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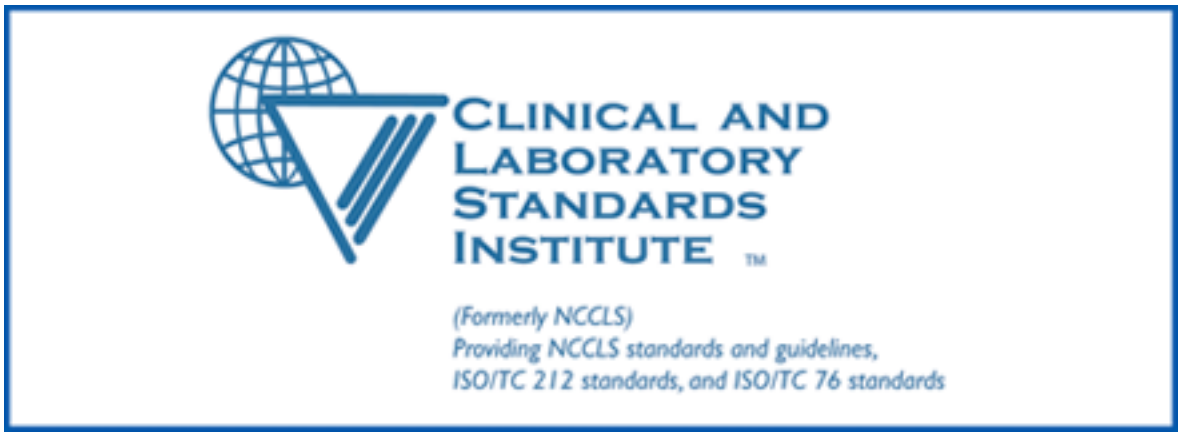
Fine Needle Aspiration Biopsy (FNAB) Techniques; Approved Guideline—Second Edition



This document contains recommended procedures for performing fine needle aspiration biopsies of superficial (palpable) and deep-seated (nonpalpable) lesions/masses, from patient preparation through staining the smear.

A guideline for global application developed through the NCCLS consensus process.

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Abstract

NCCLS document GP20-A2—*Fine Needle Aspiration Biopsy (FNAB) Techniques; Approved Guideline—Second Edition* describes procedures for collecting, handling, fixing, and staining aspiration biopsy specimens. Equipment and aspects of patient preparation necessary to obtain a fine needle biopsy specimens are also addressed. Interpretation of smears is not included in this guideline.

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Foreword

Fine needle aspiration biopsy (FNAB) begins with obtaining a pertinent history and ends with a documented interpretation of the morphologic findings. NCCLS document GP20-A2—*Fine Needle Aspiration Biopsy (FNAB) Techniques; Approved Guideline—Second Edition* is a consensus document on the performance of FNAB. As with any procedure, the quality of the test depends on the adequacy of the specimen and the appropriateness of the biopsy procedure. GP20-A2 provides practical recommendations for the performance of FNAB, including recommendations on obtaining patient consent, performing the biopsy, smearing techniques, and the use of ancillary studies. Particular emphasis is placed on adherence to standard precautions. NCCLS document GP20-A2 is not, however, intended to summarize the morphologic features used for diagnosis.

The revisions in this guideline are intended principally to achieve international harmonization. The previous edition (GP20-A) was published for wide and thorough review in the NCCLS consensus-review process. The objective of this review was to obtain specific input on the utility and applicability of the recommendations provided for fine-needle aspiration biopsy (FNAB) techniques. However, a "Summary of Consensus Comments" has not been included in this approved, second-edition document as all comments received as a result of the consensus review process were editorial in nature.

A Note on Terminology

NCCLS, as a global leader in standardization, is firmly committed to achieving global harmonization wherever possible. Harmonization is a process of recognizing, understanding, and explaining differences while taking steps to achieve worldwide uniformity. NCCLS recognizes that legally required use of terms, regional usage, and different consensus timelines are all obstacles to harmonization. In light of this, NCCLS recognizes that harmonization of terms facilitates the global application of standards and deserves immediate attention. Implementation of this policy must be an evolutionary and educational process that begins with new projects and revisions of existing documents.

In this document, the term *Accuracy* refers to the "closeness of the agreement between the result of a (single) measurement and a true value of a measurand" and comprises both random and systematic effects. *Trueness* is used in this document when referring to the "closeness of the agreement between the average value from a large series of measurements and to a true value of a measurand."

Key Words

Cytology, deep-seated lesion/mass, fine needle aspiration biopsy (FNAB), liquid-based cytology, nonpalpable lesion/mass, palpable lesion/mass, superficial lesion/mass

Fine Needle Aspiration Biopsy (FNAB) Techniques; Approved Guideline—Second Edition

1 Scope

Fine needle aspiration biopsy is a widely accepted technique for the initial work-up and management of a patient who presents with a superficial, palpable lesion/mass. This technique is also used for a deep-seated, nonpalpable lesion/mass under radiologic guidance. This minimally invasive procedure is safe, accurate, rapid, and cost effective. Patient acceptance is high and complications are minimal. The goal of this guideline is to provide recommendations for performing the procedure and optimal collection, handling, fixation, and staining of aspiration biopsy specimens. Equipment needs and patient preparation issues are addressed. NCCLS document GP20-A2 is not, however, intended to summarize the morphologic features used for diagnosis.

Standard Precautions

Because it is often impossible to know what might be infectious, all human blood specimens are to be treated as infectious and handled according to "standard precautions." Standard precautions are guidelines that combine the major features of "universal precautions and body substance isolation" practices. Standard precautions cover the transmission of any pathogen and thus are more comprehensive than universal precautions, which are intended to apply only to transmission of blood-borne pathogens. Standard precaution and universal precaution guidelines are available from the U.S. Centers for Disease Control and Prevention (*Guideline for Isolation Precautions in Hospitals*. Infection Control and Hospital Epidemiology. CDC. 1996;Vol 17;1:53-80), (MMWR 1987;36[suppl 2S]2S-18S), and (MMWR 1988;37:377-382, 387-388). For specific precautions for preventing the laboratory transmission of blood-borne infection from laboratory instruments and materials and for recommendations for the management of blood-borne exposure, refer to the most current edition of NCCLS document M29—*Protection of Laboratory Workers from Occupationally Acquired Infections.*

2 Introduction

This document provides information about key aspects of the performance of fine needle aspiration biopsy (FNAB). FNAB is a diagnostic procedure that uses thin (fine) needles (22-g or narrower) to obtain cytologic specimens. These cellular specimens are then examined microscopically to detect the presence of various diseases, including those of neoplastic or infectious origin. Often, FNAB is the preferred method of diagnostic biopsy because, in well-trained hands, it is rapid, accurate, cost effective, and safe. Extensive training or experience in the technique is necessary to provide cellular specimens that enable a definitive diagnosis. This document addresses both superficial (palpable) and deep-seated (nonpalpable) lesions/masses in separate sections; however, there is significant overlap. (See Appendix A for a flow diagram of the procedure.)

FNAB is a minimally invasive, cost-effective technique with high diagnostic trueness (in the range of 90 to 99%). For example, several studies show that introduction of FNAB resulted in a 50% reduction in the number of surgical procedures performed on the thyroid, accompanied by a corresponding increase in the percentage yield of tumors at thyroid surgery. The total number of neoplasms detected has, therefore, remained stable, even though only half as many patients underwent surgery. The overall result has been a decrease in the cost of medical care associated with management of thyroid disease.[1,2] In many

institutions FNAB has helped reduce the number of open surgical biopsies. Similar results have been demonstrated in the management of palpable breast lesions/masses.

The diagnostic sensitivity and specificity of FNAB depend on several factors, including:

- the site and type of lesion/mass aspirated;
- the experience of the aspirator (the person performing the aspiration);
- the quality of the sample preparation; and
- the diagnostic skills of the pathologist.

The influence of these factors should not be underestimated. In particular, during the performance of deep-seated aspirations, the presence of a cytotechnologist (for slide preparation) or cytopathologist (for preparation and immediate interpretation) decreases the number of unsatisfactory specimens and increases diagnostic yield.[3]

3 Definitions

Accuracy (of measurement) – Closeness of the agreement between the result of a measurement and a true value of the measurand (VIM93)[4]; **NOTE:** See the definition of **Measurand**, below.

Deep-seated lesion/mass - Situated in the thoracic or abdominal organ/cavity; **NOTE:** It is usually not palpable and is visualized radiologically.

Endoscopy - A procedure where an instrument is used for examination of the interior of a canal or hollow organ.

Ipsilateral - On the same side, e.g., arm on the same side as the breast mass.

