



MINIMUM SERVICE DELIVERY STANDARDS REFERENCE MANUAL





KP HCC-10RM-Ed1



1st Edition

Minimum Service Delivery Standards REFERENCE MANUAL

Homoeopathic Clinics

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Message from Chairman

Aristotle stated, "Quality is not an act, it is a habit." In order to ensure that quality in the health care sector becomes a habit, the government established the Khyber Pakhtunkhwa Health Care Commission (KP HCC) through the Khyber Pakhtunkhwa Health Care Commission Act, 2015. The KP HCC is a statutory



body of the Government of Khyber Pakhtunkhwa to regulate both public and private Health Care Establishments (HCEs) in the province.

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Health Institutions and Regulation of Health Care Services ordinance 2002 (Amendment Act, 2010), which was subsequently repealed through the Act of 2015.

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

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

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

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

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

Dr. Ikram Ghani Chairman, Board of Commissioners

Foreword



Quality costs but poor-quality costs higher. This is true for all walks of life; however, in the health sector its importance cannot be overemphasized. It ensures safety of patients as well health care providers. Patient safety is not new in the medical field but is relatively newer concept for general public. Regulation

of health care services is now a priority at the national and provincial government level. In order to ensure quality of care and safety in health care system of Khyber Pakhtunkhwa, the provincial government established the Khyber Pakhtunkhwa Healthcare Commission (KP HCC) through the promulgation of Khyber Pakhtunkhwa Health Care Commission Act, 2015. KP HCC is a statutory body, constituted to regulate Health Care Establishments (HCEs), both in public and private sectors in the province, to improve quality of health care, and ensure safety of patients and health care providers.

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

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

Subsequent to adoption, appropriate amendments were required to adapt the MSDS to the local context and legal provisions of Khyber Pakhtunkhwa. This was a challenging assignment and despite shortage of staff, KP HCC made the required amendments, utilizing its internal resources. I would like to thank the former Board of KP HCC for its wholehearted effort towards improving the quality of healthcare through adoption of PHC MSDS. My thanks are also due to 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 Homoeopathic Clinics comprises 17 standards and 33 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 |
|--------|---|
| BHMS | Bachelor in Homoeopathic Medical Science |
| CNIC | Computerized National Identity Card |
| СОР | Care of Patients |
| CPR | Cardio-Pulmonary Resuscitation |
| DHMS | Diploma in Homoeopathic Medical Science |
| DoB | Date of Birth |
| DRAP | Drug Regulatory Authority of Pakistan |
| EMR | Electronic Medical Record |
| EPA | Environmental Protection Agency |
| FMS | Facility Management and Safety |
| HCE | Healthcare Establishment |
| НСР | Healthcare Provider |
| HR | Human Resource |
| HRM | Human Resource Management |
| HWM | Hospital Waste Management |
| IC | Infection Control |
| ID | Identity |
| IMS | Information Management System |
| JD | Job Description |
| JCAH | Joint Commission for Accreditation of Hospitals |
| JCI | Joint Commission International |
| KP HCC | Khyber Pakhtunkhwa Health Care Commission |
| MLCs | Medico Legal Cases |
| MOM | Management of Medication |
| MSDS | Minimum Service Delivery Standards |
| NCH | National Council for Homoeopathy |
| PHC | Punjab Healthcare Commission |
| PPE | Personal Protective Equipment |
| PRE | Patient Rights and Education |

| QA | Quality Assurance |
|-----|-----------------------------------|
| QHA | Quality Holistic Accreditation |
| QI | Quality Improvement |
| ROM | Responsibilities of Management |
| UAH | Unani, Ayurdedic and Homoeopathic |
| UK | United Kingdom |
| USA | United States of America |
| WHO | World Health Organization |
| WMT | Waste Management Team |

1. Introduction

The Government of Khyber Pakhtunkhwa promulgated the Khyber Pakhtunkhwa Health care Commission Act, 2015, to establish the Khyber Pakhtunkhwa Health Care Commission (KP HCC) as a regulatory body with the prime objective to improve the quality of healthcare services and ban quackery in Khyber Pakhtunkhwa in all its forms and manifestations. The KP HCC is legally mandated¹ to regulate all Health Care Establishments (HCEs) in the public and private sectors through registration and licensing. It is the responsibility of the HCEs throughout the province to get registered with KP HCC. Moreover, the KP HCC is ensuring to improve and maintain quality of healthcare through the implementation of Minimum Service Delivery Standards (MSDS). The HCEs are required to follow these standards in order to get license. No Health care Establishment can function legally without being registered and licensed by the Khyber Pakhtunkhwa Care Commission.

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

1.1 Service Delivery Standards

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

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

1.2 Reference Manual for Homoeopathic 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 Clinics of General Practitioners and Specialists. The document comprises 17 standards with 33 associated

¹ Khyber Pakhtunkhwa Health Care Commission Act, 2015

indicators grouped in 10 universally accepted Functional Areas for such services along with Reference Material and Assessment Scoring Matrix. Keeping in view the ground realities, these standards have been kept **dynamic** and subject to evidence based improvement. All aspects of implementation, assessment and scoring have been included in this single document to better facilitate the implementers at HCEs as well as the surveyors involved in inspections.

A **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:

| Lov | vest | Shades of Levels of Implementation Highest | | | | | | | | |
|-----|------|--|---|---|---|---|---|---|---|----|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

19 indicators require full compliance and have ascribed 100% weightage while 14 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)

03 Standards & 10 Indicators

The majority of homoeopathic healthcare establishments (HCEs) are single-man clinics, with the exception of a few which have multiple homoeopathic practitioners along with assistants (homoeopathic dispensers, receptionists etc.) providing services. The prescribed standards and indicators provide a structure to help the service providers organize their HCEs (homoeopathic clinics) in a way that best serves the interest of patients. For the convenience of patients, these standards require clinics to be easily identifiable and accessible. The standards also require that only qualified and registered homoeopathic practitioner(s) should provide services at such clinics. They further demand that such services be delivered in accordance with the mandate of the NCH and the Code of Ethics for Homoeopathic Practice.

Standard 1. ROM-1: Clinic is identifiable as an entity and easily accessible.

Indicators (1-5):

Ind 1. The Homoeopathic clinic is identifiable with the name and NCH Registration number displayed on a sign board.

Survey Process:

The essence of the indicator is to ascertain that any one approaching the clinic is able to identify the location by a sign board, on which the name of the clinic/Health Care Service Provider, i.e. "Homoeopathic Clinic ABC- NCH Reg. No. 0000" is clearly written. Surveyor is required to make an assessment while approaching the clinic that the board is appropriately placed and prominently visible and patients, before entering the clinic, know that they are accessing a qualified and duly registered homoeopathic practitioner(s).

Scoring:

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

GUIDELINES

Identification as a Legal Entity

It is required that all homoeopathic clinics, as all other HCEs, are identifiable as a legal entity and that a patient/client seeking healthcare is able to identify the service provider's location and legal status. Thus, a clearly written, appropriately sized sign board is fixed at a suitable place, so that any one approaching the clinic is able to identify its location, type, name and registration status, etc. It would be mandatory to write "Homoeopathic Doctor ABC" with the qualification and NCH registration number, or "XYZ Homoeopathic Clinic," followed by name, qualification, registration number etc., with both "Homoeopathic" and "Doctor" having equal prominence, as per Section 39 (2), UAH Act, 1965, and the Code of Ethics of the NCH, Government of Pakistan. The board is also required to reflect the license number issued by the KP HCC. However, the requirement to 'display the NCH registration number and the KP HCC license number (refer to Indicator No. 3) on the main sign board' has been relaxed for a period of ONE year, after the publication of these standards. During this period, alternatively, the registration and license numbers should be displayed at any suitable place from where the same are prominently visible before, or on, entering the clinic. The qualification(s) recognized by NCH ONLY may be displayed on the sign board in the form of permitted abbreviation(s). Registration is to be reflected separately so that it does not create the impression of an additional degree or diploma. The sign board should be fixed on a wall, roof top or pole, duly complying with local government regulations, as applicable. The recommended size of the board is 4-5 feet long and 2.5-3 feet high. The recommended size for the secondary sign board is 2.5 feet long and 2 feet high.

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

Survey Process:

This indicator demands that accessibility to the clinic, for patients and relatives particularly the disabled and elderly persons is easy and that such patients are provided appropriate assistance. All ramps and slopes, entrances and washroom door(s), if applicable, are required to be non-slippery and wide enough to allow easy passage.

Scoring:

- If access to the clinic is easy, as defined above, then score as <u>fully met.</u>
- If access to the clinic is not easy, as defined above, then score as partially met.
- If access to the clinic is difficult and there is no facilitation, as defined above, then score as <u>not</u> <u>met.</u>

GUIDELINES

Easy Access

Ease of access and entering and moving within the healthcare facility are the basic and essential requirements of patients/clients, particularly the disabled and elderly. The entry/exit, if not on level ground, should have ramps for wheel chairs, stretchers etc. Un-even floors, or even small obstructions, can cause a person to tumble over and get injured. The disabled and elderly are more prone to get affected by such obstructions. All ramps/slopes are required to be non-slippery. This can either be done with fancy/costly material or simply by grinding and coarsening the surface of the Door, as it suits the service provider. The entry/exit and washroom door/s should be wide enough to allow easy passage of wheel chairs.

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

Survey Process:

The assessor is required to demand registration/license under the KP HCC Act, for verification, before proceeding any further with the assessment/inspection. The KP HCC registration/license number is to be displayed² at a prominent place, on a sign board or on the outer wall, and at a prominent place inside the clinic.³

Scoring:

- If the clinic has a license from the KP HCC and it is displayed as described above, then score as <u>fully met.</u>
- If the clinic has; 1. Certificate of registration from the KP HCC which has been displayed and 2. Evidence of having taken steps to obtain a license from the KP HCC, then score as partially met.
- If the clinic has no certification as above, then score as not met. <u>not met.</u>

² As described for display of NCH Registration in the survey process under Ind 1.

³ Relaxation for displaying the KP HCC registration/license number on the main sign board is for one year from the date of notification of this MSDS.

The Ultimate requirement is that the sign board shall have:

- □ The name(s) of the clinic/homoeopathic doctor(s), as provided in the law;
- □ The NCH registration number(s) of the homoeopathic doctor(s);
- □ The KP HCC registration/license number issued to the clinic;
- □ Consultation times of the homoeopathic doctor(s).

GUIDELINES

Registration and Licensing

As per Section 12 of the KP HCC Act, 2015, all HCEs are required to be registered and licensed with the KP HCC. After coming into force of this Act, HCEs, including Homoeopathic Clinics, cannot function without getting registered and licensed by the KP HCC. The KP HCC License number is also required to be displayed on the main board as described in explanations for Ind. No. 1. In consideration of the fact that it may not be possible for all legitimate practitioners to change their boards immediately, a grace period of one year, from the date these MSDS are published/displayed on the KP HCC website, is allowed to meet the requirement. However, during this period, the KP HCC Registration Certificate or License number which ever may be applicable at the time, may be displayed separately and prominently on the main entrance of the clinic and inside the waiting/ consultation room of the homoeopathic doctor. This display can be on a simple and small board (approximately 5 inch x 10 inch) of any suitable material with the registration/license number prominently written on it.

The registration/licensing forms, guidelines and information regarding fee etc., can be collected personally from the KP HCC office or can be downloaded from the KP HCC website: www.hcc.pk.gov.pk.

The original registration certificate/license issued by the KP HCC (as the case may be) must be available at the clinic. Copy of the same can be displayed at a prominent place in the waiting area/reception and/or inside the section of the clinic where the practitioner provides consultations. The original certificate may be shown upon demand.

Ind 4. Door plate(s) clearly display name and qualification(s) of the homoeopathic doctor

Survey Process:

Observe the placement of the door plate and assess whether the text of the qualifications is in accordance with the provisions of the UAH Act II 1965⁴ and the Code of Ethics for homoeopathic

⁴ The UAH Practitioners Act, 1965, Act No.II of 1965 (25th January, 1965): Amended vide President's Ordinance No. IV of 2002 & LXI of 2002, Section 39. In particular part 2 "Notwithstanding anything contained in any other law for the time being in force, no Tabib or Vaid shall describe himself as a Doctor but a Homoeopath may use the expression "Homoeopathic Doctor," both the words "Homoeopathic" and "Doctor" having equal prominence.

practitioners by the NCH⁵ and as described above.

Scoring:

- If the door plate is in accordance with the above, then score as <u>fully met.</u>
- If the door plate is present but does not display full information as mentioned above, then score as <u>partially met.</u>
- If the door plate does not exist, then score as <u>not met.</u>

GUIDELINES

Door Plates

The doorplate with qualifications, in accordance with the provisions of the UAH Act II, 1965 and the Code of Ethics for Homoeopathic Practitioners by the NCH,⁶ should be placed on the door of the practitioner's clinic. The plate should be unostentatious and must include qualifications, invariably indicating the granting authority. In this case, this would mean a degree/diploma which is recognized by the NCH. A higher qualification may be written but indications of specialty should be avoided. However, if a homoeopath restricts himself/herself to a particular type of work, then he/she can use the words "Specialist in XYZ" etc. The name of the homoeopathic practitioners should not be used on any other clinic/premises except the place of regular practice, where the practice timings are displayed. A plate of size not exceeding 4 x 10 inches is recommended.

The recommended wording on the door plate (internal board) consists of a maximum of three lines, in an appropriate size and font:

Homoeopathic Doctor ABC

Homoeopathic Qualification/s NCH Registration Number

Figure 1. Door Plates Template

Note:

- 1. Only homoeopathic qualification(s) in recognized abbreviation(s) is/are permitted to be displayed.
- 2. Past/present appointments and membership with associations or bodies shall not be mentioned on the board(s).

Ind 5. Consultation hours are displayed.

Survey Process:

The essence of the indicator is that clinic should function only when the homoeopathic doctor is available and demands that the timings of his/her physical availability to provide consultation are

⁵ Provision VI. (a) Premises and Door-plates, Code of Ethics for Homoeopathic Practitioners by NCH.

⁶ Provision VI. (a) 2nd para, Door-plates, Code of Ethics for Homoeopathic Practitioners by NCH.

clearly displayed at prominent places outside and inside the clinic and observed accordingly.

Scoring:

- If the timings of the homoeopathic doctor are displayed as mentioned above, then score as <u>fully</u> <u>met.</u>
- If the timings of the homoeopathic doctor are NOT displayed, then score as <u>not met.</u>

GUIDELINES

Consultation Hours

The proper display of healthcare service facility's hours of operation is important for the convenience of patients. It is important that the homoeopathic clinic should function only when the homoeopathic doctor is physically available and the timings of his/her availability for consultation are clearly displayed at prominent places outside and inside the clinic and observed accordingly. This requirement discourages the functioning of clinics beyond the practice time of a legitimate practitioner and is important in limiting quackery and developing patients' confidence.

Assessment Scoring Matrix

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

| | Indicator 1 – 5 | Max Score | Weightage (Percentage) | Score Obtained |
|--------|---|--------------|---------------------------|-------------------|
| Ind 1. | The clinic is identifiable with name and registration/ license numbers on the sign board(s) | 10 | 100% | |
| Ind 2. | The patient/client has easy access to the clinic | 10 | 80% | |
| Ind 3. | The Homeopathic clinic is registered/licensed with KP HCC | 10 | 80% | |
| Ind 4. | Door plate(s) clearly display name and qualification(s) of the Dental Surgeon | 10 | 80% | |
| Ind 5. | The staff on duty uses identity badge(s) | 10 | 100% | |
| | Total | 50 | | |

Standard 2. ROM-2: A suitably qualified/experienced individual manages⁷ the clinic.

Indicators (6-7):

Ind 6. The clinic manager has requisite qualifications.

Survey Process:

Review the roles and responsibilities of the individual(s) managing the clinic and/or providing homoeopathic services and assess if their credentials match the portrayed services.⁸

Scoring:

Score **fully met**, unless there are significant deficiencies in the credentials.

