Long, S. et al. (2017). ACR RADPEER Committee White Paper with 2016 Updates: Revised Scoring System, New Classifications, Self-Review, and Subspecialized Reports. *Journal of the American College of Radiology*, 14(8), 1080-1086. doi:10.1016/j.jacr.2017.03.023
10. Hawkins, R. C. (2007). Laboratory Turnaround Time. *Clin Biochem Rev*, 28(4), 179-194.
11. Horwitz, L. I., Moriarty, J. P., Chen, C., et al. (2013). Quality of Discharge Practices and Patient Understanding at an Academic Medical Center. *JAMA Internal Medicine*. doi:10.1001/jamainternmed.2013.9318
<https://www.osha.gov/sites/default/files/publications/OSHA3404laboratory-safety-guidance.pdf>
12. Kulshrestha, A., & Singh, J. (2016). Inter-hospital and intra-hospital patient transfer: Recent concepts. *Indian Journal of Anaesthesia*, 60(7), 451. doi:10.4103/0019-5049.186012
13. Laboratory biosafety manual, 4th edition. (2020). World Health Organisation (WHO). Retrieved on May 03 2022, from <https://www.who.int/publications/i/item/9789240011311>
14. Lippi, G., & Mattiuzzi, C. (2016). Critical laboratory values communication: summary recommendations from available guidelines. *Annals of Translational Medicine*, 4(20), 400-400. doi:10.21037/atm.2016.09.36
15. Mahgerefteh, S., Kruskal, J. B., Yam, C. S., Blachar, A., & Sosna, J. (2009). Peer Review in Diagnostic Radiology: Current State and a Vision for the Future. *RadioGraphics*, 29(5), 1221-1231. doi:10.1148/rg.295095086

16. Müller, M., Jürgens, J., Redaelli, M., et al. (2018). Impact of the communication and patient hand-off tool SBAR on patient safety: a systematic review. *BMJ Open*, 8(8), e022202. doi:10.1136/bmjopen-2018-022202
17. Occupational Safety and Health Administration. (2011). Laboratory safety Guidance. Retrieved on May 03 2022, from
18. Patel, S., Gillon, S. A., & Jones, D. A. (2017). Rapid response systems: recognition and rescue of the deteriorating hospital patient. *British Journal of Hospital Medicine*, 78(3), 143-148. doi:10.12968/hmed.2017.78.3.143
19. Patient Identification. Patient Safety Solutions (2007). Retrieved on May 03 2022, from [https://cdn.who.int/media/docs/default-source/integrated-health-services-\(ihs\)/psf/patient-safety-solutions/ps-solution2-patient-identification.pdf?sfvrsn=ff81d7f9_4&ua=1](https://cdn.who.int/media/docs/default-source/integrated-health-services-(ihs)/psf/patient-safety-solutions/ps-solution2-patient-identification.pdf?sfvrsn=ff81d7f9_4&ua=1)
20. Radiological Protection Principles. (2017). Atomic Energy Regulatory Board (AERB), Government of India. Retrieved on May 03 2022, from <https://aerb.gov.in/english/radiation-protection-principle>
21. Scope of Hospital Services: External Standards and Guidelines. (n.d.). Retrieved on May 03 2022, from <https://www.princeton.edu/~ota/disk2/1988/8832/883211.PDF>
22. Shahid, S., & Thomas, S. (2018). Situation, Background, Assessment, Recommendation (SBAR) Communication Tool for handoff in health care – a narrative review. *Safety in Health*, 4(1). doi:10.1186/s40886-018-0073-1
23. Subbe, C. (2001). Validation of a modified Early Warning Score in medical admissions. *QJM*, 94(10), 521-526. doi:10.1093/qjmed/94.10.521
24. Waring J, Marshall F, Bishop S, et al. Hospital discharge and patient safety: reviews of the literature. In: An ethnographic study of knowledge sharing across the boundaries between care processes, services and organisations: the contributions to 'safe' hospital discharge. *Health Services and Delivery Research*, No. 2.29. 2014. Retrieved on May 03 2022, from <https://www.ncbi.nlm.nih.gov/books/NBK259995/>
25. Warren, J., Fromm, R. E., Orr, R. A., Rotello, L. C., & Horst, H. M. (2004). Guidelines for the inter- and intrahospital transport of critically ill patients*. *Critical Care Medicine*, 32(1), 256-262. doi:10.1097/01.ccm.0000104917.39204.0a
26. Weston, C., Yune, S., Bass, E., et al. (2017). A concise tool for measuring care coordination from the provider's perspective in the hospital setting. *Journal of Hospital Medicine*, 12(10), 811-817. doi:10.12788/jhm.2795
27. World Health Organization. (2010). WHO guidelines on drawing blood: best practices in phlebotomy. Retrieved on May 03 2022, from http://www.euro.who.int/data/assets/pdf_file/0005/268790/WHO-guidelines-on-drawing-blood-best-practices-in-phlebotomy-Eng.pdf?ua=1
28. World Health Organization. (2011). Laboratory Quality Management System: Handbook. Retrieved on May 03 2022, from <https://www.who.int/publications/i/item/9789241548274>

29. World Health Organization. (2018). Continuity and coordination of care: a practice brief to support implementation of the WHO Framework on integrated people-centred health services. Retrieved on May 03 2022, from <https://apps.who.int/iris/bitstream/handle/10665/274628/9789241514033-eng.pdf?ua=1>
30. Wright, J., Williams, R., & Wilkinson, J. R. (1998). Health needs assessment: Development and importance of health needs assessment. *BMJ*, 316(7140), 1310-1313. doi:10.1136/bmj.316.7140.1310
31. Yemm, R., Bhattacharya, D., & Wright, D. (2014). What constitutes a high quality discharge summary? A comparison between the views of secondary and primary care doctors. *International Journal of Medical Education*, 5, 125-131. doi:10.5116/ijme.538b.3c2e

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

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

Objective Element	COP1.	COP2.	COP3.	COP4.
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.*

CORE

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

Commitment

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

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.

Commitment

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

Standard

COP.3.**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.

CORE

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

Commitment

- c. Written guidance governs the management of pain.*



Standard

COP.4.	Identification of early warning signs and Cardiopulmonary resuscitation services are provided uniformly across the clinic.
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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*
Commitment	b. Resuscitation services are available to all patients, at all times when required.



References:

1. Clinical practice Guideline for Chronic Pain. (2018). Japanese Society for the Study of Pain. Retrieved on May 03 2022, from https://plaza.umin.ac.jp/~jaspain/pdf/consortium_20180913en.pdf
2. Correction to: 2017 American Heart Association Focused Update on Adult Basic Life Support and Cardiopulmonary Resuscitation Quality: An Update to the American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. (2018). *Circulation*, 137(1). doi:10.1161/cir.0000000000000555
3. Hinkelbein, J., Lamperti, M., Akesson, J., Santos, J., Costa, J., De Robertis, E., ... Fitzgerald, R. (2017). European Society of Anaesthesiology and European Board of Anaesthesiology guidelines for procedural sedation and analgesia in adults. *European Journal of Anaesthesiology*, 1. doi:10.1097/eja.0000000000000683
4. Kleinman, M. E., Brennan, E. E., Goldberger, Z. D., Swor, R. A., Terry, M., Bobrow, B. J., ... Rea, T. (2015). Part 5: Adult Basic Life Support and Cardiopulmonary Resuscitation Quality. *Circulation*, 132(18 suppl 2), S414-S435. doi:10.1161/cir.0000000000000259
5. Kleinman, M. E., Goldberger, Z. D., Rea, T., Swor, R. A., Bobrow, B. J., Brennan, E. E., ... Travers, A. H. (2018). 2017 American Heart Association Focused Update on Adult Basic Life Support and Cardiopulmonary Resuscitation Quality: An Update to the American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. *Circulation*, 137(1). doi:10.1161/cir.0000000000000539
6. Link, M. S., Berkow, L. C., Kudenchuk, P. J., Halperin, H. R., Hess, E. P., Moitra, V. K., ... Donnino, M. W. (2015). Part 7: Adult Advanced Cardiovascular Life Support. *Circulation*, 132(18 suppl 2), S444-S464. doi:10.1161/cir.0000000000000261
7. Ministry of Health and Family Welfare, Government of India. (n.d.). Standard Treatment Guidelines (Speciality/Super Speciality wise). Retrieved on May 03 2022, from <http://clinicaestablishments.gov.in/En/1068-standard-treatment-guidelines.aspx>
8. Montori, V. M., Brito, J. P., & Murad, M. H. (2013). The Optimal Practice of Evidence-Based Medicine. *JAMA*, 310(23), 2503. doi:10.1001/jama.2013.281422
9. Practice Guidelines for Moderate Procedural Sedation and Analgesia 2018. (2018). *Anaesthesiology*, 128(3), 437-479. doi:10.1097/aln.0000000000002043
10. Preventing Falls in Hospitals. (2013). Agency for Healthcare Research and Quality. Retrieved on May 03 2022, from <https://www.ahrq.gov/professionals/systems/hospital/fallpxtoolkit/index.html>

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

MOM.1.	The clinic develops, updates and implements a formulary.
MOM.2.	Medications are stored appropriately and are available where required.
MOM.3.	Medications are prescribed safely and rationally.
MOM.4.	Medications orders are written in a uniform manner.
MOM.5.	Medications are dispensed in a safe manner wherever applicable.
MOM.6.	Medications are administered safely.
MOM.7.	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.		Core	Achievement				
h.			Core				

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.

Commitment

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

Excellence

- c. Clinicians adhere to the current formulary.

Commitment

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

Commitment

- e. The clinic adheres to 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).

Commitment

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

CORE

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

Achievement

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

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. *

Commitment

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

CORE

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

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

Standard

MOM.4.**Medications orders are written in a uniform manner.**

Objective Elements

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

Standard

MOM.5.**Medications are dispensed in a safe manner wherever applicable.**

Objective Elements

Commitment	a. Dispensing of medications is done safely. *
Commitment	b. Medication recalls are handled effectively. *
Commitment	c. Near-expiry medications are handled effectively. *
CORE	d. Dispensed medications are labelled. *
CORE	e. High-risk medication orders are verified before dispensing.

Standard

MOM.6.**Medications are administered safely.**

Objective Elements

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

Standard

MOM.7.**Patients are monitored after medication administration.**

Objective Elements

Commitment	a. Medications are changed where appropriate based on the monitoring.
CORE	b. The clinic captures near miss, medication error and adverse drug reaction. *
Commitment	c. Near misses, medication error and adverse drug reaction are reported within a specified time frame. *
Commitment	d. Near misses, medication errors and adverse drug reactions are collected and analysed.
Commitment	e. Corrective and/or preventive action(s) are taken based on the analysis.

References:

1. About Medication Errors. National Coordinating Council for Medication Error Reporting and Prevention. (2015). Retrieved May 03, 2022, from <https://www.nccmerp.org/about-medication-errors>
2. Bryan R, Aronson JK, Williams A, Jordan S. The problem of look-alike, sound-alike name errors: Drivers and solutions. *Br J Clin Pharmacol*.2021;87:386–394.
3. FDA and ISMP Lists of Look-Alike Drug Names with Recommended Tall Man Letters. Institute for Safe Medication Practices. (2016). Retrieved May 03, 2022, from <https://www.ismp.org/sites/default/files/attachments/2017-11/tallmanletters.pdf>
4. Guide on handling look alike, sound alike medications. Ministry of Health, Malaysia. (2012). Retrieved May 03, 2022, from <https://www.pharmacy.gov.my/v2/sites/default/files/document-upload/guide- handling-lasa.pdf>
5. Guidelines for Standard Order Sets. Institute for Safe Medication Practices. (2010). Retrieved May 03, 2022, from <https://www.ismp.org/guidelines/standard-order-sets>
6. High-Alert Medications in Acute Care Settings. Institute for Safe Medication Practices. (2018). Retrieved May 03, 2022, from <https://www.ismp.org/recommendations/high-alert-medications-acute-list>
7. High-Risk Medicines. Clinical Excellence Commission (CEC). (n.d.). Retrieved May 03, 2022, from <https://www.cec.health.nsw.gov.au/keep-patients-safe/medication-safety/high-risk-medicines>
8. ISMP Acute Care Guidelines for Timely Administration of Scheduled Medications. Institute for Safe Medication Practices. (2011). Retrieved May 03, 2022, from <https://www.ismp.org/sites/default/files/attachments/2018-02/tasm.pdf>
9. List of Confused Drug Names. Institute for Safe Medication Practices. (2019). Retrieved May 03, 2022, from <https://www.ismp.org/recommendations/confused-drug-names-list>
10. List of Error-Prone Abbreviations. Institute for Safe Medication Practices. (2017). Retrieved May 03, 2022, from <https://www.ismp.org/recommendations/error-prone-abbreviations-list>
11. Look-Alike, Sound-Alike Medication Names. World Health Organization. (2017). Retrieved May 03, 2022, from [https://cdn.who.int/media/docs/default-source/integrated-health-services-\(ihs\)/psf/patient-safety-solutions/ps-solution1-look-alike-sound-alike-medication-names.pdf?sfvrsn=d4fb860b_6&ua=1](https://cdn.who.int/media/docs/default-source/integrated-health-services-(ihs)/psf/patient-safety-solutions/ps-solution1-look-alike-sound-alike-medication-names.pdf?sfvrsn=d4fb860b_6&ua=1)
12. Medication Errors and Adverse Drug Events. Agency for Healthcare Research and Quality Patient Safety Network. (2019). Retrieved May 03, 2022, from <https://psnet.ahrq.gov/primer/medication-errors-and-adverse-drug-events>
13. Medication Reconciliation. Agency for Healthcare Research and Quality Patient Safety Network. (2019). Retrieved May 03, 2022, from <https://psnet.ahrq.gov/primer/medication-reconciliation>
14. Medication Safety in transition of care. World Health Organization. (2019). Retrieved May 03, 2022. <https://www.who.int/publications/i/item/WHO-UHC-SDS-2019.9> Medication errors. Technical Series on Safer Primary Care. World Health Organization (2016).

15. Medication without harm. WHO Global Patient safety Challenge. World Health Organization. (2017). Retrieved May 03, 2022. <https://www.who.int/initiatives/medication-without-harm>
16. Model Lists of Essential Medicines. World Health Organization. (n.d.). Retrieved May 03, 2022, from <https://www.who.int/groups/expert-committee-on-selection-and-use-of-essential-medicines/essential-medicines-lists>
17. National Coordinating Council for Medication Error Reporting and Prevention. (2015). Recommendations to Enhance Accuracy of Administration of Medications. Retrieved May 03, 2022, from <https://www.nccmerp.org/recommendations-enhance-accuracy-administration-medications>
18. National List of Essential Medicines. Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India. (2018, December 27). Retrieved May 03, 2022, from <https://pharmaceuticals.gov.in/sites/default/files/NLEM.pdf>
19. Promoting rational use of medicines: core components. World Health Organization. (2012). Retrieved May 03, 2022. https://apps.who.int/iris/bitstream/handle/10665/67438/WHO_EDM_2002.3.pdf
20. Recommendations to Enhance Accuracy of Dispensing Medications. National Coordinating Council for Medication Error Reporting and Prevention. (2015). Retrieved May 03, 2022, from <https://www.nccmerp.org/recommendations-enhance-accuracy-dispensing-medications>
21. R., Scudder, L., & Stokowski, L. (2015). Retrieved May 03, 2022. <https://www.medscape.com/slideshow/prescribing-errors-6007087>
22. Tully, A. P., Hammond, D. A., Li, C., Jarrell, A. S., & Kruer, R. M. (2019). Evaluation of Medication Errors at the Transition of Care From an ICU to Non-ICU Location. *Critical Care Medicine*, 47(4), 543-549.

