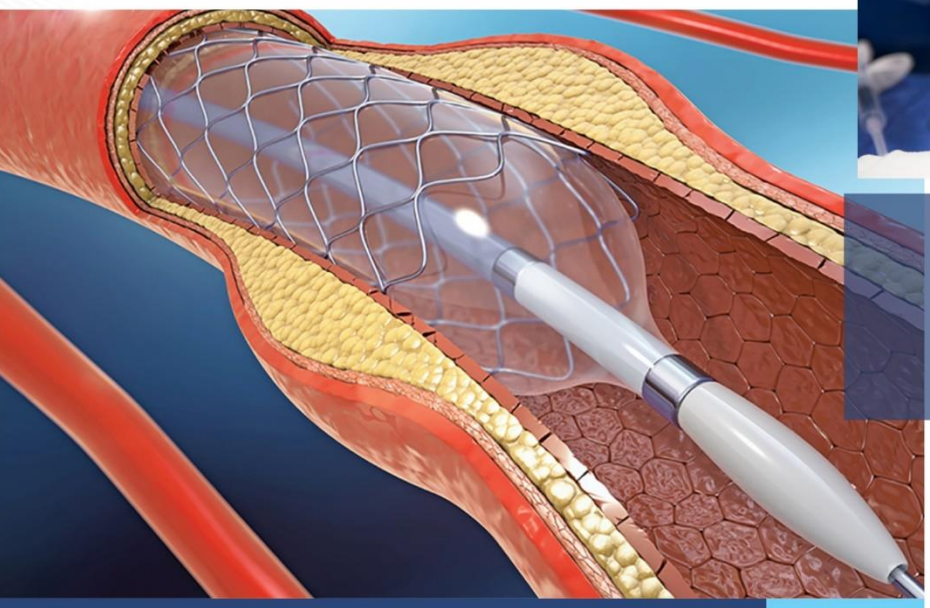
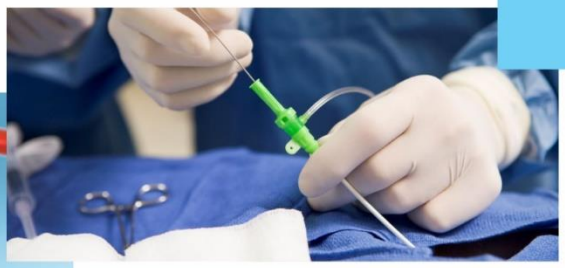
Khyber Pakhtunkhwa Health Care Commission

MINIMUM SERVICE DELIVERY STANDARDS

REFERENCE MANUAL





Cardiac Catheterization Laboratory

KP HCC-03RM-Ed1

1st Edition

Minimum Service Delivery Standards

REFERENCE MANUAL

Cardiac Catheterization Laboratory

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Health Institutions and Regulation of Health Care Services ordinance 2002 (Amendment Act, 2010), which was subsequently repealed through the Act of 2015.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 I and II hospitals, providing in-patient care. Moreover, MSDS were also developed for different kinds of Category III 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 Prof. Dr. Muhammad Hafizullah, Prof. Dr. Mahmood ul Hassan, and Assistant Prof. Dr. Jabbar Ali for their assistance in the finalization of these standards. Moreover, I am grateful to Mr. Zeeshan Khan, of KP HCC for reviewing this documents during the process of adaptation.

The MSDS Reference Manual for Cardiac Catheterization Laboratory comprises 8 standards and 27 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

INDEX OF
STANDARDS AND INDICATORS

Table of Contents

List of Acronyms & Abbreviations

ADR	Adverse Drug Reaction
APP	Authorized Primary Physician
CCL	Cardiac Catheterization Laboratory
COP	Care of Patients
CROP	Cardiac Registry of Pakistan
CT	Computed Tomography
DRAP	Drug Regulatory authority Pakistan
HCEs	Healthcare Establishments
HCSP	Healthcare Service Provider
HRC	Human Resource Case
IAoB	Intra-aortic Balloons
IPC	Infection Prevention & Control
JD	Job description
MRI	Magnetic Resonance Imaging
MSDS	Minimum Service Delivery Standards
NCDR	National Cardiovascular Data Registry
NICB	National Interventional Cardiology Board
OEM	Original Equipment Manufacturer
PMDC	Pakistan Medical & Dental Council
PSIC	Pakistan Society of Interventional Cardiologists
TIA	Transient Ischemic Attacks

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 (Up to 30 beds, 31 to 49 beds, 50 and more beds), Basic Health Units, General Practitioner and Specialist Clinics, Dental Clinics, Clinical Laboratories and Collection Points, Radiological Diagnostic Centers, Homeopathic Clinics, Tibb Clinics.

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 (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.

1.2 Reference Manual for Cardiac Catheterization Laboratory

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 Cardiac Catheterization Laboratories. The document comprises 8 standards with 27 associated indicators

[1] Khyber Pakhtunkhwa Health Care Commission Act, 2015

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 **Color Coding** scheme has been included in all the MDSD of Khyber Pakhtunkhwa Health Care Commission to facilitate the staff of Health Care Establishments (HCEs) 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 in case of YELLOW, partial compliance at least to the extent of 80% is acceptable to qualify for a license from KP HCC and accordingly these indicators have been ascribed 80% weightage. 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

For Cardiac Catheterization Laboratories the total number of indicators is 27. Out of these 25 indicators require full compliance and have been ascribed 100% weightage while 02 (Ind 06 and 10) are acceptable even at partial compliance at least to the extent of 80% (ascribed 80% weightage). 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.

PART 2

LEVELS OF CARDIAC CATHETERIZATION LABORATORY

2. Level of Cardiac Catheterization Laboratory

Level Applied For

PLEASE "✓" ONE SELECTION FROM BELOW

CCL LEVELS	DESCRIPTION	SELECTION
LEVEL- I	FULL-SERVICE LABORATORY	
LEVEL - II	LABORATORY WITHOUT ON-SITE CARDIAC SURGERY	
LEVEL – III	HOSPITAL-BASED DIAGNOSTIC ONLY LABORATORY	

LEVEL-I

FULL SERVICE LABORATORIES

Defined as those offering a wide variety of diagnostic and interventional procedures **(all sorts of coronary and peripheral endovascular interventions, Primary PCI, structural heart disease interventions)**, with on-site cardiac surgical services to accept patients requiring immediate surgery because of clinical instability or complications of procedures.

REQUIREMENTS

Full-service CCLs must document the on-site presence of:

1. Cardiovascular surgery
2. Cardiovascular anesthetists
3. Intensive care unit
4. Nephrology consultative services and dialysis (on-site or on-call)
5. Neurology consultative services (on-site or on-call)
6. Hematologic consultative and blood bank services
7. Echocardiography (TTE &TOE) and Doppler
8. MRI, CT – Optional
9. If a pediatric catheterization laboratory, similar services for pediatric-aged patients
10. Mechanical support devices are also required and, at a minimum include an adequate number of intra-aortic balloon or impella catheters to support the function of the lab 24/7 on call service to handle emergencies resulting from procedures during the day
11. Full-service CCLs must define the procedures performed and excluded in their laboratory and define the process for the introduction of new procedures into their laboratory setting.

LEVEL-II
LABORATORIES WITHOUT ON-SITE CARDIAC SURGERY

Offer a limited range of diagnostic and interventional services i.e., **coronary and peripheral endovascular interventions/ Primary PCI (subject to meeting of patient eligibility criteria mentioned below)** and require patients needing urgent surgery to be transferred to another facility.

REQUIREMENTS

Level-II CCLs must document the on-site presence of:

1. Coronary care unit
2. Intensive care unit
3. Hematologic consultative and blood bank services
4. Echocardiography (TTE&TOE) and Doppler
5. Mechanical support devices are also required and, at a minimum include an adequate number of intra-aortic balloon or impella catheters to support the function of the lab
6. A working relationship between the interventional cardiologists and cardiac surgery service at the receiving hospital documented by a letter of support from the surgical group to accept cases
7. A mechanism whereby a cardiac surgeon has the ability to review coronary angiograms before elective procedures and provide comments to the cardiologist and, if necessary, patients.
8. Surgical backup available at all hours for urgent cases and for elective cases at mutually agreeable times.
9. Confirmed availability of cardiac surgery and a next available Operating Room before elective procedures begin per written agreement.