Measurand – particular quantity subject to measurement.[4]

Superficial mass/lesion - Situated near the surface; **NOTE:** It is palpable.

Trueness (of measurement) - The closeness of agreement between the average value obtained from a large series of test results and an accepted reference value; (ISO 3534-1).[5]

4 Superficial Lesions/Masses

4.1 FNAB Preparation

Prior to the procedure, the person performing the aspiration (the aspirator) should have the following important information:

- pertinent clinical history (review the chart or consult clinical colleagues about, e.g., prior history of malignancy or infection, or previous related/pertinent pathologic results);
- any relevant imaging studies and differential diagnostic considerations;
- the questions the study is attempting to answer;

- how to perform the procedure.

4.2 Preparation for Ancillary Studies

It is prudent to be prepared for the possibility of ancillary studies, such as:

- cell-block preparation;
- cytogenetics;
- electron microscopy;
- flow cytometry;
- image analysis;
- immunocytochemistry;
- microbiology cultures;
- molecular probe studies.

The appropriate materials necessary for these ancillary studies should be available for specimen handling during the aspiration.

4.3 Patient Preparation

A pertinent clinical history is obtained and a directed physical examination is done. The FNAB technique and its potential complications are clearly explained to the patient or legal guardian.

4.4 Patient Consent

Obtain the patient's verbal consent for the performance of the procedure. Depending on the protocol of a given institution, additional written permission may or may not be necessary for the performance of superficial FNAB. Written consent should be obtained and documented if it is required by the institution or organization where the procedure is performed.

4.5 Examination

4.5.1 Positioning the Patient and Palpating the Lesion/Mass: General Considerations

Position the patient to ensure best access to the lesion/mass, as well as the maximal safety and comfort of the patient. Palpate the lesion/mass carefully, taking time to define the lesion/mass. It is often useful to palpate with the palmar surface of the four fingers of the dominant hand. Using a circular motion, move the fingers around the indicated area of the lesion/mass. Move in toward the center of the lesion/mass using a concentric circular motion. Differentiate between the normal structures and the lesion/mass.

If the lesion/mass cannot be demonstrated, ask the clinician and/or patient to demonstrate it. If no lesion/mass can be localized, consider deferring the study. A "blind" FNAB has a poor diagnostic yield and should not be performed.

If the lesion/mass cannot be palpated, but is radiologically demonstrable, then it is appropriate to defer the aspiration until imaging guidance is available.

FNAB can be performed in children. Children less than two years of age can be immobilized in a papoose. Sedation or anesthesia may also be utilized.

For general FNAB collection techniques, refer to Section 4.10.

A requisition form should be completed in accordance with the current regulatory requirements (i.e., in the U.S., Clinical Laboratory Improvement Amendments of 1988). The following information should be recorded on the form:

- patient demographics;
- pertinent patient history;
- person performing the procedure;
- persons or departments to be copied on the report;
- anatomic site sampled;
- number of passes;
- number of smears submitted;
- nature of the mass (e.g., solid, cystic, mixed); and
- quantity and gross appearance of the aspirate (e.g., mucoid, watery, bloody).

See Appendix B for an example of a requisition form.

4.5.2 Selected Site-Specific Considerations

4.5.2.1 Breast

To determine the position that best exposes the breast lesion/mass, palpate the lesion/mass while the patient is in a sitting position, and again while the patient is supine. Palpation of the lesion/mass is facilitated by having the patient lie down with the ipsilateral arm raised above the head. During aspiration, the lesion/mass should be stabilized between two fingers of the nondominant hand of the aspirator. The size of the lesion/mass should determine which two fingers to use. If the lesion/mass is larger than 2 cm, it can be held between the thumb and the index finger, if feasible. If the lesion/mass is smaller than 2 cm, stabilize it between the index and third (middle) fingers. Aspiration through the areola should be avoided, if possible. Lesions/masses under the nipple or areola can usually be aspirated by pushing the nodule away from the nipple and aspirating through the adjacent skin avoiding the areola if possible (See Figure 1) Care should be taken not to accidentally pierce the pleura when aspirating a deep-seated breast lesion/mass.

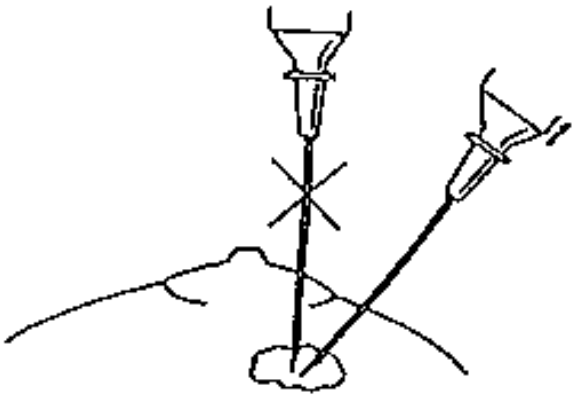

Figure 1. **Needle Aspiration of Lesion/Mass Near the Nipple.** (Adapted from Ljung BM. Principles of aspiration biopsy. (Illustrations by Hamele-Bena D.) In: Koss LG, Woyke S, Olszewski W, eds. *Aspiration Biopsy: Cytologic Interpretation and Histologic Bases*. Second Edition. New York: Igaku-Shoin. 1992:3-28. Used with permission.)

If a breast aspiration results in a clear fluid and the mass disappears, the fluid may be discarded. Bloody or cloudy fluid may yield cells that may be diagnostic, but clear fluid generally does not yield significant cells and could indicate a simple cyst, which may be curative as well as diagnostic. If a mass persists after evacuation of the cyst, reaspirate the residual mass.

4.5.2.2 Axillary Lesions/Masses

Usually, axillary lesions/masses are lymph nodes and they are often difficult to immobilize. Aspiration can be done while the patient is sitting up or lying down. Sometimes abducting the patient's arm with an assistant supporting it helps in palpation of the lesion/mass. If no assistant is available, the patient can rest the arm on the aspirator's shoulder. The aspirator can use his or her index and middle fingers to immobilize the lesion/mass by reaching above the lesion/mass and pulling it down while fixing it against the chest wall. To facilitate aspiration, use the thumb to further immobilize the lesion/mass (Figure 2). The aspirator might prefer to sit slightly lower than the patient. To prevent accidental piercing of the pleura, especially in thin patients, the needle should enter the lesion/mass almost parallel to the chest wall. (For further discussion, see Section 4.12.)

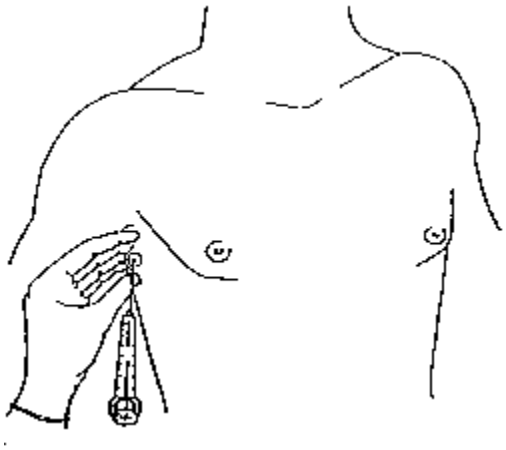

Figure 2. Needle Aspiration of Deeply Seated Axillary Lesion/Mass. (Adapted from Ljung BM. Principles of aspiration biopsy. (Illustrations by Hamele-Bena D.) In: Koss LG, Woyke S, Olszewski W, eds. *Aspiration Biopsy: Cytologic Interpretation and Histologic Bases*. Second Edition. New York: Igaku-Shoin. 1992:3-28. Used with permission.)

4.5.2.3 Thyroid

The patient may be seated or supine; a pillow placed under the patient's shoulders can extend the neck and increase exposure of the gland.

There are differing views on the optimum position of the aspirator relative to the patient. Some suggest standing above the head of a supine patient, while others advise that the aspirator be positioned at either side of the patient. While each position has its merits, the stance in which the aspirator feels most comfortable palpating and localizing the lesion/mass is most likely to yield adequate material.

The aspirator should stabilize the nodule against deeper tissue using the index and middle fingers or thumb and forefinger of the aspirator's nondominant hand. (See Figure 3.) It is useful to have the patient swallow before the biopsy to reduce the patient's urge to do so during the procedure. The aspirator stretches the overlying skin between the fingers before inserting the needle to reduce the patient's pain. The needle is inserted perpendicular to the skin and into the mass. Small gauge needles (25-g or 27-g) are often best as they result in less bleeding than larger gauge needles. Minimal (5 mL) or no suction may be applied to reduce bleeding. Instruct the patient not to swallow once the needle is inserted in the lesion/mass. In the case of a midline lesion/mass, especially those smaller than 2 cm, the trachea can be entered accidentally. If that occurs, the patient might cough. Instruct the patient to signal if a cough is imminent so that the aspiration can be terminated. Apply local pressure as soon as the needle is withdrawn. This reduces the risk of a hematoma.

