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BHUTAN STANDARD

Bhutan Healthcare Standard for Quality Assurance

ICS 11.020.10

BHUTAN STANDARDS BUREAU

The National Standards Body of Bhutan

THIMPHU 11001

April 2018 **Price group: I**

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FOREWORD

This Bhutan Standard was adopted by the Bhutan Standards Bureau after it was finalized by the Pharmaceuticals and Traditional Medicines Technical Committee (TC-05) and endorsed by the Bhutan Standards Bureau Board.

Introduction

Standards can be explicit (written) or implicit (understood). Implicit health care standards are those practices which are based on the guidance of experienced professionals in a specific environment without written policies and procedures. Converting implicit standards to explicit standards provides consensus on a way to provide quality care, reduce variation between health care providers and allows a baseline measure for monitoring quality and safety. The primary aim of the standard is to provide quality healthcare services and to meet the expectations of the public service. Therefore, this standard is intended to outline the minimum requirements for providing quality healthcare services by all the Healthcare centres in the country both private and government settings. The standard requirements may vary from one health centre to another depending on the range of services delivered. It will be the responsibility of every healthcare provider to adhere to the standards to ensure the quality and safety of the patients. The compliance with the specific requirements of the standards will be monitored using key performance indicators (KPI). HCC shall record and report the KPIs on regular intervals as defined in Bhutan Healthcare Standard for Quality Assurance (BHSQA).

1. Scope

The BHSQA applies to the following Healthcare service standards: Access, Assessment and Continuity of Care (ACC), Care of Patients (COP), Management of Medication (MOM), Patient's Rights and Education (PRE), HCC Infection Control (HIC), Continuous Quality Improvement (CQI), Responsibilities of Management (ROM), Facility Management and Safety (FMS), Human Resource Management (HRM), Information Management System (IMS) for Referral HCCs, District HCCs and BHU-Is and BHU-IIs.

2. Objectives

a) To develop a quality culture in all the healthcare centres by establishing quality assurance and management system.
b) To ensure safety, equity, accessibility and uniformity of the healthcare services.
c) To enhance the effectiveness and efficiency of the existing healthcare services.
d) To promote teamwork and ownership for quality and safety of the services being provided.
e) To encourage the environment of continuous quality improvement efforts.

3. Normative References

There are no normative references for this document.

4. Definitions

For the purposes of this standard, the following definitions shall apply. The commonly-used terminologies in the standards are briefly described and explained herein to remove any ambiguity regarding their comprehension. The definitions narrated have been taken from various authentic sources as stated, wherever possible. Notwithstanding the accuracy of the explanations given, in the event of any discrepancy with a legal requirement enshrined in the law of the land, the provisions of the latter shall apply.

4.1 Accreditation

4.1.1 A process of external review of the quality of the health care being provided by the HCC. This is generally carried out by a non-governmental HCC.

4.1.2 It also represents the outcome of the review and the decision than an eligible HCC meets and applicable set of standards.

4.2 Accreditation assessment

The evaluation process for assessing the compliance of the HCC with the applicable standards for determining its accreditation status.

4.3 Advance life support

Emergency medical care for sustaining life, including defibrillation, airway management, and drugs and medications.

4.4 Adverse drug event

Adverse event: Any untoward medical occurrence that may present during treatment with a pharmaceutical product but which does not necessarily have a causal relationship with this treatment.

Adverse Drug Reaction (ADR): 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.

Therefore ADR = adverse event with a causal link to a drug.

Adverse drug event: The FAD recognizes the term adverse drug event to be a synonym for an adverse event.

In the patient-safety literature, the terms adverse drug event and the adverse event usually denote a causal association between the drug and the event, but there is a wide spectrum of definitions for these terms, including harm caused by a

a) Drug
b) The harm caused by drug use, and
c) A medication error with or without harm.

Institute of Medicine: ―An injury resulting from medical intervention related to a drug‖, which has been simplified to “an injury resulting from the use of a drug”. Adverse drug events extend beyond adverse drug reactions to include harm from overdoses and under-doses usually related to medication errors. A minority of adverse drug events is medication errors, and medication errors rarely result in adverse drug events.

4.5 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)

4.6 Ambulance

A patient carrying vehicle having facilities to provide unless otherwise indicated at least basic life-support during the process of transportation of a patient. There are various types of ambulances that provide special services viz. coronary care ambulance, trauma ambulance, air ambulance, etc.

4.7 Anaesthesia

It consists of general anaesthesia and spinal or major regional anaesthesia and does not include local anaesthesia. Anaesthesia is a drug-induced loss of consciousness during which a patient cannot be aroused even by painful stimulation. The ability to independently maintain ventilatory function is often impaired.

4.8 Assessment

All activities including history taking, physical examination, clinical laboratory investigations that contribute to determining the prevailing clinical status of the patient.

4.9 Autopsy

4.9.1 An examination of a cadaver in order to determine the cause of death or to study pathologic changes.

4.9.2 A surgical procedure performed after death to examine body tissues and determine the cause of death

4.10 Barrier nursing

The nursing of a patient with infectious diseases in isolation to prevent the spread of infection. As the name implies, the aim is to erect a barrier to the passage of infectious pathogenic organisms between the contagious patient and other patients and staff in the HCC, and thence to the outside world. The nurses wear gowns, masks, and gloves, and they observe strict rules that minimize the risk of passing on infectious agents.

4.11 Basic life support

Basic life support (BLS) is the level of medical care which is used for patients with life-threatening illnesses or injuries until the patient can be given full medical care.

4.12 Breakdown maintenance

Activities which are associated with the repair and servicing of site infrastructure, gildings, plant or equipment within the site's agreed building capacity allocation which has become inoperable or unusable because of the failure of component parts.

4.13 Bylaws

A rule governing the internal management of HCC. It can supplement or complement the government law but cannot countermand it, e.g. municipal bylaws for construction of HCCs/nursing homes, for disposal of hazardous and/or infectious waste.

4.14 Clinical audit

A quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change. (Principles for Best Practice in Clinical Audit 2002, NICE/CHI).

4.15 Clinical practice guidelines

Clinical practice guidelines are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances. (Field and Lohr 1990. Page 38).

4.16 Competence

Demonstrated ability to apply knowledge and skills (ISO 9001:2015).

4.17 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.

4.18 Consent

4.18.1 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, an alternative procedure with their risk and benefits so as to enable the patient to take an informed decision of his/her health care.

4.18.2 In law, it means active acquiescence or silent compliance by a person legally capable of consenting. In Bhutan, 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.

4.19 Control charts

Statistical tool used in quality control to (a) analyse and understand process variables, (b) determine process capabilities, and to (c) monitor effects of the variables on the difference between target and actual performance. Control charges indicate upper and lower control limits, and often include a central (average) line, to help detect a trend of plotted values. If all data points are within the control limits, variations in the values may be due to a common cause and process is said to be in control'. If data points fall outside the control limits, variations may be due to a special cause and the process is said to be out of control.

4.20 Credentialing

The process of obtaining, verifying and assessing the qualification of a healthcare provider.

4.21 Critical path method (CPM)

The critical part method (CPM) is a step-by-step technique for process planning that defines critical and non-critical tasks with the goal of preventing time-frame problems and process bottlenecks. The CPM is ideally suited to projects consisting of numerous activities that interact in a complex manner.

In applying the CPM, there are several steps that can be summarized as follows:

a) Define the required tasks and put them down in an ordered (sequenced) list.
b) Create a flowchart or other diagram showing each task in relation to the others.
c) Identify the critical and non-critical relationships (paths) among tasks.
d) Determine the expected completion or execution time for each task.
e) Locate or devise alternatives (backups) for the most critical paths.

4.22 Data

Raw facts, clinical observations, or measurements collected during an assessment activity.

4.23 Discharge summary

A part of a patient record that summarizes 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).

4.24 Disciplinary proceedings

A sequence of activities to be carried out when staff does not conform to the laid-down norms, rules and regulations of the HCC.

4.25 Employees

All members of the HCC who are employed full item and are paid suitable remuneration for their services as per the laid down policy.

4.26 End of life

Period of time marked by disability or disease that is progressively worse until death.

4.27 Ethics

Medical ethics is the discipline of evaluating the merits, risks, and social concerns of activities in the field of medicine. (en.wikipeida.org/wiki/Medical ethics)

4.28 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.

4.29 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.

4.30 Failure Mode and Effect Analysis (FMEA)

A common process used to prospectively identifies error risk within a particular process. FMEA begins with a complete process mapping that identifies all the steps that must occur for a given process to occur (e.g., programming an infusion pump or preparing an intravenous medication in the pharmacy). With the process mapped out, the FMEA then continues by identifying the ways in which each step can go wrong (i.e., the failure modes for each step), the probability that each error will be detected (i.e., so that it can be corrected before causing harm), and the consequences or impact of the error not being detected. The estimates of the likelihood of a particular process failure, the chance of detecting such failure, and its impact are combined numerically to produce a criticality index.

This criticality index provides a rough quantitative estimate of the magnitude of hazard posed by each step in a high-risk process. Assigning a criticality index to each step allows

prioritization of targets for improvement. For instance, an FMEA analysis of the medication-dispensing process on a general HCC word might break down all steps from receipt of orders in the central pharmacy to filling automated dispensing machines by pharmacy technicians. Each step in this process would be assigned a probability of failure and an impact score so that all steps could be ranked according to the product of these tow numbers. Steps ranked at the top (i.e., those with the highest criticality indices) would be prioritized for error proofing.

4.31 Formulary

An approved list of drugs. Drugs contained on the formulary are generally those that are determined to be cost-effective and medically effective.

The list is compiled by professionals and physicians in the field and is updated at regular intervals. Changes may be made depending on availability or market.

4.32 Goal

A broad statement describing a desired future condition or achievement without being specific about how much and when. The term —goals refer 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. (MBNQA)

4.33 Grievance-handling

The sequence of activities carried out to address the grievances of patients, visitors, relatives and staff.

4.34 Hazardous materials

Substances dangerous to human and other living organisms. They include radioactive or chemical materials

4.35 Hazardous waste

Waste materials dangerous to living organisms. Such materials require special precautions for disposal. They include 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.

4.36 Healthcare-associated infection

Healthcare-associated infections (HAIs) are infections caused by a wide variety of common and unusual bacteria, fungi, and viruses during the course of receiving medical care. (CDC)This was earlier referred to as Nosocomial/HCC-acquired/HCC-associated infection(s).

4.37 HCC

A generic term is used to describe the various types of HCC that provide healthcare services. This includes ambulatory care centres, HCCs, laboratories, etc.

4.38 High-dependency unit

A high-dependency unit (HDU) is an area for patients who require more intensive observation, treatment and nursing care that are not usually provided for in a ward. It is a standard of care between the ward and full intensive care.

4.39 In service education/training

Organized 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.

4.40 Indicator

A statistical measure of the performance of functions, systems or processes over time. For example, HCC acquired infection rate, mortality rate, caesarean section rate, absence rate, etc.

4.41 Information

Processed data which lends meaning to the raw data.

4.42 Intent

A brief explanation of the rational, meaning and significance of the standards laid down in a particular standard.

4.43 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 minimize total costs

4.44 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 specialized 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.

4.45 Job description

a) It entails an explanation pertaining to duties, responsibilities and conditions required to perform a job.

b) 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.

4.46 Job specification

a) The qualifications/physical requirements, experience and skills required to perform a particular job/task.

b) A statement of the minimum acceptable qualifications that an incumbent must possess to perform a given job successfully.

4.47 Laws

Legal document setting forth the rules of governing a particular kind of activity, e.g. organ transplantation act, which governs the rules for undertaking organ transplantation.

4.48 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 (British Standard 3811:1993).

4.49 Medical equipment

Any fixed or portable non-drug item or apparatus used for diagnosis, treatment, monitoring and direct care of a patient.

4.50 Medication error

a) A medication error is any preventable event that may cause or lead to inappropriate medication use or harm to a patient (FDA)

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

4.51 Mission

An HCC's purpose (ASQ).This refers to the overall function of an HCC. The mission answers the question, —What is this HCC attempting to accomplish? The mission might define patients, stakeholders, or markets served, distinctive or core competencies or technologies used. (MBNDQA)

4.52 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 standardized procedures and methods of data collection.

4.53 Multi-disciplinary

A generic term which includes representatives from various disciplines, professions or service areas.

4.54 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. (Wikipedia) Errors that did not result in patient harm, but could have, can be categorized as near-misses.

4.55 No harm

This is used synonymously with a near miss. However, some authors draw a distinction between these tows phrases. A near-miss is defined when an error is realized just in the nick of time and abortive action is instituted to cut short its translation. In no harm scenario, the error is not recognized and the deed is done but fortunately or 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).

4.56 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 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)

The notifiable diseases are Polio, Influenza, Malaria, Rabies, HIV/AIDS, Louse-borne typhus, Tuberculosis, Leprosy, Leptospirosis, Viral hepatitis etc. The various diseases notifiable under the factories act like lead poisoning, byssinosis, anthrax, asbestosis and silicosis.

4.57 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 (ASQ).

4.58 Objective element

It is that component of the standard which can be measured objectively on a rating scale. The acceptable compliance with the measurable elements will determine the overall compliance with the standard.

4.59 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

4.60 Operational plan

The operational plan is 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 sustainability of the

HCC's achievements.

4.61 Organogram

A graphic representation of reporting relationship in HCC

4.62 Outsourcing

The hiring of services and facilities from other HCC 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 with other institutions after drawing a memorandum of understanding that clearly lays down the obligations of both HCCs: the one which is outsourcing and the one which is providing the outsourced facility. It also addresses the quality-related aspects.

4.63 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.

4.64 Patient record/medical record/clinical record

A document which contains the chronological sequence of events that a patient undergoes during his stay in the HCC. It includes demographic data of the patient, assessment findings, diagnosis, consultations, procedures undergone, progress notes and discharge summary. (Death certificate, where required)

4.65 Performance appraisal

It is the process of evaluating the performance of employees during a defined period of time with the aim of ascertaining their suitability for the job, a potential for growth as well as determining training needs.

4.66 Plan of care

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.

4.67 Policies

They are the guidelines for decision-making, e.g. admission, discharge policies, antibiotic policy, etc.

4.68 Preventive maintenance

It is a set of activities that are performed on plant equipment, machinery, and systems before the occurrence of a failure in order to protect them and to prevent or eliminate any degradation in their operating conditions. The maintenance carried out at predetermined intervals or according to prescribed criteria and intended to reduce the probability of failure or the degradation of the functioning of an item. (British Standard 3811:1993).

4.69 Privileging

It is the process for authorizing all medical professionals to admit and treat patients and provide other clinical services commensurate with their qualifications and skills.

4.70 Procedure

a) A specified way to carry out an activity or a process.
b) 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.

4.71 Process

A set of interrelated or interacting activities which transforms inputs into outputs.

4.72 Program

A sequence of activities designed to implement policies and accomplish objectives.

4.73 Project Evaluation and Review Technique (PERT)

PERT is a method to analyse the involved tasks in completing a given project, especially the time needed to complete each task and to identify the minimum time needed to complete the total project.

PERT breaks down the project into events and activities and lays down their proper sequence, relationships, and duration in the form of a network. Lines connecting the events are called paths, and the longest path resulting from connecting all events are called the critical path. The length (duration) of the critical path is the duration of the project, and any delay occurring along it delays the whole project. PERT is a scheduling tool and does not help in finding the best or the shortest way to complete a project.

4.74 Protocol

A plan or a set of steps to be followed in a study, an investigation or an intervention.

4.75 Quality

a) The degree to which a set of inherent characteristics fulfil requirements.
b) Characteristics imply a distinguishing feather Requirements are a need or expectation that is stated, generally implied or obligatory
c) The degree of adherence to pre-established criteria or standards.

4.76 Quality Assurance

Part of quality management focused on providing confidence that quality requirements will be fulfilled (Clause 3.3.6 of ISO 9000:2015).

4.77 Quality improvement

Ongoing response to quality assessment data about service in ways that improve the process by which services are provided to consumers/patients.

4.78 Re-assessment

It implies a continuous and ongoing assessment of the patient, which is recorded in the medical records as progress notes

4.79 Resources

It implies all inputs in terms of men, material, money machines, minutes (time), methods, meters (space), skills, knowledge and information that are needed for efficient and effective functioning of an HCC.

4.80 Restraints

Devices used to ensure safety by restricting and controlling a person's movement. Many facilities are —restraint free or use alternative methods to help modify behaviour. www.alz.org/Resources/Glossalry.asp. Restraint may be physical or chemical (by use of sedatives).

4.81 Risk assessment

Risk assessment is the determination of a quantitative or qualitative value of risk related to a concrete situation and a recognized threat (also called hazard). Risk assessment is a step in a risk management procedure.

4.82 Risk management

Clinical and administrative activities to identify evaluate and reduce the risk of injury.

4.83 Risk reduction

The conceptual framework of elements considered with the possibilities to minimize vulnerabilities and disaster risks throughout society to avoid (prevention) or to limit (mitigation and preparedness) the adverse impacts of hazards, within the board context of sustainable development (source: http://www.preventionweb.net/english/professional/terminology/). It is the decrease in the risk of a healthcare facility, given activity, and treatment process with respect to patient, staff, visitors and community.

4.84 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 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.

4.85 Safety

The degree to which the risk of an intervention/procedure, in the care environment is reduced for a patient, visitors and healthcare providers.

4.86 Safety program

A program focused on patient, staff and visitor safety.

4.87 Scope of services

The range of clinical and supportive activities that are provided by a healthcare HCC.

4.88 Security

Protection from loss, destruction, tampering, and unauthorized access or use.

4.89 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.

4.90 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.

4.91 Social responsibility

A balanced approach for HCC to address economic, social and environmental issues in a way that aims to benefit people, communities and society, e.g. adoption of villages for providing health care, holding of medical camps and proper disposal of HCC wastes.

4.92 Staff

All personnel working in the HCC including employees, medical professionals, part-time workers, contractual personnel and volunteers.

4.93 Standard precautions

a) 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.

b) A set of guidelines protecting first aiders or healthcare professionals from pathogens. The main message is: —Don’t touch or use anything that has the victim’s body fluid on it

without a barrier. It also assumes that all body fluid of a patient is infectious, and must be treated accordingly.

Standard Precautions apply to blood, all body fluids, secretions, and exertions (except sweat) regardless of whether or not they contain visible blood, non-intact skin and mucous membranes

4.94 Standards

A statement of expectation that defines the structures and process that must be substantially in place in HCC to enhance the quality of care.

4.95 Sterilization

It is the process of killing or removing microorganisms including their spores by thermal, chemical or irradiation means.

4.96 Strategic plan

Strategic planning is HCC'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. HCC can have a strategic plan to become the 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 HCC envisions its future and develops strategies, goals, objectives and action plans to achieve that future. (ASQ)

4.97 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.

4.98 Transfusion reaction

A transfusion reaction is a problem that occurs after a patient receives a transfusion of blood.

4.99 Triage

Triage is a process of prioritizing patients based on the severity of their condition to treat as many as possible when resources are insufficient for all to be treated immediately.

4.100 Unstable patient

A patient whose vital parameters need external assistance for their maintenance

4.101 Validation

a) Confirmation through the provision of objective evidence that the requirements for a specific intended use or application have been fulfilled.

b) The checking of data for correction or for compliance with applicable standards, rules or conventions. These are the tests to determine whether an implemented system fulfils its requirements. It also refers to what extent does a test accurately measure what it purports to measure.

4.102 Vision

The fundamental beliefs that drive HCC behaviour and decision-making. This refers to the guiding principles and behaviours that embody how HCC and its people are expected to operate. Values reflect and reinforce the desired culture of HCC.

4.103 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, those on immunosuppressive and/ chemotherapeutic agents.

5. Abbreviations

ABG	Arterial Blood Gas
ACLS	Advanced Cardiac Life Support
AERB	Atomic Energy Regulation Board
BHSQA	Bhutan Healthcare Standard for Quality Assurance
BID	"Bis In Die" which in Latin means twice a day
BLS	Basic Life Support
BMHC	Bhutan Medical and Health Council
CAPD	Continuous Ambulatory Peritoneal Dialysis
CDC	Centre for Disease Control
CID	Citizenship Identity Card
CPM	Critical Path Method
CPR	Cardiac Pulmonary Resuscitation
CQI	Continuous Quality Improvement
CSSD	Central sterile services Department
CT	Computerized Topography
DRA	Drug Regularity Authority
EMOC	Emergency Medical and Obsteritic Care
EPR	Electronic Patient Record
EPRE	Electronic patient records
EQA	External Quality Assessment
EQAP	External Quality Assessment Program
EQAS	External Quality Assessment Scheme
FIFO	First In First Out
FMEA	Failure Mode and Effects Analysis
GCP	Good Clinical Practice
HCC	Healthcare Center
HIRA	Hazard Identification and Risk Analysis
ICD	International Code for Diseases
ICMR	International Center for Materials Research
ICU	Intensive Care Unit
IPD	Inpatient Department
IQC	Internal Quality Control
ISMO	Isosorbide Mononitrate
IV	Intra Venous
LAMA	Left Against Medical Advice

MCI	Mild Cognitive Impairment
MLC	Medico-Legal Cases
MRD	Medical Record Division
MRI	Magnetic Resonance Image
MSDS	Material Safety and Data Sheets
MTP	Medical Termination of Pregnancy
NALS	Neonate advanced Life Support
NEQAS	Neonate advanced Life Support
OPD	Outpatient Department
PALS	Paediatric Advanced Life Support
PERT	Project Evaluation and Review Technique
PNDT	Prenatal Diagnostic Techniques
RBS	Random Blood Sugar
RTI	Right to Information Act
SOP	Standard Operating Procedure
SSCL	Surgical Safety Check List
TID	Thrice a Day (Latin)

6. Access, Assessment and Continuity of Care (AAC)

Preamble

Patients should be well informed of the services that a healthcare centre (HCC) provides. Patients that match the HCC resources are admitted using a defined process. Patients who do not match the HCC's resources are referred to a higher centre that has the matching resources. Patients cared for by the HCC undergo an established initial assessment and periodic and regular reassessments. Assessments include planning for the utilization of clinical laboratory and imaging services. The clinical laboratory and imaging services are provided by competent staff in a safe environment both for patients and staff. Continuity of healthcare is provided through well-defined transfer and discharge protocols which include a transfer of adequate information along with the patient.

Summary of Standards

Std.No.	Standards
AAC 6.1	The HCC defines and displays the services that it can provide.
AAC 6.2	The HCC has a well-defined registration and admission process.
AAC 6.3	There is an appropriate mechanism for transfer (in and out) or referral of patients.
AAC 6.4	Patients cared for by the HCC undergo an established initial assessment.
AAC 6.5	Patients cared for by the HCC undergo a regular reassessment.
AAC 6.6	Clinical laboratory services are provided as per the scope of services of the HCC and adhering to best practices.
AAC 6.7	There is an established clinical laboratory quality assurance program.
AAC 6.8	There is an established laboratory-safety protocol.
AAC 6.9	Radiological services are provided as per the scope of services of the HCC and adhering to the best practices.
AAC 6.10	There is an established quality assurance program for Radiological services.
AAC 6.11	There is an established radiation safety protocol.
AAC 6.12	Patient care is continuous and multidisciplinary in nature.
AAC 6.13	The HCC has a documented discharge process.
AAC 6.14	HCC defines the content of the discharge summary.
AAC 6.15	Services in the Departments/Units are provided as per the scope of services of the HCC and adhering to the best practices.
AAC 6.16	The Quality Assurance Program in the Departments/Units is documented.
AAC 6.17	There is an established Safety protocol in the Departments/Units.

Standards and Objective Elements

Standard

AAC 6.1: The HCC defines and displays the services that it can provide.

Objective Elements

6.1.1 The services being provided are clearly defined and are in consonance with the needs of the community.

Interpretation/Remarks:

a) The HCC shall define this keeping in mind the scope of services applied for.
b) The needs of the community should be considered especially when planning a new HCC or adding new services.
c) The same could be recorded through the feedback mechanism.

6.1.2 The defined services are prominently displayed.

Interpretation/Remarks:

a) The services so defined should be numbered and displayed prominently in an area visible to all patients entering the HCC.
b) The display could be of permanent nature in the form of boards, etc.
c) The display should be at least bi-lingual (Dzongkha and English/local language).

6.1.3 The staff are oriented to these services.

Interpretation/Remarks:

a) All the staff in the HCC mainly in the reception/registration, OPD, IPD are oriented to these facts through a regular training program or through manuals.
b) Records of all such training shall be documented and available.

Standard

AAC 6.2: The HCC has a well-defined registration and admission process.

Objective elements

6.2.1 Documented policies and procedures are used for registering and admitting patients.

Interpretation/Remarks:

a) HCC shall prepare documents(s) detailing procedures for registration and admission of patients which should also include unidentified patients.
b) All patients who are assessed in the HCC shall be registered.
c) All admission must be authorized by an authorized prescriber.

6.2.2 The documented procedures address outpatients, in-patients and emergency patients.

Interpretation/Remarks:

a) It is preferable if each one of these is separately addressed (Outpatients, In-patients & emergency patients).

6.2.3 A unique identification number (CID/HCC Registration Number) is generated at the end of registration.

Interpretation/Remarks:

a) The HCC shall ensure that every patient gets a unique number (CID/HCC Registration Number) which is generated at the end of registration of the first interaction that the patient has with the HCC.
b) This number shall be used for identification of the patient across the HCCs and to ensure continuity of care across the HCCs.
c) All HCC records of the patient shall have this number.
d) "Unique" implies that this is a one-time affair.
e) Please note that a particular patient can have only one unique number. However, in case of multiple visits (OP/IP), a different number could be generated in addition to the above-mentioned unique number each time.
f) To ensure continuity of care, these numbers shall be linked to the unique number.

6.2.4 Patients are accepted only if the required services are available at the HCC.

Interpretation/Remarks:

a) The staff handling admission and registration needs to be aware of the services that the HCC can provide.
b) It is also advisable to have a system wherein the staff are aware as to who to contact if they need any clarification on the services provided.
c) Patients are referred immediately to the higher healthcare centre if the required services are not available.

6.2.5 The documented policies and procedures also address managing patient when it surpasses the total capacity of the bed strength.

Interpretation/Remarks:

a) The HCC is aware of the availability of alternate arrangement where the patients may be directed in case of non-availability of beds in the desired bed category or unit.
b) In case the admitted patients are in a temporary holding area, it shall ensure that there is adequate infrastructure to take care of these patients and shall define as to how long

patients are kept on temporary beds before a decision to transfer out is taken.

c) The documented procedure also addresses managing patients when bed space is not available in the desired bed category or unit.

6.2.6 The staff are aware of these processes.

Interpretation/Remarks:

a) All the staff handling these activities should be oriented to these policies and procedures.

b) Orientation can be provided by documentation/training.

Standard

AAC 6.3: There is an appropriate mechanism for transfer (in and out) or referral of patients.

Objective Elements

6.3.1 Documented procedures guide the transfer-in of patients to the HCC.

Interpretation/Remarks:

a) This shall address both planned and unplanned transfers.

b) For unplanned transfers and in case of suspected unstable patients, the HCC could send a staff trained in basic life support with the ambulance. However, this shall be guided by the information received and policy of the HCC.

6.3.2 Documented procedures guide the transfer-out/referral of unstable patients to next higher centre in an appropriate manner.

Interpretation/Remarks:

a) The HCC shall at the outset define the unstable patient as per the National Standards for Emergency Services.

b) This shall be defined based on physiological criteria.

c) The documented procedure should address the methodology of safe transfer of the patient in a life-threatening situation (like those who are on a ventilator) to another higher centre.

d) There should be an availability of an appropriate ambulance fitted with-life support facilities and accompanied by trained personnel.

e) These patients include those who have come to the emergency but need to be transferred to another higher HCC or those already admitted but who now require care in higher HCC.

f) It also includes patients being shifted for diagnostic tests.

6.3.3 Documented procedures guide the transfer-out/referral of stable patients to another facility in an appropriate manner.

Interpretation/Remarks:

a) Patients not in a life-threatening situation (stable) should also be transported in a safe manner.

6.3.4 The documented procedures identify staff responsible during transfer/referral.

Interpretation/Remarks:

a) The staff accompanying shall at least be a trained trauma/emergency technicians or nurses. He/she shall have undergone training as per National Standards for Emergency Services. Further, the procedure shall identify the responsible staff for various steps of the procedure.

b) A competent health professional should accompany an unstable patient and criteria for the unstable patient should be defined.

6.3.5 The HCC gives a summary of the patient's condition and the treatment given.

Interpretation/Remarks:

a) The HCC gives a case summary mentioning the significant findings and treatment given in case of patients who are being transferred from an emergency. A copy of the same shall be retained by the HCC. For admitted patients, a discharge summary has to be given (refer AAC 6.14).

b) This shall include patients being transferred both for diagnostic and/or therapeutic purposes.

c) Patient under critical condition should be escorted by at least two competent health professionals.

Standard

AAC 6.4: Patients cared for by the HCC undergo an established initial assessment.

Objective Elements

6.4.1 The HCC defines and documents the content of the initial assessment for the out-patients, in- patients and emergency patients.

Interpretation/Remarks:

a) The HCC shall have a format using which a standardized initial assessment of patients is done in the OPD, emergency and in-patients. The initial assessment could be

standardized across the HCC or could be modified depending on the need of the department. However, it shall be the same in that particular, e.g. in paediatric OPD the weight and height may be a must, whereas it may not be so for orthopaedics OPD. In an emergency department, this shall include recording the vital parameters.

b) Every initial assessment shall contain the presenting complaints, vital signs (temperature, pulse, BP and respiratory rate) and salient examination findings (especially of the system concerned).

c) This shall incorporate initial assessment by doctors and nursing staff in case of in-patients.

6.4.2 The HCC determines who can perform the initial assessment.

Interpretation/Remarks:

a) The HCC determines who can do what assessment and it should be the same across the HCC. Assessments are performed by each discipline within its scope of practice as per the regulations of the BMHC.

b) Refer to HRM 14.1

6.4.3 The HCC defines the time frame within which the initial assessment is completed based on the patient's needs.

Interpretation/Remarks:

a) The HCC has defined and documented the time frame within which the initial assessment is to be completed with respect to OPD/emergency/ indoor patients. The time frame shall be from the time that the patient has registered (or in case of emergency: come to the emergency) till the time that the initial assessment is documented by the treating doctor/consultant.

b) The time frame shall be reasonable and match with the HCC resources and patient load. In case of out-patients, there could be a separate timeframe for patients coming with an appointment and for "walk-in" patients. Patient's needs mean the condition of the patient.

6.4.4 The initial assessment for in-patients is documented within 24 hours or earlier as per the patient's condition as defined in the HCC's policy/protocol.

Interpretation/Remarks:

a) This should cover history, examination including vital signs and documentation of any drug allergies. It should mention the provisional diagnosis.

b) For an admitted patient, if a detailed assessment has been done earlier (either in OPD within the past seven days or emergency), it need not be written in detail again.

c) Please note that the maximum time allowed for documentation is 24 hours. However, the

Healthcare Centre shall define and document the appropriate time depending on the patient's condition and the scope of its services.

6.4.5 Initial assessment of in-patients includes nursing assessment which is done at the time of admission and documented.

Interpretation/Remarks:

a) This shall identify the nursing needs and also help identify any special needs of the patient. It shall be completed within a defined time frame. This assessment shall help in identifying the nursing needs of the patient. It may be in form of a Nursing process/note.
b) A checklist or template could be used for the same.
c) Nursing process/note

6.4.6 Initial assessment includes screening for nutritional needs.

Interpretation/Remarks:

a) The protocol for a patient's initial assessment should cover his/her nutritional needs, height and weight.
b) This is only a screening for nutritional needs and not a complete assessment.
c) A detailed nutritional assessment shall be done wherever necessary.
d) This could be done by the treating doctor/nurse/dietician.
e) Questionnaires could be used for the same.
f) Nutritional screening shall be done for all stable patients including OP and IP.
g) Where appropriate, the HCC should consider providing a nutritional assessment for outpatients too.

6.4.7 The initial assessment results in a documented plan of care.

Interpretation/Remarks:

a) This shall be documented by the treating doctor or by a member of his team in the patient record.
b) For a definition of "plan of care", refer to the glossary. This is applicable only for day-care and inpatients.

6.4.8 The plan of care also includes preventive aspects of the care where appropriate.

Interpretation/Remarks:

a) The documented plan of care should cover preventive actions as necessary in the case and could include diet, drugs etc. In a condition where it is not possible to incorporate this at the time of assessment (e.g. diagnosis not made/unclear) the same shall be done as soon as a definite diagnosis is arrived at.

b) This could also be done through booklets/patient information leaflets etc. e.g. diabetes, hypertension.

6.4.9 The plan of care is countersigned by the clinician in-charge of the patient within 24 hours.

Interpretation/Remarks:

a) The treatment of the patient could be initiated by a junior doctor but the same should be countersigned and authorized by the treating doctor within 24 hours. The clinician in charge implies the treating doctor.

6.4.10 The plan of care includes goals or desired results of the treatment, care or service.

Interpretation/Remarks:

a) The indicative goals are curative, preventive and rehabilitative.

Standard

AAC 6.5: Patients cared for by the HCC undergo a regular reassessment.

Objective elements

6.5.1 Patients are reassessed at appropriate intervals.

Interpretation/Remarks:

a) After the initial assessment, the patient is reassessed periodically and this is documented in the case sheet. Reassessments shall also be done in response to significant changes in patient's condition.

b) Every patient shall be reassessed at least once every day by the treating doctor. Reassessments shall also be done for day-care patients (before discharging) or a patient's waiting for admission/bed.

6.5.2 Outpatients are informed of their next follow-up, where appropriate.

Interpretation/Remarks:

a) The reassessment notes shall reflect the patient's response to treatment and at a minimum capture the symptoms (change or fresh) and vital signs.

b) This would not be applicable in cases where the patient has come for just an opinion or the patient's condition does not warrant repeat visits.

6.5.3 For in-patients during reassessment, the plan of care is monitored and modified, where found necessary.

Interpretation/Remarks:

a) The plan of care shall be dynamic and modified where necessary by the treating doctor

according to the patient's condition.

6.5.4 Staff involved in direct clinical care document reassessments.

Interpretation/Remarks:

a) Action taken under reassessment is documented and the documentation shall include vitals, findings of the systemic examination and medication orders where necessary.
b) Action taken under reassessment is documented.
c) The staff could be the treating doctor or any member of the team as per their domain of responsibility of care.
d) At a minimum, the documentation shall include vitals, systemic examination findings and medication orders.
e) The nursing staff shall document the patient's vitals and other findings.
f) Only phrases like "patient well", "condition better" would not be acceptable.

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

Standard

AAC 6.6: Clinical laboratory services are provided as per the scope of services of the HCC and adhering to best practices.

Objective elements

6.6.1 The scope of the clinical laboratory services is commensurate to the services provided by the Healthcare Centre.

Interpretation/Remarks:

a) The HCC should ensure availability of clinical laboratory services round the clock and patient care does not suffer.
b) Test results required for emergency management must be available within its premises.
c) Clinical laboratory services are in consonance with the National Standards for clinical laboratory services.
d) For example, a cardiac care HCC must necessarily have facilities for cardiac enzyme

6.6.2 The infrastructure (physical and manpower) is adequate to provide for its defined scope of services.

Interpretation/Remarks:

a) The available equipment and manpower should be able to effectively deliver its clinical laboratory services.

b) Reports should not be delayed due to lack of adequate equipment or manpower (including people authorized to report results).

6.6.3 Adequately qualified and trained personnel perform, supervise and interpret the investigation.

Interpretation/Remarks:

a) The staff employed in the clinical laboratory should be suitably qualified and trained to carry out the tests.
b) Competent and qualified clinical laboratory professional supervises the other laboratory staff.
c) Only trained and qualified clinical laboratory staff are recruited who are recognized by BMHC.

6.6.4 Documented procedures guide for ordering of test, collection, identification, handling, safe transportation, processing and validation and disposal of specimens.

Interpretation/Remarks:

a) The HCC has documented SOP for ordering, collection, identification, handling, safe transportation, processing, and disposal of specimens, to ensure the quality of reports and safety of the specimen till the tests and retests (if required) are completed.
b) In addition unique identification number (CID/HCC Registration Number), the clinical laboratory could use appropriate lab number to identify the sample.
c) This should be in line with standard precautions. The disposal of waste shall be as per the rules and regulation requirements (Infection Control and Medical Waste Management Guideline 2006, Waste Management Act 2009 and Waste Prevention and Management Regulation 2012).

6.6.5 Clinical laboratory results are available within a defined time frame Results are reported in a standardized manner.

Interpretation/Remarks:

a) The HCC should ensure availability of clinical laboratory results within the defined time frame.
b) The turnaround time could be different for different tests and could be decided based on the nature of the test, criticality of test and urgency of the test result.
c) At a minimum, the report shall include the name of the HCC, the patient's name and sex, the unique identification number, and the reference range of the test (where applicable) and the name and signature of the person reporting the test result.

6.6.6 Critical results are intimated immediately to the personnel concerned.

Interpretation/Remarks:

a) The clinical laboratory shall establish its own biological reference intervals for different tests. The clinical laboratory shall establish and document critical limits for tests which require immediate attention for patient management and the same shall be documented.

b) The critical test results shall be communicated to the person concerned and this shall be documented.

c) If it is not practical to establish the biological reference interval for a particular analysis the clinical laboratory should carefully evaluate the published data for its own reference intervals.

6.6.7 Results are reported in a standardized manner.

Interpretation/Remarks:

a) At a minimum, the report shall include the name of the HCC, the patient's name, the unique identification number, and the reference range of the test (where applicable) and the name and signature of the person reporting the test result.

Standard

AAC 6.7: There is an established clinical laboratory quality management system (QMS).

