

Guidelines of the Papanicolaou Society of Cytopathology for Fine-Needle Aspiration Procedure and Reporting

The Papanicolaou Society of Cytopathology Task Force on Standards of Practice*

This guideline document was developed by the Standards of Practice Task Force of the Papanicolaou Society of Cytopathology, based on extensive literature reviews and the personal practical experience of task force members. The draft guidelines were then subjected to expert review. The task force made revisions to the drafts based on the responses received from the consultant members, who are recognized experts in fine-needle aspiration biopsy. Diagn. Cytopathol. 1997;17:239–247. © 1997 Wiley-Liss, Inc.

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Fine-needle aspiration (FNA) is a simple, safe, and cost-effective procedure for the investigation of patients with a mass.^{1–3} Clinicians, radiologists, and health care administrators have come to expect ready accessibility of this service, and with improvement of imaging equipment, even greater

demands are to be expected. Although wider application is to be encouraged, casual performance of the technique may jeopardize its credibility and may be a potential source for medical liability. Furthermore, the practice of FNA has evolved into a specialty discipline with its own language, algorithms, and diagnostic criteria. To address these issues and to ensure a uniform standard of performance among laboratories, professional groups and societies should move to establish guidelines for training, practice, and reporting.^{4–8}

Conceptually, FNA can be viewed as a coordinated sequence of events: 1) collection of pertinent clinical data, 2) needle sampling of the abnormality, 3) specimen preparation and staining, 4) interpretation, and 5) communication and reporting. It is crucial that the pathologist, radiologist, and

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clinician work closely as a team. The referring clinician ultimately determines what management is most appropriate for the patient by integrating information obtained from the clinical data, imaging findings, and the cytopathologic report.

Fine-Needle Aspiration: Indications and Contraindications

FNA is the sampling of a target lesion by a fine-needle, 22-gauge or smaller. Virtually any mass that is either palpable or visualized by an imaging method can be sampled. FNA, however, should not be used indiscriminately. There should be a reasonable expectation of obtaining useful information from the procedure. Clinically insignificant small lymph nodes, vague induration or asymmetries, and other minor abnormalities are not true indications for FNA,⁹⁻¹¹ although it is recognized that in apprehensive patients a negative report of an adequate sample can be quite reassuring.¹² FNA is a biopsy procedure and should be considered in the same light as a surgical biopsy.⁹ It is a diagnostic tool and has no role in cancer screening, even in "at-risk" individuals. In certain clinical situations, FNA can effectively triage patients for further investigation, surgery, or other therapeutic options (e.g., thyroid and breast lesions).^{6,13,14}

There are no absolute contraindications for FNA of superficial sites. An uncooperative patient may not be suitable for FNA. For deep-organ aspirations, patients with bleeding disorders or on anticoagulant therapy should receive appropriate medical consultation prior to FNA. Contraindications specifically applied to lung FNA include: advanced emphysema, severe pulmonary hypertension, marked hypoxemia uncorrected by oxygen therapy, and mechanical ventilatory assistance. Patients with suspected pheochromocytoma, carotid body tumor, echinococcal cyst, and highly vascular lesions should be aspirated with caution. Aspirations of ovarian malignancies are not recommended, unless the poor condition of patients precludes surgery or the lesion is a recurrence or metastasis of a previously diagnosed and treated cancer.¹⁵⁻¹⁷ Aspiration of a clinically and radiologically benign ovarian cyst by an experienced clinician is considered reasonable, although this practice is not universally accepted because of the fear of rupturing a malignant cyst.^{18,19} FNA of primary testicular malignancies is also controversial and is not advocated.^{20,21}

