ISQuaEEA International Society for Quality in Health Care External Evaluation Association
Accredited Organisation 2022-2026

NABH

National Accreditation Board for Hospitals and Healthcare Providers (NABH)

Certification Standards for STROKE CENTRE

World Stroke Organization

1st EDITION
SEPTEMBER 2023

QUALITY : SAFETY : WELLNESS

National Accreditation Board For Hospitals and Healthcare Providers (NABH)

Certification standards for Stroke Centre 1st Edition September 2023

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1st Edition September 2023

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

National Accreditation Board for Hospitals & Healthcare Providers (NABH)

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

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

Prof Jeffrey Braithwaite, President

Elaine O'Connor

Ms Elaine O'Connor, Head of Operations

FOREWORD

National Accreditation Board for Hospitals and Healthcare Providers (NABH), is in its third decade of creating an ecosystem of quality in healthcare in India. NABH standards focus on patient safety and quality of the delivery of services by the organizations in the changing healthcare environment. Without being prescriptive, the standards have been developed with the intent of providing information and guiding the organisation in conducting its operations with a focus on timely and coordinated care, comprehensive and specialised care with an overall intention of patient safety.

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

Stroke is a time-sensitive medical emergency, and every minute can make a difference in the outcome for the patient. Having quality standards ensures that stroke centres provide prompt and organized care, including quick diagnosis, appropriate treatment, rehabilitation services and follow established guidelines and protocols based on the latest scientific evidence. This helps in delivering consistent and effective treatments, improving patient outcomes, and reducing variations in care.

Stroke centres with quality standards are equipped with specialized medical professionals, advanced diagnostic tools, and treatment facilities required for comprehensive stroke care. This enables them to provide a higher level of care compared to general hospitals, leading to better outcomes for stroke patients. In addition, quality standards include rigorous safety measures to prevent medical errors, infections, and complications during treatment. These standards ensure that stroke centres maintain a safe environment and implement processes to reduce the risk of harm to patients. Overall, quality standards for stroke centres are crucial in ensuring that patients receive timely, standardized, and high-quality care, leading to improved outcomes and better overall stroke care delivery.

It is my privilege and pride to release and dedicate this 1st edition of NABH Certification standards for stroke care centres to all the healthcare workers. This edition is unique in its approach and has been presented based in entirety on the suggestions made by various stakeholders. This objective methodology will aid any Stroke care centre in a stepwise progression to mature quality system towards advance certification process.

I wish every success to the centres adopting these standards for implementation and congratulate them on the spirit of quality and patient safety. NABH has the mandate and remains committed to ensuring healthy lives and promote wellbeing for all at all ages (SDG-3-Target 2030), creating a culture and an ecosystem of quality in healthcare taking Quality, Safety and Wellness to the last in the line.

Jai Hind

Dr Atul Mohan Kochhar

CEO, NABH

ACKNOWLEDGEMENT

I acknowledge the contributions of the following in preparing this 1st edition of Stroke care Centre certification of NABH.

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

Prof. (Dr.) Mahesh Verma, Chairman NABH, has been the guiding light throughout the development of this first edition of Stroke care Centre Certification of NABH. I thank him for his active participation, support and invaluable suggestions despite of his busy schedule.

I sincerely thank Dr. Ravi P. Singh, Secretary General of Quality Council of India for his guidance and continuous support by making adequate resources available for this process.

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

The Technical Committee of NABH worked relentlessly and meticulously to accommodate the best practices in care homes, referred to innumerable references and incorporated suggestions made by all of the stakeholders in bringing this standard to reality. It was, indeed, a mammoth task. I profoundly thank all the members for playing a pivotal role in the development of this 1st edition of NABH Certification standards of Stroke care centre.

I thank World Stroke Organisation, President Dr. Sheila Martin, Dr Jeyaraj Durai Pandian, Professor of Neurology and Principal (Dean) of CMC Ludhiana and President Elect, World Stroke Organization for their immense support and contribution.

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

INTRODUCTION

Stroke is one of the leading causes of death and disability in the world. More than two-thirds of the strokes occur in low- and middle-income countries (LMICs). There is a huge gap in the availability of stroke care services and access to hyperacute treatments like intravenous thrombolysis and mechanical thrombectomy. World Stroke Organization (WSO) is the only global body solely focused on stroke. With around 3000 individuals and 90 society members spanning every global region, we represent over 55,000 stroke specialists in clinical, research and community settings. Our vision is a world where people live free from the effects of stroke. This vision drives our global effort to improve stroke prevention, treatment, rehabilitation, and support. One of WSOs goals is to improve access to quality stroke care and quality monitoring which will lead to improved stroke outcomes. The WSO Stroke certification program was launched in Brazil and then it has been rolled out in many Latin American countries.

In November 2022, National Accreditation Board of Hospitals (NABH) had signed a MOU with WSO to launch stroke center certification program in India. As part of this initiative the WSO standards and elements have been merged with NABH format so that this program aligns with the ongoing hospital accreditation processes followed by NABH.

We are confident that the quality of stroke care in India will improve with this joint program. We hope to scale up this process in other southeast Asian countries.

Prof Sheila Martins

President, WSO

Prof Jeyaraj D Pandian

President Elect, WSO

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About NABH

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

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

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

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

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

NABH ACTIVITIES

NABH ACCREDITATION PROGRAMMES:

NABH 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 & Naturopathy) hospitals, Wellness Centres, Medical Imaging Services, Dental Centres, Allopathic Clinics, Ethics Committees and Panchkarma Clinics.

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

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

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

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

Scope and Purpose of the Standards

SCOPE OF THE STANDARDS

These standards are applicable for certification of stroke centres which fulfil the following requirements:

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

PURPOSE OF THE STANDARDS

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

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

In addition, these standards can also be used to:

- Guide the efficient and effective management of a stroke centre;
- 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 a stroke centre;
- Provide an opportunity to explore compliance expectations of standards and the additional requirements related to safety and regulation.

How to read the standard?

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

1. Access, Assessment and Care of Patient (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)

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 Care of patient'.

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, AAPC.1.c. would mean that it is the third objective element of the first standard of the chapter titled 'Access, Assessment, and Care of patient'.

In the book, certain objective elements require mandatory system documentation. The same have been identified by the * (asterisk) mark.

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

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

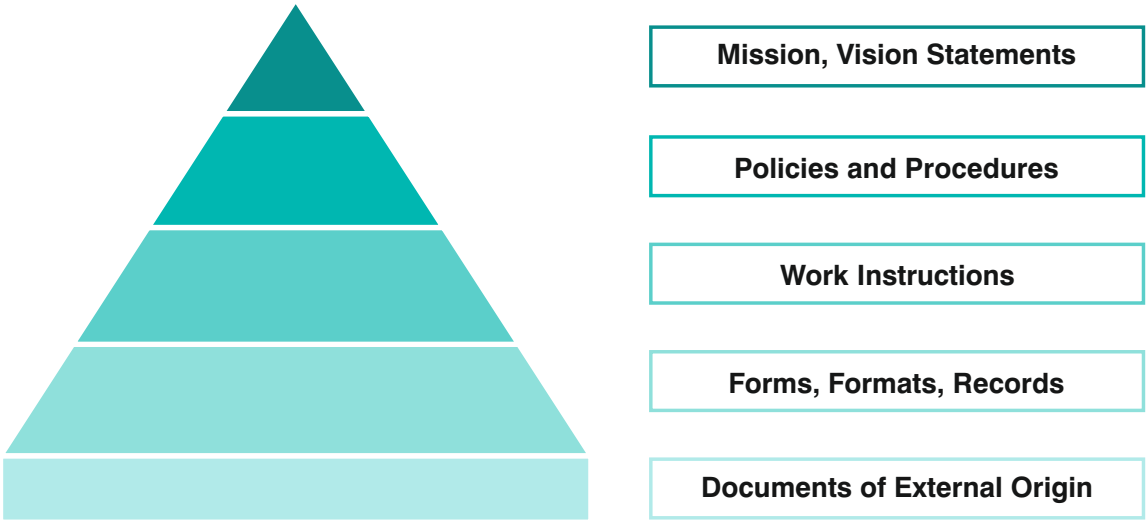
Type of documents

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

1. **Policy Documents:** Mission statement, vision statement, strategic plans, policies which transcend time and act as guidance in the changing scenarios of the operational, legal, technologically changing environment in which the organisation conducts its activities. They are the principles on which planning is based while adapting to the changes.
2. **System Documentation:** Operational and quality system documentation to carry out the activities in conformance with the mission and vision statement. This includes what is commonly known as Standard Operating Procedures or SOPs.
3. **Work Instructions:** These are instructions in a detailed manner for executing tasks, including the physical steps to be carried out.
4. **Forms and Formats:** These are various forms and formats to capture information as a record of the execution of various activities. The records are filled forms. The forms, formats, and records can be in a physical or electronic form. These can be entries as numerical, text, image, sound, etc.

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

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



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

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

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

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

Forms and Formats: For the capture of information in a complete and relevant manner, this must be done in a standardised manner. This is achieved through various forms and formats to maintain the records of activities. The forms can be a single page, multipage or a register in which the entries are made. The purposes can be from just capturing whether an activity was carried out, to a very elaborate

capture of values related to many parameters related to the activity. Example of the former being tick marking when some action was carried out and the example of the latter being an elaborate record of the initial assessment of the patient on arrival to the wards. Records are filled forms and formats. Forms and formats can be altered through the set alteration process, but records cannot be altered. Forms, formats, and registers are also a part of the system of controlled documents and must have their identity. It is not always necessary to number each form, and this will depend on whether the organisation wants to assign a separate identity to each filled form.

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

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

Overview of the Certification process

Steps in the application form

1. GAP Analysis
2. Preparation of Policies and Manuals
3. Completion of self-assessment tool kit

Documentation related to processes and procedures

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

Which processes should be documented?

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

- Procedures which are required to be followed uniformly at various locations across the organisation
- Procedures which are required to be followed uniformly across time
- Procedures which, if not followed uniformly and correctly will increase the risk to patients, staff or visitors
- Procedures which, if not followed uniformly, can lead to serious consequences concerning the loss of material, time, physical damage, equipment, etc.
- Procedures which are complicated leading to either missing of some steps or risk of variation in their execution
- Procedures which are required to be followed uniformly in spite of high turnover of human resources
- Procedures which are specific to the organisation as against procedures which are universally accepted or that are part of standard curricula of those professionals who carry out these procedures.

How to develop documentation that is easy to follow?

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

- Providing a clear plan of documentation architecture. This can be as a print map or in electronic form
- Using the uniform format for the visual appearance of the documents to cover their appearance, fonts, symbols, page layout, etc.
- Adding colour codes, font changes for different documents
- Participation of the staff that is involved in carrying out the activities in the development process for documentation
- Using the same language and form of the structure of language as per the users

- Using a direct form of speech (active) than the indirect form (passive)
- Providing Chapter Index or Index of words
- Sequencing activities as per their actual sequence of execution in time
- If necessary replicate the documentation related to specific processes and procedures within all relevant documentation with a clear reference to the original document
- Making relevant documents available at the location of use
- Keeping relevant documents available all days of the year and all times of day and night as per the requirements of execution of the activities.
- Removing obsolete documents from all locations, other than those retained for archiving

Controlled Documents

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

Characteristics of controlled documents:

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

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

An example of the control box is given below:

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

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

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

Body of document

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

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

Name of the Document:

Purpose of the Process that is documented:

Start point:

End Point:

Procedure:

Step 1: XXXXXXXXXXXXX

Step 2: XXXXXXXXXXXXX

Step 3: XXXXXXXXXXXXX

Step n: XXXXXXXXXXXXX

Related Records:

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

Manuals

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

Summary of Chapters, Standards and Objective Elements

Chapters	No. of Standards	No. of Objective Elements
Access, Assessment and Continuity of Care (AAC)	6	26
Care of Patients (COP)	13	65
Management of Medication (MOM)	5	27
Patient Rights and Education (PRE)	4	15
Infection Prevention and Control (IPC)	4	15
Patient safety and Quality Improvement (PSQ)	3	19
Responsibilities of Management (ROM)	3	13
Facility Management and Safety (FMS)	3	14
Human Resource Management (HRM)	3	17
Information Management System (IMS)	2	13
Total	**46**	**224**

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

Intent of the chapter:

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

Summary of Standards

AAC.1.	The stroke centre shall define and display the services that it provides.
AAC.2.	The stroke centre shall have a well-defined registration and admission process.
AAC.3.	There shall be an appropriate mechanism for transfer out or referral of patients to a higher level of care.
AAC.4.	Patients in the stroke centre shall be appropriately assessed and documented.
AAC.5.	The stroke centre shall provide appropriate and adequate laboratory and diagnostic imaging services.
AAC.6.	The stroke centre shall have an established discharge process, and defined content of the discharge summary.

Standards and Objective Elements

Standard

AAC. 1.	The stroke centre shall define and display the services that it provides.

Objective Elements

a. The services provided at the stroke centre shall be defined and be in consonance with the needs of the community

b. Defined service shall have diagnostic and treatment services with suitably qualified personnel who provide out-patient, in-patient and emergency cover.

c. The stroke centre's defined services shall be prominently displayed.

Standard

AAC. 2.	The stroke centre shall have a well-defined registration and admission process.

Objective Elements

a. The stroke centre shall use written guidance for registering and admitting patients.

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

Standard

AAC. 3.	There shall be an appropriate mechanism for transfer out or referral of patients to a higher level of care.

Objective Elements

a. Transfer out or referral of patients to a higher level of care shall be done appropriately.

b. If the stroke centre does transfer patients for neurosurgical emergencies, there shall be a written guidance for urgent transfer.*

c. The stroke centre shall have a written transfer protocol, transfer agreement or a memorandum of understanding (MOU) with at least one hospital being capable of providing timely and essential stroke related services immediately.

d. The stroke centre shall give a summary of the patient's condition and the treatment given.

Standard

AAC. 4.	Patients in the stroke centre shall be appropriately assessed and documented.

Objective Elements

a. Assessments shall include initial assessment and periodic re-assessment as applicable and shall be appropriate for each patient.

b. All patients (emergency and in-patients) shall undergo an assessment based on their needs.

c. All assessments shall be documented and signed appropriately by staff.

d. The doctor and nursing staff shall develop a documented care plan for the admitted stroke patient, which includes identification of individual needs for the patient, based on their condition and the family's needs.

e. The documentation of interdisciplinary findings shall be included in the plan of care, as appropriate.

Standard

AAC. 5.	The stroke centre shall provide appropriate and adequate laboratory and diagnostic imaging services.

Objective Elements

a. The scope of the laboratory and imaging services (CT, MRI and facility of imaging protocol) shall commensurate to the services provided by the stroke centre.

b. The infrastructure (physical and equipment) and human resources shall be adequate to provide the defined scope of services.

c. Imaging services shall comply with legal and other requirements.

d. Laboratory and imaging services shall be in house and available round the clock to complete and interpret initial tests within 15 minutes of being ordered.

e. Radiology technician(s) trained in CT /MRI techniques shall be available for the centre in-house, 24/7.

f. Critical results of the laboratory and imaging services are intimated immediately to the personnel concerned.

g. There is a system of laboratory and imaging equipment maintenance and calibration.

Standard

AAC. 6.	The stroke centre shall have an established discharge process, and defined content of the discharge summary.

