SOP: Care of the Patient Receiving Cytotoxic or Biologic Agents
Approved by NPC on May 20, 2010

NATIONAL INSTITUTES OF HEALTH
CLINICAL CENTER
NURSING and PATIENT CARE SERVICES

Standards of Practice: Care of the Patient Receiving Cytotoxic or Biologic Agents

Essential Information:
1. Nurses must have successfully completed their Chemotherapy/Biotherapy competency before they may administer Cytotoxic or Biologic Agents.  
2. **Patient Identification** – for patient safety and to accurately identify the “right patient,” the nurse compares the patient identification band against hospital records and/or hospital-generated labels for patient’s first & last name and date of birth. Alternatively, if a patient does not have an identification band, the nurse will ask a patient or parent/guardian to state the patient’s first & last name and date of birth. 
3. Cytotoxic or Biologic Agents are categorized as high-alert drugs and as such, are subject to the conditions described in the SOP: Medication Administration.
4. If the drug being administered is classified as a hazardous drug, also refer to the SOP: Safe Handling of Hazardous Drugs.
5. Independent double checks of Cytotoxic or Biologic Agents will be conducted as follows:
   a. Compare the nurse process of preparing a drug product for administration (e.g., IV admixtures, injections, etc.) against the medical order for the right patient, drug, concentration, dose, administration route, diluent and volume, if appropriate, date and time of administration, and product expiration date.
   b. Carry out any required calculations (i.e., drug dose and/or infusion pump settings) and compare it against the medical order.
   c. Compare all drug product labels (CC-generated drug product label and manufacturer’s drug product label, if present) against the medical order for the right patient, drug, dose, concentration, route, date and time of administration, and product expiration date.
   d. Review the ordered route of infusion and check the line attachment by tracing from the drug product along the administration set to the site of infusion.
   e. Compare the infusion pump settings (which may include the volume to be infused, the drug, concentration, basal rate, bolus dose, lockout intervals, dose limits, and range settings) against the medical order.
6. A nurse is strictly prohibited from preparing or adding to any Cytotoxic or Biologic infusions in accordance with POL: Parenteral Admixtures. All infusions are prepared and labeled by a pharmacist.

I. Assessment
   A. General
      1. Assess patient and/or parent or caregiver’s understanding of the treatment plan, expected treatment outcomes, and potential risks.
   B. Medical Record Review
      1. Assess presence of a completed consent (assent for children when appropriate) form.
      2. If appropriate, review prescriber progress note for documentation of dose level, protocol exemptions, and/or rationale for dose modifications.
      3. Review prescriber orders against clinical trial protocol, clinical map if applicable, and research data sheets if applicable for all ancillary medications and therapies.
      4. Review pre-treatment labs. Confirm the treatment plan with the prescriber if any results are abnormal or exceed protocol specifications.
      5. Review prescriber orders for treatment of extravasation and/or adverse drug reaction if applicable.
      6. Review baseline assessment including height, weight, BSA, vital signs, history, physical examination, and known allergies. A current height and weight must be obtained on first day of any treatment cycle.
      7. Review history of treatment induced side effects and successful management strategies.
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8. Assess for previous therapy related acute or delayed complications, specific toxicities or adverse reactions.  

C. Calculations/Drug Label Verification – independent double check with a second chemotherapy competent RN:
   1. Calculate the drug dosage including any dose modification and complete cytotoxic/biotherapy worksheet (Examples found in Appendix A, B, or C). This includes all routes of administration including parenteral, oral, intramuscular, intra-arterial, intra-peritoneal, intravesical, topical preparations and intrathecal cytotoxic/biologic agents.  
   2. Compare calculated dose to prescribed dose. If there is a discrepancy of 10% or more for adults and 5% or more for pediatric patients, notify the prescriber and pharmacist. Hold drug administration until the dosage is verified and documented.
   3. Check the diluent type and the drug container’s label against the prescriber order for:
      a. Patient name and medical record number.
      b. Cytotoxic/Biologic agent, diluent, route (example IV push, IV piggyback or continuous infusion), dose, volume, date, infusion start time, length of infusion, and drug expiration.
      c. Verify the infusion or ambulatory pump program against the prescriber's order.
   4. Calculate and verify the infusion or ambulatory pump settings against the prescriber’s order using independent double check system.

D. Venous Access Devices
   1. Assess pre-existing peripheral lines for patency, brisk blood return; flush solutions should flow freely to gravity. Inserting a peripheral IV just prior to administration of vesicant agents is strongly recommended.
   2. Assess CVAD for patency, brisk blood return, and ease of flushing.
   3. Assess site for swelling, erythema, pain, drainage.
   4. Assess for signs or symptoms of venous obstruction.

E. Verify that emergency medications are readily available in the area where patient will receive treatment.

II. Interventions
A. General
   1. Ensure that emergency equipment is available on patient care unit:
      a. Normal saline flush solution
      b. Oxygen
      c. Suction machine
      d. Vital sign monitor
   2. Assemble personal protective equipment (gloves, goggles, gown).
   3. Verify spill kit readily available on unit.
   4. Dispose of hazardous drug supplies according to the SOP: Safe Handling of Hazardous Drugs.
   5. Provide patient and family teaching including information about self-care and potential symptoms requiring health care provider attention.
   6. Provide patient with spill kit and instructions of use upon leaving the patient care unit.