Complications

The fine-needle technique using 22-gauge or smaller needles is minimally invasive. Complications resulting from superficial aspiration are usually limited to an occasional small hematoma. Even in patients with hemostatic defects, bleeding can be controlled by applying local pressure.²² Pneumothorax is a very rare complication of breast aspiration and

aspiration of the supraclavicular or axillary region. Fatalities from superficial FNA are almost nonexistent; however, a death has been reported following FNA of a carotid body tumor.²³ For transthoracic FNA, the pneumothorax rate can be as high as 20-30%, but most are small and only 5-10% of pneumothoraces require intercostal tube decompression.²⁴⁻²⁶ Rarely, deaths have been reported due to pulmonary hemorrhage or unrecognized tension-pneumothorax in emphysematous patients, but the majority of these deaths are associated with use of larger needles (18-gauge or larger). There was no death in one review of 5,300 transthoracic fine-needle aspirations.²⁷ In abdominal FNA, major complications may occur but are rare. These include bile peritonitis, peritonitis, pancreatitis, hemorrhage, infection, needle tract implantation of malignancy (see below), and death. It has been reported that the mortality rate was 0.008-0.031%, the rate of major complications was 0.05-0.18%, and the rate of other complications was 0.16-0.49%.²⁸⁻³¹

The problem of seeding of the needle tract with tumor cells attracts much attention in the medical literature. The frequency of needle-tract seeding, using fine needles as defined above, is between 0.003-0.009%.^{10,31-34} Studies have not shown any difference in survival of patients with malignancy who were aspirated compared with those who were not.^{35,36}

Post-FNA tissue infarction is an uncommon problem but may interfere with subsequent histologic interpretation.³⁷⁻⁴⁰ If the lesion has been previously aspirated, this information should be communicated to the surgical pathologist handling the surgical specimen.

Training and Education of Personnel

Pathologists who interpret FNA should have a sound knowledge of surgical pathology and a keen interest and demonstrable competence in cytopathology. The interpreting pathologist must ensure that his or her diagnostic accuracy is in keeping with that reported in the recent literature. Active participation in quality assurance and improvement programs is an excellent way to ensure professional competence. For pathologists who perform the FNA procedure (pathologist/clinician hybrid), basic skills in physical examination are important.^{11,41-43}

Pathology residency programs and cytopathology societies must make a firm commitment to develop and improve the interpretive and associated skills of FNA at the resident and fellow level. Undoubtedly, it is individuals with solid fellowship training who are likely to have the greatest impact on the success and utility of FNA service in large centers. All pathology residents should have a meaningful, structured training, as this is the only way to ensure the success of the technique in smaller centers and rural areas. Residents should be exposed to cytologic practice with histopathologic correlation early in their residency program,

and this involvement should continue throughout the training program with graded responsibility.⁴⁴⁻⁴⁸ A collection of reference smears prepared directly from fresh surgical specimens is an excellent training resource for learning the range of cytological appearances of disease seen in various body sites and correlating between cytology and histology.^{49,50} There is no agreement as to the minimal number of FNA to be performed before an individual should be considered qualified to practice as an independent operator. Interpretive and procedural skills depend on individualized ability, motivation, and training. The training director should establish competency-based objectives for individual residents to be met at the end of the program.

Education of Clinicians

FNA is team work. As noted, pathologists' training is crucial, but educating referring clinicians and patients about the merits and potential pitfalls of FNA is equally important. Clinicians who are new to the procedure require education, by means of personal discussion prior to the procedure, timely feedback on results, discussion at tumor rounds and clinicopathologic conferences, and dissemination of in-house manuals and relevant published articles. Currently, clinical residents' knowledge of FNA seems generally inadequate,⁵¹ and there is a need for FNA teaching in residency training programs or fellowship programs for family physicians, surgeons, oncologists, endocrinologists, and obstetricians/gynecologists.

Pre-FNA Requirements

Discussion With Patients

Informed consent should be obtained from the patient. A written consent may be required, depending on local or institutional policies. Documentation of informed consent from each patient should be made and retained in the medical record. Patient education is an integral part of informed consent. It is necessary to inform and advise the patient that FNA is a sampling test and there is always a possibility of the specimen not being representative of the entire lesion. The true lesion could even be missed by the needle. Depending on the size, the nature, and the location of the lesion, the chances of failing to find a cancer when one is present are 1–5%.^{52,53} Therefore, after a benign FNA diagnosis, any enlarging or suspicious lump, noticed by the patient or the referring physician, will require close follow-up or further investigation. An information pamphlet may be provided to patients prior to FNA, so that they can become familiar with the details of the procedure, its advantages, limitations, and complications.⁵⁴ Written information, however, does not replace informed, direct discussion with patients to ensure that they understand the information provided to them.

