



# Khyber Pakhtunkhwa Health Care Commission



## MINIMUM SERVICE DELIVERY STANDARDS

# REFERENCE MANUAL



Dental Clinics

KP HCC-07RM-Ed1







1<sup>st</sup> Edition

**Minimum Service Delivery  
Standards**

**REFERENCE  
MANUAL**

Dental Clinics



## 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Health Institutions and Regulation of Health Care Services ordinance 2002 (Amendment Act, 2010), which was subsequently repealed through the Act of 2015.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 care 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 of Board**



## 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 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 Dental Clinics comprises 23 standards and 62 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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## List of Acronyms & Abbreviations

AAC	Access, Assessment, and Continuity of Care
ADR	Adverse Drug Reaction
BLS	Basic Life Support
CNIC	Computerized National Identity Card
CQI	Continuous Quality Improvement
DoB	Date of Birth
DRAP	Drug Regulatory Authority of Pakistan
FMS	Facility Management and Safety
FPAHS	Faculty of Paramedical and Allied Health Sciences, Khyber Pakhtunkhwa
HCE	Healthcare Establishment
HCP	Healthcare Provider
HWM	Hospital Waste Management
IC	Infection Control
JD	Job Description
MLCs	Medico Legal Cases
MOM	Management of Medication
MSDS	Minimum Service Delivery Standards
PHC	Punjab Healthcare Commission
PM&DC	Pakistan Medical & Dental Council
PPE	Personal Protective Equipment
PRE	Patient Rights and Education
QA	Quality Assurance
QI	Quality Improvement
RMP	Registered Medical Practitioner
ROM	Responsibilities of Management
WM	Waste Management



# 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<sup>1</sup> 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, 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<sup>1</sup> 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 Dental Clinics

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 Dental Clinics. The document comprises 23 standards with 62 associated indicators grouped in 10 universally

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<sup>1</sup> Khyber Pakhtunkhwa Health Care Commission Act, 2015

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 **Color Coding** scheme has been included 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

46 indicators require full compliance and have ascribed 100% weightage while 16 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.

An Implementation Assessment Scoring Matrix has been given at the end of each Standard and set of Indicators for self-assessment practice by the HCE Staff, whereas additional details are provided for the assessors. It is highly desirable to achieve 100% scoring in all areas as these standards are already minimum. 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)

#### 04 Standards & 11 Indicators

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These standards provide the structure to help the manager effectively work together to enhance organizational performance. To meet their obligations, leaders/managers must collaborate and work together as a team to achieve a common objective. The leaders/managers are responsible to develop the mission, vision and goals of the organization; encourage honest and open communication and address conflicts of interest so that good relationships can thrive which enable the achievement of the stated goals.

The bigger hospitals generally have three tiers of leadership, the governing body, senior managers and clinical staff, who work together to deliver safe and quality care. The standards related to the responsibilities of management entail creating a culture that fosters safety as a priority, planning and providing services that meet patients' needs and ensuring availability of physical, financial and human resources necessary to provide care. The management is also responsible to engage all managers and clinicians in performance improvement. The standards make clear that performing management functions is the direct responsibility of all leaders and that a coherent working relationship amongst different tiers enhances the quality of care provided to the patients. In the small scale practices however, the management functions/responsibilities of management will be according to the scope of services provided at the particular HCE.

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## Standard 1. ROM-1: The clinic is identifiable as an entity and is easily accessible

### Indicators (1-6):

#### Ind 1. The clinic is identifiable with name and registration/licence numbers on the sign board(s)

##### Survey Process:

The indicator requires that any one accessing the dental clinic is able to identify the clinic by the name of the clinic/service provider clearly written on the sign board, with the PM&DC registration number and the KP HCC registration/licence number i.e. **“Clinic ABC-PM&DC Registration Number. 0000”** and **“KP HCC Registration/Licence Number 0000.”**<sup>2</sup> Surveyors are required to assess that the clinic board is appropriately placed, prominently visible and patients are able to know before entering into the clinic that they are accessing a qualified dental practitioner(s) duly registered with the PM&DC.

##### Compliance Requirements:

- ✓ Sign board of the HCE available, visible and placed appropriately with the following clearly written:
  - Name of the clinic
  - Name of service provider(s)
  - PM&DC Registration Number
  - KP HCC Registration/Licence number

##### Scoring:

- If there is a sign board which clearly identifies the clinic as above, then score as **fully met.**
- If there is no sign board or there are non-conformities to the above, then score as **not met.**

#### Ind 2. The patient/client has easy access to the clinic

##### Survey Process:

Observe that access to the dental clinic for patients/relatives, particularly for disabled/elderly persons, is easy. In case the entry/exit is not on a level ground, it should have steps and ramps/slopes for a wheel chair/stretchers etc. and the ramps/slopes should be non-slippery. The entry/exit and the washroom door(s) (if applicable) are wide enough to allow easy passage for a wheel chair.

##### Compliance Requirements:

- ✓ Non slippery steps and/or,
- ✓ Non slippery ramp/slope for wheel chair, stretcher and/or,
- ✓ Facilitation for patient access,
- ✓ Entry and exit of clinic and washrooms are wide enough to allow easy passage of wheel chairs.

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<sup>2</sup> The requirement to display PM&DC/KP HCC Registration number on the main sign board is relaxed for initial one year during which the Registration Number should be displayed at a prominent place inside the clinic.

### Scoring:

- If the access to the dental clinic is easy as defined above, then score as **fully met.**
- If the entry/exit are not on a level ground, have steps but no ramps for the wheel chair/stretchers as defined above, but facilitation is provided to the patients, then score as **partially met.**
- If the entry/exit are not on a level ground, the steps are narrow and steep and there is no other facilitation, then score as **not met.**

## Ind 3. The dental clinic is registered/licensed with KP HCC

### Survey Process:

The surveyor is required to verify Registration Certificate and the License issued under the KP HCC Act, 2015 or evidence of having applied for the License. KP HCC Registration Certificate/License is to be displayed at a prominent place inside the dental clinic.

### Compliance Requirements:

- ✓ KP HCC Registration Certificate/License is available and displayed inside the clinic OR
- ✓ KP HCC Registration Certificate is available and displayed inside the clinic and there is evidence of having applied for the License

### Scoring:

- If the dental clinic has a Registration Certificate/License from KP HCC and it is displayed as described above, then score as fully met OR if the dental clinic has; i. registration Certificate of the KP HCC which is displayed and ii. evidence of having applied for the grant of License from the KP HCC, then also score as fully met. **fully met.**
- If the dental clinic has no certification as above, then score as **not met.**

## Ind 4. Door plate(s) clearly display name and qualification(s) of the dental surgeon

### Survey Process:

Observe the placement of the door plate(s) displaying qualification(s) and having text in accordance with PM&DC Code of Ethics of Practice for Medical and Dental Practitioners<sup>3</sup> prescribed under the PM&DC Ordinance 1962 and the PM&DC (Amendment) Act 2012 as amended from time to time.

### Compliance Requirements:

- ✓ Door plate(s) displays name and qualification(s)
- ✓ Door plate(s) text according to the PM&DC Code of Ethics for the Medical and Dental Practitioners
- ✓ Door plate(s) size is according to the PM&DC Code of Ethics (not exceeding 4x10 inches)

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<sup>3</sup> Provision 7 (1): No person shall practice modern system of medicine or surgery unless that person is a doctor or dentist having registered qualification and valid registration with PM&DC, 8 (1) refers to display of valid registration of PMDC at the clinic and writing of registration number on prescriptions, certificate and fee receipts to patients and 8 (2) prohibits suffixing of degrees/diplomas with their names which are not registered with PM&DC.

*Note: PM&DC Code of Ethics prohibits suffixing of any degree/diploma with the name of practitioners which are not registered with PM&DC*

**Scoring:**

- If the door plate(s) is/are as above, then score as **fully met.**
- If the door plate(s) is/are present but full information is not displayed as above, then score as **partially met.**
- If the door plate(s) does/do not exist, or it displays superfluous information then score as **not met.**

**Ind 5. The staff on duty uses identity badge(s)<sup>4</sup>**

**Survey Process:**

The essence of the indicator is to ascertain that every employee of the dental clinic<sup>5</sup> who is on duty can be identified by means of an identity badge, having clearly written name/designation and specialty/discipline, where applicable.

**Compliance Requirements:**

- ✓ Identity badge(s) issued to staff by the administrator/in-charge of the dental clinic
- ✓ Staff on duty is identified with badges
- ✓ Badge(s) have clearly written name/designation/discipline

**Scoring:**

- If the staff is using identification badge/s as above, then score as **fully met.**
- If the identification badge/s are not in use or there are non-conformities to the above, then score as **not met.**

**Ind 6. Consultation hours are displayed**

**Survey Process:**

The dental clinic should function only when the dental surgeon is physically available to provide consultation/ services as per consultation hours prominently displayed outside and inside the clinic.

**Compliance Requirements:**

- ✓ Consultation/practice hours are displayed inside and outside the clinic
- ✓ Dental surgeon(s) is/are physically present during consultation/practice hours

**Scoring:**

- If the timings/consultation/practice hours are displayed and followed, then score as **fully met.**

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<sup>4</sup> Means a full identity card with photo and signatures of the staff and issued under the signatures of the administrator/in-charge of dental clinic.

<sup>5</sup> For female staff, like dental nurse, female dental assistant or receptionist etc., who may not like their names/photos to be displayed, a modified system having designation may be devised.

- If the timings/consultation/practice hours are NOT displayed or not followed, then score as **not met.**

## GUIDELINES

### Identification of the Dental Clinic

It is essential for every dental clinic to be clearly identified by its name, discipline, registration of the care provider with the PM&DC and status of registration/licence of the HCE from KP HCC to depict its status of being a legitimate healthcare service provider while excluding those who are not qualified/authorized to practice independently.

Dental clinics are required to install appropriate boards taking into consideration safety measures and fulfilling the regulations/by laws of municipal authorities:

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

The dental clinic/practice will be open and functional only during the presence of the dental surgeon/ dentist. In order to ensure this, the consultation/practice hours of the dental surgeon must be prominently displayed outside and inside the clinic, so that visitors have clear information about the timings of availability of the dental surgeon. The only exception may be opening for a limited time for cleaning/sterilizing or other maintenance activities.

Those dental clinics where more than one dental surgeon provides services, the timings in terms of their days and hours must be clearly mentioned. If a practitioner provides services at more than one clinic, his/her name and authorised qualification with working hours and days must be displayed accordingly.

In case a consultant dental surgeon is just on call to provide services as required, his/her name and qualification/s are to be displayed with the words 'ON CALL'.

### Location and Accessibility:

There is a tendency of encroachment on the in/out gates of the clinics/HCEs by shops, taxis, rickshaws and other vendors which hinders the traffic flow and passage of the patients. Such situations need intervention by the management of the dental clinic to coordinate with concerned authorities for remedial actions. The management of the dental clinic is required to facilitate access to the clinic for disabled and elderly patients through ramps/slopes for the movement of stretchers/wheel chairs, etc. The ramps should not be steep or slippery.

### Registration and Licensing:

Only the dental practitioners registered with the PM&DC are authorized by law to provide care to the patient independently. The registration with the PM&DC has to be renewed and updated as per the prescribed regulation. Registration and licensing of the HCEs/clinics are two separate procedures and it is mandatory for every dentist/dental surgeon to get his/her dental clinics registered and licensed with the KP HCC in terms of Section 12 of the KP HCC Act, 2015.

The HCEs have to apply for registration/license on a prescribed form along with necessary documents. In response to this application, KP HCC will issue a Registration Certificate/Provisional License, which has to be displayed in the dental clinic at a prominent place and its copy must be available in the clinic's record.



**No dental clinic can provide dental services without being registered/licensed with KP HCC and the Registration/License Certificate prominently displayed at the place of practice.**

**Staff Identity:**

Identification of the staff on duty at the dental clinic 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

**Authority for Issuing Identity Badges:**

The identity badge/s should provide correct and standardized information regarding particulars of the person to whom the card is issued to avoid impersonation.

The manager/administrator of the dental clinic is responsible to finalize the specimen and to sign the identity badge which has also to be signed by the holder/employee. The sample format of the card provided below may be followed/adapted:

<b>Clinic Name</b>	
<b>Employee No:</b> _____	
<b>Name:</b> _____	<b>Designation:</b> _____
<b>Date Of Issue:</b> _____	<b>Employee Sig:</b> _____
<b>Valid Upto:</b> _____	<b>Signature Issuing Authority:</b> _____

## Assessment Scoring Matrix

### Standard 1. ROM-1: The clinic is identifiable as an entity and easily accessible

Indicator 1-6		Max Score	Weightage (Percentage)	Score Obtained
Ind 1.	The clinic is identifiable with name and registration/ licence numbers on the sign board(s)	10	<b>100%</b>	
Ind 2.	The patient/client has easy access to the clinic	10	<b>80%</b>	
Ind 3.	The dental clinic is registered/licensed with the KP HCC	10	<b>100%</b>	
Ind 4.	Door plate(s) clearly display name and qualification(s) of the Dental Surgeon	10	<b>80%</b>	
Ind 5.	The staff on duty uses identity badge(s)	10	<b>100%</b>	
Ind 6.	Consultation hours are displayed	10	<b>100%</b>	
<b>Total</b>		60		

## Standard 2. ROM-2: The healthcare service provider(s) at the clinic is/are suitably qualified<sup>6</sup>

### Indicators (7):

#### Ind 7. PM&DC Registration Certificate of the dental surgeon is displayed

#### Survey Process:

A photo copy of the valid Registration Certificate issued by the PM&DC to the dental surgeon is displayed at a prominent place and the original is made available when demanded by the inspection team. The validity of the PM&DC registration certificate can be verified from the PM&DC, if so needed.

#### Compliance Requirements:

- ✓ Photocopy of valid PM&DC Registration is displayed inside the clinic
- ✓ Evidence of initiating renewal process of registration (if applicable) is provided

#### Scoring:

- If copy of the valid PM&DC Registration Certificate is prominently displayed in the clinic and the original is available when demanded by the inspection team, then score as **fully met.**
- If copy of the PM&DC Registration Certificate is displayed in the clinic, but is expired, and there is evidence of having applied for renewal, then score as **partially met.**
- If copy of the Registration Certificate is not available at the clinic or it is expired and the process for renewal has not been initiated, then score as **not met.**

### GUIDELINES

#### Service Provider, Owner, In-charge

Keeping in view the nature of specialized clinical services, the individual who provides healthcare services at the clinic is required to be a qualified BDS doctor, currently registered with the PM&DC. In case of a single-man clinic, the doctor himself/herself shall be considered as the person in-charge, owner or manager of the clinic, for overall administration, coordination and functioning of the dental clinic, unless some other person is hired as manager for handling non-technical matters.

In case the clinic is owned by a non-doctor, the owner shall only manage the general administrative matters, while all technical matters related to provision of dental care shall be the responsibility of the qualified doctor.

In case the clinic is owned/run by more than one practitioner, the person in charge has to be designated, clearly defining the following responsibilities as in-charge/manager of the clinic:

1. Provision of services at the clinic according to the PM&DC rules, regulations and Code of Ethics, ensuring that only admissible dental services are portrayed and provided at the clinic.
2. Regular maintenance and repair of physical infrastructure and putting in place the building

<sup>6</sup> The practitioner/care provider has to be qualified and registered as per the PM&DC Ordinance 1962 and the PM&DC (Amendment) Act 2012 or as amended from time to time.

safety requirements.

3. Maintain high standards of general hygiene and a positive approach to patient handling and facilitation by the support staff.
4. Maintain discipline amongst the staff and displaying the practice hours.
5. Ensure that medication is dispensed according to standard procedures.
6. Ensure that all records are maintained with required information and are periodically reviewed and kept in safe custody with declared responsibility.
7. Arrange requisite facilities and trained staff to deal with emergency care and referrals.
8. Establish a complaints redressing system.
9. Ensure compliance of SOPs on infection control, etc.
10. Maintain all the equipment of the clinic in functioning order.
11. Responsibility for all kinds of financial requirements of the clinic.
12. Responsibility for the training of the staff, like dental assistants, receptionists, etc.
13. Ensure that the PM&DC registration of the dentist/s providing services is valid and copies, along with the KP HCC Registration Certificate are displayed in the clinic and the original certificates are produced when asked by the surveyors.
14. Ensure that there is a process for renewal of PM&DC registration/KP HCC Licence on a regular basis, the process for renewal is initiated well before expiry and the receipt of application is kept in the record.

## Assessment Scoring Matrix

**Standard 2. ROM. 2: The healthcare service provider(s) at the clinic is/ are suitably qualified**

Indicator 7		Max Score	Weightage (Percentage)	Score Obtained
Ind 7.	PM&DC Registration Certificate of the dental surgeon is displayed	10	<b>80%</b>	
<b>Total</b>		10		

## Standard 3. ROM-3: Clinic premises support the scope of work/services

### Indicators (8-10):

#### Ind 8. The size/premises of the dental clinic is as per minimum requirement

##### Survey Process:

Observe that the dental clinic has the minimum required space for reception, seating for patients,<sup>7</sup> consultation/procedures on a dental chair (dental unit), an X-ray unit (portable/stand mounted or separately installed/mounted on wall), a sterilizer and a cabinet for instruments and for the dental materials used during the procedures.

##### Compliance Requirements:

- ✓ Premises has allocated space for the following:
  - Reception
  - Sitting arrangement for at least three patients at one given time
  - Dental chair with essential components and support systems (dental unit) for consultation and procedures
  - Dental X-ray unit mobile or separately installed (as the case may be)
  - Autoclave
  - Cabinet(s) and drawer(s) for instruments
  - Cabinet for essential dental materials

##### Scoring:

- If the dental clinic fulfills the requirements as described above, then score as **fully met**.
- If the premises of the dental clinic is as above, but the reception does not exist, then score as **partially met**.
- If the premises of the dental clinic is not as above or the sitting arrangement is not sufficient to even accommodate three patients at a time, then score as **not met**.

#### Ind 9. The dental clinic has adequate facilities for the comfort of the patients

##### Survey Process:

The surveyors should observe the presence of the following during a visit to a dental clinic.

##### Compliance Requirements:

- ✓ Sitting arrangement

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<sup>7</sup> Comfortable seating means arrangement for at least three to five patients sitting with comfortable posture at one given time, depending on the size of the practice.

- ✓ Alternate arrangements of electricity, having at least a backup time of one hour for keeping all the essential equipment operational and at least three emergency lights
- ✓ Appropriate waste containers in the consultation/procedure room as well as the patients' waiting area and places where technicians work
- ✓ Proper ventilation/air conditioning
- ✓ Clean drinking water
- ✓ Mosquito and fly proofing (wire gauze)<sup>8</sup>
- ✓ Toilet (available/accessible)

**Scoring:**

- If the dental clinic has all the seven facilities mentioned above, then score as **fully met.**
- If the dental clinic has first six facilities mentioned above, then score as **partially met.**
- If the dental clinic does not have any one of the first six facilities listed above, then score as **not met.**

**Ind 10. The dental clinic has adequate arrangements for the privacy of patients during consultation/examination/procedures**

**Survey Process:**

Observe if arrangements for patient's privacy during consultation/examination, as applicable, are available and privacy is respected.<sup>9</sup>

**Compliance Requirements:**

- ✓ Arrangements for patient's privacy and evidence that privacy is respected as per the PM&DC Code of Ethics:
  - Curtain
  - Cabin/Wooden partition

**Scoring:**

- If the Dental Clinic has arrangements for patients' privacy as defined above and evidence that the privacy is respected, then score as **fully met.**
- If privacy arrangement is not available in the Dental Clinic, then score as **not met.**

**GUIDELINES**

**The Premises**

The size and premises of the dental clinic are important for proper delivery of proper healthcare. The clinic should be designed keeping in mind the comfort of both patients and care providers.

<sup>8</sup> Essential to safeguard against diseases transmitted through mosquitos e.g. malaria, dengue, etc. and other infectious diseases spread by flies.

<sup>9</sup> Privacy of all patients during history taking/examination is important and cannot be ignored. Female patients and minors are not examined alone by the male practitioners. In such an event, the accompanying attendant, preferably a female, should be requested to remain present. The PM&DC Code of Ethics for Medical and Dental Practitioners and KP HCC Charters for Patients and others are relevant.

Dental clinics are recommended to have sufficient space designed to cater for basic needs as follows:

1. Patient reception and waiting area for three to five patients sitting in a comfortable posture at one given time. The waiting area/room needs to be appropriately furnished with chairs, settee(s), sofa(s) or benches, depending upon affordability and the number of clients to accommodate at least three to five patients and attendants at a given time, allowing movement without hindrance. The furniture should be comfortable and should preferably also have a center-table and magazine rack depending on the available space and budget. The waiting area can also have a pin-board for posting articles, appointments or general information for patients.
2. Approximately 80 sq. ft. space to accommodate a dentist, patient and one to two attendants for initial consultation and final prescription writing after performing procedure separately or as part of the dental procedure room.
3. In dental procedure room/s, it is ideal to have one dental chair in one room. However, if separate rooms for more than one dental chair are not available then two chairs may be fixed in one larger room with a mobile screen/ fixed partition between the two for performing minor procedures only. For difficult procedures and where surgery is performed, only one patient shall be managed at one time. There should be sufficient space around each dental chair for free movement of the dentist and the assistant(s). There should be sufficient space to accommodate purpose-built cabinets/drawers for sterilized instruments to be handy during the procedures.
4. Instrument washing and sterilization facility.
5. Cabinet for patients' record or the clinic may have a computer for the patient record keeping and searching reference material etc., subject to affordability and patient load.

**Practice can be started at a place, having minimum space as described above. However, availability of further space for possible expansion must be kept in mind with an increase in the number of patients. White ceilings and light colors should be used on walls and furniture to provide an overall bright ambience and clean environment.**

#### **Adequacy of the Facilities**

Generally, the patients and attendants have to wait for some time at the dental clinic(s), during which they need to be made comfortable by providing basic essential amenities. The amenities and facilities may vary depending on the scale of the practice and charges at various dental clinics/practices. However, every dental clinic is required to provide certain basic requirements like proper reception and sitting arrangements in waiting areas, arrangements of electricity with at least emergency lights for all patient areas and a UPS or electric generator for the procedure room, waste container/receptacle(s),<sup>10</sup> proper ventilation, mosquito and fly proofing (wire gauze), clean drinking water and toilets with adequate washing and air conditioning where ever required.

#### **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.....”

Respecting privacy and confidentiality of the patients during examination is a key component of the

<sup>10</sup> As per the Khyber Pakhtunkhwa Hospital Waste Management Rules, 2018, and as amended from time to time.



clinical methodology and an integral part of the PM&DC Code of Ethics reproduced below:

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

(1) A female patient shall be given consultation either by a female dental practitioner or shall be examined in the presence of a female attendant by a male doctor.

**Section 20. Permission of patient before examination**

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

**Section 27. Confidentiality**

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

**Section 36. Taking of photograph or videos for teaching purpose**

Taking of patients' photographs and videos shall be done 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: The clinic premises support the scope of work/services**

Indicator 8 - 10		Max Score	Weightage (Percentage)	Score Obtained
Ind 8.	The size/premises of the dental clinic is as per minimum requirement	10	80%	
Ind 9.	The dental clinic has adequate facilities for the comfort of the patients	10	80%	
Ind 10.	The dental clinic has adequate arrangements for the privacy of patients during consultation/ examination/ procedures	10	100%	
<b>Total</b>		30		

## Standard 4. ROM-4: The responsibilities of the management are defined

### Indicators (11):

**Ind 11. The dental clinic management intimates any change in scope or portrayal of services, the location of the HCE or the service provider(s) etc. to KP HCC**

#### Survey Process:

Review the records and check whether any changes in the ownership, managerial staff, portrayal/scope of services and any change in the location of the clinic within a building or a modification or relocation at another site has been intimated to KP HCC or not.

**Note:** If no changes have been made, mark as “Not Applicable.”

#### Compliance Requirements:

- ✓ Electronic/documented evidence of intimation of the above mentioned changes as applicable

#### Scoring:

- If there is evidence of intimation to the KP HCC of the above mentioned changes, if carried out, then score as **fully met.**
- If the evidence of intimation of any of the above mentioned changes to the KP HCC, if carried out, is not available, then score as **not met.**

### GUIDELINES

#### Intimation of Changes to KP HCC

Dental clinics are issued licenses for providing healthcare services through dental practitioner(s) currently registered with PM&DC at the premises as described and provided in the application submitted to KP HCC. Therefore, any pertinent change in the status or scope of practice as provided in the original application needs to be updated and intimated to the KP HCC. The evidence of communicating any such change to KP HCC needs to be produced to the inspection teams during inspections.

