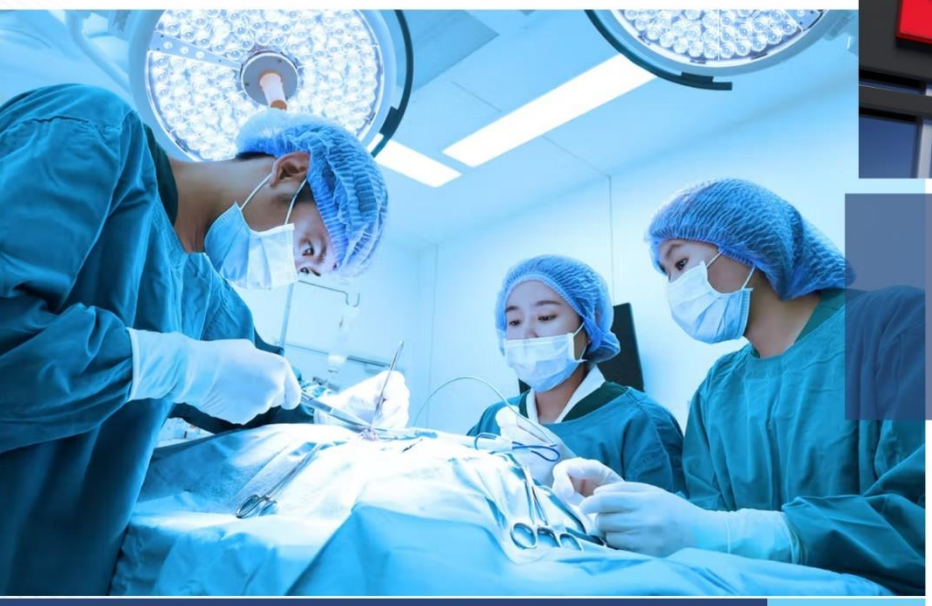
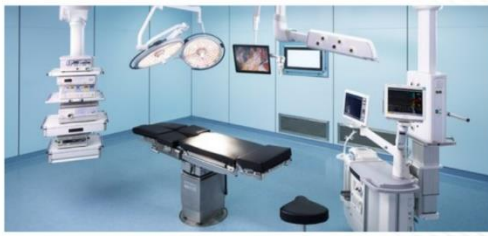
Khyber Pakhtunkhwa Health Care Commission

MINIMUM SERVICE DELIVERY STANDARDS

REFERENCE MANUAL





Category 2-B
Health Care Establishments

KP HCC-03RM-Ed1

1st Edition

Minimum Service Delivery Standards

REFERENCE MANUAL

Category 2-B
Health Care Establishments

May 2022

Message from Chairman

Aristotle stated, “Quality is not an act, it is a habit.” In order to ensure that quality in the health care sector becomes a habit, the government established the Khyber Pakhtunkhwa Health Care Commission (KP HCC) through the Khyber Pakhtunkhwa Health Care Commission Act, 2015. The KP HCC is a statutory body of the Government of Khyber Pakhtunkhwa to regulate both public and private Health Care Establishments (HCEs) in the province.

Prior to 2015 the private health institutions including hospitals, nursing homes, maternity homes, medical & dental clinics, blood banks, clinical laboratory, x-ray clinics and operation theaters etc. were registered under the Medical and Health Institutions and Regulation of Health Care Services ordinance 2002 (Amendment Act, 2010), which was subsequently repealed through the Act of 2015.

The legal mandate of KP HCC is to regulate the health care services on sound and technical footings in the public and private sectors, make provisions for safe and high quality health care services to the people of Khyber Pakhtunkhwa, and to provide mechanism for banning quackery in all its forms and manifestations.

The Government of Khyber Pakhtunkhwa through the Health Care Commission is committed to improve and maintain the quality of health care. The KP HCC is already registering the various types of Health Care Establishments. The other mechanism to ensure optimum level of safety and quality is the framework of clinical governance. To achieve this end the KP HCC initiated the process of licensing of Health Care Establishments.

The former Board of the KP HCC strived very hard and visited the sister organizations in the other provinces for experience sharing. In order to save energies and resources, the Board adopted the Minimum Service Delivery Standards (MSDS) of the Punjab Healthcare Commission (PHC). I, on behalf of the Board and Khyber Pakhtunkhwa Health Care Commission, am very grateful for support provided by PHC in this regards.

The journey of ensuring quality is not easy and assistance of various stakeholders is required. I would specifically mention the all-out support of the Government of Khyber Pakhtunkhwa and especially the Minister for Health and Secretary to the Government of Khyber Pakhtunkhwa, Health Department. Without their support, initiation of licensing of the HCEs to ensure quality was not possible.

I would take this opportunity to reach out to all the health acre establishments to get themselves registered with KP HCC and implement the Minimum Service delivery Standards in their respective establishments to achieve the required quality of health care and get a license to function. Providing health care without getting license from KP HCC is illegal and may lead to legal consequences, including, but not limited to, closure of the facility.

Dr. Ikram Ghani
Chairman, Board of Commissioners

Foreword

Quality costs but poor quality costs higher. This is true for all walks of life; however, in the health sector its importance cannot be overemphasized. It ensures safety of patients as well health care providers. Patient safety is not new in the medical field but is relatively newer concept for general public. Regulation of health care services is now a priority at the national and provincial government level. In order to ensure quality of care and safety in health care system of Khyber Pakhtunkhwa, the provincial government established the Khyber Pakhtunkhwa Healthcare Commission (KP HCC) through the promulgation of Khyber Pakhtunkhwa Health Care Commission Act, 2015. KP HCC is a statutory body, constituted to regulate Health Care Establishments (HCEs), both in public and private sectors in the province, to improve quality of health care, and ensure safety of patients and health care providers.

To ensure quality the HCEs are regulated through assessment against set standards. The Punjab Healthcare Commission (PHC) developed the Minimum Service delivery Standards (MSDS) through extensive consultations with the stakeholders. PHC developed MSDS for Category 1 and 2 hospitals, providing in-patient care. Moreover, MSDS were also developed for different kinds of Category 3 HCEs, offering out-patient services, including Basic Health Units in the public sector, and the clinics of general practitioners, dental clinics, clinical laboratories, radiological diagnostic centers, as well as homeopathic clinics and Tibb clinics.

The former Board of Khyber Pakhtunkhwa Healthcare Commission took the right decision and approved adoption of the MSDS of Punjab in its 34th meeting on 6th January 2022. The KP HCC duly acknowledges this gesture of support by the Punjab Healthcare Commission.

Subsequent to adoption, appropriate amendments were required to adapt the MSDS to the local context and legal provisions of Khyber Pakhtunkhwa. This was a challenging assignment and despite shortage of staff, KP HCC made the required amendments, utilizing its internal resources. I would like to thank the former Board of KP HCC for its wholehearted effort towards improving the quality of healthcare through adoption of PHC MSDS. My thanks are also due to the whole KP HCC team for working tirelessly and completing the process of adaptation in a very short time. The role of senior management was commendable. Moreover, I am highly grateful to Mr. Adil Waqas, Mr. Zeeshan Khan, Mr. Muhammad Latif Khan, Mr. Malik Waqar Ahmad, Mr. Zia Mohyuddin and Mr. Muhammad Farhan Khan of KP HCC for thoroughly reviewing all the manuals of MSDS, identifying the sections to be changed, and finding appropriate replacements for making the required amendments for adaptation.

The MSDS Reference Manual for Category 2-B Health Care Establishments comprises 30 standards and 122 indicators. It also provides the survey and scoring methodology, in addition to the guidelines to facilitate implementation and assessment of compliance.

Every journey begins with the first step and I firmly believe that this first step followed by implementation of the MSDS will lead to improved quality of healthcare in Khyber Pakhtunkhwa.

Dr. Nadeem Akhtar
Chief Executive Officer

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STANDARDS AND INDICATORS

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List of Acronyms & Abbreviations

AAC	Access, Assessment, and Continuity of Care
A&E	Accident and Emergency
ABG	Arterial Blood Gas (test)
ACLS	Advanced Cardiac Life Support
ADR	Adverse Drug Reaction
AFB	Acid-Fast Bacillus
ASA	American Society of Anaethesiologists
AST	Aspartate Amino Transferase
ATLS	Advanced Trauma Life Support
BB	Blood Bank
BTS	Blood Transfusion Service
BLS	Basic Life Support
CABG	Coronary-Artery Bypass Grafting
CCU	Cardiac Care Unit
CEO	Chief Executive Officer
CEmOC	Comprehensive Emergency Obstetric Care
CMC	Complaint Management Committee
CMO	Causality Medical Officer
CME	Continued Medical Education
CNIC	Computerized National Identity Card
COP	Care of Patients
CO_2	Carbon Dioxide
CPOE	Computerized Prescriber Order Entry
CPD	Continuous Professional Development
CPSP	College of Physicians and Surgeons
CQI	Continuous Quality Improvement
CRP	C-Reactive Protein
CSOs	Civil Society Organization
CSSD	Central Sterilization Services Department
CT	Computed Tomography

DCP	Diploma in Clinical Pathology
DoB	Date of Birth
DoH	Department of Health
DRA	Drug Regulatory Authority
DVT	Deep Venous (Vein) Thrombosis
ECG	Electro Cardiography
ED	Emergency Department
EMO	Emergency Medical Officer
EmOC	Emergency Obstetric Care
EmONC	Emergency Obstetric and Neonatal Care
EMR	Electronic Medical Record
EMS	Emergency Medical Services
ENC	Essential Newborn Care/ Emergency Neonatal Care
FCPS	Fellow of College of Physicians and Surgeons
FFP	Fresh Frozen Plasma
FMS	Facility Management and Safety
FP	Family Planning
FPAHS	Faculty of Paramedical and Allied Health Sciences
HAIs	Healthcare Associated Infections/ Hospital Associated Infections
HCE	Healthcare Establishment
HCP	Healthcare Provider
HIC	Hospital Infection Control
HOD	Head of Department
HR	Human Resource
HRD	Human Resource Department
HRM	Human Resource Management
HWM	Hospital Waste Management
HWMT	Hospital Waste Management Team
IBC	International Building Code
IC	Infection Control
ICC	Infection Control Committee

ICD	International Classification of Diseases
ICN	Infection Control Nurse
ICO	Infection Control Officer
ICP	Infection Control Practitioner
ICT	Information and Communication Technology
ICT	Infection Control Team
ICU	Intensive Care Unit
ID	Identity
IEC	Information, Education and Communication
IMNCI	Integrated Management of Neonatal and Childhood Illnesses
IMPAC	Integrated Management of Pregnancy and Childbirth
IMS	Information Management Systems
ISMP	Institution for Safe Medication Practices
JCAH	Joint Commission for Accreditation of Hospitals
JCI	Joint Commission International
JD	Job Description
K	Potassium
KCl	Potassium Chloride
KPBTA	Khyber Pakhtunkhwa Blood Transfusion Safety Authority
KP HCC	Khyber Pakhtunkhwa Healthcare Commission
KPIs	Key Performance Indicators
LAMA	Leaving Against Medical Advice
LASA	Look-Alike, Sound-Alike
LDH	Lactate Dehydrogenase
LHV	Lady Health Visitor
LHW	Lady Health Worker
MCH	Maternal and Child Health
MCPS	Member of College of Physicians and Surgeons
MIS	Management Information System
MLC	Medico-Legal Cases
MLR	Medico-Legal Report

MO	Medical Officer
MOM	Management of Medication
MOU	Memorandum of Understanding
MNCH	Maternal, Neonatal and Child Health
MPhil	Master of Philosophy
MRCOG	Royal College of Obstetricians and Gynaecologists
MRCPath	Member of Royal College of Pathologists
MRI	Magnetic Resonance Imaging
MS	Medical Superintendent
MSDS	Minimum Service Delivery Standards
NGO	Non-Government Organization
NIC	National Identity Card
NMNCHP	National Maternal Newborn and Child Health Promotion
OEM	Original Equipment Manufacturer
OPD	Outpatient Department
OH&S	Occupational Health & Safety
OT	Operation Theater
OTA	Operation Theatre Assistant
PACS	Picture Archiving and Communication System
PACU	Post Anaesthesia Care Unit
PALS	Paediatrics Advanced Life Support
PAR	Post Anaesthesia Recovery
PCA	Patient Controlled Analgesia
PIP	Patient Identification Procedure
PHC	Punjab Healthcare Commission
PhD	Doctor of Philosophy
PM&DC	Pakistan Medical & Dental Council
PNAC	Pakistan National Accreditation Council
PNC	Pakistan Nursing Council
PNRA	Pakistan Nuclear Regulatory Authority
PPE	Personal Protective Equipment

PRE	Patient Rights and Education
QA	Quality Assurance
QC	Quality Control
QHA	Quality Holistic Accreditation
QI	Quality Improvement
RBC	Regional Blood Centre
RBS	Random Blood Sugar
ROM	Responsibilities of Management
RTA	Road Traffic Accident
RTAT	Radiology Turn Around Time
RTI	Reproductive Tract Infection
SAM	Self-Administration of Medicine
SMPs	Standard Medical Protocols
SOPs	Standard Operating Procedure
SSI	Surgical Site Infection
SSIS	Surgical Site Infection Surveillance
STI	Sexually Transmitted Infections
SVD	Spontaneous Vaginal Delivery
TNCC	Trauma Nursing Care Course
TORs	Terms of Reference
UK	United Kingdom
USA	United States of America
WHO	World Health Organization
WM	Waste Management
WMO	Woman Medical Officer
WMT	Waste Management Team

1. Introduction

The Government of Khyber Pakhtunkhwa promulgated the Khyber Pakhtunkhwa Health care Commission Act, 2015, to establish the Khyber Pakhtunkhwa Health Care Commission (KP HCC) as a regulatory body with the prime objective to improve the quality of healthcare services and ban quackery in Khyber Pakhtunkhwa in all its forms and manifestations. The KP HCC is legally mandated[1] to regulate all Health Care Establishments (HCEs) in the public and private sectors through registration and licensing. It is the responsibility of the HCEs throughout the province to get registered with KP HCC. Moreover, the KP HCC is ensuring to improve and maintain quality of healthcare through the implementation of Minimum Service Delivery Standards (MSDS). The HCEs are required to follow these standards in order to get license. No Health care Establishment can function legally without being registered and licensed by the Khyber Pakhtunkhwa Care Commission.

The KP HCC has adopted MSDS developed by the Punjab Healthcare Commission (PHC) for the three recognized systems of treatment; Allopathy, Homeopathy, and Tibb. These Minimum Service Delivery Standards include hospitals (Upto 30 beds, 31 to 49 beds, 50 and above beds), Basic Health Units, General Practitioners/Family Physicians/Specialist Clinics, Dental Clinics, Clinical Laboratories and Collection Points, Radiological/Imaging Diagnostic Centres, Homeopathic Clinics, Tibb Clinics.

Table 1: Categorization of Hospitals

Category	Bed Strength
Category 1	50 and above beds
Category 2-A	31-49 beds
Category 2-B	01-30 beds

1.1 Service Delivery Standards

Setting service delivery standards and indicators is an established practice for continually improving the provision of quality services in the health sector. Joint Commission International (JCI) in the USA is one such organisation that sets standards to improve the quality of health services. Likewise, the Quality Care Commission in the UK ensures clinical governance with the help of a system of setting standard and facilitating compliance. The Indian Public Health Standards' were introduced in 2005 and since then the Quality Council of India expanded their scope with the launching of Standards for the Health and Wellness Industry in 2008. The Australian Council on Healthcare Standards was initiated in 1974 that has facilitated the development of the New Zealand and Singapore Councils. Accreditation Canada (formerly the Canadian Council on Health Services Accreditation) became independent from the Joint Commission for Accreditation of Hospitals (JCAH) in 1953. The Quality Holistic Accreditation

[1] Khyber Pakhtunkhwa Health Care Commission Act, 2015

(QHA) Trent Accreditation Scheme is based in the UK and Europe and has serviced hospitals in Asia. Internationally accredited hospitals can be found in Pakistan, India, Bangladesh, Kazakhstan, China and Iran.

Standardization of healthcare services by implementing Minimum Service Delivery Standards is however, a newer concept in Pakistan, and Khyber Pakhtunkhwa province has taken the initiative by establishing the Khyber Pakhtunkhwa Health Care Commission.

The primary objective of developing MSDS is to set a benchmark for health care establishments to become eligible for the grant of a license by the KP HCC. These standards are primarily designed to regulate the premises in terms of the various functional areas to improve quality of healthcare services. The issuance of a certificate of registration, allowing the health practitioners according to their mandate, however, remains the responsibility of their respective council/commission in accordance with their statutory provisions.

1.2 Reference Manual Category 2-B Health Care Establishments

Category 2-B Health care Establishments are hospitals having 01 to 30 beds. In order to meet its legal obligations towards all recognized systems of healthcare, the Commission has developed the Minimum Service Delivery Standards and Indicators for implementation at Category 2-B Hospitals/Health Care Establishments (HCEs). The document comprises 30 standards with 122 associated indicators grouped in 10 universally accepted Functional Areas for such services along with Reference Material and Assessment Scoring Matrix. Keeping in view the ground realities, these standards have been kept **dynamic** and subject to evidence based improvement. All aspects of implementation, assessment and scoring have been included in this single document to better facilitate the implementers at HCEs as well as the surveyors involved in inspections.

A **Colour Coding** scheme has been introduced to facilitate the Hospital/HCE staff responsible to implement and assess implementation status at their own level before formal assessment by the KP HCC. The RED indicators are required to be fully implemented and have been ascribed 100% weightage, while YELLOW requires partial compliance at least to the extent of 80%. This is acceptable level to qualify for a license from KP HCC. Following scoring scale shall be used for Self-Assessment by the HCE staff as well as by the KP HCC Assessors:

Lowest			**Shades of Levels of Implementation**							**Highest**
0	1	2	3	4	5	6	7	8	9	10

The compliance level for Category 2-B hospitals/HCEs is 100% for some indicators, while others require partial compliance of 80%. 89 indicators require full compliance and have ascribed 100% weightage while 33 are acceptable even at partial compliance at least to the extent of 80% (ascribed 80% weightage).

Assessment Scoring Matrix is given at the end of each standard and related set of indicators. The HCE staff is advised to have self-assessment to ensure complete implementation, before the KP HCC assessors carry out formal assessment and score the HCE for licensing on the basis of criteria described above. Summary Scoring Matrix is given at **Annexure A**.

PART 2
STANDARDS, INDICATORS AND ASSESSMENT SCORING MATRIX

2. STANDARDS, INDICATORS AND ASSESSMENT SCORING MATRIX

2.1 Responsibilities of Management (ROM)

05 Standards & 11 Indicators

These standards provide the structure to help leaders effectively work together to enhance organizational performance. To meet their obligations effectively, leaders/managers must collaborate, which means working together in a spirit of collegiality to achieve a common end. Good relationships thrive when leaders work together to develop the mission, vision, and goals of the organization, encourage honest and open communication, and address conflicts of interest.

Many hospitals have three leadership tiers, the governing body, senior managers and clinical staff who work together to deliver safe and high quality care. The leadership standards address topics such as creating a culture that fosters safety as a priority; planning and providing services that meet patient needs; ensuring availability of the physical, financial and human resources necessary to provide care and engaging in performance improvement. The standards make clear that management of these functions is the direct responsibility of all leaders and that a well-functioning relationship amongst the leadership tiers enhances the quality of care provided to the patients.

Standard 1. ROM-1: Hospital is identifiable as an entity, easily accessible and the staff on duty is identifiable.

Indicators (1-4):

Ind 1. The Hospital is identifiable with name, and KP HCC Registration / License number on sign board(s).

Survey Process:

The essence of the indicator is to ascertain that any one approaching the Hospital is able to locate it with the help of sign board(s)[2] having clearly written "Name," Discipline(s) / Specialty of the Hospital and the Registration/License number[3] issued by KP HCC as the case may be. Surveyor is required to assess this indicator while approaching the Hospital from a distance of about 30-40 Meters.[4]

Scoring:

- If there is a sign board(s) with clearly written Name of the Hospital, its Discipline(s) / Specialty and the KP HCC Registration/License number visible from a distance as above, then score as **fully met OR** if there is a main sign board/s with clearly written Name of the Hospital and the specialties in the hospital and the KP HCC Registration/License number displayed on a board inside [5] the HCE, then also score as **fully met.**
- If there is no sign board or there are non-conformities to above, then score as not met.

GUIDELINES

Identification of the HCE

Identification of the HCE is of paramount importance. It is an essential requirement that every HCE can be clearly identified by its name, discipline and status of registration / license from KP HCC. It shall create a positive impact of the HCE in terms of its being a legitimate Healthcare Service Provider while excluding those who are not qualified/authorized to practice.

HCEs are required to install appropriate boards taking into consideration safety measures and fulfilling legal/codal Municipal requirements including:

1. Size of the board in relation to the HCE building.
2. Location and fitting strength of the board in view of the wind.
3. Clear visibility from the approach road.

[2] Registration/license number can be on the main sign board or on separate smaller board or plate as considered feasible and the detailed list of specialties on a board is prominently displayed inside the hospital.
[3] All HCEs are required to get registered with KP HCC vide Section 12 of KP HCC ACT, 2015.
[4] Minimum 3x4 ft. size of the board is recommended.
[5] Relaxation in terms of displaying KP HCC Registration/License number on the main sign board is for initial ONE year.

Ind 2. The hospital is easily accessible to the people.

Survey Process:

Surveyors are to see that the hospital is easily accessible to the patient(s)/public. Main entrance is free from encroachments as far as possible[6] to facilitate smooth access to the Ambulances/Transport/Fire Fighting Vehicles in emergency[7] (Link FMS Ind. 17-20). Stretcher and wheelchair should be available at the entrance of the HCE with a RAMP to facilitate movement of the old / disabled people and emergency patients.

Scoring:

- If the HCE is accessible and there are arrangements as above, then score as **fully met.**
- If the HCE is not easily accessible as above but there are visible efforts for improvement by the management to improve the situation, then score as **partially met.**
- If the HCE is not easily accessible to patient/in emergency and there are no efforts on record by the management to improve the situation, then score as **not met.**

GUIDELINES

Location and Accessibility

There is a tendency of encroachment on the in/out gates of the HCEs by the shops, Taxis/Rickshaws and other vendors which hinders the traffic flow and passage of the patients. This scenario needs intervention by the management of the HCE who should coordinate with concerned authorities for remedial actions. The management of HCE is required to facilitate access to the disabled and old aged patients through ramps for the movement of stretcher, wheel chair etc. The ramps should not be steep or slippery. Picture of non-slippery ramp is shown below:

[6] A Hospital should preferably not be located in a commercial building where other activities are also on going. The Hospital Administration will be responsible to coordinate in writing with the relevant authorities (traffic/ TMA etc.) to keep the approach road/gate cleared but no existing HCE will be closed down on this account. The record of existing HCEs shall demonstrate efforts/plans for improvement of accessibility to achieve the standard.

[7] All new constructions/conversions will be responsible to cater for this requirement.

Ind 3. Door plate(s) at clinics/offices clearly display name qualification(s) and designation(s) of the staff[8] on duty.

Survey Process:

Observe the placement of door-plate(s), clearly indicating the name, qualification(s) and designation(s) and the text on the plates in conformity with law/regulations/ethical guidelines of the respective councils (for the medical and nursing staff). It generally means, the registered name, authorized qualification(s) and specialty in full or with permissible abbreviations as the case may be are written.

Scoring:

- If all the door-plates are according to the above, then score as **fully met.**
- If about 80% of the door-plates are present and display full information as above, then score as **partially met.**
- If less than 80% of the door-plates exist/display information as above, then score as **not met.**

GUIDELINES

Door Plates

Easy Identification of various departments / sections / offices / service points with reference to the services being provided and the level of staff appointed / providing such services at those points at HCEs is essential to facilitate the patients / relatives. This is done by affixing plates outside the door/s with such written text which conveys the required sense. For example "Medical Officer," "Senior Medical Officer," "Medical Specialist," "Administrator," "Chief Executive Officer (CEO)" preferably with their names and authorized qualifications will suit and "Dressing Room" and" Nursing Station" without names would suffice as depicted below:

[8] Administrator, Charge Nurse / Matron, Laboratory Staff, duly supported by hospitals notifications / duty roaster/daily orders. This requirement is however relaxed, in respect of nursing and paramedical staff till their abundant availability in the market.

Ind 4. The Staff on duty uses identity badge.[9]

Survey Process:

Ascertain that every employee of the hospital[10] who is on duty can be identified by means of an identity badge having clearly written name/designation, specialty/discipline, where applicable duly signed & stamped by the issuing authority.[11]

Scoring:

- If the staff is using identification badges which clearly identifies the hospital staff as above, then score as **fully met.**
- If the authorized identification badge is not in use or there are non-conformities to above, then score as **not met.**

GUIDELINES

Staff Identity and Identity Badges

Personal Identities are known through the identity badges worn by the staff. The identity badge/s should provide correct and standardized information regarding particulars of the person to whom the card is issued to avoid impersonation.

Identification of the staff on duty at HCEs is essential because;

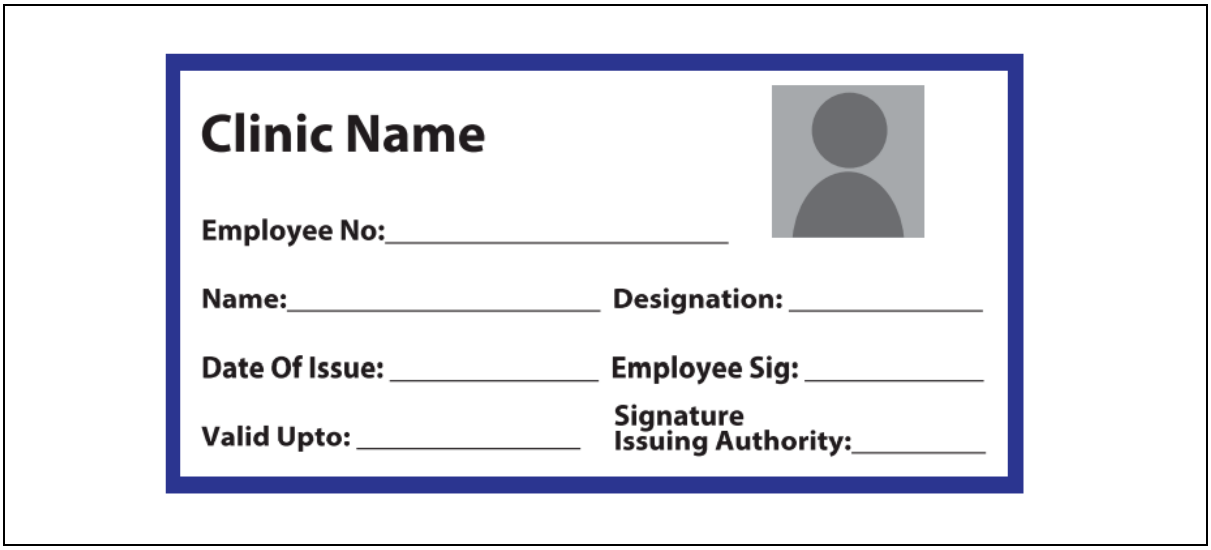
1. Patients/relatives have a right to know as to who is providing care to the patient.
2. For seeking follow up of treatment.
3. To provide feedback regarding quality of care.

The Medical Superintendent/Administrator of the HCE is responsible to finalize the specimen and to sign the identity badge. A sample format of the card is provided below for ease;

[9] Means a full identity card with photo and signatures to be issued by the Hospital/HCE.

[10] With the exception of female staff like nurses / lady doctors etc. who may not like their names / photos to be displayed, a modified system having designation and some number may be devised.

[11] Chief Executive/ Medical Superintendent or the Administrator.



Assessment Scoring Matrix

Standard 1. ROM. 1: Hospital is identifiable as an entity, easily accessible and the staff on duty is identifiable.

Indicator 1-4		Max Score	Weightage (Percent)	Score Obtained
Ind 1.	**The Hospital is identifiable with name, and KP HCC Registration / License number on sign board(s).**	10	**100**	
Ind 2.	**The hospital is easily accessible to the people.**	10	**80**	
Ind 3.	**Door plate(s) at clinics/offices clearly display name qualification(s) and designation (s) of the staff on duty.**	10	**80**	
Ind 4.	**The Staff on duty uses identity badge.**	10	**100**	
Total		40		

Standard 2. ROM-2: Responsibilities of the management are defined.

Indicators (5-8):

Ind 5. The individual who heads the Hospital has requisite qualifications and experience.

Survey Process:

Review the roles and responsibilities of the individual who is managing the hospital and assess if he/she has appropriate qualification and experience, to manage the portrayed services. In case a medical graduate heads the hospital as Medical Superintendent / Medical Director / Hospital Administrator / Chief Executive Officer (as whole time or by designating from within the medical team), he should at least have one-year experience (In addition to the experience as house officer). In case the hospital is managed by a non-medical professional, he should have a management qualification and manage the general administration only while the technical matters are to be managed by a technical advisor or technical committee designated from within the medical staff of the hospital, with clearly defined responsibilities.

Scoring:

- Score **fully met, unless** the survey team identifies significant deficiencies in the qualifications and experience.

GUIDELINES

Qualification and Experience of Hospital Administrators

Medical Superintendent/Medical Director/Administrator/In-charge of the Category 2 HCE should preferably be a Medical Graduate with 01 years' experience at a Government or Private Hospital preferably managed by a Medical Professional having Postgraduate Qualification in Hospital Management/Public Health. However, in case where the hospital administrator/manager is not a medical graduate, he/she should have a management qualification to manage the support services only while all technical matters related to patient care will be managed/supervised by the person/s having medical qualification and experience prescribed above. Following Job Description (JD) of a MS may be taken as a sample to prepare JDs for Medical Superintendent (MS)/Administrators of the same level Hospitals to suit the local needs.

1. **Job Summary**

   Medical Superintendent is the overall administrator in charge of hospital functioning. He exercises administrative and financial powers allocated to him under delegation of administrative and financial Powers / Rules. Responsible to the Government for all the functions of the Hospital. He achieves his goals by planning, budgeting, organizing, staffing, directing, coordinating, delegating, monitoring, controlling and regulating various functions. Ensures best possible medical services within the available resources. Evolves strategies to improve financial resources of the hospital and optimizes patient satisfaction.

2. Duties / Responsibilities

A. Administrative / Management

(i) Overall responsible for delivery of Respective scope of services

(ii) Ensures medical cover in emergency arising due to floods, heavy rains, epidemics or disaster situation like major accidents or earthquakes.

(iii) Sanctions leave of the officers/officials of the HCE as per delegation / Policy.

(iv) Constitutes a Continuous Quality Improvement Committee (CQI) Committee to make and execute Facility Health Plan/monitor to improve health care system and its delivery.

(v) Ensures regular maintenance / prompt repair of all the equipment of the hospital for keeping it in working order at all times.

(vi) Responsible for redressing the grievances of the public by taking quick & appropriate decisions.

(vii) Delegates powers to his subordinate administrative staff for smooth functioning of the hospital.

(viii) Responsible for developing and smooth functioning of the Information Management Systems through proper and timely collection of statistics from all source points Out Patient Department (OPD) / Indoor / Diagnostics etc.

(ix) Reviews the hospital services quarterly to know about lapses and takes measures to improve upon.

(x) Holds regular meetings with clinical staff/CQI in order to keep in touch with their problems if any, and to have an appraisal of the services provided by them.

(xi) Assigns duties to his subordinate administrative staff.

(xii) Leads the Infection Control Committee to ensure actions according to Standard Operating Procedures (SOPs).

(xiii) Adapts broader Policies/Protocols/SOPs to meet local requirements/ conditions to make those specific to the facility and ensures that every employee is conversant with these.

(xiv) Recruitment, promotion and transfer of staff within the hospital as authorized by the Hospital Policy.

(xv) Conducts round of the hospital at least once a day in order to meet the patients to ensure their satisfaction, find out their problems, to randomly check the patient charts to see written clinical notes of doctors & compliance of nurses, provision of medical facilities / treatment accordingly and ensure general cleanliness of hospital.

(xvi) Checks that expense book /log books/ Empty Vial drugs register is being maintained by the Charge Nurse/relevant staff.

(xvii) Conducts at least one surprise round of hospital departments and support services in a week in order to ensure that they are doing their Jobs as prescribed and are helping/supporting the clinical services to be delivered in conformance to Minimum Service Delivery Standards.

(xviii) Identifies the deficiencies in performance of the staff during visits and suggest corrective measures in consultation with relevant staff.

(xix) Ensures Review of the hospital record/reports and ensures corrective and

preventive actions.

(xx) Issues written Job Descriptions to each employee under their signatures and maintains that record.

(xxi) Initiates the Performance Evaluation Reports of the officers/officials of the hospital.

(xxii) Countersigns the Performance Evaluation Reports of the staff initiated by the officers under his direct control.

(xxiii) Ensures that hospital protocols and procedures are amended from time to time as per requirement / Government instructions.

(xxiv) Is aware of and ensure implementation of various health related Laws/Acts/Ordinances/ Regulations.

(xxv) Performs any other professional duty assigned by the relevant higher authority.

B. Financial

(i) Ensures timely submission of annual budget proposal from the hospital.

(ii) Ensures utilization of the budget in accordance with the Financial Rules/Policy.

(iii) Ensures that all types of receipts are timely deposited and record is accordingly maintained.

C. Logistics

(i) Participates as a member of procurement committee for procurement of the supplies and medicines.

(ii) Monitors the allocation and distribution of supplies and medicines within the hospital.

(iii) Responsible for keeping all the ambulances/equipment in running condition and getting timely repair of any out of order equipment.

D. Trainings

(i) Ensures appropriate training of concerned personnel for enabling them to perform duties effectively as laid down in the objectives of the health care deliverance.

(ii) Receives trainings as and when organized by the higher authorities.

Ind 6. The management appoints staff having qualifications according to the job description.[12]

Survey Process:

Review i. The hospital's scope of services,[13] ii. The job descriptions and iii. Credentials of the key hospital staff in that whether they fulfill the requirement of the job description. For example, review the roles and responsibilities of the individual who is heading the hospital and assess if the incumbent has appropriate qualification and experience to manage the portrayed services and connected requirements e.g. appointing qualified and experienced staff against various positions. Similarly the

[12] This indicator is applicable to every section of the hospital/HCE. However, in case of paramedics, it is relaxed till availability of sufficient qualified paramedics in the market subject to the condition that at least one qualified technical person is available in each discipline i.e. Lab Assistants, Opeartion Theatre (OT) Assistants, Radiographer etc.

[13] As portrayed within the assigned category.

heads of the sections, specialists and nurses / paramedics etc. are to have qualifications / experience commensurate to their respective roles.

Scoring:

- If all the staff appointments are as described above, then score as **fully met.**
- If 80% of the staff appointments are as described, then score as **partially met.**
- If less than 80% of the staff appointments are as described above, than score as **not met.**

GUIDELINES

Staff Appointment

The senior management e.g. Management Committee, a Board or the owner of the HCE as the case may be are responsible for appointment of the staff as depicted in the Organogram to ensure proper functioning of the system and to achieve the assigned goals. In doing so they ensure that the appointed staff has the requisite qualification(s) and experience to match the job requirements.

Ind 7. The Hospital management, monitors the performance of the Hospital.

Survey Process:

There should be indicators that allow objective monitoring of performance of the hospital. Review any documentation such as meetings of the senior administration of the hospital to review the performance of the hospital on the basis of the selected indicators and a prescribed checklist (template provided in the Reference Manual).

Scoring:

- If there is documentation of monitoring the performance of the hospitals on the basis of a prescribed checklist, then score as **fully met.**
- If there is no documentation, than score as **not met.**

GUIDELINES

Internal Monitoring and Evaluation

The HCE will be required to monitor the implementation of its performance and to report on progress towards achievement of defined objectives in line with the scope of services. As part of its monitoring responsibility, the HCE should prepare regular reports to identify the progress in terms of implementation.

Some of the questions which may be answered during the monitoring process are as follows:

Monitoring checklists may be developed related to the following areas:

1. Infrastructure(Building), Cleanliness
2. Human resource
3. Equipment
4. Scope of services being provided like OPD/ Indoor / Surgeries etc.
5. Functioning of the various Committees like CQI /Hospital Infection Control (HIC) /

Procurement etc.

6. Client satisfaction/ Client Exit Performa

Following table provides monitoring parameter format:

Table 2: Performance Monitoring Checklist Format

HCE PERFORMANCE MONITORING CHECKLIST FOR INCHARGE

Name of HCE: _____

Name of in charge:_____ Designation: _____

Date of inspection: / / Time:_____

Weekly Monitoring Tasks	Observation	Recommendation
General Cleanliness		
Washroom cleaned/Functional		
Drinking Water available		
Seating arrangement for patients		
UPS/Generator functional		
Staff Attendance: Attendance register/Biometric/ Movement register/Leave register		
Staff wearing identification badges		
Emergency room ready/ drug list/ essential supply		
Oxygen cylinder filled/ready		
Hospital waste disposed off properly		
Sterilization /Hand washing facilities		
Daily expense register maintained		
Patient registration/Guidance system		
Patients privacy ensured during consultation/examination		
Medicines are being labelled while dispensing		

Monthly /Quarterly Monitoring Tasks	Observation	Recommendation
Medicine store: • Storage as per guidelines		

• Expiry dates • Essential drug list updated		
Equipment functional status		
Fire-fighting arrangements		
Record review focus on		
Unique number, Completeness, accuracy, Authorization, Legibility		
Weekly/Monthly staff meetings conducted/Minutes recorded		
Complaint register maintained/Reviewed		
Any Sentinel event recorded		
Display of IEC Material		
High risk Obs Cases identification and documentation		
HCE/Patient rights charter displayed		
Leave register maintained		

View	Number of persons contacted in OPD/ Field	**PUBLIC OPINION**			
		Good	**Average**	**Unsatisfactory**	**No Response**
Presence of Doctors/Staff					
Attitude of staff towards patients					
Waiting Time					

No.	**Name**	**Address**	**Contact Number**

GENERAL REMARKS

Signature of In-charge with Designation

Ind 8. The management addresses the Hospital's community and social responsibilities.

Survey Process:

The HCE needs to be sensitive to the health requirements of the community it serves. Private HCEs are also expected to provide Basic Life Support (BLS) according to their capacity, to those who fall victim of accidents / emergencies or are hit by natural disasters in its catchment area before referring them to public sector facilities. It may also include participation in awareness campaigns e.g. seminars, walks and organizing medical camps for health promotion and disease prevention.

Look for documents that demonstrate that the hospital is aware and has shown sensitivity towards its community's healthcare needs through voluntary activities such as, awareness campaigns, medical camps (onsite / off site) and providing aid to people hit by calamities etc. if it occurred.

Scoring:

- If there is evidence that the hospital is sensitive to the social responsibilities mentioned as above, then score as **fully met.**
- If there is NO evidence to the above effect, than score as **not met.**

GUIDELINES

Social and Community Responsibilities

The HCE should be sensitive to the needs of the community it serves and should demonstrate awareness about prevalent health related problems in its catchment area. The demonstration may be in the form of some record that confirms voluntary "out-reach" activities catering for community's health needs such as providing out door health care by medical camping, awareness campaigns and providing aid to people hit by Calamities etc.

Private Sector HCEs are also expected to provide lifesaving care to those who fall prey to accidents/emergencies while in the close proximity of Private HCE, as transportation of a serious patient to a Public Sector HCE for want of free treatment may be at the cost of patient's life. The expected social responsibility of an HCE would be limited to providing basic life support (BLS), documenting the life saving measures taken, and referring the patient to the appropriate facility.

HCEs are expected to use the potential of Civil Society Organizations (CSOs)/Non-Government Organizations (NGOs), as they are always willing to contribute in such activities.

1. The organization should have SOPs for handling a sudden rush of victims of Natural Calamities and Disaster Situations like:
   A. Earthquakes
   B. Floods
   C. Hurricanes
   D. Plane Crashes
   E. Train Accidents
   F. Civil Unrest Outside The Organization's Premises
   G. Terrorist Attacks
   H. Bomb Blasts
   I. Major Fires
   J. Enemy Actions/War, etc.
2. The SOPs to ensure adequacy of medical supplies, equipment, materials, trained and

identified personnel, transportation means, communication aids and Mock Drill Methodology. a. The HCE should have a documented SOPs/Guidelines which incorporates required staffing, resources, roles & responsibilities Reports/Pictures of the activities performed must be available with the management. A reporting format is provided below;

Table 3: Social & Community Responsibility Report

SOCIAL & COMMUNITY RESPONSIBILITY ACTIVITY REPORT	
Name of HCE:	Date:
Name of Event:	
No. of participants / patients. Detail of event [Walk/Seminar/Medical Camp/ Road Traffic Accident (RTA) etc.]	
Outcome:	
Name of reporting officer:	
Designation:	
Signature:	

Assessment Scoring Matrix

Standard 2. ROM-2: Responsibilities of the management are defined.

Indicator 5-8		Max Score	Weightage (Percent)	Score Obtained
Ind 5.	**The individual who heads the Hospital has requisite qualifications and experience.**	10	**100**	
Ind 6.	**The management appoints staff having qualifications according to the job description.**	10	**80**	
Ind 7.	**The Hospital management, monitors the performance of the Hospital.**	10	**100**	
Ind 8.	**The management addresses the Hospital's community and social responsibilities.**	10	**100**	
Total		40		

Standard 3. ROM-3: Hospital premises support the scope of services and is adequately maintained.

Indicators (9-11):

Ind 9. The Hospital space is in accordance with the minimum requirement.

Survey Process:

Observe that the clinical and non-clinical areas have well demarcated space sufficient to cater for the minimum requirements to allow performing the functions related to patient care and support services and to allow comfortable sitting and movement for patients / staff between various areas[14] and that the premises is adequately maintained.

Scoring:

- If the hospital premises has well demarcated portions to cater for the portrayed clinical as well as the support services, it is adequately maintained and patients are comfortably placed, then score as **fully met.**
- If the hospital has well demarcated portions to cater for the portrayed clinical as well as the support services but the premises is not adequately maintained or is visibly overcrowded, then score as **partially met.**
- If the hospital does not have well demarcated portions to cater for the portrayed clinical and support services and the premises is not adequately maintained and is visibly overcrowded, then score as **not met.**

GUIDELINES
Hospital Space Parameters Clinical and non-clinical areas must have well demarcated space sufficient to cater for the minimum requirements to allow performing various administrative and service related functions. Comfortable sitting may include a comfortable posture and not touching each other while comfortable movement may include not hitting when crossing each other. Minimum 10 patients may be considered to be catered at a time in the waiting area of this level of HCEs. Per bed covered area prescribed by the Architect office Government of the Khyber Pakhtunkhwa for public sector hospitals may be followed as guidance but not as binding for the existing HCEs.

Ind 10. Hospital has adequate facilities and civic amenities for the comfort of the patients and attendants and these are adequately maintained.

[14] Comfortable sitting may include a comfortable posture and not touching each other. Comfortable movement may include not hitting/touching each other when crossing each other. Minimum 10 patients may be considered to be there in the waiting area at a time.

Survey Process:

During survey observe the presence and maintenance of the following in the Hospital:

1. Sitting arrangement in OPD, waiting areas & bedside attendants.
2. Alternate arrangements of electricity, at least emergency lights for all patient areas and an appropriate electric generator for Operation Theatre (OT), Emergency, Labor Room, Intensive Care Units (ICUs)/ Cardiac Care Units (CCUs) etc.
3. Waste container /receptacle(s).[15]
4. Proper ventilation.
5. Mosquito and fly proofing (wire gauze).
6. Clean drinking water.
7. Toilets with adequate washing and bathing facilities.
8. Air conditioning in OTs, ICU / CCU and labour room etc.
9. Parking place.
10. Playing areas preferable for admitted children (where applicable).

Scoring:

- If the hospital has facilities from 1 to 9, and these are adequately maintained then score as **fully met.**
- If any one of the facilities stated at serial No. 1 to 8 is not existing, then score as **not met.**

GUIDELINES

Adequacy of the facilities

Hospitals/HCEs are a public place where sick and wounded come for seeking medical care. As such the patients and relatives have to spend varying lengths of times at the HCE during which they are required to remain comfortable for which basic amenity provision becomes essential. The provision of amenities and facilities varies at various HCEs according to their charging rates. However every HCE is required to provide certain basic requirements like proper reception and sitting arrangements in OPD, waiting areas & bedside. Similarly alternate arrangements of electricity, at least emergency lights for all patient areas and electric generator for OT, Emergency, Labor Room and ICUs/ CCUs etc., waste container /receptacle(s), proper ventilation, mosquito and Fly proofing (Wire Gauze), Clean drinking water, toilets with adequate washing and bathing facilities and air conditioning where ever required.

Ind 11. Hospital has adequate arrangements for the privacy of patients during consultation / examination / procedures etc.

Survey Process:

Observe if arrangements for patient's privacy during consultation/examination and performing

[15] As per the Khyber Pakhtunkhwa Hospital Waste Management Rules, 2018 (amended from time to time) framed under the Environment Protection Act.

procedures are available and patient's privacy is respected.[16] It is unethical / undesirable to even take history when other unrelated persons are overhearing. The history taking and examination should not be visible to any unrelated person by any means.

Scoring:

- If the arrangements for patient's privacy during consultation / examination and performing procedures are adequate and ethical requirements are observed, then score as **fully met.**
- If arrangements for privacy are not available or if the ethical requirements are not observed, then score as **not met.**

GUIDELINES

Privacy of Patient

The script from the Hippocratic Oath signifies the entire concept of the privacy of the patient as follows:

"……I will respect the privacy of my patients, for their problems are not disclosed to me that the world may know……."

Privacy of the patients during conduct of examination for assessment is a key component of the clinical methodology taught to medical students. Respecting privacy and confidentiality of the patient/s is an integral part of the Code of Ethics of Pakistan Medical & Dental Council (PM&DC) reproduced below:

"Section 17. Examination, consultation or procedures on a female patient:

1. A female patient shall be given consultation either by a female medical or dental practitioner or shall be examined in the presence of a female attendant by a male doctor. Under no circumstances a male attendant, assistant or husband or relative etc. shall be allowed during a gynecological and obstetrical consultation, examination or during normal delivery being conducted by a female medical practitioner. However, in exceptional circumstances a patient may file a request with the medical practitioner to allow her husband to witness a normal delivery and the medical practitioner may consider the request and shall ensure that sanctity of the female patient is preserved during procedures and consultation and there is no unnecessary exposure.

Permission of patient before examination:

A doctor shall normally take permission from a patient before making a physical examination. In case of minors, the child's guardian shall be present or give permission for the examination. For any intimate examination the patient, irrespective of age, is entitled to ask for an attendant to be present. Such requests shall be acceded to whenever possible.

Confidentiality:

The physician has a right to and shall withhold disclosure of information received in a confidential

[16] Female patient and minors are not examined alone. In such an event another female/ attendant should be requested to remain present. Patients' verbal consent is obtained, before or during examination, conversation during history taking is not audible and interview/examination place not visible to others not concerned.

context, whether this is from a patient or as a result of being involved in the management of the patient, or review of a paper, except in the following specific circumstances where he may carefully and selectively disclose information where health, safety and life of other individual may be involved, namely:

1. The medical or dental practitioner cannot seek to gain from information received in a confidential context (such as a paper sent for review) until that information is publicly available;
2. There is no legal compulsion on a doctor to provide information concerning a criminal abortion, venereal disease, attempted suicide, or concealed birth regarding his patients to any other individual or organization. When in doubt concerning matters which have a legal implication, the medical or dental practitioner may consult his/her legal adviser;
3. The professional medical record of a patient shall not be handed over to any person without the consent of the patient or his/her legal representative. No one has a right to demand information from the doctor about his patient, save when the notification is required under a statutory or legal obligation and when in doubt, the medical or dental practitioner or a dentist may consult a legal advisor;
4. Confidences concerning individual or domestic life entrusted by patients to a medical or dental practitioner and defects in the disposition or character of patients observed during medical attendance shall never be revealed unless their revelation is required by law;
5. A medical or dental practitioner who gains access to medical records or other information without consent shall be guilty of invasion of privacy; and
6. The medical or dental practitioner who grants access of an information of a patient to a third person except, Councilor law enforcing agencies, without consent shall be guilty of breach of confidentiality, but where a medical or dental practitioner is of the opinion to determine it his duty to society requiring him to employ knowledge about a patient obtained through confidence as a medical or dental practitioner, to protect a healthy person against a communicable disease to which he is about to be exposed, the Medical or dental practitioner shall give out information to concerned quarters.

Taking of photograph or videos for teaching purpose:

Taking the written informed consent to take the patients' photographs and videos in such a manner that a third party cannot identify the patient concerned. If the patient is identifiable, he or she shall be informed about the security, storage and eventual destruction of the record.

Assessment Scoring Matrix

Standard 3. ROM-3: Hospital premises support the scope of services and is adequately maintained.

Indicator 9 - 11		Max Score	Weightage (Percent)	Score Obtained
Ind 9.	**The Hospital space is in accordance with the minimum requirement.**	10	**80**	
Ind 10.	**Hospital has adequate facilities and civic amenities for the comfort of the patients and attendants and these are adequately maintained.**	10	**100**	
Ind 11.	**Hospital has adequate arrangements for the privacy of patients during consultation/ examination/procedures etc.**	10	**100**	
Total		30		

2.2 Facility Management and Safety (FMS)

03 Standards & 9 Indicators

A hospital not only serves the medical needs of the society but even generates revenues that are utilized in meeting expenses and further expansions. With every passing day, the need to have excellent hospitals is on the rise. The focal point is that in a hospital there is no second chance as we are talking of human lives, so it is desirable that laboratories and theaters are in prime working condition and precision of all equipment is at the highest level. It is imperative to let professionals handle and maintain these facilities in accordance with the relevant standards because reliability, professionalism and the sustainable reputation of the hospital relies on these services and facilities.

Healthcare facility management is constantly required to maintain a clean and healthy environment. Maintenance plays a major role in keeping the hospital running in an orderly fashion. Healthcare facilities can use software to figure out how much is being spent on generators and expensive surgical equipment, parts of the building or type of maintenance problem, to enhance their efficiency and drag-and-drop labor calendars to efficiently manage overtime costs. Service requests need to be responded to quickly and efficiently and preventive maintenance schedules need to be set up in order to provide a clean, healthy environment, without interruption.

Standard 4. FMS-1: The Hospital is aware of and complies with the relevant laws, rules, regulations, bylaws and relevant building / associated codes applicable to hospitals.

Indicators (12-13):

Ind 12. The management is conversant with the relevant laws and regulations.

Survey Process:

Check to see that management is conversant with and have copies of the updated relevant laws and regulations, including building codes/specifications, fire safety requirements, codes for inspection of lifts/elevators, boilers (where applicable), handling of contaminated & nuclear waste, clean water supply, sanitation, ventilation, safe food, safe pharmaceuticals etc.

Scoring:

- If there is clear evidence that the management is conversant with the above laws, rules, regulations, bylaws and codes/specifications etc. and that these are implemented, then score as **fully met.**
- If there is no evidence of applied knowledge of above legal and regulatory requirements, then score as **not met.**

GUIDELINES

Applicability of Laws and Regulations to HCE

List of the relevant laws with the links to download is provided at **Annexure B**.

The basic design of a HCE is ideally required to support its functions e.g.

1. Emergency services
2. Outpatient-related functions
3. Indoor facilities
4. Diagnostic and treatment activities
5. Pharmacy services
6. Administration/Hospital management
7. Support and supply services
8. Catering services
9. Civic services
10. Parking areas
11. Horticulture

The legal aspect is one of the most significant considerations in planning and designing a project. Architects, engineers, planners, economists and those in allied professions must have working

knowledge of the applicable laws, rules and regulations and relevant codes before they can practice their profession.

In the private sector hospital buildings are designed by the architectural firms in accordance with the Local Development Authorities/local government Codes.

In either case, designing and planning of the hospital should be done in accordance with the relevant laws/regulations and codes including the following:

1. Zoning Regulations

With the land-use map, this regulation (Guidelines for Development and Operations) ensures that the site selected is located in the area appropriate for the intended use. A planner/designer who designs a site plan must consider the following aspects of the project while remaining within zoning restrictions of the law pertaining to the locality:

A. Access and accessibility.
B. Catchment area to be served.
C. Volumetric dimensional limits of the building in terms of site coverage.
D. Building height.
E. Distance of other facilities and utilities required.
F. Easements and rights of way, if any.
G. Sources of materials and of local skilled and unskilled labour.

Although such regulations constrain design, they also establish the criteria that help to evolve a design which is consistent with the overall plan for the community, without disturbing the local ethos and environment while ensuring safety.

2. Building Code

The building code is provided to achieve the maximum safety and to establish standard requirements for the construction of buildings that can withstand powerful earthquakes and other calamities. It contains provisions for:

A. Classification and general requirements for hospital by use or occupancy.
B. Types of construction.
C. Light and ventilation.
D. Labour safety and welfare during construction.
E. Sanitation.
F. Electrical and mechanical regulations.
G. Design, keeping in view of history of incidence of earthquakes, cyclones and other disasters/calamities.
H. Protection from ionizing radiation from X-ray equipment.
I. Permits and inspection requirements.
J. Any other code prescribed by State.

3. Fire code

The fire code should be provided by the Civil Defence/Rescue Department, however the following provisions of the fire code must be adhered to in order to minimize injury, death, and loss to the staff, patients and families and also to curtail damage to hospital infrastructure:

A. General precautions against fire.
B. Principles of fire safety in buildings/structures.

C. Fire protection appliances.
D. Maintenance of fire exits.
E. Purpose specific design of high-risk building, such as theatres and auditorium etc.
F. Suppression control in hazardous areas.
G. Specifying smoking areas as per provisions of relevant Law/Rules.
H. Management and use of combustible materials.

4. Other codes

Other relevant bylaws, regulations and codes include sanitation codes, environmental protection laws and water codes. These vary in form and content according to the requirements and need of the hospital. By complying with these, the planner and designer should ensure that:

A. Design is consistent with the national/international standards for Public Health and Safety.
B. The permits and licenses necessary for establishing the hospital, related to above mentioned codes, are obtained.

5. Inspection of Hospital Design

Hospital administration can hire some professional private construction company for inspection of the building design in addition to the indigenous systems of inspection. During inspection, application of National/International Building Codes (IBC), where necessary, must be checked in addition to the following parameters:

A. The land or site upon which hospital is being constructed.
B. Design or structure of the hospital.
C. Use of standardized raw material and its consumption.
D. Methods of construction or workmanship.
E. Sanitation codes, environmental protection laws and water codes.
F. Minimum standards for the width/size of the doors, aisles, passageways, stairways, or other means of exit.

Structural strength or the stability of the building to withstand any damages by fire, earthquake, wind, flood, or by any other cause.

Ind 13. The licenses / registrations / certifications are current and there is a mechanism to regularly update the same.

Survey Process:

Directly observe and note the validity and currency of the range of compliance documents e.g. licenses / certificates for radiology equipment, lifts, boilers and diesel generator sets and maintenance of log book / tracker sheet for this purpose.

Scoring:

- If the full range of compliance documents is current / valid, then score as **fully met.**
- If there is a full range of compliance documents however, about 20% are not current, then score as **partially met.**
- If the range of incomplete compliance documents is exceeding 20% or if above 20% are not

current, then score as **not met.**

GUIDELINES

Renewal of Licenses and Certifications

This Indicator applies to the renewals of licenses/certifications for Radiology Equipment, Lifts, Diesel Generating sets, etc. The organization should maintain a Log Book/Tracker Sheet for this purpose.

A designated official/staff member should be made responsible to enlist the licenses / registrations / certifications required under the laws and regulations applicable to the HCE. This official in turn could identify the appropriate personnel in the organization who can be made responsible to implement the respective laws and regulations ensuring the timely renewal of the pertinent licenses/certificates.

Assessment Scoring Matrix

Standard 4. FMS. 1: The Hospital is aware of and complies with the relevant laws, rules, regulations, bylaws and relevant building/associated codes applicable to hospitals.

Indicator 12-13		Max Score	Weightage (Percent)	Score Obtained
Ind 12.	**The management is conversant with the relevant laws and regulations.**	10	**100**	
Ind 13.	**The licenses / registrations / certifications are current and there is a mechanism to regularly update the same.**	10	**80**	
Total		20		

Standard 5. FMS-2: The hospital/HCE has a program for management of equipment for clinical and support services.

Indicators (14-16):

Ind 14. The Hospital/HCE plans for equipment in accordance with the scope of its services.[17]

Survey Process:

Review the documentation that includes at least: i. Inventory of ALL medical equipment in the hospital, ii. Installation/testing report, iii. Planned preventive maintenance, iv. Log books in respect of all medical equipment and iv. An evidence of a formal write-off process. While visiting patient care areas, identify five pieces of medical equipment and ask for documentation that the equipment is listed on the hospital's inventory. Preventive maintenance plan should include in house as well as outsourced maintenance arrangements.[18]

Scoring:

- If there is documented evidence as above, then score as **fully met.**
- If the documented evidence does not include testing prior to use, or there are inadequate skills for implementation of the above requirements, then score as **partially met.**
- If the documented evidence does not include the preventive maintenance plan or if there is no inventory of medical equipment, then score as **not met.**

GUIDELINES

Equipment Procurement Planning

While planning for selection and procurement of the type, number and specifications of various equipment to be installed in the HCE, the organization must keep into consideration the; i. Scope of services to be provided.

1. Catchment population to be served.
2. Burden of disease in the pertinent location.
3. Future expansion/up graduation requirements.

The plans and SOPs regarding equipment selection and procurement should be periodically reviewed and revised.

The HCEs shall ensure that the record regarding purchase and maintenance of equipment and machinery is properly documented and maintained. The facilities shall ensure that no equipment is non-functional/out of use merely for want of minor repairs, preventive maintenance, lack of

[17] Generic detail provided in the Guidelines.

[18] In case of in-house maintenance, staff training and availability of service manuals, required tools, parts and consumables to deliver the required preventive maintenance and servicing regime needs to be ensured. For the maintenance which is beyond the scope of in-house maintenance staff, outsourced arrangements need to be ensured.

essential spares and electrical faults etc. Important factors resulting into gross equipment wastage may also include the following:

1. Mishandling of equipment.
2. Untrained and unskilled manpower.
3. Purchase of highly sophisticated equipment without competent personnel to handle it.
4. Purchase of excess equipment without a justifiable demand.

This calls for an efficient system for equipment management in the form of carrying out the Equipment Audit. In other words, there is a need for periodic evaluation of the quality of performance of the equipment in a hospital. Some of the advantages of equipment audit include:

1. It helps in standardization of the equipment.
2. Concurrently evaluates performance and utility.
3. Provides a satisfactory mechanism to assist phasing out/condemnation.
4. The equipment audit reports provide an objective method for procurement of equipment in future.
5. To identify inadequacies and recommend remedial measures.
6. Cost per reportable result and cost effectiveness can be evaluated.

Equipment Procurement Committee

The Equipment Audit Committee may comprise of:

1. Health facility in-charge
2. User Head of Department (HoD) or representative
3. Technician
4. The matron or representative

The Equipment Procurement Committee shall meet once in three months and select its chairperson and secretary from among the members in the first equipment performance audit. Maintenance of the history sheet and its subsequent write-up is sine-qua-non for performance of the equipment audit by the committee. A Format of the History Sheet and Log Book is given on the following page.

Table 4: Equipment History Sheet

HISTORY SHEET	
No.	**Description**
1.	Name of Equipment
2.	Date of Purchase
3.	Cost of Equipment
4.	Name and Address of Supplier
5.	Date of Manufacture
6.	Date of Installation
7.	Department where installed
8.	Environmental Control*
9.	Spare parts inventory
10.	Technical Manual/Circuit Diagrams/Literature
11.	After Sale Service arrangement
12.	Warranty period

13.	Life of Equipment
14.	Depreciation per year
15.	Charges of Tests**
16.	Cost of maintenance
17.	Date of Condemnation
18.	Date of Replacement
19.	Other Relevant Remarks

* Proper environment control in terms of temperature, lighting, and ventilation should be ensured and recorded, wherever applicable.
** Wherever applicable, charges of tests must be specified.

The various parameters to be considered in equipment audit procedure are as follows:

Table 5: Equipment Log Book

LOG BOOK							
No.	**DESCRIPTION**						
	Name of Equipment	**Warranty Period**	**Validity Period of maintenance contract**	**Date of breakdown**	**Date of repair**	**Cost incurred**	**Details of Preventive Maintenance**
1.							
2.							
3.							

Procurement

The following need consideration:

1. Need assessment - Was the equipment required? What was the use coefficient of the equipment?
2. Were the technical specifications worked out and provided by user department?
3. Were the same specified in the tender notification?
4. Was the receipt of equipment as per the specifications of the supply order?
5. Was availability of spares ensured, after services contract specified and training arranged?