Objective Elements

6.7.1 The clinical laboratory QMS is documented.

Interpretation/Remarks:

a) The HCC has a documented QMS (quality manuals, SOPs, IQC, NEQAS & EQAS – if any for quality and competency).

b) QMS includes management and organization, internal quality control, external quality assurance, pre-analytic phase, test standardization and post-analytic phase.

c) The clinical laboratory shall participate in external quality assurance program when available. When such programs are not available, the clinical laboratory could exchange samples with another clinical laboratory for purposes of peer comparison.

6.7.2 The QMS addresses verification and/or validation of test methods.

Interpretation/Remarks:

a) This holds true for any laboratory-developed methods. Standard methods need verification to ensure that the clinical laboratory is capable of performing the analysis

b) Verification of an analytical procedure is the demonstration that a clinical laboratory is capable of replicating with an acceptable level of performance a standard method.
c) Verification under conditions of use is demonstrated by meeting system-suitability specifications established for the method, as well as a demonstration of accuracy and precision or other method parameters for the type of method.
d) Verification of Standard Method Performance is defined for two situations, (1) for verifying method performance with each analytical batch (EAB) and (2) the first use of a standard method within the laboratory.
e) Non-standard and laboratory-developed methods need method validation.
f) Methods requiring validation are:
    1) Modified official methods
    2) In-house developed methods
    3) Methods extended to a component, analysis or matrix not previously tested or included in the validation
    4) Changes involving new technology or automation
d) Verification usually includes accuracy, precision and linearity.
e) Validation, in addition, includes sensitivity and specificity.

6.7.3 The QMS addresses surveillance of test results.

Interpretation/Remarks:

a) The head of the clinical laboratory department shall periodically assess the test results. This shall be done in a structured manner. The HCC shall specify the frequency and the sample size that it shall use for the surveillance.

6.7.4 The QMS includes periodic calibration and maintenance of all equipment.

Interpretation/Remarks:

a) Refer to SOPs/manual on calibration/ISO 15189.
b) Traceability certificate(s) of all calibration done shall also be documented and maintained.

6.7.5 The QMS includes the documentation of corrective and preventive action.

Interpretation/Remarks:

a) Incident reports are well documented
b) Action plans are documented for prevention

Standard

AAC 6.8 There is an established clinical laboratory-safety protocol

Objective elements

6.8.1 The clinical laboratory-safety protocol is documented.

Interpretation/Remarks:

a) A well-documented clinical laboratory safety manual is available in the lab. This takes care of the safety of the workforce as well as the equipment available in the lab. It shall be in consonance with the risks and hazards identified.

b) This program is aligned with the HCC's safety protocol

c) This could be as per rules & regulation of Occupational Health and Safety of Bhutan 2012.

6.8.2 Written SOPs guide the handling and disposal of infectious and hazardous materials.

Interpretation/Remarks:

a) This could be as per Occupational Health and Safety Management System, Infection Control and Medical Waste Management Guideline 2006, Waste Management Act 2009, and Waste Management Rules and Regulation 2012.

6.8.3 Clinical laboratory personnel are appropriately trained in safe practices.

Interpretation/Remarks:

a) All the lab staff undergoes training regarding safe practices in the lab.

6.8.4 Clinical laboratory personnel are provided with appropriate safety equipment/devices.

Interpretation/Remarks:

a) Adequate safety devices are available in the lab, e.g. fire extinguishers, disinfectants etc. This should be sufficient to address the safety issue. At a minimum, standard precautions are adhered to.

b) All clinical laboratory staff shall be appropriately immunized especially against Hepatitis B.

Standard

AAC 6.9: Radiological and imaging services are provided as per the scope of services of the HCC and adhering to the best practices.

Objective elements

6.9.1 Imaging services comply with legal and other requirements.

Interpretation/Remarks:

a) The HCC is aware of the legal and other requirements of imaging services and the same is documented for information and compliance by all concerned in the HCC and maintains and updates its compliance status of legal and other requirements in a regular manner.

b) All the legal requirements are met with such as dosimeters, lead sheets, lead aprons, signage, display etc.

c) The HCC shall have a Radiation Safety Rules & regulation in place.

6.9.2 The scope of the radiological and imaging services is commensurate to the services provided by the Healthcare Centre.

Interpretation/Remarks:

a) For example, a neuroscience Centre shall have CT and MRI.

6.9.3 The infrastructure (physical and manpower) is adequate to provide for its defined scope of services.

Interpretation/Remarks:

a) The equipment available and manpower should be able to effectively deliver its imaging services.

b) Reports should not get delayed due to lack of adequate equipment or manpower (including people authorized to report results).

6.9.4 Adequately qualified and trained personnel perform, supervise and interpret the investigations.

Interpretation/Remarks:

a) As per the guidelines and SOPs.

6.9.5 Documented procedure guide identification and safe transportation of patients to the Radiology Department.

Interpretation/Remarks:

a) The Healthcare Centre has documented policies and procedures for informing the

patients about the radiological activities, their identification and safe transportation to the radiological services. This should also address the transfer of unstable patients to imaging services.

b) The patients shall also be transported back in a safe manner.

6.9.6 Imaging results are available within a defined time frame.

Interpretation/Remarks:

a) The HCC shall document turnaround time of imaging results for all modalities.

b) The defined time frame could be different for different types of radiological services and could be decided based on the nature, criticality and urgency of radiological service (as desired by the treating doctor).

6.9.7 Critical results are intimated immediately to the concerned clinicians.

Interpretation/Remarks:

a) Critical results shall be intimated to the treating clinician at the earliest on phone, followed by a written report. Time of communication and the person contacted should be documented.

b) The HCC shall define and document the critical results which require the immediate attention of clinician, e.g. ectopic pregnancy.

6.9.8 Results are reported in a standardized manner.

Interpretation/Remarks:

a) At a minimum, the report shall include the name of the HCC, the patient's name, the unique identification number (CID/HCC Registration Number), and the name and signature of the person reporting the test result.

b) In the case of teleradiology, there shall be the name of the reporting doctor and a remark to that effect.

Standard

AAC 6.10: There is an established quality assurance program for Radiological and imaging services.

Objective Elements

6.10.1 The quality assurance program for radiological and imaging services is documented.
Interpretation/Remarks:

a) Some examples include congruence of optical and radiation field, focal spot size, output consistency, leakage rate, etc.

6.10.2 The program addresses the verification and/or validation of radiological imaging methods.
Interpretation/Remarks:

a) This holds true for any in-house developed methods.

6.10.3 The program addresses surveillance of radiology results.
Interpretation/Remarks:

a) The head of the radiology department shall periodically assess the radiology results. This shall be done in a structured manner. The HCC shall specify the frequency and the sample size that is shall use for the surveillance.

6.10.4 The program includes periodic calibration and maintenance of all equipment.
Interpretation/Remarks:

a) Calibration and maintenance of all equipment shall be carried out by competent persons.
b) Traceability certificate(s) of all calibration done by calibrated equipment shall be documented and maintained.

6.10.5 The program includes the documentation of corrective and preventive actions.

Standard

AAC 6.11: There is an established radiation safety protocol.

Objective Elements

6.11.1 The radiation-safety program is documented.
Interpretation/Remarks:

a) Refer to protocol & SOPs

b) HOD and QA focal person shall devise implement and monitor the process.

6.11.2 This program is aligned with the HCC's safety program.

Interpretation/Remarks:

a) The radiology safety program is aligned with, and its broad principles shall be the same as that of the HCC's safety program.

6.11.3 Handling, usage of disposal of radioactive and hazardous materials is as per legal requirements.

Interpretation/Remarks:

a) Document on safe use of radioactive isotopes for radiology services shall be available and implemented.

b) Radioactive and hazardous materials shall be disposed of as per guidelines laid down by competent bodies (Infection Control and Medical Waste Management Guideline 2006, Waste Management Act 2009 and Waste Management Rules and Regulation 2012).

c) Material safety and data sheets (where applicable) shall be available and staff well versed in the same.

6.11.4 Radiology personnel are provided with appropriate radiation safety devices.

Interpretation/Remarks:

a) This includes lead aprons, shields and dosimeters to name a few.

b) The number of such devices shall be adequate to ensure that all workers have proper protection.

6.11.5 Radiation-safety devices are periodically tested and results documented.

Interpretation/Remarks:

a) Protective devices, e.g. lead aprons, should be expensed to X-ray for verification of cracks and damages.

b) It is preferable that the film of the same be stored (either physical or electronic).

c) Where appropriate corrective and/or preventive action shall be taken and documented.

d) HCC shall ensure availability of safety measures for portable X-Ray.

6.11.6 Radiology personnel are trained in radiation-safety measures.

6.11.7 Imaging signage (signs and posters) is prominently displayed in all appropriate locations.

Interpretation/Remarks:

a) This includes safety signage and display of signage.

Standard

AAC 6.12: Patient care is continuous and multidisciplinary in nature.

Objective elements

6.12.1 During all phases of care, there is a qualified individual identified as responsible for the patient's care.

Interpretation/Remarks:

a) The Department shall ensure that the care of patients is always given by appropriately qualified medical personnel (resident doctor, consultant and /or nurse).

b) Although care may be provided by a team, the Psychiatric Department record shall identify a doctor as being responsible for patient care.

6.12.2 Care of patients is coordinated in all care settings within the HCC.

Interpretation/Remarks:

a) Care of patients is coordinated among various care-providers in a given setting viz OPD, emergency, IP, ICU, etc.

b) The Psychiatric Department/unit shall ensure that there is effective communication of patient requirements amongst the care-providers in all settings.

6.12.3 Information about the patient's care and response to treatment is shared among medical, nursing and other care providers.

Interpretation/Remarks:

a) The HCC ensures periodic discussions about each patient (covering parameters such as patient care, response to treatment, unusual developments if any, etc.) amongst medical, nursing and other care providers.

b) This could be done on the basis of entries either on case sheet or on EPR (electronic patient record)

6.12.4 Information is exchanged and documented during each staffing shift, between shifts, and during transfers between units/departments.

Interpretation/Remarks:

a) For example,

    1) Nurses' handing –taking over notes

    2) Transfer summary

6.12.5 Transfers between departments/units are done in a safe manner.

Interpretation/Remarks:

a) The HCC shall ensure that intra-HCC transfers are done adhering to safe practices.

b) The patients shall be transported in a safe manner and a proper handover and takeover shall be documents.

6.12.6 The patient's record(s) is available to the authorized care-providers to facilitate the exchange of information.

Interpretation/Remarks:

a) The record could be kept in the nursing station for that area.

6.12.7 Documented procedures guide the referral of patients to other departments/specialities.

Interpretation/Remarks:

a) The HCC has clearly defined and documented the procedures to be adopted to guide the personnel dealing with referral of patients to other departments or specialities.

b) The HCC shall ensure that where appropriate a multi-disciplinary team provides care.

c) Established criteria or policies should be used to determine the appropriateness to transfers within the HCC.

d) Referral could be for opinion, co-management and takeover. It could be traded into an immediate, urgent, priority of routine category.

e) All referrals shall be based on clinical significance and for the better outcome.

f) All referrals shall be seen in a defined time frame. This could be different based on the urgency of the referral.

Standard

AAC 6.13: The HCC has a documented discharge process

Objective Elements

6.13.1 The patient's discharge process is planned in consultation with the patient and/or family.

Interpretation/Remarks:

a) The patient's treating doctor determines the readiness for discharge during regular reassessments.

b) The same is discussed with the patient and family.

6.13.2 Documented policies and procedures exist for the coordination of various departments and agencies involved in the discharge process (including medico-legal and absconded cases).

Interpretation/Remarks:

a) The discharge procedures are documented to ensure coordination amongst various departments including accounts so that the discharge papers are complete within time.
b) For Medico-Legal Cases (MLC), the HCC shall ensure that the police are informed.
c) In case of discharges not happening on a particular day, the discharges are planned keeping this in mind.

6.13.3 Documented policies and procedures are in place for patients leaving against or refusal of treatment or medical advice, and patients being discharged on request.

Interpretation/Remarks:

a) The treating doctor should explain the consequences of this action to the patient/attendant.
b) This policy could address the reasons of Left Against Medical Advice (LAMA) for any possible corrective and/or preventive action by the HCC.

6.13.4 A discharge summary is given to all the patients leaving the HCC (including patients leaving against medical advice and on request).

Interpretation/Remarks:

a) The HCC hand over the discharge papers to the patient/attendant in all cases and a copy is retained.
b) In LAMA cases, the declaration of the patient/attendant is to be recorded in a proper format.
c) Documented policies and procedures address the patients absconded from the HCC.

Standard

AAC 6.14: HCC defines the content of the discharge summary

Objective Elements

6.14.1 The discharge summary is provided to the patients at the time of discharge.

Interpretation/Remarks:

a) The discharge summary shall be signed by the treating doctor or a member of his/her team.

6.14.2 Discharge summary contains the patient's name, unique identification number, ICD, date and time of admission and date of discharge.

6.14.3 Discharge summary contains the reasons for admission, significant findings and diagnosis

and the patient's condition at the time of discharge.

6.14.4 Discharge summary contains information regarding investigation done, any procedure performed, medication administered and other treatment given.

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

Interpretation/Remarks:

a) This shall also incorporate preventive aspects, where appropriate
b) A patient who had surgery must be explained about the dressing &suture removal and to collect histopathology report where applicable
c) Patients must be explained to collect pending reports
d) The instructions shall be in a manner that the patient can easily understand and avoid the use of medical terms, e.g. BID, TID, etc.

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

Interpretation/Remarks:

a) The HCC should outline conditions regarding „when" to obtain urgent care. For example, a post-op patient should report when having a fever, bleeding/discharge from the site.
b) This could be in the form of what medicines to take, when to consult a doctor or how to seek medical help and contact number of the HCC/doctor.

6.14.7 In case of death, the summary of the case also includes the cause of death.

Interpretation/Remarks:

a) In case of MLC, this shall not be applicable.

Standard

AAC 6.15: Services in the Department/Unit of Traditional Medicines, Pharmacy, Dental, Dermatology, Ophthalmology, Medicines, Surgery, Gynae Obstetrics, Paediatrics, Psychiatrics, OT, Physiotherapy, Community Health, Forensic Medicines, ENT, and Orthopaedic are provided as per the scope of the services of the HCC and adhering to the best practices.

Objective Elements

6.15.1 The scope of all the services is commensurate to the services provided by the HCC.

Interpretation/Remarks:

a) The Department/Units shall ensure availability of services commensurate with the healthcare services offered by it.

b) The Department/Units shall ensure that the services are available round the clock and patient care does not suffer.

c) Emergency management must be available at all time.

6.15.2 The infrastructure (physical and manpower) is adequate to provide for its defined scope of services in the Department/Units.

Interpretation/Remarks:

a) The available equipment and manpower should be able to effectively deliver its services in all the departments.

b) Services should not get delayed due to lack of adequate equipment or manpower (including people authorized to provide the services).

6.15.3 Adequately qualified and trained personnel perform the treatment. Interpretation/Remarks:

a) The staff employed in the departments should be suitably qualified (appropriate certificate/diploma/degree) and trained to carry out the treatment.

b) Specialists and experienced senior staff shall supervise junior staff.

6.15.4 Documented procedures guide treatment and handling of patients in the Department/Units.

Interpretation/Remarks:

a) The Department/Unit of have documented procedures for treatment and handling of patients, to ensure the safety of the patient till the treatments (if required) are completed.

b) The HCC shall ensure that the unique identification number (CID/HCC Registration Number) is used for identification of the patient.

6.15.5 Treatments are provided within a defined time frame.

Interpretation/Remarks:

a) The Department/Unit shall define the turnaround time for all treatment and procedures.

b) The Department/Unit shall ensure the availability of adequate staff, materials and equipment to make the services available within the defined time frame.

c) The turnaround time could be different for different procedures and could be decided based on the nature of treatment/procedure, specific procedure and urgency of procedures.

6.15.6 Treatment/procedure is conducted in a standardized manner in the Department/Unit.
Interpretation/Remarks:

a) At a minimum, the procedure shall include the name of the specialists, the patient's name, the unique identification number, and type of procedure/treatment performed (where applicable) and the name and signature of the person performed the procedure/treatment.

6.15.7 Services not available in the HCC are referred to higher/next HCC.
Interpretation/Remarks:

a) The Department/Unit has documented procedure for referring to higher HCC.

AAC 6.16: The Quality Assurance Program in the Departments/Units is documented.

Objective Elements

6.16.1 The quality assurance program in the Department/Unit is documented.
Interpretation/Remarks:

a) The Department/unit has a documented quality assurance program (Particular requirements for quality and competence).
b) Quality assurance includes internal quality control, management and organization.

6.16.2 The program addresses verification and/or validation of procedures in all the departments.
Interpretation/Remarks:

a) Standard methods need verification to ensure that the department is capable of performing the analysis.
b) Verification of procedure is the demonstration that the department is capable of replicating with an acceptable level of performance standard.
c) Changes involving new technology or automation.

6.16.3 The program addresses surveillance of treatment/procedure performed.
Interpretation/Remarks:

a) The Head of department/unit shall periodically assess the treatment/procedures performed by the staff.

b) This shall be done in a structured manner.
c) The Department/Unit shall specify the frequency and the sample size that it shall use for the surveillance.

6.16.4 The program includes periodic calibration and maintenance of all equipment.
Interpretation/Remarks:
a) Refer to the protocol and SOPs.
b) Traceability certificate(s) of all calibration and maintenance performed shall also be documented and maintained.

6.16.5 The program includes the documentation of corrective and preventive action.

Standard

AAC 6.17: There are established safety protocols in the Departments/Units

Objective Elements

6.17.1 Safety protocols are documented.
Interpretation/Remarks:
a) Well-Documented safety protocols are available in the department. This takes care of the safety of the workforce as well as the equipment available. It shall be in consonance with the risks and hazards identified.
b) This could be as per Occupational Health and Safety Management System, Infection Control and Medical Waste Management Guideline 2006, Waste Management Act 2009, and Waste Management Rules and Regulation 2012.

6.17.2 This program is aligned with the HCC"s safety program.
Interpretation/Remarks:
a) Safety protocols are aligned with the safety program of the HCC.
b) The broad principles shall be the same as that of the HCC.

6.17.3 Written procedures guide the handling and disposal of infectious and hazardous materials.
Interpretation/Remarks:
a) This could be as per Occupational Health and Safety Management System, Infection Control and Medical Waste Management Guideline 2006, Waste Management Act 2009, and Waste Management Rules and Regulation 2012.
b) Material safety and data sheets (where applicable) shall be available and staff well versed

in the same.

6.17.4 Staff are appropriately trained in safe practices.

Interpretation/Remarks:

a) All the staff undergoes training regarding safe practices in the department.

6.17.5 Staff are provided with appropriate safety equipment/devices.

Interpretation/Remarks:

a) Adequate safety devices are available in the department, e.g. fire extinguishers, dressing materials, disinfectants etc.

b) This should be sufficient to address the safety issue.

c) All staff shall be appropriately immunized especially against Hepatitis B.

7. Care of Patients (COP)

Preamble

The HCC provides uniform care to all patients in different settings (outpatient departments, wards, ICUs, procedure rooms and operation theatre). Policies, procedures, applicable laws and regulations guide emergency and ambulance services, cardiopulmonary resuscitation, use of blood and blood products, care of patients in the intensive care and high dependency units. Policies, procedures, applicable laws and regulations also guide the care of vulnerable patients (elderly, physically and/or mentally-challenged and children), high-risk obstetrical patients, paediatric patients, patients undergoing moderate sedation, administration of anaesthesia, patients undergoing surgical procedures, patients under restraints, research activities and end of life care. Pain management, nutritional therapy and rehabilitative services are also addressed with a view for providing comprehensive health care. The standards aim to guide and encourage patient safety as the overall principle for providing care to patients.

Summary of standards

COP 7.1	Uniform care to patients is provided in all settings of the HCC and is guided by the applicable laws, regulations and guidelines.
COP 7.2	Emergency services are guided by documented policies, procedures and applicable laws and regulation.
COP 7.3	The ambulance services are commensurate with the scope of the services provided by the HCC.
COP 7.4	Documented policies and procedures guide the care of patients requiring cardiopulmonary resuscitation.
COP 7.5	Documented policies and procedures guide nursing care.
COP 7.6	Documented procedures guide the performance of various procedures.
COP 7.7	Documented policies and procedures define relational use of blood and blood products.
COP 7.8	Documented policies and procedures guide the care of patients in intensive care and high dependency units.
COP 7.9	Documented policies and procedures guide the care of vulnerable patients (elderly, physically and/or mentally-challenged and children).
COP 7.10	Documented policies and procedures guide obstetric care.
COP 7.11	Documented policies and procedures guide paediatric services
COP 7.12	Documented policies and procedures guide the care of patients undergoing moderate sedation.
COP 7.13	Documented policies and procedures guide the administration of anaesthesia.

COP 7.14	Documented policies and procedures guide the care of patients undergoing surgical procedures.
COP 7.15	Documented policies and procedures guide the care of patients under restraints
COP 7.16	Documented policies and procedures guide appropriate pain management.
COP 7.17	Documented policies and procedures guide appropriate rehabilitative services
COP 7.18	Documented policies and procedures guide all research activities.
COP 7.19	Documented policies and procedures guide nutritional therapy.
COP 7.20	Documented policies and procedures guide the end of life care.

Standards and objective Elements

Standard

COP 7.1: Uniform care to patients is provided in all settings of the HCC and is guided by the applicable laws, regulations and guidelines.

Objective Elements

7.1.1 Care delivery is uniform for a given health problem when similar care is provided in more than one setting.

Interpretation/Remarks:

a) The HCC shall ensure that patients with the same health problems and care needs receive the same quality of health care throughout the HCC, irrespective of the category of wards.

b) Further, in case the HCC has separate OPDs for different category of patients the methodology for care delivery shall be uniform in all OPDs.

7.1.2 Uniform care is guided by documented procedures drawn in accordance with applicable laws, regulations and guidelines.

Interpretation/Remark:

a) For example, consent before surgery, providing first aid to emergency patients and police intimation in cases of medico-legal cases.

7.1.3 The HCC adapts evidence-based medicine and clinical practice guidelines to guide uniform patient care.

Standard

COP 7.2: Emergency services are guided by documented policies, procedures, applicable laws and regulations.

Objective Elements

7.2.1 Procedures for emergency care are documented and are in consonance with legal requirements.

Interpretation/Remarks:

a) These could include SOPs/protocols to provide either general emergency care or management of specific conditions, e.g. poisoning.
b) It shall address both adults and paediatric patients.
c) The procedure shall incorporate at a minimum identification, assessment and provision of care.
d) All patients coming to the HCC shall be provided basic medical care and stabilized before transferring them to another HCC.

7.2.2 This also addresses the handling of medico-legal cases.

Interpretation/ Remarks:

a) The policy shall be in line with constitutional requirements. (Documentation and intimation to the police).
b) The HCC shall also define as to what constitutes MLC (in accordance with legal rules).

7.2.3 The patients receive care in consonance with the policies.

Interpretation/Remarks:

a) Poisoning cases, road-traffic accidents, patients with coronary disease, etc. shall be dealt with as per HCC policies and procedures.

7.2.4 Documented policies and procedures guide the triage of patients for initiation of appropriate care.

Interpretation/Remarks:

a) Triage shall be done only by trained individuals based on good clinical practices in case of emergencies.

7.2.5 Staff are familiar with the policies and trained on the procedures for the care of emergency patients.

Interpretation/Remarks:

a) All the staff working in the area should be oriented to the policies and practices through

training/documents. Staff should be trained in BLS and preferably be trained/well in ACLS also.

7.2.6 Admission or discharge to home or transfer to another HCC is also documented.

7.2.7 In case of discharge to home or transfer to next higher HCC, a discharge note shall be given to the patient incorporating salient features of investigations done and treatment.

Standard

COP 7.3: The ambulance services are commensurate with the scope of the services provided by the HCC.

Objective Elements

7.3.1 There are adequate access and space for the ambulance(s).

Interpretation/ Remarks:

a) The HCC shall demarcate a proper space for an ambulance(s).
b) This shall be demarcated keeping in mind easy accessibility for receiving patients and to enable the ambulance(s) to turn around/exit quickly.

7.3.2 The ambulance adheres to legal requirements.

Interpretation/Remarks:

a) This is in the context of the Motor Vehicle Act. E.g. License of drivers, Insurance & registration of a vehicle.

7.3.3 Ambulance(s) is appropriately equipped.

Interpretation/Remarks:

a) This shall be done based on the HCC's scope.
b) This shall be in consonance with ACLS or BLS guidelines.
c) It is expected that an ambulance shall be equipped with at least basic life support.
d) Equipment for both adult and paediatric patients shall be present.

7.3.4 Ambulance(s) is manned by trained personnel.

Interpretation/Remarks:

a) The ambulance should be manned by a trained driver, emergency medical technician/nurse and/or doctor depending on the situation.
b) Personnel shall be trained in BLS and/or ACLS.

c) The driver shall have a valid driving license.

7.3.5 Ambulance(s) is checked on a daily basis.

Interpretation/Remarks:

a) The check shall clearly indicate the functioning status of the ambulance like lights, siren, beacon lights, etc.

b) In addition, the ambulance shall undergo servicing as per the set schedule.

7.3.6 Equipment is checked on a daily basis using a checklist (ambulance guideline).

Interpretation/Remarks:

a) The check shall clearly indicate the functioning status of the equipment.

7.3.7 Emergency medications are checked daily and prior to dispatch using a checklist (ambulance guideline).

Interpretation/Remarks:

a) In case, a rapid turnaround of the ambulance is required (where checking may not be possible prior to dispatch), only the medications used could be topped up or the HCC could keep an additional set of drugs as standby.

7.3.8 The ambulance(s) has a proper communication system.

Interpretation/Remarks:

a) The ambulance shall be connected with the HCC/HHC/mobile phones.

Standard

COP 7.4: Documented policies and procedures guide the care of patients requiring cardiopulmonary resuscitation.

Objective Elements

7.4.1 Documented policies and procedures guide the uniform use of resuscitation throughout the HCC.*

Interpretation/Remarks:

a) The HCC shall document the procedure for same. This shall be in consonance with accepted practices. Where appropriate, it shall address adult, paediatric and neonatal patients.

b) The HCC shall ensure that adequate and appropriate resources (both men and material) are provided.

c) a) The protocols could be displayed prominently in critical areas such as emergency, ICU,

OT, etc.

7.4.2 Staff providing direct patient care are trained and periodically updated in cardio-pulmonary resuscitation (CPR).

Interpretation/Remarks:

a) These aspects shall be covered by hands-on training. If the HCC has a CPR team (e.g. code blue team), it shall ensure that it is trained in ACLS and is present in all shifts.
b) All doctors, paramedical staff and nursing staff must at least be trained to provide BLS.
c) All doctors and nurses working in intensive care/high dependency units should undergo appropriate training (ACLS or PALS or NALS).
d) All doctors and nurses escorting the airlifted patients should refer to the helicopter guidelines for patient care.

7.4.3 The events during cardiopulmonary resuscitation are recorded.

Interpretation/Remarks:

a) In the actual event of a CPR or a mock drill of the same, all the activities along with the personnel attended should be recorded.
b) This could be done using the pre-defined procedural checklist and by monitoring, if the prescribed activity has been performed properly and in the right sequence.

7.4.4 A post-event analysis of all cardiopulmonary resuscitations is done by a multidisciplinary committee.

Interpretation/Remarks:

a) The analysis shall include the cause, steps taken to resuscitate and the outcome.
b) A multidisciplinary committee shall be independent of the code blue team (as far as possible) and include at least one physician/cardiologist, anesthesiologist, one member from the code blue team and nurse.
c) An analysis should be completed within a defined time frame.

7.4.5 Corrective and preventive measures are taken based on the post-event analysis.

Interpretation/Remarks:

a) Corrective and preventive measures should be completed within a defined time frame.
b) During subsequent resuscitations, it is preferable that the implementation of these actions is noted and training be modified, if necessary.

Standard

COP 7.5: Documented policies and procedures guide nursing care.

Objective Elements

7.5.1 There are documented policies and procedures for all activities of the nursing services.

Interpretation/Remarks:

a) This could be in the form of a nursing manual incorporating all nursing procedures.

7.5.2 These reflect current standards of nursing services and practice, relevant regulations and purposes of the services.

Interpretation/Remarks:

a) Nursing practice is in accordance with nationally accepted standards and shall include:
    1) Documented individualized patient-focused nursing care plan for each patient to achieve appropriate outcomes;
    2) Monitoring of the patient to assess the outcome of the care of a patient;
    3) Modifying the care when necessary;
    4) Completing the care;
    5) Planning and follow-up, to include discharge planning that reflects the continuity of care.
b) These shall be documented in the nursing manual.

7.5.3 Assignment of patient care is done as per current good practice guidelines.

Interpretation/Remarks:

a) The assignment could be patient-acuity based.

7.5.4 Nursing care is aligned and integrated with overall patient care.

Interpretation/Remarks:

a) This shall be provided as per the nursing plan of care. The nursing plan of care shall be aligned with the plan of care of the patient.
b) Uniformity and continuity of care should be practised.

7.5.5 Care provided by a nurse is documented in the patient record.

Interpretation/Remarks:

a) This includes all nursing-related care and not just monitoring and documentation of medication administration.
b) The case sheet should have the continuation page with the page numbers.

7.5.6 Nurses are provided with adequate equipment for providing safe and efficient nursing services.

Interpretation/Remarks:

a) There shall be an adequate number of sphygmomanometers, thermometers, weighing scale(s), etc.

b) Nurses are empowered to take nursing-related decisions to ensure timely care of patients.

Standard

COP 7.6: Documented procedures guide the performance of various procedures.

Objective Elements

7.6.1. Documented procedures are used to guide the performance of various clinical procedures.*

Interpretation/Remarks:

a) This is a broad guideline which is common to all the procedures. It shall incorporate as to who will do the procedure, the pre-procedure instructions, the conduct of the procedure and post-procedure instructions.

7.6.2. Only qualified personnel order, plan, perform and assist in performing procedures.

Interpretation/Remarks:

a) The HCC could conduct a clinical audit of various procedures.

7.6.3. Documented procedures exist to prevent adverse events like the wrong site, wrong patient and wrong procedure.

Interpretation/Remarks:

a) The unique HCC ID shall be used for identifying patients.

b) In addition, the HCC should have a procedure to identify the site of the procedure, where appropriate.

7.6.4. Informed consent is taken by the personnel performing the procedure, where applicable.

Interpretation/Remarks:

a) Written consent shall be taken by the person performing the procedure or a member of his/her team. In case the procedure is being done by a person in training, it shall specify the same. All such procedures shall be supervised by the treating doctor.

7.6.5. Adherence to standard precautions and asepsis is adhered to during the conduct of the procedure.

Interpretation/Remarks:

a) In case the HCC has a policy of re-using single-use devices it shall ensure that they are properly sterilized. Further, the integrity of the devices shall be checked. It shall define the number of times it will be re-used and develop a mechanism to monitor the same.

7.6.6. Patients are appropriately monitored during and after the procedure.

Interpretation/Remarks:

a) At a minimum, this shall include pulse, blood pressure and respiratory rate.

7.6.7. Procedures are documented accurately in the patient record.

Interpretation/Remarks:

a) The documentation shall mention the name of the procedure, the person who performed the procedure, salient steps of the procedure, key findings and the post-procedure care.

b) All documentation shall have name, date, time and signature.

Standard

COP 7.7: Documented policies and procedures define rational use of blood and blood products.

Objective Elements

7.7.1. Documented policies and procedures are used to guide the rational use of blood and blood products.

Interpretation/Remarks:

a) Refer the Bhutan Blood and Blood Products Regulation.

b) Refer the SOPs for clinical use of blood and blood products.

7.7.2. Documented procedures govern transfusion of blood and blood products.*

Interpretation/Remarks:

a) This shall at a minimum include how the orders are written including pre-medications if any (rate needs to be mentioned for paediatric patients), transport of blood, how the blood/blood product is verified prior to transfusion, how the patient is identified and how the patient is monitored.

b) This shall include a procedure for availability and transfusion of blood/blood components

for emergency use/in an emergency.

c) Refer the SOPs for clinical use of blood and blood products.

7.7.3. The transfusion services are governed by the applicable laws and regulation.

Interpretation/Remarks:

a) Refer to Blood Safety Program guideline on blood and products and manual.

b) Refer to the DRA Act and Regulation.

7.7.4. Informed consent is obtained for donation and transfusion of blood and blood products.

Interpretation/Remarks:

a) Consent should be taken for every transfusion. However, with the same consent, you can give multiple transfusions in the same sitting. For example, two pints of blood may be transfused serially using the same consent. However, if the same is given over 24 hours apart, then a separate consent is required.

7.7.5. Informed consent also includes patient and family education about donation.

Interpretation/Remarks:

a) This could be in the form of a booklet/leaflet. This has to be given with the consent form.

7.7.6. The HCC defines the process for availability and transfusion of blood and blood products for use in an emergency.

Interpretation/Remarks:

a) The HCC shall define as to what blood and blood products are used in emergency and accordingly develop procedures.

b) This is applicable even if the HCC does not have the blood bank facility in-house.

c) It is preferable that the HCC also define the time frame within which blood must be available for use in an emergency. Use in emergency includes both for emergency use (standby) and in an emergency.

7.7.7. Post-transfusion form is collected; reactions if any identified and are analysed for preventive and corrective actions.

Interpretation/Remarks:

a) The HCC shall ensure that any transfusion reaction is reported. It is preferable that the HCC capture feedback regarding every transfusion (including the ones without reaction) as this would enable it to capture all transfusion reaction. These are then analysed (by an individual/committee as decided by the HCC) and appropriate corrective/preventive action is taken. The HCC shall maintain a record of transfusion reactions.

b) HCC shall have Haemovigilance process in place.

Standard

COP 7.8: Documented policies and procedures guide the care of patients in intensive care and high dependency units.

Objective Elements

7.8.1 Documents policies and procedures are used to guide the care of patients in intensive care and high dependency units.

Interpretation/Remarks:

a) At a minimum, this should include as to how care is organized, how patients are monitored and the nurse-patient ratio.

b) Refer to ICU policy and protocol.

7.8.2 The HCC has documented admission and discharge criteria for its intensive care and high dependency units.

Interpretation/Remarks:

a) The HCC should develop criteria based on physiologic parameters and adhere to it.

b) A good starting point could be various national and international critical care society guidelines.

7.8.3 Staff are trained to apply these criteria.

Interpretation/ Remarks:

a) This shall be done by training and/or displaying the criteria.

7.8.4 Adequate staff and equipment are available.

Interpretation/Remarks:

a) The ICU should be equipped with all necessary life-saving and monitoring equipment as well as suitably manned by trained staff. The staff deployment will be according to the HR planning but the exact requirements shall be decided by the HCC based on the scope and complexity of its services. However, the HCC is expected to follow best clinical practices.

b) National ICU policy and guideline.

7.8.5 Defined procedures for the situation of bed shortages are as below.

Interpretation/Remarks:

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

7.8.6 Infection control practices are documented and followed.*

Interpretation/Remarks:

a) These could be developed individually or it could be a part of the infection control guideline. The HCC shall ensure that the practices are in consonance with good clinical practices.

7.8.7 A quality assurance program is documented and implemented.*

Interpretation/Remarks:

a) These could be developed individually or it could be a part of the HCC's quality assurance program. The HCC shall ensure that the program is in consonance with good clinical practices.
b) Good clinical practices include monitoring infection rates, readmission rates, reintubation rates, etc.
c) Further, a good starting point could be various national and international critical care society guidelines.

Standard

COP 7.9: Documented policies and procedures guide the care of vulnerable patients (elderly, children, physically and/or mentally challenged).

Objective Elements

7.9.1 Procedures are documented and are in accordance with the prevailing laws and the national and international guidelines.

Interpretation/Remarks:

a) At a minimum, it shall incorporate as to who the vulnerable patients are, who is responsible for identifying these patients, risk management in these patients and the monitoring of these patients.
b) All these patients shall be assessed for risk of falls and the same documented.
c) Refer to the guideline on care and handling of disabled and mentally challenged Patients.
d) HCC shall ensure availability of safety measures for staff handling the mentally challenged patient.

7.9.2 Care is organized and delivered in accordance with the policies and procedures.
Interpretation/Remarks:

a) HCC develops SOPs for delivery of care.

7.9.3 The HCC provides for a safe and secure environment for this vulnerable group.
Interpretation/Remarks:

a) HCC shall provide proper environment taking into account the requirement of the vulnerable group. For example, playroom for children, anti-skid tiles for elderly, ramps with railings for disabled, etc.

7.9.4 A documented procedure exists for obtaining informed consent from the appropriate legal representative.
Interpretation/Remarks:

a) The informed consent for this group of people should be obtained from their family or legal representative.

7.9.5 Staff is trained to care for this vulnerable group.
Interpretation/Remarks:

a) All staff involved in the care of this group shall be adequately trained in identifying and meeting their needs and records of the same should be available.

Standards

COP 7.10: Documented policies and procedures guide obstetric care.

Objective Elements

7.10.1 There is a documented procedure for obstetric services.
Interpretation/Remarks:

a) At a minimum, this shall include assessment of these patients including nutrition, immunizations and education.
b) It could include prenatal safety guidelines such as monitoring standards, labour etc.

7.10.2 The HCC defines and displays whether high-risk obstetric cases can be cared for or not.
Interpretation/Remarks:

a) The HCC shall define as to what constitutes a high-risk obstetric case in consonance with best clinical practices and EMNOC guideline
b) The display should be in a prominent location (either near the entrance or registration counter or near the OPD). This is applicable only if it cares for such patients.

c) The HCC caring for high-risk obstetric cases has the facilities to take care of such mothers.

7.10.3 Persons caring for high-risk obstetric cases are competent.

Interpretation/Remarks:

a) These shall not just be doctors but shall include nursing staff also. The competency shall be based on qualification, experience and training.

b) It is preferable that persons caring for high-risk obstetric cases either have adequate experience or additional training for taking care of such patients.

7.10.4 Documented procedures guide provision of ante-natal services.

Interpretation/Remarks:

a) This shall at a minimum include assessment, immunization, diet counselling and frequency of visits.

b) There shall be an ante-natal card for every such patient.

