Presentation on Chemo and radiotherapy standards (MOM 10,11)

Group 2

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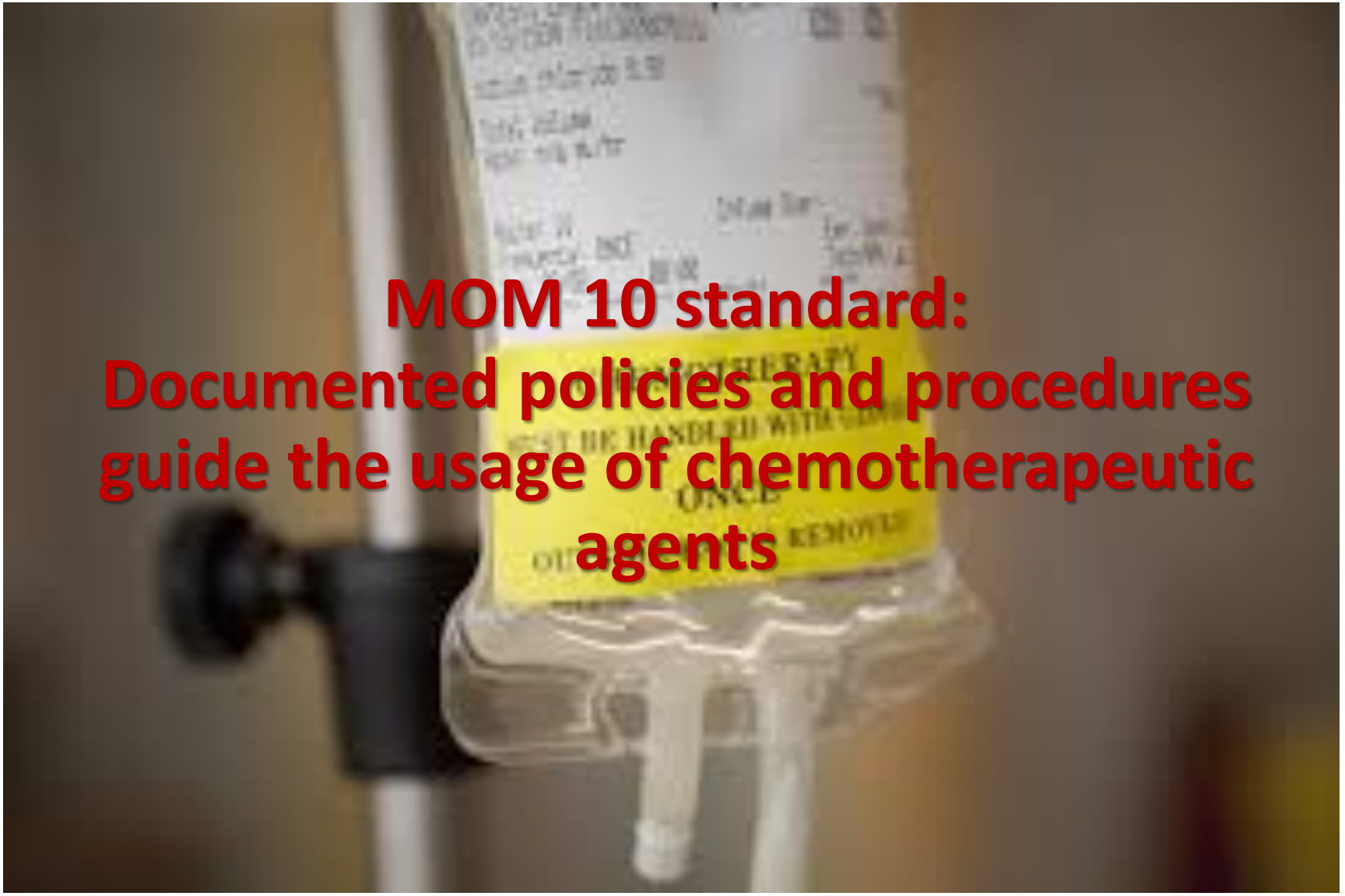
MOM 10 standard:
Documented policies and procedures guide the usage of chemotherapeutic agents

