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The American College of Radiology will periodically define new practice guidelines and technical standards for radiologic practice to help advance the science of radiology and to improve the quality of service to patients throughout the United States. Existing practice guidelines and technical standards will be reviewed for revision or renewal, as appropriate, on their fifth anniversary or sooner, if indicated.

Each practice guideline and technical standard, representing a policy statement by the College, has undergone a thorough consensus process in which it has been subjected to extensive review, requiring the approval of the Commission on Quality and Safety as well as the ACR Board of Chancellors, the ACR Council Steering Committee, and the ACR Council. The practice guidelines and technical standards recognize that the safe and effective use of diagnostic and therapeutic radiology requires specific training, skills, and techniques, as described in each document. Reproduction or modification of the published practice guideline and technical standard by those entities not providing these services is not authorized.

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PRACTICE GUIDELINE FOR THE PERFORMANCE OF PERCUTANEOUS NEPHROSTOMY

PREAMBLE

These guidelines are an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. They are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care. For these reasons and those set forth below, the American College of Radiology cautions against the use of these guidelines in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the physician or medical physicist in light of all the circumstances presented. Thus, an approach that differs from the guidelines, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in the guidelines when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations on available resources, or advances in knowledge or technology subsequent to publication of the guidelines. However, a practitioner who employs an approach substantially different from these guidelines is advised to document in the patient record information sufficient to explain the approach taken.

The practice of medicine involves not only the science, but also the art of dealing with the prevention, diagnosis,

alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment. Therefore, it should be recognized that adherence to these guidelines will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The sole purpose of these guidelines is to assist practitioners in achieving this objective.

I. INTRODUCTION

This guideline was revised by a collaborative panel of the American College of Radiology (ACR) and the Standards of Practice Committee of the Society of Interventional Radiology (SIR).

Percutaneous nephrostomy (PCN) is a well-established therapy for urinary drainage in patients with supraventricular urinary tract obstruction, and for urinary diversion, as in patients with urinary fistulae, leaks, or hemorrhagic cystitis. The procedure is also performed to gain access to the urinary tract for percutaneous stone removal and other endoscopic procedures. The collecting system can be located with fluoroscopy or by using cross-sectional techniques such as ultrasonography (US) or computed tomography (CT). Fluoroscopic localization is especially useful if a radiopaque stone or contrast opacified collecting system can serve as a target.

This guideline may be used in a quality improvement program that monitors percutaneous nephrostomies. It is not intended to include antegrade pyelography.

The most important processes of care are 1) patient selection, 2) performing the procedure, and 3) monitoring the patient. The outcome measures or indicators for these processes are 1) indications, 2) success rates, and 3) complication rates. Outcome measures are assigned threshold levels.

II. DEFINITIONS

Percutaneous nephrostomy: image-guided percutaneous placement of a catheter into the renal collecting system.

Technical success for percutaneous nephrostomy: placement of a catheter of sufficient size to provide adequate drainage of the collecting system, or to allow successful tract dilation so that the planned interventional procedure can be successfully completed through the nephrostomy tract.

Endoscopic procedure: procedure performed through the nephrostomy tract under direct visualization, using rigid or flexible nephroscopes or ureteroscopes. Flexible endoscopes require a 12-16 French tract, while rigid nephroscopes require a 24-30 French tract. Incision of a strictured ureteropelvic junction (endopyelotomy) and resection or fulguration of upper tract transitional cell carcinomas are some examples of such procedures.

Percutaneous nephrostolithotomy (PCNL): removal of calculi from the kidney or proximal ureter through a percutaneous tract that is dilated to sufficient size to allow placement of a rigid nephroscope, so that large stones can be fragmented under direct vision before removal. Smaller stones may be amenable to extraction without fragmentation. The targeted stones should be successfully removed through the percutaneous access tract. The placement of multiple nephrostomy tracts and the use of flexible instruments are often necessary for complete removal of stone material.