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

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

CORE

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

CORE

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

Standard

PRE.2.	Patient and family rights support individual beliefs, values and involve the patient and family in decision making processes.
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Objective Elements

Commitment

- a. Patient and family rights include respect for personal dignity and privacy during examination, procedures and treatment.

Commitment

- b. Patient and family rights include protection from neglect or physical abuse.

CORE

- c. Patient and family rights include treating patient information as confidential.

Commitment

- d. Patient and family rights include the refusal of treatment.

Commitment

- e. Patient and family right include right to seek additional opinion regarding clinical care.

CORE

- f. Patient and family rights include informed consent before any invasive procedure.

Commitment

- g. Patient and family rights include a right to complain and information on how to voice a complaint.

CORE

- h. Patient and family rights include information on the expected cost of the treatment.

Commitment

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

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. *

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.

Commitment

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

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.

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.

Commitment

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

Commitment

- d. Patient and families are educated about immunizations.

Commitment

- e. Patient and families are educated about their specific disease process, prognosis, complications and prevention strategies.

Commitment

- f. Patient and families are educated about preventing healthcare associated infections.

Commitment

- g. Patient and/or family are educated on various pain management techniques, when appropriate.

Standard

PRE.5.	Patient and families have a right to information on expected costs.
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Objective Elements

Commitment	a. The tariff list is available to patients.
Achievement	b. Patients are educated about the expected cost of treatment.

References:

1. Badarudeen, S. and Sabharwal, S. (2010). Assessing Readability of Patient Education Materials: Current Role in Orthopaedics. *Clinical Orthopaedics and Related Research*®, 468(10), 2572-2580. doi:10.1007/s11999-010-1380-y
2. Burgener, A. M. (2017). Enhancing Communication to Improve Patient Safety and to Increase Patient Satisfaction. *The Health Care Manager*, 36(3), 238-243. doi:10.1097/hcm.000000000000165
3. Five strategies for Providing Effective Patient Education. Lippincott Solutions. (2017). Retrieved May 08, 2022 , from <https://www.wolterskluwer.com/en/expert-insights/5-strategies-for-providing-effective-patient-education>
4. Ha JF and Longnecker N. Doctor-Patient Communication: A Review. *Ochsner J.* 2010 Spring; 10(1): 38–43. Retrieved May 08, 2022 , from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3096184/>
5. Hong, J., Nguyen, T. V., & Prose, N. S. (2013). Compassionate care: Enhancing physician–patient communication and education in Dermatology. *Journal of the American Academy of Dermatology*, 68(3), 364.e1-364.e10. doi:10.1016/j.jaad.2012.10.060
6. Human rights and health. (2017). World Health Organisation. Retrieved May 08, 2022 , from <https://www.who.int/news-room/fact-sheets/detail/human-rights-and-health>
7. Kumar, A., Mullick, P., Prakash, S., & Bharadwaj, A. (2015). Consent and the Indian medical practitioner. *Indian Journal of Anaesthesia*, 59(11), 695-700. doi:10.4103/0019-5049.169989
8. Marcus, C. (2014). Strategies for improving the quality of verbal patient and family education: a review of the literature and creation of the EDUCATE model. *Health Psychology and Behavioral Medicine*, 2(1), 482-495. doi:10.1080/21642850.2014.900450
9. Munro, C. L., & Savel, R. H. (2013). Communicating and Connecting With Patients and Their Families. *American Journal of Critical Care*, 22(1), 4-6. doi:10.4037/ajcc2013249
10. Nandimath, O. (2009). Consent and medical treatment: The legal paradigm in India. *Indian Journal of Urology*, 25(3), 343. doi:10.4103/0970-1591.56202
11. Olejarczyk JP and Young M. Patient Rights And Ethics. (2021). Retrieved May 08, 2022 , from <https://www.ncbi.nlm.nih.gov/books/NBK538279/>
12. Patient Rights: Confidentiality & Informed Consent. E medicine health. (2020). Retrieved May 08, 2022 , from https://www.emedicinehealth.com/patient_rights/article_em.htm
13. Reader, T. W., Gillespie, A., & Roberts, J. (2014). Patient complaints in healthcare systems: a systematic review and coding taxonomy. *BMJ Quality & Safety*, 23(8), 678-689. doi:10.1136/bmjqs-2013-002437
14. Roberts, H., Zhang, D., & Dyer, G. S. (2016). The Readability of AAOS Patient Education Materials. *The Journal of Bone and Joint Surgery*, 98(17), e70. doi:10.2106/jbjs.15.00658

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

IPC.1.	The clinic has an Infection Prevention and Control programme.
IPC.2.	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.
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Objective Elements

CORE	a. Written guidance for infection prevention and control is available. *
CORE	b. The clinic adheres to standard precautions at all times.
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
CORE	d. Antibiotic use is guided by standard guidelines. *
CORE	e. The clinic adheres to safe injection and infusion practices. *

Standard

IPC.2.	The clinic implements the infection prevention and control programme for support services.
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Objective Elements

Commitment	a. The clinic adheres to housekeeping services guidelines.
CORE	b. Biomedical waste (BMW) complies with national/state regulations and is handled appropriately and safely.
Commitment	c. The clinic adheres to laundry and linen management processes.
Commitment	d. The clinic adheres to kitchen sanitation and food-handling issues.

References:

1. Banach, D. B., Bearman, G., Barnden, M., et al. (2018). Duration of Contact Precautions for Acute-Care Settings. *Infection Control & Hospital Epidemiology*, 39(2), 127-144. doi:10.1017/ice.2017.245
2. Bearman, G., Bryant, K., Leekha, S., Mayer, J., Munoz-Price, L. S., Murthy, R., ... White, J. (2014). Healthcare Personnel Attire in Non-Operating-Room Settings. *Infection Control & Hospital Epidemiology*, 35(2), 107-121. doi:10.1086/675066
3. Best practices for injections and related procedures toolkit. World Health Organization. (2010). Retrieved May 08, 2022 , from https://apps.who.int/iris/bitstream/handle/10665/44298/9789241599252_eng.pdf?sequence=1
4. Bloodborne Pathogens and Needlestick Prevention. Occupational Safety and Health Administration. (2018). Retrieved May 08, 2022 , from <https://www.osha.gov/SLTC/bloodbornepathogens/index.html>
5. Compendium of Strategies to Prevent Healthcare-Associated Infections in Acute Care Hospitals. Society for Healthcare Epidemiology of America. (2008). Retrieved May 08, 2022 , from <https://shea-online.org/compendium-of-strategies-to-prevent-healthcare-associated-infections-in-acute-care-hospitals/>
6. De Sousa Martins, B., Queiroz e Melo, J., Logarinho Monteiro, J., Rente, G., et al (2019). Reprocessing of Single-Use Medical Devices: Clinical and Financial Results. *Portuguese Journal of Public Health*, 1-7. doi:10.1159/000496299
7. Dolan, S. A., Arias, K. M., Felizardo, G., et al. (2016). APIC position paper: Safe injection, infusion, and medication vial practices in health care. *American Journal of Infection Control*, 44(7), 750-757. doi:10.1016/j.ajic.2016.02.033
8. Environmental Cleaning for the Prevention of Healthcare-Associated Infections (HAI). Agency for Healthcare Research and Quality. (2014). Retrieved May 08, 2022 , from <https://effectivehealthcare.ahrq.gov/products/healthcare-infections/research-protocol>
9. Fishman, N. (2012). Policy Statement on Antimicrobial Stewardship by the Society for Healthcare Epidemiology of America (SHEA), the Infectious Diseases Society of America (IDSA), and the Pediatric Infectious Diseases Society (PIDS). *Infection Control & Hospital Epidemiology*, 33(4), 322-327. doi:10.1086/665010
10. Global Guidelines for the Prevention of Surgical Site Infection. World Health Organization. (2016). Retrieved May 08, 2022 , from <https://apps.who.int/iris/bitstream/handle/10665/250680/9789241549882-eng.pdf>
11. Guideline for Disinfection and Sterilization in Healthcare Facilities (2008). Center for Disease Control and Prevention. Retrieved May 08, 2022 , from <https://www.cdc.gov/infectioncontrol/guidelines/disinfection/index.html>
12. Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings (2007). Centers for Disease Control and Prevention. Retrieved May 08, 2022 , from <https://www.cdc.gov/infectioncontrol/guidelines/isolation/index.html>
13. Guideline for Prevention of Catheter-Associated Urinary Tract Infections (2009). Centers for Disease Control and Prevention. Retrieved May 08, 2022 , from <https://www.cdc.gov/infectioncontrol/guidelines/CAUTI/index.html>

14. Guideline for Prevention of Surgical Site Infection (2017). Centers for Disease Control and Prevention. Retrieved May 08, 2022 , from <https://www.cdc.gov/infectioncontrol/guidelines/ssi/index.html>
15. Guidelines for Environmental Infection Control in Health-Care Facilities: Recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC). MMWR 2003;52(RR10):1-42. Retrieved May 08, 2022 , from <https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5210a1.htm>
16. Guidelines for the Prevention of Intravascular Catheter-Related Infections (2011) Centers for Disease Control and Prevention. Retrieved May 08, 2022 , from <https://www.cdc.gov/infectioncontrol/guidelines/bsi/index.html>
17. Guidelines on Core Components of Infection Prevention and Control Programmes at the National and Acute Health Care Facility Level. World Health Organization. (2016). Retrieved May 08, 2022 , from <https://apps.who.int/iris/handle/10665/251730>
18. Guidelines on hand hygiene in health care. World Health Organization. (2019). Retrieved May 08, 2022 , from <https://www.who.int/publications/i/item/9789241597906>
19. Han, J. H., Sullivan, N., Leas, B. F. et al L. (2015). Cleaning Hospital Room Surfaces to Prevent Health Care–Associated Infections. *Annals of Internal Medicine*, 163(8), 598. doi:10.7326/m15-1192
20. Health Care Workers, Prevention Controls. (2016). Centers for Disease Control and Prevention. (2018). CDC -, Infectious Agents - The National Institute for Occupational Safety and Health (NIOSH). Retrieved May 08, 2022 , from <https://www.cdc.gov/niosh/topics/healthcare/prevention.html>
21. Healthcare-Associated Infections (HAIs). Centers for Disease Control and Prevention. (2021). Retrieved May 08, 2022 , from <https://www.cdc.gov/hai/index.html>
22. Hospital Infection Control Guidelines. Indian Council of Medical Research. (n.d.). Retrieved May 08, 2022 , from https://www.icmr.nic.in/sites/default/files/guidelines/Hospital_Infection_control_guidelines.pdf
23. Infection Prevention and Control in Healthcare Settings. Standard Operating Procedures. (2018). Delhi State Health Mission. Government of NCT of Delhi, India. Retrieved May 08, 2022 , from [https://dshm.delhi.gov.in/\(S\(qohk5xwyvoyrqxe20uuyb0k\)\)/pdf/QAC/SoPs/IPC_FINAL_MANUAL.doc](https://dshm.delhi.gov.in/(S(qohk5xwyvoyrqxe20uuyb0k))/pdf/QAC/SoPs/IPC_FINAL_MANUAL.doc)
24. Lee, T. B., Montgomery, O. G., Marx, J., Olmsted et al. (2007). Recommended practices for surveillance: Association for Professionals in Infection Control and Epidemiology (APIC), Inc. *American Journal of Infection Control*, 35(7), 427-440. doi:10.1016/j.ajic.2007.07.002
25. Management of Multidrug-Resistant Organisms in Healthcare Settings (2006). Centers for Disease Control and Prevention. Retrieved May 08, 2022 , from <https://www.cdc.gov/infectioncontrol/guidelines/mdro/index.html>
26. McDonald, L. C., Gerding, D. N., Johnson, S., et al. (2018). Clinical Practice Guidelines for *Clostridium difficile* Infection in Adults and Children: 2017 Update by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA). *Clinical Infectious Diseases*, 66(7), 987-994. doi:10.1093/cid/ciy149
27. Munoz-Price, L., Banach, D., Bearman, G., et al. (2015). Isolation Precautions for Visitors. *Infection Control & Hospital Epidemiology*, 36(7), 747-758. doi:10.1017/ice.2015.67

28. Munoz-Price, L., Bowdle, A., Johnston, B., et al. (2019). Infection prevention in the operating room anesthesia work area. *Infection Control and Hospital Epidemiology*, 40(1), 1-17. doi:10.1017/ice.2018.303
29. National guidelines for infection prevention and control in healthcare facilities. (2020). National Centre for Disease Control, Directorate General of Health Services. Ministry of Health & Family Welfare, Government of India. Retrieved May 08, 2022 , from <https://www.mohfw.gov.in/pdf/National%20Guidelines%20for%20IPC%20in%20HCF%20-%20final%281%29.pdf>
30. National Technical Guidelines on Anti Retroviral Treatment. National AIDS Control Organization. Ministry of Health and Family Welfare, Government of India. (2018). Retrieved May 08, 2022 , from http://naco.gov.in/sites/default/files/NACO%20-%20National%20Technical%20Guidelines%20on%20ART_October%202018%20%281%29.pdf
31. National Treatment Guidelines for Antimicrobial Use in Infectious Diseases. (2016). National Centre for Disease Control, Directorate General of Health Services. Ministry of Health & Family Welfare, Government of India. Retrieved May 08, 2022 , from <https://ncdc.gov.in/WriteReadData/l892s/File622.pdf>
32. Outline For Healthcare-Associated Infections Surveillance. Centers for Disease Control and Prevention. (2006). Retrieved May 08, 2022 , from <https://www.cdc.gov/nhsn/PDFS/OutlineForHAISurveillance.pdf>
33. Personal Protective Equipment in Medical Settings. Infectious Diseases Society of America (2022). Retrieved May 08, 2022 , from <https://www.idsociety.org/covid-19-real-time-learning-network/infection-prevention/personal-protective-equipment-in-medical-settings/>
34. Petersen, B. T., Cohen, J., Hambrick, R. D., Buttar, N., et al (2017). Multisociety guideline on reprocessing flexible GI endoscopes: 2016 Update. *Gastrointestinal Endoscopy*, 85(2), 282-294.e1. doi:10.1016/j.gie.2016.10.002
35. Post-exposure prophylaxis (PEP). Centers for Disease Control and Prevention. (2021). Retrieved May 08, 2022 , from <https://www.cdc.gov/hiv/basics/pep.html>
36. Post-exposure prophylaxis to prevent HIV infection : joint WHO/ILO guidelines on post-exposure prophylaxis (PEP) to prevent HIV infection. World Health Organization. (2007). Retrieved May 08, 2022 , from <https://apps.who.int/iris/handle/10665/43838>
37. Postexposure Prophylaxis: Viral Hepatitis. Centers for Disease Control and Prevention. (2020). Retrieved May 08, 2022 , from <https://www.cdc.gov/hepatitis/hbv/pep.htm>
38. Recommended Vaccines for Healthcare Workers. (2016). Centers for Disease Control and Prevention. Retrieved May 08, 2022 , from <https://www.cdc.gov/vaccines/adults/rec-vac/hcw.html>
39. Recommended work restrictions for communicable diseases in health care workers. Association of Occupational Health Professionals in Healthcare. (2014). Retrieved May 08, 2022 , from <https://aohp.org/aohp/Portals/0/Documents/MemberServices/templateandform/WR4CD-HCW.pdf>
40. Reprocessed Single-Use Devices. ACOG Committee Opinion No. 769. (2019). *Obstetrics & Gynecology*, 133(3), e235-e237. doi:10.1097/aog.0000000000003124