Required Clinical Information

Clinical data should include the patient's name, identification number, sex, age, tumor location and size, physical and imaging characteristics of the lesion (solid or cystic, single or multiple), presenting symptoms and duration, and working clinical diagnosis. Any relevant past or present history of infectious disease, malignancy, and use of chemotherapy or radiotherapy must be recorded. Complicated cases may require specimen triage for special studies. In these situations, discussion between the pathologist and the clinician prior to the aspiration will facilitate specimen-handling decisions. Many mistakes and loss of opportunities for the most appropriate workup of the case can be avoided if direct communication between pathologist and clinician is established.

Technical Considerations

Procurement of FNA Specimens

FNA may be performed by the pathologist, clinician, or radiologist. For superficial lesions, the trained cytopathologist is often the person best suited to perform the procedure. It has been repeatedly demonstrated that the best FNA result is obtained if the person who interprets the smears is the same person who has procured the aspirate material.^{48,55-57} On the other hand, good results can be obtained if the aspirator and interpreter are proficient but not the same person.^{48,58} For deep-seated targets that require imaging localization, experienced interventional radiologists are best suited to perform the biopsy. Exceptions to this tenet are pulmonologists well-trained in the technique of transbronchial and transthoracic FNA.

Regardless of operator, it is important that the practitioner has been adequately trained in the procedure and does it frequently enough to maintain proficiency. Suffice it to say that single-pass sampling performed by individuals poorly schooled in the technique and submitted to the laboratory on one or two slides suffering from multiple preparatory deficiencies does not generally provide diagnostic material. The percentage of unsatisfactory or inadequate specimens for each individual aspirator is a useful indicator of operative skill. Aspirators who persistently exceed acceptable rates should be identified and offered remedial training. An acceptable rate for inadequate specimens is 10–15% (Ljung BM, personal communication).⁵⁹ However, this varies widely in different clinical settings and in various anatomic sites.

The details of the actual biopsy procedure can be found in many excellent references.^{8,10,42,52,54,60,61} Generally, 22–25-gauge needles are used. For densely fibrotic lesions and highly vascular lesions, the smaller caliber (25-gauge) needles perform better. For very small cutaneous lesions, 26–27-gauge needles are useful. Except for aspiration of deep-seated lesions, the use of local anesthesia is optional. The rules for universal precautions must be observed when

handling specimens.⁶² Immediate examination of the aspirates for adequacy, while the patient remains in the biopsy suite, reduces the number of inadequate samples and decreases the number of needle passes performed. In addition, the “quick-read” identifies cases benefiting from triage of the current or additional passes for ancillary studies.

Although FNA specimens are traditionally obtained by suction, the recently described technique of needle sampling without suctioning is a good alternative for many types of cases.^{63–66} It provides the operator a better tactile sensation as the needle enters the lesion, and is ideal for small lesions. When sampling a vascular organ, such as the thyroid, the technique produces a less bloody sample. When the nonsuction technique fails to yield an adequate sample, the conventional aspiration may be used, and vice versa. Even for the aspiration of deep-seated lesions, the nonsuction technique has been successfully applied by some workers.^{67–69}

Specimen Preparation and Staining

The simultaneous use of both wet-fixed and air-dried smears is recommended, although the exclusive use of either method is acceptable. These two methods of preparation complement each other, and their concomitant use facilitates interpretation. Air-dried smears are Romanowsky-stained: many centers use a modified Wright-Giemsa stain (e.g., Diff-Quik). An ultrafast Papanicolaou staining technique has been developed recently and is used successfully for rapid staining of air-dried smears.⁷⁰ Wet-fixation is achieved by immediate immersion of slides in 95% ethanol or by spray fixation followed by alcohol immersion. Alcohol-fixed slides are stained by the Papanicolaou or hematoxylin-eosin method.

Smear large tissue fragments stain poorly and add little useful information. They should be picked up gently with a pipette or needle to avoid crush and placed directly in formalin for cell block preparation.

To maximize cell recovery, the needle may be rinsed in 1–2 ml of balanced salt solution or RPMI medium. The rinse is held in reserve to be used for cytospin, cell block preparation, or flow cytometry at the discretion of the cytopathologist.