Objective Elements

a. The stroke centre plans the discharge process in consultation with the patient and/or family.

b. Written guidance governs the discharge of patients leaving against medical advice.

c. A discharge summary shall be provided to patients at the time of discharge while leaving the stroke centre.*

d. Discharge summary shall contain the following:

   i. Patient's name,

   ii. Unique identification number,

   iii. Name of the treating doctor,

   iv. Date of admission,

   v. Date of discharge,

   vi. Reasons for admission,

   vii. Significant findings,

   viii. Final diagnosis,

   ix. Patient's condition at the time of discharge,

   x. Investigation results,

   xi. Any procedure performed,

   xii. Medication administered,

   xiii. Other treatment given (rehabilitation),

   xiv. Follow-up advice, medication, need for rehabilitation and other instructions, in an understandable manner.

e. In case of death, the summary of the case shall also include the cause of death.

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

Summary of Standards

COP. 1.	The stroke centre shall develop and implement evidenced-based clinical pathways and protocols.
COP. 2.	The stroke centre shall provide evidence-based clinical and emergency services.
COP. 3.	The stroke centre shall have a designated interdisciplinary acute stroke team.
COP. 4.	Cardio-pulmonary resuscitation services shall be provided uniformly across the stroke centre.
COP. 5.	Nursing care shall be provided to patients in the stroke centre in consonance with clinical protocols, practice guidelines and current evidence.
COP. 6.	Clinical procedures in the stroke centre shall be performed in a safe manner.
COP. 7.	The stroke centre provides care in intensive care and high dependency units in a systematic manner.
COP. 8.	Procedural sedation and anaesthesia in the stroke centre shall be provided in a consistent and safe manner.
COP. 9.	Surgical services in the stroke centre shall be provided in a consistent and safe manner.
COP. 10.	The stroke centre shall identify and manage patients who are at higher risk of morbidity/mortality.
COP. 11.	Pain management shall be done in a consistent manner for stroke patients.
COP. 12.	Rehabilitation services shall be provided to the stroke patients in a safe, collaborative and consistent manner.
COP. 13.	Nutritional therapy shall be provided to stroke patients consistently and collaboratively.

Standards and Objective Elements

Standard

COP.1.	**The stroke centre shall develop and implement evidenced-based clinical pathways and protocols.**

Objective Elements

a. The stroke centre shall develop evidence-based clinical pathways based on national and international guidelines.

b. The clinical pathways shall be implemented.

c. The clinical pathways and protocols shall be periodically reviewed by the multidisciplinary team.

Standard

COP.2.	**The stroke centre shall provide evidence-based clinical and emergency services.**

Objective Elements

a. The staff shall ensure effective communication with ambulance personnel and the stroke team.

b. Emergency services shall be planned keeping in view stroke protocols and initiation of the stroke protocol.

c. Patients shall be appropriately assessed and re-assessed as necessary, and these shall be documented.

d. Staff in the Emergency Department shall be aware of stroke protocols. There should be a rapid evaluation and activation of stroke code.

e. Patients shall be screened for dysphagia (swallowing test), before receiving any oral medications, food or fluids.

f. Patient's blood glucose levels shall be tested before thrombolytic eligibility is determined.

g. The acute stroke patient shall be assessed with the help of a validated tool/ scale, for example, NIH Stroke Scale by a qualified nurse or physician member of the acute stroke team.

h. The recognition, assessment, and management of complications of acute stroke and treatments (vital signs, neuro status, angioedema, etc.) shall be documented and the notification of deterioration of patient to medical staff and others shall be followed.

i. The patient fitness shall be assessed for endovascular treatment options stating the reasons - whether receiving thrombolytic/ Alteplase/tenecteplase or not a candidate for thrombolytic / Alteplase/ tenecteplase.

j. The emergency department shall maintain a stroke registry that includes call times, response times, patient diagnoses, treatments, outcomes and dispositions and the same shall be used for quality data review.

k. Ambulance services shall be available as per the scope of services of the stroke centre.

l. The stroke centre shall have a written plan for transporting and receiving patients with stroke symptoms.*

m. The stroke centre shall have a system of notification when a patient with suspected stroke is being transported to the centre in order to activate the stroke alert.

n. The stroke centre defines the circumstances in which it is not able to accept patients.

o. The stroke centre shall have define and structured mechanism of monitoring care bundles.

   i. Care Bundle 1- Swallowing and hydration

   ii. Care Bundle 2- Neurological monitoring

   iii. Care Bundle 3- Pre discharge education and training

Standard

COP.3.	The stroke centre shall have a designated interdisciplinary acute stroke team.

Objective Elements

a. The stroke centre shall define the criteria, qualifications, roles and responsibilities required for designation of consultant doctors, professionals and other personnel assigned to the stroke team.

b. The stroke team shall be available and on call round the clock.

c. The stroke team shall respond to stroke alerts in the Emergency Department and to inpatient stroke alerts.

d. The members of the stroke team shall receive initial orientation and ongoing education.

e. Emergency medications shall be checked daily and prior to dispatch of ambulance.

Standard

COP.4.	Cardio-pulmonary resuscitation services shall be provided uniformly across the stroke centre.

Objective Elements

a. Cardio-pulmonary resuscitation services shall be available for patients at all times.

b. Equipment and medications for use during cardio-pulmonary resuscitation shall be standardized and available in various areas of the stroke centre.

c. The events during cardio-pulmonary resuscitation shall be recorded and analyzed.

Standard

COP.5.	**Nursing care shall be provided to patients in the stroke centre in consonance with clinical protocols, practice guidelines and current evidence.**

Objective Elements

a. The stroke centre shall develop and implement nursing clinical practice guidelines reflecting current standards of practice.

b. The assignment of patient care shall be done as per current good clinical/ nursing practice guidelines.

c. All the nurses shall require training on the following, but shall not be limited to:

i. Detailed neurologic assessments and scales (i.e., NIHSS, Glasgow Coma Scale, FESS protocols/SNOBS and swallowing assessment).

ii. Nursing care of patients receiving thrombolytics and after thrombolytic therapy.

iii. Management of post thrombolysis care and other patients undergone invasive neurosurgical procedures.

iv. Treatment of blood pressure abnormalities with parenteral vasoactive agents.

v. Management of intubated/ventilated patients.

vi. Treatment of increased intracranial pressure.

For advanced stroke centres the nurses shall be trained on:

i. Nursing assessment and management of the function of ventriculostomy and external ventricular monitoring and drainage apparatus.

ii. Management of post-thrombectomy and other invasive/surgical patients.

Standard

COP.6.	**Clinical procedures in the stroke centre shall be performed in a safe manner.**

Objective Elements

a. The procedures shall be performed based on the clinical needs of the patient and according to the written guidance.*

b. Care is taken to prevent adverse events like a wrong patient, wrong procedure and wrong site.

c. Patients shall be appropriately monitored during and after the procedure.

d. The procedures shall be documented accurately in the patient record.

Standard

COP.7.	**The stroke centre provides care in intensive care and high dependency units in a systematic manner.**

Objective Elements

a. The care of patients in intensive care and high dependency unit shall be provided based on written guidance which shall include stroke specific guidelines.*

b. Adequate staff and equipment shall be available.

c. Infection control practices shall be followed.

Standard

COP.8.	**Procedural sedation and anaesthesia in the stroke centre shall be provided in a consistent and safe manner.**

Objective Elements

a. Procedural sedation and anaesthesia shall be administered in a consistent and safe manner.

b. Informed consent shall be obtained for administration of procedural sedation and anaesthesia.

c. Competent and trained persons shall administer procedural sedation and anaesthesia.

d. During anaesthesia, monitoring shall include regular recording of temperature, heart rate, cardiac rhythm, respiratory rate, blood pressure, oxygen saturation and end-tidal carbon dioxide.

e. Patients shall be monitored during and after procedural sedation and anaesthesia and the same is documented.

f. Criteria shall be used to determine the appropriateness of discharge from the observation/recovery area.

Standard

COP.9.	**Surgical services in the stroke centre shall be provided in a consistent and safe manner.**

Objective Elements

a. Surgical services shall be provided in a consistent and safe manner.

b. Surgical patients shall have a pre-operative assessment and pre-operative instructions are provided before surgery at the stroke centre.

c. Informed consent shall be obtained by a doctor/ surgeon member of Surgical team before the procedure.

d. Care shall be taken to prevent adverse events like the wrong site, wrong patient and wrong surgery.

e. An operative note shall be documented before transfer out of patient from recovery.

f. Post-operative care shall be guided by a documented plan.

g. Appropriate facilities, equipment, instruments and supplies shall be available in the operating theatre.

Standard

COP.10.	**The stroke centre shall identify and manage patients who are at higher risk of morbidity/mortality.**

Objective Elements

a. The stroke centre shall identify and manage vulnerable patients.

b. The stroke centre shall provide for a safe and secure environment for the vulnerable patients.

c. The stroke centre shall identify and manage patients who are at a risk of fall, developing/worsening of pressure ulcers and/or developing deep vein thrombosis.

Standard

COP.11.	**Pain management shall be done in a consistent manner for stroke patients.**

Objective Elements

a. Patients shall be screened for pain.

b. Patients with pain shall undergo detailed assessment and periodic reassessment.

c. Patients in pain shall be effectively managed.

Standard

COP.12.	**Rehabilitation services shall be provided to the stroke patients in a safe, collaborative and consistent manner.**

Objective Elements

a. The scope of rehabilitation services shall be commensurate with the stroke centre requirements.

b. Care shall guided by functional assessment and periodic re-assessment, which is done and documented by qualified individual(s) within the stroke centre.

c. The centre shall require physical, occupational and speech therapists to be readily available, for patient assessment and therapy during the hospitalization of patients.

d. Physiotherapists shall have adequate knowledge regarding neurology/stroke care, care coordination and levels of rehabilitation.

e. The stroke centre's post-stroke rehabilitation shall focus on:
   i. Training of patients and/ or family members for maximum recovery.
   ii. Prevent and treat comorbid conditions.
   iii. Enhance quality of life.

f. The stroke centre shall use following rehabilitation performance measures to evaluate in-patients' outcomes.
   i. Pre-Morbid Modified Rankin Score at discharge.
   ii. Modified Rankin Score at discharge.
   iii. Modified Rankin Score 90 days after discharge.

g. Rehabilitation services shall be provided by a multidisciplinary team.

Standard

COP.13.	**Nutritional therapy shall be provided to stroke patients consistently and collaboratively.**

Objective Elements

a. Nutrition screening is done for all patients admitted at stroke centre

b. Nutritional assessment shall be done for patients found at risk during nutritional screening.

c. Therapeutic diet is planned and provided in a collaborative manner.

Chapter 3
Management of Medication (MOM)

Intent of the chapter:

The centre 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 centre should have a mechanism to ensure that the medications are standardized throughout the centre, 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.	Medications are stored as per manufacturer's guidelines and shall be available where required.
MOM. 2.	Medications shall be prescribed safely and rationally at the stroke centre.
MOM. 3.	Medications shall be dispensed in a safe manner.
MOM. 4.	Medications shall be administered safely and patients are monitored after medication administration.
MOM. 5.	Narcotic drugs and psychotropic substances shall be used in a safe manner.

Standards and Objective Elements

Standard

MOM.1.	**Medications are stored as per manufacturer's guidelines and shall be available where required.**

Objective Elements

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

b. The stroke centre shall define a list of high-risk medication(s).

c. Sound-alike and look-alike medications shall be identified and stored physically apart from each other.

d. Emergency medications shall be identified and readily available for use in patient care areas.

e. Medical supplies and consumables are stored appropriately and are available where required.

Standard

MOM.2.	**Medications shall be prescribed safely and rationally at the stroke centre.**

Objective Elements

a. Medication prescription shall be in consonance with good practice and ensure the rational prescription of medications.

b. Drug allergies and previous adverse drug reactions shall be ascertained before prescribing.

c. Medication orders shall be written in a uniform location in the medical records.

d. Medication orders shall be legible, dated, timed and signed.

e. Medication orders shall contain the name of the medicine, route of administration, strength to be administered and frequency/time of administration.

f. The implementation of verbal orders shall ensure safe medication management practices.

g. Audit of medication orders/prescription shall be carried out to check for safe and rational prescription of medications, and corrective and/or preventive action(s)shall be taken based on the audit, where appropriate.

h. Reconciliation of medications shall be done at transition points of patient care, at the time of transfer or discharge of the patients.

Standard

MOM.3.	Medications shall be dispensed in a safe manner.

Objective Elements

a. Dispensing of medications shall be done safely.

b. Dispensed medications shall be labelled.

c. High-risk medication orders shall be verified before dispensing.

Standard

MOM.4.	Medications shall be administered safely and patients are monitored after medication administration.

Objective Elements

a. Medications shall be administered by those who are permitted by law to do so.

b. The patient shall be identified before administration of medications.

c. The strength, dosage, route and timing of the medication shall be verified from the medication order and physically inspected before administration.

d. Medication administration shall be documented in a uniform location.

e. Patients shall be monitored after medication administration.

f. The stroke centre has a mechanism to capture near miss, medication errors and adverse drug reactions.

g. Near miss, medication error and adverse drug reactions shall be reported, collected, analyzed and necessary corrective and/or preventive action(s) are taken based on the analysis within a specified time frame.

Standard

MOM.5.	Narcotic drugs and psychotropic substances shall be used in a safe manner.

Objective Elements

a. Narcotic drugs and psychotropic substances shall be used safely in the stroke centre.

b. Narcotic drugs and psychotropic substances shall be prescribed by appropriate caregivers.

c. Narcotic drugs and psychotropic substances shall be stored securely.

d. A proper record is kept of the usage, administration and disposal of narcotic drugs.

Chapter 4
Patient Rights and Education (PRE)

Intent of the chapter:

The centre 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 stroke centre shall protect patient and family rights and shall inform them about their responsibilities during care.
PRE. 2	The patient and/or family members shall be educated to make informed decisions and are involved in the care planning and delivery process.
PRE. 3	Patient and families shall have a right to information and education about their healthcare needs.
PRE. 4	Patient and families shall have a right to information on expected costs and there shall be a complaint redressal procedure at the stroke centre.

Standards and Objective Elements

Standard

PRE.1.	**The stroke centre shall protect patient and family rights and shall inform them about their responsibilities during care.**

Objective Elements

a. Patients and families shall be informed by the stroke centre of their rights and responsibilities; and on how to voice a complaint, if any, in a format and language that they can understand.

b. Patient and family rights and responsibilities shall be documented and displayed in the stroke centre.*

c. Patient and family rights shall include informed consent before an interventional procedure, anaesthesia, surgery, and any invasive/high-risk procedures/treatment.

d. Patient and family rights shall include information on care plan, progress and information on their health care needs and cost of treatment prior to treatment being initiated.

Standard

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

Objective Elements

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

b. The care plan shall be prepared and modified in consultation with patient and/or family members.

c. The patient and/or family members shall be informed about the results of diagnostic tests and the patient's diagnosis.

d. The stroke centre shall obtain informed consent from the patient or family for situations where informed consent is required.

e. Informed consent process shall adhere to statutory norms.

f. Staff shall be aware of the informed consent procedure.

Standard

PRE.3.	**Patient and families shall have a right to information and education about their healthcare needs.**

Objective Elements

a. Patient and/or family shall be educated about the following in a language and format that they can understand:
   i. Safe and effective use of medication and the potential side effects of the medication;
   ii. Food-drug interaction;
   iii. Diet and nutrition;
   iv. Pain management techniques;
   v. Preventing healthcare associated infections.

b. The patients and/or family members' special educational needs shall be identified and addressed.