7.10.5 Obstetric patient's assessment also includes maternal nutrition.

Interpretation/Remarks:

a) It is preferable that this is done by a dietician.

b) Physical activities for the mother should be included.

7.10.6 Appropriate pre-natal, peri-natal and post-natal monitoring is performed and documented.

Interpretation/Remarks:

a) This is the context of maternal and foetal monitoring.

7.10.7 The HCC caring for high-risk obstetric cases has the facilities to take care of neonates of such cases.

Interpretation/Remarks:

a) The HCC shall have a NICU with appropriate equipment and staff.

Standard

COP 7.11: Documented policies and procedures guide paediatric services.

Objective Elements

7.11.1 There is a documented policies and procedure for paediatric services.

Interpretation/Remarks:

a) At a minimum, this shall include assessment of these patients, HCC care and addressing

special needs.

7.11.2 The HCC defines and displays the scope of its paediatric services.

Interpretation/Remarks:

a) The scope shall also include neonatal services.
b) The display should be in a prominent location.

7.11.3 The policy for care of neonatal patients is in consonance with the national/international guidelines.

Interpretation/Remarks:

a) There are national and international guidelines available for the case of neonates.
b) The HCC shall actively promote breastfeeding practice.

7.11.4 Those who care for children have the competency to deal with all the ages of children.

Interpretation/Remarks:

a) These shall not just be for doctors but shall also include other relevant healthcare professionals. The competency shall be based on qualification, experience and training.

7.11.5 Provisions are made for special care of children.

Interpretation/Remarks:

a) Adequate amenities for the care of infants and children to be available in the HCC.
b) For example, playroom and breastfeeding room.

7.11.6 Patient assessment includes detailed nutritional, physical & mental growth, psychosocial and immunization assessment.

Interpretation/Remarks:

a) The same needs to be documented.
b) This could be done using a standard format like a checklist or questionnaire.

7.11.7 Documented policies and procedures prevent negligence in the care and treatment of children or neonates.

Interpretation/Remarks:

a) The HCC shall ensure that there is a documented procedure to prevent such happenings.

E.g. phototherapy leading to burns.

7.11.8 The children's family members are educated about nutrition, immunization and safe parenting and this is documented in the medical record.

Interpretation/Remarks:

a) For example, growth charts immunization chart, etc. This (original/copy) should be a part of the medical record.

b) The education should preferably be in the language that the family understands.

Standard

COP 7.12: Documented policies and procedures guide the care of patients undergoing sedation

Objective Elements

7.12.1 Documented procedures guide the administration of sedation.

Interpretation/Remarks:

a) At a minimum, this shall include identification of procedures where this is required, the mechanism for writing orders, the pre-procedure assessment, monitoring during and after the procedure and the discharge/transfer out criteria after the procedure.

7.12.2 Informed consent for administration of sedation is obtained by the concerned staff.

Interpretation/Remarks:

a) This shall be taken by the person performing the procedure/administering sedation.

7.12.3 Competent and trained persons perform sedation.

Interpretation/Remarks:

a) Wherever the parenteral route is used this shall be carried out by a doctor/nurse.

b) Technician shall not administer sedation except under the supervision of the competent anaesthetist or anesthesiologist.

7.12.4 The person administering and monitoring sedation is different from the person performing the procedure.

7.12.5 Intra-procedure monitoring includes at a minimum the heart rate, cardiac rhythm, respiratory rate, blood pressure, oxygen saturation, and level of sedation.

Interpretation/Remarks:

a) The same needs to be documented.

b) In addition, certain other parameters may be monitored on a case-to-case basis.

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

7.12.6 Patients are monitored after sedation and the same documented.

Interpretation/Remarks:

a) The patient's vitals shall be monitored at regular intervals till he/she recovers completely from the sedation.

b) At a minimum, the heart rate, respiratory rate, blood pressure, oxygen saturation and level of sedation are monitored. The level of sedation can be monitored by using a checklist which incorporates the various components of levels of sedation (minimal, moderate and deep).

7.12.7 Criteria are used to determine the appropriateness of discharge from the recovery area.

Interpretation/Remarks:

a) These shall be developed and documented by the HCC in consonance with physiologic parameters and good clinical practices.

b) The criteria shall be applied by a qualified individual and the same documented.

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

Interpretation/Remarks:

a) The equipment shall include emergency resuscitation equipment.

b) A person trained in airway management/anaesthesiologist shall be available in the HCC.

Standard

COP 7.13: Documented policies and procedures guide the administration of anaesthesia.

Objective Elements

7.13.1 There is a procedure for the administration of anaesthesia.

Interpretation/Remarks:

a) HCC shall document on the indications, the type of anaesthesia and procedure for the same.

b) The standard is not applicable to local anaesthesia.

7.13.2 Patients for anaesthesia have a pre-anaesthesia assessment by a qualified nurse anaesthetist/ Anaesthesiologist.

Interpretation/Remarks:

a) This shall be done before the patient is wheeled into the OT complex. It shall be applicable to both routine and emergency cases.
b) It is preferable to do an assessment in a standardized format.
c) The pre-anaesthesia assessment may even be carried out prior to admission in case of elective surgeries.

7.13.3 The pre-anaesthesia assessment results in the formulation of the type of anaesthesia, which is documented.

Interpretation/Remarks:

a) The plan should mention the pre-medications, type of anaesthesia, the drug(s) to be used for induction and the drug to be used for maintenance. It should also mention about other concomitant medications and IV fluids, special monitoring requirements where appropriate and anticipated post-anaesthesia care.
b) PAC for the routine cases shall be conducted within a week prior to the surgery.
c) PAC for an emergency case can be done in the PAC room if permitted by the time and condition of the patients otherwise it shall be done inside the OT.

7.13.4 An immediate pre-operative re-evaluation is performed and documented.

Interpretation/Remarks:

a) This is essentially a pre-induction assessment and shall be done by a nurse anaesthetist/ anesthesiologist just before the patient is wheeled into the respective OT.
b) Any planned changes to the anaesthesia plan shall be documented.
c) When anaesthesia must be provided on an urgent basis, the pre-anaesthesia assessment and pre-induction assessment may be performed immediately following one another, or simultaneously, but should be documented separately.

7.13.5 Informed consent for administration of anaesthesia is obtained by the nurse anaesthetist/ anaesthesiologist.

Interpretation/Remarks:

a) The patient and/or, the family are educated on the risks, benefits, and alternatives of anaesthesia by the anesthesiologist.
b) This shall be separate from the surgery consent.

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

Interpretation/Remarks:

a) In case of regional anaesthesia instead of end-tidal carbon dioxide, the adequacy of ventilation shall be evaluated by continual observation of qualitative clinical signs.
b) Anaesthesiologist/nurse anaesthetist shall be present throughout the procedure.
c) In addition, certain other parameters may be monitored on a case-to-case basis.
d) The cardiac rhythm may be monitored on a monitor during the procedure and the same need not be documented. However, in case of rhythm abnormalities, the same shall be documented.

7.13.7 Patient's post-anaesthesia status is monitored and documented.

Interpretation/ Remarks:

a) This shall be done in the recovery area/OT and at least include monitoring of vitals till the patient recovers completely from anaesthesia and shall be done by an anesthesiologist/nurse anaesthetist. If the patient's condition is unstable and he/she requires ICU care the same shall be monitored there.

7.13.8 The anesthesiologist/anaesthetist/recovery nurse applies defined criteria to transfer the patient from the recovery area.

Interpretation/Remarks:

a) The HCC documents these criteria which should be based on physiologic parameters and in consonance with good clinical practices.

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

Interpretation/Remarks:

a) It shall have the name of the anesthesiologist/nurse anaesthetist who performed the procedure and also the names of individuals (with their designation) who helped in the procedure.
b) The documentation shall have name, date, time and signature.

7.13.10 Procedures shall comply with infection control guidelines to prevent cross-infection between patients.

Interpretation/Remarks:

a) The guidelines shall be documented either separately or as part of the infection control manual.

b) This could include management of circuits, infection control measures during administration etc.

7.13.11 Adverse anaesthesia events are recorded and monitored.

Interpretation/Remarks:

a) All such events are documented and monitored for the purpose of taking corrective and preventive action.

b) At the outset, the HCC shall define various adverse anaesthesia events. These essentially are adverse events following the administration of anaesthesia.

c) The HCC should have a mechanism to ensure that all adverse events are captured and reported to the anesthesiologist/nurse anaesthetist.

Standard

COP 7.14: Documented policies and procedures guide the care of patients undergoing surgical procedures.

Objective Elements

7.14.1 The policies and procedures are documented.

Interpretation/Remarks:

a) This shall include the list of surgical procedures as well as competency level for performing these procedures.

7.14.2 Surgical patients have a preoperative assessment and a provisional diagnosis documented prior to surgery.

Interpretation/Remarks:

a) All patients undergoing surgery are assessed pre-operatively and a provisional diagnosis is made which is documented. This shall be applicable to both routine and emergency cases.

b) This shall be done by the operating surgeon.

7.14.3 Informed consent is obtained by a surgeon prior to the procedure.

Interpretation/Remarks:

a) The consent shall be taken by the operating surgeon or a member of his team. In case, the procedure is changed intra-operation (and was not planned or an explicit consent taken for the same) a fresh consent needs to be taken.

7.14.4 Documented policies and procedures exist to prevent adverse events like the wrong site, wrong patient and wrong surgery.

Interpretation/Remarks:

a) The procedure should be available for preventing adverse events like wrong patients, wrong site by a suitable mechanism.

b) The HCC should be able to demonstrate methods to prevent these events, e.g. identification tags, badges, cross-checks, time-outs etc. Refer to WHO "Safe surgery saves lives" initiative and surgical safety checklist (SSCL).

7.14.5 Persons certified by BMHC are permitted to perform the procedures that they are entitled to perform.

Interpretation/Remarks:

a) The HCC identifies the individuals who have the required qualification(s), training and experience to perform procedures in consonance with the law.

7.14.6 A brief operative note is documented prior to transfer out of patient from the recovery area.

Interpretation/Remarks:

a) This note provides information about the procedure performed post-operative diagnosis and the status of the patient before shifting and shall be documented by the surgeon/member of the surgical team.

b) At a minimum, it shall include the surgery performed, name of the surgeon (s), name of anaesthesiologist/nurse anaesthetist, salient steps of the procedure and the key findings intra-operation.

c) It is documented by a person other than the operating surgeon the same shall be countersigned by the head of the surgeons.

7.14.7 The operating surgeon documents the post-operative plan of care.

Interpretation/Remarks:

a) The plan shall include advice on IV fluids, medication, care of the wound, nursing care, observation for any complication, etc.

b) This plan could be written in collaboration with the anesthesiologist.

7.14.8 Patient, personnel and material flow conforms to infection control practices.
Interpretation/Remarks:

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

7.14.9 Appropriate facilities and equipment/appliances/instrumentation are available in the operating theatre.
Interpretation/Remarks:

a) The HCC shall ensure that the operating theatre has facilities for pre-operation holding, separate changing rooms for males and females, hand-washing area, operating rooms, waiting area for relatives, storage area, a collection area for waste and linen and recovery room.
b) In addition to the equipment required for anaesthesia and surgery, there shall be equipment for resuscitation, radiation protection (where applicable) etc.

7.14.10 A quality assurance program is followed for the surgical services.
Interpretation/Remarks:

a) This shall be an integral part of the HCC's overall quality assurance program. It shall focus on postoperative complications, e.g. bleeding, rational use of antibiotics, etc.

7.14.11 The quality assurance program includes surveillance of the operation theatre environment.
Interpretation/Remarks:

a) Surveillance activities include the daily monitoring of humidity and temperature; at least monthly monitoring of pressure differential, and at least six monthly monitoring of the integrity of filter.
b) In addition, the efficacy of OT cleaning and disinfection processes shall be monitored.
c) For air-conditioning of OT as per the guidelines.

Standard

COP 7.15: Documented policies and procedures guide the care of patients under restraints (physical and/or chemical).

Objective Elements

7.15.1 Documented procedures guide the care of patients under restraints.

Interpretation/ Remarks:

a) This shall clearly state the conditions/circumstances under which restraints shall be used. It shall also specify as to who can authorize the use of restraints, the frequency of monitoring these patients and the validity of restraint orders.

7.15.2 These include both physical and chemical restraint measures.

Interpretation/Remarks:

a) Physical restraints include boxer's bandage, use of cuffs, etc.
b) Chemical restraints include sedatives like diazepam.
c) Verbal consent shall be taken where applicable.
These include documentation of reasons for restraints.

7.15.3 These patients are more frequently monitored.

Interpretation/Remarks:

a) The HCC shall specify the parameters and frequency of monitoring and accordingly implement the same.

7.15.4 Staff receives training and periodic updating in control and restraint techniques.

Interpretation/Remarks:

a) It is applicable to all personnel involved in the care of patients.
b) The staff shall be updated at least once a year. Records of the same should be maintained.

Standard

COP 7.16: Documented policies and procedures guide appropriate pain management.

Objective Elements

7.16.1 Documented policies and procedures guide the management of pain.
Interpretation/Remarks:

a) It shall include as to how patients are screened for pain, the mechanism to ensure that a detailed pain assessment is done (when necessary), pain mitigation techniques and monitoring.

7.16.2 All patients are screened for pain and Patients with pain undergo detailed assessment and periodic re-assessment.
Interpretation/Remarks:

a) Every patient entering the HCC shall be screened for pain.
b) Pain shall be considered the fifth vital sign.
c) This could be done by incorporating a sub-heading in the initial assessment of pain.
d) A detailed pain assessment is done when pain is the predominant (or one of the main) symptom(s). It shall be done for all post-operative patients.
e) The pain assessment shall include the intensity of pain (can be done using a pain-rating scale), pain character, frequency, location, duration and referral and/or radiation.
f) The assessment should be done in an objective manner so that it facilitates regular reassessment.
g) For example, cancer pain, neuralgia and arthralgia.
h) This does not include chest pain due to angina or where the aetiology of pain is physiological like labour pain.

7.16.3 The HCC respects and supports management of pain for such patients.
Interpretation/Remarks:

a) In case the HCC does not have facilities for pain management, it could refer such patients to HCCs specializing in pain management.
b) Pain management includes medical, surgical and anaesthetic techniques.

7.16.4 Patient and family are educated on various pain management techniques, where appropriate.
Interpretation/Remarks:

a) This could be done only for patients who are likely to have long-term pain in view of the

underlying condition not being treatable.

Standard

COP 7.17: Documented policies and procedures guide appropriate rehabilitative services.

Objective Elements

7.17.1 Documented policies and procedures guide the provision of rehabilitative services.
Interpretation/Remarks:

a) This includes physiotherapy, orthotic, prosthetic, and occupational and speech therapy.

7.17.2 These services are commensurate with the requirements of the HCC.
Interpretation/Remarks:

a) The scope of the departments is in consonance with the scope of the HCC.
b) For example, the provision of ante-natal and post-natal exercises could form a part of women's' health rehabilitation program.

7.17.3 Care is guided by functional assessment and periodic re-assessment which is done and documented by a qualified health professional(s).
Interpretation/Remarks:

a) This can be done using a scale.

7.17.4 Care is provided adhering to infection control and safe practices.
Interpretation/ Remarks:

a) Safe practices include ensuring that when using hot wax there are no burns to the patient.

7.17.5 Rehabilitative services are provided by a multidisciplinary team.
Interpretation/Remarks:

a) The team shall have a treating doctor, a rehabilitation therapist, orthotist, prosthetist, occupational therapist, rehabilitation nurses and other professional experts.

7.17.6 There are adequate space and equipment to perform these activities.
Interpretation/Remarks:

a) The equipment shall be as per the scope of rehabilitation services provided. However, equipment for resuscitation shall be available in these areas.

Standard

COP 7.18: Documented policies and procedures guide all research and developmental activities.

Objective Elements

7.18.1 Documented policies and procedures guide all research and developmental activities in compliance with national and international guidelines.

Interpretation/ Remarks:

a) Any research undertaken is in accordance with the guideline of the REBH and HCC should have ethical approval.

b) HCC allocates budget for carrying out research and developmental activities.

7.18.2 The HCC has the ethical committee to oversee the research activities in compliance with the Research and Ethical Board of Bhutan.

Interpretation/Remarks:

a) An ethics committee should be framed in the HCC to monitor activities undertaken by various providers. The committee has the powers to discontinue a research trial when risks outweigh the potential benefits.

b) Health Research and Board guidelines.

7.18.3 The committee has the powers to discontinue a research trial when risks outweigh the potential benefits.

7.18.4 Patients' informed consent is obtained before entering them in research protocols.

Interpretation/Remarks:

a) This shall be done in a language that the patient understands.

7.18.5 Patients are informed of their right to withdraw from the research at any stage and also of the consequences (if any) of such withdrawal.

Interpretation/Remarks:

a) This shall be done in a language that the patient understands.

7.18.6 Patients are assured that their refusal to participate or withdrawal from participation will not compromise their access to the HCC's services.

Standard

COP 7.19: Documented policies and procedures guide nutritional therapy

Objective Elements

7.19.1 Documented policies and procedures guide nutritional assessment and reassessment.
Interpretation/Remarks:

a) This shall at a minimum incorporate as to whom nutritional assessment will be done, how it will be done, how the diet is prepared and ensured that the patient receives food as per the diet order.
b) A nutritional assessment shall be done by a dietician for all patients found at risk during nutritional screening.

7.19.2 Patients receive food according to their clinical needs.
Interpretation/Remarks:

a) A dietician shall do the assessment of the patient in consultation with clinician and nurses advise the patient regarding food.
b) For example, diabetic diets, high-protein diet, total parenteral nutrition, etc.

7.19.3 There is a written order for the diet.
Interpretation/Remarks:

a) The dietician shall prepare this in the form of a diet sheet and patient shall receive food accordingly.
b) This shall be written in a uniform location in the medical record.

7.19.4 Nutritional therapy is planned and provided in a collaborative manner.
Interpretation/Remarks:

a) The dietician shall ensure that nutritional therapy is planned in consultation with the treating doctors, nurses and the patient based on the nutritional requirements.

7.19.5 When families provide food, they are educated about the patients' diet limitations.
Interpretation/Remarks:

a) The dietician shall prepare this in the form of a diet sheet and patient shall receive food accordingly.
b) This shall be written in a uniform location in the medical record.
c) Patient attendants should be advised to provide nutrition based on the requirements of the patient (E.g. high protein containing diet for a patient with fever).

7.19.6 Food is prepared, handled, stored and distributed in a safe manner.

Interpretation/Remarks:

a) The dietary services to be designed in a manner that there is no criss-cross of traffic. All the activities fall in a sequence. The HCC shall ensure that hygienic conditions are followed all throughout.

7.19.7 Other indicative points are:

a) Dedicated food storage/refrigeration areas exist to ensure food preservation in the ward and food serving unit.
b) Food storage areas/refrigerators are maintained appropriately;
c) All food products are stored off the floor;
d) Cleaning supplies stored in a separate location away from food;
e) Measures are in place to ensure that flies do not come in contact with stored food.
f) Food distribution to patients occurs where possible in temperature appropriate food service trolleys.
g) Each patient is provided with diet card for identification of patients.

Standard

COP 7.20: Documented policies and procedures guide the end of life care.

Objective Elements

7.20.1 Documented policies and procedures guide the end of life care.

Interpretation/Remarks:

a) The HCC has a documented procedure for providing end of life care. This shall include:
    1) Providing appropriate pain and palliative care according to the wishes of the family and patient;
    2) Sensitively addressing such issues as autopsy and organ donation;
    3) Respecting the patient's values, religion, and cultural preferences;
    4) Involving the patient and family in all aspects of care; and
    5) Responding to the psychological, emotional, spiritual, and cultural concerns of the patient and family (where possible).

7.20.2 These procedures are in consonance with the legal requirements.

Interpretation/Remarks:

a) Decisions like “Do not resuscitate/do not intubate/Allow natural death etc.” shall be only as per the legal laws and within the guidelines framed by the legal system.

b) Since the country doesn’t have laws for the end of life care procedures, the decision will be based on the policy of the HCC.

7.20.3 These also address the identification of the unique needs of such patient and family.

Interpretation/Remarks:

a) The religious and socio-cultural beliefs of patients/family shall be addressed and respected.

7.20.4 Symptomatic treatment is provided and where appropriate measures are taken for an alleviation of pain.

Interpretation/Remarks:

a) The emphasis shall be on providing symptomatic treatment of such patients and to prevent complications to the possible extent. The patient and/or family shall be involved while taking all such decisions.

7.20.5 Staff are educated and trained in end of life care and records of the same shall be available.

a) This shall be done to the staff dealing with such patients.

b) Records of the same shall be available.

8. Management of Medication (MOM)

Preamble

The HCC 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. Medications may also include blood and blood products, implants, devices and medical gases. The pharmacy department should ensure the availability of quality medicines, good storage and dispensing practices. The process also includes monitoring of patients after administration and procedures for reporting and analysing medication errors. Safe use of high-risk medication like narcotics, chemotherapeutic agents and radioactive isotopes are guided by policies and procedures. Patients and family members are educated about safe medication and food-drug interactions.

Summary of Standards

MOM 8.1	Documented policies and procedures guide the HCC"s pharmacy services and use of medication.
MOM 8.2	There is an HCC formulary
MOM 8.3	Documented policies and procedures exist for storage of medication.
MOM 8.4	Documented policies and procedures guide the safe and rational prescription of medications.
MOM 8.5	Documented policies and procedures guide the safe dispensing of medications.
MOM 8.6	There are documented policies procedures for medication management.
MOM 8.7	Patients are monitored after medication administration.
MOM 8.8	Near misses, medication errors and adverse drug events are reported and analysed.
MOM 8.9	Documented procedures guide the use of narcotic drugs and psychotropic substances.
MOM 8.10	Documented policies and procedures guide the usage of chemotherapeutic agents.
MOM 8.11	Documented policies and procedures govern the usage of radioactive drugs.
MOM 8.12	Documented policies and procedures guide the use of implantable prosthesis and medical devices.
MOM 8.13	Documented policies and procedures guide the use of medical supplies and

Standards and Objective Elements Standard

MOM 8.1: Documented policies and procedures guide the HCC"s pharmacy services and use of medication.

Objective Elements

8.1.1 There is a documented policy and procedure for pharmacy services and medication usage.

Interpretation/Remarks:

a) The policies and procedures shall address the issues related to procurement, storage, formulary, prescription, dispensing, administration, monitoring and use of medications.

b) All the required procedures under this chapter can be clubbed together in a "Pharmacy/Medication Usage Manual".

8.1.2 These comply with the applicable laws and regulations.

Interpretation/Remarks:

a) Relevant legislation includes the Medicines Act of the Kingdom of Bhutan, Narcotic Drugs and Psychotropic Substances Act etc.

8.1.3 A therapeutic committee guides the formulation and implementation of these policies and procedures.

Interpretation/Remarks:

a) This shall be representative of major clinical departments, administration and shall include a pharmacist/clinical pharmacologist.

b) The objectives of this committee, its composition, the frequency of meetings, the quorum required and the minutes of the meeting shall be documented.

c) At a minimum, the committee shall meet once in three months.

d) For example, Hospital Therapeutic Committee, National Medicine Committee, etc.

8.1.4 There is a procedure to obtain medication when the pharmacy is closed.

Interpretation/Remarks:

a) When a pharmacy is closed, there should be an SOP to obtain the drugs.

b) It is preferable that the HCC has a 24-hour pharmacy.

Standard

MOM 8.2: There is a national formulary in the HCC.

Objective Elements

8.2.1 A list of medications appropriate for the patients and as per the scope of the HCC clinical services is developed.

Interpretation/Remarks:

a) The HCC's formulary shall be prepared and be preferably updated at regular intervals.

b) The formulary could be prepared Essential Medicines Technology Division of the Ministry of Health. Note that implants also come under drugs. The HCC could look at the possibility of having a department-wise formulary.

8.2.2 The list is developed and updated collaboratively by the therapeutic committee.

Interpretation/Remarks:

a) Refer to MOM 8.3

8.2.3 The national formulary is available for clinicians to refer and adhere to.

Interpretation/Remarks:

a) The national formulary shall be made available to all treating doctors of the HCC.

b) The HCC shall ensure that the prescriptions are as per the formulary. It shall monitor the frequency of prescriptions with non-formulary drugs.

c) The formulary could be made available in either physical or electronic form.

8.2.4 There is a defined process for acquisition of these medications.

Interpretation/Remarks:

a) The process should address the issues of vendor selection, vendor evaluation, indenting process, generation of a purchase order and receipt of goods.

b) These processes are done through DoMSHI

8.2.5 There is a process to obtain medications not listed in the formulary.

Interpretation/Remarks:

a) For example, name patient drugs.

Standards

MOM 8.3: Documented policies and procedures guide the storage of medication.

Objective Elements

8.3.1 Documented policies and procedures exist for storage of medication.
Interpretation/Remarks:

a) These should address issues pertaining to temperature (refrigeration), light, ventilation, preventing entry of pests/rodents and vermin.

8.3.2 Medications are stored in a clean, safe and secure environment; and incorporating the manufacturer's recommendation(s).
Interpretation/Remarks:

a) The HCC shall also ensure that the storage requirements of the drug as specified by the manufacturer are adhered to. This shall be applicable to all areas where medications are stored including wards.
b) Medications shall be protected from loss or theft. The overall cleanliness of the storage area shall be maintained.
c) Vaccines could preferably be kept in vaccine refrigerators (Ice Lined Refrigerator).
d) Where appropriate, temperature monitoring of the storage area/refrigerator shall be done at least once a day. In case of areas which are not open all days, it shall be done on all working days.
e) To check for loss or theft, the HCC could conduct audits at regular (as defined by the HCC) to detect such instances.
f) Expired medicines shall be segregated, labelled and stored securely for disposal.

8.3.3 Sound inventory control practices guide storage of the medications.
Interpretation/Remarks:

a) HCC shall follow or demonstrate FEFO and FIFO system.
b) The medicines shall be stored in alphabetical order by generic name or therapeutic category.

8.3.4 Sound-alike and look-alike medications are identified and stored separately.
Interpretation/Remarks:

a) Many drugs in ampoules, vials or tablets may look-alike or sound-alike. They should be documented, segregated and stored separately at all locations.
b) The HCC can follow a method of storing drugs by generic name in an alphabetical order

to address this issue.

c) The list will have to be updated at regular intervals depending on the changes in the formulary and changes in packaging (in case of look-alike).

8.3.5 The list of emergency medications is defined and is stored in a uniform manner.*

Interpretation/Remarks:

a) This list shall be prepared in consonance with good clinical practices and documented. List of drugs shall be uniform across the HCC; however, the quantity can differ.

b) A crash cart would help the HCC to store these medications in a standardized manner, i.e. the rows and drawer have defined medicines.

c) No other drugs shall be kept/stored with emergency medications.

8.3.6 Emergency medications are available all the time.

Interpretation/Remarks:

a) Adequate quantity of emergency medicines should be stocked at all times. Re-order level at definite quantity should be done.

8.3.7 Emergency medications are replenished in a timely manner when used.

Interpretation/Remarks:

a) An inventory check shall be done at least daily to ensure this.

b) In case the HCC follows a system of sealing the emergency cart then the check shall be carried out before re-sealing every time.

Standard

MOM 8.4: Documented policies and procedures guide the safe and rational prescription of medications

Objective Elements

8.4.1 Documented policies and procedures exist for prescription of medications.

Interpretation/Remarks:

a) Refer to MOM 8.1. It could also incorporate objective elements “8.1.2” and “8.1.6

8.4.2 These incorporate inclusion of good practices/guidelines for the rational prescription of medications.

Interpretation/Remarks:

a) The HCC shall ensure that the clinicians are trained/sensitized on the rational prescription

of medications.

b) WHO states: “Rational use of medicines requires that patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community.”

8.4.3 The HCC determines the minimum requirements of a prescription.

Interpretation/Remarks:

a) This shall adhere to national/international guidelines where appropriate.

b) At a minimum, the prescription shall have the name of the patient; unique HCC number; the name of the drug, dose, route and frequency of administration of the medicine; name, signature and registration number of the prescribing doctor.

c) A good reference is the Code of Medical Ethics.

8.4.4 Known drug allergies are ascertained before prescribing.

Interpretation/Remarks:

a) It is a good practice to document drug allergies in a prominent manner in the medical record, both in OPD and IPD.

b) The treatment orders shall be written daily. Phrases like “CT all”; “continue same treatment” shall not be acceptable for OPD patients.

8.4.5 The HCC determines who can write orders.

Interpretation/Remarks:

a) This shall be done by health professionals authorized to be prescribed by BMHC.

b) The orders written by the treating doctor on the case sheet could be transcribed by another person onto the indent slip (physical/electronic). However, to avoid transcription errors, which can lead to medication errors, it is better to avoid this practice.

8.4.6 Orders are written in a uniform location in the medical records.

Interpretation/Remarks:

a) All the orders for medicines are recorded on a uniform location of the case sheet. Electronic orders when typed shall again follow the same principles.

b) It is preferable that prescription and administration record is on the same sheet. This would help minimize medication errors. A drug, kardex‟ could be used for this purpose.

8.4.7 Medication orders are clear, legible, dated, timed, named and signed.
Interpretation/Remarks:

a) Only approved abbreviations shall be used.
b) The HCC can explore the possibility of writing orders in block letters so that the issue of legibility is addressed.
c) A good reference is the Institution for Safe Medication Practices Guidelines.

8.4.8 Medication orders contain the name of the medicine, the route of administration, the dose to be administered and the frequency/time of administration.
Interpretation/Remarks:

a) In case of medicine having two or more drugs (tablet/capsule/injection), the dose of all the individual drugs shall be written. For example, in a combination of Clopidogrel with Aspirin, the dose of both the drugs shall be written as 75 mg + or as 75 mg + 150 mg.
b) This is not necessary for preparations having a combination of vitamins and/or minerals. Similarly, if the combination of medication comes only in one strength, it is not necessary.
c) In case abbreviations are used, a standardized list of approved abbreviations for medications shall be used throughout the HCC.

8.4.9 Documented policy and procedure on verbal orders are implemented.
Interpretation/Remarks:

a) The HCC shall ensure that it has the policy to address this issue and it shall mention who can give verbal orders and how these orders will be validated. HCC should have approved list of drugs which can be ordered verbally. It shall ensure that the procedure incorporates good practices like “read back”.
b) Verbal orders shall be counter-signed by the doctor who ordered it within 24 hours of ordering. This is not applicable if a doctor of the treating team consulted the treating doctor and writes down the orders.

8.4.10 The HCC defines a list of high-risk medication(s).
Interpretation/Remarks:

a) High-risk medications are medications involved in a high percentage of medication errors or sentinel events and medications that carry a high risk of abuse, error, or other adverse outcomes.
b) Examples include medications with a low therapeutic window, controlled substances, psychotherapeutic medications, and look-alike and sound-alike medications.

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

Interpretation/Remarks:

a) The scope of the audit shall include:
   i. The appropriateness of the drug, dose, frequency, and route of administration;
   ii. Presence of therapeutic duplication;
   iii. A possibility of drug interaction and measures taken to avoid the same;
   iv. A possibility of food-drug interaction and measures taken to avoid the same;
   v. This shall be done at least once a month using a representative sample size.
   vi. It could preferably be done by a clinical pharmacist. In case there is no clinical pharmacist it shall be done by the pharmacologist.

8.4.12 Corrective and/or preventive action(s) is taken based on the analysis, where appropriate.

Standard

MOM 8.5: Documented policies and procedures guide the safe dispensing of medications.

Objective Elements

8.5.1 Documented policies and procedures guide the safe dispensing of medications.

Interpretation/Remarks:

a) Clear policies to be laid down for dispensing of medication, e.g. route of administration, dosage, the rate of administration, expiry date, etc.
b) This shall include both bulk and retail pharmacy.
c) Physician samples shall not be sold.

8.5.2 The procedure addresses the recall of a medicinal product.

Interpretation/Remarks:

a) Recall may result based on letters from DRA or internal feedback (e.g. visible contaminant in IV fluid bottle)

8.5.3 The expiry date is checked prior to dispensing.

Interpretation/Remarks:

a) This shall be done at all levels, e.g. pharmacy, ward, etc.

8.5.4 There is a procedure for near expiry medications.

Interpretation/Remarks:

a) This procedure shall ensure that near expiry drugs are withdrawn and that no beyond expiry date medication is available.

b) The HCC could define as to what constitutes “near expiry”. E.g. three months prior to the expiry date.

8.5.5 Labelling requirements are documented and implemented by the HCC.

Interpretation/Remarks:

a) At a minimum, labels must include the drug name, strength, frequency of administration (in a language the patient understands) and expiry dates.

b) This is applicable to all dispensing areas wherein medicines are dispensed either as cut strips or from bulk containers. It shall also be applicable where drugs are diluted. E.g. Chemotherapy.

8.5.6 High-risk medication orders are verified prior to dispensing.

Interpretation/Remarks:

a) These medications shall be given only after written orders and it should be verified by the staff before dispensing.

b) This shall adhere to statutory requirements where applicable.

Standard

MOM 8.6: Documented policies and procedures for medication management.

Objective Elements

8.6.1 Medications are administered by those professionals certified by the BMHC.

Interpretation/Remarks:

a) Refer to legal requirements.

8.6.2 Prepared medication is labelled prior to preparation of a second drug.

Interpretation/Remarks:

a) Applicable only for parenteral drugs, especially for anaesthetic drug preparation in OTs.

8.6.3 The patient is identified prior to administration.

Interpretation/Remarks:

a) Identification shall be done by unique identification number (e.g. HCC number/IP number, etc.) and/or name.

8.6.4 Medication is verified from the order prior to administration.

Interpretation/Remarks:

a) Staff administering medications should go through the treatment orders before administration of the medication and then only administer them. It is preferable that they also check the general appearance of the medication (e.g. melting, clumping etc.) before dispensing.

b) If any of the parameters with respect to an order namely name, dose, route or frequency/time are missing/incomplete the medication administration shall be deferred. However, to ensure that patient care does not suffer a verbal order may be got from the treating doctor followed by ratification of the same.

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

8.6.5 Dosage and route are verified from the order prior to administration.

Interpretation/Remarks:

a) Where applicable the site of administration shall also be verified.

8.6.6 Timing is verified from the order prior to administration.

Interpretation/Remarks:

a) The HCC needs to define the timing an administration of medication. For example, OD, BID, TID, QID, HS.

8.6.7 Medication administration is documented.

Interpretation/Remarks:

a) The HCC shall ensure that this is done in a uniform location and it shall include the name of the medication, dosage, route of administration, timing and the name and signature of the person who has administered the medication.

b) In case of infusions, it shall capture the start time, the rate of infusion and end time.

c) The records shall reflect the actual administration. For example, if brand Y was given in place of brand X (same generically) the documentation shall be of brand Y. Similarly, if the order was for a tablet of 250 mg but the administration was ½ a tablet of 500mg the later shall be documented.

8.6.8 Documented policies and procedures govern patient's self-administration of medications.
Interpretation/Remarks:

a) At the outset, the HCC could define if it would permit self-administration of medications. In case the HCC permits then the policy shall include the medications which the patient can self-administer. It is preferable that the HCC also incorporates a method to ensure that the patient is reminded to take the medication (before every dose) and documentation of self-administration.
b) For example, self-administration of insulin.

8.6.9 Documented policies and procedures govern patient's medications brought from outside the HCC.
Interpretation/Remarks:

a) These shall address as to what are prerequisites for such a medication (e.g. invoice; clear label with mention of the name, dose, expiry date, etc.)

Standard

MOM 8.7: Patients are monitored after medication administration.

Objective Elements

8.7.1 Documented policies and procedures guide the monitoring of patients after medication administration.
Interpretation/Remarks:

a) The purpose of monitoring is to verify that the medicine is having its intended effect. In addition, this would help identify near misses, medication errors and adverse drug events.

8.7.2 The HCC defines those situations where close monitoring is required.
Interpretation/Remarks

a) For example, administration of high-risk medicines, concentrated electrolytes, chemotherapeutic drugs.

8.7.3 Monitoring is done in a collaborative manner.
Interpretation/Remarks:

a) This shall be done by the clinician and nurse.
b) A clinical pharmacist may also be involved.

8.7.4 Medications are changed where appropriate based on the monitoring.
Interpretation/Remarks:

a) This also includes dose adjustment.

Standard

MOM 8.8: Near misses, medication errors and adverse drug events are reported and analysed.

Objective Elements

8.8.1 Documented procedures exist to capture near miss, medication error and adverse drug event.
Interpretation/Remarks:

a) This shall outline the process for identifying, capturing, reporting, analysing and taking action.

8.8.2 Near miss, medication error and adverse drug event are defined.
Interpretation/Remarks:

a) The HCC shall define as to what constitutes these. This shall be in consonance with best practices.

8.8.3 These are reported within a specified time frame.
Interpretation/Remarks:

a) The HCC shall define the time frame according to the pharmacovigilance.

8.8.4 They are collected and analysed.
Interpretation/Remarks:

a) All these incidents are analysed regularly by the multi-disciplinary committee.
b) The analysis shall be completed in a defined time frame.

8.8.5 Corrective and/or preventive action(s) are taken based on the analysis where appropriate.

Standard

MOM 8.9: Documented procedures guide the use of narcotic drugs and psychotropic substances.

Objective elements

8.9.1 Documented procedures guide the use of narcotic drugs and psychotropic substances which are in consonance with local and national regulations.

Interpretation/Remarks:

a) Refer Narcotic, psychotropic and Substance Abuse Act and Medicines Act and Regulations.

8.9.2 These drugs are stored in a secure manner (should be under lock and Key).

Interpretation/Remarks:

a) They shall be stored under lock and key with a designated person being responsible for the same.

8.9.3 A proper record is kept of the usage, administration and disposal of these drugs.

Interpretation/Remarks:

a) These shall be kept in accordance with statutory requirements.
b) A very strict inventory control shall be kept for these drugs.

8.9.4 These drugs are handled by appropriate personnel in accordance with the documented procedure.

Standard

MOM 8.10: Documented policies and procedures guide the usage of chemotherapeutic agents.

