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Directorate General of
Private Health Establishments

Complementary Medicine Practice Licensing Guideline

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Version One Feb 2018

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Abbreviations:

CM: Complementary Medicine

DGPHE: Directorate General of Private Health Establishments

KKT: Khan Kinetic Treatment

MoH: Ministry of Health

TCM : Traditional Chinese Medicine

TIM: Traditional Indian Medicine

Introduction

Complementary Medicine could be defined as diagnostic, therapeutic, preventive and rehabilitative health care systems and practice, with a view to health maintenance, care and protection through different methods and means and the use of diverse products; plant, animal, metal or otherwise, which does not fall under modern medicine.

Complementary Medicine Establishment is a health care facility that consists of a clinic or a group of clinics (two and above), staffed by either licensed complementary Medicine Practitioner(s), or licensed Physician(s) privileged to practice complementary medicine. These facilities provide consultation and/or services on MoH approved Complementary Medicine (CM) Specialties. It does not provide emergency services, which must be referred to a hospital.

These facilities can be established independently or within a healthcare facility providing various conventional (allopathic) medical services. It must be operated and managed by a licensed CM Healthcare professional or a licensed Physician privileged to practice complementary medicine, when established independently.

This guideline outlines a brief about each practice of complementary medicine that has been approved by MoH. It also gives general scope of practice for Complementary Medicine (CM) Specialties as well as the individual specialty. Finally, there are details about licensing regulation for Complementary Medicine (CM) Specialties clinics / Centres.

The last chapter frameworks the accreditation standards for CM facilities, which could be used to standardize the healthcare services that are provided by these clinics. The rationale behind preparing such standards is to prepare the CM clinics to raise their standards of care on order to optimize the patients' safety and quality of healthcare.

There are six types of Complementary Medicine (CM) practices approved by MoH, which include:

1. Ayurveda
2. Homeopathy
3. Traditional Chinese Medicine

Chapter One

General Requirements for Licensing Complementary Medicine Establishments

Chapter One

General Requirements for Licensing Complementary Medicine Establishments

1. Licensing Regulations:

1.1 Complementary medicine establishments shall follow the same licensing regulations subjected to other private health establishments as per the Medical Law.

1.2 It is prohibited to initiate any kind of complementary practice without getting initial approval from MoH.

1.3 It is not allowed to use the licensed facility for any kind of activities outside its scope of practice, or to use it for accommodation.

1.4 It shall be considered breech of regulation if the facility accept any staff working without being licensed by MoH.

1.5 It is not allowed to use any tools or devices without being licensed by Department of Engineering Affairs.

1.6 All type of therapeutic remedies, drugs (all forms) or supplements are subjected for approval by Department of Pharmaceutical Affairs & Drugs Control.

2. Classification of Complementary Medicine Establishments

1) Hospital: Provides all complementary medicine services, including patients' hospitalization.

2) Center: Includes more than one clinic in a single complementary field or more than one specialization.

3) Clinic: To practice one of the complementary medicine fields.

4) Unit: To practice one of the complementary medicine fields at licensed medical or surgical private health establishment.

3. Licensing Requirements for Complementary Medicine Establishments

(Note: the following regulations are general for all types of clinics, yet there shall be extra details & requirements for specific ones as per their scopes of practice)

A. Facility Requirements:

- Municipality approval for undertaking a commercial activity in the building.
- Approval of the Civil Defense of the safety requirements.
- Contracting with competent companies to transport medical waste.
- The outside environment of the establishment should be clean and well organized.
- Preferable to have the premises on the ground floor or in the upper floors with an electric elevator ready to receive patients with special needs.

- Suitable internal equipping of the building and its ability to receive maintenance works.
- Facilities and corridoes shall be wide; minimum of 1.2 meters
- Sufficient ventilation and natural lighting
- Room sizes suitable for each service; minimum of 9 square meters.
- Walls should be smooth and cleanable.
- Easy cleaning floors (Ceramics, Marble, Granite.)

B. Facility's Layout & Design

1. Reception

- Fully equipped office
- Provision of the necessary means of communication (phone, fax, and Internet service)
- Provision of adequately sealed closet cabinets and sufficient for filing.
- Setup patients' files / electronic system
- Provision of adequate and comfortable seats.
- A board to attach the instructions and circulars.

2. Waiting Room

- Size of the room shall be no less than 9 square meters or the equivalent of one square meter for each patient for males & females.
- Provision of adequate and comfortable seats, easy to clean
- The hall shall be equipped with shelves and a table to put the various publications and means of education.
- Provision of potable water and one-use cups.
- The hall shall be equipped with baskets for general waste (can be opened by foot - black bags).

3. Toilets

- One for male & one for Female (preferably another one for staff)
- Should have special needs accessories.
- Have water sink
- Provision of hands wash soup and tissue
- Baskets for general waste (can be opened by foot - black bags).

4. Staff room / Admin office

- Sofa seats with tables
- Office furniture
- Cabinets
- Baskets for general waste (can be opened by foot - black bags).

5. Store Room

- Shelves

- Boxes

6. Examination / Treatment Rooms

- Not less than 9 square meters
- The device used in examination (if applicable)
- Medical couch for examination.
- Water sink for hands wash, soup and tissue
- Tools for clinical examination of patients
- Tools for treatment according to the authorized specialization
- Tools of education and learning
- Anti-septic hands sterilizers solutions
- Baskets for public waste (can be opened by foot - black bags).
- Baskets of medical waste (can be opened by foot - yellow bags).

C. Infection Control Measures

- Suitable and sufficient sterilization devices, liquids and solutions must be provided to clean the machinery and tools used prior to reusing them.
- Bathrooms, the floors and walls of the facility should be cleaned as required, so as to remain clean of dust and debris.
- Surfaces of furniture and appliances, therapeutic devices and beds shall be cleaned using medical disinfectants at least once a day or as required to prevent infections.
- Towels, blankets and other linens or clothing shall not be used for more than one patient before they are being replaced or washed with appropriate antiseptics before reusing them and maintain their general cleanliness.

D. Disposal of Waste

Special bags shall be assigned to keep health wastes and residues, to be disposed of in a safe manner, not harmful to the environment or the public health, according to the standards, methods and regulations established by the Authorized Agent (Beah company). The contract with medical waste company should be presented and kept available for inspection.

4. Safety and Security

A. Facility Safety and Security

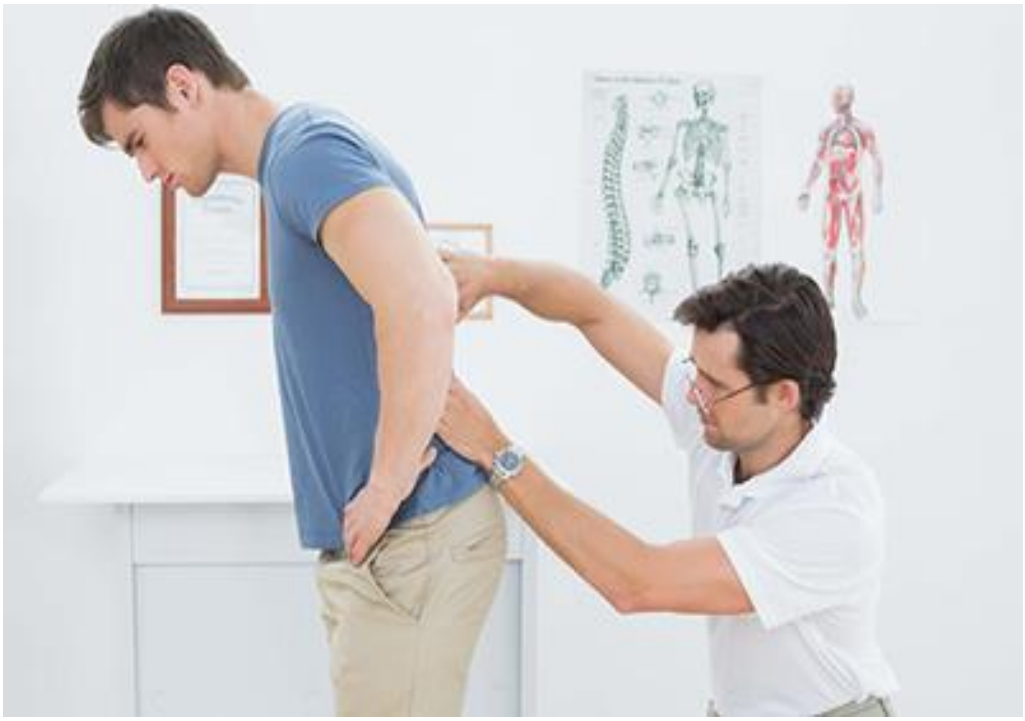
- Tools of fire prevention shall be provide along with training on them.
- There shall be backup exits connected to the institution freely and directly to be used when necessary, leading to the public roads or directly to open yard or place.
- If the nature of the institution's activities required dealing with flammable or explosive liquids or materials, a special protective room or locker shall be assigned to store them, according to the technical assets under the supervision of a specialized technician inn handling with them.

B. Staff Safety and Security

The licensee shall provide the necessary protection of the employees in the institution, working on preventing the occupational hazards, in implementation of the occupational health and safety requirements and shall provide all relevant means to achieve that in the institution, in order to prevent contracting infections or exposure to harm. The licensee shall bear that responsibility personally and the license shall not be granted to the institution unless after taking the pledges and the written acknowledgements, as follows:

- Conducting medical examination to all employees of the center through competent medical committees, to determine their health fitness prior to hiring them, reporting the results of this examination to the Authority.
- Conducting a medical examination to the employees of the institution annually, as required or at the request of the competent authority, to determine the availability of fit to continue working.
- Commitment to vaccinate all employees of the institution against infectious diseases, submitting a proof to conducting the same to the competent authority.
- Ensure that all employees of the institution have been trained or educated sufficiently to deal with the medical devices in the institution, as well as training them the methods of transferring patients by the chairs prepared for the purpose or carrying them on beds, each according to his professional specialization.
- Prohibiting smoking entirely inside the institution, putting a warning sign that indicates such prohibition, written in Arabic and English languages, to be put in a prominent place in the institution.
- Conducting periodic maintenance, as scheduled, to the devices used inside the institution to ensure the availability of safety requirements for the technicians operating these devices, as well as the patients.
- Not allowing the patients to use the medical equipment by themselves unless through one of the competent employees of the institution and under his direct supervision.
- The director of the institution or his authorized representative shall be responsible for the safety of the employees at the facility. Any failure in taking the necessary precautions to maintain the professional integrity of the employees at the facility shall be the responsibility of the director personally.

Chapter Two



General Requirements by Complementary Medicine (CM) Healthcare Professionals

Chapter Two

General Requirements by Complementary Medicine (CM) Healthcare Professionals

A. General Rules & Regulations:

- All healthcare professionals seeking to practice complementary medicine are subjected to follow the licensing regulations like other medical and nursing professionals' laws and policies.
- All complementary medicine healthcare professionals shall obtain a license certificate that is valid for two years from date of issue.
- All complementary medicine healthcare professionals shall obtain medical indemnity from authorized companies on annual basis.
- All complementary medicine healthcare professionals should follow the code of practice complementary medicine outlines below.
- All complementary medicine healthcare professionals should follow their own scope of practice according to their field specialties.
- In the event of breaching any of the professional duties and obligations, the CM healthcare professionals shall be subject to the Authority's established disciplinary committees.

B. Classification of Complementary Medicine Healthcare Professionals:

1. Complementary Medicine Physician.

2. Complementary Medicine Practitioner.

3. Complementary Medicine Therapist / Assistant

C. Codes of Practice

Complementary Medicine (CM) practitioners must practice CM services in accordance with the requirements of this MOH Standard, and the relevant MOH Policies and Standards to ensure that they provide safe and quality CM services for their patients. It is a requirement that CM Healthcare professionals apply the principles of professionalism and ethics at all times; for this purpose, this Code of Practice describes the professional and ethical duties for CM Healthcare professionals, which aims to ensure the delivery of quality, safe and ethical standards of treatment and care.

1. Ethical Practice

CM Healthcare professional's must:

1.1 Practice in a manner consistent with this code of practice.

1.2 Advocate protecting human health, safety and rights and report on acts that violate these rights
1.3 Maintain confidentiality and security of written, verbal and electronic information.
1.4 Respect and maintain the client's right to privacy and dignity.
1.5 Respect and demonstrate sensitivity to diverse cultural and religious beliefs.
1.6 limit his/her services and practices to the respective MOH approved CM scope of practice pertaining to his/her profession and license as defined in this MOH Standard;
1.7 provide comprehensive and accurate information to the patient about the treatment allowing the patient to make an educated choice of treatment;
1.8 Make a valid assessment of the patient's condition based on health history, physical examination, laboratory and other diagnostic tests.
1.9 Communicate clearly and compassionately with the patient (or patient advocate on their current state of health and wellbeing offering appropriate treatment recommendation and advice;
1.10 Consult other healthcare professionals when their expertise is required.
1.11 Respond promptly and constructively to concerns, criticisms and complaints.
1.12 Undertake regular self-assessment and review of own practice based on established criteria through reflection, peer review, critical examination and evaluation;
1.13 Identify the need for updated knowledge base and skills for practice;
1.14 Actively seek new knowledge and skills to ensure ongoing professional development and competency to practice;
1.15 Participate and maintain record of learning and professional development activities attended.
1.16 CM Healthcare professionals licensed by MOH and following the guidance in this code are able to practice their profession safely, competently and ethically. This should be in accordance with to the MOH standard for complaints management and SOPs.

2. **Good Communication**:

2.1 CM Healthcare professionals must communicate effectively with their patients by:

2.1.1 Listening to patients and responding to their concerns and preferences.

2.1.2 Clearly communicating information required by the patient concerning their wellbeing or treatment.

2.1.3 Regularly update the patient with the progress of their treatment and care.

2.2 Clarity of contract:

2.2.1 To ensure that the patient is always able to make informed choices CM Healthcare professionals must give full and clear information about their service before commencing treatment. This shall include information

about the nature of the treatment, expenses, availability for advice, confidentiality and security of records.

2.3 Informed Consent; All practitioners must:

2.3.1 Comply with the MOH Policy on Consent.

2.3.2 Communicate clearly with the patient information about the recommended treatment, its benefits and alternative treatments.

3. Records and record keeping:

3.1 All patient records must be maintained in accordance with MOH standards managing patient medical records, including developing effective electronic record systems. Case notes must be clear, accurate, legible and current. They must contain all the relevant information relating to the progress of the case, for example, treatment given, whether the patient has improved, maintained or deteriorated in their condition since they were last seen.

3.2 Basic requirements of case notes are as follows:

3.2.1Name, address, telephone number, date of birth, essential details of medical history, dates and details of treatment given.

3.2.2 A record of medication, of any kind, taken by the patient, including the names and address of the prescriber if available, also any diagnosis the patient has received from a competent medical authority. Blood pressure, pulse rate readings, other medical data such as weight loss, unusual bleeding or other information must be provided by the patient.

3.2.3 Advice given to the patient either through clinical or telephonic consultation that can help improve the patient's known condition.

3.2.4 Decisions that the practitioner makes in the management of patient's case, such as referrals, disclosure of information or request for medical tests and examinations.

3.2.5 Patient's record on no account is transferred to a new Practitioner/healthcare professional without the authorization of the patient. Where a patient requests the record of their treatment in writing, or asks the record to be forwarded to another Practitioner, it is important to send the relevant information from the patient's case notes as quickly as possible. The full original documents should be retained in accordance with the requirements of MOH standards.

4. Confidentiality and Disclosure:

4.1 All CM Healthcare professionals must ensure patient information is kept in confidence; maintaining privacy and security of information and must be in accordance with MOH policies and standards on patient confidentiality.

5. Referrals:

5.1 CM Healthcare professionals must comply with MOH Patient Referral Policy. Referrals can only be made with patient's consent, unless it is related to life saving status.

5.2 Where consulting another practitioner is necessary, a CM Healthcare professional must ensure that they obtain the patient's consent prior to doing so.

5.3 Patients may be referred to another CM Healthcare professional; such referrals must be recorded at the time of recommendation of the new CM Healthcare professional.

5.4 The CM Healthcare professional should not contact a medical doctor or another healthcare practitioner unless the patients give their consent.

5.5 Details of all the recommended referrals to other health care professionals must be recorded in the patient's records at the time of referral.

5.6 The referring CM Healthcare professional must ensure continuity of patient care when referred to another practitioner by providing the necessary history of the case to the referred practitioner.

6. Professional Practice and Obligations

6.1 Practitioners must practice their work with due diligence. (Due diligence is the level of judgment, care, prudence, determination and activity that a person would reasonably be expected to do under particular circumstances).They must always limit their practice to their area of expertise and within the MOH defined scope of practice and must ensure that treatment is not to be influenced by a client's gender, ethnicity, culture, beliefs, sexuality, life style, age, social status or language difficulty.

7. Competence and Continuing Professional Development

7.1 Practitioners must regularly evaluate and monitor their clinical skills and actively extend their knowledge base and their own personal development through continuing professional development.

8. Notifiable Diseases:

8.1 CM Healthcare professionals should be aware of those diseases which are notifiable under the law and should take appropriate action. This should also be in accordance with MOH Vital statistics Standard.

9. Inappropriate Use of Patient Related Materials:

9.1 CM Healthcare professionals must avoid recording on film, video or through digital techniques, any material or imagery concerning a patient which might be regarded as explicit, indecent or pornographic.

9.2 Practitioners may use film, tape recording or digital imagery of material concerning a patient with the patient's clear, informed, written consent to the precise use of the material.

10. Child Protection:

CM Healthcare professionals must safeguard and protect the health and wellbeing of child and young people.

10.1When communicating with a child or young person, you must:

10.2 Treat them with respect and listen to their views

10.3 Answer their questions to the best of your ability.

10.4 Provide information appropriately.

10.5 It is also advisable to undertake the physical examination of child under 18 in the presence of a parent

11. Contact with Relatives / Interested Parties:

11.1 If a member of the patient's family, friend or other person connected with the patient, communicates with the CM Healthcare professional; it is important to provide them with the information required without breach of confidentiality of patients.

12. Financial and Commercial Dealings:

CM Healthcare professionals must:

12.1 Be transparent on fees before commencing treatment.

12.2 Not exploit patient's vulnerability or lack of medical knowledge when charging for treatment or services.

12.3 Not encourage patients to give, lend or bequeath, money or gifts that will directly or indirectly benefit their practice.

