



## **CAR Standards for Percutaneous Biopsy**

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*The standards of the Canadian Association of Radiologists (CAR) are not rules, but are guidelines that attempt to define principles of practice that should generally produce radiological care. The physician and medical high-quality physicist may modify an existing standard as determined by the individual patient and available resources. Adherence to CAR standards will not assure a successful outcome in every situation. The standards should not be deemed inclusive of all proper methods of care or exclusive of other methods of care reasonably directed to obtaining the same results. The standards are not intended to establish a legal standard of care or conduct, and deviation from a standard does not, in and of itself, indicate or imply that such medical practice is below an acceptable level of care. The ultimate judgment regarding the propriety of any specific procedure or course of conduct must be made by the physician and medical physicist in light of all circumstances presented by the individual situation.*

### **I. INTRODUCTION**

Image-guided percutaneous needle biopsy (PNB) is an established, effective procedure for selected patients with suspected pathology. Extensive experience documents the safety and efficacy of this procedure. As with any invasive procedure, the patient is most likely to benefit when the procedure is performed in an appropriate environment by qualified physicians. This guideline outlines the principles for the performance of PNB.

### **II. DEFINITION**

PNB is defined as percutaneous placement of a needle into a suspected abnormal lesion for the purpose of obtaining tissue or cells for diagnosis. Following specimen procurement, the needle is removed. For purposes of this standard, successful image-guided PNB is defined as the procurement of sufficient material for a pathological diagnosis.

### **III. INDICATIONS AND CONTRAINDICATIONS**

A. Indications for PNB include, but are not limited to:

1. To establish the benign or malignant nature of a lesion.
2. To obtain material for microbiologic analysis in patients with known or suspected infections.
3. To stage patients with known or suspected malignancy when local spread or distant metastasis is suspected.
4. To determine the nature and extent of diffuse parenchymal diseases of certain organs (e.g., hepatic cirrhosis, renal transplant rejection, glomerulonephritis, etc.)

B. There are no absolute contraindications. However, there are relative contraindications, and, as with all patients considered for this procedure, the relative risks of the procedure should be weighed carefully. The relative contraindications for PNB include:

1. Known coagulopathy that cannot be adequately corrected.
2. Inability of the patient to cooperate with, or to be positioned for, the procedure.
3. Known adverse reaction to contrast media when contrast media administration is critical to the safe performance of the procedure.
4. Hemodynamic instability.
5. Lack of a safe pathway to the lesion.
6. Severely compromised pulmonary function for patients undergoing thoracic interventions when there are risks of further compromise inherent to the procedure.

Patient management should address these relative contraindications prior to the procedure. Every effort should be made to correct or control these clinical situations before the procedure, if feasible. All imaging facilities should have policies and procedures to reasonably attempt to identify pregnant patients prior to the performance of any diagnostic examination involving ionizing radiation. If the patient is known to be pregnant, the potential risk to the fetus and clinical benefits of the procedure should be considered before proceeding with this study.

#### **IV. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL**

##### **A. Physician**

Physicians involved in the performance, supervision and interpretation of PNBs should be Diagnostic Radiologists and must have a Fellowship or Certification in Diagnostic Radiology with the Royal College of Physicians and Surgeons of Canada and/or the Collège des médecins du Québec. Also acceptable are equivalent foreign Radiologist qualifications if the Radiologist is certified by a recognized certifying body and holds a valid provincial license.

Image-based diagnosis and treatment planning requires integrating the preprocedural imaging findings within the context of the patient's history and physical findings. Therefore, the physician must be clinically informed and understand the specific questions to be answered by PNB prior to the procedure in order to plan and perform it safely and effectively. The physician performing PNB must fully appreciate the benefits, alternatives, and risks of the procedure. He/she must have a thorough understanding of imaging anatomy (including congenital and developmental variants), imaging modality to be used for the PNB, radiation safety considerations, and physiologic monitoring equipment and have access to adequate supplies and personnel to safely perform the procedure.

##### **Maintenance of Competence**

Physicians must perform a sufficient number of PNBs to maintain their skills with acceptable success and complication rates as laid out in this document. Continued competence should depend on participation in a quality improvement program that monitors these rates. Appropriate attendance at postgraduate courses that provide continuing education on diagnostic advances, newer techniques, and equipment is necessary.