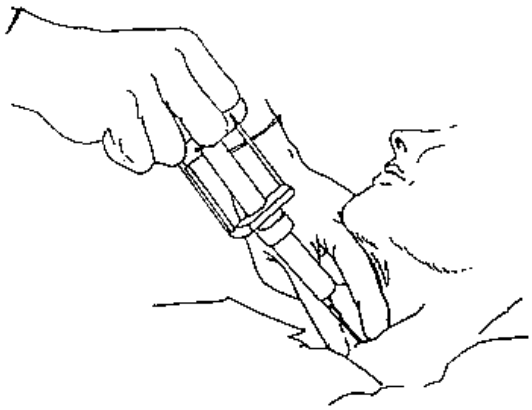

Figure 3. Stabilization of Lesion/Mass Between the Index and Middle Fingers. (Adapted from Ljung BM. Principles of aspiration biopsy. (Illustrations by Hamele-Bena D.) In: Koss LG, Woyke S, Olszewski W, eds. *Aspiration Biopsy: Cytologic Interpretation and Histologic Bases*. Second Edition. New York: Igaku-Shoin. 1992:3-28. Used with permission.)

4.5.2.4 Subcutaneous Lesions/Masses

As seen in Figure 4, lesions/masses less than 1 cm can be immobilized by advancing the nodule (A) under the skin until it will not move any further (B). Without lifting the fingers, the overlying skin is retracted (C) and the aspiration is performed in front of the fingers (D). Alternatively, if the nodule is small and freely movable, it may be grasped and lifted between the thumb and fingertips of the aspirator's nondominant hand during aspiration. In the case of a plaque-like recurrent tumor near scars, the aspiration is done by inserting the needle (26-g or narrower) parallel to the skin surface so as to take a specimen of the plaque and not the underlying adipose tissue. (See Figure 5.)

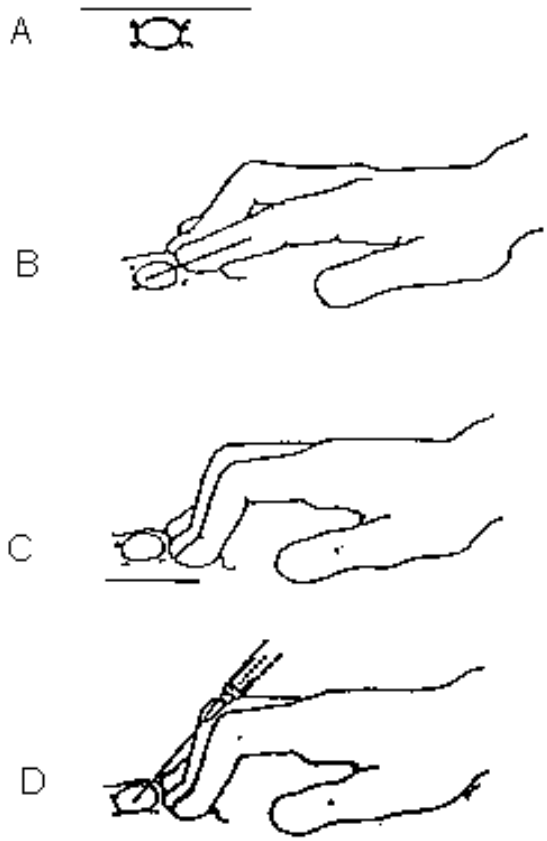

Figure 4. **Method for Immobilization of Small (<1 cm), Movable, Well-Defined, Subcutaneous Lesions/Masses.** (Adapted from Ljung BM. Principles of aspiration biopsy. (Illustrations by Hamele-Bena D.) In: Koss LG, Woyke S, Olszewski W, eds. *Aspiration Biopsy: Cytologic Interpretation and Histologic Bases*. Second Edition. New York: Igaku-Shoin. 1992:3-28. Used with permission.)

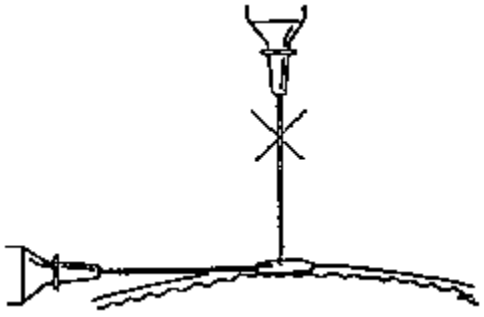

Figure 5. **Needle Aspiration of Intracutaneous Lesions/Masses.** (Adapted from Ljung BM. Principles of aspiration biopsy. (Illustrations by Hamele-Bena D.) In: Koss LG, Woyke S, Olszewski W, eds. *Aspiration Biopsy: Cytologic Interpretation and Histologic Bases*. Second Edition. New York: Igaku-Shoin. 1992:3-28. Used with permission.)

4.6 Antiseptic Preparation

For most superficial FNABs, little preparation beyond handwashing, donning suitably flexible gloves, and wiping the skin over the aspiration site with an alcohol swab is necessary. For the usual FNAB, the preparation is comparable to that performed before inserting an intravenous line or giving a parenteral injection.

4.7 Anesthesia

Most superficial FNABs are performed without local anesthesia for the following reasons:

- Injection of local anesthetic agents into the region can cause more pain than the FNAB itself.
- Infusion of the anesthetic agent can obscure anatomic detail and make the target lesion/mass difficult to palpate.
- Infusion of an anesthetic agent into the region of the target lesion/mass can cause degeneration and loss of cellular morphology.

In selected situations, a superficial injection of a small amount (one to two mL) of local anesthetic may be considered. Local anesthesia may be delivered by hypodermic needle or pneumatic injection device. Local anesthesia assumes much more importance in the pediatric population. Use of general sedation may be considered in both the pediatric and adult populations. Aspiration of superficial sites may be performed during general anesthesia for nonrelated surgery.

4.8 Equipment[6]

4.8.1 Syringes

Normally, 10- or 20-mL syringes are used for FNAB. There is no significant increase in the aspirating power of the larger syringe.[6] The syringe that is chosen for this procedure should be chosen according to individual preference. Before use, the syringe plunger should be moved to break any seal that might have occurred during manufacture or storage.

NOTE: Many aspirators draw a small amount of air (approximately 1 mL) into the syringe before aspiration to facilitate the expression of cells onto a slide. This avoids a problem with needle recapping.

There is no reason for keeping saline or other fluid in the syringe during FNAB. This practice distorts cellular morphology and makes the cells extremely difficult, or impossible, to recover.

To prevent clotting, some aspirators perform a heparin rinse of the syringe and needle before FNAB.

4.8.2 Needles

Disposable 22-g or thinner needles with a clear hub are used. The clear hub makes it easier to see the aspirated material entering the hub. The length of the needles varies from 1.0 to 1.5 inches (2.54 to 3.81 cm), depending on the depth of the lesion/mass. Occasionally, a longer (3-in, [7.62-cm]) needle may be used, if the lesion/mass is deep.

4.8.3 Syringe Holders

A number of different types of syringe holders are available. Their purpose is to enable the person performing the aspiration to comfortably direct the needle and draw back on the plunger of the syringe with only one hand, while stabilizing the lesion/mass to be aspirated with the other hand. Aspiration without a syringe holder is technically more difficult, but in experienced hands may result in a satisfactory specimen. Manufacturer's instructions should always be followed.

4.8.4 Slides

For routine FNAB smear preparations, 7.6- by 2.5-cm glass slides with a thickness of approximately 1 mm and one frosted end are recommended. The cellular material adheres to the plain glass, which avoids the need for a totally frosted slide. Also, charged or coated slides may be used to decrease potential cell loss. It is important that the slides be frosted on one end so that the patient's name, the site, and specific location (e.g., quadrant or side), and number of the needle pass can be indicated. Slides should be prelabeled with the patient's name, using a lead pencil or solvent-resistant marker, before performing the procedure.

4.9 Nonaspiration Technique[7]

The nonaspiration technique employs either a needle alone or a needle attached to the barrel of a small syringe without a plunger. To avoid direct needle manipulation and loss of material if a cyst is punctured, it is recommended that a barrel be attached. This method can decrease the amount of blood admixed with the specimen, and it affords greater tactile sensation of the texture of the lesion/mass directly through the needle. Holding the hub in a "pencil" grip (see Figure 6), the aspirator inserts the needle into the lesion/mass and moves the needle tip within the lesion/mass in an up-and-down motion in 3- to 5-mm strokes. (See Figure 7.)