12.4 Not pressure patients or their families to make donations to other people or organizations.

12.5 Not engage in fraudulent or abusive financial practices when billing for services.

13. Conflicts of Interest:

13.1 Practitioners must act in their patient's best interest when making referrals and when providing or arranging treatment or care. They must t not ask or accept any inducement, gifts or hospitality which may affect treatment or patient transfer.

13.2 If you have financial or commercial interests in organizations providing health care or in pharmaceutical or other bio medical companies, these interests must not affect the way you prescribe for, treat or refer patients

14. Research:

14.1CM Healthcare professionals intending to undertake research must seek authorization from MOH prior to conducting any research. It is a breach of the law if they conduct any research without MOH authorization. If authorised by MOH to conduct health research and/or involving patients, they must comply with MOH Research Policies and standards and abide by MOH research ethics requirements patient consent to participate in research and research governance.

14.2 The patient' refusal to participate in research must not influence the care of the patient in anyway

15. Arranging Cover:

15.1 The CM Healthcare professional should arrange effective hand-over procedures, involving clear communication with health care colleagues when he/she is off duty.

16. Professional Boundaries:

16.1 Unprofessional conduct breaches the law and is abusive.

17. Non- Acceptance or Termination of Professional Relationship:

17.1In the incidence of the patient's unreasonable behavior, and termination of treatment; alternative arrangements must be made promptly for the continuing care of the patient, if they require it.

18. Publicity and Advertising:

18.1 Only can publish promotional materials if all the information contained in those materials is factually and accurate advertisements must not contain misleading information that is intended to or does in fact take advantage of the status or of the vulnerability or lack of medical knowledge of any person by placing place unfair pressure on that person to receive treatment. All kinds of advertisements must have approval from MoH and follow the medical advertisement's policy.

19. Complaints:

19.1 CM Healthcare professionals licensed by MOH and following the guidance in this code are able to practice their profession safely, competently and ethically. This should be in accordance to MOH complaints standard and SOPs.

20. General Scope of Practice for CM Healthcare professionals

20.1Directorate general of Private Health Establishments (DGPHE) permits Complementary Medicine (CM) practitioners to act as a portal of entry and provide health care services limited to their area of training and expertise.

20.2 CM Healthcare professionals need to recognize that they are holding themselves out to practice within a system of law and medicine which will review the standard of care that has been taken in relation to a patient.

20.3 CM Healthcare professionals shall comply at all times with the requirements of Code of Practice for CM Healthcare professionals. Any CM Healthcare professional who fails to meet this CM regulation requirements of the code of practice shall be held in breach of the code of ethics and shall be subjected to disciplinary measures on the grounds of professional misconduct.

20.4. CM Healthcare professionals should ensure that their practice and procedures are well defined and transparent, they are operated in a way that is fair and hygienic and that all efforts to ensure standards of good medical practice are involved.

20.5. CM Healthcare professionals should be aware of extend and limits of their specialty. They should essentially know which conditions they will be unable to treat successfully, and be able to identify and refer patients to medically qualified physicians and specialists when necessary. A patient showing signs and symptoms of an underlying pathological condition should be advised to seek a medical diagnosis.

20.6. The practitioner should assist the patients in weighing the possible benefits and risks of other types of treatment, helping them to consider conventional diagnostic procedures; routine screening tests etc, acknowledging the usefulness of such procedures at appropriate times, even for those who may wish to avoid conventional treatment.

20.7. The CM Healthcare professionals may make a medical diagnosis and/or diagnosis according to the science and philosophy of their field of training/ specialty. However when discovering dysfunctions, they can also make mention of any believed disorder and advice the patient to see the medical doctor for further advice and/or treatment outside the scope of his practice.

20.8. Render assistance to patients in emergency situations, to the greatest extent permitted by training and circumstances.

20.9. CM Healthcare professionals can only prescribe pharmaceutical medicines and products as per their own specialty. They can also prescribe 'over the counter' products that are registered with the Ministry of Health.

20.10. When a remedy is prescribed, it is not enough to say that the remedy is traditional and considered not harmful. It is the duty of the practitioner to ensure that the remedy is in fact, not harmful or potentially harmful.

20.11. The patient has the right to know and the practitioner is obliged to offer, the name or names of the prescribed remedy or remedies unless the patient agrees otherwise. Clear instructions must be made for each prescription made. They should not use secret remedies.

20.12. The Practitioner should not alter a medical doctor's prescription to the patient. When a patient's health improves as a result of complementary treatment, the practitioner should not reduce the dosage or stop their prescribed medication. He should be aware that the responsibility for adjusting or withdrawing prescribed medication lies with the patient and the prescriber of that medication.

20.13. The CM Healthcare professionals are not allowed to treat patients with acute or critical conditions who need immediate emergency medical care. They should not perform any surgical procedure or any inoculation or injections as well as blood withdrawal from patients (Except for cupping). They are also forbidden from practicing midwifery.

20.14. Claims, whether explicit or implied, orally or in writing implying cure of any named disease must be avoided.

20.15. The CM Healthcare professionals are not allowed to treat communicable diseases.

20.16. CM Healthcare professionals can offer hope to patients, both by attempting to influence the underlying disease and, often more importantly, by addressing emotional states, energy levels, coping styles, and other aspects that contribute to quality of life. This is particularly important for patients with chronic diseases and no prospect of cure from conventional medicine.

20.17. CM Healthcare professionals must always balance their claims carefully while treating patients. They should consider the realistic chances of improvement and foresee the dangers of creating false hope and further disappointment.

20.18. CM Healthcare professionals are not allowed to sell or dispense any prescribed or advised products or preparations from his own practice clinic unless he/ she is permitted by the Directorate general of Private Health Establishments (DGPHE) to do so.

20.19. CM Healthcare professional should only use the professional title granted to him by the MoH Medical licensing committee.

20.20. The CM Healthcare professional will not draw up or sign any certificates or documents that should be statutorily filled up and signed by a registered medical doctor.

20.21. CM Healthcare professionals should be aware of those diseases that are notifiable under the law and should take appropriate actions in this regard.

20.22. CM Healthcare professionals must avoid recording on film, video or through digital techniques, any material or imagery concerning a patient which might be regarded as explicit, indecent or pornographic. They may use film, tape recording or digital imagery of material concerning a patient only with the patient's clear, informed, written consent to the precise use of the material.

20.23. CM Healthcare professional must act in the patient's best interest when making referrals and when providing or arranging treatment or care. You must not ask or accept any inducement, gift or hospitality, which may affect or be seen to affect the way you prescribe for, treat or refer patients.

20.24. CM Healthcare professionals intending to undertake research must be familiar with and abide by current research ethics requirements, research governance and statutory obligations regarding research.

20.25. Patients who complain about the care or treatment they have received have the right to expect a prompt and appropriate response. You have the professional responsibility to ensure that they have clear information about how and where to express any concern they may have.

20.26 CM Healthcare professionals are not permitted to issue sick leaves certificates for patients and their attenders.

Chapter Three

Specific Regulations for Complementary Medicine Establishments & Healthcare Professionals

Homeopathy Clinic / Centre

Homeopathy Clinic / Centre

1- About

1.1 “Homeopathy” A therapy based on the theory of treating likes with likes, which basic principles are: law of similarity, direction of cure, principle of single remedy, the theory of minimum diluted dose and the therapy of chronic diseases. Homeopathic remedies use highly diluted substances that if given in higher doses to a healthy person would produce the symptoms that the dilutions are being given to treat. In assessing the patient homeopaths often take into account a range of physical, emotional, and life style factors which contribute to the diagnosis. Rather than fighting the disease directly, medicines are intended to stimulate the body to fight the disease.

1.2 Homeopathy Clinic provides treatment by consultation and prescription for homeopathic remedies. The clinic also provides nutritional, dietary and preventive medicine advice and education regarding physical, emotional and spiritual balance as it relates to Homeopathy.

2- Homeopathy Scope of Practice

2.1 The Practice of Homeopathy shall include activities that involve:
2.1.1 Engaging in the examination, diagnosis or treatment of a symptoms or human disease.

2.1.2 Offering or attempting to prescribe or order any homeopathic medicine for the use of any other person, except as otherwise authorized by law.

2.2 The Practice of Homeopathy does not include assistance rendered in emergency situations by the Licensee.

3. Classification of Homeopathy Healthcare Professionals:

I) Homeopathy Practitioner

II) Physician Privileged to Practice Homeopathy.

III) Homeopathy Technician / Assistant

4. Eligibility Criteria of Homeopathy Healthcare Professionals

I) Homeopathy Practitioner

In determining the eligibility of an applicant for licensing with MoH as Homeopathic Practitioner, the applicant must comply with all the following requirements:

a) Professional Degree of Homeopathy (BHMS- Bachelor in Homeopathic Medicine and surgery)/ licentiate from an accredited Homeopathic program of not less than 5 years (including internship).

b) Current license/registration to practice in home country or country of last employment.

c) Experience: Not less than 2 years after internship.

OR

a) To have certified from an accredited Homeopathy program of not less than 3 years full time program.

b) Current license/ Registration to practice in home country or country of last employment.

c) Experience: Not less than 4 years after completion of the course.

II) Physician privileged to practice Homeopathy

a) Successful completion of an accredited Homeopathic program of not less than 1 year full time duration.

b) Current license/ Registration to practice in home country or country of last employment.

c) Holding a valid MoH license to practice as a physician.

III) Homeopathy Technician / Assistant

Homeopathic technician / assistants are required to have at least a high school diploma or equivalent. They should got experience in a medical or homeopathy environment. OR

A 40-hour training program and 160 hours of training under the supervision of a licensed homeopathic physician.

5. General Requirements for all Licensed Homeopath

5.1. Patient Safety and Evidence-Based Care in the Practice of Homeopathy shall be ensured by the licensed professional rendering the services.

5.2. Licensed Homeopaths shall not be permitted to expand the scope of their Professional Practice where they do not have the requisite training or experience to pursue such therapeutic approaches.

5.3. Licensed Homeopaths who also have an active physician license may use sterile homeopathic medicinal products for injections.

5.4. Licensed Homeopaths must adhere to the following principles and comply with the following obligations in his Practice of Homeopathy. These are in addition to such other requirements as are established under these Rules and the General Licensing Rules and pursuant to conditions that the MoH health regulation may attach to such Licensee's License:

5.4.1 The Licensee shall have general competence in patient oriented skills, integrating examination and diagnosis with sensitivity to patient needs and culture. They must be knowledgeable in the basic scientific approach to common illnesses and the serious or life threatening common diseases and refer when appropriate.

5.5. The decision to employ Homeopathy and its effectiveness in a given case are governed by knowledge of the individual patient in accordance with Homeopathic Principles, and with careful observance of the following specific procedures:

5.5.1 Individualization of the total symptom complex of the patient must be obtained by a detailed history when appropriate.

5.5.2 Employment of diagnostic procedures, supported by laboratory studies, when appropriate.

5.5.3 Evaluation of the sensitivity of patient to medical treatment and the probable reaction and response of the patient to administration of homeopathic medicinal products.

5.5.4 Administration of one or more single or complex homeopathic medicinal product when possible, in the dose that will evoke the desired response in the patient.

5.5.5 The Licensed Homeopaths must remember that they are treating a patient who has a disorder rather than just prescribing for a disease entity.

5.6. The Licensed Homeopath is obligated to refer to a general practitioner or specialists when there is any doubt about the patient's diagnosis or response to therapy. A referral must not be withheld or discouraged when the patient asks for a second opinion.

5.7. Licensed Homeopath bears the responsibility of maintaining a comprehensive record about their patient, including pursuit of diagnostic tests and consultations in a timely fashion and collaborating with other medical professionals.

5.8. In addition to satisfying the above requirements of a Licensed Homeopath:

5.8.1 Must fulfil the Continuous Professional Development requirements for licensure, the standards of Professional Practice and behavior expected of all Licensees.

6. Duties & Responsibilities of Homeopathy Technician / Assistant

The homeopathic technician / assistant is responsible for assisting the homeopathic practitioner in running a homeopathy clinic. The homeopathic technician / assistant shall do the following tasks:

- Greet patients when they enter the clinic and make them feel welcome and comfortable.
- All phone calls and inquires will be handled by the homeopathic technician / assistant.
- He or she will schedule appointments and maintain the homeopathy physician's calendar.
- When payment is due, the homeopathic technician / assistant will explain fees and accept payment, code and bill insurance claims, or perform routine collections on past-due accounts.
- He or she will issue receipts, guidelines for treatment, and educational materials.

- The homeopathic technician / assistant is also responsible for maintaining databases containing patient information, and either electronic or paper patient files.
- He or she will serve as the primary customer service representative for the homeopathy clinic, and as such will educate patients on treatment procedures and insurance information requirements and limitations, and liaise between the patient and the homeopathy physician.
- They will order and stock products recommended by the homeopathic physician and educate patients in their use or benefits.
- The homeopathic technician / assistant may even be specially trained to take and record the patient's vital signs and medical history.

7. Required Place & Size for Homeopathy Clinic

i. Two waiting areas for Male & Female (each could accommodate at least 6 chairs)
ii. Reception area
iii. Consultation room (9m^2)
iv. Pharmacy (9m^2) You will need this section only if you store and dispense homeopathic medicines from your own clinic. If you write prescriptions to be taken from a homeopathic pharmacist, then you can skip this one.
v. Administration office
vi. Storage area
vii. Two Toilets

8. Required Equipment for Functional Areas

Area	Equipment
Consultation	• desk with chair for doctor • computer with specialized homeopathy software • chairs for patients & attendances • examination couch • water sink • Stethoscope • BP Apparatus- Mercury type • Percussion Hammer • Torches • ENT set with Head Mirror • Weighing Scale
Pharmacy	• Metal racks to store medicines. • Dispensing desk and chair • Registered homeopathic products with labels • Computer with software homeopathic system

Traditional Chinese Medicine (TCM) Clinic / Centre

Traditional Chinese Medicine (TCM) Clinic / Centre

1- About:

1.1 'Traditional Chinese Medicine" (TCM) is a system of primary health care for the prevention, diagnosis, and treatment of human health conditions and disease; the promotion or restoration of health; and the support and stimulation of a patient's inherent self-healing processes through patient education and the use of Traditional Chinese Medicine therapies and therapeutic substances.

1.2 Traditional Chinese Medicine Centre provides services for health enhancement and treatment through consultation, prescriptions and modalities such as: acupuncture, stimulation of points, areas of the body or substances in the body using qi, needles with or without electrical stimulation (using clean needle technique), moxibustion, heat and cold, color, light, lasers, or suction (cupping –"wet" or "dry") and musculoskeletal manipulation consistent with Traditional Chinese Medicine training (Tui Na).

2. Traditional Chinese Medicine Scope of Practice

2.1 The Practice of Traditional Chinese Medicine shall not include surgical procedures or use of prescription medications.

2.2 The Practice of Traditional Chinese Medicine may include activities that involve:
2.2.1 Physical examination and request laboratory examinations consistent with Traditional Chinese Medicine education and training, for diagnostic purposes, including, but not limited to, clinical laboratory tests, and physiological functional testing.
2.2.2 Request diagnostic imaging studies consistent with their Traditional Chinese Medicine training.

2.3 All diagnostic tests not consistent with naturopathic medical education and training must be referred for performance and interpretation to an appropriately licensed healthcare professional.

2.4 A Licensed Traditional Chinese Medicine Professional may administer, order, and prescribe or perform the following:
2.4.1 The stimulation of points, areas of the body or substances in the body using qi, needles with or without electrical stimulation (using clean needle technique), moxibustion, heat and cold, color, light, lasers, or suction (cupping).

2.4.2 Cupping can be done "dry" or "wet"; if the cupping is done wet, sterile technique must be followed.

2.4.3 Therapeutic exercises, qi exercises, breathing techniques, and meditation.

2.4.4 Dietary and nutritional counselling and education regarding physical, emotional and spiritual balance as it relates or Traditional Chinese Medicine.

2.4.5 Musculoskeletal manipulation consistent with Traditional Chinese Medicine training (Tui Na).

2.5 'Medical Acupuncture refers to licensed medical doctors practicing acupuncture only, they may only practice acupuncture utilizing the stimulation of points using needles, moxibustion, heat and cold, color, light, or lasers.

2.6 The Practice of Traditional Chinese Medicine does not include assistance rendered in emergency situations by the Licensee.

3. Classification of TCM Healthcare Professionals:

I) Traditional Chinese Medicine Practitioner

II) Physician privileged to practice Traditional Chinese Medicine

III) Traditional Chinese Medicine Technician / Assistant

4. Eligibility Criteria of Traditional Chinese Medicine (TCM) Healthcare Professionals

I) Traditional Chinese Medicine (TCM) Practitioner Eligibility Criteria

In determining the eligibility of an applicant for licensing with MoH as Chinese Medicine Practitioner, the applicant must comply with all the following requirements:

a) Professional degree of Traditional Chinese Medicine (B.TCM - Bachelor of Traditional Chinese Medicine) from a recognized University of minimum five years full time duration including one year internship.
b) Current license/registration to practice in home country or country of last employment.
c) Experience: Not less than 2 years after internship.

OR

a) A Licentiate from an accredited Traditional Chinese Medicine Education program of three to four year years full time or equivalent of not less than total of 2,400 hours (consisting of 1,500 hours of theory and laboratory/clinical practice and 900 hours of clinical practicum).
b) Current license/ Registration to practice in home country or country of last employment.
c) Experience: Not less than 4 years after completion of the course.

II) Physician Privileged to Practice Traditional Chinese Medicine

a) Successful completion of an accredited training program in TCM of two to three years full time or equivalent of not less than total of 1300 hours (Consisting of 800hours of theory and laboratory/clinical practice and 500 hours of supervised clinical practicum).
b) Current license/ Registration to practice in home country or country of last employment.
c) Holding a valid MoH license to practice as a physician.

III) Traditional Chinese Medicine Technician / Assistant

a) High school diploma

b) Diploma in one of the auxiliary medical professions and attended a practical training of no less than 80 hours from certified institutions

c) Two years' experience

5. General Requirements Licensed Traditional Chinese Medicine Professionals

5.1. Patient safety and Evidence-Based Care in the Practice of Traditional Chinese Medicine or Medical Acupuncture shall be ensured by the licensed professional rendering the services.

5.2. Licensed Traditional Chinese Medicine Professionals shall not be permitted to expand the scope of their Professional Practice where they do not have the requisite training or experience to pursue such therapeutic approaches.