Objective elements

8.10.1 Documented policies and procedures guide the usage of chemotherapeutic agents.

Interpretation/Remarks:

a) This could incorporate all the objective elements of this standard.

8.10.2 Chemotherapy is prescribed by those who have the knowledge to monitor and treat the adverse effect of chemotherapy.

Interpretation/Remarks:

a) This shall preferably be an oncologist.

8.10.3 Chemotherapy is prepared in a proper and safe manner and administered by qualified personnel.

Interpretation/Remarks:

a) This shall preferably be staff, who have received special training in preparing and administration.

b) A bio-safety cabinet shall be used for preparing/mixing chemotherapeutic drugs.

8.10.4 Chemotherapy drugs are disposed of in accordance with legal requirements.

Interpretation/Remarks:

a) These shall be disposed of according to Infection Control and Medical Waste Management Guideline, Waste Management Act, or manufacturer's recommendation.

Standard

MOM 8.11: Documented policies and procedures govern the usage of radioactive drugs.

Objective Elements

8.11.1 Documented policies and procedures govern the usage of radioactive drugs.

Interpretation/Remarks:

a) The documentation shall include documentation for objective element "8.11.3" and shall adhere to objective element "8.11.4".

8.11.2 These policies and procedures are in consonance with laws and regulations.

8.11.3 The policies and procedures include the safe storage, preparation, handling, distribution and disposal of radioactive drugs.

8.11.4 Staff, patients and visitors are educated on safety precautions.

Interpretation/Remarks:

a) This refers to the layout/location of radiation waste pipes, delay tanks, etc.

Standard

MOM 8.12: Documented policies and procedures guide the use of implantable prosthesis and medical devices.

Objective Elements

8.12.1 Usage of an implantable prosthesis and medical devices is guided by scientific criteria for each individual item and national/international recognized guidelines/approvals for such specific items(s).

Interpretation/Remarks:

a) The HCC shall ensure that relevant and sufficient scientific data are available before selection. It shall also look for international (e.g. US-FDA) or national notification (DRA Act) for approval of the particular product.

b) The multidisciplinary committee (refer MOM 3.1.3) shall be responsible for approving the use of a particular implant.

8.12.2 Documented policies and procedures govern procurement, storage/stocking, issuance and usage of an implantable prosthesis and medical devices incorporating manufacturer's recommendation(s).

8.12.3 Patient and his/her family are counselled for the usage of the implantable prosthesis and a medical device including precautions if any.

Interpretation/Remarks:

a) Precautions could include non-usage of specific drugs and reporting to the HCC if a particular symptom occurs.

8.12.4 The batch and the serial number of the implantable prosthesis and medical devices are recorded in the patient's medical record and the master log book.

Standard

MOM 8.13: Documented policies and procedures guide the use of medical supplies and consumables

Objective Elements

8.13.1 There is a defined process for the acquisition of medical supplies and consumables.

Interpretation/Remarks:

a) The process should address the issues of vendor selection, vendor evaluation, indenting process, generation of a purchase order and receipt of goods.

b) Refer the National Procurement Guideline.

8.13.2 Medical supplies and consumables are used in a safe manner, where appropriate.

Interpretation/Remarks:

a) Hazardous materials are identified and kept separately.

8.13.3 Medical supplies and consumables are stored in a clean, safe and secure environment; and incorporate the manufacturer's recommendation(s).

Interpretation/Remarks:

a) The HCC shall ensure that the storage requirements are as specified by the manufacturer are adhered to. This shall be applicable to all areas where these are stored including wards. They shall be protected from loss or theft. Overall cleanliness of the storage area shall be maintained.

b) HCC shall have designated store with an appropriate layout.

8.13.4 Sound inventory control practices guide storage of medical supplies and consumable.

Interpretation/Remarks:

a) HCC shall follow or demonstrate FEFO and FIFO lead time analysis, etc.

b) HCC develop SOPs for the preparation of injectable drugs.

9. Patient Rights and Education (PRE)

Preamble

The HCC defines the patient and family rights and responsibilities. The staff is aware of these and is trained to protect patient rights. Patients are informed of their rights and educated about their responsibilities at the time of admission. They are informed about the disease, the possible outcomes and are involved in decision making. The costs are explained in a clear manner to the patient and/or family if applicable. 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 9.1	The HCC protects patient and family rights and informs them about their responsibilities during care.
PRE 9.2	Patient and family rights support individual beliefs, values and involve the patient and family in decision-making processes.
PRE 9.3	The patient and/or family members are educated to make informed decisions and are involved in the care-planning and delivery process.
PRE 9.4	A documented procedure for obtaining patient and/or family's consent exists for informed decision making about their care.
PRE 9.5	Patient and families have a right to information and education about their healthcare
PRE 9.6	Patient and families have a right to information on expected costs.
PRE 9.7	HCC has a complaint redressal procedure.

Standard and Objective Elements

Standard

PRE 9.1: The HCC protects patient and family rights and informs them about their responsibilities during care.

Objective Elements

9.1.1 Patient and family rights and responsibilities are documented and displayed.
Interpretation/Remarks:

a) HCC should respect the patient's rights and inform them of their responsibilities.
b) All the rights of the patients should be displayed, which should also give information about the charges and grievance redress mechanism.
c) The display should be at least bi-lingual (Dzongkha and English).
d) Pamphlets could be provided regarding the same.
e) For an example of "patient responsibility"

9.1.2 The HCC leaders protect patient and family rights.
Interpretation/Remarks:

a) Protection also includes addressing patient's grievances with respect to rights.

9.1.3 Staffs are aware of his/her responsibility in protecting patient and family rights.
Interpretation/Remarks:

a) Training and sensitization program shall be conducted to create awareness among the staff.

9.1.4 Violation of patient and family rights is recorded, reviewed and corrective preventive measures are taken.
Interpretation/Remarks:

a) Where patients' rights have been infringed upon, management must keep records of such violations, as also a record of the consequences, e.g. corrective actions to prevent recurrences.
b) The HCC shall have a mechanism to capture the same.
c) The HCC could develop an indicative list of such items and train the staff accordingly. For example, repeated examinations, no examination, soliciting money.
d) The patient feedback form (by incorporating patient rights worded appropriately) could be used as a tool to capture violation of patient rights.

Standard

PRE 9.2: Patient and family rights support individual beliefs, values and involve the patient and family in decision-making processes

Objective Elements

9.2.1 Patient and family rights include respect for personal dignity and privacy during examination, procedure and treatment.

Interpretation/Remarks:

a) During all stages of patient care, HCC staff shall ensure that the patient's privacy and dignity are maintained. The HCC shall develop the necessary guidelines for the same.

b) During procedures, the HCC shall ensure that the patient is exposed just before the actual procedure is undertaken.

c) With regards to photographs/recording procedures, the HCC shall ensure that explicit consent is taken and that the patient's identity is not revealed.

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

Interpretation/Remarks:

a) Special precautions shall be taken especially with respect to vulnerable patients, e.g. elderly, neonates, etc.

b) Examples of this include falling from the bed/trolley due to negligence, assault, repeated internal examinations, manhandling, etc.

9.2.3 Patient and family rights include treating patient information as confidential.

Interpretation/Remarks:

a) Staff shall avoid having patient-related discussions in public places.

b) Statutory requirements with respect to privileged communication shall be followed at all times.

c) Confidential information including HIV status shall not be revealed without the patient's permission. It shall not be written/pasted on the cover of the medical record.

9.2.4 Patient and family right include refusal of treatment.

Interpretation/Remarks:

a) The treating doctor shall discuss all the available options and allow the patient to make an informed choice including the option of refusal.

b) In case of refusal, the treating doctor shall explain the consequences of refusal of treatment and document the same.

c) However, this may not apply for the Psychiatric patients.

9.2.5 Patient and family rights include informed consent before transfusion of blood and blood products, anaesthesia, surgery, initiation of any research protocol and any other invasive/high-risk procedures/treatment.

Interpretation/Remarks:

a) Informed consent of the patient is mandatory for doing HIV test.

9.2.6 Patient and family rights include the right to complain and information on how to voice a suggestion.

Interpretation/Remarks:

a) The HCC shall ensure that every patient has access to his/her record. However, this shall be in consonance with the code of medical ethics and statutory requirements.
b) Grievance redressal mechanism must be accessible and transparent.

9.2.7 Patient and family rights include information on the expected cost of the treatment where relevant.

9.2.8 Patient and family rights include information on the plan of care, progress and information on their health care needs.

Standard

PRE 9.3: The patient and/or family members are educated to make informed decisions and are involved in the care planning and delivery process

Objective Elements

9.3.1 The patient and/or family members are explained about the proposed care including the risks, possible complications, treatment alternatives, the expected results and benefits.

Interpretation/ Remarks:

a) The plan of care as decided by the doctor on duty or the patient's management team (as the case may be) is to be discussed with the patient and/or family members. This should be done in a language the patient/attendant can understand. The above information is to be documented and signed by the doctor concerned.
b) Possible complications of the treatment and expected outcomes of such treatment if any are clearly communicated to the patient and/or family members.

9.3.2 The patient and/or family members are explained about the expected results.

Interpretation/ Remarks:

a) The patients and/or family members are explained in detail by the treating physicians or his/her team about the outcomes of such treatment.

9.3.3 The patient and/or family members are explained about the possible complications.

Interpretation/ Remarks:

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

9.3.4 The care plan is prepared and modified in consultation with the patient and/or family members.

Interpretation/Remarks:

a) During the preparation of the care plan, the patient and/or family members are explained about the various treatment options, risks and benefits.
b) The HCC could develop a structured mechanism to capture this. The feedback for this could be obtained at the time of admission and during the re-assessments.

9.3.5 The care plan respects and where possible incorporate patient and/or family concerns and requests.

Interpretation/Remarks:

a) The religious, cultural and spiritual views of the patient and/or family shall be considered during the process of care delivery.
b) Incorporating patient and/or family requests shall be limited by the statutory requirements.

9.3.6 The patient and/or family members are informed about the results of diagnostic tests and the diagnosis.

Interpretation/Remarks:

a) Confidential information like HIV test result shall only be revealed to the patient after proper counselling by a counsellor.

9.3.7 The patient and/or family members are explained about any change in the patient's condition.

Interpretation/Remarks:

a) This includes improvement, deterioration or occurrence of complications.

Standard

PRE 9.4: The documented procedure for obtaining patient and/or family's consent exists for informed decision making about their care.

Objective Elements

9.4.1 Documented procedure incorporates the list of situations where informed consent is required and the process for taking informed consent.

Interpretation/Remarks:

a) A list of procedures should be made for which informed consent should be taken.

b) The process for taking informed consent shall specify the various steps involved with the responsibility.

c) The policy for HIV testing should follow the national policy on HIV testing.

d) This shall be prepared keeping in mind the requirements of this standard and statutory requirement.

9.4.2 Patient and/or his family members are informed of the scope of such general consent.

Interpretation/Remarks:

a) The HCC shall define as to what is the scope of this consent and the same shall be communicated to the patient and/or his family members.

b) This cannot include consent for invasive procedures or other procedures for which a specific consent is required as per this standard.

9.4.3 Informed consent includes information regarding the procedure, risks, benefits, alternatives and as to who will perform the requisite procedure in a language that they can understand.

Interpretation/Remarks:

a) The consent shall have the name of the doctor performing the procedure. If it is a "doctor under training" the same shall be specified, however, the name of the qualified doctor supervising the procedure shall also be mentioned. The consent form shall be in the language that the patient understands.

9.4.4 The procedure describes who can give consent when the patient is incapable of independent decision making.

Interpretation/Remarks:

a) The HCC shall take into consideration the statutory norms.

b) This would include next of kin/legal guardian.

c) However, in case of unconscious/unaccompanied patients, the treating doctor can take a decision in life-saving circumstances.

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

9.4.5 Informed consent is taken by the person performing the procedure.

Interpretation/Remarks:

a) The person performing shall be responsible for the entire consent process including providing explanation and taking the signature.

b) For example, it is not acceptable if the person performing the procedure only explains and then the written consent is taken by the nurse.

c) A team member can take consent on behalf of the person performing the procedure.

9.4.6 Informed consent process adheres to statutory norms.

Interpretation/Remarks:

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

1) Taking consent before the procedure (either on the day or the previous day)

2) At least one independent witness signing the consent form

3) Taking consent every time (especially for procedures which the patient has to undergo lifelong)

4) Taking afresh consent (for the new procedure) in case the procedure has to be changed mid-way

5) In case the patient has to undergo a procedure for a long time (e.g. dialysis) a new consent shall be taken every time. However, this consent could be verbal. Once every six months (at a minimum) or whenever there is new information to be provided to the patient a new written informed consent shall be taken.

9.4.7 Staffs are aware of the informed consent procedure.

Interpretation/Remarks:

a) It shall be aware of the conditions which require informed consent and the process for taking informed consent.

Standard

PRE 9.5: Patient and families have a right to information and education about their healthcare needs

Objective Elements

9.5.1 The patient and/or family are educated about the safe and effective use of medication and the potential side effects of the medication, when appropriate.

Interpretation/Remarks:

a) The HCC shall make a list of such drugs and accordingly educate, e.g. digoxin. This could also include education regarding the importance of taking a drug at a specific time, e.g. sustained release medications.

9.5.2 The patient and/or family are educated about food-drug interactions.

Interpretation/Remarks:

a) Patient and family should be counselled about their diet during medication, e.g. no alcohol when taking metronidazole.

9.5.3 The patient and/or family are educated about diet and nutrition.

9.5.4 The patient and/or family are educated about immunizations.

a) More applicable for paediatric population.
b) In adults, it could be for influenza, Streptococcus pneumonia, typhoid, hepatitis B, Neisseria meningitides, etc.

9.5.5 The patient and/or family are educated about organ donation, when appropriate.

Interpretation/Remarks:

a) They should be educated in a very sensitive and courteous manner.

9.5.6 The patient and/or family are educated about their specific disease process, complications and prevention strategies.

Interpretation/Remarks*:*

a) This shall include information on lifestyle modifications, diet changes and immunizations where appropriate.
b) This is more relevant for chronic conditions.

9.5.7 The patient and/or family are educated about preventing healthcare-associated infections.
Interpretation/Remarks:

a) For example, hand washing and avoiding overcrowding near the patient.

9.5.8 The patient and/or family are educated in a language that they can understand.

Standard

PRE 9.6: Patient and families have a right to information on expected costs (If applicable).

Objective Elements

9.6.1 There is a uniform pricing policy in a given setting (out-patient and ward category).
Interpretation/ Remarks:

a) There should be a billing policy which defines the charges to be levied for various activities.

9.6.2 The tariff list is available to patients.
Interpretation/Remarks:

a) The HCC shall ensure that there is an updated tariff list and that this list is available to patients when required. Any additional charge should also be enumerated in the tariff and the same communicated to the patients. The tariff rates should be uniform and transparent.

9.6.3 The patient and/or family members are explained about the expected costs.
Interpretation/Remarks:

a) Patients should be given an estimate of the expenses on account of the treatment preferably in a written form.
b) This estimate shall be prepared on the basis of the treatment plan. It could be prepared by the OPD/Registration/Admission staff in consultation with the treating doctor.

9.6.4 The patient and/or family are informed about the financial implications when there is a change in the patient condition or treatment setting.
Interpretation/Remarks:

a) When patients are shifted from one setting to another, typically to and from ICUs, the financial implications must be clearly conveyed to them.

Standard

PRE 9.7: HCC has a complaint redressal procedure

Objective Elements

9.7.1 The HCC has a documented complaint redressal procedure.

Interpretation/Remarks:

a) This shall incorporate the mechanism for lodging complaints (including verbal, telephonic and written complaints), a method of compiling them, analysing complaints including the time frame, the person(s) responsible and documenting the action taken.

b) It is for the HCC to decide if it wants to give credence to anonymous complaints.

9.7.2 Patient and/or family members are made aware of the procedure for lodging complaints.

Interpretation/Remarks:

a) It is important that the HCC creates an environment of trust wherein the patient would be comfortable to air his/her views.

b) This shall be either by display or providing written information.

9.7.3 A suggestion box is made available and suggestions are analysed.

Interpretation/Remarks:

a) Where appropriate the patient and/or family could be involved in the discussions and also informed regarding the outcome.

b) The entire process shall be documented.

9.7.4 Corrective and/or preventive action(s) are taken based on the analysis where appropriate.

10. Infection Control (HIC) & Medical Waste Management

Preamble

The standards guide the provision of an effective infection control program in the HCC. The program aims at reducing/eliminating infection risks to patients, visitors and care providers. The HCC measures and takes action to prevent or reduce the risk of Healthcare Associated Infection (HAI) in patients and employees. The HCC provides proper facilities and adequate resources to support the Infection Control Program. The program includes an action plan to control outbreaks of infection, disinfection/sterilization activities, Waste management, and training of staff and employee health.

Summary of Standards

HIC 10.1	The HCC has a well-designed, comprehensive and coordinated HCC Infection Prevention and Control program aimed at reducing/elimination risks to patients, visitors and providers of care.
HIC 10.2	The HCC implements the procedures laid down in the Infection Control guideline.
HIC 10.3	The HCC performs surveillance activities to capture and monitor infection prevention and control data.
HIC 10.4	The HCC takes actions to prevent and control HAI in patients.
HIC 10.5	The HCC provides adequate and appropriate resources for prevention and control of HAI.
HIC 10.6	The HCC identifies and takes appropriate actions to control outbreaks of infections.
HIC 10.7	There are documented policies and procedures for sterilization activities in the HCC.
HIC 10.8	Medical waste is handled in an appropriate and safe manner.
HIC 10.9	The infection control program is supported by the management and includes training of staff and employee health.

Standards and Objective Elements

Standard

HIC 10.1: The HCC has a well-designed, comprehensive and coordinated HCC Infection Control (HIC) program aimed at reducing/eliminating risks to patients, visitors and providers of care.

Objective Elements

10.1.1 The HCC infection control program is documented which aims at preventing and reducing the risk of HAI.

Interpretation/Remarks:

a) This shall be based on current scientific knowledge, guidelines from international/national and professional bodies and statutory requirements, wherever applicable.

b) Reference documents could include WHO guidelines, CDC Guidelines and National Infection Control and Medical Waste Management Guideline.

10.1.2 The infection control program is a continuous process and updated periodically.

Interpretation/Remarks:

a) The updating shall be done based on the latest literature on infection prevention and outbreak prevention mechanisms, infection trends and outcomes of the audit processes.

10.1.3 The HCC has a multi-disciplinary infection control committee, which coordinates all infection control activities.

Interpretation/Remarks:

a) This shall preferably have HCC Administrator, Microbiologist, Physician, Surgeon, Manager – Nursing (Nursing supervisor) staff from CSSD, and other support services and the HCC infection control nurse. It could also include invitees from various departments as deemed necessary.

b) The committee shall lay down the procedures to guide the implementation.

c) The composition, the frequency of meetings, the minimum quorum required and the minutes of the meeting shall be documented.

10.1.4 The HCC has a full-time infection control officer, which coordinates implementation of all infection control activities.

Interpretation/Remarks:

a) The team is responsible for the day-to-day functioning of the infection control program. It shall support the surveillance process and detect outbreaks; it shall also participate in

audit activity and in infection control on a day-to-day basis.

b) For the composition of the team, refer to WHO and CDC guidelines.

c) The committee and the team shall not be the same. However, the team shall be represented in the committee.

10.1.5 The HCC has designated infection control officer as part of the infection control team.

Interpretation/Remarks:

a) It is preferable that he/she is an infectious diseases specialist.

b) It is preferable for them to have undergone a short-term training program on infection control by a recognized institute.

Standard

HIC 10.2: The HCC implements the policies and procedures laid down in the Infection Control and Waste Management Guideline/manual.

Objective Elements

10.2.1 The HCC identifies the various high-risk areas and procedures and implements policies and/or procedures to prevent infection in these areas.

Interpretation/Remarks:

a) The manual should clearly identify the high-risk areas of the HCC, e.g. ICU, HDU, OT, post-operative ward, blood bank, CSSD, etc.

b) Similarly, all high-risk procedures should be identified from an infection control point of view, for example, endoscopies, surgery lasting more than two hours, haemodialysis, etc.

c) The policies and procedures shall be directed at the prevention of infection in these areas and include monitoring.

d) At a minimum, the manual shall incorporate all the requirements of this chapter.

10.2.2 The HCC adheres to standard precautions at all times.

10.2.3 The HCC adheres to hand-hygiene guidelines.

Interpretation/Remarks:

a) The HCC shall adhere to international/national guidelines on hand hygiene.

b) A good reference is the WHO guidelines.

c) The HCC could display the necessary instructions near every hand-washing area.

10.2.4 The HCC adheres to safe injection and infusion practices.

Interpretation/Remarks:

a) This shall include “one needle, one syringe, only one time” as recommended by CDC.

b) A good reference guide is “WHO best practices for injections and related procedures toolkit”.

10.2.5 The HCC adheres to transmission-based precautions at all times.

Interpretation/Remarks:

a) This shall cover airborne, droplet and contact modes of transmission.

b) This shall be applicable across the HCC including ICUs and high-dependency units. Refer to international guidelines like that of CDC.

10.2.6 The HCC adheres to cleaning, disinfection and sterilization practices.

Interpretation/Remarks:

a) It shall be addressed at all levels of the HCC, e.g. ward, OT and CSSD. It is preferable that the HCC follows a uniform policy across different departments within the HCC.

b) A good reference is a national guideline on infection control and waste management, CDC Guideline for Disinfection and Sterilization in Healthcare Facilities.

c) This includes environment, fixtures, fomites, furniture, furnishings, equipment, etc., as applicable.

10.2.7 An appropriate antibiotic policy is established and implemented.

Interpretation/Remarks:

a) The HCC where culture facilities are available shall develop a system of monitoring drug susceptibility (based on culture sensitivity) and accordingly develop its antibiotic policy, which shall be reviewed at periodic intervals (maybe once in three months (but at least every year) for its continuing applicability.

b) Refer the guideline on Rationale Use of Antibiotics.

c) The HCC could also refer to international guidelines while framing the policy.

d) Use of WHO reference document global strategy for containment of antimicrobial resistance (WHO/CDS/CSR/DRS/2001.2) can be a good starting point.

10.2.8 The HCC adheres to laundry and linen management processes.

Interpretation/Remarks:

a) The laundry can be in-house or outsourced. The HCC shall have a policy for change on linen. There shall be separate washing protocols for different categories of linen including blankets (where applicable).

b) If outsourced, the HCC shall ensure that it establishes adequate controls to ensure infection prevention and control.

10.2.9 The HCC adheres to kitchen sanitation and food-handling issues.

Interpretation/Remarks:

a) The HCC shall adhere to all statutory requirements. It is preferable that they also adhere to national and international (ISO 22000:2005) guidelines while addressing this issue.

10.2.10 The HCC has appropriate engineering controls to prevent infections.

Interpretation/Remarks:

a) This shall include the design of patient care areas (optimum spacing between beds is one-two meters) radiation emission area, operating rooms, air quality and water supply.

b) Issues such as air-conditioning plant and equipment maintenance, cleaning of AC ducts, AHUs, replacement of filters, seepage leading to fungal colonization, replacement/repair of plumbing, sewerage lines (in shafts) should be included. Water-supply sources and system of supply, testing for water quality must be included.

c) Guidelines on OT air-conditioning.

10.2.11 The HCC adheres to housekeeping procedures.

Interpretation/Remarks:

a) This should include categorization of areas/surfaces, general-cleaning procedures for surfaces, furniture/fixtures, and items used in patient care. It should also include procedures for terminal cleaning, blood and body fluid clean-up, isolation rooms and all high-risk (critical) areas. The common disinfectants used, dilution factors and methodology should be specified.

Standard

HIC 10.3: The HCC performs surveillance activities to capture and monitor infection prevention and control data.

Objective Elements

10.3.1 Surveillance activities are appropriately directed towards the identified high-risk areas and procedures.

Interpretation/Remarks:

a) The HCC must be able to provide evidence of conducting periodic surveillance activities in its identified high-risk areas and procedures.

b) It shall define the frequency and mode of surveillance.
c) The surveillance system should be appropriate and adhering to national guidelines.
d) Surveillance activities include areas of demolition, construction or repairs are undertaken, especially in high-risk areas.
e) The HCC should use a judicious mix of active and passive surveillance.
f) The HCC could lay down the parameters that need to be captured and the process for reporting.

10.3.2 Collection of surveillance data is an on-going process.

Interpretation/Remarks:

a) The HCC shall ensure that it has a process in place to collect surveillance data and also to ensure that it is able to capture all such data.

10.3.3 Verification of data is done on a periodic basis by the infection control team.

Interpretation/Remarks:

a) The data collected shall be authenticated by the infection control team by going through every data or by using random sampling so that the process can be validated. The team shall preferably verify every serious infection report.

10.3.4 The scope of surveillance activities incorporates tracking and analysing of infection risks, rates and trends.

Interpretation/Remarks:

a) This shall be done at regular intervals (maybe monthly and consolidated into an annual report) and the HCC shall take suitable steps based on the analysis.
b) A simple calculation of infected patients (numerator) provides only limited information which would be difficult to interpret. Risk factor analysis would require information which would be difficult to interpret. Risk factor analysis would require information for both infected and non-infected patients, in order to calculate infection and risk-adjusted rates.

10.3.5 Surveillance activities include monitoring the compliance with hand-hygiene guidelines.

Interpretation/Remarks:

a) This shall be done at a minimum once every month. Appropriate sample size shall be chosen and all categories of staff (involved in direct patient care) shall be monitored.
b) A good tool is the WHO's Observation form.

10.3.6 Surveillance activities include monitoring the effectiveness of housekeeping services.
Interpretation/Remarks:

a) This shall be done on a regular basis. The HCC shall define the periodicity.
b) This is applicable even if the housekeeping services are outsourced.
c) It could be done using a checklist.
d) This need not mean routine environmental sampling.

10.3.7 Appropriate feedback regarding HAI rates is provided on a regular basis to appropriate personnel.
Interpretation/Remarks:

a) The feedback shall include the rates, trends and opportunities for improvement. It could also provide specific inputs to reduce the HAI rate.
b) This could be in the form of a bulletin/newsletter.

10.3.8 In cases of notifiable diseases, information (in relevant format) is sent to appropriate authorities.
Interpretation/Remarks:

a) The HCC shall identify all notifiable diseases after taking into consideration the local/state/national laws, rules, regulations and notifications thereof. The HCC shall ensure that this is sent at the specified frequency and in the format as required by statutory authorities.

Standard

HIC 10.4: The HCC takes actions to prevent and control Healthcare Associated Infections (HAI) in patients.

Objective Elements

10.4.1 The HCC takes action to prevent HCC acquired urinary tract infections, respiratory tract infections, intra-vascular device infections and surgical site infections.
Interpretation/Remarks:

a) A good reference is the CDC/WHO guidelines.

Standard

HIC 10.5: The HCC provides adequate and appropriate resources for the prevention and control of Healthcare Associated Infections (HAI).

Objective Elements

10.5.1 Adequate and appropriate personal protective equipment, liquid soaps, and disinfectants are available and used correctly.

Interpretation/Remarks:

a) They should be available at the point of use and the HCC shall ensure that it maintains an adequate inventory.
b) Personal protective equipment includes:
c) Gloves, Protective eyewear (goggles), Mask, Apron, Gown, Boots/shoe covers, and Cap/hair cover.

10.5.2 Adequate and appropriate facilities for hand hygiene in all patient-care areas are accessible to healthcare providers.

Interpretation/Remarks:

a) The HCC shall ensure that it provides the necessary infrastructure to carry out the same.
b) Optimal hand-hygiene requirements include large washbasins, soap and facility for drying hands without contamination.

10.5.3 Isolation/barrier nursing facilities are available.

Interpretation/Remarks:

a) Their HCC shall define the conditions where isolation is required and the conditions wherein barrier nursing or both are required. The HCC shall ensure that it provides the necessary resources to carry out the activity (e.g. clothing, masks, gloves, etc.).
b) Ideally, patients requiring isolation (contact, droplet and airborne) should be placed in isolation rooms and droplet cases be kept in negative pressure rooms. An air-conditioned single room with an exhaust or a well-ventilated room is an adequate option for healthcare facilities without “negative pressure” rooms. If an air-conditioned single room is not available, a fan can be placed in the room to direct airflow towards and outside the window. The door/s to the aisle or other rooms should be kept closed at all times. Appropriate signage shall be used/displayed.

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

Interpretation/Remarks:

a) Infection Control officer/nurse maintains documentation of all occupational injuries and pre-and post-exposure prophylaxis records.

b) For example, hepatitis B vaccination and PEP for needle stick injury.

Standard

HIC 10.6: The HCC identifies and takes appropriate action to control outbreaks of infections

Objective Elements

10.6.1 HCC has a documented procedure for identifying an outbreak.

Interpretation/Remarks:

a) Standard case definitions shall include a unit of time and place along with specific biological and/or clinical criteria.

b) To define as to what constitutes an outbreak, the HCC should have a baseline.

10.6.2 HCC has a documented procedure for handling such outbreaks.

Interpretation/Remarks:

a) The HCC should be able to identify the outbreak, describe the outbreak by developing a case definition, designing a data collection form, collecting data from the affected, constructing an epidemic curve.

b) Outbreak should be reported to the Royal Centre for Disease Control (RCDC) and investigated accordingly or refer to the outbreak investigation guideline.

10.6.3 After the outbreak is over appropriate corrective actions are taken to prevent recurrence.

Interpretation/Remarks:

a) The HCC should be able to implement basic procedures to prevent recurrence such as source control if the source identified, review of all infection control policies, loopholes and compliance gaps, strengthening infection control policies, etc.

Standard

HIC 10.7: There are documented policies and procedures for sterilization activities in the HCC.

Objective Elements

10.7.1 The HCC provides adequate space and appropriate zoning for sterilization activities.
Interpretation/Remarks:

a) Adequacy of space refers to the CSSD, which should have a suitable location, proper layout (unidirectional flow, zoning) and separation of clean and dirty areas. Sufficient space shall be available to ensure that the activities can be performed properly.
b) The HCC shall provide for the same in all areas where sterilization activities are carried out. It is preferable to have separate areas for receiving, washing, cleaning, packing, sterilization, sterile storage and issue.
c) A good reference is a National guideline: HCC Infection Control and Medical Waste Management Guideline.

10.7.2 Documented procedure guides the cleaning, packing, disinfection and/or sterilization, storing and the issue of items.
Interpretation/Remarks:

a) The sterilized/disinfected equipment/sets shall be stored in an appropriate manner across the HCC and not just in CSSD.
b) A good reference is “CDC Guideline for Disinfection and Sterilization in Healthcare Facilities”, other references include ISO 17665.

10.7.3 Reprocessing of instruments and equipment are covered.
Interpretation/Remarks:

a) When single-use devices and materials are reused, the HCC shall adhere to laid-down national/international guidelines.

10.7.4 Regular validation tests for sterilization are carried out and documented.
Interpretation/Remarks:

a) This shall be done by accepted methods, e.g. bacteriological strips, etc.
b) Engineering validations like Bowie Dick tape test and leak rate test need to be carried out.
c) WHO recommends each load to have a number, content description, temperature, pressure and time-record chart, physical/chemical tests daily, weekly biological tests, stem processing, and ethylene oxide processing.

10.7.5 There is an established recall procedure when the breakdown in the sterilization system is identified.

Interpretation/Remarks:

a) The HCC shall ensure that the sterilization procedure is regularly monitored and in the eventuality of a breakdown, it has a procedure for withdrawal of such items.

b) The HCC could have a batch-processing system with date and machine number for effective recall.

Standard

HIC 10.8: Biomedical waste is handled in an appropriate and safe manner.

Objective Elements

10.8.1 The HCC adheres to statutory provisions with regard to biomedical waste.

Interpretation/Remarks:

a) The HCC shall be authorized by the prescribed authority for management and handling of biomedical waste.

b) It shall adhere to the various requirements specified in the Medical waste management guidelines under the Waste Prevention and Management Regulation and Waste Prevention and Management Act of Bhutan.

10.8.2 Proper segregation and collection of biomedical waste from all patient-care areas of the HCC are implemented and monitored.

Interpretation/Remarks:

a) Wastes to be segregated and collected in different colour coded bags and containers and as per statutory provisions. Monitoring shall be done by members of the infection control committee/team. Biomedical waste shall be handled in the proper manner.

10.8.3 The HCC ensures that biomedical waste is stored and transported to the site of treatment and disposal in properly covered vehicles within stipulated time limits in a secure manner.

Interpretation/Remarks:

a) The waste is transported to the pre-defined site at definite time intervals through proper transport vehicles in a safe manner.

b) If this activity is outsourced, the HCC shall ensure that it is done through an authorized contractor. Monitoring of this activity should be done by an infection control team.

10.8.4 The biomedical waste treatment facility is managed as per legal provisions (if in-house) or Thromde office.

Interpretation/Remarks:

a) If the HCC has a waste treatment facility within its premises then it has to be in accordance with legal provisions or central facility arranged by Thromde.

b) Monitor closely to ensure waste disposal according to the Waste Prevention and Management Regulation.

10.8.5 Appropriate personal protective measures are used by all categories of staff handling biomedical waste.

Interpretation/Remarks:

a) For example, gloves and masks, protective glasses, gowns, etc.

Standard

HIC 10.9: The infection control program is supported by the management and includes training of staff.

Objective Elements

10.9.1 The management makes available resources required for the infection control program.

Interpretation/Remarks:

a) The HCC shall ensure that the resources required by the personnel should be available in a sustained manner. This includes both men and materials.

10.9.2 The HCC earmarks adequate funds from its annual budget in this regard.

Interpretation/Remarks:

a) There shall be a separate budget allocated for HIC activity. This shall be prepared taking into consideration the scope of the activity and previous years' experience.

10.9.3 The HCC conducts induction training for all staff.

Interpretation/Remarks:

a) There must be a documented evidence of induction training for all categories of staff before joining department(s) concerned. It should include the policies, procedures and practices of the infection control program.

b) Doctors also need to be trained.

10.9.4 The HCC conducts appropriate "in-service" training sessions for all staff at least once in a year.

11. Continuous Quality Improvement (CQI)

Preamble

The standards encourage an environment of continuous quality improvement. The quality and safety program should be documented and involve all areas of the HCC and all staff members. The HCC should collect data on structures, processes and outcomes, especially in areas of high-risk situations. The collected data should be collated, analysed and used for further improvements. The improvements should be sustained. The quality program of the diagnostic services should be integrated into the HCC's quality plan. Infection-control and patient-safety plans should also be integrated into the HCC's quality plan. The HCC should define its sentinel events and intensively investigate when such events occur. The quality program should be supported by the management.

Summary of Standards

CQI 11.1	There is a structured quality improvement and continuous monitoring program is the HCC.
CQI 11.2	There is a structured patient-safety program in the HCC.
CQI 11.3	The HCC identifies key indicators to monitor the clinical structures, processes and outcomes which are used as tools for continual improvement.
CQI 11.4	The HCC identifies key indicators to monitor the managerial structures, processes and outcomes, which are used as tools for continual improvement.
CQI 11.5	The quality improvement program is supported by the management.
CQI 11.6	There is an established system for clinical audit.
CQI 11.7	Incidents, complaints and feedback are collected and analysed to ensure continuous quality improvement.
CQI 11.8	Sentinel events are intensively analysed.
CQI 11.9	Regular Supervision and Monitoring

Standards and Objective Elements

Standard

CQI 11.1: There is a structured quality improvement and continuous monitoring program in the HCC

Objective Elements

11.1.1 The quality improvement program is developed, implemented and maintained by a multidisciplinary committee.

Interpretation/Remarks:

a) This committee shall have representation from management, various clinical and support departments of the HCC. This program shall be developed, implemented and maintained in a structured manner.

b) For example, core committee, quality improvement committee, etc.

11.1.2 The quality improvement program is documented.

Interpretation/Remarks:

a) This should be documented as a manual. The manual shall incorporate the mission, vision, quality policy, quality objectives, services standards, important indicators as identified, etc. The manual could be stand-alone but shall have cross-linkages with other manuals.

11.1.3 There is a designated individual for coordinating and implementing the quality-improvement program.

Interpretation/Remarks:

a) This should preferably be a person having a good knowledge of accreditation standards, statutory requirements, HCC quality improvement principles and evaluation methodologies, HCC functioning and operations.

b) For example, accreditation co-coordinator, quality management representative, quality manager.

11.1.4 The designated program is communicated and coordinated amongst all the staff or the Health Center through appropriate training mechanism.

Interpretation/Remarks:

a) This could be done through a regular training program or printed materials

11.1.5 The quality improvement program identifies opportunities for improvement based on the review at pre-defined intervals.

Interpretation/Remarks:

a) As quality improvement is a dynamic process, it needs to be reviewed at regular pre-defined intervals (as defined by the HCC in the quality improvement manual but at least once in four months). The review shall include internal audits (refer to CQI 6.1.8), HCC performance indicators (refer to CQI 6.5.3), analysis of key indicators as identified and determined by the HCC including the mandatory indicators as laid down in CQI 6.3 and 6.4. The minutes of the review meetings should be recorded and maintained.

b) This also applies to other quality-assurance programs like the lab, imaging, ICU and surgical services.

11.1.6 The quality improvement program is a continuous process and updated at least once in two years.

Interpretation/Remarks:

a) The inputs for updating could be based on the review carried out by the quality improvement committee

11.1.7 Audits are conducted at regular intervals as a means of continuous monitoring.

Interpretation/Remarks:

a) This audit shall be done by a multi-disciplinary team (preferably trained in accreditation standards) including all the applicable standards and objective elements. All the areas of the HCC shall be covered. At the end of the audit, there shall be a formal meeting to summarize the findings and corrective and preventive measures shall be taken and documented.

b) All audits shall be documented.

11.1.8 There is an established process in the HCC to monitor and improve the quality of patient care.

Interpretation/Remarks:

a) This could be done through clinical audits.

Standard

CQI 11.2: There is a structured patient-safety program in the HCC.