10. Mechanism for direct discussion between the cardiologist and cardiac surgeon should urgent transfer be necessary.
11. A written transfer agreement endorsed by both facilities and documentation of a rehearsed plan for the transport of patients to a facility with cardiac surgery and the ability to have patients on cardiopulmonary bypass within 90 minutes of the onset of the emergency.
12. A transport provider able to begin transfer within 20 minutes.
13. A PCI consent form that explains that the procedure is being performed without on-site surgery and what will occur if surgery is necessary.

Patient Eligibility Criteria:

1. CCLs without on-site surgery must define the diagnostic and interventional procedures performed and excluded from their laboratories.
2. Diagnostic procedures excluded from facilities without on-site surgery include patients with pulmonary edema due to ischemia, complex congenital heart disease, and all pediatric procedures.
3. Therapeutic procedures excluded from facilities without on-site surgery are therapeutic procedures for pediatric and adult congenital heart disease. Elective and primary PCI procedures are permitted in sites without on-site cardiovascular surgery if there is strict adherence to national guidelines and a documented working relationship with a full service facility. There must also be a tested emergency transport system in place.
4. Elective High-risk patients and high-risk lesions may be unsuitable for intervention at facilities without onsite surgery.
5. High-risk patients are defined by:
    i. decompensated CHF (Killip Class 3 to 4),
    ii. recent (<8 weeks) CVA
    iii. known clotting disorder,
    iv. left ventricular ejection fraction ≤30%,
    v. chronic kidney disease (creatinine> 2.0 mg/dL or creatinine clearance < 60 mL/min)
    vi. serious ongoing ventricular arrhythmias.
6. High-risk lesions are defined by:
    i. left main stenosis > 50% or 3-vessel disease (>70% proximal or mid lesions) unprotected by prior bypass surgery diffuse disease,
    ii. target lesion that jeopardizes an extensive amount of myocardium,
    iii. diffuse disease (> 20 mm length),
    iv. extremely angulated segment or excessive proximal or in-lesion tortuosity (defined as > two 45 degree bends before the target stenosis,
    v. greater than moderate calcification visible proximal and at the target stenosis,
    vi. inability to protect major side branches,
    vii. older degenerated vein grafts with friable lesions,
    viii. thrombus in the target vessel or at lesion site,
    ix. chronic total occlusions (defined as > 3 months in duration and or bridging collaterals),
    x. vessel characteristics that, in the operator's judgment, would impede stent deployment and k) anticipated probable need for rotational or other atherectomy device, cutting balloon etc.

LEVEL-III
HOSPITAL-BASED DIAGNOSTIC ONLY LABORATORIES

Freestanding laboratories that do not perform coronary interventions and are usually **only for elective diagnostic procedures.**

REQUIREMENTS

Level-III CCLs must document the on-site presence of:

1. Coronary care unit
2. Hematologic consultative and blood bank services
3. Echocardiography (TTE&TOE) and doppler
4. Mechanical support devices are also required and, at a minimum include an adequate number of intra-aortic balloon or impella catheters to support the function of the lab
5. Such laboratories must have a written and rehearsed plan for the transport of patients to a facility with surgery. A formal transfer agreement is a requirement.

Patient Eligibility Criteria: Patient exclusions for such laboratories should include:

1. NYHA Class 4,
2. pulmonary edema due to ischemia,
3. those with known peripheral vascular disease if no vascular surgery available,
4. complex congenital heart disease,
5. acute coronary syndromes and
6. all pediatric procedures

PART 3
STANDARDS, INDICATORS AND ASSESSMENT SCORING MATRIX

Standard 1. Portrayed invasive Cardiology services, are provided as per the statutes/ prescribed standards

Ind 1. Invasive Cardiology/Cardiac Catheterization Laboratory staff is aware of the relevant laws, prescribed rules, regulations and service specific standards

Survey Process:

The essence of this indicator is that the Invasive Cardiology/Cardiac Catheterization Laboratory Services, provided by the HCE, should comply with all legal, regulatory and safety requirements. Surveyors should look for availability of the evidence in terms of documents as well as infrastructure that reflects compliance of the regulatory requirements. Key staff should have copies or at least access to the statutes, standards & SOPs and should be aware of the pertinent regulatory requirements.

Compliance requirements	Evidence
1. Key staff should have copies/access to the statutes, standards and SOPs	Interview
2. Key staff is aware of the regulatory requirements.	Interview

Scoring:

- If the above requirements are complied, then score as **fully met.**
- If any of the above requirements are not complied, then score as **not met.**

Ind 2. Level of the Cardiac Catheterization Laboratory is displayed and the CCL is registered with PSIC

Survey Process:

This indicator requires that the particular Cardiac Catheterization Laboratory should be ascribed a Level as provided in the CCL Standards prescribed by the PSIC/NICB as Level-I, Level-II or Level-III according to its infrastructure/HR availability and the range of procedures performed.

Compliance requirements	Evidence
1. Level of the particular Cath Lab, as classified in the CCL Guidelines (Level-I, Level-II or Level-III), is displayed in a way that it is clearly understandable for the patients/clients.	Observe
2. Key staff is aware of the basis of classification of the Cath Labs in to various levels.	Interview
3. Document defining the procedures performed and excluded in the CCL is available	Document Review

Scoring:

- If the above requirements are complied, then score as **fully met.**

- If any of the above requirements are not complied, then score as **not met.**

Ind 3. Registration standards/ Regulations for the Cardiac stents, LSMDs disposables used for provision of interventional cardiology services and implanting Cardiac Stents as notified by the regulatory authority/competent forum from time to time, are followed

Survey Process:

The SCP decision on HRC Case No. 623-P/2017 in the matter of imbedding substandard cardiac stents is relevant in this regard. DRAP, a federal authority for registration as well as pricing of all drugs and medical devices including stents, vide its notification No. F. NO. l-l/2017-DD/LA dated 22/3/2017 issued an advisory for taking measures to check the quality of cardiac stents. The indicator also mandates that only the Cardiac stents registered with the national registry of DRAP/NMDR are used by the Cath Lab. The purpose of this indicator is to ensure that patients requiring cardiac intervention and cardiac catheterization can avail the services of good quality.

Compliance requirements	Evidence
1. The staff/ Cath Lab operators are aware of the registration/ regulations notified by the DRAP in respect of cardiac stents as well as LSMDs and the negative List regarding the stents and LSMDs	Interview
2. Only the Cardiac stents, LSMDs and other disposables registered with the national registry of DRAP/NMDR are used.	Document Review
3. No cardiac stent, other devices or disposables placed in the 'Negative List' by the NICB and published by DRAP for enforcement are imported or used in Pakistan by the CCL.	Document Review Interview

Scoring:

- If the above requirements are complied, then score as **fully met.**
- If any of the above requirements are not complied, then score as **not met.**

Ind 4. Pricing policy for provision of interventional cardiology services, implanting Cardiac stents and other LSMDs, as notified / fixed by the regulatory authority or the CCL/HCE from time to time, is followed

Survey Process:

The DRAP, a federal authority established under the DRAP Act 2012, is mandated, for registration as well as fixing pricing of all drugs and medical devices including stents. Further, pursuant to the orders of the Supreme Court of Pakistan, the DRAP issued an advisory for taking measures to check the quality as well as prices of cardiac stents. This indicator requires that pricing of the stents and medical devices if fixed by the regulatory authority are followed and also made known to the patients and families. In the case of devices and services for which the DRAP has not notified prices, the HCE/ CCL need to

notify cost of the procedures/ interventions and make available for information of the patients.

Compliance requirements	Evidence
1. The staff/ Cath Lab operators are aware of the prices fixed by the DRAP or notified by the CCL/HCE in respect of provision of interventional cardiology including implanting cardiac stents as well as LSMDs and other interventional procedures	Document Review
2. Pricing policy based on the regulatory directions is adopted by the service providers/ CCLs/HCEs and made known to the patients/ families.	Document Review
3. The cost of the entire process of interventional cardiology treatment is divided into following four components and prominently displayed for information of the patients; i. Cost of stents, LSMDs and other necessary devices and disposables. ii. Professional Fee of the operator/ iii. Interventionist. iv. Charges of Cath Lab. v. Room/ Ward & others costs charged by Hospital.	Document Review

Scoring:

- If the above requirements are complied, then score as **fully met.**
- If any of the above requirements are not complied, then score as **not met.**

Ind 5. Cardiac Catheterization Laboratory has all the facilities available according to its portrayed scope of services

Survey Process:

Interventional cardiology/CCL involves extremely sensitive procedures which are lifesaving and also potentially life threatening. Therefore, it is mandatory that all the relevant facilities/ services should be provided depending on the level of the Cath Lab. The on-site availability of any of the required services has an edge to that of the services available on-call only. All level I Cath labs need to have on-site facilities for Cardiovascular Surgery, Anesthesia, ICU and Blood Bank. The Level II Cath Labs are required to have a documented arrangement in the form of an MOU signed with such HCE/s having arrangements for timely availability of Cardiac Surgery, Anesthesia and Blood bank etc. in case of emergency. All the documents including MOU/ agreements between the CCL facility and the consultants needs to be thoroughly reviewed.

