

Quality Improvement Guidelines for Image-guided Percutaneous Biopsy in Adults

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PERCUTANEOUS biopsy has become established as a safe, effective procedure. Successful percutaneous needle biopsy has been applied in most organ systems with excellent results and few complications (1-19). The key to these procedures has been the use of imaging guidance, which allows for the safe passage of a needle into an organ or mass, to obtain tissue for cytologic or histologic examinations. Image-guided percutaneous biopsy is less invasive than open exploration to obtain these same tissues. Because of the lower morbidity and mortality of the noninvasive procedures, they can be applied to patients who are too ill to undergo surgery or who wish to avoid convalescence from large diagnostic laparotomy procedures. In most settings percutaneous biopsy is the first approach to diagnosis. Follow-up, with postprocedure monitoring and management of the patient, is appropriate for the radiologist and will increase the effectiveness of the procedure. These guidelines are written for

use in a quality improvement program that monitors percutaneous biopsy procedures (20). The most important processes of care in this area are: (a) patient selection, (b) performing the procedure, and (c) monitoring the patient. The outcome measures or indicators for these processes are indications, success rates, and complication rate.

DEFINITIONS

Image-guided percutaneous biopsy is defined as placement of a needle or needles into a suspected abnormal target site for the purpose of obtaining tissue or cells for diagnosis. Needles larger than 18 gauge should produce sufficient tissue for histologic examination, whereas small needles (19 gauge and smaller) should produce sufficient material for cytologic examination. After placement of the image-guided percutaneous biopsy needle and specimen procurement, the needle is removed.

For purposes of this standard, successful image-guided percutaneous biopsy is defined as the procurement of sufficient material for a pathologic diagnosis.

While practicing physicians should strive to achieve perfect outcomes (eg, 100% success, 0% complications), in practice all physicians will fall short of this ideal to a variable extent. Therefore, indicator thresholds may be used to assess the efficacy of ongoing quality improvement programs. For the purposes of these guidelines, a threshold is a specific level of an indicator

that should prompt a review. "Procedure thresholds" or "overall thresholds" reference a group of indicators for a procedure (eg, major complications). Individual complications may also be associated with complication-specific thresholds. When measures such as indications or success rates fall below a (minimum) threshold or when complication rates exceed a (maximum) threshold, a review should be performed to determine causes and to implement changes if necessary. For example, if the incidence of bleeding is one measure of the quality of image-guided percutaneous biopsy, the values in excess of the defined threshold should trigger a review of policies and procedures within the department to determine the causes and to implement changes to lower the incidence for the complication. Thresholds may vary from those listed here; for example, patient referral patterns and selection factors may dictate a different threshold value for a particular indicator at a particular institution. Therefore, setting individual thresholds is very difficult and each department is urged to alter the thresholds as needed to higher or lower values, to meet its own quality improvement program needs.

Complications can be stratified on the basis of outcome. Major complications result in admission to a hospital for therapy (for outpatient procedures), an unplanned increase in the level of care, prolonged hospitalization, permanent adverse sequelae, or death. Minor complications result in

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Table 1
Success Rate Threshold

Image-guided Percutaneous Biopsy	Threshold
Successful non-lung biopsy	80%
Successful lung biopsy	85%

Note.—These thresholds may be varied depending on the mix of organ systems that are sampled.

no sequelae; they may require nominal therapy or a short hospital stay for observation (generally overnight; see Appendix A). The complication rates and thresholds presented refer to major complications, unless otherwise noted.

INDICATIONS

The indications for percutaneous biopsy are (a) to establish a malignant diagnosis (either primary or metastatic), (b) to establish a benign diagnosis, or (c) to obtain material for culture or other laboratory studies. The threshold for these indications is 95%. When fewer than 95% of procedures are for one of these indications, the department will review the process of patient selection.

The decision to perform a biopsy should be made after considering the risks and benefits in each patient. Relative contraindications include coagulation defects that might increase the risk of bleeding after the procedure (in the liver, the alternative method of transvenous biopsy may reduce this risk). Another relative contraindication is the absence of a safe pathway from the skin to the target site. Specifically, traversing the bowel is generally avoided if alternative pathways are available. However, traversing the bowel may be required and may be performed after consideration of the risks and benefits of the alternative methods.

Image-guided percutaneous biopsy may be performed in essentially every organ system. The contraindications are relative and depend on the suitability of surgical alternatives. There is a spectrum of disease complexity. Ex-

Table 2
Specific Major Complications for Image-guided Percutaneous Biopsy

Major Complications	Reported Rate (%)	Suggested Threshold (%)
Bleeding (requiring transfusion or intervention)		
Large needle (18-gauge or larger)	5–10	10
Small needle (19-gauge or smaller)	3	6
Fine needle (21-gauge or smaller)	0.1–2.0	2
Infection (requiring hospitalization or specific therapy)		
All biopsies (sterile)	1	2
Prostate biopsy (nonsterile)	2.5–3.0	6
Peritonitis (requiring hospitalization or specific therapy)		
Abdominal biopsies	1.5	2
Hemoptysis (requiring hospitalization or specific therapy)		
Lung biopsies	0.5	1
Pneumothorax (requiring chest tube)		
All biopsies (other than lung)	0.5	1
Lung biopsies	5	10

amples of more complex situations include biopsies of targets that are protected by overlying bony structures or that require traversal of vital organs to reach the target site. Examples of relatively straightforward image-guided percutaneous biopsy and diagnostic fluid aspirations include superficial targets that are large and do not involve the traversal of vital organs.