Recently some centers have reported success with the use of thin-layer preparations for cervical/vaginal and nongynecologic exfoliative specimens,^{71,72} but their exclusive use for general diagnostic purposes in FNA specimens remains to be established.^{73,74} The use of “thin preps” is an attractive alternative to direct smears in situations in which the aspirated material is procured by clinicians lacking expertise in slide preparation.⁷⁴ Most experienced cytopathologists, however, prefer direct smears to smears prepared from material rinsed in a fixative. At present, the quantitative and qualitative criteria for FNA diagnosis are based on conventional smear preparatory methods. The extent to which these

can be recapitulated in “thin prep” materials remains to be investigated. There is concern that the architectural pattern of the smear and extracellular matrix components important to many diagnoses may not be fully preserved. Furthermore, these methods deprive one of the opportunity to prepare air-dried smears.

Ancillary Studies

Standard histochemical and immunochemical techniques can be performed on cytospin preparations, cell blocks, or direct smears. When performing immunocytochemical analyses, antibodies in general perform better on cytospins or cell block preparations than on smeared material. Cell blocks also allow for a more expanded panel of antibodies to be used. While smeared material can be used, the results must be interpreted with caution. Immunostaining of smeared material often suffers from poor staining, excessive background staining, and lack of true similarly processed controls. Other ancillary special studies, including microbiological culture, electron microscopy, flow cytometry, image analysis, evaluation of estrogen receptor/progesterone receptor status, cytogenetics, and molecular diagnostics utilizing polymerase chain reaction (PCR), fluorescence in situ hybridization (FISH), and Southern blotting techniques can all be performed on FNA material.^{75–80} The cytopathologist and cytotechnologist must be familiar with the preparatory requirements specific to each of these special procedures. These special tests should be used selectively. While some of these ancillary tests are complex and costly, they are generally available in referral or university centers. Novel sources of material and evolving diseases require that the cytopathologist and cytotechnologist be alert to and conversant with the applications of new technology and new uses of standard techniques.

Interpretation

Objective

FNA interpretation involves assessment of cell morphology, cell-to-cell interaction, tissue fragment architecture (microbiopsy), and the extracellular matrix, integrated with clinical and imaging data.⁸¹ The interpretation may equal a specific histologic diagnosis (e.g., squamous cell carcinoma), a differential diagnosis (e.g., follicular thyroid neoplasm, adenoma vs carcinoma), or a descriptive diagnosis describing components of a disease process (e.g., metaplastic apocrine cells and histiocytes consistent with fibrocystic change). It may also exclude a specific clinical diagnosis (e.g., a FNA showing a benign adrenocortical nodule rules out a metastasis in a patient with a lung malignancy). The objective of FNA is to provide the referring physician information on the nature of the sampled tissue in order to focus appropriate diagnostic and therapeutic decisions, all at minimal risk to the patient.

Diagnostic Categories

Inadequate/unsatisfactory

Inadequate or unsatisfactory FNA reports should be treated as “non-results” with further investigation required. Under no circumstances should the cytopathologist be reluctant to report that an FNA is inadequate so as not to lull the clinician and the patient into thinking that the sample is diagnostic of a benign process. A statement in the report on the reason for the unsatisfactory nature of a given aspirate can be helpful for quality assurance and quality improvement purposes, as well as for instruction of the physician taking the sample.

A smear may be inadequate or unsatisfactory for a variety of reasons, including 1) acellularity/hypocellularity, 2) poor fixation, 3) poor preparation (crush artifact), 4) poor staining, 5) excessive blood obscuring cellular details, or 6) excessive necrosis or debris. Other factors that may adversely affect specimen adequacy include irreparably broken slides, inadequate patient identification, inadequate clinical data, and lack of identification of the type and source of specimen.