GUIDELINES

Qualifications of a Clinic Manager

Keeping in view the nature of homoeopathic services, the individual who manages the homoeopathic clinic is required to be a qualified homoeopath, currently registered with the NCH. In case of a single-man clinic, the homoeopathic 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 clinic. For managers of polyclinics, an additional qualification in healthcare facility management would be preferable, whereas for those managing still larger set ups, it will be essential. In case the homoeopathic HCE is owned by a non-homoeopathic professional, the above-described principle shall prevail and the owner shall only be made responsible for any general administrative matters, while the qualified homoeopath shall be responsible for all technical matters. In case a homoeopathic clinic has more than one staff member, the person in charge has to be clearly identified and notified. Following is a list of responsibilities that are considered desirable for an in-charge of clinic to manage:

- 1. Provision of homoeopathic services at the clinic according to the NCH rules, regulations and Code of Ethics that only homoeopathic services are portrayed and provided at the clinic.
- 2. Regular maintenance and repair of physical infrastructures, both interior and exterior.
- 3. Staff providing support services (as applicable) maintain high standards of general hygiene and a positive approach to patient handling and facilitation.
- 4. Dispensing of remedies/medication is according to standard procedures.
- 5. That all records are maintained with required information and these records are checked, at least on quarterly basis, and kept in a safe custody (with declared responsibility).

⁷ As per UAH Practitioners Act, 1965.

⁸ Where a homoeopathic doctor is registered with the NCH managing the clinic and is the owner himself/herself, the issue does not arise. However, in case the clinic is owned by a person other than the homoeopathic doctor, then the responsibility of technical management should lie with the registered homoeopathic doctor who should not allow the clinic to run in absentia, while general administrative issues may be handled by the owner/administrator, as the case may be.

- 6. Availability of requisite facilities and trained staff to deal with emergency care and referrals.
- 7. The clinic has an established complaint management and redressal system.
- 8. Ensuring compliance of SOPs on infection control.

Ind 7. The NCH registration certificate of the homoeopathic doctor is displayed.

Survey Process:

A photo copy of the valid registration certificate issued to the homoeopathic doctor by the National Council for Homoeopathy (NCH) is displayed at a prominent place in the clinic, while the original is available for verification when required. The renewal and its validation can be verified from the NCH, if required.

Scoring:

- If the homoeopathic doctor's valid registration certificate is prominently displayed in the clinic and the original is available for verification, then score as <u>fully met.</u>
- If the homoeopathic doctor's registration certificate is prominently displayed in the clinic, but has expired and there is evidence of having applied for renewal, then score as **partially met.**
- If no registration certificate is available at the clinic or the certificate has expired, then score as <u>not met.</u>

GUIDELINES

Display of Registration Certificate

It is the personal responsibility of every homoeopathic doctor to get himself/herself registered with the National Council for Homoeopathy (NCH), as described in Sections 23 to 24 of the UAH⁹ Act of 1965, without which practice in homoeopathy is not allowed and defaulters are liable to be punished, as provided in Sections 37 (3) of the selfsame Act. The management/person in charge of the clinic is required to ensure that a photo copy of the valid registration certificate, issued to the homoeopathic doctor by NCH, is displayed at a prominent place in the clinic, while the original is available in the file/record. The renewal and validation can be verified from the NCH, as per the requirement.

⁹ The Unani, Ayurvedic and Homoeopathic Practitioners Act 1965 (Act no. II of 1965) amended vide President's Ordinance No. IV of 2002 and LXI of 2002, published in the gazette of Pakistan dated 17-01-2002 and 04-10-2002.

Assessment Scoring Matrix

Standard 2. ROM. 2: A suitably qualified/experienced individual manages the clinic.

| | Indicator 6 - 7 | Max Score | Weightage (Percentage) | Score Obtained |
|--------|---|--------------|---------------------------|-------------------|
| Ind 6. | The clinic manager has requisite qualifications. | 10 | 100% | |
| Ind 7. | The NCH registration certificate of the homoeopathic doctor is displayed. | 10 | 80% | |
| | Total | 20 | | |

Standard 3. ROM-3: The clinic premises support the scope of work.

Indicators (8-10):

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

Survey Process:

Observe that the clinic has the minimum required space, with portions for consultation, seating for patients and dispensing (if applicable).

Scoring:

- If the clinic is divided into portions, as described above, and patients are sitting comfortably, then score as <u>fully met.</u>
- If the clinic premises is as above but patients are not sitting comfortably, then score as <u>partially</u> <u>met.</u>
- If the internal size of the clinic premises is not sufficient to accommodate even 3 patients at a time, then score as <u>not met.</u>

GUIDELINES

The Size and Premises

The size and premises of the homoeopathic clinic are important for the comfort of both patients and healthcare service providers. Homoeopathic practice can be started in a small consultation room, with space to accommodate a practitioner, patient and an attendant. However, issues of space and comfort arise with an increase in the number of patients, with the result that people have to await their turn for consultation and medications etc. It is not desirable that while the practitioner is engaged with a patient in consultation, others are made to wait outside on the street. Such a situation would require the practitioner to arrange additional seating space for the comfort of patients waiting for their turn. If no separate rooms for dispensing and waiting are available, then one can create suitable partitions (e.g. cloth, aluminum, glass or wooden) within the available room to compartmentalize these areas. This would help maintain a sense of privacy for the patient in the consultation, while catering to the comfort of others.

Homoeopathic clinics are recommended to have sufficient space which is compartmentalized to cater to three basic needs i.e. patients sitting/waiting area, consultation and dispensing of medicine. Comfortable seating means:

- 1. Allowing patients to sit in a comfortable posture.
- 2. Accommodation of 3-5 patients at a given time.

In some settings it is acceptable to have the same area designated for dispensing and seating of waiting patients. Finally, the clinic room/space should be airy with proper ventilation.

These proposed portions/partitions of the clinic may include the following:

1. The Homoeopathic Consulting Area/Chamber

This is an important portion of any homoeopathic clinic and should have:

- i. A table and a comfortable chair for the homoeopathic doctor: A homoeopathic doctor sits for long hours, so the chair should be comfortable, with proper back-support, and preferably reclining so that he/she can lean back and rest at times.
- ii. A patient stool: Preferably a revolving, stainless stool that is commonly available in the market. However, a wooden stool for adequate height (1-1/2 ft.) can also be used.
- iii. A few chairs for patients and their attendants: A wooden bench may also be placed depending on space availability.
- iv. A small bookshelf or a book rack to accommodate some reference books which may be fixed on the wall.
- v. An examination table/couch.

In addition, depending upon affordability and usage, the clinic should have a computer for appropriate record keeping and searching of reference material etc.

2. The Dispensing Portion/Section

This portion/section is necessary if homoeopathic medicines/remedies are being issued/dispensed from the clinic's dispensary. This section would basically require wooden or metal racks, in step ladder design, to store medicines/remedies which are easily accessible to the authorized dispensing person. However, in case the practice is limited to prescribing ONLY and the patients are advised to get medicines from any store of their choice, this section would not be required.



Figure 2. Dispensing Section

There should be separate, closed racks for storing extra stocks and some odorous medicines and mother tinctures. The medicines/remedies should be stored in such a way that they are not exposed to direct sunlight or excessive heat.

3. The Waiting Area

The waiting area/room needs to be appropriately furnished. Settee(s), sofa(s), chair(s) or bench(es) are acceptable, depending upon affordability and their sufficiency to accommodate the numbers of clients. The minimum recommended waiting area should be able to accommodate at least 3-5 patients and attendants at a given time. The furniture should be comfortable and a center-table and magazine rack may be kept, if space and budget permits. The waiting area can also have a pin-board, where articles, appointments or general

information for patients can be posted.



Figure 3. Waiting Area

Color Scheme and Ambiance in the Clinic

White and light colors are preferable for clinics as they provide a feeling of openness and better opportunity for cleaning and complying with hygienic requirements. However, regardless of the color of the walls in the room, it is desirable that the ceiling should be white for uniform illumination of the clinic. Similarly, the curtains, furniture and other interior items should also have light colors and be made of a material that facilitates the maintenance of a clean and hygienic look. They should 'blend-in' and not 'stand out'. Dark colors like red, brown, black, dark blue and dark green should be avoided as they are usually not considered soothing and are also known to aggravate various moods and emotions. For a fresh and lively feeling to the interiors, dim or colored lights should be avoided. Indoor plants help create a refreshing environment. Whatever your space or budget may be, try to keep things and designs simple.

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

Survey Process:

The surveyors are required to observe the presence of the following during a visit to a homoeopathic clinic:

- 1. Seating arrangement.
- 2. Alternate arrangements of lighting in case of power outage, at least an emergency light.
- 3. Waste container(s)/receptacle(s).
- 4. Proper ventilation.
- 5. Clean drinking water.
- 6. Availability/Accessibility of toilet facilities.
- 7. Mosquito and fly proofing (wire gauze).

Scoring:

- If the clinic has facilities 1 to 7, then score as <u>fully met.</u>
- If the clinic has facilities 1 to 5, then score as partially met.

If the clinic does not have any one of the facilities listed at i. to v., then score as <u>not met.</u>

GUIDELINES

Facilities for the Comfort of Patients

The homoeopathic clinic also needs to have facilities which create a comfortable environment for patients and care providers. Each homoeopathic clinic must, at minimum, have the following facilities:

1. Sitting arrangement

Space should be available for 3-5 persons and seating arrangements may be made in a way that allows patients and attendants to sit comfortably for at least 10-15 minutes while waiting for service and to move around freely without hindrance.

2. Alternate arrangements for lighting during power outages, an emergency light at the very least:

To combat electricity interruptions or emergency situations, alternative arrangements for light/electricity must be made available. At minimum, an emergency light (torch) and/or candles must be available and kept in a safe and easy to access place.

3. Waste container/receptacle(s)¹⁰

A waste container is a container for the temporary storage of waste and is usually made out of metal or plastic. Common terms are dustbin, rubbish bin, litter bin, garbage can, trash can, trash bin, dumpster, waste basket, waste paper basket, waste receptacle, container bin and kitchen bin.

4. Ventilation:

The clinic room(s) is required to have proper ventilation. Windows and/or natural ventilation should exist for the comfort of patients during their visit to the clinic. A proper exhaust system facilitates ventilation and keeps the internal environment at a normal level. In most of the local constructions, windows, exhausts and ventilators are affixed in rooms and verandas.

5. Clean drinking water:

Safe and clean drinking water should be available in the clinic for patients, attendants and staff. The utensils used for drinking and storing the water must be kept clean.

6. Toilet availability/accessibility¹¹

Preferably, a toilet should be available within the clinic premises. However, given the circumstance that a large number of clinics are single room, established in markets where attached bath rooms are generally not available, it is desired that the toilet facility should be accessible to patients/attendants and staff in the closest proximity.

¹⁰ This is a minimum requirement so that waste being generated is temporarily stored. For any additional requirement, attention is drawn to The Waste Management Rules issued by EPA.

¹¹ In house availability mandatory for poly clinics.

7. Mosquito and fly proofing (wire gauze)

It is a well-known fact that our environment is highly conducive to mosquitoes and flies, leading to the risk of malaria, dengue and other infectious diseases. It is, therefore, desired that the management must ensure that the clinic environment is mosquito and fly free. Arrangements should be made to properly fix doors/windows with wire gauze for protection from mosquitoes and flies.

Ind 10. The clinic has adequate arrangements to maintain the privacy of patients during consultation/examination.

Survey Process:

Observe if arrangements to maintain patient's privacy¹² during consultation/examination are available.

Scoring:

- If the clinic has arrangements to maintain patients' privacy as defined above, then score as <u>fully</u> <u>met.</u>
- If privacy arrangements are not available in the clinic, then score as <u>not met.</u>

GUIDELINES

Privacy of Patients

The privacy of patients during history taking, consultation and examination, being of paramount importance, cannot be ignored and is one of the main requirements every clinic must meet. Female patients and minors are not to be examined alone by male practitioners and in such cases, the accompanying attendant, preferably a female, should be requested to remain present. If circumstances render the physical examination of a female patient or a minor without the presence of an attendant necessary, then written consent from the patient or parent/guardian in case of minor must be taken.

Additionally, appropriate partitioning of the waiting/sitting area for both male and female patients and their attendants is strongly recommended. Keeping budget and space in mind, the partition could be either a cloth curtain or a wooden or tinted glass wall installed inside the clinic.

Note: Remember that one must design the clinic keeping the patients in mind, who should feel relaxed when they visit the clinic.

¹² Code of Ethics adopted by the National Council for Homoeopathy

Assessment Scoring Matrix

Standard 3. ROM. 3: The clinic premises support the scope of work

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

2.2 Facility Management and Safety (FMS)

01 Standards & 02 Indicators

Effective and efficient facility management and safety is an important key area for every HCE, including homoeopathic clinics. It serves the mandatory function of the provision of healthcare in a safe environment which does not have any installation which is, or can be, potentially harmful to patients and care providers. The working environment is also expected to provide safety/safe exit during natural disasters or emergency situations.

Standard 4. FMS-1: The clinic has facility management and safety systems in place.

Indicators (11-12):

Ind 11. The staff has knowledge about early detection and containment of fire and non-fire emergencies¹³

Survey Process:

Interview the staff (homoeopathic practitioner, dispenser or clinic assistant, as applicable) on their knowledge about the system/process for early detection and containment of fire and non-fire emergencies.

Scoring:

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

GUIDELINES

Fire and Non-fire Emergencies

The staff of the homoeopathic clinic (homoeopathic practitioner and/or dispenser) should be well acquainted with the system/process for early detection and containment of fire and non-fire emergencies. The staff must know how and when to identify (early detection) fire and non-fire emergencies and be fully knowledgeable about containment methods and actions required. It is also important that the staff is updated annually on the early detection and containment of fire and non-fire emergencies.

Ind 12. Arrangements to combat firre and non-fire emergencies are available at the clinic.

Survey Process:

Observe that arrangements to deal with fire emergencies are available at the clinic. Interview the staff to assess whether they know how to operate/use the fire-fighting equipment/arrangement.¹⁴

Scoring:

If fire-fighting equipment/arrangement is available and staff knows how to use it, then score as

¹³ Early detection at a small scale means to quickly check in-person any extraordinary smoke, burning smells etc. Non-fire emergencies include earthquakes, floods etc.

¹⁴ Equipment/arrangement suitable for the place, like buckets of water/sand, spades or fire extinguishers etc., as the case may be.

<u>fully met.</u>

- If fire-fighting equipment/arrangement is available but staff does not know how to use it, then score as <u>partially met.</u>
- If fire-fighting equipment/arrangement is not available, then score as <u>not met.</u>

GUIDELINES

Arrangements to deal with Fire and Non-fire Emergencies

Arrangements to deal with fire and non-fire emergences are required to be made at the clinic. The staff must be fully conversant with the arrangement and should be able to access and operate/use the fire-fighting equipment. Similarly the staff should know health related laws, given at **Annexure B.** A brief description of fire and non-fire emergencies and the actions required to combat these, that all staff of the clinic should be aware of, is given below:

1. Fire emergency:

Any sudden incident, where the smell of something burning is felt, a smoke is visible or actual fire is noticed, is considered a fire emergency. Fire emergencies are to be handled urgently, but dealt with care and patience, keeping the safety of the patients and the staff in mind.

2. Non-fire emergency:

Non-fire emergencies relate to the emergency conditions caused by accidents and/or natural calamities, and may include:

- i. Earthquakes
- ii. Civil disorders affecting the HCE
- iii. Terrorist attacks
- iv. Invasion of swarms of insects and pests
- v. Invasion of stray animals
- vi. Hysteric fits of patients and/or relatives
- vii. Anti-social behavior by patients/relatives
- viii. Temperamental disorders of staff causing deterioration in patient care
- ix. Spillage of hazardous substances (acids, mercury etc.), infected materials (used gloves, syringes, tubing, sharps etc.) and medical wastes (blood, pus, amniotic fluid, vomit etc.)
- x. Building or structural collapse
- xi. Falls, slips or collision of personnel in the corridors
- xii. Fall of a patient from the bed/stretcher
- xiii. Bursting of pipelines, boilers and/or autoclaves
- xiv. Sudden flooding of areas like basements due to clogging in pipelines or heavy rains
- xv. Sudden breakdown of supply of electricity, gas, vacuum etc.