Policy

Objective elements

10 a) Documented policies and procedures guide the usage of chemotherapeutic agents

- Chemotherapy drug policy for oral and IV drugs should be made

Prescription

10 b) Chemotherapy is prescribed by those who have the knowledge to monitor and treat the adverse effects of chemotherapy

- Prescription should be given by an oncologist with experience

Safe preparation and administration

10 c) Chemotherapy is prepared in a proper and safe manner and administered by qualified personnel

- Chemotherapeutic drugs administered trained and qualified staffs/personnel
- Nursing staff can be BSc nursing or GNM with formal training in preparation in biosafety cabinet and administration of chemotherapy drugs

Biosafety cabinet

- Biosafety cabinet of class II (preferable II A) with appropriate PPE shall be used to preparing/mixing chemotherapeutic drugs

PPE

- **Gloves**
  - Select disposable, chemotherapy-qualified, nitrile gloves that extend over the gown cuffs.
  - If double-gloving, one pair should be worn under the gown cuff and the other worn over the gown cuff.
  - If single-gloving, the gloves should be worn over the gown cuff.
- **Gown**
  - Disposable, lint-free gown made from low permeability fabric, (with a solid front, long sleeves, and elastic or knit cuffs
- **Mask**
  - Usage Eye and face protection should be worn whenever there is a possibility of exposure from splashing or uncontrolled aerosolization.
  - Type
    - For splashing or spraying, select a face shield.
    - For aerosolization, select a NIOSH-approved respirator.

Guidelines published by the Oncology Nursing Society (ONS), American Society of Health System Pharmacists (ASHP), the Occupational Safety and Health Administration (OSHA), and the National Institute for Occupational Safety and Health (NIOSH)

Legal Requirements

10 d) Chemotherapeutic drugs are disposed in accordance with legal requirements

- Biomedical waste management rules 2016, 2018
- Narcotic License Schedule X

Disposal

- Disposal of waste according to BMW management and handling rules or manufacturer's recommendations
- All chemotherapeutic drugs and disposables used to be discarded in separate yellow bin with yellow plastic bag with cytotoxic symbol.

[1][FORM 20G]

[See rule 61(3)]

[2][LICENCE TO SELL, STOCK, OR EXHIBIT OR OFFER FOR SALE OR DISTRIBUTE] BY WHOLESALE DRUGS SPECIFIED IN SCHEDULE X

1. ....., is hereby licensed [2][to sell, stock or exhibit or offer for sale, or distribute] by wholesale drugs specified in Schedule X to the Drugs and Cosmetics Rules, 1945 on the premises situated at.....

2. Names of drugs .....

3. The licence shall be in force form ..... to .....

4. The licence is subject to the conditions stated below and the provisions of the Drugs and Cosmetics Act ,1940 and the Rules made thereunder.

Date.....

Licence No. ..... Licensing Authority.....

Conditions of Licence

1. This licence shall be displayed in a prominent place in a part of the premises open to the public.

2. The licensee shall comply with the provisions of the Drugs and Cosmetic s Act,1940 and the Rules made thereunder

3. No drug shall be stocked or sold unless such drug has been purchased under cash/credit memo from a duly licensed dealer or a duly licensed manufacturer.

4. The licensee shall forward to the licensing authority copies of the invoices of sales made to the retail dealers.

5. No sale of any drug by wholesale shall be made to a person not possessing the requisite licence to sell, stock or exhibit for sale or distribute the drugs specified in Schedule X:

Provided that the condition shall not apply to the sale of any drug to –

(a) An officer or authority purchasing on behalf of Government.

(b) A hospital, medical, educational or research institution, nursing home, Registered Medical Practitioner for the purpose of supply to its/his parents, or manufacturer holding a licence in Form 25E or 28B to manufacture the drugs containing drugs included in Schedule X,

[1][The licence shall inform the licensing authority in writing in the event of any change in the constitution of the firm operating under the licence . Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licencing Authority in the name of the firm with the changed constitution.]]