5.3. The Licensee shall have general competence in patient oriented skills, integrating examination and diagnosis with sensitivity to patient needs and culture. They must be knowledgeable in the basic scientific approach to common illnesses and the serious or life threatening common diseases and refer when appropriate.

5.4. The decision to employ Traditional Chinese Medicine or Medical Acupuncture and its effectiveness in a given case are governed by knowledge of the individual patient in accordance with Traditional Chinese Medicine or Medical Acupuncture principles, and with careful observance of the following specific procedures:
5.4.1 Individualization of the medical history and physical examination of the patient must be obtained.

5.4.2 Employment of diagnostic procedures, supported by laboratory studies, when appropriate as outlined in above.

5.4.3 Evaluation of the sensitivity of patient to medical treatment and the probable reaction and response of the patient to administration of the treatment chosen.

5.5. The Licensed Traditional Chinese Medicine Professionals is obligated to refer to a general medical physician or specialists when there is any doubt about the patient's diagnosis or response to therapy. A referral must not be withheld or discouraged when the patient asks for a second opinion.

5.6. The Licensed Traditional Chinese Medicine Professionals bears the responsibility of maintaining a comprehensive record about their patient, including pursuit of diagnostic tests and consultations in a timely fashion and collaborating with other medical professionals.

5.7. In addition to satisfying the above requirements, a Licensed Traditional Chinese Medicine Professionals must fulfil the Continuous Professional Development requirements for licensure, the standards of Professional Practice and behavior expected of all licensees.

6. Duties & Responsibilities of Traditional Chinese Medicine Technician / Assistant

The Traditional Chinese Medicine TCM Technician / Assistant is responsible for assisting the TCM practitioner in running a TCM clinic. The TCM technician / assistant shall do the following tasks:

- Greet patients when they enter the clinic and make them feel welcome and comfortable.
- All phone calls and inquires will be handled by the TCM technician / assistant.
- He or she will schedule appointments and maintain the TCM physician's calendar.
- When payment is due, the TCM technician / assistant will explain fees and accept payment, code and bill insurance claims, or perform routine collections on past-due accounts.
- He or she will issue receipts, guidelines for treatment, and educational materials.
- The TCM technician / assistant is also responsible for maintaining databases containing patient information, and either electronic or paper patient files.
- He or she will serve as the primary customer service representative for the TCM clinic, and as such will educate patients on treatment procedures and insurance information requirements and limitations, and liaise between the patient and the TCM physician.
- They will order and stock products recommended by the TCM physician and educate patients in their use or benefits.
- The TCM technician / assistant may even be specially trained to take and record the patient's vital signs and medical history.
- Under the direction of an TCM manual practitioner, carry out treatment programs of TCM techniques and massage.
- Assist TCM Manual Practitioner with patient intake

7. Required Place & Size for TCM Clinic

i. Two waiting areas for Male & Female (each could accommodate at least 6 chairs)
ii. Reception area
iii. Consultation room ($9m^2$)
iv. Two Treatment rooms (each $12m^2$)
v. Storage area
vi. Dirty utility room
vii. Two Toilets

8. Required Equipment for Functional Areas

Area	Equipment
Reception	• desk with chairs • computer • filling cabinet • copy machine
Waiting	• chairs • table • literature Rack • drinking water
Consultation	• desk with chair for doctor • computer with specialized Chinese Medicine software • chairs for patients & attendances • examination couch • A washbasin with a hot and cold water supply • Dispenser liquid soap and disposable paper towels
Treatment	• treatment couch • full set of cupping items • full set of acupuncture items • A washbasin with a hot and cold water supply • Dispenser liquid soap and disposable paper towels • antiseptic items (gloves, solutions, gowns,,,etc) • storage cabinets • garbage baskets (yellow and black bags)

8.1 Hand washing facilities must include:

a) A washbasin with a hot and cold water supply, preferably wrist or arm connected to the mains drainage system, located in the treatment room

b) Dispenser liquid soap and disposable paper towels

c) An adequately sized bin, pedal operated if lidded, situated close to the basin with disposable sealable polythene liner for used tissues and other similar waste matter.

8.2 The treatment room must provide:

a) Sufficient space to allow free movement, safe handling of equipment and performance of procedures.

b) Sufficient space for a clean field for acupuncture equipment

c) Sufficient clean and suitable storage for all items, so as to avoid, as far as possible, the risk of contamination

d) Furniture, which is clean and maintained in good repair

e) Smooth, easily cleanable surfaces on tabletops, shelves and all working surfaces

f) Smooth impervious surfaces on treatment couches, chairs and other furniture, which is used for treatment.

g) Smooth, impervious flooring or short-pile (not looped) commercial carpeting

h) Adequate artificial lighting, heating and ventilation.

8.3 The treatment surfaces must be:

a) Covered with fresh paper couch roll which is disposed of after treating each patient **or**

b) If covered by towels or sheets alone, only covered by those which are fresh for each patient and boiled or machine-washed on the 40-60 degrees setting before being reused

c) If covered by towels, sheets or pillowcases underneath a paper couch roll, only covered by those which are fresh each day, boiled or machine washed on a 40-60 degrees setting before being reused, and removed after treatment and placed in yellow clinical waste disposal bags if any spillage of blood or body fluid takes place during a treatment

d) Regularly cleaned with an appropriate anti-bacterial agent, at least at the beginning or end of every working day.

8.4 Equipment

The following equipment, all of which must be CE-marked and conform with current Medical Devices Agency legislation must be used for safe and hygienic practice:

a) Single-use pre-sterilized disposable solid needles (reusable needles are not acceptable).

b) Guide-tubes, which, if used, must be pre-sterilized, come packaged with each individual needle or set of needles, and must not be used or stored for use beyond the treatment session in which the seal on the package has been broken.

c) Plum blossom needles (‘seven star hammers’) which, whether plastic or stainless steel, must be pre-sterilized and single-use only.

d) Glass cups, derma rollers and other reusable clinical equipment which have been properly washed and/or sterilized and stored (see Guide to Safe Practice Appendix on Sterilization)

e) Single-use paper tissues, paper towels, and couch roll.

f) Disinfectants, including pre-packed 70% isopropyl alcohol swabs or products, which contain 0.5% chlorhexidine.

g) Sterile cotton wool and non-sterile cotton wool/buds.

h) Sharps box conforming to BS 7320:1990 and clearly marked 'Danger - Contaminated Needles - To Be incinerated' adjacent to the treatment surface and placed at a convenient height on a stable surface.

i) A First Aid kit complying with current Health and Safety (First Aid) Regulations containing a sufficient supply of suitable bandages, dressings, antiseptic creams and plasters

j) Disposable surgical gloves.

k) Non-medical supplies: cabinets, rolling carts and trays

6. Clean Hygienic Procedure

6. 1 The cleanliness of the treatment room must be maintained by:

a) Cleaning and dusting at least weekly all tabletops, shelves and impervious surfaces with a damp cloth and occasionally with hot water and detergent.

b) Washing daily all impervious floor surfaces with appropriate disinfectant cleansers.

c) vacuum-cleaning daily and professionally steam cleaning at least once every year all carpets in the areas adjacent to treatment surfaces.

d) Frequently laundering all blankets used in treatment by boiling or machine-washing on the 40-60 degrees setting**.**

6.2 You must ensure that your own health, including personal hygiene, does not endanger the health of a patient in any way. You must:

a) Cover all cuts and wounds with a waterproof dressing

b) Keep nails short and clean

c) Wear suitable clean clothing and, optionally, a clean white coat or overall

d) Refrain from smoking, eating or drinking whilst engaged in treatment

e) Wear no large, loose or dangling jewellery or rings, nor wear loose clothing or hair that might contaminate the treatment area or the patient's skin

f) Inform your general practitioner early if you suspect that you are suffering from or have been in contact with an Infectious Notifiable Disease and ensure that your general practitioner knows that you are engaged in the practice of acupuncture

g) Avoid giving treatment when suffering from an infectious or contagious condition.

6.3 You have a duty of care to protect the health and safety of the patient. You must:

a) Ensure that any planned treatment takes full account of the patient's known medical history and potential allergic reactions

b) Ensure that informed consent has been obtained in accordance with the requirements of the Code of Professional Conduct

c) Ensure that the part of the body to be treated is clean and free of any cuts or wounds and that patients are asked to cover cuts or wounds before coming for treatment

d) Ensure that you do not under any circumstances needle through clothing, even if requested or given approval to do so by the patient

e) Ensure that immediately before use, any paper or other material used as a covering on a chair, seat or couch, and any towel, cloth or other article which is applied to the patient's skin should be clean, and should not have been used in connection with any other patient without having been cleaned or, where appropriate, disinfected

f) Caution patients left unattended with needles in place during a treatment about any movement which might cause them injury through bending or damaging a needle

g) Ensure that a patient is able to call your attention immediately at any time they are left unattended with needles in place

h) Remain with your patient at all times when moxibustion is carried out in order to avoid any risk of burn injury.

6.4 In preparing to treat you must:

a) Wash your hands thoroughly with liquid soap and warm water immediately before the acupuncture procedure

b) Ensure that a clean field is established.

6.5 In order to needle hygienically and safely you must:

a) Ensure that the skin at the needle site is clean

b) Ensure that any areas of the body where moisture or exudates may collect, such as the groin and genital area, ears, feet, under arms and the area below the breasts, near the mouth, nose, scalp and other hair covered areas are swabbed with 70% isopropyl alcohol or products which contain 0.5% chlorhexidine before needling

c) If points are marked prior to needling ensure that needles are never inserted through ink marks unless gentian violet pens are used and the patient is alerted to the risk of permanent staining. Alternatively, points may be marked by using a cotton bud dipped into iodine in an alcohol solution. In this case the point can be needled through the iodine mark

d) Open all single-use pre-sterilized needles and instruments in the patient's presence and immediately before use

e) Use a fresh needle for every point needled during a treatment, or if reusing the same needle, only do so where all of the sites to be needled have been swabbed before needling and where the needle (and guidetube, if used) is not placed on any other surface in between separate insertions

f) Ensure that the sterile needles and instruments do not come into contact with anything that is not sterile before use on the patient

g) Discard, in the sharps container, any sterile needles or instruments, which are accidentally contaminated

h) Discard, in the sharps container, any sterile needles or instruments with their packaging seals broken

i) Ensure that in inserting the needle the shaft of the needle is never touched with bare fingers or with non-sterile materials

j) Use only sterile cotton wool to support the shaft of the needle once it has been inserted or if it is inserted without a guide-tube. At no stage must the needle be inserted through the cotton wool with either method of insertion

k) Ensure that hands are cleansed again, either by hand-washing or by the use of alcohol gel or products which contain 0.5% chlorhexidine, at any time during treatment if they are contaminated by contact with clothing, pens, clinic furniture, etc, between separate needle insertions

l) Ensure that any major blood or body fluid spills are cleaned up promptly with disinfectant solution

m) Ensure that you wear well-fitting disposable surgical gloves

- if the patient is bleeding profusely
- if the patient has open lesions or is known to have a contagious disease
- if you have cuts or wounds on your hands or have a skin infection or lesion
- if you are handling blood-soiled items, body fluids, excretions, and secretions, as well as surfaces, materials, and objects exposed to them.

6.6 When removing needles / cups from your patient, you must:

a) Ensure that hands are washed immediately prior to the removal of needles

b) Place each needle immediately into the sharps container without letting it touch any other surface in the treatment room

c) If blood is drawn, apply light to moderate pressure with sufficient clean cotton wool/cotton buds or a clean swab to prevent contact with the patient's body fluids and dispose of the cotton wool/bud/swab immediately in a suitable sharps container or clinical waste bag

d) If ‘sealing’ the point afterwards, use a clean swab or cotton wool/cotton bud

e) Once a point has been pierced, do not re-palpate the point with your bare finger during that treatment session unless the fingertips have been cleansed by hand-washing or by the use of alcohol gel

f) Wash your hands thoroughly at the end of the treatment to reduce the risk of cross-infection with your following patient

g) If needles are removed by someone under your direct supervision or by someone to whom you have delegated the task, you must ensure that they comply with the provisions of this section.

6.7 After the treatment has finished and needles / cups have been disposed of safely you must:

a) Replace any blankets or pillow cases which have come into contact with body fluids

b) Dispose all used materials in yellow clinic waste bags.

c) Wash any dishes used in moxibustion during the treatment

d) Store all needles, instruments and equipment in a clean and secure place

6.8 In the event of suffering a needle-stick injury, you must:

a) Encourage free bleeding from the site if possible, but not suck the wound

b) Wash thoroughly with soap and water but without scrubbing

c) Discard the needle immediately and never continue to use a needle on a patient that may have penetrated your own skin

d) Record the injury in a permanent form which can be accessed at a later date, i.e. accident book or similar

e) Seek medical advice immediately (preferably within one hour).

7. Disposal of Equipment and Clinical Waste

7.1 In disposing of equipment you must ensure that:

a) All needles, cups, plum blossom needles (‘seven star hammers’) and dermal needles (‘press-studs’) are immediately placed after use in appropriate sharps disposal containers

c) All sharps containers, when three quarters full, are disposed of in accordance with local Environmental Health Department guidelines

d) All clinical waste, which includes any paper waste, swabs, cotton wool/buds etc., which has been contaminated with spillage of body fluids such as blood, open wound abrasions or mucous membranes is segregated in sealed clinical waste bags before being collected for disposal by a licensed agent.

e) All other waste, which includes any paper waste and swabs, cotton wool/buds, etc., which has not come into contact with body fluids or spillages, as well as needle wrappings and single use guide-tubes, is carefully and separately double-bagged daily and disposed of as domestic waste

f) All waste disposed of through domestic waste collection is left for as little time as possible prior to collection in the usual collection area or location

g) All contracts agreement with Beah Company and receipts for clinical waste collection (or detailed notes kept on your own file where receipts are not issued) are retained for at least one year and available for inspection**.**

8. Register of Patients and Patient Records

8.1 You must record in electronic medical record system:

a) The names and addresses of all patients with unique register numbers for each patient.

b) The dates of attendance in the individual patient records for each visit.

c) The full information required in patients' notes as detailed in the Medical Record Policy.

8.2 In the event of your patient having a diagnosis of a Notifiable Infectious Disease you must ensure that:

a) It is safe to treat that patient and that you have advised the patient not to view acupuncture as a substitute for any treatment that a doctor has prescribed

b) In the event of your being suspected of having caused an outbreak, all records must be readily accessible and allow prompt and efficient investigation into the source of the infection

c) The register described above must be available to trace patients and to track the infection

9. Health and Safety at Work

9.1 You must be familiar with and comply with the requirements and provisions of current Health and Safety at Work legislation:

a) This places a duty on you to conduct your work in such a way as to ensure, so far as is reasonably practicable, that not only patients and employees but also the public and other visitors are not exposed to risks to their health or safety.

9.2 In ensuring that premises are safe workplaces particular attention is drawn to the following:

a) All floors, passages and stairs shall be of sound construction, properly maintained, and should be kept free from obstruction and from any substance likely to cause persons to lose their footing

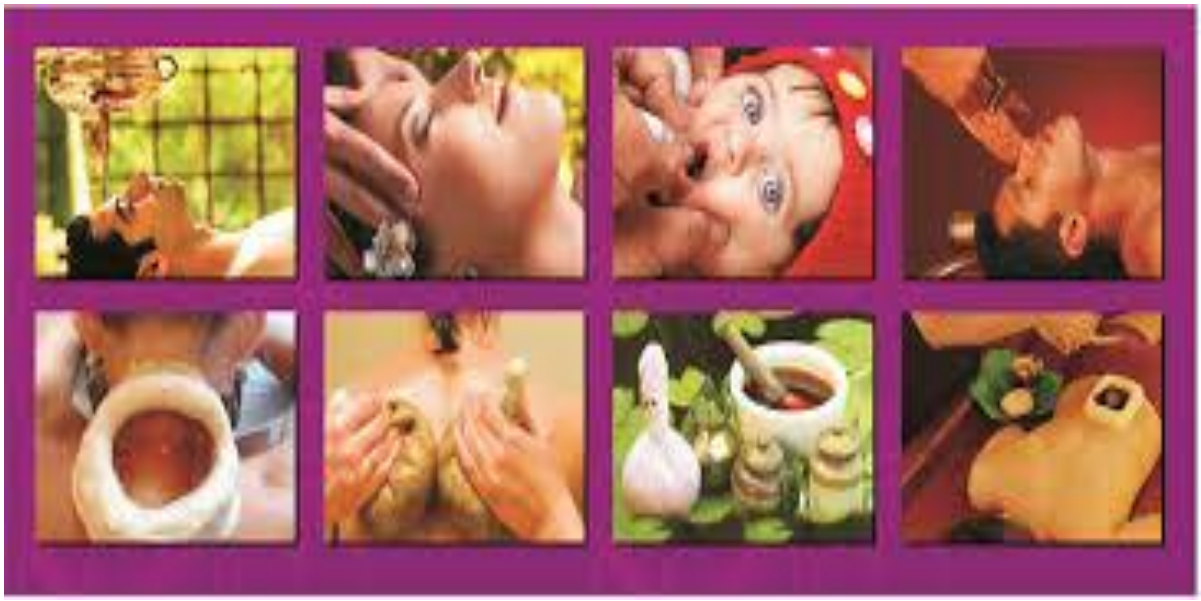
b) A substantial handrail and two-way lighting system must be provided to every staircase

c) Every dangerous part of equipment, appliances and machinery must be effectively guarded

d) Equipment and machinery should be subject to regular inspection and maintenance where necessary

g) Care should be taken to keep cables as short as possible and routed in such a way as to prevent the risk of tripping

Ayurveda Clinic / Centre



Ayurveda Clinic / Centre

1- About

"Ayurveda" is a system of primary health care that originated in India at least several thousand years ago for the prevention, diagnosis, and treatment of human health conditions and disease; the promotion and/or restoration of health; and the support and stimulation of a patient's inherent self-healing processes through patient education and the use of Ayurveda therapies and therapeutic substances.

Ayurveda Centre provides services aimed at prevention and treatment of diseases through consultation, prescriptions, lifestyle interventions, detoxification therapies, breathing exercises and meditation. The clinic may also provide services related musculoskeletal manipulation and /or therapeutic massage consistent with the training and education.