Performance

History sheet and log book may be gainfully utilized for this. It is essential that periodic scientific evaluation of the quality of performance of the equipment is carried out. The process of equipment audit will also prove to be an indispensable tool in formulating standards/specifications of medical equipment and in establishment of bench marking for medical equipment.

Maintenance or 'planned preventive maintenance' is regular and repetitive work done to keep equipment in good working order and to optimize its efficiency and accuracy. This activity involves regular, routine cleaning, lubricating, testing, calibrating and adjusting, checking for wear and tear and eventually replacing components to avoid breakdown. Productive preventive maintenance refers to the proper selection of equipment to be included in planned preventive maintenance. Decisions must be made on what to include and to reduce costs (consideration is cost-

effectiveness).

An important aspect of planned preventive maintenance is the participation and commitment of the user (Planned Preventive Maintenance). Preventive maintenance should start with users, and the bulk of the work should be their responsibility. The task must be performed daily, with joint activities involving the user and a technician engineer at the end of the week. Highly technical repairs, which are the engineer's responsibility, may be scheduled every six months or on a need basis.

Equipment Inventory

All relevant information about the equipment must be entered, including its location, records of repair and maintenance, and the manufacturer.

A reference number is given and written on a printed paper label, which is attached to each item. This number is recorded in a ledger of equipment with full identifying details.

All equipment in the hospital that is in the care of the hospital service workshop should be recorded on registers or cards, as shown in the format ahead.

Table 6: Sample Equipment Service History Format

Sample Equipment Service History Form									
Name of facility						**EQUIPMENT FUNCTION**			
Location									
Department									
Name of equipment:				Approved by:		Date installed			
Manufacturer						Manuals			
Distributer.				Power: V A no. of wires.		Freq. of P.M			
Model No.				Type of enclosure:		Remarks			
Serial No.				Type of Plugs:					
Date	C/P	WO. No.	LEAKAGE		WORK DONE	Work By	Total labour hours	Parts Cost	Remarks
			GRD	O.GRD					
C = Curative repair., P = Preventive repair., V=Volts., A=Ampere., WO.=Work Order., No.= Number., GRD=Grid., O.GRD=Off Grid., Leakage = Leakage Current									

Ind 15. Qualified and trained personnel operate and maintain[19] the equipment.

Survey Process:

To determine if appropriate personnel operate and maintain the equipment correctly, look for documented training and any data in the medical equipment department that identifies "user error."[20] Also review the job description of personnel deputed to operate and /or for maintenance of medical equipment and their personal files to verify that they have the required qualifications, knowledge and experience.

Scoring:

- If the staff are adequately qualified/trained and experienced to operate / maintain all equipment within the scope of their ability and other equipment is serviced by contracted experts, then score as **fully met.**
- If there is an evidence that staff are adequately qualified/trained and experienced to operate all equipment within the scope of their ability and a system of planned preventive maintenance but there are issues with the ability of the in house staff / contracted maintenance experts, then score as **partially met.**
- If the in house staff operating the equipment or contracted maintenance experts have inadequate expertise, then score as **not met.**

GUIDELINES

Qualified and Trained Operators

Every HCE shall ensure that all the equipment installed in the facility are operated by appropriately qualified, trained and skilled staff. The HCE should ensure that arrangements for proper calibration and maintenance of equipment are in place. Ideally, the HCE shall establish a Biomedical Engineering Department under the supervision of a qualified Biomedical Engineer/Instrument Technician. This department shall provide calibration, repair and backup support to the end users. Private hospitals may make contract arrangement with some outside firm or may establish their own department.

[19] In view of the shortage in the market, this condition in terms of qualification of paramedical staff operating the equipment is relaxed, to the extent that currently at least one qualified person in each category i.e. Lab. Assistant, Radiographer, OT Assistant etc. supported by the self -trained staff will fulfill the requirement subject to the certification by the supervising expert/ doctor in respect of knowledge and expertise/skills of such person(s).

[20] Equipment failures due to incorrect use is common in hospitals.

Ind 16. Equipment is periodically inspected, serviced and calibrated to ensure its proper functioning. There is a documented operational and maintenance (preventive breakdown and replacement) plan.

Survey Process:

The indicator requires a written schedule for inspection, servicing and calibration of the equipment based at least on manufacturer's recommendations.[21] The periodical inspection, calibration and maintenance are to be documented[22] in the log book. The surveyors should review the documentation including at least a certificate from the management / end user to the effect that periodic preventive maintenance i.e. inspection, servicing and calibration has been carried out as per his satisfaction/ manufacturers guidelines.

Scoring:

- If ALL the above requirements are documented, then score as **fully met.**
- Since this is a significant patient safety issue, if any of the requirements are not documented, then score as **not met.**

GUIDELINES

Preventive Maintenance Plan

The HCE shall ensure that the staff operating the equipment is trained in handling the equipment as per the manufacturer instruction manual. There shall be a documented preventive maintenance plan for all equipment and machinery using log book/tracker.

The organization shall develop a schedule of weekly/monthly/annual inspection and calibration of equipment which shall involve measurement in accordance with Original Equipment Manufacturer (OEM) guidelines. These services can be provided through an in house arrangement or alternatively through outsourcing. The organization shall ensure that calibration and conformance testing of the equipment has been done prior to commissioning.

Table 7: Equipment Preventive Maintenance History Format

Equipment Preventive Maintenance History Format												
No.	Name of the Equipment	Department	Date of Purchase	Name and Address of Supplier	Date of Installation	Warranty period	Date of Condemnation	Scheduled Maintenance	Date of Maintenance	Date of Calibration	Service/ Repair Date	Remarks

[21] OEM guidelines to be followed even by third party.

[22] In accordance with the log book, history sheet and preventive maintenance schedule etc. as detailed in the Guidelines. The end user /concerned specialist to certify that: i. The equipment is in working order, ii. It is being periodically serviced to his/her satisfaction.

Assessment Scoring Matrix

Standard 5. FMS. 2: The hospital/HCE has a program for management of equipment for clinical and support services.

Indicator 14-16		Max Score	Weightage (Percent)	Score Obtained
Ind 14.	**The hospital/HCE has equipment in accordance with the scope of its services.**	10	**80**	
Ind 15.	**Qualified / trained personnel operate and maintain the equipment.**	10	**80**	
Ind 16.	**Equipment is periodically inspected, serviced and calibrated to ensure its proper functioning. There is a documented operational and maintenance (preventive breakdown and replacement) plan.**	10	**100**	
Total		30		

Standard 6. FMS-3: The hospital/HCE has plans for fire and non-fire emergencies within the facilities.

Indicators (17-20):

Ind 17. The hospital has provisions for i. Early detection, ii. Containment and iii. Abatement of fire and non-fire emergencies.

Survey Process:

Review the plan to ensure that it addresses ALL 3 requirements. Then, by observation, review of documentation and interview, determine if ALL the essential requirements have been available/provided.

Scoring:

- If the plan includes ALL 3 requirements and there is evidence that ALL are available/provided, then score as **fully met.**
- Since this is an important patient safety issue, if any of the requirements are not included in the plan, or if any are not available/provided, then score as **not met.**

GUIDELINES

Emergency Plans

The disasters may include:

1. Earthquake
2. Civil disorders effecting the HCE
3. Terrorist attacks
4. Invasion of swarms of insects and pests
5. Invasion of stray animals
6. Hysteric fits of patients and/or relatives
7. Anti-social behavior by patients/relatives
8. Temperamental disorders of staff causing deterioration in patient care
9. Spillage of hazardous (acids, mercury, etc.), infected materials (used gloves, syringes, tubing, sharps, etc.) and medical wastes (blood, pus, amniotic fluid, vomits, etc.)
10. Building or structural collapse
11. Fall or slips or collision of personnel in the corridors
12. Fall of patient from the bed/stretcher
13. Bursting of pipelines
14. Sudden flooding of areas like basements due to clogging in pipelines or heavy rains.
15. Sudden breakdown of supply of electricity, gas, vacuum, etc.
16. Bursting of boilers and/or autoclaves
17. Bursting of pipelines
18. Sudden flooding of areas like basements due to clogging in pipelines or heavy rains.
19. Sudden breakdown of supply of electricity, gas, vacuum, etc.

20. Bursting of boilers and/or autoclaves

The HCE shall prepare and act according to the specific instructions of the Health Department regarding allocation of beds, calling staff on emergency duty and ensuring uninterrupted supplies etc. in case of war related emergencies.

Emergency Fire Plan

Necessary Items and Equipment

1. Buckets with sand
2. Portable fire extinguishers

Actions (Teams, responsibilities)

Detection:

All the Hospital Staff on duty especially inclusive of and not limited to the security person, receptionist, ward boys and nurses at the nursing station will be vigilant and be ready to notice any smoke, spark or smell in their respective area of duty. In such case they will send one person for help (intimating the management person at once) and take the appropriate actions like switching off the electricity, use of fire extinguisher or sand bucket etc.

Containment:

The team responsible for containment will take a quick review of the situation in order to assess if they can play their role for the purpose or simply try to initiate the alarm for evacuation and help abating the fire. General guidelines given below are helpful in carrying out the containment.

Abatement:

It is very important to decide when to try abatement and when no to. The fire resulting from short circuit should never be controlled with water unless the power is cut off through main switch or the circuit breaker. If fire doesn't seem to be controllable by the hospital internal resources, it is essential to call help (fire brigade, civil defense) immediately even before starting the efforts for abatement. General guidelines given below are helpful in carrying out the abatement.

General guidelines

1. When fire is detected, stay calm, try to oversee the situation and watch out for danger. Then the following actions should be taken in this order:
   A. Close windows and doors.
   B. Give fire alarm (shouting, telephone, fire alarm).
   C. Rescue people (and animals if present).
   D. Switch off electricity and/or gas supply.
   E. Fight fire, if possible with at least two persons.
2. Persons with burning clothing should be wrapped in a blanket on the floor, sprayed with water. A Carbon Dioxide ($CO_{2)}$ fire extinguisher can also be used, but do not spray on the face.
3. When using fire extinguishers, it is important that the fire is fought at the seat of the fire i.e. at the bottom of the flames, not in the middle of the flames.
   If gas cylinders are present there is the danger of explosion by overheating. If they cannot be removed, take cover and try to cool them with a fire-hose. When the situation looks hopeless, evacuate the building. Let everybody assemble outside and check that no one is

missing. To practice this, a Regular Mock Fire Drill (once a year), should be held.

Emergency Exit Plan

(Teams, Responsibilities, training and rehearsal schedules)

The ABC Hospital XYZ has two exits and unobstructed escape routes in case of fire. **Fire Exit Signs** are posted at appropriate places.

The emergency exits are clearly marked and obstructions must be kept away from exits at all times.

The HCE shall establish liaison with civil and police authorities, and **Rescue 1122** and the **Fire Brigade** as required by law for enlisting their help and support in case of an emergency.

Emergency Exit System

1. Lighting source is of reasonably assessed reliability, such as public utility electric service.
2. Emergency lighting facilities maintain the specified degree of illumination in the event of failure of the normal lighting for a period of at least one hour.
3. "EXIT" signs
4. Size of signs - readable from a distance of 15-20 meters.
5. Corridors, hallways and aisles must be 2.4 meters in width.
6. Use of ramps as access to second and higher floors. (where applicable)
7. Stairways with safe and adequately secured railings.
8. Stairway must be at least 112 cm. wide and made of concrete.
9. Any opening in any wall shall be protected by fire doors or fixed wire glass windows. It must have protection for vertical openings also.

Children:

Children will be given first priority while evacuation. They will be carried out by their mothers or attendant and if unattended or the attendant cannot carry the child it will be the responsibility of the duty nurse to hold the child herself or take help from the ward servants, Ayas, or even other patients who are fit for the job. The newborns and the children in incubators or under warmers shall be carried wrapped in blankets.

Patients:

The patients who can walk will be guided to the appropriate exit while those who cannot walk will be transported through wheel chairs or the stretchers as the situation and the condition of the patient permits.

Staff:

Staff will evacuate in the last however unnecessary lingering must be avoided.

All the persons will gather in the assembly area so that a head count can be done. It is necessary in order to ensure everyone in the building has been successfully evacuated.

Ind 18. The Hospital has a documented safe exit (evacuation) plan in case of fire and non-fire emergencies.

Survey Process:

Review the "evacuation" plan and the documented evidence that the plan has been tested through a "simulation" exercise to verify that the plan would work in an actual emergency. Simulation drills can be conducted for a single area or department. However, the plan should clearly define a "whole

hospital" evacuation plan (as in an earthquake), including defined alternate sites for the patients and how to transport them. This should be included in the induction orientation program for new staff. The plan should be readily available and visible.

Scoring:

- If there is a written facility evacuation plan, staff is aware of and trained in its use and it has been tested, then score as **fully met.**
- If there is a written evacuation plan but it has not yet been tested, then score as **partially met.**
- If there is no plan, then score as **not met.**

GUIDELINES

Emergency Exit Plans

All workplaces should have adequate exits and unobstructed escape routes in case of fire. The number of exits required for all employees to exit safely depends on several factors, including whether the facility uses substances that are at a high risk for combustion, the layout of the building and the type of construction materials used. Fire Exit Signs must also be posted.

All hospitals must have at least two exits, so if one is blocked during a fire, the other may be used. These exits must be clearly marked and obstructions must be kept away from exits at all times. Consult Ind.17 for plan/SOPs.

Ind 19. Staff members are trained for their role in case of such emergencies.

Survey Process:

Look for documentation of the training which should include at least key personnel from every area. They should be able to demonstrate awareness of their own role and the role of others in case of such emergencies.

Scoring:

- If there is documented evidence of training of key personnel in every area, then score as **fully met.**
- If only a few (about 20%) key personnel have not yet been trained, then score as **partially met.**
- If there has been no training or if more than 20% key personnel have not been trained, then score as **not met.**

GUIDELINES

Training in Emergency Situation Handling

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.

1. **All Hospital** Staff especially the following is required to attend a Training Course on the theory of fire and the practical use of fire extinguishers:
   A. Chefs/Kitchen staff.
   B. Staff of the Accident & Emergency (A&E) Department

C. Designated Maintenance Staff
D. Designated Technical Staff
E. Senior Residents
F. Other staff identified according to Risk Assessments

2. *Specific r*oles and responsibilities of staff, and volunteers at a fire's point of origin.

Fire Wardens are trained to respond to the enunciator panel in their area to determine location of alarm. The Fire Warden assigns additional specific duties in and away from the fire point of origin as needed.

3. Specific roles and responsibilities of staff, and volunteers away from a fire's point of origin.

When chimes sound, indicating the alarm source is on another floor, staff is trained to be on standby for further instructions. In departments away from the fire origin, staff should prepare the area in case an evacuation is necessary. At a minimum, the following is done: keep patients and visitors calm and informed, close doors in department to limit spread of smoke from a fire, and clear corridors of equipment to ensure clear evacuation route. In off-site facilities, staff, patients, and visitors exit to the exterior of the building, no matter where the fire is located.

4. Specific roles and responsibilities of staff and volunteers in preparing for building evacuation.

In the event of a total building evacuation, it is the responsibility of each area Director/ Manager/ Supervisor to insure that all staff and patients are accounted for. Nursing staff is trained and responsible to first evacuate patients from the immediate fire area. This normally includes the room that is on fire, rooms on either side or the room directly across the hall, closing all other patient room doors for temporary protection. They will then proceed with full compartment evacuation to the closest adjacent smoke compartment. They will then complete the evacuation of the involved smoke compartment. Further vertical evacuation occurs when and if the Fire Warden determines the area or building is untenable and needs to be evacuated. This will occur with the assistance of Fire Department manpower as well as a manpower pool formed by hospital employees for the specific incident.

Ind 20. Simulation exercise is held at least once in a year.

Survey Process:

See Ind 17, 18 & 20. Look for documentation that "simulation" drills have been done at least once in the past year. As for fire drills, the "simulation" drills should have involved different areas and different shifts. The drills should be fully reported noting the staff involved, major observations and any subsequent changes to the system.

Scoring:

- If there is documented evidence that simulation drills have been held at least once in the past year and that they involved different areas or shifts, then score as **fully met.**
- If no drill has been conducted, then score as **not met.**

Table 8: Sample Format of Fire Drill Report

Fire Alarm/Fire Drill Report

To be completed after every alarm or drill by designated fire safety officer

Date: _____ Time: _____

Location of Alarm/Fire sign: _____

Name of person pulling alarm: _____

1) Rounds of hospital made by: _____

1st Floor: _____ 2nd Floor: _____ Doors Closed: _____

Hallways Cleared: _____

Visitors/Patients – Instructed Appropriately: _____

Staff knows how and when to turn off 0; _____

Fire Extinguishers on Location: _____

Staff was aware of location of fire and prepared to evacuate through appropriate Exits:

_____

_____

Staff from departments other than Nursing at appropriate posts:

_____

_____

Staff Co-operation: _____

2) Reason for Alarm (if not a planned drill): _____

3) Communication to Switchboard: _____

4) Additional Comments: _____

5) Problems Identified/Recommendations: _____

Signed: _____ Position: _____

Assessment Scoring Matrix

Standard 6. FMS-3: The Hospital/HCE has plans for fire and non-fire emergencies within the facilities.

Indicator 17-20		Max Score	Weightage (Percent)	Score Obtained
Ind 17.	**The hospital has provisions for i. Early detection, ii. Containment and iii. Abatement of fire and non-fire emergencies.**	10	**100**	
Ind 18.	**The Hospital has a documented safe exit (evacuation) plan in case of fire and non-fire emergencies.**	10	**80**	
Ind 19.	**Staff members are trained for their role in case of such emergencies.**	10	**100**	
Ind 20.	**Simulation exercise is held at least once in a year.**	10	**80**	
Total		40		

2.3 Human Resource Management (HRM)

03 Standards & 05 Indicators

The goal of the Human Resource standards is to ensure that the hospital determines qualifications and competency for staff positions that match the organization's mission and patient care needs. Hospitals must provide the right number of qualified staff to meet patient care requirements. To meet this goal, the standards require the hospitals to plan for staffing; orientation, educating and training the staff. The hospital also needs to have a system for assessing, maintaining and improving staff capability and promote self-development and learning. There should be well organized HR department in each hospital and its function is not merely the hiring and firing of the staff but in fact the development of human resource and considering it an asset for the hospital.

Standard 7. HRM-1: All the Employees[23] of the hospital are oriented to the environment, respective sections, their individual jobs and the performance appraisal system.

Indicators (21-22):

Ind 21. Each regular / part time employee is appropriately oriented to the relevant section/service policies and procedures as well as his/her responsibilities, rights and patients' rights and responsibilities.

Survey Process:

The orientation should cover: i. Orientation to the overall scope of services of the hospital, fire and general safety, infection control & quality assurance, ii. Orientation to the assigned department, and iii. Orientation to the employee's rights and responsibilities and the patients' rights and responsibilities. The content of each level of orientation should be written to ensure that whoever provides the orientation always covers the same topics.

Scoring:

- If there are written orientation "guides" / manual covering the above three areas and documented participation, then score as **fully met.**
- If the orientation program covers the above three areas but no written details of what is to be covered or if it is partially conducted (two out of three areas), then score as **partially met.**
- If there is no orientation program, then score as **not met.**

GUIDELINES

General Orientation

Once the selection process is completed, the new employee must be oriented in order to become productive contributor. Orientation not only improves the ability of the employee to perform their job but also helps to satisfy their personal desire and feeling that they are part of the organization's social fabric. Supervisors, in coordination with the Human Resource (HR) Department, complete the orientation by introducing new employee to the co-workers. Every HCE/Department should recognize that its success depends upon the capacities of its staff and shall design a comprehensive induction orientation program as an integral component of capacity building for all employees. The hospital's induction and orientation processes will provide the information, guidance and support required for staff to undertake their organizational responsibilities and to develop and succeed in their new role. This will be achieved by familiarizing new staff with the hospital's significant policies, systems, procedures, governance structure and the work location, and encouraging commitment to the vision, mission and values of the hospital.

This must be explained to the employees at the induction, in order to align their daily activities with the overall organizational goals (the mission). The new employee should be briefed about past achievements, in terms of services provided, future objectives, plans and targets so as to create a

[23] Employees include all full time/regular or part time/visiting consultants/employees or staff members as the case may be.

positive image about and for the organization. General responsibilities towards the institution and as to what the staff will be required to do, should be explained to the employee.

1. Policy

The aim of the policy is to specify a program to introduce new joiners to the organization, work colleagues, its culture and environment. All new employees will go through an induction orientation program designed by the HR Department, which should include the following:

A. The vision, mission, values, objectives and policies of the HCE.
B. Overview of the organizational structure, systems and key processes.
C. Brief on key processes of the relevant department.
D. Description of the HCE's specialty/s and target population.

2. Procedure

At the time of joining the HCE, the employee will submit photocopies of his/her past credentials to the designated HR representative who will complete the necessary documentation and will get signatures of the employee where necessary. Documentations include the following:

A. Appointment letter.
B. Joining Report. (**Annexure C**)
C. Statement of ethics. (**Annexure D**)
D. Confidentiality Agreement. (**Annexure E**)
E. Reference Forms. (**Annexure F**)
F. Health Questionnaire Form. (**Annexure G**)

After completion of documentation, the designated HR Person will brief the employee about the HCE's vision, mission, values, objectives, policies and will issue the Employee Handbook to him/her in order to study all the policies in detail. The employee will also be introduced to all the colleagues through a physical tour of the HCE.

Ideally, an **Employee Handbook** should contain:

A. Mission statement, values and goals of the institution.
B. Standards of Conduct to follow (towards a client, for communication, teamwork, maintaining sense of accountability, appearance etc.).
C. Expectations from employees and their responsibilities, such as to keep personal business to a minimum, reporting procedures and, disciplinary action against personnel to be taken in various situations.
D. Policies and procedures to follow in the respective departments and in emergency situations.
E. Efficient and safe use of equipment with regards to health and safety standards.
F. Information regarding Employee Benefits schemes and special recognition / appreciation criteria etc.

After orientation, the HR Representative will issue an Orientation Checklist (**Annexure H**) to the employee, where the employee will fill the checklist and will give his/her feedback about the orientation. The orientation checklist will be filed into the employee file and feedback will also be used for further improvements in orientation program (if required).

Staff Rights and Responsibilities

1. Responsibilities

The HR Department must have well-described overall set of responsibilities covering all categories of staff, which will also be an important component of the respective personal file

duly signed by the employee.

2. Rights

The rights of the staff member should be detailed in the employee manual maintained by the HR Department which should also be shared with the employee(s).

3. Patients' Rights

The rights and responsibilities of the patients are available as Patient Charters (Section 2.9).

The following points regarding the rights and responsibilities of employees are to be considered:

A. Staff members may have cultural, religious or personal conflicts concerning their involvement with specific components in the care or treatment of patients. The HCE shall provide a mechanism for employees to submit their requests for review of work assignments by their HoD. However the continuum of patient care services shall be ensured at all levels.

B. Staff members will make their requests known to their HoD, manager or supervisor in writing. Examples of procedures, which may conflict with some staff members' beliefs include, blood administration, therapeutic abortion, circumcision and sterilization procedures etc.

C. The HoD, manager or supervisor shall make every effort to accommodate the request and maintain the duties referenced in the employees' JD.

D. The HoD, manager or supervisor shall reassign duties, if reasonable and possible, to accommodate the request and meet the needs of the patient.

E. Response to all requests for reassignment of duties, whether approved or denied will be provided in writing to the employee.

F. A record of all requests and actions taken shall be maintained in the employee's departmental file.

G. If the request of the staff member cannot be granted, the employee may appeal to the next higher authority to review the request. The decision of the HR department shall be final to the extent of respective request.

Similarly the staff is to be apprised about the rights and responsibilities of the patients and the HCEs.

Ind 22. Each Regular/Part Time Employee is made aware of his/her Job Description and the performance appraisal system.

Survey Process:

The indicator requires to stress upon the importance of the job descriptions for effectively performing the duties assigned to the employees and the system for appraisal of their performance. Each employee is provided detailed job description and is made fully aware of requirements given therein as well as of the appraisal system. The record bears the signatures of the relevant employees certifying that the job descriptions and the appraisal system has been read and fully understood.

Scoring:

- If the JDs are available and signed by all employees, who have also been made aware of the appraisal system then score as **fully met.**
- If the JDs are available but not signed by any one employee, or if they are not made aware of the appraisal system then score as **not met**.

GUIDELINES

Awareness about Job Descriptions and Performance Evaluation

This indicator would require prior availability of written JDs that define individual employee's specific responsibilities which one has to perform. The staff is required to be provided a copy of JD and made aware of each aspect of his work by the HR/section in charge as per policy as soon as one joins the duty. After this on job awareness, signatures of the employee are obtained on the JD and a copy provided to employee and originals are placed in the personal file maintained by the Human Resource Department (HRD). Employees are also to be made fully aware that their performance will be rated against this written JD.

Assessment Scoring Matrix

Standard 7. HRM-1: All the Employees of the hospital are oriented to the environment, respective sections, their individual jobs and the performance appraisal system.

Indicator 21-22		Max Score	Weightage (Percent)	Score Obtained
Ind 21.	**Ind 21. Each regular / part time employee is appropriately oriented to the relevant section/service policies and procedures as well as his/her responsibilities, rights and patients' rights and responsibilities.**	10	**80**	
Ind 22.	**Each Regular/Part Time Employee is made aware of his/her Job Description and the performance appraisal system.**	10	**100**	
Total		20		

Standard 8. HRM-2: An appraisal system for evaluating the performance of the employees exists.

Indicators (23-23):

Ind 23. The performance appraisal system for evaluating the performance of the employees is documented, appraisal is carried out at pre-defined intervals and is used as tool for further development.

Survey Process:

There is a documented performance appraisal system, conforming to the employees' job descriptions and the appraisals is based on these JDs. The system also entails appraisal at pre-defined intervals and using the appraisal for further development.

Scoring:

- If there is a documented performance appraisal system for the employees, their performance is evaluated accordingly at pre-defined intervals and the appraisal is used as tool for further development, then score as **fully met.**
- If there is no documented performance appraisal system or if it is neither carried out at pre-defined intervals nor used as tool for further development, then score as **not met**.

GUIDELINES

Career Development

There should be documented evidence (when appropriate to the employee's appraisal) that the appraisal system is used as a tool for further development (such as more experience, more training, and a different job assignment). This may not be required for every appraisal - only if the appraisal indicated the need.

A performance appraisal is a part of guiding and managing career development. It is the process of obtaining, analyzing, and recording information about the relative worth of an employee to the organization. A format for performance appraisal is provided below:

Table 9: Performance Appraisal Format

PERFORMANCE APPRAISAL FORMAT

ABC_____HOSPITAL _____XYZ

Name of the appraised: _____

Department: _____

Period of appraisal: _____

Name of the appraiser: _____

Date: _____

Knowledge:

1. ☐ 2. ☐ 3. ☐ 4. ☐ 5. ☐

Skill:

1. ☐ 2. ☐ 3. ☐ 4. ☐ 5. ☐

Attitude:

1. ☐ 2. ☐ 3. ☐ 4. ☐ 5. ☐

Performance:

1. ☐ 2. ☐ 3. ☐ 4. ☐ 5. ☐

(Grading increases with the number)

Recommendation:

_____

_____

Remarks:

_____

_____

Signature of the appraised: _____ Signature of the appraiser: _____

Assessment Scoring Matrix

Standard 8. HRM-2: An appraisal system for evaluating the performance of the employees exists.

Indicator 23		Max Score	Weightage (Percent)	Score Obtained
Ind 23.	**The performance appraisal system for evaluating the performance of the employees is documented, appraisal is carried out at pre-defined intervals and is used as tool for further development.**	10	**100**	
Total		10		

Standard 9. HRM-3: Personnel record for each employee is maintained and there is a process for collecting, verifying and evaluating the credentials (education, registration, training and experience) of medical professionals including doctors and nurses.

Indicators (24-25):

Ind 24. The personal files contain information regarding the employees' qualification/education, experience, professional training, previous employment background evaluation results and health status.

Survey Process:

Randomly select representative sample of employees (either from a list of all employees, or by name of personnel identified during visits to hospital areas). Then determine if all have a personal files containing information regarding the employee's qualification/education, experience, professional training, antecedents/ reference check/previous employment background, evaluation results (if applicable) and health status.

Scoring:

- If **ALL** reviewed files have all of the above-mentioned information, then score as **fully met.**
- If the files are not complete or any file does not contain ALL the required information, then score as **not met.**

GUIDELINES

Personal Files

The purpose of maintaining personal files is to keep an updated record of employees. The personal files of employees should be maintained because:

1. It makes good business sense to have accurate information handy and organized when you want to use it for official purpose.
2. Immediate supervisors will eventually encounter the need to produce documentation about employee performance and work history
3. Some employee records are required by federal or provincial government/other agencies and must be kept in the personal files. Organizing the record of employees in a proper manner makes access easy.

The personal file of each employee is very confidential and access to the file is only allowed after the approval from a competent authority. Access to information about employees should be strictly limited to those people in the HCE who need to use it for official purposes. Since unauthorized access to personal files can result into severe repercussions, any breach in this connection should make the responsible person liable to severe penalties. It should be ensured that personal files

(hard and soft copies) are stored in a secure physical location and are not left unattended even during working hours. When asked by the people outside the organization to provide "verification" of certain employment information about the employee(s) of the HCE, it should be ensured that only the information which has been authorized by the employee(s) is released. Employment verifications are usually required to support such things as mortgage applications, credit applications etc. Employee authorization should be in writing and specify the information they wish you to reveal. Tell your employee the policy is designed for his/her protection.

Contents of Personal Files

The HR Departments in the good organizations customarily maintain the following documents in the personal file of each employee in a standard manner;

1) Curriculum Vitae
2) Offer letter
3) Contract copy and JD
4) Joining report
5) Photograph (two, blue background, passport size)
6) CNIC copy
7) Copies of documents pertaining to all academic and professional qualifications
8) Copies of training/certifications
9) Experience certificate
10) Reference form/background check
11) Medical/personal information form
12) Leave forms (if any)
13) Notice (if any)
14) Performance Evaluation Form
15) In-service training
16) Resignation/termination letter (whichever is received in the HRD)
17) Exit interview form (whenever employee leaves office)

Review the Personal Files and check the following are maintained:

1) Qualifications of the staff member.
2) Record of in-service education/training.
3) Job description as applicable.
4) Work history / disciplinary background.
5) Results of appraisals/evaluations.

Ind 25. The hospital has a process to verify the validity and accuracy of credentials of professionals including doctors, nurses, pharmacists and others permitted by law, regulation and the hospital management to provide patient care without supervision and the same is practiced.

Survey Process:

Look for documentation of the way the hospital validates the credentials (education, registration, experience and professional training) of professionals including doctors, nurses, pharmacists and

others to ensure that its staff are legally permitted to care for patients. The hospital has a process to verify the validity and accuracy of these documents with the primary source - such as the university, the training organization or regulatory councils etc. to ensure that the professionals are currently registered with their respective councils etc. (there are multiple examples nationally and internationally of fraudulent "credentials").

While scoring, give attention to the following, that;

- ✓ Those permitted by laws, regulations, are identified and listed by the hospital to provide patient care without supervision.
- ✓ Copies of the required credentials (education, licensure, registration, among others) as determined by regulation and organization policy for each medical staff member are maintained in the personnel file or in a separate credential file for each medical staff member in the hospital.
- ✓ All credentials (education, licensure, registration, among others) are verified with the source that issued the credential preferably before the individual begins providing services.
- ✓ All credentials on file (education, licensure, registration, among others) are current and updated as required.
- ✓ At initial appointment, a firm determination is made about the current qualification of the individual to provide patient care services.
- ✓ At initial appointment, an undertaking is obtained that the employee will update any change in the current status of the qualification/certification immediately on occurrence.

Scoring:

- If there is a clearly defined process to validate the "credentials" of ALL staff members and evidenced that the same is practiced and copies are maintained in the record, then score as **fully met.**
- Since this is an important legal and patient safety issue, if there is no recognized process to validate the "credentials" or if the same is not practiced, then score as **not met**

GUIDELINES

Verification of Licensure/Certification

There should be a process to validate the accuracy of these documents (there are multiple examples of fraudulent "credentials" internationally). The hospital should have verified the documents with the primary source such as the college/university/authority or the training organization, as the case may be, as follows;

1. Current licensure/certification or registration is verified with the primary source at the time of hiring and at renewal prior to expiration.
2. Primary source verification will be obtained through a secure electronic communication. If a licensing board/agency/authority cannot provide this type of verification, a letter in that aspect must be obtained from it.
3. In the event that an employee is hired against a position that requires license, certification or registration, and the same has been revoked, suspended or rendered invalid, the HCE may terminate the concerned employee on these grounds.
4. Practitioners should have current/valid registration with the respective professional council or body e.g. PMDC for doctors, Pharmacy Council for pharmacists, Pakistan Nursing Council (PNC) for nurses, and Khyber Pakhtunkhwa Faculty of Paramedical and Allied Health

Sciences (FPAHS) for Paramedics.

5. It is the employee's responsibility to provide proof of license, certification and/or registration, and to notify their manager and HR immediately of any change in the status of the license, certification, and/or registration.

Assessment Scoring Matrix

Standard 9. HRM. 3: Personnel record for each employee is maintained and there is a process for collecting, verifying and evaluating the credentials (education, registration, training and experience) of medical professionals including doctors and nurses.

Indicator 24 - 25		Max Score	Weightage (Percent)	Score Obtained
Ind 24.	**The personal files contain information regarding the employees' qualification/ education, experience, professional training, previous employment background evaluation results and health status.**	10	**100**	
Ind 25.	**The hospital has a process to verify the validity and accuracy of credentials of professionals including doctors, nurses, pharmacists and others permitted by law, regulation and the hospital management to provide patient care without supervision and the same is practiced.**	10	**100**	
Total		20		

2.4 Information Management Systems (IMS)

02 Standards & 6 Indicators

The Standards pertaining to the information Management System (IMS) highlight the fact that patient care is highly dependent upon accurate and correct information. The standards also signify that the work of physicians and staff across the hospital must be facilitated by timely information to provide coordinated and integrated care. In addition, it is important to protect the privacy of the data collected by limiting unauthorized access.

Medical records serve many functions but their primary purpose is to support patient care. There is currently a major drive to computerize medical records, but without improvement in the quality of paper records the full benefits of computerization are unlikely to be realized. The onus for improving records lies with individual health professionals as well as the management Structuring the record can bring direct benefits to patients by improving patient care, treatment outcomes and health system performance.

Standard 10. IMS-1: The Hospital has a complete and accurate Medical Record for every patient.

Indicators (26-29):

Ind 26. Every medical record has a unique identifier.[24]

Survey Process:

The indicator stipulates that each medical record (indoor as well as outdoor) has a unique identifier. There may be more than one record for a patient and there is possibility of placing the laboratory/radiological results / other documents of the patient into the wrong patient's medical file. This is to be averted by allocating a unique identifier for each patient's record. Surveyor needs to ascertain that each medical record (indoor as well as outdoor) has a unique identifier.

Scoring:

- If there is a clear mechanism to positively identify each patient's medical record, then score as fully met **OR** if there is the possibility that an individual patient has more than one record, but there is a system to identify this and consolidate the various records, then also score as **fully met.**
- If there is no mechanism to positively identify each patient's medical record or evidence that there is more than one record for a patient but no mechanism to consolidate these records, then score as **not met.**

GUIDELINES

Unique Patient Identifiers

All documents of a patient must be consistently labelled with at least 1 unique identifier so that it can be verified that documents correspond to particular patients. Computer Generated Unique ID Number is the easiest and correct Identification Method to be adopted as early as possible. The patient's medical record always becomes a focal point whenever there is a question regarding the care and treatment rendered. It is important that the medical record be kept accurately and timely. A Sample Template for Patient Medical Record is given at **Annexure I**. The medical record serves three primary purposes: 1) to ensure quality patient care; 2) to provide documentary evidence of the patient's course of illness and treatment; and 3) to facilitate review.

One often thinks of the medical record as a means of protecting the hospital or providing a defense in a medical malpractice action. However, the purpose of the medical record is not to protect or to provide a defense only. The purpose of the medical record, as it pertains to risk management, is to preserve the truth. In reality, a complete and accurate medical record will protect the legal interests of the patient, the hospital, and the responsible practitioner. The medical record will provide a justifiable defense, if one exists, or will indict the responsible party

[24] An alpha-numeric system that gives each patient their own code number. This condition is relaxed for one year to the extent of outdoor record.

if there is no justifiable defense.

Accurate identification of a patient is the backbone of an effective and efficient medical record system. Correct identification is needed to positively identify the patient and ensure that each patient has one medical record number and one medical record with no more duplicates. In order to identify patients, we need a UNIQUE PATIENT CHARACTERISTIC. The type and number of unique patient characteristics used will change from one setting to other, and are defined as:

Something about a patient that does not change.

Some useful unique patient characteristics are:

1) Client/Patient full name.
2) Gender.
3) Date of Birth (DoB).
4) National Identity Card (NIC) Number.
5) Mother's first name.
6) Father's first name.
7) Social security number.
8) Health insurance number.
9) In the case of a new-born infant a physical/anatomical characteristic, e.g. fingerprint or footprint.

The following are NOT considered unique characteristics:

1) Where a person lives is NOT a unique patient characteristic because it can change.
2) A person's age is NOT a unique patient characteristic because it DOES change.

Although it should not change, it is important that a patient's birthplace is NOT used, as it is often identified by most people as being the place where they "come from" as opposed to the place where they were actually born. Similarly many people are born at the same place/city/hospital/town etc.

Ind 27. The staff authorized to make entries in the medical record is reflected in the Hospital's policy/SOPs[25] and is identifiable.

Survey Process:

Review IMS policy/SOPs and then during scrutiny of medical records for any of the previous reasons, confirm that only the individuals authorized in the policy/SOPs have made entries into the medical record and those who have made entries can be identified.

Scoring:

- If ALL entries are by authorized and identifiable persons, then score as **fully met.**
- If there are any entries by unauthorized persons, then score as not met OR if the persons

[25] Written Policy/SOPs on IMS is essential.

making entries are not identifiable, then also score as **not met.**

GUIDELINES

SOPs for Identification of Medical Record Entries

1. The Organization maintains a list of authorized persons along with the details of documents which they can sign. The list also contains their specimen signatures, initials and the stamps they use. Any professional who, in the execution of his or her professional duties, signs official documents relating to patient care, such as prescriptions, certificates (excluding death certificates), patient records, hospital or other reports, shall do so by signing such a document and clearly writing his/her name, appointment and the date in block letters, stamping the same.
2. Following are authorized as per defined in the list below to prescribe, dispense and administer the medication and to make their relevant entries in the medical record of the patients.
   It is hereby emphasized that only the doctors employed at……..Medical Complex ……, registered with PMDC are authorized to write prescriptions and medical orders for the patients and make entries in the medical records at the said hospital while the nurses employed at……Medical Complex……, registered with PNC are authorized to dispense and administer the medication in order to carry out the medical orders. They are also authorized to document the medication in the medical record of the patients.

Table 10: Sample Authorized Personnel List

No.	Particulars & Appointment	Authorization	Initials	Signatures	Stamp
1.	Consultant				
2.	Dr.				
3.	Staff Nurse				

3. The organization must provide the individual signatories a list of what they can sign and what not.

Ind 28. Every medical record entry is dated, timed and signed.

Survey Process:

This is a difficult standard to meet since the "timing" of ALL entries especially in the OPD record may be difficult to achieve. Focus attention on timing of medication orders, examination/progress notes and any entries in emergency and ICU's. This can be evaluated during the review of the previously selected records. Detail of weeding of old record is given at **annexure J**.

Scoring:

- If **ALL** entries are dated, timed and signed then score as **fully met**.
- If all entries are dated and signed but some entries are not timed, then score as **partially met.**
- If any entry is not dated or signed then, score as **not met.**

GUIDELINES

SOPs for Medical Record Documentation

This indicator demands that every time an entry is made in the medical records, it is timed and dated along with the particulars of the person making the entry. Recording of Date and Time starts from the time a patient enters the hospital and seeks care. The first such record is the Register at the Reception and the 'Parchi' issued for consulting a doctor. Then it is the turn of the attending doctor at OPD/Emergency who examines the patient, prescribes medicine(s) or refers the patient if required, while putting the date and time along with his/her signatures on the slip. The pharmacist also signs and puts the date and time after issuing the medicines. Similarly, in the indoor record, every entry is signed stamped, dated and timed by doctors, nurses and supervisors.

Accurate date and time recording is of paramount importance whenever there is a need to produce the documentation as a proof of certain action having been taken on time. It is a valuable source of data for coding, health research, a source of evidence and rationale for funding and resource management. Hospital authorities shall make strategies to ensure implementation of this requirement.

Ind 29. The medical record contains information regarding/diagnosis, treatment, plan, Informed Consent, care provided[26] and details if shifted/discharged[27] depicting continuity of care, copy of death certificate[28] and copy of autopsy report if applicable in chronological order.

Survey Process:

Review representatives' sample of records (they can be the same record as for previous Indicators) to determine if the reason for i. Admission, ii. The provisional diagnosis iii. The plan of care iv. Informed Consent v. The care provided and vi. Copy of Discharge/Referral Slip,[29] is documented. Ask for the medical record of 3 or more patients who were transferred to another hospital. The date of shifting, the reason for the shifting and the name of the receiving hospital is recorded. Ask for medical records of patients who had an autopsy, verify that the final report is available in the medical record.

Scoring:

- If ALL the required elements mentioned above are documented in ALL the records, then score as **fully met.**
- If any of the required elements is missing in any record, then score as **not met.**

[26] Operative and other (Diagnostic/Curative) procedures performed are incorporated in the record.

[27] A copy of the discharge note/slip duly signed by appropriately qualified/authorized staff is added.

[28] A copy of the death certificate indicating the cause, date and time of death.

[29] Including shifting to other departments of the hospital or other hospitals.

GUIDELINES

Scope of Medical Records

The medical record contains information regarding reasons for admission, diagnosis and plan of care. Accurate medical record documentation should comply with the following minimum parameters.

1. The medical record should be complete and legible.
2. The documentation of each patient contact should include: the reason for the visit, relevant history, physical examination findings, diagnostic test results, clinical impression/diagnosis, and plan for care, date and legible identity of the service provider.
3. If not documented, the rationale for ordering diagnostic and other ancillary services should be easily inferred. Past and present diagnoses should be accessible to the treating and/or consulting physician.
4. Appropriate health risk factors should be identified. The patient's progress, response to and changes in treatment and revision in diagnosis should be documented.
5. The hospital has a complete and accurate medical record for every individual assessed or treated. Every medical record entry is timed, dated and initialed and its author identified when required.
6. Record must be kept for at least 3 years, Medico-Legal Record (MLC) record for 12 years and Death/Birth (Vital Events) record for ever as per notification of the Khyber Pakhtunkhwa Govt.

Contents of the Medical Record

1. The content of the medical record, which includes written and electronic documents, must be sufficiently detailed, legible and organized to enable:
    A. The practitioner responsible for the patient to identify the patient, provide continuing care, determine the patient's condition at a specific time, review the diagnosis & therapeutic procedures performed and the patient's response to treatment.
    B. Consultant's opinion after a patient examination and review of the medical record.
    C. Another practitioner to assume patient care at any time.
    D. Retrieval of information required for utilization review, quality review and transfer recommendations, etc.
2. The medical record contains the following clinical information:
    A. The reason(s) for admission for care, treatment and services.
    B. The patient's initial diagnosis, diagnostic impression(s) or conditions(s).
    C. Findings of assessments and reassessments.
    D. Any allergies to food or latex.
    E. Any allergies to medication.
    F. Conclusions drawn from the patient's medical history and physical examination.
    G. Diagnoses/conditions established during the patient's course of care, treatment, and services.
    H. Any consultation reports.
    I. Any observations relevant to care, treatment and services.
    J. The patient's response to care, treatment and services.
    K. Any emergency care, treatment and services provided to the patient before arrival.
    L. Progress notes.

M. All orders.
N. Medications ordered or prescribed.
O. Medications administered, including the strength, dose, frequency and route.
P. Any access site for medication, administration devices used and rate of administration.
Q. Any adverse drug reactions.
R. Readmission notes.
S. Shifting record from one department to another department.
T. Treatment goals, plan of care, and revisions to the plan of care.
U. Results of diagnostic and therapeutic tests and procedures.
V. Medications dispensed or prescribed on discharge.
W. Discharge diagnosis.
X. Discharge plan and discharge planning evaluation.
Y. Follow-up plans.
Z. Referral letters.

3. The medical record contains the following information as needed to provide care, treatment and services:
   A. Any advance directives (Before admission of patient).
   B. Informed consent, when required by hospital policy.
   C. Any records of communication with the patient, such as telephone calls or email.
   D. Any patient-generated information.
4. The medical record of a patient who receives urgent or immediate care, treatment and services contain all of the following:
   A. The time and means of arrival.
   B. Indication that the patient left against medical advice, when applicable.
   C. Conclusions reached at the termination of care, treatment and services, including the patient's final disposition, condition and instructions given for follow-up care, treatment and services.
   D. A copy of information made available to the practitioner or medical organization providing follow-up care, treatment or services.
5. A summary list is initiated for the patient on third visit containing the following information:
   A. Any significant medical diagnoses and conditions.
   B. Any significant operative and invasive procedures.
   C. Any adverse or allergic drug reaction.
   D. Any current medications, over-the-counter medications and herbal preparations.
   E. The patient's summary list is updated whenever there is a change in diagnoses, medications or allergies to medications and whenever a significant procedure is performed.

Operative and Procedure Notes

An operative or other high-risk procedure report is written or dictated upon completion of the operative or other high-risk procedure before the patient is transferred to the next level of care or immediately after transferring the patient. The progress note and dictated operative report should be part of the patient's medical record and must include the following:

1. Name(s) of the independent practitioner(s) &assistant(s) who performed the procedure.
2. Name of the procedure performed.

3. Description of the procedure.
4. Findings of the procedure.
5. Procedure performed.
6. Estimated blood loss.
7. Any specimens removed.
8. The postoperative diagnosis.
9. Complications during and after surgery, if any.

The surgeon must authenticate the completed operative report as soon as possible after surgery/procedure.

SOPs for Transfer of Patients

Following the decision to refer a patient to another hospital, there should be a written communication containing the reasons of referral with date, time, name of the receiving hospital and a copy of the same should be retained in the medical record of the patient. If the patient has been transferred at his/her own request, a note to that effect is added in the patient's record. In such cases the name of the receiving hospital would be of the one where the patient desires to go to. However, if the patient has been transferred by the HCE under care with medical staff, it shall have acknowledgement from the receiving hospital.

Any element of care/treatment carried out during patient transfer must be documented.

Discharge Summary Record

A discharge summary is a summary of the patient's stay in the hospital written by the attending doctor. The summary should contain following minimum details:

1. Patient identification.
2. Reason for admission.
3. Examinations and findings.
4. Treatment while in hospital.
5. Proposed follow up.
6. Medications.
7. Diet and instructions to maintain health status.

A discharge summary may be written on a pre-printed form or on plain paper and typed or word processed in the Medical Record Department/room. Alternatively, the attending doctor writes a discharge summary in duplicate when the patient is discharged. The original is kept in the medical record and the copy given to the patient. On discharge/death of the patient the medical record, including ALL forms relating to the admission plus any previous records, should be sent to the Medical Record Department/room as soon as possible or within 72 hours. The medical record should remain in the Medical Record Department/room.

Medical record staff responsible for the discharge procedure should be trained to ensure that the medical records are completed promptly and correctly.

Discharge lists should be kept in order of date in the Medical Record Department. The list should contain the patient's name, age, treating doctor, ward, and service, i.e., medical, surgical, obstetric, orthopedic, etc., and whether the patient is alive or dead. Discharge lists are usually used to prepare the hospital inpatient statistics.

By using the discharge list, the staff responsible for the discharge procedure in the Medical Record Department can check to see if they have all the medical records of discharged/dead patients from the previous day. If any are missing, they should contact the ward to find them.

Once a patient has been discharged, the medical record should be returned promptly to the Medical Record Department and acknowledgement to this effect should be received. Failure to do so may result in a missing medical record. Once the patient is no longer in the ward, their medical record can easily be misplaced. Any qualified and trained individual can compile the discharge summary such as the patient's physician or a house medical officer.

Death Certificate Record

In case of death, details of circumstances leading to the death of patients like primary and secondary cause of death should be mentioned. The death certificate must be signed and stamped by registrar and dead body handed over to blood relations like father, mother, spouse etc. On the death of the patient, the medical record including ALL forms relating to the admission plus any previous records should be sent to the Medical Record Department as soon as possible or within 72 hours. All deaths occurring in hospital, either inpatient or outpatient must be documented in the Medical Record Department.

Autopsy Report Record

Clinical autopsies serve two major purposes. They are performed to gain more insight into pathological processes and determine what factors contributed to a patient's death. Autopsies are also performed to ensure the standard of care at hospitals. Autopsies can yield insight into how patient deaths can be prevented in the future.

Assessment Scoring Matrix

Standard 10. IMS. 1: The hospital has a complete and accurate medical record for every patient.

Indicator 26-29		Max Score	Weightage (Percent)	Score Obtained
Ind 26.	**Every medical record has a unique identifier.**	10	**100**	
Ind 27.	**The staff authorized to make entries in the medical record is reflected in the hospital's policy/ SOPs and is identifiable.**	10	**100**	
Ind 28.	**Every medical record entry is dated, timed and signed.**	10	**80**	
Ind 29.	**The medical record contains information regarding / diagnosis, treatment plan, Informed Consent, care provided and details if shifted / discharged depicting continuity of care, and copy of death certificate and copy of autopsy report if applicable in chronological order.**	10	**100**	
Total		40		

Standard 11. IMS-2: The Hospital regularly carries out review of medical records.

Indicators (30-31):

Ind 30. The medical records are reviewed regularly/periodically focusing on the timeliness, legibility and completeness of both active (current) and discharged patients records.

Survey Process:

The process for review of the medical records documented by the hospital defines the following:

- ✓ The frequency of review.
- ✓ Calculating the representative sample based on statistical principles.
- ✓ Specify the professionals to conduct the review from those who are authorized to make entries in the medical record (Review of the medical record should not be done by the statistical staff or the medical record personnel alone).
- ✓ Analyze documentation of the review to verify that it includes timeliness, legibility and completeness of both current and discharged patients' medical records.

Scoring:

- ■ If the hospital has a documented process to review the medical record as above and documentation demonstrates that the review focuses on timeliness, legibility and completeness of the medical records of both current and discharged patients, then score as **fully met.**
- ■ If the hospital does not have a medical record review process, or it has less than 80% compliance of any one of the above three requirements or if the review process does not include timeliness, legibility and completeness of both current and discharged patients' medical records, then score as **not met.**

GUIDELINES
Each hospital determines the content and format of the patient clinical record and has a process to assess the content and completeness of records. That process is a part of the hospital's performance improvement activities and is carried out regularly. Patient clinical record review is based on a sample representing the practitioners providing care and the types of care provided. The review process is conducted by the medical staff, nursing staff, and other relevant clinical professionals who are authorized to make entries in the patient record. **"THE REVIEW FOCUSES ON THE TIMELINESS, COMPLETENESS, LEGIBILITY, AND SO FORTH OF THE RECORD AND CLINICAL INFORMATION"** Clinical record content required by any existing law or regulation is included in the review process. The hospital's clinical record review process includes records of patients currently receiving care as well as records of the patients who have been discharged or died in the HCE. All entries must be legible, signed dated. Signature includes the first initial, last name and title. Initials may be used only if signatures are specifically identified elsewhere in the medical record (e.g. signature page).

Stamped signatures are acceptable, but must be authenticated. Methods used to authenticate signatures in electronic medical records will vary, and must be individually evaluated by reviewers. Date includes the day/month/year. Only standard abbreviations are used. Entries are in reasonable consecutive order by date. Handwritten documentation, signatures and initials are entered in ink that can be readily copied. Handwritten documentation does not contain skipped lines or empty spaces where information can be added later on. Entries are not backdated or inserted into spaces above previous entries. Omissions are charted as a new entry. Late entries are explained in the medical record, signed and dated.[30]

LEGIBILITY MEANS THE RECORDENTRYISREADABLEBYAPERSON OTHER THAN THE WRITER.

Although assessment of legibility may be subjective to a degree, the criterion for readability is simple: a notation can either be clearly and easily read or not. Health Care Providers (HCPs) who work together regularly may become accustomed to each other's handwriting. Even though a record may be readable between healthcare coworkers, the same concessions may not apply in legal actions. Records must be objectively reviewed for legibility. If a record fails to be readable at any level, hospital policy and medical staff bylaws should guide resultant actions. Offenders should be formally notified, corrective action taken, and improvements monitored. It is important for the HCE management to ensure the legibility of records. Illegibility patterns in patient records should be seriously considered during re-credentialing activities for credentialed and professional staffs.
Although legibility is addressed primarily as a physician issue, a number of allied health professionals have record documentation authority as well. Among them are nurses, therapists, and technicians. Legibility should be objectively measured in performance improvement activities and addressed in performance reviews as appropriate for all responsible health professionals.
Although legibility is addressed primarily as a physician issue, a number of allied health professionals have record documentation authority as well. Among them are nurses, therapists, and technicians. Legibility should be objectively measured in performance improvement activities and addressed in performance reviews as appropriate for all responsible health professionals.

Extent of Review Process

Note: This indicator demands that in the review process all the documentation pertaining to patients who are currently in the hospital and of those who are discharged is included. Review of documents of those patients who are admitted should be done strictly based on the SOPs, clearly dividing the documentation during three stages i.e. i. On admission, ii. During Stay, iii. On discharge. Typically, the review at admission and discharge should be done by the MS and AMS and the HoD must review the record for all aspects of care during stay to ensure that quality care is delivered. However the management should devise other means to have a counter check randomly, which should be recorded too. Regular review of records of patients should be done by a committee.

PROCESS FOR REVIEW OF MEDICAL RECORDS

1. The patient clinical record review will be carried out quarterly.
2. Sample size will be 10% of the patient's files admitted during the quarter.
3. Notification to conduct review by professionals will be issued by the MS/ CEO
4. The patient clinical record review will be conducted by at least one doctor and one nurse

[30] Glondys, B. (May 2003). "Ensuring Legibility of Patient Records (AHIMA Practice Brief). "Journal of AHIMA 74, no.5: 64A-D.

authorized to make entries in medical records.

5. The review focuses on the timeliness, legibility and completeness of the medical records.
6. Preparation of minutes documenting findings of the review, including deficiencies and corrective action/preventive measures

Ind 31. The review identifies, and documents any deficiencies in the record and the corrective and preventive measures undertaken are also documented.

Survey Process:

Review the minutes documenting findings of the review, including deficiencies found and also review the documentation of the corrective and preventive measures undertaken. It is highly unlikely that the hospital's review has not identified any problems with medical record documentation.

Scoring:

- If the documentation includes identification of any deficiencies as well as the corrective and preventive measure undertaken, then score as **fully met.**
- If not, then score as **not met.**

GUIDELINES

Identification and Documentation of Deficiencies in Records

It is important to understand the requirement of this indicator that it is demanding the actions which the review team/reviews are required to do and document. Therefore reviewers must be aware of at least the following types of errors which they are required to check and document. The person who makes the documentation error corrects the error. A single line is drawn through the error, with "error" written above or near the lined-through incorrect entry. The corrected information is written as a separate entry and includes date of the entry, signature (or initials), and title. There are no unexplained cross-outs, erased entries or use of correction fluid. Both the original entry and corrected entry are clearly preserved. If the person realized a documentation error, it should be corrected by that person there and then with the same pen and ink as described above but if it is a delayed realization or checked by another then it should be corrected in RED ink. Reviewers must determine method(s) used for correction of documentation errors in computerized records on a case to case basis.

No information or entry may be removed from a health record.

Documentation of Corrective and Preventive Measures

1. Indicator 30 and 31 are required to be read and evaluated together.
2. Errors inevitably occur in any medical record. They may be minor errors in transcription, inadvertently omitted test results, physicians' orders, other information omitted or deliberate falsifications.
3. First, deliberate falsifications must be avoided at all costs. This will most likely lead to allegations of a cover up which will at best, create a prima facie case of negligence.

4. Effort should be made to avoid other types of errors. However, in the event an error occurs, they can be corrected legally by the following procedure:
    A. The person who made the incorrect entry should change it and initial the correction.
    B. The person making the change should cross out the incorrect entry with a single line, enter the correct information, and enter the date and time of the correction.
    C. If the correction requires more than the available space, a supplement should be prepared and a reference to the supplement should be made in the available space by the erroneous entry.
    D. The original entry should not be obliterated or erased and following should be ensured;
        (i) Never use pencil to write entries.
        (ii) Never use "white-out."
        (iii) Do not alter past-dated notes, chart notes/progress notes (e.g., by writing alongside or adding to prior entries).
        (iv) Error corrections that are not done according to procedure will result in inadequate source documentation.
5. Guidance for when to state a reason for changes in documentation is as follows:
    A. If it is something a reviewer can "see" or is obvious, such as a transcription error, then it needs no explanation. For example, if the site corrected a lab value that was transcribed incorrectly, then an explanation for the correction is not necessary as long as it can be verified with the original lab report.
    B. If it is not clear, like a diagnosis or symptom that was deleted after initial entry, then there should be a rationale for the change. A sample format for report writing is given below:

Table 11: Medical Record Review Report

Medical Record Review Report

Date: _____ Reviewed by: _____

No. of Medical Files reviewed: _____

Detail: _____

Findings/ deficiencies: _____

Corrective/ preventive measures: _____

Assessment Scoring Matrix

Standard 11. IMS. 2: The Hospital regularly carries out review of medical records.

Indicator 30-31		Max Score	Weightage (Percent)	Score Obtained
Ind 30.	**The medical records are reviewed regularly/periodically focusing on the timeliness, legibility and completeness of both active (current) and discharged patients records.**	10	**100**	
Ind 31.	**The review identifies and documents any deficiencies in the record and the corrective and preventive measures undertaken are also documented.**	10	**100**	
Total		20		

2.5 Continuous Quality Improvement (CQI)

03 Standards & 09 Indicators

Continuous quality improvement (CQI) entails focusing on a systematic approach of using the service delivery data to monitor, assess and improve current performances for reducing actual and potential risks to patient safety. Ensuring continuous quality improvement lays emphasis on processes, systems and individual behaviors that reduce the likelihood of unanticipated adverse events. Involving the medical staff at all stages of implementation can help to improve the patient care processes, identify the data necessary to measure performance, analyze the data, and suggest and implement the process improvements.

Quality improvement plan ensures provision of healthcare services which are timely, safe, effective, and are based on recovery-oriented and patient-centered approach. It reflects commitment of the hospital to continuously improve the quality of services and the ongoing improvement of the quality is evidenced by the outcomes of the care. Essentials of a Quality Assurance (QA) plan are provided in the reference manual.

Standard 12. CQI-1: There is a structured quality improvement and continuous monitoring programme in the Hospital.

Indicators (32-33):

Ind 32. A comprehensive plan covering ALL the major elements related to quality improvement is developed, implemented and maintained by a notified committee and a designated QA coordinator.

Survey Process:

The indicator requires a written CQI plan including at least: i. A committee comprising members from relevant sections, ii. Terms of reference (TORs) with the roles, responsibilities and authorities of the committee/ members clearly defined, iii. The CQI methodology, iv. Structure for reporting CQI results, v. Recording minutes of the Committee meetings, vi. Notification of a designated QA coordinator.

Scoring:

- If there is a written plan and it includes at least the above 5 requirements and there is a designated CQI Coordinator, then score as **fully met.**
- If there is a plan but it lacks defining the responsibilities and authorities of the committee or if there is no designated CQI Coordinator, then score as **partially met.**
- If there is no plan or it includes 3 or fewer of the above requirements and there is no designated CQI Coordinator, then score as **not met.**

GUIDELINES

Quality Improvement Plan

Provision of Quality services entails timely, safe, effective, equitable, recovery-oriented and recipient- centered approach in their delivery. Quality Improvement Plan serves as the foundation of the commitment of the hospital to continuously improve the quality of the treatment and services provided to the Patients. The concerned Hospital is committed to continuous improvement of the quality of care delivered to its clients which is evidenced by the outcomes of the care.

The Essentials of CQI Plan are as follows:

1. A CQI Committee comprising members from relevant sections including the following:
   A. In charge/ MS of the HCE/ Hospital.
   B. Representative from the Hospital Board of Directors.
   C. Heads of Clinical Departments as appropriate for the facility.
   D. Managers/Directors, Ancillary Services.
   E. Nursing Managers/Senior Nurse.
   F. Quality Improvement (QI) Manager.
   G. Head of Pharmacy Department.
   H. Infection Control Nurse.