## Assessment Scoring Matrix

**Standard 4. ROM-4: The responsibilities of the management are defined**

Indicator 11		Max Score	Weightage (Percentage)	Score Obtained
Ind 11.	The dental clinic management intimates any change in scope or portrayal of services, the location of the HCE or the service provider(s) etc. to KP HCC	10	<b>100%</b>	
<b>Total</b>		10		

## 2.2 Facility Management and Safety (FMS)

### 02 Standards & 05 Indicators

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A dental clinic serves the dental care needs of the community and therefore, it needs to undertake regular maintenance of the infrastructure to ensure functional and safe optimal services. It is imperative that all dental equipment and support services at the dental clinic remain in prime working condition so that procedures/surgeries are performed with highest level of precision. It is, therefore, desirable that qualified professionals handle and maintain these facilities in accordance with the relevant standards for ensuring reliability, professionalism and sustaining the reputation of the practice/clinic.

For ensuring that the servicing and maintenance needs are responded to quickly and efficiently, the clinic is required to maintain and implement a preventive maintenance schedule in order to provide un-interrupted services in a clean, healthy and safe environment.

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## Standard 5. FMS-1: The dental clinic staff is aware of, and complies with, the relevant laws, rules, regulations, bylaws and facility inspection requirements under the applicable codes

### Indicators (12-16):

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

##### Survey Process:

The clinic staff should be knowledgeable about the extent of applicability of the laws/regulations and codes e.g. pertaining to building safety, fire safety requirements, codes related to maintenance of lifts/elevators, inspections of boilers, compressors and maintenance of generator(s) to ensure uninterrupted power supply and ventilation. The management/clinic staff also needs to know the laws governing the procurement of safe pharmaceuticals, etc., supply of clean water<sup>11</sup> and have effective contingency plans in the event of primary system failures for ensuring smooth functioning of the clinic.

##### Compliance Requirements:

- ✓ Staff is conversant with the relevant laws/regulations/codes as mentioned above
- ✓ Effective contingency plans in the event of primary system failures

##### Scoring:

- If there is clear evidence that the managerial and operational staff is aware of the relevant laws and their applicability/requirements, then score as **fully met.**
- If either there is evidence that the managerial staff is not aware of the relevant laws and their applicability or operational staff is not aware of the relevant requirements, then score as **not met.**

#### Ind 13. The management ensures implementation of relevant laws

##### Survey Process:

Check to see if documentation supports implementation of the laws mentioned in indicator 12 and that this is confirmed with observable examples.

##### Compliance Requirements:

- ✓ Evidence for implementation of all relevant laws/regulations:
  - Availability of updated/current registration, certificate(s), licence(s) by the respective authorities under the relevant laws/regulations/rules (as applicable)
  - Availability of compliance documents e.g. various SOPs (as applicable)

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<sup>11</sup> The Khyber Pakhtunkhwa Drinking Water Policy, 2015.

- Visibility/demonstration of compliance to above in routine work (as applicable)

**Scoring:**

- If there is evidence of compliance with all prevailing laws and regulations, then score as **fully met.**
- If there is evidence of non-compliance with any of the prevailing laws and regulations, then score as **not met.**

**Ind 14. There is a mechanism to regularly update licences/registrations/certifications**

**Survey Process:**

Directly note the validity and currency of the compliance documents and also review the mechanism to regularly update licences/registrations/certifications, etc.

**Compliance Requirements:**

- ✓ Valid registration certificates/licences available (as applicable)
- ✓ Valid certification of dental X-ray unit available (as applicable)

**Scoring:**

- If there is a full range of current compliance documents, then score as **fully met.**
- If even one of the current compliance documents is not available, then score as **not met.**

**Ind 15. The staff has knowledge about early detection and containment of fire and non-fire emergencies<sup>12</sup>**

**Survey Process:**

The surveyors shall ask the staff (dental surgeon as well as the support staff) of the clinic regarding knowledge about the system/process for early detection and containment of fire and non-fire emergencies.

**Compliance Requirements:**

- ✓ Evidence of awareness about detection and containment by interviewing the staff

**Scoring:**

- If the staff has knowledge about the system/process of early detection and containment of fire and non-fire emergencies, then score as **fully met.**
- If the staff has no knowledge, then score as **not met.**

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<sup>12</sup> Early detection at a small scale means to quickly check in person the extra ordinary smoke/burning smells, etc. Non-fire emergencies are earthquake, building collapse, floods, etc.

## Ind 16. Arrangements to combat fire emergencies are in place

### Survey Process:

Observe that arrangements to deal with fire emergencies are available in the clinic. Interview the staff to assess whether they know how to operate/use the firefighting equipment/other arrangements.<sup>13</sup>

### Compliance Requirements:

- ✓ Firefighting equipment/other arrangements available
- ✓ Staff aware about the firefighting system

### Scoring:

- If the arrangements to combat fire emergencies are available and the staff is aware of and knows how to use those, then score as **fully met.**
- If the arrangements to combat fire emergencies are available but the staff is not aware of and does not know how to use those, then score as **partially met.**
- If the arrangements to combat fire emergencies are not available, then score as **not met.**

## GUIDELINES

### Applicability of Laws and Regulations to Dental Clinic/Surgery

A list of the relevant laws applicable to the health sector/healthcare service delivery is provided at **Annexure B.**

The basic design of a dental clinic/surgery is required to support its functions, including the following:

1. Waiting/reception area
2. Care of patients including consultation, procedures / treatment activities and emergency services Diagnostic facilities e.g. x-rays
3. Administrative/Facility management services
4. Support and supply services
5. Parking areas, etc.

The legal aspect is the most significant consideration in planning and designing a project and the architects, engineers, planners and allied professionals must have working knowledge of the applicable laws, rules and regulations and relevant codes of practice.

In the public sector, the Communication and Works Department (C&W) is the responsible agency for planning and designing hospital and clinic buildings with an architect section headed by the Chief Architect.

In the private sector, hospital buildings are designed by architectural firms in accordance with the codes prescribed by the development authorities/local councils/TMs, etc. Private clinics on smaller setups are usually housed in the existing commercial buildings and in houses with self-designed modifications generally in disregard and consideration to the above stated statutory requirements.

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<sup>13</sup> Equipment/arrangement suitable for the dental clinic/surgery like, bucket of water/sand, spade and/or fire extinguisher, etc., as applicable.



The following laws/ regulations and codes are generally applicable for designing and planning hospital buildings and may be considered as far as possible and applicable while planning and designing the dental clinic:

### **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, designing a site plan, must consider the following aspects while remaining within zoning restrictions of the law pertaining to the locality:

- i. Access and accessibility
- ii. Catchment area to be served
- iii. Volumetric dimensional limits of the building in terms of site coverage
- iv. Building height
- v. Distance of other facilities and utilities required
- vi. Easements and rights of way, if any
- vii. Sources of materials and of local skilled and unskilled labor

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

### **2. Building Code**

The Building Code is provided to achieve maximum safety by implementation of standard requirements for construction of buildings to ensure structural stability, taking into account the following provisions so that these can withstand powerful earthquakes and other calamities:

- i. Classification and general requirements for hospital by use or occupancy
- ii. Types of construction
- iii. Light and ventilation
- iv. Labour safety and welfare during construction
- v. Sanitation
- vi. Electrical and mechanical regulations
- vii. Keeping in view the history of incidence of earthquakes, cyclones and other disasters/calamities
- viii. Protection from ionizing radiation from X-ray equipment
- ix. Permits and inspection requirements
- x. Any other applicable code

### **3. Fire Code**

The Fire Code is provided by the Rescue Department, which requires complying with the following provisions in order to minimize injury, death and loss to the staff, patients and families and also to curtail damages to hospital infrastructure:

- i. General precautions against fire
- ii. Principles of fire safety in buildings/structures
- iii. Fire protection appliances
- iv. Maintenance of fire exits
- v. Purpose specific design of high risk buildings, such as theaters, auditorium etc.

- vi. Suppression control in hazardous areas
- vii. Specifying smoking areas as per provisions of relevant law/rules
- viii. Management and use of combustible materials

#### **4. Movement of Patients, Attendants and Visitors**

- i. Patients should be requested not to leave their ward or floor while encouraging walking within the ward area when appropriate.
- ii. Children admitted to the hospital should have an attendant, preferably a female.
- iii. Ladies in the delivery suite may have their spouse or a female attendant.
- iv. Patients in private rooms should also be allowed an attendant.
- v. For all other inpatients, the ward nurse shall decide on the necessity of an attendant on the basis of the patient's clinical condition.
- vi. Where permitted, only one attendant shall be allowed per patient.
- vii. Attendants in female wards should be female.
- viii. Attendants shall be issued an entry pass to enter and remain in the hospital outside visiting hours.
- ix. All visitors should enter and leave the hospital only through the main entrance.
- x. For their own protection, children below 12 years are not allowed to visit patients.

#### **5. 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:

- i. Design is consistent with the national/international standards for public health and safety.
- ii. The permits and licenses necessary for establishing the hospital/clinics, related to the above mentioned codes, are obtained.

The following International Standards should also be considered while designing the hospital:

- i. Facility Guideline Institute (FGI) Guidelines for Design and Construction of Hospitals and Health Care Facilities
- ii. International Building Code (IBC)
- iii. National Fire Protection Agency (NFPA)
- iv. The Americans with Disabilities Act (ADA)
- v. Occupational Safety and Health Administration (OSHA)

#### **6. Inspection of Dental Clinic/Hospital Design**

The dental clinic/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, where necessary, must be checked in addition to the following parameters:

- i. The land or site upon which dental clinic/hospital is being constructed.
- ii. Design or structure of the dental clinic/hospital.
- iii. Use of standardized raw material and its consumption.
- iv. Methods of construction or workmanship.
- v. Sanitation codes, environmental protection laws and water codes.
- vi. Minimum standards for the width/size of the doors, aisles, passageways, stairways, or other

means of exit.

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

### **Compliance with Legislation and Regulations**

Dental clinics are required to abide by the relevant laws like hospital waste management, infection control and building codes etc. to ensure safety and comfort of patients and the care providers. The senior management need to be familiar with these laws/rules/regulations, any amendment thereto and ensure implementation of the same by the relevant staff.

### **Risk Management**

Every organization, depending on its size, is required to assign one or more individual/s to provide leadership and oversight for planning and effective, consistent and continuous implementation of all aspects of the risk management program, including inter-alia the following:

1. Planning all aspects of the program
2. Implementing the program
3. Educating the staff
4. Testing and monitoring the program
5. Periodical review and revision
6. Annual reports to the governing body/board on the effectiveness of the program
7. Providing consistent and continuous management support

This is particularly important during construction or renovation of a facility for which qualified engineering services are mandatory for every dental clinic/surgery.

### **Renewal of Licenses and Certifications**

This indicator applies to the renewals of licenses/certifications for radiology equipment, lifts, diesel generating sets, boilers, compressors, etc. The organization should maintain a log book/tracker sheet for this purpose.

A designated official/staff member should be responsible to enlist the licenses/ registrations/ certifications applicable to the dental clinic/surgery under the laws and regulations and to identify the appropriate personnel in the organization responsible to implement the respective laws and regulations by timely renewal of the pertinent licenses/certificates.

### **Emergency Fire Plans**

The organization shall:

1. Have a fire plan covering fire arising out of burning of inflammable items, explosions, electric short circuiting or acts of negligence or due to incompetence of the staff.
2. Deploy adequate and qualified personnel for implementation of the plan.
3. Acquire adequate firefighting equipment and ensure that records are kept up to date.
4. Have adequate training program.
5. Have schedules for, and conduct, mock fire drills
6. Maintain records of mock drills
7. Explicitly display exit plans
8. Have an alarm and dedicated emergency illumination system, which comes into effect in case of fire

### **Necessary Items and Equipment**

1. Fire-proof blanket
2. Safety shower
3. Buckets with sand
4. Portable fire extinguishers which are essentially of two types; CO<sub>2</sub> and bromochloride fluoromethane (BCF) (halon, halogenated hydrocarbons) and can be used without causing damage to electrical equipment. The extinguishing power of halon is about 6 times that of CO<sub>2</sub>. Water has the disadvantage that it conducts electricity, whereas powder extinguishers (containing salts) cause damage to instruments

### **Actions**

1. When fire is detected, stay calm, try to oversee the situation and watch out for danger and take the following actions in the same order:
  - i. Close windows and doors
  - ii. Give fire alarm (shouting, telephone, fire alarm)
  - iii. Rescue people
  - iv. Switch off electricity and/or gas supply
  - v. 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 or be pulled under a safety shower. A CO<sub>2</sub> 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 and 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**

All workplaces should have adequate exits and unobstructed escape routes in case of fire. The number of exits for all employees to exit safely depends on 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 that 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. The organization shall take care of non-fire emergency situations including the following, by and deciding appropriate course of action:

1. Earthquakes
2. Civil disorders effecting the dental clinic/surgery
3. Terrorist attacks
4. Invasion of swarms of insects and pests
5. Invasion of stray animals
6. Hysterical 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

The dental clinic 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.

The dental clinic shall establish liaison with civil and police authorities, 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. The floors of beams of egress shall be illuminated at all points including angles and intersections of corridors and passageways, landings of stairs and exit doors with bulbs of not less than one thousandth (0.001) lumens per square centimeter.
2. Lighting source is of reasonably assessed reliability, such as public utility electric service.
3. 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.
4. Illuminated 'EXIT' signs – distinctive in colour, reliable source – five thousandth lumens (0.005) per square centimeters.
5. Size of signs – plainly legible letters not less than fifteen centimeters high with the principal strokes of letters not less than nineteen millimeters wide.
6. Provide luminous directional exit signs located one foot or below floor level.
7. There should be separate ingress and egress routes.
8. Corridors, hallways and aisles must be 2.4 meters in width.
9. Use of ramps as access to second and higher floors.
10. Stairways with safe and adequately secured railings.
11. Stairway must be at least 112 cm. wide and made of concrete.
12. Any opening in wall/s shall be protected by fire doors or fixed wire glass windows and must have protection for vertical openings also.
13. Any door in a stairway, ramp, elevator shaft, stairway enclosure or light and ventilation shaft or chute, shall be self-closing, and shall normally be kept closed.

## Assessment Scoring Matrix

**Standard 5. FMS-1: The dental clinic staff is aware of, and complies with, the relevant laws, rules, regulations, bylaws and facility inspection requirements under the applicable codes**

Indicator 12 - 16		Max Score	Weightage (Percentage)	Score Obtained
Ind 12.	The clinic management is conversant with the relevant laws and regulations	10	100%	
Ind 13.	The management ensures implementation of relevant laws	10	100%	
Ind 14.	There is a mechanism to regularly update licences/ registrations/certifications	10	100%	
Ind 15.	The staff has the knowledge about early detection and containment of fire and non-fire emergencies	10	100%	
Ind 16.	Arrangements to combat fire and non-fire emergencies are in place	10	80%	
<b>Total</b>		50		

## Standard 6. FMS-2: The clinic has a program for management of dental and support service equipment

### Indicators (17):

#### Ind 17. The clinic plans and maintains equipment in accordance with its scope of services

##### Survey Process:

Review SOPs for planned periodic preventive maintenance and inventory of ALL dental equipment in the clinic. While visiting, ask for documentation that the minimum required equipment to support basic dental care services and specialized equipment, as applicable, is listed on the clinic's inventory. Confirm that, there is a plan / arrangements for in-house as well as outsourced equipment maintenance.<sup>14</sup>

##### Compliance Requirements:

- ✓ An inventory of ALL dental equipment in the clinic (minimum required equipment to support the basic dental care services and specialized equipment, as applicable)
- ✓ Planned periodic preventive maintenance (PPM) is done
- ✓ Arrangement for in house as well as outsourced equipment maintenance

##### Scoring:

- If inventory of equipment is available and periodic preventive maintenance (PPM) is done, then score as **fully met**.
- If inventory of equipment is not available and/or periodic preventive maintenance (PPM) is not done, then score as **not met**.

### GUIDELINES

#### Qualified and Trained Operators

Every dental clinic shall ensure that all the equipment installed in the facility are operated by appropriately qualified, trained and skilled staff. The dental clinic should ensure that arrangements for proper calibration and maintenance of equipment are in place. Ideally, the larger set ups of dental clinics shall establish a Biomedical Engineering section under the supervision of a qualified biomedical engineer/technician. This section shall provide calibration, repair and backup support to the end users. For specialized repair/services, the clinic may make contract arrangements with some outside firm.

#### Preventive Maintenance Plan

The dental clinic shall ensure that the staff operating the equipment is trained in handling the

<sup>14</sup> In case of in-house maintenance, the clinic needs to ensure staff training and availability of service manuals, required tools, spare parts and consumables to provide the required preventive maintenance and servicing. Outsourced arrangements need to be made for the maintenance which is beyond the scope of in-house staff.

equipment as per the manufacturer’s instruction manual. There shall be a documented preventive maintenance plan for all equipment and machinery using a log book/tracker sheet.

The clinic shall develop a schedule of weekly/monthly/annual inspection and calibration of equipment in accordance with Original Equipment Manufacturer (OEM) guidelines. These services can be provided through an in-house arrangement or alternatively through outsourcing. It shall be ensured that calibration and conformance testing of the equipment is done prior to commissioning. The dental clinic shall ensure that the record regarding purchase and maintenance of equipment and machinery is properly maintained. The facilities shall ensure that no equipment is non-functional/out of use merely for want of minor repairs, preventive maintenance, lack of essential spares, electrical faults, etc. Important factors resulting into gross equipment wastage may also include the following:

1. Mishandling of equipment
2. Use by untrained and unskilled staff
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 by introducing an Equipment Audit, particularly in larger setups, for periodic evaluation of the quality of performance of the equipment which has the following advantages:

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

*Table 1. Equipment 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. Use Coefficient\*\*\*
17. Down-time/Up Time
18. Cost of Maintenance
19. Date of Condemnation
20. Date of Replacement
21. 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.

\*\*\*Should be applied to assess the utilization of equipment.

*Table 2. Equipment Log book*

Log Book							
S/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.							

### **Performance**

It is essential that periodic scientific evaluation of the quality of performance of the equipment is carried out by using the history sheet and log book. The process of equipment audit is an indispensable tool in formulating standards/specifications of medical equipment and in establishing benchmarks for medical equipment.

Planned preventive maintenance is a regular and periodic activity carried out 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 replacing worn out components to avoid breakdown. Productive preventive maintenance refers to proper selection of equipment to be included in planned preventive maintenance and taking decisions on what to include and to reduce costs making the procurement and maintenance cost-effective.

An important aspect of planned preventive maintenance is the participation of the user who is responsible for bulk of the work. The task must be performed daily involving the end user and a technician/engineer at the end of the week. Highly technical repairs, are the responsibility of the engineering section/engineer and may be scheduled every six months or on a need basis.

### **Setting up a Planned Preventive Maintenance System**

Establishing an effective, efficient planned preventive maintenance system needs a Registry Filing System. The Manufacturer's Manual for Preventive Maintenance can be supplemented by

computer packages in setting up the system and if a computer is not available, a manual file can be used to set up the planned preventive maintenance system entailing the following:

### 1. Equipment Inventory

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

A reference number is allocated, printed on a paper label and attached to each item and also recorded in the 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 3. Sample Equipment Service History Form*

Sample Equipment Service History Form									
Name of Facility						EQUIPMENT FUNCTION			
Location									
Department									
Name of Equipment:			Approved by:			Date Installed:			
Manufacturer:						Manuals:			
Distributor:				Power: _____ v _____ a no. of wires:		Freq. of P.M:			
Model Number:				Type of Enclosure:		Remarks:			
Serial Number:				Type of Plugs:					
Date	C/P	W.O N.O.	LEAKAGE		WORK DONE	Work By	Total Labour Hour	Parts Cost	Remarks
			GRD	O.GRD					
C = Curative repair			P = Preventive repair			Leakage = Leakage current			

### 2. Establishing a "Maintenance Schedule"

After determining what is to be done, the frequency of the task must be decided. A heavily used item must be cleaned and checked more frequently than one which is used less often. However, minimum frequency must be decided based on the guidelines in the manufacturer's manual, but the actual usage should determine the maintenance procedure required.

The schedules presented in the guidelines can be modified to conform to the manufacturers' specifications. A record card will be included with each schedule for recording measurements and the engineer/technician should also note on the record card any item that needs to be replaced, if work is to be carried out later, and whether or not the same engineer is to carry out the work.

## Assessment Scoring Matrix

Standard 6. FMS-2: The clinic has a program for management of dental and support service equipment

Indicator 17		Max Score	Weightage (Percentage)	Score Obtained
Ind 17.	The clinic plans for equipment in accordance with its scope of services	10	100%	
Total		10		

## 2.3 Human Resource Management (HRM)

### **02 Standards & 03 Indicators**

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The objective of the standards under human resource management (HRM) is to ensure that the qualifications and competency for the staff positions is determined to match the patient care needs and the stated goals and mission of the organization. The dental clinic must employ the right number of qualified staff to meet the portrayed patient care requirements. The dental clinic also needs to have a system for assessing, maintaining and improving staff capability and promoting continuous professional development and learning.

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## Standard 7. HRM-1: There is documented personnel record of dental surgeon(s)<sup>15</sup> and staff

### Indicators (18):

#### Ind 18. Personnel record/credentials of all staff of the clinic are maintained

#### Survey Process:

Review the personal record of the dental surgeon(s), dental technician(s), dental nurse, dental assistant(s), dental hygienist(s) and other staff (as applicable)<sup>16</sup> to verify the credentials including professional qualifications, registration with the concerned councils/authorities, validity of registration, experience certificates, trainings, current medical fitness status, character certificate/references,<sup>17</sup> confidentiality agreement (**Annexure C**) etc.

#### Compliance Requirements:

- ✓ Availability of personal files of staff including certified copies of the following:
  - Credentials (qualification, experience and training)
  - Valid registration certificate from concerned councils/authorities
  - CNIC
  - Medical fitness
  - Character certificates (if applicable)
  - confidentiality agreement

#### Scoring:

- If all reviewed records have documented information regarding professional qualifications/credentials as above, then score as **fully met.**
- If the record of the staff is not available as above, then score as **not met.**

### GUIDELINES

#### Personal Files

The personal files provide an updated record of employees and should be maintained because:

1. It makes good business sense to have accurate information handy and organized when you want to use it for an 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 the federal or provincial government/other agencies and must be kept in the personal files.

<sup>15</sup> Dental surgeon having valid Registration with PM&DC.

<sup>16</sup> Dental technician/dental hygienist/dental assistant means a qualified person certified and registered by the FPAHS/regulatory authority and a dental nurse registered with the PNC.

<sup>17</sup> Details given in the Guidelines.

4. Organizing the record of employees in a proper manner facilitates the access for all legitimate purposes.

The personal file of each employee is very confidential and access to it is restricted and only allowed after the approval from a competent authority. Access to information about employees should be strictly limited to those people in the dental clinic who need to use it for official purposes.

Since unauthorized access to personal files has severe implications, any breach in this connection should make the responsible person liable to punitive action. It should be ensured that personal files (hard and soft copies) are in secure custody and are not left unattended even during working hours. In case an outside organization asks for 'verification' of certain information about the employee/s of the dental clinic/surgery, 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 mortgage and/or credit applications, etc. Employee authorization should be in writing and specify the information which they permit to be revealed. The employees should be informed that the policy is for their protection.

#### **Contents of Personal Files**

The HR departments in good organizations/larger set ups customarily maintain the following documents in the personal file of each employee in a standard format:

1. Curriculum vitae
2. Offer letter
3. Contract copy and JD
4. Joining report
5. Photograph (two, blue background, passport size)
6. Copy of CNIC
7. Copies of documents pertaining to all academic and professional qualifications
8. Copies of trainings/certifications
9. Salary slip/certificate (previous employer)
10. Experience certificate
11. Official email account issuance form
12. Reference form/background check
13. Medical/personal information form
14. Information for employee/business card
15. Leave forms (if any)
16. Notice (if any)
17. Performance evaluation form
18. In-service trainings
19. Salary increment/promotion
20. Resignation/Termination letter (whichever is received in the HRD)
21. Exit interview form (whenever the employee leaves the office)

## Assessment Scoring Matrix

**Standard 7. HRM-1: There is documented personnel record of dental surgeon/s and staff**

Indicator 18		Max Score	Weightage (Percentage)	Score Obtained
Ind 18.	Personnel record/credentials of all staff of the clinic are maintained	10	<b>100%</b>	
<b>Total</b>		10		

## Standard 8. HRM-2: The employees<sup>18</sup> joining the dental clinic/practice are oriented to the environment, respective sections and their individual jobs

### Indicators (19-20):

#### Ind 19. Each regular/part time employee is made aware of the job description

##### Survey Process:

The essence of the indicator is to make staff aware about the JDs for effectively performing the assigned duties. Each individual employee is made fully aware of requirements. Interview staff about their job requirements.