Objective Elements

11.2.1 The patient-safety program is developed, implemented and maintained by a multi-disciplinary committee and documented.

Interpretation/Remarks:

a) This committee shall have representation from management, various clinical and support departments of the HCC. This program shall be developed, implemented and maintained in a structured manner.

b) This committee shall have mixed members but not limited to administrators, engineers, doctors and nurses.

11.2.2 The patient-safety program is documented.

Interpretation/Remarks:

a) This should be documented as a manual. The manual shall incorporate all the requirements of this standard.

b) This should be documented keeping in mind requirements of objective elements “11.2.3”, “11.2.4”, “11.2.7”, “11.2.8”, and “11.2.9”.

11.2.3 The patient-safety program is comprehensive and covers all the major elements related to patient safety and risk management.

Interpretation/Remarks:

a) Risk management shall include risk identification and risk mitigation. It shall be done in a structured manner.

11.2.4 The scope of the program is defined to include adverse events ranging from “no harm” to “sentinel events”.

Interpretation/Remarks:

a) The HCC shall clearly define as to what constitutes no harm and sentinel events.

11.2.5 There is a designated individual for coordinating and implementing the patient-safety program.

Interpretation/Remarks:

a) This should preferably be a person having a good knowledge of both patient and general safety.

b) For example, a safety officer.

11.2.6 There is a designated program for communicating and coordinating amongst all the staff of the HCC through appropriate training mechanism.

Interpretation/Remarks:

a) This could be done through a regular training program or printed materials

11.2.7 The patient-safety program identifies opportunities for improvement based on the review at pre-defined intervals and is a continuous process and updated at least once a year.

Interpretation/Remarks:

a) As patient safety is paramount, it needs to be reviewed at regular pre-defined intervals
b) The inputs for updating could be based on the review carried out by the safety committee.

11.2.8 The patient-safety program is a continuous process and updated at least once a year.

Interpretation/Remarks:

a) The inputs for updating could be based on the review carried out by the safety committee.

11.2.9 The HCC adapts and implements national/international patient-safety goals/solutions.

Interpretation/Remarks:

a) At a minimum, the HCC shall adhere to the current national patient-safety goals or WHO patient-safety solutions.
b) It is preferable that the HCC also participates by contributing to such databases

11.2.10 The HCC adapts and implements national/international patient-safety goals/solutions.

Interpretation/Remarks:

a) This shall be used for identifying the patient for all care-related events like medication administration, conducting procedures, etc. E.g., one of the identifiers shall be the unique HCC ID generated at the time of registration/admission.

Standard

CQI 11.3: The HCC identifies key indicators to monitor the clinical structures, processes and outcomes, which are used as tools for continual improvement.

Objective Elements

11.3.1 Monitoring includes appropriate patient care plan.

Interpretation/Remarks:

a) The HCC shall develop appropriate key performance indicators suitable to it. The following is, however mandatory (Need to consult what patient records are being

maintained)

1) Time for initial assessment of indoor and emergency patients.
2) Percentage of cases (in-patients) wherein care plan with desired outcomes is documented and signed by a clinician.
3) Percentage of cases (in-patients) wherein screening for nutritional needs has been done.
4) Percentage of cases (in-patients) wherein the nursing care plan is documented.

11.3.2 Monitoring includes safety and quality-control program of all the diagnostic services.
Interpretation/Remarks:

a) The HCC shall develop appropriate key performance indicators suitable for all diagnostic services. The following is, however, mandatory:
    1) Number of errors reported in diagnostic services
    2) Percentage of reports co-relating with clinical diagnosis.
    3) Percentage of adherence to safety precautions by employees working in diagnostics.
b) Reporting errors need to be captured. It is better if the HCC captures these errors as errors picked up before dispatching the reports and errors picked after the dispatch of reports. This includes transcription errors also.
c) To capture co-relation it becomes mandatory that all investigation forms have a provisional diagnosis/relevant clinical details written on them. The HCC could decide as to which tests will be monitored. However, in case of the laboratory, it shall be captured for all histopathological tests and in case of radiology, it shall be captured for CT and MRI. The form can have the differential diagnosis also written in them.
d) To capture adherence to safety precautions the HCC needs to do a random check of all employees per month (working in these areas and including all categories of staff) and capture data.

11.3.3 Monitoring includes medication management.
Interpretation/Remarks:

a) The HCC shall develop appropriate key performance indicators suitable to it. The following is, however, mandatory:
    1) The incidence of medication errors.
    2) Percentage of admissions with adverse drug reaction(s).
    3) Percentage of patients receiving high-risk medications developing adverse drug event.
b) The HCC shall document a list of approved abbreviations for medication charts. This shall

be based on best national and international practices. For example, “ISMO List of Error-Prone Abbreviations, symbols, and dose Designations”.

11.3.4 Monitoring includes the use of anaesthesia.

Interpretation/Remarks:

a) The HCC shall develop appropriate key performance indicators suitable to it. The following is, however, mandatory:
    1) Percentage of modification of the anaesthesia plan.
    2) Percentage of unplanned ventilation following anaesthesia.
    3) Percentage of adverse anaesthesia events.
    4) Anaesthesia-related mortality rate.
b) Anaesthesia plan is prepared at the time of pre-anaesthesia assessment (COP 13.2). The same shall be reviewed during the immediate pre-operative re-evaluation (COP 13.4). Modifications done in the plan based on this assessment shall be captured.
c) Adverse anaesthesia events include events, which happen during the procedures like hypoxia, arrhythmias, cardiac arrest, etc.

11.3.5 Monitoring includes surgical services.

Interpretation/Remarks:

a) The HCC shall develop appropriate key performance indicators suitable to it. The following is, however, mandatory:
    1) Percentage of re-scheduling of surgeries.
    2) Percentage of cases where the HCC’s procedure to prevent adverse events like the wrong site, wrong patient and wrong surgery have been adhered to.
    3) Percentage of cases who received appropriate prophylactic antibiotics within the specified time frame**.**
b) Re-scheduling of patients includes cancellation and postponement (beyond four hours) of the surgery because of poor communication, inadequate preparation or inefficiency within the system.
c) Prophylactic antibiotics should be administered ideally within 30-60 minutes but certainly within two hours of the time of incision.

11.3.6 Monitoring includes the use of blood and blood products.

Interpretation/Remarks:

a) The HCC shall develop appropriate key performance indicators suitable to it in adherence to National Blood Transfusion Safety Guidelines
b) The following is, however, mandatory:

1) Percentage of transfusion reactions.
2) Percentage of wastage of blood and blood products.
3) Percentage of blood component usage.
4) Turnaround time for the issue of blood and blood components.

11.3.7 Monitoring includes infection control activities.

Interpretation/Remarks:

a) The HCC shall develop appropriate key performance indicators suitable to it. The following is, however, mandatory:
   1) Catheter-associated Urinary tract infection rate.
   2) Ventilator-associated Pneumonia rate.
   3) Central line-associated Bloodstream infection rate.
   4) A surgical site infection rate
b) The definition for identifying these infections would be as laid down by CDC (latest version).

11.3.8 Monitoring includes the review of mortality and morbidity indicators.

Interpretation/Remarks:

a) The HCC shall develop appropriate key performance indicators suitable to it. The following is, however, mandatory:
   1) Mortality rate
   2) Return to ICU within 48 hours.
   3) Return to the emergency department within 72 hours with similar presenting complaints.
   4) Re-intubation rate.

11.3.9 Monitoring includes clinical research.

Interpretation/Remarks:

a) The HCC shall develop appropriate key performance indicators suitable to it. The following is, however, mandatory:
   1) Percentage of research activities approved by the ethics committee.
   2) Percentage of serious adverse events (which have occurred in the HCC) reported to the ethics committee within the defined time frame.
b) The HCC shall keep a track of a number of research protocols submitted to the ethics committee and the number of protocols approved (including protocols approved after clarifications).
c) Refer to REBH guidelines for reporting time of serious adverse events.

d) This includes consent forms and patient information sheet.

11.3.10 Monitoring includes data collection to support further improvements.

Interpretation/Remarks:

a) The data could be collected at pre-defined intervals, e.g. monthly/quarterly. This data is analysed for improvement opportunities and the same is carried out. Also, refer to CQI 1f.

b) For example, data can be collected to study the reasons for “re-dos” in surgical patients.

11.3.11 Monitoring includes data collection to support the evaluation of these improvements.

Interpretation/Remarks:

a) All improvement activities carried out by the HCC shall have an evaluable outcome. The same shall be captured and analysed.

b) For example, once the reason for “re-dos” has been analysed and preventive and corrective measures undertaken then data can be collected to confirm that reductions have occurred in the incidence of “re-dos”

.

Standard

CQI 11.4: The HCC identifies key indicators to monitor the managerial structures, processes and outcomes which are used as tools for continual improvement.

Objective Elements

11.4.1 Monitoring includes procurement of medication essential to meet patient needs.

Interpretation/Remarks:

a) The HCC shall develop appropriate key performance indicators suitable to it.as per the national Medical Policy. The following is, however, mandatory:

1) Percentage of drugs and consumables procured by local purchase.
2) Percentage of stock outs including emergency drugs.
3) Percentage of drugs and consumables rejected before preparation of good receipt note.
4) Percentage of variation from the procurement process.

11.4.2 Monitoring includes risk management.

Interpretation/Remarks:

a) The HCC shall develop appropriate key performance indicators suitable to it. The following is, however, mandatory:
    1) The number of variations observed in mock drills.
    2) The incidence of falls.
    3) The incidence of bed sores after admission.
    4) Percentage of employees provided pre-exposure prophylaxis.

11.4.3 Monitoring includes the utilization of space, manpower and equipment.

Interpretation/Remarks:

a) The HCC shall develop appropriate key performance indicators suitable to it. The following is, however, mandatory:
    1) Bed occupancy rate and the average length of stay.
    2) OT and ICU utilization rate.
    3) Critical equipment downtime and percentage utilization of equipment
    4) The nurse-patient ratio for ICUs and wards.
b) Any equipment the failure of which could impede patient care shall be considered critical. Some examples are ventilators, cardiac monitors and pulse-oximeter. However, every HCC shall identify its list of critical equipment and accordingly capture the indicator. The downtime has to be captured irrespective of whether it has a backup or not.

11.4.4 Monitoring includes patient satisfaction which also incorporates waiting time for services. Define under the definition.

Interpretation/Remarks:

a) The HCC shall develop appropriate key performance indicators suitable to it. The following is, however, mandatory:
    1) Out-patients satisfaction index.
    2) In-patient satisfaction index.
    3) Waiting time for services including diagnostics and out-patient consultation.
    4) Time taken for discharge.

11.4.5 Monitoring includes employee satisfaction.

Interpretation/Remarks:

a) The HCC shall develop appropriate key performance indicators suitable to it. The following is, however, mandatory:
    1) Employee satisfaction index

2) Employee attrition rate.
3) Employee absenteeism rate.
4) Percentage of employees who are aware of employee rights, responsibilities and welfare schemes.

11.4.6 Monitoring includes adverse events and near misses.

Interpretation/Remarks:

a) The HCC shall develop appropriate key performances indicators suitable to it. The following is, however, mandatory:
    1) Percentage of sentinel events reported, collected and analysed within the defined time frame.
    2) Percentage of near misses.
    3) The incidence of blood body fluid exposures.
    4) The incidence of needle sticks injuries.

11.4.7 Monitoring includes the availability and content of medical records.

Interpretation/Remarks:

a) The HCC shall develop appropriate key performances indicators suitable to it. The following is, however, mandatory:
    1) Percentage of medical records not having a discharge summary.
    2) Percentage of medical records not having codification as per the International Classification of Diseases (ICD).
    3) Percentage of medical records having incomplete and/or improper consent.
    4) Percentage of missing records.

11.4.8 Monitoring includes data collection to support further improvements.

Interpretation/Remarks:

a) The data could be collected at pre-defined intervals, e.g. monthly/quarterly. This data is analysed for improvement opportunities and the same is carried out. Also, refer to CQI 1f.
b) For example, waiting time in OPD.

11.4.9 Monitoring includes data collection to support the evaluation of these improvements.

Interpretation/Remarks*:*

a) All improvement activities carried out by the HCC shall have an evaluable outcome. The same shall be captured and analysed.

Standard

CQI 11.5: The quality improvement program is supported by the management.

Objective Elements

11.5.1 The management makes available adequate resources required for quality improvement program.

Interpretation/Remarks:

a) This shall include the men, material, machine, money and method. These should be in steady supply so as to ensure that the program functions smoothly.

11.5.2 HCC earmarks adequate funds from its annual budget in this regard.

Interpretation/Remarks:

a) Appropriate fund allocation is done by the HCC for the smooth functioning of the program.
b) The budget could be earmarked based on previous year's spending. If no data is available the HCC could make a beginning by earmarking a budget but reviewing it at the end of six months to make any necessary modifications.

11.5.3 The management identifies HCC performance improvement targets.

Interpretation/Remarks:

a) The management shall identify HCC and department level quality objectives, set targets, monitor them (at least once in four months) and modify the target (at least annually).
b) The targets should be shared with the faculty and staff and regular feedback taken.

11.5.4 The management supports and implements the use of appropriate quality improvement, statistical and management tools in its quality improvement program.

Interpretation/Remarks:

a) For example, Root Cause Analysis, FMEA, Project Evaluation and Review Technique (PERT), Critical Path Method (CPM), Control Charts, etc.

Standard

CQI 11.6: There is an established system for clinical audit and documented

Objective Elements

11.6.1 Medical and nursing staff participates in this system.

Interpretation/Remarks:

a) The HCC shall identify such personnel. It could be a mix of clinicians, administrators and

nurses.

b) These could be members of the core committee/quality assurance committee, etc.

11.6.2 The parameters to be audited are defined by the HCC.

Interpretation/Remarks:

a) As these audits are retrospective/concurrent in nature, it is imperative that this is done using predefined parameters so that there is no bias. The parameters could be disease based, cost-based, community-based or based on morbidity length of stay).

b) It shall lay down the objectives, the parameters that are going to be captured, develop a checklist where required, sampling and data collection guidelines and preparation of the report.

c) The audit shall encompass all aspects of care including clinical and nursing.

11.6.3 Patient and staff anonymity is maintained.

Interpretation/Remarks:

a) This means that the names of the patients and the HCC staff who may figure in the audit documents must not be disclosed or any reference be made to them in public discussions/conferences

b) The HCC could use a checklist with the predefined parameters and the audit findings could be recorded on this sheet.

11.6.4 All audits are documented.

Interpretation/Remarks:

a) The HCC could use a checklist with the predefined parameters and the audit findings could be recorded on this sheet.

11.6.5 Remedial measures are implemented.

Interpretation/Remarks:

a) All remedial measures as ascertained should be documented and implemented and improvements thereof recorded to complete the audit cycle.

b) This should preferably be done based on the root-cause analysis.

Standard

CQI 11.7: Incidents, complaints and feedback are collected and analysed to ensure continuous quality improvement.

Objective Elements

11.7.1 The HCC has an incident reporting system.

Interpretation/Remarks:

a) The incident reporting system includes:
    1) Identification, Reporting Review and Action on incidents.
b) While capturing the HCC shall capture all incidents without going into the severity or whether harm was caused.

11.7.2 The HCC has a process to collect feedback and receive complaints.

Interpretation/Remarks:

a) This shall be communicated to the patients using displays or brochures

11.7.3 The HCC has established processes for analysis in incidents, feedbacks and complaints.*

Interpretation/Remarks:

a) The quality improvement committee (refer to CQI 1a) shall be responsible for this activity.
b) This could preferably be done by identifying the root cause.
c) Where possible, it is preferable that patients be included in analysing the feedback and complaints.

11.7.4 Corrective and preventive actions are taken based on the findings of such analysis and Feedback about care and service is communicated to staff.

Interpretation/Remarks:

a) This could be done using internal communication.
b) It is equally important that positive feedback about care and service is communicated to staff.

11.7.5 Feedback about care and service is communicated to staff.

Interpretation/Remarks:

a) At a minimum, patient satisfaction levels shall be communicated every six months.
b) This could be done using internal communication.
c) It is equally important that positive feedback about care and service is communicated to staff.

Standard

CQI 11.8: Sentinel events are intensively analysed.

11.8.1 The HCC has defined sentinel events.

Interpretation/Remarks:

a) The sentinel events relating to system or process deficiencies that are relevant and important to the HCC must be clearly defined.
b) The list of the identified and relevant sentinel events shall be documented.

11.8.2 The HCC has established processes for intense analysis of such events.

Interpretation/Remarks:

a) The established processes should include reporting the occurrence of such events on standardized incident report forms.

11.8.3 Sentinel events are intensively analysed when they occur.

Interpretation/Remarks:

a) Root-cause analysis of all such events should be carried out by a Quality committee taking inputs from the units/discipline/departments concerned.
b) All sentinel events shall be analysed within 24-working hours of occurrence.

11.8.4 Corrective and preventive actions are taken based on the findings of such analysis.

Interpretation/Remarks:

a) The findings and recommendations arrived at after the analysis should be communicated to all personnel concerned to correct the systems and processes to prevent reoccurrence.

Standard

CQI 11.9: Regular Supervision and Monitoring of HCC

Objective elements

11.9.1 All the HCCs are periodically supervised and monitored to ensure adherence to these standards.

Interpretation/Remarks

a) The QASD/QMS could define the periodicity and standardized checklist can be used for this purpose based on this standard.
b) QA focal persons shall carry out the supervision and monitoring on three cluster regional bases (East, West and Centre).

11.9.2 Regular Assessment for compliance.

Interpretation/Remarks

a) Leaders of the HCC conduct regular assessment of the compliance with this standard.

b) The assessment shall be done by using a standardized checklist

11.9.3 The system is in place to ensure timely submission of reports to the QASD.

Interpretation/Remarks

a) HAMT members shall submit the reports to the QASD on completion of the supervision.

b) HCCs could be ranked based on the performance in consonance with this standard.

12. Responsibilities of Management (ROM)

Preamble

The standards encourage the governance of the HCC in a professional and ethical manner. The responsibilities of the management are defined. The HCC complies with all applicable regulations. The HCC is led by a suitably qualified and experienced individual. The responsibilities of the leaders at all levels 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 HCC management.

Summary of Standards

ROM 12.1	The terms of reference of those responsible for governance are defined.
ROM 12.2	The HCC complies with the laid-down and applicable legislation and regulations
ROM 12.3	The services provided by each department are documented.
ROM 12.4	The HCC is managed by the leaders in an ethical manner.
ROM 12.5	The HCC displays professionalism in the management of affairs.
ROM 12.6	Management ensures that patient-safety aspects and risk-management issues are an integral part of patient care and HCC management.

Standards and Objective Elements

Standard

ROM 12.1: The terms of reference of those responsible for governance are defined.

Objective Elements

12.1.1 Those responsible for governance lay down the HCC's mission and values.
Interpretation/Remarks:

a) It is not only the head of the HCC but the members of the management board (where applicable) who need to define it.

12.1.2 Those responsible for governance approve the strategic and operational plans.

12.1.3 Those responsible for governance monitor and measure the performance of the HCC against the stated mission.

Interpretation/ Remarks:

a) The management board/committee and the head of the HCC shall develop quarterly (at least) performance reports based on the strategic and operational plans.

b) Performance shall be discussed in the management review meeting and action items are regularly followed up.

12.1.4 The Ministry of Health shall be responsible for governance and to establish the HCC's organogram.

Interpretation/ Remarks:

a) The HCC shall have a well-defined HCC structure/chart and this shall clearly document the hierarchy, line of control, along with the functions at various levels.

b) Organogram is transparent and is disseminated to all stakeholders.

c) The organogram shall incorporate various committees.

12.1.5 Those responsible for governance appoint the in-charges/focal persons in the HCC.

Interpretation/ Remarks:

a) Senior leaders include the first two rungs of the organogram.

b) Appointment of senior leaders shall be through the selection committee.

12.1.6 Those responsible for governance support safety initiatives and quality improvement plans.

Interpretation/ Remarks:

a) All risk assessment and risk reduction are known and measures to reduce are discussed for corrective actions.

12.1.7 Those responsible for governance support research activities.

Interpretation/ Remarks:

a) Support in research shall include providing resource, budget, following ethical and legal norms.

12.1.8 Those responsible for governance address the HCC's social responsibility.

Interpretation/ Remarks:

a) The Ministry of Health, governing board and head of the HCC shall wilfully develop social responsibility policy and accordingly address it.

b) For example, health camps, outreach program etc.

12.1.9 Those responsible for governance inform the public of the quality and performance of services.

Interpretation/ Remarks:

a) This could be done in the form of displays or brochures.

b) This could include results of surveys done by independent third parties and results of benchmarking done by professional bodies.

Standard

ROM 12.2: The HCC complies with the laid-down and applicable legislation and regulations.

Objective Elements

12.2.1 The management is conversant with the laws and regulations and knows their applicability to the HCC.

Interpretation/ Remarks:

a) This includes relevant legislation (Bhutan Medical and Council Act and Medical Council Regulation Medicines Act & Medicine Regulation, Waste Management and Prevention Act and Waste Prevention and Management Regulation) and other respective of other related legislation of the country.

b) A designated management functionary could be given the responsibility to enlist the laws and regulation as applicable to the HCC. This functionary, in turn, could identify the appropriate personnel in the HCC who are supposed to implement the respective laws and regulations.

12.2.2 The management ensures the implementation of these requirements.

Interpretation/ Remarks:

a) All relevant clauses under the rules and acts are abided by the HCC.

12.2.3 Management regularly updates any amendments to the prevailing laws of the land.

12.2.4 There is a mechanism to regularly update licenses/registrations/certifications.

Interpretation/ Remarks:

a) For example, timely registration and renewal of health professionals with BMHC.
b) The HCC could develop a tracker sheet for this purpose.

Standard

ROM 12.3: The services provided by each department are documented.

Objective Elements

12.3.1 The scope of services of each department is defined.

Interpretation/Remarks:

a) Each department's activity is to be predefined. This could be documented either at the individual department level or the HCC could have a brochure detailing the scope of each department.
b) This includes clinical and non-clinical departments.
c) For example, the surgical department could do all activities like biopsy, shunts, fistulas, dialysis (haemo, CAPD), etc.

12.3.2 Administrative procedures for each department are maintained.

Interpretation/ Remarks:

a) This shall include all administrative procedures like attendance, leave, conduct, replacement, etc. This shall be documented.
b) It could be common for the entire HCC.

12.3.3 Each HCC's program, service, site or department has effective leadership.

Interpretation/ Remarks:

a) There needs to be minimum essential qualification and relevant experience of the leader. The leader should have domain knowledge of that particular department.

12.3.4 Departmental leaders are involved in quality improvement.

Interpretation/ Remarks:

a) To effectively implement this, each department could have its department objectives/key performance indicators and the responsibility of achieving them could be that of the leaders.

Standard

ROM 12.4: The HCC is managed by the leaders in an ethical manner.

Objective Elements

12.4.1 The leaders make public the scope, mission, vision and values of the HCC.

Interpretation/ Remarks:

a) This shall be done by displaying the same prominently.
b) For the definition of "mission", "vision", and "values" refer to the glossary.
c) Only a display on its website would not be appropriate. It is preferable that the same be translated and displayed in the national and local language too.

12.4.2 The leaders establish the HCC's ethical management.

Interpretation/ Remarks:

a) The HCC shall function is an ethical manner.
b) Transparency in its actions shall be one of its guiding principles. Handling of complaints, grievances, clinical care delivery and research shall be some of the areas to address.
c) *Refer to* "Bhutan Medical and Health Council rules and regulations".
d) The HCC's established ethical management shall be documented.
e) Proper handling taking should be done through transparency while going for leave or transfer to other HCCs or organization.

12.4.3 The HCC discloses its ownership (If applicable).

Interpretation/ Remarks:

a) The ownership of the HCC, e.g. trust, private, the public has to be disclosed.
b) The disclosure could be in the registration certificate/quality manual, etc.

12.4.4 The HCC honestly portrays the services which it can and cannot provide.

Interpretation/ Remarks:

a) Documentation with respect to services non-availability and its communication to patients is maintained.
b) Here portrays implies that the HCC conveys to the patients clearly what it can and cannot provide. The services that it cannot provide could also be conveyed verbally. Refer to AAC 1 also.

12.4.5 The HCC honestly portrays its affiliations and accreditations (if applicable).

Interpretation/ Remarks:

a) Here implies that the HCC convey is affiliations, accreditations for specific departments or

whole HCC wherever applicable.

12.4.6 The HCC accurately bills for its services based upon a standard billing tariff (if applicable).
Interpretation/ Remarks:

a) Also, refer to PRE 6. The tariff could be devised by a tariff committee

Standard

ROM 12.5: The HCC displays professionalism in the management of affairs.

Objective Elements

12.5.1 The person heading the HCC has requisite and appropriate administrative qualifications and administrative experience.
Interpretation/ Remarks:

a) This implies to the individual looking after the day-to-day operations and not to the chairperson of the Management Board.
b) Appropriate implies qualification in HCC management/administration.

12.5.2 The HCC prepares the strategic and operational plans including long-term and short-term goals commensurate to the HCC's vision, mission and values in consultation with the various stakeholders.
Interpretation/ Remarks:

a) The leader(s) shall define and develop the process for a strategic and operational plan so as to achieve the HCC's vision and mission statement and adhere to the values. It shall be discussed with all stakeholders.
b) One of the inputs that should be considered while finalizing these plans shall be the finding of the "risk-management plan".
c) This shall at least be done on an annual basis.
d) Refer to the glossary for "strategic and operational plans".
e) Stakeholders include the community the HCC serves.

12.5.3 The HCC coordinates the functioning with departments and external agencies and monitors the progress in achieving the defined goals and objectives.
Interpretation/ Remarks:

a) The reasons for not achieving any particular goal shall be analysed and appropriate action shall be taken.
b) This could be done through management review meetings.

12.5.4 The HCC plans and budgets for its activities annually.

Interpretation/ Remarks:

a) An adequate budget shall also be allocated for infection control and quality-improvement activities.

b) The budget proposal should be made within February-March to meet the financial dateline within June and July.

12.5.5 The performance of the in-charges/focal persons is reviewed for their effectiveness.

Interpretation/ Remarks:

a) Key result areas of each leader can be established or it can be done through performance appraisal.

b) This shall be done by those responsible for governance.

12.5.6 The functioning of committees is reviewed for their effectiveness.

Interpretation/ Remarks

a) This shall be done by the management. The review at a minimum shall include if the purpose of having the committee is being met, if the committee is meeting at the prescribed frequency and if the committee is suggesting remedial measures and if there is adequate monitoring.

b) For an effective review, it is preferable that the HCC documents the scope of every committee, the roles and responsibilities assigned to various members and the frequency of meetings. Agenda shall be prepared for all meetings and documentation of each committee meeting is kept.

12.5.7 The HCC documents employee rights and responsibilities.

Interpretation/ Remarks

a) The HCC shall define the same in consonance with statutory requirements.

12.5.8 The HCC documents the service standards

Interpretation/ Remarks:

a) The HCC shall develop benchmarks for different services being provided. This shall be based on the HCC's values and focus on the development of core competency, behaviour, attitude, communication skills, etc.

12.5.9 The HCC has a formal documented agreement for all outsourced services.

Interpretation/ Remarks:

a) The agreement shall specify the service parameters.
b) Even if a sister concern is providing services, there shall be an agreement with that unit.

12.5.10 The HCC monitors the quality of the outsourced services.

Interpretation/ Remarks:

a) The frequency of monitoring shall be determined by the HCC. This shall be done keeping in mind the criticality of that service towards providing patient care.
b) It is preferable that the monitoring is done as per the service standards/Terms of Reference laid down or as per the requirements of this standard.

Standard

ROM 12.6: Management ensures that patient-safety aspects and risk-management issues are an integral part of patient care and HCC management.

Objective elements

12.6.1 Management ensures proactive risk management across the HCC.

Interpretation/ Remarks:

a) This shall include clinical and non-clinical (strategic, financial, operational and hazard) risks.
b) It shall include risk identification, prioritization and risk alleviation. This shall be documented as a “risk management plan”. It shall include the various risks identified, the action taken for risk alleviation of each of these risks and the mechanism for informing staff regarding the same.
c) Further, the risk management plan shall be monitored and reviewed for continued effectiveness at least annually. The results of the review shall be communicated to the relevant stakeholders in the HCC.
d) This could be done using a matrix.
e) The clinical risk assessment could include:
    1) Medication management, covering issues such as patient/service-user allergies and antibiotic resistance.
    2) Equipment risks, e.g. fire/injury risks from the use of a laser, and
    3) Risk resulting from the long-term condition.

12.6.2 Management provides resources for proactive risk assessment and risk-reduction activities.

Interpretation/ Remarks:

a) There shall be sufficient resources kept as a contingency to address the risk reduction activities as and when the leaders proactively suggest. The end result of these shall result in preventive actions.

12.6.3 Management ensures the implementation of systems for internal and external reporting of system and process failures.

Interpretation/ Remarks:

a) The HCC has a system in place for internal and external reporting of system and process failures.
b) The contingency plan shall be in place to deal with the situation of system and process failure anticipated within the HCC.
c) For example, MRI machine of the HCC breaks down.
d) In this case, internal reporting is to be done to the head/Administrative officer of the HCC and external reporting to be done to the patients.
e) The system for reporting shall be documented.

12.6.4 Management ensures that appropriate corrective and preventive actions are taken to address safety-related incidents.

Interpretation/ Remarks:

a) This shall be taken after an analysis.
b) The analysis could be done by the safety committee and preferably a root-cause must be identified

13. Facility Management and Safety (FMS)

Preamble

The standards guide the provision of a safe and secure environment for patients, their families, staff and visitors. To ensure this, the HCC conducts regular facility inspection rounds and takes the appropriate action to ensure safety. The HCC provides for safe water, electricity, medical gases and vacuum systems. The HCC has a program for clinical and supports service equipment management. The HCC plans for emergencies within the facilities and the community. The HCC is a no-smoking area and manages hazardous materials in a safe manner.

Summary of Standards

FMS 13.1	The HCC has a system in place to provide a safe and secure environment.
FMS 13.2	The HCC's environment and facilities operate to ensure the safety of patients, their families, staff and visitors.
FMS 13.3	The HCC has a program for engineering support services.
FMS 13.4	The HCC has a program for bio-medical equipment management.
FMS 13.5	The HCC has a program for medical gases, vacuum and compressed air.
FMS 13.6	The HCC has plans for fire and non-fire emergencies within the facilities.
FMS 13.7	The HCC plans for handling-community emergencies, epidemics and other disasters.
FMS 13.8	The HCC has a plan for management of hazardous materials.

This implies that this objective element requires documentation.

Standards and Objective Elements

Standard

FMS 13.1: The HCC has a system in place to provide a safe and secure environment.

Objective Elements

13.1.1 Safety committee coordinates the development, implementation and monitoring of the safety plan and policies.

Interpretation/Remarks

a) The HCC ensures that the above committee functions on a regular basis to coordinate the development, implementation and monitoring of the plans and policies.

b) The plans are fully implemented and there is a process for periodic review of plans.
c) The safety committee must include representatives from facility management, clinicians, administrator, nursing and paramedical staff.
d) It is preferable that the HCC conducts an exercise of Hazard Identification and Risk Analysis (HIRA) and accordingly takes all necessary steps to eliminate or reduce such hazards and associated risks.

13.1.2 Patient-safety devices are installed across the HCC and inspected periodically.

Interpretation/Remarks

a) For example, grab bars, bed rails, signposting, safety belts on stretchers and wheelchairs, alarms both visual and auditory where applicable, warning signs like radiation or biohazard, call bells, fire-safety devices, etc.

13.1.3 The HCC is prohibited area for alcohol, smoking, chewing doma, tobacco and other edibles that would litter the HCC areas.

Interpretation/Remarks

a) The HCC shall adhere to statutory requirements.

13.1.4 Facility inspection rounds to ensure safety are conducted at least twice in a year in patient-care areas and at least once a year in non-patient-care areas.

Interpretation/Remarks

a) Rounds to be carried out by safety committee.
b) The HCC plans for upgrading or replacing key systems, buildings, or components based on the facility inspections, in keeping with laws and regulations.
c) HCC plans budget allocation for each department or Unit to carry out these maintenance activities.
d) During these rounds, potential safety risks are identified. This could be carried out using a checklist incorporating some of the more common safety hazards.

13.1.5 Inspection reports are documented and corrective and preventive measures are undertaken.

Interpretation/Remarks:

a) Before and after evidence may be maintained.

13.1.6 There is a safety education program for staff.

Standard

FMS 13.2: The HCC's environment and facilities operate to ensure the safety of patients, their families, staff and visitors.

Objective Elements

13.2.1 Facilities are appropriate to the scope of services of the HCC.

Interpretation/Remarks:

a) The basis of appropriateness will be the best practices/national/international guidelines.

13.2.2 Up-to-date drawings are maintained which detail the site layout, floor plans and fire-escape routes.

Interpretation/Remarks

a) A designated person maintains the drawings.
b) In addition to fire-evacuation plans, it is preferable that separate civil, electrical, and plumbing, HVAC and piped medical gas drawings are maintained.

13.2.3 There are internal and external sign postings in the HCC in a language understood by the patient, families and community.

Interpretation/Remarks:

a) Fire signage should follow the norms laid down by National Building Code (MoWHS) and/or respective legal body (for example, fire service).
b) This signage shall guide patients and visitors. It is preferable that signage is bi-lingual.
c) The legal requirement shall be met.

13.2.4 The provision of space shall be in accordance with the available literature on good practices (National/Regional/International Standards) and directives from government agencies.

Interpretation/Remarks

a) The standard design of structures based on the levels of HCCs (example ISO 10905 for basic requirements for general HCC buildings/ international standards).

13.2.5 Safe drinking water and electricity are available round the clock.

Interpretation/Remarks

a) The HCC shall make arrangements for the supply of adequate drinking water and electricity.
b) For water quality - periodic water analysis report from public health laboratory and electricity supply based on BPC rules & regulation Bhutan Electricity Act.

13.2.6 Alternate sources for electricity and water are provided as backup for any failure/shortage.

Interpretation/Remarks:

a) At the outset, the HCC shall ensure that there is sufficient water supply to meet the requirements. Further, the electric load applied for shall be appropriate to the requirements of the HCC and adhere to the regulatory requirements.
b) In case of a shortfall in water or electricity, alternate sources shall be required.
c) A good reference for estimating the water requirement is the National Building Code.
d) Alternate electric supply could be from DG sets, solar energy, UPS and any other suitable source.
e) The HCC could consider having multiple alternate sources depending on the criticality of the activity.
f) The HCC regularly tests these alternate sources.

13.2.7 There are designated individuals responsible for the maintenance of all the facilities.

Interpretation/Remarks:

a) A person in the HCC is designated to be in-charge of maintenance of facilities. The HCC has the required number of supervisors to manage the facilities.
b) The necessary infrastructure and tools shall be provided by the HCC.

13.2.8 There is a documented operational and maintenance (preventive and breakdown) plan.*

Interpretation/Remarks:

a) This shall include facility/building/installations.

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

Interpretation/Remarks:

a) If an emergency repair is not possible by staff on duty, more qualified/experienced staff should be available.
b) Response times are monitored from reporting to inspection and implementation of corrective actions.
c) A complaint attendance register to be maintained (physical or electronic) to indicate the date and time of receipt of the complaint, allotment of job and completion of the job.
d) Completion of the job should always be ratified by the user department.

Standard

FMS 13.3: The HCC has a program for engineering support services management.

Objective Elements

13.3.1 The HCC plans for equipment in accordance with its services and strategic plan.

Interpretation/Remarks:

a) The plans should be fully implemented and there should be a process for periodic review of plans.

13.3.2 Equipment is selected, updated or upgraded by a collaborative process.

Interpretation/Remarks:

a) The collaborative process implies that during equipment selection there is involvement of end-user, management, finance and engineering departments.

13.3.3 Equipment is inventoried and proper logs are maintained as required.

Interpretation/Remarks:

a) Where applicable, the relevant quality conformance certificates/marks along with manufacturer factory test certificate need to be retained as part of the documentation for every equipment.

13.3.4 Qualified and trained personnel operate and maintain equipment and utility systems.

Interpretation/Remarks:

a) The person could be qualified by experience or training.

13.3.5 There is a documented operational and maintenance (preventive and breakdown) plan.*

Interpretation/Remarks:

a) The manufacturer's instruction manual for equipment exists. The operator is trained in handling the equipment. There shall be a planned preventive maintenance tracker.
b) This shall include all-engineering support service equipment like DG set.

13.3.6 There is a maintenance plan for water management.*

Interpretation/Remarks:

a) This shall include cleaning of water storage tanks at regular intervals and treating of water, where appropriate and should be tested for coliform bacteria. It shall also include an RO unit and STP in case it is available in the HCC.
b) In case of an RO plant of the dialysis unit, National Guideline on Dialysis should be

followed.

13.3.7 There is a maintenance plan for the electrical system.*

Interpretation/Remarks:

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

13.3.8 There is a maintenance plan for heating, ventilation and air-conditioning.*

Interpretation/Remarks:

a) This shall include chillers unit, AHU, FCU and various air-conditioners.
b) This shall adhere to manufacturer's recommendations and good infection-control practice requirement. This includes timely cleaning and/or replacement of filters.

13.3.9 There is a documented procedure for equipment replacement and disposal.*

Interpretation/Remarks:

a) The HCC shall plan for this keeping in mind the strategic plan, upgrade/update path and the equipment log.
b) HCC shall dispose of (condemn) equipment in a systematic manner
c) All records pertaining to the condemnation of equipment shall be maintained.

Standard

FMS 13.4: The HCC has a program medical equipment management.

Objective Elements

13.4.1 The HCC plans for equipment in accordance with services and strategic plan of the BMED/MOH.

Interpretation/Remarks:

a) This shall also take into consideration the existing inventory, future requirements and replacement plans.
b) The medical equipment shall be appropriate to its scope of services.
c) A good reference for minimum medical equipment is the Standard medical equipment list developed by the Ministry of Health.