I. Any co-opted member.

2. The CQI Committee is assigned the **TORs** including *inter alia* the following:
   A. Prioritizing issues referred to the QI Committee for review
   B. Assuring that the review functions outlined in the plan are completed.
   C. Assuring that the data gathered through QI activities is analyzed, recommendations for resolving problem are made and followed.
   D. Identifying other sources of Patient Safety Goals such as the KP HCC's MSDS, for incorporating into the hospitals overall quality improvement efforts.
   E. Reporting the HCE Management findings, recommendations and trends, quarterly annually or on as and when required basis, to the Board of Management/Directors.
   F. Identifying Continued Professional Development needs and assuring that continued education for quality improvement takes place.
   G. Appointing sub committees or teams to work on specific issues, as necessary.
   H. Assuring availability of necessary resources.
   I. Undertake coordinating activities with the KP HCC as and when required.

3. The CQI Methodology:

Continuous Quality Improvement refers to following an approach which entails examining work processes to make them better, effective, efficient and responsive using the following Methodology:

A. Patients and caregivers are at the center of improvement efforts.
B. Focus on work processes.
C. Involvement of interdisciplinary teams to identify issues and make improvements.
D. Use of data and information to guide changes.

4. Structured arrangements for reporting CQI results.

All executing staff reports the action taken on a prescribed format to the respective in-charge and the CQI Committee members report to the Chairperson of the Committee who in turn reports to the in charge of the HCE.

An official should be assigned the responsibilities to act as QI Manager / QI Program Coordinator to:

A. Work collaboratively with the CEO/MS, committee members and departments to facilitate the activities of the CQI program throughout the organization with the ultimate goal to improve the quality of care that is routinely provided to the patients in the HCE.
B. Be responsible for identifying quality indicators, collecting and analyzing data, developing and implementing changes to improve service delivery, and monitoring to assure that improvement is made and sustained.
C. Record the minutes of the CQI Committee Meetings on following format provided as guidance:

5. Recording Minutes of Meeting

Proceedings of all meetings must be recorded briefly as minutes and record maintained by an authorized person on any register or format.

Table 12: Template for Minutes of Meeting

Venue: Conference Room of HCE_____ Date: _____
Subject: Minutes of CQI meeting No. _____held on_____, 2021

Agenda Item	Description	Discussion	Decision	Other remarks
1.				
2.				
3.				

Ind 33. The quality improvement plan is communicated to ALL the employees of the HCE through a proper orientation mechanism.

Survey Process:

There is documented evidence that ALL the appropriate staff including at least i. All the senior managers, ii. All department heads, and iii. All members of the CQI committee have participated in a formal orientation process to ensure they fully understand the plan. Interview staff and ask regarding orientation on the CQI plan.

Scoring:

- If there is documented evidence of orientation of ALL the personnel listed above, then score as **fully met.**
- If only 1-2 department heads have not participated in orientation, then score as **partially met.**
- If there has been no orientation, or it has not included at least the senior managers, the committee members and "most" of the department heads, then score as **not met.**

GUIDELINES

Communication of QI Program

All staff is assigned the responsibility and authority to participate in the Hospital's QI Plan. To fully accomplish this, all staff shall be provided education regarding the QI Plan during their initial orientation and on an annual basis thereafter.

This education shall include a description of the QI Plan and how they fit into the plan, based on their particular job responsibilities. It shall also include education regarding the QI methodology utilized by the HCEs.

Such a plan is required to be reviewed and kept updated on regular basis which can be 6 monthly of yearly.

Assessment Scoring Matrix

Standard 12. CQI. 1: There is a structured quality improvement and continuous monitoring programme in the hospital.

Indicator 32-33		Max Score	Weightage (Percent)	Score Obtained
Ind 32.	**A comprehensive plan covering ALL the major elements related to quality improvement is developed, implemented and maintained by a notified committee and a designated QA coordinator.**	10	**80**	
Ind 33.	**The quality improvement plan is communicated to ALL the employees of the HCE through a proper orientation mechanism.**	10	**80**	
Total		20		

Standard 13. CQI-2: The key indicators to monitor the clinical structures, processes and outcomes, and used as tools for continual improvement are identified.

Indicators (34-39):

Ind 34. Monitoring includes appropriate patient assessment.

Survey Process:

During survey of the hospital, review the minutes of the QA Committee meeting to see the documentation of monitoring the patient assessment processes documented in the medical record at i. Admission (OPD / emergency), ii. During the course of treatment iii. Assessment on the basis of the condition of the patient and. The healthcare establishments can set their own benchmarks regarding monitoring of patient assessment processes.

Scoring:

- If there is documented evidence that this has been monitored, then score as **fully met.**
- If not as above, then score as **not met.**

GUIDELINES

Monitoring of Patient Assessment

The hospital shall develop appropriate key performance indicators suitable to it including but not limited to the following;

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 counter-signed by the clinician.
3. Percentage of cases (in-patients) wherein screening for nutritional needs has been done. Percentage of cases (in-patients) wherein the nursing care plan is documented.

Ind 35. Monitoring includes safety and quality control plans of the diagnostic services.

Survey Process:

Review the minutes of the QA committee meeting to see monitoring of the safety and quality control plan in the diagnostic services to observe the following: i. Documented Standard Operating Procedures, ii. Documented Occupational Health & Safety (OH&S) protocols iii. Documented training of staff in SOPs and occupational health & safety procedures, iv. Reference testing / calibration of diagnostic equipment to ensure validity.

Scoring:

- If there is documented evidence that these factors are present and related activities are being monitored and reflected in the minutes of the QA committee, then score as **fully met.**
- If not, then score as **not met.**

GUIDELINES

Monitoring of Diagnostic Services

The hospital shall develop appropriate key performance indicators suitable for all diagnostic services including but not limited to the following:

1. Number of reporting errors/1000 investigations.
2. Percentage of re-dos.
3. Percentage of reports co-relating with clinical diagnosis.
4. Percentage of adherence to safety precautions by employees working in diagnostics.

Interpretation(s): Reporting errors need to be captured. It is better if the organization captures these errors as errors picked up before dispatching the reports and errors picked after the dispatch of reports. This includes transcription errors also.

Re-dos include tests which needed to be repeated in view of poor sample or improper positioning and in case of radiology also includes film wastage.

To capture co-relation it becomes mandatory that all investigation forms have a provisional diagnosis/relevant clinical details written on them. The organization could decide which tests will be monitored. However, in case of laboratory errors shall be captured for all histo-pathological tests and in case of radiology they shall be captured for Computed Tomography (CT) and Magnetic Resonance Imaging (MRI). The form can have the differential diagnosis also written on them.

To capture adherence to safety precautions, the organization needs to do a random check of all employees per month (working in these areas and including all categories of staff) and capture data.

Ind 36. Monitoring includes ALL invasive procedures.

Survey Process:

Review the QA committee minutes to check if indicators such as reporting of all adverse occurrences[31] such as return to operating room within 24 hours and re-admissions within 24 hours if related to invasive procedures is documented.

Scoring:

- If there is documented evidence that this has been monitored, then score as **fully met.**
- If not, then score as **not met.**

GUIDELINES

Monitoring of Invasive Procedures

The hospital shall develop appropriate key performance indicators for all invasive procedures suitable to it including but not limited to the following:

[31] An unplanned event with a negative consequence for the patient.

1. Percentage of unplanned invasive procedures.
2. Percentage of rescheduling of invasive procedures.
3. Percentage of cases where the organization procedures, to prevent adverse events like wrong patient and wrong procedure, have been adhered to.
4. Percentage of cases who received appropriate prophylactic antibiotics within the specified time frame.

Interpretations: Unplanned procedure shall be captured only during the same admission. Re-scheduling of patients include cancellation and postponement (beyond four hours) of the procedure because of poor communication, inadequate preparation or inefficiency within the system.
Prophylactic antibiotics should be administered ideally within 30-60 minutes but certainly within two hours of the time of incision.

Ind 37. Monitoring includes adverse drug events.

Survey Process:

Review the documentation in the QA Committee minutes and check to see if there are references to Adverse Drug Reactions (ADRs) and events such as allergic reactions, wrong dose, wrong drug, wrong patient, contraindications and similar issues and see how these events have been managed.

Scoring:

- If there is documented evidence that this has been monitored, then score as **fully met.**
- If not, then score as **not met.**

GUIDELINES

Monitoring of Adverse Drug Events

The hospital shall develop appropriate key performance indicators for monitoring adverse drug reactions including *inter alia* the following:

1. Percentage of medication errors (Prescribing, dispensing, administration).
2. Incidence of adverse drug reactions.
3. Percentage of admissions with adverse drug react ion(s).
4. Percentage of medication charts with error prone abbreviations.
5. Percentage of patients receiving high risk medications developing adverse drug event.

Interpretations: This shall be based on best national and international practices. For example, "Institution for Safe Medication Practices (ISMP) list of Error-Prone abbreviations, Symbols, and Dose Designations."
ADR monitoring and reporting programs encourage ADR surveillance, facilitate ADR documentation, promote the reporting of ADRs, provide a mechanism for monitoring the safety of drug use in high-risk patient populations, and stimulate the education of health professionals regarding potential ADRs. A comprehensive, ongoing ADR program should include mechanisms for monitoring, detecting, evaluating, documenting, and reporting ADRs as well as intervening and providing educational feedback to prescribers, other healthcare professionals, and patients. Additionally, ADR programs should focus on identifying problems leading to ADRs, planning for positive changes, and measuring the results of these changes. Positive outcomes resulting from an

ADR program should be emphasized to support program growth and development.

A comprehensive ADR-monitoring and reporting program should be an integral part of an organization's overall drug use system.

An ADR-monitoring and reporting program should include the following features;

1. The program should establish:
   A. An on-going and concurrent (during drug therapy) surveillance system based on the reporting of suspected ADRs by pharmacists, physicians, nurses, or patients.
   B. A prospective (before drug therapy) surveillance system for high-risk drugs or patients with a high risk for ADRs.
   C. A concurrent surveillance system for monitoring alerting orders. Alerting orders include the use of "tracer" drugs that are used to treat common ADRs (e.g., orders for immediate doses of antihistamines, epinephrine, and corticosteroids), abrupt discontinuation or decreases in dosage of a drug or stat orders for laboratory assessment of therapeutic drug levels.
2. Prescribers, caregivers, and patients should be notified regarding suspected ADRs.
3. Information regarding suspected ADRs should be reported to the pharmacy for complete data collection and analysis, including the patient's name, the patient's medical and medication history, a description of the suspected ADR, the temporal sequence of the event, any remedial treatment required, and outcomes.
4. High-risk patients should be identified and monitored. High-risk patients include but are not limited to pediatric patients, geriatric patients, patients with organ failure (e.g., hepatic or renal failure), and patients receiving multiple drugs.
5. Drugs likely to cause ADRs ("high-risk" drugs) should be identified, and their use should be monitored. Examples of drugs that may be considered as high risk include aminoglycosides, amphotericin, antineoplastic, corticosteroids, digoxin, heparin, lidocaine, phenytoin, the ophylline, thrombolytic agents, and warfarin.
6. The cause(s) of each suspected ADR should be evaluated on the basis of the patient's medical and medication history, the circumstances of the adverse event, alternative etiologies, and a literature review.
7. A method for assigning the probability of a reported or suspected ADR (e.g., confirmed or definite, likely, possible, and unlikely) should be developed to categorize each ADR.
   Algorithms may be useful in establishing the causes of suspected ADRs. Subjective questions and the professional judgment of a pharmacist can be used as additional tools to determine the probability of an ADR.
   Questions might include the following:
   A. Was there a temporal relationship between the onset of drug therapy and the adverse reaction?
   B. Was there a de-challenge; i.e., did the signs and symptoms of the adverse reaction subside when the drug was withdrawn?
   C. Can signs and symptoms of the adverse reaction be explained by the patient's disease state?
   D. Were there any laboratory tests that provide evidence for the reaction being an ADR?
   E. What was the patient's previous general experience with the drug?
   F. Did symptoms return when the agent was re administered?
8. A method for ranking ADRs by severity should be established.
9. A description of each suspected ADR and the outcomes from the event should be documented in the patient's medical record.

10. Serious or unexpected ADRs should be reported to the Drug Regulatory Authority (DRA) or the drug's manufacturer (or both).
11. All ADR reports should be reviewed and evaluated by a designated multidisciplinary committee (e.g., a pharmacy and therapeutics committee).
12. ADR-report information should be disseminated to health care professional staff members for educational purposes. Good topics for medical staff education include preventing ADRs and appropriate and effective care for patients who experience ADRs. Educational programs can be conducted as morning "report" discussions, newsletters, algorithms for treatment, and multi-disciplinary reviews of drug-use evaluations. Patient confidentiality should be preserved.
13. In settings where it is possible, a pharmacy-coordinated ADR team or committee, consisting of a physician, nurse, QI leader, an administrator, and a pharmacist is recommended. The team should be charged with adopting a definition for the organization, promoting awareness of the consequences of ADRs, establishing mechanisms for identifying and reporting ADRs, reviewing ADR patterns or trends, and developing preventive and corrective interventions.
14. Continuous monitoring of patient outcomes and patterns of ADRs is imperative. Findings from an ADR monitoring and reporting program should be incorporated into the organization's on-going quality improvement activities. The process should include the following:
    A. Feedback to all appropriate health care staff.
    B. Continuous monitoring for trends, clusters, or significant individual ADRs.
    C. Educational efforts for prevention of ADRs.
    D. Evaluation of prescribing patterns, patient monitoring practices, patient outcomes, and the ADR program's effect on overall and individual patient outcomes.

An overall goal of the ADR process should be the achievement of positive patient outcomes.

Ind 38. Monitoring includes use of anaesthesia.

Survey Process:

Review the documentation in the committee minutes and observe for reporting of adverse occurrence and adequate follow up from anesthetic services.

Scoring:

- If there is documented evidence that this has been monitored and adequate follow up has been conducted, then score as **fully met.**
- If not, then score as **not met.**

GUIDELINES

Monitoring Use of Anaesthesia

The hospital shall develop appropriate key performance indicators suitable to it including but not limited to the following:

1. Percentage of modification of anaesthesia plan
2. Percentage of unplanned ventilation following anaesthesia

3. Percentage of adverse anaesthesia events
4. Anaesthesia-related mortality rate.

Interpretations: Anaesthesia plan is prepared at the time of pre-anaesthesia assessment. The same shall be reviewed during the immediate pre-operative re-evaluation. Modifications done in the plan based on this assessment shall be captured.

Adverse anaesthesia events include events, which happen during the procedure like hypoxia, arrhythmias, cardiac arrest, etc.

Ind 39. Monitoring includes use of blood and blood products.

Survey Process:

Review the documentation in the committee minutes and observe for reporting adverse occurrence and adequate follow up from the blood services.

Scoring:

- If there is documented evidence that this has been monitored and adequately followed-up, then score as **fully met.**
- If not, then score as **not met.**

GUIDELINES

Monitoring Use of Blood and Blood Products

The hospital shall develop appropriate Key Performance Indicators (KPIs) suitable to it including the following mandatory parameters:

1. Percentage of transfusion reactions.
2. Percentage of wastage of blood and blood products.
3. Percentage of blood component usage.
4. Turnaround time for issue of blood and blood components.

Interpretations: Wastage includes blood products found unfit for use.

Every blood transfusion service should develop an effective quality system to ensure the implementation of these strategies. The quality system should cover all aspects of its activities and ensure traceability, from the recruitment and selection of blood donors to the transfusion of blood and blood products to patients. It should also reflect the structure, needs and capabilities of the Blood Transfusion Services (BTS), as well as the needs of the hospitals and patients that it serves.

Assessment Scoring Matrix

Standard 13. CQI. 2: The key indicators to monitor the clinical structures, processes and outcomes, and used as tools for continual improvement are identified.

Indicator 34-39		Max Score	Weightage (Percent)	Score Obtained
Ind 34.	**Monitoring includes appropriate patient assessment.**	10	**100**	
Ind 35.	**Monitoring includes safety and quality control plans of the diagnostic services.**	10	**100**	
Ind 36.	**Monitoring includes ALL invasive procedures.**	10	**100**	
Ind 37.	**Monitoring includes adverse drug events.**	10	**100**	
Ind 38.	**Monitoring includes use of anaesthesia.**	10	**100**	
Ind 39.	**Monitoring includes use of blood and blood products.**	10	**100**	
Total		60		

Standard 14. CQI-3: Sentinel events are intensively analyzed.

Indicators (40-40):

Ind 40. The Hospital has defined sentinel events and sentinel events are intensively analyzed when they occur.

Survey Process:

Review the written definition of a sentinel event and the list which should include at least: i. All unexpected deaths including infants, mothers and suicide, ii. Serious adverse patient events that caused, or could have caused, harm to the patient including return to the operating room within 24 hours, readmission to the hospital within 24 hours, wrong-patient, wrong-site, wrong-procedure, medication error, iii. Patient violence against staff, iv. Violence against patients, 5. Infant abduction, and vi. Switching over of babies. Although not specifically required, it is good practice to also include "near misses." Review the documentation of intense analysis of any sentinel event that has occurred in the past 12 months.

Scoring:

- If there is a list and significant evidence of a rigorous documented process of monitoring, reviewing, responding to and mitigating sentinel events and evidence that any reported sentinel event was intensively analyzed, including corrective action to prevent or reduce the likelihood of reoccurrence then score as **fully met.**
- If there is no list, or the monitoring and mitigating processes are not adequate, or if there was a sentinel event, but there was either no analysis or the analysis was "superficial" such as limited to assigning blame to an individual then score as **not met.**

GUIDELINES

LIST OF SENTINEL EVENTS

Following are defined as the sentinel events at ABC Hospital XYZ:

1. Fire
2. Theft
3. Violence
4. Un-expected death
5. Re-admission/re-surgery within 24 hours
6. Abduction
7. Switching of babies
8. Surgery on wrong site
9. Rape
10. Suicide

In case of any sentinel happening the hospital staff who is affected, involved or who witnesses such event must immediately inform to the Hospital Management. MS/ CEO of the HCE will constitute a committee for intensive investigation. The committee will suggest recommendations including corrective actions to reduce or prevent likelihood reoccurrence of such event.

MS ABC Hospital
XYZ

Analysis of Sentinel Events

HCEs are expected to identify and respond appropriately to all sentinel events occurring in the hospital or associated with services that the hospital provides, or provides for. Appropriate response includes conducting a timely, thorough, and credible root cause analysis; developing an action plan designed to implement improvements to reduce risk, implementing the improvements, and monitoring the effectiveness of those improvements. Root Cause Analysis and Action Plan are described as follows:

Root Cause Analysis

Root cause analysis is a process for identifying the factors that underlie variation in performance, including the occurrence or possible occurrence of a sentinel event. A root cause analysis focuses primarily on systems and processes, not on individual performance. The analysis progresses from special causes in clinical processes to common causes in organizational processes and systems and identifies potential improvements in these processes or systems that would tend to decrease the likelihood of such events in future or determines, after analysis that no such opportunities exist.

Action Plan

The product of the root cause analysis is an action plan that identifies the strategies that the hospital intends to implement in order to reduce the risk of similar events occurring in the future. The plan should address responsibility for implementation, oversight, pilot testing as appropriate, time lines, and strategies for measuring the effectiveness of the actions.

Assessment Scoring Matrix

Standard 14. CQI. 3: Sentinel events are intensively analyzed.

Indicator 40-40		Max Score	Weightage (Percent)	Score Obtained
Ind 40.	**The Hospital has defined sentinel events and sentinel events are intensively analyzed when they occur.**	10	**100**	
Total		10		

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

03 Standards & 17 Indicators

A healthcare organization should consider the care it provides as part of an integrated system of services, healthcare practitioners and professionals, and levels of care, which make up a continuum of care. The goal is to correctly match the patient's healthcare needs with the services available, to coordinate the services provided to the patient in the organization, and then to plan for reception, registration, management, disposal and follow-up. The result is improved patient care outcomes and more efficient use of available resources.

The laboratory services are required to respond to the clinical needs of the hospital/clinicians. The reports issued by the laboratory must be legible, accurate and promptly available to the authorized persons. Reference values/normal ranges must be readily available to clinicians, preferably on the test report itself.

Similarly, the radiological/imaging services are the key diagnostic tool s for many diseases and are also important in monitoring treatment outcome/prognosis. Radiologists have been involved in technological developments and are responsible for the evaluation of strengths and weaknesses of different investigations. They have developed the knowledge of the appropriate integrated imaging algorithms to maximize clinical effectiveness. The standards described here deal with the implementation of these developments in the clinical setting and for ensuring the best use of technological resources.

Standard 15. AAC-1: Services are provided as portrayed and the HCE has a Well-established patient management system.

Indicators (41-43):

Ind 41. The services being provided at the hospital are displayed.

Survey Process:

This will require knowledge of the scope of services provided at the hospital and observation of the displayed services both for on and off site. It means that there is a board clearly displaying the menu of services[32] which a patient should expect from the hospital.

Scoring:

- If the displayed services match the services being actually delivered, then score as **fully met.**
- If there is superfluous / misleading information or no information about the scope of services is displayed, then score as **not met.**

GUIDELINES

Menu of Services

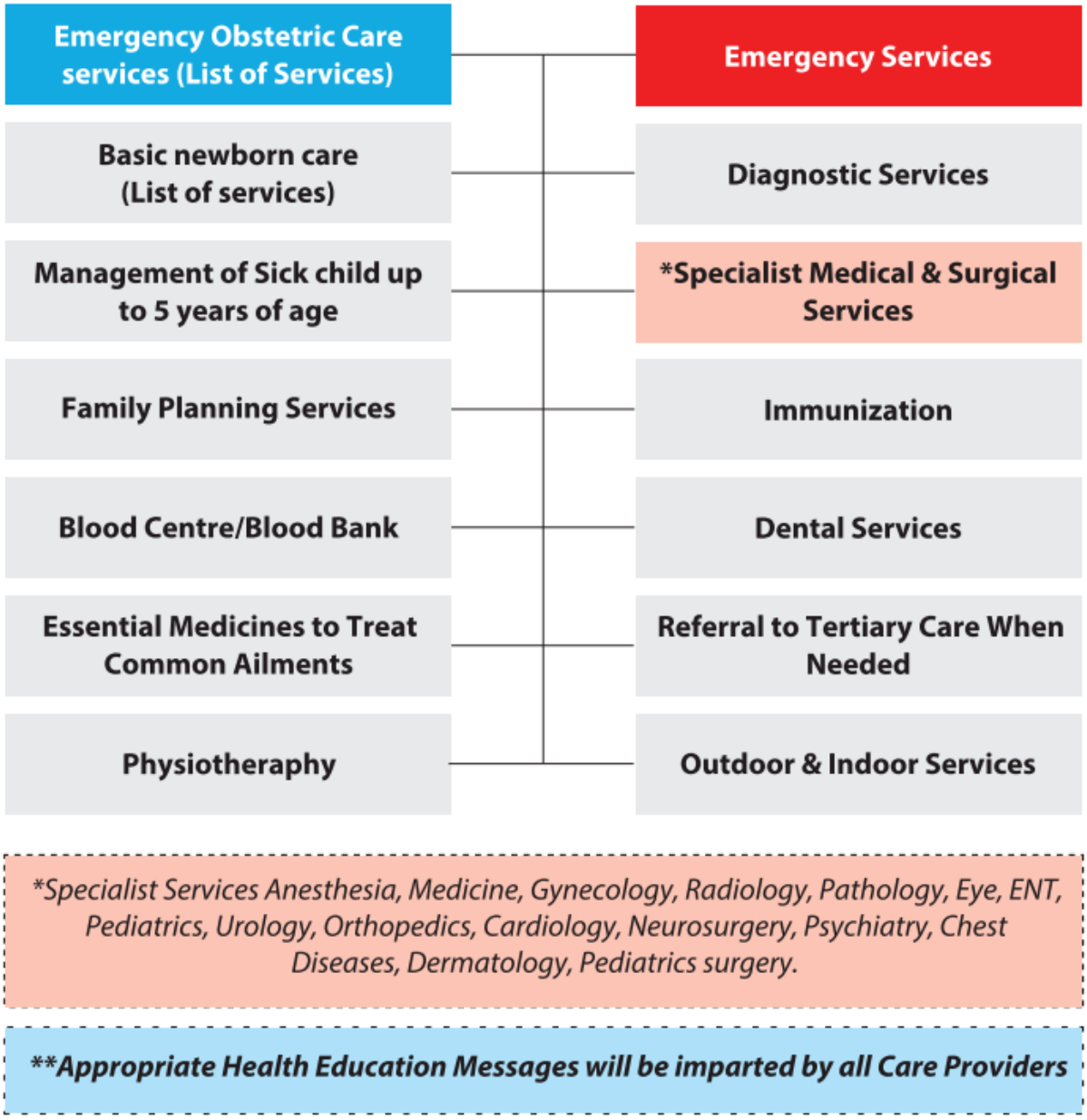
It is of immense importance for patients to be aware of the services available at a particular HCE. Therefore, correctness of information being displayed is vital[33]. The services being provided may be titled as "menu of services" and are to be displayed considering the following;

1. Purpose of Menu is to display information about available Services in the Facility.
2. It is to be clearly & boldly written on a large board proportionate to the facility & fixed at the entry points, (Main Gate), Key Turning Points & Receptions/Waiting Areas.
3. Only Services available are to be shown in this Menu.
4. A suggested sample is provided as Figure 1: Menu of Services

[32] Further explained and a format provided in the Guidelines.

[33] Malafide intention can be considered if a service provision is displayed from the beginning and continues to do so but the service has never been created. Whereas a service created and displayed then discontinued but the display remained can well be taken as an oversight.

Figure 1 Menu of Services



Ind 42. There is a well-established registration and guidance process.

Survey Process:

Observe as well as check from the record that there is a well-established reception, registration and guidance[34] process with written SOPs to cater for the needs of the patients. The reception staff is polite and guides the patients to the facility/professionals where they are examined and assessed for further management or explained such other requirements.

[34] It means direction/guidance to patients regarding further steps in connection with their medical needs and its management i.e. OPD or laboratory or medical store/dispensary etc.

Scoring:

- If the registration and guidance process based on written SOPs is being practiced, then score as **fully met.**
- If there are non-conformities to the above then, score as **not met.**

GUIDELINES

Registration and Disposal

A well-functioning Registration and Disposal Process is an important indicator of established Patient Management System. If the patients are received, registered and appropriately guided for further relevant actions, it confirms the satisfaction of the patients and other care providers. Following SOPs can be adopted and used as guidelines by appropriate modification in respect of a particular HCE to suit the local needs.

Registration and Disposal SOPs

1. A senior, preferably dispenser/computer literate is appointed to perform duty as Receptionist at central registration point.
2. Information to patients is provided both verbally & on telephone in a pleasant manner.
3. Patient is received at reception desk, particulars are recorded in the register as per format given at the end of these SOPs, a prescription slip prepared accordingly for doctor to write on.
4. Patients are guided to reach the required service/facility.
5. If the doctor or care provider is busy, the patient is requested to wait for a while.
6. MO / WMO & all other concerned Health Care providers take actions as per their level/Job Description.
7. All Health Care providers talk to their patients on prevention of disease, sanitation issues & educate them on Common Health Problems.
8. Patients are prescribed medicines which they obtain from the Pharmacy and go home or are admitted as per advice of the treating doctor.
9. Patients are referred for investigations & consultations and management when ever considered essential.
10. The particulars of patients are entered in a register having following format:

Table 13: Patient Registration Format

Date	Time	Unique No.	Name	S/o, W/o etc.	Age/Sex	Address	Contact No.	Required service doctor	Disposal

Ind 43. There is a well-established patient assessment process.

Survey Process:

Check the records if patients are assessed by the Doctor(s) documenting the presenting

complaints/symptoms, signs and relevant diagnostic evaluations,[35] as applicable with the objective of providing quality care at outdoor/indoor or for referral within the facility or to some other facility, in line with the prescribed Code of Ethics.[36] Review the representative sample of patients' record to see the documentary evidence.

Scoring:

- If all checked records show documentation of patients' assessments according to the above, then score as **fully met.**
- If less than 20% of the record is deficient on the above, then score as **partially met.**
- If the record shows more than 20% deficiency on the above, then score as **not met.**

GUIDELINES

Patient Assessment and Management Methodology

The standard way of patient assessment and management is to follow the Clinical Methods viz Observation, History of Present illness, History of Past illnesses for picking up any relevant point, Social Habits, recording/noting the symptoms, examining and eliciting the signs for reaching at a Provisional Diagnosis/Differential Diagnosis and then deciding about the laboratory tests/investigations to be done and line of management to be advised (Disposal). At this stage, patient shall have a Prescription if medication is required along with advised tests and clear advice in writing to be followed after going home or admission or referral to another facility as the case may be. Doctors must follow the Standardized Medical Protocols when managing any particular disease, at the same time using their own clinical acumen in treating and saving the patients' lives.

[35] The practice of documenting patient particulars, temperature, pulse & BP etc. by the assistant followed by consultation by the doctor, who records presenting complaints/symptoms, signs and relevant evaluations to reach a diagnosis/provisional diagnosis and advises further tests (if required) and advises treatment.

[36] Section 13 Code of Ethics of practice for Medical and Dental Practitioners published by PM&DC on their website.

Assessment Scoring Matrix

Standard 15. AAC. 1: Services are provided as portrayed and the HCE has a Well-established patient management system.

Indicator 41 - 43		Max Score	Weightage (Percent)	Score Obtained
Ind 41.	**The services being provided at the hospital are displayed.**	10	**100**	
Ind 42.	**There is a well-established registration and guidance process.**	10	**100**	
Ind 43.	**There is a well-established patient assessment process.**	10	**100**	
Total		30		

Standard 16. AAC-2: Laboratory services are provided as per the requirements of patients.

Indicators (44-49):

Ind 44. Scope of the laboratory services caters for the emergency and the clinical services provided at the HCE.

Survey Process:

This will require an understanding of the full scope of clinical services provided at the healthcare establishment and observation of the diagnostic facilities provided both on and off site. Check the outsourced laboratory arrangements to confirm that those are according to the scope of services of the hospital.[37] An indicative list of tests required to be performed at this level of HCE is provided at **Annexure K**.

Scoring:

- If the in-house laboratory and any outsourced facility[38] support the scope of services, then score as **fully met.**
- If the in house laboratory / diagnostic services or an outsourced laboratory do not support the scope of services provided by the hospital then score as **not met.**

GUIDELINES

Scope of Laboratory Services

1. The hospital shall have a well-organized, adequately supervised laboratory with adequate space, facilities and optimum temperature for equipment to perform services commensurate with the hospital's needs for its patients.
2. Basic clinical laboratory services necessary for routine examinations shall be available regardless of the size, scope and nature of the hospital. Provision shall be made to carry out adequate clinical laboratory examinations including Chemistry, Microbiology, Hematology, Serology, and Clinical Microscopy.
3. Laboratory facilities and services shall be available for emergency tests at all times.
4. Some services may be provided through arrangements (Contacts/TORs) with other Licensed Hospitals and Laboratories/Diagnostic Centers in the Public/Private Sector which have the appropriate facilities.

   The Healthcare Establishment (HCE) should ensure the availability of laboratory services commensurate to the healthcare services provided by it during hospital working hours, either by in house or outsource arrangement, however the emergency tests directly affecting the patient's emergent care should be available in house for example RBS, Arterial Blood Gases (ABG), Cardiac Enzymes etc.

[37] Patients should be informed about laboratory tests that are outsourced.

[38] Showing satisfactory performance as per hospital's experience till registered / licensed by the KP HCC.

Ind 45. Adequately qualified and trained personnel perform and/or supervise the investigations.

Survey Process:

Each laboratory personnel has a job description to accomplish the assigned duties. Review the personal files for laboratory technical and supervisory staff to determine if their credentials (qualifications, experience and training) match the requirements of the respective position and the job description including handling the equipment being used. A system of Continuous Professional Development (CPD)[39]/ Continued Medical Education (CME) to be practiced.

Scoring:

- If qualifications of all the individuals match the requirements of the job description, or if there are only minor variances (such as only 4 years of experience instead of 5), then score as **fully met.**
- If only one technician does not have the qualifications required by the job description, then score as **partially met,** provided that there is evidence of enhanced supervision or training of this individual.
- If two or more technicians do not have the required qualifications (in the job description), then score as **not met.**

GUIDELINES

Staff Authorized to Perform or Supervise

The HCE identifies the laboratory staff members performing tests, including those who are approved to perform point of care screening tests at the bedside, and those who direct or supervise staff performing tests. Supervisory and technical staff should have appropriate and adequate qualifications (Histopathology, Microbiology, Immunology, Hematology and Chemical Pathology etc.), training, experience, skills and are oriented to their work. The technical staff is given work assignments consistent with their qualification, training and experience. In addition, the HCE shall ensure that there is a sufficient number of staff to perform tests promptly and to provide necessary laboratory services during all hours of operation and for emergencies. Staff with proper qualifications, appropriate training and experience shall interpret tests and write reports.

Clinical laboratory services are under the direction of an individual who is qualified by virtue of documented training, expertise, and experience. This individual assumes professional responsibility for the laboratory facility and the services provided in the laboratory, as well as tests performed outside the laboratory such as the testing performed at bedside (point of care testing). The oversight of services outside of the laboratory includes ensuring consistent organization wide policies and practices, such as training, supply management etc., but not daily supervision of those activities. Daily supervision remains the responsibility of the leaders of the department or unit in which the testing is conducted.

1. A Laboratory Manager/Director with the following qualifications may be positioned at a hospital:

[39] A recognized program administered by a professional college/council or equivalent.

A. A medical graduate qualified in any discipline of pathology. He/she may be a Doctor of Philosophy (PhD), Fellow of College of Physicians and Surgeons (FCPS), Member of Royal College of Pathology (MRCPath), Master of Philosophy (M.Phil) or some equivalent degree, OR
B. A person with Diploma in Clinical Pathology (DCP)

The Manager/Director is responsible for testing, Quality Assurance, personnel training, equipment and inventory.

2. Other required staff are given below:
   A. Technicians and Technologists, with a Diploma in Laboratory Technology/Bachelor of Science/Master of Science, who are responsible for conducting testing.
   B. Support Staff
      (i) Phlebotomists: They should be given in-house training on the Sample Collection Manual
      (ii) Typist/Administrative staff
      (iii) Cleaning staff

Ind 46. SOPs and procedures guide the: i. Collection, ii. Identification, iii. Handling, iv. Safe transportation, v. Processing and vi. Disposal of specimens.

Survey Process:

Review the laboratory procedure manual to validate that it covers ALL the 6 requirements. It is important to verify that the procedures/SOPs are not just written, but are actually implemented and followed. Ask operational staff about the 6 policy requirements to establish if they are aware of the SOPs and procedures and have received appropriate orientation and training. Then, by observation check, how a patient whose blood is being drawn was positively identified and how the specimen was labelled.

Scoring:

- If there are SOPs and procedure manual for ALL the 6 requirements, the manual is present at the work place and evidence that the staff has been trained and that the procedures are followed, then score as **fully met.**
- Since this is significant for patient safety (misidentified patient and mislabeled specimens are a common source of laboratory errors), if the SOPs/ procedures for ALL 6 requirements are not implemented, then score as **not met.**

GUIDELINES

SOPs for Handling of Specimens

1. **Sample Collection:**
   A. Specimen collection is the first phase of interaction between the patient and the laboratory.
   B. Appropriate counseling should be done before specimen collection, and consent taken whenever needed.
   C. A phlebotomist/laboratory technician will be responsible for collecting the sample.

(i) Specimen collection can be done at the patient's bedside, in the laboratory or in the field.
(ii) Trained manpower should be employed for specimen collection.
(iii) A Laboratory should have a "Primary Specimen Collection Manual," containing information on patient preparation before specimen collection (if any), and the exact methodology of specimen collection, labelling, handling, transportation and storage of the specimens. In addition, the laboratory should provide adequate and appropriate information/instructions to patients wherever necessary. All pre-analytical factors that may influence the test results should be identified. This manual should be available for reference and should be used for the training of staff engaged in specimen collection.

Guidelines for obtaining/collecting specimens:

Any error in specimen collection can lead to erroneous results. It is therefore considered an important step of good clinical laboratory practice and is referred to as "pre-analytic control" which covers the following:

1. Collect the material from the site in which the etiologic agent will most likely be found.
2. Collect the specimen at the optimum time (e.g., early morning sputum for Acid-Fast Bacillus (AFB).
3. Obtain cultures prior to administration of antibiotics whenever possible.
4. Collect adequate volume of material. Inadequate amounts of specimen may yield false negative results.
5. Collect the specimen in a manner that minimizes or eliminates contamination from indigenous flora as much as possible, to ensure that the sample will be representative of the infected site.
6. Use appropriate collection devices, transport media and sterile, leak proof containers.
7. Sterile equipment and aseptic technique to collect the specimen, to prevent introduction of microorganisms during invasive procedures.
8. Clearly label the specimen including specific information regarding the site of collection and complete the ordering process.
9. Identify the specimen source and/or specific site correctly so that proper processing methods and culture media will be selected by the laboratory personnel.
10. If the specimen is collected through intact skin, cleanse the skin first with 70% alcohol followed by an iodine solution (e.g. povidone-iodine) or chlorhexidine/alcohol combination. If iodine is used, remove excess iodine after the specimen has been collected.
11. Provide clear instructions to patients if they are collecting their own specimen (e.g., clean catch urine, or stool) in order to obtain the best quality specimen and allay their fears.
12. Deliver the specimen promptly to the laboratory. Delay in transport may compromise the specimen.
13. As with all patient contact episodes, consistent attention must be given to hand hygiene and use of appropriate Personal Protective Equipment (PPE).
14. Use appropriate safety devices to minimize risk of accidental needle stick, cut or puncture. It is advisable to make sure the user is knowledgeable about how the safety device works prior to its use.

Identification and Labelling:

A properly labelled sample is essential so that the results of the test match the patient. The key elements in labelling are:

1. Patient's surname, first and middle.
2. Patient's Identity (ID) number.

NOTE: Both of the above MUST match the same on the requisition form.

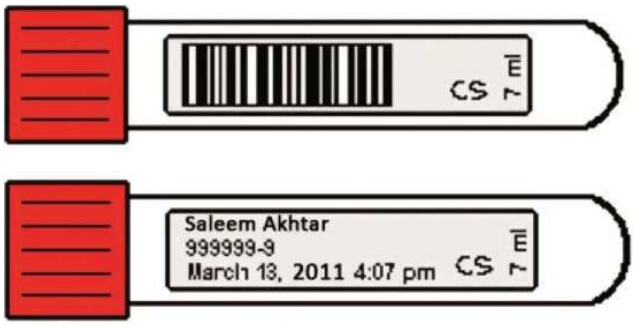
3. Date, time and initials of the sample collector must be on the label of EACH tube.
4. Automated systems may include labels with bar codes.

The date and signature/initials of the collector must be recorded after the specimen has been collected and after verifying that the patient's name and ID on the label agrees with that on the test requisition. This is the single most important factor in preventing errors in a patient's specimen identification. ***Use of a request form wrapped around the container is not acceptable as a specimen label.*** Specimens will not be accepted if the information on the specimen label does not match the information on the accompanying requisition.

Figure 2 Labelling Sample

Examples of labelled collection tubes are shown below:

Figure 3 Labelling Sample Tubes



Handling

1. There is clearly a difference between the hazards posed by packages sent to a specialist or reference laboratory and those to a routine diagnostic laboratory.
2. The former are likely to contain cultures or concentrates of infectious agents whereas the bulk of the latter is not particularly infectious.
3. It is advisable that cultures and such specialized materials are unpacked in the laboratory by professional staff.
4. There is concern over the use of clerical staff for receiving and documenting specimens.

5. It is not unusual to see food and drink being consumed by clerical staff near the specimens.
6. The disturbingly large numbers of untrained staff who acquire infections in the laboratory undoubtedly include clerical and reception staff. Therefore, **it is essential that clerical staff handling specimens should be given some form of training in the safe handling of specimens.**
7. Any specimen in a plastic bag which carries a "Danger of Infection" label should not be removed from that bag.
8. The **accession number** can be put on the outside of that bag. Leaking or broken specimens should not be touched.
9. Provision should be made for a member of the professional staff to deal with such samples. These specimens should not be allowed to be moved to other parts of the room.

Figure 4 Protective Measures

Note: Handle all samples as if infectious.

Safe Transportation

Figure 5 Safe Transportation

Transport within hospitals and to referral labs.

All employees are required to take reasonable care of their own health and safety as well as that of all other persons who may be affected by their acts or omissions at work. Responsibility for the safe collection and packaging of clinical samples shall rest entirely upon the sender, it is therefore imperative that all areas where clinical materials are generated remain conversant with up to date

safety codes of practice.

Figure 6 Safe Transportation

All laboratory specimens are potentially hazardous.

It is important that care is taken when collecting and handling clinical samples to ensure that the risk of infection to staff is kept to an absolute minimum. These rules must be observed at all times and never allowed to lapse at busy periods or because of a failure to maintain adequate supplies of bags or containers. Members of staff employed within the laboratory must not be put at risk because of ignorance, negligence or bad technique.

Note: Never leave samples unattended in a public area.

Storage of Specimens and Blood in the Wards, Labs and in other Departments

It is the responsibility of the laboratory staff that:

1. Specimens should be stored in wards or labs, for a limited time period, and arrangements should be made for processing or disposal as early as feasible.
2. Proper storage facility should be provided in the wards and labs (storage cabinets, freezers etc.).
3. Ensure the appropriate labelling of the specimen container and the pathology request form if the patient is known or suspected of having a disease considered as “high risk."
4. Ensure that the specimen is packaged and stored in a suitable and safe manner.
5. Routine Histology specimens must be placed directly into formalin and can be stored at room temperature until transported to the Histology Laboratory.
6. Frozen Section specimens must be sent dry, directly to the Histology Laboratory.
7. FNA slides for Cytology Referral should be stored at room temperature until transported to the Histology Laboratory.

Transport of Samples using Courier Services

1. Samples must always be carried in closed boxes, which are clearly marked as **Biological Substance.**
2. Samples must be individually bagged, placed in a secondary bag containing absorbent material, sealed and carefully placed in the transport container.
3. Two storage boxes will be provided for each surgery or clinic, one for holding blood specimens and one for non-blood specimens.
4. On collection by the couriers, the samples will be transferred by the couriers into two separate transport boxes, one for blood, and one for non-blood, lined with a clear plastic bag containing absorbent material and which can be secured with a cable tie when full.
    A. Where a patient's pathology request requires both blood and non-blood samples, these should be placed in the non-blood containers.
    B. Blood and tissue slides should be regarded as sharps and placed in an appropriate

plastic slide transport box before packaging.

C. Handle specimen containers gently at all times.
D. Samples must never be carried unprotected in the open hand or given to other members of staff in this way.
E. Samples must not be left unattended when not secured in the van.

5. The patient's confidentiality must be preserved at all times.
6. In the event of a vehicle breakdown or a road traffic accident, do not allow persons other than courier or laboratory staff to handle specimens.
   A. Any spillage must be reported immediately to a designated senior member of the department concerned.
   B. Decontamination materials shall be carried in each vehicle to enable small spillages to be contained. In the event of major contamination, the Pathology Support Services must be contacted before any material is touched.
7. The response by the Pathology laboratory staff will depend upon the size and extent of the spillage and upon the level of contamination.
8. All decontamination shall be in accordance with the Pathology Safety Policy which should be available as SOPs. Always wash hands thoroughly before rest breaks and at the end of a work period.

Sample Processing

1. Collect the required amount of specimen. While small amounts of blood are now used for many automated tests, there are minimum requirements. Optimum collection volumes allow for the test to be repeated and verified, if necessary.
2. Minimum volumes are to be used for patients where unnecessary blood loss may affect the patient's status.
3. When difficulties are encountered with blood volumes, consult the laboratory. Avoid haemolysis, which can elevate certain analytes (e.g., LDH, K, AST).
4. Follow specific specimen processing instructions. The laboratory should develop its SOPs in this regard.
5. A Quality Control manual should be developed by each laboratory.
6. Instrument and method of testing for each test should be defined.
7. Periodic calibration of equipment as per laboratory/manufacturer guidelines should be conducted and records should be documented.
8. Never decant or aliquot the specimen from one type of container to another.
9. Unusual specimens (lipemic, icteric, hemolyzed) may require a repeat specimen.
10. When using tubes with anticoagulants, especially for coagulation tests, a sufficient fill volume is required to ensure the appropriate specimen dilution.
11. Use the proper container and mix all specimens containing anticoagulant or preservative by gentle inversion 8 to 10 times.

Reference ranges and critical values should be defined for each test.

Figure 7 A View of Laboratory

Sample Disposal

1. Make an inventory of toxic compounds in the laboratory and prepare a protocol for their collection and disposal.
2. Waste sample remains should never be disposed of by washing down a drain. Use proper receptacles for this purpose. Nevertheless, sinks and gullies should be fitted with removable SILT TRAPS which should be emptied regularly. In certain cases, heavily polluted samples may have to be treated as toxic chemical waste.

Figure 8 Packing for Disposal

General guidelines for hazardous materials disposal are given on the following page.

1. INFECTIOUS WASTE

A. General

(i) Infectious waste must be disposed of in a carefully controlled manner in accordance with National Guidelines on Hospital Management.

(ii) Infectious waste has been defined to include biological waste, cultures and stocks, pathological waste, and sharps.

(iii) Infectious waste must either be incinerated or treated prior to disposal.

(iv) The term infectious waste is synonymous with biohazard; it does NOT include chemical agents, such as carcinogens, which affect living organisms through chemical means.

B. Definitions

(i) Biological Waste

a. Includes blood and blood products, excretions, exudates, secretions, suctions and other body fluids that cannot be directly discarded into the municipal sewer system.
b. **EXCLUDES** articles contaminated with fully absorbed or dried blood.
c. Biological waste must either be incinerated or sterilized with steam in a dedicated autoclave.
d. After treatment, biological waste may be treated as normal refuse.

(ii) Cultures and Stocks

a. Includes etiologic agents and associated biologicals, including specimen cultures and dishes and devices used to transfer, inoculate and mix cultures.
b. Includes wastes from the production of biologicals, serums, and discarded live or attenuated vaccines.
c. Cultures and stocks must be treated in the same way as biological waste.

(iii) Pathological Waste

a. Includes biopsy materials, all human tissues and anatomical parts from surgery and other procedures.
b. Includes carcasses and bedding from animals exposed to pathogens in research, but does NOT include teeth or preservative agents such as formaldehyde.
c. Pathological waste must be incinerated.

(iv) Sharps

a. Includes needles, scalpel blades, lancets and syringes that have been removed from their original sterile containers.
b. Sharps must be incinerated.
c. The definition DOES NOT EXEMPT needles or syringes used for non-infectious materials, such as transferring chemical solutions.

C. Disposal

(i) Waste which is to be incinerated must be collected and taken to an infectious waste incinerator.
(ii) Waste which may be disposed in the ordinary trash should be clearly marked "NON-INFECTIOUS" or "STERILE" and put inside outer packaging which is NOT red or orange in color.
(iii) Autoclaves used for infectious waste treatment must be designated and tested.
(iv) Autoclave users must develop written operating procedures to keep records with detailed parameters for treatment, methods for monitoring, methods for indicating adequate sterilization conditions during each treatment, and monthly tests of sterilization conditions using a specified biological indicator.

D. Storage

(i) Infectious waste should be segregated from other wastes by puffing it in separate containers at the point of generation.

(ii) Locate containers to minimize access by unauthorized persons and clearly identify as containing infectious waste.

(iii) Except for sharps, store infectious waste in red plastic bags OR containers made of other materials impervious to moisture and strong enough to prevent tearing under normal use conditions.

(iv) Pathological, biological and culture/stock wastes should be treated or disposed within 7 days of generation, or within 30 days if refrigerated or frozen.

(v) If a generator (laboratory or department) produces less than 50 pounds of waste in a calendar month, the 7 day storage limitation does not apply.

(vi) Sharps should be contained in leak proof, rigid, puncture resistant RED containers which have tight lids or are taped closed.

(vii) There is no limit on the length of storage for sharps.

2. CHEMICAL WASTE

GENERAL

A. Prior to disposal of any chemical waste, a designated person must perform an official hazardous waste determination to see if the waste is hazardous.

B. A short list of non-hazardous chemicals can be notified; all others should be considered hazardous until the determination has been made.

C. Hazardous waste is incinerated, at off-site locations, whenever possible. Departments are encouraged to employ waste reduction procedures to limit costs. Use these guidelines to prepare and request disposal of hazardous chemical waste.

DEFINITIONS

Hazardous chemical waste refers to any material substance that is;

(i) CORROSIVE (pH<2 or pH>12)

(ii) REACTIVE (oxidizers, water reactive)

(iii) FLAMMABLE (flash point <140 F)

(iv) TOXIC

Containers

A. All waste must be in appropriate NON-LEAKING containers with lids that are non-leaking, tight fitting and are not cracked, broken, or chemically damaged.

B. The container size should match the amount of waste.

C. Containers must be compatible with the waste contained.

D. Liquid containers must be less than 5 gallons and weigh less than 45 pounds.

E. Paper or cardboard primary containers should be put into sealed plastic bags.

F. Except for common solvents which can be bulked together, waste disposal charges are related to container volume rather than solely a weight basis; a partially full container may cost the same as a full one.

Labels

A. All unused chemicals in original non-leaking containers with the manufacturer's label will be accepted as it is.
B. All other waste requires a hazardous waste label. The labels must be completed and attached to each waste container, except for very small containers.
C. Labels should be affixed in a manner that does not cover existing labels or markings.
D. Solvent labels should preferably be put onto string tags attached to containers.
E. Complete the LOWER part of the label with your name, building, room number, department, and identification of contents. Include total weight or volume and percent ranges for all constituents.

Packing

A. Generators should find cardboard boxes and make them available to the designated staff at the time of waste removal.
B. DO NOT pack waste in boxes, since waste containers will be examined by visual inspection.
C. Sanitary staff will pack waste in boxes according to compatibility.
D. Boxes should be sealable when necessary, and sturdy enough to transport the material.
E. Boxes exceeding 45 pounds or 18 inches on a side cannot be safely handled by one person, and will not be picked up.

3. EMERGENCIES

A. **HAZARDOUS MATERIAL SPILLS** are an inevitable part of most work environments. To effectively combat spills, it is necessary to prepare for them beforehand. Whenever employees work with a substance, they should be aware of its characteristics, and should have formulated plans of what to do in case of a spill, including what steps to take, who to call for assistance, what PPE is necessary, and what material is appropriate to contend with a spill, and where to find appropriate spill-response equipment. Departments are encouraged to have spill response kits at strategic locations.

B. **GENERAL GUIDELINES** The first step in dealing with any chemical spill is to assess the magnitude of spilled material and the associated level of hazard. No one should attempt to deal with a spill until properly equipped with adequate PPE and spill treatment materials. Risk assessment is successful only if personnel are familiar with the hazardous properties of the material they are handling and have developed methods to follow in the event of a spill.

C. **PROCEDURES** If the risk assessment suggests you can safely and properly clean up the spill:
   (i) **Get personal protective equipment.** Do not attempt spill response until you have put on PPE appropriate for the situation. Available equipment may include respiratory protection, goggles, gloves, impervious shoes/boots, and body protection. All equipment will not be necessary for every situation, but should be available. If you are unsure about your ability to control a spill, get assistance. Any

spill for which respiratory protection is needed must not be conducted without backup personnel equipped in the same manner.

(ii) **Get spill control equipment** from your department's spill kit. Spill control materials are sold in two general forms: loose materials (vermiculite, cat litter) and spill control pillows, which are produced in various shapes and contain different types of absorbents. Spill control pillows are preferred because they are much easier to pick up when finished. Also available are materials designed for specific types of chemical spills such as acids or solvents. In general, spilled liquids present more danger than solids, and quick response is therefore critical. For flammable liquids, special attention should be paid to potential ignition sources in the vicinity.

(iii) **Absorb** the spill. If there is danger the spill may spread, dike the perimeter with absorbent, then absorb. "Floor chemistry" should not be attempted. If you desire to perform simple neutralization/treatment schemes, first absorb and contain the material.

(iv) **Collect** the contaminated absorbent and put into a sturdy leak proof container. Close the container if there are volatile substances which may continue to pose a threat.

(v) **Dispose** of the contaminated absorbent in the same manner you would dispose of the substance that was spilled. If the spilled chemical is hazardous, do not put the clean-up residue in the dumpster. If hazardous, contact professionals to dispose.

4. DISPOSAL GUIDELINES

A. Empty Containers

(i) Containers that have held hazardous substances are empty by definition when one of two following conditions is met. For one group of materials, a container is empty when all contents have been removed by techniques ordinarily used for that type of material (e.g., pouring for liquids), and the container has less than 3% of the original contents. For another group, a container is only empty when it has been triple rinsed with a solvent capable of removing the remaining contents. Contact the manufacturer for specific discussions of which group a material falls into.

(ii) In all cases, remove as much of the contents as possible before disposal (including recycling). For liquids, this would be turning the container upside down and letting it drain until no more drops will come out. For low viscosity liquids such as aqueous solutions, let drip no less than 60 seconds.

B. NON-HAZARDOUS CHEMICALS

(i) A designated person must perform an official hazardous waste determination for disposal of all chemicals.

(ii) Collect solids in disposable, non-leaking containers, labelled with contents, clearly marked as non-hazardous, and prepared for disposal.

(iii) Solutions containing only non-hazardous, water miscible liquid materials, with pH between 6 and 9.5, can be disposed through the sewer system.

(iv) Remember: **"hazardous" includes flammable liquids even if water soluble.**

The items listed below are considered NON-hazardous:

- Acetates: Ca, K, Na, K, Mg, NH4

- Naturally occurring amino acids and salts
- Citric acid and salts of Na, K, Mg, NH4, Ca
- Bicarbonates: Na, K
- Borates: Na, K, Mg, Ca
- Bromides: Na, K, NH4
- Carbonates: Na, K, Mg, Ca, NH4
- Chlorides: Na, K, Mg, Ca, NH4
- Formates: Na, K, Mg, Ca, NH4
- Lactic acid and salts of Na, K, Mg, NH4, Ca
- Sugars and sugar alcohols
- Starch
- Iodides: Na, K, Ca
- Oxides: B, Mg, Ca, Al, Si, Fe, Zn
- Phosphates: Na, K, Mg, Ca, NH4
- Silicates: Na, K, Mg, Ca
- Sulfates: Na, K, Mg, Ca, NH4

Caution: Chemicals and chemical products should not be given or sold to the general public or offered as surplus property. Commercial chemical products may be offered as surplus property if reasonable cautions are followed.

C. Treatment

(i) Elementary neutralization can be performed on wastes which are hazardous only because they are corrosive (acids, bases).

(ii) A neutralized solution should have a final pH value between 6 and 9. Corrosive waste should not be discharged through the sewer system.

(iii) Treatment of other materials to lessen the hazard or amount of waste can be included as part of the SOPs in laboratories.

(iv) Such procedures should be written and made a part of specific experimental protocol.

D. Waste Storage

The storage of hazardous materials must be in compliance with National Guidelines on Hospital Management. Your methods of handling waste are subject to unannounced inspections by regulatory inspectors.

(i) All containers need to have a **label** at all times indicating the contents. For waste materials, this could be a simple label such as "WASTE SOLVENT" or "USE D ACETONE."

(ii) Put the label on the container **BEFORE ADDING WASTE.**

(iii) All containers need a lid at all times when not actively adding or removing waste. Evaporation in a hood is **not** a legal disposal method. **Funnels do not count as lids.**

(iv) Secondary containment is advised for liquid containers.

(v) Storage limits and locations are the same for waste as for new materials. For example, storage of flammable liquids in excess of 10 gallons requires a flammable

liquid storage cabinet. Glass bottles may **not** be stored on the floor because they can easily be broken by accidental kicking.

Figure 9 Hazardous Materials Warning Sign

Ind 48. Critical results are reported immediately to the concerned personnel.

Survey Process:

The laboratory should have defined critical values for ALL relevant tests and should have documentation (log book) that the critical results were reported as soon as available. This is a significant patient safety issue.

Scoring:

- If there are defined critical values and there is documentation that they are reported as soon as available, then score as **fully met.**
- If the critical values are not defined or if there is no consistent and defined process to report them as soon as available, then score as **not met.**

GUIDELINES

SOPs for Reporting Critical Laboratory Results

1. Critical test results are defined as any values/interpretations for which delays in reporting can result in serious adverse outcomes for patient care. These values should be defined by the laboratory director, in consultation with the concerned clinicians. The scope includes laboratory, cardiology, radiology, and other diagnostic tests in the inpatient, emergency, and ambulatory settings.[40]
2. All critical reports are verbally informed to the concerned consultant immediately by the pathologist. The laboratory should have procedures for immediate notification of a physician, or other clinical personnel responsible for patient care, when results of certain tests fall within established "alert" or "critical" ranges.
3. As soon as the technical validity of the results has been established by a senior technician/technologist, the requesting doctor must be contacted without delay. If the identity of the requesting doctor is not obvious from the request form, his/her identity must be ascertained from the ward. If this fails, urgent results can be phoned to the ward or clinic sister or the most senior nurse on duty.
4. When results are transmitted verbally, in all cases the request form must be signed to indicate when and to whom and by whom the results are communicated. This must always

[40] Joint Commission on Accreditation of Healthcare Organizations (JCAHO) Standards.

be followed by a written report.

5. Such results will be telephoned to any patient-care unit lacking a computer terminal. A written record of test results telephoned to patient care areas must be made by the physician, nurse or other individual who receives the report.
6. The process developed by the organization for managing the critical results of diagnostic tests must include a definition of critical tests and critical values for each type of test, by whom and to whom the critical test results are reported, the established time frames for reporting and follow-up and an established method for monitoring compliance.
7. Advanced technologies and innovations may be used for prompt reporting/communication of results to the requesting clinicians.

Note: Blood Group results must never be conveyed telephonically

Ind 49. Laboratory tests not available in the HCE are outsourced to laboratories, based on their quality assurance system.

Survey Process:

Determine which referral/outsourced laboratory or laboratories the hospital uses and then look for documentation that the laboratory or laboratories have demonstrated quality [for example accreditation by the Pakistan National Accreditation Council (PNAC) or any other evidence of quality assurance e.g. provisionally licensed by the KP HCC]. If the hospital has used a referral laboratory for some time which is provisionally licensed by the KP HCC and is comfortable that the results are accurate and timely, this experience can also be sufficient. The arrangements including quality indicators and turnaround times should be specified in the formal contractual arrangement.

Scoring:

- If there is documented evidence that the referral laboratory or laboratories deliver quality indicators (even if only by the hospital's experience in the first year), then score as **fully met.**
- If there is no or limited evidence that the referral laboratory demonstrates quality, then score as **not met.**

GUIDELINES

Outsourcing Specialized Tests

Specialized tests not performed in the hospital are referred to external laboratories. The laboratory director shall select the reference laboratory. Specimens for referral laboratories are dispatched from the Pathology Department. When results are received from the referral laboratory, the original report is always forwarded to the requesting clinician. A list of the referral laboratories currently being used should be displayed. Laboratory management, with the advice of users where appropriate, shall establish a procedure(s) for the referral of specimens to other laboratories and to consultants who are to provide second opinions, which includes:

1. Evaluating and selecting referral laboratories and consultants in terms of competence to perform the requested examinations and ensuring that there are no conflicts of interest.
2. Maintaining a record of all referral laboratories.
3. Maintaining a record of all specimens referred.
4. Recording of dispatch dates.

5. Maintaining a record of reports.
6. Monitoring the return of reports from the referral laboratory or referral consultant.
7. Defining the respective responsibilities for the interpretation and reporting of referred examinations.
8. Periodically reviewing the arrangements with referral laboratories to ensure that requirements including terms of EQA performance and turnaround times continue to be met.

   Note: Referral laboratories should, where possible, be accredited by some accreditation body or meet the requirements of the sender's quality management system.
9. Memorandum of Understanding (MOU) For Outsourcing Diagnostic Services (Between ABC Hospital & XYZ Lab) is given at **Annexure L**.

Assessment Scoring Matrix

Standard 16. AAC. 2: Laboratory services are provided as per the requirements of patients.