A major cause of inadequate specimen reports is a scanty or acellular sample. However, the required minimal number of cells present that defines specimen adequacy is variable, influenced by the intrinsic nature of the lesion and operator skill. When the cytopathologist receives insufficient clinical data, he or she must rely on smear cellularity as the dominant criterion for specimen adequacy, otherwise assessment of specimen adequacy should incorporate clinical findings.^{12,82} Clearly, when there is a strong clinical or radiologic suspicion of malignancy, a hypocellular sample containing no malignant cells is not adequate. In other cases, however, such a sample may be adequate.⁸³ For instance, FNA of a poorly defined, fibrotic induration of the breast (e.g., fibrocystic lesion) is typically hypocellular. What is considered adequate for evaluation of such a lesion may not be an adequate sampling of a well defined solid lesion, especially if it is suspicious clinically or mammographically (“triple test” approach).^{84,85}

Operator skill and experience play a role in determining specimen adequacy. Hypocellular specimens obtained from clinically and radiographically benign fibrotic breast lesions by expert aspirators may well be representative of a benign lesion and hence sufficient. Similar aspirates obtained by aspirators with little training and experience are most likely insufficient and should be so designated.⁸² Similarly, an aspirate of an enlarged salivary gland showing only normal tissue would suggest the diagnosis of sialosis, if the lesion after careful examination was sampled by an experienced aspirator.⁸⁶ A similar aspirate taken awkwardly by a novice is considered inadequate, since it is not certain if the target has been properly sampled.

Benign

This is an adequate sample showing no evidence of malignancy. This diagnostic category can be further divided into two subgroups.

- 1) Aspirates in which a specific diagnosis can be rendered because the benign cells show characteristic cytologic features enabling the pathologist to arrive at a specific diagnosis, such as Hashimoto’s thyroiditis, pulmonary hamartoma, and tuberculosis or fungal disease, among many others.
- 2) Aspirates in which only a negative, narrative diagnosis is possible. For instance, a description of the presence of metaplastic apocrine cells and histiocytes would be consistent with fibrocystic disease. Note that to issue a statement that simply says “no malignancy is identified” can be misleading. It implies that the cytopathologist sees no malignant cells. However, it does not mean that a malignant tumor can be absolutely excluded. To ensure that the clinician understands the implication, the use of the longer statement “no malignancy is identified in this sample” is preferred. A report of “no malignancy” is a valuable piece of information to the clinician, if it is based on adequate sampling from different parts of the lesion and correlated with clinical/imaging findings.

The frequency, nature, and clinical significance of these types of interpretation vary widely for different body sites and for various patient presentations.

Atypical cells present

This interpretation is applied to an adequate sample containing mostly benign cells but including a few that are atypical in appearance where malignancy is an unlikely possibility. An interpretation of “atypical cell present” should not be a “stand-alone” diagnosis, but should be accompanied by a recommendation for clinical correlation, follow-up, and/or further investigation for confirmation of the process. (The acceptance of the “atypical” category is not unanimous among expert consultants. A minority express the view that the use of this category may cause diagnostic confusion, and that the “atypical” category should not be separated from the “suspicious” category. Cytopathologists should make a decision as to whether cellular features are benign, suspicious, or malignant.)

Suspicious for malignancy

This interpretation is applied to a sample on which a definite diagnosis of malignancy cannot be rendered because:

- 1) The sample contains a few malignant-appearing cells which are poorly preserved, or too few cells for

confident diagnosis, or is obscured by inflammation, blood, or cell debris.

- 2) The sample is adequate and there are some features of malignancy, but it lacks overtly malignant cells.
- 3) The clinical history suggests caution despite a few malignant-appearing cells present (e.g., cavitating TB or bronchiectasis, viral cytopathic effect, and chemotherapy or radiotherapy effect).
- 4) The smear background suggests tumor necrosis, although well-preserved malignant cells are not identified.
- 5) The cytologic criteria of malignancy overlap with benign lesions. Clinical data and physical findings are critical for interpretation (e.g., low-grade lymphoma, soft-tissue spindle cell lesions, breast lesions with atypical change, and some endocrine neoplasms).

A “suspicious” diagnosis should not be a “stand-alone” diagnosis, but should be accompanied by a recommendation for confirmation of the disease process.

Malignant

This category is used for adequate samples containing cells diagnostic of malignancy. In most cases, the type and primary site of the malignancy can be determined on routine microscopic examination aided by clinical and/or imaging findings. The extent to which special stains and other special laboratory techniques are used to pursue the histogenesis and functional characteristics of a poorly differentiated tumor is dictated by the clinical situation and therapeutic options.