##### **B. Radiologic Technologist**

The medical radiation technologist must have Canadian Association of Medical Radiation Technologists certification or be certified by an equivalent licensing body recognized by the CAMRT. Under the overall supervision of the radiologists, the technologist will have responsibility for patient comfort and safety, for examination preparation and performance, and for image technical evaluation and quality and applicable quality assurance, under the supervision of the physician performing the biopsy.

The training of technologists engaged in specialty activities shall meet with applicable and valid national and provincial specialty qualifications. Continued education of technologists is encouraged by the C.A.M.R.T. and should meet pertinent provincial regulations.

The technologist, together with the physician and nursing personnel (or other appropriately trained individual for conscious sedation), should have responsibility for patient comfort. The technologist should be able to prepare and position the patient for the image-guided percutaneous procedure and, together with the nurse, monitor the patient during the examination. The technologist should obtain the imaging data in a manner prescribed by the supervising physician. The technologist should also perform regular quality control testing of the equipment under supervision of the physicist.

##### **C. Nursing Services**

Nursing services are an integral part of the team for pre- and postprocedure patient management and education and are recommended in monitoring the patient during the procedure.

##### **D. Qualified Medical Physicist**

The Qualified Medical Physicist should have the responsibility for overseeing the equipment quality control program and for monitoring fluoroscopy and other cross-sectional imaging equipment both upon installation and routinely on an annual basis.

#### **V. SPECIFICATIONS AND PERFORMANCE OF THE PROCEDURE**

## A. Imaging Equipment and Facilities

1. The minimum requirements for facilities in which PNB is performed include:

a. A high-resolution imaging chain with adequate shielding and collimation are essential for fluoroscopic guidance. Ability to perform complex angle (e.g., antero-posterior [AP], lateral, or oblique) views is often necessary during fluoroscopically guided procedures to ensure proper needle placement. Overhead fluoroscopic tube suites are less desirable because of increased radiation exposure to personnel during this procedure.

b. When appropriate, availability of ultrasound is desirable. Appropriate high-resolution real-time imaging, with a selection of transducers of proper frequency, is required to direct and monitor needle placement.

c. When appropriate, computed tomography (CT) capability is desirable to better demonstrate anatomy, particularly in:

i. Patients with lesions in unusual or difficult to access locations.

ii. Locating the optimal access route to avoid, when possible, transgressing vital structures.

iii. Patients with unusual anatomy.

d. The facility should provide an area within the institution appropriate for patient preparation prior to the procedure and for observation of patients after the procedure. This might be within the radiology department, in a short-stay unit, or in a routine nursing unit as outlined in Section V.D below. There should be immediate access to emergency resuscitation equipment.

e. For patients undergoing thoracic procedures, a full array of percutaneous catheterization equipment for treatment of pneumothorax should be available.

f. Laboratory facilities should be available with expertise in histopathology, cytopathology, micro-biology, and chemistry.

2. Performance guidelines

When using fluoroscopy for PNB, a facility should meet or exceed the following imaging practices:

a. Fluoroscopic time should be kept to a minimum. The operator will use only as much fluoroscopy as is necessary to complete the biopsy, consistent with the as low as reasonably achievable (ALARA) radiation safety guidelines.

b. Tight collimation and, when appropriate, shielding (e.g., thyroid, gonadal) should be used.

3. An emergency cart containing appropriate medication and resuscitation equipment must be available to treat adverse reactions.

## B. Physiologic Monitoring and Resuscitation Equipment

1. Sufficient equipment should be present to allow for monitoring the patient's heart rate, cardiac rhythm, and blood pressure. For facilities utilizing conscious sedation, a pulse oximeter should be available.

2. There should be ready access to equipment and drugs for emergency resuscitation. The equipment should include an emergency defibrillator with paper recorder and quick-view capability, oxygen supply and appropriate tubing and delivery systems, suction equipment, tubes for endotracheal intubation, laryngoscope, ventilation bag- valve-mask apparatus, and central venous line sets. Drugs for treating cardiopulmonary arrest, contrast reaction, vasovagal reactions, narcotic or benzodiazepine overdose, bradycardia, and ventricular arrhythmias should also be readily available.