Standard

PRE.4.	**Patient and families shall have a right to information on expected costs and there shall be a complaint redressal procedure at the stroke centre.**

Objective Elements

a. There shall be uniform pricing policy in a given setting (out-patient and inpatient category).

b. Patients and family shall be informed about the financial implications when there is a change in the patient condition or treatment setting.

c. The stroke centre shall have a documented complaint redressal procedure and corrective and preventive actions are taken after analysing the complaint.*

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

The centre 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 stroke centre shall implement the infection prevention and control programme in clinical areas and support services.
IPC. 2.	The stroke centre shall take actions to prevent healthcare associated infections in patients and perform surveillance to capture and monitor infection prevention and control data.
IPC. 3.	Infection prevention measures shall include sterilisation, and/or disinfection of instruments, equipment and devices in the stroke centre.
IPC. 4.	The stroke centre shall take action to prevent or reduce healthcare associated infections in its staff.

Standards and Objective Elements

Standard

IPC.1.	**The stroke centre shall implement the infection prevention and control programme in clinical areas and support services.**

Objective Elements

a. The stroke centre shall adhere to standard precautions at all times. Adequate and appropriate personal protective equipment, soaps/ alcohol based hand rub, and disinfectants shall be available and used correctly.

b. The stroke centre shall adhere to hand hygiene guidelines; cleaning, disinfection and sterilization practices, transmission-based precautions, safe injection and infusion practices.

c. The stroke centre shall implement the antimicrobial usage policy and monitor the rational use of antimicrobial agents.

Standard

IPC.2.	**The stroke centre shall take actions to prevent healthcare associated infections in patients and perform surveillance to capture and monitor infection prevention and control data.**

Objective Elements

a. The stroke centre shall take action to prevent:

   i. Catheter-associated urinary tract infections

   ii. Ventilator-associated event / Infection-related ventilator-associated complication / Ventilator-associated pneumonia

   iii. Central line-associated blood stream infections

   iv. Surgical site infections;

b. The scope of surveillance activities shall incorporate tracking and analyzing of infection risks, rates and trends.

c. Surveillance shall be directed towards the identified high-risk activities.

d. Surveillance shall include mechanisms to capture the occurrence of multi-drug-resistant organisms

Standard

IPC.3.	**Infection prevention measures shall include sterilisation, and/or disinfection of instruments, equipment and devices in the stroke centre.**

Objective Elements

a. The stroke centre shall have an identified area with adequate space and appropriate zoning for sterilization activities.

b. Cleaning, packing, disinfection and /or sterilisation, storing and the issue of items shall be done as per the written guidance.*

c. Reprocessing of single-use instruments, equipment and devices shall be done as per written guidance.*

d. Regular validation tests for sterilisation shall be carried out and documented.

e. The established recall procedure shall be implemented when a breakdown in the sterilisation system is identified.

Standard

IPC.4.	**The stroke centre shall take action to prevent or reduce healthcare associated infections in its staff.**

Objective Elements

a. The stroke centre shall implement occupational health and safety practices to reduce the risk of transmitting microorganisms amongst health care providers.

b. Appropriate post-exposure prophylaxis shall be provided to all staff members concerned.

c. The stroke centre shall implement an immunisation policy for its staff.

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 centre and all staff members. The centre 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 stroke centre shall develop and implement a structured patient-safety and quality improvement programme.
PSQ. 2.	The stroke centre shall identify key indicators to monitor the clinical and managerial structures, processes and outcomes which shall be used as tools for continual improvement.
PSQ. 3.	Incidents shall be collected and analysed to ensure continual quality improvement.

Standards and Objective Elements

Standard

PSQ.1.	**The stroke centre shall develop and implement a structured patient-safety and quality improvement programme.**

Objective Elements

a. The patient-safety programme shall be developed, implemented and maintained by a multidisciplinary safety committee which covers all the major elements related to patient safety and risk management.*

b. The programme shall cover incidents ranging from "no harm" to "sentinel events".

c. The stroke centre shall perform proactive analysis of patient safety risks and make improvements accordingly.

d. The patient-safety programme shall be reviewed and updated at least once a year.

e. The stroke centre shall adapt and implement patient-safety goals/solutions.

f. The quality improvement programme shall be reviewed and updated at least once a year.

g. Audits shall be conducted at regular intervals as a means of continuous monitoring.

h. There shall be an established process in the stroke centre to monitor and improve the quality of nursing care

Standard

PSQ.2.	**The stroke centre shall identify key indicators to monitor the clinical and managerial structures, processes and outcomes which shall be used as tools for continual improvement.**

Objective Elements

a. The stroke centre shall define and measure key indicators for clinical structure, process and outcomes defined below

b. The stroke centre shall monitor key clinical indicators given below to oversee:

   i. Adherence to appropriate assessment of patient's neurological status

   ii. Medication errors;

   iii. Vulnerable patients indicators.

c. There shall be rehabilitation performance indicators to evaluate patient outcomes (functional status and potential discharge needs):

   i. Percentage of stroke patients who receive the appropriate level of rehabilitation services in the system.

ii. Percentage of assessments of patients and identification of impairments within 24 hours of admission or when feasible once the patient is medically stable. If assessment is not performed within 24 hours of admission, there must be documentation of attempt or order to not assess due to patient condition.

iii. Percentage of reassessments within 24 hours of admission by speech therapists to evaluate a stroke patient for dysphagia, if patient has been made NPO and/or failed an initial swallow screen.

iv. Rehabilitation performance measures to evaluate in patient's outcomes at discharge and 90 days after discharge.

d. There shall be a mechanism for analysis of data which results in identifying opportunities for improvement

e. The organisation identifies and monitors following key indicators to oversee the clinical & rehabilitation structures, processes and outcomes.(refer OE a,b&c above).

i. Time for first brain imaging scan (first slice time) from patient arrival to hospital (recorded triage time)

ii. Percentage of patients managed with intravenous thrombolysis (recombinant Tissue Plasminogen Activator) as indicated with in the defined timeframe.

iii. Percentage of patients with symptomatic intracranial haemorrhage within 24 hours of receiving Intravenous thrombolysis

iv. Time taken for detailed initial neurological assessment of indoor patients.

v. Percentage of patients wherein initial dysphagia screening during admission in the emergency department or acute inpatient unit/ward is documented.

vi. Percentage of patient referred to a physiotherapist/rehabilitation with in the defined time frame.

vii. Favourable functional outcome at the end of follow up.

viii. Incidence of medication errors.

ix. Percentage of acute stroke patients who die in hospital of all causes within 7 days of hospital admission for an index stroke.

x. Percentage of patients undergoing CEA, or carotid angioplasty or stenting, having stroke or death within 30 days of the procedure.

xi. Percentage of patients with stroke or death within 24 hours of diagnostic cerebral-angiography.

For advanced stroke centres

i. Percentage of ischemic stroke patients who receive acute endovascular treatment as indicated within the defined timeframe.

ii. Percentage of patients with symptomatic intracranial haemorrhage within 24 hours of receiving acute endovascular treatment.

iii. Percentage of patient wherein reassessment by a speech therapist within 24 hours of admission to evaluate a stroke patient for dysphagia is documented.

iv. Percentage of patients undergoing intracranial angioplasty and/or stenting for atherosclerotic disease having stroke or death within 30 days of the procedure

v. Percentage of patients who have a diagnosis of ischemic stroke who undergo EVD and then develop ventriculitis.

vi. Percentage Ischemic stroke patients with a post-treatment reperfusion grade of TICI 2B or higher in the vascular territory beyond the target arterial occlusion at the end of treatment with intra-arterial (IA) thrombolytic (t-PA) therapy and/or mechanical endovascular reperfusion therapy

vii. Percentage Ischemic stroke patients with a large vessel cerebral occlusion (i.e., internal carotid artery (ICA) or ICA terminus (T-lesion; T-occlusion), middle cerebral artery (MCA) M1 or M2, basilar artery) who receive mechanical endovascular reperfusion (MER) therapy (time of first pass or deployment of device) within 120 minutes (≥ 0 min. and ≤150 min.) of hospital arrival and achieve TICI 2B or higher at the end of the treatment.

viii. Percentage Ischemic stroke patients with a large vessel cerebral occlusion (i.e., internal carotid artery (ICA) or ICA terminus (T-lesion; T-occlusion), middle cerebral artery (MCA) M1 or M2, basilar artery) who receive mechanical endovascular reperfusion (MER) therapy (time of first pass or deployment of device) and achieve TICI 2B or higher ≤60 minutes from the time of skin puncture

f. The organisation identifies and monitors the key indicators to oversee vulnerable patients.

i. Incidence of hospital associated pressure ulcer after admission

ii. Incidence of deep venous thrombosis after admission

iii. Incidence of patient Falls.

g. The organisation identifies and monitors key indicators to oversee the managerial structures, processes and outcomes.

i. Waiting time for imaging services

ii. Number of stock out of thrombolytic agent

Standard

PSQ.3.	**Incidents shall be collected and analysed to ensure continual quality improvement.**

Objective Elements

a. The stroke centre shall have an incident management system.

b. Corrective and preventive actions shall be taken based on the findings of such analysis.

c. The stroke centre shall define sentinel events and have established processes for analysis of incidents.

d. Corrective and preventive actions shall be taken based on the findings of such analysis.

Chapter 7
Responsibilities of Management (ROM)

Intent of the chapter:

The standards encourage the governance of the centre 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 centre management.

Summary of Standards

ROM. 1.	Those responsible for governance shall be identified at the stroke centre and their roles are defined.
ROM. 2.	The stroke centre shall display professionalism in its functioning.
ROM. 3.	The stroke centre management shall ensure that patient safety aspects and risk management issues are an integral part of patient care and hospital management.

Standards and Objective Elements

Standard

ROM.1.	**Those responsible for governance shall be identified at the stroke centre and their roles are defined.**

Objective Elements

a. Those responsible for governance shall be identified and their roles and responsibilities defined.*
b. Those responsible for governance support safety initiatives and quality improvement plans.
c. Those responsible for governance support the ethical management framework of the stroke centre.

Standard

ROM.2.	**The stroke centre shall display professionalism in its functioning.**

Objective Elements

a. The person heading the stroke centre shall have requisite and appropriate qualification and experience.
b. The stroke centre shall coordinate the functioning with departments and external agencies, and monitor the progress in achieving the defined goals and objectives.
c. The stroke centre shall plan and budgets for its activities annually.
d. The functioning of committees shall be reviewed for their effectiveness.
e. The stroke centre shall document the service standards that are measurable and monitor them.
f. The stroke centre shall have a formal documented agreement for all outsourced services which shall include service parameters and mechanism of monitoring.

Standard

ROM.3.	**The stroke centre management shall ensure that patient safety aspects and risk management issues are an integral part of patient care and hospital**

Objective Elements

a. The management shall ensure proactive risk management across the stroke centre.
b. The management shall provide resources for proactive risk assessment and risk-reduction activities.
c. The management shall ensure integration between quality improvement, risk management and strategic planning within the stroke centre.
d. The management shall ensure implementation of systems for internal and external reporting of system and process failures.

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

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

The centre manages its hazardous materials safely.

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

Summary of Standards

FMS. 1.	The stroke centre shall have a programme for the facility, engineering support services and utility systems.
FMS. 2.	The stroke centre shall have a programme for medical gases, vacuum and compressed air.
FMS. 3.	The stroke centre shall have plans for fire and non-fire emergencies within the facility.

Standards and Objective Elements

Standard

FMS.1.	**The stroke centre shall have a programme for the facility, engineering support services and utility systems.**

Objective Elements

a. The stroke centre shall plan for utility and engineering equipment in accordance with its services and strategic plan.
b. Equipment shall be inventoried and proper logs shall be maintained as required.
c. The documented operational and maintenance (preventive and breakdown) plan shall be implemented.
d. There shall be a maintenance plan for water management and for electrical systems.
e. There shall be a maintenance plan for heating, ventilation and air-conditioning.
f. Medical and utility equipment, shall be periodically inspected and calibrated (wherever applicable) for their proper functioning.
g. Competent personnel shall operate, inspect, test and maintain equipment and utility systems.

Standard

FMS.2.	**The stroke centre shall have a programme for medical gases, vacuum and compressed air.**

Objective Elements

a. Written guidance shall govern the procurement, handling, storage, distribution, usage and replenishment of medical gases.*
b. Medical gases shall be handled, stored, distributed and used in a safe manner.
c. There shall be an operational, inspection, testing and maintenance plan for piped medical gas, compressed air and vacuum installation.*

Standard

FMS.3.	**The stroke centre shall have plans for fire and non-fire emergencies within the facility.**

Objective Elements

a. The stroke centre shall have plans and provisions for early detection, abatement and containment of fire, and non-fire emergencies.*
b. The stroke centre shall have a documented and displayed exit plan in case of fire and non-fire emergencies.*
c. Mock drills shall be held at least twice a year.
d. There shall be a maintenance plan for fire-related equipment and infrastructure.*

Chapter 9
Human Resource Management (HRM)

Intent of the chapter:

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

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

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

c. Motivation related to job design, performance appraisal and discipline.

d. 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 stroke centre shall have a documented system of human resource planning and training
HRM. 2.	Staff shall be appropriately trained based on their specific job description, and safety and quality-related aspects .
HRM. 3.	There shall be a process for credentialing and privileging of medical, nursing and para-clinical professionals who are permitted to provide patient care, without supervision.

Standards and Objective Elements

Standard

HRM.1.	**The stroke centre shall have a documented system of human resource planning and training**

Objective Elements

a. The stroke centre shall maintain an adequate number and mix of staff to meet the care, treatment and service needs of the patient.

b. The job specification and job description shall be defined for each category of staff.

c. Staff shall be provided with induction training which shall contain orientation to the following

   i. Stroke centre's vision, mission and values;

   ii. Staff rights and responsibilities;

   iii. Patient rights and responsibilities;

   iv. Safety and risk management;

   v. Cardio-pulmonary resuscitation;

   vi. Stroke centre's infection prevention and control;

   vii. Stroke centre's service standards;

d. The stroke centre shall maintain the training record;

e. Training shall also occur when job responsibilities change/new equipment is introduced.

Standard

HRM.2.	**Staff shall be appropriately trained based on their specific job description, and safety and quality-related aspects .**

Objective Elements

a. Staff shall be trained in identifying a stroke and calling out the stroke team as well as in basic emergency care of acute stroke patients.

b. Staff are provided continuing education on stroke management protocols, changes in guidelines and other equivalent training.

c. Staff shall be trained in handling vulnerable patients.

d. Staff shall be trained in control and restraint techniques.

e. Staff involved in direct patient care shall be provided training on cardiopulmonary resuscitation periodically.

f. Staff shall be provided training in the detection, handling, minimisation and elimination of identified risks within the stroke centre's environment.

g. Staff shall be trained in handling fire and non-fire emergencies.

h. Staff in the Emergency Department shall demonstrate knowledge in the delivery of treatment that can improve a patient's outcome which shall include but not be limited to:

i. Intravenous thrombolytics administration;

ii. Reversal of coagulopathies;

iii. Control of seizures;

iv. Blood pressure management;

v. Management of relevant comorbidities;

vi. Oxygenation management.