Compliance requirements (Availability of the following)	Evidence
1. Cardiovascular Surgery	Observe/ Document Review
2. Cardiovascular Anesthetists	Observe/ Document Review
3. Intensive Care Unit	Observe/ Document Review
4. Coronary Care Unit	Observe/ Document Review
5. Echocardiography (TTE & TOE)	Observe/ Document Review

6. Blood Bank Services	Observe/ Document Review
7. In case of pediatric catheterization laboratory, similar services for pediatric-	Observe/ Document Review

Scoring:

- If the above requirements are complied, then score as **fully met.**
- If any of the above requirements are not complied, then score as **not met.**

Ind 6. Cardiac Catheterization Laboratory has all the services available according to its portrayed scope of work

Survey Process:

The cardiac patients undergoing Cardiac Catheterization Intervention frequently need consultation for opinion of this nephrologists, haematological and Neuro Physicians. They might also need to undergo CT scanning or MRI for diagnostic purposes. The on-site availability of any of the following services has an edge to that of the services available on-call only. The indicator requires thorough review of all the documents including MOU/ agreements between the CCL facility and the consultants or the HCEs providing such services.

Compliance requirements	Evidence
1. Nephrology consultative services and dialysis. On-site On-call	**Document Review:** Agreement Observe
2. Neurology Consultative Services On-site On-call	**Document Review:** Agreement Observe
3. Hematologic Services On-site On-call	**Document Review:** MOU Observe
4. MRI, CT – Optional	Observe

Scoring:

- If all the above services are available on-site, then score as **fully met**
- If all or above consultative services are available on call only, then score as **partially met.**
- If any of the above requirements are neither available on site nor on call, then score as **not met.**

Ind 7. There is 24/7 on call Specialized care service are available to handle emergencies 24/7 on call

Survey Process:

This indicator aims to ensure, 24/7 availability of specialized care services in the HCE/ CCL on-call.

Compliance requirements	Evidence

1. 24/7 on call specialized service to handle emergencies.	Observe
2. Evidence that such services were made available in case of emergency	Document Review

Scoring:

- If the above requirements are complied, then score as **fully met.**
- If any of the above requirements are not complied, then score as **not met.**

Ind 8. There is an established process for the introduction of new procedures into the lab setting

Survey Process:

This indicator aims at reviewing the policy of introduction of new procedures in the Cath Lab. The SOPs/protocols followed to inform the staff about the new procedures and availability of the equipment required, should be assessed.

Compliance requirements	Evidence
1. Document defining the process for the introduction of new procedures into the Cath Laboratory setting.	Document Review
2. SOPs/Protocols to inform the staff about the new procedures are implemented	Document Review

Scoring:

- If the above requirements are complied, then score as **fully met.**
- If any of the above requirements are not complied, then score as **not met.**

GUIDELINES

Relevant Statutues/ Laws for Cardiac Cath Labs:

Copy of following should be available with staff;

1. SCP HRC Case No. 623-P/2017 in the matter of imbedding substandard cardiac stents along with CCL Standards.
2. PMDC Act 2022.
3. PNC Act 1967.
4. DRAP ACT 2012.
5. DRAP-Medical Devices Rules 2017.
6. The Khyber Pakhtunkhwa Environmental Protection Act, 2014
7. The Khyber Pakhtunkhwa Blood Transfusion Safety Authority Act, 2016
8. PNRA Ordinance 2001 as amended.
9. PNRA Regulations for the Licensing of Radiation Facilities other than Nuclear Installations (PAK/908).
10. PNRA Regulations on Radiation Protection (PAK/904); as amended up to March 28, 2012.
11. PNRA Guidelines on Protection of Patients in Diagnostic Radiology-2017.

CCL LEVELS

LEVEL-I (FULL SERVICE LABORATORIES) are those Cardiac Cath Labs that offer a wide variety of diagnostic and interventional cardiac procedures e.g. all sorts of coronary and peripheral endovascular interventions, Primary PCI, structural heart disease interventions, with on-site availability of cardiac surgical services to accept patients requiring cardiac surgery (CABG) based on clinical diagnosis immediate surgery because of clinical instability or complications of procedures.

LEVEL-II (LABORATORIES WITHOUT ON-SITE CARDIAC SURGERY) offer a limited range and interventional services i.e. coronary and peripheral endovascular interventions/ Primary PCI subject to meet patient eligibility criteria mentioned below and require transfer of patients needing urgent surgery, to another contracted facility/ documented working relationship.

Patient Eligibility Criteria for Level-II CCLs

1. CCLs without on-site surgery must define the diagnostic and interventional procedures performed and excluded from their laboratories.
2. Diagnostic procedures excluded from facilities without on-site surgery include patients with pulmonary edema due to ischemia, complex congenital heart disease, and all pediatric procedures.
3. Therapeutic procedures excluded from facilities without on-site surgery are therapeutic procedures for pediatric and adult congenital heart disease.
4. Elective and primary PCI procedures are permitted in sites without on-site cardiovascular surgery if there is strict adherence to national guidelines and a documented working relationship with a full service facility having Level-I Cath Lab with a tested emergency transport system in place.
5. Elective High-risk patients and high-risk lesions may be unsuitable for intervention at facilities without onsite surgery.
6. High-risk patients are defined by:
    i. decompensated CHF (Killip Class 3 to 4)
    ii. recent (<8 weeks) CVA
    iii. known clotting disorder,
    iv. left ventricular ejection fraction <30%,
    v. chronic kidney disease (creatinine> 2.0 mg/dl or creatinine clearance < 60 mL/min)
    vi. serious ongoing ventricular arrhythmias.
7. High risk lesions are defined by:
    i. left main stenosis > 50% or 3-vessel disease (>70% proximal or mid lesions) unprotected by prior bypass surgery diffuse disease,
    ii. target lesion that jeopardizes an extensive amount of myocardium,
    iii. diffuse disease (>20 mm length),
    iv. extremely angulated segment or excessive proximal or in-lesion tortuosity (defined as > two 45-degree bends before the target stenosis,
    v. greater than moderate calcification visible proximal and at the target stenosis,
    vi. inability to protect major side branches,
    vii. older degenerated vein grafts with friable lesions,
    viii. thrombus in the target vessel or at lesion site,
    ix. chronic total occlusions (defined as >3 months in duration and or bridging collaterals)

x. vessel characteristics that, in the operator's judgment, would impede stent deployment
xi. anticipated probable need for rotational or other atherectomy device, cutting balloon etc.

LEVEL-III (HOSPITAL-BASED ONLY DIAGNOSTIC CATH LABORATORIES) and freestanding Cardiac Catheterization laboratories that do not perform coronary interventions and usually perform elective diagnostic procedures only.

Patient Eligibility Criteria for Level-III CCLs

1. Patient exclusions for such laboratories should include, those with:
2. NYHA Class 4,
3. pulmonary edema due to ischemia
4. known peripheral vascular disease if no vascular surgery available
5. complex congenital heart disease
6. acute coronary syndromes
7. all pediatric procedures

Standard 2. Cardiac Catheterization Laboratory has a programme for management of support service equipment

Ind 9. Cardiac Catheterization Laboratory has all the general equipment according to its portrayed scope of service/level

Survey Process:

Interventional Cardiology/CCL involves extremely sensitive procedures while using advanced technology which may prove to be life threatening. Therefore, having all the required equipment and supplies which are of approved standard and well maintained, is of utmost importance. It is mandatory for all CCLs to have the required equipment/consumables and disposables which is essential for their level/scope of service in addition to other essential general equipment for all support functions.