41. Sfeir, M., Simon, M. S., & Banach, D. (2017). Isolation Precautions for Visitors to Healthcare Settings. *Infection Prevention*, 19-27. doi:10.1007/978-3-319-60980-5_4
42. Standard precautions in health care. World Health Organization. (2007). Retrieved May 08, 2022 , from <https://www.who.int/docs/default-source/documents/health-topics/standard-precautions-in-health-care.pdf>
43. Summary of WHO Position Papers – Immunization of Health Care Workers. World Health Organization. (2019). Retrieved May 08, 2022 , from https://cdn.who.int/media/docs/default-source/immunization/immunization_schedules/immunization-routine-table4.pdf?sfvrsn=714e38d6_4&download=true
44. Swachhta Guidelines for Public Health Facilities. Ministry of Health & Family Welfare, Government Of India. (2015). Retrieved May 08, 2022 , from <http://tripuranrh.m.gov.in/QA/Guideline/SwachhtaGuidelinesforPublicHealthFacilities.pdf>
45. Transmission-Based Precautions. Centers for Disease Control and Prevention. (2016). Retrieved May 08, 2022 , from <https://www.cdc.gov/infectioncontrol/basics/transmission-based-precautions.html>
46. Treatment Guidelines for Antimicrobial Use in Common Syndromes. Indian Council of Medical Research. (2019). Retrieved May 08, 2022 , from https://main.icmr.nic.in/sites/default/files/guidelines/Treatment_Guidelines_2019_Final.pdf

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	PSQ1	PSQ2
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.

Commitment

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

CORE

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

Standard

PSQ.2.**There is a structured quality improvement and continuous monitoring programme.**

Objective Elements

Commitment

a. The quality improvement programme is documented. *

Commitment

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

References:

1. Canadian Incident Analysis Framework. (2012). Canadian Patient Safety Institute. Retrieved May 08, 2022, from <https://www.patientsafetyinstitute.ca/en/toolsResources/IncidentAnalysis/Documents/Canadian%20Incident%20Analysis%20Framework.PDF>
2. Charles, R., Hood, B., Derosier, J. M., et al. (2016). How to perform a root cause analysis for workup and future prevention of medical errors: a review. *Patient Safety in Surgery*, 10(1). doi:10.1186/s13037-016-0107-8
3. Detection of Safety Hazards. (2019). Agency for Healthcare Research and Quality. Patient Safety Primers. Retrieved May 08, 2022, from <https://psnet.ahrq.gov/primers/primer/24/Detection-of-Safety-Hazards>
4. Donabedian, A. (1983). Quality Assessment and Monitoring. *Evaluation & the Health Professions*, 6(3), 363-375. doi:10.1177/016327878300600309
5. Ewen, B. M., & Bucher, G. (2013). Root Cause Analysis. *Home Healthcare Nurse*, 31(8), 435-443. doi:10.1097/nhh.0b013e3182a1dc32
6. Fung, C. H., Lim, Y., Mattke, S., Damberg, C., & Shekelle, P. G. (2008). Systematic Review: The Evidence That Publishing Patient Care Performance Data Improves Quality of Care. *Annals of Internal Medicine*, 148(2), 111. doi:10.7326/0003-4819-148-2-200801150-00006
7. Gruen, R. L., Gabbe, B. J., Stelfox, H. T., & Cameron, P. A. (2011). Indicators of the quality of trauma care and the performance of trauma systems. *British Journal of Surgery*, 99(S1), 97-104. doi:10.1002/bjs.7754
8. How can leaders influence a safety culture? (2012). The Health Foundation. Retrieved May 08, 2022, from <https://www.health.org.uk/sites/default/files/HowCanLeadersInfluenceASafetyCulture.pdf>
9. Hughes, R. (2008). Chapter 44 Tools and Strategies for Quality Improvement and Patient Safety. In *Patient Safety and Quality: An Evidence-based Handbook for Nurses*.
10. Jones, P., Shepherd, M., Wells, S., Le Fevre, J., & Ameratunga, S. (2014). Review article: What makes a good healthcare quality indicator? A systematic review and validation study. *Emergency Medicine Australasia*, 26(2), 113-124. doi:10.1111/1742-6723.12195
11. Kötter, T., Blozik, E., & Scherer, M. (2012). Methods for the guideline-based development of quality indicators--a systematic review. *Implementation Science*, 7(1). doi:10.1186/1748-5908-7-21
12. Krause, C. (2017). The Case for Quality Improvement. *Healthcare Quarterly*, 20(1), 25-27. doi:10.12927/hcq.2017.25138
13. Leotsakos, A., Zheng, H., Croteau, R. et al Loeb, J. M., Sherman, H., Hoffman, C., ... Munier, B. (2014). Standardization in patient safety: the WHO High 5s project. *International Journal for Quality in Health Care*, 26(2), 109-116. doi:10.1093/intqhc/mzu010
14. Medicine, I. O., Board on Health Care Services, & Committee on Patient Safety and Health Information Technology. (2012). *Health IT and Patient Safety: Building Safer Systems for Better Care*. Washington, DC: National Academies Press.

15. Patient safety incident reporting and learning systems: technical report and guidance. (2020). World Health Organization. Retrieved May 08, 2022, from <https://www.who.int/publications/i/item/9789240010338>
16. Patient Safety Solutions. (2017). World Health Organization. Retrieved May 08, 2022, from <https://www.who.int/teams/integrated-health-services/patient-safety/research/patient-safety-solutions>
17. Quality Improvement Essentials Toolkit. (n.d.). Institute for Healthcare Improvement. Retrieved May 08, 2022, from <http://www.ihl.org/resources/Pages/Tools/Quality-Improvement-Essentials-Toolkit.aspx>
18. Quality Statistics - Statistical Methods for Quality Improvement. (n.d.). American Society for Quality. Retrieved May 08, 2022, from <https://asq.org/quality-resources/statistics>
19. RCA2 Improving Root Cause Analyses and Actions to Prevent Harm. (2015). National Patient Safety Foundation. Retrieved May 08, 2022, from <https://www.ashp.org/-/media/assets/policy-guidelines/docs/endorsed-documents/endorsed-documents-improving-root-cause-analyses-actions-prevent-harm.ashx>
20. Reporting Patient Safety Events. (2019). Agency for Healthcare Research and Quality. Patient Safety Network. Retrieved May 08, 2022, from <https://psnet.ahrq.gov/primers/primer/13/reporting-patient-safety-events%20on%20April%2016>
21. Root Cause Analysis. (2019). Agency for Healthcare Research and Quality. Patient Safety Network. Retrieved May 08, 2022, from <https://psnet.ahrq.gov/primers/primer/10/Root-Cause-Analysis>
22. Rubin, H. R. (2001). The advantages and disadvantages of process-based measures of health care quality. *International Journal for Quality in Health Care*, 13(6), 469-474. doi:10.1093/intqhc/13.6.469
23. Seven basic quality tools for process improvement. (n.d.). American Society for Quality. Retrieved May 08, 2022, from <https://asq.org/quality-resources/seven-basic-quality-tools>
24. Shaikh U. Strategies and Approaches for Investigating Patient Safety Events. (2022). Retrieved May 08, 2022, from <https://psnet.ahrq.gov/primer/strategies-and-approaches-investigating-patient-safety-events>
25. Swensen, S. J., Dilling, J. A., Mc Carty, P. M., et al. (2013). The business case for health-care quality improvement. *J Patient Saf*, 9(1), 44-52. doi:10.1097/PTS.0b013e3182753e33
26. Systematic review: the evidence that publishing patient care performance data improves quality of care. (2009). *Clinical Governance: An International Journal*, 14(1). doi:10.1108/cgij.2009.24814aae.006
27. Thomas, E. J. (2015). The future of measuring patient safety: prospective clinical surveillance. *BMJ Quality & Safety*, 24(4), 244-245. doi:10.1136/bmjqs-2015-004078
28. Tsai, T. C., Jha, A. K., Gawande, A. A., Huckman, R. S., Bloom, N., & Sadun, R. (2015). Hospital Board And Management Practices Are Strongly Related To Hospital Performance On Clinical Quality Metrics. *Health Affairs*, 34(8), 1304-1311. doi:10.1377/hlthaff.2014.1282
29. What is Risk Management in Healthcare? (2019). *NEJM Catalyst*. Retrieved May 08, 2022, from <https://catalyst.nejm.org/what-is-risk-management-in-healthcare/>

30. What is Root Cause Analysis (RCA)?. (n.d.). American Society for Quality. Retrieved May 08, 2022, from <https://asq.org/quality-resources/root-cause-analysis>

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

ROM.1.	The responsibilities of the management are defined.
ROM.2.	The clinic is managed by the leaders in an ethical manner.
ROM.3.	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.	Achievement	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*
Commitment	b. Those responsible for governance establish the clinic's organogram, as applicable. *
Achievement	c. Administrative written guidance for each section is maintained. *
CORE	d. The clinic complies with the laid down, applicable legislations and regulations at all times.
CORE	e. In cases of notifiable diseases, information (in relevant format) is sent to appropriate authorities.

Standard

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

Objective Elements

CORE	a. The clinic functions in an ethical manner.
CORE	b. The clinic honestly portrays its affiliations and accreditation.
Commitment	c. The clinic accurately bills for its services based upon a standard billing tariff.

Standard

ROM.3.**The clinic participates in health promotion and disease prevention.**

Objective Elements

Achievement	a. There is a process and mechanism in place to ensure health promotion and disease prevention.
Commitment	b. The clinic cooperates and collaborates with the community partners in provision of surveillance, epidemiological investigations, data collection, when required.

References:

1. Biller-Andorno, N. (2004). Ethics, EBM, and hospital management. *Journal of Medical Ethics*, 30(2), 136-140. doi:10.1136/jme.2003.007161
2. Bruning, P. (2013). Improving Ethical Decision Making in Health Care Leadership. *Business and Economics Journal*, 04(02). doi:10.4172/2151-6219.1000e101
3. Chatterjee, C., & Srinivasan, V. (2013). Ethical issues in health care sector in India. *IIMB Management Review*, 25(1), 5. doi:10.1016/j.iimb.2012.12.007
4. Clay-Williams, R., Ludlow, K., Testa, L., Li, Z., & Braithwaite, J. (2017). Medical leadership, a systematic narrative review: do hospitals and healthcare organisations perform better when led by doctors? *BMJ Open*, 7(9), e014474. doi:10.1136/bmjopen-2016-014474
5. Common Ethical Dilemmas for Doctors. Medscape. (n.d.). Retrieved May 08, 2022, from <https://www.medscape.com/courses/section/898063>
6. Determining Your Core Values, Mission, and Vision. (2015). *Complete Guide to Practice Management*, 3-18. doi:10.1002/9781119204312.ch1
7. Doran, E., Fleming, J., Jordens, C., Stewart, C. L., Letts, J., & Kerridge, I. H. (2015). Managing ethical issues in patient care and the need for clinical ethics support. *Australian Health Review*, 39(1), 44. doi:10.1071/ah14034
8. Govind, N. (2014). Between families and doctors. *Indian Journal of Medical Ethics*. doi:10.20529/ijme.2014.016
9. India Code: Home. Digital repository of all central and state acts. (n.d.). Government of India. Retrieved May 08, 2022, from <https://indiacode.nic.in/>
10. Ingersoll, G. L., Witzel, P. A., & Smith, T. C. (2005). Using Organizational Mission, Vision, and Values to Guide Professional Practice Model Development and Measurement of Nurse Performance. *JONA: The Journal of Nursing Administration*, 35(2), 86-93. doi:10.1097/00005110-200502000-00008
11. McSherry, R., Wadding, A., & Pearce, P. (n.d.). Healthcare Governance Through Effective Leadership. *Effective Healthcare Leadership*, 58-75. doi:10.1002/9780470774984.ch5
12. Phrampus PE. Building a Safety Program in a Vast Health Care Network. (2019). Agency for Healthcare Research and Quality. Retrieved May 08, 2022, from <https://psnet.ahrq.gov/perspective/building-safety-program-vast-health-care-network>
13. Quality and Patient Safety Directorate. (2012). Quality and Patient Safety Clinical Governance Development: an assurance check for health service providers. Retrieved May 08, 2022, from <https://www.pna.ie/images/0405124.pdf>
14. Rego, A., Araújo, B., & Serrão, D. (2015). The mission, vision and values in hospital management. *Journal of Hospital Administration*, 5(1). doi:10.5430/jha.v5n1p62

15. Stern RJ and Sarkar U. Update: Patient Engagement in Safety. (2018). Agency for Healthcare Research and Quality. Patient Safety Network. Retrieved May 08, 2022, from <https://psnet.ahrq.gov/perspective/update-patient-engagement-safety>
16. Strategic Planning: Why It Makes a Difference, and How to Do It. (2009). Journal of Oncology Practice, 5(3), 139-143. doi:10.1200/jop.0936501
17. Suchy, K. (2010). A Lack of Standardization: The Basis for the Ethical Issues Surrounding Quality and Performance Reports. Journal of Healthcare Management, 55(4), 241-251. doi:10.1097/00115514-201007000-00005
18. Trybou, J., Gemmel, P., Desmidt, S., & Annemans, L. (2017). Fulfilment of administrative and professional obligations of hospitals and mission motivation of physicians. BMC Health Services Research, 17(1). doi:10.1186/s12913-017-1990-0

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

Summary of Standards

FMS.1.	The clinic shall operate in an environment which ensures safety of patients, staff and visitors.
FMS.2.	The clinic has a programme for equipment and facility management.
FMS.3.	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	Achievement	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.
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Objective Elements

Commitment	a. Updated drawings are maintained with details of site layout, floor plans and fire escape routes.
CORE	b. There are internal and external sign posting in the Clinic in a language understood by patient, families and community.
Commitment	c. Facilities and space provisions are appropriate to the scope of clinic.
Achievement	d. Patient safety devices and infrastructure are installed across the clinic.