##### Compliance Requirements:

- ✓ Awareness of staff about their job requirements

##### Scoring:

- If the staff is aware of their job requirements, then score as **fully met.**
- If the staff is not aware of their job requirements, then score as **not met.**

#### Ind 20. Each regular/part time employee is made aware of his/her rights and responsibilities and patient rights and responsibilities

##### Survey Process:

The Charter for Patients, Carers and Others and Charter for HCEs providing detailed rights and responsibilities are available on the KP HCC website as downloadable documents for information and compliance. Check awareness of staff about KP HCC charter of rights and responsibilities.

##### Compliance Requirements:

- ✓ The KP HCC Charter for Patients and Charter for HCEs providing detailed rights and responsibilities are available
- ✓ All staff members are made aware of the Charters

##### Scoring:

- If the staff is aware of their rights and responsibilities as per KP HCC Charters, then score as **fully met.**
- If the staff is not aware of their rights and responsibilities as per KP HCC Charters, then score as **not met.**

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<sup>18</sup> Employees include all full time/regular or part time/visiting consultants/employees and staff members.



## GUIDELINES

### General Orientation

Once the selection process is completed, the new employee must be oriented in order to improve his/her ability to perform the job and also to satisfy the personal desire and feeling that he/she is a productive contributor and part of the organization's social fabric. Supervisors, in coordination with the human resource (HR) department, complete the orientation by introducing the new employee to the co-workers. Every dental clinic should recognize that its success and the quality of care provided by it depends upon the capacities of its staff and shall

### 1. Procedure

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

- i. Appointment letter
- ii. Joining report
- iii. Statement of ethics
- iv. Confidentiality agreement
- v. Reference forms for at least two referees will be filled by the employee (referees must not be blood relations)
- vi. Employee will fill a Health Questionnaire Form

### Job Specific Orientation

This can be made part of the general orientation or can be done as part of a separate detailed departmental orientation. All employees like to know what is expected of them and how they will be evaluated. JDs can also be a great value to employers as it often results in a thought process that helps determine how critical the job is, how this particular job relates to others and identify the characteristics needed by a new employee filling the role. A JD is a detailed narration of actions that an employee must take to achieve the objective, provides the necessary skills, training and education needed by an employee and spells out duties and responsibilities of the job. It serves as a basis for interviewing the candidates, orientation of a new employee and in the evaluation of the performance. Using job descriptions is part of good management and always produces better results.

### Components of a Job Description

1. **Job Code:** It is a specific number assigned to the document e.g. 001, 004, etc.
2. **Position Name:** It is exactly the title which the employee will use and conveys the main function of the job/position.
3. **Physical location and surroundings:** This description provides information about the place where a particular dental clinic/surgery is located and what are its surroundings and communication links.
4. **Reporting:** Name of the authority to whom the employee has to report.
5. **A Summary statement:** It includes the scope of duties.
6. **Functions of the position:** It provides details of what the job actually entails and can be quite specific. It should also provide any supervisory functions in addition to being as specific as

possible while describing tasks the employee will face every day. This is also the best place to indicate whether the person will deal with customers, the public or only internal employees. This section can also be used to prioritize the activities.

7. **Attributes needed for the position:** If the position involves the use of machinery (or computers), spell out what type of machines or software the employee will use. Also detail any technical or educational requirements that may be critical or desired. This will also provide an insight into the type of work environment to be maintained.
8. **Reporting:** Provide details on the reporting and organizational structure to help the employee better understand how their activities fit into the total organization.
9. **Compensation:** Including a grade/range instead of a specific figure will give you more flexibility, but most people will feel they should be at the top of the range. It is usually better to have a specific amount, especially when the job description is being given to the employee.
10. **Evaluation criteria:** This section will define what is most important for the organization as well as the employee in specific terms. The evaluation criteria of the position will promote the type of activities to enhance the success of the business and will also provide details on when evaluations will take place.
11. **Acknowledgment:** This includes the signatures of the authorized person of the dental clinic/surgery, who usually is Manager HR/HOD/MS/CEO, and the employee, to confirm that he/she has read and is aware of the JD.

The JD of a senior dental surgeon at a government tehsil level hospital is given below, as a sample.

### Sample Job Description

Senior Dental Surgeon	
Job Code:	
Job Title:	Senior Dental Surgeon
Qualification & Experience:	BDS and FCPS/MDS (if person possessing FCPS/MDS is not available, then MCPS or other equivalent qualification recognized by PMDC)
BPS:	18
Recruitment:	Initial/Transfer
Position Type:	Full Time
Dress Code:	
Jurisdiction:	THQH
Reports to:	MS

### Job Summary

In-charge of the dental unit for deliverance of optimal standard of dental care. Scope of work includes dental OPD, admission of patients needing indoor dental care, care of admitted patients and planned procedures on specific days (only applies to OMFS department).

### Duties/Responsibilities

#### 1. Curative/Clinical

- i. Overall in charge of the dental OPD and admitted patients.

- ii. Conducts dental OPD regularly on notified days and time.
- iii. Reviews referrals by MOs/other specialists and from the lower facilities to establish diagnosis and proper management.
- iv. Plans and performs procedures e.g. RCT, surgical extraction, IMF, etc. on specified days and time as per hospital policy.
- v. Performs emergency dental procedures on patients admitted through A&E. Department as and when required.
- vi. Writes post procedural notes and instructions for each case.
- vii. Takes one planned round of the wards daily along with doctors and staff nurse to review/follow-up the old cases and examines in detail the newly admitted. Round is repeated if required (only applies to OMFS department).
- viii. Ensures that treatment prescribed is being administered to the patients.
- ix. Ensures availability of medicines/functioning of equipment to handle emergencies at all times in the unit.
- x. Exercises authority for discharge of patients from the ward/emergency.
- xi. Explains the patients about the use and effects of prescribed drugs.
- xii. Refers the patients to other specialists within the hospital and/or to higher level facilities if needed.

## **2. Preventive/Promotive**

- i. Ensures compliance of SOPs particularly on infection control and waste management in the OPD, dental clinics and surgical wards.
- ii. Ensures that instruments/equipment being used in examinations and procedures are properly sterilized.
- iii. Ensures that all staff participating in the procedures are physically well protected by wearing of proper dress i.e. gowns, masks, caps, gloves and shoes.
- iv. Provides educational information about common diseases and ways to promote physical health.

## **3. Rehabilitative**

- i. Provides psychological, social and nutritional rehabilitative measures to patients if required.
- ii. Teaching/Supervision.
- iii. Trains dental, nursing and paramedical staff as per departmental/specialty requirements/protocols and work instructions.

## **4. General**

- i. Checks the cleanliness and up keep of the unit.
- ii. Ensures that responsible staff regularly upkeeps and maintains electro-medical equipment of the unit to ensure their functionality at all the time.
- iii. Ensures that responsible staff is regular in supply/replenishments of medicines and stores.
- iv. Provides technical assistance to the management for purchase of new equipments/instruments needed from time-to-time for the unit.
- v. Ensures the preparation and implementation of the duty roster for his unit.
- vi. Checks that the subordinate staff performs their duties as per JDs, SOPs and SMPs.
- vii. Writes objective Performance Evaluation Reports of subordinate staff.
- viii. Performs outreach duties to lower facilities as required.
- ix. Performs any other professional duty assigned by higher authorities.

I have read and accept the job description.

Signature of the incumbent:

Using JDs helps a dental clinic to better understand the experience and skill base needed to improve service delivery. They help in hiring, evaluation and termination of employees when required. Quite often, there is a misunderstanding of what a position entails and in that case, a well-prepared job description can help both sides share a common understanding.

### **Patients' Rights**

The rights and responsibilities of the patients are available as Patient Charters (Section 2.9 PRE). The following points regarding the rights and responsibilities of employees are to be considered:

1. Staff members may have cultural, religious or personal conflicts concerning their involvement with specific components in the care or treatment of patients. The dental clinic 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.
2. The HoD, manager or supervisor shall make every effort to accommodate the request and maintain the duties referenced in the employees' JD.
3. The HoD, manager or supervisor shall reassign duties, if reasonable and possible, to accommodate the request and meet the needs of the patient.
4. Response to all requests for reassignment of duties, whether approved or denied will be provided in writing to the employee.
5. A record of all requests and actions taken shall be maintained in the employee's departmental file.
6. 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 human resources 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 dental clinic, as provided in the KP HCC Charters for Patients and HCEs.

## Assessment Scoring Matrix

**Standard 8. HRM-2: The employees joining the dental clinic/practice are oriented to the environment, respective sections and their individual jobs**

Indicator 19 - 20		Max Score	Weightage (Percentage)	Score Obtained
Ind 19.	Each regular/part time employee is made aware of the job description	10	<b>100%</b>	
Ind 20.	Each regular/part time employee is made aware of his/her rights and responsibilities and patient rights and responsibilities	10	<b>100%</b>	
<b>Total</b>		20		

## 2.4 Information Management System (IMS)

### **01 Standards & 04 Indicators**

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The standards pertaining to 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 dental surgeons and staff in the clinic must be facilitated by timely information to provide coordinated and integrated care. In addition, it is important to protect the confidentiality of the data/patient information collected during the course of treatment by limiting unauthorized access.

Medical/dental records serve many functions, primarily to support patient care. Currently, there is great tendency to computerize medical/dental records, which is however less likely to deliver desired benefits unless the quality of manual records is improved. The onus for improving records lies with individual health professionals as well as the management of the HCE/practice. Structuring the record can bring direct benefits by improving patient care, treatment outcomes and health system performance and ensure safety of services.

---

## Standard 9. IMS-1: Patient clinical record is maintained at the dental clinic

### Indicators (21-24):

#### Ind 21. Every patient's records has a unique identifier and particulars for identification

##### Survey Process:

Check that a system of record keeping (computerized or manual) is in place. The patient record should contain information including serial number, date, name, parentage/husband name, age, gender, address, etc. and the symptoms/provisional diagnosis, treatment/procedures and referrals (if any) as per the prescribed format.<sup>19</sup> NIC and contact number may be noted as a routine if convenient and will only be mandatory when a patient is referred/transferred or is a medico legal case. Patient record should be maintained in the clinic at least for one year (ideally 3 years) for general records and 12 years for medico legal cases<sup>20</sup> (if applicable), as given at **Annexure D**.

##### Compliance Requirements:

- ✓ The system of record keeping (computerized or manual) covering the following parameters is in place:
  - Serial number
  - Date
  - Name
  - Parentage/Husband name
  - Age
  - Gender
  - NIC/Contact number (mandatory when a patient is referred/transferred or is a medico legal case)
  - Address

**Note:** Patient record should be maintained in the clinic at least for one year for general records, 12 years or longer as required for medico legal cases and lifelong for vital events. Private clinics are not authorized for medico-legal cases.

##### Scoring:

- If the patient record is maintained as above, then score as **fully met**.
- If the patient record is maintained but the information is deficient by about 20% only, then score as **partially met**.
- If no record is maintained or the deficiency is more than 20%, then score as **not met**.

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<sup>19</sup> Detailed format given in the Guidelines as well as in the DHIS of the Health Department.

<sup>20</sup> As explained in the guidelines, retention of the record for a longer period may become applicable if some other statutes so require.

## Ind 22. Only authorized person(s) make entries in the record

### Survey Process:

If a person other than the dental surgeon is delegated to make entries in the record of the patients, he/she should be duly authorized in writing to do so and the entries in the record are traceable/identifiable when required. Name and designation of the dental surgeon writing the prescriptions and the person making entries in other records must be mentioned therein, in pen or by stamp and signed.<sup>21</sup>

### Compliance Requirements:

- ✓ Evidence of delegating a person other than the dental surgeon, to make entries in the record of the patients
- ✓ Evidence that only the authorized person(s) make entry in the record

### Scoring:

- If the person writing prescriptions/making entries in the patient records can be identified by name and designation from the records checked, then score as **fully met.**
- If the person writing prescriptions/making entries in the patient records can be identified as above in 80% of the records checked, then score as **partially met.**
- If the person writing prescriptions/making entries in the patient records can be identified as above but in less than 80% of the records checked, then score as **not met.**

## Ind 23. Every record entry is dated, timed and signed

### Survey Process:

Correct recording of time of arrival of a patient to a clinic and the time at which he/she is attended to and leaves, is very important as the same may be required to be produced as an evidence. Focus attention on timing of patient's arrival, clinical notes including patient's complaints, oral examination, investigations, type of anesthesia (if applicable), treatment provided/procedure performed, materials used and medication prescribed/dispensed, etc. Any emergent situation dealt with or referral is also documented. This can be evaluated during the review of the previously selected records.

### Compliance Requirements:

- ✓ Record of clinical notes as stated above

### 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.**

---

<sup>21</sup> As per details given in the guidelines, the dental surgeon him/herself in case of single person clinic is responsible for making entries in the record, as such under his/her signatures. The person responsible to prescribe and perform the required procedure etc. should write full name or use stamp under signatures.



## Ind 24. The record provides an up-to-date and chronological account of patient care

### Survey Process:

Review the record to determine if the record adequately documents the care and treatment plan for all patients. Check the system of record storage to ensure they are in good order and stored for a period in compliance with the statutes.

### Compliance Requirements:

- ✓ System of record keeping (about the care and treatment plan for all patients) and storage for a period in compliance with the statutes available

### Scoring:

- This should default to a score of **fully met** unless the survey team identifies significant deficiencies in the dental records.

## GUIDELINES

### Unique Patient Identifiers

All documents of a patient must be consistently labelled with at least one 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 entries in the medical record are documented timely and it is kept accurately. The medical record serves three primary purposes: i. to ensure quality of patient care; ii. to provide evidence of the patient's course of illness and treatment; and iii. to facilitate review of the record/ treatment provided.

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 only to protect or to provide a defense, and since the medical record pertains to risk management, its purpose is to preserve the truth also. 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 if there is no justifiable defense.

Accurate identification of a patient is pivotal for 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 another and are defined as below.

### 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. Computerized national identification number (CNIC number)
5. Mother's first name
6. Father's first name
7. Social security number
8. Health insurance number

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.
3. 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.

#### **SOPs for Identification of Medical Record Entries**

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 and clearly writing his/her name, appointment/designation and the date in block letters, stamping the same. A sample of such a list is given below:

*Table 4. Sample Authorized Personnel List*

Sr.#	Particulars & Appointment	Authorization	Initials	Signatures	Stamp
1.	Prof. Dr. (HOD Surgery)				
2.	Dr. (Registrar)				
3.	Dr. (PG Trainee)				

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

#### **SOPs for Medical Record Documentation**

This indicator requires 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 date and time starts from the point a patient enters the clinic and seeks care. The first such record is the register at the reception for consulting a doctor. Then, the time the patient is attended/examined by the doctor who performs the dental procedure and prescribes medicine/s or refers the patient, if required, while putting the date and time along with his/her signatures on the prescription.

Accurate date and time recording is of paramount importance whenever there is a need to produce the documentation as a proof of certain timely action. It is a valuable source of data for coding, health research and source of evidence and rationale for resource management.

#### **Up-to-date Chronological Record**

Information documented during or immediately after providing care or about an event which has

occurred, is considered to be a more reliable and more accurate record than the information recorded later, based on memory.

Chronological entries present a clear picture of the sequence of care provided/of events over time and facilitates better communication amongst care providers. Late entries should be appropriately recorded as soon as possible, but these should be endorsed by the in-charge.

### **Minimum Requirements for Patients' Medical Records<sup>22</sup>**

Upon completion, medical records for inpatients and outpatients shall contain, at a minimum, the documents as specified below. Records for patients at the hospital for other specialized services, such as emergency services or surgical services, shall contain such additional documentation as required for those services.

1. **Outpatient Records:** Medical reports for outpatients shall contain at least the following:
  - i. A unique identifying number and a patient identification form.
  - ii. Name, address, DoB, gender and person to be notified in an emergency.
  - iii. Diagnosis of the patient's condition.
  - iv. The name of the dental surgeon ordering treatment or procedures.
  - v. Patient allergies.
  - vi. Dental surgeon's orders or orders from another practitioner authorized by law to give dental or treatment orders as applicable.
  - vii. Documentation that the patient has been offered the opportunity to consent to procedures for which consent is required by law/regulations.
  - viii. Reports from any diagnostic testing.
  - ix. Sufficient information to justify any treatment or procedure provided, report of outcome of the treatment or procedure, progress notes and the disposition of the patient after treatment.
2. **Inpatient Records (Not applicable to outpatient clinics):** Medical records for inpatients shall contain at least the following:
  - i. A unique identifying number and a patient identification form.
  - ii. Name, address, DoB, gender person to be notified in an emergency.
  - iii. The date and time of the patient's admission.
  - iv. The admitting diagnosis and clinical symptoms.
  - v. The name of the attending dental surgeon.
  - vi. Any patient allergies.
  - vii. Documentation regarding advanced directives.
  - viii. The report from the history and physical examination.
  - ix. The report of the nursing assessment performed after admission.
  - x. Laboratory, radiological, electrocardiogram and other diagnostic assessment data or reports as indicated.
  - xi. Reports from any consultations.
  - xii. The patient's plan of care.
  - xiii. Dental surgeon's orders or orders from another practitioner authorized by law to give

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<sup>22</sup> Authority O.C.G.A. Sec. 31-7-2.1. History. Original Rule entitled "Medical Records" adopted. F. Nov. 22, 2002; eff. Dec. 12, 2002.

dental or treatment orders.

- xiv. Progress notes from staff members involved in the patient's care, which describe the patient's response to medications, treatment, procedures, anaesthesia and surgeries.
- xv. Data, or summary data where appropriate, from routine or special monitoring.
- xvi. Medication, anaesthesia, surgical and treatment records.
- xvii. Documentation that the patient has been offered the opportunity to consent to procedures for which consent is required.
- xviii. Date and time of discharge.
- xix. Description of condition, final diagnosis and disposition on discharge or transfer.
- xx. Discharge summary with a summary of the hospitalization and results of treatment.
- xxi. If applicable, the report of autopsy results.

## Assessment Scoring Matrix

**Standard 9. IMS-1: Patient clinical record is maintained at the dental clinic**

Indicator 21 - 24		Max Score	Weightage (Percentage)	Score Obtained
Ind 21.	Every patient's record has a unique identifier and particulars for identification	10	80%	
Ind 22.	Only authorized person(s) make entries in the record	10	80%	
Ind 23.	Every record entry is dated, timed and signed	10	80%	
Ind 24.	The record provides an up-to-date and chronological account of patient care	10	100%	
<b>Total</b>		40		

## 2.5 Quality Assurance (QA)/Quality Improvement (QI)

### 03 Standards & 07 Indicators

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Continuous quality improvement (CQI) has been used in the manufacturing settings more extensively than in the field of healthcare service delivery. Safety and quality of healthcare service delivery is however, quite closely linked to the principles of CQI. This includes the observation of a phenomenon, identifying variables and changing the process, observing the results and taking action. If the results show improvement, continue with the changed process and look for the next area to improve. If the results do not show desired improvement, discontinue the intervention and re-strategize. Continue to observe the results until a pattern of foreseeable positive results emerges from the actions.

CQI is easy for healthcare professionals to learn since it is based on the basic model of scientific discovery. As healthcare professionals learn the concepts and strategies behind CQI, they will infuse their scientific experience into the program. Innovative measures for quality control (QC) lead to positive results, including delivery of higher quality services, patient satisfaction and lowering of costs.

The standards under quality assurance (QA) focus on a systematic approach of using data to assess the current performance against the set quality benchmarks, identify gaps and take measures to improve the same. This continuous process focuses on outcomes of the care, and must include reducing actual and potential risks to patient safety. Accordingly, the standards emphasize on the processes, systems and individual behaviors that reduce the likelihood of unanticipated adverse events as well as near misses.

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## Standard 10. QA-1: The dental clinic has a quality assurance/quality improvement system in place

### Indicators (25-26):

#### Ind 25. Service provision is as per portrayal

##### Survey Process:

The indicator focusses on ascertaining that services provided by the clinic staff to the patients are as per the facilities portrayed in the application for registration/licensing with KP HCC. There should be no superfluous displays/portrayals.

##### Compliance Requirements:

- ✓ Services provided by the clinic staff to the patients are in accordance with those listed in the application for registration/licensing
- ✓ There are no superfluous displays

##### Scoring:

- If the dental services provided are in accordance with those listed in the application form for registration/licensing with KP HCC and there is no superfluous display, then score as **fully met.**
- If either the dental services provided are not in accordance with those listed in the application for registration/licensing with KP HCC or there is/are superfluous display(s), then score as **not met.**

#### Ind 26. A quality improvement system is in practice

##### Survey Process:

This indicator is to demonstrate actions taken by the dental surgeon/administrator/manager to make improvements in the quality of care based on the observations as recorded during his/her monitoring/evaluations.

The clinic in-charge should periodically check how the patients are being received and seated while waiting. He/She should also check that the facilities for the comfort of patients like sitting arrangements, drinking water, ventilation, etc. are intact. The clinic in-charge shall use a quality assurance checklist<sup>23</sup> for checking on a daily/weekly/monthly/yearly basis that the services provided at the clinic conform to the minimum standards. The duties assigned to the staff should be included in the JDs and evaluated on the basis of the checklist which shall be dated and signed and kept in record.

##### Compliance Requirements:

- ✓ Checklist developed and in use by the dental surgeon/administrator/manager

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<sup>23</sup> Format of the Checklist provided in the Guidelines can be adapted as per requirement of the clinic.

- ✓ Evidence regarding any improvement made by dental surgeon/administrator/manager based on the observations documented during periodic evaluations/inspections

**Scoring:**

- If there is a written record of actions taken as above, then score as **fully met.**
- If there is no written record of actions taken as above, but quality improvement/Quality Assurance is demonstrated, then score as **partially met.**
- If there is no record of actions taken, nor is quality improvement demonstrated, then score as **not met.**

GUIDELINES		
<b>Quality Improvement System</b>		
Provision of quality services requires that these are timely, safe, effective, equitable, recovery-oriented and recipient-centered. A QI system reflects the commitment of the healthcare service provider (HSP) to consistently improve the quality of the treatment and care provided to the patients which is evidenced by the outcomes of the treatment and patient satisfaction.		
<b>The Quality Improvement Methodology</b>		
QI refers to an approach which entails examining work processes to bring improvement so that these are effective, efficient and responsive using the following methodology:		
<ol style="list-style-type: none"> <li>1. Patients and caregivers are at the center of improvement efforts</li> <li>2. Focus on the work processes</li> <li>3. Involvement of interdisciplinary teams to identify issues and make improvements as applicable</li> <li>4. Use of data and information to guide changes</li> </ol>		
The following formats are provided as guidance for monitoring the activities, recording the observations and documenting the actions taken for improvement of the system/processes:		
Format-1 HCE Performance Measuring Checklist for In-Charge		
Name of HCE:		
Name of In-charge	Designation:	
Date & Time of Inspection:	Date:	Time:
Daily/Weekly Monitoring Tasks	Observation	Recommendation
General cleanliness		
Washroom cleaned/functional		
Drinking water available		
Seating arrangement for patients		
UPS/Generator/Emergency light functionality		
Staff attendance register/Biometric/Movement register/Leave register		
Staff wearing identification badges		
Emergency room ready/drug list/essential supply		
Oxygen cylinder filled/ready (where applicable)		
Clinic waste segregated and disposed of properly		



Sterilization/Hand washing facilities		
Daily expense register maintained		
Patient registration/guidance system		
Patients privacy ensured during consultation/examination		
Medicines are being labeled while dispensing		
Availability of complaints register		
Additional points for implementation of MSDS		

**Actions Taken for Improvement of Services**

Date: x.y.z

No. \_\_\_\_\_ held on. \_\_\_\_\_, 2018

#	Observation	Decision for Improvement	Other Remarks
1.			
2.			
3.			
4.			

## Assessment Scoring Matrix

**Standard 10. QA-1: The dental clinic has a quality assurance/improvement system in place**

Indicator 25 – 26		Max Score	Weightage (Percentage)	Score Obtained
Ind 25.	Service provision is as per portrayal	10	<b>100%</b>	
Ind 26.	A quality improvement system is in practice	10	<b>80%</b>	
<b>Total</b>		20		

## Standard 11. QA-2: The clinic identifies key indicators to monitor the inputs, processes and outcomes which are used as tools for continual improvement

### Indicators (27-30):

#### Ind 27. Monitoring includes ALL invasive procedures

##### Survey Process:

Review the documentation and check that reporting of all adverse occurrences,<sup>24</sup> such as return to dental surgery within 24 hours and re-doing the procedure within 24 hours, is included in the QI program.

##### Compliance Requirements:

- ✓ Documentary evidence of reporting all adverse occurrences such as return to dental surgery within 24 hours and re-doing the procedure within 24 hours

##### Scoring:

- If there is documented evidence that this has been monitored as above, then score as **fully met.**
- If there is no evidence as above, then score as **not met.**

#### Ind 28. Monitoring includes adverse drug events

##### Survey Process:

Review the documentation and check that there are references to adverse drug reactions (ADRs) e.g. allergic reactions and events such as wrong drug, wrong dose, wrong patient, contraindications and similar issues and see how these events have been managed.