Compliance requirements (Availability of the following)	Evidence
1. Digital fluoroscopy	Observe Document / Inventory Review Interview
2. Angiography with multiple image intensifier /flat panel sizes	
3. On-line image storage and retrieval capabilities	
4. Physiologic monitoring with pressure, pulse oximetry & ECG channels	
5. Appropriate inventory of disposable supplies for: i. Vascular access management ii. Diagnostic coronary angiography iii. Ventriculography	
6. Varied inventory of: i. Coronary guiding catheters ii. Coronary guide wires iii. Angioplasty balloons iv. Coronary stents v. Other treatment devices commensurate with the scope of services provided by the Cath lab.	Observe Document/Inventory Review
7. Expiry date in respect of cardiac stents as well as LSMDs and disposables is monitored and followed.	Document Review

Scoring:

- If the above requirements are complied, then score as **fully met.**
- If any of the above requirements are not complied, then score as **not met.**

Ind 10. All the emergency management equipment to cater for the claimed scope of service/level is installed

Survey Process:

This indicator requires ensuring availability of emergency management equipment apart from the

presence of general equipment. Inventory should be checked for availability and reporting of non-functional equipment and corrective action for the repair of the same.

Compliance requirements	Evidence
1. Presence of following emergency management equipment: i. Resuscitation Equipment ii. Biphasic Defibrillator iii. Vasoactive and Antiarrhythmic Drugs iv. Endotracheal intubation v. Temporary trans-venous pacemakers vi. Intra-aortic balloon pump vii. Pericardiocentesis equipment	**Document Review:** Purchase Order / Inventory Observe
2. Mechanical support devices: i. Intra-aortic balloon pump and /or ii. Impella catheters	Observe
3. Expiry date in respect of drugs and disposables is monitored and followed	Document Review
4. Personnel trained on the indications and use of the emergency management equipment	Interview

Scoring:

- If all the above requirements including the IAoBP and Impellla Catheters, both, are available, then score as **fully met.**
- If all the above requirement and either the IAoBP or Impellla Catheters are available, then score as **partially met.**
- If any of the above requirements, and the neither IAoBP nor Impellla Catheters, are available then, score as **not met.**

Ind 11. The Cardiac Catheterization Laboratory has the radiographic equipment according to its claimed scope of service

Survey Process:

This indicator pertains to assessing the availability, functioning and quality of results of radiographic equipment required and used at the CCL.

Compliance requirements	Evidence
1. The radiographic equipment is capable to ensure /provide for the following: i. Image quality ii. Dynamic range iii. Modulation transfer function iv. Fluoroscopic spatial resolution v. Fluoroscopic field of view size accuracy vi. Low contrast resolution vii. Record fluoroscopic mode viii. Automatic exposure control under standard conditions and at maximum output	Observe **Document Review:** For specifications and inventory

ix. Calibration of integrated radiation Dosimeter	
2. Qualified and trained staff to operate this radiographic equipment	Review

Scoring:

- If the above requirements are complied, then score as **fully met.**
- If any of the above requirements are not complied, then score as **not met.**

Ind 12. Preventive maintenance and calibration programme for all equipment is documented and implemented

Survey Process:

This indicator aims at validating that the equipment used at CCL, meet the recommended manufacturers' standards and they are performing at the required level to provide safe and effective care. Periodic preventive maintenance and calibration extends equipment life and allows its use to be at peak efficiency to deliver accurate results.

Compliance requirements	Evidence
1. A process documenting routine preventive maintenance and testing calibration of Cath Laboratory equipment based on vendor recommendations/ OEM guidelines is established and implemented	**Document Review:** MoU SOPs
2. The operational efficiency of infrequently used equipment is ensured through regular assessment of their functions with logs kept that also include personnel training updates	**Document Review** Log Book
3. Functional UPS/Generator	**Document Review:** Service Log Book

Scoring:

- If the above requirements are complied, then score as **fully met.**
- If any of the above requirements are not complied, then score as **not met.**

Ind 13. The CCL has a valid license issued by the PNRA

Survey Process:

The angiography equipment used at the CCLs emit radiations and as such all the CCLs are required to have a valid license from Pakistan Nuclear Regulatory Authority (PNRA) ensuring radiation safety for the patients and the staff. Surveyors are required to check the validity of the license, compliance with the licensing requirements and any observations by the PNRA. The surveyors also need to assess and observe that the CCL staff radiation uses radiation safety measure e.g. lead aprons etc.

Compliance requirements	Evidence
1. The CCL is licensed by the PNRA and the License is valid.	Document Review

2. The comprehensive radiation safety programme is documented and implemented	
3. The CCL staff uses radiation protection equipment e.g. Lead aprons, neck shields and dosimeter etc.	

Scoring:

- If the above requirements are complied, then score as **fully met.**
- If any of the above requirements are not complied, then score as **not met.**

Standard 3. A credentialing committee is established with defined/ notified TORs

Ind 14. The CCL credentialing committee reviews the individual physician`s credentials to authorize/ grant privileges to CCL operators to carry out defined procedures

Survey Process:

This indicator is to ensure that appointment of all the staff/operators of the CCL is in accordance with the eligibility criteria defined for the assigned job. The Credentialing Committee must include the senior management, senior interventional cardiologist/s and Director/Head of HR in addition to any other member/s as specified in the CCL Guidelines 2017.

Compliance requirements	Evidence
1. Established/ notified Credentialing Committee with defined role/ TORs	**Document Review:** Notification, TORs Notification of the Meetings/ minutes
2. The Credentialing Committee includes the senior managers, senior Interventional Cardiologists/ Director/ head of HR, as members	**Document Review** List of Committee Members
3. The credentialing committee reviews the credentials of the Cath Lab Operators to authorize / grant privileges as per the defined eligibility criteria	**Document Review**

Scoring:

- If all the above requirements are complied, then score as **fully met.**
- If any of the above requirements are not complied, then score as **not met.**

Ind 15. The eligibility criteria for the Cath Lab Director is defined and followed as per the CCL guidelines

Survey Process:

This indicator requires the Cardiac Catheterization Laboratory to define the eligibility criteria for the Cath-Lab Director in accordance with the guidelines provided in the CCL Standards and appointment of the CCL Director is made in accordance with the defined criteria i.e. a senior Interventional Cardiologists with five or more years' experience. The Organogram and the staff appointed in the Cath lab is in accordance with the Guidelines/ Standards.

Compliance requirements	Evidence
1. Eligibility criteria of the Cath Lab Director is defined	**Document Review:**

	Notification of the Cath- Lab director PSIC Registration
2. Appointment of the CCL Director is as per eligibility criteria i.e. Interventional Cardiologist with five or more years of 3. experience	**Document Review:** Credentials of Cath- Lab Director Experience Certificates

Scoring:

- If the above requirements are complied, then score as **fully met.**
- If any of the above requirements are not complied, then score as **not met.**

Ind 16. The eligibility criteria of all Cath Lab Operators based on Practice and Training pathways, as defined in the CCL Standards and Best Practices Guidelines is followed

Survey Process:

The essence of this indicator is that every CCL operator is allowed to perform procedures in accordance with the defined eligibility criteria. All operators should have prescribed qualification registered with relevant regulatory authority e.g. PMDC, the registration should be valid and have certificate/s issued by the PSIC certifying that the operator is eligible to perform as interventional cardiologist. The prescribed qualification includes:

1. FCPS in Interventional Cardiology
2. Diplomate American board of Interventional Cardiology
3. MRCP with specialized cardiology training
4. FCPS Cardiology with specialized training in Interventional cardiology
5. Performed at least 75 procedures/ year as primary operator

Compliance requirements	Evidence
1. Eligibility Criteria for the CCL operators is defined as per CCL Standards	**Document Review:** Degrees/Fellowships/Diplomas / Training Certificates PSIC Registration
2. Evidence that the eligibility criteria is followed	

Scoring:

- If the above requirements are complied, then score as **fully met.**
- If any of the above requirements are not complied, then score as **not met.**

Ind 17. The Physician Extenders and Cardiology Fellows are allowed to work as primary operators for training purpose only.

Survey Process:

The Cardiology fellows are enrolled in the recognized Institutions for training purpose. The SOPs for working and training of such professionals should be defined specifying that the Physician Extenders and Cardiology Fellows are authorized as primary operators for training purpose only. There should

be evidence that the practice/ SOPs is followed. Further the Non-Physician extenders need to be appropriately trained and credentialed by the CCL. The documented policy of the Cath Lab should define the supervisory role of the Primary Operating Physician / CCL Operator.