Standard

FMS.2.	The clinic has a programme for equipment and facility management.
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Objective Elements

Achievement	a. The clinic plans for equipment in accordance with its services and strategic plan.
Commitment	b. Equipment is periodically inspected and calibrated for their proper functioning.
Commitment	c. Safe water and uninterrupted electrical supply is available.
CORE	d. Written guidance governs procurement, handling, storage, distribution, usage and replenishment of medical gases.*

Standard

FMS.3.	The clinic has plans for emergencies (fire and non-fire) and hazardous materials within the facility.
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Objective Elements

CORE	a. The clinic has plans and provisions for early detection, abatement and containment of fire and non-fire emergencies.*
Commitment	b. The staff is trained for their role in case of such emergencies.
CORE	c. The clinic has addressed identification, sorting, storage, handling, transportation, disposal mechanism, and method for managing spillages of hazardous materials.

References:

1. Aggarwal, R., Mytton, O. T., Greaves, F., & Vincent, C. (2010). Technology as applied to patient safety: an overview. *Quality and Safety in Health Care*, 19 (Suppl 2), i3-i8. doi:10.1136/qshc.2010.040501
2. Medical Gases. (n.d.). British Compressed Gases Association. Retrieved May 08, 2022, from http://www.bcgas.co.uk/pages/index.cfm?page_id=29&title=medical_gases
3. National Building Code of India, 2016. (2016). Bureau of Indian Standards. New Delhi. Retrieved May 08, 2022, from <https://www.bis.gov.in/index.php/standards/technical-department/national-building-code/>
4. Coulliette, A. D., & Arduino, M. J. (2015). Hemodialysis and Water Quality. *Semin Dial*, 26(4), 427-438.
5. Biomedical Equipment Management and Maintenance Program. Government of India. National Health Mission. (n.d.). Retrieved May 08, 2022, from https://nhm.gov.in/New_Updates_2018/NHM_Components/Health_System_Stregthening/BEMMP/Biom edical_Equipment_Revised_Guidelines.pdf
6. Gudlavalleti, V. (2018). Challenges in Accessing Health Care for People with Disability in the South Asian Context: A Review. *International Journal of Environmental Research and Public Health*, 15(11), 2366. doi:10.3390/ijerph15112366
7. Hart, J. R. (2018). *Medical Gas and Vacuum Systems Handbook*. National Fire Protection Association.
8. Infrastructures to improve patient safety. *Health Facilities Management*. (2015, December 2). Retrieved May 08, 2022, from <https://www.hfmmagazine.com/articles/1827-infrastructures-to-improve-patient-safety>
9. Medical Gas Cylinder Storage. (2018). National Fire Protection Association. Retrieved May 08, 2022, from <https://www.nfpa.org/~media/4B6B534171E04E369864672EBB319C4F.pdf>
10. Indian Public Health Standards. (2022). National Health Mission. Ministry of Health & Family Welfare, Government of India. Retrieved May 08, 2022, from <https://nhm.gov.in/index1.php?lang=1&level=2&sublinkid=971&lid=154>
11. Sarangi, S., Babbar, S., & Taneja, D. (n.d.). Safety of the medical gas pipeline system. *Journal of Anaesthesiology Clinical Pharmacology*, 34(1), 99-102. Retrieved May 08, 2022, from <http://www.joacp.org/text.asp?2018/34/1/99/227571>
12. Guidelines for Drinking-water Quality (4th Edition). World Health Organization. (2011). Retrieved May 08, 2022, from https://apps.who.int/iris/bitstream/handle/10665/44584/9789241548151_eng.pdf?sequence=1
13. Safe Management of Wastes from Health-Care Activities (2nd ed.). World Health Organization. (2014). Retrieved May 08, 2022, from https://apps.who.int/iris/bitstream/handle/10665/85349/9789241548564_eng.pdf?sequence=1
14. Hospital safety index: guide for evaluators – 2nd ed. World Health Organization. (2015). Retrieved May 08, 2022, from https://www.who.int/hac/techguidance/hospital_safety_index_evaluators.pdf

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.
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Objective Elements

CORE

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

Commitment

b.	The clinic defines and implements a code of conduct for its staff.
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Commitment

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

Commitment

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

Commitment

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

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.
----	---

Commitment

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

Standard

HRM.3.	There is a process and mechanism in place to ensure staff health and safety programme.
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Objective Elements

Commitment

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

Commitment

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

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

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

1. Aswathappa, K. (2013). Human Resource Management 6E (7th ed.). New York, NY: Tata McGraw-Hill Education.
2. Barnett, S. D. (2015). Growing Pains of Credentialing Research: Discussions from the Institute of Medicine Workshop. *The Journal of Continuing Education in Nursing*, 46(2), 53-55. doi:10.3928/00220124-20150121-11
3. Baumann, A., Norman, P., Blythe, J., Kratina, S., & Deber, R. (2014). Accountability: The Challenge for Medical and Nursing Regulators. *Healthcare Policy | Politiques de Santé*, 10(SP), 121-131. doi:10.12927/hcpol.2014.23911
4. Chhabra, S. (2016). Health hazards among health care personnel. *Journal of Mahatma Gandhi Institute of Medical Sciences*, 21(1), 19. doi:10.4103/0971-9903.178074
5. Chhabra, T. N., & Chhabra, M. S. (2014). Human Resources Management (1st ed.). India: Sun publications.
6. Cook, D. A., Blachman, M. J., Price, D. W., West, C. P., Berger, R. A., & Wittich, C. M. (2017). Professional Development Perceptions and Practices Among U.S. Physicians. *Academic Medicine*, 92(9), 1335-1345. doi:10.1097/acm.0000000000001624
7. Credentialing and privileging of pharmacists: A resource paper from the Council on Credentialing in Pharmacy. (2014). *American Journal of Health-System Pharmacy*, 71(21), 1891-1900. doi:10.2146/ajhp140420
8. Gesme, D. H., Towle, E. L., & Wiseman, M. (2010). Essentials of Staff Development and Why You Should Care. *Journal of Oncology Practice*, 6(2), 104-106. doi:10.1200/jop.091089
9. Gillespie, G. L., Fisher, B. S., & Gates, D. M. (2015). Workplace Violence in Healthcare Settings. *Work*, 51(1), 3-4. doi:10.3233/wor-152017
10. Gillespie, G. L., Gates, D. M., Miller, M., & Howard, P. K. (2010). Workplace Violence in Healthcare Settings: Risk Factors and Protective Strategies. *Rehabilitation Nursing*, 35(5), 177-184. doi:10.1002/j.2048-7940.2010.tb00045.x
11. Gorman, T., Dropkin, J., Kamen, J., et al. (2014). Controlling Health Hazards to Hospital Workers: A Reference Guide. *NEW SOLUTIONS: A Journal of Environmental and Occupational Health Policy*, 23(1_suppl), 1-169. doi:10.2190/ns.23.suppl
12. Guidelines for Preventing Workplace Violence for Healthcare and Social Service Workers. (2016). Occupational Safety and Health Administration. Retrieved May 08, 2022, from <https://www.osha.gov/Publications/OSHA3148.pdf>
13. Health Care Workers. (2019). National Institute for Occupational Safety and Health. Retrieved May 08, 2022, from <https://www.cdc.gov/niosh/topics/healthcare/default.html>
14. Healthcare. (2019). Occupational Safety and Health Administration. United States Department of Labor. Retrieved May 08, 2022, from <https://www.osha.gov/SLTC/healthcarefacilities/index.html>
15. Hravnak, M., & Baldisseri, M. (1997). Credentialing and Privileging. *AACN Clinical Issues: Advanced Practice in Acute and Critical Care*, 8(1), 108-115. doi:10.1097/00044067-199702000-00014

16. Is credentialing a solution to the workforce crisis? (2017). *Emergency Nurse*, 25(1), 5-5.
doi:10.7748/en.25.1.5.s1
17. Izadi, N. (2018). Occupational Health Hazards among Health Care Workers. *Public Health Open Access*, 2(1).
doi:10.23880/phoa-16000120
18. Jones, L., & Moss, F. (2018). What should be in hospital doctors' continuing professional development? *Journal of the Royal Society of Medicine*, 112(2), 72-77. doi:10.1177/0141076818808427
19. Kirkpatrick, J. D., & Kirkpatrick, W. K. (2016). *Kirkpatrick's Four Levels of Training Evaluation*. Association for Talent Development.
20. Medical Surveillance for Healthcare Workers Exposed to Hazardous Drugs. (2013). Department of Health and Human Services, Centers for Disease Control and Prevention National Institute for Occupational Safety and Health. Retrieved May 08, 2022, from <https://www.cdc.gov/niosh/docs/wp-solutions/2013-103/pdfs/2013-103.pdf>
21. Niles, N. J. (2012). *Basic Concepts of Health Care Human Resource Management* (1st ed.). Burlington, MA: Jones & Bartlett Publishers.
22. Position Statement on Credentialing and Privileging for Nurse Practitioners. (2016). *Journal of Pediatric Health Care*, 30(2), A20-A21. doi:10.1016/j.pedhc.2015.11.006
23. Sarre, S., Maben, J., Aldus, C., Schneider, J., Wharrad, H., Nicholson, C., & Arthur, A. (2018). The challenges of training, support and assessment of healthcare support workers: A qualitative study of experiences in three English acute hospitals. *International Journal of Nursing Studies*, 79, 145-153.
doi:10.1016/j.ijnurstu.2017.11.010
24. Singh, S. (2014). Credentialing and Privileging in Healthcare Organizations. *Handbook of Healthcare Quality and Patient Safety*, 114-114. doi:10.5005/jp/books/12287_9
25. Srinivasan, A. V. (2008). *Human Resource Management in Hospitals*. In *Managing a Modern Hospital* 2nd ed.). New Delhi, India: SAGE Publications India.
26. Steege, A. L., Boiano, J. M., & Sweeney, M. H. (2014). NIOSH Health and Safety Practices Survey of Healthcare Workers: Training and awareness of employer safety procedures. *American Journal of Industrial Medicine*, 57(6), 640-652. doi:10.1002/ajim.22305
27. STRESS...At Work. (2018). National Institute for Occupational Safety and Health. Retrieved May 08, 2022, from <https://www.cdc.gov/niosh/docs/99-101/default.html>
28. The Kirkpatrick Model. (2019). Kirkpatrick Partners. Retrieved May 08, 2022, from <https://kirkpatrickpartners.com/Our-Philosophy/The-Kirkpatrick-Model>
29. Wilburn, S. Q., & Eijkemans, G. (2004). Preventing Needlestick Injuries among Healthcare Workers: A WHO-ICN Collaboration. *International Journal of Occupational and Environmental Health*, 10(4), 451- 456.
doi:10.1179/oeh.2004.10.4.451

30. Work Organization and Stress. WHO/SDE/Objective ElementH/01.10. World Health Organization. (2003). Retrieved May 08, 2022, from <https://apps.who.int/iris/bitstream/handle/10665/42625/9241590475.pdf>
31. Workload indicators of staffing need. (2010). World Health Organization. Retrieved May 08, 2022, from <https://www.who.int/publications/i/item/9789241500197>
32. Zhao, S., Liu, H., Ma, H., Jiao, M., Li, Y., Hao, Y., ... Qiao, H. (2015). Coping with Workplace Violence in Healthcare Settings: Social Support and Strategies. *International Journal of Environmental Research and Public Health*, 12(11), 14429-14444. doi:10.3390/ijerph121114429

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	Achievement	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.
Commitment	b. Medical record provides a complete, up-to-date and chronological account of patient care as applicable.
Commitment	c. Every medical record entry is dated, timed and the author of the entry can be identified.
Commitment	d. Care providers have access to current and past medical record.
Commitment	e. Retention period and process of destruction of medical records is defined as per national and State Laws/Guidelines.

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.*
Achievement	b. Information management and technology acquisitions are commensurate with the identified information needs.
Commitment	c. Clinic develops, maintains, and tests a program for response to planned and unplanned downtime of data systems.

Standard

IMS.2. Telemedicine services are provided as per regulatory guidelines.

Objective Elements

Commitment	a. Telemedicine facility is provided safely and securely based on National/Local Guidelines.*
Commitment	b. The clinic ensures quality of patient care, confidentiality and security of information.
Achievement	c. There is a defined process for community linkages and outreach activities through Telemedicine consultation service.

References:

1. Aguiar T, Gomes SB, de Cunha PR, da Silva MM. (2021). Identifying the Practices of Digital Transformation: Based on a Systematic Literature Review. ISACA Journal, Vol1. Retrieved May 08, 2022, from https://www.isaca.org/-/media/files/isacadp/project/isaca/articles/journal/2021/volume-1/identifying-the-practices-of-digital-transformation_joa_eng_0121.pdf
2. Alotaibi, Y., & Federico, F. (2017). The impact of health information technology on patient safety. Saudi Medical Journal, 38(12), 1173-1180. doi:10.15537/smj.2017.12.20631
3. Anderson, J. G. (2010). Improving Patient Safety with Information Technology. Handbook of Research on Advances in Health Informatics and Electronic Healthcare Applications, 144-152. doi:10.4018/978-1-60566-030-1.ch009
4. Blum, B. I. (1986). Clinical Information Systems—A Review. West J Med., 145(6), 791-797. Retrieved May 08, 2022, from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1307152/pdf/westjmed00160-0055.pdf>
5. Borycki, E., & Kushniruk, A. (2017). Patient Safety and Health Information Technology. E-Health Two- Sided Markets, 19-31. doi:10.1016/b978-0-12-805250-1.00004-6
6. Electronic Health Record (EHR) Standards for India -2016. Ministry of Health and Family Welfare, Government of India. (2016). Retrieved May 08, 2022, from <https://www.nhp.gov.in/NHPfiles/EHR- Standards-2016-MoHFW.pdf>
7. Feldman, S. S., Buchalter, S., & Hayes, L. W. (2018). Health Information Technology in Healthcare Quality and Patient Safety: Literature Review. JMIR Medical Informatics, 6(2), e10264. doi:10.2196/10264
8. Generic medical record keeping standards. Royal College of Physicians. (2015). Retrieved May 08, 2022, from <https://www.rcplondon.ac.uk/projects/outputs/generic-medical-record-keeping-standards>
9. Guidance Document of ABDM Compliant HMIS/LMIS. (2022). Ayushman Bharat Digital Mission (ABDM). National Health Authority. Ministry of Health and Family Welfare. Government of India. Retrieved May 08, 2022, from https://abdm.gov.in/assets/uploads/Guidance_Document_for_ABDM_Compliant_HMIS_LMIS.pdf
10. Haux, R. (2006). Health information systems – past, present, future. International Journal of Medical Informatics, 75(3-4), 268-281. doi:10.1016/j.ijmedinf.2005.08.002
11. Health Informatics -- Information Security Management in Health Using ISO/IEC 27002. ISO 27799:2016. International Organization for Standardization. (2016). Retrieved May 08, 2022, from <https://www.iso.org/standard/62777.html>
12. Koppel R. (2012). Patient Safety and Health Information Technology: Learning from Our Mistakes. Patient Safety Network, Agency for Healthcare Research and Quality. (2012). Retrieved May 08, 2022, from <https://psnet.ahrq.gov/perspective/patient-safety-and-health-information-technology-learning-our-mistakes>
13. Mann, R., & Williams, J. (2003). Standards in medical record keeping. Clinical Medicine, 3(4), 329-332. doi:10.7861/clinmedicine.3-4-329
14. Mathiharan, K. (2001). Medical Records. Indian Journal of Medical Ethics, 1(2), 59. doi:10.20529/IJME.2004.029