The person in charge of the homoeopathic clinic shall take care of non-fire emergency situations by identifying them and taking appropriate course of action.

3. Awareness of rapid response:

Above all, rapid response time is a pivotal advantage of fire service-based, pre-hospital emergency systems. The Emergency Services **Rescue 1122** is one of the major sources of clinic-to-hospital emergency referrals, as well as other emergencies including fire emergencies.

Assessment Scoring Matrix

Standard 4. FMS-1: The clinic has facility management and safety systems in place.

| | Indicator 11 - 12 | Max Score | Weightage (Percentage) | Score Obtained |
|---------|---|--------------|---------------------------|-------------------|
| Ind 11. | The staff has knowledge about early detection and containment of Fire and non- Fire emergencies. | 10 | 100% | |
| Ind 12. | Arrangements to combat fire and non-fire emergencies are available at the clinic. | 10 | 80% | |
| | Total | 20 | | |

2.3 Human Resource Management (HRM)

01 Standard & 01 Indicator

The goal of the standard relating to Human Resource (HR) is to ensure that the homoeopathic clinic determines qualifications and competencies for staff positions, which are required to match the clinic's functions. The clinic must have qualified and competent staff to meet patient care requirements. To meet this goal, the standard requires clinics to plan for staffing; orient, educate, train, assess, maintain and improve staff capability and promote self-development and learning. There should be well organized HR records to recognize the credibility and proficiency of the HR in the field of homoeopathic system of patient care and management.

Standard 5. HRM-1: There is documented personnel record of homoeopathic doctor and staff

Indicators (13-13):

Ind 13. Personal record/credentials in respect of all staff are maintained.

Survey Process:

Surveyors are required to review the credentials of homoeopathic practitioners, homoeopathic dispensers¹⁵ and other staff (as applicable). This should include professional qualifications, registration of the practitioners with council & its validity. The surveyors should also review the personal record of the homoeopathic dispenser and other staff employed, i.e. job descriptions signed the employer as well as the employee and experience certificate/ training, character certificate/ references, confidentiality agreement (**Annexure C**) etc. duly verified as the case may be.

Scoring:

- If the record has documented information regarding personnel credentials as mentioned above, then score as <u>fully met.</u>
- If the record of the staff is not available as mentioned above, then score as <u>not met.</u>

GUIDELINES

Purpose of Personal Files

The purpose of maintaining personnel credentials is to keep an updated record of the staff at the homoeopathic clinic. The personnel record/credentials of employee(s) should be maintained because:

- 1. It makes good sense to have accurate information handy and organized when it is to be used for official purposes.
- 2. Immediate supervisors, if applicable, will eventually encounter the need to produce documentation about an employee's performance and work history.
- 3. Some employee records are required by federal, provincial or district governments/other authorities and must be kept in the personnel files. Organizing the record of employees in a proper manner makes access easy.

The personal record of each employee is confidential and access to the record is only allowed after approval from a competent authority. Access to employee information should be strictly limited to those individuals at the HCE who require this information for official purposes.

Since unauthorized access to personnel record can result in severe repercussions, any breach in this regard should make the responsible person liable to severe penalties. It should be ensured that personnel files (hard and/or soft copies) are stored in a secure location and are not left unattended even during working hours. When asked by the people outside the organization to provide

¹⁵ The person who has 6-12 months' work experience under a registered homoeopathic practitioner, having completed matriculation by way of academic qualification, at a minimum, will be acceptable till the NCH develops a system to train and certify homoeopathic dispensers.

'verification' of certain employment information about the employee(s) of the HCE, it should be ensured that only the information which has been authorized by the employee(s) is released. Employment verifications are usually required to support certain claims and requests, such as mortgage applications, credit applications etc. In this case, employee authorization should be in writing and should specify the information they wish you to reveal.

Tell your employees that the policy is designed for their protection. It may be noted that the above details are equally applicable for both single-man clinics and HCEs having multiple employees.

Contents of Personal Files

All good organizations maintain the following documents in an employee's personal record, as applicable:

- 1. Curriculum vitae.
- 2. Photographs, x2 passport size.
- 3. A copy of the CNIC.
- 4. Copies of documents pertaining to all academic and professional qualifications and copies of trainings/certifications.
- 5. Experience certificate(s) from previous employer(s), if any.
- 6. Offer letter and acceptance.
- 7. A signed copy of the job description (JD).
- 8. Medical/personal information form duly completed.
- 9. Leave record (if any).
- 10. Salary Increment/Promotion.
- 11. Appraisal/Evaluation forms (if applicable)
- 12. Resignation/termination letter (whichever is received).

However, the owner, person in charge or manager of the clinic should ensure that at least the following credentials, **duly verified and updated**, are available in personal records:

- 1. Educational degrees/diplomas, both undergraduate and postgraduate.
- 2. Registration with registering/licensing body.
- 3. Pre-service and in-service trainings.
- 4. Related experience, both local and foreign.

Verification of Licensure/Certification

There should be a process to validate the authenticity of the documents in the personal records. The person in charge should verify documents from the primary source, such as the college, university, authority or training organization, as applicable and as per the following:

- 1. Current licensure, certification or registration is verified with the primary source at the time of hiring and prior to renewal of employment.
- 2. Primary source verification will be obtained through secure electronic communication. If a licensing board/agency/authority cannot provide this type of verification, a letter in that respect must be obtained from it.
- 3. In the event that an employee is hired against a position that requires a license, certification or registration, and the same has been revoked, suspended or rendered invalid, the HCE may terminate the concerned employee on these grounds.
- 4. Practitioners should have current/valid registration with the respective professional council or body e.g. the NCH. It is the employee's responsibility to provide proof of license, certification

and/or registration and to notify any change in the status of the license, certification and/or registration to the manager immediately.

5. Periodic updating of credentials is required to be a regular feature.

Orientation of the Staff

The staff must go through important documents related to the homoeopathic system of care and practices including, but not limited to, the following:

- 1. The Unani, Ayurvedic and Homoeopathic Practitioners Act, 1965 (Act no. II of 1965).
- 2. (Amended vide president's ordinance no. IV of 2002 and LXI of 2002 published in the gazette of Pakistan dated 17-01-2002 and 04-10-2002).
- 3. The NCH Code of Ethics.
- 4. SRO 412 related to the Homoeopathic Sector, notified (dated May 2014) by the Drug Regulatory Authority of Pakistan Draft Rules, 2013.
- 5. Minimum Service Delivery Standards (MSDS) for Homoeopathic Clinics, prescribed by KP HCC.
- 6. Charters of rights and responsibilities for both HCEs and patients, developed and notified by KP HCC.

Assessment Scoring Matrix

Standard 5. HRM-1: There is a documented personnel record of homoeopathic doctors and staff.

| | Indicator 13 - 13 | Max Score | Weightage (Percentage) | Score Obtained |
|---------|---|--------------|---------------------------|-------------------|
| Ind 13. | Personal record/credentials in respect of all staff are maintained. | 10 | 100% | |
| | Total | 10 | | |

2.4 Information Management System (IMS)

01 Standards & 02 Indicators

The standard pertaining to information management highlights the fact that patient care is highly dependent upon relevant information. It demands that the work of homoeopathic doctors and staff at the Clinic must be facilitated by timely and accurate information in order to provide coordinated and integrated care. In addition, it is also important to protect the privacy of the data collected and limit unauthorized access.

Medical records serve many purposes but the primary focus is to support patient care. Currently, there is a major drive to shift to computerized electronic medical records (EMR), but without improvement in the quality of paper/manual records, full benefits of computerization are unlikely to be achieved. Cost should not remain a barrier in the computerization of patient records at the clinic. However, this is not binding and the record may be maintained manually. The responsibility for maintaining and improving records lies with individual practitioners. Structuring the record can bring direct benefits to patients by enhancing patient outcomes and improving practitioner's performances.

Standard 6. IMS-1: The patient's clinical record (manual or computerized) is maintained.

Indicators (14-15):

Ind 14. Every patient's record has a unique serial number and particulars for identification

Survey Process:

Check that a system of record keeping (manual or computerized) is in place. At least a register should be maintained in the clinic, with information including unique serial number, date, name, parentage/husband's name, age, sex and (address, CNIC, contact number, if possible), along with symptoms/condition, treatment and referrals (if any). The general patient record should be maintained at the clinic for at least **ONE YEAR**, while records of Medico Legal Cases (MLCs) and vital events must be maintained as per legal requirements, as given at **Annexure D**.

Scoring:

- If the record of patients is maintained as above, then score as <u>fully met.</u>
- If the record of patients is maintained but the information is deficient by about 20%, then score as <u>partially met.</u>
- If no record of patients is maintained or the deficiency is more than 20%, then score as <u>not</u> <u>met.</u>

GUIDELINES

Clinical Records

Although there are a number of standards pertaining to the Information Management System (IMS) prescribed in the MSDS for Hospitals (Category I and Category II HCEs), depending on the nature and types of services provided, only one standard and one indicator has been prescribed as minimum requirement for homoeopathic clinics. However, the entire IMS process, including patient records/instruments, forms and methods of collection and responsibilities are given in detail in this manual for the benefit of homoeopathic practitioners wishing to adopt good practices and those with larger homoeopathic service facilities:

1. Unique serial number and particulars of patient as identifiers

All documents of a patient must be consistently labeled with ONE unique number as an identifier so that it can be verified that documents correspond to a particular patient. A computer/manually generated unique serial number is the easiest and most accurate identification method. The patient's clinical record always becomes a focal point when there are questions regarding the care and treatment rendered. Therefore, it is important that the clinical record be maintained accurately and updated timely. The clinical record serves the following three primary purposes:

i. Provides documentary evidence of the patient's course of illness and treatment.

ii. Ensures quality patient care.

iii. Facilitates review, as and when needed.

The purpose of the clinical record, as it pertains to risk management, is to preserve the truth. In reality, a complete and accurate patient clinical record will protect the legal interests of both the patient and the healthcare service provider. The clinical record, if it exists, will provide justifiable defense, or will indict the responsible party where there is no justifiable defense. Accurate identification of a patient is the most important element in an effective and efficient clinical record keeping system and is needed to identify the patient and to ensure that each patient has only one record number, with one clinical record and no duplicates. In order to identify patients, UNIQUE PATIENT CHARACTERISTICS are required. The type and number of the unique patient characteristics used may change from one setting to the other. Recommended standard features are given here under:

The following are NOT considered permanent characteristics:

- i. Where a person lives is NOT a permanent patient characteristic because it can change.
- ii. A person's age is NOT a permanent patient characteristic because it DOES change.
- iii. 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. Further, while this characteristic is not subject to change, other patients may share the same.

2. SOPs for identification of medical record entries

i. The clinic maintains a list of authorized persons along with details of the documents they can sign. The list also contains their specimen signatures, initials and the stamps they use. Specimens of both initials and full signatures are important for identification of a person as they are used in different situations and in different documents/records. Any professional who, in the execution of his or her professional duties, signs official documents relating to patient care, such as prescriptions, patient records and other reports (excluding death, birth or fitness certificates as these are not allowed to be issued by homoeopathic practitioners, as per the NCH Act), shall do so by signing such a document and clearly writing his/her name, title and the date in block letters and stamping the same. A sample of such an authorization is given in the table below:

| Sr.# | Name/Position | Authorization | Initials | Signature | Stamp |
|------|------------------------|---------------|----------|-----------|-------|
| 1. | Homoeopathic Doctor | | | | |
| 2. | Homoeopathic Dispenser | | | | |
| 3. | Clerk/Assistant | | | | |

Table 1. Identification of Medical Record Entries

- ii. The Clinic must keep this authorization in a file which should be updated as and when new staff/signatories are added, along with a list containing details of the individuals who can and cannot sign.
- iii. In case of a single-man clinic, the homoeopathic doctor may also place his/her specimen

signature, both initials and full signature, on record.

iv. In case computerized records are maintained, the Table of Authority should also reflect the name and designation of person responsible for the same.

3. SOPs for chronology of the documentation

This SOP demands that every time an entry is made in the records, it is dated and timed along with the particulars of the person making the entry.

Recording of date and time starts when a patient enters the clinic and seeks care. The first such record is entered in the register at the reception, when the 'purchi'/slip is issued for consulting a doctor. Then, the attending doctor who examines the patient, prescribes medicines/remedies or refers the patient to a dispensary, putting the date and time along with his/her signature on the slip. The homoeopathic dispenser must also sign and put the date after issuing the medicines/remedies.

Recording accurate date and time in the record is an important proof of required action having been taken on time. It is a valuable source of data and an evidence for cost and resource management besides being helpful for coding and health research.

4. Up-to-date chronological record

Information recorded during or immediately after the occurrence of an event or provision of care, is more reliable and accurate record of care rendered than information recorded later on the basis of memory. Chronological entries present a clear picture of the sequence of care provided and lists the events over time besides facilitating better communication amongst the care providers and patients. Late entries should be appropriately recorded as soon as possible and duly endorsed by the homoeopathic doctor (in case of a single-man clinic) or the person authorized to do so.

Minimum Requirements for Patients' Clinical Records

A patient's clinical record shall contain at least the following:

- 1. The unique identifying number of the patient.
- 2. Name, address, date of birth, sex and person to be informed in case of an emergency.
- 3. Symptoms, history and condition of the patient.
- 4. Signature of the treating homoeopathic doctor.
- 5. The date and time of the current visit.

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 |
|--------|------|------|-------|------|------|-----|-----|--------|-----|------|---------|-------|---------|-----------|
| Unique | Date | Time | Visit | Name | %age | Age | Sex | Weight | Ph. | Add. | Allergy | S/H/C | Finding | Treatment |
| ID | | | No. | | | | | | | | | | | |
| | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | |

Table 2. Patient's Clinical Record Template

SOPs for Referral of Patients:

In case of a decision to refer a patient to another hospital, written communication is to be sent from the referring clinic, while a copy of the same is to be retained in the patient's record. If the patient is transferred at his/her own request, a note to that effect should be added in the patient's record mentioning the name of the hospital where the patient desires to be shifted. The care/treatment carried out during patient transfer must be documented.

Death Record

In case of death of a patient at the clinic, preliminary details of circumstances leading to the death of patient, like primary and secondary cause of death, along with date and time should be documented on a death register separately maintained for this purpose. However, the homoeopathic doctor must refer the patient to a nearby hospital/healthcare service provider authorized to certify the death of a patient or otherwise as the case may be.

Note: As per the UAH Act of 1965, no homoeopathic doctor is allowed to issue a death certificate.

Ind 15. The clinic has designated a person to maintain records.

Survey Process:

Review patients' records to see that entries are made by authorized persons only, who can be identified.¹⁶

Scoring:

- If all the entries are made by authorized persons as above, then score as <u>fully met.</u>
- If all entries are not made by authorized persons, then score as <u>not met.</u>

GUIDELINES

Responsibility for Designation

The management of the homoeopathic clinic is responsible to designate and authorize, in writing, a person who shall maintain the records, especially updating entries related to patient care, dispensing, stocks of medicines/remedies, clinic staff, other legal documents etc.

¹⁶ Authorized person means a homoeopathic doctor, an assistant or a dispenser authorized by the owner/manager/practitioner. A homoeopathic practitioner owning the clinic can authorize himself for any permissible/required action in this regard.

Assessment Scoring Matrix

Standard 6. IMS-1: The patient's clinical record (manual or computerized) is maintained.

| | Indicator 14 - 15 | Max Score | Weightage (Percentage) | Score Obtained |
|---------|---|--------------|---------------------------|-------------------|
| Ind 14. | Every patient's record has a unique serial number and particulars for identification. | 10 | 80% | |
| Ind 15. | The clinic has designated a person to maintain records. | 10 | 100% | |
| | Total | 20 | | |

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

01 Standard & 01 Indicator

Quality Assurance (QA) is used in the context of the manufacturing industry more extensively than in that of healthcare service delivery systems. However, the underlying principles of medicine are in fact quite closely linked to the principles of QA. The Quality Control for efficacy and safety of homoeopathic products is of paramount importance for providing the standard remedies to the patients. In this document, the quality assurance mainly pertains to delivery of care and processes at the level of homoeopathic clinic.