Compliance requirements	Evidence
1. SOPs defining that Interventional Fellows/ Residents are recognized as primary operators for training purpose only.	Document Review Interview
2. Evidence that the physician extenders and non- physician extenders are proficient.	Document Review Interview
3. Physicians Extenders are appropriately trained and credentialed	Document Review: Credentials
4. Presence of documented policy regarding the supervisory role of Primary Operating Physician/CCL Operator	Document Review

Scoring:

- If the above requirements are complied, then score as **fully met.**
- If any of the above requirements are not complied, then score as **not met.**

Ind 18. The nursing personnel in the CCL is qualified and have specific experience and well-defined role/ JDs

Survey Process:

This indicator entails assessment of Nursing personnel deputed in the CCL in terms of their qualification, training and experience. The nursing staff working in the CCL should be supervised by a senior registered Nurse having relevant experience of working in a Cath Lab and her supervisory role should be defined. The nurses deputed in the Cath Lab should be trained and skilled as per guidelines (preferably include one-year critical care practice, complete knowledge of cardiovascular medications). The nurses working in Cath Labs should have prior working experience of working at such setting and the nursing staff should be supported by nursing assistants.

Compliance requirements	Evidence
1. A registered Nurse with relevant experience functions as Nursing Supervisor for the CCL	**Document Review:** Credentials and Certificates of Training of Nursing Personnel. Document defining the role of Nursing supervisor
2. The role of nursing supervisor is defined	
3. The nurses deputed in the CCL are qualified, trained and skilled.	
4. Nursing assistants are appointed in the CCL as required	

Scoring:

- If the above requirements are complied, then score as **fully met.**
- If any of the above requirements are not complied, then score as **not met.**

Ind 19. The technologists at the CCL have specific experience and well-defined role/ JD

Survey Process:

The technologists/ Radiological Technician need to have prescribed qualification and training as well as skilled to work in CCL settings. The surveyors should assess that the technologists are dully qualified and trained as radiological technologists and have experience of working in the Cath Lab.

Compliance requirements	Evidence
1. Presence of Technologist/certified Radiological Technologist in the CCL as per	**Document Review:** Credentials and Certificates of Training of Technologists. Document defining the role of Technologists
2. The technologists are qualified, trained and skilled as per guidelines	

Scoring:

- If the above requirements are complied, then score as **fully met.**
- If any of the above requirements are not complied, then score as **not met.**

GUIDELINES

Cath Lab Director

All Cath Labs should have a designated Cath Lab- Director who should be a credentialed Interventional Cardiologist, registered with the PMDC and certified by the PSIC and preferably have 5 years of experience as Interventional Cardiologist.

Job Description of the Cath Lab Director including his supervisory role should be defined/documented. The Cath- Lab Director should be familiar with his JD.

Cath Lab Operators Eligibilty Criteria:

TRAINING PATHWAY

1. FCPS in interventional cardiology/ Diplomate American Board of Interventional Cardiology MRCP with specialized Cardiology training in Interventional Cardiology post fellowship (completed certificate of specialized training in Cardiology (CCT) UK, or equivalent.
2. FCPS Cardiology, or equivalent, with at least 3 years post fellowship adequate supervised training/experience in interventional cardiology at CPSP recognized and PSIC registered Cardiac Catheterization Laboratory under the supervision of a certified interventional cardiologist. He /she should have done at least 75 procedures/year as primary operator. Training experience certificate to this effect should be provided by the catheterization laboratory director/HOD or Head of Institute.

Practice Pathway:

1. FCPS medicine/MRCP (Diplomate American Board in Medicine) or equivalent with at least 15 years of practical experience in interventional cardiology with at least 75 procedures per year in last 2 years. This exemption is given till 2023 only after which formal 2 years training for

second FeIlowship in Interventional cardiology will be mandatory.

2. One-time exemption would be given to all senior cardiologists with MBBS, having at least 25 years of active interventional cardiology practice within the country or outside. (This relaxation will be considered a one-time exemption only and will NOT be applicable to anyone in future).
3. These Criteria would be monitored on yearly basis till 2023 when FCPS in interventional cardiology or equivalent training abroad, would become mandatory to practice interventional cardiology in country. If demand of interventional cardiology fellows is not met by 2023 than time line for implementation of this relaxation/exemption may be extended.

Credentialling Commiittee

All Cath- Labs need to establish a credentialing Committee with nominated members with the key role of Credentialing Committee to:

1. Review the individual physician's credentials
2. Allows them privileges of carrying out defined procedures in the hospital.

The KP HCC assessor needs to verify notification of the credentialing Committee clearly nominating its members and TORs. Also review proceedings of the Committee in terms of granting privileges to the operators performing procedures in the CCL.

The Assessor needs to verify that the Cath Lab Credentialing Committee or such other body of the Hospital is maintaining such record/ documentary evidence that the physician extenders are periodically evaluated on the basis of prescribed parameters and that they possess requisite knowledge and skills.

NURSING SUPERVISOR

There must be a Registered Nurse to perform functions as Nursing Supervisor for the CCL.

Role of the nursing supervisor:

The Nursing Supervisor has a defined role and He/ She to be a senior registered nurse with training and experience of working in the CCL and fulfil the following requirement as per guidelines.

1. Must be familiar with the overall function of the laboratory.
2. May or may not also function as the Technical Supervisor of the CCL.
3. Is in charge of the pre and post procedure areas as well as the procedure laboratories.
4. Must ensure that all local patient care policies and procedures of the CCL are followed.
5. Must ensure that all CCL nurses are properly trained for the level of patient care they deliver.

Number & type of nursing personnel:

The number and type of nursing personnel required depend on the laboratory caseload and types of procedures performed. Personnel may include nurse practitioners, registered nurses, licensed vocational practical nurses, or nursing assistants.

Experience/training criteria of cath lab nurses:

The experience of catheterization laboratory registered nurses should preferably include one-year critical care practice, knowledge of cardiovascular medications, ability to start IVs and administer drugs, sterile technique, skills in monitoring vital signs, neurologic status and pain level. Nurses administering conscious or deep sedation require additional training established by the facility and demonstration of competence. Properly trained nursing assistants may also be deputed for some functions in laboratories.

The skilled Allied Health Professionals should be trained and experienced in evaluating patients before and after Catheter based Interventional Procedures.

Role of technologists:

Each CCL should have at least one technologist. The role and responsibilities of the technologists should be defined as per Guidelines.

Preferably a certified and qualified radiological Technologists should be deputed in the CCL. If not a certified radiological technologist, there should be at least one certified technologist who should be skilled and familiar with:

1. Radiographic and Angiographic imaging principles
2. The performance of X-ray generators
3. Cine-pulse systems
4. Image intensification
5. Video and digital image storage
6. Radiation safety principles
7. Pressure injection systems.

The responsibilities of technicians in the laboratory should be defined and include the following:

1. The routine maintenance of radiological equipment
2. Monitoring Radiation Safety
3. Management of blood samples and calculations
4. Monitoring and recording of ECG and hemodynamic data
5. Data storage
6. Operation of other equipment (i.e. IABP, MJS, rotational atherectomy, etc.)
7. And other responsibilities as established by the HCE/ Facility including administration of relevant medications.

Physician Extenders and Cardiology Fellows:

1. The primary operator should always be a physician. Non-physician health care providers should always be viewed as extensions of the primary operator's hands, with the responsibility for safety ultimately lying with the invasive cardiologist. Interventional fellows may be considered primary operators for training purposes only at PSIC approved lab or equivalent foreign facility. An attending Cardiologist must be administratively identified as the primary operator.
2. Appropriately trained and credentialed non-physician providers may perform pre-procedural evaluation and post procedural follow-up care.
3. Physician extenders should be proficient in both the technical and cognitive aspects of cardiac catheterization and Percutaneous intervention including:
    i. pre-procedure evaluation,
    ii. indications,
    iii. the anatomy and pathophysiology of the conditions in which they will assist the Physician,
    iv. emergency cardiac care,
    v. radiation safety, and
    vi. the application of diagnostic data to the management of patients.
4. Facilities should have policies regarding the supervisory role of the primary operating physician during the procedure when secondary operators are performing the procedure and direct the non-physician provider or cardiology fellow in addition to providing all clinical decision making.