Standard

HRM.3.	**There shall be a process for credentialing and privileging of medical, nursing and para-clinical professionals who are permitted to provide patient care, without supervision.**

Objective Elements

a. Medical, nursing and para-clinical professionals who are permitted by law, regulation and the hospital to provide patient care without supervision are identified.

b. The education, registration, training and experience of the identified medical, nursing and para-clinical professionals shall be documented and updated periodically.

c. Medical, nursing and para-clinical professionals shall be granted privileges to admit/ care for patients in consonance with their qualification, training, experience and registration.

d. The requisite services to be provided by the medical, nursing and para-clinical professionals shall be known to them as well as the various departments/units of the stroke centre.

Chapter 10
Information Management System (IMS)

Intent of the chapter:

This chapter emphasizes the requirements of a medical record in the centre. 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 centre will lay down policies and procedures to guide the contents, storage, security, issue and retention of medical records.

Summary of Standards

IMS. 1.	The stroke centre shall have processes in place for effective management and control of data and information.
IMS. 2.	The patients cared for by the stroke centre shall have a complete and accurate medical record.

Standards and Objective Elements

Standard

IMS.1.	**The stroke centre shall have processes in place for effective management and control of data and information.**

Objective Elements

a. Information management and technology acquisitions shall be commensurate to the identified information needs to stroke centre.

b. The stroke centre shall contribute to external databases, as per national requirements.

c. The stroke centre shall store and retrieve data according to its information needs.

d. The stroke centre shall maintain confidentiality, integrity and security of records, data and information.

Standard

IMS.2.	**The patients cared for by the stroke centre shall have a complete and accurate medical record.**

Objective Elements

a. A unique identifier shall be assigned to the medical record.

b. The contents of the medical record shall be identified and documented.

c. The medical record provides a complete, up-to-date and chronological account of patient care.

d. Authorised staff shall make entries in the medical record.

e. Entry in the medical record shall be signed, dated and timed.

f. The author of each entry can be identified.

g. The medical record shall have only authorised abbreviations.

h. The medical record shall include documentation indicating reason, if an eligible ischemic stroke patient does not receive IV thrombolytic therapy.

i. The medical record shall include documentation indicating the assessments of all stroke patients, including whether they received IV thrombolytic therapy or not, to determine the eligibility/recommendation for endovascular intervention.

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Glossary

The commonly-used terminologies in the NABH standards are briefly described and explained herein to remove any ambiguity regarding their comprehension. The definitions narrated have been taken from various authentic sources as stated, wherever possible. Not with standing the accuracy of the explanations given, in the event of any discrepancy with a legal XE "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.
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)
Assessment	All activities including history taking, physical examination, laboratory investigations that contribute towards determining the prevailing clinical status of the patient.
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.
Clinical practice guidelines	Clinical practice guidelines are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.
Competence	Demonstrated ability to apply knowledge and skills (para 3.9.2 of ISO 9000: 2015). Knowledge is the understanding of facts and procedures. Skill is the ability to perform a specific action.

Confidentiality	Restricted access to information to individuals who have a need, a reason and permission for such access. It also includes an individual's right to personal privacy as well as the privacy of information related to his/her healthcare records.
Consent	1. The willingness of a party to undergo examination/procedure/ treatment by a healthcare provider. It may be implied (e.g. patient registering in OPD), expressed which may be written or verbal. Informed consent is a type of consent in which the healthcare provider has a duty to inform his/her patient about the procedure, its potential risk and benefits, alternative procedure with their risk and benefits so as to enable the patient to make an informed decision of his/her health care. 2. In law, it means active acquiescence or silent compliance by a person legally capable of consenting. In India, the legal age of consent is 18 years. It may be evidenced by words or acts or by silence when silence implies concurrence. Actual or implied consent is necessarily an element in every contract and every agreement.
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 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 Baldridge National Quality Award)
Grievance- handling procedures	The sequence of activities carried out to address the grievances of patients, visitors, relatives and staff.
Hazardous materials	Substances dangerous to human and other living organisms. They include radioactive or chemical materials.
Hazardous waste	Waste materials dangerous to living organisms. Such materials require special precautions for disposal. They include the biologic waste that can transmit disease (for example, blood, tissues) radioactive materials, and toxic chemicals. Other examples are infectious waste such as used needles, used bandages and fluid soaked items.

Healthcare- associated infection	Healthcare-associated infection (HAI), also referred to as "nosocomial" or "hospital" infection, is an infection occurring in a patient during the process of care in a hospital or other health care facility which was not present or incubating at the time of admission. (Reference: World Health Organization)
Healthcare organisation	The generic term is used to describe the various types of organisation that provide healthcare services. This includes ambulatory care centres, hospitals, laboratories, etc.
High-dependency unit	A high-dependency unit (HDU) is an area for patients who require more intensive observation, treatment and nursing care than are usually provided for in a ward. It is a standard of care between the ward and full intensive care.
High Risk/High Alert Medications	High-risk/high-alert medications are medications involved in a high percentage of medication errors or sentinel events and medications that carry a high risk for abuse, error, or other adverse outcomes. Examples include medications with a low therapeutic index, controlled substances, psychotherapeutic medications, and look-alike and sound-alike medications.
Incident reporting	It is defined as written or verbal reporting of any event in the process of patient care, that is inconsistent with the deserved patient outcome or routine operations of the healthcare facility.
In-service education/training	Organised education/training usually provided in the workplace for enhancing the skills of staff members or for teaching them new skills relevant to their jobs/tasks.
Indicator	A statistical measure of the performance of functions, systems or processes over time. For example, hospital acquired infection rate, mortality rate, caesarean section rate, absence rate, etc.
Information	Processed data which lends meaning to the raw data.
Intent	A brief explanation of the rationale, meaning and significance of the standards laid down in a particular chapter.
Inventory control	The method of supervising the intake, use and disposal of various goods in hands. It relates to supervision of the supply, storage and accessibility of items in order to ensure an adequate supply without stock-outs/excessive storage. It is also the process of balancing ordering costs against carrying costs of the inventory so as to minimise total costs.

Isolation	Separation of an ill person who has a communicable disease (e.g.,measles, chickenpox, mumps, SARS) from those who are healthy. Isolation prevents transmission of infection to others and also allows the focused delivery of specialised health care to ill patients. The period of isolation varies from disease-to-disease. Isolation facilities can also be extended to patients for fulfilling their individual, unique needs.
Job description	1.It entails an explanation pertaining to duties, responsibilities and conditions required to perform a job. 2.A summary of the most important features of a job, including the general nature of the work performed (duties and responsibilities) and level (i.e., skill, effort, responsibility and working conditions) of the work performed. It typically includes job specifications that include employee characteristics required for competent performance of the job. A job description should describe and focus on the job itself and not on any specific individual who might fill the job.
Job specification	1.The qualifications/physical requirements, experience and skills required to perform a particular job/task. 2.A statement of the minimum acceptable qualifications that an incumbent must possess to perform a given job successfully.
Maintenance	The combination of all technical and administrative actions, including supervision actions, intended to retain an item in, or restore it to, a state in which it can perform a required function. (Reference: British Standard 3811:1993)
Medical equipment	Any fixed or portable non-drug item or apparatus used for diagnosis, treatment, monitoring and direct care of a patient.
Medication error	A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labelling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use. (Reference: The National Coordinating Council for Medication Error Reporting and Prevention)
Medication Order	A written order by a physician, dentist, or other designated health professionals for a medication to be dispensed by a pharmacy for administration to a patient. (Reference: Mosby's Medical Dictionary, 10th edition, Elsevier)

Mission	An organisation's purpose. This refers to the overall function of an organisation. The mission answers the question, "What is this organisation attempting to accomplish?" The mission might define patients, stakeholders, or markets served, distinctive or core competencies or technologies used.
Monitoring	The performance and analysis of routine measurements aimed at identifying and detecting changes in the health status or the environment, e.g. monitoring of growth and nutritional status, air quality in operation theatre. It requires careful planning and use of standardised procedures and methods of data collection.
Multidisciplinary	A generic term which includes representatives from various disciplines, professions or service areas.
Near-miss	A near-miss is an unplanned event that did not result in injury, illness, or damage--but had the potential to do so. Errors that did not result in patient harm, but could have, can be categorised as near-misses.
No harm	This is used synonymously with a near miss. However, some authors draw a distinction between these two phrases. A near-miss is defined when an error is realised just in the nick of time, and abortive action is instituted to cut short its translation. In no harm scenario, the error is not recognised, and the deed is done, but fortunately for the healthcare professional, the expected adverse event does not occur. The distinction between the two is important and is best exemplified by reactions to administered drugs in allergic patients. A prophylactic injection of cephalosporin may be stopped in time because it suddenly transpires that the patient is known to be allergic to penicillin (near-miss). If this vital piece of information is overlooked, and the cephalosporin administered, the patient may fortunately not develop an anaphylactic reaction (no harm event).
Notifiable disease	Certain specified diseases, which are required by law to be notified to the public health authorities. Under the international health regulation (WHO's International Health Regulations 2005), the following diseases are always notifiable to WHO: a. Smallpox b. Poliomyelitis due to wild-type poliovirus c. Human influenza caused by a new subtype d. Severe acute respiratory syndrome (SARS).

Notifiable disease	In India, the following is an **indicative list of diseases** which are also notifiable, **but may vary from state to state:** a. Polio b. Influenza c. Malaria d. Rabies e. HIV/AIDS f. Louse-borne typhus g. Tuberculosis h. Leprosy I. Leptospirosis j. Viral hepatitis k. Dengue fever
Objective	A specific statement of a desired short-term condition or achievement includes measurable end-results to be accomplished by specific teams or individuals within time limits. (Reference: American Society for Quality)
Objective element	It is that component of standard which can be measured objectively on a rating scale. Acceptable compliance with the measurable elements will determine the overall compliance with the standard.
Occupational health hazard	The hazards to which an individual is exposed during the course of the performance of his job. These include physical, chemical, biological, mechanical and psychosocial hazards.
Operational plan	The operational plan is the part of your strategic plan. It defines how you will operate in practice to implement your action and monitoring plans - what your capacity needs are, how you will engage resources, how you will deal with risks, and how you will ensure the sustainability of the organisation's achievements.
Organogram	A graphic representation of the reporting relationship in an organisation.
Outsourcing	Hiring of services and facilities from other organisation based upon one's own requirement in areas where such facilities are either not available or else are not cost-effective. For example, outsourcing of house-keeping, security, laboratory/certain special diagnostic facilities. When an activity is outsourced to other institutions, there should be a memorandum of understanding that clearly lays down the obligations of both organisations: the one which is outsourcing and the one who is providing the outsourced facility. It also addresses the quality-related aspects.

Patient-care setting	The location where a patient is provided health care as per his needs, e.g. ICU, speciality ward, private ward and general ward.
Patient record/ medical record/ clinical record	A document which contains the chronological sequence of events that a patient undergoes during his stay in the healthcare organisation. It includes demographic data of the patient, assessment findings, diagnosis, consultations, procedures undergone, progress notes and discharge summary.
Patient 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)
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	1. A specified way to carry out an activity or a process (Para 3.4.5 of ISO 9000: 2015). 2. A series of activities for carrying out work which when observed by all help to ensure the maximum use of resources and efforts to achieve the desired output.
Process	A set of interrelated or interacting activities which transforms inputs into outputs (Para 3.4.1 of ISO 9000: 2015).
Programme	A sequence of activities designed to implement policies and accomplish objectives.
Protocol	A plan or a set of steps to be followed in a study, an investigation or an intervention.
Quality	1. Degree to which a set of inherent characteristics fulfil requirements (Para 3.1.1 of ISO 9000: 2015). Characteristics imply a distinguishing feature (Para 3.5.1 of ISO 9000: 2015). Requirements are a need or expectation that is stated, generally implied or obligatory (Para 3.1.2 of ISO 9000:2015). 2. Degree of adherence to pre-established criteria or standards.
Quality assurance	Part of quality management focussed on providing confidence that quality requirements will be fulfilled (Para 3.2.11 of ISO 9000:2015).
Quality improvement	Ongoing response to quality assessment data about a service in ways that improve the process by which services are provided to consumers/patients.
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 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.
Root Cause Analysis (RCA)	Root Cause Analysis (RCA) is a structured process that uncovers the physical, human, and latent causes of any undesirable event in the workplace. Root cause analysis (RCA) is a method of problem-solving that tries to identify the root causes of faults or problems that cause operating events. RCA practice tries to solve problems by attempting to identify and correct the root causes of events, as opposed to simply addressing their symptoms. By focusing correction on root causes, problem recurrence can be prevented. The process involves data collection; cause charting, root cause identification and recommendation generation and implementation.
Safety	The degree to which the risk of an intervention/procedure, in the care environment is reduced for a patient, visitors and healthcare providers.
Safety programme	A programme focused on patient, staff and visitor safety.
Scope of services	Range of clinical and supportive activities that are provided by a healthcare organisation.
Security	Protection from loss, destruction, tampering, and unauthorised access or use.

Sedation	The administration to an individual, in any setting for any purpose, by any route, moderate or deep sedation. There are three levels of sedation: Minimal sedation (anxiolysis) - A drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are not affected. Moderate sedation/analgesia (conscious sedation) - A drug-induced depression of consciousness during which patients respond purposefully to verbal commands either alone or accompanied by light tactile stimulation. No interventions are needed to maintain a patent airway. Deep sedation/analgesia - A drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully after repeated or painful stimulation. Patients may need help in maintaining a patent airway.
Sentinel events	A relatively infrequent, unexpected incident, related to system or process deficiencies, which leads to death or major and enduring loss of function for a recipient of healthcare services. Major and enduring loss of function refers to sensory, motor, physiological, or psychological impairment not present at the time services were sought or begun. The impairment lasts for a minimum period of two weeks and is not related to an underlying condition.
Staff	All personnel working in the organisation including employees, “fee-for-service” medical professionals, part-time workers, contractual personnel and volunteers.
Standard precautions	1. A method of infection control in which all human blood and other bodily fluids are considered infectious for HIV, HBV and other blood-borne pathogens, regardless of patient history. It encompasses a variety of practices to prevent occupational exposure, such as the use of personal protective equipment (PPE), disposal of sharps and safe housekeeping 2. A set of guidelines protecting first aiders or healthcare professionals from pathogens. The main message is: "Don't touch or use anything that has the victim's body fluid on it without a barrier." It also assumes that all body fluid of a patient is infectious, and must be treated accordingly. 3. Standard Precautions apply to blood, all body fluids, secretions, and excretions (except sweat) regardless of whether or not they contain visible blood, non-intact skin and mucous membranes

Standards	A statement of expectation that defines the structures and process that must be substantially in place in an organisation to enhance the quality of care.
Sterilisation	It is the process of killing or removing microorganisms including their spores by thermal, chemical or irradiation means.
Strategic plan	Strategic planning is an organisation's process of defining its strategy or direction and making decisions on allocating its resources to pursue this strategy, including its capital and people. Various business analysis techniques can be used in strategic planning, including SWOT analysis (Strengths, Weaknesses, Opportunities and Threats), e.g. Organisation can have a strategic plan to become a market leader in the provision of cardiothoracic and vascular services. The resource allocation will have to follow the pattern to achieve the target. The process by which an organisation envisions its future and develops strategies, goals, objectives and action plans to achieve that future.
Surveillance	The continuous scrutiny of factors that determines the occurrence and distribution of diseases and other conditions of ill health. It implies watching over with great attention, authority and often with suspicion. It requires professional analysis and sophisticated interpretation of data leading to recommendations for control activities.
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	Turn-around-time (TAT) means the amount of time taken to complete a process or fulfil a request.
Validated tool	A validated tool refers to a questionnaire/scale that has been developed to be administered among the intended respondents. The validation processes should have been completed using a representative sample, demonstrating adequate reliability (the ability of the instrument to produce consistent results) and validity (the ability of the instrument to produce true results).
Validation	Validation is verification, where the specified requirements are adequate for the intended use.
Values	The fundamental beliefs that drive organisational behaviour and decision-making. This refers to the guiding principles and behaviours that embody how an organisation and its people are expected to operate. Values reflect and reinforce the desired culture of an organisation.