These standards relating to quality assurance/improvement, mainly focus on a systematic approach of using data to measure, assess and improve current performance of the services provided at the clinic. The continuous process focuses on outcomes of care, and must include reducing actual and potential risks to patient safety. The standards emphasize on the processes, systems and individual behaviors that reduce the likelihood of unanticipated adverse events. Homoeopathic doctors must ensure QA at all stages of patient care. It can help design patient care processes, identify the data necessary to measure performance, analyze this data, and suggest and implement the process improvements.

For homoeopathic clinics, the requirement has been simplified to the extent of just maintaining a list of sentinel events/incidents which can possibly occur, or have occurred. The sentinel events are required to be investigated and corrective/preventive measures to be adopted to obviate recurrence.

Standard 7. QA-1: Sentinel events are assessed and managed.

Indicators (16-16):

Ind 16. The clinic has enlisted the sentinel events to be assessed and managed.

Survey Process:

Check for a list of possible sentinel events and the record of any sentinel event which was assessed and managed in the last 12 months, with its results used for quality assurance/improvement.

Scoring:

- If there is a list of possible sentinel events and evidence of a sentinel event being assessed and managed as above, OR if there is no evidence of a sentinel event, but a system is in place to manage it, then score as <u>fully met.</u>
- If there is no system in place to manage a sentinel event, then score as <u>not met.</u>

GUIDELINES

Sentinel Events

Quality assurance and improvement is one of the most important and critical standards for any HCE, irrespective of its size or scope of services. However, in case of single-man homoeopathic clinics only one standard and one indicator has been prescribed.

It is essential for the person in charge, owner or manager of the homoeopathic clinic to have a better understanding of the QA program and plan. The most suitable standard for application at homoeopathic clinics is the analysis and management of sentinel events. A brief definition of a sentinel event and its assessment and management process are given below:

Definition

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. The phrase, 'or risk thereof' includes any recurring process variations that carry a significant chance of serious adverse outcomes. Such events are called 'SENTINEL' because they signal the need for immediate investigation and response. Medication errors, while significant and deserving attention, aren't the only type of medical errors the clinic needs to pay attention to. Most of the medical mistakes are preventable.

In the homoeopathic clinic, the agreed understanding of a sentinel event is:

"Unforeseen events like severe drug aggravation, wrong prescription, wrong patient, patient violence against clinic staff and violence against patients"

The homoeopathic clinic has to put monitoring procedures in place, as part of an action plan to detect these events and determine a procedure for (i) analyzing the root cause, (ii) taking appropriate corrective action and (iii) maintaining a record.

1. Analysis of Sentinel Events

Homoeopathic practitioners are expected to identify and appropriately respond to all sentinel events occurring in the clinic or associated with the services provided at their clinics. Appropriate response includes conducting a timely, thorough and credible analysis; developing an action plan designed to implement improvements to reduce risk of recurrence, implementing the improvements and monitoring the effectiveness of the improvements.

2. Root Cause Analysis

Root cause analysis is a process for identifying the factors that underlie variation in performance, including the occurrence or possible occurrence of a sentinel event and focuses primarily on systems and processes, not on individual performances. The analysis ranges from extraordinary discrepancies in clinical processes to common deviations from organizational processes and systems and identifies potential improvements in these processes or systems to decrease the likelihood of such events in the future.

3. Maintaining Record

Keeping the record of all sentinel events includes recording results of root cause analyses and maintaining the same at the clinic preferably using a standard format.

4. Preventive and Corrective Action Plan:

The outcome of the root cause analysis is an action plan that measures the methods which the clinic intends to employ in order to reduce the risk of the occurrence of similar events in the future. The plan should address responsibilities for pilot testing, implementation and supervision and include appropriate time lines and tools for measuring the effectiveness of the actions.

Assessment Scoring Matrix

Standard 7. QA-1: Sentinel events are assessed and managed.

| | Indicator 16 – 16 | Max Score | Weightage (Percentage) | Score Obtained |
|---------|---|--------------|---------------------------|-------------------|
| Ind 16. | 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)

02 Standards & 03 Indicators

The care provided at the homoeopathic clinics should be a part of an integrated system of services delivered by qualified homoeopathic practitioners, and make up a continuum of care. The objective is to correctly match the patient's healthcare needs with the services offered, and would include coordination of services provided to the patient at the clinic, follow up for subsequent care and referring the patient to an appropriate HCE for the care which is out of the scope of the homoeopathic clinic. Such an integration of services would result in improved patient care, efficient use of available resources and better treatment outcomes.

Standard 8. AAC-1: Portrayed¹⁷ service(s) conform to the legal provisions

Indicators (17-17):

Ind 17. Only the homoeopathic services being provided at the clinic are displayed.

Survey Process:

This will require displaying the scope of services provided at the homoeopathic clinic. It means that there should be a board clearly displaying the services being provided at the homoeopathic clinic, e.g. "Homoeopathic System of Treatment Only."

Scoring:

- If the displayed services are being provided, then score as <u>fully met.</u>
- If there is superfluous/misleading information or no information is displayed, then score as <u>not</u> <u>met.</u>

GUIDELINES

Portrayal of Services

In the field of homoeopathy, services are provided to patients in line with the homoeopathic principles of treatment and therapeutics on the basis of symptomatology.

It is important that homoeopathic practitioners provide services to their patients according to their legitimate knowledge and skills, and the scope of services they are authorized to deliver on the basis of the terms of registration with the NCH, Pakistan. This will require clearly displaying the scope and nature of services provided at the homoeopathic clinic through the words "Homoeopathic System of Treatment Only.¹⁸

¹⁷ Code of Ethics adopted by the NCH for Homoeopathic Practitioners in general refers to portrayal of services.

¹⁸ Provision VI (a), Code of Ethics for Homoeopathic Practitioners by NCH does not allow display of unauthorized qualifications. Section 38 & 39 of the UAH Practitioners Act II of 1965 are also relevant.

Assessment Scoring Matrix

Standard 8. AAC-1: Portrayed service/s conform to the legal provisions

| | Indicator 17 - 17 | Max Score | Weightage (Percentage) | Score Obtained |
|---------|--|--------------|---------------------------|-------------------|
| Ind 17. | Only the homoeopathic services being provided at the clinic are displayed. | 10 | 100% | |
| | Total | 10 | | |

Standard 9. AAC-2: The clinic has a well-established patient management system.

Indicators (18-19):

Ind 18. The clinic has an established registration and guidance process.¹⁹

Survey Process:

Observe and review the record to check that a reception, registration and guidance²⁰ system is practiced, to facilitate the patient. Patients must be able to comfortably access the reception/reception staff, get themselves registered and obtain the parchi/token/token number/time. The reception staff must be polite and may guide patients to wait for their turn/time for consultation/examination by the homoeopathic doctor.

Scoring:

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

GUIDELINES

Registration and Guidance

This standard and indicator requires that a reception, registration and guidance process, supported by written SOPs/guidelines/checklists, should exist to match the needs of the patients. There shall also be a record depicting that these SOPs/procedures are being followed. Whether the reception, registration and guidance system is in place to facilitate and guide patients will be evident from the registers, sign boards, directional arrows signs and printed/handwritten chart(s). The essentials of the process include, but are not limited to, the following:

- 1. Patients can comfortably access the reception desk and get registered without facing problems.
- 2. The staff at the reception desk is polite and courteous.
- 3. The staff at the reception desk take down initial patient data as registration and every new patient is allotted a unique ID number on the prescription form or slip and asked to wait for their turn for consultation.
- 4. For patients coming for follow up visit/s, the reception staff verifies and retrieves their previous record from the computer or the register to entertain them as old patients.
- 5. The staff guides the patients to the homoeopathic doctor's consultation room for examination/ assessment and further management.
- 6. Once seen by the homoeopathic doctor, patients may be guided to proceed to the dispensary

¹⁹ Applicable for homoeopathic clinics where prior appointments may be necessary/desirable e.g. polyclinics.

²⁰Direction/guidance to patients regarding further actions in connection with their health needs and management i.e. consultation, dispensing, referral etc. The homoeopathic doctor himself/herself or the qualified and authorized assistant must explain the processes involved in safety/infection control etc. This requirement has to be included in the JDs of all relevant staff.

to present their prescription and collect the medicine/remedy.

7. In case no formal reception desk is available at the clinic due to less workload, the above functions shall be performed by the Homoeopathic doctor himself/herself or by the clinic assistant/dispenser.

Ind 19. Standard/Ethical practice is evident from patients' treatment records.

Survey Process:

Review the records to check if patients are assessed by the homoeopathic doctor by history taking, physical examination and documenting the related signs, symptoms, conditions and relevant evaluations²¹ (where applicable), with the objective of providing quality care/treatment or referral within or outside the facility, according to the prescribed Code of Ethics.²² Check for documentary evidence of assessment, treatment and/or referral,²³ as the case may be, by reviewing a representative sample of patient records, which can be a register/copy of prescriptions and/or an elaborate record depending on the extent of the practice.

Scoring:

- If all checked patient records have documentation of patients' assessments and disposal according to the above, then score as <u>fully met.</u>
- If less than 20% of the above record is deficient, then score as partially met.
- If the above record shows more than 20% deficiency, then score as <u>not met.</u>

GUIDELINES

Ethical Practices

As per the academic and professional training of homoeopathic doctors (DHMS or BHMS) and their code of ethics, it is expected that homoeopathic doctors assess patients by documenting signs, symptoms and relevant evaluations (where applicable), with the objective of providing quality care/treatment or referral within the facility or outside the facility. Statement of Ethics is given at **Annexure E**.

For this purpose, details regarding patient assessment, clinical management and the disposal process are given below:

Homoeopathic Methodology

Complete symptomatology gives the Homoeopathic Practitioner a comprehensive understanding of the patient's personality; the mechanism of the production of both objective and subjective

²¹ Clinical methodology to be adopted while examining the patients.

²² Code of Ethics published by the NCH.

²³ The practitioner is required to refer all those patients to appropriate HCE who cannot, or should not, be managed at his/her clinic due to the nature of their ailment or an emergency. This involves critical judgment and an ethical decision by the homoeopathic doctor. Check whether records of patients referred in the past 12 months are available at the clinic, with details such as serial number, name/son/daughter of/wife of/, address, contact no., symptoms, reasons for referral, date and time of referral, place of referral, etc.

symptoms and the induced systemic disturbances. Prescriptions in homoeopathy are determined by the detailed study of symptomatology.

Tools:

The clinical record must contain the following:

- 1. History (in the patient's own words) and the intensity of symptoms, indicated in numerals e.g. burning, itching, numbness).
- 2. Additional symptomatology from interrogation and evaluation.
- 3. General line of treatment.
- 4. First prescription.
- 5. Follow up notes, prescriptions and instructions.

Assessment Scoring Matrix

Standard 9. AAC-2: The Clinic has a well-established Patient Management System.

| | Indicator 18 - 19 | Max Score | Weightage (Percentage) | Score Obtained |
|---------|--|--------------|---------------------------|-------------------|
| Ind 18. | The clinic has an established registration and guidance process. | 10 | 100% | |
| Ind 19. | Standard/Ethical practice is evident from patients' treatment records. | 10 | 80% | |
| | Total | 20 | | |

2.7 Care of Patients (COP)

01 Standards & 01 Indicators

The process of patient care includes planning care, providing care, evaluating the patient's response and planning follow-up treatment. Care provided at homoeopathic clinics may involve different processes. Provision of excellent healthcare is the overarching goal of this standard.

Standard 10. COP-1. Emergency services are guided by policies and procedures.

Indicators (20-20):

Ind 20. The homoeopathic clinic has essential arrangements to cater for emergency care.

Survey Process:

Check for a list of emergencies the clinic claims to manage and the availability of the required emergency remedies.²⁴

Scoring:

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

GUIDELINES

Essential Emergency Arrangements

Policies and procedures to deal with emergencies have to be tailored according to homoeopathic principles of treatment. The emergencies would pertain to medical ailments either reporting to the clinic as such or developing such symptoms while present at the clinic. There are two major courses of action based on an accurate and ethical judgment/decision by the homoeopathic doctor: (1) treat the patient or (2) refer them to an appropriate HCE.

It is essential for all homoeopathic doctors/practitioners to use their homoeopathic acumen to identify the ailments which can be easily and safely treated by them at their clinics. Some of the conditions which require immediate attention and provision of supportive care / first aid treatment include the following:

- 1. Respiratory distress.
- 2. Anaphylactic shock.
- 3. Snake bite.
- 4. Bleeding.
- 5. Splinting the fractures.
- 6. Pain management.

Arrangements to manage at least one patient each, with the above conditions at a time are required to be there. The initial treatment for stabilizing the patient with above conditions may be followed by referral to an appropriate HCE.

Some of the conditions which can be managed at homoeopathic clinics include the following:

²⁴ List of Standard First Aid remedies guidelines/SOPs and a list of the types of emergencies that the homoeopathic practitioner may be able to manage. Arrangements to manage 1. Respiratory distress, 2. Anaphylactic shock, 3. Control of bleeding and 4. Splinting of fractures of at least one patient at a time should be available at the clinic.

- 1. Colds, flu and sore throat.
- 2. Effects of fear and fright.
- 3. Chicken pox and croup.
- 4. Burning and stinging pains, insect stings, and swelling of the lower eyelids, edema, and swollen joints after injury.
- 5. Mental and physical shock.
- 6. Control of bleeding, healing of wounds, bruising and swelling.
- 7. Shock, exhaustion, muscular pain and sprains.
- 8. Stomach upsets, food poisoning, diarrhea and vomiting.
- 9. Acute hay fever.
- 10. Some dry skin conditions.
- 11. Flushing of face and facial neuralgia.
- 12. Throbbing headache and earache.
- 13. Boils, chickenpox, measles and mumps.
- 14. Dry coughs.
- 15. Burns and scalds before the formation of blisters, and sunburn.
- 16. Constant urge to pass urine and dribbling of urine.

Any of the above conditions that do not respond to homoeopathic medication would require a referral to an appropriate HCE.

The Homoeopathic emergency remedies alone are not to be considered a substitute for seeking emergency care from a hospital.

Guidelines for Treatment of Emergencies in Homoeopathic Clinics

- When a patient comes to a homoeopathic clinic in an emergency condition, preference should be given to treatment/referral instead of documentation. The patient's particulars, name of person who brought them to the clinic, time of receiving the patient etc. are to be recorded after the emergency has been dealt with.
- 2. After providing first aid treatment to the emergency patient, medicines should be noted on a register. If the patient does not improve, he/she should be referred to an appropriate HCE by calling an ambulance/rescue service, as the case may be, for transportation. Time of referral of patient and HCE referred to should be recorded. If the patient improves with the treatment at the clinic, the time of discharge should be recorded.
- 3. If the patient comes in with a surgical emergency, like an injury, it may be managed with first aid procedures, e.g. supporting or pressure bandaging, cardio-pulmonary resuscitation (CPR) etc.
- 4. The clinic staff should explain the condition of the patient to the relatives/attendants accompanying the patient. In case the patient is brought in by others, the family, relatives or friends of the patient are to be contacted to inform them regarding the patient's emergency.
- 5. The referral data should contain the following:
 - i. Patient's name.

- ii. Unique identification number.
- iii. Date and time the patient was attended.
- iv. Significant findings.
- v. Symptoms.
- vi. Patient's condition on referral.
- vii. First aid support provided.
- viii. Medication administered.
- ix. Follow up advice and other instructions deemed necessary.

List of Referral Situations:

- i. Patient with serious injury, particularly head injury.
- ii. Patient with profound bleeding.
- iii. Patient with suspected heart attack.
- iv. Patient in severe unrecognizable pain.
- v. Patient with severe vomiting and diarrhea (dehydration).
- vi. Patient with high grade fever.
- vii. Patient with pregnancy related complaints
- viii. Patient in shock due to electrocution.
- ix. Patient with burns.
- x. Patient with snake bite.
- xi. Insect bite.