Standard 4. Pre-procedure good practices are defined and followed.

Ind 20. Informed consent (IC) for performing cardiac procedure is obtained as per guidelines

Survey Process:

By reviewing the sample records, determine if the medical record of ALL the patients who underwent Interventional procedures have a documented informed consent. The hospital must have a written policy on Informed Consent that describes the process used to obtain consent, including documentation and surrogate decision-maker issues. Each facility must have an approved consent form present in the medical record that includes risks, benefits, and alternatives to the procedure in a form and language that the patient or a layperson can understand. This should include the potential for adhoc PCI and its risks/benefits, and alternatives when appropriate. The IC should be in the patient's native language and for the consent to be valid, the patient must be competent to voluntarily provide consent.

This documentation can either be a signed consent form or written note by the responsible physician that contextually accommodates ALL patient levels of understanding. The written informed consent may be obtained by trained secondary operators or non-physician providers. Confirmation of consent should be obtained during 'preparation' or 'time out'.

Procedures that the patient has not consented to must not be performed unless it is a life- threatening emergency and the reasons for this must be documented by the physician.

Compliance requirements	Evidence
1. Documented Policy on taking informed consent	**Document Review:** Documented Policy
2. Each patient's medical record has a documented informed, valid consent as per guidelines	**Template of IC:** Patients' Medical records showing informed consent for all procedures

Scoring:

- If the above requirements are complied, then score as **fully met.**
- If any of the above requirements are not complied, then score as **not met.**

Ind 21. Pre-procedure assessment protocols are compiled and there is a documented evidence.

Survey Process:

Pre-procedural assessment requires consideration of ethical issues, any allergies that patient may have, evaluation of lab values and outside reports and the medications etc. The respect for autonomy mandates that patients be given appropriate and un-coerced choices about their health and potential

medical care and requires that physicians provide accurate and unbiased information about the patient's medical condition, and disclose all potential avenues of care. The physician is responsible for documentation of the indication for the procedure and to document review of appropriate data (e.g., noninvasive tests). In addition, the physician must be transparent regarding any and all potential ethical or financial conflicts concerning therapies or devices employed in the patient's care. Many challenges involved in the Cardiac Interventions inter alia, include maintaining high ethical standards, maintenance of proficiency, avoidance of real or perceived financial conflict of interest, disclosure of potential conflicts, and, most importantly, maintaining the patient's best interest at the top.

Compliance requirements	Evidence
1. Documented pre-procedure assessment protocols	**Document Review:** Pre-Procedure Checklist
2. The pre-procedure assessment/ protocols covers: i. Review of Ethical concerns ii. Prior knowledge of allergies iii. Management of medication iv. Documentation of allergic reactions v. Protocol for preventing contrast reaction vi. Review of Lab Values/ Reports	**Document Review:** Written protocol for the treatment of patients with known radiographic contrast allergy Protocol for patients using anti-coagulants Medical record showing review of relevant Lab reports
3. The evidence that pre-procedure assessment protocols are followed	Document Review

Scoring:

- If the above requirements are complied, then score as **fully met.**
- If any of the above requirements are not complied, then score as **not met.**

Standard 5. Prescribed Intra Procedure Protocols are defined and complied.

Ind 22. Documented intra-procedure protocols are available and practiced by the operators.

Survey Process:

The primary requirement of this indicator is that written Intra-procedural protocols are available in the procedure room for instant reference and to be followed by the operators. These protocols are printed boldly and displayed in such a way that these remain visible and operators can read from their place of procedure. Assessors need to see the documented intra- procedural protocols and the evidence that they are followed.

Compliance requirements	Evidence
1. Documented intra-procedure protocols/ Pre-procedure checklist	**Document Review:** Treatment Plan clearly showing reason for selection of access site and access related risks
2. Intra-procedure monitoring must include: i. Noninvasive hemodynamic and oximetric monitoring of patient's vitals. ii. Defibrillation pads should be attached to all STEMI patients	
3. The technologists are trained and skilled to follow intra-procedure protocols as per guidelines	Document Review

Scoring:

- If the above requirements are complied, then score as **fully met.**
- If any of the above requirements are not complied, then score as **not met.**

Standard 6. Prescribed Post Procedure Protocols are complied

Ind 23. Patient is communicated his post procedural clinical status by the Physician

Survey Process:

The indicator requires that the physician should communicate to inform the patient about his clinical condition actually observed during the procedure, procedure actually undertaken and difficulties encountered and/or complication encountered if any and the post-procedural management plan. Discussions with patients should be delayed until cognitive impairment due to sedation has resolved.

Compliance requirements	Evidence
1. Documented post-procedure protocols/ SOPs and defined mechanism of physician to patient communication as per guidelines	Document Review Interview
2. Evidence that the SOPs are complied	Document Review

Scoring:

- If the above requirements are complied, then score as **fully met.**
- If any of the above requirements are not complied, then score as **not met.**

Ind 24. Record of prescriptions is available at the clinic.

Survey Process:

The requirement is to ensure that the selected access site is properly managed that includes its closure according to the most current and acceptable practices. The surveyors should ensure that following compliance requirements are met.

Compliance requirements	Evidence
1. Choice of Access site is as per guidelines	Document Review
2. Access site closure/management is as per guidelines	
3. Procedure notes including details regarding access site management and closure devices used are recorded	

Scoring:

- If the above requirements are complied, then score as **fully met.**
- If any of the above requirements are not complied, then score as **not met.**

GUIDELINES

Informed Consent:

Following aspects of informed consent should be considered:

1. Informed consent is necessary before every procedure and is consistent with the ethical principles of patient autonomy.
2. Informed consent for non- emergent procedures must be obtained and documented before the procedure and in a non-pressured environment before any sedation is given.
3. To be valid, the patient must be competent and voluntarily provide consent; otherwise, a person with power of attorney may act as a surrogate.
4. Ideally, the Informed Consent process should be witnessed by a third party, preferably by the patient's family or a staff member independent of the CCL, and subsequently entered into the medical record.
5. The consent must' be obtained within 30 days (sooner, if indicated by hospital policy), and must be reaffirmed on the day of the procedure.
6. The hospital must have a written policy on Informed Consent that describes the process used to obtain consent, including documentation and surrogate decision-maker issues.
7. Each facility must have an approved consent form present in the medical record that includes risks, benefits, and alternatives to the procedure in terms the patient or a layperson can understand. This should include the potential for adhoc PCI and its risks/benefits, and alternatives when appropriate.
8. The Informed Consent should be in the patient's native language.
9. The written informed consent may be obtained by trained secondary operators or non-physician providers.
10. Confirmation of consent should be obtained during preparation or time out.
11. Procedures that the patient has not consented to, must not be performed unless it is a life-threatening emergency and the reasons for this must be documented.
12. If possible informed consent should be obtained for emergent procedures. However, it is recognized that there are circumstances where written informed consent may not be feasible, in which case local standards for necessary documentation should apply and the need clearly documented in the patient's records.

Ethical concerns:

1. A physician's primary obligation is to act in the best interest of his/ her patient; to take care of other associated ethical concerns and it is the obligation to "do not harm," and respect patient autonomy.
2. The respect for autonomy mandates that patients be given appropriate and un-coerced choices about their health and potential medical care and requires that physicians provide accurate and unbiased information about the patient's medical condition, and disclose all potential avenues of care.
3. The physician is responsible for obtaining satisfactory informed consent, and delineating the potential risks, benefits, and alternatives of the agreed-upon diagnostic and/or therapeutic strategy.
4. The physician is responsible for documentation of the indication for the procedure and to document review of appropriate data (e.g., noninvasive tests).

5. In addition, the physician must be transparent concerning any and all potential ethical or financial conflicts regarding therapies or devices employed in the patient's care.
6. Although many challenges face cardiologists today, high ethical standards, including maintenance of proficiency, avoidance of real or perceived financial conflict of interest, disclosure of potential conflicts, and, most important, maintaining the patient's best interest as primary, remain of paramount importance.

Allergies:

1. Allergies to latex, contrast, heparin (and heparin-induced thrombocytopenia), aspirin, narcotics, and other medications should be documented.
2. Each CCL should have a protocol for preventing contrast reactions, written protocols for the treatment of patients with known radiographic contrast allergy and a protocol for the treatment of anaphylaxis should it occur.

