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STANDARD OPERATING PROCEDURE

Procedure for Preparing & Administering Parenteral Medicines and Fluids-Kerala Govt.Hospitals

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1. Purpose

To enable correct administration of parenteral medications to patients avoiding, incompatibilities, microbial contamination, drug instability and adverse effects.

2. Scope

Applies to all staff who administer intravenous medications including IV fluids in Public Health Facilities under Kerala Department of Health& Family Welfare, Government of Kerala.

3. Introduction

Patients frequently require administration of parenteral preparations as a mode of drug delivery. This mode of delivery process is having both benefits and risks compared to other modes of drug delivery. It is therefore imperative to lay down procedures for preparing and administering parenteral drugs to ensure proper results and to avoid adverse effects.

Patient and personnel safety related to the preparation and administration of parenteral preparations depend up on many factors, which include the quality and specificity of the drug itself, competency of the person preparing/administering drug, injecting the drug, use of proper device for the administration of the drug, look out for possible anaphylactic and other undesired reactions, patient care, availability of appropriate antidote and or other facilitywherever neededto manage untoward developmentsand proper disposal of the discarded devices, drug container etc. Safety, and proper frame of mind of those involved in the processes. also play important roles. Parenteral articles are drugs intended for administration by injection to the patient sub-cutaneously or intra muscular or intravenous or intra spinal or into other such body organs or systems directly. Parenteral articles are prepared scrupulously by methods designed to ensure that they meet pharmacopeia requirements for sterility, pyrogens, particulate matter, and other contaminants, and, where appropriate, contain inhibitors of the growth of microorganisms. An Injection is a preparation intended for parenteral administration and/or for constituting or diluting a parenteral article prior to administration.

Labeling details: Every drug should bear on its container a label containing all details relating to it namely its name, ingredients, quality specifications, batch/lot number. dates of manufacture and expiry, storage and usage instructions where ever applicable etc. No drug that does not bear a label shall be used. No drug the label of which has been tampered or modified or altered or re-labeled unless such modification etc is duly authorized. The following procedures apply before use of the drug with specific reference to its label,

1) Labeling should be read clearly before administration of the drug to patients

2) Where special storage condition is applicable, check and ensure that the drug had been stored accordingly.

3) Where the label specifies administration under medical supervision/ monitoring, ensure availability of appropriate medical supervision/ monitoring.

4) Check patient's medical chart for previous administration of the drugs and administration of other drugs not compatible with the injection to be administered and ensure proper conditions.

Verify:

5) The name of the drug;

6) The name(s) of the active ingredients.

7) The amount of the active ingredient(s) in a suitable dose volume and the volume in the container; for powder for injections: the amount of the active ingredient(s) in the container and a statement of the net contents (e.g. number of dosage units)

8) The specifications for the diluent to be used, if any.

9) The batch number assigned by the manufacturer;

10) Manufacturing date and the expiry date;

11) Any special storage conditions or handling precautions that may be necessary;

12) Directions for use, warnings and precautions that may be necessary, for example, that the product has to be used together without or with….;

13)The name and address of the manufacturer or the person responsible for placing the product on the market;

14)Where applicable, information on any added antimicrobial preservative.

15)Note the details of the drug namely its name, batch number and manufacturer for future reference as may be needed in the event of adverse reactions occurring.

Parenteral preparations are defined as solutions, suspensions, emulsions for injection or infusion, powders for injection or infusion, gels for injection and implants. They are sterile preparations intended to be administrated directly into the systems or organs in human beings or animals.

Parenteral preparations that are solutions or dispersions the concentration of the active ingredient(s) should be given in terms of mass or biological activity per volume. For concentrated solutions, labels should state the composition and the dilution to be carried out before use. Where a diluents is to be used before administration verify the specifications for the diluents and prepare the injection for administration strictly in accordance with the instructions applicable.

Five golden rules of administration of medications

One of the recommendations to reduce medication errors and harm is to use the "six rules":

- the right patient,
- the right drug,
- the right dose,
- the right route,
- the right time and
- The right documentation

4. Precautions during Administration of Parenteral Preparation.

- Hands must be sterilized with a suitable sterilizer prior to accessing the cannula
- Gloves (and other standard precautions when necessary) must be worn and a clean no touch procedure must be adopted.

- Clean the connectors/ports with 70% isopropyl alcohol / 2% Chlorhexidine impregnated swab for 30 seconds and allow to dry before and after procedure. Ensure that the sterilizer used does not contaminate the drug.
- Use a 10ml syringe or larger for the initial flush to prevent damage to cannula and reduce pressure on the vein.
- Prepare and administer the drug, as labeled to ensure correct dilution and rate of administration.
- Flush with a compatible fluid (A few drugs are incompatible with 0.9% sodium chloride –
- Dispose of waste and sharps according to our safety standards.

A vein can be damaged during injection or by the use of an IV catheter line. This can cause infiltration, When this occurs, medication leaks into surrounding tissue instead of going into the bloodstream. IV administration can also cause phlebitis, or inflammation of the veins.