13.4.2 Equipment is selected, rented, updated or upgraded by a collaborative process.
Interpretation/Remarks:

a) The collaborative process implies that during medical equipment selection respective departments should be consulted.

13.4.3 Medical equipment is inventoried and proper logs are maintained.
Interpretation/Remarks:

a) Medical equipment inventory should include details on the name of HCC, type and name of medical equipment, acquisition cost, installation date, model and serial no., manufacturer, the source of funding, year of manufacture, etc
b) Medical equipment logbook should record a detailed history of its utilization, breakdown, maintenance, etc.
c) HCC should maintain a fixed asset register of all medical equipment installed at the HCC.
d) The relevant quality conformance certificates/marks along with manufacturer factory test certificate need to be retained for all medical equipment.
e) This includes medical equipment on a rental basis as well as that medical equipment kept for demonstration purpose.

13.4.4 Qualified and trained personnel operate and maintain the medical equipment**.**
Interpretation/Remarks:

a) Maintenance of medical equipment shall be done by a biomedical engineers/technicians or other personnel with relevant training and experience authorized by Bio-Medical Engineering Division under the Department of Medical Supplies and Health Infrastructure, Ministry of Health.
b) Only qualified and trained personnel shall operate respective medical equipment

13.4.5 Medical equipment is periodically inspected and verified for their proper performance.
Interpretation/Remarks:

a) The HCC has weekly/monthly/annual schedules of inspection and calibration of equipment, which involve measurement, in an appropriate manner.

13.4.6 There is a documented operational and maintenance (preventive and breakdown) plan.*
Interpretation/Remarks:

a) The manufacturer's instruction manual for equipment exists. The operator is trained in handling the equipment. There shall be a planned preventive maintenance tracker.

13.4.7 There is a documented procedure for medical equipment replacement and disposal.

Interpretation/Remarks:

a) The HCC shall plan in close collaboration with BMED keeping in mind the strategic plans, upgrade/update path and the equipment log.
b) HCC shall dispose medical equipment in a systematic manner.

13.4.8 There is documented system for validation and verification of the equipment with a certificate of performance after installation, repairing or maintenance services.

Interpretation/Remarks:

a) Maintenance log should be completed and documented
b) QC should be done by the operator of the equipment and results verified jointly with biomedical engineering personnel before the certificate is issued to the HCC.

13.4.9 There is documented system for quality inspection of equipment to validate and verify the functionality and performance characteristics.

Interpretation/Remarks:

a) The HCC shall ensure that conformance testing of the equipment in terms of accuracy and precision of the results are done prior to commissioning.
b) The HCC shall ensure that calibration of the equipment has been done prior to commissioning.
c) The HCC either calibrates the equipment in-house or outsources, maintaining traceability to national or international or manufacturer's guidelines/standards.

Standard

FMS 13.5: The HCC has a program for medical gases, vacuum and compressed air.

Objective Elements

13.5.1 Documented procedures govern procurement, handling, storage, distribution, usage and replenishment of medical gases.

Interpretation/Remarks:

a) This shall be applicable to all gases used in the HCC. It shall also address the issue of statutory requirements and approval wherever applicable. It shall follow a uniform colour coding system.
b) Proper signage is kept for used, full, empty cylinders.
c) A good reference is HTM 2022 or NFPA's Medical Gas and Vacuum Systems Installation

Handbook (NFPA's new NFPA 99C solution and Explosives Act, Gas Cylinder rules and Static and Mobile Pressure Vessel (unfired) rules.

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

a) It is mandatory that compressed air purity is checked (at the level of terminal outlet) once in a year.

b) Good references can be obtained from the following guidelines and link: NFPA 99: Health Care Facilities Code (2015); Jump up^ ISO 7396-1:2016 Medical gas pipeline systems - Part 1: Pipeline systems for compressed medical gases and vacuum; Jump up^ http://www.frca.co.uk/article.aspx?articleid=100342.

13.5.3 The procedures for medical gases address the safety issues at all levels.
Interpretation/Remarks:

a) This shall include from the point of storage/source area, gas supply lines and the end-user area.

b) This shall include alarm units and valve boxed installation at various locations and 24x7 monitoring of plant alarm unit for gas pressure going beyond the set limit, pin-indexed medical gas outlets, etc.

13.5.4 Alternate sources for medical gases, vacuum and compressed air are provided for, in case of failure.
Interpretation/Remarks:

a) In case of the air compressor and vacuum pump, it could be the standby air compressor and vacuum pump unit.

13.5.5 There is an operational and maintenance plan for piped medical gas, compressed air and vacuum installation.
Interpretation/Remarks:

a) This shall adhere to the manufacturer's recommendations.

Standard

FMS 13.6: The HCC has plans for fire and non-fire emergencies within the facilities.

Objective Elements

13.6.1 The HCC has plans and provisions for early detection, abatement and containment of fire and non-fire emergencies.

Interpretation/Remarks:

a) The HCC shall:

1) Have a fire plan covering fire arising out of the burning of inflammable items, explosion, electric short-circuiting or acts of negligence or due to the incompetence of the staff on duty;
2) Deploy adequate and qualified personnel;
3) Acquire adequate firefighting equipment and records are kept up-to-date;
4) Have adequate training plans;
5) Have schedules for the conduct of mock fire drills;
6) Maintain mock drill records;
7) Display exit plans well;
8) Have a dedicated emergency illumination system, which comes into effect in case of fire.

13.6.2 The HCC shall take care of non-fire emergency situations by identifying them and by deciding the appropriate course of action.

Interpretation/Remarks:

a) These may include:

1) Invasion of swarms of insects and pests,
2) Earthquake,
3) Invasion of stray animals,
4) Hysteric fits of patients and/or relatives,
5) Civil disorders affecting the HCC,
6) Anti-social behaviour by patients/relatives,
7) Temperamental disorders of staff causing deterioration in patient care,
8) Spillage of hazardous (acids, mercury, etc.), infected materials (used glove, syringes, tubing, sharps, etc.) medical wastes (blood, pus, amniotic fluid, vomits, etc.),
9) Building or structural collapse,
10) Fall or slips (from a height or on a floor) or collision of personnel in a

passageway.

11) Fall of a patient from the bed,
12) Bursting of pipelines,
13) Sudden flooding of areas like basements due to clogging in pipelines,
14) Sudden failure of supply of electricity, gas, vacuum, etc, and
15) Bursting of boilers and/or autoclaves.

13.6.3 The HCC shall establish liaison with civil and police authorities and fire brigade as required by law for enlisting their help and support in case of an emergency.

Interpretation/Remarks:

a) The National Building Code is a good reference guide.

13.6.4 The HCC has a documented safe-exit plan in case of fire and non-fire emergencies.

Interpretation/Remarks:

a) The fire-exit plan shall be displayed on each floor particularly close to the lifts. Exit doors should remain open all the time.
b) The signage of fire exits shall be as per the National Building Code and/or respective statutory body (for example, fire service).

13.6.5 Trained for its role in case of such emergencies.

Interpretation/Remarks:

a) In case of fire, a designated person is assigned a particular work.
b) The training shall include various classes of fire, information and demonstration on how to use a fire extinguisher and the procedure to be followed in case of fire and non-fire emergencies.

13.6.6 Mock drills are held at least twice a year.

Interpretation/Remarks:

a) This shall test all the components of the plan and not just awareness/demonstration on the use of firefighting equipment. Simulated patients (not real) shall be used for evacuation.
b) This is only the minimum frequency and this may be increased.
c) At the conclusion of every mock drill, the variations are identified, the reason for the same analysed, debriefing of the drill conducted and, where appropriate, the necessary corrective and/or preventive actions are taken.

13.6.7 There is a maintenance plan for fire-related equipment.

Interpretation/Remarks:

a) This shall adhere to manufacturers and/or statutory recommendations.

Standard

FMS 13.7: The HCC plans for handling community emergencies, epidemics and other disasters.

Objective Elements

13.7.1 The HCC identifies potential emergencies.

Interpretation/Remarks:

a) The HCC has a documented plan and procedure for handling the situations like a sudden rush of victims of
    1) Earthquake,
    2) Flood,
    3) Public transport accident,
    4) Civil unrest outside the HCC's premises,
    5) Major fire and invasion by any sort.

b) These plans and procedures cover ensuring adequacy of medical supplies, equipment, materials, identified-trained personnel, transportation aids, communication aids and mock-drill methodology.

13.7.2 The HCC has a documented disaster management plan.

Interpretation/Remarks:

a) The disaster plan must incorporate essential elements of alert code, information and communication, action cards for each of the staff, availability and earmarking of resources, the establishment of command nucleus, training and mock drills.

a) Refer to National Disaster Management guidelines.

b) Emergency room could follow triage policy according to guidelines.

13.7.3 Provision is made for the availability of medical supplies, equipment and materials during such emergencies.

Interpretation/Remarks:

a) Resource availability should be according to threat perception.

b) The quantity of resources, i.e. medical stores, etc., to be cross-checked with the expected workload.

13.7.4 Staffs are trained in the HCC's disaster management plan.

Interpretation/Remarks:

a) The training shall include the various elements of the disaster plan.

13.7.5 The plan is tested at least twice a year.

Interpretation/Remarks:

a) This shall test all the components of the plan and not just awareness. Simulated patients (not real) shall be used.

b) This is only the minimum frequency and this may be increased.

c) At the conclusion of every mock drill, the variations are identified, the reason for the same is analysed, debriefing of the drill conducted and where appropriate the necessary corrective and/or preventive action are taken.

Standard

FMS 13.8: The HCC has a plan for management of hazardous materials.

Objective Elements

13.8.1 Hazardous materials are identified within the HCC.

Interpretation/Remarks:

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

b) The hazardous materials as notified by National Environment Commission.

c) In addition, biological materials like blood, body fluids and microbiological cultures, mercury, nuclear isotopes, medical gases, LPG gas, steam, ETO, etc., are some of the other common hazardous materials.

13.8.2 The HCC implements processes for sorting, labelling, handling, storage, transporting and disposal of hazardous material.

Interpretation/Remarks:

a) The HCC shall conduct an exercise of hazard identification and risk analysis (HIRA) associated with the handling of hazardous materials and accordingly taken all necessary steps to eliminate or reduce such hazards and associated risks.

b) The HCC has ensured display of Material Safety Data Sheets (MSDS) for all hazardous materials and has accordingly arranged training of personnel who handle such materials.

c) The situational hazards also need to be covered in HIRA so that any emergency arising out of the process of storing, handling, storage, transportation and disposal of such hazardous materials are met effectively.

13.8.3 Requisite regulatory requirements are met in respect of radioactive materials.
Interpretation/Remarks:

a) The appropriate personnel in the HCC are aware of the International rules and regulations of radioactive materials.

13.8.4 There is a plan for managing spills of hazardous materials.
Interpretation/Remarks:

a) The HCC could have a HAZMAT kit(s) for handling spills.

13.8.5 Staff are educated and trained for handling such materials.

14. Human Resource Management (HRM)

Preamble

Human resources are an asset for the effective and efficient functioning of an HCC. Without an equally effective human resource management system, all other inputs like technology, infrastructure and finances come to nought. 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 HCC Human resources is based on the HCC's objectives, 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 relate to the performance in the present and future anticipated jobs. The employees are provided with opportunities to advance personally as well as professionally.
c) Motivation relates to job design, performance appraisal and discipline.
d) Maintenance related to safety and health of the employees.

Summary of Standards

HRM 14.1	The HCC has a documented system of human resource planning.
HRM 14.2	The HCC has a documented procedure for recruiting staff and orienting them to the HCC's environment.
HRM 14.3	There is an ongoing program for professional training and development of the staff.
HRM 14.4	Staffs are adequately trained on various safety-related aspects.
HRM 14.5	An appraisal system for evaluating the performance of an employee exists as an integral part of the HRM process.
HRM 14.6	The HCC has documented disciplinary grievance handling policies and procedures.
HRM 14.7	The HCC addresses the health needs of the employees.
HRM 14.8	There is a documented personal record for each staff member.
HRM 14.9	There is a process for credentialing and privileging of medical professionals permitted to provide patient care without supervision.
HRM 14.10	There is a process for credentialing and privileging of nursing professionals, permitted to provide patient care without supervision.

Standards and Objective Elements

HRM 14.1: The HCC has a documented system of human resource planning.

Standard

Objective Elements

14.1.1 Human resource management should adhere to the Bhutan Civil Service Rules and Regulations 2018 and the Bhutan Civil Service Act of Bhutan 2010.

14.1.2 Human Resource Planning should support the HCC's current and future ability to meet the care, treatment and service needs of the patient.

Interpretation/Remarks:

a) This shall be done in a structured manner keeping in mind the scope of services, mission and the healthcare needs of the community that it serves.

b) It shall match the strategic and operational plan of the HCC.

14.1.3 The HCC maintains an adequate number and mix of staff to meet the care, treatment and service needs of the patient.

Interpretation/Remarks:

a) The staff should be commensurate with the workload and the clinical requirement of the patients.

b) A good reference could be the Bhutan Civil Service Regulation.

14.1.4 The required job specification and job description are well defined for each category of staff.

Interpretation/Remarks:

a) The content of each job should be well defined and the qualification, skills and experience required for performing the job should be clearly laid down. The job description should be commensurate with the qualification.

b) Refer to the glossary for definition of "job description" and "job specification". For a job which requires the skills of a doctor, Dungtsho, Nurse, Menpas and technicians, the minimum qualification shall have MBBS for doctors; Bachelor degree or Diploma for Nurses and Menpas and BSc. or certificates for technicians.

14.1.5 The HCC verifies the potential employee with regards to criminal/negligence background.

Interpretation/Remarks:

a) This report can be obtained from the previous employer. In case of fresh graduates, the same could be obtained from the last institution attended.

b) In case of a doctor or a nurse, a "good standing certificate" may be obtained from the BMHC regulatory body.

Standard

HRM 14.2: The HCC has a documented procedure for recruiting staff and orienting them to the HCC's environment.

Objective Elements

14.2.1 There is a documented procedure for recruitment.

Interpretation/Remarks:

a) The recruitment process ensures an adequate number and skill mix of staff to provide the HCC's services. The procedure shall ensure that the staff have the necessary registration, qualifications, skills and experience to perform its work.

b) Recruitment is undertaken in accordance with legal requirements, where applicable.

14.2.2 Recruitment is based on pre-defined criteria.

Interpretation/Remarks:

a) The laid-down recruitment procedure shall be adhered to.

b) The entire process shall be documented.

c) It shall ensure that the recruitment is done in a transparent manner.

14.2.3 Every staff member entering the HCC is provided induction training.

Interpretation/Remarks:

a) The HCC shall conduct induction training within the 15 days of the date of joining the HCC.

b) However, it shall be within 15 days of the staff joining.

c) Similarly, all other requirements of this standard could be covered.

d) There can be separate induction training at the HCC level and for the respective departments.

14.2.4 The induction training includes orientation to the HCC's vision, mission and values.
Interpretation/ Remarks:

a) The HCC's staff including the outsourced staff should be aware of and should correctly interpret the vision, mission and values of the HCC.

14.2.5 The induction training includes awareness of employee rights and responsibilities.

14.2.6 The induction training includes awareness on patient's rights and responsibilities.
Interpretation/Remarks:

a) The employees should be able to identify and report the violation of patient rights as and when it occurs.

14.2.7 The induction training includes orientation to the service standards of the HCC.
Interpretation/ Remarks:

a) The employees should be trained to implement the service standards of the HCC.

14.2.8 Every staff member is made aware of HCC's wide policies and procedures as well as relevant department/unit/service/program's procedures.
Interpretation/Remarks:

a) The HCC's staff including the outsourced staff should be aware and should correctly interpret the policies and operating procedures of the HCC as well as that of the department/unit/service in which he is performing the requisite duties.
b) It also requires continuous on the job training to reinforce the correct interpretation of policies and procedures.

Standard

HRM 14.3: There is an ongoing program for professional training and development of the staff.

Objective Elements

14.3.1 A documented training and development policy exist for the staff.
Interpretation/Remarks:

a) A training manual incorporating the procedure for identification of training needs, the training methodology, documentation of training, training assessment, the impact of training and the training calendar should be prepared.
b) The training shall be for all categories of staff including doctors and outsourced staff (wherever applicable).

14.3.2 The HCC maintains the training record.

Interpretation/Remarks:

a) The HR department shall maintain a record of all training provided. At a minimum, it shall include the title of the training, the trainer(s), a list of trainees (with signatures) and the post-training feedback.

b) Where possible, the contents of the training may also be captured.

14.3.3 Training also occurs when job responsibilities are changed/new equipment is introduced.

Interpretation/Remarks:

a) The training should focus on the revised job responsibilities as well as on the newly introduced equipment and technology.

b) In case of new equipment, the operating staff should receive training on operational as well as daily-maintenance aspects.

14.3.4 Feedback mechanisms for assessment of training and development program exist and the feedback is used to improve the training program.

Interpretation/Remarks:

a) This shall include both internal and external training.

b) For external training, it could be done either by the HCC itself or by the external agency, which imparted the training. Impact of training at user level should also be documented.

Standard

HRM 14.4: Staffs are adequately trained on various safety-related aspects.

Objective Elements

14.4.1 Staff are trained on the risks within the HCC's environment.

Interpretation/Remarks:

a) The HCC shall define such risks that shall include patient, visitors and employee-related risks.

b) For example, fire and non-fire emergency, needle stick injury, etc.

14.4.2 Staff members can demonstrate and take actions to report, eliminate/minimize risks.

Interpretation/Remarks:

a) Staff should be able to practically demonstrate actions like taking care of blood pills, medication errors and other adverse event reporting systems.

14.4.3 Staff members are made aware of procedures to follow in the event of an incident.

Interpretation/Remarks:

a) The staff should be able to intimate the sequence of events that they will undertake in the eventuality of occurrence of any adverse event.

14.4.4 Staff are trained in occupational safety aspects.

Interpretation/Remarks:

a) This shall include making them aware of the possible risks involved and preventive actions to avoid risks.

b) Some examples are Needle Stick Injury and Blood/Body Fluid Exposure.

Standard

HRM 14.5: An appraisal system for evaluating the performance of an employee exists as an integral part of the human resource management process.

Objective Elements

14.5.1 A documented performance appraisal system exists in the HCC.

Interpretation/Remarks:

a) This shall be done for all categories of employees starting from the person heading the HCC and including doctors who are employees.

b) For a definition of "performance appraisal" refer to the glossary.

14.5.2 The employees are made aware of the system of appraisal at the time of induction.

Interpretation/Remarks:

a) This could be incorporated in the service booklet and included in the induction training.

14.5.3 Performance is evaluated based on the pre-determined criteria and is used as a tool for further development.

Interpretation/Remarks:

a) This can be done by identifying training requirements and accordingly providing for the same (wherever possible).

b) Key result areas are identified for each staff and training need assessment is also done.

14.5.4 The appraisal system is used as a tool for further development.

Interpretation/Remarks:

a) Self-explanatory.

b) This can be done by identifying training requirements and accordingly providing for the same (wherever possible).

c) Key result areas are identified for each staff and training need assessment is also done.

14.5.5 Performance appraisal is carried out at pre-defined intervals and is documented.

Interpretation/Remarks:

a) This shall be done at least once a year.

Standard

HRM 14.6: The HCC has documented disciplinary and grievance-handling policies and procedures.

Objective Elements

14.6.1 Documented procedures exist.

Interpretation/Remarks:

a) For a definition of “disciplinary procedure” and “grievance handling” refer to definitions

14.6.2 The procedures are known to all categories of staff of the HCC.

Interpretation/Remarks:

a) All the staff should be aware of the disciplinary procedure and the process to be followed in case they feel aggrieved.

14.6.3 The disciplinary policy and procedure is based on the principles of justice and is in consonance with the prevailing laws.

Interpretation/Remarks:

a) This implies that both parties (employee and employer) are given an opportunity to present their case and decision is taken accordingly.

14.6.4 There is a provision for appeals in all disciplinary cases.

Interpretation/Remarks:

a) The HCC shall designate an appellate authority to consider appeals in disciplinary cases.

14.6.5 The redress procedure addresses the grievance and actions are taken to redress the grievance.

Interpretation/Remarks:

a) This shall be documented and communicated to the aggrieved staff.

Standard

HRM 14.7: The HCC addresses the health needs of the employees.

Objective elements

14.7.1 A pre-employment medical examination is conducted on all the employees.

Interpretation/ Remarks:

a) This shall, however, be in consonance with the law of the land.

b) For example, performing pre-employment HIV testing without consent is illegal.

14.7.2 Health problems of the employees are taken care of in accordance with the HCC's policy.

Interpretation/Remarks:

a) This shall be in consonance with the law of the land and good clinical practices.

b) For example, employee health and safety policy.

14.7.3 Regular health checks of staff dealing with direct patient care are done at least once a year and the findings/results are documented.

Interpretation/Remarks:

a) The results should be documented in the personal file.

b) The HCC could define the parameters and it could be different for different categories of personnel. The HCC could also identify competent individuals to perform the same.

c) This staff member shall not be charged for this health check.

14.7.4 Occupational health hazards are adequately addressed.

Interpretation/ Remarks:

a) Appropriate personal protective equipment is provided to the staff concerned and they are educated on how to use them.

standard

HRM 14.8: There is documented personal information for each staff member.

Objective Elements

14.8.1. Personal files are maintained in respect of all staff.

14.8.2. The personal files contain personal information regarding the staff's qualification, disciplinary background and health status.

14.8.3. All records of in-service training and education are contained in the personal files.

Interpretation/ Remarks*:*

a) In case of internal training, the HCC could file a summary of all training attended by the employee on an annual basis.

b) Personal files contain results of all evaluations.

c) Evaluations would include performance appraisals, training assessment and outcome of health checks.

Standard

HRM 14.9: There is a process for credentialing and privileging of medical professionals, permitted to provide patient care without supervision.

Objective Elements

14.9.1 Medical professionals permitted by law, regulation and the HCC to provide patient care without supervision is identified.

Interpretation/Remarks:

a) The HCC identifies the individuals who have the required qualification(s), training and experience to provide patient care in consonance with the law.

14.9.2 The education, registration, training and experience of the identified medical professionals is documented and updated periodically (done by BMHC).

Interpretation/Remarks:

a) Updating is done after the acquisition of new skills and/or qualification.

14.9.3 All such information pertaining to the medical professionals is appropriately verified when possible.

Interpretation/Remarks:

a) The HCC shall do the same by verifying the credentials from the HCC which has awarded the qualification/training.

b) A good reference could be BMHC's website.

14.9.4 Medical professionals are granted privileges to admit and care for patients in consonance with their qualification, training, experience and regulations of the registration.

Interpretation/Remarks:

a) The HCC shall identify services which each medical professional is authorized to do.

b) This shall be done based on qualification, experience and any additional training received.

c) For example, radiotherapy can only be given by a radiation oncologist.

14.9.5 The requisite services to be provided by the medical professionals are known to them as well as the various departments/units of the HCC.

Interpretation/Remarks:

a) This could be done by internal communication.

14.9.6 Medical professionals admit and care for patients as per their privileging.

Interpretation/Remarks:

a) A standardized format can be used for each faculty and a norm for providing privilege should be practised uniformly. New faculty members can be user proctorship till independent privileges are provided.

b) The HCC could evolve a mechanism to ensure that medical professionals are providing only those services that they have been privileged to offer.

Standard

HRM 14.10: There is a process for credentialing and privileging of nursing professionals, permitted to provide patient care without supervision.

Objective Elements

14.10.1 Nursing staff permitted by law, regulation and the HCC to provide patient care without supervision are identified.

Interpretation/Remarks:

a) The HCC identifies the individual who has the required qualification(s), training and experience to provide patient care in consonance with the law.

b) Refer to BMHC Act and nursing administration manual.

14.10.2 The education, registration, training and experience of the nursing staff is documented and updated periodically.

Interpretations/Remarks:

a) Updating is done after the acquisition of new skills and/or qualification.

14.10.3 All such information pertaining to the nursing staff is appropriately verified when possible.

Interpretation/Remarks:

a) The HCC shall do the same by verifying the credentials from the HCC which has awarded the qualification/training.

14.10.4 Nursing staff are granted privileges in consonance with their qualification, training, experience and registration.

Interpretation/Remarks:

a) The HCC shall identify as to what each nurse is authorized to do.

b) For example, an Infection Control focal person should have and requisite in-house/external training and experience and the aptitude and knowledge to perform the tasks required of her.

14.10.5 The requisite services to be provided by the nursing staff are known to them as well as the various departments/units of the HCC.

Interpretation/Remarks:

a) This could be done by internal communication.

14.10.6 Nursing professionals care for patients as per their privileging.

Interpretation/Remarks:

a) New staff members can be under the proctorship till independent privilege is being provided for each staff.

b) The HCC could evolve a mechanism to ensure that nursing professionals are providing only those services that they have been privileged to offer.

15. Information Management System (IMS)

Preamble

Provision of health care and its continued improvement is dependent to a large extent on the information generated, stored and utilized appropriately by the HCCs. One of the major intent of this standard is to ensure data and information meet the HCC's needs and support the delivery of quality care and service. The goal of information management in the HCC is to ensure that the right information is made available to the right person. An effective Information management system is based on the information needs of the HCC. The system is able to capture, transmit, store, analyse, utilize and retrieve information as and when required for improving clinical outcomes as well as individual and overall HCC performance. Although a digital-based IMS improves efficiency, the basic principles of a good information management system apply equally to a manual/paper-based system. These standards are designed to be equally compatible with non-computerized systems and future technologies.

Summary of Standards

IMS 15.1	Documented policies and procedures exist to meet the information needs of the care providers, management of the HCC as well as other agencies that require data and information from the HCC.
IMS 15.2	The HCC has processes in place for the effective management of data.
IMS 15.3	The HCC has a complete and accurate medical record for every patient.
IMS 15.4	The medical record reflects the continuity of care.
IMS 15.5	Documented policies and procedures are in place for maintaining confidentiality, integrity and security of records, data and information.
IMS 15.6	Documented policies and procedures exist for a retention time of records, data and information.
IMS 15.7	The HCC regularly carries out a review of medical records.

Standards and Objective Elements

Standard

IMS 15.1: Documented policies and procedures exist to meet the information needs of the care providers, management of the HCC as well as other agencies that require data and information from the HCC

Objective Elements

15.1.1 The information needs of the HCC are identified and are appropriate to the scope of the services being provided by the organization.

Interpretation/Remarks:

a) The HCC has manual and/or electronic HCC information system and/or management information system which provide relevant information to all stakeholders concerned.

b) This shall include the information needs of care providers, management and external agencies/governmental bodies.

c) For example, daily census report, utilization rates, etc.

d) The identified information needs shall be documented.

15.1.2 Documented policies and procedures to meet the information needs exist.

Interpretation/Remarks:

a) A policy document is available where HIS/MIS is described.

b) This shall also specify the frequency of data collection and the person(s) responsible.

15.1.3 These policies and procedures are in compliance with the prevailing laws and regulations.

Interpretation/Remarks:

a) Some of these include: IT Act 2000 for computer-based records, Code of Medical Ethics, Bhutan information, communications and media Act.

15.1.4 All information management and technology acquisitions are in accordance with the documented policies and procedures.

Interpretation/Remarks:

a) The HCC shall define the needs for software and hardware solutions as per the information requirements and future necessities.

b) The HCC shall ensure that it has the necessary license for the software.

15.1.5 The HCC contributes to external databases in accordance with the law and regulations.

Interpretation/Remarks:

a) The HCC shall define the system of releasing the relevant information to the authority as per statutory norms.

b) For example, sending birth and death statistics, notifiable diseases (refer to glossary) and acute flaccid paralysis reporting.

Standard

IMS 15.2: The HCC has processes in place for the effective management of data.

Objective elements

15.2.1 Formats for data collection are standardized.

Interpretation/Remarks:

a) MIS/HIS data are collected in a standardized format (DHIS 2) from all areas/services in the HCC.

b) This is in the context of the frequency of capturing data, namely daily, weekly, monthly, quarterly, yearly etc. (Statistical bulletin).

15.2.2 Necessary resources are available for analysing data.

Interpretation/Remarks:

a) The HCC shall make available men, material, space and budget.

15.2.3 Documented procedures are laid down for timely and accurate dissemination of data.

Interpretation/Remarks:

a) Timely feedback is given to relevant stakeholders after data generation and analysis.

b) The HCC could decide on which data needs to be shared with whom and also the modalities (e.g. memos, circulars, etc.) for the dissemination of such data.

15.2.4 Documented procedures exist for storing and retrieving data.

Interpretation/Remarks:

a) The HCC shall define data management policy and ensure adequate safeguards for the protection of data, wherever physical or electronic data is stored.

b) Storage could be physical or electronic. Wherever electronic storage is done, the HCC shall ensure that there are adequate safeguards for the protection of data.

15.2.5 Appropriate clinical and managerial staff participates in selection, integrating and using data.

Interpretation/Remarks:

a) They are responsible for the appropriate selection of indicators, measurement of trends and initiating action, wherever required.

b) This could be done by a multi-disciplinary committee.

Standard

IMS 15.3: The HCC has a complete and accurate medical record for every patient.

Objective Elements

15.3.1 Every medical record has a unique identifier.

Interpretation/Remarks:

a) This shall also apply to records on digital media.

b) Every sheet in the medical record shall have this unique identifier. In case of electronic records, all entries for one unique identifier shall be available in one place.

c) For example, ID number, HCC number, etc.

15.3.2 HCC policy identifies those authorized to make entries in the medical record.

Interpretation/Remarks:

a) HCC shall have a written policy authorizing who can make entries and the content of entries.

b) This could be a different category of personnel for different entries, but it shall be uniform across the HCC, e.g. progress record by doctor and medication administration chart by a nurse.

15.3.3 Entry in the medical record is named, signed, dated and timed.

Interpretation/Remarks:

a) All entries should be documented immediately but not later than one hour of completion of the assessment/procedure.

b) For records on electronic media, it is preferable that the date and time are automatically generated by the system.

15.3.4 The author of the entry can be identified.

Interpretation/Remarks:

a) This could be by writing the full name or by mentioning the employee code number, with the help of stamp, etc. In case of electronic-based records, authorized e-signature provision as per statutory requirements must be kept.

15.3.5 The contents of the medical record are identified and documented.

Interpretation/ Remarks:

a) The HCC identifies which documents form part of the medical records, documents and implements the same.
b) For example, admission orders fact sheet, IP sheet, discharged summary, doctor's order sheet, TPR chart, consent form, etc.

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

Interpretation/Remarks:

a) Every medical record has all the identified sheets filed in the proper order.
b) The HCC shall decide the format for maintaining the continuity in the medical records.
c) It shall ensure that all medico-legal case records have the mandatory information.
d) In case a particular sheet is missing a not to that effect would be put in the medical record.

15.3.7 Provision is made for 24-hour availability of the patient's record to healthcare providers to ensure continuity of care.

Interpretation/Remarks:

a) In case of physical records when the MRD is not open, there should be a system in place by which authorized personnel can open the MRD and retrieve the record.
b) For all readmission patients coming to the emergency room, medical records shall be easily retrieved.

Standard

IMS 15.4: The medical record reflects the continuity of care.

Objective Elements

15.4.1 The medical record contains information regarding reasons for admission, diagnosis and plan of care.

Interpretation/Remarks:

a) The final diagnosis (IP) must be documented by the treating doctor in all records. This could preferably be as per ICD. However, in the medical records department, all such diagnoses shall be codified as per ICD (latest edition)

15.4.2 The medical record contains the results of tests carried out and the care provided.

Interpretation/Remarks:

a) It is preferable that the medical record also reflects any delay in tests and treatment planned or provided for the patient. This could be taken up for clinical audit.

15.4.3 Operative and other procedures performed are incorporated in the medical record.

Interpretation/Remarks:

a) Refer COP 7.14.6

15.4.4 When the patient is transferred to another HCC, the medical record contains the date of transfer, the reason for the transfer and the name of the receiving HCC.

Interpretation/Remarks:

a) It is mandatory to mention the clinical condition of the patient before transferring the patient to the next higher HCC.

b) If the patient has been transferred at his/her request, a note may be added to that effect. In such instances, the name of the receiving HCC could be the name of patient desires to go to. However, if the patient has been transferred by the HCC, it shall have an acknowledgement from the receiving HCC.

c) Any element of care carried out during the patient transfer is documented, where appropriate.

15.4.5 The medical record contains a copy of the discharge summary duly signed by appropriate and qualified personnel.

Interpretation/Remarks:

a) A copy of the discharge summary should be sent back to referring HCC for referral cases.
b) In case of ex-country referral, the HCC should ensure a copy of the discharge summary is collected from the Liaison Officer based in referral centres.

15.4.6 In case of death, the medical record contains a copy of the death certificate.

Interpretation/Remarks:

a) This shall mention the cause, date and time of death. The HCC provides the death certificate.
b) Cardiac and respiratory arrest is an event of death and not the cause of death.

15.4.7 Whenever a clinical autopsy is carried out, the medical record contains a copy of the report of the same.

15.4.8 Healthcare providers have access to current and past medical record.

Interpretation/Remarks:

a) Healthcare providers can access medical records after prior approval from HCC for e.g. research, case study.
b) For readmitted patient healthcare providers have access to current and past medical record.
c) For medico-legal cases only authorized personnel to have access to the past medical record.
d) For electronic medical record system, every facility shall have a user ID and a password.

Standard

IMS 15.5: Documented policies and procedures are in place for maintaining confidentiality, integrity and security of records, data and information

Objective Elements

15.5.1 Documented policies and procedures exist for maintaining confidentiality, security and integrity of records, data and information.

Interpretation/Remarks:

a) The HCC shall control the accessibility of the MRD and to its HCC Information System. For physical records, it shall ensure the usage of tracer cared for movement of the file in

and out of the MRD.

b) It shall have a system in place to ensure that only the relevant care providers have access to the patient's record. Similarly, for data and information, it shall ensure that records and data are not taken out from the areas where they are stored. In case of electronic systems, it shall ensure that these cannot be copied at all locations. The procedure shall also address how entries in the patient record are corrected or overwritten.

15.5.2 Documented policies and procedures are in consonance with the applicable laws.
Interpretation/Remarks:

a) This is in the context of the Penal Code and Code of Medical Ethics.
b) For example, privileged communication.

15.5.3 The policies and procedure(s) incorporate safeguarding of data/record against loss, destruction and tampering.
Interpretation/Remarks:

a) For physical, records the HCC shall ensure that there are adequate pest and rodent control measures. For electronic data, there should be a protection against virus and also a proper backup procedure.
b) To prevent tampering of physical records access shall be limited only to the healthcare provider concerned.
    i. The HCC should have a system to keep a track of changes made in the medical rerecord or data.
    ii. In case of physical records and data, there must be a provision to either store in fire safety cabinets or there must be adequate (and appropriate) fire-fighting equipment.
    iii. It is preferable that software, when used, shall be validated and duly authenticated.

15.5.4 The HCC has an effective process of monitoring compliance of the laid down policy and procedure.
Interpretation/Remarks:

a) The HCC carries out regular audits/rounds to check compliance with policies.

15.5.5 The HCC uses developments in appropriate technology for improving confidentiality, integrity and security.
Interpretation/Remarks:

a) The HCC shall review and update its technological features so as to improve confidentiality, integrity and security of information.
b) For example, moving from physical to electronic format, remote backup of data, etc.

15.5.6 Privileged health information is used for the purposes identified or as required by law and not disclosed without the patient's authorization.

Interpretation/Remarks:

a) The HCC shall define the procedure for privileged communication. The authorization from the patient shall be obtained in writing.
b) Special care should be taken in medico-legal cases and other special cases as identified by MoH, BMHC and the HCC.

15.5.7 A documented procedure exists on how to respond to patients/physicians and other public agencies requests for access to information in the medical record in accordance with the local and national law.

Interpretation/Remarks:

a) In this context, the release of information in accordance with the Code of Medical Ethics should be kept in mind.
b) Grievances with respect to RTI shall be addressed by government and other applicable bodies, as per the laid down policies.

Standard

IMS 15.6: Documented policies and procedures exist from retention time of records, data and information

Objective Elements

15.6.1 Documented policies and procedures are in place on retaining the patient's clinical records, data and information.

Interpretation/Remarks:

a) The HCC shall define the retention period for each category of medical records: Outpatient, in-patient and medico-legal cases and LAMA.
b) It shall also do the same for various data and the formats (e.g. registers and forms) that have been used for capturing this data.

15.6.2 The policies and procedures are in consonance with the local and national laws and regulations.

Interpretation/Remarks:

a) Some of the related laws in this context are Code of conduct and Ethics (BMHC) and relevant laws of the country if any.

15.6.3 The retention process provides expected confidentiality and security.

Interpretation/Remarks:

a) This is applicable to both manual and electronic system.

15.6.4 The destruction of medical records, data and information are in accordance with the laid-down policy.

Interpretation/Remarks:

a) Destruction can be done after the retention period is over and after taking approval of the competent authority.

Standard

IMS 15.7: The HCC regularly carries out the review of medical records.

Objective Elements

15.7.1 The medical records are reviewed periodically.

Interpretation/Remarks:

a) The HCC could define the periodicity.

b) A standardized checklist can be used for this purpose.

15.7.2 The review uses a representative sample based on statistical principles and is conducted by identified care providers.

Interpretation/Remarks:

a) The HCC shall define the principles on which sampling as based. For example, simple random, systemic random sampling, etc.

b) The review shall be based on total discharges including deaths, total indoor patients, etc.

c) The HCC shall identify and authorize such individuals.

15.7.3 The review is conducted by identified care providers.

Interpretation/Remarks:

a) The HCC shall identify and authorize such individuals.

15.7.4 The review focuses on the timeliness, legibility and completeness of the medical records.

15.7.5 The review process includes records of both active and discharged patients.

Interpretation/Remarks:

a) An adequate mix of both active and discharged patients should be used.

15.7.6 The review points out and documents any deficiencies in records.

Interpretation/Remarks:

a) For example, missing a final diagnosis, the absence of OT notes in an operated patient, etc.