B. Venous Access
   1. Obtain peripheral IV access in a vessel of the upper extremity. Peripheral venous access in a lower extremity is not recommended.
   2. Avoid:
      a. Areas of hematoma, edema, impaired lymphatic drainage, phlebitis, inflammation, induration, or obvious infection and sites of previous irradiation.
      b. Fragile, small, or low flow vessels such as the dorsal aspect of the wrist.
      c. Using veins that have been accessed within the previous 24 hours.
d. Sites distal to previous IV sites or previous sites of extravasation.  
e. Vessels of the hand, wrist, and antecubital fossa for administration of vesicants/irritants.  
3. If local anesthetics, e.g. EMLA®, are used to facilitate venous cannulation, ensure that the effects of anesthesia have subsided prior to administration of cytotoxic agents.  
4. IV site dressing must allow for continuous visual inspection before, during, and post drug administration.  
5. Verify patency and blood return of venous access pre- and post-administration.  
6. At the completion of cytotoxic/biologic agent administration, flush the line with a compatible flush solution. For specific research studies, check protocol and consult pharmacy for any special guidelines on drug administration.  

C. Administration  
1. Refer to PRO for Extravasations and Flares with Vesicant and Irritant Drugs.  
2. IV Push Administration of Vesicants/Irritants via peripheral IV and CVAD  
   a. Infuse a free-flowing compatible flush solution during administration of the cytotoxic/biologic agent.  
   b. Administer agent through the IV administration set at the most proximal port to the patient.  
   c. Check for blood return pre-administration, every 2-5 ml of drug administration, and post-administration.  
   d. Monitor IV site for signs of extravasation.  
3. Peripheral Administration  
   a. General  
      i. If administering the cytotoxic/biologic agent as the secondary infusion, piggyback to the primary line at the most proximal port above the pump.  
      ii. Verify that all tubing connection sites are secured with a locking device. Do not tighten connections with hemostats because it causes the plastic connections to crack and leak.  
   b. Vesicants  
      i. Use of an infusion pump is prohibited.  
      ii. Avoid an infusion greater than 60 minutes.  
      iii. Check for brisk blood return pre-administration, every 5-10 minutes during administration, and post-administration.  
      iv. Monitor IV site for signs of extravasation.  
      v. Peripheral continuous (large volume = 500 ml or greater) infusion of vesicants is strictly prohibited.  
   c. Irritants  
      i. Check for brisk blood return pre- and post-administration.  
      ii. Observe the IV site every 15 minutes until infusion completed.  
      iii. Peripheral continuous infusion of irritants requires an IV infusion pump. Consult with the LIP.  
         • It is recommended that a central line be used with continuous infusions of irritants.  
4. CVAD Administration  
   a. Infusion device required.  
   b. Verify that all tubing connection sites are secured with a locking device. Do not tighten connections with hemostats because it causes the plastic connections to crack and leak.  
   c. If administering the cytotoxic/biologic agent as the secondary infusion, piggyback to the primary line at the most proximal port above the pump.  
   d. Monitor IV site for signs of extravasation and observe connections: for inpatients every hour; for outpatients monitor the site frequently and instruct the patient to call for any complications.  
5. CVAD Continuous (large volume) Infusion of Vesicants/Irritants
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a. An infusion device is required.  
b. Verify that all tubing connection sites are secured with a locking device. Do no tighten connections with hemostats because it causes the plastic connections to crack and leak.  
c. Monitor IV site for signs of extravasation and observe connections every 4 hours for inpatients. Instruct outpatients to monitor site frequently.

III. Documentation

A. Document in the approved electronic medical record and/or other approved medical record form:  
1. Protocol, cycle, day, week, and dose level, if appropriate.  
2. Laboratory test results reviewed.  
3. Cytotoxic/Biologic agent, dose, route, container number if applicable, lot number if applicable, time of administration, and length of infusion.  
4. Rationale for dose modification.  
5. Patient/Family teaching.  
6. Presence of a complete consent or assent (minors only) form.  
7. Presence of Durable Power of Attorney document as required by treatment protocol  
8. Name of staff who performed double independent check of the cytotoxic/biologic agent dose calculations, drug label, and infusion device settings.  
9. Venous access device, location, patency and site assessment pre-, during, and post-administration.  
10. Patient’s tolerance of procedure and interventions.  
11. Complications or adverse drug reactions as well as interventions provided.  
12. In the event of an extravasation document per the PRO for Extravasations and Flares with Viscant and Irritant Drugs including the following:  
a. Date and time of extravasation  
b. Patient complaints before, during and after extravasation  
c. Estimated amount of extravasation  
d. Agent extravasated; antidote administered.  
e. Document date, time and those notified (prescriber, clinical pharmacy specialist).  
f. The dimensions of the injured site and the site assessment.  
g. The date and time of any photographs.  
h. Dates of any follow-up evaluations and/or consultations such as surgery, dermatology, or rehabilitation.

IV. References

V. Appendices

Appendix A: Cytotoxic/Biologic Worksheet (general)
Appendix B: Cytotoxic/Biologic Worksheet (single)
Appendix C: Cytotoxic/Biologic Worksheet (multi-cycle)

Approved:

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