Laboratory values and outside reports:

1. Should be available and reviewed by the physician before the procedure.
2. Hemoglobin, platelet count, electrolyte panel, renal function testing and, in the anti- coagulated patient or one with known liver disease a prothrombin time/INR should be obtained on all patients within 30 days of the procedure.
3. A pre-procedure type and screen is optional.

Medications:

1. Initiate antiplatelet therapy prior to the procedure when PCI is possible/likely.
2. Review potential issues with long-term DAPT for these patients.
3. Discontinue warfarin with goal NR <1.8 on day of procedure. (Consider radial access especially for emergency cases).
4. Discontinue novel oral anticoagulants 1-2 days prior to procedure.
5. Adjust insulin dosing for NPO status.
6. Hold Metformin on day of procedure and restart a minimum of 48 hours after the procedure.

Intra-Procedure Practice:

Upon arrival to the procedure room, a nurse, technologist, Authorized Primary Physician (APP), physician extender, or physician should review the pre-procedure checklist.

Noninvasive hemodynamic and oxi-metric monitoring of patient vital signs should be a routine. Defibrillation pads should be attached to all STEMI patients.

Access related risks should be considered with the goal of choosing the optimal access site to reduce complications.

CCL staff should ensure that at least one working IV line is in place prior to the start of the procedure.

Standards for post procedure practice:

Physician to Patient Communication:

1. The physician should discuss the findings, interventions performed, and complications directly with the patient and family.

2. The post procedure management plan should also be addressed
3. Discussions with patients should be delayed until cognitive impairment due to sedation has resolved.

Access Site Management and Closure Devices:

1. **Femoral:**
   Manual compression, compression devices, and VCDs are all options in cases of femoral access.

2. **Radial:**
   Hemostasis by manual compression for the radial access site is usually obtained with wristband compression devices.

Standard 7. Patient outcomes are documented in the interest of patients

Ind 25. Results of interventional procedures are reported as per protocols and regulatory requirements

Survey Process:

There must be enough information documented in the medical record of the patients regarding the procedure, immediately after the procedure is completed. The plan to manage the patient throughout the post-procedure period should also be documented in the medical record. This information could be entered as the preliminary procedure report or as a hand-written operative note immediately after procedure to provide pertinent information for those attending, the patient for post procedure management. It further implies documenting the progress note after completion of the procedure and before the patient is shifted to the next level of care.

Compliance requirements	Evidence
1. Preliminary procedure reports/ notes are documented (written or dictated) immediately after the procedure and added in the medical record of the patient.	**Document Review:** Check the record to make sure that the Preliminary Procedure Reports are being written or dictated immediately after the procedure.
2. Procedural notes are documented in the record as per guidelines	**Document Review:** Check the record of Procedural reports, if the information added is as per guidelines
3. Progress notes are entered in the record are entered as per guidelines before the patient is shifted to the next level of care.	**Document Review:** Check the record of progress notes, if the information provided is as per guidelines.

Scoring:

- If the above requirements are complied, then score as **fully met.**
- If any of the above requirements are not complied, then score as **not met.**

Ind 26. Complications and adverse in-hospital outcomes are reviewed for diagnostic interventional procedures

Survey Process:

Adverse in-hospital patient outcomes (complications) must be reviewed for diagnostic procedures. Participation in the NCDR or CROP-Cath PCI Registry i.e. National database or an International database fulfills the data collection requirements for interventional procedure outcomes / complications.

Compliance requirements	Evidence
1. Documented SOPs to review the adverse in-hospital outcomes/ complications	**Document Review**
2. Evidence that the adverse in-hospital outcomes / complications are documented in the medical records and are reviewed for diagnostic interventional procedures 3. for diagnostic interventional procedures	**Document Review:** Documents consisting details of all adverse in-hospital patient outcomes
4. Evidence of Participation in NCDR or CROP-Cath PCI Registry	**Document Review**
5. In case of non-participation in NCDR or CROP-CATH PCI Registry, assessment of complications is in accordance with the guidelines as under: 6. As per guidelines that i.e. i. Assessed complications are based on the list provided in the guidelines ii. System for follow-up of renal functions in high risk patients is established	**Document Review:** Document with written definitions of the complications with risk-adjustment of these complications Document with written definitions of the complications that are consistent with and allow comparisons to NCDR/CROP benchmarks

Scoring:

- If the above requirements are complied, then score as **fully met.**
- If any of the above requirements are not complied, then score as **not met.**

GUIDELINES

1. Adverse in-hospital patient outcomes (complications) must be reviewed for diagnostic procedures.
   i. Participation in the NCDR or CROP-Cath PCI Registry fulfills the data collection requirements for reviewing in for reviewing the complications for diagnostic procedures. All Cath Labs must become part of NCDR or CROP — Cath PCI Registry.
   ii. In the absence of participation in the NCDR or CROP —Cath PCI Registry, the
   iii. complications assessed must include:
      a. In-hospital mortality for patients with STEMI and without STEMI,
      b. Rate of unplanned CABG
         - Same Day
         - Same Hospitalization
         - Emergent
         - Urgent
         - Elective
      c. Proportion of STEMI patients receiving immediate PCI within 90 minutes,
      d. Rate of procedure-related q-wave MI or ischemia,
      e. Rate of post procedure stroke, Transient Ischemic attack (TIA) or other neurological event,
      f. Rate of vascular complication
      g. Rate of arrhythmia requiring treatment

h. Rate of cardiac arrest in the Cath Lab.
i. Rate of new hemodynamic instability in the Cath Lab.
j. Rate of non-obstructive disease (all stenoses in major arteries < 50% diameter reduction in severity for elective procedures)

2. Although risk adjustment for mortality and bleeding are reported for NCDR Cath PCT Registry by participants, it is recognized that these algorithms may not be available for those facilities not participating in the registry.
3. Facilities must have written definitions of the complications that are consistent with and allow comparisons to NCDR/CROP benchmarks. Complications should be assessed through hospital discharge notes.
4. Facilities should have an established system for the follow-up of renal function in patients at high-risk (i.e. GFR <60) for contrast nephropathy).
5. Participation in a national database or international database fulfills all the data collection requirements for interventional procedure outcomes and complications.
6. If the facility does not participate in any registry, the complications assessed must include death, MI, stroke, cardiogenic shock, emergency CABG, peripheral vascular/access site complications (significant hematoma, pseudoaneurysm, AV fistula, loss of radial pulse, need for vascular surgery or blood transfusion), pericardial tamponade, and the occurrence of contrast-associated nephropathy.
7. Facilities must have written definitions of the complications with risk-adjustment of these complications using a documented methodology, Complications should be assessed through hospital discharge notes/ summaries. Many laboratories also have mechanisms to assess 30-day outcomes and this is suggested.

Progress note:

If the procedure report is not placed in the medical record immediately after the procedure due to transcription or filing delay, then a progress note should be entered in the medical record immediately after the procedure to provide pertinent information for anyone required to attend to the patient for providing post procedure management. **Immediately after the procedure** is defined as "upon completion of procedure, before the patient is transferred to the next level of care." defined as **"upon completion of procedure, before the patient is transferred to the next level of care."**

The procedure progress note should contain at a minimum the information including the following:

1. name of the operator,
2. procedures performed and description of each procedure,
3. findings,
4. estimated blood loss,
5. specimens removed if applicable
6. complications if any
7. post-operative diagnosis and
8. recommendations

Reporting of results:

1. Preliminary procedure reports must be written or dictated immediately after the procedure.
2. There must be enough information in the record immediately after the procedure to manage the patient throughout the post-procedure period. This information could be entered as the

procedure report or as a hand-written operative progress note.

Procedure Report:

All procedure reports at a facility should be individualized to the institution, standardized among operators and contain relevant content on each of the following topics:

1. Patient demographics, primary operator and supporting staff present and procedures performed.
2. Indications for each component of the procedure (e.g. right heart catheterization, renal angiography, etc.)
3. Appropriate supporting history, physical findings, and laboratory findings.
4. The time course and procedural events with technical comments if helpful.
5. Access site information.
6. All catheters, sheaths, guide wires, and interventional equipment used should be reported in a procedural section.
7. Drugs and doses given during the procedure, type and amount of radiographic contrast used, estimation of radiation exposure should be included in the procedure report.
8. Clear description of any complications or a positive statement that there were no apparent complications.
9. For diagnostic procedures a complete summary of hemodynamic findings (pressures, outputs, resistances, valve areas, etc.)