Homoeopathic clinics are required to prepare and keep a list of emergency situations, extracted from the above-mentioned conditions, which can be dealt with at the clinic.

Records of all referred patients, with details such as serial number, name, son of, daughter of, wife of, address, contact no., symptoms/condition, reasons for referral, date and time of referral, place of referral etc. should be available at the clinic.

For evidence, review the record of up to 10 patients referred in past 12 months, or from the date of dissemination, whichever is earlier.

Assessment Scoring Matrix

Standard 10. COP-1: Emergency services are guided by policies and procedures.

| | Indicator 20 - 20 | Max Score | Weightage (Percentage) | Score Obtained |
|---------|---|--------------|---------------------------|-------------------|
| Ind 20. | The homoeopathic clinic has essential arrangements to cater for emergency care. | 10 | 100% | |
| | Total | 10 | | |

2.8 Management of Medication (MOM)

02 Standards & 07 Indicators

Medication errors are one of the most common healthcare issues, presenting a number of preventable drug-related problems a patient could face. Medication (remedy) related errors are also amongst the most frequently reported types of adverse events. Management of medication helps homoeopathic practitioners support patient safety and improve the quality of care by creating a system for selecting, procuring, storing, ordering, transcribing, preparing, labelling, dispensing, administering and monitoring medications (remedies). These standards are designed to reduce errors, misusage and variations in practice; encourage better monitoring; improve the quality and safety of medication (remedy) management processes; promote the use of evidence-based good practices and standardize processes at homoeopathic clinics.

Standard 11. MOM-1: Prescribing practices conform to the standards

Indicators (21-23):

Ind 21. Standards for prescription writing are followed

Survey Process:

Check that prescriptions are written according to the prescribed format and contain information such as serial number, name of patient, son of, daughter of, wife of, age, sex, date of visit(s), symptoms and instructions regarding dosage/duration of use are clear.

Scoring:

- If prescriptions are written as per the above instructions, then score as <u>fully met.</u>
- If prescriptions are not written as per the above instructions, then score as <u>not met.</u>

GUIDELINES

Prescription Writing

A prescription is one of the most important elements of patient care and safety, but procedures of writing prescriptions vary from practitioner to practitioner, clinic to clinic and across disciplines of treatment. This standard and its related indicators provide guidelines with the minimum requirements that homoeopathic practitioners must follow while writing prescriptions²⁵. These include form used²⁶ and details of record to be maintained such as serial number, name of patient, s/o, d/o, w/o, age, sex, date of visit(s), symptoms and remedies prescribed. Instructions for use, with duration, should also be clearly mentioned. A description of a homoeopathic prescription and the information it should contain is given below to help the homoeopathic clinic staff/dispenser to dispense the remedies.

Homoeopathic Prescription²⁷

'Prescription' is derived from the Latin word 'prescripto' (pre: before, scripto: write). Prescription is a written document (order) given by a practitioner to the patients/dispenser for the preparation of the required medication/remedy and contains instructions regarding the use of the remedies for a particular patient at a particular time. The homoeopathic practitioner may choose to dispense the medication himself, instead of getting it done by a trained and authorized person/homoeopathic dispenser, but the patient has to be provided the prescription and the record thereof must be maintained.

A homoeopathic prescription is an instrument used by the practitioner, dispenser and patient. The

²⁵ Provisions V, VI (g)(3) of the Code of Ethics for Homoeopathic Practitioners (use of only homoeopathic pharmacopeia and NO secret wording).

²⁶ A sample of a prescription slip/form is provided at the end of this description.

²⁷ Extract from an article by Sumit Goel at http://www.homeoresearch.com/2010/09/homoeopathic-prescription.html

homoeopathic doctor writes the prescription, the dispenser dispenses the medication/remedy according to the prescription and the patient uses the prescribed medication/remedy as per the instructions given in the prescription.

The generally prevailing practice among homoeopathic doctors is to write the medications on a small chit (parchi) used for dispensing purposes by the dispensers. The medication/remedy is dispensed to the patient in a small plastic bottle, either in the form of tablets or a liquid, or wrapped in a small piece of paper, with little or NO information regarding the name, date, frequency of use, etc. The prescription or dispensed medication remedies only have code numbers on them. In order to change this practice for improving the quality of care and better record keeping, a standard procedure is being presented.

Prescription Writing Guidelines

- Prescriptions must always be written in a definite pattern, following a standard and universal arrangement, to ensure uniformity. It should be legible and neatly written without any coding, so as to be easily interpreted.
- The information should be complete, accurate and unambiguous.
- The homoeopathic doctor should avoid prescribing inimical homoeopathic medicines/remedies, as well as those medications that are not homoeopathic.
- Prescriptions may be written in simple form.

Figure 4. Prescription Writing Guidelines

Form of the Prescription

Prescriptions are usually written on printed forms, with the name, address, telephone number, registration number and other relevant information printed on them. A standard prescription must contain the following information, in a definitive order:

- Superscription includes patient related information, such as the name age, sex and address of the patient. Full name and address of the patient is necessary on the prescription for identification purposes. The physician should always place it at the top of the prescription and the name of the patient should be copied on to the label, by the dispenser, for identification purposes. It would then possible to identify or contact the patient with the help of the address, in case of an emergency.
- 2. Inscription *Rx is the body of the prescription which includes the name of the medicine/remedy, its potency and quantity. This is the actual treatment decided by the homoeopathic doctor for the patient. The name of the remedy, along with its potency, is written in this part of the prescription. The quantity of the medication/remedy, as well as its form, is also noted.



* The symbol 'Rx' was originally employed as the sign of Jupiter in the days when medicine was thought to be under astrological influence. Gradual distortion through the years has led to the symbol's current use. It is now used as an abbreviation for the Latin word 'recipe', i.e. receive. Similarly, French prescriptions contain the superscription 'P' as an abbreviation of 'prenez'.

- 3. Subscription includes instructions and directions for the dispenser regarding the mode of preparation, the dosage, the form of the medication prescribed by the practitioner and the vehicle for dispensing of the medication.
- 4. Instruction includes directions to the patient. In this portion of the prescription, the prescriber writes directions for the use of the medication/remedy by the patient. This should be short, simple, comprehensible and complete and must include:
 - i. How to take the medicine/remedy, the route of administration and the time of administration/ intake
 - ii. When to report back
 - iii. Advice regarding diet and regimen to be followed
 - iv. Any other instructions or caution to the patient

The dispenser must also transfer these directions onto the label of the container of the dispensed medication/remedy.

- 5. The signature of the homoeopathic doctor, along with his/her NCH registration number, is essential as this makes the prescription valid and authentic. In cases where name and NCH registration number of the homoeopathic doctor is printed on the prescription pad/slip, signatures only will be deemed sufficient.
- 6. Date and time must be mentioned on the prescription when it is written and again, when it is received and dispensed at the pharmacy. The date is important in establishing the record of the patient and helps the pharmacist to detect cases where prescriptions were brought in for dispensing, a long time after they were issued. A lapse of time should be questioned and it should be determined whether the needs of the patient can still be met.

| HOMOEOPATHIC CLINIC xxx | | |
|--|---------------|--|
| | Ph: | Homoeopathic Dr. X.Y. DHM NCH Reg. No.010 : 0423-0000000 Cell: 0300-00000 |
| Ref. No. (Unique Identifier) Time Patient Name: Age:Sex:Weight (kg) Co | S/o, D/o, W/o | |
| | | |
| Address: | | |
| Allergies: Symptoms: Findings: | | |
| Allergies: | | |

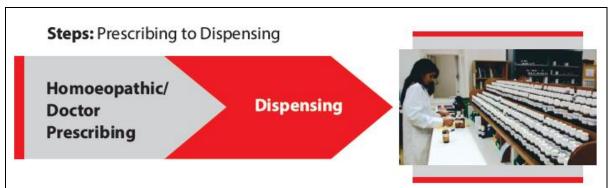


Figure 5. Steps: Prescribing to Dispensing

Dispensing takes place at the homoeopathic clinic's pharmacy, where the homoeopathic doctor himself, or the dispenser, interprets the prescription and delivers the medicine/remedy to the patient. The doctor may do so himself or may give written instructions to the dispenser. The prescription order is part of the professional relationship between the prescriber, dispenser and the patient. It is the responsibility of the dispenser to provide the medication/remedy to the patient and to maintain the trust of both the prescriber and the patient, including maintenance of confidentiality. Medicines being taken by a patient and the nature of his/her illness is a private matter, which must be respected and kept confidential.

Processing the prescription order: dispensing the medication/remedy

A strict dispensing routine is essential to ensure safety, speed, neatness and efficiency. Proper procedures include reading, checking, putting number and date, preparing, labelling, packaging, rechecking, delivering and guiding, recording, filing and pricing the prescriptions.

1. Checking the prescription

The prescription order should be read completely and carefully. There should be no doubt as to the nature and quantity of the prescription. If something is illegible or confusing or if there appears an error, the prescriber should be consulted. The dispenser should never attempt to guess, making it essential to take every precaution so as to eliminate mistakes in interpreting the prescription. It is the responsibility of the pharmacist to detect prescriptions that have been forged by the patient.

2. Putting number and date

It is advisable to number and date the prescription order and place the same on the label. This serves to identify the prescription for future reference.

3. Labeling

A prescription should have an aesthetic and professional-appearing label, the size of which should be in conformance with the size of the container. Prepare the labels, 'for internal use' and 'for external use only' properly and distinctly. A separate label should be made for each medication/remedy.

4. Preparation of remedies as per the prescription

This requires adequate care and precaution by the dispenser, who must always carry the prescription along while dispensing the remedies in the dispensary. It serves as a constant

reminder of the name and potency of the medicine/remedy and helps avoid mistakes.

5. Rechecking

Every prescription should be rechecked and details on labels must be verified against the prescription order to crosscheck the minutest details. Before handing over the medications/remedies to the patient, the dispenser must crosscheck again to ensure that the correct preparation for the correct patient has been provided and correct directions have been stated on the label.

6. Delivering and patient counseling

When presenting the medication/remedy to the patient, the dispenser should draw attention to any auxiliary labeling instructions. It is advisable for the dispenser to reinforce the directions to the patient while dispensing the medication/remedy. Written directions outlining the proper use of the prescribed medication/remedy should be provided. In most homoeopathic clinics, it is a routine practice to place the medicine/remedy in a small paper/plastic envelope and/or a 'Purria' and label it with the numbers 1, 2, 3 etc. signifying 'morning or day 1, afternoon or day 2, evening/night or day 3' and so on. Color coding is also used to guide illiterate patients regarding medication administration times.

7. Recording and filing

Proper filing of the copies of prescriptions is to be carried out for maintaining records, as well as reference and research.

8. Pricing and receipt preparation

The prescription is ultimately priced and a receipt is delivered, if required by the patient, to complete the process.

Ind 22. Record of prescriptions is available at the clinic.

Survey Process:

Review the process whereby the record of the prescriptions is maintained. The record can either be a register, a carbon copy of the prescription or both.

Scoring:

- If a clinic maintains record of prescriptions and also provides prescription slips to all patients, then score as <u>fully met.</u>
- If a clinic maintains record of prescriptions and provides prescription slips to 80% or more patients, then score as <u>partially met.</u>
- If a clinic does not maintain record of prescriptions and or does not provide prescription slips to patients in more than 20% of the cases, then score as <u>not met.</u>

GUIDELINES

Prescription Record Keeping

As per current practice, the majority of homoeopathic prescriptions are written on a small paper

chit/slip ('purchi'). Generally, it has only three types of data: (i) name, (ii) date seen or date of follow up visit (iii) medicines/remedies prescribed, abbreviated or using roman numbers as identification of remedy, with potency. These chits/slips are stacked as monthly record and then further stacked at the end of the year. These records are either kept with the dispenser (if the clinic has one) or with the homoeopathic doctor.

For retrieval, the patient has to recall the prescription visit date, or bring his empty bottle or pouch marked with the date and name, to locate his 'prescription slip'. Mostly, homoeopathic doctors rely on memory and the remedy prescription to identify the previous line of treatment. Following SOPs for maintaining the Manual Prescription record is recommended and the dispenser (if available) or homoeopathic doctor shall keep a record of the copies of prescriptions, containing following information:

- 1. Patient Unique ID.
- 2. Date/time of first visit and/or subsequent visits.
- 3. Name of the patient.
- 4. Age and sex.
- 5. Brief Address and contact no.
- 6. Symptoms.
- 7. Treatment; Medication/remedy prescribed.
- 8. Signature with date.

If this record is transferred to the permanent register, then all above details are to be maintained in the record and signed/countersigned by the authorized person. The register or carbon copies of the prescriptions are either kept with the dispenser or the homoeopathic doctor, as per the decision of the owner or manager of the homoeopathic clinic. This procedure of record keeping shall replace the conventional/previously followed procedure of stacking of slips (Purchis).

SOPs for Computerized Record Keeping:

Homoeopathic clinics with computers, or those that can afford this facility, should ensure that all above- mentioned information is computerized and printed copies of prescriptions are provided to patients for their record and follow up visits.

Ind 23. Only the person(s) authorized by law write the prescription.

Survey Process:

There should be a record that identifies person(s) who write prescription slips or writes in a medical record register. The name and designation of the person writing prescriptions must be mentioned in pen, or by stamp, on the prescription slip and/or patient record and must be identifiable/traceable.²⁸

Scoring:

- If the person writing the prescriptions or making entry in the patient records can be identified by name and designation in the records checked, then score as <u>fully met.</u>
- If the person writing the prescriptions or making entries in the patient records can be identified

²⁸ Homoeopathic doctor himself in case of single person clinic. "The person responsible to prescribe medications/remedies should advise the proper use of medication/remedies, dosage, etc." and use stamp under signatures.

as above in 80% of the records checked, then score as partially met.

If the person writing the prescriptions or making entries in the patient records can be identified as above in less than 80% of the records checked, then score <u>not met.</u>

GUIDELINES

Authorization to Write Prescriptions

In a common homoeopathic clinic setting, the system of patient prescription and record keeping is currently not standardized. It varies according to the convenience of individual homoeopathic practitioners, or by persons managing homoeopathic stores, whether inside the clinic or outside. There should be a record identifying persons who write prescription slips or write in registers/patient records, ensuring that only authorized persons are writing. This may be the homoeopathic doctor himself, in a single-man setting, or another practitioner legally permitted to do the same. Name and designation of the person writing prescriptions must be mentioned in pen or by stamp on the prescription slip and/or patient record and must be identifiable/traceable.²⁹ A sample prescription slip is provided in the guidelines for Indicator 21.

²⁹ Homoeopathic doctor himself in case of a single-person clinic.

Assessment Scoring Matrix

Standard 11. MOM-1: Prescribing practices conform to the standards

| | Indicator 21 - 23 | Max Score | Weightage (Percentage) | Score Obtained |
|---------|--|--------------|---------------------------|-------------------|
| Ind 21. | Standards for prescription writing are followed. | 10 | 100% | |
| Ind 22. | A record of prescriptions is available at the clinic. | 10 | 80% | |
| Ind 23. | Only the person(s) authorized by law write the prescription. | 10 | 80% | |
| | Total | 30 | | |

Standard 12. MOM-2: Procedures guide the safe storage and dispensing of medications (remedies).

Indicators (24-27):

Ind 24. Remedies are stored as per guidelines for safe storage.

Survey Process:

The guidelines for safe storage include, inter alia, i. proper stacking in groups to differentiate common remedies/medication (tablet, powder, drops, etc.), look-alike and sound-alike remedies within the rack/cupboard; ii. labelling; iii. ventilation; iv. temperature control; v. protection of high-risk drugs/ingredients and vi. record of expiry dates (as applicable). The permissibility of sale of medicines and or appliances or equipment etc. shall be governed by the relevant law.