2- Ayurveda Scope of Practice

2.1 The central principal of Ayurvedic medicine is that health is present when the three fundamental doshas called Vata, Pitta and Kapha are in a balance. Vata is the air principle and is linked to the function of the nervous system Pitta is the fire principle and is linked to digestion, and metabolism via the venous system. Kapha is the water principle and is related to mucous, lubrication and the carrier of nutrients via the arterial system. Patients are commonly of a predominant dosha or constitution, but all doshas have the basic elements within them. Ayurvedic therapies include herbs, nutrition, panchakarma cleansing, massage, and therapeutic Yoga.

2.2 The Practice of Ayurveda shall not include surgical procedures or use of prescription medications. The Practice of Ayurveda may include, activities that involve:

2.2.1 Physical examination and request laboratory examinations consistent with Ayurveda education and training, for diagnostic purposes, including, but not limited to, clinical laboratory tests, and physiological functional testing.

2.2.2 Request diagnostic imaging studies consistent with their Ayurveda training.

2.3 A Licensed Ayurveda Professional may administer, order, and prescribe or perform the following:

2.3.1 Therapeutic yoga exercises, pranayama exercises, and meditation.

2.3.2 Dietary and nutritional counselling and education regarding physical and emotional balance as it relates or Ayurveda.

2.3.3 The prescription of Ayurvedic herbal medicines (single or in combination as tinctures, granules or raw herbs) as long as it is consistent with CM facility guidelines.

2.3.4 Musculoskeletal manipulation and massage consistent with Ayurveda training.

2.4 The Practice of Ayurveda does not include assistance rendered in emergency situations by the Licensee.

3. Classification of Ayurveda Healthcare Professionals:

I) Ayurveda (Traditional Indian Medicine) Practitioner

II) Physician privileged to practice Traditional Indian Medicine (TIM)

III) Ayurveda (Traditional Indian Medicine) Technician / Therapist

4. Eligibility Criteria of Ayurveda (Traditional Indian Medicine) Healthcare Professionals:

I) Ayurveda (Traditional Indian Medicine) Practitioner eligibility criteria

In determining the eligibility of an applicant for licensing with MoH as Ayurveda Practitioner, the applicant must comply with all the following requirements:

a) Professional Degree of Indian medicine - Ayurveda (BAMS- Bachelor of Ayurvedic Medicine and surgery) or equivalent of not less than 5 years full time duration including internship (comprising not less than 4500 hours of classroom theory and practical sessions and 1000 hours of internship training).

b) Current license/registration to practice in home country or country of last employment.

c) Experience: Not less than 2 years after internship.

OR

a) Licentiate from an accredited Ayurveda Medicine program over a three to four years full time / equivalent, comprising not less than 2500 hours (classroom theory and practical sessions) followed by 500 hours of supervised internship training.

b) Current license/ Registration to practice in home country or country of last employment.

c) Experience: Not less than 4 years after internship.

II) Physician privileged to practice Traditional Indian Medicine (TIM)

a) Successful completion of an accredited Ayurveda program of not less than one-year full time duration.

b) Current license/ Registration to practice in home country or country of last employment.

c) Holding a valid MoH license to practice as a physician.

III) Traditional Indian Medicine (TIM) Technician / Therapist:

Professional Degree of Indian medicine – Ayurveda not less than (6-12 months) duration from recognized institutions with two years' experience after graduation.

5. General Requirements for all Licensed Ayurveda Professionals

5.1. Patient safety and Evidence-Based Care in the Practice of Ayurveda shall be ensured by the licensed professional rendering the services.

5.2. Licensed Ayurveda Professionals shall not be permitted to expand the scope of their Professional Practice where they do not have the requisite training or experience to pursue such therapeutic approaches.

5.3. A Licensee who holds an Ayurveda License must adhere to the following principles and comply with the following obligations in their practice of Ayurveda:

5.3.1. The Licensee shall have general competence in patient oriented skills, integrating examination and diagnosis with sensitivity to patient needs and culture. They must be knowledgeable in the basic scientific approach to common illnesses and the serious or life threatening common diseases and refer when appropriate.

5.3.2. The decision to employ Ayurveda and its effectiveness in a given case are governed by knowledge of the individual patient in accordance with Ayurveda principles, and with careful observance of the following specific procedures:

5.3.2.1 Individualization of the medical history and physical examination of the patient must be obtained.

5.3.2.2 Employment of diagnostic procedures, supported by laboratory studies, when appropriate as outlined above.

5.3.2.3 Evaluation of the sensitivity of patient to medical treatment and the probable reaction and response of the patient to administration of the treatment chosen.

5.4. The Licensed Ayurveda Professionals is obligated to refer to a general medical physician or specialists when there is any doubt about the patient's diagnosis or response to therapy. A referral must not be withheld or discouraged when the patient asks for a second opinion.

5.5. The Licensed Ayurveda Professionals bears the responsibility of maintaining a comprehensive record about their patient, including pursuit of diagnostic tests and consultations in a timely fashion and collaborating with other medical professionals.

5.6. In addition to satisfying the above requirements, Licensed Ayurveda Professionals must fulfil the Continuous Professional Development (CPD) requirements for licensure, the standards of Professional Practice and behavior expected of all Licensees.

6. Duties & Responsibilities of Traditional Indian Medicine (TIM) Technician / Therapist:

The **Traditional Indian Medicine (TIM) Technician / Therapist:** is responsible for assisting the TIM practitioner in running a TIM clinic. The TIM technician / assistant shall do the following tasks:

- Greet patients when they enter the clinic and make them feel welcome and comfortable.
- All phone calls and inquires will be handled by the TIM technician / assistant.
- He or she will schedule appointments and maintain the Ayurveda physician's calendar.
- When payment is due, the TIM technician / assistant will explain fees and accept payment, code and bill insurance claims, or perform routine collections on past-due accounts.
- He or she will issue receipts, guidelines for treatment, and educational materials.
- The TIM technician / assistant is also responsible for maintaining databases containing patient information, and either electronic or paper patient files.
- He or she will serve as the primary customer service representative for the TIM clinic, and as such will educate patients on treatment procedures and insurance information requirements and limitations, and liaise between the patient and the TIM physician.
- They will order and stock products recommended by the TIM physician and educate patients in their use or benefits.
- The TIM technician / assistant may even be specially trained to take and record the patient's vital signs and medical history.
- Under the direction of an TIM practitioner, carry out treatment programs of TIM techniques and massage.
- Assist TIM Practitioner with patient intake

7. Required Place & Size for TIM Clinic

i. Two waiting areas for Male & Female (each could accommodate at least 6 chairs)
ii. Reception area
iii. Consultation room (9m^2)
iv. Two Treatment rooms (each 12m^2)
v. Pharmacy (9 m^2)
vi. Storage area
vii. Two Toilets

8. Required Equipment for Functional Areas

Area	Equipment
Reception	• desk with chairs • computer • filling cabinet • copy machine
Waiting	• chairs • table • literature Rack • drinking water
Consultation	• desk with chair for doctor • computer with specialized Ayurveda software • chairs for patients & attendances • examination couch • water sink • Stethoscope – 1 • B.P. apparatus – 1 • Torch – 1 • Thermometer – 1 • Tongue depressor – 1 • Weighing machine – 1 • X – Ray view box – 1 • Hammer – 1 • Others as required
Treatment	**Equipment / Instruments** • Measuring Glasses • Gas/Stove/heater with fittings • Abhyanga (Massage)Table/Droni • Steel bowls • Towels, Dusters • Plastic aprons **For Shirodhara** :Shirodharayantra, Stand, Dharapatra **For Shirobasti:** Plastic Caps/Leather caps, Holder (Chimata/Pakkad), Big spoons, Tea spoons , Steel Pots (Patila) **Materials:** • Til Oil , Dashmoola Oil, Different Medicated Oils, Masjapishta (Blackgram Flour), Bandage, Cotton, Gauge Piece

Chapter Four

Accreditation Standards for Complementary Medicine Clinics

Accreditation Standards for Complementary Medicine Clinics

Complementary Medicine Clinics accreditation standards are advocated as an important means of improving clinical practice and organisational performance. The requirements of these Standards are designed to support the development and continual improvement of healthcare quality and patient safety in the healthcare providers. Standards promote responsibility and accountability for the quality and safety of services provided. By incorporating national and international best available evidences, this Standard also promote healthcare that is up to date, effective and consistent. Importantly, Standard for healthcare provides a basis for planning and managing services and measuring improvements as well as identifying and addressing gaps and deterioration in the quality and safety of the services provided.

There are 10 domains of accreditation used to evaluate each complementary medicine clinics. Each domain contains standards that are formulated in order to promote the quality of the services, which are provided in these clinics. For each standard, there are few remarks and certain objectives given to help the healthcare providers to understand the rationale behind them.

The list of domains

Part 1	Access, Assessment and Continuity of Care (AAC)
Part 2	Care of Patients (COP)
Part 3	Management of Medication (MOM)
Part 4	Patient Rights and Education (PRE)
Part 5	Infection Control (IC)
Part 6	Continuous Quality Improvement (CQI)
Part 7	Responsibilities of Management (ROM)
Part 8	Facility Management and Safety (FMS)
Part 9	Human Resource Management (HRM)
Part 10	Information Management System (IMS)

The Complementary medicine clinic participating in accreditation will be expected to provide three types of evidence:

- Approved documents that identify relevant service policy, protocols and/or strategies and set out how the clinic plans to deliver each standard and objective element therein.

- Evidence that demonstrate that the Complementary medicine clinic is implementing these policies, protocols and/or strategies.
- Evidence that demonstrates that the Complementary medicine clinic is monitoring and evaluating its performance regularly in the implementation of its policies, protocols and strategies.

Part 1: Access Assessment and Continuity of Care (AAC)

Intent of the chapter:

Patients are well informed of the services that a Complementary medicine clinic provides. This will facilitate appropriately matching patients with the clinic's resources.

Patients that match the Complementary medicine clinic s resources are treated using a defined process. Patients treated, undergo an established assessment and periodic and regular reassessments. Patient care is continuous and multidisciplinary in nature.

The intent of this document is to establish a standardized health care process where a patient and health care personnel interact with the aim to directly or indirectly improve the health state of that patient. The accompanying clinical processes are health care processes where subjects of care and health care personnel interact encompassing all health care activities related to one or more health issues.

Summary of Standards

AAC.1. The Complementary medicine clinic defines and displays the services that it provides.

AAC.2. The Complementary medicine clinic has a defined patient registration process

AAC.3. There is an appropriate mechanism for transfer or referral of patients who do not match the Complementary medicine clinic resources.

AAC.4. Patients cared for by the Complementary medicine clinic undergo an established initial assessment.

AAC.5 All patients cared for by the Complementary medicine clinic undergo a regular reassessment.

AAC.6 Patient care is continuous and multidisciplinary in nature.

AAC.7 Complementary medicine clinic defines the content of the prescription including procedural details if any.

Standard AAC.1. The Complementary medicine clinic defines and displays the services that it provides

Objective Elements

a. The services provided are defined and displayed prominently.

Interpretation: The services so defined should be displayed prominently in an area visible to all patients entering the Complementary medicine clinic . The display could be in the form of boards, citizen's charter, scrolling messages etc. Display should be at least bi-lingual (Arabic & English).

Remark(s): Claims of services should commensurate with the available expertise.

Care should be taken to ensure that the services are explained in a language the patient understands.

This standard outlines a clinical process that comprises of all kinds of health care activities, mainly those provided by health care professionals.

Standard AAC.2. The Complementary medicine clinic has a defined patient registration process.

Objective Elements

a. The Complementary medicine clinic has documented policies and procedures for registering the patients.

Interpretation: Complementary medicine clinic shall prepare document (s) detailing the policies and procedures for registration of patients. All patients who are assessed in the Complementary medicine clinic shall be registered.

b. Patients are accepted only if the Complementary medicine clinic can provide the required service.

Interpretation: The staffs handling registration needs to be aware of the services that the Complementary medicine clinic can provide. It is also advisable to have a system wherein the staffs are aware as to whom to contact if they need any clarification on the services provided.

Remark(s): The patient's registration and assessment process is designed to give priority to those who are obviously sick or those with urgent needs.

c. A unique identification number is generated at the end of registration.

Interpretation: The Complementary medicine clinic shall ensure that every patient gets a unique number which is generated at the end of registration of the first interaction that the patient has with the Complementary medicine clinic. This number shall be used for identification of the patients across the Complementary medicine clinic and to ensure continuity of care across the Complementary medicine clinic. All Complementary medicine clinic records of the patients shall have this number. "Unique" implies that this is a one-time affair. Please note that a particular patient can have only one unique number.

d. The staff are aware of these processes.

Interpretation: All the staff handling these activities should be oriented to these policies and procedures. Orientation can be provided by documentation/ training.

Standard AAC.3. There is an appropriate mechanism for transfer or referral of patients who do not match the Complementary medicine clinic resources.

Objective Elements

a. Documented policies and procedures guide the transfer of patients to another facility in an appropriate manner.

Interpretation: The documented procedure should address the methodology of safe transfer of the patients in a life-threatening situation to another health establishment. It also includes patients being shifted for diagnostic tests.

b. The Complementary medicine clinic gives a summary of patient's condition and the treatment given.

Interpretation: The Complementary medicine clinic gives a case summary mentioning the significant findings and treatment given in case of patients who are being transferred from emergency. A copy of the same shall be retained by the Complementary medicine clinic.

Standard AAC.4. Patients cared for by the Complementary medicine clinic undergo an established initial assessment.

Objective Elements

a. The Complementary medicine clinic defines and documents the content of Initial assessment.

Interpretation: The Complementary medicine clinic shall have a format using which a standardized assessment of patient is done.

Remark(s): Every assessment shall contain the presenting complaints, past medical history, drugs history, allergy history, vital signs (temperature, pulse, BP and weight) and complete medical examination.

b. Care plan has to be documented and is monitored after the initial assessment.

Interpretation: This shall be documented by the treating physician or by a member of his team in the patient record. For definition of "care plan" refer to glossary

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

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

This could also be done through booklets/patient information leaflets etc.

Standard AAC.5. All patients cared for by the Complementary medicine clinic undergo a regular reassessment

Objective Elements

a. All Patients are reassessed at appropriate intervals.

Interpretation: After the initial assessment, the patient is reassessed periodically and this is documented in the medical record. The frequency may be different for different areas based on the setting and the patient's condition, e.g. patients undergoing Complementary medicine practice treatment to be reassessed frequently. Reassessments shall also be done in response to significant changes in patient’s condition.

b. Patients are informed of their next follow-up, where appropriate.

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

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

c. Staff involved in direct clinical care document reassessments.

Interpretation: Actions taken under reassessment are documented. The staff could be the treating physician or any member of the team as per their domain of responsibility of care.

Only phrases like "patient well"; "condition better" would not be acceptable.

d. Patients are reassessed to determine their response to treatment and to plan further treatment.

Interpretation: Self-explanatory.

e. Continual improvement

Interpretation: Continual improvement of the Complementary medicine clinic's overall performance should be a permanent objective of the Clinic.

Standard AAC.6. Patient care is continuous and multidisciplinary in nature.

Objective Elements

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

Interpretation: The Complementary medicine clinic shall ensure that appropriately qualified Complementary medicine healthcare professionals always give the care of patients.

Remark(s): Although care may be provided by a team, the Complementary medicine clinic record shall identify the in-charge staff as being responsible for patient care.

b. Care of patients is coordinated in all care settings within the clinic

Interpretation: Care of patients is co-ordinated among various care-providers in a Complementary medicine clinic. The Complementary medicine clinic shall ensure that there is effective communication of patient requirements amongst the care-providers.

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

Interpretation: The Complementary medicine clinic ensures periodic discussions about each patient (covering parameters such as patient care, response to treatment, unusual developments if any, etc.) amongst medical, nursing and other care-providers.

Remark(s): This could be done on the basis of entries either on case sheet or on electronic patient records (EPR).

d. Top management shall ensure that

i. Appropriate communication processes are established within the Complementary medicine clinic and that communication takes place regarding the effectiveness of the quality management system,

ii. Communication is established to facilitate the cooperation of different parts of the clinical processes in the delivery of health care services,

iii. Communication takes place to achieve awareness of the effectiveness of the quality management system results related to the quality characteristics,

The Complementary medicine clinic has an efficient and transparent information flow, in order to facilitate communication of clinical and other data related to the quality characteristics in the cooperation and interaction of different clinical processes, functions and specialties in the delivery of health care services, which include:

i. Information relating to new statutory and other requirements affecting:

ii. The provision of care,

iii. Changes in medical or technical equipment,

iv. Information from risk assessments,

v. Accidents, incidents and near misses

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

Interpretation: Self-explanatory.

Standard AAC.7. The Complementary medicine clinic defines the content of the prescription including procedural details if any.

Objective Elements

a. Documented policies and procedures exist for the prescription including procedural details.

Interpretation: Prescription including procedural details are documented to ensure coordination amongst various departments.

b. Prescription including procedural details contains the patient's name, unique identification number, date and time of procedure, significant findings and diagnosis, investigation results, any procedure performed, medication administered and other treatment given, follow-up advice, medication and other instructions in an understandable manner.

Interpretation: Self-explanatory.

Remark This shall also incorporate preventive aspects, where appropriate. The instructions shall be in a manner that the patient can easily understand and avoid use of medical terms, e.g. BID, TID, etc.

Part 2: Care of Patients (COP)

Intent of the chapter:

The Complementary medicine clinic provides uniform care to all patients. Policies, procedures, applicable laws and regulations guide all patient care activities.

Policies, procedures, applicable laws and regulations also guide care of vulnerable patients elderly, physically and/or mentally-challenged and children), paediatric patients, patients undergoing Complementary medicine practice procedures, patients undergoing procedures and research.

The standards aim to guide and encourage patient safety as the overall principle for providing quality care to patients.

Summary of Standards

COP 1 Care and treatment is provided in a uniform manner.

COP 2 Patients with special needs & disabilities (vulnerable) shall be identified and treated accordingly.

COP 3 Documented policies and procedures guide appropriate pain management

COP 4 Documented policies and procedures guide appropriate rehabilitative services if any.

COP 5 Policies and procedures guide the Complementary medicine practice therapy

COP 6 Policies and procedures guide all research activities, if applicable

Standard COP.1. Care and treatment is provided in a uniform manner

Objective Elements

a. Care of patients shall be in consonance with the defined scope.