Indicator 44-49		Max Score	Weightage (Percent)	Score Obtained
Ind 44.	**Scope of the laboratory services caters for the emergency and the clinical services provided at the HCE.**	10	**100**	
Ind 45.	**Adequately qualified and trained personnel perform and/or supervise the investigations.**	10	**80**	
Ind 46.	**SOPs and procedures guide the: i. Collection, ii. Identification, iii. Handling, iv. Safe transportation, v. Processing and vi. Disposal of specimens.**	10	**100**	
Ind 47.	**Laboratory results are available within a defined time frame.**	10	**80**	
Ind 48.	**Critical results are reported immediately to the concerned personnel.**	10	**100**	
Ind 49.	**Laboratory tests not available in the HCE are outsourced to laboratories, based on their quality assurance system.**	10	**100**	
Total		60		

Standard 17. AAC-3: Imaging services are provided as per the clinical requirements of the patients.

Indicators (50-57):

Ind 50. Imaging services comply with legal and other regulatory requirements[41]

Survey Process:

There should be documentation in the Radiology Department of its compliance with ALL legal and regulatory requirements. Key staff should be aware of the regulatory requirements.

Scoring:

- If supporting documents regarding legal and regulatory requirements are present in the department and staff is aware of the content and is clearly applying the requirements, then score as **fully met.**
- If the documents regarding regulatory requirements are not present and most of staff members are unaware of their compliance obligations, then score as **not met.**

GUIDELINES

Compliance with Statutes

A request for a Radiological Examination/Diagnostic Imaging will be regarded as a request from a Clinician or Health Professional to the Radiology Department for an opinion based upon a radiological examination, to assist in the management of a clinical problem.

1. Diagnostic Imaging or radiological procedures will only be performed upon a written request signed by a Registered Medical or Dental Practitioner.
2. Signed referrals (request form or letter) must precede or accompany the patient. Signed faxes are also accepted. Only doctors are permitted to sign, not nurses or other paramedical staff. There should be an appropriate use of the PMDC ID i.e. the Registration Number.
3. All requests must carry sufficient information to identify the patient. This normally consists of the first name, middle name if any, and family name, date of birth and address.
4. All requests must carry sufficient clinical information to enable the requested examination to be justified. The referral forms should contain adequate information to justify the procedure requested. The radiologist is responsible for justifying the procedure.
    A. All requests shall clearly state the examination requested.
    B. All requests must include the contact details of the Referring Clinician, including the address and telephone number.
    C. All requests for X-ray examinations (between the diaphragm and the knees) for all

[41] Building Code of Pakistan Nuclear Regulatory Authority (PNRA) and management of ionizing radiation.

fertile females must state the date of the first day of the patient's menstrual period.

D. The organization shall have a system for providing radiology and diagnostic imaging services required by its patient population, clinical services offered and Health Care Provider (HCP) needs.
E. Radiology and diagnostic imaging services, including those required for emergencies, may be provided within the HCE, by agreement with another organization, or both. Radiology and diagnostic imaging services are available after normal working hours for emergencies.
F. Outside sources are convenient for the patient to access, and reports are received in a timely way that supports continuity of care. The HCE selects outside sources based on the recommendation of the director or other individual responsible for radiology and diagnostic imaging services. Radiology and diagnostic imaging services, in house as well as outside sources, must meet applicable laws and regulations [enforcement of Pakistan Nuclear Regulatory Authority (PNRA) regulations and other statutory requirement] and have an acceptable record of accurate and timely services. Patients are informed when an outside source of services is owned by the referring physician.
G. Every HCE should have SOPs for outsourcing (from the request to the assessment of service provider and turnaround time of the report).
H. All the statutory requirements e.g. clearance from Pakistan Nuclear Regulatory Authority, use of dosimeters, lead sheets, lead aprons, signage, display as per relevant regulations are to be met with.

Ind 51. Scope of the imaging services is in accordance with the clinical services provided by the Hospital.

Survey Process:

This requires an understanding of the full scope of services provided at the hospital and observation of the diagnostic facilities provided both on and off site. A full complement of imaging services should also be provided to cater for emergency situations that may arise from the services delivered by the hospital. Where invasive imaging services are provided there must be adequate support service in the event of an emergency. This involves resuscitation, and in some cases, emergency surgery when cardiac or other invasive procedures are involved.

Scoring:

- If there is access to a full range of imaging services in accordance with the scope of hospital services, then score as **fully met.**
- If there is insufficient scope and number of imaging services to support the services within the hospital, then score as **not met.**

GUIDELINES

Scope of Imaging Services

The Radiological/Diagnostic Imaging Services shall aim at providing safe, efficient, and quality services as required for good patient care. Specific radiological and diagnostic imaging services

provided shall depend upon the size and scope of the facility (to be enlisted by the HCE). Staff strength shall be commensurate with the number of beds, patient load and investigations performed.

A full complement of imaging services (to be enlisted by the HCE) should also be provided to cater to the emergency situations arising from the services delivered by the HCE. Adequate support service must be available at places where invasive imaging services are provided, to meet with an event of emergency. This involves resuscitation and in some cases emergency surgery/ Coronary-Artery Bypass Grafting (CABG) when cardiac procedures e.g., angioplasty etc. are involved.

Ind 52. Adequately qualified and trained personnel perform, supervise and interpret the investigations.

Survey Process:

Each member of radiology department has a job description to accomplish the assigned role. Review the personal files of technical and supervisory staff of radiology department to determine if their credentials (qualifications, experience and training) match the requirements of the respective position and the job description including handling the equipment being used. A system of Continuous Professional Development[42] should be in place.

Scoring:

- If qualifications of all the individuals match the requirements in the job description, or if there are only minor variances (such as only 4 years of experience instead of 5), then score as **fully met.**
- If only one technician does not have the experience required by the job description, then score as **partially met,** provided that there is evidence of enhanced supervision or training of this individual.
- If any technician does not have the required qualifications (in the job description), then score as **not met.**

GUIDELINES

Authorization to Perform, Supervise and Interpret

Radiology and diagnostic imaging services, provided at any location in the organization, are under the direction of an individual who is qualified by documented training, expertise and experience, consistent with applicable laws and regulations. This individual assumes professional responsibility for the radiology and diagnostic imaging facility and the services provided. When this individual provides clinical consultation or medical opinion, he/she is a qualified/authorized radiologist.

The radiology and diagnostic imaging director's responsibilities include:

1. Developing, implementing, and maintaining policies and procedures.
2. Administrative oversight.
3. Maintaining any necessary quality control program.
4. Recommending outside sources of radiology and diagnostic imaging services.
5. Monitoring and reviewing all radiology and diagnostic imaging services.

[42] A recognized program administered by a professional college/council or equivalent

The organization identifies which radiology and diagnostic imaging staff members perform diagnostic and imaging studies, those who are approved to perform point of care tests at the bedside, those who are qualified to interpret the results or verify and report results, as well as those who direct or supervise the processes. Supervisory staff and technical staff have appropriate and adequate training, experience, and skills and are oriented to their work. Technical staff members are given work assignments consistent with their training and experience. In addition, there is a sufficient number of staff to perform, interpret and report studies promptly and provide necessary staffing during all hours of operation and for emergencies.

Human Resource for Diagnostic Radiological and Imaging Services:

1. The radiologist in charge of the diagnostic imaging services may be available full-time or part-time depending on the size and complexity of the department.
2. The authority and accountabilities (e.g. Error report, Audit report) of the person in charge are clearly delineated.
3. The diagnostic imaging services shall be staffed with a qualified radiologist, qualified radiographers, nursing, clerical and administrative staff.
4. Sufficient numbers of qualified personnel and support staff are employed to enable the services to meet the documented purposes.
5. A qualified radiologist and radiographer shall be on duty or be available on-call after normal working hours.
6. There is evidence of a staff development plan, which provides the knowledge and skills required for staff to maintain competency in their current positions as the demands on the positions evolve. There is evidence of competency assessment.
7. There is a structured orientation programme where new staff is briefed on their services and relevant aspects of the facility to prepare them for their roles and responsibilities.
8. There are continuing education activities for staff to pursue professional interests and to prepare for current and future changes in practice. There is evidence that staff education and development needs have been appraised and identified.
9. Staff receive written evaluations of their performance at the completion of the probationary period and annually thereafter, or as defined by the facility.
10. Proper instructions are provided and safety precautions are implemented for the protection of patients and staff who are exposed to the hazardous equipment.
11. In a teaching hospital, the diagnostic imaging services, subject to requirements of safety and comfort, provide for the relevant educational needs of under-graduates and post-graduates.
12. In facilities which have teaching and research responsibilities, the staff of the diagnostic imaging services gives their cooperation or participate in the teaching and research programmes related to the field of diagnostic imaging.
13. A radiologist performing a therapeutic interventional procedure is considered a treating physician. A radiologist performing a diagnostic interventional or diagnostic procedure is not considered a treating physician.
14. A physician should supervise diagnostic tests. Supervision may be of following type:
    a. General Supervision: This means the procedure is performed under the physician's overall direction and control, but the physician's presence during the performance of the procedure is not required. Under general supervision, training of the non-physician personnel who actually performs the diagnostic procedure, and maintenance of necessary equipment and supplies are the continuing responsibility of the physician.

b. Direct Supervision: This means a physician must be in attendance in the room during the performance of the procedure and be available to furnish immediate assistance and direction throughout the performance of the procedure.

15. Interpretation of results is an important component of the service provided by the Radiology and Diagnostic Imaging Department.
16. The frequency of such comments may vary between specialties;
17. The management of the Laboratory/Radiology Department shall ensure that advice on examinations and the interpretation of results is available to meet the needs and requirements of users.
18. Interpretive comments on reports shall be clear, succinct and unambiguous.
19. Clinical advice and interpretive comments shall only be provided by authorized personnel with appropriate training.
20. There shall be systematic communication between Laboratory/Radiology and clinical staff to promote effective utilization of services and to consult on scientific and logistic matters. Where appropriate, a record of such meetings shall be kept.

Ind 53. SOPs for identification and safe transportation of patients to imaging services are defined and implemented.

Survey Process:

Look for the SOPs how the patient is positively identified to ensure that the correct imaging procedure is done on a right patient. Look for evidence that specific medical attendant or equipment is available and provided if needed to accompany the patient during transportation to the imaging department and that there is a clear process to ensure this happens. Specifically look for evidence (by observation and interview of staff) that the patient is positively identified and safely transported.

Scoring:

- If there are documented SOPs for patient identification and safe transportation and the same are being followed, then score as **fully met.**
- If either there are no SOPs or there is no evidence that these have been implemented and are being followed, then score as **not met.**

GUIDELINES

Identification and Safe Transportation of Patients

1. Identification

Identification of a patient is done by asking the patient/relatives and comparing the particulars on a Request Form which is on a standard format and contains:

A. Client's/Patient's name
B. Identification number
C. National identity card (NIC) number
D. Address
E. Date of birth (if not available, then age)
F. Examination requested
G. Previous examinations

H. Clinical diagnosis/indications/relevant history
I. Information relating to the gestational status in women of childbearing age
J. Identity of the requesting physician
K. History of allergy, in red ink
L. The Radiologist is responsible for the justification of any radiological investigation
M. He/she will also have to communicate with the primary referring physician and obtain optimum clinical information to perform the investigation.
N. For Medical Legal Cases (MLC), a mark of identification of the client/patient and name of the police official bringing the client/patient.
O. Fee to be charged/not to be charged.

2. Safe Transportation

A. Some radiology tasks demand the usage of some push or pull force that radiographers must exert when moving patients from one area to another. Exertion of an excessive force may increase the risk of injury to the back, legs, shoulders or any other part. Fragile bodies of older patients/already injured are more prone to further trauma or harm.
B. For the safety of the human resource, use mechanical power assisted devices whenever heavy patients or large equipment are required to be moved for longer distances. Ensure that a sufficient number of employees are available to move heavy patients. Employee/s should not exert excessive force at any point during the transportation/shifting.
C. For example, radiographers should be trained to use correct body mechanics when moving patients during procedures, including inter alia the following;
   (i) Push instead of pull. Lean slightly into the load to let your body weight assist with force exertion.
   (ii) Push at about chest height.
   (iii) Push smoothly and slowly to start.
   (iv) Do not bend or twist while exerting force.
   (v) Keep wrists straight.
   (vi) Keep elbows close to the body.

3. Transferring Patients to and from the Examination Table

A. Radiographers may need considerable support and assistance to move patients to or from examination tables.
B. Use mechanical powered transfer devices such as lifts or hoists to move patients, especially non-ambulatory, from wheelchairs, beds, or stretchers.
C. When appropriate, use multi-use devices such as chairs that can open up into beds. These allow patients to move from a sitting position to a prone position, without transfer.
D. Additional employees should assist in moving and transferring equipment or patients if:
   (i) A mechanical powered device is not available.
   (ii) Awkward postures are forced to be used. Excessive push force or lifting or supporting a heavy weight is required.

Ind 54. Imaging results are available within a defined time frame.

Survey Process:

While visiting the radiology department, review the written time frames both for the availability of the procedures and the availability of the reports. Then, see if the department has data to show that the times are being met. For further validation, review representative sample of medical records while on an in-patient unit. Look for the time of the physician order for the procedure, and compare with when the result was available.

Scoring:

- If there are defined times for the procedures to be available and the results to be reported and these times are met, then score as **fully met.**
- If there are defined time frames, but they are met in up to 80 percent of the cases, then score as **partially met.**
- If there are no defined time frames or they are met in less than 80 percent of the cases, then score as **not met.**

GUIDELINES

Scope of Imaging Services

The organization defines the time period for reporting diagnostic radiology and diagnostic imaging study results. Results are reported within a time frame based on patient needs, services offered, and the clinical staff's needs. Emergency tests, after-hours and weekend testing needs are included. Results from urgent radiology and diagnostic imaging studies, such as those from the Emergency Department, Operating Theatres, and Intensive Care Units, are given special attention in the planning and monitoring process. Radiology and diagnostic imaging studies performed by outside contractors of services are reported according to organizational policy or contract requirement. Radiology Turnaround Time (RTAT) means the time from the examinations until the reports are completed;

1. It would be feasible to have all the inpatient reports within 24 hours and all the outpatient report within 48 hours.
2. The referring physician should formally communicate with the radiologist for all emergency procedures (RTAT should be one hour).
3. All verbal communications have to be followed by written documentation. Use of Picture Archiving and Communication System (PACS)/ Electronic Medical Record (EMR)/ Information and Communication Technology (ICT) should be encouraged.
4. Reports can be amended only by adding addendums (timed and signed).

Ind 55. Critical results are intimated immediately to the concerned personnel.

Survey Process:

Unlike the laboratory, critical findings on images depend to a great extent on the clinical judgment of the radiologist. However, the department should at least have some general guidelines and a way to

document that the findings were reported as soon as possible. This is a significant patient safety issue.

Scoring:

- If there are documented guidelines to manage critical findings and there is evidence that they are reported as soon as available/noted, then score as **fully met.**
- If there is no understanding of what constitutes a critical imaging finding, or if there is no consistent and defined process to report those as soon as available/noted, then score as **not met.**

GUIDELINES

SOPs for Reporting Critical Radiology Results

Critical results MUST be communicated in a timely manner, within one hour. Communication of these results to the physician has to be ensured using any one or a combination of forms of communication e.g. Telephone/fax/email - PACS/EMR/ICT.

1. Appropriate people for communication:
   A. MUST be a trained HCP responsible for the patient.
   B. The patient/next of kin if the HCP is not accessible.
2. Not acceptable for communication:
   A nurse or physician or an employee of the unit with no responsibility for the patient.
3. When communication is verbal it MUST be documented, including:
   A. Person communicating and person to whom the communication is made.
   B. Time and date of communication.

List of Radiology Critical Results (Findings)

1. General: Retained sponge or other clinically significant foreign body, new/unexpected and clinically significant mass/tumor or arterial dissection/occlusion.
2. Acute Abdomen: Life-threatening obstruction; previously undiagnosed abscess, acute thrombotic or embolic event, including Deep Vein Thrombosis (DVT); unexpected or previously undiagnosed free air or active leakage; previously undiagnosed, clinically significant hemorrhage or vascular disruption, ectopic pregnancy and intestinal ischemia.
3. Acute Chest: New, unexpected, clinically significant collapse of lung, pneumothorax and pulmonary artery embolus.
4. Acute Skeletal: Impending pathologic fracture and new, unexpected, clinically significant fracture.
5. Foreign Body

Ind 56. Quality assurance activities are evident in the imaging department.

Survey Process:

There should be documented evidence that a quality assurance system is implemented in the department. This should include observation of activities such as a register of repeat images due to image quality related reasons and recording of adverse occurrences.

Scoring:

- If a QA system is in place along with evidence that the staff is aware of it and the associated

activities, then score as **fully met.**

- If there is no evidence of a QA system or the staff is not aware of it, then score as **not met.**

GUIDELINES

Quality Assurance (QA) Program

Quality Assurance Activities in X Ray Department ABC Hospital.

XYZ Measures taken by the Hospital to assure quality:

1. Registration with PNRA and following their instruction regarding safety and optimum functioning
2. Qualified staff
3. Strict compliance of SOPs
4. Good quality X-ray machine
5. Record keeping

A format for record of quality issues and the remedial/preventive measures is given below:

Table 14: Quality Issues Recording Template

Date	No.	Patient: Name and MR No.	Test advised	Quality Issue	Reason	Corrective Action	Preventive Measure

Ind 57. Imaging tests not available in the hospital are outsourced on the basis of quality assurance system and compliance with applicable laws and regulations.

Survey Process:

There should be documented evidence that the radiology services to which patients are referred have been approved by the Pakistan Nuclear Regulatory Authority and that the hospital has a history of receiving timely and accurate reports from the referral radiology service commensurate with the clinical needs of the patient.

Scoring:

- If the referral imaging services are approved by the PNRA and the hospital demonstrates sufficient experience that reports are timely and accurate, then score as **fully met.**
- This should only be scored as **not met** if a majority of the survey team agrees that there are significant problems with the referral radiology services regarding timely and accurate reporting.

GUIDELINES

Outsourcing of Radiological Tests

When the organization uses outside sources of radiology and diagnostic imaging services, it should regularly receive and review the Quality Control (QC) results of that outside source through

qualified individuals. When diagnostic imaging QC of outside sources is difficult to obtain, the manager develops an alternative approach for quality oversight. Mechanism/SOPs have to be developed e.g., who will approve/call/respond and what would the turnaround time of the service be.

Outside sources are convenient for the patient to access, and reports are received in a timely way that supports continuity of care. Outside sources of radiology and diagnostic imaging services should meet applicable laws and regulations (as specified by PNRA) and should have an acceptable record of accurate and timely services.

Note: Referral Radiology and Diagnostic Imaging Services should where possible, be accredited by some accreditation body or meet the requirements of the sender's Quality Management system.

Memorandum of Understanding (MOU) for Outsourcing Diagnostic Services (between ABC Hospital & XYZ Radiological Diagnostic Center) **Annexure M**.

Assessment Scoring Matrix

Standard 17. AAC. 3: Imaging services are provided as per the clinical requirements of the patients.

Indicator 50-57		Max Score	Weightage (Percent)	Score Obtained
Ind 50.	**Imaging services comply with legal and other regulatory requirements.**	10	**100**	
Ind 51.	**Scope of the imaging services is in accordance with the clinical services provided by the Hospital.**	10	**80**	
Ind 52.	**Adequately qualified and trained personnel perform, supervise and interpret the investigations.**	10	**100**	
Ind 53.	**SOPs for identification and safe transportation of patients to imaging services are defined and implemented.**	10	**80**	
Ind 54.	**Imaging results are available within a defined time frame.**	10	**100**	
Ind 55.	**Critical results are intimated immediately to the concerned personnel.**	10	**100**	
Ind 56.	**Quality assurance activities are evident in the imaging department.**	10	**100**	
Ind 57.	**Imaging tests not available in the hospital are outsourced on the basis of quality assurance system and compliance with applicable laws and regulations.**	10	**100**	
Total		80		

2.7 Care of Patients (COP)

05 Standards & 29 Indicators

The process of patient care includes planning of care, providing care, evaluating the patient's response to care, and planning follow-up care. Care may be provided in multiple locations, by multiple disciplines, and it may involve different processes. The following standards for the Care of Patients address essential principles and processes for the clinical care of patients who come to hospitals for their treatment, with excellent care being the overarching goal. These standards offer guidance on multidisciplinary patient care, especially in the fields of Emergency Services, Blood Transfusion, Obstetrics, Anesthesia and Surgery. Comprehensive treatment shall take place in the respective clinical specialty areas with strict adherence to the Standards of Care.

Standard 18. COP-1: Emergency services are guided by policies, procedures and applicable laws and regulations.

Indicators (58-61):

Ind 58. SOPs for emergency care including handling medicolegal cases are documented and available.

Survey Process:

Review the SOPs, which should cover the administration of the emergency area including prioritization, waiting times, admission/registration, discharge, referral and legal reporting requirements (only providing BLS and referring to the appropriate level with necessary documentation). The HCE should have emergency procedure manual and an evidence that staff members are conversant with the SOPs in the procedure manual.[43]

Scoring:

- If there are SOPs and the staff is conversant as described above, then score as **fully met.**
- If there are no written SOPs, or there is any deficiency, then score as **not met.**

GUIDELINES

Policies and Procedures

Each HCE should have well thought out and documented policies and procedures for emergency care, in line with statutory requirements. These policies and procedures, developed in the light of applicable laws, shall guide and encourage patient safety as the overall principle for providing healthcare services to patients. These documents include SOPs/Protocols to provide either general emergency care or management of specific conditions, e.g. myocardial infarction, acute abdomen, poisoning etc. and shall address both adult and pediatric patients. The procedure shall incorporate at least identification, assessment and provision of care. The HCE policy should spell out and ensure availability of all the necessary equipment in working order, in line with the international standards, required in the Emergency Department (ED) to function round the clock (24/7) without interruption of its services. Hospitals should make policies i.e. SOPs/SMPs, on at least the following topics:

1. Emergency Department design
2. Staffing of emergency services
3. Patient assessment and care
4. Emergency Medical Services (EMS)
5. Medications
6. Equipment and supplies
7. Power failure
8. Security/traffic control
9. Consent

[43] An outline / format of emergency procedure manual comprising SOPs provided in the Guidelines.

10. Confidentiality of patient information
11. Triage
12. Patient belongings and valuables
13. Reporting of criminal injury
14. Invasive procedures
15. Admission criteria
16. Patient discharge Criteria
17. Inter-hospital transfers
18. Release of information to media
19. Infection control
20. Visitors policy
21. Patients pronounced dead in the ED
22. Major adult trauma
23. Adult Medical Resuscitations
24. Continuous Quality Improvement (CQI)
25. The ED should be appropriately staffed and must have one to two Casualty Medical Officers (CMOs)/Emergency Medical Officers (EMOs) depending upon the patient load of the HCE in each shift of 8-1/2 hours, with a half hour overlap of duties for handing/taking over of charge. Night duty of 12 hours i.e. from 8PM to 8AM, currently in vogue, hampers the quality of service and therefore a uniform duty of 8-1/2 hour must be enforced. It should be mandatory to have sufficient experience and/or a house job in Medicine/Allied and Surgery/Allied specialties for the appointment of CMO/EMO.

SOPs on Emergency Services provided at ABC Hospital XYZ

1. Emergency services are provided round the clock at the hospital.
2. Basic emergency lifesaving medicines and equipment is made available in the hospital.
3. The doctor and the nurse performing the ward duty shall attend the patient in emergency.
4. The patient needing healthcare beyond the scope of the hospital are provided basic life support and first aid treatment and then referred to the appropriate facility.
5. All the patients presenting in emergency department in acute medical/surgical condition will be treated until initially stabilized.
6. However once the emergency situation is over and patient condition is stabilized, then the patient can be discharged, admitted or referred to other hospital on relevant consultant /specialist advice.
7. Patient is referred in an ambulance along with the nursing assistant/doctor according to the requirement of the patient judged by the concerned Medical Officer (MO)/ specialist. In case of walk in patient without any emergency, patient is referred by using in by his own transport. Patient will be referred/transferred on referral slip mentioning date, time, reason of referral/transfer, and name of the receiving hospital along with all investigations carried out.
8. Medico-legal cases are not entertained at the hospital but first aid is provided and then the patient is referred to the appropriate facility.
9. In case of a potential medico-legal case (e.g. poisoning, dubious history, stab wound or fire arm) the respective Police Station is contacted.

   Patient are attended on the Triage prioritization basis however in usual circumstances 'first come, first served' rule applies. Anyhow it is advisable not to lengthen the time of seeing any patient unduly.

Ind 59. SOPs guide the prioritization of patients for initiation of appropriate care.

Survey Process:

Look for the SOPs for formal prioritization process based on an evaluation of the patient's presenting complaint and / or clinical condition / need. The prioritization process for emergency care need not be on the basis of arrival time (first come, first served) or mode of arrival (ambulance versus walk-in) as a walk-in patient may have more emergent needs than the patient who arrived by ambulance.[44]

Scoring:

- If there are SOPs for: 1. Prioritization of the patients, 2. Is based on actual clinical evaluation, 3. Is carried out by appropriately trained staff 4. Using appropriate facilities and 5. Staff members are aware and 6. Applying the process, then score as **fully met.**
- If there is noncompliance of prioritization process or if it is only on first come, first served basis, then score as **not met.**

GUIDELINES

Triage and Treatment

Triage and Treatment is a protocol based Clinical Care/Management system, aimed at early and appropriate care and discharge from the ED.

Triage is the process of determining the priority of treatments based on the severity of the condition of patient. This rations patient treatments efficiently when resources are insufficient for all to be treated immediately. Triage may result in determining the order and priority of emergency treatment, emergency transport or the transport destination for the patient.

Triage may also be used for patients arriving at the ED, or to telephone medical advice systems among others, and cater for medical emergencies, including the pre-hospital setting, disasters and emergency room treatment.

Triage SOPs

Patients are TRIAGED on the Basis of the Urgency with which they need medical attention. The nurse allocates a Triage Category to a patient based on the statement and/or the condition of the patient as evaluated by the Emergency Doctor.

1. **Triage Categories**
   - **A. Immediate Resuscitation**
     Patients who need treatment immediately or within two minutes are categorized as having a life-threatening condition. Most of them would have arrived in the ED by ambulance and would probably be suffering from a critical injury or cardiac arrest.
   - **B. Emergency**
     Patients who need to be treated within 10 minutes are categorized as having an

[44] Existing standards on emergency management and disaster response by the National Disaster Management Agency and Government of Khyber Pakhtunkhwa hospital requirements for the management of disasters and standards framed by The Society of Emergency Physicians Pakistan (SEPP). Details / format provided in the Guidelines.

imminently life-threatening condition. This group of patients includes those suffering from a critical illness or are in very severe pain e.g. chest pain, difficulty in breathing and fractures etc.

C. **Urgent**

This group of patients requires treatment within 30 minutes and is categorized as having a potentially life-threatening condition. These include patients suffering from severe illnesses, bleeding heavily from cuts/wounds, have major fractures, or are dehydrated.

D. **Semi-Urgent**

People in this group are having a potentially serious condition with less severe symptoms or injuries, such as a foreign body in the eye, sprained ankle, migraine or earache etc. and need to be treated within one hour.

Ind 60. Staff members are familiar with the SOPs for care of emergency patients and trained on the same and the patients receive care in consonance with the SOPs.

Survey Process:

This is surveyed by observation and interview with HCE staff. Participation in Training and orientation should be documented in terms of content as given in **Ind. 58, 59 & 61.** The SOPs should be readily available and understood by staff and embrace ALL the aspects of care being received by patients.

Scoring:

- If the documentation regarding training of staff on SOPs is available, staff is aware of relevant SOPs and practices the same, then score as **fully met.**
- If there is inconsistency in any of the above described requirements, then score as **not met.**

GUIDELINES

Training in Policies and Procedures

A specialist in emergency medicine is appointed to assume overall responsibility of the A&E services. The specialist shall regularly review the facilities, equipment and training of the staff for services. The CMO should remain in the A&E Department 24/7. A registered nurse who is trained and experienced in the practice of emergency nursing is available at all times to supervise nursing care in the A&E services.

An appropriate number of suitably qualified and experienced staff is in attendance. The hospital shall have a policy in place to mobilize additional personnel to attend to emergency situations.

The hospital maintains an up-to-date roster of specialty doctors who are readily available to render consultation service and necessary assistance.

All medical and nursing staff deployed to the A&E Department shall also receive training on the following courses:

1. Advanced Trauma Life Support (ATLS);
2. Advanced Cardiac Life Support (ACLS);
3. Trauma Nursing Care Course (TNCC);

4. Paediatrics Advanced Life Support (PALS).

The HCE shall evolve a solid and comprehensive policy for the SOPs/Standard Medical Protocols (SMPs) for Accident and Emergency (A&E) Department encompassing all the details regarding assessment and treatment protocols to be followed in the department. Cases/patients requiring immediate attention e.g. victims of road traffic accidents, patients with cardiac complaints, poisoning cases etc., shall be handled according to set HCE policies and procedures.

Ind 61. Admission, discharge or referral to another HCE is documented.

Survey Process:

Review a sample of at least 10 medical records, files or other documentation (emergency services log book) of patients who were treated in the emergency department to determine the admission, discharge and referral process. Review the advice and information provided to the patient or to other clinician or treatment facility and determine if it is adequate to ensure ongoing treatment and follow-up that is clinically required.

Scoring:

- If this is 100 percent documented, then score as **fully met.**
- If only 1-2 cases fail to meet this requirement, then score as **partially met.**
- If 3 or more of the cases reviewed do not document this, then score as **not met.**

GUIDELINES

Emergency Admission, Discharge and Transfer Policy

All patients who present an Emergency Medical Condition must receive treatment to the extent that their emergency condition is medically "stabilized," irrespective of their ability to pay for such treatment, in case of a Private HCE.

An Emergency Medical Condition is defined as one that manifests itself by acute symptoms of sufficient severity (including severe pain, psychiatric disturbance, and/or symptoms of substance abuse) such that the absence of immediate medical attention could reasonably be expected to result in the following:

1. Placing the health of the individual (or unborn child) in serious jeopardy.
2. Serious impairment of a bodily function.
3. Serious dysfunction of any bodily function or part.
4. Inadequate time to affect a safe transfer of a pregnant woman to another hospital before delivery or, that the transfer may pose a threat to the health or safety of the woman or unborn child.

"Stabilization" means "that no material deterioration of the condition is likely, within reasonable medical probability, to result from or occur during the transfer or discharge of the patient from a facility."

However, once the emergency is over and a patient's condition is stabilized, the patient can be discharged and refused further treatment by private hospitals. If the individual seeks routine medical care or schedules a doctor's appointment for non-emergency medical problems, doctors have a general right to refuse treatment if they have no insurance or any other means of paying for the provided care.

The **Discharge Procedures** are documented to ensure coordination amongst various departments including Accounts so that the discharge papers are complete well within time. For MLC/Medico-Legal Record (MLR), the HCE shall ensure that the police are informed.

The HCE hands over the **discharge papers** to the patient/attendant in all cases and a copy is retained. In Leaving Against Medical Advice (LAMA) cases, the declaration of the patient/attendant is to be recorded and signed on a proper format. In case of discharge to home, a Discharge Summary shall be given to the patient. The patient's treating doctor determines the readiness for discharge during regular reassessments. The same is discussed with the patient and his/her family.

The **Discharge Summary** shall be signed by the treating doctor or a member of his/her team and should contain the following:

1. Patient's name & Unique identification number
2. Date of admission and discharge.
3. Reasons for admission with significant findings & Diagnosis.
4. Patient's condition on discharge.
5. Investigation results if any.
6. Medication administered & any procedure performed/Treatment given.
7. Follow up advice and other instructions deemed necessary
   (The instructions shall be in a manner that the patient can easily understand)

The HCE should have a documented policy for clients/patients LAMA and those being Discharged on Request. The treating doctor should explain the consequences of this action to the patient/attendant. This policy could address the reasons of being LAMA for any possible corrective and/or preventive action by the HCE.

In case of transfer to another facility, details regarding medical history of the patient, investigations/ procedures performed, treatment provided, reasons for referral and the name of the HCE to be referred will be recorded in the prescribed referral form. In such cases, SOPs regarding patient transfer (Reproduced below) shall be strictly followed so as to ensure proper care during transportation and handing over of the patient to referred facility takes place.

SOPs for Transfer of Patients:

Following the decision to refer a patient to another hospital, there should be a written communication containing the reasons of referral with date, time, name of the receiving hospital and a copy of the same should be retained in the medical record of the patient.

If the patient has been transferred at his/her own request, a note to that effect is added in the patient's record. In such cases the name of the receiving hospital would be of the one where the patient desires to go to.

However, if the patient has been transferred by the HCE under care with medical staff, it shall have acknowledgement from the receiving Hospital.

Assessment Scoring Matrix

Standard 18. COP. 1: Emergency services are guided by policies, procedures and applicable laws and regulations.

Indicator 58-61		Max Score	Weightage (Percent)	Score Obtained
Ind 58.	**SOPs for emergency care including handling medicolegal cases are documented and available.**	10	**100**	
Ind 59.	**SOPs guide the prioritization of patients for initiation of appropriate care.**	10	**100**	
Ind 60.	**Staff members are familiar with the SOPs for care of emergency patients and trained on the same and the patients receive care in consonance with the SOPs.**	10	**100**	
Ind 61.	**Admission, discharge or referral to another HCE is documented.**	10	**80**	
Total		40		

Standard 19. COP-2: Policies and procedures define rational use of blood and blood products.

Indicators (62-65):

Ind 62. SOPs to guide rational use of blood and blood products are documented and the staff members are trained to implement the SOPs.

Survey Process:

While visiting the blood bank review the SOPs/manual which should be in line with the approved guidelines and at least cover: i. Donor screening, ii. Processing of blood, iii. Storage of blood, iv. Administration of blood, v. Use of blood products, vi. Identification and analysis of real or suspected transfusion reactions and vii. Disposal of blood and related products. (See Standards & Guidelines of Blood Transfusion Safety Authority, established under the Blood Transfusion Safety Authority Act, 2016, Government of Khyber Pakhtunkhwa)

Look for compliance with the documented SOPs and discuss with staff and also review the staff training records.

Scoring:

- If the SOPs are present in the blood bank, they include at least the above 7 requirements (relevant to the scope of services available in the hospital) and staff has been trained to apply those, then score as **fully met.**
- Since blood services are critical patient safety issue, if any of the 7 requirements (relevant to the scope of service in the hospital) are not present or if the staff has not been trained to apply them, then score as **not met.**

GUIDELINES

Standard Operating Procedure (SOP)

1. **SOPs for Blood Transfusion**
   - **A. Blood Screening**

     WHO recommends protocols for screening all donated blood for five Blood Transmitted Infections namely Hepatitis B and C, HIV, Malaria and Syphilis, and this should be practiced.
   - **B. Processing of Donated Blood**

     Blood collected in an anticoagulant can be stored and transfused to a patient in an unmodified state. This is known as 'whole blood' transfusion. However, blood may be used more effectively if component therapy is practiced. One unit of donated blood may be divided into components, including red cell concentrates, fresh frozen plasma, cryoprecipitate and platelet concentrates, to meet the needs of more than one patient. The following elements are essential for safe and effective blood component processing:

(i) Commitment and support by health authorities for sustainable, well-organized, coordinated blood transfusion services, with adequate resources and quality system for all areas.
(ii) Centralization of blood processing and testing within major centers to permit economies of scale by maximizing utilization of personnel and equipment and enforcing uniform standards.
(iii) Effective and timely testing of all donated blood to ensure maximum safety and availability of blood components.
(iv) Promotion of appropriate blood component therapy.
(v) Using surplus plasma for the production of plasma-derived medicinal products through fractionation.

2. Storage and Collection of Blood from Blood Refrigerator

A. Incorrect collection, labelling and storage of blood are the major source of errors leading to transfusion of wrong blood.
B. Blood is to be stored only in designated blood refrigerators or blood boxes, and never refrigerators.
C. The blood refrigerator must be secured to prevent unauthorized access and it must be alarmed to the Blood Bank in the event of a malfunction.
D. The whole blood units and the packed red cells shall be stored at a constant T° of +4°C (between +2 and +6°C). The duration for whole blood and red cell concentrates varies between 21, 35 and 42 days depending on the composition of the preservative solution.
E. The Fresh Frozen Plasma (FFP) and the Cryoprecipitate shall be stored at -30°C during two years.
F. The platelet concentrates shall be stored between 20 and 24°C during 3 to 5 days, under a constant T° and agitation.
G. The mentioned T° must be respected all along the blood or blood products transport.
H. Only suitably trained nursing staff are authorized to collect blood and they should ensure that:
    (i) The patient identity is confirmed.
    (ii) The patient is still consenting to the transfusion.
    (iii) The patient has a patent cannula of the right size.
I. The staff member collecting blood must bring documentation (drug chart and compatibility form) bearing full patient identification details -name, surname, DoB and hospital number, to the blood refrigerator.
J. The person collecting blood must check the patient identification details on the documentation against the unit/s being collected
K. The blood bag must be matched with the patient's identity and the particulars mentioned on the compatibility card which should also include the blood groups of the patient and the donor.
L. Only one unit of blood should be removed at any one time.
M. Do not remove blood from the refrigerator if the alarm sounds; (inform the Blood Transfusion Laboratory immediately).
N. The delivery of blood to a ward should be brought to the attention of a senior member of staff to avoid undue delay in starting the transfusion. A unit of blood should not be left out of the refrigerator or blood box for more than 30 minutes.

O. Platelet concentrates should be kept at room temperature at all times and should not be placed in a blood refrigerator.

P. FFP should be collected and transfused as soon as possible (or within four hours) after thawing by the Blood Transfusion Laboratory (if not used, return to the issuing Blood bank for disposal).

Q. If there is no blood refrigerator available, blood can only be stored in a blood box with cool packs for a maximum of four hours.

Figure 10 Storage and Collection of Blood

3. Administration of Blood and Blood Products

A. The final identity check must be done next to the patient, by matching the bag of blood or blood product with the patient's identity. It is mandatory for hospital staff to properly identify the patient as per hospital record and match it with the blood bag before starting transfusion.

B. A double entry check system requiring checking and recording one event by two person involved in transfusion is to be adopted for this purpose.

Note: No Transfusion without confirming Identity first.

C. ID details must be identical in the:

(i) Patient's notes
(ii) Blood collection slip
(iii) Drug chart
(iv) ID wristband (Where applicable)
(v) Compatibility form
(vi) Compatibility label

D. Also check that the:

(i) Unit number matches the Blood bag
(ii) Expiry date matches the Compatibility label
(iii) Blood product matches Compatibility form

E. Also check the bag of blood for:

(i) Integrity of the bag
(ii) Haemolysis or plasma interface
(iii) Large clots

(iv) Turbidity or discoloration
(v) Special transfusion requirements being met

F. When these checks have been completed, the drug chart should be signed immediately, timed and dated.
G. The blood is now ready to be administered.
H. All blood should be administered via an administration set containing a 200-micron filter.
I. No other medication may be added to the blood or administered through the same cannula. The red cell administration set should be changed after two units, and must be changed if blood of a different group is to be transfused, i.e. homologous blood following the transfusion of emergency O Rh D negative blood.
J. If the blood is not set up i.e. transfusion started, within 30 minutes of leaving the refrigerator, it must be considered unsafe. It should be labelled as "Dangerous to Patient" and returned to the blood bank for disposal and an Incident Report Form completed. The transfusion must be completed within four hours of blood leaving the refrigerator.
K. If the transfusion cannot start within 30 minutes the unit should be returned to the blood refrigerator before the 30 minutes is exceeded. The unit of red cells must be signed back into the refrigerator on the refrigerator log form (located on top of the refrigerator), giving a clear indication of the date and time returned.
L. Transfusion of platelets should be commenced as soon as possible after it is received and in case of any delay in transfusion, platelets should be returned to blood bank. Platelet packs must not be refrigerated.
M. If there are any discrepancies found in the checking procedure, the blood should not be transfused. The blood bank must be informed and the unit and the blood transfusion compatibility report form returned to the blood bank.
N. Empty bags must be plugged and will be collected from the blood refrigerators by the blood bank staff.

Ind 63. The transfusion services are governed by the applicable laws and regulations.

Survey Process:

The surveyors will need to be aware of the applicable laws and regulations on blood transfusion.[45] This is surveyed by reviewing documentation (such as an external official inspection, copies of the legislation and compliance requirements), interviews, and observation. This includes an observable mechanism to ensure that only blood and blood products derived employing approved guidelines and procedures is provided to patients. This is a significant patient safety issue.

Scoring:

- If the laws, regulations and guidelines are present and being complied with by all staff, then score as **fully met.**
- Considering the critical nature and risk with blood services, if there are any examples of non-

[45] See the Khyber Pakhtunkhwa Blood Transfusion Safety Act, 2016.

compliance that compromise the safety of patients, then score as **not met.**

GUIDELINES

Compliance to Statutes

The Khyber Pakhtunkhwa Blood Transfusion Safety Authority Act was promulgated in 2016 and the Khyber Pakhtunkhwa Government constituted the Khyber Pakhtunkhwa Blood Transfusion Safety Authority (KPBTA) under the Act to monitor private blood banks in Khyber Pakhtunkhwa.

An Act to regulate collection, testing, processing, storage, distribution, issuance, transfusion of human blood, blood components, ensuring health protection and prevention of transfusion transmissible diseases, the Khyber Pakhtunkhwa Blood Transfusion Safety Authority Act 2016 has been promulgated by the Government of Khyber Pakhtunkhwa, which extends to whole of the Khyber Pakhtunkhwa and has repealed the Khyber Pakhtunkhwa Transfusion of Safe Blood Act, 1999 (IX of 1999).

Some of the pertinent features of the Blood Transfusion Safety Authority Act, 2016 are as under:

Regional Blood Center (RBC) as defined under Section 2 (n) means any structure or body which manufactures blood and blood components and performs processes related to the promotion of blood donations, collection, testing, proceeding, storage, transport, distribution of blood and blood components, whether maintained by public or private sector at such regional level as may be determined by the Authority. Section 15 of the Act describes the Functions of the Regional Blood Center.

Blood Bank (BB) as defined in Section 2 (b), includes all organisations carrying out all or any of the purposes of receiving, preserving, storing, analysing, screening, processing and issuing of blood or blood products, whether maintained by public or private sector. Section 16 of the Act describes the Functions of the Blood Bank.

KP HCC considers that establishing a Blood Bank is a mandatory requirement for HCEs where Comprehensive Emergency Obstetric and Neonatal Care (CEmONC) and surgical services are provided; and at other HCEs where blood transfusions are performed. Category 2-B hospitals are exempt from having mandatory blood bank (BB), subject to the condition that the HCEs maintain a written contract with a nearby RBC/BB duly licensed by the KPBTA. The contract shall include a binding clause that the licensed RBC/BB will take back the unused blood for separate temporary storage to avoid wastage or misuse. The contract shall also specifically define the responsibilities of the individuals and the organizations (each party) regarding compliance with all legal requirements, end to end traceability and maintaining the cold chain during transportation and storage.

Ind 64. Informed consent is obtained for donation and transfusion of blood and blood products.

Survey Process:

Review the medical records of those patients[46] who have received blood transfusion to determine if there is documented 'informed consent' and if the consent adequately informs the patient. If the

[46] Surveyors should decide the representative sample size according to work load/size of the hospital.

hospital processes donors, also review a representative sample of patient's record to determine if the donor gave informed consent and this was appropriate for the individuals concerned. It is important to note that evidence of informed consent can be either a signed form or a note by the physician that the patient's verbal consent was obtained. Informed consent must be designed to ensure that people of ALL backgrounds truly understand the risks and options involved and the evidence provided must clearly support this. This includes information and education of the patient and their family, when present.

Scoring:

- If informed consent is obtained for 100 percent of cases,[47] then score as **fully met.**
- Since this is a significant patient safety and medico-legal issue, if ANY case does not have a documented informed consent, then score as **not met.**

GUIDELINES

Informed Consent for Donation and Transfusion

It is important to note that evidence of informed consent can be either a signed form or a note by the physician that the patient's verbal consent was obtained in emergency which should be documented later.

Informed consent for transfusion includes two main processes:

1. The medical officer communicates with the patient or guardian in terms they clearly understand about the transfusion of blood or blood components, necessity in the particular circumstance, probable complications, possible medical consequence of refusal, and available alternatives.
2. The patient or guardian after expressing satisfaction with the information provided, asks pertinent questions with regards to the process, and agrees or not (in writing) to be transfused.

In life-threatening emergencies when uncross-matched blood may be necessary or in the absence of serologically compatible components, signed consent for their use must be obtained from the attending medical officer.

Informed consent will have to be incorporated in the donor history card accordingly. A Sample Format for Informed Consent is given on the following below:

Table 15: Sample Format for Informed Consent

CONSENT FORM FOR BLOOD OR BLOOD COMPONENT TRANSFUSION
Date: _____
Patient's Name: _____ Age:_____
Identity Card No.: _____Sex: Male/Female*_____
Address: _____
Attending Medical Practitioner: Dr. _____
Identity Card No./PMDC Reg. No.: _____
I, the parent/guardian/spouse/next-of-kin of the above-named*, have been informed of the

[47] There are exceptions when the recipient is an emergency unconscious patient without family or guardians present at the time.

need for a blood transfusion for the patient. The attending medical practitioner has explained to me the risks and benefits involved in the transfusion as well as answered all my inquiries satisfactorily. I understand that despite testing and screening on the blood/blood components for HIV, hepatitis B, hepatitis C and syphilis, there are still risks of developing the disease. I also understand that unavoidable complications of transfusion may also occur.

I fully understand the above and hereby agree to the blood/blood component transfusion.

_____ _____

Signature of the patient/ parent/guardian/spouse/next-of-kin*
Thumb Impression

Signature of Attending Medical Practitioner

Name of parent/guardian/spouse/next-of-kin** _____

Identity Card No. of the above: _____

I was present while the above matter was explained to the patient/parent/guardian/spouse/ next-of-kin* whose signature appears above. In my opinion, the person referred to has understood the contents of this form and agreed to the transfusion willingly.

_____

Signature and thumb Impression of Witness

Name of Witness: _____

Identity Card No.: _____

* Delete appropriately ** If necessary

Ind 65. Transfusion reactions are analysed for preventive and corrective actions.

Survey Process:

Ask for documentation that reports transfusion reactions. Evaluate whether the documentation demonstrates adequate analysis and remedial actions. In the case where no reactions are reported,[48] the surveyors should evaluate whether there are adequate clearly written procedures for analysis and remedial action if a reaction does occur. Check that staff members are aware of the reporting process.

Scoring:

- If there had been a transfusion reaction and it was fully analyzed and remedial action proposed or if there are written procedures to follow if one occurs, then score as **fully met.**
- If there had been a transfusion reaction and there is no documented evidence of how it was analyzed, or if there had been no transfusion reaction and the blood bank also does not have any written procedure for analysis, then score as **not met.**

[48] This would be highly unlikely.

GUIDELINES

Transfusion Reaction Analysis

Corrective and preventive actions are part of the QA process. Recognized principles of quality management include a component for process improvement, comprising largely of corrective and preventive actions taken in response to identified problems. The importance of identifying and investigating problems has been clearly established in transfusion medicine. Such problems can be identified in the following ways: error, incident, and accident reports; adverse reaction reports; customer complaints; process indicator measurements; results of proficiency testing; and results of internal or external audits, inspections, or assessments. Responses to reported events can be remedial, in which the symptom is addressed, or corrective, in which the underlying cause is addressed with the intent to prevent recurrence. If identified problems or their root causes are trended to look for patterns or problems not yet occurring but are anticipated, the action taken is proactive and considered preventive.

A brief description of both actions is given below:

1. **Corrective Action**

   Procedures for corrective action shall include an investigative process to determine the underlying cause or causes of the problem. Laboratory management shall record and monitor the results of any corrective action taken, in order to ensure that they have been effective in overcoming the identified problems.

2. **Preventive Action**

   The laboratory shall have procedures for preventive actions that allow for identifying needed improvements and potential sources of nonconformities, either technical or concerning the quality management system. If preventive action is required, action plans shall be developed, implemented, and monitored to reduce the likelihood of the occurrence of such nonconformities. The preventive action shall be recorded.

   The transfusion service should complete and send out a preliminary report of the reaction as soon as possible after receiving the specimens. A full report shall be dispatched after completion of serological and/or bacteriological investigation, and will include advice for further transfusion therapy. The report must be inserted into the patient's file.

   A Sample Form for Corrective and Preventive Action is given ahead.

Table 16: Sample Format for Corrective and Preventive Action

Institution Name	Document	Version	Number
TITLE	Managing Corrective and Preventive Action		

1. Description
a) Corrective Action b) Preventive Action
Description of the problem:
Problem Causes:

Person In charge/Date:
2. Suggested Action
1st action:
Person In charge/Date:
Effective a) Yes b) No c) Go on to next action Person In charge/Date:
2nd action:
Person In charge/Date:
3. Closing the file
Long-term effectiveness: a) Yes b) No Person In charge/Date: _____ Comment: _____
Closed by: _____ Date: _____

Table 17: Blood Transfusion Reaction Report Format

Date	S/no.	Patient Name, MR no. Diagnosis	Blood Group		Blood Group on re-verification		Transfusion Reaction Type	Possible Reason	Remarks/ Analysis
			Recipient	Donor	Recipient	Donor			

Assessment Scoring Matrix

Standard 19. COP-2: Policies and procedures define rational use of blood and blood products.

Indicator 62-65		Max Score	Weightage (Percent)	Score Obtained
Ind 62.	**SOPs to guide rational use of blood and blood products are documented and the staff members are trained to implement the SOPs.**	10	**100**	
Ind 63.	**The transfusion services are governed by the applicable laws and regulations.**	10	**100**	
Ind 64.	**Informed consent is obtained for donation and transfusion of blood and blood products.**	10	**100**	
Ind 65.	**Transfusion reactions are analysed for preventive and corrective actions.**	10	**100**	
Total		40		

Standard 20. COP-3: Policies and procedures guide the care of high risk obstetrical patients.

Indicators (66-69):

Ind 66. The Hospital defines and displays whether high-risk obstetric cases and their neonates can be cared for or not.

Survey Process:

Since many patients will not know if they are high risk or not, it is important that the hospital informs its obstetrical patients about the definition of **high risk** and its capability **(Link with Ind. 68)** to provide services for elective high-risk obstetric cases and their neonates. The second important issue for the hospital is to create awareness for those practitioners and health facilities that might refer high-risk obstetric cases, about the hospital's capability to provide care to such patients. At the minimum, this information should be displayed on the board depicting menu of services at the main entrance and in the patient waiting areas where ante natal assessments are done.

Scoring:

- If the hospital has defined high risk obstetric cases, informs its own obstetric patients, displays requisite information as above and pro-actively informs the referring practitioners / health facilities regarding its capability to care for elective high-risk obstetric cases & neonates, then score as **fully met.**
- If the hospital has defined high risk obstetric cases, informs its own obstetric patients, displays requisite information as above but does not pro-actively inform the referring practitioners / health facilities regarding its capability to care for elective high-risk obstetric cases & neonates, then score as **partially met.**
- If the hospital has not defined high risk obstetric cases, neither informs its own patients nor displays requisite information for referring healthcare providers / health facilities, then score as **not met.**

GUIDELINES

High Risk Obstetrical Cases

A high risk pregnancy is one in which some condition puts the mother, the developing fetus, or both, at a higher risk than normal for complications during or after the pregnancy and birth. At a HCE, high-risk pregnancies may present with any of the following conditions:

1. Haemorrhage
2. Prolonged or obstructed labour
3. Postpartum sepsis
4. Complications of abortion
5. Pre-Eclampsia or Eclampsia
6. Ectopic pregnancy
7. Ruptured uterus

8. Foetal Distress/Newborn Distress (intrapartum)
9. Pregnancy with medical disorders
10. Malpresentation
11. Twin pregnancy
12. Pregnancy with scarred uterus

Women visiting the HCE with a high-risk pregnancy (not necessarily limited to above conditions only) will need closer monitoring than the average pregnant woman and availability of Comprehensive Emergency Obstetric Care (CEmOC) Services 24/7 is mandatory to save the mother's life. Signal functions[49] used to identify CEmOC Services include:

1. Administer parenteral antibiotics.
2. Administer uterotonic drugs (i.e. Parenteral Oxytocin).
3. Administer parenteral anticonvulsants for preeclampsia and Eclampsia (i.e. Magnesium sulfate).
4. Manually remove the placenta.
5. Remove retained products (e.g. Manual vacuum extraction, dilatation and curettage)
6. Perform assisted vaginal delivery (e.g. Vacuum extraction, forceps delivery)
7. Perform basic neonatal resuscitation (e.g. with bag and mask).
8. Perform surgery (e.g. Caesarean section [C-Section]).
9. Perform blood transfusion

Note: As per WHO definition, Sr. No. 1-6 constitute Basic EmOC Services, Sr.No. 1-7 constitute Basic EmONC [Emergency Obstetric and Neonatal Care] Services and Sr. No. 1-9 constitute Comprehensive EmONC Services.

Written procedures and guidelines, consistent with the facility policies and functions, should be used for:

1. Antenatal care and booking/registration
2. Postnatal care
3. Perinatal care
4. Counselling for parenthood e.g. Family planning, genetic, referral and IEC material
5. Identifying high risk pregnancy
6. Admission to labor room/ward
7. Planning treatment and mode of delivery
8. Plan for managed pain during labor and delivery
9. Delivery monitoring process
10. Referral
11. Discharge, including discharge summary
12. Birth record and certificate
13. Labor register
14. Immunization for mother and baby
15. Infection control
16. Disposal of placentas

Identifying high risk pregnancy

1. Routine antenatal care of all pregnant patients includes identification and management of

[49] WHO. (2003). Managing complications in pregnancy and childbirth: a guide for midwives and doctors. Retrieved from http://www.who.int/making_pregnancy_safer/documents/9241545879/en/index.html

high-risk pregnancies.

2. The attending HCP must inform the patient about the high-risk nature of the pregnancy and counsel the patient on adopting appropriate measures of care.
   A. In addition to routine examinations, special radiological or blood examinations should be conducted in high-risk pregnancies, if indicated.
   B. The patient and the caregiver must be appraised about the imminent risks and educated on how to minimize the risk, including when to seek emergency care.
   C. If the facilities (human and material resources) available in the hospital are considered insufficient, referral of the patient must be made at the earliest to the nearest competent health facility.

The HCE should ensure that:

1. A separate room for seriously ill or intensive patients e.g. Eclampsia, is available.
2. The area for labor provides space for the woman and a female companion, alternative birthing methods, ambulation throughout labor, washing and toilet facilities for the comfort of the mother and companion.
3. Lighting is versatile enough to provide a restful environment and allow birthing procedures to be performed.
4. The post-natal ward provides sufficient room for the babies to room-in with mothers.
5. Privacy for mothers e.g. when breast-feeding.
6. Intensive care set up should be available, with multidisciplinary team support for critical cases.
7. Disposal of placentas as well as other waste material should be ensured according to SOPs.
8. A signed agreement and close professional links with a referral hospital (Providing Specialized Care) offering more comprehensive services, ensures provision of necessary emergency maternity services not available in the hospital.

Ind 67. Persons caring for high-risk obstetric cases are competent.

Survey Process:

Surveyors should look for the availability of round the clock specialized care[50] (24 hours/day, 7 days/week coverage) by the staff who are fully qualified in obstetrics and who have advanced training in high-risk obstetrics and documented experience. In addition, there should be evidence that members of the nursing staff who care for such patients have advanced qualifications and documented experience.

Scoring:

- This standard should default to a score of **fully met** unless there is lack of evidence that ALL personnel who provide care to high-risk obstetric patients have appropriate qualifications.

[50] This is the absolute minimum to provide 24hrs, 7 days per week service based on 3 shifts per day and 270 productive workdays per employee per year.

GUIDELINES

High Risk Obstetrical Cases

Consultant/Head of Department (HOD)/Head of Clinical Unit will be required to provide clinical care to patients and oversee clinical and administrative functioning of the Maternity Department. Responsibilities should be as recommended by PMDC, however a general description of his/her assignment is given below:

The HOD/Head of Clinical Unit will be responsible for the management of human and material resources and the implementation of existing hospital polices for provision of quality services to patients and their attendants.

1. Candidates considered eligible for the post of HOD/Head of Clinical Unit include:
   A. MBBS qualified physician with FCPS Obstetrics and Gynaecology/ Member of Royal College of Obstetricians and Gynaecologists (MRCOG)/ American Board Certification in Obstetrics and Gynaecology or any other equivalent degree, or
   B. MBBS qualified physician with Member of College of Physicians and Surgeons (MCPS) and 2 years post-qualification experience, or
   C. MBBS qualified physician with Diploma in Obstetrics and Gynaecology and 2 years post-qualification experience.
2. Formal assignment to the position will include verification of:
   A. Certification of the concerned candidate.
   B. Registration with PMDC.
   C. Formal complaints/malpractice cases registered with the previous employer or with PMDC concerning the candidate.
3. Following induction to the post, the HOD/Head of Clinical Unit must be provided with and explained the hospital policies regarding patient care, quality of care and HR management.
4. The job summary of the HOD/Head of Clinical Unit includes being responsible for a high standard of gynaecological work in the hospital.
5. The scope of work of the HOD/Head of Clinical Unit includes being in-charge of the Department of Gynecology, and personally ensuring the smooth functioning of the department, through staff and colleagues. This includes conducting Antenatal Clinics, Gynecological OPD, admission of patients requiring surgical intervention, conduct planned, emergency surgeries (on specific/notified days or as per need), postoperative care of patients in the ward, follow up of surgeries in OPD as per need, teaching by lectures/tutorials in the ward and bedside coaching of medical and nursing staff.
6. Duties/Responsibilities of the HOD/Head of Clinical Unit include:

   A. Administrative

   (i) The HOD/Head of Clinical Unit is the Administrative and Technical in-charge of the Department of Gynaecology.
   (ii) She/he has to remain available during working hours for routine/emergency cases and teaching.
   (iii) She/he is second on-call after working hours.
   (iv) She/he ensures attendance of subordinate staff through the Registrar.
   (v) She/he checks punctuality of the staff attached to her/his section.
   (vi) She/he checks cleanliness and up keep of the Gynaecological/Obstetric ward.

(vii) She/he ensures regular upkeep and maintenance of departmental electro-medical equipment to ensure their functionality at all times.

(viii) She/he ensures that responsible staff is regular in maintaining supply/replenishment of medicines and stores.

(ix) She/he guides the Management for purchase of new equipment/instruments needed from time to time for OPD, Wards and OT.

(x) She/he checks and controls subordinate staff to ensure their performance as per Job Description, SOPs and SMPs.

(xi) She/he allocates duties to other specialists/doctors from within the defined framework of particular JDs.

B. Preventive

(i) Antenatal Care

- She/he thoroughly examines pregnant women, whether referred or reporting directly, and advises on all aspects of pregnancy, Tetanus Toxoid immunization, any abnormality (if detected) and discusses arrangements for the conduct of delivery.
- She/he will conduct surprise visits to check validity of reports and on ground performance of Maternal and Child Health (MCH) staff.

(ii) Care during delivery

She/he examines and identifies pregnant women with abnormalities (in particular) and conducts the delivery her/himself at the health facility. The number of deliveries performed at the health facility is an indicator of her/his performance.

(iii) Postnatal Care

- She/he arranges post-natal examination of all mothers, particularly those with intra-partum and/or postnatal complications, either her/himself or by out-reach MCH staff.
- She/he advises mothers on family planning and child spacing during these visits.

(iv) Care of Infant

She/he ensures resuscitation of the new born, care of the cord and examines for abnormalities (if any).

(v) Family Planning

- She/he performs invasive Family Planning (FP) procedures at the health facility.
- She/he practices prevention of Sexually Transmitted Infections (STIs) and Reproductive Tract Infection (RTIs).
- She/he advises ladies/couples on how to safe guard themselves from STIs and RTIs.

(vi) Major Micronutrient Deficiencies

She/he persuades the use of and prescribes micronutrients.

(vii) Health Promotion

- During antenatal and postnatal sessions and while attending patients for treatment of diseases in general, the Gynecologist will disseminate

information on nutrition and other health issues, particularly related to MCH.

- She/he will participate in the establishment and conduct of Medical Camps pertaining to MCH and FP activities.
- She/he will ensure compliance of SOPs, especially Infection Control (IC) and Waste Management (WM) in the OPD, Wards, Operation Theatres, Pre and Postoperative Wards.
- She/he will ensure that instruments/equipment used in surgeries are properly sterilized.
- She/he will ensure that all staff participating in surgery/procedures are physically well protected by wearing assigned protective gear i.e. Gowns, Masks, Caps,
- Gloves and theatre shoes.