15. National Digital Health Mission: Health Data Management Policy. (2020). Ayushman Bharat Digital Mission (ABDM). National Health Authority. Ministry of Health and Family Welfare. Government of India. Retrieved May 08, 2022, from https://abdm.gov.in/publications/policies_regulations/health_data_management_policy
16. National Digital Health Mission: Personal Data Processing Model Consent Form. (2020). Ayushman Bharat Digital Mission (ABDM). National Health Authority. Ministry of Health and Family Welfare. Government of India. Retrieved May 08, 2022, from <https://abdm.gov.in/documents/hdmpolicy/consentform>
17. Patient Safety and Health Information Technology. (2015). Committee Opinion; 621. American College of Obstetricians and Gynaecologists. Retrieved May 08, 2022, from <https://www.acog.org/-/media/project/acog/acogorg/clinical/files/committee-opinion/articles/2015/01/patient-safety-and-health-information-technology.pdf>
18. Planning for and Implementing ISO 27001. (2011). ISACA Journal. Retrieved May 08, 2022, from <https://www.isaca.org/resources/isaca-journal/past-issues/2011/2011-planning-for-and-implementing-iso-27001>
19. Schneider EC, Ridgely MS, Meeker D, Hunter LE, Khodyakov D, Rudin R. (2014). Promoting Patient Safety Through Effective Health Information Technology Risk Management. RAND Health. Washington, DC: Office of the National Coordinator for Health Information Technology; May 2014. RR-654- DHHSNCH. Retrieved May 08, 2022, from https://www.healthit.gov/sites/default/files/rr654_final_report_5-27-14.pdf
20. Schweitzer, M., & Hoerbst, A. (2015). A Systematic Investigation on Barriers and Critical Success Factors for Clinical Information Systems in Integrated Care Settings. Yearbook of Medical Informatics, 24(01), 79-89. doi:10.15265/iy-2015-018
21. Thomas, J. (2009). Medical records and issues in negligence. Indian Journal of Urology, 25(3), 384. doi:10.4103/0970-1591.56208
22. Winter, A., Ammenwerth, E., Bott, O., et al. (2001). Strategic information management plans: the basis for systematic information management in hospitals. International Journal of Medical Informatics, 64(2- 3), 99-109. doi:10.1016/s1386-5056(01)00219-2

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

MDS.1.	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.
Commitment	b. Patients requiring continuous monitoring beyond clinical timings shall be referred to an identified facility.
Commitment	c. All patients are assessed before a procedure.
CORE	d. Informed consent is taken before a procedure.
CORE	e. Care is taken to prevent adverse events like wrong site, wrong patient and wrong procedure.
Commitment	f. Written guidance governs procedural sedation.
Commitment	g. Written guidance governs administration of anaesthesia.
Commitment	h. The operative procedure note is documented.
Commitment	i. The Dermatology clinic develops appropriate key performance indicators suitable to monitor clinical structures, processes and outcomes.

References:

1. David SN, Valas S. National Accreditation Board for Hospitals and Healthcare Providers (NABH) Standards: A review. *CurrMed Issues* 2017;15:231-6.
2. Bodade AG, Bodade RG. National Accreditation Board for Hospitals and Healthcare Accreditation System for healthcare sector in India: An overview. *MGM Journal of Medical Sciences*. 2021 Jan 1;8(1):66.
3. Jha AK. Accreditation, Quality, and Making Hospital Care Better. *JAMA*. 2018;320(23):2410–2411.
4. Alkhenizan A, Shaw C. Impact of accreditation on the quality of healthcare services: a systematic review of the literature. *Annals of Saudi medicine*. 2011 Jul;31(4):407-16.

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

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

References:

1. Ministry of Health and family welfare, Govt of India Standard of care for Maintenance Hemodialysis in India Retrieved March 15, 2023, from <http://clinicalestablishments.gov.in/WriteReadData/358.pdf>
2. Record Keeping, Reporting and Hemodialysis, Indian J Nephrol. 2020 Jul; 30(Suppl 1): S89–S91, Retrieved March 15, 2023 from , <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7598403/>
3. Reuse of Hemodialysis, Retrieved March 15, 2023, from <https://dialysiswatersolution.com/regulations-and-guidelines/ansiaami/rd-47-reuse-of-hemodialyzers/>
4. Core curriculum for the dialysis technician, 5th edition,
5. Hepatitis C management and Hemodialysis Retrieved March 15, 2023, from <https://www.kidney.org/professionals/KDOQI/12-10-1601>

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.

Accreditation	Accreditation is self-assessment and external peer review process used by health care organisations to accurately assess their level of performance in relation to established standards and to implement ways to improve the health care system continuously.
Accreditation assessment	The evaluation process for assessing the compliance of an organisation with the applicable standards for determining its accreditation status.
Advance life support	Emergency medical care for sustaining life, including defibrillation, airway management, and drugs and medications.
Adverse drug reaction	A response to a drug which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease or for the modification of physiologic function.
Adverse event	An injury related to medical management, in contrast to complications of the disease. Medical management includes all aspects of care, including diagnosis and treatment, failure to diagnose or treat, and the systems and equipment used to deliver care. Adverse events may be preventable or non-preventable. (WHO Draft Guidelines for Adverse Event Reporting and Learning Systems)
Anaesthesia Death	It is defined as death occurring within 24 hours of administration of anaesthesia due to cases related to anaesthesia. However, death may occur even afterwards due to the complications.
Assessment	All activities including history taking, physical examination, laboratory investigations that contribute towards determining the prevailing clinical status of the patient.
Barrier nursing	The nursing of patients with infectious diseases in isolation to prevent the spread of infection. As the name implies, the aim is to erect a barrier to the passage of infectious pathogenic organisms between the contagious patient and other patients and staff in the hospital, and hence 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.
Basic life support	Basic life support (BLS) is the level of medical care which is used for patients with life-threatening illnesses or injuries until the patient can be given full medical care.
Breakdown maintenance	Activities which are associated with the repair and servicing of site infrastructure, buildings, plant or equipment within the site's agreed building capacity allocation which have become inoperable or unusable because of the failure of component parts.
Byelaws	A rule governing the internal management of an organisation. It can supplement or complement the government law but cannot countermand it, e.g. municipal by-laws for construction of hospitals/nursing homes, for disposal of hazardous and/or infectious waste

Calibration	Set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realised by standards.
Care Plan	A plan that identifies patient care needs, lists the strategy to meet those needs, documents treatment goals and objectives, outlines the criteria for ending interventions, and documents the individual's progress in meeting specified goals and objectives. The format of the plan may be guided by specific policies and procedures, protocols, practice guidelines or a combination of these. It includes preventive, promotive, curative and rehabilitative aspects of care.
Citizen's charter	Citizen's Charter is a document which represents a systematic effort to focus on the commitment of the organisation towards its citizens in respects of standard of services, information, choice and consultation, non-discrimination and accessibility, grievance redress, courtesy and value for money. (Reference: https://goicharters.nic.in/faq.htm)
Clinical autopsy	It is a surgical procedure that consists of an examination of a corpse by dissection to identify the cause, mode and manner of death or to evaluate any disease or injury that may be present for research or educational purposes.
Clinical practice guidelines	Clinical practice guidelines are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.
Competence	Demonstrated ability to apply knowledge and skills (para 3.9.2 of ISO 9000: 2015). Knowledge is the understanding of facts and procedures. Skill is the ability to perform a specific action.
Confidentiality	Restricted access to information to individuals who have a need, a reason and permission for such access. It also includes an individual's right to personal privacy as well as the privacy of information related to his/her healthcare records.
Consent	<ol style="list-style-type: none"> 1. The willingness of a party to undergo examination/procedure/ treatment by a healthcare provider. It may be implied (e.g. patient registering in OPD), expressed which may be written or verbal. Informed consent is a type of consent in which the healthcare provider has a duty to inform his/her patient about the procedure, its potential risk and benefits, alternative procedure with their risk and benefits so as to enable the patient to make an informed decision of his/her health care. 2. In law, it means active acquiescence or silent compliance by a person legally capable of consenting. In India, the legal age of consent is 18 years. It may be evidenced by words or acts or by silence when silence implies concurrence. Actual or implied consent is necessarily an element in every contract and every agreement.
Control Charts	The statistical tool used in quality control to (1) analyse and understand process variables, (2) determine process capabilities, and to (3) monitor effects of the variables on the difference between target and actual performance. Control charts indicate upper and lower control limits, and often include a central (average) line, to help detect the trend of plotted values. If all data points are within the control limits, variations in the values may be due to a common cause and process is said to be 'in control'. If data points fall outside the control limits, variations may be due to a special cause, and the process is said to be out of control.
Correction	Action to eliminate the detected non-conformity (Reference: ISO 9000:2015)

Corrective action	Action to eliminate the cause of a non-conformity and to prevent recurrence. (Reference: ISO 9000:2015)
Credentialing	The process of obtaining, verifying and assessing the qualification of a healthcare provider.
Data	Data is a record of the event.
Discharge summary	A part of a patient record that summarises the reasons for admission, significant clinical findings, procedures performed, treatment rendered, patient's condition on discharge and any specific instructions given to the patient or family (for example follow-up medications).
Disciplinary procedure	A sequence of activities to be carried out when staff does not conform to the laid-down norms, rules and regulations of the healthcare organisation.
Drug dispensing	The preparation, packaging, labelling, record keeping, and transfer of a prescription drug to a patient or an intermediary, who is responsible for the administration of the drug. (Reference: Mosby's Medical Dictionary, 9th edition, 2009, Elsevier.)
Drug Administration	The giving of a therapeutic agent to a patient, e.g. by infusion, inhalation, injection, paste, pessary, suppository or tablet.
Effective communication	Effective Communication is a communication between two or more persons wherein the intended message is successfully delivered, received and understood. The effective communication also includes several other skills such as non-verbal communication, engaged listening, ability to speak assertively, etc.
Employees	All members of the healthcare organisation who are employed full time and are paid suitable remuneration for their services as per the laid-down policy.
Enhanced communication	Enhanced communication is using the methods of communication to ensure meaning and understanding through the recognition of the limitations of others. The intent is to ensure purposeful, timely and reliable communication. The communication must be sensitive, empathetic and inclusive.
Ethics	Moral principles that govern a person's or group's behaviour.
Evidence-based medicine	Evidence-based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients.
Family	The person(s) with a significant role in the patient's life. It mainly includes spouse, children and parents. It may also include a person not legally related to the patient but can make healthcare decisions for a patient if the patient loses decision-making ability.
Failure Mode and Effect Analysis (FMEA)	A method used to prospectively identify error risks within a particular process.
Formulary	An approved list of drugs. Drugs contained in the formulary are generally those that are determined to be cost-effective and medically effective.
Goal	A broad statement describing a desired future condition or achievement without being specific about how much and when. (Reference: American Society for Quality) The term "goals" refers to a future condition or performance level that one intends to attain. Goals can be both short- and longer-term. Goals are ends that guide actions. (Reference: Malcolm Baldrige National Quality Award)

Grievance- handling procedures	The sequence of activities carried out to address the grievances of patients, visitors, relatives and staff.
Hazardous materials	Substances dangerous to human and other living organisms. They include radioactive or chemical materials.
Hazardous waste	Waste materials dangerous to living organisms. Such materials require special precautions for disposal. They include the biologic waste that can transmit disease (for example, blood, tissues) radioactive materials, and toxic chemicals. Other examples are infectious waste such as used needles, used bandages and fluid soaked items.
Healthcare- associated infection	Healthcare-associated infection (HAI), also referred to as "nosocomial" or "hospital" infection, is an infection occurring in a patient during the process of care in a hospital or other health care facility which was not present or incubating at the time of admission. (Reference: World Health Organization)
Healthcare organisation	The generic term is used to describe the various types of organisation that provide healthcare services. This includes ambulatory care centres, hospitals, laboratories, etc.
High-dependency unit	A high-dependency unit (HDU) is an area for patients who require more intensive observation, treatment and nursing care than are usually provided for in a ward. It is a standard of care between the ward and full intensive care.
High Risk/High Alert Medications	High-risk/high-alert medications are medications involved in a high percentage of medication errors or sentinel events and medications that carry a high risk for abuse, error, or other adverse outcomes. Examples include medications with a low therapeutic index, controlled substances, psychotherapeutic medications, and look-alike and sound-alike medications.
Incident reporting	It is defined as written or verbal reporting of any event in the process of patient care, that is inconsistent with the deserved patient outcome or routine operations of the healthcare facility.
In-service education/training	Organised education/training usually provided in the workplace for enhancing the skills of staff members or for teaching them new skills relevant to their jobs/tasks.
Indicator	A statistical measure of the performance of functions, systems or processes over time. For example, hospital acquired infection rate, mortality rate, caesarean section rate, absence rate, etc.
Information	Processed data which lends meaning to the raw data.
Intent	A brief explanation of the rationale, meaning and significance of the standards laid down in a particular chapter.
Inventory control	The method of supervising the intake, use and disposal of various goods in hands. It relates to supervision of the supply, storage and accessibility of items in order to ensure an adequate supply without stock-outs/excessive storage. It is also the process of balancing ordering costs against carrying costs of the inventory so as to minimise total costs.
Isolation	Separation of an ill person who has a communicable disease (e.g., measles, chickenpox, mumps, SARS) from those who are healthy. Isolation prevents transmission of infection to others and also allows the focused delivery of specialised health care to ill patients. The period of isolation varies from disease-to-disease. Isolation facilities can also be extended to patients for fulfilling their individual, unique needs.