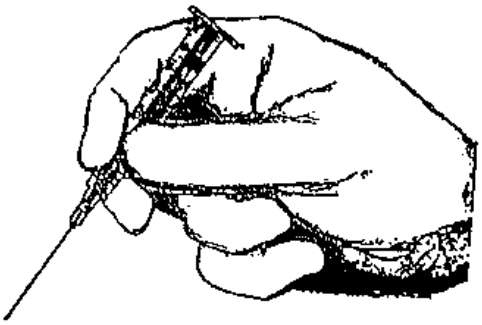

Figure 6. Holding the Hub in a Pencil Grip

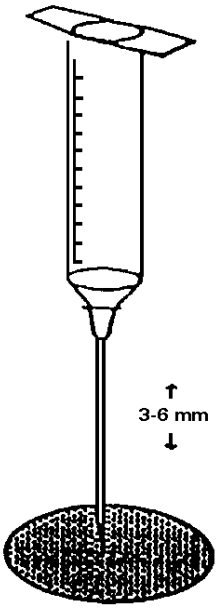

Figure 7. **Puncturing the Lesion/Mass**

Generally, *fifteen to twenty strokes* are considered necessary to get adequate material within the needle. The needle should be removed sooner if blood or tissue is visible in the needle hub.

4.10 Aspiration Technique for Superficial FNAB

4.10.1 Mass Stabilization

Before puncture and during aspiration, the aspirator should stabilize the lesion/mass against deeper tissues with the index and middle fingers, or thumb and forefinger, depending on individual preference. (See Figure 8.) To help stabilization, the skin over the lesion/mass may be stretched.

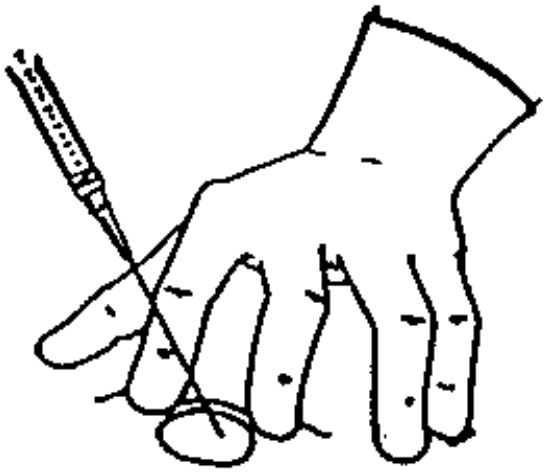

Figure 8. **Immobilization and Aspiration of a Lesion/Mass.** (Adapted from Ljung BM. Principles of aspiration biopsy. (Illustrations by Hamele-Bena D.) In: Koss LG, Woyke S, Olszewski W, eds. *Aspiration Biopsy: Cytologic Interpretation and Histologic Bases*. Second Edition. New York: Igaku-Shoin. 1992:3-28. Used with permission.)

4.10.2 Skin Piercing

Draw back on the syringe just slightly (l mL of air) before skin piercing. Air in the syringe allows easier expulsion of contents of the syringe after aspiration is complete. Using a smooth motion, pierce the skin and advance the needle carefully into the lesion/mass, without applying suction. A change in the resistance of the tissue can be felt through the needle and syringe as a lesion/mass is entered. Note that many lesions/masses are actually deeper than one would estimate by palpation; therefore, the aspirator has to be prepared with a needle of suitable length and be willing to progress a bit deeper.

4.10.3 Applying Suction

Apply and maintain negative pressure by drawing back on the plunger of the syringe. (See Figure 9.) *Do not pump back and forth on the syringe plunger during aspiration*.

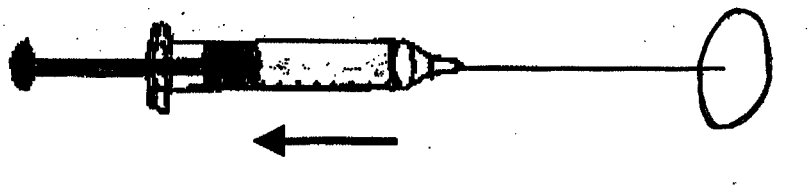

Figure 9. Drawing Back the Plunger

4.10.4 Lesion/Mass Sampling

Move the needle back and forth in rapid 3-to-5-mm strokes. Discontinue aspiration after blood or material is visible in the hub of the needle. *A single pass is defined as one entrance into the skin using one new needle*. If a cyst is encountered, it should be completely drained and the area re-examined for a residual mass. (See Section 4.10.10.)

4.10.5 Needle Withdrawal

Release suction before removing the needle from the patient. (See Figure 10.) Withdrawing the needle while maintaining suction will pull material back into the syringe, making the material virtually impossible to recover. Unless there has been an air leak, the plunger will be drawn back down the barrel spontaneously to equalize pressure in the barrel.

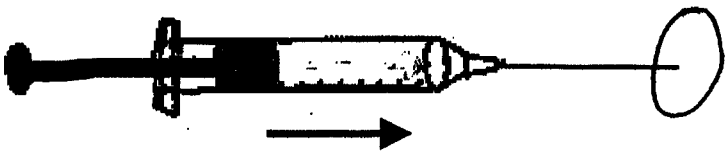

Figure 10. Suction Release

4.10.6 Smear Preparation

The needle should be touched to the slide, bevel side down, while pushing the plunger forcibly to express the material. (See Figure 11.) Care should be taken not to spray the material. A second slide may be used as a shield to prevent the aspirated material from spraying. (See Figure 12.)

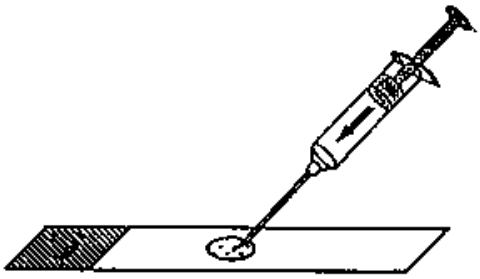

Figure 11. **Expression of Aspirated Material onto a Glass Slide.** (Note that the bevel side of the needle should be touching the slide.)

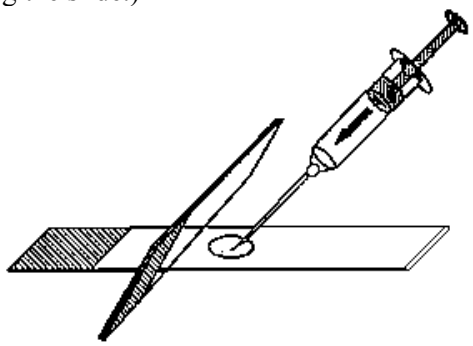

Figure 12. Expression of the Material onto a Glass Slide Using a Second Slide as a Shield

Express only 1 to 2 drops of material onto the slide near the label end. The remaining material may be placed on additional slides or rinsed in a fixative or media for transport to the laboratory. Rinsing of the needle maximizes the recovery of any residual specimen and allows flexibility for the preparation of slides (e.g., cytocentrifuge samples, smears, filters, or cell blocks). (See Section 4.10.8.)

Alternatively if a liquid-based technique is to be used, the material may be rinsed in a liquid preservative/fixative vial with the patient's name and identification. The sample is processed according to manufacturer's instructions.

Proper smear preparation in the FNAB procedure is critical. Several different methods are acceptable. This guideline focuses on the one- and two-step smear preparatory techniques. (See Figures 13 and 14.) The latter is particularly important for vascular organs (e.g., thyroid), where blood clotting can lead to the trapping of diagnostic elements within the clot. For specific details, see Abele[8] or Grohs.[9]

4.10.6.1 One-Step Method for Smear Preparation

The following procedure outlines the one-step method for smear preparation (see Figure 13):

1. Hold the stationary slide (A) firmly in one hand.

2. With the other hand, rest the edge of the spreader slide (B) that is closer to the aspirator on the stationary slide and tilt the spreader slide until the aspirated material begins to spread.

3. Move the spreader slide towards you, while applying slight pressure to the aspirated material. Do not lift either end of the spreader slide until smear preparation is complete (see 1a and 2a).

   Depictions of the shape and approximate size of well-made smears are provided (see 1a and 2b).