##### Compliance Requirements:

- ✓ Documentary evidence for management of ADRs e.g. allergic reactions and events such as wrong drug, wrong dose, wrong patient, contraindications and similar issues, etc.

##### Scoring:

- If there is documented evidence that the ADRs/adverse events have been monitored, then score as **fully met.**
- If there is no evidence of the above, then score as **not met.**

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<sup>24</sup> An unplanned event with a negative consequence for the patient.

## Ind 29. Monitoring includes use of anesthetics

### Survey Process:

Review the documentation and observe for reporting of adverse occurrence and adequate follow up from use of anesthetics.

### Compliance Requirements:

- ✓ Documentary evidence of reporting adverse occurrences during or soon after administration of anesthetics
- ✓ Evidence of adequate management/follow up

### Scoring:

- If there is documented evidence that adverse occurrences from use of anesthetics have been monitored and adequately followed up, then score as **fully met.**
- If there is no evidence of the above, then score as **not met.**

## Ind 30. Monitoring includes availability and content of the clinic records

### Survey Process:

Check the evidence regarding the review of the quality of clinic records. The records should be standardized across the clinic with specific entries for a specific service/specialty and entries for each visit, all procedures and the status of the patient, as applicable. In case of settings where more than one healthcare service provider is involved, integrated notes are preferred.<sup>25</sup>

### Compliance Requirements:

- ✓ Evidence of review of the clinic records by the dental surgeon

### Scoring:

- If there is evidence of the review of the clinic records as above, then score as **fully met.**
- If there is no evidence of the review as above, then score as **not met.**

## GUIDELINES

### Monitoring of Patient Assessment

The dental clinic shall develop appropriate SOPs to ensure key performance indicators suitable to it, including inter-alia the following:

1. Time for initial assessment and emergency patients
2. Percentage of cases wherein screening for nutritional needs (where applicable) has been done
3. Percentage of cases wherein the nursing care plan (where applicable) is documented

### Monitoring of Diagnostic Services

The dental clinic shall develop appropriate SOPs to monitor the performance of all diagnostic

<sup>25</sup> Integrated notes involve all care providers writing in the notes in a chronological order and in the same section of the notes. Details added in the Guidelines.

services covering the following:

1. Percentage of re-dos
2. Percentage of reports co-relating with clinical diagnosis
3. Percentage of adherence to safety precautions by employees working in diagnostics

**Interpretation(s):** Reporting errors including transcription errors need to be captured as under:

1. Errors picked up before dispatching the reports
2. Errors picked after the dispatch of reports

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.

### **Monitoring of Invasive Procedures**

The clinic shall develop appropriate SOPs to monitor all invasive procedures, including but not limited to, the following:

1. Percentage of unplanned invasive procedures
2. Percentage of rescheduling of invasive procedures
3. Percentage of cases where the 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
5. Percentage of written post procedural advice provided

**Interpretations:** Unplanned procedures shall be captured only during the same treatment session. Re- scheduling of patients include cancellation and postponement (beyond 4 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 2 hours of the treatment.

### **Monitoring of Adverse Drug Reactions/Events**

The clinic shall develop appropriate SOPs to ensure monitoring of ADRs/events including inter- alia the following:

1. Percentage of medication errors (prescribing, dispensing, administration)
2. Incidence of ADRs
3. Percentage of revisit with ADRs
4. Percentage of error prone abbreviations in the prescriptions/advice
5. Percentage of patients receiving high-risk medications developing adverse drug reaction

**Interpretations:** The clinic should document a list of abbreviations for medication based on best national and international practices, for example, "Institute for Safe Medication Practices (ISMP) list of Error-Prone Abbreviations, Symbols and Dose Designations."

The following format should be used for reporting ADRs:

<b>ADVERSE DRUG REACTION REPORTING FORMAT</b>	
<b>Name of dental clinic reporting the problem of pharmaceutical product:</b>	
Name of contact person:	Position:
Address:	
E-mail address:	

Tel: (Office)	(Fax)	(Mobile)
Date of receiving complaint:		
Source of complaint	<input type="checkbox"/> Patient	<input type="checkbox"/> Attendant
	<input type="checkbox"/> Self-inspection	Other:
Number of similar reports received:		Attach Results of tests if conducted:
Has manufacturer/distributor been contacted earlier? <input type="checkbox"/> No <input type="checkbox"/> Yes (If yes attach details)		
Attach photocopies, package insert and press clipping about the product (if any)		

Detail of the Product	
Name of the product:	Pack size:
Active ingredients and strength:	
Registration number:	Dosage: Form: Tablet/Syrup/Powder/Injection/Drip
Batch number:	Expiry date:
Manufacturer name:	
Address:	
Tel:	Fax:                      Manufacture date:
Name of reporting person: _____ Post: _____	
Mobile #: _____ Phone#: _____ Date: DD/MM/YYYY	
Sig. of reporting person: _____ PMDC/PCP/PNC Registration Number: _____	

### Additional Information

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 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:
  - i. An on-going and concurrent (during drug therapy) surveillance system based on the reporting of suspected ADRs by pharmacists, physicians, nurses, or patients.
  - ii. A prospective (before drug therapy) surveillance system for high-risk drugs or patients with a high risk for ADRs.
  - iii. 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 the outcomes.

4. High-risk patients should including the pediatric patients, geriatric patients, patients with organ failure (e.g. hepatic or renal failure), and patients receiving multiple drugs be identified and monitored.
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, antineoplastics, corticosteroids, digoxin, heparin, lidocaine, phenytoin, theophylline, 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 including the following and the professional judgment of a pharmacist can be used as additional tools to determine the probability of an ADR:
  - i. Was there a temporal relationship between the onset of drug therapy and the adverse reaction?
  - ii. Was there a de-challenge; i.e. did the signs and symptoms of the adverse reaction subside when the drug was withdrawn?
  - iii. Can signs and symptoms of the adverse reaction be explained by the patient's disease state?
  - iv. Were there any laboratory tests that provide evidence for the reaction being an ADR?
  - v. What was the patient's previous general experience with the drug?
  - vi. 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 through multidisciplinary approach and be disseminated to health care professionals for educational purposes, preserving patient's confidentiality with an overall goal to achieve positive patient outcomes.<sup>26</sup>

### **Monitoring Use of Anesthetics**

The clinic shall develop appropriate SOPs to monitor the use of anesthetics suitable to it, including the following as applicable:

1. Percentage of modification of anesthetics
2. Percentage of adverse anesthesia events
3. Anesthesia-related mortality rate

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<sup>26</sup> Society of Health-System Pharmacists. (1995). AHSP guidelines on adverse drug reaction monitoring and reporting. American Journal of Health-System Pharmacy. 52:417-9.

**Interpretation(s):** Anesthesia plan, where applicable, is prepared at the time of pre-anesthesia assessment and reviewed during the immediate pre-operative re-evaluation. Modifications when done should be recorded.

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

### **Monitoring Availability and Contents of Documentation**

The clinic shall develop appropriate SOPs suitable for monitoring the quality of clinic record including inter- alia the following:

1. Percentage of medical records not having post procedural follow up notes
2. Percentage of medical records having incomplete and/or improper consent (where applicable)
3. Percentage of missing records

**Interpretation(s):** Missing records include records within the retention time only. The content, completeness, timeliness and accuracy of medical record (documentation) have a direct impact on the evaluation of the quality of assessment, planning and delivery of quality services. Documentation has a universal effect on organizational operations, evaluation of care and services, reimbursement and survey compliance. The quality and type of care and services delivered to the patient are determined in part through documentation. On-going planning and assessment rely heavily on the quality and accuracy of the documentation in the chart.

Proactive concurrent monitoring of the completeness, timeliness and accuracy of the medical record documentation is critical. Both the need for good documentation and risk factors hindering quality, support the importance of on-going, scheduled audits and monitoring for every patient's medical record. Some of the alerts and QA monitors may be included in the clinical and administrative software used. The quality monitoring process will focus on the combination of using manual and computerized clinical and billing data as well as standards/requirements. Establishing the qualitative and quantitative monitoring process is expected to be tailored to the dental clinic/surgery, their needs, the services they provide, workflow issues, survey findings and overall management of the facility.

#### **1. Internal Qualitative vs. Quantitative Audits and Monitoring**

There are various types of audits/monitoring systems - qualitative, quantitative and self-monitoring including manual and automated methods. Qualitative audits look at the quality of documentation assessing adherence to clinical practice guidelines, evaluating consistency in charting, and adherence to regulations, standards and interpretations. This type of audit is usually completed by a staff member or consultant who has professional training, education or experience. Qualitative audits adhere to the SOPs on qualitative patient care protocols, both internal and those prescribed by the regulatory agencies. Qualitative protocols include increased knowledge and skills of the reviewer to evaluate documentation that focuses on the clinical practice and standards. The results or findings from the qualitative monitoring provide the data for QA reviews of the quality of care, in relationship to standards, clinical practices and regulatory requirements.

The dental clinic staff can be trained and internal systems can be established for self-monitoring to complete quantitative audits which focus on whether a document is complete (all sections of a form), authenticated, or timely. This type of audit is more objective than a qualitative audit.



Increased self-reliance and self-monitoring is within reach of the clinical staff documenting, using the following methods:

- i. Self-auditing; before you put the pen down, look for those clinical interventions, observations or assessment that would demonstrate the quality of care you just provided or are planning for the future.
- ii. Look at the automated edits or warning/alerts for inconsistencies of documentation based on the software criteria.
- iii. Set an expectation to periodically run reports to identify areas of deficiencies or information to evaluate the documentation, examples, un-noted orders report, alerts for individuals – to check against the charting planned or just completed.
- iv. Establish 'shift to shift' or 'person to person' monitoring of documentation with a 'sign-off' either manual/or electronic to indicate self-monitoring. Some examples are medication and treatment, ADL monitoring, etc.

On an on-going basis, facilities should have quantitative and qualitative monitoring in place to assure complete and timely records. Admission, current and discharged, record monitoring assures that analysis is completed throughout the patient stay. The goal to continuous monitoring throughout a patient stay is to identify problems or omissions when correction is possible. Analyzing the record on discharge makes it virtually impossible to legally and ethically address or correct documentation problems when it can still impact the patient during their stay while maintaining the integrity of the medical record. For example, if an assessment is not completed on admission nothing can be done on discharge, but if it is found during an admission audit, the assessment can still be completed in order for the facility to provide appropriate care and services for the patient. Signatures for manual systems shall meet the requirements for a full signature, initials that are referenced by the clinician's full name, including title.

## **2. Routine Audits/Monitoring (Criteria and Timeframes)**

Every clinic should have systems in place for monitoring completeness of their documentation on an on-going basis. At a minimum, records should be reviewed on a monthly/quarterly basis. Not all audit findings will be correctable. For findings that cannot be corrected, the information should be gathered for training/retraining, system evaluation and improvement. The QA process should incorporate the findings into their overall quality management program.<sup>27</sup>

### **i. Maintaining a Unit Record**

A unit record and unit numbering system is recommended for health care facilities. With a unit record, the patient is assigned a medical record number on the first visit to the dental clinic/surgery. This number is retained for each subsequent visit, and is used for both paper and electronic portions of the record.

Availability/instant access to previous records forward provides the most comprehensive picture for use in the assessment and care planning process.

### **ii. Defining what is Part of the Medical Record**

The medical record includes, but is not limited to, the following types of information: patient identification, advance directives and consents, history and physical exams and other related records, assessments, care plan, orders, progress notes, medication and

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<sup>27</sup> American Health Information Management Association (AHIMA), 2012

treatment records, reports from lab, X-rays and other diagnostic tests, rehabilitation and restorative therapy and other miscellaneous records including correspondence and administrative documents.

A dental clinic's/surgery's policy should specifically be outlined in the format of a chart order depicting the exact documents and records that will be considered part of the medical record.

**iii. Maintenance of the Medical Record**

This means that all records have an established order of filing that is followed. All records should be readily accessible, maintained in an organized chart order, filed in an easily retrievable manner, and maintained in folders or chart holders sufficient in size for the volume of the record. The chart holders and folders should be kept neat, clean and orderly. Products are available for cleaning/disinfecting the chart holders (binders).

**iv. Identification (Name and Number) on the Pages of the Medical Record**

From a legal perspective, each page or individual documents in the medical record should contain the patient identification information. At a minimum, both the patient name and medical record number should be on each form. If labels/label paper is used, the patient identification information must be included on the label. The patient name and number should be placed on both sides of a two-sided form/page because records are frequently copied. Identification information appearing on both sides of a form helps to ensure that the copy is not lost or misplaced. If the back of the form is blank, no identification information is required on the blank side. There should be no documentation on the back of a one-sided form. If, for any reason, documentation is placed on the back of a one-sided form, a label or identifying information must be added and any blank space on the form lined or X'd out to prevent further documentation that may be out of sequence.

Patient identification information can be noted on forms by methods such as writing on the page in permanent ink, stamping by an addressograph, or affixing a printed or manually completed label. Regardless of the method used, identification information should not obscure any content on the form. Patient specific documents printed from a computer system to be filed in the medical record, such as physician orders, care plans, etc., should include patient identification information on each page.

## Assessment Scoring Matrix

**Standard 11. QA-2: The clinic identifies key indicators to monitor the inputs, processes and outcomes which are used as tools for continual improvement**

Indicator 27 - 30		Max Score	Weightage (Percentage)	Score Obtained
Ind 27.	Monitoring includes ALL invasive procedures	10	100%	
Ind 28.	Monitoring includes adverse drug events	10	100%	
Ind 29.	Monitoring includes use of anesthetics	10	100%	
Ind 30.	Monitoring includes availability and content of the clinic records	10	100%	
<b>Total</b>		40		

## Standard 12. QA-3: Sentinel events are assessed and managed

### Indicators (31):

**Ind 31. The clinic has enlisted the sentinel events to be assessed and managed**

#### Survey Process:

Surveyor asks for a list of possible 'sentinel events,' record of any sentinel event assessed and managed in the last 12 months<sup>28</sup> and results used for QA/QI.

#### Compliance Requirements:

- ✓ List of possible sentinel events
- ✓ Documentary evidence if any sentinel event assessed and managed in the last 12 months
- ✓ Evidence of using results for QA/QI

#### Scoring:

- If there is a list of possible sentinel events and evidence of having a sentinel event which was assessed and managed as above, then score as **fully met** OR if there is no evidence of having a sentinel event but the system is in place to manage if one occurs, then score as **fully met**.
- If there is no system in place to manage the sentinel events, then score as **not met**.

### GUIDELINES

#### Sentinel Events

A sentinel event is defined as 'an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof.' Serious Injury specifically includes loss of limb or function or jaw fracture during tooth extraction. The phrase, 'or risk thereof' includes any process variation for which a recurrence carries a significant chance of a serious adverse outcome.

Such events are called "SENTINEL" because they signal the need for immediate investigation and response. The real tragedy is that most of these medical mistakes are preventable and they are most often caused by systems that break down and don't support the highly qualified and dedicated hospital/clinic caregivers the way they should.

While significant and attracting attention, medication errors aren't the only types of medical errors that hospitals/clinics need to pay attention to.

Sentinel events also include the following, even if the outcome was not death or major permanent loss of function:

1. Wrong tooth extraction/treatment

<sup>28</sup> Unforeseen event like severe drug aggravation, wrong prescription, wrong patient, wrong tooth extraction, jaw fracture during tooth extraction, needle breakage while injecting anesthesia, reamers/files breakage during RCT, any foreign object swallowed (artificial crown/endodontic instrument/dental implant or its abutment etc.), patient violence against clinic staff, violence against patients, etc. as detailed in the guidelines.

2. Surgery on the wrong individual or wrong body part
3. Surgical instrument or object left in a patient after surgery or another procedure
4. Reamer or file broken in the root canal
5. Hemolytic transfusion reaction due to blood group incompatibilities
6. Crown accidentally swallowed
7. Needle breakage during local anesthesia injection

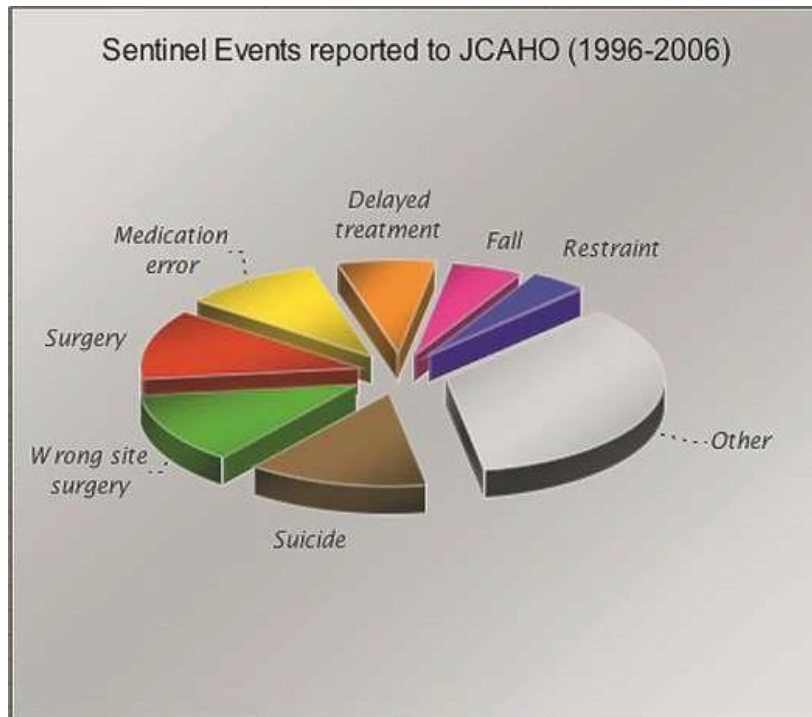


Figure 1. Sample of Sentinel Events

## Assessment Scoring Matrix

### Standard 12. QA-3: Sentinel events are assessed and managed

Indicator 31		Max Score	Weightage (Percentage)	Score Obtained
Ind 31.	The clinic has enlisted the sentinel events to be assessed and managed	10	100%	
Total		10		

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

### 01 Standard & 06 Indicators

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A dental clinic should consider the care it provides as part of an integrated system of services, healthcare practitioners/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/clinic, 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.

Similarly, the radiological/imaging services are the key diagnostic tools 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.

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## Standard 13. AAC-1: Portrayed service(s) conform to the legal provisions

### Indicators (32-37):

#### Ind 32. The services being provided at the clinic are displayed as per Code of Ethics

##### Survey Process:

There should be a board clearly displaying the scope of services provided at the clinic which are in consonance with the ethical provisions. This means that only those services are to be offered for which the particular registered dental practitioner is qualified and competent to provide.<sup>29</sup>

##### Compliance Requirements:

- ✓ Board, clearly displaying the scope of services provided at the clinic, in consonance with the legal/ethical provisions
- ✓ Services provided at the clinic are in consonance with the legal/ethical provisions

##### Scoring:

- If the displayed services are in compliance with the code of ethics, then score as **fully met**.
- If there is superfluous/misleading information or no information displayed, then score as **not met**.

Statement of Ethics is given at **Annexure E**.

#### Ind 33. Specialized services being provided conform to the standards<sup>30</sup>

##### Survey Process:

The indicator implies that the specialized services inclusive of consultation and specialized equipment based evaluation are consistent with qualification, training, experience in the portrayed field as prescribed by the respective councils.

**Note:** In case, no specialized services are provided, mark as “Not Applicable.”

##### Compliance Requirements:

- ✓ The specialized consultations are provided by the professionals who are accordingly registered with the council
- ✓ The evaluations and procedures using specialized equipment are consistent with the qualification/training/experience of the HSP

##### Scoring:

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<sup>29</sup> PM&DC Code of Ethics of Practice for Medical and Dental Practitioners in general and provision 11.3 in particular refers.

<sup>30</sup> Applicable only when portrayed.



- If the specialized services are in compliance with the above parameters, then score as **fully met.**
- If the specialized services do not meet the above parameters, then score as **not met.**

### Ind 34. The use and maintenance of specialized equipment conforms to the standards<sup>31</sup>

#### Survey Process:

The use and maintenance of specialized equipment is ensured in accordance with the manufacturers guidelines on safety, infection control and for accuracy of results. Surveyors are required to check knowledge of relevant staff, guidelines provided to them and the log book of the equipment to check the maintenance history.

**Note:** In case, no specialized equipment is used, mark as “Not Applicable.”

#### Compliance Requirements:

- ✓ Specialized equipment is used and maintained according to the manufacturer's guidelines.

#### Scoring:

- If the use and maintenance of specialized equipment is based on the manufacturer's guidelines covering safety, infection control and accuracy of results evidenced as above, then score as **fully met.**
- If the use and maintenance of specialized equipment is not based on guidelines as required above, then score as **not met.**

### Ind 35. Dental laboratory services, provided, conform to the respective standards

#### Survey Process:

If the dental clinic provides on-site dental laboratory services, those should conform to the respective standards in terms of equipment, staff and SOPs.

**Note:** In case, no dental laboratory services are provided, mark as “Not Applicable.”

#### Compliance Requirements:

- ✓ Dental laboratory services, **if provided on-site,** conform to the respective standards in terms of equipment, staff and SOPs
- ✓ Dental surgeons obtain **off-site services** from qualified dental technicians only, for preparing dentures, etc.

#### Scoring:

- If the laboratory services are in compliance with the above parameters, then score as **fully met.**
- If the laboratory services do not meet the above parameters, then score as **not met.**

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<sup>31</sup> Applicable only when portrayed and in accordance with recommendations of equipment manufacturer.

## Ind 36. Dental radiological diagnostic services, if being provided, conform to the respective standards

### Survey Process:

This means if x-ray machine(s) is/are used in the clinic for facilitating diagnosis and treatment plan, those should conform to the respective PNRA/DRAP standards, as amended from time to time, in terms of equipment, staff and SOPs.

### Compliance Requirements:

- ✓ Applicable guidelines issued by PNRA/DRAP are available and followed in case dental X-ray unit is used
- ✓ Valid certification, as required for the particular radiological equipment in use, is available

**Note:** In case, no x-ray machine(s) is/are used, mark as “Not Applicable.”

### Scoring:

- If the radiological diagnostic services are in compliance with the above parameters, then score as **fully met.**
- If the radiological diagnostic services do not meet the above parameters, then score as **not met.**

## Ind 37. Dental health education is provided as per guidelines

### Survey Process:

The surveyor is required to look for display of relevant dental health educational messages on prevention of dental disease and promotion of oral health. IEC material and/or written instructions delivered to the patients by the dental care provider should be relevant and as per approved guidelines.

### Compliance Requirements:

- ✓ IEC material including dental health educational messages on prevention of dental disease and promotion of oral health are displayed
- ✓ Evidence of written instructions delivered to the patients by the dental care provider are as per approved guidelines and are relevant

### Scoring:

- If there is a display of relevant dental health educational messages/IEC material and consistent evidence that patients are guided on it accordingly, then score as **fully met.**
- If there is a display of relevant dental health educational messages/IEC material, but inconsistent evidence of patients being guided on it, then score as **partially met.**
- If there is neither a display of relevant dental health educational messages/IEC material, nor any evidence that patients are accordingly guided on it, then score as **not met.**

## GUIDELINES

### **Portrayal of Services<sup>32</sup>**

It is of immense importance for patients to be aware of the services available at a particular dental clinic. It means that a BDS dental surgeon having valid registration with PM&DC should display only those services which are related to general dentistry and for which he/she is trained and certified to perform.

Any specialized service provided, must be as per standards specified for that particular service and the health care provider must have requisite post graduate qualification duly registered with the Council.

### **Compliance with Statutes**

As per section 19 (1a) of Pakistan Nuclear Regulatory Authority Ordinance 2001, any premises, in which a radiation facility is provided, shall require registration/licensing by the Authority. PNRA registration/license is mandatory for possession, installation or operation of any radiation apparatus including Dental X-Ray machines. Use of radiation apparatus without PNRA valid license inter alia, is clear breach of Section 19 of the PNRA Ordinance. This regulatory approach is adopted for safe guarding both the patients/clients and the dental healthcare providers.

Following dosimetry information may be taken as an eye opener in this regard;

“Radiation doses that exceed a minimum (threshold) level can cause undesirable effects such as depression of the blood cell-forming process (threshold dose = 500 mSv, 50 rem) or cataracts (threshold dose = 5,000 mSv, 500 rem)\*. The scope and severity of these effects increases as the dose increases above the corresponding threshold. Radiation also can cause an increase in the incidence, but not the severity, of malignant disease (e.g., cancer). With this type of effect, the probability of occurrence increases with dose rather than the severity. For radiation protection purposes it is assumed that any dose above zero can increase the risk of radiation-induced cancer (i.e., that there is no threshold). Epidemiologic studies have found that the estimated lifetime risk of dying from cancer is greater by about 0.004% per mSv (0.04% per rem) of radiation dose to the whole body (NRC, 1990).”<sup>33</sup>

Dental radiology and diagnostic imaging services, may be provided within the dental clinic or by agreement with another organization, or both. The contracted outside source selected by the dental clinic must have KP HCC registration/licence. The in house, as well as contracted radiology services, must comply with laws and regulations and must provide safe and quality services of acceptable standards in accordance with the defined time frame.