(viii) Curative/Clinical

- She/he will be in-charge of the functioning of Antenatal/ Gynecological OPD, admitted patients of the Gynecological/Obstetric Wards and Gynecological/ Obstetrical patients admitted in private rooms.
- She/he will conduct Antenatal/Gynecological OPD with her his team regularly on specified/notified days and time as per hospital policy.
- She/he will attend all Gynecological patients screened by the departmental doctors and referred by other departments/hospitals before they are admitted through OPD.
- She/he will plan and perform surgeries on specified days and time as per hospital policy.
- She/he will conduct complicated deliveries her/himself.
- She/he will perform emergency Gynecological/Obstetrical Surgeries on patients admitted through the A&E Department, as and when required.
- She/he will write postoperative notes and postoperative instructions for each admitted patient.
- She/he will take one planned round of the wards daily along with all departmental doctors for the review/follow-up of old cases and examination (in detail) of newly admitted patients. The clinical round is to be repeated (with or without MO in charge of the ward), if so required due to patient condition.
- She/he will ensure that treatment prescribed is being administered to the patients.
- She/he will ensure availability of medicines/functioning equipment for emergencies at all times.
- She/he will attend to patients with Gynecological problems admitted in other wards as and when required.

(ix) Rehabilitative

She/he will recommend physiotherapy and other rehabilitative measures to women in the post-natal period for early return to normal life.

(x) Referrals

- She/he will provide consultation to patients referred by MOs/Specialists from Primary or Secondary Health Care facilities, or the same facility.

- She/he will refer clients to appropriate specialist/services within and outside the hospital.

(xi) Teaching

She/he will teach and train WMOs, LHVs, LHWs, Midwives, Nursing and Paramedical Staff as per departmental/specialty requirements/protocols and SOPs as per routine and under special arrangements.

(xii) Research

She/he will write a Research Article based on local experiences every year.

(xiii) Supervisory

- She/he will supervise and control functioning of Registrar/Woman Medical Officers of the department.
- She/he will supervise Technical functioning of Paramedical staff of the department.

(xiv) Representation

- She/he will inform the Medical Superintendent (MS) about matter/s which need her/his attention.
- She/he will report and returns statistics of the department to the MS.

(xv) Medico-Legal

She/he will follow established and approved SOPs on the subject.

(xvi) Quality Control/Conformance to Standards

She/he will comply with standards of service delivery as provided in the MSDS SOPs especially on IC and WM and SMPs.

(xvii) Performance Evaluation

- She/he will conduct an evaluation based on achievements against set targets.
- She/he will write Objective Performance Evaluation Reports of subordinate staff.
- She/he will perform any other professional duty which may be assigned by the MS from time to time.

Continued Medical Education (CME) program for Staff

1. All personnel attached with the Maternity Department and involved in the provision of healthcare services must undergo continuous trainings in Maternal, Neonatal and Child Health (MNCH). These trainings should include, but not be restricted, to
   A. EmONC
   B. Emergency Neonatal Care (ENC)
   C. Integrated Management of Neonatal and Childhood Illnesses (IMNCI)
   D. Integrated management of Pregnancy and Childbirth (IMPAC)
   E. FP Surgical and Counselling
   F. Client Centeredness
   G. Basic Life Support (BLS)
   H. Advanced Cardiac Life Support (ACLS)
   I. General First Aid
   J. Correct and appropriate use of biomedical equipment
2. Specialists (Gynaecologists, Paediatricians and Anaesthetists) and Auxiliary staff (including

Technicians) posted to the Maternity and Surgical Departments should be assigned the task of conducting ongoing trainings of staff.

   A. Workload of trainings should be divided equally among all Specialist and Auxiliary staff by conducting trainings on rotation basis.
   B. Standardized Training Manuals available with National Maternal Newborn and Child Health Programme (NMNCHP), World Health Organization (WHO) and the European Resuscitation Guidelines should be acquired and used to conduct these trainings.

3. Individual HCPs, including medical staff, midwives and nurses must be trained in each of the preceding training areas at least once in two years.
   A. Newly assigned Staff to the Maternity Department should be provided these trainings at the time of induction into service.
   B. Attendance of nominated persons for the full duration of the course must be noted.
   C. Only that staff who has attended the entire course should be considered "fully- trained" and accordingly be certified by Trainers.
4. A record of trainings attended by each member of staff should be maintained in the Maternity Department by the Administration staff. A signed two-monthly record of conducted trainings along with planned training must be submitted by the HOD/Head of Clinical Unit to the MS Office for record keeping and future planning.

   Written procedures are followed by staff to arrange for consulting physicians, surgeons, and paediatric physicians and surgeons, for women or babies with medical or surgical needs such as multiple, high risk deliveries, instrument deliveries or C-sections.

Ind 68. The Hospital caring for high risk obstetric cases has the facilities and technically competent staff to take care of neonates of such cases.

Survey Process:

Technically competent staff with the following minimum requirements should be present (in working condition) in order to provide intensive care to neonates of such cases:

1. Neonatal Emergency resuscitation drugs,
2. Ambu bag with
3. Appropriate neonatal size facemasks,
4. Laryngoscope with neonatal size blades,
5. Neonatal size endo-tracheal tubes,
6. An oxygen source
7. Suction pump,
8. A warmer,
9. Incubator(s),
10. Infusion pumps to assure no volume overload to the neonate
11. Trays to allow cannulation of an umbilical artery,
12. Exchange transfusion trays.

Applicability of this indicator is linked with Indicator 66.

Scoring:

■ If ALL the above listed requirements are present and are in good working order, then score as

fully met.

- If ALL the required equipment and supplies defined at serial No. i to x above are present, and the hospital has safely defined alternatives for serial No. xi and xii, then score as **partially met.**
- If the critical requirement are not fulfilled, then score as **not met.**

GUIDELINES

Scope of Neonatal Care

Majority of neonatal deaths are due to neonatal asphyxia. All HCPs delivering midwifery services must be trained in new born resuscitation. Five days in-service training on "Essential Newborn Care" (ENC) has been designed to develop the newborn resuscitation skills in these HCPs. The HCE must get their staff trained in such compulsory trainings and provide logistics to implement these skills. The HCE must make sure that:

SOPs/Protocols for proper identification of the newborn, including placing an ID tag while handing over baby to the relatives, is developed. SOPs for handing over of the baby should also be in place.

Figure 11 New-born ID Tag

1. Nurseries should be located close to post-natal wards and be accessible only to nursery staff and parents of the new-born.
2. Temperature and humidity control of nurseries is essential. Heating should be provided by working radiant warmers or electric fans, maintaining ambient temperatures at 28-30^{o}C and 50% humidity.
3. All windows should have functioning and tight-fitting screens during summer months and covered during winter months.
4. Care must be taken to prevent cross contamination from other areas of the hospital.
   A. This can be achieved through ensuring double-door entry in the nursery.
   B. Provision of shoe covers after the first door or provision of a change of outside shoes for indoor shoes for patients and nursery staff.
   C. Hand washing facilities should be available and functional outside and inside the nursery. One basin per 6 children is recommended by the WHO.
      - Each basin should have facilities of running hot and cold water, soap, nail files and clean disposable towels.
      - All staff and mothers are required to be trained in hand-washing techniques and should adhere to these practices when handling or examining new-born.
      - Visual signs should be posted at nursery doors to remind personnel to wash hands before entering the nursery.

- A separate area should be available for seating of groups of mothers (3-5) for education sessions conducted by nursery staff. These sessions should include general health and hygiene of the new-born and the mother, techniques of breast feeding and post-partum contraception. Pamphlets, brochures or posters should be used for visual re-enforcement of health education messages.

The following minimum should be present, in working order:

1. Emergency resuscitation drugs.
2. Ambu bag.
3. Appropriate neonatal size facemasks.
4. Laryngoscope with neonatal size blades.
5. A selection of neonatal size endo-tracheal tubes.
6. An oxygen and suction source.
7. A warmer work stations.
8. Incubators.
9. Trays to allow cannulation of an umbilical artery.
10. Exchange transfusion trays.
11. Infusion pumps to assure no volume overload

Ind 69. No treatment is administered until the identity of the patient is guaranteed.

Survey Process:

The surveyor should look for a system[51] of safe patient identification and confirm that the administration of ALL treatments and therapies are preceded by confirming the identity of the patient.

Scoring:

- If the identification of the patient is clearly observable and fail safe for ALL patients and staff confirm identity, then score as **fully met.**
- If there is no fail-safe system of identification, then score as **not met.**

GUIDELINES

Identity of the Patient

Administration of ALL treatments and therapies should be preceded by confirming the identity of the patient.

There are different manual and technology-based methods of confirming the identity of patient. In addition to already defined traditional methods in other sections of manual, there are few other examples which are given as follows:

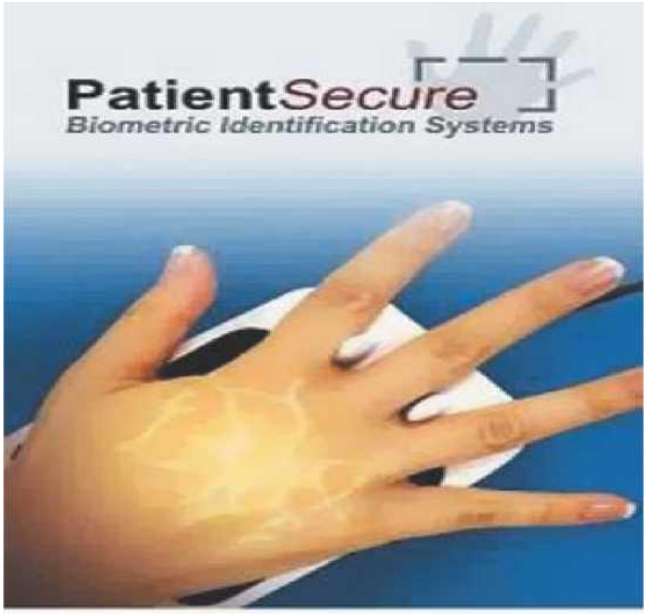
1. Bedside identity checking.
2. Automated identification methods such as use of barcodes in blood, patient samples and medication.
3. Ask the name of patient before receiving blood transfusions.
4. Double independent checking for high-risk tasks.
5. Wrist bands having two unique IDs

[51] For ALL patients the system employed must be permanently with the patient and fail-safe.

6. Card based technologies (magnetic strip, IC chips) may be used i.e. using cards which incorporate a magnetic stripe digitally encoded with information.
7. Biometrics (for example, finger printing and iris scan) may also be made use of i.e. using automated methods of identifying or authenticating a living person based on physiological or behavioral characteristics.

Figure 12 Methods of Identification

Figure 13 Methods of Identification



Assessment Scoring Matrix

Standard 20. COP. 3: Policies and procedures guide the care of high risk obstetrical patients.

Indicator 66-69		Max Score	Weightage (Percent)	Score Obtained
Ind 66.	**The Hospital defines and displays whether high-risk obstetric cases and their neonates can be cared for or not.**	10	**80**	
Ind 67.	**Persons caring for high-risk obstetric cases are competent.**	10	**100**	
Ind 68.	**The Hospital defines and displays whether high-risk obstetric cases and their neonates can be cared for or not.**	10	**80**	
Ind 69.	**No treatment is administered until the identity of the patient is guaranteed.**	10	**100**	
Total		40		

Standard 21. COP-4: The hospital policy guides the administration of anesthesia.

Indicators (70-77):

Ind 70. SOPs for the administration of anesthesia including a pre-anesthetic assessment and an anesthetic plan are documented.

Survey Process:

The surveyor should look for at least the SOPs for following:

1. Pre-anesthesia evaluation leading to anesthesia plan by an anesthetist or another specialist authorized by the hospital
2. Assignment of an anesthesia risk scoring (**Annexure N**)
3. Documentation requirements during anesthesia
4. Recording of any complications
5. Post-anesthesia monitoring requirements, and
6. Criteria for discharge

Scoring:

- If there are documented SOPs that cover ALL the 6 requirements including pre-anesthesia assessment and an anesthetic plan by an anesthetist or qualified/authorized doctor with documented appropriate training and same are implemented, then score as **fully met.**
- If either there are no SOPs, or if there is any non-compliance to any of the above requirements, then score as **not met.**

GUIDELINES

Anesthesia SOPs

The plan should mention the pre-medications, type of anesthesia i.e. general anesthesia, regional or local, the drugs 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 with appropriate and anticipated post-anesthesia care. However, the plan and the anesthesia professionals should be responsive to the condition of the patient on the Operation Table and any changes made in the Anesthesia Plan must be documented with justification.

The pre-anesthesia assessment should identify any risks and determines the appropriate anesthetic approach (for example, a patient with multiple back injuries or surgeries might not be a safe candidate for a spinal anesthesia or a patient with chronic obstructive pulmonary disease might not be a safe candidate for inhalation anesthesia).

1. Pre-operative admission is indicated in patients who require further medical evaluation or prior to major surgery. Admission should not be merely for pre-operative investigations which can be done as an out-patient.
2. The pre-anesthesia assessment may be conducted as a personal interview in the ward, OT or pre-anesthesia clinic using pre-set questionnaires assisted by trained nursing or

paramedical staff under the supervision of an anesthetist.

3. Input from other medical specialties may be required in the pre-anesthesia management of the patient. However, only the anesthetist may determine a patient's fitness to undergo anesthesia.
4. In the case of emergency surgery where early consultation is not always possible, the anesthetist is still responsible for the pre-anesthesia assessment. If surgery cannot be delayed in spite of increased anesthetic risks, documentation to that effect should be made.

Detecting Disease and Assessing Severity

A patient's medical history provides vital information to identify disease that may affect perioperative outcomes. Medical history should include medical problems, current medication and allergies, previous anesthesia and family history of anesthesia complications. System review should focus on those pertinent to anesthesia and surgery. Menstrual history may be important in women of child-bearing age. Useful information may be obtained from the patient's family doctor or relatives.

Physical examination of the patient is an essential part of the pre-anesthesia assessment. Although the cardiovascular and respiratory systems (including the airway) are important in the assessment of the patient, other systems i.e. the renal, hepatic and central nervous systems may also require detailed attention as guided by the history.

Laboratory and radiological investigations complement history and physical examination in detecting and assessing disease. These investigations should not be done as a routine but ordered as guided by the history and physical examination.

Multidisciplinary management, subspecialty referral and medical record retrieval may be helpful in the overall assessment of the patient.

Pre-operative Medication

Pre-operative medication may be prescribed to facilitate the anesthetic management. The patient's current medication should be reviewed and continued when necessary.

Consent

The pre-anesthesia assessment should include confirmation with the patient or the patient's guardian, in the case of children below 18 years or the intellectually challenged, of the nature of the anesthetic procedure and his/her consent for anesthesia.

Documentation

A written summary of the pre-anesthesia assessment, orders or arrangements should be explicitly and legibly documented in the patient's anesthetic record.

Pre-Induction Re-Evaluation

This is essentially a Pre-Induction Assessment and shall be done by the anesthetist just before the patient is shifted into the respective OT. Any planned changes to the anesthesia plan shall be documented. When anesthesia must be provided on an urgent basis, the pre-anesthesia assessment may be performed immediately following one another, or simultaneously, but should be documented separately.

An immediate pre-evaluation of the patient is done by the anesthetist to assess the status prior to the surgery. The pre-evaluation includes recording of patient's vitals, amount of drugs etc.

The intent of this standard is to compare the findings and management plan in the formal pre-

anesthesia assessment with the immediate pre-operative anesthetic assessment and to see if the management of the patient is to be changed, if required. The immediate pre-anesthesia repeat evaluation should be documented on the anesthesia record that becomes part of the patient's medical record.

The **Pre-Anesthesia Re-Evaluation SOPs** include, at a minimum;

1. Review of the medical history, including anesthesia, drug and allergy history.
2. Interview and examination of the patient.
3. Notation of anesthesia risk according to established standards of practice.
4. Identification of potential anesthesia problems, particularly those that may suggest potential complications or contraindications to the planned procedure (e.g., difficult airway, ongoing infection, limited intravascular access).
5. Additional pre-anesthesia evaluation, if applicable and as required in accordance with standard practice prior to administering anesthesia (e.g., stress tests, additional specialist consultation).
6. Development of the plan for the patient's anesthesia care, including the type of medications for induction, maintenance and postoperative care and discussion with the patient (or patient's representative) of the risks and benefits of the delivery of anesthesia.
7. The patient's evaluation or re-evaluation must be performed and documented within 48 hours prior to the delivery of first dose of medication(s) given for the purpose of inducing anesthesia for surgery or a procedure requiring anesthesia services.

Table 18: Recommended Pre-Anesthesia Investigations

RECOMMENDED PRE-ANAESTHESIA INVESTIGATIONS	
Electrocardiogram Age above 50 Cardiovascular disease Diabetes Mellitus Renal disease	**Chest X-ray** Age above 60 Significant respiratory disease Cardiovascular
Full Blood Count Age above 60 Clinical anemia Hematological disease Renal disease Chemotherapy	**Renal Profile** Age above 60 Renal disease
Coagulation Profile Hematological disease Liver disease Anticoagulation	**Random Blood Sugar** Age above 60 Diabetes Mellitus Liver dysfunction
Liver Function Tests Hepatobiliary disease Alcohol abuse	

Risk Assessment

1. The patient's pre-operative condition is not the only determinant of perioperative outcome. Other factors such as complexity of surgery, urgency of surgery, surgical skill and factors related to anesthesia also contribute to outcome.
2. In assessing risk factors and optimizing the patient for anesthesia and surgery, the anesthetist may need to consider the nature and urgency of the surgery, social and economic factors, or any financial constraints that prevail. It is imperative that the anesthetist be knowledgeable and well informed to make a balanced judgment with regard to the benefit-risk ratio of anesthesia and surgery for the high-risk patient. In such cases, risks associated with anesthesia should be discussed with the surgeon and conveyed to the

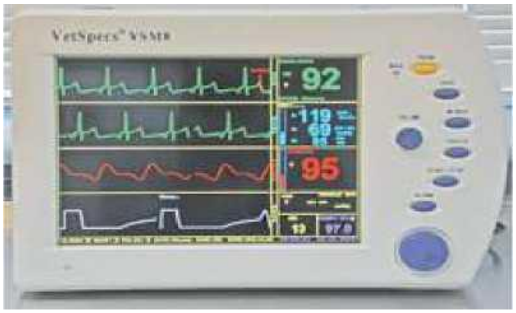
patient and/or the next-of-kin. It should also be documented in the consent form or the patient's case notes.

Documentation required during anesthesia:

The patient is monitored since there are rapid changes in the patient status during anesthesia. The following parameters need to be monitored and recorded on the Monitoring Sheet:

1. Patient Heart rate
2. Cardiac Rhythm
3. Respiratory rate
4. Arterial Blood Pressure
5. Oxygen Saturation
6. Airway Security
7. Patency
8. Level of Anesthesia
9. Evaluation of the Circulatory Function
10. Temperature (in case clinically significant changes in body temperature are intended, anticipated or suspected)

Figure 14: Vital Signs Monitor



In case of regional anesthesia, instead of end tidal carbon dioxide, the adequacy of ventilation shall be evaluated by continual observation of qualitative clinical signs.

The anesthetist shall be present throughout the procedure. In addition, certain other parameters may be monitored on a case-to-case basis. The cardiac rhythm may be monitored on a monitor during the procedure, and the rhythm as well as rhythm abnormalities shall be documented.

The time based events, any unusual occurring during the administration of anesthesia and the status of the patient at the conclusion of anesthesia are recorded.

Basic Anesthetic Monitoring

These standards apply to all anesthesia care although, in emergency circumstances, appropriate life support measures take precedence. These standards may be exceeded at any time based on the judgment of the responsible anesthetist. They are intended to encourage quality patient care, but observing them cannot guarantee any specific patient outcome. They are subject to revision from time to time, as warranted by the evolution of technology and practice. They apply to all general anesthetics, regional anesthetics and monitored anesthesia care.

This set of standards address only the issue of basic anesthetic monitoring, which is one component of anesthesia care. In certain rare or unusual circumstances, some of these methods of monitoring may be clinically impractical, and appropriate use of the described monitoring methods may fail to detect untoward clinical developments. Brief interruptions of continual monitoring may be unavoidable. These standards are not intended for application to the care of the obstetrical patient in labor or in the conduct of pain management.

Standard: 1

Due to the rapid changes in patient status during anesthesia, the anesthetist/qualified anesthesia personnel shall be continuously present throughout the conduct of all general anesthesia and regional anesthesia, monitor the patient and provide anesthesia care. In the event that there is a direct known hazard, e.g., radiation to the anesthesia personnel which might require intermittent remote observation of the patient, some provision for monitoring the patient must be made. In the event that an emergency requires the temporary absence of the person primarily responsible for the anesthetic, the best judgment of the anesthetist will be exercised in comparing the emergency with the anaesthetized patient's condition and in the selection of the person left responsible for the anesthetic during the temporary absence.

Standard: 2

During all anesthetics, the patient's oxygenation, ventilation, circulation and temperature shall be continually evaluated.

1. **Oxygenation**

   A. Objective

   To ensure adequate oxygen concentration in the inspired gas and the blood, during all anesthetics.

   B. Measuring

   (i) **Inspired gas:** During every administration of general anesthesia using an anesthesia machine, the concentration of oxygen in the patient breathing system shall be measured by an oxygen analyzer with a low oxygen concentration limit alarm in use.

   (ii) **Blood oxygenation:** During all anesthetics, a quantitative method of assessing oxygenation such as pulse oximetry shall be employed.
   When the pulse oximeter is utilized, the variable pitch pulse tone and the low threshold alarm shall be audible to the anesthetist or the anesthesia care team personnel. Adequate illumination and exposure of the patient are necessary to assess color.

2. **Ventilation**

   A. Objective

   To ensure adequate ventilation of the patient during all anaesthetics.

   B. Methods

   (i) Every patient receiving general anaesthesia shall have the adequacy of ventilation continually evaluated. Qualitative clinical signs such as chest excursion, observation of the reservoir breathing bag and auscultation of breath sounds are useful. Continual monitoring for the presence of expired carbon dioxide shall be performed unless invalidated by the nature of the patient, procedure or equipment. Quantitative monitoring of the volume of expired gas is strongly encouraged.

   (ii) When an endotracheal tube or laryngeal mask is inserted, its correct positioning must be verified by clinical assessment and by identification of carbon dioxide in the expired gas. Continual end tidal carbon dioxide analysis, in use from the time of endotracheal tube/laryngeal mask placement, until extubation/removal or initiating transfer to a postoperative care location, shall be performed using a quantitative method such as capnography, capnometry or mass spectroscopy. When capnography or capnometry is utilized, the end tidal carbon dioxide alarm shall be audible to the anaesthetist or the anaesthesia care team personnel.

(iii) When ventilation is controlled by a mechanical ventilator, a device that is capable of detecting disconnection of components of the breathing system, the device shall remain in continuous use. The device must give an audible signal when its alarm threshold is exceeded.

(iv) During regional anaesthesia (with no sedation) or local anaesthesia (with no sedation), the adequacy of ventilation shall be evaluated by continual observation of qualitative clinical signs. During moderate or deep sedation, the adequacy of ventilation shall be evaluated by continual observation of qualitative clinical signs and monitoring for the presence of exhaled carbon dioxide unless precluded or invalidated by the nature of the patient, procedure, or equipment.

C. Circulation

A. Objective

To ensure the adequacy of the patient's circulatory function during all anaesthetics.

B. Methods

(i) Every patient receiving anaesthesia shall have the electrocardiogram continuously displayed from the beginning of anaesthesia until preparing to leave the anaesthetizing location.

(ii) Every patient receiving anaesthesia shall have his/her arterial blood pressure and heart rate determined and evaluated at least every five minutes.

(iii) Every patient receiving general anaesthesia shall have, in addition to the above, circulatory function continually evaluated by at least one of the following: palpation of a pulse, auscultation of heart sounds, monitoring of a tracing of intra-arterial pressure, ultrasound peripheral pulse monitoring, or pulse plethysmography/oximetry.

D. Body Temperature

A. Objective

To aid in the maintenance of appropriate body temperature during all anaesthesia.

Methods

(i) Every patient receiving anaesthesia shall have their temperature monitored when clinically significant changes in body temperature are anticipated or suspected.

(ii) Under extenuating circumstances, the responsible anaesthetist may waive some of the predetermined requirements. It is recommended that when this is done, it should be so stated (including the reasons) in a note in the patient's medical record.

E. Post-anesthesia monitoring requirements:

A. This shall be done in the recovery area/OT and at least include monitoring of vitals till the patient recovers completely from anesthesia and shall be done by an anesthetist. If the patient's condition is unstable and he/she requires ICU care, the same shall be monitored there.

B. There should be documented evidence of Post-Anesthesia Monitoring that includes at the least:

(i) Blood pressure
(ii) Pulse rate
(iii) Respiratory status
(iv) Oximetry
(v) Level of consciousness
(vi) Pain.

C. Additional considerations are as follows:

A Post-Anesthesia Care Unit (PACU) sometimes referred to as Post-Anesthesia Recovery (PAR), is a vital part of hospitals, ambulatory care centers, and other medical facilities. It is an area, normally attached to OT suites, designed to provide care for patients recovering from anesthesia, whether it be general anesthesia, regional anesthesia, or local anesthesia. The essential activities of PACU Staff include:

(i) Monitoring vital signs (heart rate, blood pressure, temperature and respiratory rate)
(ii) Managing post-operative pain.
(iii) Treating symptoms of Postoperative Nausea and Vomiting
(iv) Treating post anesthesia shivering
(v) Monitoring surgical site(s) for excessive bleeding, discharge, swelling, hematoma, redness etc.

D. These common activities may often need supplementing with more intensive care or treatment which may require:
   (i) Preparation and education for the use of Patient Controlled Analgesia (PCA) units.
   (ii) Preparation and establishment of IV, epidural or perineural infusions.
   (iii) Preparation and establishment of invasive monitoring such as arterial lines, central venous lines etc.

Note: Unless complications occur, most patients will only stay in the PACU for a few hours, before returning home or to another department of the hospital.

E. All patients who have received general anesthesia, regional anesthesia or monitored anesthesia care shall receive appropriate post-anesthesia management.
F. A PACU or an area which provides equivalent post-anesthesia care (for example, a surgical ICU) shall be available to receive patients after anesthesia care. All patients who receive anesthesia care shall be admitted to the PACU or its equivalent except by specific order of the anesthetist responsible for the patient's care.
G. The medical aspects of care in the PACU (or equivalent area) shall be governed by policies and procedures which have been reviewed and approved by the Department of Anesthesiology.
H. A patient transported to the PACU shall be accompanied by a member of the anesthesia care team who is knowledgeable about the patient's condition. The patient shall be continually evaluated and treated during transport with monitoring and support appropriate to the patient's condition.
I. Upon arrival in the PACU, the patient shall be re-evaluated and a verbal report provided to the responsible PACU nurse by the member of the anesthesia care team who accompanies the patient.
J. The patient's status on arrival in the PACU shall be documented.
K. Information concerning the preoperative condition and the surgical/anesthetic course shall be transmitted to the PACU nurse.
L. The member of the anesthesia care team shall remain in the PACU until the PACU nurse accepts responsibility for the nursing care of the patient in writing. The patient's condition shall be evaluated continually in the PACU.
M. The patient shall be observed and monitored by methods appropriate to the patient's medical condition. Particular attention should be given to monitoring oxygenation, ventilation, circulation, level of consciousness and temperature. During recovery from all anesthetics, a quantitative method of assessing oxygenation such as pulse oximetry

shall be employed in the initial phase of recovery. This is not intended for application during the recovery of the obstetrical patient in whom regional anesthesia was used for labor and vaginal delivery.

N. An accurate written report of the PACU period shall be maintained. Use of an appropriate PACU scoring system is encouraged for each patient on admission, at appropriate intervals prior to discharge and at the time of discharge.
O. General medical supervision and coordination of patient care in the PACU should be the responsibility of an anesthetist.
P. There shall be a policy to assure the availability in the facility of a physician capable of managing complications and providing cardiopulmonary resuscitation for patients in the PACU.
Q. A physician is responsible for the discharge of the patient from the post-anesthesia care unit.
R. When discharge criteria are used, they must be approved by the Department of Anesthesiology and the medical staff. They may vary depending upon whether the patient is discharged to a hospital room, to the ICU, or home.
S. In the absence of the physician responsible for the discharge, the PACU nurse shall determine that the patient meets the discharge criteria. The name of the physician accepting responsibility for the discharge shall be noted on the record.

F. Discharge from post anesthesia/post-operative care (Recovery Room):

The following criteria must be fulfilled:

A. The patient is fully conscious without excessive stimulation, able to maintain a clear airway and exhibits protective airway reflexes.
B. Respiration and oxygenation are satisfactory.
C. The cardiovascular system is stable with no unexplained cardiac irregularity or persistent bleeding. The specific values of pulse and blood pressure should approximate to normal pre-operative values or be at an acceptable level commensurate with the planned postoperative care. Peripheral perfusion should be adequate.
D. Pain and Emesis should be controlled and suitable analgesic and anti-emetic regimens prescribed.
E. Temperature should be within acceptable limits. Patients should not be returned to the ward if significant hypothermia is present.
F. Oxygen and intravenous therapy, if appropriate, should be prescribed.
G. Shifting from the recovery room is the responsibility of the anesthetist. If the discharge criteria are not achieved, the patient should remain in the recovery room and the anesthetist informed. An anesthetist must be available at all times when a patient who has not reached the criteria for discharge is present in the recovery room.
H. If there is any doubt as to whether a patient fulfills the criteria, or if there has been a problem during the recovery period, the anesthetist who administered the anesthetics (or another anesthetist with special duties in the recovery room) must assess the patient. After medical assessment, patients who do not fulfill the discharge criteria may be transferred to an ICU.

Handing over to Ward Staff

Patients should be transferred to the ward accompanied by a suitably trained member of staff and a caretaker. The anesthetic record, together with the recovery and prescription charts, must

accompany the patient. The recovery nurse must ensure that full clinical details are relayed to the ward nurse with particular emphasis on problems and syringe pump settings.

Ind 71. Informed consent for administration of anesthesia is obtained by the anesthetist.

Survey Process:

By reviewing the same sample records[52] as in Ind 70, determine if ALL patients who underwent anesthesia have a documented informed consent.[53] This documentation can either be a signed consent form or written note by the responsible anesthetist that contextually accommodates ALL patient levels of understanding.

Scoring:

- If ALL records contain documentation of informed consent, then score as **fully met.**
- Since this is a significant patient safety as well as medico-legal issue, if ANY of the reviewed record does not contain documentation of informed consent, then score as **not met.**

GUIDELINES

Informed Consent

The patient and/or their family are educated on the risks, benefits, and alternatives of anesthesia by the anesthetist. This shall be separate from the surgery consent. Prior to the administration of anesthesia, the patient/relative is informed about the planned anesthetic procedure, risk and benefits involved etc. An informed consent is obtained from the patient by the concerned anesthetist. In case the patient is incapable or a minor etc., consent is obtained from the patient's relatives as specified by the hospital.

Consent should be obtained for all medical treatment. It is a basic tenet of our society that everyone has a right to determine what is done to his/her own body, and is entitled to know the implications of any treatment before it is administered and to seek clarification of any issues that may be of concern.

1. **Elements of Consent**
   A. Consent must be given voluntarily and without coercion; refusal or withdrawal of consent must be a realistic option. The environment, and timing of the consent process, and presence of support people (if so desired by the patient), are important in this regard.
   B. Consent may only be given by a person capable of doing so.
   C. All persons are presumed to be competent to give consent, unless there are reasonable grounds for believing otherwise. A judgment that the patient is incapable of giving consent must be supported by appropriate evidence, such as that of:
      (i) Very young age
      (ii) Lack of mental capacity

[52] Surveyors should decide the representative sample.

[53] Informed consent must truly be appropriate for each patient and include reference to the associated risks involved.

(iii) Unconsciousness
(iv) Presence of sedative medication

D. The criterion at which a young person is able to consent independently to medical treatment depends not only upon their age, but also the nature of the proposed treatment and local legislative requirements. To be able to give consent, the young person should be able to understand;
   (i) The nature, purpose and possible consequences of the treatment, as well as
   (ii) The consequences of non-treatment. If in any doubt, consult appropriate management representatives or legal or other advisers.
E. In the absence of a capacity to give consent, another person can give consent on behalf of the patient in certain legally defined circumstances, such as the parent or legal guardian of a child. In such circumstances, the person giving consent has a legal duty to always act in the best interests of the person for whom the consent is being given.
F. If no person is able to give consent, then treatment can only proceed if it is in the patient's best interests, reasonable steps have been taken to ascertain the views of the patient, the doctor believes that it would have been chosen by the patient if he/she was competent to do so, or the doctor takes into account the views of other suitable persons who are interested in the welfare of the patient, and that further delay is likely to be detrimental to the patient. It may be necessary to arrange for a legal guardian to be appointed. In these cases, it is strongly recommended that appropriate legal or other advice be obtained.
G. If the situation is so urgent that immediate intervention is necessary to preserve life or prevent serious harm, it may not be possible or sensible to obtain full consent. In such cases, there must be provision of information and discussion of the treatment undertaken with the patient, or other suitable persons, as soon as possible.
H. In some circumstances, Statutory Bodies, such as a Guardianship Board or Legal Representative may give consent or authorize others to give consent.
I. It must be recognized that the patient can withdraw the given consent which must be respected (e.g. during multiple attempts at regional blockade).
J. Consent must be informed.
K. The patient should be provided with the information that a reasonable patient in the position of that patient might wish to know, and to which the patient might attach significance. It is necessary to provide information about all material risks inherent in any proposed treatment.
L. Information about the proposed treatment should be provided, even if the patient requests no information. Where the patient clearly does not wish for further information, and states this wish, information should still be firmly offered and if still refused, that fact should be documented, and no further information forced on the patient.
M. The discussion of risks and benefits should include those associated with the proposed treatment, alternative treatments, or no treatment at all.
N. In considering risks to be discussed with the patient, ask:-
   (i) Would a reasonable person, in the position of the patient, be likely to attach significance to the risk?
   (ii) Are you aware, or should you be reasonably aware, that this particular patient would be likely to attach significance to that risk?
   (iii) In other words, is it possible that the patient, if informed of that risk, would change

his mind about having the procedure?

2. Risks

A. Discussion of risks should be based on the provider's assessment of the proposed treatment, the seriousness and nature of the patient's condition, the complexity of the proposed treatment, the questions asked by the patient, and the patient's attitude and apparent level of understanding.

B. Known risks should be explained when an adverse outcome is rare.

C. The uncertainty of adverse outcomes/events should be explained, as should the difficulty of relating the incidence of such events to the patient.

D. Where blood products may be required, discussion should take place concerning the advantages, disadvantages and alternatives to blood products.

E. The risk of doing nothing should be discussed.

F. Opportunity must be given to discuss the nature and risks of the treatment, and the alternative treatment(s), and to have questions answered honestly and accurately.

G. Where appropriate, the financial implications of the proposed treatment should be discussed.

H. Information should be provided in a form the patient is likely to understand. This may include the option of presenting information in the printed form or via computer or other electronic means (e.g. by video). Printed and visual aids are useful. Prepared information sheets or "consent forms" can help understanding, but are not a substitute for the required discussion with the patient.

3. Documentation of Consent

The extent of documentation may vary but it is wise to record significant details of the consent as part of the patient's notes, including reference to the discussion of relevant material risks and the agreement by the patient to undergo the treatment.

In order to defend claims that "informed consent" information was not given or was inadequate, it is highly recommended that detailed notes of the discussion and all risks considered are kept by the provider.

4. Standard Consent Forms and Information Sheets

The use of standard "consent forms" and information sheets will not necessarily be sufficient to maintain "informed consent". Standard information forms are useful, but are no substitute for personal information to an individual patient. Under the requirements of "informed consent", the information to be given to a patient must be specific to the particular patient. It must take into account the particular circumstances, and requirements, of the patient.

Similarly, a simple form signed by a patient is not conclusive proof that valid consent has been obtained. It therefore, should be countersigned by designated persons.

Prepared consent forms and prepared information sheets certainly can have their place and can be used as an aid or educational tool, as well as a prompt or **Checklist** for the **discussion that must take place between doctor and patient.** They are also useful for the patient to take away after the discussion as a reminder of some of the issues that have been considered. However, they are not, **in themselves**, adequate to ensure that informed consent has been obtained.

5. Personnel

A. Disclosure of information and discussion must be performed by a person who

understands and is able to discuss the risks and benefits of the proposed treatment and the alternative treatments, which includes no treatment.

B. A qualified interpreter (not a family member) should be used wherever necessary.
C. Disclosure of information and discussion is best performed by the anaesthetist who will be conducting the treatment.
D. Ideally, consent should be obtained by the anaesthetist who will be conducting the treatment. (The anaesthetist may be liable if inadequate consent is obtained by another person on the anaesthetist's behalf).
E. When the procedural anaesthetist can only see the patient immediately prior to anaesthesia, a separate anaesthetist may interview the patient and provide information for the elements of consent noted above.
F. The procedural anaesthetist must still discuss the proposed treatment with the patient to ensure that all appropriate preparation has occurred. The need for this interview must be considered when sedative premedication is to be given.
G. Those involved with the consent process are individually responsible for appropriate documentation.

6. **Examples of Risk** which might be discussed with the person giving consent include:
   A. Common adverse effects of general anaesthesia, which include fatigue, altered mental state, sleep disturbance, nausea, vomiting, sore throat and/or bruising from vein-puncture.
   B. Less common but not rare adverse effects such as "Spinal Headache due to Epidural Block or Spinal Tap etc. and Dental Trauma due to intubation.
   C. Rare adverse effects which are unpredictable, such as anaphylaxis, awareness, neurological damage or death in healthy people.
   D. Adverse effects which are related to pre -existing disease, such as death in a patient with recent myocardial infarction undergoing emergency surgery.

Table 19: Sample Anaesthesia Consent Form

Sample Anaesthesia Consent Form **Basic Information:**
Patient's Name: _____Sex:_____ Medical Record Number: _____ Date of Birth:_____ Name of anaesthetist: _____
I. Proposed Type of Anaesthesia Technique (explain briefly in non-medical terms):
1. Surgical intervention to be administered by the surgeons: 2. Proposed anaesthesia technique(s): General _____ Regional _____ Nerve Block _____
II. Physician's[54] Statements
1. I have adequately assessed the patient's physical condition prior to the anaesthesia. 2. I have given a verbal explanation to the patient, in a way that the patient can understand, concerning

[54] The word "Physician" used in general term. Here it means the anaesthetist. In case of doubt he/she may obtain opinion from other relevant consultant.

the anaesthesia intervention to be carried out, as following:

- *Anaesthetic procedure*
- *Anaesthesia-related risks*
- The potential adverse symptoms following the anaesthesia

I have rendered the patient with supplementary information regarding the anaesthesia

3. I have also provided the patient with sufficient time to inquire about the following quest ions concerning the anaesthesia to be undertaken in this surgery, and I have answered these questions as below:

Signature of anaesthetist: _____

Date: _____ / _____ Time: _____ : _____

III. Patient's Statements

1. I understand that the anaesthesia procedure is necessary for undertaking this surgery in order to alleviate pain and fear during the operation.
2. The anaesthesia doctor has explained the risks and procedure of anaesthesia to me.
3. I fully understand the information provided relating to the anaesthesia.
4. I had addressed my concerns and doubts regarding the anaesthesia to the anaesthesia doctor who has given me satisfactory responses.

Relationship to the Patient:

Authorized Signature: _____ Relationship to Patient: _____

Address: _____ Tel No.: _____

Date: _____ /_____ / _____ Time: _____ : _____

Witness: _____ Signature of Witness: _____

Date: _____ /_____ / _____ Time: _____ : _____

Note: Please specify the relationship to the patient if the authorized signer is not the patient himself/herself. Please leave the space blank if witness is not required.

Ind 72. An immediate pre-operative (pre-induction) re-evaluation is documented.

Survey Process:

The intent of this standard is to compare the findings and management plan in the formal pre-anesthesia assessment with the immediate pre-operative anesthetic assessment and to see if the management of the patient is changed if required. The immediate pre-anesthesia repeat evaluation should be documented on the anesthesia record that becomes part of the patient's medical record.

Scoring:

- If the immediate pre-induction re-evaluation is documented in ALL records, then score as **fully met.**
- If the immediate pre-induction re-evaluation is NOT documented in ALL records, then score as **not met.**

GUIDELINES

Anaesthetic Plan

The plan should mention the pre-medications, type of anesthesia i.e. general anesthesia, regional or local, the drugs 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 with appropriate and anticipated post-anesthesia care. However, the plan and the anesthesia professionals should be responsive to the condition of the patient on the Operation Table and any changes made in the Anesthesia Plan must be documented with justification.

The pre-anesthesia assessment should identify any risks and determines the appropriate anesthetic approach (for example, a patient with multiple back injuries or surgeries might not be a safe candidate for a spinal anesthesia or a patient with chronic obstructive pulmonary disease might not be a safe candidate for inhalation anesthesia). A Checklist adapted from WHO is given below:

Table 20: Pre-Anesthesia check list

Before Induction of Anesthesia		Yes	No	Not Applicable
1	Site, procedure and consent?			
2	Is the side marked?			
3	Is the anesthesia machine and medication check complete?			
4	Is the pulse oximeter on the patient and functioning?			
5	Does the patient have a known allergy?			
6	Difficult airway or aspiration risk?			
7	Risk of >500ml blood loss (7ml/kg in children)?			
Before Skin Incision				
1	Confirm all team members have introduced themselves by name and role.			
2	Confirm the patient's name, procedure, and where the incision will be made.			
3	Has antibiotic prophylaxis been given within the last 60 minutes?			

Anticipated Critical Events for Surgeon:

1. What are the critical or non-routine steps?
2. How long will the case take?
3. What is the anticipated blood loss?

For Anesthetist:

Are there any patient-specific concerns?

For Nursing Team:

1. Has sterility (including indicator results) been confirmed?
2. Are there any issues concerning equipment?
3. Is essential imaging displayed?
   A. Yes
   B. Not applicable

Anticipated Critical Events
Before patient leaves operating room
Nurse Verbally Confirms:

1. The name of the procedure.
2. Completion of instrument, sponge and needle counts.
3. Specimen labelling (read specimen labels aloud, including patient name).
4. Whether there are any equipment problems to be addressed.

To Surgeon, Anesthetist and Nurse:
What are the key concerns for recovery and management?
This checklist is not intended to be comprehensive. Additions and modifications to fit local practice are encouraged.

Ind 73. During anesthesia, monitoring includes regular and periodic recording of heart rate, cardiac rhythm, respiratory rate, blood pressure, oxygen saturation, airway security and patency, and level of anesthesia.

Survey Process:
This indicator is surveyed by observation. While visiting the operating theatre look for the presence and fully functional equipment that supports ALL the requirements in this standard.

Scoring:

- This Indicator should default to a score of **fully met** unless a majority of the survey team agrees that there are significant deficiencies in the hospital's ability to monitor patients during anesthesia (for example, only one monitor for two or more rooms such that some patients are not monitored).

GUIDELINES

Monitoring in Anaesthesia
The patient is monitored since there are rapid changes in the patient status during anaesthesia. The following parameters need to be monitored and recorded on the **Monitoring Sheet**:

1. Patient Heart rate
2. Cardiac Rhythm
3. Respiratory rate
4. Arterial Blood Pressure
5. Oxygen Saturation
6. Airway Security

7. Patency
8. Level of Anaesthesia
9. Evaluation of the Circulatory Function
10. Temperature (in case clinically significant changes in body temperature are intended, anticipated or suspected).

Ind 74. No anaesthetic is administered unless the identity of the patient is guaranteed.

Survey Process:

The surveyor should look for a system for safe Identification of patients (Patients ID system)[55] and confirm that the administration of anesthesia is preceded by confirming the identity of the patient.

Scoring:

- If the identification of the patient is clearly observable and fail safe for ALL patients and staff confirm identity prior to induction, then score as **fully met.**
- If there is no "fail safe" system of identification or any patient's identity is not confirmed, then score as **not met.**

GUIDELINES

Identity of the Patient

Every hospital should develop a safe patient ID system and confirm that the administration of anaesthesia is preceded by confirming the identity of the patient. There are many instances when patient misidentification can occur, including invasive procedures, medication administration, transfusion of blood/blood products, and matching pathology specimens to the correct patient. There are some Recommended Practices that are meant to contribute to the efforts of patient safety and reduce the risk of patient misidentification. The following are the Recommended Practices related to the proper identification of the surgical patient and recognizing the mistakes that can be made in order to prevent operating on the wrong patient.

Standard Practices[56]

The patient should have at least two corroborating patient identifiers as evidence to confirm identity. The use of two patient identifiers improves the reliability of the patient identification process and decreases the chance of performing the wrong procedure on the wrong patient. Examples of acceptable patient identifiers include:

1. Name
2. Assigned identification number
3. Telephone number
4. Date of birth
5. Social security number

[55] For ALL patients the system employed must be permanently with the patient and fail-safe.

[56] Strelec, S. R. (1996). Anaesthesia and surgery: Not always a onesided affair. American Society of Anaesthetists Newsletter, 60. From http://www.asahq.org/Newsletters/1996/06_96/feature4.htm

6. Address

The patient's room number should not be used as a patient identifier; room numbers are not person-specific identifiers, since patients can be moved from room to room.

Ind 75. Each patient's post-anaesthetic status is monitored and documented.

Survey Process:

Review representative sample medical records[57] of patients in the recovery area or who have been there previously. There should be documented evidence of post-anesthetic monitoring that includes at least: i. Blood pressure, ii. Pulse rate, iii. Respiratory status, iv. Level of consciousness, and v. Pain.

Scoring:

- If ALL reviewed records document the above requirements, then score as **fully met.**
- If even one record does not document ALL the requirements, then score as **not met.**

(Guidelines as under Ind.70)

Ind 76. A qualified individual applies defined criteria to transfer the patient from the recovery area.

Survey Process:

Look first for the written criteria for shifting/ transfer /discharge of patients from the recovery area. Then while reviewing the records as in **Ind 74,** determine if an anesthetist or other qualified person with appropriate training[58] has ordered shifting / transfer / discharge of patients from the recovery area.

Scoring:

- If there is an observable documented process that ensures safe transfer of post anesthetic patients by a qualified individual and it is practiced, then score as **fully met.**
- If there is non-compliance to any of the above criteria, then score as **not met.**

(Guidelines as under Ind.70)

Ind 77. ALL adverse anaesthesia events are recorded and monitored.

Survey Process:

Ask for the report(s) of any anesthesia related adverse events. Review the analysis and any specific corrective action. If there have been no adverse events, which is unlikely unless a new service, validate that there is a process to identify and to intensively analyze the event and recommend corrective actions if it occurs.

[57] Surveyors should decide the representative sample size according to work load/size of the hospital.

[58] This may include nurses who have received documented training

Scoring:

- If there has been an adverse anesthesia event and there is evidence of meaningful evaluation/ analysis and appropriate corrective action if warranted, then score as fully met OR if there has been no adverse anesthesia event but the hospital has a process to identify such events and also has a process to analyze these, then also score as **fully met.**
- If there was an anesthesia related adverse occurrence and it was not either reported or analyzed, or if there is no process to analyze an adverse event if it were to occur, then score as **not met.**

GUIDELINES

Documenting and Monitoring of Adverse Anesthesia Events

All such events are documented and monitored for the purpose of taking corrective and preventive action. There should be a documented process to identify the event and to intensively analyze it, including recommended corrective actions.

Precisely because anesthesia care has become so safe in terms of the reduction of major intra-operative anesthesia accidents, very few anesthesia practitioners today have any first-hand experience dealing in real time with a major anesthesia adverse event. While from an overall anesthesia patient safety statistical perspective, this fact is highly desirable, it also functionally represents a new danger. There is absence of experience, training, or even thought about what to do in the extremely unlikely, but yet still possible, event of coming face-to-face with an intra-operative anesthesia catastrophe. This deficit might prevent definitive action that can help the specific patient in a particular incident and patients in general who can benefit by lessons learned from that adverse incident.

The Basic Plan[59]

Upon recognition that a major adverse anaesthesia event is in progress or has occurred:

1. Get help and mobilize according to the protocol.
2. The primary caregiver(s) should continue patient care. Except in the very unusual circumstance that the anaesthesia provider becomes ill or disabled or is so shocked by the realization of the accident that s/he cannot function, s/he should devote full attention to direct clinical care rather than to the necessary organizational and administrative considerations.
3. Immediately designate an Incident Supervisor (e.g., a senior practitioner, department leader) who:
   A. Assumes overall direction and control of the event.
   B. Organizes help and assigns tasks.
   C. Verifies that the incident has ended and there is no immediate recurrence (e.g. correct intubation and ventilation in the prototype example, continued availability of tank oxygen after a central oxygen supply failure, etc.)
   D. Involves consultants and advisors as indicated, including specifically the Chief/Chair of Anaesthesiology or appropriate designee, and any others who may help with care or recovery, such as neurologists, cardiologists, etc.
   E. Coordinates and facilitates communications.

[59] Eichhorn, J.H. Patient perspectives personalize patient safety. APSF Newsletter Winter 2005-06; 20:61-66.

F. Alter nothing (no cleaning, no disassembly, no repair); if it appears likely or even possible that an equipment failure (anaesthesia machine ventilator, bubble detector on a rapid infuser, or whatever) contributed to an accident, it may be indicated that an inspection/testing session should be conducted involving the real-time participation of representatives of the involved practitioners, the equipment manufacturers, the equipment maintenance personnel, facility administration, and involved insurance companies/attorneys.

G. Discard nothing; sometimes the solution to a mystery can later be discovered in unexpected tiny details, such as an empty or missing or extra medication vial that suggests an accidental wrong drug administration may have caused the accident.

H. Lock away all of the above (this may be difficult in a busy facility, be reasonable, for example, if it is accepted by all involved that there was an unrecognized esophageal intubation involving apparent human error, it would be possible to release the OR and its equipment for use the next day and dispose of the trash).

4. Contact the care facility's administrator and risk manager (possibly also the practitioner's attorney if indicated).
5. Arrange immediate comfort and support for patient and/or family. Share as much information as possible.
6. Designate a Follow-up Supervisor (who may or may not be the same as the Incident Supervisor) who will:
   A. Verify that the elements of this protocol have been applied.
   B. Consider whether to organize a group debriefing (e.g., the day of the event or the following day) involving all those present during the event, and function as assigned if indicated (note that there may be medico-legal implications of this and appropriate advice of counsel may be indicated).
   C. Maintain ongoing communications with all involved caregivers and patient representatives, coordinating and facilitating as much integration as possible.
   D. Pursue the accident investigation in conjunction with involved quality assurance and risk management systems and personnel; eventually prepare a report as indicated, particularly focusing on lessons learned and actions needed to help prevent similar accidents in future and participate in any peer-review activities conducted regarding the event.
7. Document everything:
   A. Put strictly objective narrative entries in the medical record and incident report (but these can include background details on the involved thinking, such as, for example, the indication for invasive monitoring based on symptoms and signs of congestive heart failure).
   B. If possible make additional detailed (including subjective impressions or value judgments) personal notes for later use created specifically while sitting with an attorney (personal or from the practitioner's insurance carrier) who keeps them as attorney-client work product.
8. Try to review formal reports submitted by the institution to the authorities, both in order to know what they contain and also to add your observations or commentary if indicated.
9. Continue involvement after the event when the patient survives:
   A. Talk to surgeons and consultants about care; make suggestions as indicated.
   B. Be visible, supportive, and not defensive with all involved.

C. Communicate as much as possible.

Implications

Note that lack of communication from caregivers and facilities involved in the immediate and longer-term aftermath of major anaesthesia accidents leads to great distress and even pain from the patient/family survivor's perspective.

Guidelines for Action Following an Adverse Anaesthesia Event[60]

Objectives: To limit patient injury from a specific adverse event associated with anaesthesia and to ensure that the causes of the events are identified so that a recurrence can be prevented.

Protocol: When a patient has died or has been injured from causes suspected to be related to anaesthesia management, the following should occur;

Immediate

1. The primary anaesthetist/anaesthesiologist should concentrate on continuing patient care. The primary anaesthetist/anaesthesiologist should notify a physician responsible for supervision of anaesthesia activities in the relevant patient care area, e.g., Anaesthesia Clinical Director or the Team Leader, as soon as possible (at least before the anaesthetist transfers direct responsibility for that patient). The person so contacted will direct the process of immediate prevention of recurrence (if necessary), events documentation and continued investigation or will delegate responsibility to someone other than the primary anaesthetist or consultant anaesthetist. The individual performing these tasks is designated as the incident supervisor.

   Rationale: Information vital to reconstructing events may be accidentally discarded. The highest priority for the primary caregivers must be the care of the patient, so responsibility for administrative and investigate activities must be assigned to others. Typically, an anaesthetist supervising a primary anaesthetist/anaesthesiologist should not be the incident supervisor. However, out of normal working hours, a primary or supervising anaesthetist may choose to act as incident supervisor and may exercise discretion in calling for assistance or advice.
2. Anaesthesia equipment or supplies associated with the case, whether thought to be materially involved or not, should be sequestered before subsequent use. Nothing must be altered or discarded. The primary anaesthetist/anaesthesiologist or incident supervisor shall immediately contact the hospital individual responsible for management of anaesthesia equipment and supplies (equipment supervisor). The equipment supervisor or his designee shall supervise the impoundment of involved supplies and equipment (including the anaesthesia machine) in consultation with the hospital Risk Manager. A preliminary decision to continue the usage of urgently needed equipment may be made, following a safety inspection, at the discretion of the incident supervisor in consultation with the hospital Risk Manager.

   Rationale: Equipment or supplies involved in the event may be accidentally altered or discarded, preventing determination of cause. The incident supervisor or attending

[60] Cooper J.B, Cullen D.J, Eichhorn J.H, Holzman R.S., Philip J.H. (1993). Administrative guidelines for response to an adverse anaesthesia event. Journal of Clinical Anaesthesia 1993; 5:79-84).

anaesthetist should contact the hospital Risk Manager immediately following the anaesthetic event for additional administrative support.

Rationale: Individual caregivers will rarely be experienced in dealing with an adverse occurrence.

The Risk Manager can advise on the ways to communicate information to the patient or to the patient's family in a way that is forthright and comforting, but which does not unintentionally alarm, misinform, or render judgment.

3. The primary anaesthetist/anaesthesiologist and other individuals involved must document relevant information about the incident.
4. The primary anaesthetist/anaesthesiologist, after discussion with the incident supervisor, must write relevant information about what happened and what actions were taken on the patient's medical record. Do not erase or obscure information on the record. If a correction is necessary, lightly cross out the original; initial and date. Additions to and explanations of notations on the record can be made, for example, to explain issues where professional judgment was involved.
5. The primary anaesthetist/anaesthesiologist must complete and file an incident report as soon as practical.
6. Others individuals involved in the incident should document their observations soon after the event. The documentation should be returned to the hospital Patient Care Assessment Coordinator or other appropriately designated individual.
7. When writing about the events.
   A. State only the facts as you know them.
   B. Do not make judgments about causality or responsibility
8. Do not use judgmental terms or phrases.
   A. Give the highest priority to continue involvement in follow-up care of the patient.
   B. Consult early and frequently with the surgeon.
   C. Immediately call upon other consultants who may help improve long term care or recovery.

Follow-up Investigations

The HoD shall be informed of each adverse event and will designate who shall supervise the event follow-up and investigation beyond the immediate actions. The follow-up supervisor shall:

1. Notify the individuals involved of their responsibilities as defined in this document.
2. Be responsible for assuring that procedures are followed to the extent necessary, reasonable and possible.
3. Maintain communication with those who are providing continuing anaesthesia care, providing guidance and advice as needed.
4. Ensure that information regarding the adverse event is communicated through the proper channels to the departmental quality assurance program.
5. The need to maintain equipment sequestration shall be determined by the incident follow-up supervisor and the individual responsible for managing anaesthesia technology.
6. If it is unlikely the equipment was related to the event, the equipment can be returned to service after routine inspection.

7. If it is possible that the equipment was related to the event, the following procedures should be implemented and supervised by the individual responsible for managing anaesthesia technology or his designee:
   A. Store the equipment in a secure location. Label it DO NOT DISTURB.
   B. Document its physical condition and notable features as received and record its identification, e.g., serial number.
   C. Do not alter or inspect the equipment in any way that could affect further investigation.
   D. Conduct a thorough inspection of the equipment in the presence of the primary anaesthetist/consultant anaesthetist, the insurance carrier, hospital Risk Manager, equipment manufacturers or any of their designees.
   E. Continue to verify and document medical care provided to the patient following the event.

Assessment Scoring Matrix

Standard 21. COP-4: The hospital policy guides the administration of anesthesia.

Indicator 70-77		Max Score	Weightage (Percent)	Score Obtained
Ind 70	**SOPs for the administration of anesthesia including a pre-anesthetic assessment and an anesthetic plan are documented.**	10	**100**	
Ind 71.	**Informed consent for administration of anesthesia is obtained by the anesthetist.**	10	**100**	
Ind 72.	**An immediate pre-operative (pre-induction) re-evaluation is documented.**	10	**100**	
Ind 73.	**During anesthesia, monitoring includes regular and periodic recording of heart rate, cardiac rhythm, respiratory rate, blood pressure, oxygen saturation, airway security and patency, and level of anesthesia.**	10	**100**	
Ind 74.	**No anesthetic is administered unless the identity of the patient is guaranteed.**	10	**100**	
Ind 75.	**Each patient's post-anesthetic status is monitored and documented.**	10	**100**	
Ind 76.	**A qualified individual applies defined criteria to transfer the patient from the recovery area.**	10	**100**	
Ind 77.	**ALL adverse anesthesia events are recorded and monitored.**	10	**100**	
Total		80		

Standard 22. COP-5: Policies and procedures guide the care of patients undergoing surgical procedures.

Indicators (78-86):

Ind 78. The surgery-related SOPs are documented.

Survey Process:

There are written SOPs that include pre-operative, intra-operative and postoperative care. Staff members are aware of the SOPs and there is observable evidence that they are being applied.

Scoring:

- If there are written SOPs for pre-operative, intra-operative and postoperative care, and these are implemented then score as **fully met.**
- If there is no sign board or there are non-conformities to above, then score as **not met.**

GUIDELINES

SOPs relating to the Surgical Procedures

Pre-Operative Assessment

It shall be mandatory that all elective patients are assessed pre-operatively on a Pre-Operative Assessment Form covering the following;

1. Diagnosis
2. Required Surgical Procedure.
3. Fitness for undergoing the required surgical procedure.

The assessment will be completed in the OPD/respective unit for which patients will be referred to various physicians/anesthetists for expert advice to bring their co-morbidities such as hypertension, ischemic heart disease, diabetes mellitus etc. within acceptable control.

Informed Consent for Surgery

It is mandatory that the patient/next of kin have the need for the surgery/procedure explained to them in detail, along with how it will be carried out and the pros and cons of the procedure/operation. It is essential that the consent is taken (preferably) by the surgeon him/herself or one of the doctors from his team, after properly introducing him/herself and explaining the requirement of the operation/procedure. The consent shall be taken on Informed Consent for Surgery Form.

In order to ensure that the correct patient undergoes the correct clinical activity/procedure on the correct site, the following five fundamental points need to be verified immediately prior to the procedure in the OT:

TIME OUT Protocol

1. Confirming identification of the patient.
2. Checking and confirmation of consent by the patient.
3. Checking the Correctness of Procedure or Surgery to be performed.

4. Marking of the Correct Site for surgery or other invasive procedures, as applicable.

Verification that diagnostic images (and/or other relevant test results) are available and are correct, as applicable.

Operation Notes

Operation notes are recorded in the patient chart immediately following surgery and the same is entered in the OT Register/EMR. 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 surgical assistant, countersigned by the operating surgeon. The record includes the following:

1. Date and duration of operation.
2. Anatomical site/place where surgery is undertaken.
3. The name of the operating surgeon(s), operating assistants including scrub nurse and the name of the consultant.
4. Description of the findings.
5. Details and serial and instrument count.
6. Immediate post-operative instructions.

Post-Operative Plan of Care

Postoperative care includes, care given during the immediate postoperative period, both in the OR and post-opt recovery area, as well as during the days following surgery.

The postoperative care aims to ensure smooth and uneventful recovery after the surgical procedures. The plan shall include advice on IV fluids, medication, care of wound, nursing care and observing for any complications, etc. A good outcome includes adequate pain management and recovery without complications, such as Surgical Site Infection (SSI), perioperative myocardial infarction, venous thromboembolism, post-operative pneumonia). It promotes healing of the surgical incision and returns the patient to a state of health. Another objective of postoperative care is to assist patients in taking responsibility for regaining optimum health.

Postoperative care involves assessment, diagnosis, planning, intervention, and outcome evaluation. The extent of postoperative care required depends on the pre-operative health status of the individual and type of surgery. Patients admitted to the hospital may require days or weeks of postoperative care by hospital staff before they are discharged. Post-OP recovery area should be adequately staffed.