15.7.7 Appropriate corrective and preventive measures are undertaken within a defined period of time and are documented.

Reference

1. National Accreditation Board for HCC (NABH) India, Malaysian Society for Quality in Health (MSQH) Malaysia, Taiwan Society for Accreditation and International Society for Quality in Healthcare (ISQua) document on 'Standards for HCC's is used as base documents.

2. Ministry of Health in Bhutan. *Annual health bulletin 2008: Century of progress in health.* [Online]. 2008[cited 2009 May 20]; Available from:URL:http://www.health.gov.bt/statistics/bulletins/ahb2008/healthFacilities.pdf

3. Ministry of Health in Bhutan. Report on the national health survey in Bhutan. [Online].2000 [cited 2010 Oct 25]. Available from: URL:http://www.health.gov.bt/healthsurvey2000.pdf.

4. Quality Assurance Standardization Division. Clinical Laboratory standards in Bhutan. 1st ed. Thimphu; 2008.

5. ISO 9001:2015 Quality management systems -Requirements

ANNEX 01

Guidelines for Key Performance indicators to measure the quality and process improvement and monitoring clinical services

Key Performance Indicators (KPIs) are used to measure the function and progress of different levels of healthcare centres. The KPIs are broken down and set as targets for achievement by department and sections. The achievement of these targets is reviewed at regular intervals. KPIs assist the healthcare centres to define and measure progress towards achieving goals and objectives. Therefore, the KPIs provide a measurement tool in the organization.

KPI-1: Time for initial assessment of emergency /indoor patient	
Definition	The time shall begin from the time that the patient reaches the emergency until the time that the initial assessment has been completed by a doctor
Formula	$\frac{Sum\ of\ time\ taken}{Total\ number\ of\ patients}$
Purpose	• To monitor the time taken for an initial assessment to ensure timely assessment of emergency patients. • To ensure that patients receive appropriate medical care depending on their triage level.
Sample Size	For HCCs with < 20 patients/day:100% For HCCs with 20-50 patients/day: 50% For HCCs with>50 patients/day: 20% (Selection of patients will be stratified, to enable comprehensive overview)
Sample size JDWNRH 17-18	Total patient seen in ER 28,225 (Annual report 2016) Total sample = 2823 (10% of total)
Area of data collection	Emergency Department
Data source	This indicator will be capture during clinical auditing.
The frequency of data collection	Half -yearly

Forms if any	Survey form
Note	The average time should be reviewed by the HCC, to see if this has impacted on clinical care, outcome. The outlier: those taking more than 20% of the average time shall be audited. The HCC will make effort to keep this measure at low levels, and track trend in times of increased patients" flows.

KPI-2: Percentage of cases (in-patient) wherein care plan with the desired outcome is documented by clinicians	
Definition	The main focus of a care plan is to facilitate standardized, evidence-based and holistic care. It includes the following components: assessment, diagnosis, expected outcomes, interventions, rationale and evaluation. The desired outcome includes curative, preventive, and rehabilitative.
Formula	$\frac{\text{Number of inpatient case records wherein the care plan with desired outcomes has been documented}}{\text{Total Number of patients}} X100$
Purpose	To facilitate standardized, evidence-based and holistic patient care by the clinicians after admission.
Sample Size	For HCCs with < 20 admission/day: 100% For HCCs with 20-50 admissions/day: 50% For HCCs with >50% admission/day: 20%
The sample size for JDWNRH 2017-18	Total admission was 17,523 (Annual report, 2016) Total sample = 1752 (10% of total) Patient complete 24 hours patient stay
Data collection Area	All Inpatient departments
Data Source	This indicator will be captured monthly for the above sample or half-yearly during the clinical audit
The frequency of Data collection	Monthly or half yearly
Forms if any	Clinical pathway form

Note	The indicator shall be captured during the stay of the patient and not from the medical record department. It shall be collated on a monthly basis. The sampling base shall be patients who have completed 24 hours of stay in the hospital. However, immediate correction is to be initiated, when gaps are seen on a real-time basis.

KPI-3: Percentage of cases (in-patient) wherein screening for nutritional needs has been done.	
Definition	Nutritional screening is a quick, simple procedure that should be undertaken during the first meeting with the patient. Best practice is to undertake this screening as a part of the admission or initial assessment of a person and that it is completed within the first 24 hours of arriving in a care setting.
Formula	$\frac{\text{Number of admitted patients screened for nutrition}}{\text{Total Number of patients}} X100$
Purpose	To monitor the nutritional needs of the patient and to make sure that the patients who are nutritionally affected are taken care in the ward.
Sample Size	For HCCs with < 20 admission/day: 100% For HCCs with 20-50 admissions/day: 50% For HCCs with >50% admission/day: 20%
The sample size for 2017	Total admission was 17,523 (Annual report, 2016) Total sample: 1752 (10% of the total) Patient completed 24 hours patient stay
Data collection area	All IPDs
Data source	This indicator will be captured monthly for the above sample or half -yearly during the clinical audit.
The frequency of data collection	Half-yearly
Forms if any	Nutritional assessment form in Nursing assessment form

Note	The indicator shall be captured during the stay of the patient and not from the medical record department. It shall be collated on a monthly basis. The sampling base shall be patients who have completed 24 hours of stay in the hospital. However, immediate correction is to be initiated, when gaps are seen on a real-time basis.

KPI-4: Percentage of cases wherein nursing care plan is documented	
Definition	Nursing care plan shall be the outcome of the nursing assessment done at the time of the admission
Formula	$\frac{\text{Number of cases wherein nursing care plan documented}}{\text{Total Number of patients}} X100$
Purpose	To monitor the patient care process during a hospital stay
Sample Size	For HCCs with < 20 admission/day: 100% For HCCs with 21-50 admission/day: 50% For HCCs with >50 admission /day: 20%
The sample size for 2017-18	Total admission was 17,523 (Annual report, 2016) Total Sample: 1752 (10% of total) Patient completed 24 hours patient stay
Area of data collection	All IPDs Exclude: Emergency department & Haemodialysis Unit
Data source	This indicator will be captured either monthly for above sample or during the half-yearly clinical audit
The frequency of data collection	Monthly basis / half-yearly
Forms if any	Nursing care plan
Note	The indicator shall be captured during the stay of the patients and not from the medical record department. The sample shall be patients who have completed 24 hours.

KPI-5: Number of errors reported in diagnostic services	
Definition	Errors in diagnostic services are pre-examination, examination and post-examination errors in clinical laboratory and radiology departments. Pre-examination errors include errors such as the patient not meeting pre-examination requirements, wrong identification of patient and specimen, specimen collected in wrong containers, delay in specimen transportation, etc. Examination errors include errors such as wrong test, wrong position/site, wrong specimen, wrong results, etc. Post-examination errors include errors such as misinterpretation, wrong reports, transcription errors, etc.
Formula	$\frac{\text{Number of errors}}{\text{Number of test performed}} X100$
Purpose	To provide accurate and precise reports for diagnosis and management of patients.
Sample Size	Not Applicable
Area for the collection of	Department of Pathology and Laboratory Medicine & Department of Radiology and Imaging; and all relevant clinical departments.
Data source	Incident registry for reporting errors in laboratories (Biochemistry, Blood bank, Histopathology, Cytology, Microbiology, Haematology). Register for reporting errors in Radiology (ultrasound, x-ray, CT, MRI, Mammography, diagnostic intervention).Register for reporting errors in clinical departments. These departments will have to be instructed to record reporting errors. Any errors must be recorded in the respective clinical departments and the same must be communicated to the clinical laboratory and radiology for prompt rectification.
The frequency of	Monthly. QM Focal person will maintain a daily record and report monthly
Forms if any	Incident register maintained in the units
Note	This shall be captured in the clinical laboratory and radiology. Although the indicator is captured on monthly basis, immediate corrections are to be initiated when such instances happen

KPI-6: Percentage of reports correlating with the clinical diagnosis	
Definition	Co-relation means that the test results should match with the diagnosis or differential diagnosis written in the requisition form
Formula	$\frac{\text{Number of report co} - \text{relating with clinical diagnosis}}{\text{Number of tests}} X100$
Purpose	To minimize irrational testing
Sample Size	For HCCs with < 100 tests/month: 100% For HCCs with 100-200 tests/month: 50% For HCCs with 201-300 tests/month: 25% For HCCs with 301-500 tests/month: 25% For HCCs with >500 tests/month: 15%
Sample size JDWNRH 2017-18	As per 2016 annual report : CT recorded 5500 cases (458/month); Total sample for CT : 550 (10% of total) MRI recorded 5804 cases (483/month); Total sample for MRI: 580 (10% of total) Histopathology recorded 73,350 tests (6112/month) ; Total sample for Histopathology: 7335 (10% of total)
Area of data collection	Histopathology in Department of Pathology and Laboratory Medicine; and CT and MRI in Department of Radiology and imaging
Data source	This indicator will be captured from register maintained at the units. Each unit will maintain a daily record of correlation and report monthly to the office of Quality Management Services.
The frequency of data collection	Monthly
Forms if any	Register
Note	This shall be captured in the clinical laboratory (Histopathology) and radiology (at least CT and MRI)

KPI-7: Incidence of medication errors	
Definition	A medication error is any preventable event that may cause or lead to inappropriate medication use or harm to a patient (US-FDA). Examples include, but are not limited to: • Errors in the prescribing, transcribing, dispensing, administering, and monitoring of medications; • Wrong drug, wrong strength, or wrong dose errors; • Wrong patient errors; • Wrong route of administration errors; and • Calculation or preparation errors.
Formula	$\frac{\text{Total number of medication errors}}{\text{Number of patient days}} X\ 100$
Purpose	To monitor and minimize the incidence of medication errors through corrective and preventive action.
Sample Size	For HCCs with average occupancy <50 patients/day: 10% of patients/day For HCCs with average occupancy 51-100 patients/day:5% of patients/day For HCCs with average occupancy 101-300 patients/day: 3%pf patients/day For HCC with average occupancy 501-1000 patients/day:1% of patients/day For HCCs with average occupancy> 1000 patients/day: 0.5% of patients/day
Sample Size for JDWNRH 17-18	Refer sample size range for clinical audit purpose.
Area of data collection	Ward, ICU, Emergency, Injection Room
Data source	Record of incidences of medication error Record of total patient days Drug chart, QM Focal person will maintain record daily and report monthly
The frequency of data collection	Monthly
Forms if any	Incident register/ incident form

KPI-8: Percentage of the patient who develops adverse drug reaction(s)	
Definition	A response to a drug which is noxious and unintended and which occurs at doses normally used in IPD patients for prophylaxis, diagnosis, or therapy or disease or for the modification of physiologic function, It includes harm from overdose and under-dose usually related to medication errors.
Purpose	To monitor and minimize the incidence of adverse drug reaction through corrective and preventive action.
Formula	$\frac{\text{Number of adverse drug reaction}}{\text{Number of discharges and death}} X\ 100$
Sample Size	Not applicable
Area of data collection	Ward
Data source	Record of incidences of adverse drug reaction Record of total discharges and deaths Incident forms, QM Focal person will maintain record daily and report monthly.
The frequency of data collection	Monthly
Form if any	Incident reporting form / Incident register
Note	Incidences of ADR can be captured from adverse event reporting systems.

KPI-9: Percentage of modification of anaesthesia plan	
Definition	The anaesthesia plan is the outcome of the pre-anaesthesia assessment. Any changes done after this shall be considered as a modification of anaesthesia plan
Purpose	• To ensure appropriate anaesthesia was given for specific surgery as planned in the pre-anaesthesia-check up • To monitor the anaesthesia plan to ensure the safety of the patients by ensuring the correct dosage, correct site of administration and following a correct procedure.
Formula	$\frac{\text{Number of the patient in whom the anaesthesia plan was modified}}{\text{Number of patients who underwent anaesthesia}} X\ 100$
Sample Size	Not applicable
Area of data collection	Recovery room
Data source	Register/system maintained at OT
The frequency of data collection	Monthly, QM focal person will maintain a daily record and report monthly
Forms if any	Register/ Registry
Note	The modification in the anaesthesia plan could be captured in a register/system in a recovery room before the patient is shifted out of the OT

KPI-10: Percentage of unplanned ventilation following anaesthesia in operation theatre	
Definition	Patients who were put on ventilator support postoperatively without a prior plan.
Purpose	To ensure risk stratification of patients during perioperative period
Formula	$\frac{\text{Number of a patient requiring unplanned ventilation following anaesthesia}}{\text{Number of patients who underwent anaesthesia}} X\ 100$
Sample Size	Not applicable
Area of data	Recovery room (OT)

collection	
Data source	Record of a patient requiring unplanned ventilation following anaesthesia. Record of a total patient who underwent anaesthesia
The frequency of data collection	Monthly, QM focal person will record the incidences and report monthly
Forms if any	Register/Registry
Note	Every anaesthesia plan shall invariably mention if there is a possibility of the patient requiring ventilation following anaesthesia. Every case wherein a patient required ventilation but this was not captured in the anaesthesia plan shall be a part of the numerator.

KPI-11: Percentage of adverse anaesthesia events	
Definition	Adverse anaesthesia* event is any untoward medical occurrence that may present during treatment with an anaesthetic product but which does not necessarily have a causal relationship with this treatment.
Purpose	To monitor and minimize the incidence of adverse anaesthesia events through corrective and preventive action.
Formula	$\frac{\text{Number of patients who developed adverse anaesthesia event}}{\text{Number of a patient who underwent anaesthesia}} X\ 100$
Sample Size	Not applicable
Area of data collection	OT, ICU, Birthing,
Data source	Record of incidences of adverse anaesthesia event Record of total number of patients who underwent anaesthesia Incident form /Adverse event form
The frequency of data collection	Monthly, QM Focal person will maintain a daily record and submit monthly
Forms if any	Adverse anaesthesia event form
Note	Incidences of ADR can be captured from adverse event reporting systems. Anaesthesia consists of general anaesthesia and spinal or major regional anaesthesia and does not include local anaesthesia.

KPI-12: Anaesthesia-related mortality rate	
Definition	Any death where the cause is possible, probable (likely) or certain to be due to anaesthesia shall be included.
Purpose	To monitor and minimize the anaesthesia related death.
Formula	$\frac{\text{Number of patients who died due to anaesthesia}}{\text{Number of a patient who underwent anaesthesia}} X\ 100$
Sample Size	Not applicable
Area of data collection	OT, ICU, Birthing
Data source	Record of death related to anaesthesia Record of total number of patients who underwent anaesthesia
The frequency of data collection	Monthly, QM focal person will maintain the record and report monthly
Forms if any	Register, adverse event form
Note	Anaesthesia consists of general anaesthesia and spinal or major regional anaesthesia and does not include local anaesthesia

KPI-13: Percentage of re-scheduling of surgeries	
Definition	Re-scheduling of patients includes cancellation and postponement (beyond 4 hours) of the surgery
Purpose	• To ensure closest estimate number of cases to be posted for the day's surgery to avoid unnecessary cancellation and postponement. • To analyse the cause and effect of rescheduling of surgeries to ensure timely surgical intervention.
Formula	$\frac{\text{Number of cases cancelled or postponed beyond 4 hours}}{\text{Number of patients scheduled for that day}} X\ 100$
Sample Size	Not applicable
Area of data collection	OT
Data source	Record of cases that got operation cancelled/postponed beyond 4 hours. Record of number of patients scheduled
The frequency of data collection	Monthly. QM Focal person will maintain the record daily and report monthly
Forms if any	Register / registry

Note	Surgeons will have to give an approximate time of operation and delay beyond 4 hours of the given time will be captured as a numerator.

KPI-14: Percentage of cases where the HCC's procedure to prevent adverse events like the wrong site, wrong patient and wrong surgery have adhered	
Definition	The adverse event is an unintended incident in care with reference to surgery here that may result in adverse outcomes like the wrong site, wrong patient and wrong surgery and may require additional care and effort due to non-adherence to safety procedures of HCC. These should be "never event" as occurrences of any such event would indicate serious safety problems.
Purpose	• To monitor the compliance with standard procedures for surgery to ensure the safety of the patients during care. • To ensure patient safety by strictly following checklists.
Formula	$\frac{\text{Number of cases where the procedure was followed}}{\text{Number of surgeries performed}} X\ 100$
Sample Size	Not applicable
Area of data collection	OT
Data source	Record of cases where the procedure was followed Record of surgeries performed
The frequency of data collection	Monthly, QM focal person will compile a surgical checklist and report monthly
Forms if any	Surgical checklist
Note	This could be checked in the post-op/recovery room and documented in a register/system

KPI-15: Percentage of cases who received appropriate prophylactic antibiotics within the specified time frame	
Definition	Patients who received appropriate prophylactic antibiotics within 2 hours prior to the incision.
Purpose	Ensure that those patients who require prophylactic antibiotics for surgery are provided with an appropriate and within the specified time frame.
Formula	$\frac{\text{Number of patients who received appropriate prophylactic antibiotics}}{\text{Total number of surgeries requiring prophylaxis}} X\ 100$
Sample Size	Not applicable
Area of data collection	OT
Data source	Record of a patient who did and did not receive appropriate antibiotics Record of total number of surgeries requiring prophylaxis
The frequency of data collection	Monthly, QM Focal person will have to maintain a daily record and submit monthly
Form if any	Register that will record the administration of prophylactic antibiotics before the patient enters OT
Note	It is equally important that the antibiotics should have been given not more than two hours prior to the incision. This indicator could be captured in a register/system before the patient enters the OT. Appropriate prophylactic antibiotics should be according to HCC policy.

KPI-16: Percentage of Transfusion reactions	
Definition	An adverse reaction is a suspected or proven unexpected and undesirable response or effect in the patient associated with the administration of blood or blood products. It is manifested by signs and /or symptoms in reference to transfusion
Purpose	All transfusion reactions are to be reported as a part of the Hemovigilance program of Bhutan. The Purpose is to: 1. Monitor the reactions 2. Increase awareness of transfusion and its complications among hospital clinical and clinical laboratory staff. 3. Improve processes and procedures involved in handling and administration of blood and its components to identify potential hazards which may be

	present but unrecognized
Formula	$\frac{\text{Number of transfusion reactions}}{\text{Total number of issues made from the Blood Bank}} X\ 100$
Sample Size	Not Applicable
Area for the collection of data	Blood bank
Data source	Record of blood and its components issued/transfused Record of transfusion reactions Adverse drug event form
Data collection	Blood bank Quality Representative will maintain a record in a standard format and report to QM unit focal person
The frequency of data collection	Monthly, QM focal person will maintain a record and report monthly
Note	Any adverse reaction to the transfusion of blood or blood components shall be considered as transfusion reaction. It may range from all allergic reaction to a life-threatening complication.

KPI-17: Percentage of a waste of blood and blood products wasted	
Definition	The proportion of the discarded blood and its components because of an inappropriate blood bank or clinical transfusion practices or adverse events. A. Criteria for discard due to clinical transfusion practices or adverse events: 1. Unit of blood or blood product transfused to the wrong patient by a staff nurse and then returned to the blood bank 2. Unit of unused blood or product returned to the blood bank after 30 minutes or more from its issued time(reason could be patient „s vein inaccessible, unstable vitals, refusal to transfuse, busy staff) 3. Unit of an unused unit but with bag's sterility broken (blood bag port spiked) returned to the blood bank (patient „s vein inaccessible, unstable vitals, patient's refusal to transfuse, busy staff) B. Criteria for discards of units of whole blood or blood products due to inappropriate Blood bank procedures or unacceptable quality/safety. 1. Incomplete blood donation(very low or high volume collected) 2. Reactive for TTIs 3. Passed the expiry date 4. Storage problems 5. Transportation problems 6. Processing problems 7. Wrong blood or blood products issued by blood bank staff and then returned by the staff nurse
Purpose	To monitor the errors and incorrect practices occurring in the blood bank and clinical areas due to deviation from SOPs
Formula	$\frac{\text{Number of blood and blood products wasted}}{\text{Total number of blood and blood products issued from the blood bank}} X\ 100$
Sample Size	Not Applicable
Area for the collection	Blood Bank and clinical areas (keep a record of discarded blood only to avoid double reporting)
Data source	Record of blood &blood products issued Record of blood and its products returned (used/unused) Record of blood discarded

The frequency of data	Monthly, Blood bank Quality Representative will maintain a record in a standard format and report to QM
Note	This also includes blood products found unfit for use. It is important that HCC capture the number of blood and blood products used and not just the number of transfusion carried out. At times more than one blood bag or components may have been given in a single transfusion or issued and not just the number of transfusion carried out. At times a blood/blood product unit may be re-issued to same or a different patient after being returned to the blood bank and found suitable for transfusion.

KPI-18: Percentage of blood products used	
Definition	The proportion of each blood products utilized or transfused: Platelets, PRC, Fresh Frozen plasma& whole blood
Purpose	For estimating blood and blood product requirements to meet the clinical demands.
Formula	$\frac{\text{Number of each product used/transfused}}{\text{Number of blood and blood products issued/transfused}} X\ 100$
Sample Size	Not Applicable
Area for the collection of data	Blood Bank
Data source	Record of different types of product used/transfused Record of total number of products used/transfused
The frequency of data collection	Quarterly, Blood bank Quality Representative will maintain a record in a standard format and report to QMS
Forms if any	Register
Note	None

<table>
<tr><th colspan="2">KPI-19: Turnaround time (TAT) for STAT blood orders</th></tr>
<tr><td>Definition</td><td>The sum of the time taken from the time that the order is raised to the blood bank for whole blood/PRC either by sending requisition form or by calling, till the time blood reaches the clinical unit for all STAT orders</td></tr>
<tr><td>Definition of STAT order</td><td>Whole Blood or PRC is required or potentially required within one hour. The type of request will depend on the patient’s condition.
<table>
<tr><th>Degree of urgency</th><th>TAT</th></tr>
<tr><td>Cross-matched but “urgent request”</td><td>30min</td></tr>
<tr><td>“Abbreviated cross match blood request</td><td>15min</td></tr>
<tr><td>Uncross matched -Group specific blood request</td><td>10min</td></tr>
<tr><td>Uncross matched- Group „O“ PRC request</td><td>5min</td></tr>
</table></td></tr>
<tr><td>Purpose</td><td>To monitor that the blood /PRC is made available to clinical units within the defined time period for all urgent transfusions</td></tr>
<tr><td>Formula</td><td>Sum of total time taken in minutes</td></tr>
<tr><td>Sample Size</td><td>Not Applicable</td></tr>
<tr><td>Area for the collection of data</td><td>wards</td></tr>
<tr><td>Data source</td><td>• Record of the blood request form
• Record of the worksheet of cross-matching tests. Crossmatched
• Register</td></tr>
<tr><td>The frequency of data collection</td><td>Quarterly</td></tr>
<tr><td>Note</td><td>None</td></tr>
</table>

KPI-20: Catheter-Associated Urinary Tract Infection (CAUTI)	
Definition	As per CDC/NHSN Patient must meet 1, 2, and 3 below: 1. The patient had an indwelling urinary catheter that had been in place for > 2 days on the date of the event (day of device placement = Day 1) AND was either: □Present for any portion of the calendar day on the date of the event, OR □Removed the day before the date of the event 2.Patient has at least one of the following signs or symptoms: • fever (>38.0°C) • suprapubic tenderness* • costovertebral angle pain or tenderness* • urinary urgency ^ • urinary frequency ^ • dysuria ^ *With no other recognized cause ^ These symptoms cannot be used when the catheter is in place. An indwelling urinary catheter in place could cause patient complaints of "frequency" "urgency" or "dysuria". Note: Fever is a non-specific symptom of infection and cannot be excluded from UTI determination because it is clinically deemed due to another recognized cause. 3. Patient has a urine culture with no more than two species of organisms identified, at least one of which is a bacterium of ≥10^5 CFU/ml. All elements of the UTI criterion must occur during the Infection Window Period
Purpose	To monitor and minimize the incidence of catheter-associated urinary tract infection through timely intervention and preventive action.
Formula	$\frac{\text{Number of urinary catheters associated UTIs in a month}}{\text{Number of urinary catheter days in that month}} X\ 100$
Sample Size	Not applicable
Area of data collection	• Inpatient department • Microbiology Laboratory

Data source	Patient case sheet & denominator data (catheter-days) clinical laboratory report (Microbiology) Record of patient catheter day and incidences of CAUTI Record of urine culture test positive for a bacterium of ≥10^5 CFU/ml
Frequency of data	Monthly

Reference

1. Ref: CDC Pneumonia (Ventilator-associated [VAP] and non-ventilator-associated Pneumonia [PNEU]) Event access from :https://www.cdc.gov/nhsn/PDFs/pscManual/6pscVAPcurrent.pdf
2. CDC Ventilator-Associated Event (VAE):https://www.cdc.gov/nhsn/PDFs/pscManual/10-VAE_FINAL.pdf

KPI-21: Central line-associated bloodstream infection (CLABSI)		
Definition	As per CDC/NHSN Date of the event for infection occurs within 30 days after any operative procedure (where day 1 = the procedure date) and the patient has at least one of the following: purulent drainage Organisms identified from an aseptically obtained specimen from the superficial incision or subcutaneous tissue by a culture or non- culture based microbiologic testing method which is performed for purposes of clinical diagnosis or treatment (e.g., not Active Surveillance Culture/Testing (ASC/AST). The incision that is deliberately opened by a surgeon, attending physician** or other designee and culture or non-culture based testing is not performed. a deep incision that spontaneously dehisces An abscess or other evidence of infection involving the organ/space that is detected on the gross anatomical or histopathologic exam, or imaging test evidence suggestive of infection. Diagnosis of an SSI by the surgeon or attending	As per CDC/NHSN Central line-associated BSI (CLABSI): A laboratory-confirmed bloodstream infection (LCBI) where the central line (CL) or umbilical catheter (UC) was in place for >2 calendar days on the date of the event, with a day of device placement being Day 1, and the line was also in place on the date of the event or the day before. If a CL or UC was in place for >2 calendar days and then removed, the date of the event of the LCBI

	physician** or other designees. Patient has at least one of the following signs or symptoms: pain or tenderness; localized swelling; erythema; or heat.	must be the day of discontinuation or the next day to be a CLABSI (clarification) Definition: relook
Purpose	To monitor and minimize the incidence of surgical site infection through timely intervention and preventive action.	
Formula	$\frac{\text{Number of surgical site infections in a given month}}{\text{Number of surgeries performed in that month}} X\ 100$	
Sample Size	Not applicable	
Purpose		To monitor and minimize the incidence of Central line-associated bloodstream infection through timely intervention and preventive action.
Formula		Number of central line-associated bloodstream infections in a month x 1000 Number of central line days in that month
Sample Size		Not applicable
Area of data collection		ICU (PICU, NICU, AICU) Haemo Dialysis Unit, General Wards and

	Units
Data source	Case sheet
The frequency of data collection	Monthly, QM Focal person will maintain a record and report monthly
Forms if any	HAI Form
Note	None

Reference: www.cdc.gov/nhsn/xls/icd10-pcs-pcm-nhsn-opc.xl

KPI-22: Return to ICU within 48 hours	
Definition	Patients previously discharged to a non-ICU inpatient location (Emergency, Unit/Ward) and readmitted to the intensive care unit within 48 hours.
Purpose	To study the cause of relapse of diseases and to ensure timely intervention for the patients returning to ICU within 48 hours after discharge.
Formula	$\frac{\text{Number of returns to ICU within 48 hours}}{\text{Total number of (discharges + transfers or referral) in ICU}} X\ 100$
Sample Size	Not applicable
Area of data collection	ICU (PICU, NICU & AICU)
Data source	Record of number of return to ICU within 48 hours Record of total number of discharge, transfer and referral in particular month
The frequency of data collection	Monthly
Forms if any	Register to maintain at ward

KPI-23: Return to the emergency within 72 hours with similar presenting complaints	
Definition	Number of returns to the emergency department within 72 hours with similar presenting complaints
Purpose	To study the cause of relapse of diseases and to ensure timely intervention for the patients returning to the emergency within 72 hours after discharge.
Formula	Number of returns to the emergency within 72 hrs with similar presenting complaints x 100 Number of patients who have come to the emergency
Sample Size	Not applicable
Area of data collection	Emergency Department
Data source	Record of the number of return patient maintained by each shift nurse at Triage. Record of a total number of patients who have come during a particular shift. The indicator to be captured at the triage.
The frequency of data collection	Monthly
Forms if any	An additional column in the triage record form
Note	To capture this indicator it may be a good practice to capture during initial assessment itself if the patient had come within 72 hours for similar complaints.

Reference:

1. Tracy R. McMillan, MD; Robert C. Hyzy, Bringing quality improvement into the intensive care unit Crit Care Med 2007; 35[Suppl.]: S59–S65).
2. Maria Cruz Martin Delgado, LluisCabrePericas, Javier Ruiz Moreno et al. Quality indicators in critically ill patients. SEMICYUC workgroups. First edition May 2005. ISBN 609- 5974.

KPI-24: Incidence of fall in IPD	
Definition	Loss of upright position that results in landing on the floor, ground or an object or furniture or a sudden uncontrolled, unintentional, non-purposeful, downward displacement of the body to the floor/ground or hitting another object like a chair or stairs". It is an event that results in a person coming to rest inadvertently on the ground or floor or other lower level
Purpose	To monitor and prevent the incidence of injuries to the patients caused by falls.
Formula	$\frac{\text{Number of falls}}{\text{Number of patients days}} X\ 100$
Sample Size	Not applicable
Area of data collection	IPD
Data source	Incident register maintained at respective units
The frequency of data collection	Monthly
Forms if any	Incident register
Note	Falls may be: -at different levels – i.e. from one level e.g. from beds, wheelchairs or downstairs -on the same level as a result of slipping, tripping, or stumbling, or from a collision, pushing, or shoving, by or with another person. -below ground level, i.e. into a hole or other opening in the surface. All type of falls is to be included whether they result from physiology reasons (fainting) or environmental reasons. Assisted falls (when another person attempts to minimize the impact of the fall by assisting the patient's descent to the floor) should be included. (NDNQI, 2005)

KPI-25: Incidence of bed sores after admission	
Definition	A pressure ulcer is a localized injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with shear and/or friction.
Purpose	To monitor and minimize the incidence of bed sores through timely intervention and preventive action.
Formula	$\frac{\text{Number of patients who develop new or worsening of pressure ulcer}}{\text{Number of discharges and deaths}} X\ 100$
Sample Size	Not applicable
Area of data collection	IPD
Data source	Incident register maintained at respective units Office of Nursing and administration
The frequency of data collection	Monthly
Annexure	Incident register
Note	HCC shall use the particular Grading system. This will help in capturing worsening ulcer which is included in the numerator.

KPI-26: Critical equipment downtime	
Definition	The period when a system is unavailable. Downtime or outage duration refers to a period of time that a system fails to provide or perform its primary function either due to the operator or spare parts. Critical equipment is that equipment essential for patient care under normal operating conditions and whose failure could cause imminent serious injury or death to patients or users. It includes diagnostic equipment such as CT scanner and clinical laboratory equipment (e.g. biochemistry analysers, CBC analysers, blood culture system) whose unavailability can delay Physicians" decision and interventions to the point of harming not just one but several patients.
Purpose	To monitor the frequency of breakdown of critical equipment in respective wards and units To monitor the types of equipment that requires frequent maintenances To ensure uninterrupted functionality of all the critical equipment.

Formula	Sum of downtime for all critical equipment in hours (absolute)
Sample Size	Not applicable
Area of data collection	All 20 Departments, both OPD and IPD.
Data source	Record of the register maintaining the details of utilization, breakdown time, and maintenance attempt signed by service engineer and In charge.
The frequency of data collection	Monthly basis.
Forms if any	Record register
Note	Checklist of all equipment should be updated in the unit on daily basis to monitor equipment utilization and downtime. The In-charge will submit the report to the Nursing Administration and Management office for further action. Rationale: The nursing service office will coordinate with Biomedical Engineering Services (BMS), Hospital Administration and Quality Management Services (QMS) for Medical Equipment Maintenance quality improvement initiatives

KPI-27: Nurse-Patient ratio for ICUs and ward	
Definition	The ratio of nurses on a particular ward or unit to the number of patients.
Purpose	• To monitor the nursing staffing patterns in the in-patient department • To recommend the Human Resource Division on standard Nurses-Patient ratio to ensure efficient and timely care of the patients in ICUs and wards
Formula	$\frac{\text{Number of staff/shifts}}{\text{Number of bed}} X\ 100$
Sample Size	Not applicable
Area of data	Nursing administration and management office.
Data source	Department of nursing administration and management
Frequency of data collection	Quarterly. Spot survey half yearly

Note	The staffing patterns should be calculated separately for ICUs and for the wards. Standard requirement as per RCSC for general ward and unit = 1: 6 (Nurse: Patient) and for critical care unit = 1: 1 The In-charge /supervisor of the area shall not be included for calculating the number of staff. It is preferred that in case of ICU, the HCC capture the ratio for ventilated and non-ventilated patients separately. Calculation method: for example if in the ICU there are a total of 15 nurses who work in 3 shifts, the numerator will be 5 (15/3) and if there are 5 beds, the ratio is 1:1. Similarly for the wards.

KPI-28: Outpatient satisfaction Index	
Definition	Patient Satisfaction is defined in terms of the degree to which the patient's expectations are fulfilled. It is an expression of the gap between the expected and perceived characteristics of a service (Lochoro, 2004)
Purpose	To study patients expectation from healthcare centres and to draw an action plan for continuous quality improvement through patients" feedback at the OPD.
Formula	$\frac{\text{Score achieved}}{\text{Maximum possible score}} X\ 100$
Sample Size	For HCCs with < 20 patients/day: 100% For HCCs with 21-50 patients/day: 50% For HCCs with 51-100 patients/day: 20% For HCCs with 101-200 patients/day: 10% For HCCs with 201-400 patient/day: 2% (selection of patients will be stratified to enable comprehensive overview)
The sample size for 2017	497,604 outpatient (Annual report, 2016) Average of 1382 patients/day. The average patient per day is 3 times more than the highest reference range given above. Will interview .25% of total OPD which equals approximately **1000 OPD patients**. Selection of patients will be stratified to enable comprehensive overview.
Data source	OPD Chambers

The frequency of data collection	Twice in a year over 2 month's period: June and July, December& January. Each time it will be collected from 1000 patients. Involve volunteers and students during a vacation to collect the data.
Forms if any	Outpatient satisfaction form
Note	The sample shall include both old and new patients.

KPI-29: In-Patient Satisfaction Index	
Definition	Patient Satisfaction is defined in terms of the degree to which the patient's expectations are fulfilled. It is an expression of the gap between the expected and perceived characteristics of a service (Lochoro, 2004)
Purpose	To study patients expectation from healthcare centres and to draw an action plan for continuous quality improvement through patients‟ feedback in the ward.
Formula	$\frac{\text{Score achieved}}{\text{Maximum possible score}} X\ 100$
Sample Size	For HCCs with < 20 discharges/day: 100% For HCCs with 21-50 discharges/day: 50% For HCCs with 51-100 discharges/day: 20% For HCCs with >100 discharges/day: 10%
The sample size for 2017-18	Total of 16,844 discharges (Annual report, 2016) Average of 46 discharges/day. To begin with, will interview 10% which is approximately 1600 inpatients.
Data source	Inpatient department
The frequency of data collection	Twice in a year over 2months period: June & July, December & January. The survey will involve volunteers and students on vacation to collect the data.
Forms if any	Inpatient satisfaction survey form
Note	The sample shall include both new and old patients

KPI-30: Employee Satisfaction Index	
Definition	Employee satisfaction is an index to measure the satisfaction of employee in an HCC
Purpose	To ensure job satisfaction of the staff through incentives and encouragements.
Formula	$\frac{\text{Score achieved}}{\text{Maximum possible score}} X\ 100$
Sample Size	For HCCs with < 100: 100% For HCCs with 101-200 staff: 50% For HCCs with 501-1000: 15% For HCCs with >1000 staff: 10%
The sample size for 2017-18	Hospital has 1300 staffs (2016) Interview 10% of 1300 which is 130 staff (Stratify)
Data source	20 Departments
The frequency of data collection	The satisfaction shall be captured from all categories of staff and at least once a year. Will involve HODs for collecting self-administered survey form from the staff of the respective department.
Forms if any	Employee satisfaction survey form
Note	The satisfaction shall be captured from all categories of staff.

KPI-31: Employee Attrition rate	
Definition	Attrition rate is the percentage of people leaving the HCC
Purpose	To study the cause of attrition and to ensure job satisfaction of the staff.
Formula	$\frac{\text{Number of the employee who has left}}{\text{Number of employees at the beginning of month } + \text{ newly joined}} X\ 100$
Sample Size	Not applicable
Data source	Human Resource Division
The frequency of data collection	Six monthly. May and November Will involve HRO for compiling the data and submitting quarterly A record will have to be maintained of the number of employees at the beginning of every month and newly joined in that month for the given period.
Forms if any	Record register
Note	None

KPI-32: Incidence of blood body fluid exposures	
Definition	Exposure is when blood, blood components or other potentially infectious materials come in contact with staffs eyes, mucous membranes, non-intact skin or mouth. (adopted from Joan Viteri Memorial clinic "PEM" post-exposure Prophylaxis)
Purpose	To monitor and minimize the incidence of blood and body fluid exposures through timely intervention and preventive action.
Formula	$\frac{\text{Number of blood or body fluid exposures}}{\text{Number of inpatients days}} X\ 100$
Sample Size	Not applicable
Area of data collection	Wards, ICU, ER, Laboratory, Some OPDs at CHD
Data source	Incident register maintained at respective units
The frequency of data collection	Monthly
Forms if any	Incident register, an incident form
Note	All exposures to blood/body fluids should be assessed on a case-by-case basis.