All the statutory requirements including Pakistan Nuclear Regulatory Authority (PNRA) regulations e.g. use of dosimeters, lead sheets, lead aprons, thyroid guard, signage, and display etc. and applicable provision of the Drug Regulatory Authority of Pakistan (DRAP), as amended from time to time, are to be complied with.

### **Scope of Laboratory Services**

1. The dental prosthetic lab, if available, shall be a well-organized, adequately supervised with adequate space, facilities and optimum temperature for equipment to perform properly.
2. Basic clinical laboratory services necessary for routine examinations, if available on-site, should conform to the applicable standards.

<sup>32</sup> Refer to provision Nos. 7, 8, 18, 24, 25, 31 and 39 of Code of Ethics of Practice for Medical and Dental Practitioners published by PM&DC.

<sup>33</sup> [https://www.mun.ca/biology/scarr/Radiation\\_definitions.html](https://www.mun.ca/biology/scarr/Radiation_definitions.html)

## Assessment Scoring Matrix

### Standard 13. AAC-1: Portrayed service/s conform to the legal provisions

Indicator 32 - 37		Max Score	Weightage (Percentage)	Score Obtained
Ind 32.	The services being provided at the clinic are displayed as per Code of Ethics	10	100%	
Ind 33.	Specialized services being provided conform to the standards	10	100%	
Ind 34.	The use and maintenance of specialized equipment conforms to the standards	10	100%	
Ind 35.	Dental laboratory services, provided, conform to the respective standards	10	100%	
Ind 36.	Dental radiological diagnostic services, if being provided, conform to the respective standards	10	100%	
Ind 37.	Dental health education is provided as per guidelines	10	80%	
<b>Total</b>		60		

## 2.7 Care of Patients (COP)

### **02 Standards & 05 Indicators**

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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 may involve different processes. The standards under the functional area 'Care of Patients' address essential principles and processes for the clinical care of patients who come to a dental clinic for treatment, with excellent care being the overarching goal. The standards further entail that comprehensive treatment shall be provided in the respective clinical specialty, with strict compliance to the prescribed standards of care.

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## Standard 14.COP-1: The clinic has a well-established patient management system

### Indicators (38-41):

#### Ind 38. The clinic has an established registration and guidance process

##### Survey Process:

Observe as well as check from the record that a reception, registration and guidance<sup>34</sup> system is practiced to facilitate the patients. Patients can comfortably reach the reception and communicate with the reception staff, get registered and obtain token number/time for an appointment. The reception staff is polite and guides the patients to wait for their turn/time for consultation/examination by the dental surgeon and/or explains such other requirement(s).

##### Compliance Requirements:

- ✓ The reception, registration and guidance system to facilitate the patient is in place
- ✓ Patients can comfortably access the reception/reception staff, get registered and obtain token number/ time for appointment
- ✓ The reception staff is polite and guides the patients to wait for their turn/time for consultation/ examination by the dental surgeon and/or explains such other requirement(s)

##### Scoring:

- If the reception, registration and guidance provided to patients is evident as described above, then score as **fully met**.
- If there are non-conformances to the above, then score as **not met**.

#### Ind 39. Standard/ethical practice is evident from the patient record

##### Survey Process:

Observe and check that patients are assessed by the dental surgeon by history taking, physical examination (oral examination basically, and blood pressure, pulse, temperature, etc. if indicated) and documenting the signs related to patient's complaints/symptoms, diagnosis/differential diagnosis and relevant evaluations for every affected tooth, as applicable with the objective of providing quality dental care/treatment and follow up,<sup>35</sup> in line with the prescribed Code of Ethics or for referral to the

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<sup>34</sup> Direction/guidance to patients regarding further actions in connection with their dental treatment needs and its management i.e. consultation/specialized testing on equipment/dispensing/referral etc. The dental surgeon him/herself or the qualified and authorized technician/assistant must explain the processes involved in safety/infection control/post op /post procedure complications etc. This requirement has to be included in the JDs of relevant staff as further explained in the Guidelines.

<sup>35</sup> Standard Clinical Methodology respecting patient's privacy is to be adopted while examining the patients.

higher level facility. Check documentary evidence of assessment, treatment or referral<sup>36</sup> (as applicable), by reviewing the representative sample of record of patients which can be a register/copies of prescription and/or an elaborate record, depending on the scale /scope of practice.

**Compliance Requirements:**

- ✓ Documentary evidence of patient's assessment (history taking, physical examination basically oral examination and taking blood pressure, pulse, temperature, etc. if indicated and documenting the related signs, symptoms, diagnosis/differential diagnosis and relevant evaluations for every affected tooth, as applicable with the objective of providing quality dental care/treatment and follow up, in line with the prescribed Code of Ethics or for referral to the higher level facility
- ✓ Register/copies of prescription and/or an elaborate record, depending on the scale/scope of practice

**Scoring:**

- If all checked records of the patients show documentation of patient's assessments and management as 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.**

**Ind 40. The clinic has referral SOPs**

**Survey Process:**

Check the availability and practice of written SOPs for safe and speedy transfer of patients/victims in emergency which describe how a patient is to be cared for during transportation and to avoid confusion and delay in taking over the patient at the receiving facility.

**Compliance Requirements:**

- ✓ Written SOPs for safe and speedy transfer of patients/victims in emergency which describe how a patient is to be cared for during transportation and to avoid confusion and delay in taking over at the receiving facility
- ✓ Evidence that the referral SOPs are complied

**Scoring:**

- If the clinic has written referral SOPs and practices it, then score as **fully met.**
- If the clinic does not have written referral SOPs or does not practice it, then score as **not met.**

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<sup>36</sup> A dental surgeon is required to refer all those patients to an appropriate dental clinic/surgery, who cannot be/should not be managed at his/her clinic due to the limited scope of services, nature of their ailment or due to an emergency or medico legal nature. This needs critical judgment and ethical decision by the dentist. Check the referral record to ascertain whether the required details such as serial number, name, son/ daughter of/wife of /address, contact no., symptoms/provisional diagnosis, prognosis, reasons for referral, date and time of referral, place of referral, etc. referred in past 12 months, are available at the clinic.

## Ind 41. The clinic has list of contact numbers of the referral facilities, medico legal authorities, concerned police stations, and ambulance/rescue services

### Survey Process:

Check the availability of a list of contact numbers for the transfer of patients/victims in emergency to obviate confusion and delay in transfers.

### Compliance Requirements:

- ✓ List of contact numbers of the following for use in emergency is displayed:
  - Rescue 1122
  - Other ambulance services
  - Nearest referral hospitals/clinics
  - Police station
  - Fire brigade

### Scoring:

- If the clinic maintains contact numbers as described above, then score as **fully met.**
- If the clinic does not maintain contact numbers as described above, then score as **not met.**

## GUIDELINES

### Registration and Disposal

A well-functioning registration and disposal process is an important indicator of an established patient management system. If the patients are received, registered and appropriately guided for further actions, it confirms the satisfaction of the patients and other care providers. The following SOPs can be adopted and used as guidelines by appropriate modification in respect of a particular dental clinic/surgery to suit the local needs.

#### 1. Reception / Registration

- i. Receptionist(s)/Computer Operator(s) to perform duty according to type of facility/workload
- ii. Information is provided to the patients both verbally and on telephone in a pleasant manner
- iii. Patient is sent/guided/ taken to the relevant section/department
- iv. Particulars of patients are entered in the register/computer and a form or slip is provided after data entry
- v. Minimum time is consumed up to this stage

#### 2. Guidance of Patients/Visitors

- i. Sign boards showing services available in a particular setup (menu of services) are clearly displayed at the key point/s (gates), key turning points, reception, sections/areas so that users are facilitated to know and access the services available in a particular facility
- ii. Sign boards with directional arrows, indicating the location of service areas/specific departments, are placed and maintained as required except in the settings which do not require such directional boards



- iii. Services available at a particular service area should also be displayed within that area
- iv. Leaflets providing information about the services in simple language are prepared, distributed/kept at key point/s to create awareness amongst the patients/visitors about the available services in the facility
- v. Services which are not available are not displayed
- vi. Use of close circuit TV and public address system may be considered for information and education of clientele on health matters

### **Patient Assessment and Management Methodology**

The standard way of patient assessment and management is to follow the clinical methods; i. observation, ii. history of present and past illnesses (pertaining to dental are in particular and any other considered relevant e.g. hypertension/taking of blood thinning agents) for picking up any relevant points which can be of significance in treatment and/or avoiding post-operative/post procedural complications, iii. social habits, iv. recording/noting the symptoms, v. oral examination vi. decision about the required laboratory tests and vii. the line of management to be advised (disposal). At this stage, the patient shall either have a prescription if only medication is required, along with advised tests, etc., or have had explained and obtained the consent about the dental procedure/surgery to be undertaken, followed by post procedure/surgery advice in writing to be followed or referral to another facility as applicable. The dental surgeon must follow the standardized dental protocols when managing any particular disease, at the same time using their own clinical acumen in treating and saving the patient's oro-dental health.

### **Possible Referral Conditions**

Patients may need to be referred for several reasons, including one or combinations of the following conditions, which provide an appropriate rationale to the dentist for referring a patient:

1. Level of training and experience of the dentist
2. Dentist's areas of interest
3. Extensiveness of the problem and complexity of the treatment
4. Medical complications
5. Patient load
6. Availability of special equipment and instruments
7. Staff capabilities and training
8. Patient desires
9. Behavioral concerns
10. Desire to share responsibility for patient care
11. Geographic proximity of the specialist or consulting dentist

The referring dentist should convey appropriate information to the specialist or consulting dentist, which may vary on an individual patient basis, and could include the following:

1. Name and address of the patient
2. Scheduled appointment date and time with the specialist or consulting dentist
3. Reason for the referral
4. General background information about the patient which may affect the referral
5. Authorization or release of records
6. Medical and dental information, which may include, medical consultations and specific

problems, contributory dental history, diagnostic casts, radiographic or digital images

7. Future treatment needs beyond referral
8. Urgency of the situation, if an emergency

Both practitioners should discuss the referral treatment period and the return of the patient to the referring dentist. This arrangement may be enhanced by an exchange of business cards, referral forms and patient instructional materials. Availability for emergency treatment during the referral period should be discussed.

The dental clinic should display on a chart all the contact numbers of the local police station, fire brigade, rescue services, electricity complaint cell, ambulance service, etc. so that it is easy to contact these services in an emergency situation.

## Assessment Scoring Matrix

**Standard 14. COP-1: The clinic has a well-established patient management system**

Indicator 38 - 41		Max Score	Weightage (Percentage)	Score Obtained
Ind 38.	The clinic has an established registration and guidance process	10	<b>100%</b>	
Ind 39.	Standard/Ethical practice is evident from the patient record	10	<b>80%</b>	
Ind 40.	The clinic has referral SOPs	10	<b>100%</b>	
Ind 41.	The clinic has list of contact numbers of the referral facilities, medico legal authorities, concerned police stations, and ambulance/rescue services	10	<b>100%</b>	
<b>Total</b>		40		

## Standard 15. COP-2: The clinic has essential arrangements for providing care to emergency cases

### Indicator (42):

#### Ind 42. The clinic has essential arrangements to cater for emergency care

#### Survey Process:

Check for the portrayal of the list of emergencies to be managed and the required arrangements/emergency/ first aid kits.<sup>37</sup>

#### Compliance Requirements:

- ✓ List of emergencies portrayed to be managed
- ✓ The required emergency/first aid kits
- ✓ The contents of the emergency kits are up to date

#### Scoring:

- If the clinic has arrangements to manage the portrayed/listed emergencies, then score as **fully met.**
- If any deficiency in the arrangements as described above exists, then score as **not met.**

### GUIDELINES

#### Emergency Service

Dentists shall be obliged to make reasonable arrangements for the emergency care of their patients of record. Dentists shall also be obliged, when consulted in an emergency, by patients not of record to make reasonable arrangements for emergency care. If treatment is provided, the dentist, upon completion of such treatment, is obliged to return the patient to his/her regular dentist, unless the patient expressly reveals a different preference.

#### Policies and Procedures

Each dental clinic/surgery 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. These documents include SOPs/protocols to provide care either for common emergencies as it may occur at any place/time, e.g. syncope, cardiac arrest, choking, acute bronchospasm, bleeding, fracture, etc. or for management of specific conditions, e.g. acute pulpitis, acute alveolar abscess, tooth fractures and oral and maxillofacial trauma, etc. and shall address

<sup>37</sup> List of standard first aid kits/boxes/trays/trolleys with guidelines/SOPs and listing of the types of emergencies portrayed to be managed are included in the guidelines. Arrangements to manage; i. syncope, ii. respiratory distress, iii. anaphylactic shock, iv. control of bleeding and v. fracture of mandible and other long bones for at least one patient at a time should be available at the clinic. Additional portrayal will be checked accordingly as an optional binding of the service provider. This is to be linked with sentinel events (Ind 31).

both adult and pediatric patients. The procedure shall incorporate at least identification, assessment and provision of appropriate care followed by referral if required. The policy/SOPs/SMPs of the dental clinic/surgery should spell out and ensure availability of all the necessary equipment in working order during the operational time of the clinic.

### **SMPs For Medical Emergencies in the Dental Clinics<sup>38</sup>**

#### **Introduction**

One cannot be certain that medical emergencies will not occur in a dental clinic and should therefore, be prepared to manage such an occurrence. HCPs must have basic knowledge of the signs and symptoms of these emergency situations to act quickly, efficiently and effectively. In case of uncertainty, the practitioner should call (shout if so required) for help from a senior clinician or colleague. Most of the emergencies can be dealt satisfactorily if more than one HCP is competent to attend to the situation. The basic guidelines to manage such an emergency are given below.

#### **Preparatory SOPs**

FIVE steps to prepare and manage a medical emergency:

1. Medical history including history of allergy and drug history
2. Assessment of patient's condition
3. Resuscitation knowledge, training and practice
4. Proficiency in the use of emergency medications and devices
5. Calling for medical assistance

#### **Inhalation and/or Ingestion of Foreign Object**

If a dental instrument or object disappears into the throat (oropharynx) during dental treatment, one must pursue the following steps:

1. Stop the dental procedure, inform the patient on what has happened and try to calm the patient by providing reassurance.
2. Look for the missing instrument/object in the oral cavity, in and around the orofacial region, neck and drape.
3. Put the patient into an upright position and check vital signs.
4. Do not offer anything to drink. If the patient is coughing, encourage the patient to relax, cough and breathe deeply and observe for the missing object in the expectorant and spit (if any).
5. If the patient is not showing any discomfort or coughing, send the patient for a chest X-ray within the first hour since the object in the gastrointestinal tract will remain in the upper portion for an hour and may be detected in the radiograph.
6. If the patient is showing signs of partial or complete respiratory obstruction, Call 1122 for shifting to appropriate facility.

#### **Signs of partial obstruction**

1. Wheeze
2. Stridor
3. Labored breathing
4. Coughing spasms

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<sup>38</sup> Readiness in terms of these SOPs/SMPs is considered essential for ensuring safety of patients.

**Signs of complete obstruction**

1. Inability to breath, speak, cry or cough
2. Agitation, gripping of the throat
3. Cyanosis
4. Bulging of the neck veins
5. Rapid development of respiratory failure
6. Cardiac failure
7. Loss of consciousness

**ACTIONS****In partial obstruction:**

1. Call 1122, and
2. Meanwhile, encourage coughing

**Total obstruction:**

1. Call 1122 for referral
2. Keep the patient in recovery position
3. Try to remove obstruction manually, only if possible
4. Check breathing and if no breathing
5. Give five back blows to the space between shoulder blades using the heel of the hand
6. If no breathing, give five hard chest compressions (same as cardiac compressions but much harder)
7. Continued obstruction is indicative of a cricothyroidectomy

**Ptosis of the Eye**

Ptosis of the eye, sometimes accompanied by double vision, can be a complication of maxillary injections. If these symptoms should occur the following treatment is the correct management:

1. Reassure the patient that the symptoms will disappear when the anesthetic ceases to act.
2. Place an eye patch over the affected eye. These are available in the first aid kit on the clinic floor and you should ask the senior dental assistant for help.
3. If the patient has double vision and no one to accompany, then arrange for a taxi to take the patient home.
  - i. Instruct the patient to:
  - ii. Remove the eye patch when the anesthetic ceases to act and inform the patient of the estimated time for this to occur, which will depend on the type of anesthetic used.
  - iii. Contact the dental clinic should there be any further problems.

**Anaphylactic Reaction**

Note history of any allergy from the medical history form, and if not mentioned, ask about the details before initiating any dental procedure.

If an anaphylaxis is suspected in an adult with the following:

1. Angioedema
2. Urticaria
3. Hypotension
4. Abdominal pain
5. Conjunctivitis

6. Erythema
7. Pruritus
8. Vomiting
9. Rhinitis

**Take the following actions:**

1. CALL THE NUMBER 1122 and ask for ambulance service, brief them with the situation and try to answer all their questions.
2. Administer oxygen by mask @10L/min.
3. Give IM Adrenaline on the lateral aspect of thigh (0.5ml of 1 in 1000) (1mg/m1).
4. If there is NO response AFTER 5 minutes, REPEAT STEP 3.
5. If the patient losses consciousness, give basic life support (CPR), continue treatment until ambulance or other medical assistance is available.

**Cardiac Arrest**

**If cardiac arrest is suspected in an adult with the following presentation:**

1. Loss of consciousness
2. No breathing
3. No pulse

**Take the following actions:**

1. CALL THE NUMBER 1122 and ask for ambulance service and brief them with the situation. Try to answer all their questions.
2. Institute basic life support (CPR).
3. Use automated defibrillator.
4. Maintain the above until help arrives.

**Epileptic Seizure**

The safety of the patient and those attending the patient are important during a seizure attack in a dental clinic.

**The seizure may present as:**

1. Sudden loss of consciousness
2. Temporary apnea and cyanosis
3. Tonic and clonic jerking movements
4. May become incontinent
5. Tongue biting

**Take the following actions:**

1. Stop the dental procedure; remove instruments from the mouth and surrounding.
2. Avoid and/or prevent patient falling from the dental chair (by lowering the chair if raised).
3. Avoid and/or prevent patient injuring herself/himself from dental equipment and instruments.
4. Avoid restraining the patient unless essential to prevent injury.
5. Call 1122 if seizure persists for more than a few minutes.

**If the seizure subsides, ensure the following:**

1. Protection of patient in 'recovery position.'
2. Monitor consciousness state (responding to commands).
3. Maintain airway.

4. Remove vomitus (if any) from the oral cavity by suction.
5. Keep under observation for 30 minutes.
6. Instruct the patient to report to his/her doctor about the incident and let the patient go home.

### **Stroke**

**If a patient shows signs of 'stroke', follow the steps below:**

1. CALL RESCUE 1122 for ambulance.
2. Stop the dental procedure.
3. Administer oxygen.
4. Maintain airway.

### **Asthma**

Most asthma-related deaths occur outside the hospital.

#### **Management**

Assess severity.

1. Acute severe - patient unable to speak in complete sentences, pulse rate greater than 110 per minute, respiratory rate greater than 45 per minute.
2. Life threatening asthma- 'silent chest', cyanosis, sweating, hypercarbic flush, bradycardia/hypertension, confusion and agitation.
3. If more than one feature is severe, or if any feature is life-threatening, arrange hospital transfer.

### **Diabetes**

The most common diabetic emergencies are:

1. Low blood sugar— hypoglycaemia in patients on anti-diabetic medications
2. High blood sugar— hyperglycaemia, particularly diabetic ketoacidosis

#### **Hyperglycaemia**

Clinical symptoms include:

1. Thirst
2. Increased urine output and dehydration
3. A progressive reduction in conscious level ensues with hypotension, coma and cessation of urine output in severe cases

#### **Management**

1. Primary assessment and resuscitation (DRS-ABC) to secure the airway, breathing and circulation
2. Transport to a hospital facility

#### **Hypoglycaemia**

Clinical symptoms include:

1. Sweating
2. Hunger
3. Tremor
4. Agitation
5. Progress, drowsiness, confusion and coma
6. Assume that any diabetic with impaired consciousness has hypoglycaemia until proven



otherwise

### **Management**

1. Conscious patients can usually be treated with oral carbohydrates, e.g. fruit juice, packets of granulated sugar, glucose powder neat or dissolved in water.
2. After 10 minutes, this short acting carbohydrate should be followed up with food which contains longer acting carbohydrate.
3. It is important that the victim is not left alone until the danger of hypoglycaemia has passed.
4. If the patient is unconscious, attend to the airway, breathing and circulation.
5. Protect the victim from injury.
6. Call Rescue 1122 for an ambulance.

### **Hyperventilation**

Prolonged rapid deep breathing often in very anxious patients can lead to profound metabolic changes that may result in loss of consciousness. A fall in arterial carbon dioxide concentration causes cerebral vasoconstriction and respiratory alkalosis.

### **Presentation**

1. The patient may notice tingling of the fingers or lips.
2. Tetanic spasm of the peripheries.
3. Dizziness.
4. These symptoms tend to increase anxiety and respiratory rate and depth.
5. Eventually the patient will become unconscious due to a relative cerebral hypoxia.
6. The patient is apnoeic for a period due to reduced respiratory drive with low arterial carbon dioxide concentration.
7. As the arterial carbon dioxide level rises and cerebral vasoconstriction reverses, the patient starts breathing again and regains consciousness.
8. Hyperventilation recommences, and the cycle continues with further loss of consciousness.

### **Management**

1. Reassure patient.
2. If patient is conscious, encourage re-breathing into a paper bag to increase inspired carbon dioxide.
3. If patient is unconscious, maintain airway until consciousness is regained.
4. Place in the recovery position and give reassurance, while the patient continues re-breathing into paper bag.

## Assessment Scoring Matrix

Standard 15. COP-2: The clinic has essential arrangements for providing care to emergency cases

Indicator 42		Max Score	Weightage (Percentage)	Score Obtained
Ind 42.	The clinic has essential arrangements to cater for emergency care	10	100%	
Total		10		

## 2.8 Management of Medication (MOM)

### **02 Standards & 07 Indicators**

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Medication errors are one of the most common healthcare issues, with a number of preventable drug-related mortalities/morbidities occurring each year. Medication errors are also among the most frequently reported types of adverse events. Medication management standards help support patient safety and improve the quality of care by creating a system for selecting, procuring, storing, ordering, transcribing, preparing, labeling, dispensing, administering and monitoring medications. The 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 in the dental clinic.

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## Standard 16. MOM-1: Prescribing practices conform to the standards

### Indicators (43-45):

#### Ind 43. Standards for prescription writing are followed

##### Survey Process:

Check that the prescription is written according to the prescribed format<sup>39</sup> and contains information such as serial number, name of patient, s/o, d/o, w/o, age, gender, date of visit(s), symptom(s), findings of oral/relevant physical examination, provisional diagnosis and instructions/post procedural instructions regarding dosage/duration of use/revisit or additional procedure later etc. are clear.

##### Compliance Requirements:

- ✓ Prescribed format for prescriptions, having space for the above mentioned information is practiced

##### Scoring:

- If prescriptions are written as per the instructions above, then score as **fully met.**
- If prescriptions are not written as per the instructions above, then score as **not met.**

#### Ind 44. Prescriptions are clear, legible, dated, timed, named/stamped and signed

##### Survey Process:

Surveyors are required to check that prescriptions are legible, dated, timed, named and signed by the dental surgeon. Names of the medicines (trade or generic) are clearly written and there is no coding.

##### Compliance Requirements:

- ✓ Prescriptions are legible, dated, timed, named and signed by the dental surgeon
- ✓ Names of the medicines (trade or generic) are clearly written and there is no coding

##### Scoring:

- If the representative sample of prescriptions are as described above, then score as **fully met.**
- If only up to 20% prescriptions are not as above, then score as **partially met.**
- If more than 20% prescriptions are not as above, then score as **not met.**

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<sup>39</sup> A format of prescription slip/form and SOPs is provided in the Guidelines.

## Ind 45. Prescriptions are provided to the patients

### Survey Process:

Provision of prescription having information about the dental procedure performed can be checked by observing the practices, as well as interviewing the patient/s who come for revisit, or substantiated by checking the record maintained at the clinic (carbon copy, register, computer or a combination).

### Compliance Requirements:

- ✓ Record of prescriptions is maintained at the clinic

### Scoring:

- If the clinic provides the prescription slip to the patient as above, then score as **fully met**.
- If the clinic does not provide the prescription to the patient, then score as **not met**.

## GUIDELINES

### SOPs on Prescription of Medications

In dental clinics/hospitals, only medical doctors and dental surgeons are authorized for prescription writing in their own fields.

