CRITERIA FOR ANTI-NEOPLASTIC THERAPY UNITS

FACILITIES AND PERSONNEL REQUIRED FOR THE ADMINISTRATION OF SYSTEMIC ANTI-NEOPLASTIC THERAPY

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(As adapted from American Society of Clinical Oncology 1997 recommendations)

An Anti-Neoplastic Unit is defined as a facility where the administration of anti-neoplastic agents is carried out under constant medical and nursing supervision. Resuscitation equipment should be available. Anti-Neoplastic drugs should be kept in an appropriate separate storage facility and under appropriate recommended conditions. Anti-Neoplastic agents will be reconstituted by suitably qualified personnel on the handling of anti-neoplastic agents, and under a laminar flow hood, with disposal of anti-neoplastic and medical waste as per the relevant legislation.

The purpose of this document is to identify the standards and criteria as set by the representative societies which facilities need to comply with in order to render such services, and to charge the appropriate fees.

Anti-Neoplastic units must comply with the following criteria:

1 PHYSICAL PLANT

1.1 Patient Areas

The facility must comply with the general building criteria as set out in section (7).

The facility must have adequate waiting areas, examination rooms and treatment rooms/areas, per doctor present:

1.1.1 Control desk and reception area.

1.1.2 Waiting areas should be adequate enough to contain 2 to 3 chairs per consulting doctor, with at least 4-6 chairs per facility and must be provided with adequate lighting and ventilation.

1.2 Examination / Consultation Room

1.2.1 At least one examination / consultation room per doctor present.

1.2.2 Hand wash basins with soap and paper towel dispensers.

1.3 Treatment Area

1.3.1 Satisfactory treatment areas will include at least 2 chairs and / or beds per doctor with adequate space for drip stands, appropriate monitors and resuscitation equipment. At least 1 oxygen point / cylinder and 1 suction machine are required per treatment area. An on-site emergency resuscitation equipment / trolley are mandatory as listed.

1.3.2 Not more than 4 patient positions per oncology skilled nurse employed, with an ideal ratio of 3 patient positions per oncology skilled nurse.

1.3.3 Each treatment room must be provided with adequate lighting and ventilation.

1.3.4 Clinical hand wash basins with soap, paper towel dispensers and waste bins.

1.4 Anti-neoplastic, Storage and Mixing Areas

1.4.1 Anti-Neoplastic agents' storage and mixing must be done in an area that is separate area from the treatment area.

1.4.2 Chemotherapy storage includes secure areas for room temperature storage away from direct sunlight. On-site refrigeration with alarm for refrigeration failure is required. An appropriate log must be kept of all temperatures.

1.4.3 Mixing of ampoules must be carried out in a clean area with at least a Class I Hazardous substance hood (laminar flow type hood), which must be serviced at appropriate intervals (at least annually).

1.4.4 Disposal of vials, syringes and sharps into appropriate protected containers.

1.4.5 Disposal of anti-neoplastic and medical waste as per the relevant legislation.

1.4.6 Clinical hand wash basin with soap, paper towel dispensers and waste bins.

2 STAFF QUALIFICATIONS AND REQUIREMENTS

2.1 Current HPCSA registered doctors who order, administer and / or supervise the administration of anti-neoplastic agents should be adequately qualified. Such qualifications are restricted to registration in Clinical/ Medical/Radiation Oncology

or Clinical Haematology with skills and experience in administering anti-neoplastic agents and managing their side-effects.

2.2 If an anti-neoplastic agent is not personally administered by a qualified doctor as described above, the administration must be under the supervision of such a doctor by a registered nurse who has undergone appropriate skills training and / or experience in the administration and management of anti-neoplastic agents.

2.3 Minimum staffing requirements – 1 current SA Nursing Council oncology trained and / or experienced registered professional nurse per 3 (optimum) to 4 (maximum) patients in the treatment room.

2.4 Minimum of one suitably CPR trained and accredited staff member must be on duty at all times.

2.5 A doctor as defined in 2.1 should be physically present in the facility when a drug or biological that is known to cause anaphylaxis is administered.