Scoring:

- If the remedies are stored as per above referred guidelines, then score as <u>fully met.</u>
- If only the implementation of i. or iii. is inconsistent, then score as partially met.
- If the implementation of either of ii. iv., v. or vi. is inconsistent, then score as <u>not met.</u>

GUIDELINES

Safe Storage and Care of Remedies- Procedures and Precautions

Special handling and safe storage of homoeopathic medicines are needed in order to avoid possible contamination. Since it is very difficult to determine if the medicines have been contaminated, the following precautions should be taken to prevent potential problems:

- 1. The medicines should be kept away from direct sunlight, higher temperatures and exposure to strong odors like camphor, menthol, mothballs, or perfumes.
- 2. The medicines should always be kept in the container in which they were supplied and never be transferred to any other bottle which previously contained other substances.
- 3. During administration of the medicines, containers should be opened for the minimum possible time.
- 4. One should be careful not to contaminate the cap or cork before replacement.
- 5. If a larger number of pills, than those specified in the prescribed dose, are taken out of the bottle, these should not be returned to the container and the excess number should be discarded to avoid possible contamination.
- 6. Homoeopathic remedies are light sensitive and are always supplied in amber, light-resistant containers. The range of homoeopathic remedies is also supplied in boxed packaging, which provides additional light protection, besides enabling the provision of additional information for consumers. For maximum protection, homoeopathic remedies should always be left in their original containers and packaging.³⁰

Homoeopathic remedies should be stored at an appropriate temperature and additional

³⁰ "How to store homoeopathic remedies," Naturo Pharm Limited, PO Box 952, Rotorua, New Zealand.

precautions should be taken to avoid exposure to excessive heat. Remedies should not, therefore, be kept in the glove box of a motor vehicle or in direct sunlight.

SOPs for Safe Storage/Administration of Remedies

- ✓ Keep in properly designed wooden, steel or glass cabinets in an orderly way.
- ✓ Keep the storage area clean and dry.
- ✓ Avoid exposure to SUN LIGHT.
- ✓ Keep at room temperature and DO NOT refrigerate.
- ✓ Use clear and clean bottles for dispensing to avoid contamination.
- ✓ Use the cap to pour the tablets in to the mouth while administering. Do not touch with hands, unless they are clean.

Homoeopathic remedies should not undergo pro-longed exposure to sunlight because of the possibility of degradation. Amber bottles are, therefore, used for storage to limit exposure to light. Experience has shown that exposure to high magnetic fields may interfere with a remedy's therapeutic effect. Do not place homoeopathic remedies on, or near, a television or microwave. The most important warning, however, is to avoid exposing homoeopathic remedies/medications to strong smelling substances (such as perfume, nail polish and liniments etc), as these may be inactivated if contaminated in this way. As bathroom cupboards are commonly used to store a variety of household medicines, as well as strong smelling cosmetics, homoeopathic remedies should be stored in a cool place away from other substances. Homoeopathic remedies have an excellent safety record. However, all medicines, whether allopathic, homoeopathic or complementary, should be kept under lock and key and well out of the reach of children.

Remedies should not be stored in a damp place or the refrigerator. Moisture will melt these into a glob, making it difficult to extract them from the bottle. Besides, if water entered the medicine living organisms present in water might contaminate the remedy, making it harmful for the patient. It is recommended that homoeopathic remedies should not be placed near a microwave, refrigerator, electric blanket, cell phone and other places where ambient energies are likely to be around.³¹ If remedies appear not working, it should be noted if they have been exposed to these energies for a long period, in which case replacements should be ordered.

Matching the Order/Prescription of Remedies:

This aspect is primarily linked with safe remedies, stored and dispensed by matching the prescription of the homoeopathic doctor. It is the responsibility of the homoeopathic doctor and/or dispenser to ensure homoeopathic medicines/remedies are given to right patient, in the right dose and with the right label documenting required details, such as patient's name, date, remedy name with potency, dosage and expiry (if applicable). Touching the remedies: Both patients and persons dispensing should take precaution against touching the remedies. These should be poured into the cap of the container, and not into a dirty hand, before administration into the mouth. If it is not advisable to touch a remedy, while administering, hands should be cleaned before and after administering the same.

³¹ "Care and storing of homoeopathic remedies", Part of the "Become Informed" Series, by WHP www.hmedicine.com/homeopathy/information/storing_remedies.php

If too many remedies have been poured into the cap, the excess amount may be restored to the bottle. However, if too many have been poured into the hand, the desired amount may be consumed (provided the hand is clean) but the rest should not be poured back into the bottle as contaminating all the remedies to save some of the pills is not worth it.

Ind 25. Expiry dates/shelf life are checked prior to dispensing, as applicable

Survey Process:

Check 5 randomly selected medicines/remedies that have been dispensed or are to be dispensed. Verify that the medicines/remedies are within the expiry dates printed on the labels, as per applicable regulations.

Scoring:

- If all 5 randomly selected medicines/remedies dispensed, or to be dispensed, are found to be within the expiry dates, then score as <u>fully met.</u>
- If any of randomly selected medicines/remedies dispensed, or to be dispensed, are not found within the expiry dates, then score as <u>not met.</u>

GUIDELINES

Importance of Expiry Dates

Homoeopathic medicines/remedies are known to be safe in terms of their use due to their manufacturing techniques and biochemical properties. Expiry dates and shelf lives of these products have not been given priority in the past. Dr. Rajesh Barve from Virar Homoeopathic College, India, presented his valuable paper titled 'Stability and Expiry Date Evaluation of Homoeopathic Mother Tincture' at the International Conference and Exhibition on Traditional and Alternative Medicine, held from December 09th to 11th, 2013, at Radisson Blue Plaza, Hyderabad, India. The abstract of this paper provides an interesting analysis of, and justification for, the importance of expiry dates. It is worth mentioning that most homoeopathic products currently being marketed in Pakistan have the date of expiry mentioned on the label. Some of the manufacturers have recently started printing manufacturing and expiry dates, along with the maximum price, in compliance with DRAP regulations. In India, most homoeopathic medicines have a 5-year expiration date. The expiration date is based on stability studies which determine how long the active and inactive ingredients remain stable. The ranges vary from drug to drug stability evaluations.³²

This practice has been introduced in an attempt to comply with WHO requirements for allopathic medicines where "manufacturers and distributors are under obligation to clearly mention manufacturing and expiry dates on the labels." The most prominently held belief of experts in homoeopathy states that if a homoeopathic remedy is kept in an alcohol base in an air tight bottle, it can remain effective for centuries, whereas if it is sugar based, it is better to use it within a few years after which it should be discarded. However, technically there is no expiry date prescribed for these remedies.³³

³² Homeopathy - Shelf life of Drug; http://www.medindia.net/alternativemedicine/homeopathy/Homeopathy

³³ Homoeopathy FAQs; publix.aisle7.net/publix/assets/generic/homeopathy-faqs/~default

Ind 26. Labeling requirements are implemented

Survey Process:

Observe that prior to dispensing a medicine/remedy to a patient, the bottle or sachet has instructions on how to use the medicine/remedy, which is labeled with patient's name, medicine name, date of issue, dosage and the patient's reference record number. Check a sample of 4-6 dispensed medications/remedies to determine how they are labeled.

Scoring:

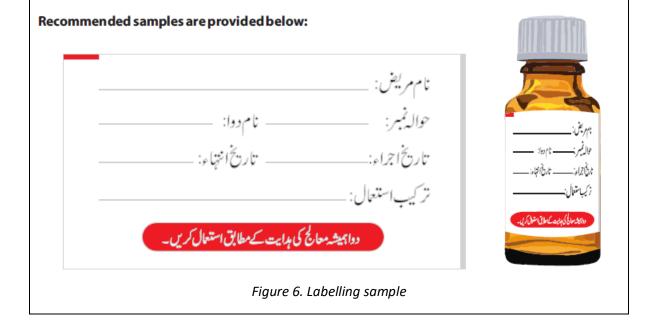
- If all medications are labeled as above, then score as <u>fully met.</u>
- If all items are not labeled as above, then score as <u>not met.</u>

GUIDELINES

Labelling

As explained in the standards and indicators mentioned earlier, correct labeling is beneficial for both patients and homoeopathic practitioners. It helps patients understand that they are using the right remedy and the right dose, as prescribed by the homoeopathic doctor. At the same time, it helps homoeopathic doctors and dispensers maintain correct records and gives them the satisfaction that they have provided the patient with necessary instructions on taking the medicine/remedy.

It is important for the homoeopathic doctor and/or dispenser to ensure that the bottle or sachet has instructions on using the medicine/remedy and the label has the patient's name and reference record number, date of issue and dosage.



Ind 27. Homoeopathic medications/remedies are dispensed by an authorized person.

Survey Process:

The essence of the indicator is that the person responsible for, or authorized to, dispensing the homoeopathic medications/remedies is either a qualified and registered professional or is able to correctly read and identify the medicines prescribed by the doctor from those in the store/cabinet. He/she is also able to correctly distinguish look-alike and sound-alike medications/remedies and dispense correctly under the supervision of the homoeopathic doctor.

Scoring:

- If the dispensing of the medications/remedies is by an authorized person, as described above, then score as <u>fully met.</u>
- If the dispensing of the medicines /remedies is by an authorized person who is not qualified and registered professional but is experienced and can perform as described above, then score as <u>partially met.</u>
- If the person dispensing is neither qualified/registered, nor able to perform as described above, then score as <u>not met.</u>

GUIDELINES

Eligibility and Authorization for Dispensing

As there is currently no system of training/registration of homeopathic dispensers or any person as explained in the Ind. 13 and footnote no. 24 who is capable of dispensing according to the prescription, guidance and satisfaction of a qualified homoeopathic doctor, registered with the NCH, will be considered eligible, till such time that the NCH devises a system for the training and registration of homoeopathic dispensers. Such a person should be able to correctly read and identify the medicines/remedies prescribed by the homoeopathic doctor from those in the store/cabinet. He/she should also be able to correctly distinguish look-alike and sound-alike remedies and be able to dispense correctly.

However, for further improvement in service delivery, it is recommended that the following requirements regarding qualification and training of homoeopathic dispensers should be made essential to facilitate compliance of the UAH Act II of 1965 and the Provision VI (d)(2) of the Code of Ethics for Homoeopathic Practitioners by the NCH:

- 1. Matriculation (preferably with science)
- 2. 12 Month certificate course including hands on training in Homoeopathic Dispensing.

Assessment Scoring Matrix

Standard 12. MOM-2: Procedures guide the safe storage and dispensing of medications (remedies).

| | Indicator 24 - 27 | Max Score | Weightage (Percentage) | Score Obtained |
|---------|---|--------------|---------------------------|-------------------|
| Ind 24. | Remedies are stored as per guidelines. | 10 | 80% | |
| Ind 25. | Expiry dates/shelf life are checked prior to dispensing, as applicable | 10 | 100% | |
| Ind 26. | Labeling requirements are implemented | 10 | 100% | |
| Ind 27. | Homoeopathic medications/remedies are dispensed by an authorized person | 10 | 80% | |
| | Total | 40 | | |

2.9 Patient Rights/Responsibilities and Education (PRE)

04 Standards & 05 Indicators

This section pertains to the patient's rights and emphasizes that the HCE staff are required to respect these rights and conduct themselves accordingly. The HCE shall define patient and family rights and responsibilities in line with the charters for patients and HCEs approved by KP HCC. The staff is required to be aware of these charters and trained to protect patients' rights. Patients are to be educated about their rights and responsibilities at the time of accessing healthcare services. They are to be informed about the disease, available remedies and possible outcomes and be involved in decision making. The costs are to be educated about the mechanisms available for addressing grievances.

The 'Charter for Patients and Others' and the 'Charter for Healthcare Establishments', are available on the **KP HCC website http://www.hcc.kp.gov.pk** and as explained under indicator No. 32, are required to be displayed in all client/patient areas.

Standard 13. PRE-1: A system for obtaining informed consent exists.³⁴

Indicators (28-28):

Ind 28. The situations requiring specific informed consent³⁵ from a patient or family³⁶ are listed at the clinic.

Survey Process:

Review the listed conditions requiring informed consent. Subsequently, review the records of patients from whom specific informed consent should have been taken. Informed consent includes providing detailed information in a language and detail that patient/attendant can understand on risks, benefits and alternatives and as to who will provide the treatment or remedy. Informed consent is also required for taking photographs or making videos during the treatment, either for record keeping/preservation of identity or educational/research purposes, as it can compromise the individual's religious, social or cultural beliefs.³⁷

Scoring:

- If relevant records document informed consent accordingly, then score as <u>fully met.</u>
- If relevant records do not document consent as above, then score as <u>not met.</u>

GUIDELINES

List of Conditions Requiring Informed Consent

The patient has the right to have correct information about their health status (unless he/she has explicitly waived the right to such information), proposed treatment plan and all related issues in general. This information should be conveyed to the patient, by the attending staff, in a clear and simple way, using appropriate language. The patient should be provided sufficient information to help them understand the issue and make informed decisions regarding treatment and management.

Currently, the practice of obtaining prior consent from a patient accessing treatment from a homoeopathic practitioner does not exist. Since the homoeopathic system of healthcare is different from the allopathic system of treatment, it is advisable that the homoeopathic doctor ask the patient if he/she has gone for, or is undergoing, any treatment from a medical doctor. The homoeopathic doctor is advised to ask the following essential questions from patients:

- 1. Is this his/her first visit to the homoeopathic clinic?
- 2. Has he/she been referred by a medical practitioner to seek homoeopathic treatment?

³⁴ Conditionally applicable keeping in view the relevant laws.

³⁵ See Consent Form.

³⁶ Family consent is required if the patient is not capable to give consent. Family means; immediate relatives mother, father, brother & sister, son & daughter, wife & husband.

³⁷ Refer to KP HCC Patient Charters.

3. Does he/she have a serious and prolonged illness?

4. Is he/she willingly seeking homoeopathic treatment?

Additionally, informed consent of the patient is a prerequisite for his/her participation in clinical trial, teaching or scientific research.

A proposed format for informed consent is given below. However, it is the duty of the homoeopathic doctor and/or his staff to ensure that the patient has been explained, and has read, all the information provided in the consent form before signing. In case the patient is illiterate (cannot read or write), all the details should be explained in the language he/she, or his/her attendant, can easily understand and verbal consent is obtained. The homoeopathic doctor should ensure that the date and time that verbal consent was obtained is recorded on the register/form/prescription note and is signed by the homoeopathic doctor.

It is suggested that information regarding symptoms related to following medical conditions may be asked from the patient:

- 1. Renal failures
- 2. Chronic liver ailments
- 3. Ischemic heart diseases
- 4. Hemiplegic disorders
- 5. Leukemia and malignancies
- 6. Autoimmune ailments

Table 4. Form H-1

Form: H-1

Informed Consent for Homoeopathic Treatment

Homoeopathy and other holistic methodologies view health and illness from a perspective different from the standard allopathic medical approach, one which restricts its concerns to an individual's symptoms. Homoeopaths do not practice diagnosis, as referred to in medical terms and it is therefore essential for patients to maintain a relationship with a licensed medical doctor or primary care provider for appropriate evaluations and check-ups. It is further recommended that patients inform their primary care provider that they are receiving homoeopathic treatment. Under no circumstances should any suggestions be taken as medical diagnosis or directions followed against the advice of a licensed medical or mental healthcare professional.

A sample of the patient consent form is provided below.

I understand that rather than medical/unani advice or treatment, I am seeking holistic treatment and following homoeopathic advice and/or recommendations. I understand that the goal of homoeopathy to provide medication/remedy is in line with 'Homoeopathic Materia Medica', as recommended by the Pakistan National Council for Homoeopathy.