KPI-33: Incidences of needle stick injuries	
Definition	Needlestick injury is a penetrating stab wound from a needle (or other sharp objects) that may result in exposure to blood or other body fluids. Needlestick injuries are wounds caused by needles that accidentally puncture the skin. Needlestick injuries are a hazard for people who work with hypodermic syringes and other needle equipment. These injuries can occur at any time when people use, disassemble, or dispose of needles. When not disposed of properly, needles can become concealed in linen or garbage and injure other workers who encounter them unexpectedly.
Purpose	To monitor and minimize the incidence of needlestick injuries through timely intervention and preventive action.
Formula	Absolute number from all units
Sample Size	Not applicable
Area of data collection	All units including supporting unit

Data source	Incident register maintained at respective units
The frequency of data collection	Monthly
Annexure	Incident register format
Note	Parenteral exposures mean injury due to any sharp. All incidences of needlestick injuries should be assessed on a case by case basis. Analyse needle stick and another workplace to identify hazards and injury trends. Data from injury reporting should be compiled and assessed to identify: 1. Where, how, with what devices, and when injuries are occurring and 2. The groups of health care workers being injured.

KPI-34: Percentage of medical records not having discharge summary or incomplete	
Definition	A discharge summary is a part of a patient record that summarizes 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 medication). It is a summary of the patient's stay in HCC written by the attending doctor.
Purpose	To monitor the medical record section to ensure complete information of the patients in the medical record.
Formula	$\frac{\text{Number of medical records not having discharge summary or incomplete}}{\text{Number of discharges and deaths}} X\ 100$
Sample Size	Not applicable
Area of data collection	Medical Record
Data source	Record maintained by Medical Record
The frequency of data collection	Monthly
Note	Every medical record that comes to the MRD from the clinical unit following the discharge of a patient shall be immediately checked for the presence of discharge summary and its completeness. If this is not present at this stage it shall be captured as a part of the numerator.

KPI-35: Percentage of medical records not having codification as per International Classification of Diseases (ICD)	
Definition	The ICD is the international standard diagnostic classification for all general epidemiological, many health management purposes and clinical use. These include the analysis of the general health situation of population groups and monitoring of the incidence and prevalence of diseases and other health problems in relation to other variables such as the characteristics and circumstances of the individuals affected, reimbursement, resource allocation, quality and guidelines (WHO)
Purpose	To make sure that all the records are codified with ICD for easy tracing and reference.
Formula	$\frac{\text{Number of medical records not having ICD codification}}{\text{Number of discharges and deaths}} X\ 100$
Sample Size	For HCCs with < 20 discharges/day: 100% For HCCs with 21-50 discharges/day: 50% For HCCs with 51-100 discharges/day: 20% For HCCs with > 100 discharges/day 10%
Sample size JDWNRH 17-18	The sample will be used as per above reference during the clinical audit.
Area of data collection	Medical Record
Data source	Record maintained by Medical Record
The frequency of data collection	Monthly
Note	ICD codification shall be done by the doctor who signs the discharge summary and audit shall be done (using sample size mentioned in the previous column) by an independent person to capture this.

KPI-36: Percentage of missing records	
Definition	A medical record is considered as missing when the record could not be found out from the MRD after the 72 hours of the record request.
Purpose	To make sure that all the records are safely maintained in the record section.
Formula	$\frac{\text{Number of missing record}}{\text{Number of records}} X\ 100$
Sample Size	Not applicable
Area of data collection	Medical Record
Data source	Record maintained by Medical Record
The frequency of data collection	Monthly
Note	Regular checks should be in place to ensure that there are no missing medical records or medical records are filed in the wrong place.

KPI-37: Percentage of adherence to safety precautions by employees working in diagnostics.	
Definition	Safety precautions in diagnostics require adherence to national and international guidelines/standards for occupational health and safety; and infection control and waste management. All personnel working in diagnostics shall adhere to these safety precautions while performing the test/procedures as specified in their respective standard operating procedures for every test. These include the use of personal protective equipment such as lab coat, gloves, facemasks, thermoluminescent dosimeter (TLD device) and lead coat in X-ray, etc.; and a proper system of infection control and waste management.
Purpose	To monitor the compliance of staff to the standard procedures for safety while performing diagnostic tests.
Formula	$\frac{\text{Number of employees adhering to safety precaution}}{\text{Number of employees sampled}} X\ 100$
Sample Size	For HCCs with < 25 employees working in these areas: 100% For HCCs with 26-50 employees working in these areas: 50% For HCCs with 51-100 employees working in these areas: 30% For HCCs with >100 employees working in these areas: 20%
The sample size for	The number of staff in each area will be sampled based on the given reference range.

Area for the collection of data	Department of Pathology and Laboratory Medicine & Department of Radiology and Imaging
Data source	This indicator shall be captured by doing an audit on a monthly basis
The frequency of data collection	Monthly by doing the clinical audit
Forms if any	Checklist and SOPs
Note	These indicators shall be calculated separately for clinical laboratory and radiology.
KPI-38: Patient discharged before 11 AM	
Definition	Patient discharged from the healthcare centre 11 AM
Purpose	Minimize waiting time for discharge & the next admission Minimize waiting time for OPD patients
Purpose	To monitor the efficiency of discharge and admission process and to ensure timely attendance of physicians in the OPD chambers.
Formula/Unit	$\frac{\text{A number of hospital beds vacated between 9am} - \text{11am}}{\text{A total number of patients being discharged. Reported as percentage}} X\ 100$
Sample Size	Not applicable
Data source	IPD, Medical Record
The frequency of data collection	Monthly, QM Focal person will maintain the record and report monthly
Forms if any	Record register
Note	There will be circumstances where some patient may have to be discharged after 11 am. Therefore, in such a situation, the patient can be discharged after 11 am (20% will be acceptable). This is to avoid unnecessary withhold of discharge after 11 am in an effort to achieve this indicator of discharge before 11 am.

KPI-39: Average Length of Stay	
Definition	The average number of days a patient spends in the health facility (internationally 3-5 days). Calculated as total inpatients days during the given period/total admission
Purpose	Track utilization of beds Minimize the secondary infections Avoid unnecessary occupancy
Formula/Unit	$\frac{\text{Total inpatients day}}{\text{Total number of admission reported in days}} X\ 100$
Sample Size	Not Applicable
Data source	IPD/ Record Unit

The frequency of data collection	Monthly
Note	The outliers will be audited.

KPI-40: OPD waiting time	
Definition	Time taken by a patient from reception counter till examination by a health professional in the chamber.
Purpose	To assess and improve turnaround time for diagnostic purposes.
Formula/Unit	Average waiting time at a chamber in minutes
Sample Size	Same sample size will be used as in the survey of outpatient satisfaction index (0.25% of the total OPD which is equivalent to 1000 OPD patients) Selection of patients will be stratified to enable comprehensive overview.
Area of data collection	OPD chambers, Departments of clinical laboratory and Department of radiology and imaging.
Source of data collection	This indicator will be captured during clinical auditing.
The frequency of data collection	Half Yearly
Forms if any	Survey form to assess waiting time.
Note	1. To assess waiting time at chambers: time will begin from the time patient gets token at the general reception until patient sees Doctor in the chamber. 2. To assess waiting time for diagnostics: time will begin from the time patient is registered at individual diagnostics counter until the patient is seen for the diagnostic test.

KPI-41: Emergency Response Time	
Definition	The time gap between emergency patients reporting to the healthcare centre and being examined by the clinical staff at the healthcare centre.
Purpose	Determine efficient utilization of resources and facilities; Determine treatment outcome
Formula/Unit	Average emergency response time
Sample Size	10% of total patients seen in emergency department
Area of data collection	Emergency Department
Data source	This indicator will be captured during clinical auditing.
The frequency of data collection	Half-yearly
Note	None

KPI-42: Follow up of Referrals	
Definition	Percentage of patients being followed up with feedback after referral to higher healthcare centre within the country or outside the country.
Purpose	Improve efficiency of referral system To track treatment outcome
Formula/Unit	$\frac{\text{Number of feedbacks}}{\text{Total number of the patient referred outside}} X\ 100$
Sample Size	Not applicable
Area of data collection	Referral Section
Data source	Record register
The frequency of data collection	Monthly
Note	If patients are not returning to the Health centre following the referral, this can be captured from Liaison officer based in the referred centre. The Liaison officer should send the feedback report every month.

KPI-43: Unavailability of Reagents	
Definition	Unavailability of test services as a consequence of unavailability of clinical laboratory reagents. This shall be captured as a number of days test services were interrupted due to unavailability of reagent/s.
Purpose	To ensure continuity and availability of lab test services. To track minimum recorder level
Formula/Unit	Number of days reagent/s was not available
Sample Size	Not applicable
Area of data collection	Department of clinical laboratory and Department of radiology and imaging, Department of Dentistry.
Data source	Record of unavailability of reagents in each unit of clinical laboratory (Biochemistry, Blood bank, Histopathology, Cytology, Microbiology, Haematology), Similarly in each unit of Department of Radiology and Imaging and Department of Dentistry.
The frequency of data collection	Monthly Quality Focal person/In-charge in all units shall record the number of days reagent/s were not available and report monthly to the departments" Quality manager
Forms if any	Unavailability of reagent form.
Note	None

KPI-44: Clinical laboratory results turnaround time (TAT)	
Definition	Turnaround time (TAT) is the time of patient/sample registration in the clinical laboratory until reports are ready.
Purpose	To enhance the efficiency of clinical laboratory services by adhering to the defined TAT for each test as specified in the Clinical Laboratory Quality Manual.
Benchmark	90% of the routine test completed within the specified TAT
Formula/Unit	$\frac{\text{Number of tests completed within the specified TAT}}{\text{Number of tests sampled}} X\ 100$

Sample Size	For HCCs with < 100 tests/month: 100% For HCCs with 100-200 tests/month: 50% For HCCs with 201-300 tests/month: 25% For HCCs with 301-500 tests/month: 25% For HCCs with >500 tests/month: 15%
Sample size JDWNRH 2017-18	Since JDWNRH has a test load much greater than the above statistical standard, the following is derived for use: As per annual report 2016 Microbiology reported 181576 test (15131/month & 504/day) Total sample 1816 (1% of total test) Histopathology reported 60216 tests (5018/month & 167/day) Total sample 1204 (2% of total) Haematology reported 138652 tests (11554/month & 385/day) Total sample 1387 (1% of total) Biochemistry reported 1014784 test (84565/month & 2818/day) Total sample 1014 (0.10% of total) Immunochemistry reported 60711 tests (5059/month & 169/day) Total sample 1214 (2% of total) Cytology reported 11024 tests (919/month & 31/day) Total sample 1102 (10% of total)
Area of data collection	Department of Pathology and Laboratory Medicine (Biochemistry, Blood bank, Histopathology, Cytology, Microbiology, Haematology)
Data source	This indicator will be captured during the clinical audit.
The frequency of data collection	Quarterly
Note	Every quarterly all the units in the clinical laboratory will randomly sample 100 tests and their TAT

KPI-45: Drugs Reorder Levels in Medical Store	
Definition	List of drugs where stocks are below an agreed minimum reorder level in the health care centre.
Purpose	To maintain adequate stock of drugs in the health facility
Formula/Unit	$\frac{\text{Number of drugs which are below agreed minimum level}}{\text{No. of drugs supplied to the health facility}} X\ 100$

Sample Size	Not applicable
Area of data collection	Pharmacy Department
Data source	Record register
The frequency of data collection	Monthly
Note	None

KPI-46: Staff Unavailability	
Definition	Unavailability of staff in the health care centre due to leave and training (Exclude Maternity, paternity leaves & bereavement leave, long-term study up to 6 months, ORC, Patient escorts and school visits) expressed in percentage
Purpose	Track utilization of human resources Minimize the wastage of human resources
Formula/Unit	Number of staff on all type of leaves and training (exclude those mentioned above)
Sample Size	Not applicable
Area of data collection	HR Division
Data source	HR Division
The frequency of data collection	Monthly
Note	None

KPI-47: Infection Control and Medical Waste Management	
Definition	Assessment of healthcare centres by evaluating various activities of infection control and medical waste management using a standard checklist (HHICA)
Purpose	Improve patient safety and reduce hospital-acquired infections
Formula/Unit	$\frac{\text{Score achieved}}{\text{Maximum possible score}} X\ 100$
Sample Size	Not applicable

Area of data collection	All reception counter
Data source	This indicator will be captured during the clinical audit
The frequency of data collection	Quarterly
Forms if any	Checklist
Note	Infection control team shall evaluate quarterly.

ANNEX 02

Reference Guide on Sentinel Events

Definition:

An unexpected incident, related to system or process deficiencies, which leads to death or major and enduring loss of function "for a recipient of 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 it not related to an underlying condition.

Event type description

a. Surgical events

- Surgery performed on the wrong body part
- Surgery performed on the wrong patient
- A wrong surgical procedure performed on the wrong patient
- Retained instruments in patient discovered after surgery/procedure
- Patient death during or immediately post-surgical procedure
- Anaesthesia-related event

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

- The use of contaminated drugs, devices, products supplied by the HCC
- The use or function a device in a manner other than the device's intended use
- The failure or breakdown of a device or medical equipment
- Intravascular sir embolism

c. Patient protection events

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

d. The environmental events. Patient death or serious disability while being cared for in a healthcare facility associated with:

- A burn incurred from any source
- A slip, trip, or fall
- An electric shock
- The use of restraints or bedrails

e. Care management events

- Patient death or serious disability associated with a haemolytic reaction due to the administration of ABO-incompatible blood or blood products
- Maternal death or serious disability associated with labour or delivery in a low-risk pregnancy
- Medication error leading to the death or serious disability of patient due to incorrect administration of drugs, for examples due to the errors of omission, dosage, preparation, timing, rate of administration, administering technique, wrong patient etc.
- Patient death or serious disability associated with an avoidable delay in treatment or response to abnormal test results

f. Criminal events

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

ANNEX 03

Guide for Clinical Audit

A write-up for carrying out the clinical audit is given below for comprehending the process of auditing of the healthcare services. The test has been simplified so as to explain all aspects of the subject without compromising the basic tenants of the audit.

a. What is an audit?

- It is the process of reviewing of delivery of care to identify deficiencies so that they may be remedied.

b. What is clinical audit (CA)?

- It may be defined as peer review for evaluation of medical care through retrospective and concurrent analysis of the medical record.

c. What is the primary aim of CA?

- To improve the quality of healthcare services rendered to the patients.

d. What is CA not?

- A fault-finding mission
- A punitive action
- An external quality-control method
- To be conducted by any professional other than medical professional.

e. Who will carry out CA? Clinical Audit Committee

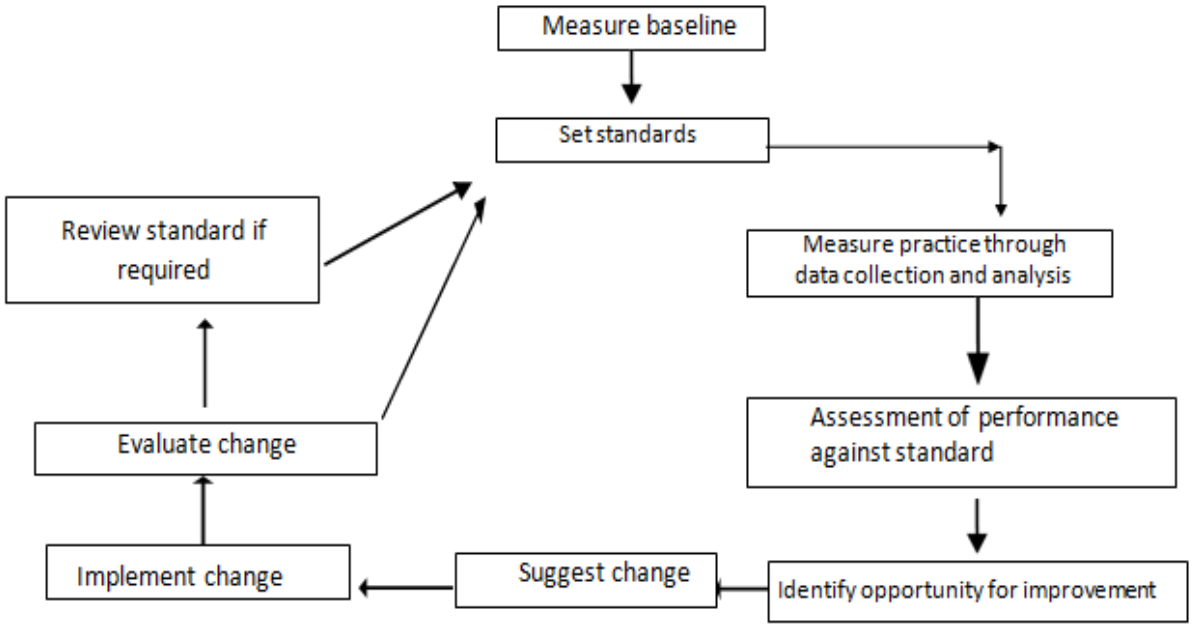
- MS/Coordinator/HCC Administrator
- Representatives of all disciplines
- Nursing representatives

f. What are the prerequisites?

- Good record-keeping system
- Should be carried out by fair and impartial professionals
- Clinicians, nursing and other staff as well as patient anonymity to be maintained
- The initiative should come from within
- The purpose should be simple and clearly stated
- The intention should be to effect change for the better

g. How to audit?

The Audit Cycle



Methodology

a. Selection of Topics.

- Should be common because it is common or high risk or bears a high cost.
- Should be having a local clinical concern or known wide variance in clinical practice.
- The topic should be well defined, focused and amenable to standard setting.

b. Some topics

- Long/short stay cases
- Specific disease/specific operations
- Vulnerable groups
- Increase the incidence of a disease
- Post-operative infection/complication

c. Setting of standard

- To be sent prior to the study
- Criteria to be based on objective measures
- Criterion is an item of care or sure aspect of care that can be used to assess quality. It is a written statement. For example,
    - ✓ Patients requiring urgent appointment will be seen that day only.
    - ✓ Patients with epilepsy should be seen once a year
    - ✓ Patients on oral anticoagulants should have their INR within recommended limits.
- Criteria should be well justified.

d. Target should be set at a realistic level for defined patient groups and take into account local circumstances.

- A target describes the level of care to be achieved for any particular criteria, example,
    - ✓ 98 per cent of patients requesting for urgent appointment will be seen on that day.
    - ✓ 90 per cent of patients with epilepsy must be seen at least once a year.
    - ✓ 100 per cent of patients on oral anticoagulants will have the INR within the recommended level.

Example of Criteria and Target Applicable to Structure, Process and Outcome Variables

	Structure	**Process**	**Outcome**
Criteria	Staffing of ICU	BT during surgery	Case fatality
Target	Not < 1 per two occupied beds	Not < 5 per cent and not > 20 per cent of average cases	Not to exceed 0.1 per cent for specified procedures

- Objective criteria are explicit but clinical judgment can be used to answer the question: “Was the management of this case satisfactory”? This is an implicit criterion.
- Use of explicit criteria should be preferred. The problem with implicit criteria is that important deficiencies in care may be overlooked and rates may differ in their assessments of the acceptability of management.

a. Worksheet preparation and methodology of administration

- Simplest for the purpose
- Only essential data is collected
- The suitable sample size is to be selected
  - Random sampling – generate
  - Stratified samples
  - Systematic sampling
  - Cluster sampling

b. The probability of bias is to be considered

- Non-response to a survey
- Unavailability of the certain type of case note
- Selective referral of certain types of patients
- Failure of the patient to turn up for follow up

c. Tabulation of evaluation

Interpretations

- Deficiency of care recognized
- Specific solutions are proposed. They may not be possible every time. E.g. a study of the way cervical screening is organized identified deficiencies but concluded only that other schemes needed to be examined.
- Education impact is appreciated

Effecting change

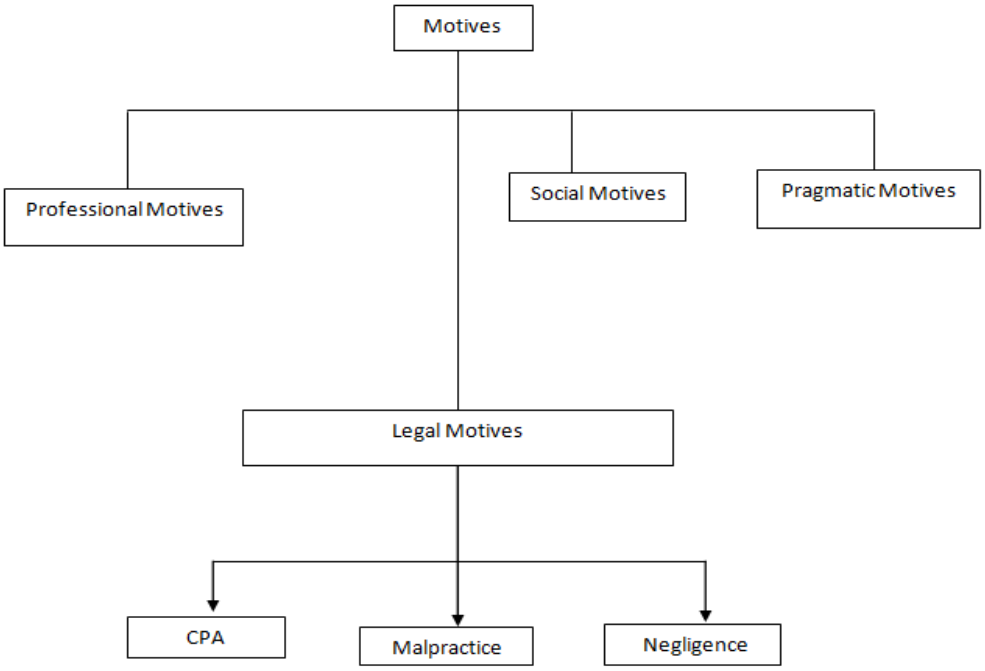
- Planned program for change
- All staff is involved
- Active feedback
- Audit is evaluated
- Certain additional questions related to clinical audit

d. Q). why audit?

- It improves the quality of care
- It is an aid to continuous medical education
- There is a sense of personal and professional achievement

- Q) What are the motives for doing an audit?

They can be broadly categorized as under, Professional, Social, Pragmatic and Legal a diagrammatic representation of the motives is given below:



- To identify deficiencies
- Educational needs
- Self-correction and regulation
- To present patient from inappropriate treatment
- To reduce patient suffering

a. Q) What are the key questions to be asked while doing a clinical audit?

- What do we do?
- Do we do what we think we do?
- What should we do?
- Are we doing what we should be doing?
- How can we improve what we do?
- How do we improve?

b. Q) What are the benefits of an audit?

a) Professional benefits

- Change in prescribing behaviour
- Updating clinical knowledge
- Increase in staff enthusiasm and satisfaction
- Teamwork

b) Patient care and service delivery

- Improvements in patient care
- Improved patient satisfaction
- Better patient feedback

c. Q) What are the perceived disadvantages?

- Increase in workload
- Restriction of clinical feedback
- Professional threat

d. Q) What are the barriers to audit?

- Lack of resources
- Lack of expertise in design and analysis
- Lack of an overall plan for audit
- Relationships problem
- HCC impediments – disputes between views of clinicians and managers

e. Q) What are the factors which promote success?

- Supportive HCC environment
- Sound leadership and direction of the audit program
- Strategy and planning in the audit program
- Resource and support for the audit program
- Monitoring and reporting of audit activity
- Commitment and participation

f. Q) What are the key lessons from various audits?

1. Foster an environment for audits?
    - The audit is a valued activity
    - Can augment both carrier and professional development
    - Provision of protected time for the audit
    - Commitment from staff to provide a request and act on the study findings

2. Tackle the problems of multidisciplinary audit
    - Can be seen as threatening
    - Exposing one mistake to another
    - Staff training in interpersonal skills and in dealing with conflict
    - Benefits outweigh disadvantage

3. Review staff training program
    - Importance of planning
    - Benefits of pilot study

4. Emphasize audit facilitation

5. Establish confidentiality of finding

6. Ensure all relevant staff are involved

7. Establish evaluation program Checklist

Sl. No	Question	Criteria
1	Why was the audit done?	Reason for choice (a) Should be clearly defined (b) Should include the potential for change
2	How was the audit done?	(a) Criteria choice i. Should be relevant to the subject ii. Should be justified, e.g. literature surveys iii. Preparation and planning should show adequate teamwork and methodology in carrying out the audit iv. If standards are set they should be appropriate and justifiable
3	What was found?	Interpretation of the data Should use all relevant data to allow the appropriate conclusion to be drawn
4	What next?	A detailed proposal for change should show explicit details of the proposed change

Conclusion

Audit appears deceptively simple. Current care is observed so that it can be compared with standards and the necessary changes in patient care are implemented.

In practice

- ✓ Topics for audit need to be chosen with care and refined to make them suitable.
- ✓ Standard setting requires clarity of thought and careful definition.
- ✓ Data collection to observe practice can consume endless time and money.
- ✓ Lasting change is notoriously difficult to achieve.

Notwithstanding the above, once the audit is understood and planned, it is one of the best ways to check the quality of care being rendered, to bring about changes for improving care, to improve patient and employee satisfaction and for professional development.

ANNEX 04

Patient Responsibilities (Indicative guide)

- Provide complete and accurate information about his/her health, including present condition, past illnesses, HCCs, medications, natural products and vitamins, and any other matters that pertain to his/her health.
- Provide complete and accurate information including full name, address and other information.
- To ask questions when he/she does not understand what the doctor or other members of the healthcare team tells about diagnosis or treatment. He/she should also inform the doctor if he/she anticipates problems in following prescribed treatment or considering alternative therapies.
- Abide by all HCC rules and regulations.
    - Comply with the no-smoking policy.
    - Comply with the visitor policies to ensure the rights and comfort of all patients. Be considerate of noise levels, privacy, and safety. Weapons are prohibited on premises.
- To be on time in case of appointments. To cancel or reschedule as far in advance as possible in case of cancellation or rescheduling of the appointments.
- Not to give medication prescribed for him/her to others.
- Provide complete and accurate information for insurance claims and work with the HCC and physician billing offices to make payment arrangements.
- To communicate with the healthcare provider if his/her condition worsens or does not follow the expected course.
- To pay for services billed for in a timely manner as per the HCC policies.
- To respect that some other patients' medical condition may be more urgent than yours and accept that your doctor may need to attend them first.
- To respect that admitted patient and patients requiring emergency care take priority for your doctor.
- To follow the prescribed treatment plan and carefully comply with the instructions given.
- To accept, where applicable, adaptations to the environment to ensure a safe and secure stay in HCC.
- To accept the measures taken by the HCC to ensure personal privacy and confidentiality of medical records.
- To attend the follow-up appointment as requested.
- Not to take any medications without the knowledge of doctor and healthcare professionals.
- To provide correct and truthful history.
- To understand the charter of rights and seek clarification, if any.

ANNEX 05

BHSQA Checklist

Sl. No.	Name of healthcare	Rating Level	Scoring Criteria
1	Name of CMO:	L0	Not implemented
2	Dzongkhag:	L1	Implemented but not
3	Date of	L2	Fully Completed

Instruction: This checklist is to be used for all the four levels of healthcare centres (Referral hospitals, District Hospitals, BHU-Is and BHU-II to assess and evaluate the status of implementing BHSQA by each healthcare centre. The checklist has been finalized and unanimously accepted by experts from Quality Management Service (QMS) at JDWNRH. Evaluators should assess the healthcare centre based on the availability of services. The questions which are not applicable for particular healthcare centre should be noted as "NA" and should not be included in score count.

BHSQA 1: Access, Assessment and Continuity of Care (AAC)

Sl.No	Std. No.	BHSQA Checklist questions	L0	L1	L2
1	AAC 6.1	The HCC defines and displays the services that it can provide.			
2	AAC 6.2	The HCC has a well-defined registration and admission process.			
3	AAC 6.3	There is an appropriate mechanism for transfer (in and out) or referral of patients.			
4	AAC 6.4	Patients cared for by the HCC undergo an established initial assessment.			
5	AAC 6.5	Patients cared for by the HCC regular reassessment.			
6	AAC 6.6	Clinical laboratory services are provided as per the scope of services of the HCC.			
7	AAC 6.7	There is an established laboratory-quality assurance program.			
8	AAC 6.8	There is an established laboratory-safety program.			

9	AAC 6.9	Imaging services are provided as per the scope of services of the HCC			
10	AAC 6.10	There is an established quality-assurance program for imaging services.			
11	AAC 6.11	There is an established radiation-safety program.			
12	AAC 6.12	Patient care is continuous and multidisciplinary in nature			
13	AAC 6.13	The HCC has a documented discharge process			
14	AAC 6.14	HCC defines the content of the discharge summary			
15	AAC 6.15	Services in the Pharmacy are as per the scope of services of the HCC and adhering to the best practices.			
16	AAC 6.16	There is documented Quality Assurance Program in the Pharmacy.			
17	AAC 6.17	There is an established Safety protocol in the Pharmacy.			
BHSQA 2: Care of Patients (COP)					
42	COP 7.1	Uniform care to patients is provided in all settings of the HCC and is guided by the applicable laws, regulations and guidelines.			
43	COP 7.2	Emergency services are guided by documented policies, procedures and applicable laws and regulation.			
44	COP 7.3	The ambulance services are commensurate with the scope of the services provided by the HCC.			
45	COP 7.4	Documented policies and procedures guide the care of patients requiring cardiopulmonary resuscitation.			
46	COP 7.5	Documented policies and procedures guide nursing care.			

47	COP 7.6	Documented procedures guide the performance of various procedures.			
48	COP 7.7	Documented policies and procedures define relational use of blood and blood products			
49	COP 7.8	Documented policies and procedures guide the care of patients in intensive care & high dependency units.			
50	COP 7.9	Documented policies and procedures guide the care of vulnerable patients (elderly, physically and/or mentally-challenged and children).			
51	COP 7.10	Documented policies and procedures guide obstetric care.			
52	COP 7.11	Documented policies and procedures guide paediatric services.			
53	COP 7.12	Documented policies and procedures guide the care of patients undergoing moderate sedation.			
54	COP 7.13	Documented policies and procedures guide the administration of anaesthesia.			
55	COP 7.14	Documented policies and procedures guide the care of patients undergoing surgical procedures.			
56	COP 7.15	Documented policies and procedures guide the care of patients under restraints.			
57	COP 7.16	Documented policies and procedures guide appropriate pain management.			
58	COP 7.17	Documented policies and procedures guide appropriate rehabilitative services			
59	COP 7.18	Documented policies and procedures guide all research activities.			
60	COP 7.19	Documented policies and procedures guide nutritional therapy.			

61	COP 7.20	Documented policies and procedures guide the end of life care.			
BHSQA 3: Management of Medication (MOM)					
62	MOM 8.1	Documented policies and procedures guide the HCC's pharmacy services and use of medication.			
63	MOM 8.2	There is an HCC formulary			
64	MOM 8.3	Documented policies and procedures exist for storage of medication.			
65	MOM 8.4	Documented policies and procedures guide the safe and rational prescription of medications.			
66	MOM 8.5	Documented policies and procedures guide the safe dispensing of medications.			
67	MOM 8.6	There are documented policies procedures for medication management.			
68	MOM 8.7	Patients are monitored after medication administration.			
69	MOM 8.8	Near misses, medication errors and adverse drug events are reported and analysed.			
70	MOM 8.9	Documented procedures guide the use of narcotic drugs and psychotropic substances.			
71	MOM 8.10	Documented policies and procedures guide the usage of chemotherapeutic agents.			
72	MOM 8.11	Documented policies and procedures govern the usage of radioactive drugs.			
73	MOM 8.12	Documented policies and procedures guide the use of implantable prosthesis and medical devices.			
74	MOM 8.13	Documented policies and procedures guide the use of medical supplies and consumable			
BHSQA 4: Patient Rights and Education (PRE)					

75	PRE 9.1	The HCC protects patient and family rights and informs them about their responsibilities			
76	PRE 9.2	Patient and family rights support individual beliefs, values and involve the patient and family in decision-making processes.			
77	PRE 9.3	The patient and/or family members are educated to make informed decisions and are involved in the care-planning and delivery process.			
78	PRE 9.4	A documented procedure for obtaining patient and/or family's consent exists for informed decision making about their care.			
79	PRE 9.5	Patient and families have a right to information and education about their healthcare needs			
80	PRE 9.6	Patient and families have a right to information on expected costs.			
81	PRE 9.7	HCC has a complaint redressal procedure.			
BHSQA 5: HCC Infection Control (HIC) & Waste Management					
82	HIC 10.1	The HCC has a well-designed, comprehensive and coordinated HCC Infection Prevention and Control program aimed at reducing/elimination risks to patients, visitors and providers of care			
83	HIC 10.2	The HCC implements the procedures laid down in the Infection Control guideline.			
84	HIC 10.3	The HCC performs surveillance activities to capture and monitor infection prevention and control data.			
85	HIC 10.4	The HCC takes actions to prevent and control HAI in patients.			
86	HIC 10.5	The HCC provides adequate and appropriate resources for prevention and control of HAI.			

87	HIC 10.6	The HCC identifies and takes appropriate actions to control outbreaks of infections.			
88	HIC 10.7	There are documented policies and procedures for sterilization activities in the HCC.			
89	HIC 10.8	Medical waste is handled in an appropriate and safe manner.			
90	HIC 10.9	The infection control program is supported by the management and includes training			
BHSQA 6: Continuous Quality Improvement (CQI)					
91	CQI 11.1	There is a structured quality improvement and continuous monitoring program is the			
92	CQI 11.2	There is a structured patient-safety program in the HCC.			
93	CQI 11.3	The HCC identifies key indicators to monitor the clinical structures, processes and outcomes which are used as tools for continual improvement.			
94	CQI 11.4	The HCC identifies key indicators to monitor the managerial structures, processes and outcomes, which are used as tools for continual improvement.			
95	CQI 11.5	The quality improvement program is supported by the management.			
96	CQI 11.6	There is an established system for clinical audit.			
97	CQI 11.7	Incidents, complaints and feedback are collected and analysed to ensure continuous quality improvement.			
98	CQI 11.8	Sentinel events are intensively analysed.			
99	CQI 11.9	Regular Supervision and Monitoring			
BHSQA 7: Responsibilities of Management (ROM)					

100	ROM 12.1	The terms of reference of those responsible for governance are defined.			
101	ROM 12.2	The HCC complies with the laid-down and applicable legislation and regulations			
102	ROM 12.3	The services provided by each department are documented.			
103	ROM 12.4	The HCC is managed by the leaders in an ethical manner.			
104	ROM 12.5	The HCC displays professionalism in the management of affairs.			
105	ROM 12.6	Management ensures that patient-safety aspects and risk-management issues are an integral part of patient care and HCC management.			
BHSQA 8: Facility Management and Safety (FMS)					
106	FMS 13.1	The HCC has a system in place to provide a safe and secure environment.			
107	FMS 13.2	The HCC's environment and facilities operate to ensure the safety of patients, their families, staff and visitors.			
108	FMS 13.3	The HCC has a program for engineering support services.			
109	FMS 13.4	The HCC has a program for bio-medical equipment management.			
110	FMS 13.5	The HCC has a program for medical gases, vacuum and compressed air.			
111	FMS 13.6	The HCC has plans for fire and non-fire emergencies within the facilities.			
112	FMS 13.7	The HCC plans for handling-community emergencies, epidemics and other disasters			
113	FMS 13.8	The HCC has a plan for management of hazardous materials.			

BHSQA 9: Human Resource management (HRM)					
108	HRM 14.1	The HCC has a documented system of human resource planning.			
109	HRM 14.2	The HCC has a documented procedure for recruiting staff and orienting them to the HCC's environment.			
110	HRM 14.3	There is an ongoing program for professional training and development of the staff.			
111	HRM 14.4	Staff are adequately trained in various safety-related aspects.			
112	HRM 14.5	An appraisal system for evaluating the performance of an employee exists as an integral part of the HRM			
113	HRM 14.6	The HCC has documented disciplinary grievance handling policies and procedures.			
114	HRM 14.7	The HCC addresses the health needs of the employees.			
115	HRM 14.8	There is a documented personal record for each staff member.			
116	HRM 14.9	There is a process for credentialing and privileging of medical professionals permitted to provide patient care without supervision.			
BHSQA 10: Information Management System (IMS)					
118	IMS15.1	Documented policies and procedures exist to meet the information needs of the care providers, management of the HCC as well as other agencies that require data and information from the HCC.			
119	IMS15.2	The HCC has processes in place for the effective management of data.			

120	IMS15.3	The HCC has a complete and accurate medical record for every patient.			
121	IMS15.4	The medical record reflects the continuity of care.			
122 122	IMS15.5	Documented policies and procedures are in place for maintaining confidentiality, integrity and security of records, data and information.			
123 123	IMS15.6	Documented policies and procedures exist for a retention time of records, data and information.			
124	IMS15.7	The HCC regularly carries out a review of medical records.			

Comments and Suggestions by Evaluator
…… …….. …… …….. …… ……
Comments and recommendations from the Healthcare Centre
…… …… …… …… …… …… …… …… …… ……

Technical Committee Composition

PHARMACEUTICAL AND TRADITIONAL MEDICINE TECHNICAL COMETTEE

(TC-05)

Organization	Representative(s)
Essential Medicines and Technology Division, Ministry of Health	Mr Dechen Chophel (Chairman)
Medical Supplies and Procurement Division, DOMSHI, Ministry of Health	Mr Rudra Mani Dhimal (Member)
Menjong Sorig Pharmaceuticals Corporation Ltd., Thimphu	Mr Sherab Tenzin (Member)
Registration Division, Drug Regulatory Authority	Ms Jambay Wangmo (Member)
Quality Assurance and Standardization Division, Ministry of Health	Mr Rixin Jamtsho (Member)
Drugs vaccines and Equipment Unit, National Centre for Animal Health, Serbithang, Dept. of Livestock, MoAF	Dr Kinzang Dukpa (Member)
National Drug Testing Laboratory, Dept. of Public Health, Ministry of Health	Mr Kelzang Wangdi (Member)
Bioprospecting and ABS Program, National Biodiversity Centre, MoAF	Mr Chencho Dorji (Member)
Consumer Grievance and Redressal Division, Office of Consumer Protection, Department of Trade, MoEA	Mr Tshering Wangchuk (Member)
Standardization Division Bhutan Standards Bureau	Ms Cheten Zangmo (Member Secretary)