I. Definition

The removal of ductal epithelial cells via random fine needle aspiration to look for the presence of pre-malignant cellular changes. This procedure is utilized in patients with an increased risk of developing breast cancer who are participating in the random fine needle aspiration study.

II. Background Information

A. Setting:
The setting (inpatient vs outpatient) and population (adults 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 resolved
3. Outcome of the procedure other than expected

C. Indications

This procedure is indicated in patients with increased risk of developing breast cancer who are participating in a random fine needle aspiration study or a study that requires random fine needle aspiration as part of the evaluation.

D. Precautions/Contraindications

A history of bleeding or coagulation disorders or concurrent use of aspirin or blood thinners.

III. Materials

A. Consent form
STANDARDIZED PROCEDURE
FINE NEEDLE ASPIRATION (Adult, Peds)

B. Gloves
C. Alcohol pads
D. 1ml syringe filled with 1% lidocaine
E. 10 ml syringe
F. 21-23 gauge needles
G. Cameco syringe holder
H. 2 x 2 gauze
I. Cytolyt tube
J. Band-Aid

IV. Procedure

A. Pre-treatment evaluation
   1. History: Family history of breast cancer, personal history of breast cancer, history of atypia with previous fine needle aspirations or biopsies, BRCA 1,2 positive, medication history, history of bleeding or coagulation disorders.
   2. History of nipple discharge or recent changes to breast.
   4. Diagnostics: mammogram and ultrasound as indicated.

B. Set up (if applicable)
   Assemble above materials from section III.

C. Patient Preparation
   1. Ensure correct patient by obtaining two patient identifiers.
   2. Consent signed
   3. Patient provided with information about steps in procedure.
   4. Time out prior to procedure

D. Perform Procedure:
   1. Cleanse area with alcohol and then inject 0.5 – 1.0 ml of 1% lidocaine subcutaneously into upper outer quadrant of breast within 2cm of areolar edge.
   2. Using a 10ml syringe with cameco syringe holder and 23-21 gauge needle, insert the needle in the upper outer quadrant of the breast within 2 cm of areolar edge at a 45 degree angle
   3. Apply 2ml of suction
4. Move the needle tip within the breast tissue using 1 cm back and forth motions as the sample is collected
5. Release the suction and remove the needle
6. Apply pressure to the area for hemostasis for a minimum of 2 minutes.
7. Place the sample into tubes with cytolyt (common cytopathology fixative) and send to the lab for preparation of the sample
8. Apply a Band-Aid to site
9. Repeat the procedure in the upper inner quadrant of the breast

E. Post-procedure: assess patient for possible side effects
   Document informed consent and timeout performed, procedure results, patient response, characteristics of sample, and patient follow-up instructions.

F. Follow-up treatment
   The Advanced Health Practitioner will review all cytology findings with supervising physician, who will decide appropriate follow-up.

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, 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 fine needle aspiration
         b. Risks and benefits of the procedure
         c. Related anatomy and physiology
         d. Consent process (if applicable)
STANDARDIZED PROCEDURE
FINE NEEDLE ASPIRATION (Adult, Peds)

e. Steps in performing the procedure
f. Documentation of the procedure
g. Ability to interpret results and implications in management.

3. The Advanced Health Practitioner will observe this procedure at least 3 times in its entirety.

4. The Advanced Health Practitioner will perform three treatments/procedures under the direct observation of the supervising physician and such additional procedures as may be necessary to verify clinical competence.

5. The Advanced Health Practitioner will ensure the completion of competency sign off documents and send them directly to the medical staff office.

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, 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 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

Revised April 2012 by Subcommittee of the Committee for Interdisciplinary Practice
Reviewed April 2012 by the Committee on Interdisciplinary Practice
Prior revision April 2008
Approved April 2012 by the Executive Medical Board and the Governance Advisory Council.

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