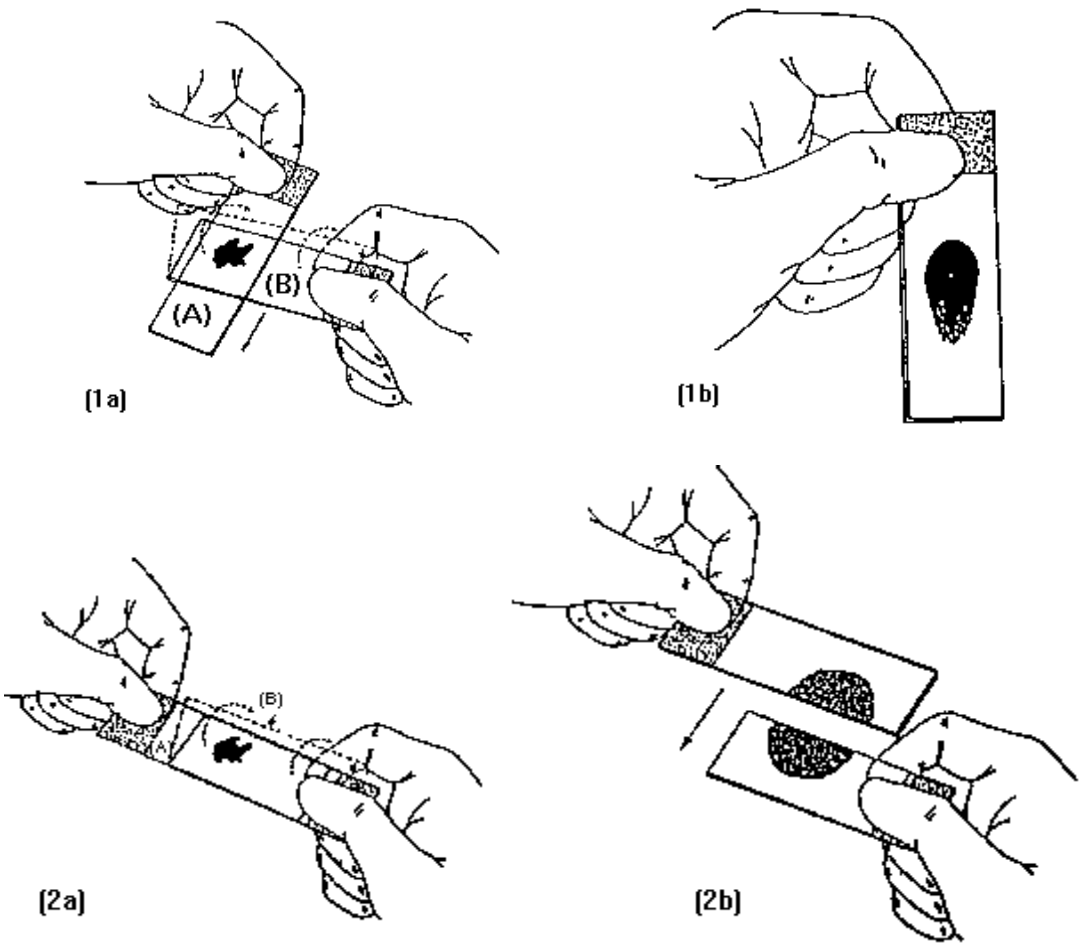

Figure 13. **Approaches for the One-Step Method for Smear Preparation.** (Figures 1a and 1b were modified with permission from Grohs HK. *Fine Needle Aspiration—Principles of Aspiration Technique and Smear Preparation—An Illustrative Guide*. Wichita, KS: FNA/Services.)

4.10.6.2 Two-Step Method for Smear Preparation

The following procedure outlines the two-step method for smear preparation (see Figure 14).

1. Hold the stationary slide (A) firmly in one hand. Hold the spreader slide (B) firmly in the other hand. Use the edge of the nonfrosted side to collect the aspirated material and form a linear accumulation of the aspirate.

2. Move the entire aspirate towards the middle of the stationary slide.

3. Detach the spreader slide from the stationary slide by lifting the spreader slide perpendicular from the stationary slide.

4. Tilt the stationary slide to enable fluid to run in the direction of the frosted end, leaving small particles at the leading edge of the smear.

5. Conclude smear preparation with the one-step method using the leading edge of the smear only.

6. The majority of the particles will be found in the half opposite the frosted end (C).

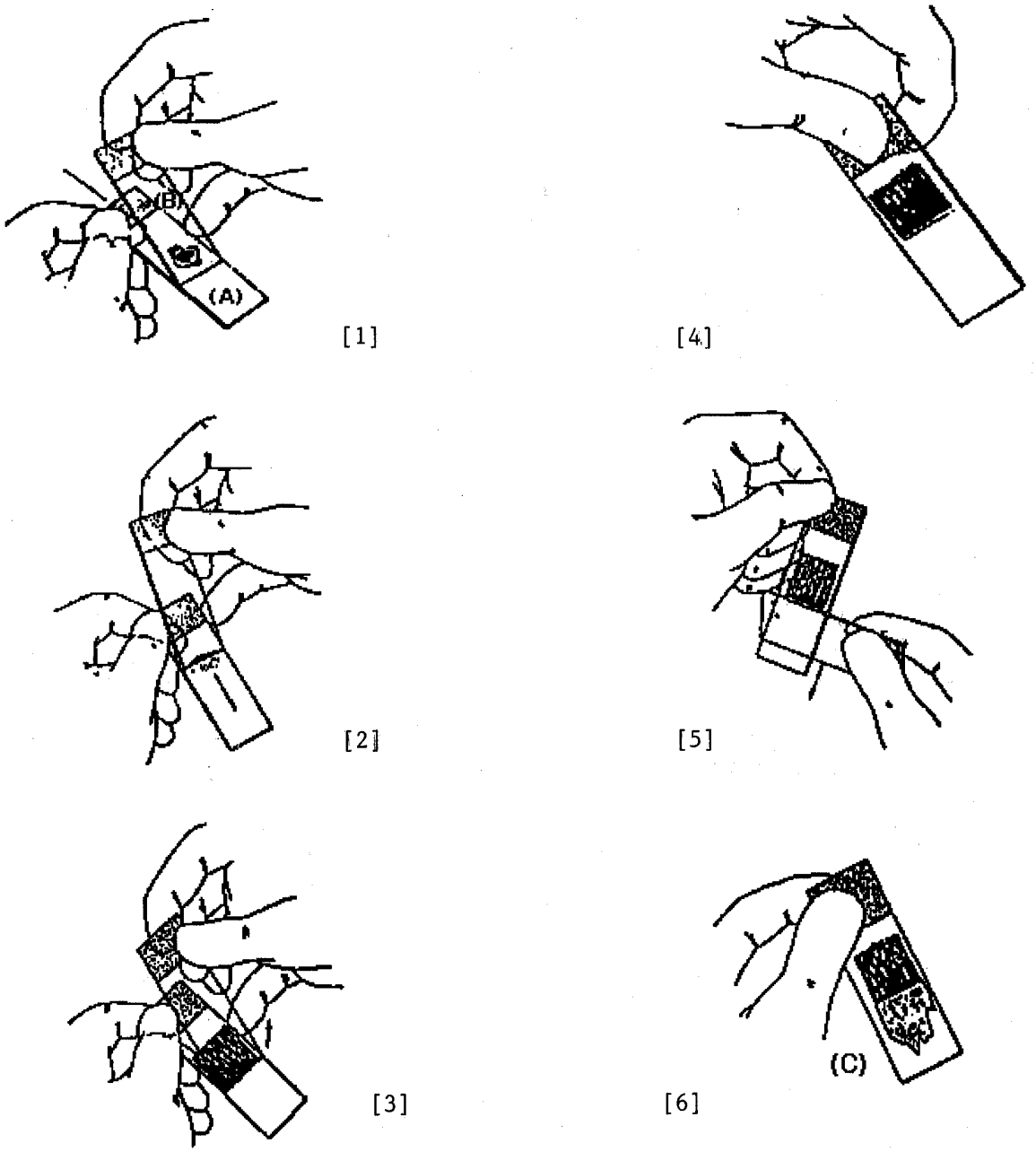

Figure 14. **Two-Step Method for Smear Preparation.** (Modified with permission from Grohs HK. *Fine Needle Aspiration—Principles of Aspiration Technique and Smear Preparation—An Illustrative Guide*. Wichita, KS: FNA/Services.)

4.10.7 Slide Fixation

Fixatives are agents used to prevent cell distortion and to maintain morphologic detail. Distortion due to improper fixation nearly always prevents proper and accurate evaluation of the cell population.

4.10.7.1 Timing

After the sample has been spread evenly onto the slide, the slide should be fixed *immediately*. The interval between application and smearing of the sample onto the slide and subsequent fixation should be kept to a minimum.