Verbal order	Verbal orders are those orders given by a physician with prescriptive authority to a licensed person who is authorised by the organisation.
Verification	Verification is the provision of objective evidence that a given item fulfils specified requirements.
Vision	An overarching statement of the way an organisation wants to be, an ideal state of being at a future point. This refers to the desired future state of an organisation. The vision describes where the organisation is headed, what it intends to be, or how it wishes to be perceived in the future.
Vulnerable patient	Those patients who are prone to injury and disease by virtue of their age, sex, physical, mental and immunological status,e.g. infants, elderly, physically- and mentally-challenged, semiconscious/unconscious, those on immunosuppressive and/or chemotherapeutic agents.

ANNEXURE-1

NABH Key Performance Indicators

Key performance indicators help to systematically monitor, evaluate and continually improve service performance.

Well-designed KPIs should help the organization 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

NABH KEY PERFORMANCE INDICATORS

The Key performance indicators expected to be monitored by healthcare organisation:

Sl. No	Standard	Indicators	Formula		Frequency of data collection / monitoring	Remarks
1	PSQ.3.c	Time taken for first slice of brain imaging for acute stroke cases.	Sum of time taken for the first slice of brain imaging for acute stroke cases Total No. of acute stroke cases undergone brain imaging	X100	Monthly	Measure of stroke centre system efficiency. Benchmark as per the defined time frame Target defines less than 30 mins. This shall be captured either through the HIS or through audit. This shall include both emergency, IP patients

Sl. No	Standard	Indicators	Formula		Frequency of data collection / monitoring	Remarks
2	PSQ.3.c	Percentage of patients managed with intravenous thrombolysis within the defined time frame	No. of patients managed with Intravenous thrombolysis within defined time frame Total No. of acute stroke cases with indications of intravenous thrombolysis	x100	Continous	Measure of access appropriateness Target: If (> 75% compliance) ≤60 min [Achieving Door to needle times (time of bolus administration) within 60 minutes in 75% or more of acute ischemic stroke patients treated with IV thrombolytic agent] If (≥50% compliance) ≤45 min [Achieving Door to needle times (time of bolus administration) within 45 minutes in 50% or more of acute ischemic stroke patients treated with IV thrombolytic agent]
3	PSQ.3.c	Percentage of patients with symptomatic intracranial haemorrhage within 24 hours of receiving Intravenous thrombolysis	No. of patients with symptomatic intracranial haemorrhage within 24 hours of receiving Intravenous thrombolysis Total No. of patients received intravenous thrombolytic therapy	x100	Monthly	Target: (i.e., clinical deterioration ≥ 4-point increase on NIHSS and brain image finding of parenchymal hematoma, or subarachnoid hemorrhage, or intraventricular hemorrhage) within (≤) 36 hours after the onset of treatment with intra-venous (IV) or intra-arterial (IA) thrombolytic (t-PA) therapy,
4		Time taken for detailed initial neurological assessment of indoor patients.	Sum of time taken for detailed initial neurological assessment Total No. of admissions		Monthly	Measure appropriateness process, responsiveness – promote improved documentation, data quality, accuracy. Target: As defined by the organization

Sl. No	Standard	Indicators	Formula		Frequency of data collection / monitoring	Remarks
5		Percentage of patients wherein initial dysphagia screening during admission in the emergency department or acute inpatient unit/ward is documented.	No. of patients wherein initial dysphagia screening documented at the time of admission Total No. of patients admitted	x100	Monthly	Measure of access appropriateness and outcome Target :As defined by the organization
6		Percentage of patients referred to a physiotherapist/ rehabilitation within the defined time frame.	No. of patients referred to a physiotherapist/ rehabilitation within the defined time frame Total No. of Patients admitted with stroke	x100	Monthly	Measure of access appropriateness and outcome Proportion of stroke patients who have an initial rehabilitation assessment within 48 hours of hospital admission for acute stroke by at least one stroke rehabilitation specialist. Target :As defined by the organization
7		Favorable Functional outcome at the end of follow up.	No. of stroke patients with a modified Rankin Scale score of 0 – 2 at 90 days following onset of stroke Total No. of stroke follow up patients	x100	Monthly	Measure of effectiveness, outcome. Target for patients who receive EVT is > 50%.
8		Incidence of medication errors	Total No. of medication errors Total No. of opportunities of medication errors	x100	Monthly	Measures, effectiveness Target: As defined by the organization

Sl. No	Standard	Indicators	Formula		Frequency of data collection / monitoring	Remarks
9		Percentage of acute stroke patients who die in hospital of all causes within 7 days of hospital admission for an index stroke	No. of acute stroke patients who die in hospital of all causes within 7 days of hospital admission for an index stroke Total No. of acute stroke patients admitted	x100	Monthly	Measure of effectiveness, outcome.
10		Percentage of patients undergoing CEA, or carotid angioplasty or stenting, having stroke or death within 30 days of the procedure	No. of patients underwent CEA, or carotid angioplasty or stenting, having stroke or death within 30 days of the procedure Total No. of patients undergoing CEA, or carotid angioplasty or stenting	x100	Monthly	Measure of effectiveness, outcome.
11		Percentage of patients with stroke or death within 24 hours of diagnostic cerebral-angiography	No. of patients with stroke or death within 24 hours of diagnostic cerebral-angiography Total No. of patients undergone diagnostic cerebral angiography	x100	Monthly	Measure of effectiveness, outcome.

Sl. No	Standard	Indicators	Formula		Frequency of data collection / monitoring	Remarks
12		Incidence of hospital associated pressure ulcer after admission	No. of patients who develop new/ worsening of pressure ulcer Total No. of patient days in stroke unit	x100	Monthly	The organization shall use the European and US national Pressure Ulcer Advisory panels (EPUAP and NPUAP) staging system to look for worsening pressure ulcers
13		Incidence of deep venous thrombosis after admission	No. of patients with deep venous thrombosis after admission Total No. of admissions		Monthly	Measures effectiveness and outcome
14		Waiting time for imaging services	Sum total time Number of patients reported in Diagnostics		Monthly	Waiting time for diagnostics is the time from which the patient has come to the imaging service (requistion form has been presented to the counter) till the time that the test is initiated. It is applicable only for IP and emergency patients. In case of appointment patients, the time shall begin with the scheduled appointment time and end when the imaging procedure begins.
15		Number of stock out thrombolytic agent	No. of Stockouts of thrombolytic agent Number of drugs listed as thrombolytic agents in hospital formulary	x100	Monthly	To capture this, organization should maintain a register in the pharmacy and stores (and also if necessary in the wards) wherein all such events are captured. The organization shall capture the number of instances.

SI. No	Standard	Indicators	Formula		Frequency of data collection / monitoring	Remarks
16		Incidence of patient falls	No. of patient falls	x1000	Monthly	Falls may be: • At different levels- i.e., from one level to ground level e.g. from beds, wheelchairs or down stairs • On the same level as a result of slipping, tripping, or stumbling, or from a collision, pushing, or shoving, y or with another person • Below ground level, i.e., into a hole or other opening in surface All types of falls are to be included whether they result from physiological reasons (fainting) or environmental reasons. Assisted falls should be included.

For advanced stroke centres

SI. No	Standard	Indicators	Formula		Frequency of data collection / monitoring	Remarks
17	PSQ 3 c	Percentage of ischemic stroke patients who receive acute endovascular treatment as indicated within defined time frame	No. of ischemic stroke patients undergone acute endovascular treatment within defined time frame Total No. of acute stroke patients with indication for acute endovascular treatment	x100	Monthly	Measure of access appropriateness and outcome Target: Door to device time shall be within 90 minutes for direct arriving patients and 60 minutes for transfer patients

Sl. No	Standard	Indicators	Formula		Frequency of data collection / monitoring	Remarks
18		Percentage of patients with symptomatic intracranial haemorrhage within 24 hours of receiving acute endovascular treatment	No. of patients with symptomatic intracranial haemorrhage within 24 hours of receiving acute endovascular treatment Total No. of patients received acute endovascular treatment	x100	Monthly	Measure of effectiveness, outcome. Target: < 6% clinical deterioration ≥ 4-point increase on NIHSS and brain image finding of parenchymal hematoma, or subarachnoid hemorrhage, or intraventricular hemorrhage) within (≤) 36 hours after the onset of treatment with mechanical endovascular reperfusion procedure (i.e., mechanical endovascular thrombectomy with a clot retrieval device).
19		Percentage of patient wherein reassessment by a speech therapist within 24 hours of admission to evaluate a stroke patient for dysphagia is documented	No. of patient wherein reassessment by a speech therapist documented within 24 hours of admission Total No. of patients admitted	x100	Monthly	Measure of access, process. Target :As defined by the organization(>80% (based on Canadian Stroke Audit)
20		Percentage of patients undergoing intracranial angioplasty and/or stenting for atherosclerotic disease having stroke or death within 30 days of the procedure	No. of patients undergone intracranial angioplasty and/or stenting for atherosclerotic disease having stroke or death within 30 days of the procedure Total No. of patients undergoing intracranial angioplasty and/or stenting for atherosclerotic disease	x100	Monthly	Measure of effectiveness, outcome.

Sl. No	Standard	Indicators	Formula		Frequency of data collection / monitoring	Remarks
21		Percentage of patients who have a diagnosis of ischemic stroke who undergo EVD and then develop ventriculitis	No. of patients who have a diagnosis of ischemic stroke who undergo EVD and then develop ventriculitis Total No. of ischemic stroke patients	x100	Monthly	Measure of effectiveness, outcome.
22		Percentage Ischemic stroke patients with a post-treatment reperfusion grade of TICI 2B or higher in the vascular territory beyond the target arterial occlusion at the end of treatment with intra-arterial (IA) thrombolytic (t-PA) therapy and/or mechanical endovascular reperfusion therapy	No. of patients with a post-treatment reperfusion grade of TICI 2B or higher in the vascular territory beyond the target arterial occlusion at the end of treatment with intra-arterial (IA) thrombolytic (t-PA) therapy and/or mechanical endovascular reperfusion therapy Number of Ischemic stroke patients underwent treatment with intra-arterial (IA) thrombolytic (t-PA) therapy and/or mechanical endovascular reperfusion therapy	x100	Monthly	Measure of effectiveness, outcome.

Sl. No	Standard	Indicators	Formula		Frequency of data collection / monitoring	Remarks
23		Percentage Ischemic stroke patients with a large vessel cerebral occlusion (i.e., internal carotid artery (ICA) or ICA terminus (T-lesion; T-occlusion), middle cerebral artery (MCA) M1 or M2, basilar artery) who receive mechanical endovascular reperfusion (MER) therapy (time of first pass or deployment of device) within 120 minutes (≥ 0 min. and ≤150 min.) of hospital arrival and achieve TICI 2B or higher at the end of the treatment.	Ischemic stroke patients with a large vessel cerebral occlusion achieved TICI 2B or higher Ischemic stroke patients with a large vessel cerebral occlusion who received mechanical endovascular reperfusion (MER) therapy within 120 minutes	x100	Monthly	Measures outcome. Refine prediction of early neurological improvement. Target: time of first pass or deployment of device within 120 minutes (≥ 0 min. and ≤150 min.) of hospital arrival and achieve TICI 2B or higher at the end of the treatment.
24		Percentage Ischemic stroke patients with a large vessel cerebral occlusion (i.e., internal carotid artery (ICA) or ICA terminus (T-lesion; T-occlusion), middle cerebral artery (MCA) M1 or M2, basilar artery) who receive mechanical endovascular reperfusion (MER) therapy (time of first pass or deployment of device) and achieve TICI 2B or higher ≤60 minutes from the time of skin puncture	No. of Ischemic stroke patients with a large vessel cerebral occlusion who receive mechanical endovascular reperfusion (MER) therapy achieve TICI 2B or higher =60 minutes from the time of skin puncture Total No. of Ischemic stroke patients	x100	Monthly	Measures outcome. Refine prediction of early neurological improvement. Target: achieve TICI 2B or higher ≤60 minutes from the time of skin puncture

Sample size calculation (Monthly)

Solvent formula

n=N/(1+Ne2)

(Where n=Number of samples, N = Total population and e=Error tolerance)

Using 95% confidence interval (margin of error 95%), the values are calculated as follows:

Screening Population#	Sample Size*
50	44
100	79
150	108
200	132
500	217
1000	278
2000	322
5000	357
10000	370
20000	377

Screening population is the 'base' from which the samples would be selected. The 'base' shall be the average of the previous three months. For example, in the case of time for initial assessment of patients, this would be the average number of patients admitted per month in the preceding three months. Assuming that the average is 200, this would constitute the screening population and the organisation would have to sample 132 patients over the entire month.

* It is preferred to take samples on Stratified random basis where indicated to eliminate the bias that can occur due to convenient sampling. No sampling means that all the occurrence in the numerator shall be recorded irrespective of rate of occurrence.

ANNEXURE-2

Guidance on Monitoring Medication Errors

DEFINITION

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

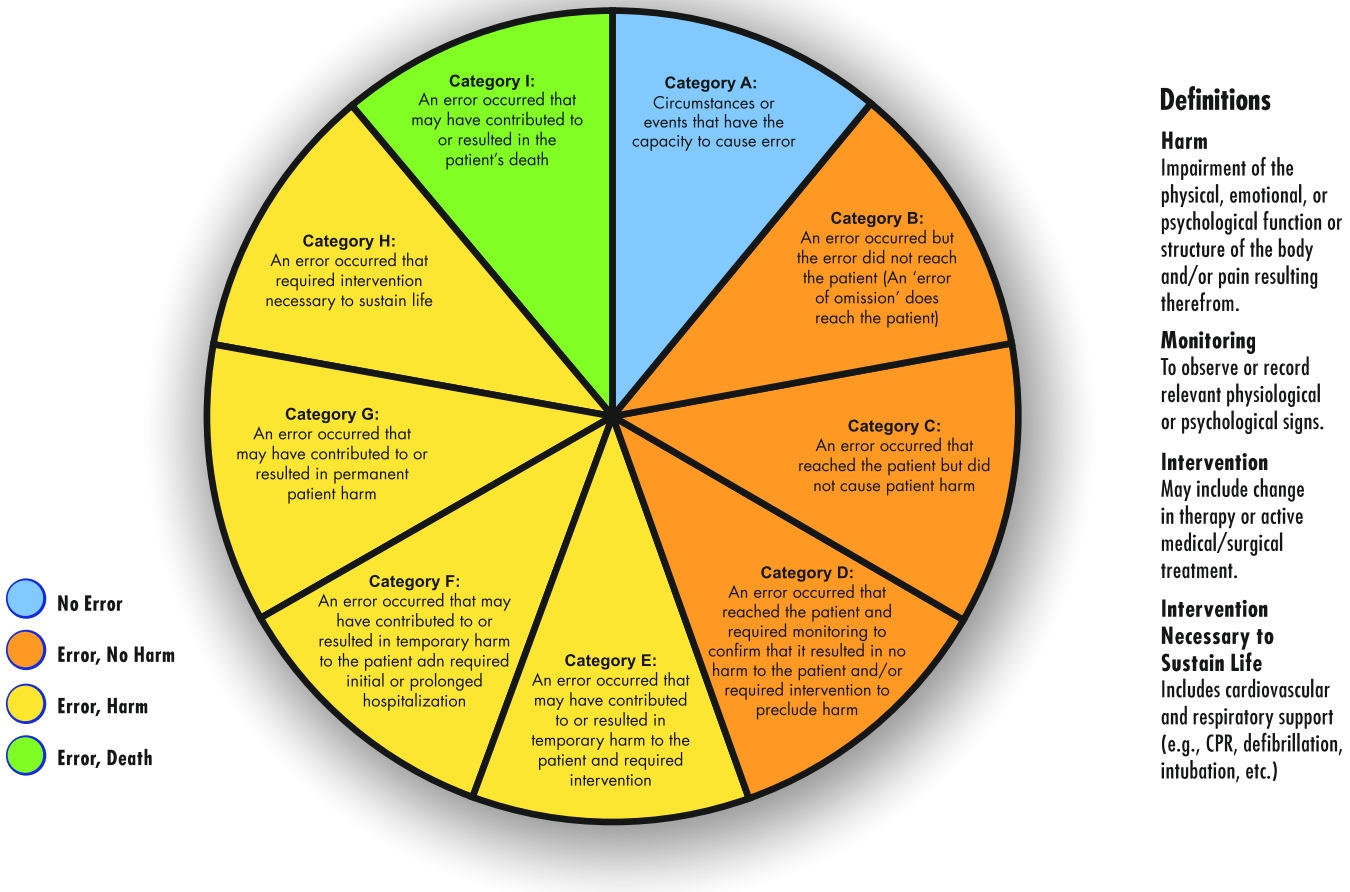
"A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient or consumer. Such events may be related to professional practice, health care products, procedures and systems, including prescribing, order communication, product labelling, packaging and nomenclature, compounding, dispensing, distribution, administration, education, monitoring and use."

