IMPLANTABLE PROSTHESIS

GROUP 4
Dr. Amrita Saha
Anamika
Shweta
Abhilasha Sonkar

Reviewed by:
Dr. Lallu Joseph
Secretary General
CAHO

Faculty:
Ms. Devasri Chatterjee
Dr. Swati Makashir
Dr. Ramanjeet Kaur

Chapter, Standard & Objective Element

- As per Pre-Entry Level HCO Guidelines:
- Chapter – Management of Medication
- Standard – MOM1
  - Documented procedures guide the organization of pharmacy services and usage of medications
- Objective Element – MOM1b
  - Documented procedure address procurement and usage of implantable prosthesis
- Intent: To ensure the procurement and usage of good quality implants to ensure safety and quality.

Discussion Points

- Understanding Medical Implants
- Role of Pharmacy Department
  - Who can select the implants?
- Storage
- Family and patient education
- Sterilization
- Documentation

Understanding Medical Implants

- **Medical Implants**: are devices/tissues that are placed inside the body or under the surface of the body.
- Implants can be prosthetics that are intended to replace missing body parts or to deliver medication, monitor body function or support organs and tissues
- Implants are made from bone, skin or tissues and can also be made with metal, plastic etc.
- Implants can be place permanently or they can be removed once they are no longer needed
  - Stents or hip implants are intended to be permanent, but chemotherapy ports or screws to repair bones can be removed once they are no longer needed

Role of Pharmacy Department

- The Pharmacy department in the hospital needs to have a list of all the medical implants that is being used as per the scope of services
- This list shall include medical implants which will be selected and approved by the “Multidisciplinary Committee” of the hospital
- Implants needs to be purchased through pharmacy requests
- The selection of implants shall be based on national / international approval or Good manufacturing Practices (GMP) certificates
  - Reference – International notification from US-FDA, National notification from CDSCO (Central Drugs Standard Control Organization)

Storage of Medical Implants

- Documented procedures are necessary for procurement, storage, issuing and recording and are generally carried out by the operating room staff
- This shall all be done as per the manufacture's recommendations
- This document will be available in the OR along with the current stock indication /OT log book
- Hospital gives the list of doctors privileged to use them

Family and Patient Education

- Patient and family should be counseled about the implants
  - About the risks and complications – include bruising at the surgical site, pain, swelling and redness while removing and inserting the implants, infection and implant failures
  - Infections are common. If you get infection you may need to have a drain inserted near the implant, take medication or even have implant removed
  - Over time implant could move, break or stop working properly. If this happens one may require additional surgery to repair or replace the implant
- They need to be educated about the type and material of implant and possible allergies
- They need to be briefed on non-usage of specific drug
- When to report to hospital if a particular symptom occurs
- Benefits of the device and how it will affect their quality of life

Sterilization of Medical Implants

- Ethylene oxide gas and gamma sterilization are the two most common forms of sterilization used for medical implants
- Ethylene oxide gas treatment penetrates all porous materials and kills every known microorganism
- Gamma radiation makes use of highly penetrative radioisotope emission and is often used to sterilize the surface of disposable medical equipments
- Two most common packages for medical implant devices are pouches and trays.
- Sealed packages must undergo packaging validation and sterilization validation to increase the shelf life of the product.

Sterilization of Medical Implants

Method	Principle	Advantages	Disadvantages
Steam sterilisation	Saturated steam in the range of 121–134 °C	Sterilises penetrable materials and exposable surfaces	Microcavitation in case of hydrophilic polymers Altered biocompatibility of heparinised surfaces
Dry heat sterilisation	Carried out in electrically heated ovens at 160–180 °C	Ability to penetrate solids Lack of corrosion in case of non-stainless steel metals	Rubbers, plastic, etc. do not withstand high temperature
Ethylene oxide	Biocidal activity is achieved at 30 % humidity, 45 °C temperature levels with >450 mg/l gas concentration	Suitable for heat-sensitive implants	EO residues after sterilisation cause: Anaphylactoid reactions in dialysis patients Serious tissue reactions in pump oxygenators Mutagenicity and carcinogenicity
Radiation sterilisation	Primary biocidal action is via aqueous free radical formation following the primary physical interaction of the ionising radiation with the biological material	High-energy irradiation sterilisation	Degradation and/or cross-linking of polymers Gas evolution and free radical formation from polymers

Documentation

- Implant details such as
  - Name of patient
  - UHID number
  - DOB/age/sex
  - Patient address
  - Procedure carried out
  - Date of admission of implant
  - Date of removal (if the implant is to be removed)
  - Manufacturer
  - Type of implant
  - Size of implant use
  - Batch number
  - Serial number
  - Any other details shall be documented in the **implant register** in OT, **patient record** and **discharge summary** along with the stickers

Thank You !!!