4.10.7.2 Air Drying

Air-drying is the absence of fixation and is desirable for Romanowsky and ultrafast Papanicolaou staining techniques.[10]

4.10.7.3 Types of Fixatives

- *Coating Surface Fixatives*

Coating fixatives (alcohol with polyethylene glycol) are those that cover the surface of the prepared smears. The coating fixative may be applied by pressure spraying from a commercial cytofixative spray, by electric pump, by a dropper from a dropper bottle, or by pouring from an individual envelope from a commercially available kit. When coating or spray fixatives are used, the nozzle of the spraying apparatus should be held approximately 30 cm from the slide. Holding the spray fixative container too close to the slide can result in the development of cellular artifacts or result in flooding the slide and washing or blowing away the cells. Holding the spray fixative container too far from the slide may result in drying artifacts or uneven fixation.

- *95% Ethanol (Wet Fixation)*

A widely accepted, ideal cellular fixative for cytologic smears is 95% ethanol. Place 95% ethanol in an appropriate container and immerse the freshly prepared smear immediately into the fixative. (See Figure 15.) Fixation occurs in 5 to 30 minutes. If the fixative is to be reused, it should be filtered.

Figure 15. Fixation of Smear by Immersion in 95% Ethanol

4.10.7.4 Choosing a Fixative

The following points should be considered when choosing a fixative:

- If using charged or coated slides, immersion directly into 95% ethanol is preferred, and will result in minimal cell loss.

- Excessively thick, bloody, or necrotic samples have a high potential for shearing when placed directly into 95% ethanol. To minimize cell loss, coat slides with a spray fixative before immersion in 95% ethanol. Do not spray slides with coating fixative before placing the cells on the slide.

- For thin smears or uncoated slides, spray fixatives can be used.

4.10.7.5 Rapid Assessment

The advantage of a rapid assessment is that the adequacy of the biopsy can be immediately assessed. This leads to a lower rate of inadequate samples, false-negative results, a lower rate of morbidity, and, potentially, a lower rate of mortality. The other important advantage of this approach is that additional material can be obtained for ancillary studies, e.g., immunocytochemistry, flow cytometry, molecular or microbiologic studies, if the smear patterns suggest that these be performed. Consideration should be given to the amount of sample necessary to perform these studies.

4.10.8 Needle Rinses

Depending on institutional policy and aspirator preference, needle rinses may be performed in an attempt to increase cell recovery.

Needles may be rinsed with a variety of solutions (e.g., cell-culture media, balanced electrolyte solution, or denatured alcohol solution; saline and formalin are not recommended) into a container prelabeled with the patient's name. This material can then be used for cell-block preparations and ancillary studies.

The same needle should not be used for another pass. Discard the needle in an appropriate sharps container. It is not appropriate to submit a needle to a laboratory for processing under any circumstances.

4.10.9 Staining/Cover Slipping

Several different stains are available for the evaluation of FNAB materials. The two most commonly available preparations include the alcohol-fixed Papanicolaou stain and the air-dried Romanowsky stain. While the use of an individual stain is at the discretion of the person examining the smears, there are clear advantages and disadvantages to using either alcohol-fixed or air-dried smear preparations. These are outlined in Table 1 below.

Table 1. Comparison of Stains

	Papanicolaou	Romanowsky*
Nuclear detail	+	–
Identification of keratin	+	–
Identification of mucin/stroma/colloid	±	+
Drying artifact	±	+
Evaluation of lymphoid lesions/lymphoglandular bodies	±	+

*Wrights, May-Grünwald-Giemsa; (+) Advantage; (-) Disadvantage; (±) Suboptimal.

However, because these two types of smear preparations give complementary information, it is recommended that both types of smear preparations, i.e., alcohol-fixed and air-dried smears, be prepared during FNAB. Hematoxylin and eosin stains can be used, but some find them less desirable because of the lack of cytoplasmic transparency and differential cytoplasmic staining.

4.10.10 Representative Sampling

Representative sampling of a lesion/mass can be enhanced by making systematic, multiple passes, using a new needle for each pass. *Three to four passes are generally recommended*.

Lesions/masses can have a necrotic center and needles directed into that center might not obtain diagnostic material. (See Figure 16.) Alternatively, a single stroke can pass through the edges of an

irregularly shaped lesion/mass and miss the tissue of interest. (See Figure 17.) Specimens from fibrotic lesions/masses should be taken with smaller-gauge needles.

If a cyst is encountered, it should be completely drained and the area reexamined for a residual lesion/mass. If a lesion/mass is still palpable, the aspiration should be repeated (Figures 18 and 19).

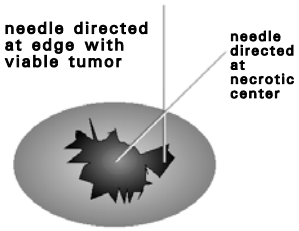

Figure 16. Lesion/Mass with Necrotic Center

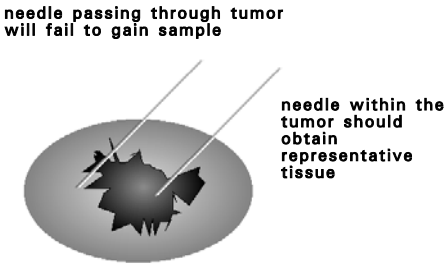

Figure 17. A Potential Sampling Limitation

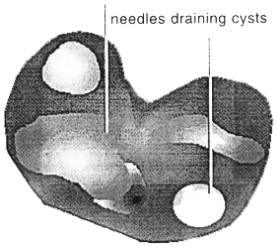

Figure 18. Cystic Lesion/Mass with Residual Lesion/Mass

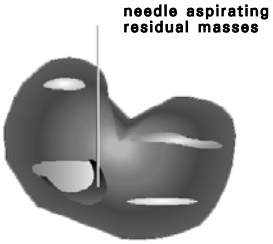

Figure 19. Cysts Drained and Aspiration of Residual Lesion/Mass

4.11 Postaspiration Patient Care

Between passes and after the procedure, a sterile gauze pad should be pressed against the puncture site. Gentle pressure should help prevent the formation of a hematoma, which is the most common complication of FNAB.

Before the patient leaves, after-care instructions should be given. Oral analgesics may be prescribed. (Aspirin-containing products should be avoided.)

The patient should be advised that, after salivary gland aspiration, they can experience the taste of blood following the procedure, as well as experience local discomfort during meals for a couple of days.

If the patient notices an increase in the size of the lesion/mass after leaving, instruct the patient to seek medical advice.

Infection can occur (rarely); if the patient has a fever, local pain and tenderness, or respiratory distress, a physician should be consulted.

4.12 Complications

Overall, FNAB is a safe procedure when performed by persons experienced in the technique; however, complications do occur.

Hematoma formation is the most common complication of superficial FNAB. The use of thinner (22- to 27-g) needles, guarding against overvigorous or multidirectional sampling, and the application of direct pressure to the puncture site minimizes bleeding. FNAB can also (rarely) induce hemorrhage or infarction of a lesion/mass, thus obscuring subsequent histopathologic evaluation.

Theoretical concerns about tumor implantation along the aspiration tract have not been borne out in practice with the use of fine-gauge needles. The incidence of tumor seeding is low, approximately 0.005%.[11] However, it may be prudent, when feasible, to include the needle tract in the subsequent surgical excision of a malignancy.

It is important to emphasize that, overall, the diagnostic value of FNAB far outweighs the (low) rate of complications associated with the technique.

4.13 Progress/Procedure Notes

To chronicle the patient's condition and the FNAB procedure, progress/procedure notes should be kept on each patient. All entries should include the date, the author, and the author's title and signature or initials. Notes should be written so that another provider can assume care of the patient. The following information *may* be included (see Sections 4.1 through 4.4):

- clinician and patient expectations concerning the procedure;
- vital signs (as necessary);
- notes on the physical examination and the FNAB procedure;
- relevant diagnoses;
- patient risk factors;
- preliminary results of the FNAB, if available;
- outcome of the procedure including the patient's tolerance of the procedure;
- presence or absence of residual mass; and
- any communication with the patient about the procedure or subsequent treatment plan.

5 Deep-Seated Lesions/Masses

Generally, deep-seated lesions/masses are nonpalpable. Those amenable to image-directed biopsy can aid in the diagnosis of abnormalities usually identified during other imaging procedures. Biopsies can be directed with computed tomography (CT), ultrasound (US), or fluoroscopy. The procedures are safe, accurate, and can usually be performed on an outpatient basis. FNAB can also be performed during endoscopy (bronchoscopy, esophagoscopy, gastroscopy) with ultrasound guidance.