Standard 8. Radiation exposure safety programme is deployed at the CCL.

Ind 27. CCL has implemented a documented radiation exposure safety programme for patients and staff

Survey Process:

Each CCL facility must establish a radiation safety programme and education of staff on radiation safety, either in conjunction with the hospital Health Physics Department/Medical Physicist and/or an outside consultant and/or assistance from a web-based tutorial. Training provided to the staff in radiation safety must be documented. Each facility must monitor staff radiation dose through the use of personal dose monitors. Follow-up is warranted if an individual's dosimeter readings are substantially above or below the expected range for individual's in-laboratory responsibilities. All CCL procedures are performed with the goal of keeping radiation doses to patients and operators as low as reasonably achievable (ALARA).

Compliance requirements	Evidence
1. A documented Radiation exposure/ Safety Programme to document radiation exposure	**Document Review:** Document showing Safety Programme Outline Record of personnel trainings conducted in radiation safety Record of hands on training of new staff or training related to new equipment Document showing follow-up protocol if an individual's dosimeter readings are substantially above or below the expected range Review record of any patient to check if patient radiation dose is monitored as per guidelines Document showing details of surveillance Programme for Radiation safety Follow-Up record for Patients with potential adverse effects from radiation. **Observe:** Presence of personal dose monitors. Staff wearing PPE Use of Lead glasses by the team members closest to the radiation source
2. Established radiation safety education Programme	
3. SOPs for monitoring of Staff Radiation dose and evidence of monitoring	
4. Evidence that the procedures are performed with the goal of keeping radiation doses as low as reasonably achievable (ALARA)	
5. All the related personnel in the Cath Lab / Cath Lab should wear personal protective equipment including lead aprons, neck shields etc.	
6. Evidence of implementation of strategies to reduce radiation exposure	
7. Patient radiation dose is monitored as per guidelines	
8. Surveillance Programme for radiation safety is documented and implemented	

Scoring:

- If the above requirements are complied, then score as **fully met.**
- If any of the above requirements are not complied, then score as **not met.**

GUIDELINES

1. Each CCL should have a programme to document the radiation exposure to patients and staff.
2. Each CCL facility must establish a radiation safety education programme either in conjunction with the hospital Health Physics Department/ Medical Physicist and/or an outside consultant and/or assistance from a web-based tutorial.
3. Documentation of personnel training in radiation safety must be provided.
4. Each facility must monitor staff radiation dose through the use of personal dose monitors. Follow-up should occur if an individual's dosimeter readings are substantially above or below the expected range for them in-laboratory responsibilities.
5. This programme should have the following mandated components:
   i. Initial training or verification of prior training for all physicians and staff using fluoroscopy in the CCL;
   ii. Annual updates on radiation safety;
   iii. Hands on training for new operators in a facility and existing operators on newly purchased equipment.
6. All CCL procedures should be performed with the goal of keeping radiation doses as low as reasonably achievable (ALARA).
7. All personnel in the room should wear personal protective equipment, including lead aprons and thyroid shields as well as radiation badges.
8. For team members closest to the radiation source, leaded glasses should be used.
9. A wide array of strategies to reduce radiation exposure to patients and operators should be practiced.
10. Patient radiation dose needs to be monitored and recorded. This should include the following:
    i. Fluoroscopic time (FT, min)
    ii. Total air kerma at the interventional reference point (Ka,r, Gy) and/or air kerma area product (PKA , Gycm2).
    iii. Peak skin dose (PSD, Gy) should be included if technology permits its measurement.
11. A surveillance programme should be in place for patients whose recorded total air kerma at the interventional reference point (Ka, r,) is 5 Gy or greater, Pka of 500 Gycm2, and/or fluoroscopy doses that exceed 60 minutes.
12. This programme should include the dose and a reason for this dose, patient notification, medical physicist/health physics involvement for Ka,r > IOGy, and a mechanism for patient follow up of potential adverse effects from rad radiation.

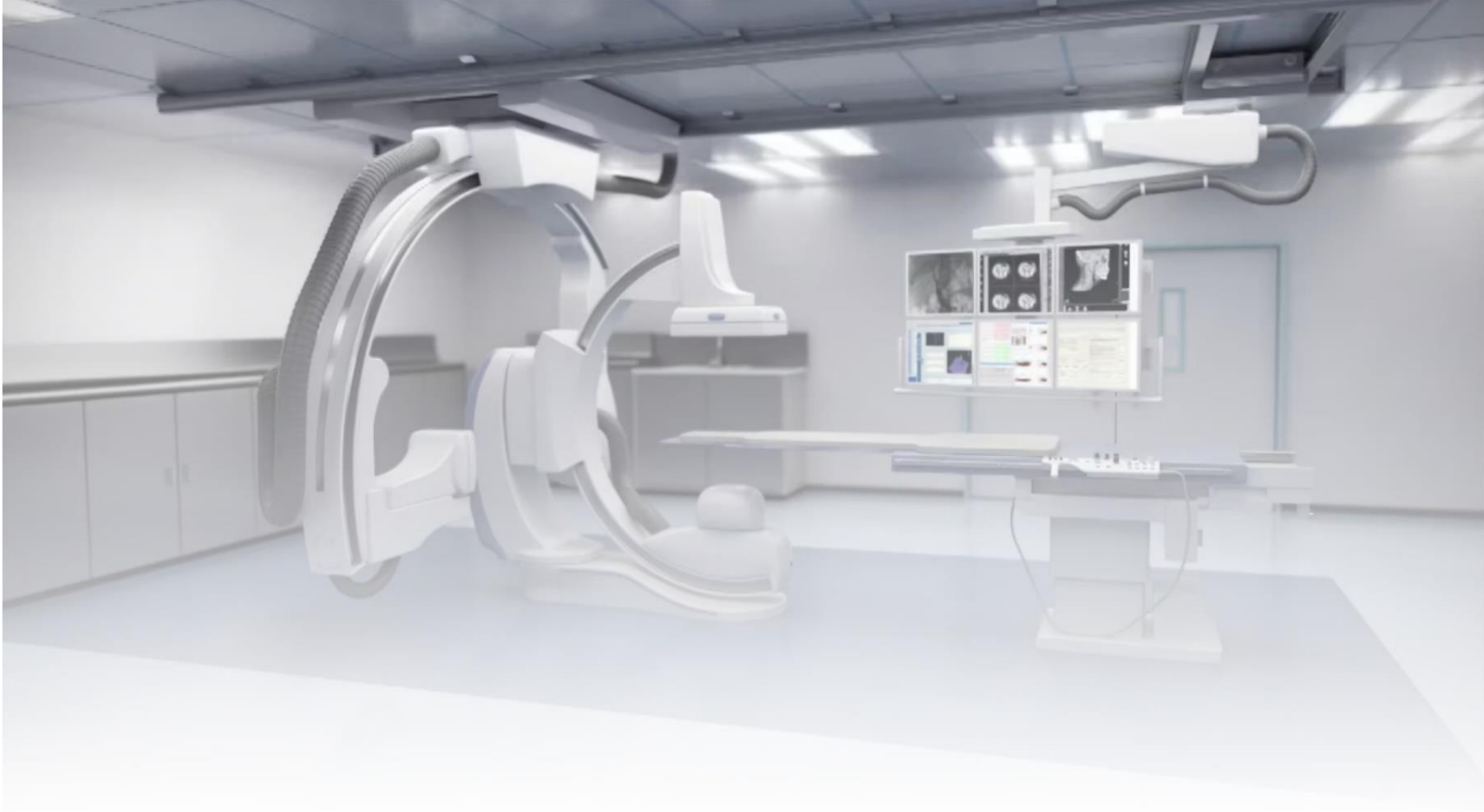
3. Recommendation on the Basis of Assessment

LEVEL OF CARDIAC CATHETERIZATION LABORATORY

PLEASE "✓" ONE SELECTION FROM BELOW

On the Basis of assessment the team of assessors will recommend the appropriate level of cardiac catheterization laboratory for grant of licence by Khyber Pakhtunkhwa Health Care

CCL LEVELS	DESCRIPTION	SELECTION
LEVEL- I	FULL-SERVICE LABORATORY	
LEVEL - II	LABORATORY WITHOUT ON-SITE CARDIAC SURGERY	
LEVEL – III	HOSPITAL-BASED DIAGNOSTIC ONLY LABORATORY	



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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