CATEGORIES OF MEDICATION ERROR

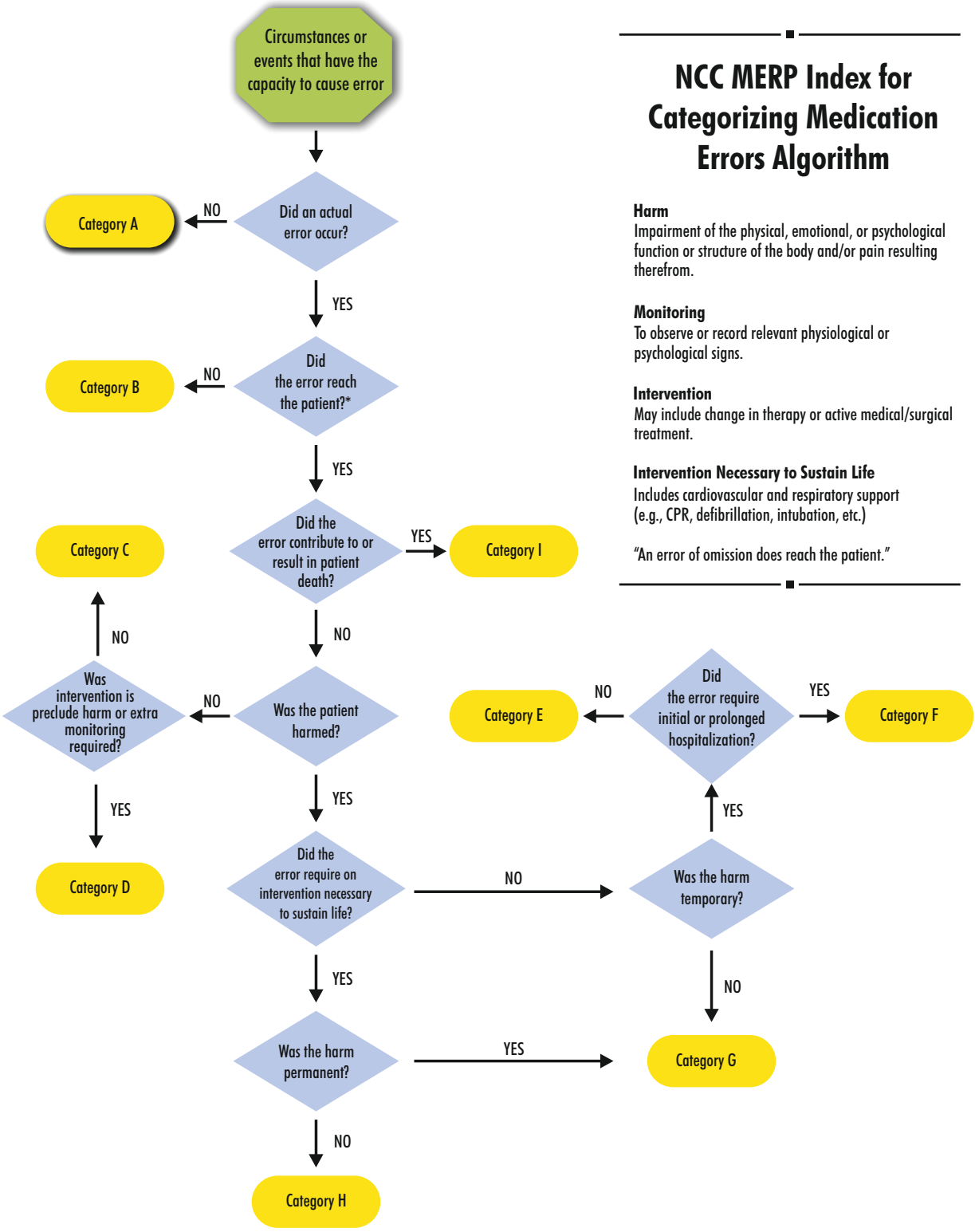
Level of Harm	Category of Error	Explanation of events/ error
NO ERROR	Category A	Circumstances or events that have the capacity to cause error
ERROR, NO HARM	Category B	An error occurred, but the error did not reach the patient (An "error of omission" does reach the patient.)
	Category C	An error occurred 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

Level of Harm	Category of Error	Explanation of events/ error
	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



National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) index for categorizing medication errors. © 2001 National Coordinating Council for Medication Error Reporting and Prevention.



NCC MERP Index for Categorizing Medication Errors Algorithm

Harm
Impairment of the physical, emotional, or psychological function or structure of the body and/or pain resulting therefrom.

Monitoring
To observe or record relevant physiological or psychological signs.

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

Intervention Necessary to Sustain Life
Includes cardiovascular and respiratory support (e.g., CPR, defibrillation, intubation, etc.)

"An error of omission does reach the patient."

Algorithm developed by the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) for applying the NCC MERP index for categorizing medication errors. © 2001, National Coordinating Council for Medication Error Reporting and Prevention.

METHODOLOGY

Chart Review, Audit and Self Reporting of Medication Errors are preferred methods in case medication charts are documented manually in the HCO. Software programmes can be used where prescriptions are generated online.

The format for capturing medication errors by routine chart review is provided in Annexure.

The idea of trying to identify personnel involved in errors is to ensure that the organisation does a proper root cause analysis and takes appropriate corrective and/or preventive action. It is not meant for punitive action. Process improvements are a must to reduce errors.

FORMULA

Total number of errors identified	X 100
Total number of opportunities	

Note: Self-reported medication errors, medication errors identified during audits or medication errors identified by any other methodology shall be added to the numerator i.e. the total number of errors identified.

SAMPLE SIZE

Adhere to the formula stated by NABH in its document on indicators for sample size calculation. The 'population' would be calculated from the running average of the previous three months of admissions.

Care needs to be taken to ensure that files from all clinical specialities are included. Stratified sampling will help the organisation achieve this.

CORRECTION

Pending analysis, it is imperative that the organisation do a correction to mitigate the effect(s) of the error. An example of how correction could be done is provided below.

For Category A and B	Administer the drug within a reasonable time frame
For Category C and D	Consult the clinician and follow orders accordingly

ANALYSIS

The first step in the analysis is the collation of data. This would help identify

- Categories of error
- Personnel involved in error

The data could be collated as per the table below.

	A	B	C	D	E	F	G	H	I	TOTAL
DOCTORS										
NURSES										
PHARMACISTS										
TOTAL										

The organisation should identify the proper root cause to ensure that effective corrective and/ or preventive action are taken. It is suggested that appropriate tools are used for the same.

Some of the possible causes of medications errors are provided in the table below.

People	Environment	Equipment	Process
Casual Attitude	Pharmacy- poor drug storage- poor ventilation, lighting, humidity	Defective syringe pumps	'Ten' rights not observed
Inexperienced/ New staff	Pharmacy space constraint for storage		Wrong stocking
Untrained staff	Pharmacy manpower constraint for dispensing		Wrong labelling
Shift change time/ in a hurry			Inappropriate syringe/ diluent
Emotionally unfit			No cross-checking
Physically unfit			Stock-outs
Wrong indent/ receiving			Unauthorized replacement of the drug

People	Environment	Equipment	Process
Patient identification error			LASA medicine error
Wrong dispensing pharmacy			
Wrong distribution GDA			
Illegible handwriting of doctors			

Some of the common corrective actions include

- Training
- Manpower recruitment
- Pharmacy stock rectification
- Equipment replacement/ rectification

SUGGESTED READING

1. www.nccmerp.org. National Coordinating Council for Medication Error Reporting and Prevention
2. American Society of Health-System Pharmacists. ASHP guidelines on pre- venting medication errors in hospitals. Am J Health-Syst Pharm. 2018; 75:1493–1517.
3. Nrupal Patel, Mira Desai, Samdih Shah et al. A study of medication errors in a tertiary care hospital. Perspect Clin Res. 2016 Oct-Dec; 7(4): 168–173.
4. Khandelwal AK. Getting it Right. Healthcare Radius 2014; March: 32-34

ANNEXURE-3

Medication Chart Review Checklist

Auditor: Date of Audit: Location:

UHID: Date of Admission:

Primary Consultant:

Drug allergies documented: Yes/No

	Error Perpetuation (Write Category of error from A to I)# In case of no error, kindly write 0; if a particular parameter is not applicable, kindly write NA (Multiple errors can be there and documented for each row and column)									
	Drug 1	Drug 2	Drug 3	Drug 4	Drug 5	Drug 6	Drug 7	Drug 8	Drug 9	Drug 10
Doctors										
1. Incorrect drug selection										
2. No/wrong dose										
3. No/wrong unit of measurement										
4. No/wrong frequency										
5. No/wrong route										
6. No/wrong concentration										
7. No/wrong rate of administration										
8. Illegible handwriting										
9. Non-approved abbreviations used										
10. Non-usage of capital letters for drug names										
11. Non-usage of generic names										
12. Non-modification of drug dose keeping in mind drug-drug interaction										

	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
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 X 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 ½ tablet of 500 mg is administered, stating that 1 tablet of 250 mg was administered (based on how the medication order was written) or not stating the actual brand that was administered in cases of brand substitution.

ANNEXURE-4
Quality tools

Quality Tools: QI data should be analysed using statistical/quality tools to assess compliance with the targets and identify areas for improvement.

Root Cause Analysis(RCA): RCA a very commonly used tool and is carried out for establishing causality when adverse trends are noted for any parameter or in the case of errors/incidents. RCA is a systematic, extensive and in-depth analysis of a problem with the view to get to the bottom of the problem. RCA is carried out by using either the 5 Why's Tool or the Cause and Effect Diagram.

5 Whys' tool(Taiichi Ohno), helps teams look beyond obvious and initial symptoms by asking "Why?" five times, sequentially in response to the first answer, till one reaches the root cause. As a result the focus (blame) shifts from individuals to the process. There may be multiple root causes of a problem; different people who see different parts of the system may answer the questions differently. The 5 whys has come under criticism for overly simplifying the problem on hand. The cause(s) of a problem and how to address them are likely to be understood more effectively by using multiple 5 Whys in conjunction with a Cause and Effect Diagram.