1. Post-operative Care in Recovery Room

The patient is transferred to the Recovery Room or PACU after recovery from the effects of anesthesia.

2. First 24 hours

After the patient is transferred from the post-op recovery area, the nurse taking charge over his or her care should quickly assess the patient's overall condition and carefully read and follow the post-operative instructions written by the surgeon and anesthetist. As a routine, the following parameters of patients who underwent general or spinal anesthesia or received intra-venous sedation, are frequently monitored and assessed every 15 to 30 minutes depending upon the patient's over all status during first 24 hours and management instituted, if required, in consultation with the doctor on call:

A. Neurological, respiratory and circulatory status.
B. Any pain and nausea (any need for medication).
C. Body temperature (any need a warming blanket or warmed IV fluids or cold sponging).
D. The status of incision, any drainage tubes.
E. Fluid intake and urine output (the doctor on duty should be notified if the patient has not urinated in 6-8 hours after surgery).

Effective preoperative counselling has a positive impact on the first 24 hours after surgery. It shall be ensured that patients and attendants are communicated the importance of the following information pertaining to post-operative period:

A. Respiratory exercises prevent post-op pneumonia.
B. Movement is imperative for preventing blood clots, (sequential compression devices are recommended for patients who are not able to sit up in bed due to the surgery).
C. Pain should be kept under control to allow breathing and movement. (The patient should be encouraged to splint any chest and abdominal incisions with a pillow to decrease the pain caused by coughing and moving).
D. Patients need to be kept NPO (Nothing per Oral i.e. nothing by mouth) if ordered by the surgeon, at least until the return of cough and gag reflexes.
E. Patients often have a dry mouth following surgery, which can be relieved with oral sponges dipped in ice water or lemon ginger mouth swabs.
F. Patients should have easy access to call bell or lights to call staff.

Patients who are discharged home after a day surgery procedure are given prescriptions for their pain medications, and are responsible for their own pain control and respiratory exercises. Their families (or caregivers) should be included in preoperative counselling so that they can assist the patient at home. The patient should be reminded to call his or her physician if any complications or uncontrolled pain arise. These patients are often managed at home on a follow-up basis by a hospital-connected visiting nurse or homecare service.

3. After 24 hours

A. Routine monitoring continues but is less frequent (every 4-8 hours, if the patient is stable).
B. The patient should be sitting up in a chair at the bedside and ambulating with assistance by this time. Respiratory exercises continue and limited oral intake may be permitted as per surgeon's instruction and gradually increased.
C. The patient is monitored for any evidence of potential complications, such as Deep Vein Thrombosis (DVT), pulmonary embolism, wound dehiscence and paralytic ileus etc. In case of any complication the surgeon should be notified immediately.
D. Patients should receive a great deal of information regarding postoperative care so that they have a clear understanding of what to expect postoperatively.

4. Aftercare

Aftercare should ensure that patients are comfortable either in the bed or chair and their dressings are changed in time. Patients are given the opportunity to ask questions and to learn certain techniques/exercises to be performed once they return home.

5. **Handing over of post-operative patient in PACU to ward staff**

Patients should be accompanied by a suitably trained staff and porter during transfer to the ward. The anesthetic record, recovery note and prescription charts must accompany the patient. The recovery nurse must ensure that full clinical details are relayed to the ward nurse with particular emphasis on problems and syringe pump setting (if in place).

6. **Procedures for pre-operative and post-operative handover of the patients**

Continuity of information through different shifts of duty staff posted in surgical departments is vital to the safety of patients. With the increase in the number of individuals caring for patients, the need of handing over comprehensive clinical information is of critical importance. Good handover does not happen by chance and requires concerted and coordinated effort by both the incoming and outgoing members of the team. Broad guidelines regarding proper handover and improved outcome are as under:

A. Shifts must coordinate.
B. Adequate time must be allowed.
C. Handover should have clear leadership.
D. Information technology support may be provided.
E. Sufficient and relevant information should be exchanged to ensure patient safety.
F. Junior members of the team are adequately briefed about the clinically unstable patients.
G. Tasks not yet completed should be clearly understood by the incoming team.

7. **Action to be taken subsequent to Handover**

A. Prioritizing the tasks.
B. Putting plans for further care into place.
C. Review unstable patients more frequently.

The changing patterns of work in the HCEs have created a need for improved handover of clinical responsibility and information. In order to maintain high standards of clinical care, developing protocols for effective and safe handover, enhanced training and good communication amongst the staff are essential to protect the safety of patients when shifts are introduced.

Formal handover shall be part of good professional practice as a failure in this process, or poor quality handover, is a significant risk to patients

It is the shared responsibility of the staff and the HCE to ensure safe continuity of information and responsibility between the changing shifts, as it influences the delivery of care to the patient for the whole shift.

Ind 79. Documented SOPs address the prevention of adverse events like wrong site, wrong patient and wrong surgery.

Survey Process:

This is a critically important patient safety issue. Review a representative sample of medical records of patients who have had surgery, look for the implementation and documentation of processes including; i. marking of the surgical site when there is the possibility of bilateral confusion, ii. a pre-operative checklist to ensure that ALL documents (X-rays, medical records, etc.) and needed equipment is available, and iii. a "time out" prior to induction of anesthesia to ensure that ALL

members of the surgical team are in agreement that this is the correct patient, this is the correct procedure for this patient, and that this is (if relevant) the correct side/site for procedure/ surgery. This process should be led and duly authenticated by the surgeon.

Scoring:

- If ALL 3 requirements (marking when relevant, use of a checklist, and a "time-out" recorded) are used and documented in the medical record, then score as **fully met.**
- If ANY of the three requirements are not documented in the medical record, then score as **not met.**

GUIDELINES

Prevention of Adverse Events

In order to ensure patient safety, care shall be taken and “Time Out" protocols shall be used to avert potential blunders regarding operating on the wrong site, wrong patient and performing the wrong procedure.

Identification of clients/patients:

Purpose

To establish the identity of the patient and match the correct patient for an intended clinical procedure on the correct site.

Scope

The SOP applies to establishing patient identity and confirming consent prior to any clinical activity including withdrawal of blood sample, introduction of oral/parenteral medication, performance of medical imaging and non-invasive/invasive and non-surgical/surgical procedures in the OT. In case of a surgical procedure, patient/client identification process also includes the verification of correct side/site of surgery. The SOP shall also be applied for reviewing imaging or other investigations in the OT.

Procedure

The identification processes are applicable differently in different settings and staff shall apply Patient Identification Procedure (PIP) as appropriate to the setting and intended clinical activity. Responsibility for ensuring the correct patient for a specific clinical activity/procedure generally lies with all staff concerned with the care of the patient. However, the surgeon and nurse responsible to assist the procedure are ultimately responsible for the verification of proper identification of the patient. In order to ensure that the correct patient undergoes the correct clinical activity/procedure on the correct site, the following five fundamental points need to be verified immediately prior to the procedure in the OT.

TIME OUT Protocol

1. Confirming identification of the patient.
2. Checking and confirmation of consent by the patient.
3. Checking the Correctness of Procedure or Surgery to be performed.
4. Marking of the Correct Site for surgery or other invasive procedures, as applicable.
5. Verification that diagnostic images (and/or other relevant test results) are available and are correct, as applicable.

Patients shall be encouraged to actively participate in the identification process. Staff shall explain to the patient the importance of repeatedly asking about identification, reassuring that this measure is to ensure patient's safety. For example, the patient can be explained that:

1. To ensure your safety, each time you are moved within the hospital or before having any treatment, you need to tell your name and DoB to make sure you are the correct person and get the correct treatment.
2. For an un-conscious patient or infant, name tags (as bracelets or wrist bands) shall be applied at the time of admission to facilitate identification process and shall be referred to each time any clinical activity is intended.

In case of any discrepancy, the intended clinical activity must not proceed until it has been resolved. Any member of the treating team can ask to stop the procedure in case there are any concerns.

Marking the Site for Surgery or other Invasive Procedures

Site marking is essential in cases where there is potential for error involving left/right distinction, multiple structures (e.g. fingers/toes, lesions) or levels (e.g. spine). In such cases the site should be marked:

1. With an indelible skin marker where practical using initials, 'yes' or a line representing the proposed incision. Using 'X' shall be avoided as this may be interpreted incorrectly.
2. While marking the site/side, the patient should be awake, aware and involved if possible and should occur before the patient enters the operating/procedure room.
3. Note: an exception may be made for pediatric patients who may be marked under anesthesia to avoid causing distress. In this instance, the correct site/side must be confirmed verbally by a parent/guardian, where possible.
4. The site must be marked, and initialed, by the person performing the procedure (or another senior team member who has been fully briefed about the operation or procedure).
5. Skin preparation and draping, once appropriate marking has been completed, must be documented in the clinical record.
6. A patient's refusal to have the site marked must also be documented in the clinical record.

The patient should have at-least two corroborating identifiers as evidence to confirm identity using two patient identifiers improves the reliability of the patient identification process and decreases the chance of performing wrong procedure on the wrong patient. Examples of acceptable patient identifiers include:

1. Name
2. Assigned identification number
3. Telephone number
4. DoB
5. Social security number
6. Address
7. Photograph

Prior to starting the surgical procedure, patient identification must be cross checked to verify correct patient, correct procedure to be performed, and correct surgery site.

1. All patients undergoing a surgical procedure should wear an identifying marker.
2. The wristband should be placed on the wrist of the non-operative/non-affected side of the body.
3. If the wristband is required to be removed, it is recommended to be placed with the patient chart in order to be immediately replaced on the wrist at the end of the procedure, or a new wristband is obtained and placed with the patient chart for immediate placement on the wrist.

Note: Verifying the correct operative site is the responsibility of the surgical team members.

Ind 80. Surgical patients have a pre-operative assessment and a provisional diagnosis documented prior to surgery

Survey Process:

Review a representative sample of medical records of patients who underwent surgery to determine if a pre-operative assessment (surgeon's history and physical examination or pre-operative note) is present and that a pre-operative provisional diagnosis was documented.

Scoring:

- If there is a pre-operative history and physical examination or a pre-operative note by the surgeon that includes a provisional pre-operative diagnosis, then score as **fully met.**
- If there is a pre-operative history and physical examination or surgeon's note, but no pre-operative provisional diagnosis, then score as **partially met.**
- If there is no pre- operative history and physical examination or surgeon's note, then score as **not met.**

GUIDELINES

Pre-Operative Assessment

It shall be mandatory that all elective patients are assessed pre-operatively on a Pre-Operative Assessment Form covering the following:

1. Diagnosis
2. Required Surgical Procedure
3. Fitness for undergoing the required surgical procedure

The assessment will be completed in the OPD/respective unit for which patients will be referred to various physicians/anesthetists for expert advice to bring their co-morbidities such as hypertension, ischemic heart disease, diabetes mellitus etc. within acceptable control.

Ind 81. An informed consent is obtained by an authorized member of the surgical team prior to the procedure.

Survey Process:

Review the same representative records as in Indicator 80 to determine if an informed consent was obtained and documented in the medical record. The informed consent must include evidence that the patient was educated/informed. This is surveyed in the same way as for the consent for the administration of anesthesia.

Scoring:

- If ALL the reviewed medical records document an informed consent (a signed form or a note by the surgeon, then score as **fully met.**
- Since this is a significant medico-legal issue, if ANY of the reviewed records does not have

documentation of informed consent, then score as **not met.**

GUIDELINES

Informed Consent for Surgery

It is mandatory that the patient/next of kin have the need for the surgery/procedure explained to them in detail, along with how it will be carried out and the pros and cons of the procedure/operation. It is essential that the consent is taken (preferably) by the surgeon him/herself or one of the doctors from his team, after properly introducing him/herself and explaining the requirement of the operation/procedure. The consent shall be taken on Informed Consent for Surgery Form.

Details regarding informed consent of the patient have been discussed in Section 2.9 covering Patient's Rights and Education.

Ind 82. Persons qualified by law are permitted to perform the procedures that they are entitled to perform.

Survey Process:

The surveyors should look for documents that demonstrate a process to validate the qualifications, experience and registration status of physicians / surgeons to ensure that they are legally permitted and competent to perform specific procedures. The scope of clinical practice shall be defined and documented for all surgeons in line with the parameters defined by the PMDC and the College of Physicians and Surgeons (CPSP).

Scoring:

- If there is a recognized process to validate that the physician / surgeon is authorized (currently registered) and competent (based on academic credentials, experience, training and internal recognition) to perform the procedure he/she is conducting, then score as **fully met.**
- If there is no process to validate the authorization or competence to perform the procedure(s), then score as **not met.**

GUIDELINES

Authorization to Perform Procedures

It is the prime duty of all inclusive: the HCE's Executive staff, governing body and the HR Department, to ensure that the credentials of the doctor/surgeon/professionals are correct and required and/or the declared qualification should be properly verified by at least the PMDC, CPSP and/or any other recognized regulatory body in the country. A Credential Verification Form is required to be maintained by the HR Staff.

Table 21: Sample Credential Verification Form

CREDENTIAL VERIFICATION FORM
Serial No. _____
Name of Healthcare Provider: _____

Designation: _____

Registration Valid Until: _____

Verified By: _____

The surgeon/proceduralist should be allowed to practice only after necessary verification of his/her credentials and requisite experience as required, and the HCE shall also issue a notification to this effect.

Table 22: Sample Incumbency List

No.	Name	Qualifications	Appointment	Remarks
1.	Prof. Dr. (HOD Surgery)	MBBS, FRCS	Prof. of	
2.	Dr. (Registrar)			
3.	Dr. (PG Trainee)			
Signatures and Stamp of Hospital Administrator				

Ind 83. A brief operative note is documented by the surgeon or a doctor in the surgical team prior to transferring the patient out of the recovery area.

Survey Process:

Review the same representative medical records as noted for Ind 80. Determine if there is a documented operative note that was recorded and signed by the surgeon or a doctor in the surgical team prior to transferring the patient from the recovery area. Also, while in the recovery area, review the medical records of patients who are about to be transferred out of the recovery area to determine if an operative note signed by the surgeon or a doctor in the surgical team is in the medical record.

Scoring:

- If there is an operative note and it was documented in the medical record prior to transfer from the recovery area, then score as **fully met.**
- If there is either no operative note, or it was completed after the patient was transferred out of the recovery area, then score as **not met.**

GUIDELINES

Post-Operation Notes

Operation notes are recorded in the patient chart immediately following surgery and the same is entered in the OT Register/EMR. 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 surgical assistant, countersigned by the operating surgeon. The record includes the following given on a Post-Operative Note Format:

1. Date and duration of operation.
2. Anatomical site/place where surgery is undertaken.
3. The name of the operating surgeon/s, operating assistants including scrub nurse and the name of the consultant.
4. Number of prosthetics used.
5. Details of the sutures used.
6. Swab count.
7. The International Classification of Diseases (ICD)-10 Coded diagnosis made and the procedure performed.
8. Description of the findings.
9. Details and serial and instrument count.
10. Immediate post-operative instructions.

It is mandatory for the surgeon or his first assistant to put down everything he does in the OR to the patient/client during a surgical procedure. As the record may have lot of bearing on the patient's health in future, it is important not to leave anything essential. A typical Operating note delineates all such aspects to ensure that every necessary detail is entered, as is described in the following sample operating note format. It has three major sections; the first two are filled by the operating surgeon or his first assistant and the 3rd section is filled by the scrub nurse.

Table 23: Sample Operating Note

Operating Note

Section-I:

Patient's Name _____ Age/Sex _____

Bed/Room No. _____

Date of admission _____ Admission No. _____

Date of Operation _____

Emergency/OPD No. _____

Referring Consultant _____

Pre-op diagnosis _____ (ICD Code: _____)

Post-op diagnosis _____ (ICD Code: _____)

Surgeon _____

Assistant/s _____

Anesthetist/s _____

Anesthesia given _____

Name of the procedure _____ (ICD Code: _____)

Duration of procedure _____

It is mandatory that the patient/next of kin have the need for the surgery/procedure explained to them in detail, along with how it will be carried out and the pros and cons of the procedure/operation. It is essential that the consent is taken (preferably) by the surgeon him/herself or one of the doctors from his team, after properly introducing him/herself and explaining the requirement of the operation/procedure. The consent shall be taken on Informed Consent for Surgery Form.

Details regarding informed consent of the patient have been discussed in Section 2.9 covering

Patient's Rights and Education.

Section-II: To be filled by Surgeon or First Assistant

1. **Procedure:**
   The procedure describes all steps from skin incision (or entry of endoscope) till the closure of wound (or removal of scope)- name of the procedure is also mentioned (if known).
   It must also mention the following:
   A. Anatomical site surgery performed.
   B. All types of sutures used and the layers of tissues closed by them.
   C. Sites and types of drains inserted.
   D. Type and serial no of prosthesis used.
2. **Findings:**
   A. Must describe all that is found relevant to the pathological nature and extent of disease.
   B. Must also mention if encountered any unexpected pathology or intra -operative complication.
3. **Post- op instructions:**
   A. Whether to send patient/client back to ward/room or ICU from Recovery Area.
   B. Any specific instructions to be followed immediately in the recovery area.
   C. Instructions for next 24- 48 hours (specific management and treatment).
   D. Instructions regarding pathological specimen - specific test required - from where.

Surgeon's/first assistant's signature

Section-III: To be filled by scrub nurse

1. Intra operative estimated blood loss
2. Intra operative IV fluid/blood transfused
3. Intra operative urine output (if catheterized)
4. Whether swab and instrument count was complete

Scrub nurse name and signature

Anaesthetic Records contain:

1. Date and duration of anaesthesia.
2. Operation performed.
3. Name of the anaesthetist, anaesthesia assistant and, where relevant, the name of the consultant anaesthetist responsible.
4. Pre-operative assessment by the anaesthetist.
5. Drugs and doses given during anaesthesia and route of administration.
6. Monitoring data.
7. Intravenous fluid therapy.
8. Post-anaesthetic instructions.
9. Any complications or incidents during anaesthesia.
10. Signatures of anaesthetist and anaesthesia assistant.

Perioperative monitoring and evaluation is carried out by the anaesthesia team and the record is

maintained for future reference. Provision of safe and effective anaesthesia demands proper and thorough perioperative assessment and care of every patient and to choose the type of anaesthesia best suited to the patient's instant need and requirement. This is continued in four phases:

1. Pre-anaesthesia period
2. Intra operative period
3. Immediate post-surgical period (up to 36 hours)
4. Post-operative period

Pre-Anaesthesia Assessment is usually initiated an evening before the patient is put on the list by the concerned anaesthetist, who may ask for more tests before giving his/her final approval for the surgical plan. Comprehensive evaluation of the patient shall entail taking into account the patient's past medical and surgical history as well as the outcome of complete systemic physical examination and necessary investigations.

Ind 84. The operating surgeon or the surgical assistant[61] documents the post-operative plan of care.

Survey Process:

Review representative sample of records as noted for Ind 103 and validate that the surgeon or the surgical assistant has written post-operative orders.

Scoring:

- If there are post-operative orders, then score as **fully met.**
- If there are no post-operative orders, then score as **not met.**

GUIDELINES

Post-Operative Plan of Care

Postoperative care includes, care given during the immediate postoperative period, both in the OR and post-opt recovery area, as well as during the days following surgery.

The postoperative care aims to ensure smooth and uneventful recovery after the surgical procedures. The plan shall include advice on IV fluids, medication, care of wound, nursing care and observing for any complications, etc. A good outcome includes adequate pain management and recovery without complications, such as Surgical Site Infection (SSI), perioperative myocardial infarction, venous thromboembolism, post-operative pneumonia). It promotes healing of the surgical incision and returns the patient to a state of health. Another objective of postoperative care is to assist patients in taking responsibility for regaining optimum health.

Postoperative care involves assessment, diagnosis, planning, intervention, and outcome evaluation. The extent of postoperative care required depends on the pre-operative health status of the individual and type of surgery. Patients admitted to the hospital may require days or weeks of postoperative care by hospital staff before they are discharged. Post-OP recovery area should be adequately staffed.

Details as under Ind.78

[61] Medical practitioner directly involved with the surgical procedure

Ind 85. The surgical quality assurance program includes surveillance of the operation theatre environment is followed for surgical services.

Survey Process:

Review documentation such as minutes of Surgical Department meeting to ascertain that quality indicators of surgical care are defined and are being monitored. The following evidence should be reviewed: i. Infection control surveillance,[62] ii. Medical equipment maintenance, and iii. Cleaning of the theatres between cases. The results of these surveillance activities should be documented and presented in the relevant committee meetings and minutes recorded.

Scoring:

- If there is evidence that the quality indicators of the surgical care including safety and cleanliness of the operation theatre environment is monitored / evaluated, then score as **fully met.**
- If the quality indicators of the surgical care including safety and cleanliness of the operating theatre is not monitored / evaluated as above, then score as **not met.**

GUIDELINES

Surveillance of Operation Theatre Environment

The set of activities related to QA and surveillance of the OT environment have been mentioned in the survey process for Indicator No. 85. The following factors requiring special consideration are elaborated;

Surveillance activities include:

1. Daily monitoring of humidity and temperature.
2. At least monthly monitoring of pressure differential.
3. At least a six-month monitoring of integrity of filter.
4. Medical equipment maintenance.*
5. In addition to this, efficacy of the OT cleaning and disinfection processes shall be monitored.

Monitoring of humidity and temperature at least thrice daily at regular intervals by a designated staff of the OT maintenance team is considered important for patients as well as staff comfort. Similarly, a regular monthly check of the OT pressure differential and negative air pressure vented to the OT and a twice daily environmental cleaning of OTs should be done. Do not waste chemicals; only remove the dust with moist cloth, use chemicals/disinfectants only when contaminated with blood or body fluids.

Caring for floors:

1. Use only vacuum cleaners.
2. Do not use a broom.
3. Use a mop and keep it dry.
4. A simple detergent reduces flora by 80%.

[62] Explained in the Guidelines.

5. Addition of disinfectant reduces to 95%.
6. In busy hospitals counts raise in 2 hours. However only 1% is pathogenic. Counts depend on the number of persons and only people needed for procedures should enter the theatres. Unnecessary movements disturb the flora. Most important component of bacteria is water; dry areas cause natural death.

Care of Walls and Roofs of OTs:

Frequent cleaning has little effect; do not disturb these areas unnecessarily. Do not use ceiling fans as they cause aerosol spread. Clean only when remodeling or dust is accumulated.

Sterilization and Disinfection Policies:

1. An Infection Control (IC) team shall be notified by the HCE.
2. The IC team decides the policies.
3. Educate the staff on methods and policies in hospital safety and hygiene.

Surveillance for Microbes:

Bacteriological surveillance testing at regular intervals is not warranted and is only conducted in case of modification of OTs or in case of any unforeseen increase of incidence of infection for any particular OT as per decisions of the ICC with specific inputs from Microbiologist. *Roles of SSIS Committee (Ind. 86), IC Committee (Ind. 115-116), IC Team (Ind. 117), ICO/ICN (Ind. 115-116), CQI Committee and QI Program Activities (Ind. 32-33) are referred to for further details regarding Bacteriological Surveillance.*

Between Procedures in the OTs:

1. Operation tables and theatre equipment to be cleaned with disinfectant solution and detergent.
2. In case of spillage of blood/body fluids, disinfect with bleaching powder/chlorine solution.
3. Waste to be discarded in prescribed plastic bags.
4. Bio hazard waste should not be allowed to accumulate in the OT.

Procedure at the end of Day:

1. Table tops, sinks, and door handles all to be cleaned with detergent/low level of disinfectant.
2. Floors to be cleaned with detergents and warm water.
3. Final mopping with disinfectant like phenol in the conc. 1:10 is recommended.

Medical Equipment Maintenance:

All electro medical equipment also needs to be regularly cleaned and disinfected after use.

Ind 86. The surveillance program also includes monitoring of surgical site infection rates.

Survey Process:

This should be found in the minutes of an Infection Control Committee. Specifically look for evidence that the infection rates are physician / surgeon, procedure, and room specific as aggregate rates without organizing the data into categories are of little use. Determine the action taken in the light of the reports and determine if this is able to reduce the rate of infection.

Scoring:

- If there is data about surgical site infections and it is segregated into individual physicians / surgeon, procedures, and rooms, with evidence that remedial measures have been initiated, then score as **fully met.**
- If there is data about surgical site infections, but only in the aggregate without specific analysis and evidence of corrective measures, then score as **partially met.**
- If there is no data about surgical site infections or no evidence of corrective measures, then score as **not met.**

GUIDELINES

Monitoring of Surgical Site Infection Rate

Monitoring of Surgical Site Infection (SSI) rate is an integral part of effective surgical services feedback and is incorporated as one of the major performance indicators for quality assurance programme for surgical services. SSI is the second most common type of nosocomial infection acquired by the patients. These infections are responsible for increased hospital costs, increased mortality rates, increasing length of stay and consequently increased risk of harm to the patient.

Monitoring of the SSI rate advocates a preventive strategy through proper investigation, identification and rectification of the issue as soon as possible. It is imperative that each and every case of SSI be comprehensively put on paper for further review by the designated Surgical Site Infection Surveillance (SSIS) Committee of the hospital. Therefore, a robust documentation should be mandatory with daily follow ups and a well prepared preventive guide lines for SSI needs to be in place, in the QA plan.

Assessment Scoring Matrix

Standard 22. COP. 5: Policies and procedures guide the care of patients undergoing surgical procedures.

Indicator 78-86		Max Score	Weightage (Percent)	Score Obtained
Ind 78.	**The surgery-related SOPs are documented.**	10	**100**	
Ind 79.	**Documented SOPs address the prevention of adverse events like wrong site, wrong patient and wrong surgery.**	10	**100**	
Ind 80.	**Surgical patients have a pre-operative assessment and a provisional diagnosis documented prior to surgery.**	10	**80**	
Ind 81.	**An informed consent is obtained by an authorized member of the surgical team prior to the procedure.**	10	**100**	
Ind 82.	**Persons qualified by law are permitted to perform the procedures that they are entitled to perform.**	10	**100**	
Ind 83.	**A brief operative note is documented by the surgeon or a doctor in the surgical team prior to transferring the patient out of the recovery area.**	10	**100**	
Ind 84.	**The operating surgeon or the surgical assistant documents the post-operative plan of care.**	10	**100**	
Ind 85.	**The surgical quality assurance program including surveillance of the operation theatre environment is followed for surgical services.**	10	**100**	
Ind 86.	**The surveillance program also includes monitoring of surgical site infection rates.**	10	**80**	
Total		90		

2.8 Management of Medications (MOM)

03 Standards & 18 Indicators

Medication errors are one of the most common healthcare issues, with a number of preventable drug related injuries occurring in hospitals each year. Medication errors are also among the most frequently reported types of adverse events. Medication management standards help hospitals support patient safety and improve the quality of care by creating a system for selecting, procuring, storing, ordering, transcribing, preparing, labelling, dispensing, administering and monitoring medications. The following standards are designed to reduce practice variations, errors and misuse; encourage monitoring of the efficiency, quality and safety of medication management processes; promote the use of evidence-based good practices; and standardize processes throughout the hospital.

Standard 23. MOM-1: Policies and procedures for the prescription of medications are defined.

Indicators (87-91):

Ind 87. SOPs for the prescription of medications are documented.

Survey Process:

Review pharmacy and medication policies that relate to prescribing staff, administering staff and pharmacy staff. The important issue is that the policies explicitly define.

1. How medication orders/prescriptions must be written in the in-patient record and on an outpatient form.
2. Which staff can prescribe and which staff can administer medication.
3. The SOPs should also inform what is done when the order or prescription is not accepted because of confusion about the order.[63]

Scoring:

- If there are SOPs for prescription/ordering of medications and the same explicitly define what is done when the prescription/order is not clear, then score as **fully met.**
- If there are SOPs for prescription/ordering of medication, but the same do not define what is to be done when the prescription/order is not clear, then score as **partially met.**
- If there are no documented SOPs, then score as **not met.**

GUIDELINES

SOPs on Prescription of Medications

In ABC Hospital XYZ, only Medical Doctors and Dental Surgeons are authorized for Prescription Writing in their own fields. The following need to be complied with:

1. Authorized Physicians and prescribers (registered with PMDC) should prescribe in Public and Private settings and drugs should only be administered against a Written Order of a Physician.
2. Medicine prescribed by an outside medical doctor will not be administered in the hospital settings, except in case a patient is a long term old case of an illness and he is on maintenance therapy; these drugs can be administered in the hospital with the approval of the treating Consultant. Use of the patient's own medication should be discouraged on account of abundance of counterfeit medications in the market. The patient's own medications should only be dispensed if not in hospital formulary. These drugs must be inspected by the Pharmacy Department to ensure that these are still valid and not deteriorated.
3. No drug will be administered to a patient without a valid prescription of the treating doctor. In an emergency when a consultant is contacted on the phone and the drug is prescribed by him, the medicine may be given to the patient under the signature of the locally available

[63] Example - contraindicated due to other drugs prescribed or allergy, adult dose for child or restricted; wrong patient name or illegible

treating doctor and this should be authenticated by the Prescribing Consultant within 24 hrs.

4. Elements of drug orders or prescriptions must be defined as follows;
   A. Name.
   B. Age of the Patient.
   C. Any known allergies or contraindications; if no allergy is known then it states 'NKA'; information must not be omitted.
   D. In the paediatric population, **Weight** is mandatory.
5. Drugs must be written legibly and clearly, preferably according to the Generic Name, Brand name can be used in brackets.
6. Directions must be clearly stated. 'As directed' or 'when needed' must be avoided and should be qualified e.g. "Take one or two tablets for pain or headache" cautioning "Not to be taken empty stomach."
7. The hospital must have approved abbreviations.

Policy on Self Administration

At ABC Hospital XYZ self-administration of medication by the patients is not allowed.

Ind 88. The HCE formally determines who can write medication orders.

Survey Process:

There should be a policy that identifies practitioners who may write medication orders in the medical record or on a prescription. However, determine if any other professionals who should not have been authorized (such as midwives, anaesthetic nurses, emergency nurses, dental assistants/technicians, podiatrists and psychologists) are permitted to write prescriptions or order medication. The policy should delineate which practitioners can prescribe restricted classes of drugs.[64]

Scoring:

- If there is a policy and the clinical staff members are fully aware of who may write orders and this is supported by evidence in the medication chart, then score as **fully met.**
- If there is evidence of any confusion or the policy is not clear about who (which professionals) is permitted to order or prescribe medication, then score as **not met.**

GUIDELINES

SOPs on Prescription of Medications

Only a registered Medical Practitioner (Medical and Dental) is authorized to write prescriptions/prescribe medicines on their own, in accordance with the parameters of the hospital formulary. A patient specific direction is an instruction given by an independent prescriber to another professional to administer a medicine to a specific patient.

[64] Example - chemotherapy or very expensive drugs or unlicensed drugs administered as part of a research program

Ind 89. Medication orders are written in a uniform location in the medical records.

Survey Process:

While reviewing medical records, determine if medication orders are uniformly written in the same location in the patients' record across the various wards in the healthcare establishment.

Scoring:

- If ALL of the medication orders are in the specified area of the reviewed medical record, then score as **fully met.**
- Since this is a common source of "oversight" errors, if any orders are not in the designated location, then score as **not met.**

GUIDELINES

Uniformity of Documentation

Each patient care plan includes written orders by individuals qualified to order and record patient orders, for example diagnostic tests orders for laboratory testing, orders for surgical and other procedures, medications orders, nursing care orders, and nutrition therapy orders.

Figure 15: ample Medical Record Form

A uniform location in the patient's medical record or on a common order sheet, which is then transferred to the patient's medical record periodically or at discharge, facilitates understanding the specifics of an order, when the order is to be carried out, and who is to carry out the order. It also creates easy accessibility to the orders so that orders can be acted upon in a timely manner.
Efforts must be made that Medication Orders are at least transcribed and shall be reviewed by the pharmacist before administration of the dose. Data shows that most errors occur at the point of transcription i.e. what the physician has prescribed and what has been dispensed and administered.
Hospital staff should be aware and practice hospital policy which, amongst other policy statements, also states policies based on which orders must be uniformly written at specified sections on forms and then placed sequentially. Diagnostic imaging and clinical laboratory test orders must provide a clinical indication/rationale. There are exceptions in specialized settings, such as EDs and ICUs, where orders are to be located in the patient's medical record in a different manner.[65]

[65] Joint Commission International. (2010). Joint Commission International Accreditation Standards For Hospitals 4th edn. JCI, USA.

Ind 90. Medication orders are clear, legible, dated, timed, named / stamped and signed.

Survey Process:

While reviewing medical records, determine if ALL medication orders are legible, dated, timed (at least the emergency and HDUs), named, and signed. Determine what is done if a medication order is not legible. The score is based on the cumulative findings of ALL the records reviewed.

Scoring:

- If ALL orders are legible, dated, timed, named, and signed, then score as **fully met**.
- If only 1-2 orders (max 20%) are not timed, then score as **partially met.**
- If 3 or more orders are not legible, dated, timed, named, and signed, then score as **not met.**

GUIDELINES

Clarity of Medication Orders

All medication orders are to be prescribed in writing which should be dated, timed and signed by the prescribing doctor. There must be a written physician's order for prescription and non-prescription medications. The prescriber must also note if the patient has any known allergies, contraindications and body weight, particularly for the pediatric population. Diagnosis is becoming an integral part of the medication prescription, due to 'drug to drug,' 'drug to disease' interaction. The pharmacist should have an access to medication history i.e. pre admission medication, to avoid therapeutic duplication and to ensure continuity of therapy.

To have a complete Prescription Order (**Annexures O_1 - O_3**), the following eight items must be included:

The client's full name and parentage etc.

1. Weight
2. Allergies/Contraindications
3. The date of the order
4. Name of the medication
5. Dosage and administration information
6. Route of administration
7. Physician's Signature & Name or/and Stamp (containing name of Physician)

Ind 91. SOPs on verbal orders are documented and implemented.

Survey Process:

Interview nurses and other personnel who receive verbal orders. Observe a staff member receiving a verbal order. The SOPs and practice should clearly describe the process including writing down the verbal order and reading it back to ensure that it was clearly understood by both, the person who gave the order and the person who received the order (Option of sending SMS or voice message as further explained in the Reference Manual may also be considered).

Scoring:

- If there are clear SOPs for verbal orders and same are practiced, then score as **fully met.**
- If there are SOPs but the process is not consistently followed, then score as **partially met.**
- If there are neither SOPs nor a practice to verify verbal orders then score as **not met.**

GUIDELINES

SOPs on Verbal Orders

In order to ensure patient safety, care shall be taken and “Time Out" protocols shall be used to avert potential blunders regarding operating on the wrong site, wrong patient and performing the wrong procedure.

1. Verbal orders should only be used in exceptional circumstances. The diagnosis and health status as evaluated and documented by a doctor must be available if the prescribing doctor is not the one who made the initial assessment.
2. Only one stat dose may be prescribed verbally.
3. Verbal orders shall initially be taken by a Nurse, and repeated to a second Nurse.
4. The Nurse receiving the order must record the order on the drug treatment sheet. The entry is to be in red ink and should also include the time, date, name of prescriber and the Nurse's signature, as well as the second Nurse's signature.
5. The Nurse should repeat the order to the doctor to ensure that the details are correct.
6. The drug treatment sheet is to be countersigned by the doctor who gave the verbal order at the earliest possible time, within 24 hours.
7. If they are in any doubt, the Registered Nurse should seek clarification from the doctor until they are satisfied about the correctness of the
8. The medication is now to be administered as per the Administration of Medication Procedure and the Medication Policy.
9. A verbal order should be reconfirmed if the nurse believes that it may compromise the patient's care and treatment.
10. NO Verbal Orders for High Alert Medications and High Risk Medications.

Assessment Scoring Matrix

2.8 Management of Medication (MOM)

Standard 23. MOM. 1: Policies and procedures exist for the prescription of medications.

Indicator 87-91		Max Score	Weightage (Percent)	Score Obtained
Ind 87.	**SOPs for the prescription of medications are documented.**	10	**80**	
Ind 88.	**The HCE formally determines who can write orders.**	10	**100**	
Ind 89.	**Orders are written in a uniform location in the medical records.**	10	**100**	
Ind 90.	**Medication orders are clear, legible, dated, timed, named / stamped and signed.**	10	**80**	
Ind 91.	**SOPs on verbal orders are documented and implemented.**	10	**80**	
Total		50		

Standard 24. MOM-2: The SOPs for the safe storage and dispensing of medication are documented.

Indicators (92-97):

Ind 92. Documented SOPs guide the safe storage and dispensing of medications.

Survey Process:

The SOPs including at least;

1. Safe storage practices,
2. Matching the order with the correct patient and medication,
3. Confirming look alike drugs, and
4. Labelling etc. are in place.

Scoring:

- If there are SOPs and there is evidence that they are implemented, then score as **fully met.**
- If there are SOPs, but implementation is inconsistent, then score as **partially met.**
- If there are no SOPs or if none have been implemented, then score as **not met.**

GUIDELINES

Pre-Operative Assessment

Storage/warehousing is an important aspect of the total drug control system. Proper environmental control (i.e., proper temperature, light, and humidity, conditions of sanitation, ventilation, and segregation) must be maintained wherever drugs and supplies are stored. Storage areas must be secure; fixtures and equipment used to store drugs should be constructed so that drugs are accessible only to designated and authorized personnel. Safety is also an important factor, and proper consideration should be given to the safe storage of poisons and flammable compounds. External medications should be stored separately from internal medications. Medications must be stored in a refrigerator containing only medicines, and items other than drugs should be kept in a separate refrigerator.

Storage at Room Temperature:

1. Temperature
2. No humidity
3. No sun light
4. Away from wall, raised from floor
5. Stacked in order of the companies' names Refrigerated Items:
6. Insulin, Vaccines, eye drops
7. Temperature 2-8 C
8. Temperature record twice daily 8 AM and 8 PM

Drug Storage Site Inspections

A minimum of quarterly inspections shall be carried out, under the direction of the pharmacist, of

all medication storage areas within the hospital. A Written Record shall verify that Safe Storage Practices including the following are implemented:

1. The storage is properly maintained using stacks, bin cards and inventory control documents.
2. Medications are stored securely in the ward and available to the authorized personnel only.
3. Narcotic and controlled drugs are stored with proper measures of security.
4. Standards of neatness and cleanliness are consistent with good medication handling practices.
5. Reconstituted medications are properly labelled with expiry and preparation date.
6. Illegible labels are replaced.
7. Liquid bottles are clean and free of spills.
8. The patient's own medications are stored securely and separately.
9. Disinfectants and drugs for external use are stored separately from internal and injectable medications.
10. Medications are stored properly and medications requiring special environmental conditions for stability are properly stored.
11. Non-pharmaceuticals are stored separately from medications in the medication room fridge.
12. Expired or obsolete medications are not stocked.
13. Medications no longer required are returned to the pharmacy.
14. Medications are not overstocked.
15. Medications which may be required on an urgent or emergency basis are in adequate supply and readily available (Emergency Box, Crash Carts).
16. Medication room door/cart is closed when supervised and locked when unsupervised.

Dispensing shall be restricted to the Pharmacist or Pharmacy Technicians/Dispenser.

1. Stat Orders shall be processed and dispensed according to specific written procedures in accordance with hospital policy.
2. No dispensing shall be done without the written order of the treating doctor.

Ind 93. High-risk medication is defined and listed.

Survey Process:

Review the list defining the high-risk medicine which must be readily available to staff. The list of high-risk medications must include at least: concentrated electrolytes such as KCl, chemotherapy, very high cost drugs, look alike medications, sound alike medications, biogenic products and psychotropic etc.

Scoring:

- If the hospital has a written list of high-risk medications, then score as **fully met.**
- If the hospital has a list of high-risk medications, but it does not include both look alike or sound alike medications, then score as **partially met.**
- If there is no list of high-risk medications, then score as **not met.**

GUIDELINES

Defining and Listing of High Risk Medications

High-alert (or high-hazard) medications are medications that are most likely to cause significant harm to the patient, even when used as intended. Following are some well-known high risk medicines;

1. Anticoagulants,
2. Narcotics,
3. Opiates,
4. Insulin,
5. Concentrated Electrolytes e.g. KCl,
6. Chemotherapeutics and,
7. Sedatives etc.
8. Sound alike medicines.
9. Look alike medicines.

Although any medication used improperly can cause harm, high-alert medications cause harm more commonly and the effect they produce is likely to be more serious and lead to the patient's suffering, and additional costs associated with care of these patients.

Known Safe Practices can reduce the potential hazard and harm. Although the list of high risk medications includes many, but some of them have been associated more frequently with harm, such as anticoagulants, narcotics and opiates, insulin, concentrated electrolytes e.g. KCl, chemotherapeutics and sedatives etc. The most common types of harm associated with these medications include hypotension, bleeding, hypoglycemia, delirium, lethargy, and bradycardia.[66]

Ind 94. High-risk medication orders are verified prior to dispensing.

Survey Process:

Interview both pharmacy and nursing staff since the safety issue is not just dispensing, but also administration.

Scoring:

- If there is a clear practice (based on interviews with pharmacy and nursing personnel) of verifying the order for high-risk medications, then score as **fully met.**
- If there is no formally defined process, or if there is no list of high-risk medications (Ind 93), then score as **not met.**

GUIDELINES

Double-Checking SOP

Caregivers should be mandated to Double Check all High Risk Medications before administering. Double-checking SOP is given below;

1. Independently comparing the Label and Product Contents in hand versus the written order or pharmacy-generated Medication Administration Record (MAR).

[66] Institute for healthcare improvement. (2013). High alert medication safety. Retrieved from http://www.ihi.org/explore/highalertmedicationsafety/pages/default.aspx

2. Independently verifying any calculations for doses that require preparation (e.g., any time the medication is not dispensed in the exact patient-specific unit).
3. Assuring the accuracy of infusion pump programming for continuous intravenous infusions of medications.
4. A Certificate to the effect that the Nurse/Dispenser has actually verified the High risk Medication Order before administration, has to be inserted in the record of the patient and signed by the administering professional.

Circumstances Increasing Risks/Errors in High Risk Medications

1. Poorly handwritten medication orders.
2. Verbal directixons/orders.
3. Similar product packaging.
4. Similar medication name.
5. Improper packaging leading to improper route of administration e.g. Oral liquid in IV syringe, Topical products stored in IV vials.
6. Storage of products with similar names in the same location.
7. Similar abbreviations.
8. Improper storage of concentrated electrolytes.
9. Branded Products i.e. "Auto Dispensing Modules" are to be avoided.

Strategies to Avoid Errors Involving High Risk Medications

1. Medication arrangement:
   A. Avoid storing Look-Alike, Sound-Alike (LASA) drugs next to each other (example: instead of storing by generic name (e.g. vincristine and vinblastine) store drugs by brand name (e.g. Oncovin and Velban).
   B. Limit/eliminate high risk drug storage in Pyxis (i.e. list and store separately).
2. Formulary selection: Minimize LASA formulary combinations.
3. Tallman lettering:
   A. All medicines should be written in capital letters to eliminate illegible hand writing.
   B. Labelling to emphasize differences in medication names (example: hydroxyzine vs. hydralazine).
4. Computerized Prescriber Order Entry (CPOE):
   A. Eliminates illegible handwriting.
   B. Reduces opportunities for misinterpretation of verbal orders.
5. LASA drugs could still be confused by Nurses/Dispensers:
   A. System alerts are in place to safeguard selection.
   B. Bar coding can serve as a double check system during medication, selection, preparation, and prior to administration.
   C. Scanning a bar coded medication just prior to administration can detect many types of medication errors before they occur.
6. Alert notes:
   A. Highlighted stickers on packaging.
   B. Pop-up messages attached to LASA drugs.
   C. Highlighted drug storage areas.

Ind 95. The procedure for medication recall is defined.

Survey Process:

While visiting the pharmacy, review the procedure for medication / drugs recall. If there had been a recall, review the documentation of how it was done.

Scoring:

- If there is a procedure for medication recall, then score as **fully met.**
- If there is no procedure, then score as **not met.**

GUIDELINES

Medication Recall Procedure

Recall is a process[67] for withdrawing or removing a pharmaceutical product from the pharmaceutical distribution chain because of defects in the product, complaints of serious adverse reactions to the product and/or concerns that the product is or may be counterfeit. The recall might be initiated by the manufacturer, wholesale license holder, regulatory agency or Department of Health. A statement by a practitioner can be the reason for recall. Recall might be initiated as a result of reports or complaints on quality or safety of a pharmaceutical product referred to the Licensee from a variety of sources. The reports or complaints may be referred by manufacturers, wholesalers, retailers and hospital pharmacies, research institutes, medical practitioners, dentists and patients. Recall might also be initiated as a result of analysis and testing of samples of pharmaceutical products by the manufacturers and/or by the Department of Health (DoH). Recall of pharmaceutical products manufactured overseas might be initiated by the local or overseas health authorities, or from information received directly from such authorities.

Certain information is essential to permit assessment of the validity of the report of quality defects, safety or efficacy problem with pharmaceutical products, the potential danger to consumers and the action appropriate to the situation.

An Adverse Drug Reaction Form as per the specimen format given below can be used to report problems:

Table 24: Pharmaceutical Product Problem Reporting Form

DETAIL OF THE PROBLEM		
Reporting Institution (institution reporting the problem of Pharmaceutical Product to DoH)		
Name of contact	Position/Occupation	
Organization		
Address		
E-mail address		
Tel: (Office)	(Mobile)	Fax:
Pharmaceutical product problem occurred in _____ (location)		
Nature of the problem		
Date of receiving complaint		

[67] Department of Health Hong Kong, China. (2011). Pharmaceutical Products Recall Guidelines

Source of Complaint	a) Patient b) Customer c) Retailer d) Self-inspection Other: _____
Number of similar reports received _____	
Description of the problem (use separate sheet if space is inadequate)	
Results of tests/investigation on suspect or other samples	
Has manufacturer/distributor been contacted? _____ No _____ Yes (please write down their names)	
Other relevant information (attach photocopies, package insert and press release of oversea authority of the product if any)	

DETAIL OF THE PRODUCT		
Name of the product (as in product registration certificate)	Registration number	
Active Ingredients and Strength		
Indications		
Dosage form	Pack Size	
Batch number	Expiry Date	
Manufacturer		
Name		
Address		
Tel	Fax	Manufacture Date
Quantity of the batch manufactured		Date and quantity released
Quantity on hold		Quantity distributed: local overseas
Importer		
Name		
Address		
Tel.	Fax	Import date
Quantity of the batch imported	Date and quantity released	
Quantity on hold	Quantity Distributed: Local Re-exported	
Local Distributors (please attach distribution list)		
No. of local distributors		
Name		
Address		
Contact Person	Tel (office & mobile)	
Quantity on hold	Quantity distributed: Local Re-Exported	
Exporter		
Has the product been exported outside _____ (Location)? a) Yes b) No If yes, specify the exported countries.		

Name of Reporter: _____ Post: _____
Contact No. (Mobile): _____ Date: _____
Signature of Reporter: _____

Recall must be reported to the Department of Health within 24 hours of receipt of the complaint or report for investigation. The abovementioned Pharmaceutical Product Problem Reporting Form, together with opinions on toxicological or therapeutic hazards, and the action proposed by the authorities/organization should be referred onto the Department of Health.

Ind 96. Expiry dates / shelf life is monitored and are checked and documented prior to dispensing.

Survey Process:

This is best surveyed by observation. While visiting emergency, out-door, indoor, pharmacy/dispensary and store/s check a sample of medications for their expiry date. Check the procedure how the stocks are kept/used to ensure rotation.

Scoring:

- If no expired medications are found, then score as **fully met.**
- If there is any expired medication found, then score as **not met.**

GUIDELINES

Monitoring of Expiry Dates

The Pharmacy Department is responsible for conducting physical examinations of all medication to ensure their being intact and in date at the time of use. The pharmacy in-charge shall ensure implementation of the following SOPs for the Monitoring of Expiry Dates;

1. The orders for responsibility to check the Expiry Dates on Daily/Monthly/ Quarterly/Yearly basis should exist.
2. Once a drug is re-packaged in a separate container there is a reduction in the shelf life of the product, therefore, original expiry dates should not be used. It is the responsibility of the re-packaging technician to inspect these products for date of manufacturing and then proposed expiry.
3. Expired stock or products which expire within a month are pulled from the shelves and the purchasing cell notified of the need for additional stock.
4. The pharmacists and pharmacy technicians in the dispensing areas are responsible for the inspection of all drugs products in the working stock. Each technician will have a portion of the stock from the central pharmacy assigned for monthly inspection. A visual inspection for deterioration and expiry date shall be a normal part of the dispensing and checking procedure.
5. All expired repackaged products shall be pulled from the shelves and held in a segregated area for disposal.
6. All expired drugs which are in the original package shall be stored in a segregated area in the stockroom and will be processed as per hospital policy.

Ind 97. Labelling requirements prior to dispensing are implemented.

Survey Process:

The hospital should have defined what is to be included on the label. When being dispensed directly to the patient this should include at least: i. Patient's name, ii. Generic and proprietary name of medication, iii. Concentration (dose/ strength), iv. Directions for use, v. Prescribing practitioner and vi. Date of dispensing. When dispensed to a patient care unit, the label should include ALL the above information. Check a representative sample of dispensed medications to determine how they are labelled.[68]

Scoring:

- If ALL medications are appropriately labelled, then score as **fully met.**
- Since this is an important patient safety issue, if any are not completely labelled, then score as **not met.**

GUIDELINES

Labelling and Packing Rules

The Government of Pakistan Drugs (Labelling and Packing) Rules of 1986 govern the manner of labelling of pharmaceutical products and the hospital pharmacy shall ensure compliance of these labelling requirements and conformance to the terms and conditions of the contract agreement and before acceptance of received supplies.

HCPs shall label all medications, medication containers (syringes, medicine cups, basins), or other solutions. This ensures safe medication practices and addresses a recognized risk point in the safe administration of medications in perioperative and other procedural settings. Errors, sometimes tragic, have resulted from medications and other solutions removed from their original containers and placed into unlabeled containers.

A standardized method[69] for labelling all medications will minimize errors. Anytime one or more medications are prepared but are not administered immediately, the medication syringe/vial will be labelled with drug strength, date, time and secured in such a way that it can be readily determined that the contents are intact and have not expired. At a minimum, all medications are labelled with the following information:

Medication Labelling Checklist

1. Patient's Name.
2. Medication name, strength (concentration), and amount.
3. Expiry date when not used within 24 hours.
4. Expiry time when expiry occurs in less than 24 hours.
5. The date prepared and the diluents, for all compounded IV admixtures and parenteral nutrition solutions.

[68] It is recognized that the establishment of appropriate systems may require a negotiated implementation time frame in some institutions.

[69] Department of Pharmacy Policies and Procedures. (2011). Medication Labeling. Retrieved from http://pharmacy.uams.edu/PNP/PNP523.htm

When preparing medications for multiple patients, or when the person preparing the medications is **NOT THE PERSON** administering the medication, the label must include the **"Patient name."**
In surgical or other procedural settings (radiology, other imaging services, endoscopy units, and patient care units) where "bedside" procedures are done, when medications are drawn up and put on the sterile field for **use during that specific procedure, at a minimum,** the label will include the following:

Bedside Medication Labelling Check List

1. Medication name.
2. Medication strength (concentration).
3. Medication amount (if not apparent from the container).
4. Expiry date is required if the medication will not be used within 24 hours.
5. Expiry time is required if the expiry will occur in less than 24 hours.
6. Date prepared and the preparer's initials.
7. Any remaining medication must be discarded immediately after the case/procedure.

If, during the perioperative or peri-procedural process, a solution or medication is poured, drawn into a syringe, or otherwise used from its original container and immediately administered, or disposed of in some fashion, labelling is not required.

Assessment Scoring Matrix

Standard 24. MOM. 2: The SOPs for the safe storage and dispensing of medication are documented.

Indicator 92-97		Max Score	Weightage (Percent)	Score Obtained
Ind 92.	**Documented SOPs guide the safe storage and dispensing of medications.**	10	**80**	
Ind 93.	**High-risk medication is defined and listed.**	10	**80**	
Ind 94.	**High-risk medication orders are verified prior to dispensing.**	10	**100**	
Ind 95.	**The procedure for medication recall is defined.**	10	**100**	
Ind 96.	**Expiry dates / shelf life is monitored and are checked and documented prior to dispensing.**	10	**100**	
Ind 97.	**Labelling requirements prior to dispensing are implemented.**	10	**100**	
Total		60		

Standard 25. MOM-3: There are defined procedures for medication administration.

Indicators (98-104):

Ind 98. Prepared medications are labelled prior to preparation of a second drug.

Survey Process:

Observe a nurse or an anesthetist preparing medication / dose and verify that each medication is labelled prior to preparing the next one.

Scoring:

- If all drugs are labelled prior to preparing subsequent medications/ dose, then score as **fully met.**
- If one or more violations of this requirement are noticed, then score as **not met.**

GUIDELINES

Instant Labelling

Prepared medicines are labelled immediately upon preparation, including, at minimum;

1. Patient's full name and a second patient identifier (e.g., medical record number, DOB).
2. Full generic drug name.
3. Drug administration route.
4. Total dose to be given.
5. Total volume required to administer this dosage.
6. Date of administration.
7. Date and time of preparation.
8. Date and time of expiration when not for immediate use.

Immediate use must be defined by institutional policy (e.g. use within 2 hours):

Practitioners/institutions are not expected to be in full compliance with this standard if they currently have electronic systems that are unable to meet these labelling requirements. Appropriate changes should be implemented as soon as possible to ensure that electronic labels integrate all of these elements.

Practitioners/institutions that administer intrathecal medication maintain policies specifying that intrathecal medication will ***not be prepared during preparation of any other agents.***[70]

[70] American Society of Clinical Oncology. (2011). ASCO-ONS Standards for Safe Chemotherapy Administration.

Ind 99. Medications are administered (dispensed) by those who are permitted by law and authorized to do so.

Survey Process:

Review the law, authorization and then review a representative sample of medical records to validate that only those permitted by law and authorized to do so, have administered medication.

Scoring:

- If all drugs are administered by authorized staff, then score as **fully met.**
- If there is an evidence of medication administered by someone not authorized to do so, then score a **not met.**

GUIDELINES

Authorization to Administer the Drugs/Medications

Administering a medication to treat a patient requires specific knowledge and experience. Each HCE is responsible for identifying those individuals with the requisite knowledge and experience, and who are also permitted by licensure, certification, laws or regulations to administer medications (PMDC Act 2022, PNC Ordinance, Pharmacy Council Act, Khyber Pakhtunkhwa Faculty of Paramedical Allied Health Sciences Act, Pakistan Injured Person Act etc.) An organization may place limits on medication administration by an individual, such as for controlled substances or radioactive and investigational medications. In emergency situations, the organization identifies any additional individuals permitted to administer medications. A Specimen for Listing of Professionals Authorized to Administer the Drugs/Medications is provided below:

Table 25: Specimen List of Professionals Authorized to Administer the Drugs/Medications

No.	Particulars of Professionals	Authorization PMDC/PNC/FPAHS etc.	Validity Date
1.			
2.			
3.			
4.			
5.			

Signatures of Administrator HCE _____
Date_____

Ind 100. Patient is identified prior to administration.

Survey Process:

Review the procedure which should include at least 2 separate ways of positively identifying the patient. Then interview a nurse to find out what is practiced when administering medication and observe how the nurse identifies the patient. Patients should have a system of identification that is

reliable and is with them at all times. Records to validate that only those permitted by law and authorized to do so, have administered medication.[71]

Scoring:

- If 2 identifiers are routinely used, then score as **fully met.**
- If this practice is not uniformly followed (1 or more examples where there is failure to follow the procedure), then score as **not met.**

GUIDELINES

Identification of Patient being Administered Medication

In order to make sure that you are about to administer medications to the right individual, you have to know the individual. Even when you know the individual well, mistakes can happen. Sometimes, when medications are being administered to more than one individual in a setting, or if you prepare medications for more than one individual at a time, you can be distracted and give the medications to the wrong individual. So authorized Person/Nurse administering the medication should identify the patient every time and reflect on the patient's record.

Avoid Serious Mistakes by Complying with the following SOPs:

1. Prepare medication for one individual at a time.
2. Give the medication to the individual as soon as you prepare it.
3. Do not talk to others and ask them not to talk to you when you are giving medication.
4. Do not stop to do something else in the middle of giving medications.
5. Pay close attention at all times when you are giving medications.
6. Must compare the individual's name on the prescription label, the medication order and the medication log. Make sure that they match. If they do not match, or if there is any doubt about whether you are giving the medication to the right individual, **ASK QUESTIONS!**

If you make a mistake, follow the SOPs for reporting medication errors. You may need to call the individual's physician, or take the individual to the emergency room for evaluation.*[72]

Ind 101. Medication is verified from the order prior to administration.

Survey Process:

Observe nurses or doctors preparing medication and verify that the medication order was readily available and the type of medication was checked prior to preparing the medication.

Scoring:

- If there is clear evidence that the order was checked by name, then score as **fully met.**
- If ANY example of medication not being checked against the order is seen, then score as **not met.**

[71] For ALL patients the system employed for identification must be permanently with the patient and fail-safe.

[72] Not doing so may result in serious/life threatening consequences.

GUIDELINES

Medication Verification Instructions

In order to ensure that right medication is being administered, the ahead mentioned points converted to a Checklist, should be used;

1. Read the medication label carefully (remember that some medications have more than one name: a brand name and at least one generic name).
2. Check the spelling of the medication carefully. If there is any doubt about whether the medication name is correct, stop and call the pharmacist before you give the medication.
3. Read the medication order carefully. Make sure that the medication name on the order matches the medication name on the label.
4. Read the medication log carefully. Make sure that the medication name on the label, the medication order and medication log match before giving the medication.
5. Look at the medication. If there is anything different about the size, shape or color of the medication, call the pharmacist before you give it. It could be that you have been given a different generic brand of the medication. But sometimes when a medication looks different it means that you have the wrong medication.
6. All high-risk medications which are known to cause serious reactions, should be checked for hypersensitivity reactions before administration (intra dermal check) e.g. Penicillin, ATS etc.

Note: Prescription drugs shall be dispensed only pursuant to a valid prescription or a valid order. A pharmacist shall not dispense a prescription which the pharmacist knows or should know is not a valid prescription.

Ind 102. Dosage, route and timing is verified from the order prior to administration.

Survey Process:

Observe nurses or doctors preparing medication and verify that the medication order was readily available and the dose was checked in terms of dosage, route and timing prior to preparing and administering the medication.

Scoring:

- If there is clear evidence that the order was checked for dose, route and timing then score as **fully met.**
- If ANY example of dosage, route or timing of medication not being checked against the order is seen, then score as **not met.**

GUIDELINES

Dosage Verification

The right dose is how much of the medication you are supposed to give the individual at one time. To determine the dose, you need to know the strength of each medication. In the case of liquid medications, you need to know the strength of the medication in each liquid measure. The dose equals the strength of the medication multiplied by the amount.

Ensure the following Dose Verification SOPs by comparing the Dose on the:

1. Prescription Label
2. The Medication Order
3. The Medication Log

ALERT! Always ask the pharmacist about any order that requires administering more than 3 tablets or capsules of the same medication in one dose. This could be an over-dosage! If still there is some doubt, the prescribing doctor should be asked.

Route Verification

The route means how and where the medication goes into the body. Most medication is taken into the mouth and swallowed, but others enter the body through the skin, rectum, vagina, eyes, ears, nose, and lungs, through an NG-tube or by injection. The use of multiple routes of administration in one prescription must be avoided for the same high risk medicine (e.g. IV/Oral).

Sometimes mistakes happen when you are giving several medications by different routes at the same scheduled time. For example, you may be giving an eye drop and an eardrop to the same individual at the same time. If you become distracted, you could accidentally put the eardrops in the individual's eye. This would be a very serious mistake.

When measuring and administering medicine doses, ensure required devices are used according to manufacturers' specifications and that they are used according to their stated purpose.

Ensure that strengths of medicines are clearly visible in terms of the dosage unit or dose per volume of liquid e.g. mg/ml.

Ensure the following Route Verification SOP by comparing the Route on the:

1. Prescription Label
2. Medication Order
3. Medication Log

Additional care is taken when administering the following dosage forms:

1. Transdermal patches
2. Modified release oral medicines
3. Inhaled Medicines
4. Parenteral fluids.

Timing Verification

The general principles are that it is very important for medication to be given at the time of day that is written on the medication order. Some medications must be administered only at very specific times of the day. For other medications, the time of day that you give the medication is less critical. For example, some medications must be given before meals, one hour after meals or at bedtime in order to work best.

If no specific time is written on the medication order, ask the pharmacist about the best time of day to give the medication. Write this down on the medication log.