## C. Surgical Support

Although complications of PNB only rarely require urgent surgery, these procedures should be performed in an environment where operative repair can be instituted promptly. Ideally, this would be a facility with adequate surgical, anesthesia, and ancillary support. When these procedures are performed in a freestanding centre, detailed protocols for the rapid transport or admission of patients to an acute-care hospital should be formalized in writing.

#### D. Patient Care

##### 1. Preprocedure care

a. The physician performing the procedure must have knowledge of the following:

- i. Clinically significant history, including indications for the procedure.
  - ii. Clinically significant physical examination, including an awareness of clinical or medical conditions that may necessitate specific care.
  - iii. Possible alternative methods, such as surgery, to obtain the desired diagnostic information or therapeutic result.
  - iv. Laboratory values of patient, necessary to the procedure (INR, etc.).
- b. Informed consent is required.

##### 2. Procedural care

- a. During the use of fluoroscopy, the physician should use exposure factors that comply with the ALARA principle.
- b. Nursing personnel, technologists, and those directly involved in the patient's care during PNB should have protocols for use in standardizing care. These should include, but are not limited to, the following:
  - i. Equipment needed for the procedure.
  - ii. Patient monitoring.Protocols should be reviewed and updated periodically.

##### 3. Postprocedure care

- a. Orders for postprocedure patient care should include frequency of obtaining vital signs, discharge instructions, etc.
- b. Specific anatomic considerations
  - i. Thoracic cavity: pulmonary and appropriate imaging assessment for the presence of pneumothorax.
  - ii. Peritoneal and other solid organ biopsies: appropriate imaging to exclude post-biopsy bleeding if indicated.

#### E. Specifics of the Procedure

1. All invasive image-guided percutaneous procedures involving needle biopsy are performed for specific indications and the examination/procedure should therefore be tailored accordingly.
2. The physician should be aware of the various types of aspiration and core cutting needles that are available.
3. The physician should be aware of the diagnostic possibilities involved and request the appropriate laboratory studies.
4. Prior consultation with pathology may be helpful in selected cases.

## VI. DOCUMENTATION

Reporting should be in accordance with the [CAR Standard for Communication in Diagnostic Radiology](#)

## VII. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION CONCERNS

Policies and procedures related to quality, patient education, infection control, and safety, should be developed and implemented.

## VIII. QUALITY IMPROVEMENT

While practicing physicians should strive to achieve perfect outcomes (e.g., 100% success, 0% complications), in practice all physicians will fall short of this ideal to a variable extent. Thus, indicator thresholds may be used to assess the efficacy of ongoing quality improvement programs. For the purposes of this standard, a threshold is a specific level of an indicator that should prompt a review. Procedure thresholds or overall thresholds refer to a group of indicators for a procedure (e.g., 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 PNB, then 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. Each department is urged to alter the threshold as needed to higher or lower values, to meet its own quality improvement program needs.

#### A. Success Rates and Threshold

There are many variables that affect the eventual success of the percutaneous needle biopsy 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.

Note: These thresholds may vary depending on the mix of organ systems that are sampled. Suggested Thresholds are listed in Reference 1.

#### B. Complication Rates and Threshold

Complications can be stratified on the basis of outcome. Major complications result in admission to the 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 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. Indicator thresholds may be used to assess the efficacy of ongoing. The complications of percutaneous biopsies are divided into 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. 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 this type require surgery or other interventions in less than 2% of patients. Regardless of the organ system in which biopsy is performed; generally the risk of complication from bleeding is higher with large needles than with small needles.

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. Other complications occur but rarely require therapy. These include hematuria after renal or prostate biopsy and hemoptysis after lung biopsy. In developing the following set of thresholds, we have listed the reported rate for a given complication and a suggested threshold that should prompt a review. In addition, there are certain complications that are almost always associated with a single organ. Very rare complications, such as hypertensive crisis after adrenal biopsy, pancreatitis, and tumor seeding of the needle track, are not given thresholds. Each major incident should be investigated as appropriate. Some suggested Thresholds are listed in Reference 1.

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#### APPENDIX A

#### Classification of Complications by Outcome

##### Minor Complications

A. No therapy, no consequence.

B. Nominal therapy, no consequence; 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.

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