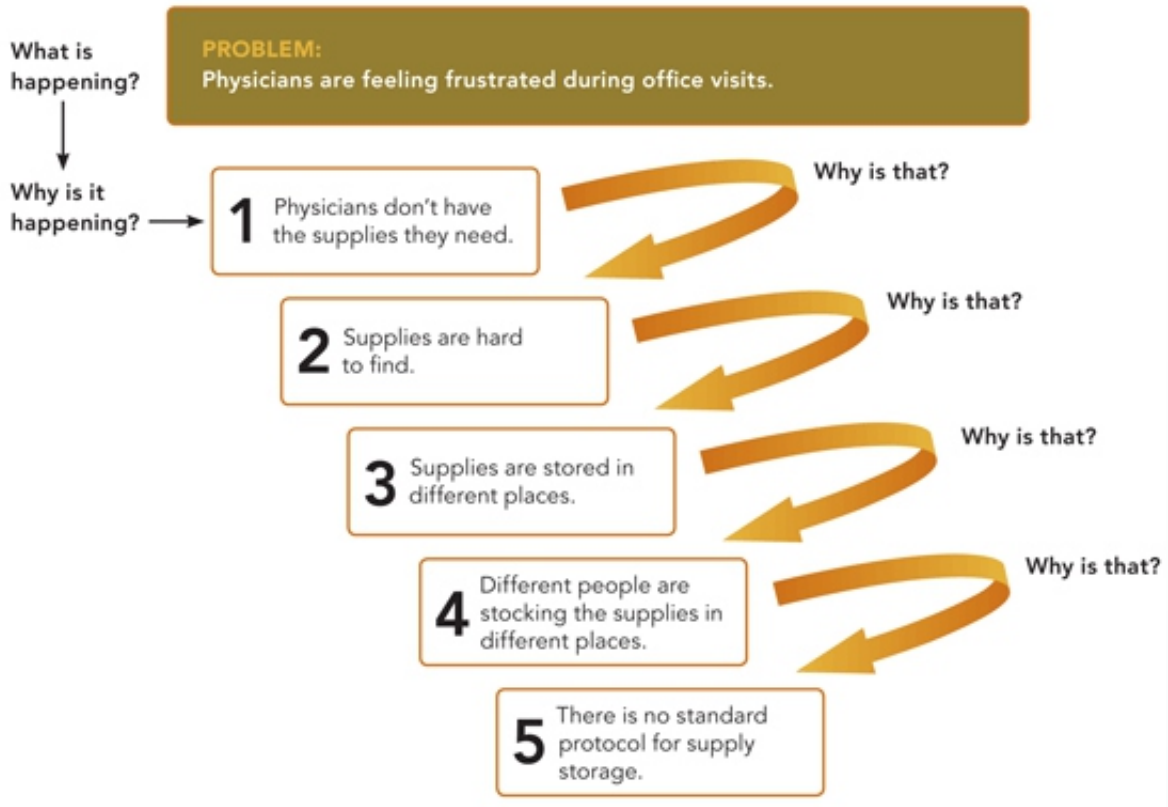


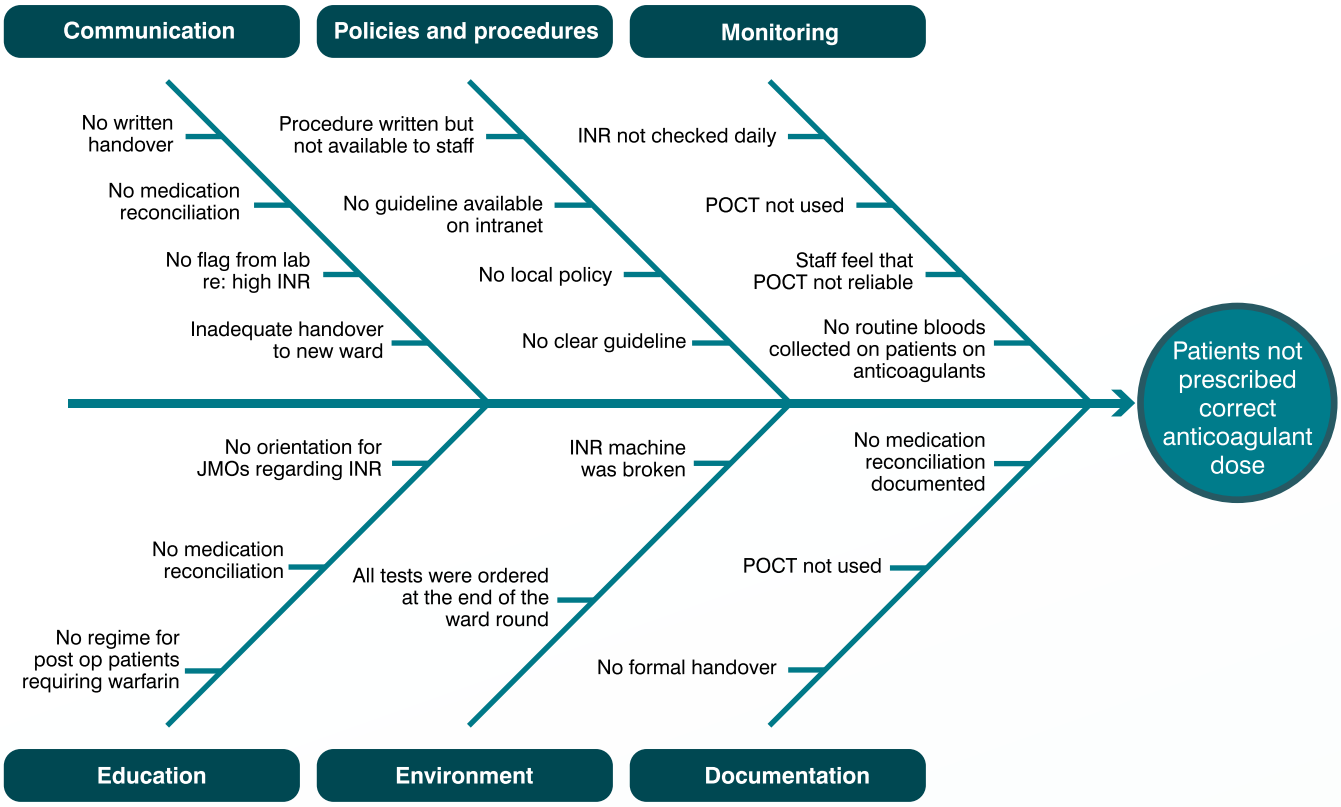
Figure 1. Illustration of 5-Why's Approach for carrying out a root cause analysis.
(https://www.aafp.org/fpm/2007/0500/p30.html accessed on April 30, 2022)

Cause and Effect Diagram: Also known as Ishikawa or fishbone diagram, graphically displays the relationship of the many causes to the effect, and to each other; helping teams identify areas for improvement. A line runs horizontally from the tail to the head of the fish, where the effect is written. Causes are grouped under the categories of Materials, Methods, Equipment, Environment, and People or as required.

The tool is used extensively to reach the root cause of deviations from any policy, procedure or protocol and outliers for indicator data and for detailed analysis of incidents and adverse events.

For e.g. Fish bone/cause and effects diagrams can be used to identify the causes of underuse of the electronic health records in a hospital setting by the doctors and nurses.

Affinity Diagram: These diagrams serve the same purpose as the Ishikawa charts but the visual presentation differs.



INR - International Normalised Ratio
POCT - Point of care testing

Figure 2. 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.

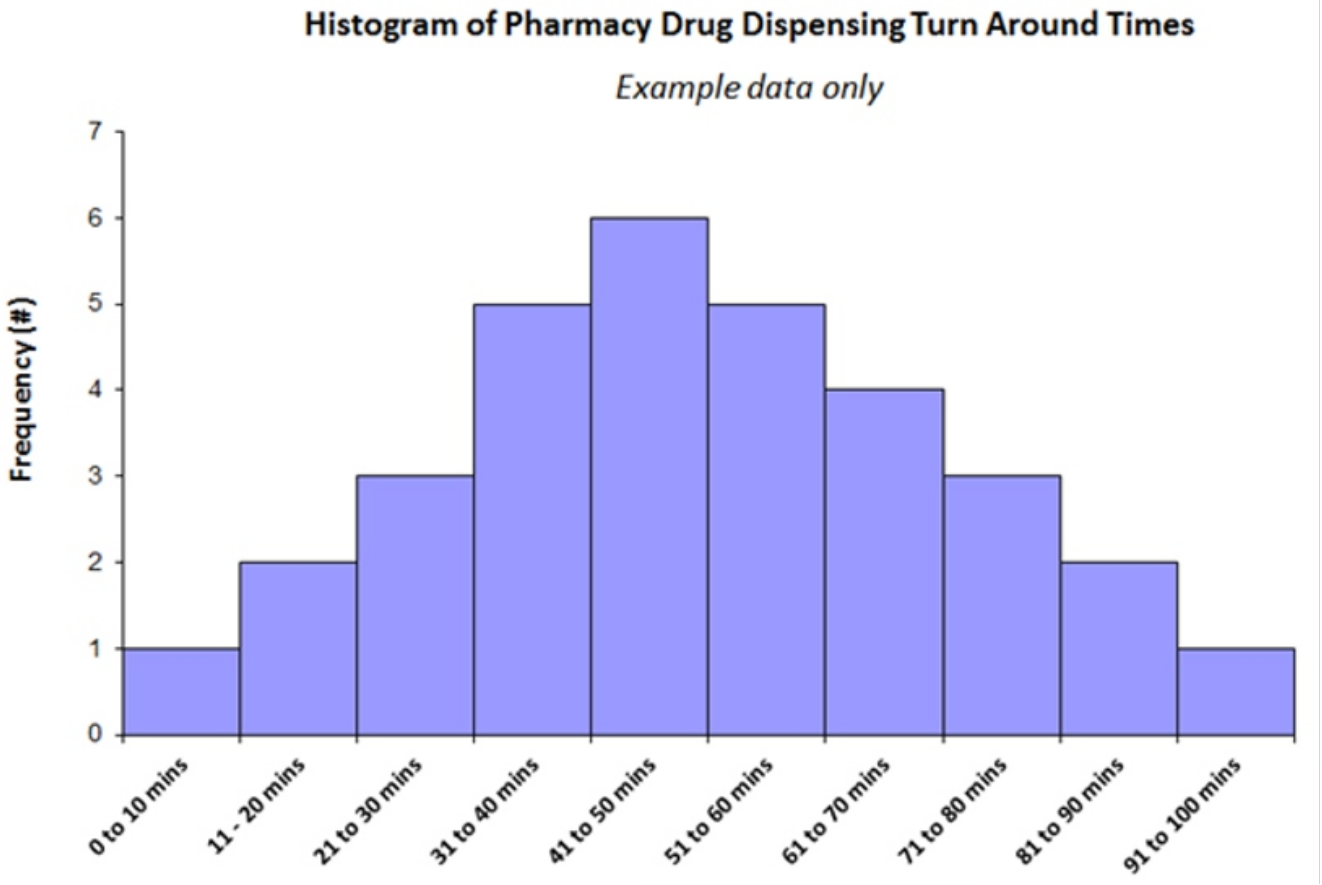


Figure 3. Histogram on turnaround time for dispensing of the drug
(https://www.cec.health.nsw.gov.au/CEC-Academy/quality-improvement-tools/histogram accessed on April 30, 2022)

Failure Modes and Effects Analysis (FMEA): FMEA is a tool for conducting a systematic, proactive analysis of a process in which harm may occur and prevent it by correcting the processes proactively, rather than reacting to adverse events after failures have occurred. The FMEA tool prompts teams to review, evaluate, and record the following:

- Steps in the process
- Failure modes (What could go wrong?)
- Failure causes (Why would the failure happen?)
- Failure effects (What would be the consequences(severity and frequency) of each failure?)
- How can the failure be prevented?

The tool forms the core of risk assessment and risk mitigation. FMEA is particularly useful in evaluating a new process prior to implementation and in assessing the impact of a proposed change to an existing process.

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.ihi.org/resources/Pages/Tools/Quality-Improvement-Essentials-Toolkit.aspx accessed on April 30, 2022)

Flowchart (process map): Flow charts help understand a process in depth through visual representation of its steps; and should be prepared in early phase of improvement work. It is a road map of where things are happening, the order in which things happen and the relationships between parts of a process. A Flow Chart is recommended as the first step in almost any study. Often a Flow Chart may reveal that a process does not operate the way management or the operators in the process actually think it does. A high level flow is chart is prepared first to give a helicopter's view of the process followed by a detailed flow chart. Flow charts help identify gaps in the process, it's 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-

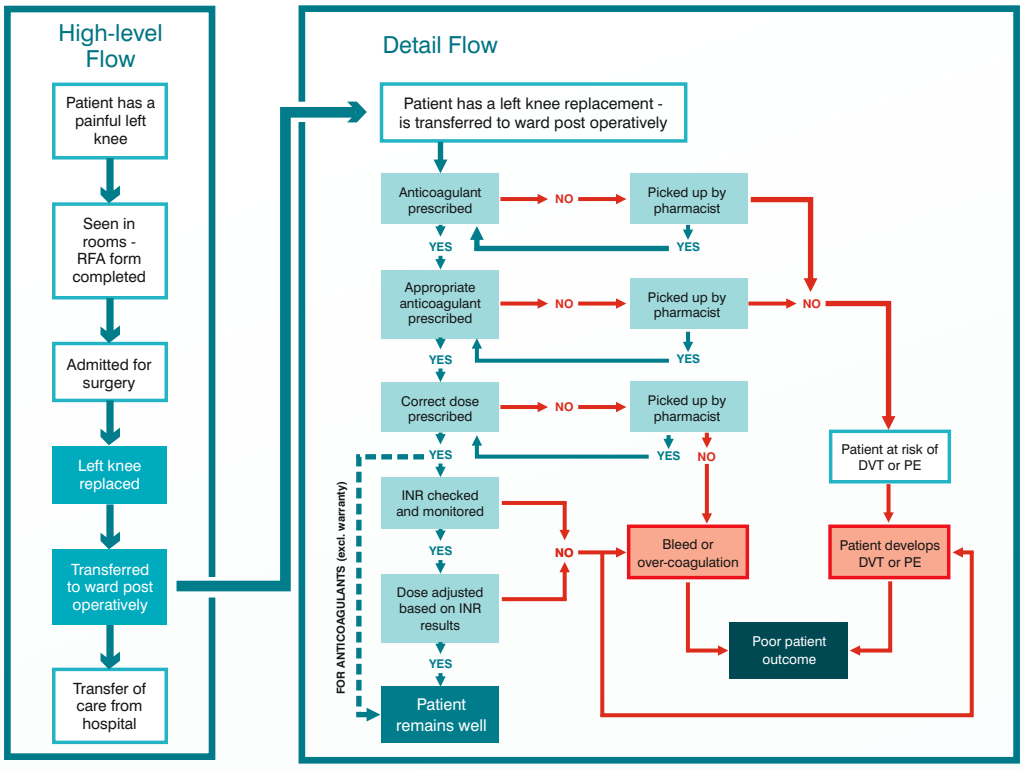


Figure 5. Flow chart of a patient's journey within the hospital
(https://www.cec.health.nsw.gov.au/CEC-Academy/quality-improvement-tools/flow-charts accessed on April 30, 2022

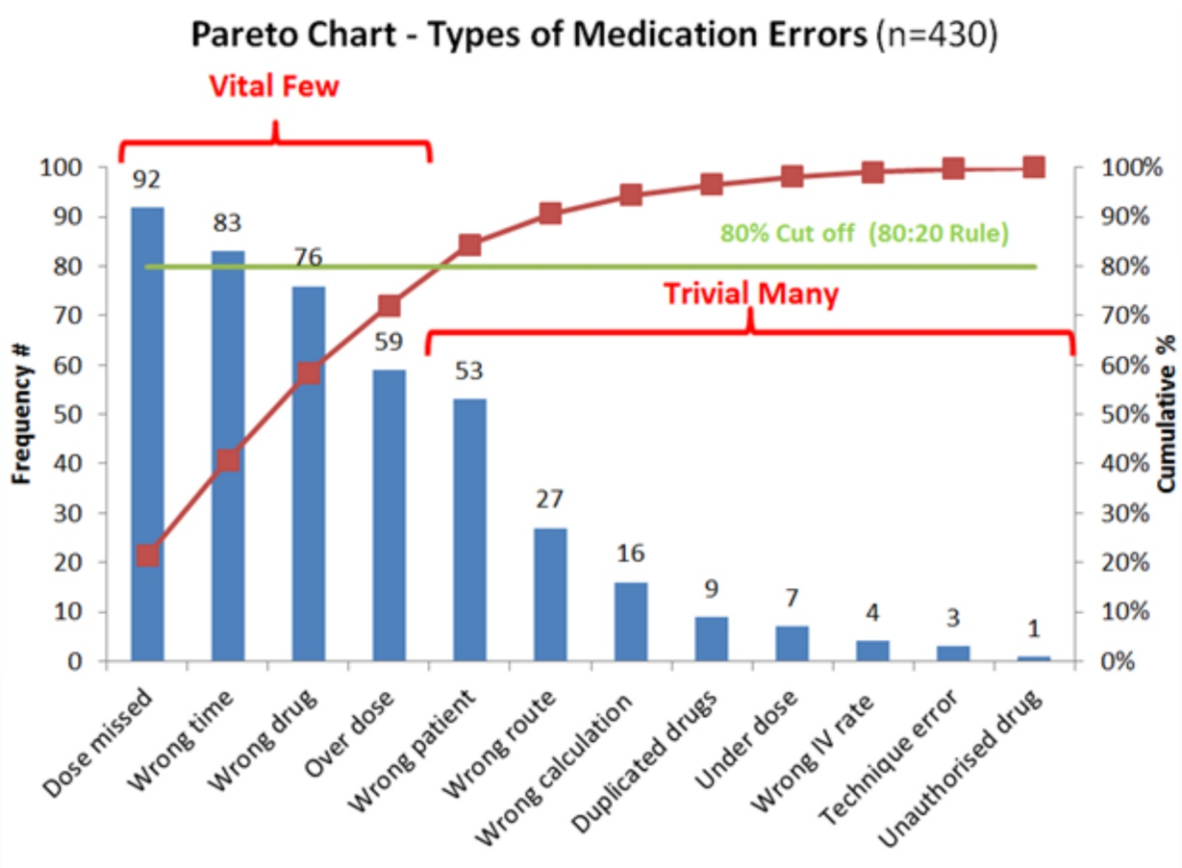
Pareto Chart: The "Pareto Principle" is the "80/20 rule" and works on the theory that roughly 80% of the effect comes from 20%("the vital few") of the causes. The "vital few" are easily distinguished from the "useful many" by plotting them as a bar diagram. Teams can prioritize and focus improvement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