2.6 A doctor as defined in 2.1 should be available to the staff in the facility at all times.

2.7 Appropriate doctor supervision of all professional staff that provides patient care.

3 LABORATORY ACCESS

3.1 Patients should have access to an accredited laboratory either at the chemotherapy facility or through another facility.

3.2 The laboratory facility must be qualified to perform basic blood tests including blood count and routine biochemical measurements timeously so that required results are available prior to the administration of any anti-neoplastic agents.

4 EMERGENCY PROCEDURES

4.1 Access to life support procedures by suitably trained staff.

4.2 Suitable documented evidence of occupational health procedures

4.3 A suitably qualified or experienced doctor to be readily available for any emergency.

4.4 Each section in the chemotherapy unit must have access to a single fully integrated emergency trolley as per current CPR guidelines / algorithm.

4.5 An Emergency Trolley should contain the following basic requirements:

4.5.1 Defibrillator.

4.5.2 Oxygen cylinder fitted with a flow meter and all the necessary ancillary fittings for administration.

4.5.3 Suction, portable unit, with all necessary ancillary fittings.

4.5.4 AMBU-bags as required for patients seen.

4.5.5 CPR board if there are any beds within unit.

4.5.6 Blood Pressure monitoring.

4.5.7 Appropriate facilities for the following:

- Intravenous therapy
- Intubation and oxygen administration
- Drug administration.

4.5.8 Standard drugs suitable for the resuscitation of patients in the following emergency situations:

- Cardiac arrest
- Respiratory arrest
- Coma
- Fits, convulsions, and seizures
- Shock.

4.5.9 A daily check list should be attached to each trolley and signed by a person in authority.

4.5.10 The following is a comprehensive list for the Emergency Trolley in specific categories for ease of reference:

4.5.11 Equipment:

- Ambubags in accordance with patients treated
- Blood Pressure apparatus
- CPR board if appropriate
- Defibrillator
- Diagnostic set (available in unit)
- ECG machine (unless part of defibrillator)
- Suction unit with tubing and suction nozzle/catheter
- Laryngoscope set
- Oxygen cylinder with fittings
- Artery forceps
- E.T. tube introducers (S, M and L)
- Magills forceps (S and L)

- Mouth gag
- Patella hammer
- Scissors
- Stethoscope
- Tongue depressor
- Xylocaine spray.

4.5.12 Disposables:

- Butterflies – assorted sizes
- Syringes – assorted
- Intracaths
- Jelcos assorted
- Syringes – assorted sizes
- Cardiotrace electrode gel
- KY jelly sachets
- Remicaine jelly
- Elastoplast / Micropore / Tegaderm
- Oxygen mask (variable sizes in accordance with patients treated)
- Nasogastric tubes & bags
- Suction catheters – assorted sizes
- Alcohol swabs
- Blades (Swan Morton) – assorted sizes
- Electrodes – assorted sizes in accordance with patients treated
- Gauze dressings / Cotton wool balls / Crepe bandages.

4.5.13 Airways:

- Assorted Sizes.

4.5.14 Endo-Tracheal Tubes:

- Assorted sizes.

4.5.15 Intravenous Drugs:

- Adrenaline 1:1000
- Atropine 0.5mg
- Injectable Calcium
- Injectable Cortisone
- Dextrose 50%
- Lasix/ Furosimide 20 mg / ml

- Magnesium Sulphate 1g / 2ml
- Narcan / Naxolone 0.4 mg / ml
- Phenergan / Promethazine 25mg / ml
- Potassium Chloride 15% 10ml
- Remicaine / Lignocaine
- Sodium Chloride 10ml
- Valium / Diazepam10mg
- Water for injection.

4.5.16 Intravenous Fluids:

- Volume Expanding fluid
- Sodium Chloride 0.9%.

4.5.17 Administration Sets:

- Admin Set 15 drop / ml.

4.5.18 Blood Tubes:

- Assortment.

4.5.19 Gloves:

- Assortment.

5 OFFICE AND ADMINISTRATIVE PROCEDURES

5.1 Appropriate doctor supervision of all professional staff who provide patient care.

5.2 Retention of adequate records to include evaluation and management services and recording dosage, route and type of anti-neoplastic therapy and supportive care treatments.