Reporting and Communication

Reports of FNA should be precise and clinically relevant, should use consistent terminology readily understood by clinicians, and should be generated in a timely fashion.^{87,88} The ability to clearly communicate complex and varied findings to the referring physician is crucial. Since the FNA report may be read and interpreted in the future by different clinicians who may not be familiar with the technique, it is important that the report should stand on its own as a complete document. The report should clearly state the name of the aspirator, number of lesions that have been aspirated, the exact location of each lesion, and the number of punctures performed for each lesion.

The report may follow a surgical pathology format, using the terminology of surgical pathology. A section containing a microscopic description of the aspirate may be included if the pathologist thinks it is indicated. Specific diagnoses or descriptive diagnoses could be given, depending on the confidence of the cytopathologist and the complexity of the case. If a definitive diagnosis is not possible, a statement indicating the differential diagnostic possibilities and their

relative likelihood may be included. Comments may be included in the microscopic description section or as a separate section. It is appropriate for the cytopathologist to make recommendations for surgical excision, clinical follow-up, or any other tests. If a cytologic diagnosis requires histologic or frozen-section confirmation prior to institution of definitive therapy, this instruction should be clearly stated in the final diagnosis or comment. Microscopic description and recommendation need not be a part of every report if the diagnosis is obvious or uncomplicated. Histologic type, degree of differentiation, and the suggested primary site of the tumor can all be given in the final diagnosis.

Turnaround Time (TAT)

Rapid reporting is one of the major assets of FNA. Timely communication of results relieves patient anxiety, obviates further unnecessary investigations, shortens or eliminates the hospital stay, and ensures prompt therapeutic action. It is recommended that the TAT be of the same order as for a high-priority surgical biopsy. When an on-site cytopathologist is present and “quick-read” of aspirates is the usual practice, an immediate preliminary diagnosis can be provided.⁸⁹⁻⁹¹ When an interpretation is truly “preliminary” and subject to substantial amendment or revision later, this should be clearly communicated. Like frozen sections, difficult cases should be deferred. In the majority of cases it is possible to issue a final report within 24 hr of the receipt of the aspirate specimen. If delay is expected, an oral report can be given by the cytopathologist, with the understanding that the final written report might have to be modified in light of the information later provided by special stains and/or other ancillary studies. All such verbal communications should be documented in written form.

Quality Assurance and Improvement

Quality assurance (QA) and quality improvement (QI) programs are an integral part of FNA practice. The laboratory must comply with relevant federal, state, and local legislation. In the US, each cytology laboratory must satisfy the regulations and standards of the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88)⁹² or equivalent standards developed by professional societies that have received deemed status. Useful information and guidance for implementing QA/QI programs are described in the College of American Pathologists' *Quality Improvement Manual in Anatomic Pathology*⁹³ and other publications.^{94,95} Each laboratory should document its performance and compare with the results reported in the literature.

Cytology/Histology Correlation and Clinical Follow-up

Clinical follow-up of cases with cytology-histology correlation is one of the best monitors for evaluation of outcome.⁹⁶

This quality control measure is greatly facilitated by computerization of the laboratory. Surgical pathology and autopsy files are searched at regular intervals, and in some cases a letter may be sent to the clinician for follow-up information. Discrepant cytologic/histologic cases are excellent resources for self-assessment, quality improvement, and minimizing future errors. These cases must be carefully reviewed and the cause of a discrepancy resolved and documented in quality assurance records.

Summary

- As medical care moves toward outpatient and managed care, FNA becomes an indispensable biopsy procedure that can replace many surgical biopsies.
- The reliability of the procedure is maximized by rapid assessment of the aspirates and by the team approach (the cytopathologist, radiologist, and clinician working closely together).
- Proper training and maintenance of competency are central to success.
- QA and QI programs are excellent means to monitor competency and improve performance.
- Aspirators who persistently produce a high rate of unsatisfactory aspirates (>15%) should be identified and given remedial training.
- Clear, precise communication and rapid turnaround time for reporting are critical.

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