- 1. I understand that minor aggravation or worsening of some symptoms may occur temporarily as part of the healing process.
- 2. I authorize discussion of my case notes with other professional homoeopaths if my/my child's best interests are served by such a consultation. My right to privacy will be protected by withholding my name and any other identifying information.
- 3. I am over 18 years of age and have voluntarily chosen homoeopathic treatment for myself/my child.

| 4. I am aware that the outcome and duration of homoeopathic treatment varies across individuals and cannot be guaranteed. I am also aware of the cost of treatment. |
|---|
| Patient: |
| NameDOB |
| Parent Name (if minor) |
| |
| Postal Address: |
| |
| E-mail: Home phone: |
| Cell phone: |
| |
| Primary Care Provider |
| |
| |
| Signature & Thumb Impression of Patient or Guardian |
| CNIC:Place: |
| I certify that I have explained the above details to the patient in a language he/she understands: |
| |
| Signature and Stamp of the Practitioner: |

Assessment Scoring Matrix

Standard 13. PRE-1: A system for obtaining informed consent exists.

| | Indicator 28 - 28 | Max Score | Weightage (Percentage) | Score Obtained |
|---------|---|--------------|---------------------------|-------------------|
| Ind 28. | The situations requiring specific informed consent from a patient or family are listed at the clinic. | 10 | 100% | |
| | Total | 10 | | |

Standard 14. PRE-2: Patients and families have a right to information about expected costs.

Indicators (29-29):

Ind 29. The patient/family is informed about the cost of treatment.

Survey Process:

Customarily, the consultation fee is displayed or patients are informed about the fee and the charges for medicines etc. at the reception desk (as applicable), and the cost list is shown if requested.

Scoring:

- If there is evidence that the patients/families are informed about the treatment costs, then score as <u>fully met.</u>
- If the patients/relatives are not informed about the expected costs of treatment, then score as <u>not met.</u>

GUIDELINES

Tariff List

Customarily, the consultation fee is displayed or patients are informed about the fee and the charges for medicine etc. at the reception desk (as applicable). A detailed cost list is shown if requested. There should be a general tariff/billing system which defines the charges to be levied for the services provided by the homoeopathic clinic.

The services may include:

- 1. Consultation fee at the Clinic.
- 2. Home visiting consultation fee.
- 3. Costs of medicines/remedies dispensed at the clinic.
- 4. Transportation charges (if referred to another healthcare facility i.e. a hospital).

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, dispenser or homoeopathic 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 treatment of prolonged illness. It is preferable that this information be given in the written form.

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 homoeopathic consultation area.

Assessment Scoring Matrix

Standard 14. PRE-2: Patients and families have a right to information about expected costs.

| | Indicator 29 - 29 | Max Score | Weightage (Percentage) | Score Obtained |
|---------|--|--------------|---------------------------|-------------------|
| Ind 29. | The patient/family is informed about the costs of treatment. | 10 | 100% | |
| | Total | 10 | | |

Standard 15. PRE-3: Patients and families have a right to refuse treatment and complain.³⁸

Indicators (30-31):

Ind 30. Patients and families have a right to refuse the treatment.

Survey Process:

Patient and families are expected to respect the instructions/medication orders/remedies prescribed by the homoeopathic doctor, but they do have the right to refuse the treatment and seek advice from any other healthcare service provider of choice, as provided in the KP HCC Charters. This necessitates specifically displaying the right of refusal. In cases where patients refuse advice, procedures or treatment, this must be recorded in their record.

Scoring:

- If the above requirement is displayed, then score as <u>fully met.</u>
- If the above requirement is not displayed, then score as <u>not met.</u>

GUIDELINES

Right to Refuse Treatment

While patients and families are expected to respect the instructions/medication orders/remedies prescribed by the homoeopathic 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, see indicator no. 32).

Ind 31. Patients and families have a right to complain and a mechanism exists to address the grievances.

Survey Process:

Patients and families have a right to complain and put forward their grievances/concerns and there must be a mechanism to handle the complaints effectively. Complaints can be lodged on the spot-on occurrence, with some delay, verbally or in writing. A functional complaint box or file record is evidence of the system being in place and observed.

Scoring:

- If there is a display guiding patients about their right of complaint and there is evidence of practice being followed, then score as <u>fully met.</u>
- If there is a no display guiding patients about their right of complaint or there is no evidence of

³⁸ Provisions VI. (f)(a) to (g), Code of Ethics for Homoeopathic Practitioners allows refusal to treat a patient.

practice being followed, then score as not met.

GUIDELINES

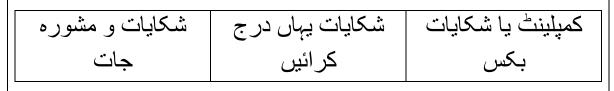
Complaint Management

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 homoeopathic 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:



- 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 F**).

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 redressal procedure. A proposed format for the complaint management procedure is attached as **Annexure G**.

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 15. PRE-3: Patients and families have a right to refuse treatment/complain.

| | Indicator 30 - 31 | Max Score | Weightage (Percentage) | Score Obtained |
|---------|--|--------------|---------------------------|-------------------|
| Ind 30. | Patients and families have a right to refuse the treatment. | 10 | 100% | |
| Ind 31. | Patients and families have a right to complain and a mechanism exists to address the grievances. | 10 | 100% | |
| | Total | 20 | | |

Standard 16. PRE-4: Patients and families are responsible for respecting the clinic environment.

Indicators (32-32):

Ind 32. The HCE Charter is displayed and patients/families are guided.

Survey Process:

Check that HCE Charters regarding the rights and responsibilities of the patients and families are displayed at a prominent place in the clinic, like the waiting area or the main entrance. Patients or families are expected to observe social norms by waiting their turn, avoiding conflict situations and following the instructions of the homoeopathic doctor regarding the date and time of the re-visit. Also, observe that guidance is routinely provided on the above aspects.

Scoring:

- If there is a board displaying the HCE Charters and evidence that patients/families are also guided to observe the same, then score as <u>fully met.</u>
- If there is no board displaying the HCE Charters, but there is evidence that patients/families are guided to observe the same, then score as partially met.
- If there is no board displaying the HCE Charters and there is no evidence that patients /families are guided to observe the same, then score as <u>not met.</u>

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 homoeopathic 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 at **Annexure H.**

Assessment Scoring Matrix

Standard 16. PRE-4: Patients and Families are responsible for respecting the clinic environment.

| | Indicator 32 - 32 | Max Score | Weightage (Percentage) | Score Obtained |
|---------|--|--------------|---------------------------|-------------------|
| Ind 32. | The HCE Charter is displayed and patients/families are guided. | 10 | 80% | |
| | Total | 10 | | |

2.10 Infection Control (IC)

01 Standard & 01 Indicator

'Infection' is defined as the entry and multiplication of a germ in a human or animal, which may or may not cause disease. A person can be infected with a germ without it causing any symptoms or damage to the body. The following states act as a chain for infection to take place:

- 1. Source of Infection.
- 2. Transmission.
- 3. Contracting of the infection by a healthy person.

All the steps in the chain, including existence/source of germs, spread/ transmission and contacting of the infection by a person occur sequentially for the infection to spread from one person to another. Spread of infections can be prevented by breaking the chain at any step. In a homoeopathic clinic, spread of nosocomial infections is rare as the patients do not stay for long. However, infected patients sitting in close proximity with each other while waiting, and with the homoeopathic doctor during consultation, presents risks if protective measures are not taken.

Standard 17. IC-1: The clinic has an infection control system in place.

Indicators (33-33):

Ind 33. The clinic has arrangements for infection control aimed at preventing and reducing the risk of infections.

Survey Process:

Observe if there are written instructions on infection control which cover at least the following aspects:

- 1. Maintaining general cleanliness / hygiene in the clinic premises.
- 2. Facility of hand washing with soap and water or an alternative (disinfectant), as the case may be, before and after examination.
- 3. Arrangements for controlling/preventing/reducing the risk of infections during the process of patient assessment.
- 4. Use of disposable gloves, mask etc. by the homoeopathic doctor while examining the patient for certain specific conditions.
- 5. Adherence of the above-mentioned infection control instructions by the homoeopathic dispenser/ assistant, while assisting the homoeopathic doctor.
- 6. Safe handling of medical/clinical waste.³⁹

Scoring:

- If there is evidence of observing the infection control procedures and all above mentioned aspects are covered, then score as <u>fully met.</u>
- If there is evidence of observing the infection control procedures covering up to 80% of abovementioned aspects, then score as <u>partially met.</u>
- If there are no infection control procedures or less than 80% of the above-mentioned aspects are being practiced, then score as <u>not met.</u>

GUIDELINES

Infection Control

The prevention and control of infection in homoeopathic clinic settings can cover a wide range of aspects and activities which can minimize the risk of spread of infection, as far as reasonably possible for the homoeopathic doctor, as well as the staff and the patients of the homoeopathic clinic. Some of the roles and responsibilities given hereunder must be understood and practiced.

1. Roles and Responsibilities

Clinic in-charge has the overall responsibility to ensure that appropriate controls and

³⁹ In the light of latest instructions on Clinical Waste Management issued by Environment Protection Agency, as applicable.

procedures are in place to minimize the risks of infection to staff and patients. Homoeopathic doctor and staff are responsible to ensure good infection prevention and control so that they do not put themselves, other colleagues or patients at risk of infection. Patients should cover their face (nose/mouth) with a handkerchief or tissue paper while coughing or sneezing, to block the spread of germs. The infected person should be kept away from other patients (particularly children) to avoid the spread of infection.

2. Infection Control Guidance

Patients/healthcare providers may acquire infections during clinical checkups or healthcare interventions. Healthcare workers commonly spread a wide variety of microorganisms, including Methicillin Resistant Staphylococcus Aureus, Influenza, Noro-virus and Clostridium Difficile via contaminated hands and equipment. Many of these infections are avoidable. A homoeopathic doctor and staff working in a clinic may put patients at risk in the following ways:

- i. Direct contact through hands
- ii. The emergency environment

Practicing good hand hygiene, taking aseptic precautions and a clean working environment can minimize the risk of transmitting infection to patients or staff. Good hand hygiene has been described as the most important intervention in reducing the risk of cross infection. Use of soap and warm water is the most effective method of cleaning hands so as to remove dirt, organic material and transient micro-organisms. The technique of hand washing is more important than the solution used and involves three stages: preparation, washing/rinsing and drying.

| Taking a break/going home Undertaking a procedure Putting on protective clothing Eating, drinking and handling food Smoking Going to the toilet Blowing nose or covering a sneeze Examining a patient Handling contaminated items such as dressings etc. Cleaning equipment/environment Handling dirty linen or waste Hands become visibly soiled Cleaning up spills Removal of gloves Smoking | Before | After |
|--|---|---|
| | Undertaking a procedure Putting on protective clothing Eating, drinking and handling food | Blowing nose or covering a sneeze Examining a patient Handling contaminated items such as dressings etc. Cleaning equipment/environment Handling dirty linen or waste Hands become visibly soiled Cleaning up spills Removal of gloves |

Hands should be washed:

| Fiaure 7. | Moments o | of Hand | Wash |
|-----------|--------------|---------|--------|
| riguic /. | monitentes o | ' inana | •• asn |

Appropriate hand washing can minimize spread of infection through micro-organisms, acquired on the hands by contact with bodily fluids and contaminated surfaces, by breaking the transmission chain and reducing person-to-person transmission. All healthcare personnel and family caregivers of patients must practice effective hand washing and need to know proper techniques and situations for hand washing. Washing with soap and water kills many transient micro-organisms and allows them to be mechanically removed by rinsing. Washing with antimicrobial products kills or inhibits the growth of micro-organisms in the deep layers of the skin. Use of alcohol-based gel is the preferred method of hand cleansing.

i. Types of Hand Washing

- a. Simple hand washing is usually limited to hands and wrists where the hands are washed with soap (plain or antimicrobial) and water for a minimum of 10 15 seconds.
- b. Hand antisepsis/decontamination removes or destroys transient micro-organisms and confers a prolonged protective effect and may be carried out in one of the following two ways:

ii. Facilities and Materials Required for Hand Washing

a. Running water

Access to clean water is essential and it is preferable to have running water in washbasins having anti-splash devices. When running water is not available, use either a bucket with a tap, which can be turned on and off; a bucket and pitcher or 60% - 90% alcohol hand rub.

iii. Materials Used for Hand Washing/Hand Antisepsis

Use plain or antimicrobial soap depending on the procedure.

Plain Soap: Used for routine hand washing and available in bar, powder or liquid form. Antimicrobial Soap: Used for hand washing as well as hand antisepsis.

- a. If bar soaps are used: Use small bars with soap racks that can be drained.
- b. Do not allow bar soap to sit in a pool of water as it encourages the growth of some micro-organisms such as pseudomonas.
- c. Clean dispensers of liquid soap thoroughly every day.
- d. Empty liquid soap containers must be discarded, not refilled with soap solution.

Specific antiseptics recommended for hand antisepsis:

- a. 2%-4% chlorhexidine
- b. 5%-7.5% povidone iodine
- c. 1% triclosan
- d. 70% alcoholic hand rubs

Waterless, alcohol-based hand rubs: with antiseptic and emollient gel and alcohol swabs, which can be applied to clean hands.

iv. Facilities for Drying Hands

- a. Disposable towels, reusable single-use towels or roller towels, which are suitably maintained, should be available.
- b. If there is no clean dry towel, it is best to air-dry hands.
- c. Flexibility in using equipment products and procedures, sensitive to local needs, will improve compliance.
- d. In all cases, the best possible procedure should be instituted.

v. Hand Washing Instructions

- a. Remove jewellery (rings, bracelets etc.) and watches before washing hands.
- b. Ensure that the nails are clipped short (do not wear artificial nails).
- c. Roll the sleeves up to the elbow.
- d. Wet the hands and wrists, keeping hands and wrists lower than the elbows which permits the water to flow to the fingertips, avoiding arm contamination.
- e. Apply soap (plain or antimicrobial) and lather thoroughly.
- f. Use firm, circular motions to wash the hands and arms up to the wrists, covering all areas including palms, back of the hands, fingers, between the fingers and the lateral side of the fifth finger, knuckles and wrists and rub for a minimum of 10-15 seconds.
- g. Repeat the process if the hands are very soiled.

- h. Clean under the fingernails.
- i. Rinse hands thoroughly, keeping the hands lower than the forearms.
- j. If running water is not available, use a bucket and pitcher.
- k. Do not dip your hands into a bowl to rinse, as this re-contaminates them.
- I. Collect used water in a basin and discard in a sink, drain or toilet.
- m. Dry hands thoroughly with a disposable paper towel or napkins. Clean dry with towel or air dry them.
- n. Discard the towel if used, in an appropriate container without touching the bin lids with the hand.
- o. Use a paper towel, clean towel or your elbow/foot to turn off the faucet to prevent recontamination.
- vi. Hand washing steps using antiseptics, hand rubs, gels or alcohol swabs.

(A general procedure for hand washing is given in the figure below and must be conducted over at least one full minute).

- a. Apply the product to the palm of one hand. The volume needed to apply varies by product.
- b. Rub hands together, covering all surfaces of hands and fingers, until the hands are dry.
- c. Do not rinse.
- d. When there is visible soiling of hands, they should first be washed with soap and water before using waterless hand rubs, gels or alcohol swabs.
- e. If soap and water are unavailable, hands should first be cleansed with an alcohol-based hand rub, gel or swab.



Figure 8. Handwashing steps are pictorially summarized

vii. Personal Protective Equipment (PPE)

Adequate and appropriate PPE, soaps, and disinfectants should be available and used correctly. These should be available at the point of use and the clinic shall maintain an adequate inventory and stock of items, as applicable.