Interpretation: The Complementary medicine clinic shall have appropriate Staff, facilities, protocols and procedures in consonance with the scope of service.

Remark(s): The access and appropriateness of the care do not mismatch the scope of services.

b. Evidence based medicine and Clinical practice guidelines, as envisaged by respective systems of medicine, are adopted to guide patient care.

Interpretation: The Complementary medicine clinic could develop Clinical protocols based on these and the same could be followed in management of patients. These could then be used as parameters for audit of patient care.

Remark(s): e.g. Standardized protocols for care of diabetes, asthma, arthritis etc.

Standard COP.2. Patients with special needs & disabilities (vulnerable) shall be identified and treated accordingly.

Objective Elements

a. Patients with special needs & disabilities (vulnerable) shall be identified and treated accordingly.

Interpretation:

- The vulnerable patients include children, elderly, physically and/or mentally challenged.
- The Complementary medicine clinic provides for a safe and secure environment for this vulnerable group.
- Staff is trained to care for this vulnerable group.
- The Complementary medicine clinic shall provide proper environment taking into account the requirement of the vulnerable group.

b. A Documented procedure shall govern related aspects (do's and don'ts) of Complementary medicine therapy practiced in the clinic.

Interpretation: A detailed description of various procedure of Complementary medicine practice should be displayed at the Complementary medicine clinic for the proper understanding of the procedure along with the do and don'ts of the procedure.

c. A documented procedure exists for obtaining informed consent from the appropriate legal representative.

Interpretation: The informed consent for this group of people should be obtained from their family representative.

d. Staffs are trained to care for this vulnerable group.

Interpretation: All staff involved in the care of this group shall be adequately trained in identifying and meeting their needs. Records of the same should be available.

Standard COP.3. Documented policies and procedures guide appropriate pain management.

Objective Elements

a. Documented policies and procedures guide the management of pain.

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

b. The Complementary medicine clinic respects and supports appropriate assessment and management of pain.

Interpretation: Self-explanatory.

c. Patient and family are educated on various pain management techniques, where appropriate.

Interpretation: Self-explanatory.

Remark(s): This could be done only for patients who are likely to have long-term pain in view of the underlying condition not being treatable.

Standard COP.4. Documented policies and procedures guide appropriate rehabilitative services.

Objective Elements

a. Documented policies and procedures guide the provision of rehabilitative services.

Interpretation: Self-explanatory.

Remark(s): This includes physiotherapy, occupational therapy and speech therapy.

b. These services are commensurate with the clinic requirements.

Interpretation: The scope of the services is in consonance with the scope of the Complementary medicine clinic .

c. There is adequate space and equipment to perform these activities.

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

Standard COP.5. Policies and procedures guide the complementary medicine practice therapy.

Objective Elements

a. The policies and procedures are documented.

Interpretation: Self-explanatory.

b. An informed consent is obtained by a practitioner prior to the treatment process.

Interpretation: The consent shall be taken by the practitioner or a member of his team before any Complementary medicine practice procedure.

c. Documented policies and procedures exist to prevent adverse events

Interpretation: Procedure should be available for preventing adverse events like for example injuries or falls caused by excessive exercise. The clinic should be able to demonstrate methods to prevent these events.

d. Persons qualified are permitted to perform the procedures that they are entitled to perform.

Interpretation: The Complementary medicine clinic identifies the individuals who have the required qualification(s), training and experience to perform complementary medicine practice procedures in consonance with the law.

e. A brief note is documented prior to transfer of patient from procedure room

Interpretation: This note provides information about the procedure performed and the status of the patient before shifting and shall be documented by the practitioner. At a minimum, it shall include the Complementary medicine practice procedure performed, name of the practitioner, salient steps of the procedure and the key findings. It includes monitoring of the procedure.

f. The staff documents the post-procedure plan of care.

Interpretation: Post-procedure plan shall include advice on medication, nursing care, observing for any (complication) etc. For post- procedures, the plan shall include advice back home, nursing care, observing for any side effects or complications etc.

g. A procedure to check the maintenance of Complementary medicine practice procedure room.

Interpretation: For Complementary medicine practice procedures, the Complementary medicine clinic hand-washing area, Complementary medicine practice therapy rooms, storage area, recovery room, collection area for waste and linen toilet and bathroom with hot water facility should be available. The rooms shall have sufficient light and ventilation.

h. Guidelines for various complementary therapies are prepared separately and adhered.

Interpretation: All Complementary medicine practice therapy and other Treatment procedures there shall be documented. For Complementary medicine practice therapy and other Treatment procedures, SOP for the documented procedures are prepared based on classical texts and evidence based references.

i. Complementary medicine practice therapies are done only under the guidance of CM practitioners.

Interpretation: Self-explanatory.

j. Patients shall have a pre-procedure Complementary medicine practice assessment and a provisional diagnosis documented prior to procedures

Interpretation All Complementary medicine practice procedures are assessed before the procedure by the practitioners, and diagnosis which is made shall be documented.

k. A quality assurance program (Clinical Audit) is followed for the Complementary medicine practice and other treatment services.

Interpretation: This shall be an integral part of the Complementary medicine clinic's overall quality assurance programme. It shall focus on post procedure complications.

Standard COP.6. Policies and procedures guide all research activities if applicable.

Objective Elements

a. Policies and procedures guide all research activities in compliance with the applicable law and national and international guidelines.

Interpretation: Self explanatory

b. Policies and procedures address Patient's informed consent, their right to withdraw, their refusal to participate in the research activities.

Interpretation: Patients are informed of their right to withdraw from the research at any stage and also of the consequences (if any) of such withdrawal. Patients are assured that their refusal to participate or withdrawal from participation will not compromise their access to the Complementary medicine clinic 's services.

c. Patient's informed consent is obtained before entering them in research protocols.

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

d. The objective of the research process is to contribute to knowledge and subsequently improvement in health care.

Interpretation: Self explanatory

Part 3: Management of Medication (MOM)

Intent of the chapter:

The Complementary medicine clinic has a safe and organised medication process. The process includes policies and procedures that guide the availability, safe storage, prescription, dispensing and administration of medications.

The standards encourage integration of the pharmacy into everyday functioning of Complementary medicine clinic s and patient care. The pharmacy should guide and audit medication process. The pharmacy should have oversight of all medications stocked out of the pharmacy. The pharmacy should ensure correct storage (as regards to temperature, lookalike, sound-alike etc.), expiry dates and maintenance of documentation.

The process also includes monitoring of patients after administration and procedures for reporting and analyzing medication errors.

Patients and family members are educated about safe medication and food-drug interactions.

Summary of Standards

MOM.1. Documented policies and procedures guide the Complementary medicine clinic pharmacy services and usage of medication.

MOM.2. There is a Complementary medicine clinic formulary.

MOM.3. Documented policies and procedures exist for storage of medication.

MOM.4. Documented policies and procedures exist for prescription of medications.

MOM.5. Documented policies and procedures guide the safe dispensing of medications .

MOM.6. There are defined procedures for medication management.

MOM.7. Patients are monitored after medication administration.

MOM.8. Near misses, medication errors and adverse drug events are reported and analysed.

MOM.9. Documented policies and procedures guide the use of medical supplies and consumables.

Standards and Objective Elements

Standard MOM.1. Documented policies and procedures guide the Complementary medicine clinic of pharmacy services and usage of medication.

Objective Elements

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

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

Standard MOM.2. There exists a Complementary medicine clinic formulary.

Objective Elements

a. A list of medication appropriate for the patients and Complementary medicine clinic's resources is developed.

Interpretation: The Complementary medicine clinic's formulary shall be prepared and be preferably updated at regular intervals.

b. The formulary is available for specific complementary therapy to refer and adhere to.

Interpretation: The formulary shall be made available to all treating conditions at the Complementary medicine clinic. The Complementary medicine clinic shall ensure that the prescriptions are as per the formulary. It shall monitor the frequency of prescriptions being rejected because it contained non-formulary drugs. The formulary could be made available in either physical or electronic form.

c. There is a defined process for preparation of these medications.

Interpretation: SOP will be developed for preparation of medications required for out-Patients, Complementary medicine practice therapies, other treatment procedures, etc The medicine preparation of Complementary medicine practice therapies and other treatment procedures may be included in the "Guideline for Complementary medicine practice therapies and other treatment procedures".

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

Interpretation: For example, local purchase (for immediate requirement).

Standard MOM.3. Documented policies and procedures exist for storage of medications.

Objective Elements

a. Documented policies and procedures exist for storage of medications.

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

b. Medications are stored in a clean, safe and secure environment; and incorporating manufacturer's recommendation(s).

Interpretation: The Complementary medicine clinic shall also ensure that the storage requirements of the drug as specified by the manufacturer are adhered to. Medication shall be protected from loss or theft. The overall cleanliness of the storage area shall be maintained.

c. Sound inventory control practices guide storage of the medications..

Interpretation:. The medication shall be stored in alphabetical or company's name.

d. Sound alike and look alike medications are identified and stored separately.

Interpretation: Many drugs may look-alike or sound-alike. They should be documented, segregated and stored separately at all locations. The complementary medicine clinic can follow a method of storing drugs in an alphabetical order to address this issue. The list will have to be identified at regular intervals depending on the changes in the formulary and changes in packaging (in case of look-alike).

Standard MOM.4. Documented policies and procedures exist for prescription of Medications

Objective Elements

a. Documented policies and procedures exist for prescription of medications.

Interpretation: Refer to MOM 1a. It could also incorporate objective elements "b", "f" and "g" of MOM 4.

b. The Complementary medicine clinic determines the minimum requirements of a prescription.

Interpretation: This shall adhere to national/international guidelines where appropriate. At a minimum, the prescription shall have the date, name of the patient, unique Complementary medicine clinic number, name of the drugs, dose, route and frequency of administration of the medicine, name, and signature of the prescribing practitioner.

c. The Complementary medicine clinic determines who can write orders.

Interpretation: This shall be done by a practitioner who at a minimum holds a recognized qualification in complementary medicine specialties.

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

Interpretation: All the orders for medicines are recorded on a uniform location in the medical record. Electronic orders when typed shall again follow the same principles. It is preferable that prescription and administration record is on the same sheet. This would help minimize medication errors.

e. Medication orders are clear, legible, dated, timed, named and signed.

Interpretation: Only approved abbreviations by the Complementary medicine clinic shall be used. The Complementary medicine clinic can explore the possibility of writing orders in block letters so that the issue of legibility is addressed.

f. Medication orders contain the name of the medicine, route of administration, dose to be administered and frequency/time of administration.

Interpretation: Medication orders include for those medications required for Complementary medicine practice therapies and other procedures. In case of a medication, having two or more drugs (tablet/capsule/churna) the dose of all the individual drugs shall be written. For example, in a combination of medicines a, b & c the individual dose of a, b & c and the dose of such mixture to be administered is clearly written. In case abbreviations are used, a standardized list of approved abbreviations for medications shall be used throughout the Complementary medicine clinic.

g. The Complementary medicine clinic defines a list of high alert medication.

Interpretation: High-Alert medications are medications involved in a high percentage of medication errors or sentinel events and medications that carry a high risk for abuse, error, or other adverse outcomes. Examples include look-alike and sound-alike medications.

h. High Alert medication orders are verified prior to dispensing.

Interpretation: Self-explanatory.

Standard MOM.5. Documented policies and procedures guide the safe dispensing of medications

Objective Elements

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

Interpretation: Clear policies to be laid down for dispensing of medication e.g. route of administration, dosage, rate of administration, expiry date etc. This shall include both bulk and retail pharmacy..

b. Expiry dates are checked prior to dispensing, wherever applicable.

Interpretation: This shall be done at all levels e.g. pharmacy,

c. Labeling requirements are documented and implemented by the complementary medicine clinic.

Interpretation: At a minimum, labels must include the drug name, quantity, frequency of administration (in a language the patient understands) and expiry dates. This is applicable to all dispensing areas wherein medicines are dispensed either as cut strips or from bulk containers.

Standard MOM.6. There are documented policies and procedures for medication management.

Objective Elements

a. Medications are administered by those who are permitted to do so.

Interpretation: Refer to statutory requirements. In addition to doctors, Nursing staff, Panchkarma therapist, Paricharakas may also administer. This does not apply to topical administration.

b. Prepared medication is labeled prior to preparation of a second drug.

Interpretation: E.g., while preparing multiple complementary threrapies, the first drug is prepared & labeled and then the subsequent drugs should be prepared & labeled.

c. Patient is identified prior to administration.

Interpretation: Identification shall be done by unique identification number (e.g. Complementary medicine clinic number and/or name.

d. Medication is verified from the order prior to administration.

Interpretation: Staff administering medications should go through the treatment orders before administration of the medication and then only administer them. It is preferable that they also check the general appearance of the medication (e.g. broken tablet, clumped choorna etc.) before dispensing.

If any of the parameters with respect to an order namely name, dose, route or frequency/time are missing/incomplete the medication administration shall be deferred.

However, to ensure that patient care does not suffer a verbal order may be got from the treating doctor followed by ratification of the same (refer to MOM 4e).

In case of high alert medication, at least two staff shall do the verification, independently and documented.

e. Dosage is verified from the order prior to administration.

Interpretation: Self-explanatory.

f. Route is verified from the order prior to administration.

Interpretation: Where applicable the site of administration shall also be verified.

g. Timing is verified from the order prior to administration.

Interpretation: The Complementary medicine clinic needs to define the timing of administration of medications. e.g. o.d, b.i.d, t.i.d, q.i.d, h.s., stat, sos.

h. Medication administration is documented.

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

i. Polices and procedures govern patient's self administration of medications.

Interpretation: The policy shall include the medications which the patient can self-administers.

Standard MOM.7. Patients are monitored after medication administration.

Objective Elements

a. Documented policies and procedures guide the monitoring of patients after medication administration.

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

b. The Complementary medicine clinic defines those situations where close monitoring is required.

Interpretation: E.g. observation after administration of swedana yoga

c. Monitoring is done in a collaborative manner.

Interpretation: This shall be done by the complementary medicine practitioner or assistant

d. Medications are changed where appropriate based on the monitoring.

Interpretation: This also includes dose adjustment

Standard MOM 8. Near misses medication errors and adverse drug events are reported and analyzed

Objective Elements

a. Documented procedure exists to capture near miss, medication error and adverse drug event.

Interpretation: This shall outline the process for identifying, capturing, reporting, analyzing and taking action.

b. Near miss, medication error and adverse drug event are defined.

Interpretation: The Complementary medicine clinic shall define as to what constitutes these. This shall be in consonance with best practices. Refer to glossary for "near miss", "medication error" and "adverse drug event".

c. These are reported within a specified time frame.

Interpretation: The Complementary medicine clinic shall define the time frame for reporting once any of this has occurred.

d. They are collected and analysed.

Interpretation: All these incidents are analysed regularly. The analysis shall be completed in a defined time frame.

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

Interpretation: Self-explanatory.

Standard MOM 9. Documented policies and procedures guide the use of medical supplies and consumables.

Objective Elements

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

Interpretation: Self-explanatory.

b. Medical supplies and consumables are stored in a clean, safe and secure environment and incorporating manufacturer's recommendation(s).

Interpretation: The Complementary medicine clinic shall ensure that the storage requirements are as specified by the manufacturer as are adhered to. Complementary medicine clinic should mention their Source of Raw material either wet or dry drugs used for various treatment procedures. They shall be protected from loss or theft. Overall cleanliness of the storage area shall be maintained at all times.

Part 4: Patient Rights and Education (PRE)

Intent of the chapter:

The Complementary medicine clinic defines the patient and family rights and responsibilities. The staffs are aware of these and are trained to protect patient rights. Patients are informed of their rights and educated about their responsibilities. They are informed about the disease, the possible outcomes and are involved in decision making. The costs are explained in a clear manner to patient and/or family. The patients are educated about the mechanisms available for addressing grievances.

A documented process for obtaining patient and/or families consent exists for informed decision making about their care.

Patient and families have a right to information and education about their healthcare needs in a language and manner that is understood by them.

Summary of Standards

PRE 1: The Complementary medicine clinic protects patient and family rights.

PRE 2: Patient rights support individual beliefs, values and involve the patient and family in decision making processes.

PRE 3: A documented process for obtaining patient and / or families consent exists for informed decision making about their care.

PRE 4: Patient and families have a right to information and education about their healthcare needs.

PRE 5: Patient and families have a right to information on expected costs.

Standard PRE.1. The Complementary medicine clinic protects patient and family rights.

Objective Elements

a. Patient and family rights and responsibilities are displayed.

Interpretation: The Complementary medicine clinic should respect patient's rights and inform them of their responsibilities.

All the rights of the patients should be displayed.

b. Staff is aware of their responsibility in protecting patient's rights.

Interpretation: Training and sensitization programs shall be conducted to create awareness among the staff.

c. Appropriate corrective/preventive measures are taken in case patient's rights are violated.

Interpretation: Where patients' rights have been infringed upon, Complementary medicine clinic must keep records of such violations, as also a record of the consequences, e.g.corrective actions to prevent recurrences.

d. Patients and families are informed of their rights and responsibilities in a format and language that they can understand.

Interpretation: This could be done in the form of permanent displays at strategic locations within the Complementary medicine clinic. Pamphlets could be provided regarding the same

Standard PRE.2. Patient rights support individual beliefs, values and involve the patient and family in decision making processes.

Objective Elements

a. Patient rights include respect for personal dignity and privacy during examination, procedures and treatment.

Interpretation: During all stages of patient care, be it in examination or carrying out a procedure, staff shall ensure that patient's privacy and dignity is maintained. The Complementary medicine clinic shall develop the necessary guidelines for the same. During procedures the Complementary medicine clinic shall ensure that the patient is exposed just before the actual procedure is undertaken.

With regards to photographs/recording procedures; the Complementary medicine clinic shall ensure that consent is taken and that the patient's identity is not revealed.

b. Patient rights include protection from physical abuse or neglect.

Interpretation: Special precautions shall be taken especially w.r.t vulnerable patients e.g. elderly, neonates etc.

Remark(s): Examples of this include falling from the bed/trolley due to negligence, assault, repeated internal examinations, manhandling etc.

c. Patient and family rights include treating patient information as confidential.

Interpretation: The Complementary medicine clinic shall keep the records in a secure manner and will release only under authorization of the patient except under statutory obligation.

d. Patient has the right to make an informed choice including the option of refusal.

Interpretation: The treating practitioner shall discuss all the available options and allow the patient to take the decision.