Job description	<ol style="list-style-type: none"> 1. It entails an explanation pertaining to duties, responsibilities and conditions required to perform a job. 2. A summary of the most important features of a job, including the general nature of the work performed (duties and responsibilities) and level (i.e., skill, effort, responsibility and working conditions) of the work performed. It typically includes job specifications that include employee characteristics required for competent performance of the job. A job description should describe and focus on the job itself and not on any specific individual who might fill the job.
Job specification	<ol style="list-style-type: none"> 1. The qualifications/physical requirements, experience and skills required to perform a particular job/task. 2. A statement of the minimum acceptable qualifications that an incumbent must possess to perform a given job successfully.
Maintenance	The combination of all technical and administrative actions, including supervision actions, intended to retain an item in, or restore it to, a state in which it can perform a required function. (Reference: British Standard 3811:1993)
Medical equipment	Any fixed or portable non-drug item or apparatus used for diagnosis, treatment, monitoring and direct care of a patient.
Medication error	<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>
Medication Order	A written order by a physician, dentist, or other designated health professionals for a medication to be dispensed by a pharmacy for administration to a patient. (Reference: Mosby's Medical Dictionary, 10th edition, Elsevier)
Mission	An organisation's purpose. This refers to the overall function of an organisation. The mission answers the question, "What is this organisation attempting to accomplish?" The mission might define patients, stakeholders, or markets served, distinctive or core competencies or technologies used.
Monitoring	The performance and analysis of routine measurements aimed at identifying and detecting changes in the health status or the environment, e.g. monitoring of growth and nutritional status, air quality in operation theatre. It requires careful planning and use of standardised procedures and methods of data collection.
Multidisciplinary	A generic term which includes representatives from various disciplines, professions or service areas.
Near-miss	<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>

No harm	<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>
Notifiable disease	<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"> (a) Smallpox (b) Poliomyelitis due to wild-type poliovirus (c) Human influenza caused by a new subtype (d) Severe acute respiratory syndrome (SARS). <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"> (a) Polio (b) Influenza (c) Malaria (d) Rabies (e) HIV/AIDS (f) Louse-borne typhus (g) Tuberculosis (h) Leprosy (i) Leptospirosis (j) Viral hepatitis (k) Dengue fever
Objective	<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>
Objective element	<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>
Occupational health hazard	<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>
Operational plan	<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>
Organogram	<p>A graphic representation of the reporting relationship in an organisation.</p>

Outsourcing	Hiring of services and facilities from other organisation based upon one's own requirement in areas where such facilities are either not available or else are not cost-effective. For example, outsourcing of house-keeping, security, laboratory/certain special diagnostic facilities. When an activity is outsourced to other institutions, there should be a memorandum of understanding that clearly lays down the obligations of both organisations: the one which is outsourcing and the one who is providing the outsourced facility. It also addresses the quality-related aspects.
Patient-care setting	The location where a patient is provided health care as per his needs, e.g. ICU, speciality ward, private ward and general ward.
Patient record/ medical record/ clinical record	A document which contains the chronological sequence of events that a patient undergoes during his stay in the healthcare organisation. It includes demographic data of the patient, assessment findings, diagnosis, consultations, procedures undergone, progress notes and discharge summary.
Patient Satisfaction	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.
Patient Experience	Patient Experience is the sum of all interactions, shaped by an organisation's culture, that influence patient perceptions across the continuum of care. It is a holistic perception that the patient forms about the healthcare provider based on the overall interactions/ care touchpoints.
Performance appraisal	It is the process of evaluating the performance of staff during a defined period of time with the aim of ascertaining their suitability for the job, the potential for growth as well as determining training needs.
Point of care equipment	Medical Equipment that is used to deliver care/intervene at or near the site of patient care. These are primarily Point-of-care testing (POCT), or bedside testing equipment that helps in reducing turn-around times. POCT Machine examples; Glucometer, ABG Analyser, Stat Lab at ICU/ER, portable USG etc.
Policies	They are the guidelines for decision-making, e.g. admission, discharge policies, antibiotic policy, etc.
Preventive action	Action to eliminate the cause of a potential non-conformity. (Reference ISO 9000:2015)
Preventive maintenance	It is a set of activities that are performed on plant equipment, machinery, and systems before the occurrence of a failure in order to protect them and to prevent or eliminate any degradation in their operating conditions. The maintenance carried out at predetermined intervals or according to prescribed criteria and intended to reduce the probability of failure or the degradation of the functioning of an item.
Prescription	A prescription is a document given by a physician or other healthcare practitioner in the form of instructions that govern the care plan for an individual patient. Legally, it is a written directive, for compounding or dispensing and administration of drugs, or for other service to a particular patient. (Reference: Miller-Keane Encyclopedia and Dictionary of Medicine, Nursing, and Allied Health, Seventh Edition, Saunders)
Privileging	It is the process for authorising all medical professionals to admit and treat patients and provide other clinical services commensurate with their qualifications and skills.

Privileged communication	Confidential information furnished (to facilitate diagnosis and treatment) by the patient to a professional authorised by law to provide care and treatment.
Procedural sedation	Procedural sedation is a technique of administering sedatives or dissociative agents with or without analgesics to induce a state that allows the patient to tolerate unpleasant procedures while maintaining cardiorespiratory function. Procedural sedation and analgesia (PSA) is intended to result in a depressed level of consciousness that allows the patient to maintain oxygenation and airway control independently. (Reference: The American College of Emergency Physicians)
Procedure	<ol style="list-style-type: none"> 1. A specified way to carry out an activity or a process (Para 3.4.5 of ISO 9000: 2015). 2. A series of activities for carrying out work which when observed by all help to ensure the maximum use of resources and efforts to achieve the desired output.
Process	A set of interrelated or interacting activities which transforms inputs into outputs (Para 3.4.1 of ISO 9000: 2015).
Programme	A sequence of activities designed to implement policies and accomplish objectives.
Protocol	A plan or a set of steps to be followed in a study, an investigation or an intervention.
Quality	<ol style="list-style-type: none"> 1. Degree to which a set of inherent characteristics fulfil requirements (Para 3.1.1 of ISO 9000: 2015). Characteristics imply a distinguishing feature (Para 3.5.1 of ISO 9000: 2015). Requirements are a need or expectation that is stated, generally implied or obligatory (Para 3.1.2 of ISO 9000:2015). 2. Degree of adherence to pre-established criteria or standards.
Quality assurance	Part of quality management focussed on providing confidence that quality requirements will be fulfilled (Para 3.2.11 of ISO 9000:2015).
Quality improvement	Ongoing response to quality assessment data about a service in ways that improve the process by which services are provided to consumers/patients.
Radiation Safety	<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 & 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>
Re-assessment	It implies a continuous and ongoing assessment of the patient, which is recorded in the medical records as progress notes.

Reconciliation of medications	Medication reconciliation is the process of creating the most accurate list possible of all medications a patient is taking — including drug name, dosage, frequency, and route — and comparing that list against the physician's admission, transfer, and/or discharge orders, with the goal of providing correct medications to the patient at all transition points within the hospital. (Reference: Institute for Healthcare Improvement)
Resources	It implies all inputs in terms of men, material, money, machines, minutes (time), methods, metres (space), skills, knowledge and information that are needed for the efficient and effective functioning of an organisation.
Risk abatement	Risk abatement means minimising the risk or minimising the impact of that risk.
Risk assessment	Risk assessment is the determination of the quantitative or qualitative value of risk related to a concrete situation and a recognised threat (also called hazard). Risk assessment is a step in a risk management procedure.
Risk management	Clinical and administrative activities to identify, evaluate and reduce the risk of injury.
Risk mitigation	Risk mitigation is a strategy to prepare for and lessen the effects of threats and disasters. Risk mitigation takes steps to reduce the negative effects of threats and disasters.
Risk reduction	<p>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.</p> <p>It is the decrease in the risk of a healthcare facility, given activity, and treatment process with respect to patient, staff, visitors and community.</p>
Root Cause Analysis (RCA)	<p>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.</p> <p>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.</p>
Safety	The degree to which the risk of an intervention/procedure, in the care environment is reduced for a patient, visitors and healthcare providers.
Safety programme	A programme focused on patient, staff and visitor safety.
Scope of services	Range of clinical and supportive activities that are provided by a healthcare organisation.
Security	Protection from loss, destruction, tampering, and unauthorised access or use.

Sedation	<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>
Sentinel events	<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>
Social responsibility	<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>
Sound clinical practice	<p>Practitioner decisions based on available knowledge, principles and practices for specific clinical situations.</p>
Special Educational needs of the patient	<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>
Staff	<p>All personnel working in the organisation including employees, "fee-for-service" medical professionals, part-time workers, contractual personnel and volunteers.</p>
Standard precautions	<ol style="list-style-type: none"> 1. A method of infection control in which all human blood and other bodily fluids are considered infectious for HIV, HBV and other blood-borne pathogens, regardless of patient history. It encompasses a variety of practices to prevent occupational exposure, such as the use of personal protective equipment (PPE), disposal of sharps and safe housekeeping 2. A set of guidelines protecting first aiders or healthcare professionals from pathogens. The main message is: "Don't touch or use anything that has the victim's body fluid on it without a barrier." It also assumes that all body fluid of a patient is infectious, and must be treated accordingly. <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>
Standards	<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>

Sterilisation	It is the process of killing or removing microorganisms including their spores by thermal, chemical or irradiation means.
Strategic plan	Strategic planning is an organisation's process of defining its strategy or direction and making decisions on allocating its resources to pursue this strategy, including its capital and people. Various business analysis techniques can be used in strategic planning, including SWOT analysis (Strengths, Weaknesses, Opportunities and Threats), e.g. Organisation can have a strategic plan to become a market leader in the provision of cardiothoracic and vascular services. The resource allocation will have to follow the pattern to achieve the target. The process by which an organisation envisions its future and develops strategies, goals, objectives and action plans to achieve that future.
Surveillance	The continuous scrutiny of factors that determines the occurrence and distribution of diseases and other conditions of ill health. It implies watching over with great attention, authority and often with suspicion. It requires professional analysis and sophisticated interpretation of data leading to recommendations for control activities.
Table-top exercise	A table-top exercise is an activity in which key personnel assigned emergency management roles and responsibilities are gathered to discuss, in a non-threatening environment, various simulated emergency situations. (Reference: https://uwpd.wisc.edu/content/uploads/2014/01/What_is_a_tabletop_exercise.pdf)
Traceability	Traceability is the ability to trace the history, application, use and location of an item or its characteristics through recorded identification data. (Reference: ISO 9000:2015)
Transfusion reaction	A transfusion reaction is a problem that occurs after a patient receives a transfusion of blood.
Triage	Triage is a process of prioritising patients based on the severity of their condition so as to treat as many as possible when resources are insufficient for all to be treated immediately.
Turn-around-time	Turnaround Ttime (TAT) means the amount of time taken to complete a process or fulfil a request.
Unstable patient	A patient whose vital parameters need external assistance for their maintenance.
Validated tool	A validated tool refers to a questionnaire/scale that has been developed to be administered among the intended respondents. The validation processes should have been completed using a representative sample, demonstrating adequate reliability (the ability of the instrument to produce consistent results) and validity (the ability of the instrument to produce true results).
Validation	Validation is verification, where the specified requirements are adequate for the intended use.
Values	The fundamental beliefs that drive organisational behaviour and decision-making. This refers to the guiding principles and behaviours that embody how an organisation and its people are expected to operate. Values reflect and reinforce the desired culture of an organisation.
Verbal order	Verbal orders are those orders given by a physician with prescriptive authority to a licensed person who is authorised by the organisation.

Verification	Verification is the provision of objective evidence that a given item fulfils specified requirements.
Vision	<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>
Vulnerable patient	Those patients who are prone to injury and disease by virtue of their age, sex, physical, mental and immunological status, e.g. infants, elderly, physically- and mentally-challenged, semiconscious/unconscious, those on immunosuppressive and/or chemotherapeutic agents.
Workplace violence	Incidents where staff are abused, threatened or assaulted in circumstances related to their work, including commuting to and from work, involving an explicit or implicit challenge to their safety, well-being or health. (Adapted from European Commission)

ANNEXURE 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.	Total number of medication errors	X 100	Percentage	Monthly	The methodology for capture shall be as stated in NABH's document on medication errors. The indicator shall be captured for admitted patients Sampling: Yes Sampling methodology: Stratified random *Total number of opportunities monitored.
				Total number of opportunities*				
2.	PSQ2a	Compliance to Hand hygiene practice.		Total number of actions performed	X 100	Percentage	Monthly	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: http://www.who.int/gpsc/5may/tools/en/ http://www.who.int/entity/gpsc/5may/Observation_Form.doc?ua=1 Sampling: Yes Sampling methodology: Stratified random
				Total number of hand hygiene opportunities				

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		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
				Number of patients reported in OPD				
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	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
				Number of OPD's				
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	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)
				Number of procedures performed				

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.	<div>Average Score achieved</div> <div>Maximum possible score Maximum possible score</div>	X 100		Continuous	

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

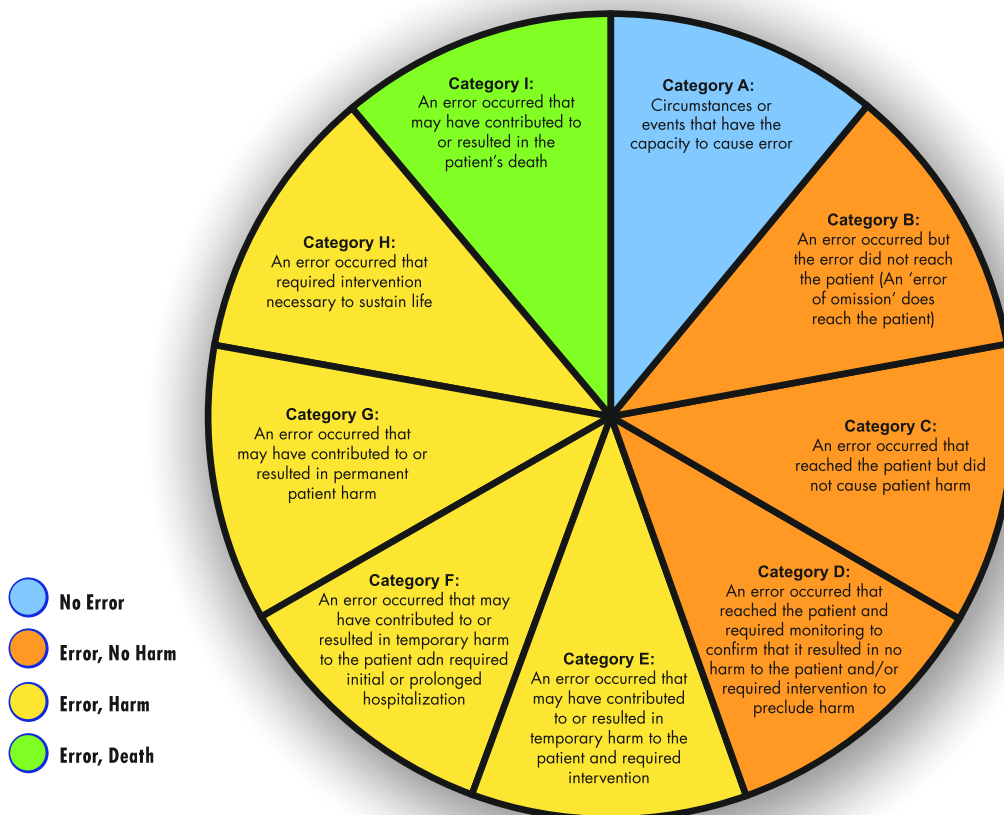
Definition: NCC-MERP (National Coordinating Council for Medication Error Reporting and Prevention) defines medication error as

"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.