Using PPE provides a physical barrier between micro-organisms and the wearer and offers protection by helping to prevent micro-organisms from:

- a. Contaminating hands, eyes, clothing, hair and shoes.
- b. Being transmitted to other patients and staff.

a. PPE includes:

- Gloves
- Disposable protective clothing e.g. plastic aprons
- Eye protection
- Face masks

b. PPE should be used by:

- 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.
- Support staff including medical aides, cleaners and laundry staff in situations where they may have contact with blood, body fluids, secretions and excretions.

c. Principles for use of PPE

PPE reduces, but does not completely eliminate, the risk of acquiring an infection. It is important that it is used effectively, correctly, and at all times where contact with blood and bodily fluids of patients may occur. Continuous availability of PPE and training for its adequate use are essential. Staff must also be aware that use of PPE does not replace the need to follow basic infection control measures such as hand hygiene. The following principles guide the use of PPE:

- PPE should be chosen according to the risk of exposure. The healthcare worker should assess whether they are at risk of exposure to blood, body fluids, excretions or secretions and choose the items of personal protective equipment according to the risk.
- Avoid any contact between contaminated (used) PPE and surfaces, clothing or people outside the patient care area.

d. Examples of use of PPE

- Discard the used PPE in appropriate disposal bags and dispose of, as per the policy of the clinic.
- Do not share PPE.
- Change PPE completely and thoroughly wash hands each time you leave a patient to attend to another patient or another duty.

v. Cleaning of the Clinic Environment

Routine cleaning is important to ensure a clean and dust-free clinic environment. There are usually many micro-organisms present in 'visible dirt' and routine cleaning helps to eliminate this dirt. Administrative and office areas with no patient contact require normal domestic cleaning. Most patient care areas should be cleaned by wet mopping as 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. Areas visibly contaminated with blood or body fluids should be cleaned immediately with detergent and water. Rooms and other areas that have been exposed to patients with known transmissible infectious diseases should be cleaned with a detergent/disinfectant solution. All horizontal surfaces and all toilet areas should be cleaned daily.

vi. Management of Healthcare Waste

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

vii. Additional Precautions (transmission-based)

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

- a. Airborne precautions
- b. Droplet precautions
- c. Contact precautions

viii. Training in Safe Handling of Medical Waste

The clinic in-charge should be oriented towards the importance of the IC program. Healthcare workers should be equipped with requisite knowledge, skills and attitudes for good IC practices. In case of single-person clinics, the homoeopathic doctors should be responsible for ensuring that they are fully knowledgeable and trained in safe handling of medical waste. In case of poly-clinics, the in-charge should:

- a. Assess training needs of the staff and provide required training through awareness programs, in-service education and on-the-job training.
- b. Organize regular training programs for the staff for essential IC practices that are appropriate to their job description.
- c. Provide periodic re-training or orientation of staff.
- d. Review the impact of training.

All staff that work in areas where infectious waste is handled are to be 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**:

- a. Collection
- b. Segregation at source
- c. Storage
- d. Transportation

Medical waste in Khyber Pakhtunkhwa is regulated by the Khyber Pakhtunkhwa Hospital Waste Management (HWM) Rules, 2018. According to the rules, every clinic/HCE shall be responsible for the proper management of waste, through developing a 'Waste Management Plan'. The plan will be facility specific, containing a list of activities and quantities of required materials, with costs and timelines. Development of the plan is the responsibility of the clinic in charge or the Waste Management Officer, if designated as member of the Waste Management Team (WMT) (details are given in the relevant section). The plan will be reviewed and finalized by the clinic in charge/WMT and should aim to:

- a. Protect public health and safety.
- b. Provide a safer working environment.
- c. Minimize waste generation and environmental impacts of waste treatment/disposal.
- d. Ensure compliance with legislative requirements

ix. Minimum Requirement on Infection Control for a Homoeopathic Clinic

Although the above-mentioned details related to infection control at the primary healthcare level, are given for better understanding and making the clinic staff well-oriented to the roles, responsibilities and risk prevention methods but in a homoeopathic clinic, the following instructions on infection control must be made available:

- a. Maintaining general cleanliness/hygiene in the clinic premises.
- b. Facility of hand washing with soap and water, or an alternative (disinfectant), as the case may be before and after examination.

- c. Arrangement for controlling/preventing/reducing the risk of infections during the process of patient assessment.
- d. Abiding by the above-mentioned infection control instructions by the homoeopathic dispenser/assistant while assisting the homeopathic doctor.
- e. Use of disposable gloves and mask by the homoeopathic doctor while examining the patient for certain specific conditions.
- f. Safe handling of medical/clinical waste.⁴⁰

⁴⁰ In the light of the latest instructions on Clinical Waste Management issued by the Environment Protection Agency, as applicable locally.

Assessment Scoring Matrix

Standard 17. IC-1: The clinic has an infection control system in place.

| | Indicator 33 - 33 | Max Score | Weightage (Percentage) | Score Obtained |
|---------|--|--------------|---------------------------|-------------------|
| Ind 33. | The clinic has arrangements for infection control aimed at preventing and reducing the risk of infections. | 10 | 80% | |
| | Total | 10 | | |

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) | 100 | 88 | |
| 2.2 | Facility Management and Safety (FMS) | 20 | 18 | |
| 2.3 | Human Resource Management (HRM) | 10 | 10 | |
| 2.4 | Information Management System (IMS) | 20 | 18 | |
| 2.5 | Quality Assurance (QA) | 10 | 10 | |
| 2.6 | Access, Assessment, and Continuity of Care (AAC) | 30 | 28 | |
| 2.7 | Care of Patients (COP) | 10 | 10 | |
| 2.8 | Management of Medication (MOM) | 70 | 62 | |
| 2.9 | Patient Rights and Education (PRE) | 50 | 48 | |
| 2.10 | Infection Control (IC) | 10 | 10 | |
| | Total | 330 | 302 | |

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

| | Type of Record | Period of retaining | |
|---|--|--|--|
| Official RecordPersonal Files, Services books, Financial Record auditable and non-auditable,Gover Pakht | | In accordance with the Government of Khyber Pakhtunkhwa Financial Rules or as per necessity, whichever is later. | |
| Medical Record | Patient charts, Reports, X-Ray, CT Scan MRI, Pathology reports OPD Registers. | 03 Years or later as per necessity. | |
| Medico-legal | Medico-Legal report/registers | 12 years or later as per necessity | |
| Demographic Record | Birth and Death record | Birth and Death Registers to be kept forever. | |

ANNEXURE E: Statement of Ethics

| co | | | | |
|----------------|--|--|--|--|
| | | | | |
| + | competitors before clients. We only believe in servicing our client's needs to | | | |
| U | the best of our efforts. | | | |
| Guideline 2 W | We perform our work according to the specified quality standards. | | | |
| Guideline 3 W | We avoid conflicts of interest either of a financial or personal nature; these | | | |
| co | could compromise the objectivity and integrity of our work. | | | |
| Guideline 4 W | We exercise our professional judgment impartially while taking any decisions | | | |
| re | related to work, keeping all pertinent facts, relevant experience and the | | | |
| a | advice of our management in mind. | | | |
| Guideline 5 W | We hold the affairs of our clients in the strictest confidence. We do not | | | |
| di | disclose propriety information obtained in the course of work or derive | | | |
| b | benefit from using information outside the company. | | | |
| Guideline 6 W | We act with courtesy and consideration towards all with whom we come into | | | |
| co | contact in the course of our professional work. | | | |
| Guideline 7 W | /e do not accept any favors, gifts or inducements, including undue | | | |
| h | ospitality and entertainment, from the clients. The only expectations would | | | |
| b | be if the gifts are of promotional nature (diaries, calendars, etc.) or of a | | | |
| n | nominal value, the indulgence of which would not damage the company's | | | |
| re | reputation. | | | |
| Guideline 8 W | /e are fully committed to the principle of equality and non-discrimination | | | |
| 0 | n the grounds of disability, sex, age, race, color, ethnicity, origin or marital | | | |
| st | status. We do not indulge in any intimidation and harassment of any sort at | | | |
| w | work. | | | |
| Guideline 9 W | /e will communicate with our clients and its representative in an effective | | | |
| a | and timely manner. | | | |
| Guideline 10 W | /e would be perceived by clients and other thought leaders as setting the | | | |
| st | standards in client focus and client service among professional service | | | |
| co | ompanies. | | | |

Declaration

I have read and understood the "Statements of Ethics" and stand committed to it.

| Date of Joining: | |
|------------------|--|
|------------------|--|

ANNEXURE F: Template of 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) | Convenient to reach the facility. Required guidance provided. Services available as portrayed. Services are affordable. Staff is courteous. Relevant staff is available. Privacy is observed. Female staff is available. Test results provided in time. Other(specify)) | | |
| 3 | If NO, why? (You can circle more than one) response and write below) | Issues of confidentiality. Issues of privacy. Lack of attention. Inadequate guidance provided. I was asked to come another time without taking the sample. Tests/services are costly. Waiting time is too long. Staff is discourteous/unsatisfactory behavior. Staff is not competent. Relevant staff NOT available. Female staff NOT available (gender issue). Other (specify) | | |
| | Signatures of patient/relative | | | |
| | Action by the person in charge with date: | | | |

CLIENT SATISFACTION PROFORMA

ANNEXURE G: 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 منتظم کو دفتر یا ٹیلی فون نمبر پر کرسکتے ہیں یا استقبالیہ ہیلپ ڈیسک / ريسييشن پر موجود شكايات رجستر ميں اپني شكايات درج كرسكتے ہيں۔

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:

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 | CNIC | Contact | Address | Detail of the | Signature/thumb | Date seen & | |
| | | Name | No. | No. | | Complaint | impression of the | Signature | Date seen & |
| | | | | | | | complainant | Manager | 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

- A. Inform the complainant about the progress of the investigation at regular intervals and inform him/her about the outcome.
- B. Stay in contact with the complainant and regularly update him/her about the progress made in investigation.
- C. Record the outcome of the investigation and inform the complainant accordingly.
- D. Don't indulge in argumentation. Be polite and empathetic.

7. QUALITY IMPROVEMENT

- A. Use the results of the complaints investigation as part of the quality improvement process.
- B. The registers should be perused by the Chief Executive of the establishment, at least once a month.
- C. Make necessary changes in policy and procedures to improve the quality of healthcare services.

ANNEXURE H: 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;
- 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;
- Access his own medical records, including but not limited to, comprehensive medical history, Examination(s), investigation(s) and treatment along with the progress notes, and obtain copies thereof;
- 11. Not to be discriminated against because of age, disability, gender1, marriage, pregnancy, maternity, race, religion, cultural beliefs, color, caste and/or creed;
- 12. Expect that any care and/or treatment being received is provided by duly qualified and experienced staff;
- 13. Expect that the healthcare service provider or the Healthcare Establishment, as the case may be, has the capacity and required necessary equipment in order and working condition, for rendering the requisite services, including but not limited to treatment;
- 14. Receive emergency healthcare, unconditionally. However, once the emergency has been dealt with, he may be discharged or referred to another Healthcare Establishment [emergency requiring healthcare, is a situation threatening immediate danger tolife2 or severe irreversible disability, if healthcare is not provided urgently];
- 15. Be treated with respect, empathy and dignity irrespective of age, disability, gender, marriage, pregnancy, maternity, race, religion, socio -economic status, cultural beliefs, color, caste and/or creed;
- 16. Be treated in privacy and with dignity, and have his religious and cultural beliefs respected throughout the duration of care, including but not limited to, taking history, examination or adopting any other course of action;
- 17. Be made aware of procedures for complaints and resolution of disputes and conflicts;

- 18. File a written complaint to the concerned healthcare service provider, official of the Healthcare Establishment or such other organization/person, as the case may be and be associated throughout the progress of the complaint and its outcome;
- 19. Seek compensation if he has been harmed by, including but not limited to maladministration, malpractice, negligent treatment, or failure on the part of a healthcare service provider or any staff/employee or others rendering services at the Healthcare Establishment;
- 20. Be informed and to refuse to participate in research, or any project dealing with his disease, care and treatment;
- 21. Be accompanied by a family member or career, as the case may be, particularly in cases of children, females, elderly and disabled. The healthcare service provider and/or the Healthcare Establishment, as the case may be, are to ensure that in cases of children and females in the immediate post anesthesia phase, a female staff shall be present until a family member or career can join the patient/client, The healthcare service provider and/or the Healthcare Establishment, as the case may be, are also to ensure that in cases of children and females an authorized family member or a career or if not so possible, at least a female staff is present during physical examination and investigation procedures where physical contact and or exposure of body part(s) is required.
- 22. Expect that the Healthcare service provider, the Healthcare Establishment, and/or such other person rendering similar services, as the case may be, shall not misuse nor abuse their fiduciary position *vis-a-vis* him or his career(s) or family members, as the case may be, for undue favor(s) including but not limited to sexual favor(s) or any other undue or uncalled for reward or privileges in terms of professional fee or gifts etc.
- 23. Be informed as early as possible regarding cancellation and/or postponement of any appointment, surgery, procedure, treatment or meeting, as the case may be;
- 24. Be made aware of the costs, fee and/or expenses, prior to the consultation, treatment or other services, and/or operation/procedure, as the case may be, and receive payment receipt(s) for the same;
- 25. Be given written instructions regarding his treatment, including instructions at the time of discharge;
- 26. Examine and receive an explanation for the bill(s) regardless of the source of payment;
- 27. End of life care;

Nothing in this Charter prevents any organization/healthcare service provider/Healthcare Establishment from recognizing additional rights of the Patient/Client and/or the career, as the case may be. The purpose of this Charter is to inculcate and invigorate in the community the understanding and recognition of the fact that health, care and/or treatment is a right of an individual even when he is unborn and the same continues from his cradle to coffin.

This document will be reviewed annually or earlier, as deemed appropriate by the Khyber Pakhtunkhwa Healthcare Commission, in view of its experiences, through a consultative process involving patients, former patients, family members, related professionals, staff and other stakeholder groups.

Explanatory Notes

- 1. Gender includes male, female, transgender and intersex individuals.
- 2. Life, in the context of mental emergency, includes those of others.

3. End of Life Care includes healthcare, not only of patients in the final hours or days of their lives, but more broadly, care of all those with terminal illness or terminal condition that has become advanced, progressive and incurable. Accordingly, it may so happen that no treatment may be advisable and or given but the care should continue, keeping in view the ethics of the profession.

Part B: Responsibilities of Patients and Others

The patient/client or career, as the case may be, is responsible to the Healthcare Establishment, its staff or the Healthcare Service Provider for: -

- 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:

- 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;
- 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.

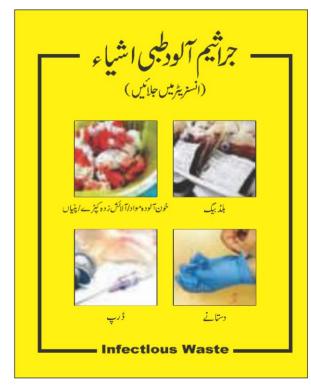
Part B: Responsibilities of Healthcare Establishments/Healthcare Service Providers

The Healthcare Establishment or the Healthcare Service Provider, as the case may be, shall be responsible for:

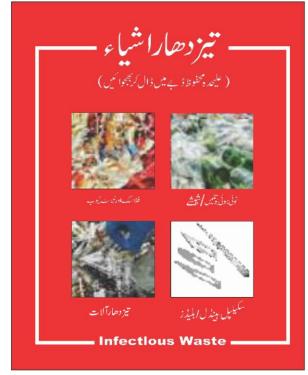
- 1. Ensuring the safety of patient/client.
- 2. Establishing such systems which enable easy access to services as are required by the patient/client.
- 3. Maintaining the services being provided through fully competent professionals.
- 4. Establishing systems to ensure that the rights of the patient/client 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 I: Segregation of Waste (both Clinical & Municipal) for Disposal

1. Yellow Colour

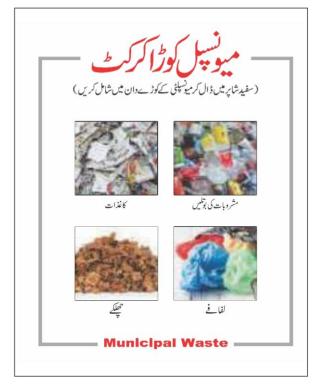


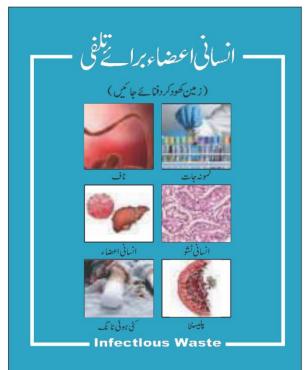
2. Red Colour



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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