Remark(s): In case of refusal, the treating practitioner shall explain the consequences of refusal of treatment and document the same.

e. Patient and family rights include informed consent any invasive / high risk procedures / treatment.

Interpretation: Self-explanatory.

f. Patient has a right to have an access to his / her Clinical records.

Interpretation: The Complementary medicine clinic shall ensure that every patient has access to his/her record. This shall be in consonance with the code of medical ethics and statutory requirements.

g. Patient and family rights include information on the expected cost of the treatment.

Interpretation: Refer PRE5

h. Patient and family rights include information on care plan, progress and information on their health care needs.

Interpretation: The care plan as decided by the practitioner on duty or the patient management team (as the case may be) is to be discussed with the patient and/or family members. This should be done in a language the patient/attendant can understand. The above information is to be documented and signed by the practitioner concerned. Refer AAC 4 c,d and PRE 4

Standard PRE.3. A documented process for obtaining patient and / or families consent exists for informed decision making about their care.

Objective Elements

a. The Complementary medicine clinic has listed those procedures and treatment where informed consent is required.

Interpretation: A list of procedures should be made for which informed consent should be taken.

b. Informed consent includes information on risks, benefits, alternatives and as to who will perform the requisite procedure in a language that they can understand.

Interpretation: The consent shall have the name of the practitioner performing the procedure. Consent form shall be in the language that the patient understands.

c. The policy describes who can give consent when patient is incapable of independent decision-making.

Interpretation: The Complementary medicine clinic shall take into consideration the statutory norms. This would include next of kin/legal guardian. However in case of unconscious/ unaccompanied patients the treating practitioner can take a decision in life saving circumstances.

d. Documented procedure incorporates the list of situations where informed consent is required and the process for taking informed consent.

Interpretation: The process for taking informed consent shall specify the various steps involved with the responsibility. A list of procedures should be made for which informed consent should be taken. This shall be prepared keeping in mind the requirements of this standard and statutory requirement. E.g pre procedure consent.

Standard PRE.4. Patient and families have a right to information and education about their healthcare needs.

Objective Elements

a. When appropriate, patient and families are educated about the safe and effective use of medication and the potential side effects of the medication.

Interpretation: Self-explanatory.

Remark(s): Education regarding the importance of taking a medicine at a specific time e.g. Accha snehapana

b. Patient and families are educated about diet and nutrition.

Interpretation: Self-explanatory.

c. Patient and families are educated about their specific disease process, prognosis, complications and prevention strategies.

Interpretation: Self-explanatory. This could also be done through patient education booklets/videos/leaflets etc.

d. Patient and families are educated about preventing infections.

Interpretation: Self-explanatory.

Remark(s): For example, hand washing and avoiding overcrowding near the patient.

e. Patient and/or family are educated in a language and format that they can understand.

Interpretation: Self-explanatory.

Standard PRE.5. Patient and families have a right to information on expected costs.

Objective Elements

a. The tariff list is available to patients.

Interpretation:

• Ethical billing practices are ensured.

• The Complementary medicine clinic shall ensure that there is an updated tariff list and that this list is available to patients.

• The Complementary medicine clinic shall charge as per the tariff list. Additional charges should also be enumerated in the tariff and the same communicated to the patients.

• The tariff rates should be uniform and transparent.

b. Patients are informed about the estimated costs of treatment.

Interpretation: The patients are informed about the approximate cost of treatment in lieu with the line of treatment followed and the tariff list.

Remark(s): The inference should be drawn based on the recorded line of management collaborating the cost.

c. Billing, receipts and records are maintained as per statutory requirements.

Interpretation: Self-explanatory.

Part 5: Infection Control (IC)

Intent of the chapter:

The standards guide the provision of an effective infection control programme in the Complementary medicine clinic . The programme is documented and aims at reducing /eliminating infection risks to patients and providers of care.

The Complementary medicine clinic measures and takes action to prevent or reduce the risk of Complementary medicine practice associated Infection in patients and employees.

The Complementary medicine clinic provides proper facilities and adequate resources to support the Infection Control Programme.

The programme includes an action plan to control outbreaks of infection, disinfection activities, biomedical waste (BMW) management, training of staff and employee health.

Summary of Standards

IC.1. The Complementary medicine clinic has a well-designed, comprehensive and coordinated infection control programme aimed at reducing/ eliminating risks to patients, visitors and providers of care.

IC.2. The Complementary medicine clinic provides adequate and appropriate resources for prevention and control of Healthcare Associated Infections (HAI).

IC.3. Biomedical waste (BMW) is handled in an appropriate and safe manner.

IC.4. The infection control programme is supported by the Complementary medicine clinic ’s management and includes training of staff

Standard IC. 1. The Complementary medicine clinic has a well designed, comprehensive and coordinated infection control programme aimed at reducing/ eliminating risks to patients, visitors and providers of care

Objective Elements

a. The Complementary medicine clinic infection control programme is documented which aims at preventing and reducing risk of healthcare associated infections.

Interpretation: This shall be based on current scientific knowledge, guidelines from international/national and professional bodies and statutory requirements, wherever applicable. Reference documents could include WHO guidelines, CDC Guidelines and Manual for Control of Hospital Associated Infections, Ministry of Health.

b. The infection prevention and control programme is a continuous process and updated at least once in a year.

Interpretation: The updating shall be done based on newer literature on infection prevention and outbreak prevention mechanisms, infection trends and outcomes of the audit processes.

c. The Complementary medicine clinic adheres to hand-hygiene guidelines.

Interpretation: The Complementary medicine clinic shall adhere to international/national guidelines on hand hygiene. A good reference is the latest WHO guidelines. The Complementary medicine clinic could display the necessary instructions near every hand-washing area.

d. The Complementary medicine clinic adheres to cleaning and disinfection practices.

Interpretation: It shall be addressed at all levels of the Complementary medicine clinic, example Complementary medicine practice therapy room It is preferable that the Complementary medicine clinic follows a uniform policy across different departments within the Complementary medicine clinic .

e. Laundry and linen management processes are also included

Interpretation: The laundry can be in-house or outsourced. The Complementary medicine clinic shall have a policy for change of linen. There shall be separate washing protocols for different categories of linen including blankets (where applicable). If outsourced, the Complementary medicine clinic shall ensure that it establishes adequate controls to ensure infection prevention and control.

f. Engineering controls to prevent infections are included.

Interpretation: This shall include design of patient care areas, Complementary medicine practice therapy room, air quality and water supply. Issues such as air-conditioning plant and equipment maintenance, cleaning of AC ducts, replacement of filters, seepage leading to fungal colonisation, replacement/repair of plumbing, sewer lines (in shafts) should be included. Water-supply sources and system of supply, testing for water quality must be included. Any renovation work in Complementary medicine clinic patient-care areas should be planned with infection control team with regard to architectural segregation, traffic flow, use of materials, etc.

g. The Complementary medicine clinic adheres to housekeeping procedures.

Interpretation: This should include categorization of areas/surfaces, general- cleaning procedures for surfaces, furniture/fixtures, and items used in patient care. It should also include procedures for terminal cleaning, blood and body fluid cleanup and all high-risk (critical) areas. The common disinfectants used, dilution factors and methodology should be specified.

Standard IC. 2. The Complementary medicine clinic provides adequate and appropriate resources for prevention and control of Healthcare Associated Infections (HAI).

Objective Elements

a. Adequate and appropriate personal protective equipment, soaps, and disinfectants are available and used correctly.

Interpretation: They should be available at the point of use and the complementary Clinic shall ensure that it maintains an adequate inventory.Personal protective equipment includes:

i. Gloves

ii. Protective eye wear (goggles)

iii. Mask

iv. Apron

v. Gown

b. Adequate and appropriate facilities for hand hygiene in all patient-care areas are accessible to healthcare providers.

Interpretation: The Complementary medicine clinic shall ensure that it provides necessary infrastructure to carry out the same.

Standard IC. 3. Biomedical waste (BMW) is handled in an appropriate and safe manner.

Objective Elements

a. The Complementary medicine clinic adheres to statutory provisions with regard to biomedical waste.

Interpretation: The Complementary medicine clinic shall be authorized by the prescribed authority for management and handling of biomedical waste. The occupier shall apply in the prescribed form and get approval from the prescribed authority e.g. pollution control board/committee. It shall adhere to the various requirements specified in the bio-medical waste management rules

b. Proper segregation and collection of biomedical waste from all patient-care areas of the Complementary medicine clinic is implemented and monitored.

Interpretation: Wastes to be segregated and collected in different colour coded bags and containers as per statutory provisions. Monitoring shall be done by members of the infection control committee/team. Biomedical waste shall be handled in the proper manner.

c. The Complementary medicine clinic ensures that biomedical waste is stored and transported to the site of treatment and disposal in proper covered vehicles within stipulated time limits in a secure manner.

Interpretation: The waste is transported to the pre-defined site at definite time intervals (maximum within 48 hours) through proper transport vehicles in a safe manner. If this activity is outsourced, the Complementary medicine clinic shall ensure that it is done through an authorized contractor. Monitoring of this activity should be done by an infection control team.

d. Biomedical waste treatment facility is managed as per statutory provisions (if in-house) or outsourced to authorized contractor(s).

Interpretation: If the Complementary medicine clinic has waste treatment facility within its premises then it has to be in accordance with statutory provisions or it can outsource it to a central facility.

e. Appropriate personal protective measures are used by all categories of staff handling biomedical waste.

Interpretation: Example gloves and masks, protective glasses, gowns, etc.

Standard IC. 3. The infection control programme is supported by the complementary clinic's management and includes training of staff.

Objective Elements

a. Complementary medicine clinic management makes available resources required for the infection control programme.

Interpretation: The Complementary medicine clinic shall ensure that the resources required by the personnel should be available in a sustained manner. This includes both men and materials.

b. The Complementary medicine clinic conducts induction training for all staff.

Interpretation: There must be a documented evidence of induction training for all categories of staff before joining department(s) concerned. It should include the policies, procedures and practices of the infection control programme. Doctors also need to be trained.

c. The Complementary medicine clinic conducts appropriate "in-service" training sessions for all staff at least once in a year.

Interpretation: Self-explanatory.

Part 6: Continual Quality Improvement (CQI)

Intent of the chapter:

The standards encourage an environment of continual quality improvement. The quality and safety programme should be documented and involve all aspects of the Complementary medicine clinic including the staff members. The Complementary medicine clinic should collect data on structures, processes and outcomes, especially in areas of high-risk situations. The collected data should be collated, analyzed and used for further improvements. The improvements should be sustained. Infection-control and patient safety plans should also be integrated into the Complementary medicine clinic ’s quality plan.

The Complementary medicine clinic should define its sentinel events and intensively investigate when such events occur.

To be able to define and describe the quality in health care the quality characteristics need to be identified and described. A quality characteristic always relates to a quality requirement.

Therefore eleven quality characteristics of health care services with interrelated quality requirements are identified as:

- appropriate, correct care;
- availability;
- continuity of care;
- effectiveness;
- efficiency;
- equity;
- evidence/knowledge based care;
- patient centred care including physical, psychological and social integrity;
- patient involvement;
- patient safety;
- timeliness/accessibility

Summary of Standards

CQI 1: There is a structured quality improvement and continuous monitoring programme.

CQI 2: The Complementary medicine clinic identifies key indicators, which are used as tools for continual improvement.

CQI.3. Incidents, complaints and feedback are collected and analyzed to ensure continual quality improvement.

Standard CQI.1. There is a structured quality improvement and continuous monitoring programme.

Objective Elements

a. The quality improvement programme is commensurate with the size and complexity of the Complementary medicine clinic and is documented.

Interpretation: This should be documented as a manual. The manual shall incorporate the mission, vision, quality policy, quality objectives, service standards, important indicators as identified etc. The manual could be stand alone and should have cross linkages with other manuals.

b. The quality improvement programme is reviewed at predefined intervals and opportunities for improvement are identified.

Interpretation:

As quality improvement is a dynamic process, it needs to be reviewed at regular predefined intervals (as defined by the Complementary medicine clinic in the quality improvement manual but at least once in a year) by conducting internal audits.

The Complementary medicine clinic shall do the needful to identify the areas for improvement and the corrective measures shall be documented.

Standard CQI.2. The Complementary medicine clinic identifies key indicators which are used as tools for continual improvement.

Objective Elements

a. The Complementary medicine clinic develops appropriate key performance indicators suitable to monitor clinical structures, processes and outcomes.

Interpretation:

• Monitoring may include:

• Appropriate patient assessment.

• Safety and quality control programmes of the diagnostics services.

• Adverse drug events.

• Content of medical records.

• Infection control activities.

• Clinical research.

• Complementary medicine practice therapies and treatment procedures

Remark(s): Refer to ICMR guidelines and GCP for reporting time of serious adverse events.

b. The Complementary medicine clinic develops appropriate key performance indicators suitable to monitor managerial structures, processes and outcomes.

Interpretation:

• Monitoring may include

• Procurement of medication essential to meet patient needs.

• Reporting of activities as required by laws and regulations.

• Risk management.

• Patient satisfaction

• Staff satisfaction.

• Data collection to support further study for improvements.

• Adverse events and near misses.

c. Corrective and preventive actions are taken and monitored for effectiveness with respect to activities being managed or monitored.

Interpretation: This data is analyzed for improvement opportunities and the same are carried out.

Standard CQI.3. Incidents complaints and feedback are collected and analyzed to ensure continual quality improvement.

Objective Elements

a. The Complementary medicine clinic has an incident reporting system.

Interpretation: The incident reporting system includes:

i. Identification ii. Reporting iii. Review iv. Action on incidents

While capturing the Complementary medicine clinic shall capture all incidents without going into the severity or whether harm was caused.

b. The Complementary medicine clinic has a process to collect feedback and receive complaints.

Interpretation: This shall be communicated to the patients using displays or brochures.

c. The Complementary medicine clinic has established processes for analysis of incidents, feedbacks and complaints.

Interpretation: This could preferably be done by identifying the root cause. Where possible, it is preferable that patients be included in analyzing the feedback and complaint.

d. Corrective and preventive actions are taken based on the findings of such analysis.

Interpretation: The objective of this is to continually improve the quality of patientcare services. All such action shall be documented.

e. Feedback about care and service is communicated to staff.

Interpretation: At a minimum, patient satisfaction levels shall be communicated on a monthly basis. This could be done using internal communication. It is equally important that positive feedback about care and service is communicated to staff.

f. The focus of this activity includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system as a system and also through feedback received from all stakeholders.

Interpretation: Self-explanatory.

Part 7: Responsibilities of Management (ROM)

Intent of the chapter:

The standards encourage the governance of the Complementary medicine clinic in a professional and ethical manner. The responsibilities of the management are defined. The Complementary medicine clinic complies with all applicable regulations. The Complementary medicine clinic is led by a suitably qualified and experienced individual.

Complementary medicine clinic ensures that patient safety and risk-management issues are an integral part of patient care.

Summary of Standards

ROM 1: The Complementary medicine clinic shall identify a responsible person, who has the defined responsibility and authority to ensure that the quality programme is maintained and run in an ethical manner.

ROM 2: The Complementary medicine clinic is managed by the leaders in an ethical manner.

ROM 3: Those responsible for management have addressed all applicable aspects of human resource management.

Standard ROM.1. The Complementary medicine clinic shall identify a responsible person who has the defined responsibility and authority to ensure that the quality programme is maintained and run in an ethical manner.

Objective Elements

a. The Complementary medicine clinic identifies documents and records evidence of compliance to applicable legislations and regulations from (MoH, Municipalities, Manpower and ROP).

All records established to provide evidence of conformity to requirements and of the effective operation of the quality management system shall be controlled.

The Complementary medicine clinic shall establish a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records.

Records shall remain legible, readily identifiable and retrievable.

b. Appropriate authorities shall be informed about the notifiable diseases.

Interpretation: Self-explanatory.

c. Those responsible for governance support safety initiatives and quality improvement plans.

Interpretation: All risk assessment and risk reduction is known and measures to reduce are discussed for corrective actions.

d. The individual and the system collective has to ensure that processes needed for the quality management system are established, implemented and maintained.

Interpretation: Self-explanatory.

Standard ROM.2. The Complementary medicine clinic is managed by the leaders in an ethical manner.

Objective Elements

a. The Complementary medicine clinic functions in an ethical manner.

Interpretation: "Code of medical ethics" to be followed.

b. The Complementary medicine clinic discloses its ownership.

Interpretation: The ownership of the Complementary medicine clinic e.g. trust, private, public has to be disclosed.

Remark(s): The disclosure could be in the registration certificate/quality manual etc.

c. The Complementary medicine clinic honestly portrays its affiliations and accreditation.

Interpretation: Here portrays implies that the Complementary medicine clinic conveys its affiliations, accreditations for specific services or whole center wherever applicable.

d. The Complementary medicine clinic accurately bills for its services based upon a standard billing tariff.

Interpretation: Self-explanatory.

Standard ROM.3. Those responsible for management have addressed all applicable aspects of human resource management.

Objective Elements

a. The Complementary medicine clinic maintains an adequate number and mix of staff to meet the care, treatment and service needs of the patient.

Interpretation: The staff should be commensurate with the workload.

b. The required job specifications and job description are well defined for each category of staff.

Interpretation: The content of each job should be well defined and the qualifications, skills and experience required for performing the job should be clearly laid down.

c. The job description should be commensurate with the qualification.

d. The Complementary medicine clinic verifies the antecedents of the potential employee with regards to credentials, criminal/negligence background, training, education and skills.

Interpretation: Due registration with respective Councils/Boards, police verification as applicable.

e. Each staff member, employee and voluntary worker is appropriately oriented to the mission of the Complementary medicine clinic , policies and procedures as well as relevant department / unit / service/ programme's policies and procedures.

Interpretation: This includes patient rights, employee rights and all departmental policies, safety, grievance redressal etc.

f. The Complementary medicine clinic staff participates in continuing professional education programs.

Interpretation: Self-explanatory.

g. Performance evaluation systems are in place, as applicable.

Interpretation: Appraisal, training needs identification, support for training, CMEs etc is provided.

h. Staff Health Problems are addressed.

Interpretation: This includes occupational health issues, medical checkups as applicable and preventive immunization.

Part 8: Facility Management and Safety (FMS)

Intent of the chapter:

The standards guide the provision of a safe and secure environment for patients and their families. The Complementary medicine clinic shall take steps to ensure this.