The **Dispensing Time SOPs** for Standardized Dose Administration throughout the hospital is that medications must be given within a V hour of the time that is listed on the medication log. This means that you have V hour before the medication is due, and V hour after it is due to administer the medication in order to be on time with medication administration.

Ind 103. Medication administration is documented.

Survey Process:

On the same representative medical records in Ind 122, review the physician order then verify that ALL administered medications are documented in the record.

Scoring:

- If ALL administered medications are documented, then score as **fully met.**
- If only 1-2 (cumulative from findings in ALL representative records a max 20%) examples of failure to document administration are observed, then score as **partially met.**
- If more than 3 documentation failures are observed, then score as **not met.**

GUIDELINES

Documentation of Medication

The following instructions must be acted upon for proper documentation;

1. Each time a medication is administered, it must be documented and signed with full name/stamp.
2. Medication must be documented at the time of actual administration.
3. All documentation required for the patient, must be completed on the medication log individually and not all together as a batch.
4. Documentation should be done in BLUE or BLACK ink.
5. NO PENCIL or WHITE OUT can be used.
6. NEVER OVER WRITE documentation.
7. In case of a mistake in documenting the medication log, CIRCLE the MISTAKE and write a note on the log to explain what happened.
8. Double check documentation done by you after finishing the medication process and again at the end of the duty.
9. Coordinate with a colleague to have documentation done by you double-checked for you, ask him/her to go over your medication log documentation to make sure that it is complete and vice versa.

Ind 104. SOPs regarding patient's self-administration of medications are defined.

Survey Process:

Review the policy on self-administration. Interview a nurse to see if the policy is understood and speak with a patient to determine if they understand the instructions they have been given.

Scoring:

- If the SOPs exist and same are understood, then score as **fully met.**
- If there are no SOPs or if nurses are unaware of the SOPs, then score as **not met.**

GUIDELINES

SOPs for Self-Administration of Medicines

Self-Administration of Medicines (SAMs) is very useful as it enables patients in the hospital to manage their medication under supervision of health professionals in a way that mirrors their home situation and allows an assessment of the way they will cope after discharge.

The HCEs should adopt the following SOPs:

1. The SAM, either those brought into the organization or those prescribed or ordered within the organization, is known to the patient's physician and noted in the patient's record.
2. The organization controls the availability and use of medication samples.
3. The information given to the patient is reinforced verbally at the point the Medicine Information Card is handed over, and is checked and further reinforced on a continual basis.
4. Patients will receive the manufacturer's Patient Information Leaflet with their medicines.
5. The in-patient prescription chart is checked by the nurse for any changes at least once a day and the Medicine Information Card updated as necessary.
6. Patients entered in the self-medicine scheme may continue to administer their medicines pre-operatively, but must be given clear guidance on any medicine that must be omitted on the day of operation.
7. All medicines self-administered by patients must be presented and labelled in a form that provides all the information necessary for the patient to self-administer without risk of error. This is achieved in one of two ways:
   A. **Patients' own medicine may be reused** for self-administration provided they meet the requirements of the HCE Policy for Safe and Secure Handling of Medicines.
   B. **Individually dispensed items from the pharmacy** will be supplied from the Pharmacy Department fully labelled for use by the patient and will include the manufacturer's Patient Information Leaflet.
8. The quantity of medicine supplied will be sufficient to cover the patient's anticipated length of stay plus a further fourteen days' supply following discharge.
9. Any dosage alteration to a SAM by a prescriber must be brought to the attention of a nurse and pharmacist at the earliest opportunity to allow re-labelling/re-supply and alteration of the Medicine Information Card to occur.
10. Any discontinuation of a SAM must be brought to the attention of a nurse and pharmacist at the earliest opportunity to allow the medicine to be removed from the cabinet.

Assessment Scoring Matrix

Standard 25. MOM. 3: There are defined procedures for medication administration.

Indicator 98-104		Max Score	Weightage (Percent)	Score Obtained
Ind 98.	**Prepared medications are labelled prior to preparation of a second drug.**	10	**100**	
Ind 99.	**Medications are administered (dispensed) by those who are permitted by law and authorized to do so.**	10	**100**	
Ind 100.	**Patient is identified prior to administration.**	10	**100**	
Ind 101.	**Medication is verified from the order prior to administration.**	10	**100**	
Ind 102.	**Dosage, route and timing is verified from the order prior to administration.**	10	**100**	
Ind 103.	**Medication administration is documented.**	10	**80**	
Ind 104.	**SOPs regarding patient's self-administration of medications are defined.**	10	**100**	
Total		70		

2.9 Patient Rights and Education (PRE)

03 Standards & 10 Indicators

The HCE shall define patient and family rights and responsibilities as per the guidelines provided by the KP HCC. The staff is aware of these and is trained to protect patients' 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. Patients are educated about the mechanisms available for addressing grievances.

A Client/Patient Rights and Responsibilities Charter, as given at Annexure P, is displayed in all client/patient areas.

Standard 26. PRE-1: Process for obtaining patient and/or family consent for informed decision making about their care is documented.

Indicators (105-108):

Ind 105. General Consent for treatment / declaration on admission is obtained, Patient and Family Members are informed of its Scope.

Survey Process:

Review representative sample of medical records (this can be done simultaneously with review for other reasons). Determine if ALL records contain a general consent/declaration on admission. Also determine if the content of the general consent is made clear to the patient and/or family.

Scoring:

- If ALL records have a documented general consent, then score as **fully met.**
- Since this is a medico-legal issue, if ANY record does not have a general consent, then score as **not met.**

GUIDELINES

Scope of General Consent

The client has the right to have correct information about his/her health status (unless explicitly requested not to do so), proposed treatment plan and all related issues in general. This information should be conveyed by the attending staff in a clear way and appropriate language. The client should have sufficient information to help him/her understand the issue and have informed decisions regarding treatment and management. A proposed format of General Consent Form is as given below:

Table 26: General Consent Form for Treatment

GENERAL CONSENT FOR TREATMENT

Patient Name: _____ S/O, D/O.W/O _____

Patient Birth Date: _____ NIC: _____ Next of kin: _____

Address: _____

1. **Treatment:**
   I request and authorize the provision of treatment and related Healthcare Services to me by _____ Hospital/Physician/authorized designees. This may include routine diagnostics and medications.
2. **Rights and Responsibilities:**
   I have been informed by the Hospital about my Rights and Responsibilities i.e. what I am to expect from the hospital/staff and how I/my attendants are expected to conduct while in the hospital and in other aspects relevant to hospital/staff.

3. **Valuables:**
   I understand that _____ Hospital is not responsible for my/my attendants valuables or personal articles.
4. **Release of Information:**
   I understand that the confidentiality of all medical records will be protected to the full extent of the law. I authorize _____ Hospital to release all information from my medical record, as applicable, to:
   A. Payers, organizations or insurance companies which are responsible, in whole or in part, for obtaining insurance benefits for me, for billing and/or paying my physician(s) bill, and for filing appeals of denial of benefits, so that the physician may be paid for the services provided to me;
   B. Independent auditors or review agencies retained by any third-party payers and insurers to analyze the charges for services rendered to me.
   C. In order to improve service and provide valuable input, I also authorize _____ Hospital to release my demographic information to organizations retained by them for customer satisfaction surveys.
5. **Payment:**
   I assign and authorize payment, for any treatment and all services rendered, directly to _____ Hospital from my insurance company or third-party payer including, but not limited to commercial health insurance, automobile no-fault insurance and workers disability compensation insurance etc. In consideration of the professional services provided or to be provided to me, I agree to pay all charges not covered by my insurance company or any applicable health benefit including, but not limited to, deductibles, co-payments, non-covered services. I understand that it is my personal responsibility to pay _____ Hospital all charges for services rendered despite of any disputes or disagreements between my insurance company and myself.

I have read the consent form or it has been read to me and I am satisfied that I understand its contents. My questions have been answered to my satisfaction.

By signing this form, **I acknowledge that I have been offered and/or received the _____ Hospital Patients Charter and shall abide by it.**

_____

(Signature and Thumb Impression of Patient/Legal Guardian/Patient Advocate/Parent/Next of Kin-Circle One)

(Date) _____

Ind 106. The situations where specific informed consent is required are enlisted.

Survey Process:

Review any written policy or list of situations where specific informed consent is required. Then review medical records of representative sample of patients who should have (by hospital policy) a specific informed consent to validate that it is documented in the record. This would include consent related to procedures and therapies with particular concern for anesthesia, surgery, sterilization, termination

of pregnancy and high-risk medications.

Scoring:

- If ALL reviewed records contain / document an informed consent, then score as **fully met.**
- Since this is also a medico-legal issue, if ANY records do not contain / document informed consent, then score as **not met.**

GUIDELINES

Scope of Informed Consent

Policies regarding specific informed consent

A specific informed consent shall be taken from the patient in following situations:

1. Before Surgery
2. Before anesthesia administration
3. Before transfusion of blood
4. Before any invasive procedure
5. Any High risk service or medicine

If the patient is incapable of giving consent, the next of kin or the attendant will provide consent on his/her behalf. If such patient is un-attended too, the treating doctor can give consent in the best interest of the patient.

Although the Client/Patient's general consent is obtained for the proposed care or treatment, a written consent is mandatory for any invasive procedures or operations.

The client's informed consent is a prerequisite to carry out any medical intervention and the patient has the right to refuse or to halt a medical intervention.

In different situations of health care provision or involvement of the client in any research activity, the mode of consent and action will be:

1. When a patient is unable to express his or her will and a medical intervention is urgently needed, the consent of the patient may be presumed, unless it is obvious from a previous declared 'Expression of Will' that consent would be refused in the situation.
2. When the consent of a legal representative is required and the proposed intervention is urgently needed, that intervention may be made if it is not possible to obtain the representative's consent in time.
3. When the consent of a legal representative is required, patients (whether minor or adult) must nevertheless be involved in the decision-making process to the fullest extent which their capacity allows.
4. If a legal representative refuse to give consent and the physician or other provider is of the opinion that the intervention is in the interest of the patient, then in case of a non-emergency situation, the decision must be referred to a court or some form of arbitration.

Ind 107. Informed Consent includes Information on Risks, Benefits, and Alternatives and as to who will perform the requisite procedure in a language that they can understand.

Survey Process:

This standard relates to the "informed" part of Informed Consent.[73] Review the same representative sample of records as for Ind 105 above to verify if the required information is included or not.

Scoring:

- If ALL records contain consent comprising the above information, then score as **fully met.**
- Since this is also a medico-legal issue, if ANY records do not contain consent comprising the above information, then score as **not met.**

GUIDELINES

Information about Risks, Benefits and Alternatives

It is the responsibility of the healthcare service provider that he/she should take the time to explain/discuss with the patient and his/her attendant about the:

1. Health status/clinical facts
2. Diagnosis of the problem
3. Proposed management plan
4. Expected outcome
5. Costs (expected)
6. Risks
7. Preferences/choices of patients
8. Follow up to the clients/patients
9. Right to read own medical record/file

After giving information about diagnosis, management and follow-up, the HCP should check to ensure that client/patient has understood the advice. Obtaining this feedback is vital in assessing to what extent the instructions have been understood.

Treating clients/patients with respect, actively listening to them, asking questions about their choices/preferences, praising, explaining diagnosis and management, describing the follow-up plan, and taking feedback about their understanding of the given advice/choice are all very important components of health care delivery.

The person performing the procedure shall be responsible for the entire consent process including providing explanation and taking the signature. A team member can take consent on behalf of the person performing the procedure, but their name and designation must be clearly mentioned in the chart.

When the patient does not speak or understand the predominant language of the community, the hospital will make efforts to ensure that proper interpretation is done if it is possible to provide an appropriate interpreter for the same.

The informed consent process adheres to statutory norms including:

[73] Sample provided in Guidelines.

1. Taking consent before the procedure
2. At least one independent witness signing the form.
3. Taking consent every time (especially for procedures which the patient has to undergo their whole lives). However, the repeat consent could be verbal for the same procedure e.g. dialysis.
4. Taking a fresh consent (for the new procedure) in case the procedure has to be changed during course of treatment/procedure.
5. Appropriate information is provided to clients/patients and their families, in a way that they can understand, on the proposed treatment, the costs, the risks and benefits of the proposed treatment or investigation, and the alternatives available.
6. Clients/Patients and their families are fully informed about the client's/patient's health status, including the clinical facts about their condition, unless there is an explicit request not to disclose a particular information to the patient/relatives.

Table 27: Sample Consent Form

<table>
<tr><td rowspan="6">Patient's Informed Consent to Treatment or Investigation
{To be filled by Treating Consultant}
(Page l of 2)</td><td>Name of HCE:</td><td>Patient's Reg. #:</td></tr>
<tr><td colspan="2">Patient's name:</td></tr>
<tr><td colspan="2">NIC#:</td></tr>
<tr><td colspan="2">S/O, D/O, W/O:</td></tr>
<tr><td>Age:</td><td>Sex:</td></tr>
<tr><td colspan="2">Address:</td></tr>
<tr><td colspan="3">Diagnosis:</td></tr>
<tr><td colspan="3">Declaration of Doctor/Proceduralist (to be completed by the clinician obtaining consent)</td></tr>
<tr><td colspan="3">Tick the boxes or cross out and initial any changes or information not appropriate to the stated procedure
1. I have informed the patient of the treatment options available, and the likely outcomes of each treatment option, including known benefits and possible complications. (State options)
2. I have recommended the treatment/procedures/investigations noted below on this form.
3. I have explained the treatment/procedures/investigations, identified below, and what is entailed for the patient.
4. I have provided the patient with information specific to the procedure identified. The patient has been asked to read information provided and ask the doctor/proceduralist questions about anything that is unclear.
5. I have provided to the patient an identifiable copy of the information which has been kept on the patient's medical record.
6. Information provided to the patient includes:

Open access procedures
I have given the patient opportunity to discuss the proposed procedure, benefits and risks, both general and specific, and the risk of not having the procedure.

Other procedures
I have discussed the alternative procedures, benefits and risks, both general and specific, and the risks of not having the procedure.</td></tr>
</table>

Prepared medications are labelled prior to preparation of a second drug

List the treatment/procedures/investigation to be performed, noting correct side/correct site

This procedure requires:

a) General and/or Regional Anaesthesia b) Local Anaesthesia c) Sedation

An anaethetist will explain the risk of general or regional anaesthesia to the patient at least 12 hours prior to the treatment.

Disclosure of material risks

Material risks or specific risks particular to this patient that have arisen as a result of our discussions are:

Signature of doctor/proceduralist obtaining consent

Full name (please print) _____
Position/Title _____

Signature _____

Date _____

Signature of doctor/proceduralist with overall responsibility for treatment (if different)

Full name (please print) _____
Position/Title _____

Signature _____

Date _____

Please Note: A separate consent form (signed by the patient/relative) for blood transfusion as per relevant protocols is mandatory.

Patient Consent to Treatment or Investigation **(Page 2 of 2)**	Name of HCE:	Patient's Reg. #:
	Patient's name:	
	NIC#:	
	S/O, D/O, W/O:	
	Age:	**Sex:**
	Address:	
	Diagnosis:	

Patient's declaration

Please read the information carefully and tick the following to indicate you have understood and agreed with the information provided to you. Any specific concerns should be discussed with your doctor or proceduralist performing the procedure ***prior to signing the consent form***.

1. The doctor/proceduralist has explained my medical condition and prognosis to me. The doctor/proceduralist also explained the relevant diagnostic, treatment options that are

available to me and associated risks, including the risks of not having the procedure.

2. The risks of the procedure have been explained to me, including the risks that are specific to me and the likely outcomes. I have had an opportunity to discuss and clarify any concerns with the doctor or proceduralist.
3. I understand that the result/outcome of the treatment/procedure cannot be guaranteed.
4. I understand that if I am treated as a public patient, no guarantee can be provided that a particular doctor/proceduralist will perform the procedure, and that the doctor/proceduralist performing the procedure may be undergoing Post Graduate training under supervision of the consultant. (The hospital should define that a PG trainee is authorized to perform a procedure in which year and whether supervised or unsupervised).
5. I understand that tissue samples and blood removed as part of the procedure or treatment will be used for diagnosis and common pathology practices (which may include audit, training, test development and research), and will be stored or disposed of sensitively by the hospital.
6. I understand that a photograph, if taken during examination/procedure or treatment, will be used for academic purposes only and that too ensuring confidentiality and privacy.
7. If a staff member is exposed to my blood, I consent to a sample of blood being collected and tested for infectious diseases. I understand that I will be informed if the sample is tested, and that I will be given the results of the tests.
8. I agree for my medical record to be accessed by staff involved in my clinical care and for it to be used for approved quality assurance activities, including clinical audit.
9. I understand that if immediate life-threatening events happen during the procedure, I will be treated accordingly.
10. I understand that I have the right to change my mind at any time before the procedure is undertaken, including after I have signed this form. I understand that I must inform my doctor if this occurs.
11. I consent to undergo the procedure/s or treatment/s as documented on this form.
12. I consent to a blood transfusion, if needed O Yes O No

Please Note: A separate consent form for blood transfusion as per relevant protocols is also to be signed.

Patient's full name: _____

Patient's signature: _____

Date/Time: _____

Parent/guardian signature: _____

Date/Time: _____

(if desired for mature minor)

Interpreter's declaration

Specific language requirements (if any): _____

Interpreter services required: O Yes O No

I declare that I have interpreted the dialogue between the patient and health practitioner to the best of my ability, and have advised the health practitioner of any concerns about my performance.

Interpreter's signature: _____

Date: _____

Full name (please print): _____

Confirmation of consent at pre-admission or admission to hospital

I confirm that the request and consent for the operation/procedure/treatment above remains current.

Patient's signature: _____

Date/Time: _____

(Patient/Person responsible)

Ind 108. The policy describes who can give Consent when patient is incapable of independent decision-making.

Survey Process:

Review the policy to determine who is authorized to give consent in addition to the patient when the patient is incapable of independent decision making.

Scoring:

- If there is a policy describing who, other than the patient, may give informed consent, then score as **fully met.**
- If there is no policy, then score as **not met.**

GUIDELINES

Policy Regarding Consent for Incapacitated Patient

The HCE shall take into consideration the statutory norms. This would include taking of consent from next of kin/legal guardian. The order of preference is; spouse, son, daughter, brother, sister, parents. However, in case of unconscious/unaccompanied patients the treating doctor can take a decision in life-saving circumstances.

Scope of Informed Consent

Although the Client/Patient's general consent is obtained for the proposed care or treatment, a written consent is mandatory for any invasive procedures or operations.

The client's informed consent is a prerequisite to carry out any medical intervention and the patient has the right to refuse or to halt a medical intervention.

In different situations of health care provision or involvement of the client in any research activity, the mode of consent and action will be:

1. When a patient is unable to express his or her will and a medical intervention is urgently needed, the consent of the patient may be presumed, unless it is obvious from a previous declared 'Expression of Will' that consent would be refused in the situation.
2. When the consent of a legal representative is required and the proposed intervention is urgently needed, that intervention may be made if it is not possible to obtain the representative's consent in time.
3. When the consent of a legal representative is required, patients (whether minor or adult)

must nevertheless be involved in the decision-making process to the fullest extent which their capacity allows.

4. If a legal representative refuses to give consent and the physician or other provider is of the opinion that the intervention is in the interest of the patient, then in case of a non-emergency situation, the decision must be referred to a court or some form of arbitration.
5. In all other situations where the patient is unable to give informed consent and where there is no legal representative or representative designated by the patient for this purpose, appropriate measures should be taken to provide for a substitute decision making process, taking into account what is known and, to the greatest extent possible, what may be presumed about the wishes of the patient.
6. The consent of the patient is required for the preservation and use of all substances of the human body. Consent may be presumed when the substances/body part are to be used in the current course of diagnosis, treatment and care of that patient.
7. The informed consent of the patient is needed for participation in clinical teaching/research.

Assessment Scoring Matrix

Standard 26. PRE-1: PRE-1: Process for obtaining patient and/or family consent for informed decision making about their care are documented.

Indicator 105-108		Max Score	Weightage (Percent)	Score Obtained
Ind 105.	**General Consent for treatment / declaration on admission is obtained, Patient and Family Members are Informed of its Scope.**	10	**100**	
Ind 106.	**The situations where specific informed consent is required are enlisted.**	10	**100**	
Ind 107.	**Informed consent includes information on risks, benefits, and alternatives and as to who will perform the requisite procedure in a language that they can understand.**	10	**100**	
Ind 108.	**The policy describes who can give consent when patient is incapable of independent decision-making.**	10	**100**	
Total		40		

Standard 27. PRE-2: Patient and families have a right to information on expected costs.

Indicators (109-111):

Ind 109. There is uniform category specific Pricing Policy in a given setting (outdoor/In door/diagnostics) and the charges list is available to the patient.

Survey Process:

Visit the finance or billing office and review the policy and verify that it is uniformly applied to the respective categories of patients / for various categories of procedures/ interventions / treatments. Also review the charges list and then ask how it is made available to a patient. Customarily this is only upon the patient's request who should be made aware that the charges list is available on demand.

Scoring:

- If the policy is uniformly applied across the categories of patients and for the respective treatments and charges list is available to the patients on demand, then score as **fully met.**
- If there is evidence that it is not uniformly applied, then score as **not met.**

GUIDELINES

Tariff Policy

There should be a Tariff/Billing/Price policy which defines the charges to be levied for various activities/procedures. The policy shall be clearly activity/procedure based.

The HCE shall ensure that there is an updated tariff list and that this is available to patients when required. The HCE shall charge as per the tariff list without any hidden costs whatsoever. Any additional charge should also be enumerated in the tariff and the same communicated to the patients with a clear and justified explanation. Tariff rates should be uniform and transparent.

The Reception Area/Almoner Department/Account Section and wards display information about the tariff/Price policy of the HCE which shall include:

1. The rights of the clients/patients.
2. Services and facilities available in the hospital.
3. Costs of services.
4. Feedback and complaints pathways.

Ind 110. Patients and family are educated about the estimated costs of treatment.

Survey Process:

Review the process used to inform/educate the patient and/or family about the estimated costs /

charges. Also determine if this is done by someone who is authorized.[74]

Scoring:

- If there is a process to inform patients and/or families about the estimated costs and it is done by an Authorized person, then score as **fully met.**
- If there is a process to inform patients and/or families about the estimated costs but it is not done or is done by an unauthorized person, then score as **partially met.**
- If there is no process, then score as **not met.**

GUIDELINES

Information about Estimated Cost of Treatment

The patient and/or family members are explained about the expected costs.

Patients should be given an estimate of the expenses on account of the treatment/investigations to be performed in different settings, preferably in a written form. This estimate shall be prepared on the basis of the treatment/management plan. For example, a family attending the hospital for antenatal care must be informed about the cost of prospective C-Section, in case the Spontaneous Vaginal Delivery (SVD) does not take place. Similarly, a patient requiring long term care such as cases of chronic illnesses/cancerous diseases should also be informed of the likely expenses.

It could be prepared by the OPD/Registration/Admission staff in consultation with the treating doctor.

Ind 111. Patients and family are informed about the financial implications when there is a change in the patient condition or treatment setting.

Survey Process:

Review the process. Determine what prompts informing the patient and/or family about the financial implication when there is change in the treatment setting on the basis of patient condition and also determine who makes the decision and who provides the information.

Scoring:

- If there is a consistent process, including when it is done, who makes the decision, and who provides the information, then score as **fully met.**
- If there is a process, but there are no clear guidelines of when it is done, then score as **partially met.**
- If there is no process, then score as **not met.**

GUIDELINES

Information about Financial Implications

When patients are shifted from one setting to another, typically to and from ICUs, other specialized care facilities, the financial implications must be clearly conveyed to them. This information should

[74] A person authorized by the management should have adequate knowledge for satisfying the patients/relatives.

be communicated by a person who is authorized and fully conversant with the process, outcome of such communications and is able to answer the counter questions amicably with a cool mind and correctly.

For example, a family attending the hospital for antenatal care must be informed about the cost of prospective C-Section, in case the SVD does not take place. Similarly a patient requiring long term care such as cases of chronic illnesses/cancerous diseases should also be informed of the likely expenses.

Assessment Scoring Matrix

Standard 27. PRE. 2: Patient and families have a right to information on expected costs.

Indicator 109-111		Max Score	Weightage (Percent)	Score Obtained
Ind 109.	**There is uniform category specific pricing policy in a given setting (outdoor/Indoor/diagnostics) and the charges list is available to the patient.**	10	**100**	
Ind 110.	**Patients and family are informed about the estimated costs of treatment.**	10	**80**	
Ind 111.	**Patients and family are informed about the financial implications when there is a change in the patient condition or treatment setting.**	10	**80**	
Total		30		

Standard 28. PRE-3: Patient Rights for Appeals and Complaints.

Indicators (112-114):

Ind 112. The patients are informed of the right to express relevant concern or complain either verbally or in writing and the documented process for receiving and investigating complaints is fair and timely.

Survey Process:

Review the process about informing the patient of his / her right to complain and determine how policies are implemented. Also review the process of receiving and investigating the complaints and determine through records how the same are implemented.

Scoring:

- If there are processes to handle complaints including receiving and investigating and records that these are implemented according to the prescribed processes, then score as **fully met.**
- If there are processes to handle complaints but no record available how these are implemented, then score as **partially met.**
- If there is no appeal process, then score as **not met.**

GUIDELINES

Right to Express Concern or Complain

An institutionalized, accessible and transparent grievance redress mechanism must be in place. The information as how to lodge a complaint must be clearly displayed in the local language at prominent places.

Complaint is an expression of client dissatisfaction and a way of feedback on the quality of care which needs a response. Every Healthcare facility should inform the clients/patients about their right to complain and the complaint handling procedures. A complaint may be written or verbal and be lodged by the patient, his/her attendants or a legally authorized person. Various ways should be adopted, for example:

1. Display the message clearly in the local language at prominent places in the facility such as registration desk, waiting area, OPDs, main entrance and private rooms etc.
2. Pertinent information may be made available in the form of leaflets/brochures at appropriate places.
3. Client feedback/satisfaction must be sought on a prescribed but simple format at the time of discharge. (Format attached as **Annexure Q**).

Complaint Management Procedure

To become a quality driven service, a facility should encourage the clients and their family members to freely raise and discuss their views, concerns or complaints with the concerned staff. These

dialogues help and serve as opportunities for improvement. Every HCE must have a documented grievance redressal procedure, entailing collecting, prioritizing, investigating, resolving and reporting complaints. A proposed format for the Complaint Management Procedure is attached at **Annexure R**. The complaints against service providers that carry client's perspective should be handled first by the manager/concerned HoD/unit. For example, the OPD in-charge should tackle the complaints, verbal or written, related to the OPD and should take remedial action there and then. In case actions are beyond his/her mandate he/she, must refer it to the Complaint Cell.

A Complaint Cell should be established at every hospital and resourced properly. The complaint cell shall essentially comprise of a core staff and be headed by a manager appointed by the HCE and be supported by a team of experts Complaint Management Committee (CMC). The department/specialist against whom a complaint is received/under investigation will not be part of the committee for that particular case. The CMC may co-opt an expert for assistance. Every complaint must be thoroughly investigated and documented. The complaint cell will maintain department wise records of complaints investigated and actions taken. A record of the Complaint Register must lie in the office of the MS or In-charge of the health facility, with the complete number and details of complaints received and action taken.

The detailed policy of the HCE for documentation of the processes should define credible and transparent mechanism for receiving and handling complaints against the functioning of the HCE and practice of its staff. This mechanism should be used fairly and timely for collecting, prioritizing, reporting and investigating complaints. To ensure that measures for patient complaint system are effective and efficient, they should be well-targeted and focused to address the identified problems.

Ind 113. The Hospital informs the patient of the progress of the investigation at regular intervals and informs about the outcome.

Survey Process:

Review the process and determine how the policies are implemented. Review files that include all the elements associated with managing a complaint and demonstrate the progressive follow-up with complainants.

Scoring:

- If there are processes to inform the patients about the progress of the investigation and the outcome, and records reflect that the policies are implemented, then score as **fully met.**
- If there are processes to inform the patients about the progress of the investigation and about the outcomes but no record available on how the policies are implemented, then score as **partially met.**
- If there are no processes to inform the patients about the progress and the outcome of the investigation, then score as **not met.**

GUIDELINES

Information about Progress of Investigation and Outcome

It is important that client/patient is informed of the level at which the complaint can be handled. This duty should be clearly entrusted to a designated staff member of the complaint cell/department of the HCE. The client should be kept informed about the progress of the

investigation at regular intervals, in case these are prolonged, and also of the outcome. This will help to build the credibility of the process/facility.

Ind 114. The Hospital uses the results of complaints investigations as part of the quality improvement process.

Survey Process:

Review the process and documentation to identify and observe actual examples of changes in the policy and procedure that have been made as a result of complaints analysis.

Scoring:

- If there is a quality improvement process which uses complaint-handling data and reports in this regard are available, then score as **fully met.**
- If there is a quality improvement process to use complaint handling data but no evidence available how that data was used for improvement, then score as **partially met.**
- If there is no quality improvement process about using complaint-handling data, then score as **not met.**

GUIDELINES

Feedback and Quality Improvement

Transparency of decisions must be ensured and the verdicts of inquiries should not be biased in favour of the facility staff. If professional misconduct or negligence is involved then it should be forwarded to the professional regulatory body at the appropriate level, by the in charge of the HCE. Most importantly the result of the inquiry should be taken in a positive manner and an executive committee of the HCE should ensure that the remedial measures suggested by the CMC as an outcome of the inquiry should be implemented/enforced for the improvement of the system forthwith.re such as cases of chronic illnesses/cancerous diseases should also be informed of the likely expenses.

Feedback from clients includes both compliments (satisfaction) and complaints (dissatisfaction) about quality of care. Client/patients feedback should be valued, as this would help the HCE to improve quality of services.

The hospital should have mechanisms to obtain feedback as an on-going process. The feedback mechanisms should be culturally appropriate and feasible and may include:

1. A suggestion/complaint box at the facility that may be used by the literate clients.
2. Periodic clients exit interviews.
3. Key informant interviews on periodic basis (within community).
4. Mystery client survey.
5. Focus group discussions.

HCEs should devise a method and frequency of feedback mechanisms to seek the experiences of clients about the quality of care. The HCE management should decide on a method for itself, depending upon its needs and resources. However, a hospital should allocate sufficient resources, as these will be required to hire people for conducting and analyzing such exercises.

Assessment Scoring Matrix

Standard 28. PRE. 3: Patient Rights for Appeals and Complaints.

Indicator 112-114		Max Score	Weightage (Percent)	Score Obtained
Ind 112.	**The patients are informed of the right to express relevant concern or complain either verbally or in writing and the documented process for receiving and investigating complaints is fair and timely.**	10	**80**	
Ind 113.	**The Hospital informs the patient of the progress of the investigation at regular intervals and informs about the outcome.**	10	**80**	
Ind 114.	**The Hospital uses the results of complaints investigations as part of the quality improvement process.**	10	**80**	
Total		30		

2.10 Hospital Infection Control (HIC)

02 Standards & 08 Indicators

Prevention of Healthcare Associated Infections (HAIs) represents one of the major safety initiatives a hospital can undertake. A large number of patients admitted to hospitals acquire infections that were not related to the condition for which they were hospitalized, which results in a considerable number of deaths and add to treatment costs. These standards provide the framework for hospitals to develop and implement plans to prevent and control infections by using an integrated approach across all programs, services and settings. The standards call on healthcare establishments to educate and collaborate with leaders throughout the hospital, including physicians, to participate in the design and implementation of an effective Infection Control Program.

Standard 29. HIC-1: The Hospital has a comprehensive infection control programme aimed at reducing/eliminating risks to patients, visitors and care providers.

Indicators (115-119):

Ind 115. The hospital infection control plan is documented which aims at preventing and reducing risk of nosocomial infections.

Survey Process:

There should be a written hospital infection control plan. The plan should identify at least: 1. The surveillance activities, 2. Hand hygiene procedures, 3. Isolation procedures, and 4. The responsibilities and authorities of an Infection Control Committee.

Scoring:

- If there is a documented infection control plan that includes at least surveillance activities, hand hygiene procedures, isolation procedures, and the responsibilities and authorities of an Infection Control Committee, then score as **fully met.**
- If there is either no written plan, or it does not include any one of the above 4 requirements, then score as **not met.**

GUIDELINES

Documented Hospital Infection Control (HIC) Program

Nosocomial Infection Surveillance

Surveillance is a systematic, active on-going observation of the occurrence and distribution of a disease within a population and of the events that increase or decrease the risk of the disease occurrence.

Types of surveillance.

Surveillance can be passive or active, depending on the way the data is collected.

1. **Passive surveillance**

   Criteria are established for reporting diseases, risk factors or health-related events. Health practitioners are notified of the requirements and they report events as they come to their attention. This is the more common type of surveillance.

2. **Active surveillance**

   Criteria are established for reporting disease (or its absence), risk factors or health events, but those maintaining the surveillance system initiate reporting. Active surveillance is used when there is an indication that something unusual is occurring.

Nosocomial Infection Rate as the first step to identify local problems and priorities, and evaluate the effectiveness of IC activity. Surveillance, by itself, is an effective process to decrease the frequency of hospital-acquired infections.

1. **Objectives:**

   The ultimate aim of surveillance programme is the reduction of nosocomial infections and the

cost of treatment whereas the specific objectives include:

A. To improve awareness of the clinical staff and other hospital workers (including administrators) about nosocomial infections and antimicrobial resistance so that they may appreciate the need for preventive action.
B. To identify possible areas for improvement in patient care.

2. Implementation at the hospital level

A. General Surveillance: The Infection Control Team is responsible for general monitoring and surveillance of the hospital including the patients' beds, wash rooms, corridors and other patient care area. The team will see if the waste segregation is practiced from the point of generation to the disposal. In view of the Dengue fever risk it will be ensured that water is not let to stay uncovered.

B. Microbial Surveillance: Operation Theatre Sterilization by Fumigation.docx Swabs from OT are collected every month for culture. The OT Assistant (member of the HIC Committee). The swabs are collected from the 6 sites including OT table, floor, light, air, Anesthesia Machine and AC filter. External validation will be carried out every six months. The periodicity of microbial surveillance can be shortened as per the advice of the surgeon or the anesthetist depending upon the number of surgeries and nature of the procedures.

3. Infection Control Practices

Infection control practices can be grouped in two categories:

A. Standard Precautions: Transmission of infections in healthcare facilities can be prevented and controlled through the application of basic IC precautions which can be grouped into Standard Precautions, that must be applied to all patients at all times, regardless of diagnosis or infectious status

B. Additional Precautions: Which are specific to modes of transmission or transmission-based i.e. airborne, droplet and contact.

Standard Precautions:

Treating all patients in the healthcare facility with the same basic level of "standard" precautions involves work practices that are essential to provide a high level of protection to patients, healthcare workers and visitors.

These include the following:

1. Hand washing and antisepsis (hand hygiene).
2. Use of Personal Protective Equipment (PPE) when handling blood, body substances, excretions and secretions.
3. Appropriate handling of patient care equipment and soiled linen.
4. Prevention of needle prick/sharp injuries.
5. Environmental cleaning and spills-management.
6. Appropriate handling of waste.

1. HAND HYGIENE

Appropriate hand washing can minimize micro-organisms acquired on the hands by contact with body fluids and contaminated surfaces. Hand washing breaks the infection transmission chain and reduces person-to-person transmission. All healthcare personnel and family caregivers of patients must practice effective hand washing. Patients and primary care givers need to be instructed in proper techniques and situations for hand

washing.

Compliance with hand washing is, however, frequently sub -optimal. Reasons for this include: lack of appropriate equipment; low staff to patient ratios; allergies to hand washing products; insufficient knowledge among staff about risks and procedures; the ti me required; and casual attitudes among staff towards bio-safety.

Purpose:

Hand washing helps to remove micro-organisms that might cause disease. Washing with soap and water kills many transient micro-organisms and allows them to be mechanically removed by rinsing. Washing with antimicrobial products kills or inhibits the growth of micro-organisms in deep layers of the skin. Use of alcohol-based gel is the preferred method of hand cleansing.

Types of Hand Washing:

Simple hand washing is usually limited to hands and wrists; the hands are washed for a minimum of 10 - 15 seconds with soap (plain or antimicrobial) and water.

Hand antisepsis/decontamination removes or destroys transient micro-organisms and confers a prolonged protective effect. It may be carried out in one of the following two ways;

A. Wash hands and forearms with antimicrobial soap and water, for 15-30 seconds (following manufacturer's instructions).
B. Decontaminate hands with a waterless, alcohol-based hand gel or hand rub for 15-30 seconds. This is appropriate for hands that are not soiled with protein matter or fat. Immersion of hands in bowls of antiseptics is not recommended.

Surgical hand antisepsis removes or destroys transient micro-organisms and confers a prolonged effect. Hands and forearms are washed thoroughly with an antiseptic soap for a minimum of 2-3 minutes and are dried using a sterile towel. Surgical hand antisepsis is required before performing invasive procedures.

Facilities and Materials Required For Hand Washing

Running water

Access to clean water is essential. It is preferable to have running water, large washbasins having anti-splash devices, hands-free controls requiring little maintenance.

When running water is not available use either a bucket with a tap, which can be turned on and off, a bucket and pitcher, or 60% - 90% alcohol hand rub.

Materials Used For Hand Washing/Hand Antisepsis:

Use plain or antimicrobial soap depending on the procedure.

Plain Soap: Used for routine hand washing, available in bar, powder or liquid form.
Antimicrobial Soap: Used for hand washing as well as hand antisepsis.

A. If bar soaps are used: Use small bars with soap racks that can be drained.
B. Do not allow bar soap to sit in a pool of water as it encourages the growth of some micro-organisms such as pseudomonas.
C. Clean dispensers of liquid soap thoroughly every day.
D. When liquid soap containers are empty they must be discarded, not refilled with soap solution.

Specific antiseptics recommended for hand antisepsis:

A. 2%-4% chlorhexidine
B. 5%-7.5% povidone iodine

C. 1% triclosan
D. 70% alcoholic hand rubs

Waterless, alcohol-based hand rubs: with antiseptic and emollient gel and alcohol swabs, which can be applied to clean hands. Dispensers should be placed outside each patient room.

Facilities for Drying Hands:

A. Disposable towels, reusable single use towels or roller towels, which are suitably maintained, should be available.
B. If there is no clean dry towel, it is best to air-dry hands.
C. Equipment and products are not equally accessible to all HCEs. Flexibility in products and procedures, and sensitivity to local needs will improve compliance.
D. In all cases, the best possible procedure should be instituted.

Hand Washing Steps:

Preparing for hand washing:

A. Remove jewelry (rings, bracelets) and watches before washing hands.
B. Ensure that the nails are clipped short (do not wear artificial nails).
C. Roll the sleeves up to the elbow.
D. Wet the hands and wrists, keeping hands and wrists lower than the elbows (permits the water to flow to the fingertips, avoiding arm contamination).
E. Apply soap (plain or antimicrobial) and lather thoroughly.
F. Use firm, circular motions to wash the hands and arms up to the wrists, covering all areas including palms, back of the hands, fingers, between fingers and lateral side of fifth finger, knuckles, and wrists. Rub for minimum of 10-15 seconds.
G. Repeat the process if the hands are very soiled.
H. Clean under the fingernails.
I. Rinse hands thoroughly, keeping the hands lower than the forearms.
J. If running water is not available, use a bucket and pitcher.
K. Do no dip your hands into a bowl to rinse, as this re contaminates them.
L. Collect used water in a basin and discard in a sink, drain or toilet.
M. Dry hands thoroughly with disposable paper towel or napkins, clean dry towel, or air dry them.
N. Discard the towel if used, in an appropriate container without touching the bin lids with hand.
O. Use a paper towel, clean towel or your elbow/foot to turn off the faucet to prevent recontamination.
P. A general procedure for hand washing is given in the figure below and must be conducted over at least one full minute using antiseptics, hand rubs, gels or alcohol swabs for hand antisepsis.
Q. Apply the product to the palm of one hand. The volume needed to apply varies by product.
R. Rub hands together, covering all surfaces of hands and fingers, until hands are dry.
S. Do not rinse.
T. When there is visible soiling of hands, they should first be washed with soap and water before using waterless hand rubs gels or alcohol swabs.
U. If soap and water are unavailable hands should first be cleansed with detergent

containing towelettes, before using the alcohol-based hand rub, gel or swab.

Figure 16 Hand Washing Steps Summarized

A surgical scrub is performed before each surgical procedure with the aim of removing and killing the transient flora and decreasing the resident flora in order to reduce the risk of wound contamination if surgical gloves become damaged. It ensures the removal or killing of transient micro-organisms and a substantial reduction and suppression of the resident microbial flora. Agents are the same as for the hygienic hand wash.

2. Personal Protective Equipment (PPE)

Adequate and appropriate PPE, soaps, and disinfectants should be available and used correctly. These should be available at the point of use and the organization shall ensure that it maintains an adequate inventory and stock of items.

Using PPE provides a physical barrier between micro-organisms and the wearer and offers protection by helping to prevent micro-organisms from:

A. Contaminating hands, eyes, clothing, hair and shoes.
B. Being transmitted to other patients and staff.

PPE includes:

A. Gloves
B. Protective eye wear (goggles)
C. Masks
D. Aprons
E. Gowns
F. Boots/shoe covers
G. Caps/hair covers

PPE should be used by:

A. Healthcare workers who provide direct care to patients and who work in situations where they may have contact with blood, body fluids, excretions or secretions.
B. Support staff including medical aides, cleaners, and laundry staff in situations where they may have contact with blood, body fluids, secretions and excretions.
C. Laboratory staff, who handle patient specimens.
D. Family members who provide care to patients and are in a situation where they may have contact with blood, body fluids, secretions and excretions.

Principles for use of PPE:

PPE reduces, but does not completely eliminate, the risk of acquiring an infection. It is important that it is used effectively, correctly, and at all times where contact with blood and body fluids of patients may occur. Continuous availability of PPE and adequate training for its proper use are essential. Staff must also be aware that use of PPE does not replace the need to follow basic IC measures such as hand hygiene.

The following principles guide the use of PPE:

A. PPE should be chosen according to the risk of exposure. The healthcare worker should assess whether they are at risk of exposure to blood, body fluids, excretions or secretions and choose their items of personal protective equipment according to this risk.
B. Avoid any contact between contaminated (used) PPE and surfaces, clothing or people outside the patient care area.

Examples of use of PPE:

A. Discard the used PPE in appropriate disposal bags, and dispose off as per the policy of the hospital.
B. Do not share PPE.
C. Change PPE completely and thoroughly wash hands each time you leave a patient to attend to another patient or another duty.

3. Patient care equipment

Handle patient care equipment soiled with blood, body fluids secretions or excretions with care, in order to prevent exposure to skin and mucous membranes, clothing and the environment. Ensure all reusable equipment is cleaned and reprocessed appropriately before being used on another patient.

4. Prevention of needle prick/sharps injuries

Take care to prevent injuries when using needles, scalpels and other sharp instruments or equipment. Place used disposable syringes and needles, scalpel blades and other sharp items in a puncture-resistant container with a lid that closes and is located close to the area in which the item is used. Take extra care when cleaning sharp reusable instruments or equipment. Never recap or bend needles. Sharps must be appropriately disinfected and/or destroyed as per the national standards or guidelines.

5. Cleaning of the hospital environment

Routine cleaning is important to ensure a clean and dust-free hospital environment. There are usually many micro-organisms present in "visible dirt", and routine cleaning helps to eliminate this dirt. Administrative and office areas with no patient contact require normal domestic cleaning. Most patient care areas should be cleaned by wet mopping. Dry sweeping is not recommended. The use of a neutral detergent solution improves the quality of cleaning.

Hot water (80°C) is a useful and effective environmental cleaner. Bacteriological testing of the environment is not recommended unless seeking a potential source of an outbreak. Any areas visibly contaminated with blood or body fluids should be cleaned immediately with detergent and water.

Isolation rooms and other areas that have patients with known transmissible infectious diseases should be cleaned with a detergent/disinfectant solution at least daily. All horizontal surfaces and all toilet areas should be cleaned daily.

6. Management of Healthcare Waste

A. Uncollected, long stored waste or waste routing within the premises must be avoided.
B. A sound waste management system needs to be developed and closely monitored.

Additional Precautions (transmission- based)

Additional (transmission-based) precautions are taken while ensuring Standard Precautions are maintained. Additional precautions include:

A. Airborne precautions
B. Droplet precautions
C. Contact precautions

Isolation Procedures

Isolation for the control of infection (Infection Control Measures Against Viral Infections) is used to prevent infected patients from infecting others (source isolation), and/or prevent susceptible patients from being infected (protective isolation). The methods of physical protection are:

A. Barrier nursing - special nursing procedures which reduce the risks of person to person transmission, especially by direct contact or by fomites.
B. Segregation into single rooms, cubicles, or plastic isolators - which reduces airborne spread to and from patients, and facilitates nursing techniques.
C. Mechanical ventilation - which reduces the risks of airborne spread by removing bacteria from the patient's room and by excluding bacteria present in the outside air from the room.

The transfer of infection by the airborne route can be controlled only by confining the patients in a single room, whether source or protective isolation. On the other hand, diseases spread by contact such as enteric fever, depends primarily on barrier nursing. The term isolation is commonly used in the sense of segregation of the patient in a single room. Barrier nursing is one of the basic components of patient isolation and can be used on its own or together with the other components. There are various **types of isolation** offering different **degrees of protection**:

A. High security isolation units: These are usually part of an infectious diseases hospital. Total environmental control is usually achieved by the use of negative pressure plastic isolators. These units are designed for treating viral pathogens such as Lassa, Marburg, and Ebola fevers.
B. Infectious diseases hospitals: These units are usually separate from other hospitals but may be situated in the premises of a general hospital with separate ventilation and nursing staff.
C. General hospital isolation units: These provide source isolation facilities for hospital-acquired infections; they also provide facilities for protective isolation and for the screening of patients with suspected infections before admission to a general ward or transfer to a communicable diseases unit.
D. Single rooms of a general ward: These provide less secure source isolation than the above because of the close proximity to other patients and sharing of nursing and

domestic staff with a general ward. Their value in protective isolation depends on the type of patient in the general ward, on the thoroughness of barrier nursing, on whether the room is self-contained (with WC), and on the type of ventilation used.

E. Barrier nursing in open wards: This can be effective in controlling infections transferred by contact but not by air.

F. Isolators in open wards: Plastic enclosures for individual patients have been shown to be of value as a form of protective isolation for high risk patients and of source isolation for infected patients.

G. Ultra-clean wards: Experimental units have been set up in specialized centers for organ transplantation, treatment of leukaemia and other diseases associated with extreme susceptibility to infection.

Ind 116. The hospital has an Infection Control Committee and designated a qualified infection control nurse / officer for this activity.

Survey Process:

Review the constitution and the minutes of meeting of the Infection Control Committee which should include doctors and nurses. Also review the job description of the infection control nurse / officer to determine the required qualifications. Then review the personal file/s for the individual(s) to validate if the qualifications match the requirements of the job description. (Roles, responsibilities of committee are provided in the Guidelines).

Scoring:

- If there is an Infection Control Committee which includes at least doctors and nurses, meets regularly with documented minutes of meeting and a designated infection control nurse / officer then score as **fully met.**
- If there is no committee, or it does not meet regularly as above and or no designated infection control nurse / officer, then score as **not met.**

GUIDELINES

Notification of Infection Control Committee

To provide a forum for multidisciplinary input, cooperation, and information sharing, the Management of the HCE must notify the Infection Control Committee (ICC) with its Composition and Responsibilities as given below;

1. Wide representation from the relevant departments: e.g.
   A. Management (Medical Superintendent/Administrator or AMS/DMS)
   B. Medical Specialist
   C. Surgical Specialist
   D. Microbiologist
   E. Operation theatre in-charge
   F. Infection Control Nurse
   G. Pharmacist
   H. In Charge Central Sterilization Services Department (CSSD)

I. In Charge Maintenance
J. In Charge Catering
K. In Charge Housekeeping
L. In Charge Sanitary services
M. Bio-Medical/Civil Engineer
N. In Charge Training

2. One member of the committee should be elected as the chairperson (who should have direct access to the head of the hospital administration, to promote program visibility and effectiveness).
3. Responsibilities of HIC Committee
4. Must meet regularly on Quarterly basis.
5. In case of an emergency, such as on an outbreak of disease, this committee must be able to meet earlier than quarterly on emergent basis.
6. Appoint an Infection Control Practitioner (ICP) (health care worker trained in the principles and practices of infection control, e.g. a doctor/physician, microbiologist or a nurse) as secretary.
7. Secretary of the Infection Control Committee (ICC) will be responsible for taking notes and preparing minutes of each meeting and reminding the Chairperson to follow up on the recommendations.
8. Oversee, monitor and evaluate the performance of the IC program and team.
9. Enforce compliance with basic IC standards.
10. Review and approve a yearly program of activity for surveillance and prevention.
11. Assess and promote improved practice at all levels of the health facility.
12. Ensure appropriate staff training in IC and safety management, provision of safety materials such as PPE and products.
13. Oversee training of health workers.
14. Oversee the development of facility specific IC manual, if needed.
15. Review epidemiological surveillance data and identify areas for intervention.
16. Report directly to the MS or Hospital Administrator and the ICC

Infection Control Nurse / Infection Control Officer

1. The criteria for designating shall either be the qualification or training or preferably a combination of both. It is preferable for Infection Control Officer (ICO)/ Infection Control Nurse (ICN) to have undergone a short term training program on IC nursing by a recognized institution. The nurse/officer in charge of IC is a member of the ICC and leads the IC Team for ensuring implementation of IC SOPs.
2. Responsibilities of ICO/ICN
   A. Develop/adapt and get IC Manual endorsed.
   B. Disseminate SOPs of IC based on the IC Manual.
   C. Coordinate and conduct training activities related to IC.
   D. Enforce minimum IC standards.
   E. Identifying and Investigating nosocomial infections.
   F. To collaborate with the microbiologist on surveillance of infection and detection of outbreaks due to improper sterilization of instruments.
   G. To liaise between Sterilization Department and clinical departments for detection and control of Hospital Acquired Infection (HAI).
   H. Carry out the surveillance program and monitor and manage critical incidents.

I. Ensuring compliance with local and national regulations.
J. Liaison with public health and with other facilities where appropriate.
K. Providing expert consultative advice to staff health and other appropriate hospital programmes in matters relating to transmission of infections.
L. Compile periodic (at least 3 monthly) reports of hospital infections.

Ind 117. The hospital has an Infection Control Team.

Survey Process:

Customarily the infection control team consists of a senior doctor, infection control nurse, a laboratory scientist/technician, someone from housekeeping, and a safety/admin officer to coordinate. The team composition can vary with the type, needs and resources of the HCEs. The role of the team is to respond to, and inform, the findings / directions of the Infection Control Committee (Ind 116) and take daily rounds in the hospital to verify that infection control policies and procedures are effectively followed. The findings of the rounds and actions taken should be documented.

Scoring:

- If there is a team having appropriate membership, it takes rounds daily which are documented as above, then score as **fully met.**
- If there is no team or its membership is not appropriate, or it takes rounds rarely or these are not documented as above, then score as **not met.**

GUIDELINES

Notification of Infection Control Team

1. An IC team will be put together with responsibility for the day-to-day activities of the IC program. Ideally 2 members (Infection Control Officer [ICO] and/or Infection Control Nurse [ICN]) should suffice as IC Team Leader 1 and 2 for most facilities although in smaller facilities this could mean a single person (part or full time) with additional IC responsibilities. These professionals may be administratively part of another unit (e.g. a microbiology laboratory, medical or nursing administration, public health services). The optimal structure shall include one Ward Nurse or other suitably trained Paramedic from each ward/department, sanitation staff and waste disposal staff but it will vary with the type, needs, and resources of the facility.
2. The In-Charge ICO/ICN is required to enforce approved IC practices directly by the ward/departmental staff as needed and enjoy a direct daily/incidental reporting relationship with senior administration.
3. The team is responsible for the day-to-day functions of IC, as well as preparing the daily/monthly/quarterly/yearly work plan for review by the infection control committee and administration.
4. These teams/individuals should be notified/put on rosters by the HCE and should have scientific and technical support/responsibilities, e.g. surveillance and research, developing and assessment policies and practical supervision, evaluation of material and products, overseeing sterilization and disinfection, ensuring the sound management of medical waste and the implementation of training programs.
5. HCEs must have access to specialists in IC, epidemiology, and infectious disease, including

physicians and infection control practitioners. Often this would mean that such access may be arranged so that these resources are available at district or provincial levels in resource constrained situations.

Ind 118. The establishment has appropriate consumables, collection and handling systems, equipment and facilities for control of infection.

Survey Process:

Observe the clinical areas and check for the presence and use of hand washing facilities in ALL care and treatment areas. Determine if there is 1. Hand washing soap/liquid, 2. Gloves, 3. Masks, 4. Single use syringes and Syringe Cutters, 5. Sharps collection containers 6. A full System of Hospital Waste Management from the point of generation to the point of destruction including hospital waste management plan and Hospital Waste Management (HWM) team, adequate cleaning equipment, consumables and the staff trained to use it effectively.

Scoring:

- If there is full system of hospital infection control including all above mentioned elements from 1-6, to serve all care and treatment areas, then score as **fully met.**
- If any one of the elements in the hospital infection control from 1-6 above is not complied with, then score as **not met.**

GUIDELINES

Resources/Facilities for Infection Control

Requirement of various materials will depend on the workload of the healthcare facility. The calculation of the daily requirement of gloves, gowns, masks, etc., helps in organizing the everyday logistics, and annual planning. An example to this calculation is given as follows:

Table 28: Calculation of Materials

Disposable Gloves		
Number of staff using gloves	S =	
Average number of gloves pairs used per staff per day	Id =	
Total number of gloves pairs used daily	Sd =	Sd = S x Id
Disinfectants		
Number of locations that need disinfectants	S =	
Average amount (***nos. or liters)*** of disinfectants used per location per day	Id =	
Total amount (***nos. or liters) of*** disinfectants used daily	Sd =	Sd = S x Id

Some general considerations are given below:

1. Use of protective clothes, shoes, gloves and masks has been described in Ind No. 144.
2. Gloves should be worn when handling bedpans and urinals. The contents should be disposed of directly into the sluice or bedpan disinfector. The bedpan or urinal should then be heat disinfected and dried. A bedpan washer/disinfector and a high temperature washing-up machine should be available in the ward.
3. All clinical waste should be disposed of in a color-coded bag for incineration.
4. Disposable or autoclavable equipment should be used whenever possible. Essential items of patient care such as sphygmomanometers and stethoscopes should be left in the room and disinfected when the patient is discharged or before being used on another patient. Hard surfaces may be disinfected by wiping with a phenolic or hypochlorite solution. Other equipment may be disinfected by wiping with 70% alcohol. Sphygmomanometer cuffs may be disinfected by low temperature steam. Thermometers should be kept in the isolation room until the patient is discharged.
5. Needles and syringes should be disposable and placed in a hardened container which is sealed before disposal.
6. Linen from infected patients should be placed in a color-coded linen bag for transfer to the laundry. Linen which may present a hazard to the laundry staff e.g. hepatitis B should first be sealed in labelled bag.
7. Disposable items may be used when a dishwasher heating the items to over 80°C is not available. Food should be placed in polythene bags and discarded with ward waste.
8. **Immunization** against Viral hepatitis and Tetanus is recommended for all personnel handling waste and infectious material with Hepatitis B vaccination/immunoglobulin if a hospital employee has not been vaccinated against Hepatitis B:
   A. Hep. B results show insufficient antibodies, Hep. B immunoglobulin must be administered within 72 hours.
   B. If sufficient antibodies are present, a Hep. B vaccination booster will only be required.
   C. A Tetanus injection will be required if not received within the last 5 -10 years.
   D. HIV/Hep. C results must be collected (in person) within 7 days.
      (i) Follow-up blood tests (after 1st initial blood test)
      (ii) Further blood tests will be required for

E.	Hepatitis B	3 months after injury (titer levels)
F.	Hepatitis C	3 months after injury, then 6 months
G.	HIV	3 months after injury, then 6 months

Ind 119. ALL staff involved in the generation, handling and disposal of medical waste shall receive regular training and ongoing education in the infection control and safe handling of medical waste.

Survey Process:

Identify the staff who conducts training in infection control and review the training manual. Speak with a range of staff involved with the generation, handling and management of medical waste to determine their level of training and applied knowledge. This should include the staff hired on temporary or short-term basis. The system employed by the healthcare establishment should

encompass the full process on site and include what happens once the waste leaves the site. Adequate systems, facilities, safety equipment/consumables and training should be observable.

Scoring:

- If there is evidence of training of the staff on infection control including HWM System at induction and when the new System are introduced, or when new component, consumables or equipment related to IC and hospital waste are employed, then score as **fully met.**
- If there is no training at all or training takes place when ONLY some of the above factors prevail, OR if any one of the above conditions are not fulfilled, score as **not met.**

GUIDELINES

Training in Safe Handling of Medical Waste

1. Health administrators should be oriented towards the importance of the IC program. Healthcare workers should be equipped with requisite knowledge, skills and attitudes for good IC practices. The ICC should:
   A. Assess training needs of the staff and provide required training through awareness programs, in-service education and on-the-job training.
   B. Organize regular training programs for the staff for essential IC practices that are appropriate to their job description.
   C. Provide periodic re-training or orientation of staff.
   D. Review the impact of training.
2. All staff who work in areas where infectious waste is handled, is trained on the hazards of waste, management of waste and IC. All staff shall be trained in and use procedures for different types of waste;
   A. Collection
   B. Segregation at source
   C. Storage
   D. Transportation
3. Hospital waste is regulated by the Khyber Pakhtunkhwa Hospital Waste Management Rules, 2018. According to the rules, every hospital shall be responsible for the proper management of the waste, through developing a 'Hospital Waste Management Plan'. The plan will be facility specific, containing a list of activities, quantify of required materials with cost and timeline. Development of the plan is the responsibility of Waste Management Officer (a designated member of the Hospital Waste Management Team (HWMT), detail are given under relevant Section. The plan will be reviewed and finalized by the Hospital WMT and should aim to:
   A. Protect public health and safety.
   B. Provide a safer working environment.
   C. Minimize waste generation and environmental impacts of waste treatment/disposal.
   D. Ensure compliance with legislative requirements.

Clinical and municipal waste is segregated at the point of source in colour coded bins, as given at ***Annexure S****.*

Assessment Scoring Matrix

Standard 29. HIC. 1: The Hospital/HCE has a well-designed, comprehensive and coordinated infection control programme aimed at reducing/ eliminating risks to patients, visitors and care providers.

Indicator 115-119		Max Score	Weightage (Percent)	Score Obtained
Ind 115.	**The hospital infection control plan is documented which aims at preventing and reducing risk of nosocomial infections.**	10	**100**	
Ind 116.	**The hospital has an Infection Control Committee and designated a qualified infection control nurse / officer for this activity.**	10	**100**	
Ind 117.	**The hospital has an infection control team.**	10	**100**	
Ind 118.	**The establishment has appropriate consumables, collection and handling systems, equipment and facilities for control of infection.**	10	**100**	
Ind 119.	**ALL staff involved in the generation, handling and disposal of medical waste shall receive regular training and ongoing education in the infection control and safe handling of medical waste.**	10	**100**	
Total		50		

Standard 30. HIC-2: There are documented procedures for sterilization activities in the Hospital/HCE.

Indicators (120-122):

Ind 120. There is adequate space available for sterilization activities.

Survey Process:

The definition of "adequate" includes enough space (or at least physical barriers) to ensure separation of 'clean' and 'dirty' areas.

Scoring:

- If there is adequate space including clear separation of 'clean' and 'dirty' areas with adequate barriers, then score as **fully met.**
- If there is no separation or there is evidence of inadequacy of separation, then score as **not met.**

GUIDELINES

Documented Layout and Processes

The definition of 'adequate' includes enough space (or at least physical barriers) to ensure separation of 'clean' and 'dirty' considering the workload. The defined Sterilization department/area should have provision to physically separate the functions of cleaning, processing, sterile storage and distribution. This includes suitable location, proper layout and separation of clean and dirty areas. Sufficient space as recommended by the Original Equipment Manufacturer (OEM) shall be available to ensure that the activities can be performed properly. It is preferable to have separate areas for receiving, washing, cleaning, sterilization, packing, sterile storage and dispatch. This entire layout is required to be documented and displayed like a Layout Map.

Each HCE needs to develop a programme for the implementation of good IC practices. ICC, besides other functions also oversees the provision of sterile supplies to the Facility.

1. **Central Sterilization Services Department (CSSD)**

   A CSSD is vital for an effective Infection Control and Prevention program. The expertise and knowledge of CSSD personnel is important to ensure high standards of sterilization. CSSD typically comprises of four major areas to accomplish the functions of sterilization; collection/washing/packaging, sterile processing, sterile storage, and sterile distribution.