Both a radiologist/endoscopist and pathologist are usually involved in deep-seated lesion/mass biopsies. Communication between the radiologist/endoscopist and pathologist during aspiration biopsy can confirm needle placement and adequate cellularity of the specimens, thereby increasing the diagnostic yield of the aspiration biopsy.

5.1 Patient Preparation

As with the superficial FNAB procedures, an appropriate history should be obtained from the patient, and a directed physical examination should be performed. (See Section 4.3.) Also, the procedure and its potential complications should be explained.

5.2 Patient Consent

Before deep FNAB procedures are performed, the patient or his/her legal guardian should sign an informed consent form and have it witnessed, as required by the imaging facility.

5.3 Examination

Position the patient for best access to the lesion/mass and maximal safety and comfort. (See Section 4.5.1.)

5.4 Antiseptic Preparation

For radiologically guided FNABs, a more elaborate povidone iodine-type preparation with sterile draping may be performed.

5.5 Anesthesia

Because there tends to be more manipulation and discomfort with deep FNAB procedures, local anesthesia is generally used.

5.6 Equipment

5.6.1 Needles

A fine needle for deep aspirations is 22-g or thinner with a length appropriate for the depth of the organ and lesion/mass (typically, 5- to 20-cm in length). A stylet minimizes tissue coring during insertion and provides additional support and rigidity. The cannula can be marked in centimeter graduations to indicate the depth of cannula penetration. Bevels are usually short in design; distal tips can be modified with slots/holes to increase the area for cytologic material collection.

5.6.2 Syringes

Depending on the organ and the density of the lesion/mass, 10- or 20-mL syringes can be attached to the needle. Syringes may be modified to provide mechanisms to maintain the plungers in a retracted position.

5.6.3 Assist Devices

Syringe holders provide an added degree of freedom and can facilitate the aspirator's ability to perform the procedure. Tubing extension sets allow the aspirator the use of both hands while an assistant applies negative pressure with the syringe. A needle depth stop can be attached to the needle to limit the insertion depth during the procedure.

5.6.4 Introducers/Guides

Needle guides (20-g or thinner) can be used to guide the biopsy needle to the lesion/mass traversing the intervening soft tissue. This technique enables multiple samples to be collected through one needle insertion and reduces the risk of pneumothorax during lung FNAB.

5.7 Technique

The performance of biopsies requires knowledge of three-dimensional anatomy and minimal interventional techniques. Most approved radiology residency programs include FNAB in their curricula.

The most frequent sites of biopsy are the liver, lymph nodes, pancreas, lung, and mediastinum. Most biopsies are performed using a 22-g needle. Occasionally, when hematologic neoplasms are suspected, 22-g FNAB is supplemented by additional aspirations for flow cytometry, immunologic markers, and/or molecular diagnostic techniques.

5.8 Postaspiration Patient Care

Vital signs are monitored every 30 minutes for 4 hours after the procedure. If the patient is stable, then the patient can be released. Standard precautions, including post-aspiration chest x-rays for thoracic biopsies, should be performed.

5.9 Complications

The incidence of complications is higher with deep-seated FNAB than with superficial FNABs. As with superficial FNABs, bleeding and infection can be encountered. There have been no documented reports of distant tumor dissemination as a result of the performance of an FNAB of a nonpalpable lesion/mass. Complications are site-specific. For example, significant pneumothorax is a recognized but uncommon occurrence in lung aspirations.[12] About 3 to 5% of patients develop a significant pneumothorax and require insertion of a chest tube for 24 to 48 hours. Inflammation is a well-recognized complication of pancreatic FNAB in the absence of a discrete mass, i.e., pancreatitis. The mortality rate ranges from 0.006 to 0.031%. Deaths due to hemorrhage have been reported after biopsy of the liver.

5.10 Sample Adequacy

Rapid assessment of the aspirate material obtained from the deep-seated lesion/mass should be performed immediately after the biopsy procedure. There are two main options, which are modifications of the staining procedures listed in Section 4.10.9. The smears that are prepared in the radiologic suite may be air-dried and stained with a Romanowsky-type stain. This procedure is relatively rapid. Alternatively, an ultrafast Papanicolaou stain may be used on air-dried smears.[10]

The advantage of a rapid assessment is that the adequacy of the biopsy can be immediately assessed. This leads to a lower rate of inadequate samples, false-negative results, a lower rate of morbidity, and, potentially, a lower rate of mortality. The other important advantage of this approach is that additional material can be obtained for ancillary studies, e.g., immunocytochemistry or microbiologic studies, if the smear patterns suggest that these be performed. Consideration should be given to the amount of sample necessary to perform these studies.

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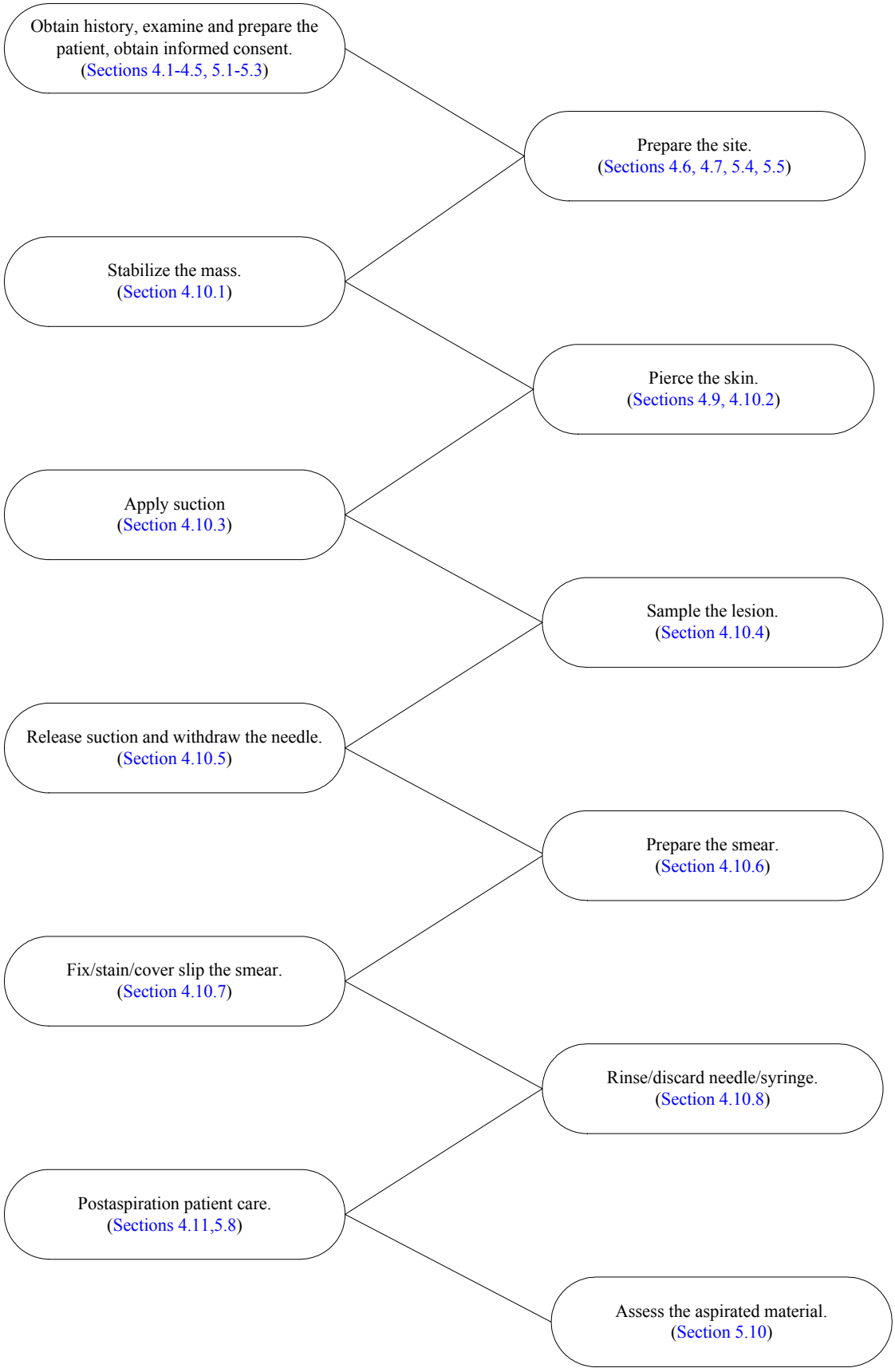
Ljung BM, et al. Diagnostic accuracy of fine-needle aspiration biopsy is determined by physician training in sampling techniques. *Cancer Cytopathol.* 2001;93:263-268.