5.3 Professional review of laboratory and radiology reports before anti-neoplastic agent administration.

5.4 A doctor to be available by telephone for an emergency.

6 POLICIES, PROCEDURES AND PROTOCOLS

Policies and Procedures must conform to the relevant legislation.

6.1 Policies

6.1.1 Safe Handling of anti-neoplastic agents

6.1.2 Anti-neoplastic drug preparation

6.1.3 Administration guidelines for anti-neoplastic agents

6.1.4 Storage and mixing guidelines for anti-neoplastic agents

6.1.5 Handling Schedule 5,6,7 drugs

6.1.6 Emergency Trolley usage

6.1.7 Managing of anaphylactic reactions

6.1.8 Obtaining Informed consent

6.1.9 Infection control

6.1.10 Waste disposal

6.1.11 Needle prick injury

6.1.12 Occupational preventative medicine.

6.2 Procedures

6.2.1 Infusions / Injections

6.2.2 Port-a-cath

6.2.3 Administering anti-neoplastic agents in hospital.

6.3 Nursing Guidelines

6.3.1 Management of anti-emetics

6.3.2 Management of common side effects

6.3.3 Management of haematological problems

6.3.4 Management of pain

6.3.5 Management of Oncological emergencies.

6.4 Forms

6.4.1 Nursing process documents for anti-neoplastic treatment

6.4.2 Schedule 5,6,7 drug register

6.4.3 Emergency trolley check forms.

7 BUILDING REQUIREMENTS

All areas must conform to the relevant legislation. The following minimum physical requirements should be met:

7.1 All buildings should comply with the National Building Regulations SABS 040.

7.2 Doors from patient ablution and toilet facilities must be equipped with a standard emergency release lock. The doors must be able to be opened from the outside, and an audible emergency alarm available which is linked to the treatment areas.

7.3 All areas should have either natural or artificial ventilation in compliance with National Building Regulations.

7.4 All areas should be provided with adequate lighting of 160 Lux (dimmable if appropriate) for general areas and 320 Lux for examination and general administrative tasks and 400 Lux for mixing and administration areas.

7.5 Cleaning services should be provided on a daily basis in accordance with good hospital practice.

7.6 Clean utility services must be provided for the storage of clean linen, sterilized packs, dressings, sterile equipment and pharmaceutical supplies respectively.

7.7 Dirty utility services must be provided for collection and temporary storage of used equipment and any soiled linen.

7.8 Medical waste disposal services for the safe, effective and hygienic disposal of medical waste should be provided.

7.9 Sluice facilities should be provided for the emptying, cleaning and storage of bedpans and urine bottles where appropriate.

7.10 All surfaces in the anti-neoplastic mixing and storage areas should be "impervious" - meaning impenetrable to liquid substances. The floors should not be fitted with a carpet, must be constructed of a concrete base and finished with a smooth impervious washable surface or covered with a suitable impervious washable material.

7.11 Hand wash basins should be provided in the anti-neoplastic mixing area with drying facilities adjacent to it. The wall behind such hand wash basins must have an additional washable impervious covering panel up to a height of at least 500 mm to the width of the basin and a distance of at least 150 mm on each side of such fitting.

7.12 All units should at least have mobile oxygen and suction facilities.

7.13 A safe and secured area must be provided for storage of drugs in accordance with manufacturers' instructions or other legal requirements.

7.14 Where applicable Pharmaceutical products must be stored in accordance with the Pharmacy Act 1974 (Act 53 of 1974) as well as the Medicines and Related Substances

Control Act 1965 (Act 101 of 1965). The temperature within the pharmacy must be monitored and recorded on a regular basis. Air conditioning must be supplied.

8 EMERGENCY PLAN

8.1 Should have a floor plan of each unit, specific where to find extinguishers and emergency exits.

8.2 Card system; each person's responsibilities are written on a separate card.

8.3 Regular fire drills; documented on allocated record.

8.4 All staff should attend training on the use of fire extinguishing equipment- record of training.

8.5 Each unit should document the management of emergencies.

9 INFECTION CONTROL MEASURES

9.1 Expiry dates on hand rub solution bottles.

9.2 Solution bottles should be clean and clearly marked.

9.3 Correct management of waste products; all units should have a plastic bag in each drum – cleaners should not have any direct contact with waste.

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