### Clarity of Medication Orders

All medication orders should be prescribed in writing and 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 pediatric patients. Writing diagnosis is an integral part of the medication prescription, due to 'drug to drug', 'drug to disease' interaction. A complete prescription order must include the following eight items:

1. The client's/ name, parentage, etc.
2. Weight
3. Allergies/Contraindications
4. The date of the order
5. Name of the medication(s)
6. Dosage and administration information
7. Route of administration
8. Doctor's signature and name or/and stamp (containing the name of the doctor)

Drugs must be written legibly and clearly, preferably according to the generic name, while brand name can be used in brackets.

Directions must be clearly stated and should be qualified e.g. 'Take one or two tablets for pain or headache' cautioning 'Not to be taken empty stomach' and/or 'Take one Capsule every 6 hours for five days' in case of an antibiotic course for chest infection, etc. 'As directed' or 'when needed' must be avoided.

Every patient coming to the dental clinic and getting dental treatment must get a clearly written detail of procedural notes, medications and instructions. No verbal instructions regarding taking medications are acceptable.

Post-procedure written instructions in the form of pamphlet/leaflet for the awareness of patients having any surgical procedure, in addition to written specific instructions, should be used, rather than to communicate only verbally.

## Assessment Scoring Matrix

### Standard 16. MOM-1: Prescribing practices conform to the standards

Indicator 43 - 45		Max Score	Weightage (Percentage)	Score Obtained
Ind 43.	Standards for prescription writing are followed	10	<b>100%</b>	
Ind 44.	Prescriptions are clear, legible, dated, timed, named/ stamped and signed	10	<b>80%</b>	
Ind 45.	Prescriptions are provided to the patients	10	<b>100%</b>	
<b>Total</b>		30		

## Standard 17. MOM-2: Storage and dispensing/usage conforms to the guidelines<sup>40</sup>

### Indicators (46-49):

#### Ind 46. Medicines/disposables/dental materials are stored as per guidelines

##### Survey Process:

The guidelines for safe storage include inter-alia;<sup>41</sup> i. proper stacking in groups to differentiate common drugs, injections, anesthetics, look alike and sound alike medicines/cements/materials within the rack/cupboard; ii. labeling; iii. ventilation; iv. temperature control/refrigerator for sensitive drugs/materials, etc.; v. protection of high risk and narcotic drugs as the case may be, and vi. record of expiry dates.

##### Compliance Requirements:

- ✓ Documented guidelines covering at least the following six elements for safe storage are practiced:
  - Proper stacking in groups to differentiate common drugs/materials, injections, look alike and sound alike medicines/cements/materials within the rack/cupboard
  - Labeling
  - Ventilation
  - Temperature control/refrigerator for sensitive drugs/materials, etc.
  - Protection/safe custody of high risk and narcotic drugs as the case may be
  - Record of expiry dates

##### Scoring:

- If the medicines/materials are stored as per the above referred guidelines, then score as **fully met.**
- If implementation of parameters at serial numbers i, ii and iii is inconsistent, then score as **partially met.**
- If implementation of any one of the parameters at serial numbers. iv, v and vi is inconsistent then score as **not met.**

#### Ind 47. Expiry dates/shelf life are checked prior to administering, as applicable

##### Survey Process:

Check 5 randomly selected medicines administered/materials being used or to be administered/used. Verify that the items are within the expiry date printed on the label as per Drug Act/Rules.

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<sup>40</sup> Details in the Guidelines.

<sup>41</sup> Full details available in the manufactures instructions/as per the DRAP Act 2012.



### Compliance Requirements:

- ✓ Check 5 randomly selected medicines administered/materials being used or to be administered/used
- ✓ Items are within the expiry date printed on the label as per Drug Act/Rules

### Scoring:

- If all 5 randomly selected medicines/materials administered/used or to be administered/used are within the expiry date, then score as **fully met.**
- If any of the randomly selected medicines/materials administered/used or to be administered/used are not within the expiry date, then score as **not met.**

## Ind 48. Labeling requirements are implemented

### Survey Process:

The indicator requires that all records like patient's impression/wax bites and x-rays, when taken, are correctly labeled for later identification/reference. If prescribed medicines are provided from the clinic, these are to be correctly dispensed and utilized by the patient. Observe that the dispensed medicine/s bottle or sachet/envelope indicates patient's name/record number, instructions for use, dosage and date of issue. Check 4-6 dispensed medications/taken impressions/x-rays to determine how they are labeled.

### Compliance Requirements:

- ✓ Records of patients' impression/wax bites and x-rays, when taken, are correctly labeled for later identification/reference
- ✓ Evidence that the dispensed medicine/s bottle or sachet/envelope indicates patient name/record number, instructions for use, dosage and date of issue

### Scoring:

- If all items are labeled as above, then score as **fully met.**
- If all items are not labeled as above, then score as **not met.**

## Ind 49. Dispensing/utilization is by an authorized person

### Survey Process:

The surveyors should see that the person made responsible to dispense the medicines or use the dental materials, is a qualified professional registered with the Khyber Pakhtunkhwa Faculty of Paramedical and Allied Health Sciences (FPAHS)<sup>42</sup> and is able to correctly read and identify the medicines/dental materials prescribed/required by the dental surgeon from those in the store/cabinet. He/she is also able to correctly distinguish look alike and sound alike (LASA)

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<sup>42</sup> This requirement is relaxed for the initial one year from the notification of this MSDS to facilitate availability/employment of such registered professional(s) by the dental surgeon. In such cases, certification by the dental practitioner to effect that he/she is satisfied with the skill, knowledge and performance of the person trained by him/her will suffice.

medicines/dental materials and to dispense/use correctly under the supervision of the dentist as required.

**Compliance Requirements:**

- ✓ The person responsible to dispense the medicines is qualified and registered with the Khyber Pakhtunkhwa Faculty of Paramedical and Allied Health Sciences OR
- ✓ The person responsible to dispense the medicines is:
  - Matriculate, preferably with science
  - Able to correctly read and identify the medicines/dental materials prescribed/required by the dental surgeon from those in the store/cabinet
  - Able to correctly distinguish look alike and sound alike medicines/dental materials and to dispense/use correctly under the supervision of the dentist as required

**Scoring:**

- If the dispensing/use of the medicines/dental materials is by an authorized person as described above, then score as **fully met.**
- If the person dispensing/using the medicines/dental materials is neither qualified/registered nor able to perform as described above, then score as **not met.**

GUIDELINES
<p><b>Storage and Dispensing Policy</b></p> <p>Storage/warehousing is an important aspect of the total drug control system. Proper environmental control (i.e., proper temperature, light, humidity, conditions of sanitation, ventilation, segregation, etc.) must be maintained wherever drugs and supplied are stored. Storage areas must be secure; fixtures and equipment used to store drugs should be such that drugs are accessible only to designated and authorized personnel. Safety is an important factor and proper consideration should be given to the safe storage of poisons and flammable compounds. Medications meant for external use should be stored separately from those for internal use. Temperature sensitive medications must be stored in a refrigerator containing only medicines, and items other than drugs should be kept in a separate refrigerator, e.g; dental materials which need to be stored in the refrigerator should have a separate storage arrangement.</p>
<p><b>Drug Storage Site Inspections</b></p> <p>A minimum of quarterly inspections shall be carried out, under the direction of the pharmacist/dentist, of all medication storage areas within the hospital/clinic. A written record shall verify that Safe Storage Practices, including the following, are implemented:</p> <ol style="list-style-type: none"><li>1. The storage is properly maintained using stacks, bin cards and inventory control documents.</li><li>2. Medications are stored securely and are available to the authorized personnel only.</li><li>3. Narcotic and controlled drugs are stored under lock and key by the authorized person.</li><li>4. Standards of neatness and cleanliness are consistent with good medication handling practices.</li><li>5. Reconstituted medications are properly labeled with expiry and preparation date.</li><li>6. Illegible labels are replaced.</li><li>7. Liquid bottles are clean and free of spills.</li><li>8. The patient's own medications are stored securely and separately.</li></ol>

9. Disinfectants and drugs for external use are stored separately from internal and injectable medications.
10. 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, etc.).
16. Medication room door/cart is locked when unsupervised.

**Dispensing** shall be restricted to the pharmacist or pharmacy technicians under the direction and supervision of the pharmacist.

1. An automatic **Stop-Order** Procedure shall be developed for antibiotics, narcotics and other classes of drugs for which a limited duration of therapy is desirable. There shall be a system in place to notify the physician of the impending expiration of the duration of prescribed medication to ensure appropriate patient reassessment.
2. **Stat Orders** shall be processed and dispensed according to specific written procedures in accordance with hospital policy.
3. **Multi-Dose Vials** are dated upon first puncture; their maximum use should be defined.
4. The pharmacist may **Substitute Therapeutically Equivalent Products** without consulting the prescriber, provided the substitution has been approved by the hospital/clinic authorities (i.e. therapeutic interchange, equivalent oral dosage form substitution, dosage interval substitution, etc.). In most of the cases, it is the generic substitute.
5. **A Prescription Drug Order** must be **communicated directly to a pharmacist/pharmacy technician**, or when recorded, in such a way that the pharmacist may review the prescription drug order as transmitted. If transmitted orally or electronically, the prescription drug order shall be filed and maintained on paper of permanent quality by the pharmacist.

#### **Monitoring of Expiry Dates**

The pharmacy department is responsible for conducting physical examinations of all medication/dental materials 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 section 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 products shall be pulled from the shelves and held in a segregated area clearly marked for disposal.

### **Labeling and Packing Rules**

The Government of Pakistan Drugs (Labeling and Packing) Rules of 1986 govern the manner of labeling of pharmaceutical products and the hospital/clinic pharmacy shall ensure compliance of these labeling requirements and conformance to the terms and conditions of the contract agreement before acceptance of received supplies.

HCPs shall label all medications, medication containers (syringes, medicine cups, basins, etc.) or other solutions. This ensures safe medication practices and addresses a recognized risk point in the safe administration of medications in preoperative 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<sup>43</sup> for labeling all medications will minimize errors. If one or more medications are prepared but are not administered immediately, the medication syringe/vial will be labeled with drug strength, date and 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 labeled 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

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 and patient care units) where 'bedside/dental chair side' 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/Dental Chair Side Medication Labeling 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

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<sup>43</sup> Department of Pharmacy Policies and Procedures (2011). Medication Labeling. Retrieved from <http://pharmacy.uams.edu/PNP/PNP523.htm>

If, during the preoperative 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, labeling is not required.

**Authorization to Administer the Drugs/Medications/Dental Materials**

Administering a medication to treat a patient requires specific knowledge and experience. Each dental clinic/surgery/hospital is responsible for identifying individuals with the requisite knowledge and experience who are also permitted by licensure, certification, laws or regulations to administer medications (PM&DC Ordinance 1962, Allopathic System (Prevention of Misuse) Ordinance No. Lxv of, 1962, PM&DC Amendment Act 2012, PNC Ordinance, Pharmacy Council Act, the Khyber Pakhtunkhwa Faculty of Paramedical and Allied Health Sciences (FPAHS) Act, 2016, 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 5. Specimen list of professionals Authorized to administer the drugs/medications*

Sr. No.	Particulars of Professionals	Authorization PM&DC/PNC/PMF, etc.	Validity Date
1.			
2.			
3.			
4.			
5.			

Signature of the Administrator of the Dental Clinic \_\_\_\_\_  
 Date \_\_\_\_\_

## Assessment Scoring Matrix

**Standard 17. MOM-2: Storage and dispensing/usage conforms to the guidelines**

Indicator 46 - 49		Max Score	Weightage (Percentage)	Score Obtained
Ind 46.	Medicines/disposables/dental materials are stored as per guidelines	10	80%	
Ind 47.	Expiry dates/shelf life are checked prior to administering, as applicable	10	100%	
Ind 48.	Labeling requirements are implemented	10	100%	
Ind 49.	Dispensing/utilization is by an authorized person	10	100%	
<b>Total</b>		40		

## 2.9 Patient Rights/Responsibilities and Education (PRE)

### **04 Standards & 06 Indicators**

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The dental clinic/surgery 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 clinic. 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/complaints.

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## Standard 18. PRE-1: There is a system for awareness/education of patients and others regarding the Charter of Rights and Responsibilities for compliance

### Indicators (50):

#### Ind 50. The Charter of Rights and Responsibilities are displayed

#### Survey Process:

The surveyor is required to see that KP HCC Charter of Rights and Responsibilities for Patients, Carers and Others, is displayed at a prominent place in the clinic, like the waiting area or main entrance, for awareness. Also, check that clinic staff is well aware of the charters for compliance at their end and provide guidance on above aspects as and when required.

Patient and others are expected to observe the social norms by waiting for their turn, avoid conflict situations, following the instructions of the dental surgeon regarding re-visit date and time, etc.

#### Compliance Requirements:

- ✓ KP HCC Charters of Rights and Responsibilities for Patients and HCEs are displayed at a prominent place in the clinic, like the waiting area or main entrance for awareness
- ✓ Clinic staff is well aware of the charters, compliance at their end and provide guidance on the above aspects as and when required

*Note: Patients and others are expected to observe the social norms by waiting for their turn, avoid conflicting situations, following the instructions of the dental surgeon regarding re-visit date and time, etc.*

#### Scoring:

- If the Charters are displayed as required above, then score as **fully met.**
- If the Charters are available but not displayed as required above, then score as **partially met.**
- If the Charters are not available as required above, then score as **not met.**

### GUIDELINES

In the healthcare delivery system, rights of patients and service providers are equally important. The KP HCC Act, 2015, also recognizes the rights and responsibilities of both patients and healthcare service providers. The charters of rights and responsibilities of the patients and families and HCEs are to be displayed at a prominent place in the clinic, like the waiting area or the main entrance. Patients and their families should follow social norms while waiting for their turn, avoid conflicts and follow the instructions of the doctor regarding the date and time of re-visit. Guidance is routinely provided to the patients and families on above aspects. The KP HCC charters are attached as **Annexure F.**



## Assessment Scoring Matrix

**Standard 18. PRE-1: There is a system for awareness/education of patients and others regarding the Charter of Rights and Responsibilities for compliance**

Indicator 50		Max Score	Weightage (Percentage)	Score Obtained
Ind 50.	The Charter of Rights and Responsibilities are displayed	10	80%	
<b>Total</b>		10		

## Standard 19. PRE-2: There is a system for obtaining consent for treatment

### Indicators (51-52):

#### Ind 51. The dental surgeon obtains consent from a patient before examination<sup>44</sup>

##### Survey Process:

Dental surgeons are required to politely seek permission from the patient/parents/attendants before dental examination. This should include the need/role of a chaperon if so required.<sup>45</sup> The 'verbal consent' so 'obtained' is required to be endorsed in the documentation/prescription at the minimum as 'VCO.' To validate the 'VCO', the surveyors are required to review the register/copy of prescription.

##### Compliance Requirements:

- ✓ Documentary evidence that the 'verbal consent obtained' is endorsed in the documentation/prescription at the minimum as 'VCO'

##### Scoring:

- If there is evidence of VCO, then score as **fully met.**
- If there is evidence of VCO in up to 80% of cases, then score as **partially met.**
- If there is no evidence of VCO as above, then score as **not met.**

#### Ind 52. The clinic has listed those situations where specific informed consent<sup>46</sup> is required from a patient or family<sup>47</sup>

##### Survey Process:

Review the listed conditions requiring informed consent. Then review records of patients from whom specific informed consent should have been taken. The informed consent includes providing information in a language and detail that patient/attendant can understand<sup>48</sup> on risks, benefits, and alternatives and as to who will provide the treatment or perform the procedure/investigation/test. Informed consent is also required for taking photographs or making movies during the procedures either for record keeping/preservation of identity or educational/research purposes, as it can

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<sup>44</sup> This is to maintain the privacy, respect, dignity and honor of the patients while examining intimately and providing care and to comply with the Patients Charters and the Code of Ethics.

<sup>45</sup> 'Intimate examinations and chaperones (2013)' GMC Good Medical Practices.

<sup>46</sup> This is important for informed decision making as well as patient & care provider's safety. See consent form in the Guidelines.

<sup>47</sup> Family consent is required if the patient is not capable to give consent or is a minor. Family means; immediate relatives—mother, father, brother & sister, son & daughter, wife & husband.

<sup>48</sup> Further explained in the Guidelines.

compromise the individual's religious/social/cultural beliefs.<sup>49</sup>

### Compliance Requirements:

- ✓ Procedures/conditions requiring informed consent listed
- ✓ Specific informed consent taken as per list
- ✓ The format of specific informed consent is available in local language
- ✓ Informed consent is also required for taking photographs or making movies during the procedures either for record keeping/preservation of identity or educational/research purposes as it can compromise the individual's religious/social/cultural beliefs

### Scoring:

- If relevant records document an informed consent accordingly, then score as **fully met**.
- If relevant records do not document consent as above, then score as **not met**.

## GUIDELINES

### Scope of Informed Consent

Although the client's/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 surgical intervention and the patient has the right to refuse or to halt the 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 as follows:

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 previously 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.

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<sup>49</sup> Refer to KP HCC Patient Charter.

7. The informed consent of the patient is needed for participation in clinical teaching.
8. The informed consent of the patient is a prerequisite for participation in scientific research. All protocols must be submitted to a proper ethical review committee. Such research should not be carried out on those who are unable to express their will, unless the consent of a legal representative has been obtained and the research would likely be in the interest of the patient.

As an exception to the requirement of involvement being in the interest of the patient, an incapacitated person may be involved in observational research which is not of direct benefit to his or her health provided that, that person offers no objection, that the risk and burden is minimal, that the research is of significant value and that no alternative methods and other research subjects are available.

### **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 himself/herself or, one by of the doctors from his team, after properly introducing himself/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.

### **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 healthcare service provider should check to ensure that the 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 of taking the consent 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,

efforts should be made to ensure that proper interpretation is done.

The informed consent process is in conformity to the statutory norms including:

1. Taking consent before the procedure.
2. At least one independent witness signing the form.
3. Taking a fresh consent (for the new procedure) in case the procedure has to be changed during course of treatment/procedure.
4. 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.
5. 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/relative.

<b>Patient's Informed Consent Treatment or Investigation</b>	
Treating Consultant fills for specified conditions	Patient's Name:
	CNIC:
Name of HCE:	S/O, D/O, W/O:
Patient's Reg. #:	Age: <span style="float: right;">Gender:</span>
Address:	Diagnosis:
<b>Declaration of Doctor/Proceduralist (to be completed by the clinician obtaining consent)</b>	
Tick the boxes or cross out and initial any changes or information not appropriate to the stated procedure	
<input type="checkbox"/>	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) 1. _____ 2. _____
<input type="checkbox"/>	I have recommended the treatment/procedures/investigations noted below on this form.
<input type="checkbox"/>	I have explained the treatment/procedures/investigations, identified below, with benefits/risks.
<input type="checkbox"/>	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.
<input type="checkbox"/>	An identifiable copy of the information about the procedure to the patient provided with copy in the medical record (MR).
<b>Treatment/Procedure/Investigation</b>	
List the treatment/procedures/investigations to be performed, noting correct side/correct site	
This procedure requires: 1) General or Regional Anesthesia      2) Local Anesthesia      3) Sedation Specific risks to this patient explained by the anesthetist at least 12 hours before procedure are: 1. _____	

2. \_\_\_\_\_

**Patient's Informed Consent Treatment or Investigation**

Full name: _____	Full name: _____
Position/Title: _____	Position/Title: _____
Signature: _____	Signature: _____
PM&DC Reg#: _____	PM&DC Reg#: _____
Date: _____	Date: _____

Patient's Declaration (Patient required to read carefully, discuss with the doctor if there are any concerns and tick the understood and agreed points)

1. The doctor/proceduralist has explained my medical condition and prognosis as well as explained the relevant diagnostic and 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 which are specific to me and the likely outcomes. I have had an opportunity to clarify my concerns with the doctor/specialist.
  3. I understand that the result/outcome of the treatment/procedure cannot be guaranteed.
  4. 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 HCE.
  5. 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.
  6. 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 given the results of the tests of the taken sample.
  7. 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, etc.
  8. I understand that if immediate life-threatening events happen during the procedure, I will be treated accordingly.
  9. I understand that I have the right to change my mind at any time before the procedure is undertaken, including even after signing this form. I understand that I must inform my doctor if this occurs.
  10. I consent to undergo the procedure/s or treatment/s as documented on this form.
  11. I understand that conditions requiring blood transfusions are not treated in clinics and require a proper hospital setup, as required under other laws requiring a separate consent.
- ( ) Yes ( ) No

Patient's Full Name: _____	<b>Pre-Procedural Confirmation of Consent:</b> I Certify that I have reconfirmed the validity of the above details to the patient in a language he/she understands:  Signature and Stamp of the Practitioner: CNIC: _____
Patient's Signature: _____	
Date/Time: _____	
Parent/Guardian Signature: _____	
CNIC: _____	

## Assessment Scoring Matrix

**Standard 19. PRE-2: There is a system for obtaining consent for treatment**

Indicator 51 - 52		Max Score	Weightage (Percentage)	Score Obtained
Ind 51.	The dental surgeon obtains consent from a patient before examination	10	80%	
Ind 52.	The clinic has listed those situations where specific informed consent is required from a patient or family	10	100%	
<b>Total</b>		20		

## Standard 20. PRE-3: Patients and families have a right to information about expected costs

### Indicators (53):

**Ind 53. The patient/family is informed about the cost of treatment and fee list is displayed**

#### Survey Process:

Customarily, the fee is displayed and patients are informed about the fee, the charges for procedure, etc. by the dentist personally, or by the staff at the reception desk (as applicable).

#### Compliance Requirements:

- ✓ The fee is displayed
- ✓ Patients are informed about the fee and the charges for medicines/procedures at the reception desk (as applicable)
- ✓ Cost list is shown if requested

#### Scoring:

- If fee list is displayed, then score as **fully met**.
- If fee list is not displayed, then score as **not met**.

### GUIDELINES

#### Tariff List

Customarily, the **consultation fee is displayed** and patients are informed about the fee and the charges for medicines, etc., at the reception desk (as applicable). A detailed cost list is displayed. There should be a general tariff/billing system which defines the charges to be levied for the services provided by the clinic which may include the following:

1. Consultation fee
2. Cost of dental procedure/surgery
3. Cost of investigations if required and carried out onsite
4. Cost of medicines to be dispensed or to be purchased if prescribed (as applicable)
5. Costs of dentures, bridges, caps and implants, braces, etc., to be provided by the clinic as indicated

The above-mentioned service charges should be a part of the tariff/billing system and must be available in a file maintained at the clinic. Sometimes, the consultation fee for the first visit and for subsequent visits (for new and old patients) may be different. It will be the duty of the receptionist, technician or doctor to inform the patient of such tariff differences prior to the treatment. Patients/Families/Attendants should be given an estimate of the expenses, particularly in case of prolonged treatment. It is preferable that this information be given in writing. However, at minimum, tariff related to consultation fee (which is usually fixed) must be displayed at a prominent place, either at the reception or inside the consultation room.



## Assessment Scoring Matrix

Standard 20. PRE-3: Patients and families have a right to information about expected costs

Indicator 53		Max Score	Weightage (Percentage)	Score Obtained
Ind 53.	The patient/family is informed about the cost of treatment and fee list is displayed	10	100%	
Total		10		

## Standard 21. PRE-4: Patients and families have a right to refuse treatment and lodge a complaint

### Indicators (54-55):

#### Ind 54. Patients and families have a right to refuse the treatment

##### Survey Process:

Patient and families are expected to respect the instructions/medication orders prescribed by the dental surgeon, but they have a right to refuse the treatment<sup>50</sup> and seek advice from any other dentist of their choice<sup>51</sup> as provided in the PM&DC Code of Ethics and the KP HCC Charters. This necessitates specifically displaying the right of refusal. In cases where patients refuse advice, procedures or treatment, it has to be recorded in the patient's record.

##### Compliance Requirements:

- ✓ The right of refusal for treatment by the patient is displayed in KP HCC Charter for Patients
- ✓ The record of patient's refusal (if applicable) is available

##### Scoring:

- Unless the surveyors have a reason to believe that the above provision of the Charters are not being complied with, the score should default to **fully met**.

#### Ind 55. Patients and families have a right to complain and there is a mechanism to address the grievances

##### Survey Process:

Patients and families have a right to complain and put forward their grievances/concerns. There is a mechanism to handle the complaints effectively. The complaints can be lodged on the spot on occurrence, with some delay, verbally, in writing or by any other means. A complaint box or a complaint register, display of KP HCC helpline/web address and/or availability of a complaint form and file record are evidence of the system being in place.

##### Compliance Requirements:

- ✓ Functional Complaint Management System, evidenced by the following:
  - A complaint register/box
  - Display of KP HCC helpline/web address
  - Availability of complaint form

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<sup>50</sup> Provisions 12. ©, PM&DC Code of Ethics of Practice for Medical and Dental Practitioners allows refusal to treat a patient.