Appendix A. FNAB Flow Diagram



Appendix B. Specimen Requisition Form

Cytology		
Date:	Location/Room No.	
Collected by/Time		Cytology Account No.
Diagnosis/ICD-9 Code		
Ordering/Referring Physician		Phone No.
Copies to:		Phone No.

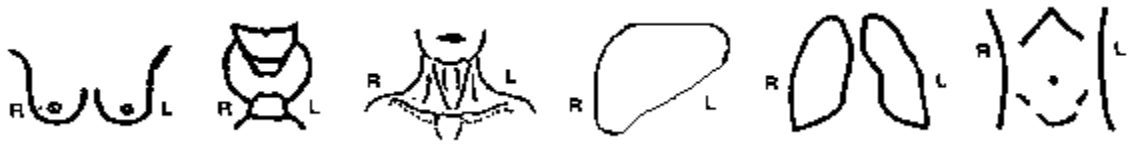
*** Absence of history can limit the ability of the laboratory to fully evaluate the specimen.**

Pertinent History/Previous Biopsy/Treatment: _____ _____ _____	Previous Cytology ☐ Yes ☐ No Date performed:_____ Diagnosis: _____ Colposcopic findings: _____

	GYNECOLOGIC
☐ BRUSHINGS (Specify site)_____ ☐ BODY FLUID ☐ Pleural ☐ Peritoneal ☐ Cerebrospinal fluid ☐ Other (Specify site)_____ ☐ NIPPLE SECRETIONS ☐ SPUTUM ☐ URINE Catheter ☐ Yes ☐ No ☐ WASHINGS (Specify site)_____ ☐ PCP Stain ☐ Lipid Laden Macrophage Stain ☐ SPECIAL REQUEST (Specify)_____	☐ CERVIX ☐ ENDOCERVIX ○ Cytobrush ○ Swab ☐ CUFF ☐ VAGINA ☐ VULVA ☐ LATERAL VAGINAL WALL FOR M.I. LMP (Date)_____Gravida_____ Para_____ MENOPAUSE (Date)_____ HORMONES_____ PREGNANT ☐ Yes ☐ No ABNORMAL BLEEDING ☐ Yes ☐ No_____ (Type) DISCHARGE ☐ Yes ☐ No_____ (Type) CERVICAL LESION ☐ Yes ☐ No_____ (Describe)

FINE NEEDLE ASPIRATION BIOPSY

Specify site/source_____ FNAB performed by_____
Gross appearance_____ No. of passes_____
(Indicate on illustration below.) Technologist ☐ Yes ☐ No



Breast Thyroid Head & Neck Liver Chest/Lungs Abdomen

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NCCLS consensus procedures include an appeals process that is described in detail in Section 8 of the Administrative Procedures. For further information contact the Executive Offices or visit our website at www.nccls.org.

Summary of Delegate Comments and Working Group Responses

GP20-A2: *Fine Needle Aspiration Biopsy (FNAB) Techniques; Approved Guideline—Second Edition*

Section 4.3, Patient Preparation (Formerly Section 5.3)

1. In Section 5.3 it would be helpful to have the potential complications outlined, in terminology that would be appropriate for consenting a patient. It would be helpful to address all that would be communicated to the patient.

- **The potential complications are listed in Section 4.12, Complications and also in Section 4.11, Postaspiration Patient Care.**

Section 4.5.2.1, Breast (Formerly Section 5.5.2.1)

2. In Section 5.5.2.1, I suggest adding the following as the last sentence: "Document the presence or absence of a residual palpable mass in the procedure note after draining a cystic lesion."

- **Text has been added as suggested to Section 4.13, Progress/Procedure Notes.**

Section 4.8.4, Slides (Formerly Section 5.8.4)

3. In Section 5.8.4, I do not agree with the requirement that "slides should be prelabeled with the patient's name, using a permanent marker." A pencil or diamond-tipped marker is preferred, because the permanent marker is erased by the alcohol and xylene.

- **Text has been added as suggested to reflect the use of a lead pencil or solvent-resistant marker.**

Section 4.10.2, Skin Piercing (Formerly Section 5.10.2)

4. Putting air in the syringe is an acceptable, safe technique. However, many experienced aspirators prefer to remove the needle and fill the syringe with air after aspiration, since the larger volume of air results in more of the section being expressed onto the slides. This alternative should be included in Section 5.10.2.

- **The working group believes that removing the needle once it has been used and reattaching after adding air to the syringe increases the risk of needlesticks and goes against OSHA regulations for handling blood-borne pathogens.**

Section 5.10, Sample Adequacy (Formerly Section 6.10)

5. In Section 6.10, I suggest adding the following: "Rapid assessment should not be used to render a preliminary diagnosis but rather to assess the adequacy of the aspirated material." This is important to add, because clinicians often press hard to have a prelim diagnosis and will at times begin treatment based on a rapid assessment preliminary diagnosis.

- **The working group agrees that rapid assessment is for assessment of adequacy. However, rendering a preliminary diagnosis is at the discretion of the pathologist doing the assessment.**

Figure 14, Two-Step Method for Smear Preparation

6. The diagram in Figure 14 is difficult to follow.

- **The legend below the diagram explains the two-step method for smear preparation shown in Figure 14.**

The Quality System Approach

NCCLS subscribes to a quality system approach in the development of standards and guidelines, which facilitates project management; defines a document structure via a template; and provides a process to identify needed documents through a gap analysis. The approach is based on the model presented in the most current edition of NCCLS HS1—*A Quality System Model for Health Care.* The quality system approach applies a core set of "quality system essentials (QSEs)," basic to any organization, to all operations in any healthcare service's path of workflow. The QSEs provide the framework for delivery of any type of product or service, serving as a manager's guide. The quality system essentials (QSEs) are:

Documents & Records	Equipment	Information Management	Process Improvement
Organization	Purchasing & Inventory	Occurrence Management	Service & Satisfaction
Personnel	Process Control	Assessment	Facilities & Safety

GP20-A2 addresses the quality system essentials (QSEs) indicated by an "X." For a description of the other NCCLS documents listed in the grid, please refer to the Related NCCLS Publications section on the following page.

Documents & Records	Organization	Personnel	Equipment	Purchasing & Inventory	Process Control	Information Management	Occurrence Management	Assessment	Process Improvement	Service & Satisfaction	Facilities & Safety
											M29-A2

Adapted from NCCLS document HS1— *A Quality System Model for Health Care.*

Path of Workflow

A path of workflow is the description of the necessary steps to deliver the particular product or service that the organization or entity provides. For example, GP26-A2 defines a clinical laboratory path of workflow which consists of three sequential processes: preanalytical, analytical, and postanalytical. All clinical laboratories follow these processes to deliver the laboratory's services, namely quality laboratory information.

GP20-A2 addresses the clinical laboratory path of workflow steps indicated by an "X." For a description of the other NCCLS documents listed in the grid, please refer to the Related NCCLS Publications section on the following page.

Preanalytic					**Analytic**		**Postanalytic**	
Patient Assessment	Test Request	Specimen Collection	Specimen Transport	Specimen Receipt	Testing Review	Laboratory Interpretation	Results Report	Post-test Specimen Management
X	X	X GP15-A2 GP23-A	X GP15-A2 GP23-A	X GP15-A2 GP23-A	GP15-A2 GP23-A			

Adapted from NCCLS document HS1— *A Quality System Model for Health Care.*

Related NCCLS Publications*

GP15-A2 **Papanicolaou Technique; Approved Guideline—Second Edition (2001)**. GP15-A2 gives recommendations on how to collect and process a quality Pap smear specimen for analysis. The document offers practical recommendations on patient preparation; collection of exocervical and endocervical specimens, including a discussion of collection devices and anatomical illustrations; the design of a test requisition form with a sample form included; slide preparation and fixation; staining methods and techniques, including preparation, storage, safe use, and maintenance of reagents; and mounting, storage, and retention of slides. GP15-A2 is a vital educational and procedural resource for hospital and referral laboratories, cytopathologists, family practitioners, obstetrician/gynecologists, and cytotechnologists.

GP23-A **Nongynecologic Cytologic Specimens: Collection and Cytopreparatory Techniques; Approved Guideline (1999).** This document provides recommended procedures for the collection, handling, transport, and processing of cytologic specimens from nongynecologic sources.

M29-A2 **Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline—Second Edition (2001)**. Based on U.S. regulations, this document provides guidance on the risk of transmission of hepatitis viruses and human immunodeficiency viruses in any laboratory setting; specific precautions for preventing the laboratory transmission of blood-borne infection from laboratory instruments and materials; and recommendations for the management of blood-borne exposure.

* Proposed- and tentative-level documents are being advanced through the NCCLS consensus process; therefore, readers should refer to the most recent editions.

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