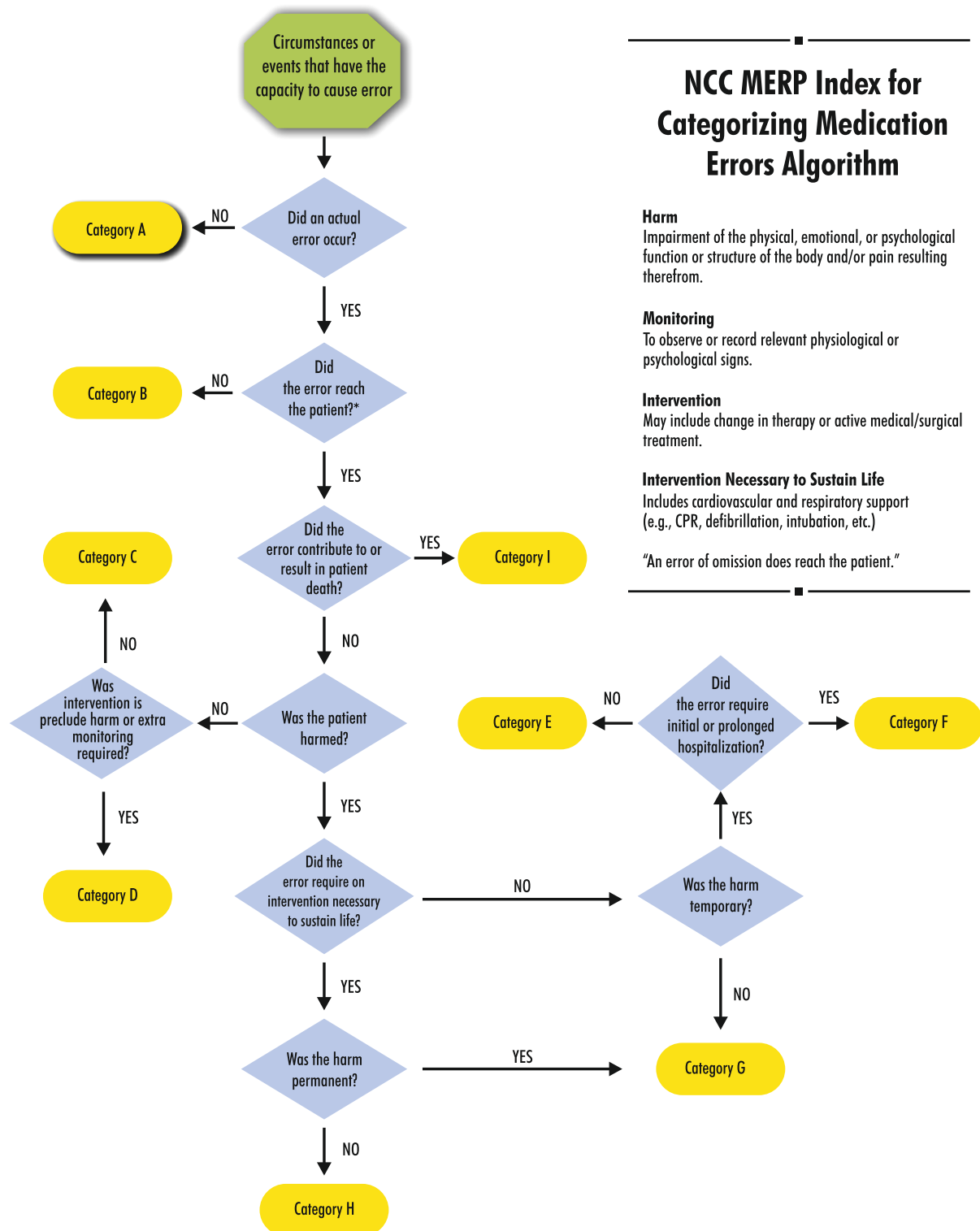
Intervention

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. 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.
3. Nrupal Patel, Mira Desai, Samdih Shah et al. A study of medication errors in a tertiary care hospital. *Perspect Clin Res*. 2016 Oct-Dec; 7(4): 168–173.
4. Khandelwal AK. Getting it Right. *Healthcare Radius* 2014; March: 32-34

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.

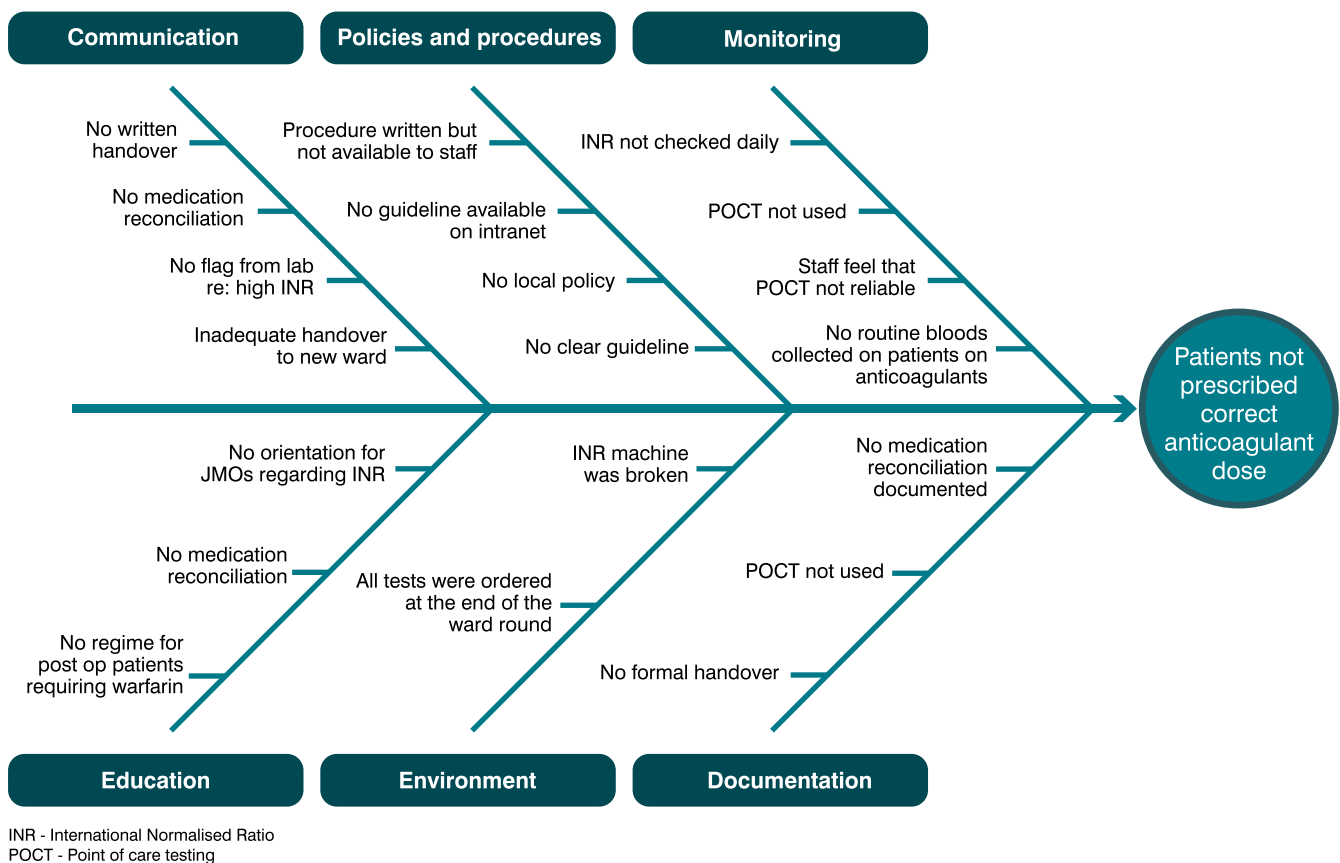


Figure Example of a Cause and Effect Diagram by Clinical Excellence Commission. Reasons why patients are not on a standardised anticoagulation pathway (<https://www.cec.health.nsw.gov.au/CEC-Academy/quality-improvement-tools/cause-and-effect-diagrams>)

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.

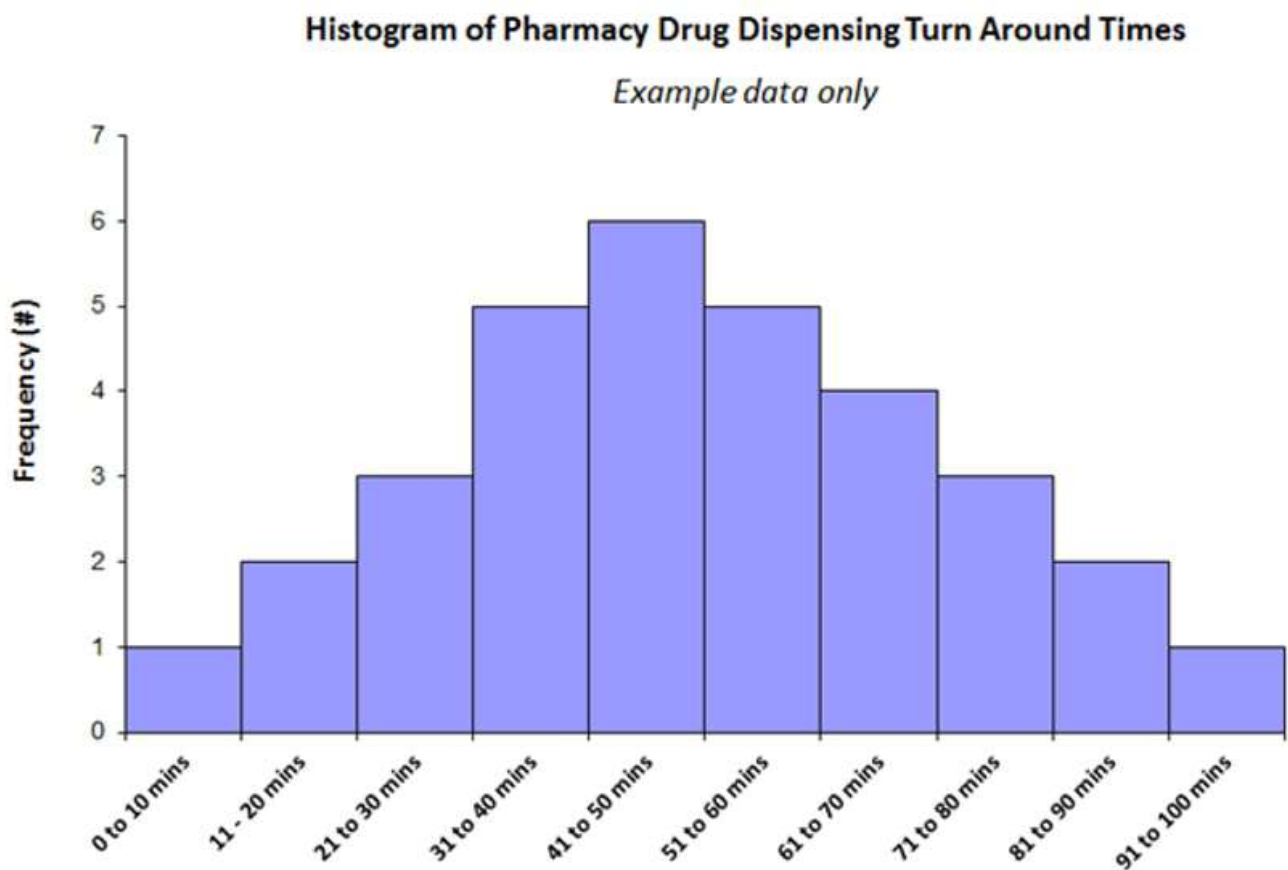


Figure Histogram on turnaround time for dispensing of the drug
(<https://www.cec.health.nsw.gov.au/CEC-Academy/quality-improvement-tools/histogram> accessed on April 30, 2022)

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-

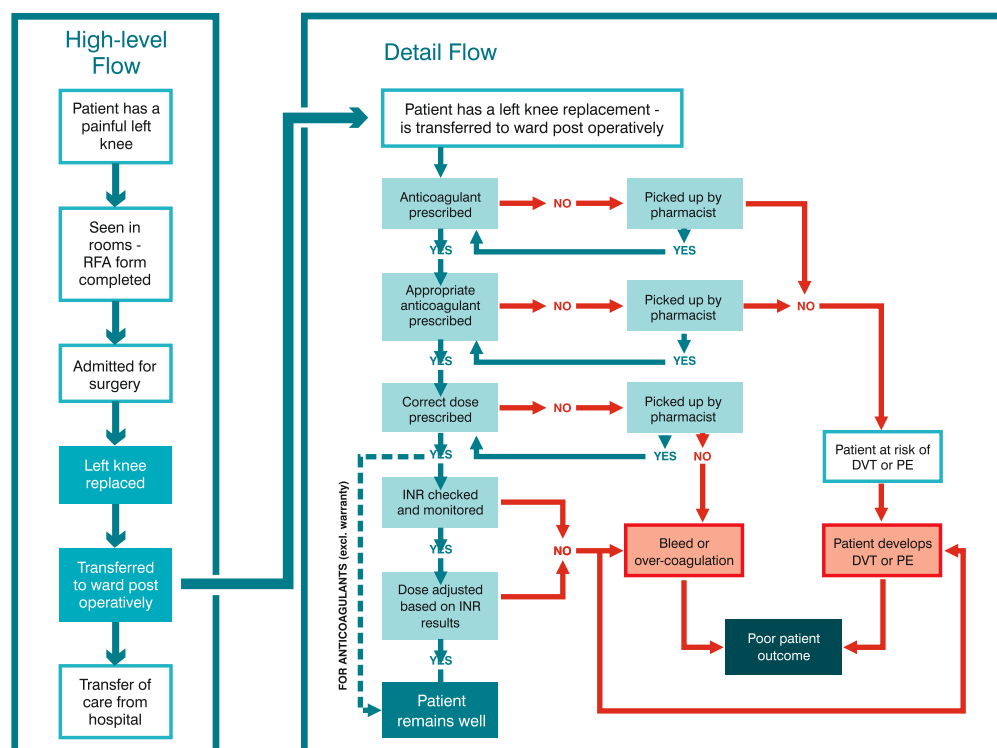


Figure 5 Flow chart of a patient's journey within the hospital
(<https://www.cec.health.nsw.gov.au/CEC-Academy/quality-improvement-tools/flow-charts> accessed on April 30, 2022)

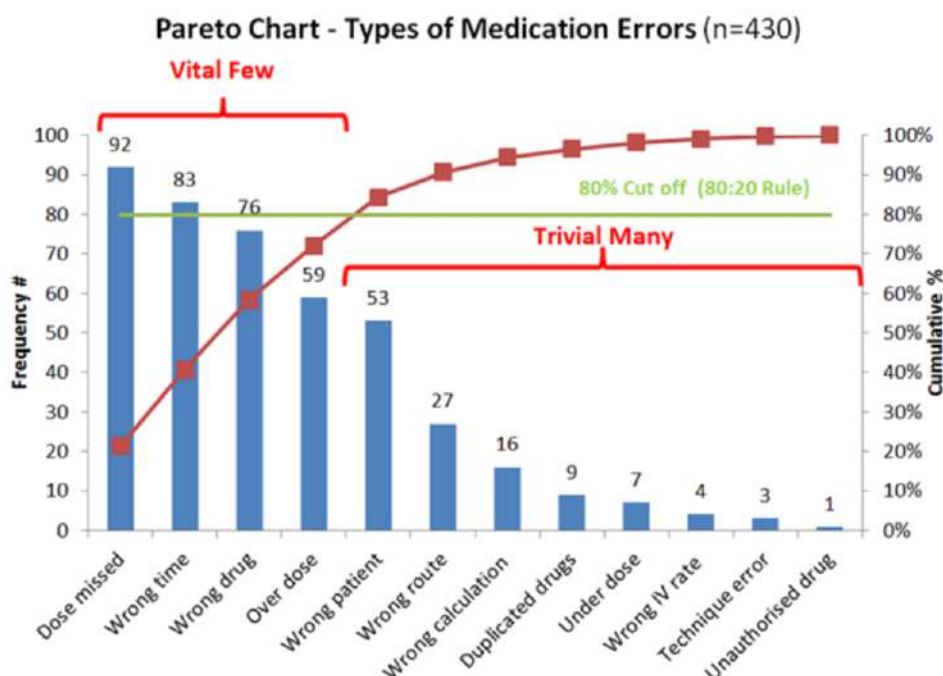
Pareto Chart: The “Pareto Principle” is the “80/20 rule” and works on the theory that roughly 80% of the effect comes from 20% (“the vital few”) of the causes. The “vital few” are easily distinguished from the “useful many” by plotting them as a bar diagram. Teams can prioritize and focus improvement 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.