SUCCESS RATE

Setting an appropriate success rate threshold for percutaneous biopsy is difficult. There are many variables that will affect the eventual success of the procedure. These include the number of samples that are obtained, the size of the target abnormality, the organ system in which biopsy is performed, the availability of an on-site cytopathologist, the experience of the institution's pathology staff, the imaging equipment available, and the skill of the operating physician (Table 1).

COMPLICATIONS

The complications of percutaneous biopsies are of two types, generic and organ-specific. Generic refers to complications that are common to all biopsies. The major generic complications include bleeding, infection, and unintended organ injury. Clinically significant bleeding is infrequent, although there is increased risk in core renal biopsies (21–24). Infection as a result

of biopsy is also rare. Injury may occur to the target organ or to a nearby organ that is traversed by the needle. Injuries of these types require surgery or other interventions in less than 2% of patients (1,3,9,18,25). Regardless of the organ system in which biopsy is performed, in general, the risk of complication from bleeding is higher with larger needles than with small needles (26–29,31).

Organ-specific complications are those that are only associated or most commonly associated with biopsy of a specific organ. For example, pneumothorax is most commonly associated with lung biopsy, but can occur during vertebral, rib, liver, spleen, and breast biopsies or aspirations (4–9, 30,31). Other complications occur, but rarely require therapy. These include hematuria after renal or prostate biopsy and hemoptysis after lung biopsy. In developing this set of thresholds, we have listed a rate of a given complication and a suggested threshold that should prompt a review. In addition, there are certain complications that are essentially always associated with a single organ. Very rare complications, such as hypertensive crisis (22) after adrenal biopsy, pancreatitis (32), and tumor seeding of the needle track (19,22,23), are not given thresholds. Each major incident should be investigated as appropriate (Table 2).

Published rates for individual types of complications are highly dependent

Table 3
Complication Rate for Image-guided Percutaneous Biopsy

Biopsy Location	Complication Rate
Lung	10%
Nonlung	2%

on patient selection and are based on series comprising several hundred patients, which is a volume larger than most individual practitioners are likely to treat. Therefore, we recommend that generally complication-specific thresholds be set at twice the complication-specific rates listed previously. It is also recognized that a single complication can cause a rate to cross above a complication-specific threshold when the complication occurs in a small volume of patients (eg, early in a quality improvement program). In this situation, the overall procedure threshold is more appropriate for use in a quality improvement program.

OVERALL PROCEDURAL THRESHOLD

All major complications resulting from image-guided percutaneous biopsy and aspiration biopsy are shown in **Table 3**.

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APPENDIX A

Society of Interventional Radiology Standards of Practice Committee Classification of Complications by Outcome

Minor Complications

- No therapy, no consequence.
- Nominal therapy, no conse-

quence; includes overnight admission for observation only.

Major Complications

C. Require therapy, minor hospitalization (<48 hours).

D. Require major therapy, unplanned increase in level of care, prolonged hospitalization (>48 hours).

E. Permanent adverse sequelae.

F. Death.

APPENDIX B

Technical documents specifying the consensus and literature review methodologies utilized in writing this clinical practice guideline are available

upon request from the Society of Interventional Radiology, 10201 Lee Highway Suite 500, Fairfax, VA 22030.

Consensus statements and thresholds in this document was obtained utilizing a modified Delphi technique (33,34).

ADDENDUM

Dr. John Cardella authored the first draft of this document and served as topic leader during subsequent revisions of the first draft. Dr. Curt Bakal is Chairman of the Standards of Practice Committee for the purpose of this document. All other authors are listed alphabetically. Other members of the Standards of Practice Commit-

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The clinical practice guidelines of the Society of Interventional Radiology attempt to define practice principles that generally should assist in producing high-quality medical care. These guidelines are voluntary and are not rules. A physician may deviate from these guidelines, as necessitated by the individual patient and available resources. These practice guidelines should not be deemed inclusive of all proper methods of care or exclusive of other methods of care that are reasonably directed toward the same result. Other sources of information may be used in conjunction with these principles to produce a process leading to high-quality medical care. The ultimate judgment regarding the conduct of any specific procedure or course of management must be made by the physician, who should consider all circumstances relevant to the individual clinical situation. Adherence to the SIR Quality Improvement Program will not assure a successful outcome in every situation. It is prudent to document the rationale for any deviation from the suggested practice guidelines in the department policies and procedure manual or in the patient's medical record.