<sup>51</sup> Provisions 12. (b) and 13., PM&DC Code of Ethics of Practice for Medical and Dental Practitioners allows independent additional opinions.

- File record

**Scoring:**

- If there is a display which facilitates/guides the patients about their right of complaint and the system is being followed as above (including zero report recording in the register), then score as **fully met**.
- If there is no display to facilitate/guide the patients about their right of complaint and/or the system described above is not being followed, then score as **not met**.

**GUIDELINES**

**Right to Refuse Treatment**

While patients and families are expected to respect the instructions/medicines prescribed by the doctor, they have a right to refuse treatment and seek advice from any other doctor of their choice. The clinic manager must ensure that all such related information, regarding the rights and responsibilities of patients and others and the rights and responsibilities of HCEs, is displayed (KP HCC charters).

**Complaint Management:**

Patients and families have a right to complain and put forward their grievances/concerns and there should be a mechanism to handle these complaints effectively. Complaints can be lodged either on-the-spot as they occur or with some delay, verbally or in writing.

The records of all complaints/grievances addressed must be placed in a file maintained at the clinic. In a single-man clinic, the doctor is required to ensure that such a complaints management mechanism is in place. He/she should do his best to address the complaints to the satisfaction of the patients.

**Right to Express Concern or Complain:**

An institutionalized, accessible and transparent grievance-redress mechanism (complaint management) must be in place at the HCE. Information on how to lodge a complaint must be clearly displayed in the local language at prominent places. A complaint is an expression of client dissatisfaction and a means of providing feedback on the quality of care received, and should be urgently addressed. Every healthcare facility should inform its clients/patients about their right to complain and the complaint handling procedures in place. A complaint may be written or verbal and be lodged by a patient, his/her attendants or a legally authorized person. Various means may be adopted to communicate this. For instance, the healthcare facility may:

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., recommended as under:

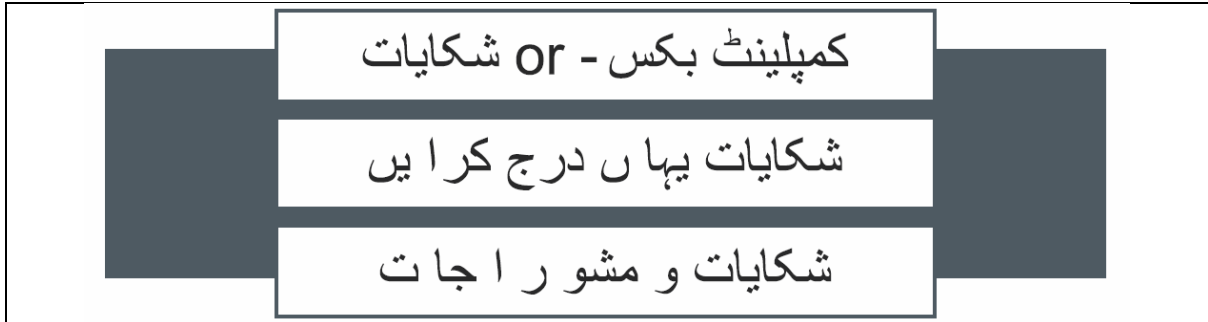


Figure 2. Complaints and Suggestions Box Signage

2. Communicate pertinent information in the form of leaflets/brochures placed at appropriate places.
3. Obtain client feedback/comments on a prescribed, but simple, format during the visit (a sample format is attached at **Annexure G**).

**Complaint Management Procedure:**

To become a quality-driven service providing establishment, the facility should encourage clients and their family members to freely raise and discuss their views, concerns or complaints with the concerned staff. This dialogue serves as an opportunity for improvement. Every clinic must have a documented, grievance redressing procedure. A proposed format for the complaint management procedure is attached as **Annexure H**.

**Feedback mechanisms** should be culturally appropriate, feasible and may include:

1. A suggestion/complaint box at the facility that may be used by the literate clients.
2. Periodic client exit interviews.
3. Key informant interviews within the community.

Depending upon their needs and resources, the clinic management should devise methods, and determine frequencies, of feedback mechanisms in order to seek clients' views on the quality of care.

## Assessment Scoring Matrix

**Standard 21. PRE-4: Patients and families have a right to refuse treatment and lodge a complaint**

Indicator 54 - 55		Max Score	Weightage (Percentage)	Score Obtained
Ind 54.	Patients and families have a right to refuse the treatment	10	<b>100%</b>	
Ind 55.	Patients and families have a right to complain and there is a mechanism to address the grievances	10	<b>100%</b>	
<b>Total</b>		20		

## 2.10 Infection Control (IC)

### **02 Standards & 07 Indicators**

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Prevention of healthcare associated infections (HAIs) represents one of the major safety initiatives a dental clinic is required to undertake. The standards related to the infection control provide the framework for dental surgeries 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 all members of the clinic, including support staff, to participate in the design and implementation of an effective infection control program.

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## Standard 22. IC-1: The clinic has a well-designed, comprehensive and coordinated infection control system aimed at reducing/ eliminating risks to patients, visitors and care providers

### Indicators (56-59):

**Ind 56. The infection control plan is documented which aims at preventing and reducing the risk of nosocomial infections**

#### Survey Process:

There should be a written infection control plan (IC plan) which should identify at least: i. the surveillance activities, ii. hand hygiene procedures, and iii. the responsibilities and authorities of an infection control team/person, preferably headed by the dental surgeon himself/herself. Check the written IC plan to verify that it includes instructions/SOPs on infection control and clinical waste management, covering at least the following aspects

1. Maintaining general cleanliness/hygiene in the clinic premises
2. Facility of hand washing before and after examination/procedure<sup>52</sup> with soap and water/an effective disinfectant
3. Arrangement for controlling/preventing/reducing the risk of cross infections during the process of patient assessment/procedures<sup>53</sup>
4. Use of disposable gloves, masks, etc., by the dental surgeon while examining the patient and during all dental procedures
5. Abiding by infection control measures by the person assisting the dental surgeon
6. Safe handling/disposal of contaminated waste and sharps<sup>54</sup> including segregation at source, collection and safe storage for appropriate disposal

#### Compliance Requirements:

- ✓ Availability of a documented IC plan covering the following:
  - SOPs for infection control
  - Arrangements for infection control practices

#### Scoring:

- If there is a documented IC plan that includes at least surveillance activities, hand hygiene procedures, disposal of waste and the responsibilities and authorities of an infection control team/person, 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**.

<sup>52</sup> All instruments, etc., required/used for procedures should either be disposable or properly sterilized.

<sup>53</sup> Listed/explained in the Guidelines.

<sup>54</sup> In line with the Khyber Pakhtunkhwa Hospital Waste Management Rules, 2018, as amended from time.

## Ind 57. The clinic has designated staff and defined responsibilities for infection control and waste management activities

### Survey Process:

Review the documentation regarding designation/appointment and assigned responsibilities (JDs) in that the staff is assigned the role/s in writing to implement the IC plan and clinical waste management, as stipulated in the relevant statutes updated from time to time.

### Compliance Requirements:

- ✓ Staff designated and responsibilities assigned in respect of infection control activities, including medical waste management as per KP HWM Rules, 2018 (as amended from time to time) are defined
- ✓ JDs of the nurse/technician/dental surgeon on infection control are available and match the requirements of the IC plan and KP HWM Roles, 2018

### Scoring:

- If the qualification/credentials of the designated staff match the requirements in the job description, and their number is adequate to manage the workload, then score as **fully met.**
- If the credentials of the designated staff do not match the requirements in the job description, and/or their number is not adequate to manage the workload, then scored as **not met.**

## Ind 58. The clinic 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 i. hand washing soap/liquid, ii. gloves, iii. masks, iv. single use syringes, syringe cutters, reamers and grinding tips, etc., v. sharps collection containers, and vi. a full system<sup>55</sup> of clinical waste management from the point of generation to the point of destruction, including a clinical waste management plan and waste management team, adequate cleaning equipment, consumables and the staff are trained to use it effectively.

### Compliance Requirements:

- ✓ The following facilities are available:
  - Hand washing soap/liquid
  - Gloves
  - Masks
  - Single use syringes as required and syringe cutters
  - Containers for hospital waste (for infectious, non-infectious and sharps)
- ✓ Clinical waste management plan

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<sup>55</sup> As per Khyber Pakhtunkhwa Hospital Waste Management (KP HWM) Rules, 2018, as amended from time to time.



- ✓ Evidence of waste management for consumables including the following components in practice:
  - Segregation
  - Collection
  - Disposal
- ✓ Staff is trained on cleaning and re-use of non-consumables
- ✓ Availability of safety equipment/consumables
- ✓ Evidence of sterilization practices for non-consumables

#### Scoring:

- If there is a full system of clinical infection control, including all the above-mentioned elements from i-vi, to serve all care and treatment areas, then score as **fully met.**
- If any one of the elements in the clinical infection control from i-vi is not complied with, then score as **not met.**

**Ind 59. ALL staff involved in the creation, handling and disposal of dental/clinical waste receive regular training and ongoing education in the infection control and safe handling of dental waste**

#### Survey Process:

Identify the staff that conduct training in infection control, including the clinical waste management and review the training material. Speak with staff<sup>56</sup> involved in infection control and the generation, handling and management of medical waste to determine their level of training and applied knowledge. The training system employed by the clinic should encompass all the infection control activities, including clinical waste management system, covering full process on site as per clinic's local policy based on KP HWM Rules, 2018 (as amended from time to time) and what happens once the waste leaves the site. Adequate training on the systems, facilities and safety equipment/consumables should be observable.

#### Compliance Requirements:

- ✓ Evidence of following available:
  - Training of staff on infection control including clinical waste management
  - The training material/training should cover all the infection control activities including waste management system, full process on site and what happens once the waste leaves the site
  - Applied knowledge of staff on infection control and the generation, handling and management of medical waste

#### Scoring:

- If there is evidence of training of the staff on infection control including clinical waste management system at induction and when new systems are introduced, or when new components, consumables or equipment related to infection control and clinical waste are employed, then score as **fully met.**

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<sup>56</sup> Staff means permanent, temporary or short term employees of the HCEs / any third party.

- 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

### **Documented Infection Control (IC) Program**

It is required that the dental clinics must have a documented IC program which aims at preventing and reducing the risk of nosocomial infections. National<sup>73</sup>and international guidelines, scientific knowledge, professional bodies and statutory requirements shall be considered for developing an IC program. CDC and WHO guidelines should be used as reference documents. Each dental clinic must:

1. Develop an IC program (or use the national guidelines) to ensure the wellbeing of both patients and staff.
2. Provide sufficient resources to support the IC program.
3. Ensure that risk prevention for patients and staff is a concern of everyone in the facility, and must be supported by the senior administration.

### **Salient Components of the Infection Control Program:**

1. Basic measures for IC, i.e. standard and additional precautions.
2. Education and training of healthcare workers.
3. Protection of healthcare workers, e.g. immunization, post exposure prophylaxis.
4. Identification of hazards and minimizing risks.
5. Routine practices essential to IC such as aseptic techniques, use of single use devices, reprocessing of instruments and equipment, antibiotic usage, sound management of medical waste.
6. Effective work practices and procedures, such as environmental management practices including management of clinical waste, support services, use of therapeutic devices.
7. Incidence monitoring.
8. Outbreak investigation.
9. Surveillance.
10. IC in specific situations.
11. Research.

Of these, the first 8 are absolutely essential regardless of the size of the facility or resources since they directly determine the quality and nature of the care that is provided. In addition to implementing basic measures for infection control, healthcare facilities should prioritize their IC needs to match the portrayed services and design their programs accordingly.

For sustained effectiveness, the IC program will have to be comprehensive, include surveillance and prevention activities and staff training. It must also be able to draw upon effective support at national and regional levels.

### **Organization of an Infection Control Program**

The primary responsibility lies with the dental surgeon who should:

1. Designate an IC team.
2. Provide adequate resources for effective functioning of the IC program.

3. An IC team (or an officer in smaller facilities) with dedicated and protected time which can enforce rules and attend to daily needs of the program in real time.

### **Implementation**

The dental clinic/surgery must ensure that a valid surveillance system, with specific objectives for IC and WM, is in place and functioning.

### **Organization or Efficient Surveillance**

Nosocomial infection surveillance includes data collection, analysis and interpretation, feedback leading to interventions for preventive action and evaluation of the impact of these interventions. The Infection Control Officer (ICO)/physician and/or nurse from the IC team must be a trained professional, specifically responsible for surveillance, including training of personnel for data collection.

A written protocol must describe the methods to be used, the data to be collected (e.g. patient inclusion criteria, definitions), the analysis that can be expected, and preparation and timing of reports.

The optimal method is dependent on characteristics of the clinic, the desired objectives, resources available (computers, investigators, etc.) and the level of support of the hospital staff (both administrative and clinical). The surveillance system must report to clinic's administration, usually through the IC team, and must have a dedicated resources to support its operation.

### **Priority Infections and their Definitions**

Surveillance of infectious conditions requires strict definitions. In many cases, there are no universally agreed definitions. Therefore, the infection rate will vary with the definition used. For this reason, comparisons can be made between units or institutions only if the same set of definitions is used and applied in exactly the same way. It is often more meaningful and more useful to use surveillance data from a single institution to measure trends over time, either to alert staff to increasing problems or to monitor the effectiveness of interventions.

### **Surveillance Methods:**

Simply counting infected patients (numerator) provides only limited information which may be difficult to interpret. Further data is necessary to fully describe the problem on a population basis, to quantify its importance, to interpret variations, and to permit comparisons. Risk factor analysis requires information for both infected and non-infected patients. Infection rates, as well as risk-adjusted rates, can then be calculated. The clinic shall imply a combination of passive and active surveillance techniques to control nosocomial infection.

### **Outcome of Surveillance**

An effective surveillance system must identify priorities for preventive interventions and improvement in quality of care. By providing quality indicators, surveillance enables the IC program, in collaboration with patient care units, to improve practice, and to define and monitor new prevention policies. The ultimate aim of surveillance is to decrease nosocomial infections and reduce costs.

### **Evaluation of Surveillance**

Surveillance is a continuous process which needs to evaluate the impact of interventions to validate the prevention strategy, and determine if initial objectives are attained.

A surveillance system must be continuing if it is to be credible. Periodic contacts with staff will also help to maintain a high level of compliance. Once the surveillance system is functioning, validation of the surveillance methods and data should be undertaken at regular intervals.

Principal Points for Surveillance of Infections:

1. Valid quality indicators (risk-adjusted rates, etc.)
2. Effective, timely feedback (rapid and useful)
3. Appropriate implementation of interventions
4. Evaluation of the impact of interventions by continued surveillance (trends) and other studies

### **Infection Control Practices**

IC practices can be grouped in two categories:

Standard Precautions, that must be applied to all patients at all times, regardless of diagnosis or infectious status and 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/barriers techniques
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

Specific antiseptics recommended for hand antisepsis:

1. 2%-4% chlorhexidine
2. 5%-7.5% povidone iodine
3. 1% triclosan
4. 70% alcoholic hand rubs
5. Waterless, alcohol-based hand rubs: with antiseptic and emollient gel and alcohol swabs, which can be applied to clean hands.

### **Facilities for Drying Hands**

1. Disposable towels, reusable single use towels or roller towels, which are suitably maintained, should be available.
2. If there is no clean dry towel, it is best to air-dry hands.
3. Equipment and products are not equally accessible to all dental clinics. Flexibility in products and procedures, and sensitivity to local needs will improve compliance.
4. In all cases, the best possible procedure should be instituted.

### **Personal Protective Equipment**

1. 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.
2. Using PPE provides a physical barrier between micro-organisms and the wearer and offers protection by helping to prevent micro-organisms from:
  - i. Contaminating hands, eyes, clothing, hair and shoes
  - ii. Being transmitted to other patients and staff

### **Personal Protective Equipment includes**

1. Gloves
2. Protective eye wear (goggles)
3. Masks
4. Aprons
5. Gowns
6. Boots/shoe covers
7. Caps/Hair covers

### **Personal Protective Equipment should be used by**

1. 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.
2. Support staff including medical aides, cleaners, and laundry staff in situations where they may have contact with blood, body fluids, secretions and excretions.
3. Laboratory staff, who handle patient specimens.
4. Family members who provide care to patients and are in a situation where they may have contact with blood, body fluids, secretions and excretions.

### **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.

### **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 re-cap or bend needles. Sharps must be appropriately disinfected and/or destroyed as per the guidelines provided in the KP HWM Rules 2019.

### **Cleaning of the Dental Surgery Environment**

Routine cleaning is important to ensure a clean and dust-free environment. There are usually many micro-organisms present in 'visible dirt,' and routine cleaning helps to eliminate these. Administrative and office areas with no patient contact require normal domestic cleaning. 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.

### **Management of Healthcare Waste**

Uncollected, long stored waste or waste routing within the premises must be avoided. A sound waste management system needs to be developed and closely monitored.

### **Additional Precautions (transmission- based)**

Additional (transmission-based) precautions are taken while ensuring that standard precautions are maintained. Additional precautions include:

1. Airborne precautions
2. Droplet precautions
3. Contact precautions

**Mechanical Ventilation** - 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 either by confining the affected patient in a separate room or by rapidly removing the internal air by forced mechanical ventilation.

### **Prevention of Infection Spread by Direct Contact**

Infection is transmitted by direct contact when the infected blood or saliva of one person comes in contact with another person's exposed skin or mucous membrane. Direct contact is important because the skin of the dentist's hand is often not intact due to the presence of small cuts and abrasions.

### **Prevention of Infection Spread by Indirect Contact**

Indirect contact involves microbial spread through contaminated instruments, operatory equipment, or environmental surfaces that are touched by many individuals and the HCPs during the delivery of care, e.g., patient charts, radiographs, handles, switches, doorknobs, etc.

### **Prevention of Infection Spread by Contact with Airborne Microorganisms**

Coughing, sneezing or talking may also cause droplet formation. Saliva or blood may also splash or spatter out of the oral cavity during procedures. Microorganisms suspended in air may be inhaled into the lungs. They may also come in contact with the oral or nasal mucosa or the eye conjunctiva.

### **Standard Precautions, Universal Precautions**

Precautions taken to prevent cross infection are called standard precautions or universal precautions. These precautions must be taken for all patients. It is difficult to identify high-risk patients, and many patients hide information about infectious diseases. Standard precautions apply to all patients in health care settings, regardless of their diagnosis or presumed infection status. These are devised to reduce the risk of transmission of microorganisms from both recognized and unrecognized sources of infection.

Standard precautions are used when coming in contact with blood, body fluids, secretions (except sweat), non-intact skin and mucous membranes. In all dental work, contact with saliva is expected. The saliva frequently contains the patient's blood. Standard precautions need to be used for all patient contact.

### **Personal Protective Equipment**

Personal protective equipment is equipment used for the protection of the dentist and assistant. This equipment includes:

1. Mask
2. Protective eyewear
3. Gloves
4. Appropriate clothes

### **Masks**

Disposable masks should be worn for all patient contact and when using rotary instruments in the dental laboratory. Masks protect the mucous membranes of the mouth and nose from contact with airborne microorganisms present in aerosols, splash/spatter, etc. Masks also prevent inhalation of microorganisms into the lungs. Masks protect the patient from respiratory infections that the dentist or assistant may have. Ideally, a new mask should be worn for every patient. Masks should be changed if they become wet. Passage of air is restricted when masks become wet, and contaminated air from the sides of the mask may be inhaled.

Face shields and masks with face shields are available. These are useful in management of high-risk patients and where there is increased risk of aerosol/splash/spatter.

### **Protective Eyewear**

Eyes must be protected in all procedures that have the possibility of aerosol generation, splash and spatter. Protective eyewear should be worn by the dentist, assistant and the patient.

Prescription eyeglasses provide partial protection, but there is no side protection, and thus the risk of exposure to aerosols and splash. Therefore, use of protective eyewear with side protection is recommended. Protective eye goggles provide the best eye protection and may be worn over prescription eyeglasses.

Eyewear should also be used when using masks with face shields.

All protective eyewear should be cleaned and disinfected or autoclaved between patients. Manufacturer's recommendations for disinfection/sterilization should be followed.

### **Gloves**

Gloves have small pores and may have microscopic tears. Therefore, hand washing is essential before wearing gloves and after removing gloves.

1. Gloves should be changed immediately if they are torn or punctured.
2. Gloves once used on patients are contaminated and should be disposed accordingly.
3. Once washed up and the gloves are on, the doctor or assistant should not touch any item/surface other than the sterile instruments to be used on the patient as the other surfaces are bound to be harboring microorganisms which can be harmful.

### **Over-gloving Using Plastic Gloves over Latex Gloves**

Over-gloving is useful during procedures when the operator needs to touch non-sterile items like the curing light, x-ray films and radiology equipment during a procedure. The over-glove is a larger sized glove, usually of plastic and should be discarded before returning to the procedure.

### **Appropriate Clothing**

The dental staff should wear protective clothing in the clinics which should be removed before leaving the clinic. The clothes become potentially contaminated in dental procedures and can lead to indirect transfer of infection. Children and other family members at home are at risk of acquiring infections from these clothes.

Clothes worn in dental clinics should be washed separately from other household clothes. Protective clothing should ideally be made from material impervious to moisture. Pure cotton clothes contain pores, and are thus not suitable.

The clothes should be changed as soon as possible if they become wet.

The clothes should cover the chest of the dentist, all the way up to the neck and cover the arms of the dentist down to the wrists. Elastic bands in the wrist area should be used. White overalls available in the market are thus not suitable for dentistry.

Disposable gowns and disposable plastic aprons are available. Aprons should be worn by the cleaning staff, and may be worn in procedures with the risk of splash/aerosol, especially when treating high risk patients.

### **Environmental Infection Control**

Environmental surfaces are those surfaces or equipment that the patient does not contact directly. These surfaces may be contaminated with microorganisms if touched by the dentist or assistant during a procedure. When these surfaces are contacted again with instruments or hands, the microorganisms spread.

### **Environmental Barriers**

The surfaces may be covered by barriers before procedures. The barriers should be discarded after the procedure.

Barriers include clear plastic wrap, cling film, bags, sheets, tubing, plastic-backed paper, aluminium foil, or other materials resistant to moisture. Pieces of aluminum foil may be wrapped in pouches or included in instrument packs before autoclaving. Sterile foil can then be used as barriers for sterile procedures like minor oral surgery or root canal treatment.

Wrapping of aluminum foil around light handles, handpiece tubing, and on switches is easier to use than many other barriers. After use, if the foil is not damaged or visibly contaminated, it may be cleaned, disinfected, and autoclaved once more for use before discard. If surfaces are not covered by barriers, the surfaces may be touched during the procedure using a barrier like cotton gauze or sterile paper, or plastic wrap. Once used, the gauze/paper/plastic should be discarded. Plastic/Cellophane over-gloves, worn over the latex gloves, can also be used to touch non-sterile surfaces during a procedure.

Cell phones harbor the microorganisms, therefore use of cell phones during a procedure must be avoided. Cell phones should be thoroughly cleaned just before leaving the clinic to avoid family members being infected.



### **Notification of Infection Control Team**

The management of every dental clinic/surgery must notify an IC team which may include:

1. Manager/Dental Surgeon/CEO
2. Any other dental surgeon working as partner or employee
3. Dental hygienist if available
4. Chair Side Assistants
5. Infection Control Nurse
6. In-charge CSSD/Sterilization
7. In-charge Maintenance
8. In-charge Sanitary Services
9. Bio-Medical/Civil Engineer

(The membership may vary from small to larger set ups and magnitude of work without affecting the required output)

### **Responsibilities of Infection Control Team**

1. Must meet regularly on daily basis
2. Enforce compliance with basic IC standards
3. Develop a yearly program of activity for surveillance and prevention
4. Ensure appropriate staff training in IC and safety management, provision of safety materials, such as PPE and products
5. Oversee training of dental assistants in IC

### **Notification of Infection Control Team**

An IC team will be put together with the 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.

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 in-charge.

These teams/individuals should be notified by the dental clinic/surgery and should have scientific and technical support/responsibilities, e.g., practical supervision, evaluation of material and products, overseeing sterilization and disinfection, ensuring the sound management of medical waste and the implementation of training programs.

### **Infection Control Nurse/Infection Control Technician**

The criteria for designating this shall either be the qualification or training or preferably, a combination of both. It is preferable for ICO/ICN to have undergone a short-term training program on IC nursing by a recognized institution or at the least, by the incharge doctor. The clinic in-charge leads the IC team for ensuring implementation of IC SOPs.