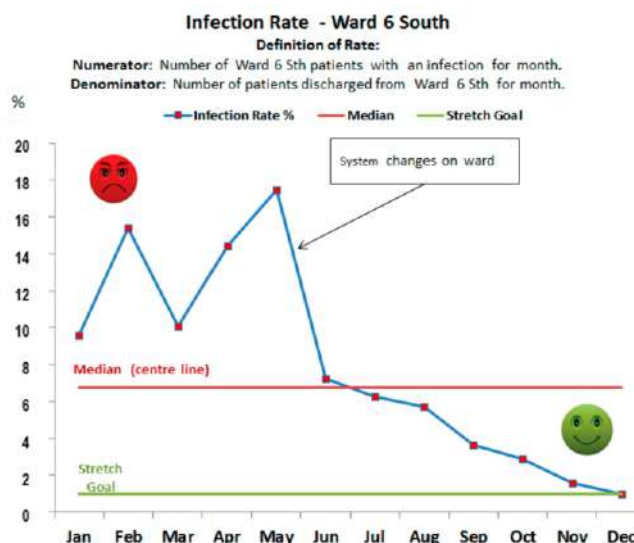


Figure 7. Simple Annotated Run chart with UCL and LCL of an infection rate over time
 (<https://www.cec.health.nsw.gov.au/CEC-Academy/quality-improvement-tools/run-charts> accessed on April 30, 2022)

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.

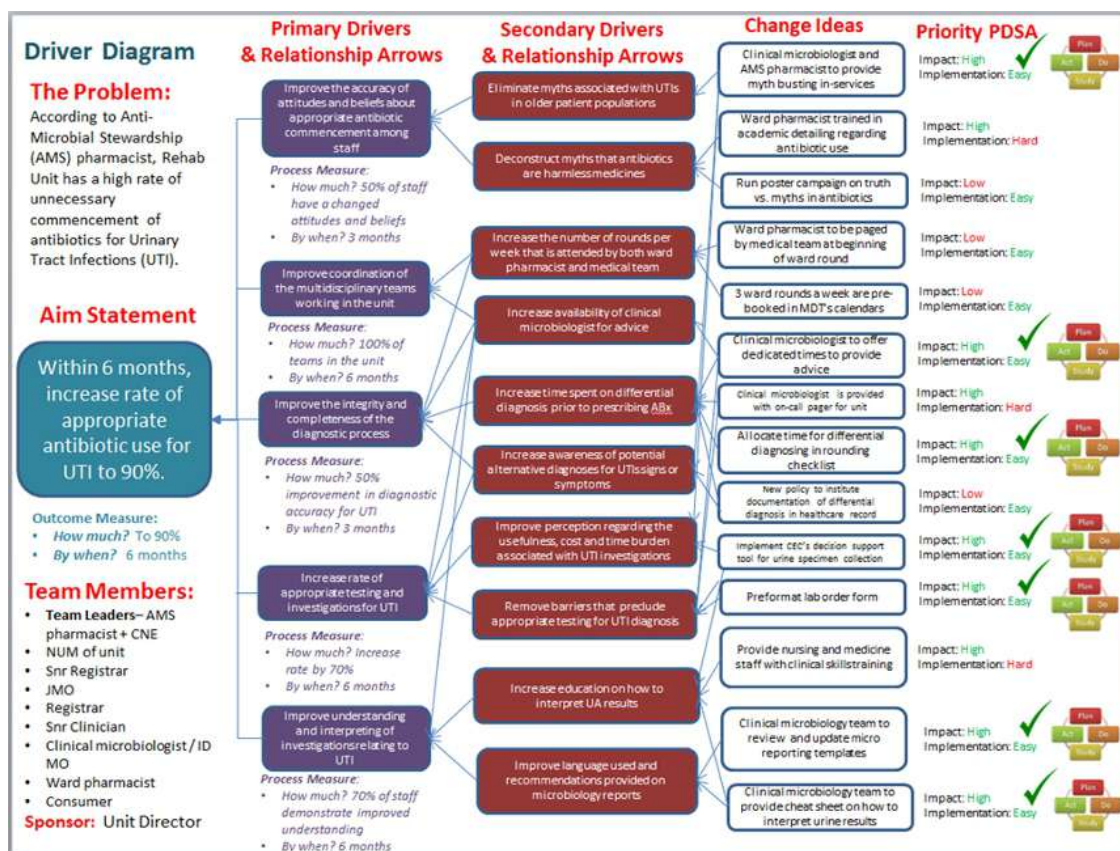


Figure 8 Driver Diagram
 (<https://www.cec.health.nsw.gov.au/CEC-Academy/quality-improvement-tools/driver-diagrams> accessed on April 30, 2022)

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

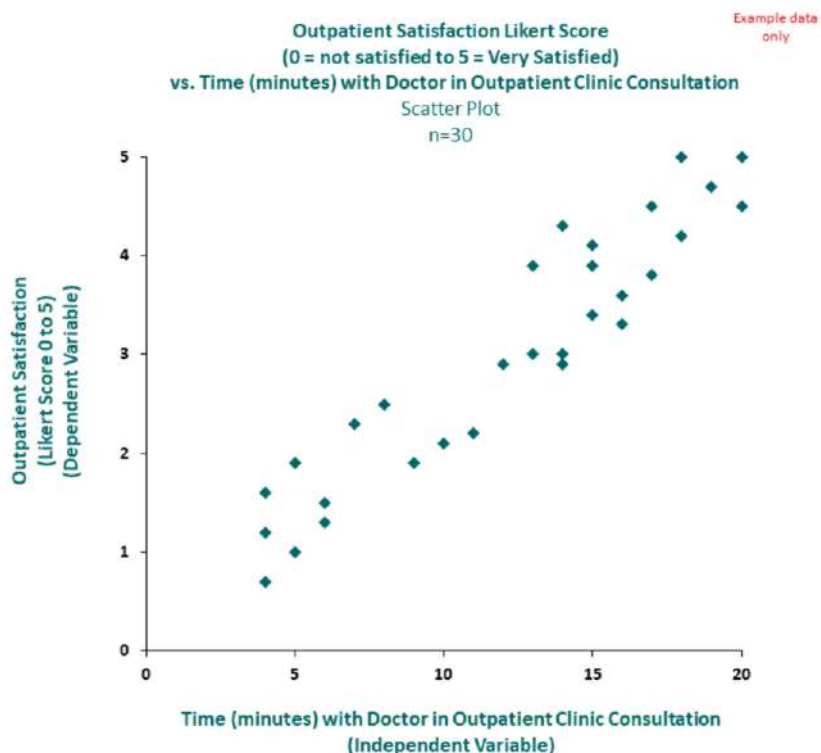


Figure 9 Scatter diagram showing patient satisfaction using likert's score v/s time with doctor consultation
(<https://www.cec.health.nsw.gov.au/CEC-Academy/quality-improvement-tools/scatter-plot> accessed on April 30, 2022)

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.

Model for Improvement

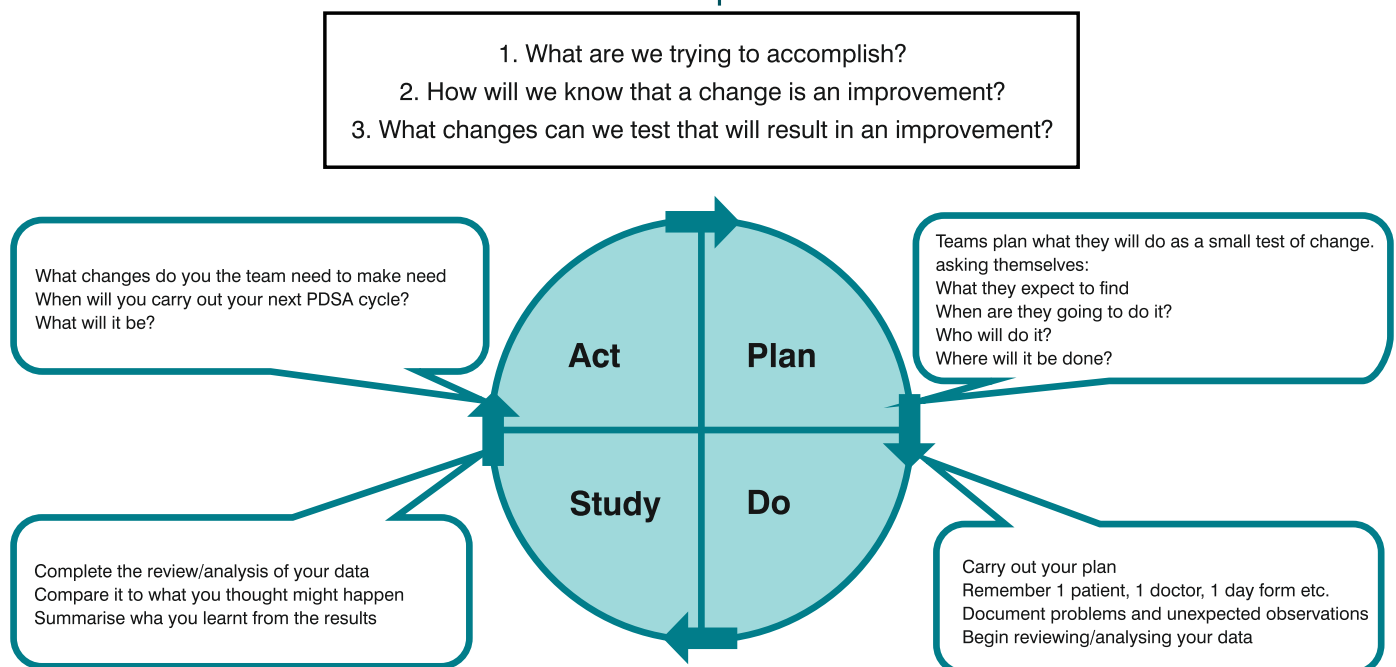


Figure 10: Model for Improvement and PDSA

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

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.

References:

1. Quality Improvement Essentials Toolkit, Institute of Healthcare Improvement, launched on February 22, 2019. Accessed on September 27, 2021.
2. Card AJ The problem with '5 whys' BMJ Quality and Safety 2016;0:1–7. doi:10.1136/bmjqs-2016-005849
3. Butch SH. Applying Quality Improvement Tools in the Transfusion Service Clin Lab Sci 2007;20(2):113
4. Brian O'Donnell; Vikas Gupta. Continuous Quality Improvement. Treasure Island (FL): StatPearls Publishing; 2021 Jan-. Last updated April 7, 2021. <https://www.ncbi.nlm.nih.gov/books/NBK559239/>.
5. Varkey P, Reller K, Bsn, RN, Resar RK, Basics of Quality Improvement in Health Care, concise review for clinicians, 2007;82(6):735-739.
6. Juran, J.M. 1988. Juran on Planning for Quality. New York:1994. Achieving Sustained Quantifiable Results in an Interdepartmental Quality Improvement Project. Joint Commission Journal on Quality Improvement 20;3:105–19.
7. Langley GL, Nolan KM, Nolan TW, Norman CL, Provost LP. The Improvement Guide: A Practical Approach to Enhancing Organizational Performance (2nd edition). San Francisco: Jossey-Bass Publishers; 2009
8. Speroff T, O'Connor GT. Study designs for PDSA quality improvement research. Qual Manag Health Care. 2004;13:17-32.
9. Gerard J, Arnold FL: Performance improvement with a hybrid FOCUS-PDCA methodology. Jt Comm J Qual Improv 1996; 22:660–672
10. Designs for PDSA quality improvement research. Qual Manag Health Care. 2004;13:17-32.
11. Niñerola A, Rebull M2, Lara A Quality improvement in healthcare: Six Sigma systematic review 2020 Apr;124(4):438-445. doi:10.1016/j.healthpol.2020.01.002. Epub 2020 Feb 28.
12. Rogenski LL, Wilson K, Turner M, et al.: Six sigma applied to capacity utilization. Transfusion 2005; 45(Suppl. AP29):168A
13. Suman G, Prajapati Utilization of Lean & Six Sigma quality initiatives in Indian healthcare sector. DR.PLoS One. 2021 Dec 23;16(12):e0261747. doi: 10.1371/journal.pone.0261747. eCollection 2021. PMID: 34941958
14. Quality Improvement Tools - Clinical Excellence Commission <https://www.cec.health.nsw.gov.au/CEC-Academy/quality-improvement-tools>
15. Section 4: Ways to Approach the Quality Improvement Process <https://www.ahrq.gov/cahps/quality-improvement/improvement-guide/4-approach-qi-process/index.html>
16. Healthcare Management Workflow Diagrams | How to Create a Healthcare Management Workflow Diagram | Flowchart Marketing Process. Flowchart Examples | Hospital Management Application Flowchart
17. <https://www.conceptdraw.com/examples/hospital-management-application-flowchart>

18. NAPA Advisory Council 2018 Meeting Material | ASPE January 26, 2018 - Advisory Council Meeting. <https://aspe.hhs.gov/.../napa-past-meetings/napa-2018-meeting-material>
19. Ahmed, Selim. (2019). Integrating DMAIC approach of Lean Six Sigma and theory of constraints toward quality improvement in healthcare. *Reviews on Environmental Health*. 34. 427-434. 10.1515/reveh-2019-0003.
20. Scatter Plot - Clinical Excellence Commission <https://www.cec.health.nsw.gov.au/CEC-Academy/quality-improvement-tools/scatter-plot>
21. Quality Digest https://www.qualitydigest.com/june08/articles/03_article.shtml
22. Chandrasekar, Thangavelu & Sharma, Asheesh & Tennent, Lucinda & Wong, Christopher & Chamberlain, Peter & Abraham, Kottarathil. (2017). A Whole System Approach to Improving Mortality associated with Acute Kidney Injury. *QJM : monthly journal of the Association of Physicians*. 110. 10.1093/qjmed/hcx101.
23. Pareto Chart - MITE MMC Institute for Teaching Excellence <https://www.mitemmc.org/monthly-tips/pareto-chart/>
24. Pawar M. Getting beyond blame in your practice (5Why's). *Fam Pract Manag*. 2007 May;14(5):30-4. PMID: 17523378.

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 Clinic 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 it.

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 for the OPG machine.
9. AERB approval for the layout plan of the OPG x-ray room
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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