Run Chart & Control Chart : A run chart is a graph of data over time and assess variations in performance over a period of time and indicate trends. A control chart, with an upper(UCL) and a lower control limit (LCL), distinguishes between common and special causes of variation within a process

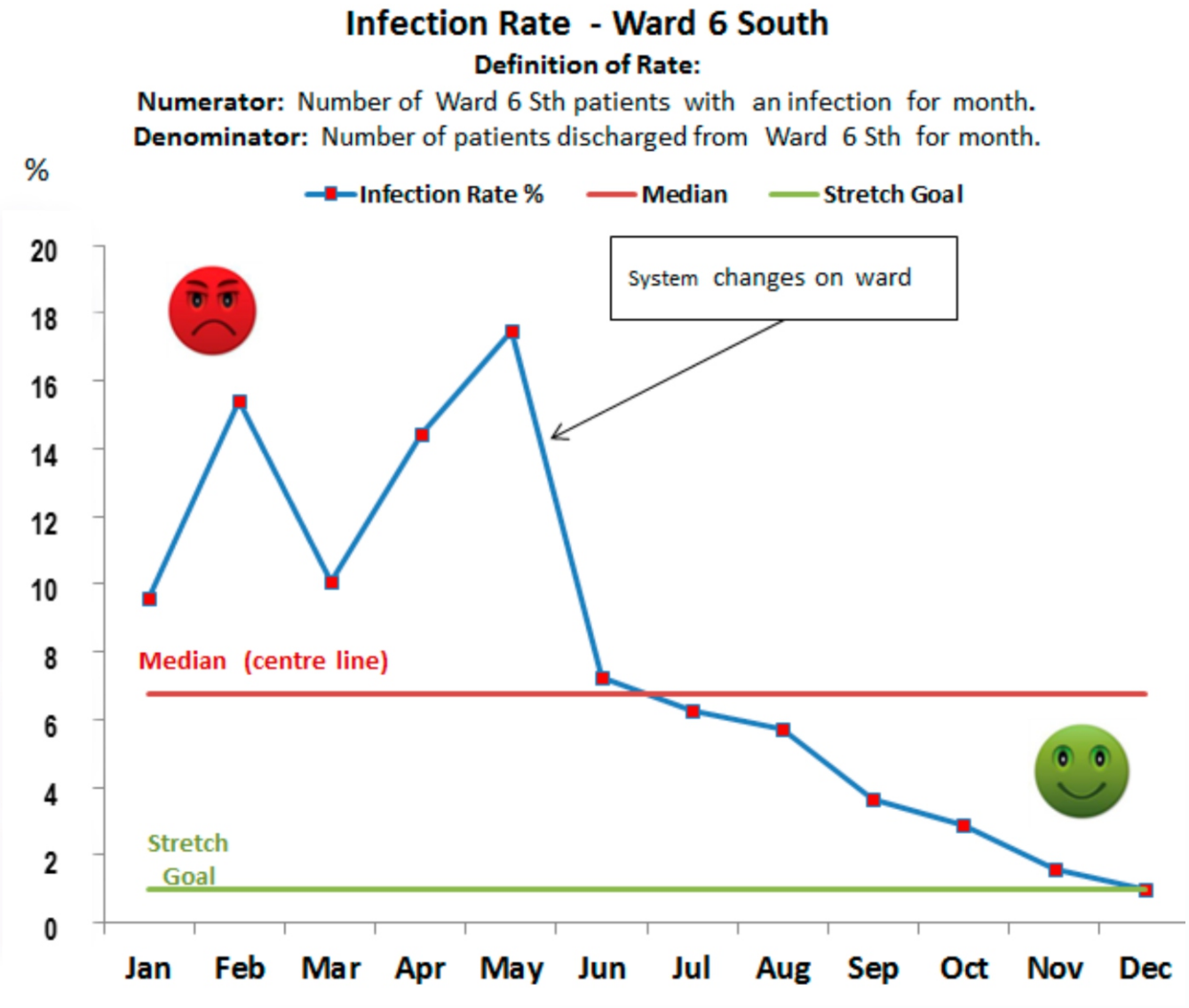


Figure 6. Simple Annotated Run chart with UCL and LCL of an infection rate over time
(https://www.cec.health.nsw.gov.au/CEC-Academy/quality-improvement-tools/run-charts accessed on April 30, 2022)

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.

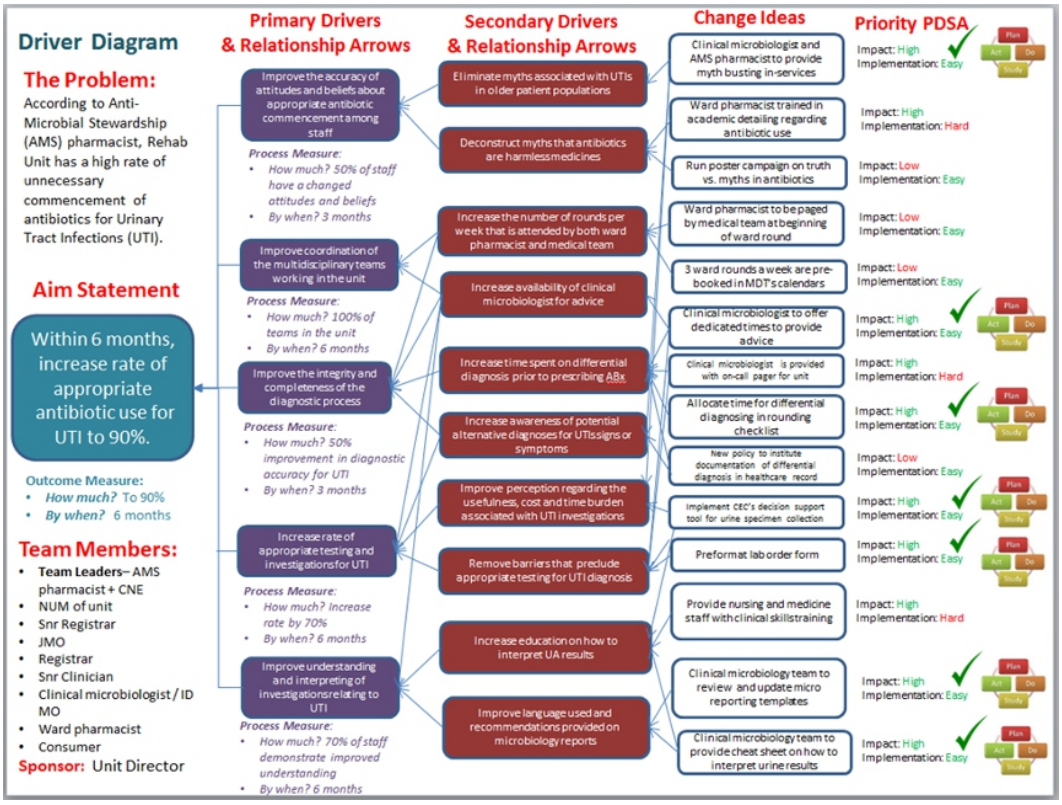


Figure 7 Driver Diagram
(https://www.cec.health.nsw.gov.au/CEC-Academy/quality-improvement-tools/driver-diagrams accessed on April 30, 2022)

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

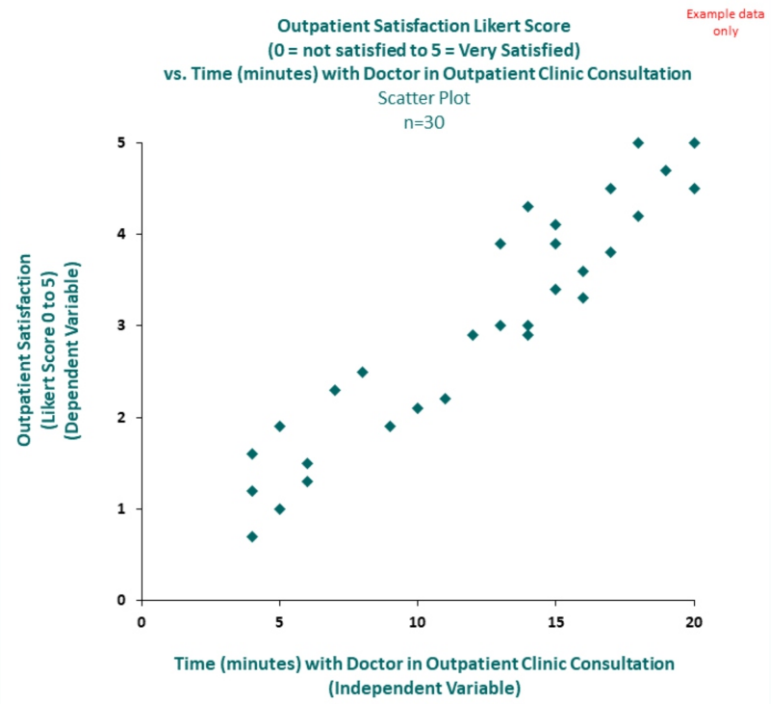


Figure 8 Scatter diagram showing patient satisfaction using likert's score v/s time with doctor consultation
(https://www.cec.health.nsw.gov.au/CEC-Academy/quality-improvement-tools/scatter-plot accessed on April 30, 2022)

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

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

Quality improvement technique/tool	Decisions	Describe problem	Cause analysis	Develop action plan	Monitor progress
Histogram		Yes		Yes	Yes
Pareto Chart	Yes	Yes		Yes	Yes
Driver Diagram	Yes	Yes		Yes	
Flow chart/Process Map		Yes		Yes	
Run chart	Yes				Yes
Scatter Diagram/Plot	Yes	Yes			
Fishbone diagram		Yes	Yes		

Continuous Quality Improvement(CQI): CQI is a progressive incremental improvement of processes, safety, and patient care. Introduced by Shewhart and propagated by Deming, CQI is an analytical decision making tool which allows one to see when a process is working predictably and when it is not.

The Model for Improvement(MFI): The MFI asks three fundamental questions before embarking on a quality improvement project, which can be addressed in any order.

- What are we trying to achieve?
- What changes can we make that will result in an improvement?
- How will know that the change is an improvement?

This is followed by PDSA cycles to test changes in real work settings to determine if the change is an improvement.

Models for CQI : The most common CQI methodologies used in healthcare are the API's Model for improvement(MFI), FOCUS plan-do-study-act (PDSA), Six-Sigma, and Lean strategies. They typically include testing of ideas and redesign of process or technology based on lessons learned. Steps involved in CQI are Plan-Do-Study-Act (PDSA) cycle. The MFI and FOCUS frameworks have been developed to precede the use of PDSA and PDCA cycles respectively.

PDSA/PDCA cycle: Involves a sequence of 4 repetitive steps, Plan-Do-Study/Control-Act, eventually leading to exponential improvements 'Plan' phase involves detailing ideas for improvement, 'Do' phase involves implementation and defect prevention. 'Study' phase involves review and analysis of data(Adapt/Adopt/Abandon the change and repeat PDSA). 'Act' phase includes incorporation of lessons learnt into the test cycle. The cycle is repeated again and again as waves of small improvements are considered, tested, evaluated, and incorporated, if effective. This is the most commonly used tool for clinical audits.

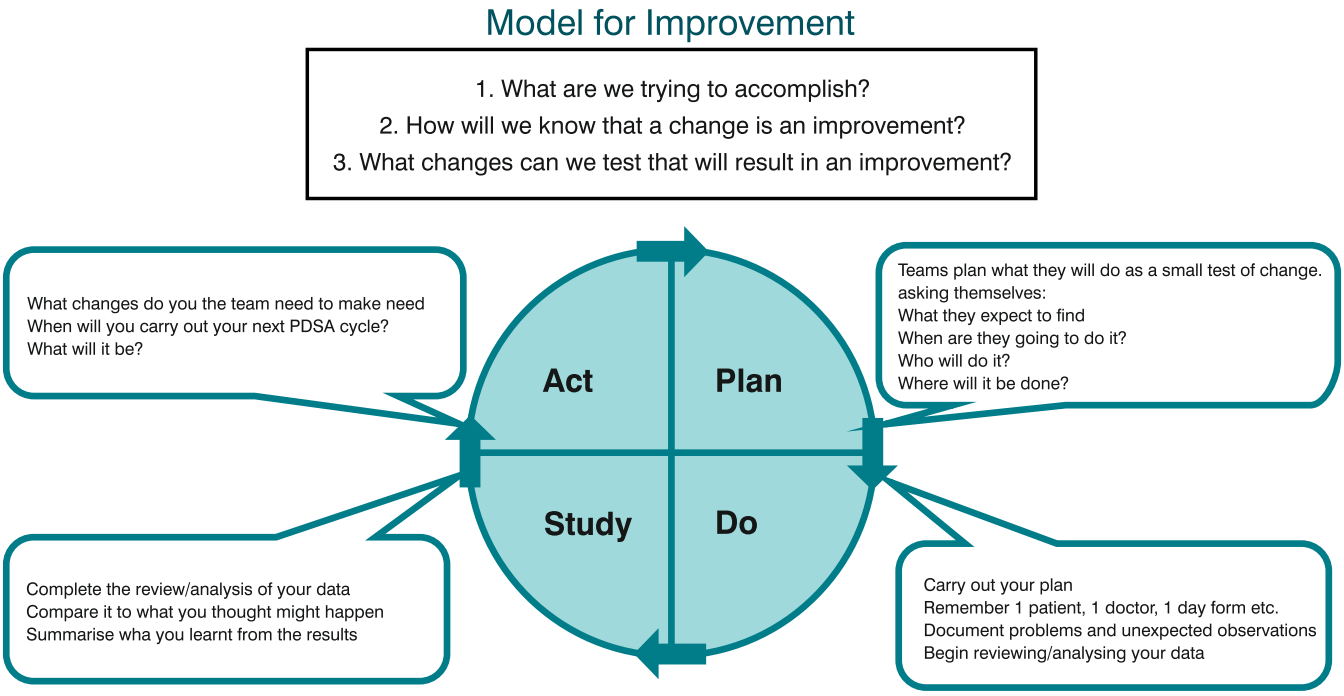


Figure 10. Model for Improvement and PDSA
(https://www.cec.health.nsw.gov.au/CEC-Academy/quality-improvement-tools/model-for-improvement-and-pdsa-cycles accessed on April 30, 2022)

FOCUS-PDCA: This model also has two phases. The 'FOCUS' phase focusses attention at the opportunity to improve, and the 'PDCA' phase for pursuit of improvement and assessment of effectiveness of the interventions.

- F = Find what needs to be improved on;
- O = Organize team with good knowledge in the process
- C = Clarify the present knowledge of the process
- U = Understand factors responsible for variations
- S = Select interventions that evidently might improve process

Six-sigma: Six-sigma is a widely used model that is now making steady in-roads into medicine. It seeks to improve performance through identifying causes of process defects/errors and eliminating them. At Six Sigma, error rates should be less than 3.7/million opportunities. Two methods have mainly been employed- DMAIC and DMADV. DMAIC is applicable for existing process improvement; DMADV is used for new design process optimization.

Lean and Lean-Sigma : Originated by Toyota Inc., Japan, this model is essentially geared towards improving process/product/service flow and eliminates waste by identifying and removing non-value added steps Embracing Lean in healthcare, eliminates waste throughout the entire operational system; whilst simplifying and improving the processes, resulting in low cost of production and fast through-put times. A few establishments, have combined Lean and Six Sigma concepts to obtain better quality improvement effects. Such a combination is known as Lean-Sigma.

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