STANDARDIZED PROCEDURE
HEPATIC ARTERY INFUSION OF CHEMOTHERAPY (Adults, Peds)

I. Definition

Hepatic arterial infusion (HAI) of chemotherapy is accomplished by a small drug delivery system or pump that is implanted in a subcutaneous pocket in the lower abdomen. The pump reservoir stores and releases prescribed amounts of medication through a catheter whose tip is sutured into the gastroduodenal or other suitable artery for delivery of chemotherapy to the liver.

The purpose of this Standardized Procedure is to allow the Advanced Health Practitioner (AHP), who has satisfactorily completed the education and performance criteria, to safely access the HAI pump for the administration or removal of prescribed medication as dictated by the particular chemotherapy protocol.

II. Background Information

A. Setting

The setting (inpatient vs outpatient) and population (adult's vs pediatrics) for the Advanced Health Practitioner (AHP) is determined by the approval of the privileges requested on the AHP Privilege Request Form. If the procedure is being done on a Pediatric patient, make sure Child Life is involved and use age appropriate language and age appropriate developmental needs with care of children, as appropriate to the situation.

B. Supervision

The necessity of this procedure will be determined by the Advanced Health Practitioner in collaboration with the supervising physician or his/her designee. Designee is defined as another attending physician who works directly with the supervising physician and is authorized to supervise the Advanced Health Practitioner.

Direct supervision will not be necessary once competency is determined, as provided for in the procedure. The Advanced Health Practitioner will notify the physician immediately upon being involved in any emergency or resuscitative events or under the following circumstances:

1. Patient decompensation or intolerance to the procedure;
2. bleeding that is not resolving; and/or
3. outcome of the procedure other than expected.

C. Indications

The procedure will be performed on patients with an implanted HAI pump for chemotherapy.

D. Precautions/Contraindications

The patient's physician will be notified in the event of suspected pump site infection (swelling, erythema, and tenderness to palpation), or if the patient's blood cell counts decrease, or liver function tests increase, to a level consistent with bone marrow or liver toxicity.
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III. Materials
The following items are needed to access and refill the HAI pump. In the inpatient setting, they may be obtained by requesting an "HAI Pump Refill Kit" from Materiel Services.

1. 22-gauge 1 ½-inch non-coring needle
2. Extension tubing set with y-connector and clamp
3. 20, 30 or 60 ml Luer-lok syringe, barrel size depending upon volume of pump's drug reservoir
4. Heparin sodium
5. Bacteriostatic normal saline
6. Sterile gloves
7. Mask
8. Nonabsorbent fenestrated drape
9. 4 x 4 gauze sponges
10. Povidone iodine solution
11. Isopropyl alcohol
12. Adhesive bandage

IV. Hepatic Artery Infusion of Chemotherapy
A. Pre-treatment evaluation
   1. Review laboratory data to assure cell counts and liver function tests permit the safe administration of chemotherapy.
   2. Calculate chemotherapy dose according to treatment protocol and at the direction of supervising MD.
B. Set up - gather all necessary supplies
C. Patient Preparation
   Inform patient of the treatment plan which includes hepatic artery infusion of chemotherapy. Perform a time out which includes a two RN check for chemotherapy drug administration.
   1. Place patient in supine position.
   2. Expose pump pocket site.
   3. Palpate pump site and locate center reservoir fill port.
   4. Wash hands thoroughly.
   5. Using sterile technique, open individual refill procedure components.
   6. Using Povidone iodine solution on 4x4 gauze sponge, prep pump site in a circular fashion, extending the prepped area beyond the periphery of the pump. Allow prepped area to dry.
   7. Assure chemotherapy refill syringe has been prepared by Pharmacy Services, or prepare syringe with heparin/normal saline solution if indicated by treatment protocol.
   8. Don mask and sterile gloves.
   9. Place fenestrated drape over pump site.
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D. Procedure
1. Attach needle and appropriate size empty syringe to extension tubing. Tighten all connections.
2. Re-palpate pump site and locate center reservoir fill port.
3. Insert needle perpendicular to the fill port septum. Advance needle until it is in direct contact with the needle stop, and reservoir fluid from previous refill begins to fill syringe.
4. Allow pump reservoir to empty. Keep downward pressure on the needle throughout the procedure. Note the returned volume (ml) for patient's records. Disconnect syringe from the extension tubing.
5. Attach refill syringe to the proximal end of extension tubing and confirm that the needle is still in contact with the needle stop.
6. Keep downward pressure on the needle and begin to inject refill solution into the pump. Release pressure on plunger at 5 ml increments and allow 1 ml of solution to return to syringe. This will verify that the needle is in the correct position and the pump reservoir is being filled. Continue to inject and check needle placement until the syringe is emptied.
7. After injecting the entire contents of the refill syringe, close clamp on the extension tubing and pull needle out of the fill port septum.
8. Remove drape and iodine with isopropyl alcohol on 4x4 gauze sponge. Apply adhesive bandage to access site.