### **Responsibilities of ICO/ICN**

1. Develop/adapt and get IC Manual endorsed
2. Disseminate SOPs of IC based on the IC Manual
3. Coordinate and conduct training activities related to IC
4. Enforce minimum IC standards

5. Identifying and investigating nosocomial infections
6. Ensuring compliance with local and national regulations
7. Liaison with public health and with other facilities where appropriate
8. Report directly to the CEO or manager or in-charge (dental surgeon)

**Resources/Facilities for Infection Control**

The 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 6. 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 × Id
Disinfectants		
Number of locations that need disinfectants	S =	
Average amount (nos. or litres) of disinfectants used per location per day	Id =	
Number of locations that need disinfectants	Sd =	Sd = S × Id

**Some general considerations are given below:**

1. Gloves should be worn when handling spittoons of dental units. The contents should be disposed of directly into the sluice.
2. All clinical waste should be disposed of in a colour-coded bag for incineration.
3. 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. Needles and syringes should be disposable and placed in a hardened container which is sealed before disposal.
4. Linen from infected patients should be placed in a colour-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 a labeled bag.
5. Disposable items may be used when a dishwasher heating the items to over 80°C is not available.
6. Immunization against viral hepatitis and tetanus is recommended for all personnel handling waste and infectious material with hepatitis B vaccination/immunoglobulin if a clinic employee has not been vaccinated against hepatitis B.
7. Hepatitis B results show insufficient antibodies, hepatitis B immunoglobulin must be administered within 72 hours.

8. If sufficient antibodies are present, a Hep. B vaccination booster will only be required.
9. A Tetanus injection will be required if not received within the last 5-10 years.
10. HIV/Hepatitis C results must be collected (in person) within 7 days.
11. Follow-up blood tests (after 1st initial blood test)
  - Further blood tests will be required for
  - Hepatitis B                                    3 months after injury (titer levels)
  - Hepatitis C                                    3 months after injury, then 6 months
  - HIV                                                3 months after injury, then 6 months

### **Training in Safe Handling of Medical Waste**

1. Clinic managers should be oriented towards the importance of the IC program and be equipped with requisite knowledge, skills and attitudes for good IC practices. The IC team should:
  - i. Assess training needs of the staff and provide required training through awareness programs, in-service education and on-the-job training.
  - ii. Organize regular training programs for the staff for essential IC practices that are appropriate to their job description.
  - iii. Provide periodic re-training or orientation of staff.
  - iv. 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 (**Annexure I**):
  - i. Collection
  - ii. Segregation at source
  - iii. Storage
  - iv. Transportation
3. Hospital/Clinical waste in Khyber Pakhtunkhwa is regulated by the Khyber Pakhtunkhwa Hospital Waste Management Rules, 2018.
 

According to the rules, every clinic shall be responsible for the proper management of the waste, through developing a 'Clinical Waste Management Plan'. The plan will be facility specific, containing a list of activities and quantity of required materials. Development of the plan is the responsibility of The Waste Management Officer a designated member of the clinic's Waste Management Team (WMT).

The plan will be reviewed and finalized by the clinic WMT and should aim to:

  - i. Protect public health and safety
  - ii. Provide a safer working environment
  - iii. Minimize waste generation and environmental impacts of waste treatment/disposal
  - iv. Ensure compliance with legislative requirements

### **Disposal of Contaminated Waste Material**

Contaminated waste should be disposed in yellow biohazard bags. These bags should line the waste bins/baskets present in the clinic. Once filled, the yellow bags should be sealed and sent for incineration. A separate waste basket for household waste should also be present in the clinic next to the yellow contaminated waste bin/basket for collection and disposal of non-contaminated items.

**Contaminated waste items**

1. Gloves and gauze pieces or cotton rolls contaminated with large amounts of liquid or semi-liquid blood/saliva that could release such fluids if squeezed
2. Pathological waste (teeth and other body tissues)
3. Sharps (e.g., needles, scalpel blades, sutures and wires)
4. Potential sharps such as anesthetic cartridges which, if broken, could expose people to
5. aspirated patient body fluids
6. Sharp Items
7. Syringes
8. Needles
9. Local anesthetic cartridges
10. Scalpel blades
11. Sutures
12. Orthodontic wires
13. Endodontic files
14. Reamers or broaches

**Handling of Sharp Items and Needles**

There are numerous sharp items in dental surgeries that can cause needle stick injuries if not handled and disposed properly. These sharps include syringes, needles, local anesthetic cartridges, scalpel blades, sutures, orthodontic wires, endodontic files, reamers or broaches. Do not re-cap used needles using both hands. Use a one-handed scoop technique.

Sharp items should be disposed in a puncture proof sharps box, and not in the yellow bags. Or use a mechanical device designed for holding the needle cap when re-capping needles.

**Disposal of Sharp Items**

All these sharp items should be disposed in sharp containers that are impervious to puncture. These are commonly made of thick plastic and should be sent for incineration when 2/3rd full.

## Assessment Scoring Matrix

**Standard 22. IC-1: The clinic has a well-designed, comprehensive and coordinated infection control system aimed at reducing/eliminating risks to patients, visitors and care providers**

Indicator 56 - 59		Max Score	Weightage (Percentage)	Score Obtained
Ind 56.	The infection control plan is documented which aims at preventing and reducing the risk of nosocomial infections	10	<b>100%</b>	
Ind 57.	The clinic has designated staff and defined responsibilities for infection control and waste management activities	10	<b>100%</b>	
Ind 58.	The clinic has appropriate consumables, collection and handling systems, equipment and facilities for control of infection	10	<b>100%</b>	
Ind 59.	ALL staff involved in the creation, handling and disposal of dental/clinical waste receive regular training and ongoing education in the infection control and safe handling of dental waste	10	<b>100%</b>	
<b>Total</b>		40		

## Standard 23. IC-2: There are documented procedures for sterilization activities in the clinic

### Indicators (60-62):

#### Ind 60. There is adequate space available for sterilization activities

##### Survey Process:

The definition of 'adequate' includes enough space as specified by the manufacturer of the sterilizing equipment (or at least physical barriers) to ensure separation of 'clean' and 'dirty' areas. Cleaning and washing of the used instruments are not allowed inside the dental unit area/surgery. Separate rooms or physically separated areas in a larger room for cleaning, washing, drying and packing and for autoclaving and storing of autoclaved/sterilized packs should be available.

##### Compliance Requirements:

- ✓ Separate rooms or physically separated space as specified by the manufacturer of the sterilizing equipment/autoclave, to ensure that the 'clean' and 'dirty' areas do not mix

##### 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 if it is inadequate, then score as **not met.**

#### Ind 61. Regular validation tests for sterilization are carried out and documented

##### Survey Process:

This is an important patient safety issue. Review the procedure to validate that complete sterilization has occurred. This should be uniformly done on each batch that is sterilized. There are several methods, such as color change strips, that can be used. Whatever method is used, it must be effective and documented. Observe that the date of sterilization and expiry are clearly indicated on the packaging.

##### Compliance Requirements:

- ✓ Complete sterilization process is documented for each batch that is sterilized (can be confirmed by using color change strips, etc.)
- ✓ Date of sterilization and expiry are clearly indicated on the packaging

##### Scoring:

- If there is a procedure to verify that complete sterilization has occurred, it is used for ALL batches that are sterilized, it is documented and sterilization and validity dates are indicated, then score as **fully met.**

- If there is no procedure, or if it is rarely (once a day) used, or if it is not documented, or dates are not indicated, then score as **not met.**

## Ind 62. 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 in the 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.

### Compliance Requirements:

- ✓ Staff members are aware and trained on recall procedure
- ✓ Recall procedure, if employed in case of breakdown in the sterilization system, is documented

### Scoring:

- If a written recall procedure exists and staff is aware of it, then score as **fully met**
- If there is no written recall procedure, then score as **not met.**

## GUIDELINES

### Documented Layout and Processes

1. 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 the taken 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. The entire layout map is required to be documented and displayed.
2. Each dental clinic/surgery needs to develop a program for the implementation of good IC practices. The IC team, besides serving other functions, is also required to oversee the provision of sterile supplies to the dental surgeon.
3. Sterilization Workflow  
In the dental surgery, dirty re-usable instruments are collected and put into clearly labeled containers and shifted for sterilization. Cotton wool and dressings should be discarded as clinical waste for incineration. The dirty instruments are then received in the allocated dirty area. 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 sets for use in clinics and autoclaved and/or disinfected, as required. The packaged sets are then inspected to ensure that they are dry. The sterile packs should be stored in a well-ventilated room ready for use. There should be a written

record of sterilized material and its issue for use.

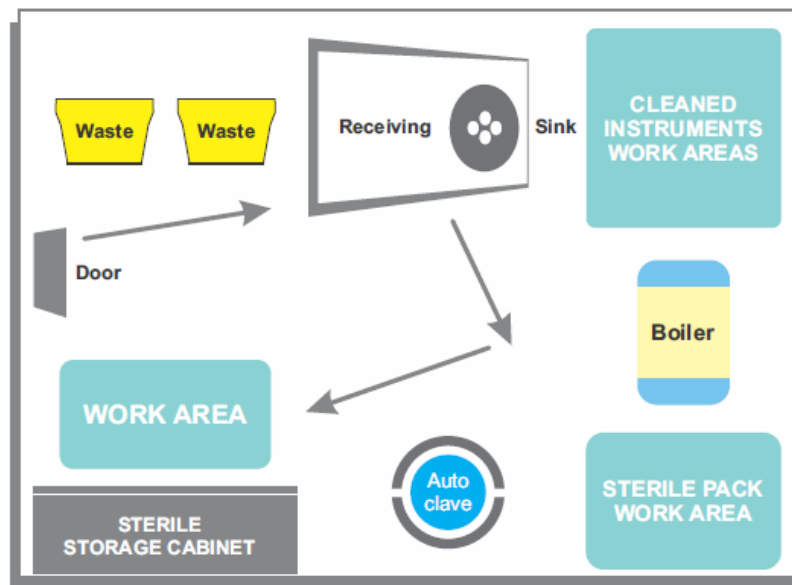


Figure 3. Sample of Sterilization Workflow

#### 4. Disinfection/Sterilization of Instruments

It is mandatory for the HSP 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, which can live on instruments. Liquid bleach, as well as isopropyl and ethyl alcohol, are extremely effective in disinfecting dental instruments.

##### SOPs for Disinfection

- i. Place your washbasins and supplies in a cleaning station or utility room. Decide which chemical you will use to disinfect the dental instruments - germicidal spray, liquid bleach or alcohol. These are all highly effective disinfectants and the medical community approves of them.
- ii. 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.
- iii. 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.
- iv. 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.
- v. 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 dental 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

- i. Remove debris and residue from the instruments by rinsing them under sterile water and using a toothbrush or other scrubbing tools.
- ii. 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's instructions.
- iii. Place the instruments in the container with the enzymatic detergent and sterile water formula, making sure that they are fully covered by the solution.
- iv. Soak the tools in the solution for 20 minutes to effectively sterilize the instruments before reuse.

#### **Breakdown Recall**

The dental clinic/surgery should develop and maintain a written recall procedure and the staff members should be trained on these procedures. The dental clinic/surgery 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 have been supplied. The packs called back should be sent for re-sterilization using a proper machine/technique.

The IC team shall ensure that institutional policies are consistent with provincial/national guidelines (if existing) and conduct IC audit periodically (e.g., at least monthly in areas where materials are reprocessed to ensure policy compliance). Breaches in policy should be documented and corrective action instituted.

#### **Sterilization**

Sterilization is a procedure that kills all life forms. Viruses, bacteria, fungi/mold and spores are all destroyed.

#### **Sterilization of Patient Care Items**

All reusable dental instruments and equipment should be sterilized before each use. This includes hand pieces, scalers, burs, extraction forceps, elevators endodontic files and reamers, matrix band, rubber dam frames and clasps, impression trays, sharpening stones, bite blocks and glass slabs.

A number of other items e.g., sheets of paper, cotton cloth, patient napkin, cotton gauze, cotton wool, paper cups, unused latex disposable gloves and aluminum foil may also be sterilized to aid in cross infection control.

### **Recommended Method of Heat Sterilization**

The recommended method of heat sterilization in dentistry is autoclaving. Autoclaves use steam under pressure to sterilize the items. The autoclaving process, including drying of instruments, takes up to one hour. This short cycle duration is suitable for dental practices. All the items mentioned above may be sterilized in the autoclave. All items should be cleaned and wrapped before autoclaving. Manufacturer's recommendations for sterilization should be followed wherever applicable.

The instrument processing area should have five distinct sections ensuring physical separation/barrier between clean and dirty areas:

1. Receiving
2. Decontamination and cleaning
3. Wrapping
4. Sterilization
5. Storage

### **Sterilization/Instrument Processing Area**

An area in the clinic should be designated for instrument processing. Tea-making or laboratory work should not be carried out in this area.

### **Monitoring of Sterilization**

The date of sterilization should be recorded on the package, along with the sterilization cycle number/code. If using wrapping material that does not have sterilization indicators, the packages should be sealed using autoclave tape. This tape has indicator strips that change color after sterilization. Packages should not be sealed with staples. The holes created by staples allow entry of microorganisms after sterilization and reduce the shelf life of the sterilized package.

Chemical indicator strips are also available independently. These can be placed inside large packages or containers, to ensure penetration of heat.

### **Tips on Packaging**

A paper sheet or patient napkin may also be packed inside the pouch/package. Once sterile, this paper sheet can be used to line the instrument tray.

All items necessary for a procedure should be packed in one instrument pouch. For example, in a filling set add paper, cotton wool, matrix band and retainer, amalgam gun, spatula, suction tip, air-water syringe tip, hand piece with bur changer and burs.

### **Record of Validation Tests**

Documented processes/procedures should be there to provide guidelines 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.

For further reference regarding sterilization and cross-infection control in dentistry, please consult

the Summary of Infection Prevention Practices in Dental Settings: Basic Expectations for Safe Care, published by the National Center for Chronic Disease Prevention and Health Promotion, United States. This is very detailed and comprehensive report and the guidelines given in this document are very useful for practicing dentistry.

## Assessment Scoring Matrix

**Standard 23. IC-2: There are documented procedures for sterilization activities in the clinic**

Indicator 60 - 62		Max Score	Weightage (Percentage)	Score Obtained
Ind 60.	There is adequate space available for sterilization activities	10	<b>100%</b>	
Ind 61.	Regular validation tests for sterilization are carried out and documented	10	<b>100%</b>	
Ind 62.	There is an established procedure for recall in case of breakdown in the sterilization system	10	<b>100%</b>	
<b>Total</b>		30		

**PART 3**  
**ANNEXURES**

### 3. Annexures

#### ANNEXURE A: Summary Assessment Scoring Matrix

Functional Area		Max Score	Required Score	Score Obtained
2.1	Responsibilities of Management (ROM)	110	100	
2.2	Facility Management and Safety (FMS)	60	58	
2.3	Human Resource Management (HRM)	30	30	
2.4	Information Management System (IMS)	40	34	
2.5	Quality Assurance (QA)	70	68	
2.6	Access, Assessment, and Continuity of Care (AAC)	60	58	
2.7	Care of Patients (COP)	50	48	
2.8	Management of Medication (MOM)	70	66	
2.9	Patient Rights and Education (PRE)	60	56	
2.10	Infection Control (IC)	70	70	
<b>Total</b>		<b>620</b>	<b>588</b>	

## 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
13.	Khyber Pakhtunkhwa Hospital Waste Management Rules, 2018
14.	Injured Persons Act, 2004
15.	Khyber Pakhtunkhwa Injured Persons and Emergency (Medical Aid) Act, 2014

## ANNEXURE C: Confidentiality Agreement

In the course of your work at \_\_\_\_\_ Clinic 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 Clinic's confidential records. Such confidential information must at all times be kept in a secure place on the Clinic'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 Clinic, or within one year thereafter, shall be regarded as made by employee solely and exclusively for the benefit of the Clinic. These shall not be disclosed to others without the Clinic's written consent, and shall be the sole and exclusive property of the Clinic.

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.

Signature: \_\_\_\_\_

Name: \_\_\_\_\_

Date of Joining: \_\_\_\_\_



## ANNEXURE D: Weeding of Old Record

	<b>Type of Record</b>	<b>Period of retaining</b>
<b>Official Record</b>	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.
<b>Medical Record</b>	Patient charts, Reports, X-Ray, CT Scan MRI, Pathology reports OPD Registers.	03 Years or later as per necessity.
<b>Medico-legal</b>	Medico-Legal report/registers	12 years or later as per necessity.
<b>Demographic Record</b>	Birth and Death record	Birth and Death Registers to be kept forever.

## ANNEXURE E: Statement of Ethics

<b>Guideline 1</b>	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.
<b>Guideline 2</b>	We perform our work according to the specified quality standards.
<b>Guideline 3</b>	We avoid conflicts of interest either of a financial or personal nature; these could compromise the objectivity and integrity of our work.
<b>Guideline 4</b>	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.
<b>Guideline 5</b>	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.
<b>Guideline 6</b>	We act with courtesy and consideration towards all with whom we come into contact in the course of our professional work.
<b>Guideline 7</b>	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.
<b>Guideline 8</b>	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.
<b>Guideline 9</b>	We will communicate with our clients and its representative in an effective and timely manner.
<b>Guideline 10</b>	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 F: 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, gender<sup>1</sup>, 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 to life<sup>2</sup> 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 G: Template of Client Satisfaction Proforma

## CLIENT SATISFACTION PROFORMA

No.	Questions	Response	
1	Are you satisfied with the services, behavior of staff and environment at the laboratory ABC_____?	Yes	No
2	If YES, how? (You can circle more than one response and write below)	1. Convenient to reach the facility. 2. Required guidance provided. 3. Services available as portrayed. 4. Services are affordable. 5. Staff is courteous. 6. Relevant staff is available. 7. Privacy is observed. 8. Female staff is available. 9. Test results provided in time. 10. 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 guidance provided. 5. I was asked to come another time without taking the sample. 6. Tests/services are costly. 7. Waiting time is too long. 8. Staff is discourteous/unsatisfactory behavior. 9. Staff is not competent. 10. Relevant staff NOT available. 11. Female staff NOT available (gender issue). 12. Other (specify)	
Signatures of patient/relative			
Action by the person in charge with date:			



## ANNEXURE H: HCE Complaints Management

### 1. OBJECTIVE

To ensure that complaints are handled in a standardized manner at all Healthcare 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 سروس کے متعلق تحریری یا زبانی شکایات کرنے کا حق حاصل ہے۔ آپ اپنی شکایات منظم کو دفتر یا ٹیلی فون نمبر پر کر سکتے ہیں یا استقبالیہ ہیلپ ڈیسک / ریسپشن پر موجود شکایات رجسٹر میں اپنی شکایات درج کر سکتے 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.
- All complaints should be resolved expeditiously.
- Enter important points of the complaint in the register. Take notice of allegations and requests made.
- Investigate in an impartial manner.
- Keep the time factor in mind because any undue delay will reflect poorly on the management.

## **6. COMMUNICATION**

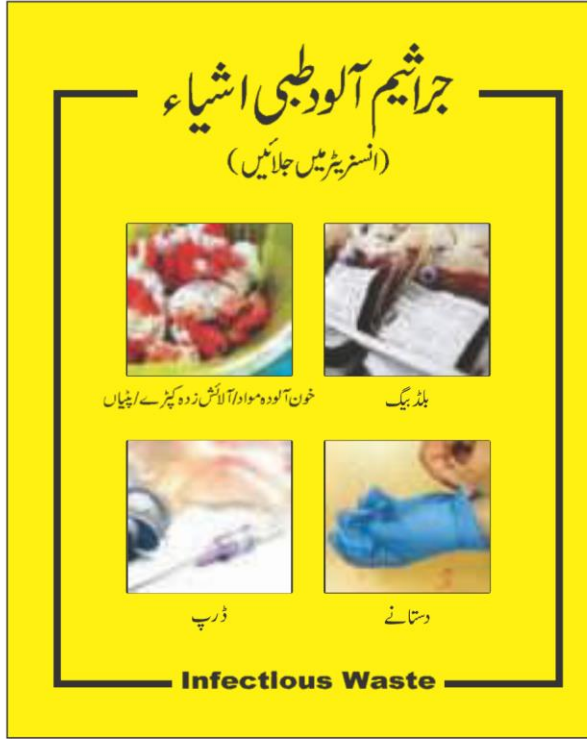
- Inform the complainant about the progress of the investigation at regular intervals and inform him/her about the outcome.
- Stay in contact with the complainant and regularly update him/her about the progress made in investigation.
- Record the outcome of the investigation and inform the complainant accordingly.
- Don't indulge in argumentation. Be polite and empathetic.

## **7. QUALITY IMPROVEMENT**

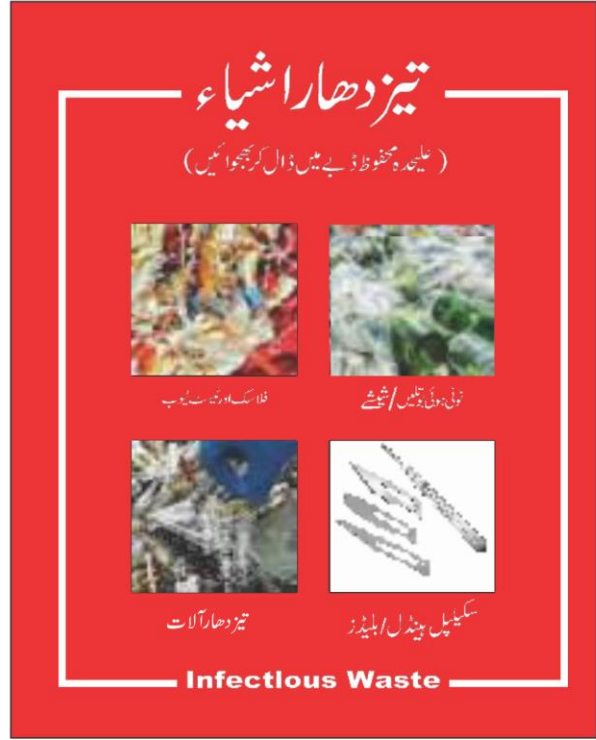
- Use the results of the complaints investigation as part of the quality improvement process.
- The registers should be perused by the Chief Executive of the establishment, at least once a month.
- Make necessary changes in policy and procedures to improve the quality of healthcare services.

## ANNEXURE I: Segregation of Waste (both Clinical & Municipal) for Disposal

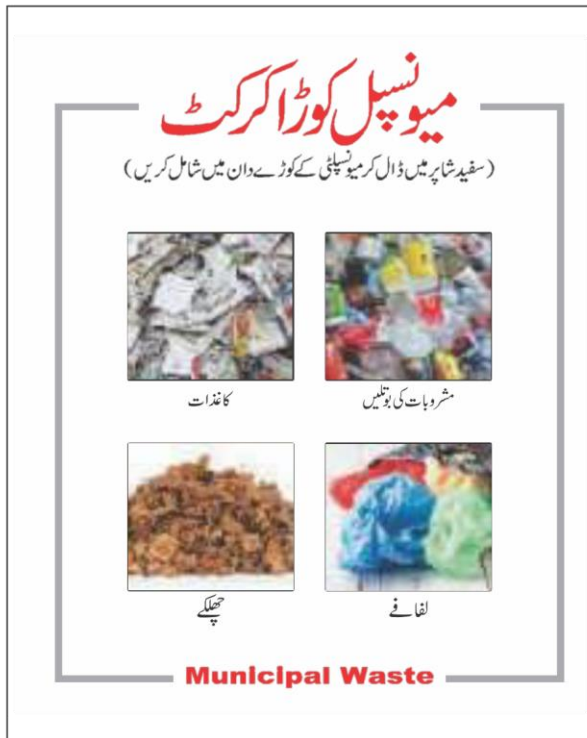
### 1. Yellow Colour



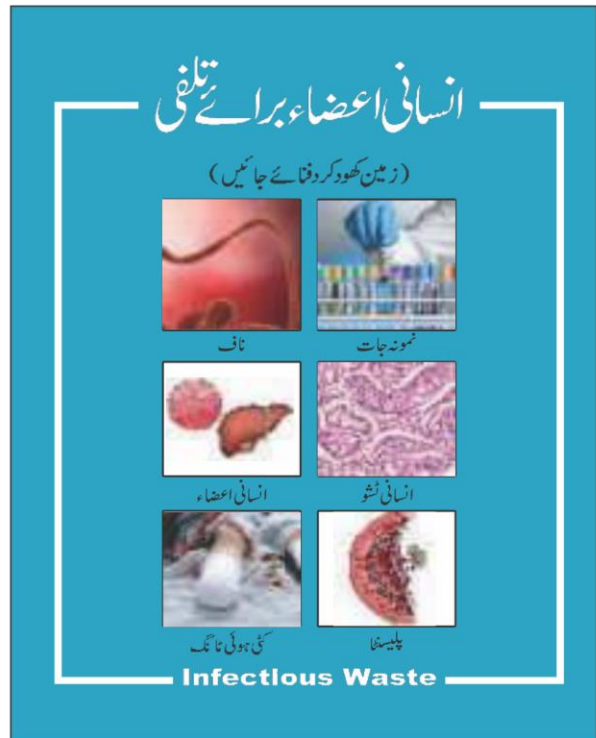
### 2. Red Colour



### 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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