The Complementary medicine clinic provides safe water and electricity. The Complementary medicine clinic has a programme for clinical and support service equipment management.

Summary of Standards

FMS 1: The Complementary medicine clinic's environment and facilities operate to ensure safety of patients, their families and staff.

FMS 2: The Complementary medicine clinic has a programme for equipment management, safe water and electricity, as applicable.

FMS 3: The Complementary medicine clinic has plans for emergencies (fire and non-fire) and hazardous materials within the facilities.

FMS.4. The Complementary medicine clinic has a programme for engineering support services and bio-medical equipment management.

Standard FMS.1. The Complementary medicine clinic's environment and facilities operate to ensure safety of patients their families and staff.

Objective Elements

a. Up-to-date drawings are maintained which detail the site layout, floor plans and fire escape routes.

Interpretation: Self explanatory

Remark(s): Appropriate to the size of the clinic.

b. There is internal and external sign posting in the Complementary medicine clinic in a language understood by patient, families and community.

Interpretation: Self-explanatory.

Remark(s): These signages shall guide patients and visitors. It is preferable that signage's are bi-lingual. Statutory requirements shall be met.

Standard FMS.2. The Complementary medicine clinic has a programme for equipment management safe water and electricity as applicable.

Objective Elements

a. The Complementary medicine clinic plans for equipment in accordance with its services and strategic plan.

Interpretation: Self-explanatory. This shall also take into consideration future requirements.

b. Potable water and electricity are available.

Interpretation: The Complementary medicine clinic shall make arrangements for supply of adequate potable water and electricity.

Standard FMS.3. The Complementary medicine clinic has plans for emergencies (fire and non-fire) and hazardous materials within the facilities.

Objective Elements

a. The Complementary medicine clinic has plans and provisions for early detection, abatement and containment of fire and non-fire emergences.

Interpretation: The Complementary medicine clinic has conducted an exercise of hazard identification and risk analysis (HIRA) and accordingly taken all necessary steps to eliminate or reduce such hazards and associated risks.

• Fire plan-covering fire arising out of burning of inflammable items, explosion, and electric short circuiting or acts of negligence or due to incompetence of the staff on duty.

• Acquired adequate fire fighting equipment for this which records are kept up-to-date.

• Adequate training of staff.

• Exit plans well displayed.

• Emergency illumination system which comes into effect in case of a fire

• Non-fire emergency situations include :

• Infected materials (used gloves,) medical wastes (blood, pus,vomits, etc.)

• Fall or slips (from height or on floor) or collision of personnel in passageway

• Fall of patient from bed

• The Complementary medicine clinic has established liaison with civil and police authorities and fire brigade as required by law for enlisting their help and support in case of an emergency.

b. Staffs are trained for their role in case of such emergencies.

Interpretation: In case of fire designated person are assigned particular work. Mock drills are also held.

c. The Complementary medicine clinic defines and implements its policies to eliminate smoking.

Interpretation: Smoking in public places including Complementary medicine clinic has been banned in this country.

Standard FMS.4. The Complementary medicine clinic has a programme for bio-medical equipment management.

Objective Elements

a. The Complementary medicine clinic plans for equipment in accordance with its services and strategic plan.

Interpretation: This shall also take into consideration future requirements. The equipment shall be appropriate to its scope of services.

b. All equipments are inventoried and proper logs are maintained as required.

Interpretation: This includes equipment on a rental basis and equipment kept for demonstration purpose. The relevant quality conformance certificates/marks along with manufacturer factory test certificate needs to be retained as part of documentation for all equipment.

c. Qualified and trained personnel operate and maintain the medical equipment.

Interpretation: Maintenance of bio-medical equipment shall be done by a bio- medical engineer/technician or instrumentation engineer/technician with relevant training and experience.

d. Equipment are periodically inspected and calibrated for their proper functioning.

Interpretation: The Complementary medicine clinic has weekly/monthly/annual schedules of inspection and calibration of equipment, which involve measurement, in an appropriate manner. The Complementary medicine clinic either calibrates the equipment in-house, maintaining traceability to national or international or manufacturer's guidelines/standards. The

Complementary medicine clinic shall ensure that calibration and conformance testing of the equipment has been done prior to commissioning.

Part 9: Human Resource Management (HRM)

Intent of the standards

The most important resource of a Complementary medicine clinic is the human resource. Human resources are an asset for effective and efficient functioning of a Complementary medicine clinic. Without an equally effective human resource management system, all other inputs like technology, infrastructure and finances come to naught. Human resource management is concerned with the "people" dimension in management.

The goal of human resource management is to acquire, provide, retain and maintain competent people in right numbers to meet the needs of the patients and community served by the Complementary medicine clinic. This is based on the Complementary medicine clinic mission, objectives, goals and scope of services.

Effective Human Resource Management involves the following processes and activities:

a. Acquisition of Human Resources, which involves human resource planning, recruiting and socialization of the new employees.

b. Training and development relates to the performance in the present and future anticipated jobs. The employees are provided with opportunities to advance personally as well as professionally.

c. Motivation relates to job design, performance appraisal and discipline.

d. Maintenance relates to safety and health of the employees.

The term "staff/ employee" refers to all salaried personnel working in the Complementary medicine clinic as well as contractual personnel. It does not refer to "fee for service" medical professionals.

The Complementary medicine clinic shall:

a. Determine the necessary competence for personnel performing work affecting conformity to product requirements,

b. Where applicable, provide training or take other actions to achieve the necessary competence,

c. Evaluate the effectiveness of the actions taken,

d. Ensure that the necessary competence has been achieved,

e. Ensure that all personnel perform their tasks in accordance with evidence and knowledge-based best practice,

f. Ensure that all personnel are trained concerning all relevant aspects of their role including clinical risk management for patient safety,

g. Ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality characteristics and quality objectives, and

h. Maintain appropriate records of education, qualification, training, skills and experience.

Summary of Standards

HRM.1. The Complementary medicine clinic has a documented procedure for recruiting staff and orienting them to the Complementary medicine clinic ’s environment.

HRM.2. Staffs are adequately trained on specific job duties or responsibilities related to safety.

HRM.3. An appraisal system for evaluating the performance of an employee exists as an integral part of the human resource management process.

HRM.4. A grievance handling mechanism exists in the Complementary medicine clinic.

HRM.5. There is a documented personal record for each staff member

HRM 6. The organisation addresses the health needs of the employees.

Standard HRM. 1 The Complementary medicine clinic has a documented procedure for recruiting staff and orienting them to the Complementary medicine clinic ’s environment.

Objective Elements

a. There is a documented procedure for recruitment.

Interpretation: The recruitment process ensures an adequate number and skill mix of staff to provide the Complementary medicine clinic’s services. The procedure shall ensure that the staffs have the necessary registration, qualifications, skills and experience to perform its work. Recruitment is undertaken in accordance with statutory requirements, where applicable.

b. Recruitment is based on pre-defined criteria.

Interpretation: The laid-down recruitment procedure shall be adhered to. The entire process shall be documented. This shall ensure that the recruitment is done in a transparent manner.

c. Every staff member entering the Complementary medicine clinic is provided induction training.

Interpretation: The Complementary medicine clinic shall determine as to when induction training shall be conducted. However, it shall be within 15 days of the staff joining.

Objective elements "d" to "g" shall be covered in this training. Similarly, all other requirements of this standard could be covered. The contents of this training could be provided to every staff in the form of a booklet. There can be separate induction training at the Complementary medicine clinic al level and for the respective departments.

d. The induction training includes awareness on patient's rights and responsibilities.

Interpretation: The employees should be able to identify and report violation of patient rights as and when it occurs. For patient rights refer to PRE 1.

Standard HRM. 2. Staffs are adequately trained on specific job duties or responsibilities related to safety.

Objective Elements

a. All staff is trained on the risks within the Complementary medicine clinic environment.

Interpretation: The Complementary medicine clinic shall define such risks that shall include patient, visitors and employee-related risks. For example, fire and non-fire emergency etc.

b. Staff can demonstrate and take actions to report, eliminate/minimize risks.

Interpretation: Staff should be able to practically demonstrate actions like taking care of blood spills, medication errors and other adverse event reporting systems.

c. Staffs are made aware of procedures to follow in the event of an incident.

Interpretation: Self-explanatory.

d. Staff is trained on occupational safety aspects.

Interpretation: This shall include making them aware of the possible risks involved and preventive actions to avoid risks. E.g. burns or scalds during treatment procedure.

Standard HRM.3. An appraisal system for evaluating the performance of an employee exists as an integral part of the human resource management process

Objective Elements

a. A documented performance appraisal system exists in the Complementary medicine clinic.

Interpretation: This shall be done for all categories of employees starting from the person heading the Complementary medicine clinic.

b. The employees are made aware of the system of appraisal at the time of induction.

Interpretation: This could be incorporated in the service booklet and included in the induction training.

c. Performance is evaluated based on the pre-determined criteria

Interpretation: Self-explanatory.

d. The appraisal system is used as a tool for further development.

Interpretation: This can be done by identifying training requirements and accordingly providing for the same (wherever possible). Key result areas are identified for each staff and training need assessment is also done.

e. Performance appraisal is carried out at pre defined intervals and is documented.

Interpretation: This shall be done at least once a year.

Standard HRM.4. A grievance handling mechanism exists in the Complementary medicine clinic

Objective Elements

a. Documented policies and procedures exist.

Interpretation: The documentation shall be done keeping in mind objective elements "c and d".

b. The policies and procedures are known to all categories of staff of the Complementary medicine clinic .

Interpretation: All the staff should be aware of the disciplinary procedure and the process to be followed in case they feel aggrieved.

c. The redress procedure addresses the complaints.

Interpretation: Self-explanatory.

d. Actions are taken to redress the complaints.

Interpretation: This shall be documented and communicated to the aggrieved staff.

Standard HRM.5. There is a documented personal record for each staff member

Objective Elements

a. Personal files are maintained in respect of all staff.

Interpretation: Self-explanatory.

b. The personal files contain personal information regarding the staff qualification, trainings, disciplinary background and health status.

Interpretation: Self-explanatory.

c. The education, training and experience of Complementary medicine practice are documented and updated periodically.

Interpretation: Updating is done after acquisition of new skills and/or qualification.

d. Complementary medicine practice are granted privileges in consonance with their qualification, training, experience and registration.

Interpretation: The Complementary medicine clinic shall identify as to what Complementary medicine healthcare professionals are authorized to do. For example, they should have had requisite /external training and experience and the aptitude and knowledge to perform the tasks required of him/her.

Standard HRM.6. The establishment addresses the health needs of the employees

Objective Elements

a. A pre-employment medical examination is conducted on all the staff

Interpretation: Self-explanatory.

b. Health problems of the employees are taken care of in accordance with the establishment's policy.

Interpretation: Self-explanatory.

c. Regular health checks of staff dealing with direct patient care are done at least once a year and the findings/results are documented.

Interpretation: Self-explanatory.

Part 10: Information Management System (IMS)

Intent of Standards

Information is an important resource for effective and efficient delivery of Complementary medicine clinic.

Provision of health care and its continued improvement is dependent to a large extent on the information generated, stored and utilized appropriately by the Complementary medicine clinic s.

The goal of Information Management in a Complementary medicine clinic is to ensure that the required inputs are available to the right personnel. This is provided in an authenticated, secure and accurate manner at the right time and place. This helps to achieve the ultimate Complementary medicine Clinical goal of a satisfied and improved provider and recipient of health care.

An effective Information Management system is based on the information needs of the Complementary medicine clinic. The system is able to capture, transmit, store, analyze, utilize and retrieve information as and when required for improving clinical outcomes as well as individual and overall Complementary medicine clinic al performance. Although a digital based information system improves efficiency, the basic principles of a good information management system apply equally to a manual/paper based system.

The quality management system documentation shall include:

a. documented statements of a quality policy and quality objectives,

b. a quality manual,

c. documents, including records, determined by the organization to be necessary to ensure the effective planning, operation and control of its processes.

d. an overview and description of the clinical processes and other processes included in the quality management system,

e. how clinical risks are managed in the clinical and other processes

f. documents relating to the management of clinical processes across health care units in the Complementary medicine clinic including those outsourced to an external party.

Summary of Standards

IMS.1. The Complementary medicine clinic has processes in place for effective management of data.

IMS.2 The Complementary medicine clinic has a complete and accurate medical record for every patient which reflects continuity of care.

IMS.3. Documented policies and procedures are in place for maintaining confidentiality, integrity and security of information.

IMS.4. Documented policies and procedures exist for retention time of records, data and information.

Standard IMS. 1 The Complementary medicine clinic has processes in place for effective management of data

Objective Elements

a. Formats for data collection are standardized.

Interpretation: MIS/HIS data are collected in standardized format from all areas/services in the Complementary medicine clinic, the frequency of the data collection and the person(s) responsible is also specified. The frequency of capturing data namely daily, weekly, monthly, quarterly, yearly etc.

b. Necessary resources are available for analyzing data.

Interpretation: The Complementary medicine clinic shall make available men, material, space and budget.

c. Documented procedures are laid down for timely and accurate dissemination of data.

Interpretation: All timely feedback is given to relevant stakeholders after data generation and analysis. The Complementary medicine clinic could decide on which data needs to be shared with whom and also the modalities (e.g. memos, circulars, etc.) for dissemination of such data.

d. Documented procedures exist for storing and retrieving data.

Interpretation: The Complementary medicine clinic shall define data management policy and ensure adequate safeguards for protection of data, wherever physical or electronic data is stored. Storage could be physical or electronic. Wherever electronic storage is done the Complementary medicine clinic shall ensure that there are adequate safeguards for protection of data.

Standard IMS. 2 The Complementary medicine clinic has a complete and accurate medical record for every patient which reflects continuity of care

Objective Elements

a. Every medical record has a unique identifier.

Interpretation: This shall also apply to records on digital media e.g. EMR. Every sheet in the medical record shall have this unique identifier. In case of electronic records, all entries for one unique identifier shall be available in one place. E.g. CR number, Complementary medicine clinic number, etc.

b. Complementary medicine clinic policy identifies those authorized to make entries in medical record.

Interpretation: Complementary medicine clinic shall have a written policy authorizing who can make entries and the content of entries. This could be different category of personnel for different entries, but it shall be uniform across the Complementary medicine clinic e.g. progress record by Complementary medicine healthcare practitioners.

c. Every medical record entry is dated and timed.

Interpretation: All entries should be documented immediately but no later than one hour of completion of the assessment/procedure. For records on electronic media, it is preferable that the date and time is automatically generated by the system.

d. The author of the entry can be identified.

Interpretation: This could be by writing the full name or by mentioning the employee code number, with the help of stamp, etc. In case of electronic-based records, authorized e-signature provision as per statutory requirements must be kept.

e. The contents of medical record are identified and documented.

Interpretation: The Complementary medicine clinic identifies which documents form part of the medical records, documents and implements the same. Example practitioner's order sheet, consent form, etc.

f. The record provides an up-to-date and chronological account of patient care.

Interpretation: Every medical record has all the identified sheets filed in the proper order. The Complementary medicine clinic shall decide the format for maintaining the continuity in the medical records. It shall ensure that all medico-legal case records have the mandatory information. In case a particular sheet is missing a note to that effect would be put in the medical record.

g. The medical record contains the results of tests carried out and the care provided.

Interpretation: It is preferable that the medical records also reflect any delay in tests and treatment planned or provided for the patient. This could be taken up for clinical audit.

h. Procedures performed are incorporated in the medical record.

Interpretation: Also refer to COP5 h and g.

i. Care providers have access to current and past medical record.

Interpretation: The Complementary medicine clinic provides access to medical records to designated healthcare providers (those who are involved in the care of that patient). For electronic medical record system, every faculty shall have a user ID and a password.

Standard IMS. 3 Documented policies and procedures are in place for maintaining confidentiality integrity and security of information

Objective Elements

a. Documented policies and procedures exist for maintaining confidentiality, security and integrity of information.

Interpretation: The Complementary medicine clinic shall control the accessibility to the MRD and to its Complementary medicine clinic Information System. For physical records, it shall ensure the usage of tracer card for movement of the file in and out of the MRD. It shall have a system in place to ensure that only the relevant care providers have access to the patient's record. Similarly, for data and information, it shall ensure that records and data are not taken out from the areas where they are stored. In case of electronic systems it shall ensure that these cannot be copied at all locations. The procedure shall also address how entries in the patient record are corrected or overwritten. Objective element "c" could also be included in this procedure. The documentation shall be done keeping in mind objective element "b".

b. Documented policies and procedures are in consonance with the applicable laws in the country.

Interpretation: This is in the context of MoH regulation, Documents and Archives regulations, etc.

c. The policies and procedures incorporate safeguarding of data/record against loss, destruction and tampering.

Interpretation: For physical records, the Complementary medicine clinic shall ensure that there are adequate pest and rodent control measures. For electronic data, there should be protection against Virus/Trojans and also a proper backup procedure. To prevent tampering of physical records access shall be limited only to the healthcare provider concerned. In electronic format, this could be done by adequate passwords. In electronic systems, the access should be different for different types of personnel and specific for that user. The Complementary medicine clinic should have a system to keep a track of changes made in the medical record or data.

In case of physical records and data, there must be a provision to either store in fire safe cabinets or there must be adequate (and appropriate) fire-fighting equipment. It is preferable that software, when used, shall be validated and duly authenticated.

d. The Complementary medicine clinic has an effective process of monitoring compliance of the laid down policy.

Interpretation: The Complementary medicine clinic carries out regular audits/rounds to check compliance with policies.

e. The Complementary medicine clinic uses developments in appropriate technology for improving confidentiality, integrity and security.

Interpretation: The Complementary medicine clinic shall review and update its technological features so as to improve confidentiality, integrity and security of information. E.g. moving from physical to electronic format, remote backup of data etc.

f. Privileged health information is used for the purposes identified or as required by law and not disclosed without the patient's authorization.

Interpretation: The Complementary medicine clinic shall define the procedure for privileged communication. The authorization from the patient shall be obtained in writing.

g. A documented procedure exists on how to respond to patients/physicians and other public agencies requests for access to information in the medical record in accordance with the local and national law.

h. The Complementary medicine clinic needs to ensure that both individual patient records, which contain confidential information about a single patient, and collated records where accumulated information on patients are collected. The privacy of all such information and documentation will be aligned to national regulation.

Interpretation: Self-explanatory.

i. All records established to provide evidence of conformity to requirements and of the effective operation of the quality management system shall be controlled.