5. Procedures to be followed when administering a medication by continuous & Intermittent Intravenous Infusion.

- If the infusion is not provided in a ready prepared formulation, follow the label instructions of the drugfor preparing the infusion using a diluent.
- Check infusion solution visually for clarity and absence of particles/clarity and where consultation is needed, consult the pharmacy.
- Clean connectors / ports with 70% isopropyl alcohol / 2% Chlorhexidine impregnated swab for 30 seconds and allow to dry before connecting and after disconnecting.
- Always document and evaluate actions.
- All syringes containing drawn-up medication or flushing solution must be labelled with name of the medicine or flushing solution and the dose/strength, unless the risk of doing so (eg contaminating a sterile field) outweighsother risks. The individual practitioner is then responsible for ensuring that any un-labelled syringes are not mis-identified. Administration sets should be dated.
- Where drug administration requires simultaneous use of two continuous infusions, use a solution set for each, connected via a multi lumen closed connector.

- Flush cannula before and after infusion, usually with 0.9% Sodium Chloride, but only if this is compatible with the medication that is to be infused, using 10ml or larger syringe.
- Ensure that the line is primed before attaching to the patient. This will prevent Air Embolism.

6. Procedure for adding Drugs to Infusion Fluids.

- The persons checking and preparing the IV infusion must be the persons administering and checking the IV infusion at the patient's bedside.
- Before making any addition, check for availability of a suitable ready prepared solution from Pharmacy.
- Refer to the appropriate drug monograph for suitable diluents and infusion fluids to ensure drug stability.
- Drugs other than multi-dose preparations are for single use only. Bags of saline or glucose must not be kept on the ward or at the bedside for repeated use to prepare drug infusions for syringe drivers. These must be discarded after single use. Multidose containers shall be secured properly in accordance with the procedure prescribed after every withdrawal and shall be stored and used as per the norms applicable.
- Mix the drug thoroughly with the contents of the infusion container

Caution: Insufficient mixing can result in inadvertent administration of highly concentrated drug, potentially causing serious adverse effects.

- Check the infusion for cloudiness or particles
- Cover the infusion container, if protection from light is required.
- Once prepared a drug infusion is for immediate administration and should not be kept or stored for administration at a later point in time

NEVER add drugs to parenteral nutrition solutions, lipid preparations or infusions of mannitol or sodium bicarbonate

NEVER add any drugs to blood or blood products.

Avoid multiple drug additions as compatibility cannot be guaranteed.

Monitor the IV infusions and the patient as required and ensure 100% proper and safe administration. Ensure that the patient or by-standers of the patient or others do not disturb the flow of the infusion.

Note:- ***Please Note That The Infusion Set is Always Considered As a Possible Source of Infection/contamination***

Note: whenever dry powder (injection) administered, use the solvent which, is recommended in the label. If there is no specific instruction for the dilution, use "sterile water for injection I.P" or other such diluent/ solvent as specified in the pharmacopoeia.

If single dose liquid injection is to be administered, avoid injecting along with IV fluid, unless otherwise instructed in the label.

Please note that Injections are sterile, pyrogen-free solutions or dispersions (emulsions or suspensions) of one or more active ingredients in a suitable vehicle. If rigor or pyrexia occurs to the patient during the administration of infusion, stop the infusion and notify the medical personnel concerned and take appropriate measures as per their instruction. If rigor or pyrexia occurs to the patient or if any anaphylactic/ other undesirable reaction occurs during or after the administration of the drug, notify the medical personnel and take appropriate steps for administration of antidote or for managing the situation otherwise.

Injections that are dispersions should remain sufficiently stable so that, after shaking, a homogeneous dose can be withdrawn. Single-dose injections should not contain antimicrobial preservatives unless justified and authorized.

Injections containing an antimicrobial preservative must not be administered intra-cisternally, intrathecally, epidurally or by any route giving access to the cerebrospinal fluid, or intra- or retro-ocularly.

Intravenous infusions are sterile, pyrogen-free aqueous solutions or emulsions with water as continuous phase, usually prepared to be isotonic. They are intended for administration in large volumes (usually more than 100 ml) and do not contain any antimicrobial preservatives.

On visual inspection, emulsions for intravenous injection should show no evidence of phase separation.

Powders for injections or intravenous infusions are sterile, pyrogen-free solid substances (including freeze-dried materials), distributed in their final containers and which, when the prescribed volume of the appropriate sterile liquid is added, rapidly form either clear and practically particle-free solutions or uniform suspensions. Powders for injections or intravenous infusions, after dissolution or suspension, comply with the requirements for injections or intravenous infusions, as appropriate.

7. **Training:**

All technical staff and relevant persons must receive full training in this procedure and their competence recorded in their training record.

8. **Disposal of the used container/ device:**

All used containers and devices shall be disposed of in accordance with the procedures applicable / laid down specific approved house norms if no written procedure exists and follow.