E. Post-Procedure
1. Schedule next refill appointment, determined by the chemotherapy protocol.
2. Order laboratory studies (CBC, differential, platelets, alkaline phosphatase, AST, LDH, total bilirubin) to be obtained prior to next refill appointment.
3. After three cycles of chemotherapy, order abdominal CT scan and CEA level to assess treatment outcome, and chest x-ray to screen for metastases.

F. Follow-up treatment
   Instruct patient on wound care, as needed, and on signs and symptoms of infection.

V. Documentation
A. Documentation is in the electronic medical record
   1. Documentation of the pretreatment evaluation and any abnormal physical findings.
   2. Record the time out, indication for the procedure, procedure, two RN checks for high risk medication administration, EBL, the outcome, how the patient tolerated the procedure, medications (drug, dose, route, & time) given, complications, and the plan in the note, as well as any teaching and discharge instructions.

B. All abnormal findings are reviewed with supervising physician.
VI. Competency Assessment

A. Initial Competence
   1. The Advanced Health Practitioner will be instructed on the efficacy and the indications of this therapy and demonstrate understanding of such.
   2. The Advanced Health Practitioner will demonstrate knowledge of the following:
      a. Medical indication and contraindications of Hepatic Arterial Infusion of Chemo
      b. Risks and benefits of the procedure
      c. Related anatomy and physiology
      d. Consent process (if applicable)
      e. Steps in performing the procedure
      f. Documentation of the procedure
      g. Ability to interpret results and implications in management.
   3. Advanced Health Practitioner will observe the supervising physician perform each procedure three times and perform the procedure at least three times under direct supervision.
   4. Supervising physician will document Advanced Health Practitioner's competency prior to performing procedure without supervision.
   5. The Advanced Health Practitioner will ensure the completion of competency sign off documents and provide a copy for filing in their personnel file and a copy to the medical staff office for their credentialing file.

B. Continued Proficiency
   1. The Advanced Health Practitioner will demonstrate competence by successful completion of the initial competency.
   2. Each candidate will be initially proctored and signed off by an attending physician. Advanced Health Practitioner must perform this procedure at least three times per year. In cases where this minimum is not met, the attending physician must again sign off the procedure for the Advanced Health Practitioner. The Advanced Health Practitioner will be signed off after demonstrating 100% accuracy in completing the procedure.
   3. Demonstration of continued proficiency shall be monitored through the annual evaluation.
   4. A clinical practice outcome outcomes log is to be submitted with each renewal of credentials. It will include the number of procedures performed per year and any adverse outcomes. If an adverse outcome occurred, a copy of the procedure note will be submitted.

VII. Responsibility
Questions about this procedure should be directed to the Chief Nursing and Patient Care Services Officer at 353-4380.

VIII. History of Policy
Reviewed by Interdisciplinary Practice Committee: April 2016
Reviewed by Credentials Committee: May 2016
Reviewed/Approved by Med Staff Executive Committee: May 2016