Interpretation: Self-explanatory.

j. The Complementary medicine clinic shall establish a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records.

Interpretation: Self-explanatory.

k. Records shall remain legible, readily identifiable and retrievable.

Interpretation: Self-explanatory.

Standard IMS. 4 Documented policies and procedures exist for retention time of records data and information

Objective Elements

a. Documented policies and procedures are in place on retaining the patient's clinical records, data and information.

Interpretation: The Complementary medicine clinic shall define the retention period for each category of medical records: Out-patient and MLC. It shall also do the same for various data and the formats (e.g. registers and forms) that have been used for capturing this data. The documentation shall be done keeping in mind objective element "b".

b. The Documented policies and procedures are in consonance with the local and national laws and regulations.

Interpretation: Some of the related laws in this context are Code of Medical Ethics, Documentation & Archives Regulations.

c. The retention process provides expected confidentiality and security.

Interpretation: This is applicable for both manual and electronic system.

d. The destruction of medical records, data and information is in accordance with the laid down policy.

Interpretation: Destruction can be done after the retention period is over and after taking approval of the competent authority.

e. The clinic shall exercise care with customer property while it is under the clinics control or being used by the clinic. The clinic shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, the clinic shall report this to the customer and maintain records.

I**nterpretation**: Information in health records can be regarded as patient property, in accordance with national legislation. The clinic has the responsibility for protecting the integrity of this information against loss, damage and unauthorized access according to security and confidentiality requirements, set by the patient, the clinic and applicable legislation.

The Basic Complementary Medicine Facility licensure requirements

Audit Checklist Standard

Standard (Desired Outcome)	Criteria	Criteria requirements
Management & Human Resources	1.1	Licence is displayed
	1.2	Scope of service offered within facility are displayed, within the licensing scope & practised.
	1.3	Professional Staff have a valid professional licence to practise.
	1.4	Scope of service defined for professional staff are within the professional licensing scope.
	1.5	List of all current staff detailing their title, position, qualification & signature.
	1.6	Staff are appropriately attired and wear ID badges
	1.2	Scope of service offered within facility are displayed, within the licensing scope & practised.
Complaint Management	2.1	Patients 'Rights & Responsibilities are displayed in different locations in the facility
	2.2	A designated staff is responsible for managing complaints
	2.3	Complaint process is implemented
Facility Maintenance	3.1	Facility's physical working space is suitable to comfortably accommodate equipment, staff and patients.
	3.2	Facility is well maintained i.e. AC, illumination, ventilation, good storage practice, hygiene and housekeeping.
Fire & Safety	4.1	Exit signs are clearly marked lighted & exit routes are unobstructed.
	4.2	Fire fighting resources including fire extinguishers (red & black), smoke detectors and fire safety posters e.g. RACE PASS signs are available and are regularly inspected
Medical Equipment Management	5.1	Relevant equipment available to fulfil scope of services & connected with 3 pin plugs.
	5.2	Equipment are calibrated according to manufacturer's standards, well maintained, regularly, serviced by a qualified biomedical

		technician & signed service reports are available.
	5.3	Refrigerators are temperature monitored
	5.4	Out of service equipment clearly marked and stored
Infection Control	6.1	Supplies are available for cleaning of surfaces and patient contact points on equipment.
	6.2	Single use/disposable supplies are used wherever possible.
	6.3	Good hand hygiene & cleaning practices are followed.
Supplies/Medications	7.1	Expiry of supplies, material & medications are tracked regularly by a designated responsible staff.
	7.2	Medications/material available comply with facility's license & scope of services offered.
	7.3	Facility contains an emergency medication kit(s) evenly distributed across the facility & containing the minimum requirements to manage an emergency situation.
Clinical Practice	8.1	List of services/procedures professional staff is allowed to do is displayed
	8.2	Professional staff practise according to international clinical practice guidelines.
	8.2a	Professional staff demonstrate knowledge of specific related conditions
	8.2b	Professional staff recognise their limitation in clinical competencies and refrain from practising beyond their clinical competencies.
	8.3	Client records are kept in a secure location for privacy & confidentiality.
	8.4	Client records are allocated a unique identification number, completed in legible handwriting, signed & stamped by professional staff.
	8.5	Patients' care is documented, dated, timed & signed.
	8.5a	General consents are signed for all patients on the first visit.
	8.5b	Patient signs consent before every procedure to be conducted. Procedure is to be explained to the patients & possible risks to be documented within the consent.
	8.6	Daily register is kept of all patients consulted.

	8.7	Desired outcome of patients' condition is achieved & registered
	8.8	Staff demonstrate knowledge and evidence of implementation of a defined referral process for patients to other facilities.
	8.9	Professional staff are certified in ACLS & demonstrate competent knowledge on managing emergency conditions

Glossary

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

Accreditation

1. A process of external review of the quality of the health care being provided by a clinic. This is generally carried out by a nongovernmental organization

2. It also represents the outcome of the review and the decision that an eligible organization meets an applicable set of standards.

Accreditation assessment

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

Adverse drug event

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

Adverse Drug Reaction:

A response to a drug which is noxious and unintended and ***which occurs at doses normally used in man*** for prophylaxis, diagnosis, or therapy of disease or for the modification of physiologic function.

Therefore ADR = Adverse Event with a causal link to a drug.

Adverse drug event: The FDA recognises the term *adverse drug event to be* a synonym for *adverse event.*

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

• drug

• harm caused by drug use, and

• a medication error with or without harm

Institute of Medicine:

"An injury resulting from medical intervention related to a drug", which has been simplified to "***an injury resulting from the use of a drug***"

Adverse drug events extend beyond adverse drug reactions to include harm from overdoses and under-doses usually related to medication errors.

A minority of adverse drug events is medication errors, and medication errors rarely result in adverse drug events.

Adverse event:

An injury related to medical management, in contrast to complications of disease. Medical management includes all aspects of care, including diagnosis and treatment, failure to diagnose or treat, and the systems and equipment used to deliver care. Adverse events may be preventable or non-preventable. (WHO Draft Guidelines for Adverse Event Reporting and Learning Systems)

Basic life support (BLS):

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

Breakdown maintenance

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

Care Plan

A plan that identifies patient care needs, lists the strategy to meet those needs, documents treatment goals and objectives, outlines the criteria for ending interventions, and documents the individual's progress in meeting specified goals and objectives. The format of the plan may be guided by specific policies and procedures, protocols, practice guidelines or a combination of these. It includes preventive, promotive, curative and rehabilitative aspects of care.

Clinical audit

Analysis of clinical aspects of patient care for improving the quality of health care services.

Clinical practice guidelines

Guidelines that assist practitioners to provide appropriate clinical care for specific clinical conditions. The guidelines include relevant history taking, physical signs to look for, lab investigations to be carried out and treatment to be prescribed.

Competence Demonstrated ability to apply knowledge and skills.

Knowledge is the understanding of facts and procedures. Skill is the ability to perform specific action.

Confidentiality

Restricted access to information to individuals who have a need, a reason and permission for such access. It also includes an individual's right to personal privacy as well as privacy of information related to his/her health care records.

Consent

1. Willingness of a party to undergo examination/procedure/ treatment by a health care provider. It may be implied (e.g. patient registering in OPD), expressed which may be written or verbal. Informed consent is a type of consent in which the health care provider has a duty to inform his/her patient about the procedure, its potential risk and benefits, alternative procedure with their risk and benefits so as to enable the patient to take an informed decision of his/her health care.

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

It may be evidenced by words or acts or by silence when silence implies concurrence. Actual or implied consent is necessarily an element in every contract and every agreement.

Credentialing

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

Data

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

Drug dispensing

The preparation, packaging, labeling, record keeping, and transfer of a prescription drug to a patient or an intermediary, who is responsible for administration of the drug.

Drug Administration

The giving of a therapeutic agent to a patient, e.g. by infusion, inhalation, injection, paste, suppository or tablet. It includes aerosol, oral, transtracheal infusion, subcutaneous, intramuscular, intravenous, intrauterine, intraperitoneal, intra-articular, intramammary, intrathecal, subconjunctival, percutaneous, percutaneous intraruminal, gas inhalation.

Effective communication

A two way information sharing process which involves the communicator, communicating a message that is easily understood by the recipient.

Good medical care depends upon effective communication between patients and providers. Effective communication with persons who have limited language proficiency or understanding of the subject due to lack of familiarity, often requires interpreters, special efforts or other services.

Employees

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

Ethics

Medical ethics is the discipline of evaluating the merits, risks, and social concerns of activities in the field of medicine.

Evidence based medicine

1.It is the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patient

2. It also implies making medical decisions and applying the same to patients based on the best external evidence combined with the physician's clinical expertise and the patient's desires.

Family

The person(s) with a significant role in the patient's life. It mainly includes spouse, children, and parents. It may also include a person(s) not legally related to the patient but can make health care decisions for a patient if the patient loses decision making ability.

Formulary

An approved list of prescription drugs that the clinic may provide to their patients.

The list is updated preferably each year. Changes may be made depending on availability or market.

Grievance / complaint handling procedures

Sequence of activities carried out to address the grievances of patients, relatives and staff.

Hazardous materials

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

Healthcare organisation

Generic term is used to describe the various types of organisation that provide healthcare services. This includes ambulatory care centres, hospitals, laboratories, etc.

Incident reporting

It is defined as written or verbal reporting of any event in the process of patient care, that is inconsistent with the deserved patient outcome or routine operations of the healthcare facility.

Indicator

A statistical measure of the performance of functions, systems or processes overtime. For example, hospital acquired infection rate, staff absence rate, etc.

Information

Processed data which lends meaning to the raw data.

Intent

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

Inventory control

The method of supervising the intake, use and disposal of various goods in hands. It relates to supervision of the supply, storage and accessibility of items in order to ensure adequate supply without stock outs/excessive storage. It is also the process of balancing ordering costs against carrying costs of the inventory so as to minimise total costs.

Job description

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

2. A summary of the most important features of a job, including the general nature of the work performed (duties and responsibilities) and level (i.e., skill, effort, responsibility and working conditions) of the work performed. It typically includes job specifications that include employee characteristics required for competent performance of the job. A job description should describe and focus on the job itself and not on any specific individual who might fill the job.

Job specification

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

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

Laws

Legal document setting forth the rules of governing a particular kind of activity.

Maintenance

The combination of all technical and administrative actions, including supervision actions, intended to retain an item in, or restore it to, a state in which it can perform a required function

Medical audit

A peer review carried out by analysis of medical records with a view to improve the quality of the patient care

Medication error

A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packing and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use. (Zipperer, et al)

Medication Order

A written order by a physician, dentist, or other designated health professional for a medication to be dispensed by a pharmacy for administration to a patient. *(Reference: Mosby's Medical Dictionary, 9th edition, Elsevier)*

Primary difference between *Prescription & Medication Order* is that the medication order is used after Prescription, to get medicines issued/ dispensed from Pharmacy.

Medication Order is an active Record, while Prescription is a Document.

Medical equipment

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

Mission

A written expression that sets forth the purpose of the organization. It usually precedes the formation of goals and objectives.

Monitoring

The performance and analysis of routine measurements aimed at identifying and detecting changes in the health status or the environment. It requires careful planning and use of standardised procedures and methods of data collection.

Multi-disciplinary

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

Near-miss

A near-miss is an unplanned event that did not result in injury, illness, or damage--but had the potential to do so. Errors that did not result in patient harm, but could have, can be categorised as near-misses.

No harm

This is used synonymously with near miss. However, some authors draw a distinction between these two phrases.

A near-miss is defined when an error is realised just in the nick of time and abortive action is instituted to cut short its translation. In no harm scenario, the error is not recognised and the deed is done but fortunately for the healthcare professional, the expected adverse event does not occur. The distinction between the two is important and is best exemplified by reactions to administered drugs in allergic patients. A prophylactic injection of cephalosporin may be stopped in time because it suddenly transpires that the patient is known to be allergic to penicillin (near-miss). If this vital piece of information is overlooked and the cephalosporin administered, the patient may fortunately not develop an anaphylactic reaction (no harm event).

Notifiable disease

Certain specified diseases which are required by law to be notified to the public health authorities.

The various diseases notifiable under the factories act are lead poisoning, bysinnosis, anthrax, asbestosis and silicosis.

Objective

A specific statement of a desired short-term condition or achievement includes measurable end-results to be accomplished by specific teams or individuals within time limits. (ASQ)

Objective element

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

Organogram

A graphic representation of reporting relationship in an organisation.

Outsourcing

Hiring of services and facilities from other organisation based upon one’s own requirement in areas where such facilities are either not available or else are not cost-effective. For example, outsourcing of house-keeping, security, laboratory/certain special diagnostic facilities with other institutions after drawing a memorandum of understanding that clearly lays down the obligations of both organisations: the one which is outsourcing

and the one which is providing the outsourced facility. It also addresses the quality-related aspects.

Patient record/ medical record/ clinical record

A document which contains the chronological sequence of events that a patient undergoes during his stay in the health care organization. It includes demographic data of the patient, assessment findings, diagnosis, consultations, procedures undergone, progress notes and discharge summary.

Patient satisfaction

Is a measure of the extent to which a patient is content with the health care which they received from their health care provider. Patient satisfaction is thus a proxy but a very effective indicator to measure the success of Health care providers.

Patient Experience

Is the sum of all interactions, shaped by an organisation's culture, that influence patient perceptions across the continuum of care.

It is a holistic perception that the patient forms about the healthcare provider based on the overall interactions/ care touch points.

Performance appraisal

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

Plan of care

A plan that identifies patient care needs, lists the strategy to meet those needs, documents treatment goals and objectives, outlines the criteria for ending interventions, and documents the individual's progress in meeting specified goals and objectives. The format of the plan may be guided by specific policies and procedures, protocols, practice guidelines or a combination of these. It includes preventive, promotive, curative and rehabilitative aspects of care.

Policies

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

Preventive maintenance

It is a set of activities that are performed on plant equipment, machinery, and systems before the occurrence of a failure in order to protect them and to prevent or eliminate any degradation in their operating conditions.

The maintenance carried out at predetermined intervals or according to prescribed criteria and intended to reduce the probability of failure or the degradation of the functioning of an item.

Prescription

A prescription is a document given by a physician or other healthcare practitioner in the form of instructions that govern the care plan for an individual patient.

Legally, it is a written directive, for compounding or dispensing and administration of drugs, or for other service to a particular patient.

Privileging

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

Procedure

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

2. A series of activities for carrying out work which when observed by all help to ensure the maximum use of resources and efforts to achieve the desired output.

Process

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

Program

A sequence of activities designed to implement policies and accomplish objectives

Protocol

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

Quality

1.Degree to which a set of inherent characteristics fulfil requirements .Characteristics imply a distinguishing feature

Requirements are a need or expectation that is stated, generally implied or obligatory

2. Degree of adherence to pre-established criteria or standards.

Quality assurance

Part of quality management focussed on providing confidence that quality requirements will be fulfilled.

Quality improvement

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

Re-assessment

It implies continuous and on-going assessments of the patient which are recorded in the medical records as progress notes.

Resources

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

Risk management

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

Risk reduction

The conceptual framework of elements considered with the possibilities to minimise vulnerabilities and disaster risks throughout a society to avoid (prevention) or to limit (mitigation and preparedness) the adverse impacts of hazards, within the broad context of sustainable development.

It is the decrease in the risk of a healthcare facility, given activity, and treatment process with respect to patient, staff, visitors and community.

Root Cause Analysis (RCA)

Root Cause Analysis (RCA) is a structured process that uncovers the physical, human, and latent causes of any undesirable event in the workplace. Root cause analysis (RCA) is a method of problem solving that tries to identify the root causes of faults or problems that cause operating events.

RCA practice tries to solve problems by attempting to identify and correct the root causes of events, as opposed to simply addressing their symptoms. By focusing correction on root causes, problem recurrence can be prevented. The process involves data collection; cause charting, root cause identification and recommendation generation and implementation.

Safety

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

Safety programme

A programme focused on patient, staff and visitor safety.

Scope of services

Range of clinical and supportive activities that are provided by a health care organization.

Security

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

Sentinel events

A relatively infrequent, unexpected incident, related to system or process deficiencies, which leads to death or major and enduring loss of function for a patient.

Major and enduring loss of function refers to sensory, motor, physiological, or psychological impairment not present at the time services were sought or begun.

Special Educational needs of the patient

In addition to routine carried by the healthcare professionals, patients and family have special educational needs depending on the situation. E.g.: a post surgical patient who has to take care of his wound, NG tube feeding, Patient on tracheostomy getting discharged who has to be taken care by the family etc. The special educational needs are also greatly influenced by the literacy, educational level, language, emotional barriers and physical and cognitive limitations. Hence it is important for the staff to determine the special educational needs and the challenges influencing the effective education.

Staff

All personnel working in the clinic either as full paid employees or as consultants on honorarium basis

Standard precautions

1. A method of infection control in which all human blood and other bodily fluids are considered infectious for HIV, HBV and other blood borne pathogens, regardless of patient history. It encompasses a variety of practices to prevent occupational exposure, such as the use of personal protective equipment (PPE), disposal of sharps and safe housekeeping

2. A set of guidelines protecting first aiders or healthcare professionals from pathogens. The main message is "Don't touch or use anything that has the victim's body fluid on it without a barrier." It also assumes that all body fluid of a patient is infectious, and must be treated accordingly

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

Standards

A statement of expectation that defines the structures and process that must be substantially in place in an organization to enhance the qualify of care.

Surveillance

The continuous scrutiny of factors that determines the occurrence and distribution of diseases and other conditions of ill health. It implies watching over with great attention, authority and often with suspicion.

It requires professional analysis and sophisticated interpretation of data leading to recommendations for control activities.

Unstable patient

A patient whose vital parameters need external assistance for their maintenance.

Values

The fundamental beliefs that drive organisational behaviour and decision-making.

This refers to the guiding principles and behaviours that embody how an organisation and its people are expected to operate. Values reflect and reinforce the desired culture of an organisation.

Validation

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

Objective Evidence – Data supporting the existence or variety of something

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

Vision

An overarching statement of the way an organisation wants to be, an ideal state of being at a future point. This refers to the desired future state of an organisation. The vision describes where the organisation is headed, what it intends to be, or how it wishes to be perceived in the future.

Vulnerable patient

Those patients who are prone to injury and disease by virtue of their age, sex, physical, mental and immunological status, e.g. infants, elderly, physically and mentally challenged.

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