   In the disinfection area, reusable equipment, instruments, and supplies are cleaned and disinfected using manual or mechanical cleaning processes and chemicals.

   From the washing area, clean items are moved to the assembly/packaging area. Instruments and OT linen are then packed with indicators, sterilized in the sterilization section, storage and issue/dispatch. The sterile packs should be stored in well ventilated clean stores ready for dispatch to the wards and OT. Collection should be regular and there should be a written record of receipt and delivery. This helps to monitor the use and the loss of instruments.

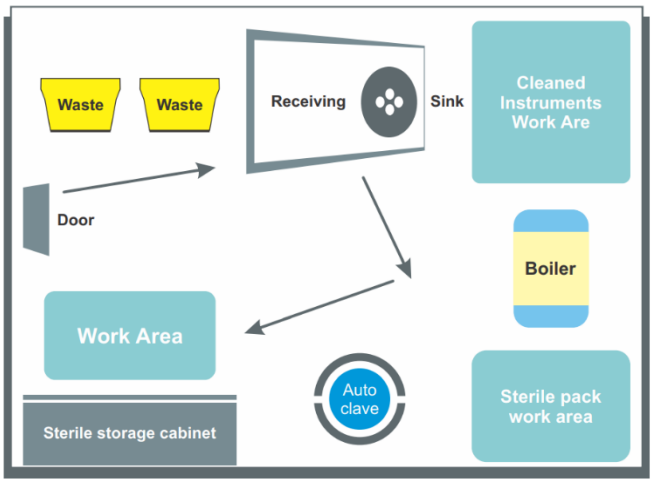
2. Layout of the CSSD

Ideally, physical barriers should separate dirty and clean areas in the reprocessing room. However, if this is not possible due to shortage of space or funds, the same room can be used with partitions, provided that:

A. The air moves from the clean area to the dirty area to avoid cross-contamination.
B. Both areas have separate storage facilities.
C. There are adequate hand disinfection facilities.
D. SOPs are established to ensure that soiled objects never cross paths with clean, sterilized, or high-level disinfected instruments and other items.
E. The doors are kept closed in the reprocessing rooms in order to minimize dust contamination and to eliminate insects.
F. There is separate equipment for each area.
G. The staff works in either area, never in both.

Figure 17 Sample Layout of CSSD

Figure 18 Sample of CSSD Workflow



3. Workflow of the CSSD

In the ward, dirty re-usable instruments are collected and put into clearly labelled containers and delivered to the CSSD. Cotton wool and dress ing should be discarded as

clinical waste for incineration. The dirty instruments are then received in the dirty area of the CSSD. All equipment is first washed in hot water and detergent either mechanically or manually. Manual washing requires the use of appropriate protective clothing such as heavy-duty gloves, plastic aprons, and eye-protection. The equipment is then inspected for cleanliness and damage. Instruments are then packed into individual trays for use in wards and autoclaved and/or disinfected as required. The packaged trays are then inspected to ensure that they are dry and then sorted for collection for use in wards. The sterile packs should be stored in well-ventilated rooms ready for dispatch to the wards. Collections should be regular and there should be a written record of receipt and delivery.

4. Disinfection/Sterilization of Instruments

It is mandatory for healthcare workers to disinfect soiled medical instruments before using them on other patients. Sterilization of medical instruments prevents the spread of infectious diseases and is the first sterilization process to protect patients from contaminants like HIV and Hepatitis C that can live on instruments. Liquid bleach, as well as isopropyl and ethyl alcohol, are extremely effective in disinfecting medical instruments if a hospital grade germicidal cleanser is not available.

SOPs for Disinfection

A. Place your washbasins and supplies in a cleaning station or utility room. Decide which chemical you will use to disinfect the medical instruments - germicidal spray, liquid bleach or alcohol. These are all highly effective disinfectants and the medical community approves of them.
B. Put on your protective wear - gloves, goggles, mask and apron. Gloves should be the heavy-duty utility style for handling sharp instruments like scalpels and knives. Dispose of gloves and use a new pair if they tear during the disinfecting process.
C. Spray each individual instrument heavily with germicidal spray and disinfect one piece at a time. Allow each item to stay for two minutes in the washbasin. Place the instruments into a separate basin of clean water to rinse. Dried blood or fluids on instruments may require an additional application of germicidal spray and light scrubbing with a toothbrush for removal.
D. In case of liquid bleach, mix one ounce of bleach with one quart of boiled water in a washbasin and add the soiled medical instruments. Allow the instruments to stay in the bleach solution for five minutes to kill any infectious organisms. Remove the instruments and check for any remaining blood or fluids. Use a toothbrush to remove any visible contaminants left on the instruments and rinse the instruments with clean water in a separate basin.
E. In case of using isopropyl or ethyl alcohol, place the soiled instruments in the washbasin, pour alcohol into a spray bottle and spray the instruments thoroughly. Use a toothbrush to remove any dried fluids. Apply more spray and scrub vigorously if the contaminant is still visible on the object. Place the instruments into another basin and rinse with clean water.

5. Cleaning Instruments with Sterile Water

While using medical equipment or instruments that need to be sterilized for safety and disinfection, use a solution of sterile water to ensure that all bacteria and viruses are killed and eliminated from the instrument or the tool. Using a mix of enzymatic detergent and sterile water can assist you in effectively cleaning and eliminating unwanted microbes from

surgical and medical tools and equipment.

SOPs for Cleaning Instruments with Sterile Water

A. Remove debris and residue from the instruments by rinsing them under sterile water and using a toothbrush or other scrubbing tools.
B. Mix proper amounts of sterile water and enzymatic detergent in a clean container large enough to hold the instruments. The proper ratio of enzymatic detergent and sterile water will be determined and followed as per manufacturer instructions
C. Place the instruments in the container with the enzymatic detergent and sterile water formula, making sure that they are fully covered by the solution.
D. Soak the tools in the solution for 20 minutes to effectively sterilize the instruments before reuse.

Ind 121. Regular validation tests for sterilization are carried out and documented.

Survey Process:

This is an important patient safety issue. Review the process/procedure to validate that complete sterilization has occurred. This should be uniformly done on each "batch" that is sterilized. There are several methods that can be used (such as color change strips). Whatever method is used, it must be effective and documented. Observe that the date of sterilization and expiry are clearly indicated on the packaging.

Scoring:

- If there is a process/procedure to verify that complete sterilization has occurred, it is used for ALL "batches" that are sterilized, it is documented and production/ sterilization and expiry dates are indicated, then score as **fully met.**
- If there is no process/procedure to verify that complete sterilization has occurred, or if it is not used for all batches that are sterilized, or if it is not documented, or if production/ sterilization and or expiry dates are not indicated, then score as **not met.**

GUIDELINES

Record of Validation Tests

Documented processes/procedures should be there to provide guideline for complete sterilization. This should be uniformly done on each "batch" that is sterilized. There are several methods that can be used (such as color change strips). Every method used must be documented and effective. The date of sterilization and expiry are clearly indicated on the packaging. This should be done by accepted methods, e.g., bacteriologic, strips, etc. Engineering validations like Bowie Dick tape test and leak rate test need to be carried out. WHO recommends each load to have number, content description, temperature, pressure and time-record chart, physical/chemical tests daily, weekly biological tests and steam processing.

Ind 122. There is an established procedure for recall in case of breakdown in the sterilization system.

Survey Process:

Review any written recall procedure employed in case of breakdown of sterilization system. If an actual breakdown had occurred, review how the recall was implemented. Check to see if staff members are aware and receive training in the procedure.

Scoring:

- Score as **fully met** if a written recall procedure exists and staff is aware of it.
- If there is no written recall procedure, then score as **not met.**

GUIDELINES

Breakdown Recall

The HCE should develop and have a written recall procedure and the staff members should be trained on these procedures. The HCE 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. A batch processing system with date and machine number for effective recall should be in place. Whenever a breakdown in the sterilization system is noted, all packs sterilized by the faulty machine should immediately be called back from the respective area where the sterile packs has been supplied. The packs called back should be sent for re-sterilization using a proper machine/technique.

The format of the register is as follows:

Table 29: Sterilization Breakdown Recall Register Format

No.	Date of sterilization	Batch no.	Items	Expiry date	Issued to	Sterilization Validation Tests Result	Person Responsible	Signature	Recall notes

Assessment Scoring Matrix

Standard 30. HIC. 2: There are documented procedures for sterilization activities in the Hospital/HCE.

Indicator 120-122		Max Score	Weightage (Percent)	Score Obtained
Ind 120.	**There is adequate space available for sterilization activities.**	10	**100**	
Ind 121.	**Regular validation tests for sterilization are carried out and documented.**	10	**100**	
Ind 122.	**There is an established procedure for recall in case of breakdown in the sterilization system.**	10	**100**	
Total		30		

PART 3
ANNEXURES

3. Annexures

ANNEXURE A: Summary Assessment Scoring Matrix

Functional Area		Max Score	Weightage (percent)	Score Obtained
2.1	**Responsibilities of Management (ROM)**	110	102	
2.2	**Facility Management and Safety (FMS)**	90	80	
2.3	**Human Resource Management (HRM)**	50	48	
2.4	**Information Management System (IMS)**	60	58	
2.5	**Continuous Quality Improvement (CQI)**	90	86	
2.6	**Access, Assessment, and Continuity of Care (AAC)**	170	162	
2.7	**Care of Patients (COP)**	290	280	
2.8	**Management of Medication (MOM)**	180	168	
2.9	**Patient Rights and Education (PRE)**	100	90	
2.10	**Hospital Infection Control (HIC)**	80	80	
Total		**1,220**	**1,144**	

ANNEXURE B: Health Related Laws in Khyber Pakhtunkhwa

No.	Health Related Laws
1.	Pakistan Medical Commission Act, 2020
2.	Khyber Pakhtunkhwa Food Safety & Halal Food Authority Act, 2014
3.	The Khyber Pakhtunkhwa Healthcare Commission Act, 2015
4.	The Khyber Pakhtunkhwa Public Procurement Regulatory Authority Act 2012
5.	The Khyber Pakhtunkhwa Consumer Protection (Amendment) Act, 2017
6.	The Khyber Pakhtunkhwa Blood Transfusion Safety Authority Act, 2016
7.	The Khyber Pakhtunkhwa Environmental Protection Act, 2014
8.	Pakistan Nursing Council (Amendment) Act, 2021
9.	Allopathic System (Prevention of Misuse) Rules, 1968
10.	Pharmacy Act, 1967
11.	The Unani Ayurvedic And Homoeopathic Practitioners Act, 1965
12.	The Allopathic System (Prevention of Misuse) Ordinance, 1962

ANNEXURE C: Joining Report

EMPLOYEE DETAILS	
Name	
Phone Number Home:	**Mobile Number:**
Email ID:	
Residential Address:	
Date of Joining	

EMPLOYEE'S JOINING CONFIRMATION

I _____ do hereby confirm that I have accepted your offered job as _____ in_____Department and have accordingly joined with effect from _____.

(Employee Signature) (Date)

EMPLOYEE'S JOINING VERIFICATION

The date of joining mentioned above is correct.
Verified By:
Name: _____ Designation: _____
Signature: _____ Date: _____
Note: Submission of this REPORT is mandatory. A copy of this report will be sent to the Accounts Department.

ANNEXURE D: Statement of Ethics

Guideline 1	We do not make misleading claims for our services or criticize our competitors before clients. We only believe in servicing our client's needs to the best of our efforts.
Guideline 2	We perform our work according to the specified quality standards.
Guideline 3	We avoid conflicts of interest either of a financial or personal nature; these could compromise the objectivity and integrity of our work.
Guideline 4	We exercise our professional judgment impartially while taking any decisions related to work, keeping all pertinent facts, relevant experience and the advice of our management in mind.
Guideline 5	We hold the affairs of our clients in the strictest confidence. We do not disclose propriety information obtained in the course of work or derive benefit from using information outside the company.
Guideline 6	We act with courtesy and consideration towards all with whom we come into contact in the course of our professional work.
Guideline 7	We do not accept any favors, gifts or inducements, including undue hospitality and entertainment, from the clients. The only expectations would be if the gifts are of promotional nature (diaries, calendars, etc.) or of a nominal value, the indulgence of which would not damage the company's reputation.
Guideline 8	We are fully committed to the principle of equality and non-discrimination on the grounds of disability, sex, age, race, color, ethnicity, origin or marital status. We do not indulge in any intimidation and harassment of any sort at work.
Guideline 9	We will communicate with our clients and its representative in an effective and timely manner.
Guideline 10	We would be perceived by clients and other thought leaders as setting the standards in client focus and client service among professional service companies.

Declaration

I have read and understood the "Statements of Ethics" and stand committed to it.

Signature: _____

Name: _____

Date of Joining: _____

ANNEXURE E: Confidentiality Agreement

In the course of your work at _____ Hospital you are likely to receive, from time to time, information which is not in the public domain. You are reminded that such information must be kept confidential and release of such information could lead to termination of employment, civil or criminal prosecution.

All memoranda, notes, reports and other documents will remain part of the Hospital's confidential records. Such confidential information must at all times be kept in a secure place on the Hospital's premises and disclosed to others only in accordance with our duties as an employee of _____.

Inventions, copyrights and other intellectual property, when conceived, developed or made during employment by the Hospital, or within one year thereafter, shall be regarded as made by employee solely and exclusively for the benefit of the Hospital. These shall not be disclosed to others without the Hospital's written consent, and shall be the sole and exclusive property of the Hospital.

The employee agrees to make prompt and full written disclosure of such inventions, copyrights and other intellectual property, and when requested by the Hospital to do so, either during or after employment.

By signing this agreement you confirm that you will comply with these requirements and you further undertake to preserve, even after you cease to be an employee, the confidentiality of information received by you during your employment at _____ .

I hereby confirm that I accept the set out above.

Signed: _____

Name: _____

Date of Joining: _____

ANNEXURE F: Reference Form

Kindly provide us the detail of at least 2 people, other than relatives, who have knowledge of your work experience and/or education.

Name of Candidate: _____ Position: _____

Reference 1	
Name:	Designation:
Company Name:	Address:
Telephone # (Home):	Telephone # (Office):
Mobile #:	Email:
Fax:	Other:

Reference 2	
Name:	Designation:
Company Name:	Address:
Telephone # (Home):	Telephone # (Office):
Mobile #:	Email:
Fax:	Other:

Reference 3	
Name:	Designation:
Company Name:	Address:
Telephone # (Home):	Telephone # (Office):
Mobile #:	Email:
Fax:	Other:

Reference 4	
Name:	Designation:
Company Name:	Address:
Telephone # (Home):	Telephone # (Office):
Mobile #:	Email:
Fax:	Other:

ANNEXURE G: Health Questionnaire Form

(To be filled by the employee)

Employee Name: _____ Designation: _____

Please read the following questions carefully and answer each question in Yes or No. If the answer to any question is "Yes", please give full detail.

No.	Question	Answer
1.	Have you ever been advised by a physician to have medical treatment or surgery/ procedure/investigation for any of the following: 1. Heart disease 2. High blood pressure 3. Diabetes 4. Kidney disease 5. Cancer or brain tumor 6. Back pain including any muscular problem 7. Digestive problems 8. Liver disease including hepatitis B 9. AIDS	
2.	Do you have any health problem due to smoking	
3.	Are you currently taking any treatment or medication or awaiting medical investigations, laboratory test, treatment or surgery	
4.	Have you been absent from work due to medical reasons for a continuous period of a week or more during the last 2 years	
5.	Other (please specify)	

Please give detail of any "Yes" answer to the above questions in the following form.

Q#	Type of Disease	Date (from)	Date (to)	Treatment from (Name and address of Doctor)

DECLARATION:

I hereby declare that what has been stated above is true and complete to the best of my knowledge and if found that I have some health problem then I could be sent to the hospital, recommended by the HR Department, for complete checkup and test. In case of wrong information, I could be terminated from employment.

Signature: _____ Date of Joining: _____

ANNEXURE H: Orientation Checklist

Employee's Name: _____ Designation: _____

Department: _____ Date: _____

In order to avoid duplication of the instructions, the Information checked ( ) below has been given or explained to the employee by the HR department.

Introduction:		**Time Schedule:**	
Company Introduction	( )	Work Schedule/Lunch timings	( )
Mission & Vision	( )	Attendance & Punctuality	( )
Corporate Values	( )	Public Holidays	( )
Organizational Structure	( )	Leave	( )
Employment:		**Employee Relations:**	
Recruitment & Selection	( )	Violation of company rules	( )
Appointment Letter issued	( )	Disciplinary Policy	( )
Confidentiality Agreement signed	( )	Internal Communication	( )
Statements of Ethics signed	( )	Employee Records	( )
Probation & Confirmation	( )	Code of Conduct	( )
Resignation /Termination	( )		
Compensation & Benefits:		**Career Development:**	
Job Description issued	( )	Performance Management System	( )
Medical Facility	( )	Promotion/increments	( )
Parking Facility	( )	Training	( )
Provident Fund	( )		

Others:

Other Benefits	( )
Tour of the company	( )
Issuance of Employee Handbook	( )
Salary Administration:	
Salary Process	( )
Email address sent for addition	( )
Advance Salary	( )
Outstation Travel	( )

How satisfied are you with the orientation process?

a) Not Satisfied b) lmprovement Needed c)satisfied
4. Very Satisfied e) Outstanding

Additional Comments/Suggestions:

_____

_____

Orientation Conducted by:

Employee's Signature: _____

Supervisor's Signature: _____

ANNEXURE I: Patient Record Template

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Unique ID	**Date**	**Time**	**Visit#**	**Name**	**Parentage**	**Age**	**Sex**	**Weight**	**Ph.**	**Add.**	**Allergy**	**Symptom**	**Finding**	**Provisional/ Diagnosis**

Note: Column Nos. are only for reference.

ANNEXURE J: Weeding of Old Record

	Type of Record	**Period of retaining**
Official Record	Personal Files, Services books, Financial Record auditable and non-auditable, excisable/non-excisable record.	In accordance with the Government of Khyber Pakhtunkhwa Financial Rules or as per necessity, whichever is later.
Medical Record	Patient charts, Reports, X-Ray, CT Scan MRI, Pathology reports OPD Registers.	03 Years or later as per necessity.
Medico-legal	Medico-Legal report/registers	12 years or later as per necessity.
Demographic Record	Birth and Death record	Birth and Death Registers to be kept forever.

ANNEXURE K: List of Tests

Cardiology

1. Total Cholesterol
2. LDL-C
3. HDL-C
4. Triglyceride
5. C-reactive protein
6. Fibrinogen
7. Homocysteine
8. Fasting Insulin
9. Ferritin
10. Lipoprotein(a) - Lp(a)
11. Calcium Heart Scan
12. Cardiac catheterization and angiography
13. Echocardiography (echo)
14. Electrocardiogram (ECG or EKG)
15. Electrophysiology study (EP study)
16. Holter monitor and event recorder
17. MUGAscan
18. Stress testing
19. Thallium and sestamibi (Cardiolite) scans
20. Tilt Table Testing
21. Transesophageal echocardiography (TEE)
22. Ultrafast CT scan
23. Cardiac MRI
24. Creatine kinase (total)
25. Creatine kinase (MB fraction)
26. Troponin I and T
27. Myoglobin
28. Lactate dehydrogenase

Thyroid Tests

1. **Thyroid hormones**
   - A. Thyroid-stimulating hormone
   - B. Total thyroxine
   - C. Free thyroxine
   - D. Total triiodothyronine
   - E. Free triiodothyronine
2. **Carrier proteins**
   - A. Thyroxine-binding globulin
   - B. Thyroglobulin
   - C. Other binding hormones
3. **Protein binding function**
   - A. Thyroid hormone uptake
   - B. Other protein binding tests
4. **Mixed parameters**
   - A. Free thyroxine index
5. **Structure parameters**
   - A. Secretory capacity (GT)
   - B. Sum activity of peripheral deiodinases (GD)
   - C. TSH index

Assay used for blood screening

1. Immunoassays (IAs)
   - A. Enzyme immunoassays (ElAs)
   - B. Chemiluminescent immunoassays (CLIAs)
2. Haemagglutination (HA)/particle agglutination (PA) assays
3. Rapid/simple single-use assays (rapid tests)

Liver Function Tests

1. Proteins
2. Albumin
3. Globulin
4. Total Protein
5. Enzymes
6. Total Bilirubin
7. Alkaline Phosphatase
8. GGTP
9. LDH

4. Nucleic acid amplification technology (NAT) assays. 5. The following tests are mandatory on all units of blood collected for transfusion: 6. ABO group and Rh type 7. Serologic test for syphilis, HIV and Hepatitis B and C	10. SGOT (also called AST) 11. ALT (SGPT)
Renal Function tests 1. Routine urinalysis 2. Creatinine clearance test 3. Urea clearance test 4. Urine osmolality test 5. Urine protein test 6. Blood urea nitrogen test (BUN) 7. Creatinine test 8. Other blood tests like urine sodium, potassium, chloride, calcium, glucose, etc.	**Transplantation Tests** 1. Matching blood group 2. Matching tissue type 3. Testing for viruses 4. Electrocardiogram (ECG 5. Echocardiogram (echo) 6. Chest X-ray
Electrolyte Tests 1. Ca (Calcium) 2. P04 3. Mg (Magnesium) 4. K (Potassium) 5. Na (Sodium) 6. C02 (Bicarbonate) 7. Cl (Chloride)	**Paediatrics** 1. Albumin 2. Bilirubin 3. Complete blood count (CBC) 4. Electrolyte tests 5. Fecal fat test 6. Fecal occult blood test 7. Hydrogen breath test 8. Lactose tolerance test 9. Liver enzymes 10. Prothrombin time (PT) test 11. Stool culture 12. Urea breath test
Gastroenterology Tests and Procedures 1. Abdominal Angiogram 2. Abdominal Ultrasound 3. Abdominal X-rays 4. Barium Enema 5. Barium Swallow 6. Cholecystography 7. Colonoscopy 8. CT Scan of Liver and Biliary Tract 9. CT Scan of the Abdomen 10. CT Scan of the Pancreas	**Tests in ICU** 1. EUC Electrolytes (Sodium/Potassium/Chloride)/Urea/Creatinine 2. Arterial Blood Gas - ABG 3. Liver Function Tests - LFTs 4. Full Blood Count - FBC 5. Coagulation Studies - Coags 6. Blood sugar level - BSL 7. Urinalysis 8. Pathology Tests to identify possible infection

11. Endoscopic Cholangiopancreatography 12. Esophagogastroduodenoscopy 13. Gallbladder Scan 14. Laparoscopy 15. Liver Biopsy 16. Liver Scan 17. Pancreas Scan 18. Sigmoidoscopy 19. Upper Gastrointestinal Series	9. Blood Cultures 10. MSU - mid stream urine test 11. Sputum Specimen 12. Wound Swabs 13. CSF - Cerebrospinal Fluid 14. Other body fluids
Oncology Tests 1. AMAS - Anti-malignin antibody screen test 2. Biological Terraine Assessment (BTA) 3. Cancer Marker Tests, which include: A. Alpha fetoprotein (AFP) B. CA 15.3 C. CA 19.9 D. CA125 E. Carcinoembryonic antigen (CEA) 4. CBC Blood test 5. Dark field Microscopy 6. DR-70 7. Electro Dermal Screening (EDS) 8. Endoscopic ultrasound 9. Lymphocyte Size Analysis 10. Maverick Monitoring Test (MMT) 11. Positron Emission Tomography - PET scan 12. Thermography 13. Whole Body CT Scans	**Additional tests to detect specific cancers:** **1. Tests for Bladder Cancer:** A. These tests include the bladder-tumor-associated antigen test (BTA™), the BTA stat test, the BTA TRAK* test, the fibrin/fibrinogen degradation products test (FDP™), and the NMP22™ assay B. New protein test **2. Tests for Breast Cancer:** A. Acuity ductoscopy B. Amas test C. Cancer Marker Tests - CA 15.3 and CA125 D. DR-70 E. Ductal lavage F. Mammography/Thermography - Computed Tomography Laser Mammography and Full Field Digital Mammography G. Thermography T/Tn Antigen Test H. Ultrasound or sonogram I. Other Imaging Methods. These include: (i) Scintigraphy (ii) MRI (iii) PET scan (iv) Magnetic resonance (MR) elastography J. Additional Tests to see if cancer has spread: K. Mammotome® Breast Biopsy System **3. Tests for Colon/Colorectal Cancer:** A. Carcinoembryonic antigen (CEA) B. Hemoccult Test C. PreGen-26

	4. Tests for Lung Cancer: A. Sputum cytology B. PET Scans C. CA125, DR-70, and the T/Tn antigen test **5. Tests for Ovarian and Cervical Cancer:** A. CA125 levels B. DR-70 C. Pap Smears/PAPNET D. Ampersand Medical's InPath™ System is a biomolecular-based technology for screening for cervical dysplasia and cervical cancer E. Positron emission tomography with a glucose analog (PET-FDG) **6. Cancer Marker for Nasophrvngeal Cancer:** A. EVP **7. Cancer Marker for Pancreatic/Stomach Cancer:** A. CA 19.9 B. DR-70 **8. Tests for Prostate Cancer:** A. The Digital Rectal Exam (DRE) B. PSA - Prostate Specific Antigen C. Beckman Coulter's Hybritech free PSA (fPSA) test D. PSA density test E. Telomerase Test **9. Tests for Thyroid Cancer** A. CEA markers can also help detect Medullary thyroid cancer (MTC) B. DMSAscan **C.** DR-70
Haematology Tests 1. BCR-ABL 2. Bleeding Time 3. Bone Marrow Aspiration 4. CD4/8 counts 5. Chimerism studies 6. Chromosome studies for hematological investigation 7. Coagulation factor assay 8. Glandular Fever screen (Paul Bunnell, infectious mononucleosis, EBV)	**Neurological Diagnostic Tests and Procedures** 1. Laboratory screening tests of blood, urine, or other substances 2. Genetic testing, which include the following: A. Amniocentesis B. Chorionic villus sampling or CVS 3. Uterine ultrasound 4. X-rays of the patient's chest and skull 5. Fluoroscopy

9. Glucose-6-phosphate dehydrogenase screen (G6PD) 10. Flaemoglobinopathy screen (includes HbA2, HbF quantitation) 11. Flemosiderin 12. Fleinz bodies 13. Heparin Assay (Anti-Xa) 14. Heparin Induced Thrombocytopenia test (urgent) 15. HLA-B27 16. Immunohaematology Tests 17. INR 18. JAK2 mutation 19. Leukaemia immunophenotyping 20. Lupus anticoagulant 21. Lymphocyte subsets (B, T, NK cell counts) 22. Malarial parasites 23. Plasma viscosity 24. Platelets 25. Platelet Aggregation 26. Platelet Function Studies 27. Protein C 28. Protein S 29. Prothrombin gene mutation 30. Pyruvate kinase, red cell 31. Red cell mass/plasma volume estimation 32. Red cell osmotic fragility 33. Reticulocytes 34. Sickle Cell screen 35. APTT ratio - Therapeutic Heparin Ratio 36. B12 (vitamin BI2) 37. APTT ratio (activated partial thromboplastin time ratio) 38. APC resistance 39. Antithrombin activity 40. White Cell Enzymes 41. Von Willebrand screening 42. Thrombophilia screen 43. Thrombin time 44. Therapeutic Heparin Ratio 45. Thalassemia screen 46. T lymphocyte subsets **47.** Schilling Test	6. Diagnostic tests used to diagnose neurological disorders 7. Angiography 8. Biopsy 9. Brain scans 10. Cerebrospinal fluid analysis 11. Computed tomography 12. Discography 13. Intrathecal contrast-enhanced CT scan (also called cisternography) Electroencephalography. 14. Electromyography or EMG 15. An EMG is usually done in conjunction with a nerve conduction velocity (NCV) test 16. Electronystagmography (ENG) 17. Evoked potentials (also called evoked response) 18. Auditory evoked potentials 19. Visual evoked potentials 20. Somatosensory evoked potentials 21. Magnetic resonance imaging (MRI) 22. Myelography 23. Positron emission tomography (PET) 24. Single photon emission computed tomography (SPECT) 25. Thermography 26. Ultrasound imaging

Orthopedics	Rheumatology
1. Arthrography 2. Blood Tests 3. Bone Scan 4. Computed Tomography (CT Scan) 5. Discography 6. Doppler Ultrasound 7. Dual-Photon Absorptiometry 8. Dual-Energy X-ray Absorptiometry 9. Electromyography 10. Flexibility Tests 11. Intrathecal Contrast Enhanced CT Scan 12. Joint Aspiration and Analysis 13. Laboratory Studies 14. Magnetic Resonance Imaging (MRI) 15. Muscle Tests 16. Nerve Conduction Study (NCS) 17. Peripheral Bone Density Testing 18. Quantitative Computed Tomography 19. Radiographs (X-rays) 20. Range of Motion Testing 21. Single Photon Absorptiometry 22. Stress Tests 23. Ultrasonography 24. Venography	1. CBC 2. ESR 3. CRP 4. RF 5. ANA 6. Uric acid 7. HLAB27 8. SFA

List of Emergency Tests After Office Hours, Weekends and Public Holidays

1. BUSE (Blood urea serum electrolytes)
2. Blood sugar
3. Urine FEME (for suspected acute appendicitis, molar, and ectopic pregnancy, urinary tract infection)
4. Infant serum bilirubin (total)
5. Serum/plasma calcium
6. Urine serum amylase (for suspected pancreatitis case)
7. Urine pregnancy test (for ectopic pregnancy and choriocarcinoma)
8. Urine parquet
9. Cerebrospinal fluids (CSF) for cell count, sugar, protein, chloride, smear for GC organism, AFB, Cryptococcus and culture.
10. Throat swab for C. diphtheria.
11. Eye swab for gonococcus in neonates
12. Hanging drop for cholera suspect
13. Blood film for malaria parasites.
14. Hemoglobin
15. Total white cell count (for suspected acute appendicitis)
16. Platelet count

17. Packed cell volume (in severely burnt case)
18. Prothrombin Time (PT)
19. Partial Prothrombin Time (PTT)
20. Fibrinogen Degradation Product (FDP)
21. Fibrinogen level (semi-quantitative)
22. Blood cross-matching for possible immediate transfusion

ANNEXURE L: Memorandum of Understanding for Outsourcing Diagnostic Services

(Between ABC Hospital & XYZ Lab)

This Memorandum of Understanding (MOU) is a voluntary agreement between the above listed hospital and Clinical Laboratory to provide diagnostic services for indoor/outdoor patients or at the time of disaster or other emergency situation on the following terms and conditions.

A. Services:

i. The XYZ Laboratory agrees to provide Services for Facility on an as-needed basis and in accordance with all applicable federal, provincial and local laws, rules and regulations, as well as any applicable policies.
ii. Services shall include, but are not limited to, the following:

a) Histopathology
b) Microbiology
c) Hematology
d) Biochemical testing

iii. The Lab and its employees shall maintain all required Registration and license from Khyber Pakhtunkhwa Health Care Commission and other regulatory bodies as applicable.
iv. The Lab shall also maintain quality assurance system as prescribed by the Khyber Pakhtunkhwa Health Care Commission / other accreditation bodies.
v. The lab will ensure the provision of all lab test within Lab premises as list provided by Hospital. (Attach Annex-I)
vi. It is certified that the incharge of ABC lab is a qualified pathologist (name of Pathologist) having post-graduation in pathology subject and registered with PMDC, Registration No. (Attach Annex- II)
vii. The PMDC Registration of Pathologist is valid up to and it will be responsibility of Pathologist to renew PMDC Registration before expiry.
viii. The Lab Shall be responsible to provide Diagnostic services round the clock 24/7 and have sufficient qualified staff in each shift to perform the test precisely under the supervision of qualified pathologist (name of Pathologist) (duty roaster of MLTs with name, qualification and FPAHS Reg. No.) (Attach Annex-III)
ix. The Diagnostic Lab Shall be responsible to provide services as per agreed SOPs of (a) Sample Collection (b) Sample labelling for identification (c) Handling (d) safe transportation (e) processing (f) safe disposal of specimen. (Attach Annex-IV)
x. If the hospital staff will collect the sample, then it will be the responsibility of HCE to follow the SOPs of Sample collection, Labelling and safe Transportation.
xi. The Diagnostic lab shall be responsible to provide tests result within the agreed time frame of emergency & indoor /outdoor patients to the HCE. (Attach Annex-V) and Lab will ensure to maintain the record accordingly.
xii. The lab Shall also define the critical values of diagnostic tests and provide any critical results of the patients referred by HCE immediately to the concerned doctor telephonically, SMS/ what's App, Lab will also maintain the record of critical results by recording time and name of doctor provided the result.
xiii. The lab will maintain the record of all tests (EMR / Manual) at least for three years. In case of Medico-legal result will be kept safe up to 12 years or till the decision of case.

xiv. The Lab will provide and also display tariff list within the lab to inform the cost of diagnostic tests to the patients and their families. (Attach Annex- VI)

xv. The Lab will establish Complaint management system. If any patient has complaint about Laboratory arrangements or employees behavior, then he should have a right to lodge complaint to lab incharge accordingly.

B. Service Orders:

Every specimen must be sent to the laboratory with the appropriate test requisition form dually signed by a qualified consultant/ Medical officer.

C. Payments:

All kind of payments for diagnostic services provided to the referred patient will be paid by the patient/ attendants in advance or any other mode/agency already defined, in term of cash or at the time of collection of lab test results. ABC hospital will not be held responsible for any kind of payment by XYZ Lab unless specified otherwise as special arrangements.

D. Confidentiality:

Privacy and confidentiality of the Patient/Client will be ensured by the Laboratory.

E. Termination:

Notwithstanding anything herein to the contrary, this Agreement may be terminated at any time as follows:

a. By mutual agreement of the Parties; or

b. With cause by the Lab or Facility upon the default by the other of any term, covenant or condition of this Agreement, where such default continues for a period of ten (10) business days after the defaulting Party receives written notice thereof from the other Party specifying the existence of the such default; or

c. Without cause by the lab or Facility upon at least thirty (30) days prior written notice to the other Party in which case the Agreement shall terminate on the future date specified in such notice.

1. Name & Address of Hospital Signature Designation Date	2. Name & Address of Lab. Signature Designation Date
3. Witness No. 1 Signature	4. Witness No. 2 Signature

Designation Date	Designation Date

All Documents, Annexures should be dually signed by both the parties.

ANNEXURE M: Memorandum of Understanding for Outsourcing Diagnostic Services

(BETWEEN ABC HOSPITAL & XYZ RADIOLOGICAL DIAGNOSTIC CENTER)

This Memorandum of Understanding (MOU) is a voluntary agreement between the above listed hospital and Radiology center to provide diagnostic services for indoor/outdoor patients or at the time of disaster or other emergency situation on the following terms and conditions.

A. Services:

i. The XYZ Radiology center agrees to provide Services for Facility on an as-needed basis and in accordance with all applicable federal, provincial and local laws, rules and regulations, as well as any applicable policies.

ii. Services shall include, but are not limited to, the following:

a.	Plain X-Rays	
b.	Contrast X-Rays	(if applicable)
c.	USG	(if applicable)
d.	CT Scan	(if applicable)
e.	MRI	(if applicable)

iii. The Radiology center and its employees shall maintain the required Registration and license from Khyber Pakhtunkhwa Health Care Commission and other regulatory bodies as applicable.

iv. The Radiology center shall also maintain quality assurance system as prescribed by the Khyber Pakhtunkhwa Health Care Commission / other accreditation bodies.

v. The Radiology center will ensure the provision of all diagnostic tests within Radiology center premises as list provided by Hospital. (Attach Annex-I)

vi. It is certified that the incharge of Radiology center is a qualified Radiologist (name of Radiologist) having post-graduation in Radiology subject and registered with PMDC, Registration #. (Attach Annex- II)

vii. The PMDC Registration of Radiologist is valid up to and it will be responsibility of Radiologist to renew PMDC Registration before expiry.

viii. The Radiology center shall be responsible to provide Diagnostic services round the clock/ 24/7 and have sufficient qualified staff in each shift to perform the test precisely under the supervision of qualified Radiologist (name of Radiologist) (duty roaster of RG with name, qualification and FPAHS Reg. No.) (Attach Annex-III)

ix. The Radiology center shall be responsible to provide services as per agreed SOPs of (a) Patient identification (b) safe transportation. (c) Safe disposal of nuclear waste (as applicable). (Attach Annex-IV)

x. The Radiology center shall be responsible to provide tests result within the agreed time frame of emergency & indoor /outdoor patients to the HCE. (Attach Annex-V) and Radiology center will ensure to maintain the record accordingly.

xi. The Radiology center shall also define the critical values of diagnostic tests and provide any critical results of the patients referred by HCE immediately to the concerned doctor telephonically, SMS / WhatsApp. Radiology center will also maintain the record of critical results by recording time and name of doctor provided the result.

xii. The Radiology center will maintain the record of all tests (EMR / Manual) at least for three years.

xiii. The Radiology center will provide and also display tariff list within the Radiology center to inform the cost of diagnostic tests to the patients and

their families. (Attach Annex- VI)

xiv. The Radiology center will establish Complaint management system. If any patient has complaint about Radiology center arrangements or employees behavior, then he should have right to lodge complaint to Radiology center incharge accordingly.

xv. Arrangement of backup support/resuscitations must be available in case of any anaphylactic /untoward incidence following contrast procedure.

B. Service Orders:

Every diagnostic test must be sent to the Radiology center with the appropriate test requisition form dually signed by a qualified consultant/ Medical officer.

C. Payments:

All kind of payments for diagnostic services provided to the referred patient will be paid by the patient/ attendants in advance or any other mode/agency already defined, in term of cash or at the time of collection of lab test results. ABC hospital will not be held responsible for any kind of payment by XYZ Radiology unless specified otherwise as special arrangements.

D. Confidentiality:

Privacy and confidentiality of the Patient/Client will be ensured by the Radiology center.

E. Consent:

Consent of the patient/attendant will be obtained for all invasive/Contrast procedures.

F. Termination:

Notwithstanding anything herein to the contrary, this Agreement may be terminated at any time as follows:

a. By mutual agreement of the Parties; or

b. With cause by the Radiology center or Facility upon the default by the other of any term, covenant or condition of this Agreement, where such default continues for a period of ten (10) business days after the defaulting Party receives written notice thereof from the other Party specifying the existence of the such default; or

c. Without cause by the Radiology center or Facility upon at least thirty (30) days prior written notice to the other Party in which case the Agreement shall terminate on the future date specified in such notice.

5. Name & Address of Hospital	6. Name & Address of Radiology Centre
Signature Designation Date	Signature Designation Date

7. Witness No. 1 Signature Designation Date	8. Witness No. 2 Signature Designation Date

All Documents, Annexures should be dually signed by both the parties.

ANNEXURE N: Physical Status Classification & Scoring

AMERICAN SOCIETY OF ANAESTHESIOLOGISTS (ASA)

ASA Physical Status 1	A normal healthy patient
ASA Physical Status 2	A patient with mild systemic disease
ASA Physical Status 3	A patient with severe systemic disease
ASA Physical Status 4	A patient with severe systemic disease that is a constant threat to life
Status 5	A moribund patient who is not expected to survive without the operation
ASA Physical Status 6	A declared brain-dead patient whose organs are being removed for donor purposes

- If the surgery is an emergency, the physical status classification is followed by "E" (for emergency) for example "3E."
- Class 5 is usually an emergency and is therefore usually "5E."
- The class "6E" does not exist and is simply recorded as class "6," as all organ retrieval in brain-dead patients is done urgently.

(These definitions appear in each annual edition of the ASA Relative Value Guide.)

ANNEXURE O_1: Prescription Sample 1

ABC HOSPITAL

Dr. X.Y.Z

M.B.B.S, FRCP, FCPS Child Specialist

Ph: 0423-0000000 Cell: 0300-00000

Ref. No. (Unique Identifier) _____ Time _____ Date/s_____ No. of Visit _____

Patient Name _____ S/o, D/o, W/o _____

Age _____ Sex _____ Weight (kg) _____ Contact No. _____

Address _____

Allergies _____

Symptoms _____

Findings _____

Provisional/Diagnosis _____

℞

(Signature & Stamp)

24/7 Emergency Call Number 01010101

OPD Consultation Days xyz OPD Consultation Timings 00:00 to 00:00

ANNEXURE O_2: Prescription Sample 2

DEF Hospital, UVW Road, Peshawar

041-0000000/ 0300-0000000000

Ref. No. (Unique Identifier) _____ Time _____ Date/s_____ No. of Visit _____

Patient Name _____ S/o, D/o, W/o _____

Age _____ Sex _____ Weight (kg) _____ Contact No. _____

Address _____

Allergies _____

Symptoms _____

Findings _____

Signature with Name

Stamp

ANNEXURE O_3: Prescription Sample 3

Dr. X.Y.Z

M.B.B.S, FRCP, FCPS Child Specialist

Ph: 0423-0000000 Cell: 0300-00000

Ref. No. (Unique Identifier) _____ Time _____ Date/s_____ No. of Visit _____

Patient Name _____ S/o, D/o, W/o _____

Age _____ Sex _____ Weight (kg) _____ Contact No. _____

Address _____

Allergies _____

Symptoms _____

Findings _____

Provisional/Diagnosis _____

℞

(Signature & Stamp)

ANNEXURE P: KP HCC Charters for Patients and HCEs

KP HCC CHARTER FOR PATIENTS & OTHERS

Part A: Rights of Patients and Others

A patient/client or his career, as the case may be, or any other person to whom healthcare services are being rendered, shall have a right to:

1. Health, well-being and safety;
2. Easy access to registration/help desk to get registered and be guided to the respective services as per requirement;
3. Special arrangements for elderly people and disabled to have easy access to required health services;
4. Be attended to, treated and cared for with due skill, and in a professional manner for the accepted standard of health in complete consonance with the principles of medical ethics;
5. Be made aware of the full identity and professional status of the Healthcare Service Provider(s) and other staff providing services;
6. Be given information to make informed choices about his healthcare and treatment options and/or to give informed consent, in terms and in a language that he understands;
7. Seek second opinion when making decisions about his healthcare, and may be assisted by the Healthcare Establishment/healthcare service provider in this regard;
8. Accept or refuse any treatment, examination, test or screening procedure that is advised to him, exceptions being in cases of emergencies and/or mental incapacity in accordance with the relevant law;
9. Personal health information to be kept secure and confidential;
10. Access his own medical records, including but not limited to, comprehensive medical history, Examination(s), investigation(s) and treatment along with the progress notes, and obtain copies thereof;
11. Not to be discriminated against because of age, disability, gender1, marriage, pregnancy, maternity, race, religion, cultural beliefs, color, caste and/or creed;
12. Expect that any care and/or treatment being received is provided by duly qualified and experienced staff;
13. Expect that the healthcare service provider or the Healthcare Establishment, as the case may be, has the capacity and required necessary equipment in order and working condition, for rendering the requisite services, including but not limited to treatment;
14. Receive emergency healthcare, unconditionally. However, once the emergency has been dealt with, he may be discharged or referred to another Healthcare Establishment [emergency requiring healthcare, is a situation threatening immediate danger tolife2 or severe irreversible disability, if healthcare is not provided urgently];
15. Be treated with respect, empathy and dignity irrespective of age, disability, gender, marriage, pregnancy, maternity, race, religion, socio -economic status, cultural beliefs, color, caste and/or creed;
16. Be treated in privacy and with dignity, and have his religious and cultural beliefs respected throughout the duration of care, including but not limited to, taking history, examination or adopting any other course of action;
17. Be made aware of procedures for complaints and resolution of disputes and conflicts;

18. File a written complaint to the concerned healthcare service provider, official of the Healthcare Establishment or such other organization/person, as the case may be and be associated throughout the progress of the complaint and its outcome;
19. Seek compensation if he has been harmed by, including but not limited to maladministration, malpractice, negligent treatment, or failure on the part of a healthcare service provider or any staff/employee or others rendering services at the Healthcare Establishment;
20. Be informed and to refuse to participate in research, or any project dealing with his disease, care and treatment;
21. Be accompanied by a family member or career, as the case may be, particularly in cases of children, females, elderly and disabled. The healthcare service provider and/or the Healthcare Establishment, as the case may be, are to ensure that in cases of children and females in the immediate post anesthesia phase, a female staff shall be present until a family member or career can join the patient/client, The healthcare service provider and/or the Healthcare Establishment, as the case may be, are also to ensure that in cases of children and females an authorized family member or a career or if not so possible, at least a female staff is present during physical examination and investigation procedures where physical contact and or exposure of body part(s) is required.
22. Expect that the Healthcare service provider, the Healthcare Establishment, and/or such other person rendering similar services, as the case may be, shall not misuse nor abuse their fiduciary position *vis-a-vis* him or his career(s) or family members, as the case may be, for undue favor(s) including but not limited to sexual favor(s) or any other undue or uncalled for reward or privileges in terms of professional fee or gifts etc.
23. Be informed as early as possible regarding cancellation and/or postponement of any appointment, surgery, procedure, treatment or meeting, as the case may be;
24. Be made aware of the costs, fee and/or expenses, prior to the consultation, treatment or other services, and/or operation/procedure, as the case may be, and receive payment receipt(s) for the same;
25. Be given written instructions regarding his treatment, including instructions at the time of discharge;
26. Examine and receive an explanation for the bill(s) regardless of the source of payment;
27. End of life care;

Nothing in this Charter prevents any organization/healthcare service provider/Healthcare Establishment from recognizing additional rights of the Patient/Client and/or the career, as the case may be. The purpose of this Charter is to inculcate and invigorate in the community the understanding and recognition of the fact that health, care and/or treatment is a right of an individual even when he is unborn and the same continues from his cradle to coffin.

This document will be reviewed annually or earlier, as deemed appropriate by the Khyber Pakhtunkhwa Healthcare Commission, in view of its experiences, through a consultative process involving patients, former patients, family members, related professionals, staff and other stakeholder groups.

Explanatory Notes

1. Gender includes male, female, transgender and intersex individuals.
2. Life, in the context of mental emergency, includes those of others.

3. End of Life Care includes healthcare, not only of patients in the final hours or days of their lives, but more broadly, care of all those with terminal illness or terminal condition that has become advanced, progressive and incurable. Accordingly, it may so happen that no treatment may be advisable and or given but the care should continue, keeping in view the ethics of the profession.

Part B: Responsibilities of Patients and Others

The patient/client or career, as the case may be, is responsible to the Healthcare Establishment, its staff or the Healthcare Service Provider for: -

1. Providing, accurate and complete information, to the best of his knowledge, regarding medical history, including but not limited to, present medical condition and complaints, medications, allergies and special needs, past illnesses, prior hospitalizations etc., as is required;
2. Reporting unexpected changes in his condition;
3. Adhering to the treatment plan prescribed to him;
4. Keeping appointments and when he is going to be late or is unable to do so for any reason, notify the concerned about the same, as soon as possible;
5. Taking responsibility for his actions if he refuses treatment or does not follow the given instructions;
6. Ensuring that the financial obligations of his care are fulfilled as promptly as possible;
7. Following the Healthcare Facilities' Rules and Regulations relating to patient care and conduct of others, including careers and or visitors;
8. Behaving in a courteous and polite manner which is non-threatening;
9. Refraining from conducting any illegal activity while he is at their premises;
10. Informing of any change of address and other requisite information.

KP HCC CHARTER FOR HEALTH CARE ESTABLISHMENTS

Part A: Rights of Healthcare Establishments/Healthcare Service Providers

The Healthcare Establishment or the Healthcare Service Provider, as the case may be, shall have the right to:

1. Collect accurate and complete information from the patient/client or career, to the best of his knowledge, regarding medical history including but not limited to, present medical condition and complaints, medications, allergies and special needs, past illnesses, prior hospitalizations etc., as is required;
2. Require the patient/client to follow treatment instructions, including the written instructions explained at the time of discharge;
3. Require all patients to abide by its rules and regulations regarding admission, treatment, safety, privacy and visiting schedules etc.;
4. Limit visiting hours and number of visitors in the best interest of the patient/client and that of the others in the Healthcare Establishment;
5. Limit number of careers in the best interest of the patient/client, and that of the others, while keeping in view the special needs of particular patients, for example, minor children, women, elderly and/or seriously ill patients;
6. Be timely notified by the patient/client regarding cancellation of appointment, consultation, procedure, surgery, etc. or delay in his arrival at the Healthcare Establishment;
7. Require the patient/client and/or career(s) to cooperate with Healthcare Establishment staff in carrying out assessments, prescribed investigations and treatment procedures.
8. Require from the patient/client or careers and visitors, as the case may be, to understand the role and dignity of the Healthcare Establishment, its staff and/or the Healthcare Service Provider, as the case may be, and treat them with due respect at all times;
9. Report and take legal action against the patient/client and/or his career(s), visitors, in case of harassment of its staff, damage to its property and disturbance to other patient(s), as the case may be;
10. Demand abstinence from the use of violent and disruptive behaviors or language abuse and take appropriate legal action in case of breach;
11. Prohibit smoking and/or substance/drug abuse on the premises and take appropriate legal action in case of breach;
12. Limit its liability for misplacement or theft of valuables and belongings of the patient/client, career and visitor;
13. Be paid for all services rendered to the patient/client, either personally or by the career or through the third party, e.g. insurance company.
14. Be notified of any change of contact, address and other details of the patient/client, as the case may be;
15. Ask for information from the patient/client regarding its services for the purposes of improving the healthcare services/systems within the Healthcare Establishment;
16. Maintain and utilize the data collected from the patient/client, subject to the principles and law relating to confidentiality, for the purposes of improving the healthcare services/systems within the Healthcare Establishment;

17. Ensure that while using the available facilities and equipment, due care and caution is taken by the patient/client and/or their careers and visitors, as the case may be.

The Khyber Pakhtunkhwa Healthcare Commission while recognizing the fact that each Healthcare Establishment is a "House of Hope" where advice and treatment, including other services, are rendered to the public at large, has developed this Charter of Rights for all Healthcare Establishments/Healthcare Service Providers in the Province of Khyber Pakhtunkhwa. All these rights are to be exercised with a view to make better services available to the masses.

The Khyber Pakhtunkhwa Healthcare Commission further assures that it stands committed to the cause of the Healthcare Establishments/Healthcare Service Providers in the exercise of these rights and shall always be ready and willing to support in the implementation and enforcement of the rights envisaged herein.

This document will be reviewed annually or earlier, as deemed appropriate by the Khyber Pakhtunkhwa Healthcare Commission, in view of its experiences, through a consultative process involving patients, former patients, family members, related professionals, Healthcare Establishments/Healthcare Service Providers, staff and other stakeholder groups.

Part B: Responsibilities of Healthcare Establishments/Healthcare Service Providers

The Healthcare Establishment or the Healthcare Service Provider, as the case may be, shall be responsible for:

1. Ensuring the safety of patient/client.
2. Establishing such systems which enable easy access to services as are required by the patient/client.
3. Maintaining the services being provided through fully competent professionals.
4. Establishing systems to ensure that the rights of the patient/client and others are enforced and fully protected.
5. Adopting open policies regarding its procedures in relation to treatment of the patients/clients including but not limited to, their care and complaints etc.
6. Invigorating in their staff including but not limited to, Consultants and other professionals rendering services at the Healthcare Establishment, the importance and thorough practice of professional ethics.
7. Complying with all the governing laws, rules and regulations while operating, maintaining and rendering services.

ANNEXURE Q: Template of Client Satisfaction Proforma

CLIENT SATISFACTION PROFORMA

Name of Hospital: _____ Unit/Ward/OPD: _____

Patient Name: _____ Dated: _____

No.	Questions	Response	
1	**Are you satisfied with the health services available and behavior of Health Care Providers at Hospital?**	Yes	No
2	**If YES, how? (You can circle more than one response and write below)**	**1.** Complete information provided. **2.** No physical complication at the time of service. **3.** Services available when needed. **4.** Medicines available. **5.** Services are not costly. **6.** Convenient to reach the facility. **7.** Staff is courteous. **8.** Relevant staff is available. **9.** Female staff is available. 10. I recovered after treatment. 11. Other (specify)	
3	**If NO, why? (You can circle more than one) response and write below)**	**1.** Issues of confidentiality. **2.** Issues of privacy. **3.** Lack of attention. **4.** Inadequate information provided. **5.** Physical complication at the time of service. 6. I was asked to come another time. 7. Medicines not available. 8. Medicines are costly. 9. Services are costly. 10. The facility is too far away from my home. 11. Waiting time is too long. 12. Staff is discourteous/Unsatisfactory behavior. 13. Staff is not competent. 14. Relevant staff NOT available. 15. Female staff NOT available/Gender difference. 16. I suffered from side effects of the treatment. 17. Language barrier in communication with HCP. 18. Other (specify)	
4	**Are you satisfied with the techniques used by care providers for diagnosis and treatment purpose?**	Yes	No
5	**Reasons for non-satisfaction**	1. Procedures are painful 2. Culturally not acceptable	

		3. Past experience not good 4. Other (specify)	
6	**Are you satisfied with the environment of the health facility?**	Yes	No
7	**Reasons for non-satisfaction**	1. Unhygienic 2. No separate facility for females regarding a) Waiting area b) Toilet c) Examination space 3. Other (specify)	

ANNEXURE R: HCE Complaints Management

1. OBJECTIVE

To ensure that complaints are handled in a standardized manner at all Health Care Establishments (HCEs) in Khyber Pakhtunkhwa.

2. SCOPE

This document provides general guidelines to HCEs to develop or improve their Complaint Management Systems.

3. RESPONSIBILITY

The responsibility of complaints handling rests with the HCP; however, all staff members of the establishment are responsible for providing the necessary support.

4. DISPLAY OF INFORMATION

A. Inform the patient of his/her right to express his/her concern or complain either verbally or in writing.

B. This shall be done by clearly displaying the following information, in Urdu, at the entrance, help desk, every department and at the back of admission and discharge slips:

آپکو ہسپتال کی سروس کے متعلق تحریری یا زبانی شکایات کرنے کا حق حاصل ہے۔
آپ اپنی شکایات ہسپتال کے منتظم کو دفتر یا ٹیلی فون نمبر --------- پر کرسکتے ہیں یا استقبالیہ ہیلپ ڈیسک / ریسیپشن پر موجود شکایات رجسٹر میں اپنی شکایات درج کرسکتے ہیں۔

5. COMPLAINT HANDLING

A. Put into place a documented process for collecting, prioritizing, reporting and investigating complaints, which is fair and timely.

B. Registration

(i) A number of Complaint Registers shall be maintained by each HCE, one of which shall be available at istaqbaliah/help desk/reception, round the clock.

(ii) Each Complaint Register shall have:

- A 3" X 4" white chit pasted on the cover page with the following:

Complaint Register No. (Register No./Total number of Complaint Registers)
Opened on: **(Mention date as XX-XX-XXXX)**

- The following certificate on the inner side of the cover page:

"It is certified that this register contains _____ pages; each page has been numbered (at the top centre), stamped with the HCE seal (at top right corner) and initialed by me." Date: XX-XX-XXXX (Signature and Name of Authorized Person)

- The following page format:

1	2	3	4	5	6	7	8	9	10
No.	Date	Complainant's Name	CNIC No.	Contact No.	Address	Detail of the Complaint	Signature/thumb impression of the complainant	Date seen & Signature Manager	Date seen & Signature CEO

Column 2-8 shall either be filled by the complainant or someone else (whom the complainant trusts) on his/her behalf.

- Every written or verbal complaint directly made to the HCE/Authorized Person shall be entered in the register within 24 hours.

C. Processing

(i) A Complaint Processing Register shall be maintained by each HCE.

(ii) The Complaint Processing Register shall have:

- A 3" X 4" white chit pasted on the cover page with the following:

Complaint Processing Register Opened on: (Mention date as XX-XX-XXXX)

- The following certificate on the inner side of the cover page:

"It is certified that this register contains _____ pages; each page has been numbered (at the top centre), stamped with the HCE seal (at top right corner) and initialed by me." Date: XX-XX-XXXX (Signature and Name of Authorized Person)

- The following page format:

1	2	3	4	5	6	7	8	9	10
No	Complainant's Name	Contact No,	Description of the Complaint	Priority	Detail of the Investigation	Date(s) Complainant contacted	Outcome	Date Complainant informed	Quality improvement Policy or Procedure Change

- No. of the complaint shall be the same on both the registers.
- Enter important point of the complaint in the register. Take notice of allegations and requests made.
- Assign priority according to the nature of the complaint.
- Investigate in an impartial manner.
- Keep the time factor in mind because any undue delay will reflect poorly on the management.

6. COMMUNICATION

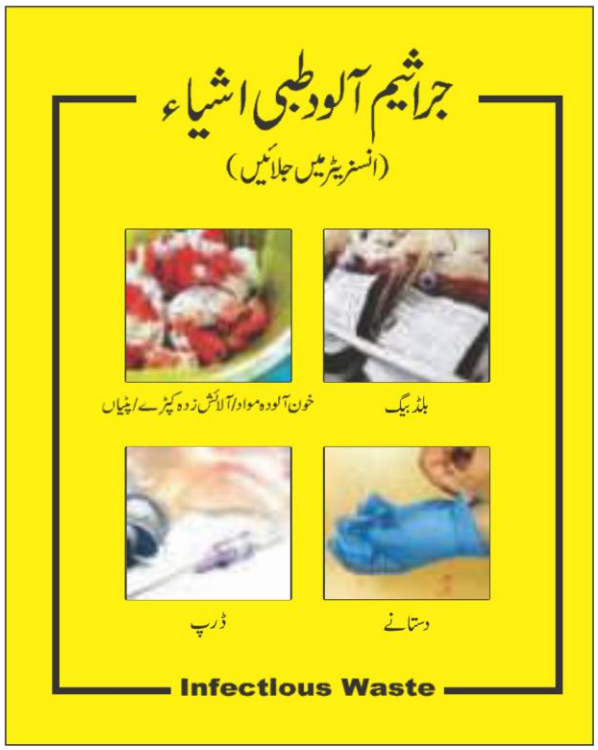
A. Inform the complainant about the progress of the investigation at regular intervals and inform him/her about the outcome.
B. Stay in contact with the complainant and regularly update him/her about the progress made in investigation.
C. Record the outcome of the investigation and inform the complainant accordingly.
D. Don't indulge in argumentation. Be polite and empathetic.

7. QUALITY IMPROVEMENT

A. Use the results of the complaints investigation as part of the quality improvement process.
B. The registers should be perused by the Chief Executive of the establishment, at least once a month.
C. Make necessary changes in policy and procedures to improve the quality of healthcare services.

ANNEXURE S: Segregation of Waste (both Clinical & Municipal) for Disposal

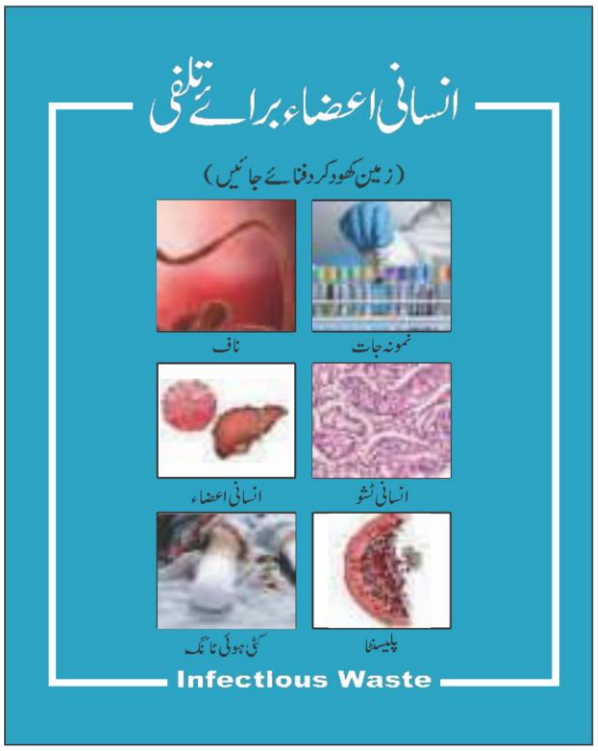
1. Yellow Colour



2. Red Colour

3. White Colour

4. Light Blue



The Khyber Pakhtunkhwa Health Care Commission (KP HCC) has the legal mandate (Khyber Pakhtunkhwa Health Care Commission Act, 2015) to regulate the health care services in both public and private sectors in the province. The objective is to improve and maintain quality of healthcare, and ensure safety of patients and healthcare providers. The Health Care Establishments (HCEs) are assessed against set standards for this purpose. It is mandatory for the HCEs, including primary, secondary and tertiary levels to acquire license from the KP HCC through the implementation of the Minimum Service delivery Standards.

Khyber Pakhtunkhwa
Health Care Commission

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