Patient and family education

10 e) Patient and family are educated regarding benefits/risks of chemotherapy, precautions to be taken and possible adverse reactions

- Should be documented in the case sheet- Family Counselling Chart with family members acknowledgement signature

SOP

- **Chemotherapeutic Drug Policy**
  - Handling , usage and disposal by competent staff
  - Handling Spillage
- Requirement for patient and family education

Chemotherapy check list

- **Documentation**
  - ✓SOP and forms
  - ✓Prescription
  - ✓Drug chart
  - ✓Training records
- **Inspect**
  - **Preparation**
    - ✓Biosafety cabinet
    - ✓PPE
    - ✓BMW
  - **Interview**
    - ✓Staff –prep, admin, monitoring and treatment of adverse effects
    - ✓Patients- education

MOM 11: Standard Documented policies and procedures govern usage of radioactive drugs

Objective elements

11 a) Documented policies and procedures govern usage of radioactive drugs

- Document incorporates all the objective elements

11 b) These policies and procedures are in consonance with laws and regulations

- According to AERB guidelines

AERB guidelines

- Site and layout plan approval for radiotherapy installation
- Equipment and source procurement permission
- Loading of the source (obtain the source supervision authorization)
- Commissioning of radiotherapy equipment
- Staff (Radiation Oncologist(s), Medical Physicist(s) and Radiation Therapy Technologists)
- Appointment of Radiation safety officer
- Personnel monitoring devices
- Survey report and radiation related QA tests
- Quality assurance and dose reports
- License for operation
- Disposal and transport of disused radioactive substance
- Measuring and monitoring equipments
- Annual reports on status of radiation safety in radiotherapy department

11 c) The policies and procedures include the safe storage, preparation, handling, distribution and disposal of radioactive drugs

- For Storage, Preparation, handling, distribution- Refer to AERB guidelines

11 d) Staff, patients and visitors are educated on safety precautions

AERB safety codes

- Located away from general wards
- Radiation signage and legend for the isolated area
- Walls, floors, doors and work surfaces should be non-porous and leak proof
- Leak-proof plumbing directly to the delay tank
- Unidirectional ventilation from areas of low activity to high activity
- Radiation measuring monitors like decontamination monitors
- Personal monitoring and protective devices for all
- Radiation hazard emergency management

Radiological hazard signage and radiological waste bin

Radioactive waste management

- Radioactive waste segregation at source
- Collect in foot operated plastic bins with polythene lining and avoid glasswares
- Different isotopes with different radioactivity to be disposed separately eg Tc-99 and I-131
- Hospital waste is mainly low level and medium level waste with short half-lives

- **Types of disposal**
  - Dilute and disperse
  - Delay and decay
  - Concentrate and contain (rarely used)
  - Incineration (rarely used)
- Disposal of radioactive drugs, MoU with external agency, date and frequency of disposal, storage area of the waste etc need to recorded.

Radiotherapy check list

- **Documentation**
  - ✓Legal : AERB
  - ✓SOP
  - ✓QA test of the teletherapy/brachytherapy unit
  - ✓Personnel monitoring dose reports
- **Inspect**
  - ✓Badges, gonad shields, lead aprons, thyroid shields
  - ✓Records of all protective equipments
  - ✓Waste disposal
- **Interview**
  - ✓Staff:
  - ✓Patients- education

Quality indicators to track

Indicator	Formula
Incidence of medication errors	Total no of medication error/no of patient days
Percentage of patients receiving high risk medications developing adverse drug events	No of patients receiving high risk medications who have an adverse drug event/ no of patients receiving high risk medications

Training for chemo or radiotherapy

- **Frequency:** At induction, atleast once every 6 months.
- **Target audience:** Administration, designated personnel- oncologist, medical personnel, chemotherapeutic nursing staffs, HIC team, BMW handling staffs for chemotherapy and radiation safety officer, radiologist, medical personnel trained in radiotherapy administration.
- **Training records-** register and attendance records
- **Assessment:** pre and post training assessment

Contents of training session

- Training on environment and routine procedures
- Training on patient education and planning the treatment
- Training on ordering, preparing, and administering the drugs
- Training on various toxicity from chemo/radiotherapy, adherence to therapy
- Training on pain assessment, psychological and behavioral aspects
- Training on family counseling

Thank you