III. INDICATIONS AND CONTRAINDICATIONS

A. Indications include, but are not limited to:

1. Obstruction with infection
2. Obstruction without infection
3. Complications of stone disease
4. Prelude to endoscopic/interventional procedures
5. Delivery of medications, chemotherapy, etc.
6. Urinary leaks
7. Urinary diversion for hemorrhagic cystitis
8. Pyonephrosis

The indications for percutaneous nephrostomy in renal transplants are largely the same as in native kidneys. Occasionally, percutaneous nephrostomy drainage may be performed as a therapeutic trial to differentiate between renal failure due to urinary obstruction from that related to rejection.

The threshold for these indications is 95%. When fewer than 95% of procedures are performed for one of these indications, the department will review the process of patient selection.

B. Absolute Contraindications

There are no absolute contraindications. As with all patients considered for invasive procedures, the relative risks of the procedure should be weighed carefully.

C. Relative Contraindications

1. Uncorrectable severe coagulopathy (e.g., patient with liver or multisystem failure).
2. Terminally ill patient for whom death is imminent.
3. First trimester pregnancy, when a procedure requires fluoroscopy.¹

All imaging facilities should have policies and procedures to reasonably attempt to identify pregnant patients prior to the performance of any examination involving ionizing radiation. If the patient is known to be pregnant, the potential radiation risks to the fetus and clinical benefits of the procedure should be considered before proceeding with the study. (1995, 2005 - ACR Resolution 1a)

IV. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Physician

Percutaneous nephrostomy should be performed under the supervision of and interpreted by a physician who has the following qualifications:

1. Certification in Radiology or Diagnostic Radiology by the American Board of Radiology, the American Osteopathic Board of Radiology, the Royal College of Physicians and Surgeons of Canada, or Le College des Medecins du Quebec, and performance of 15 PCNs as primary operator with acceptable success and complication rates.

or

¹It should be noted that fluoroscopy can be completely eliminated in most cases by performing the procedure solely under US guidance. If fluoroscopy is absolutely necessary in the first trimester, dosimetry studies have shown that fetal radiation exposure can be almost totally eliminated by proper shielding.

2. Successful completion of an Accreditation Council for Graduate Medical Education (ACGME) approved radiology residency training program or an American Osteopathic Association (AOA) approved radiology residency training program that includes at least 3 months of interventional techniques, including PCN procedures and catheter manipulation. This should include performance (with supervision) of at least 15 PCNs as primary operator procedures, documented by a log of cases performed.

or

3. A physician who successfully completes an ACGME approved radiology or nonradiology residency or fellowship training program that did not include the above may still be considered qualified to perform PCN providing the following can be demonstrated:

The physician must have at least 2 years of interventional radiology experience during which the physician was supervised and during which he/she performed 15 PCNs as primary operator with outcomes within the quality improvement thresholds of this guideline.

and

4. Substantiation in writing by the director of interventional radiology or the chair of the department of the institution in which the physician will be providing these services that the physician is familiar with all of the following:
 - a. Indications and contraindications for the procedure.
 - b. Periprocedural and intraprocedural assessment, monitoring, and management of the patient and potential complications.
 - c. Pharmacology of moderate or “conscious” sedation medications and recognition and treatment of adverse reactions and complications.
 - d. Fluoroscopic and radiographic equipment and other electronic imaging systems that may be used as guidance during percutaneous procedures.
 - e. Principles of radiation protection, hazards of radiation exposure to both patients and radiologic personnel, and monitoring requirements.
 - f. Pharmacology of contrast agents and recognition and treatment of potential adverse reactions.
 - g. Percutaneous needle introduction techniques.

- h. Technical aspects of performing the procedure.
- i. Anatomy, physiology, and pathophysiology of the structures being considered for PCN.

Maintenance of Competence

Physicians must perform a sufficient number of PCNs to maintain their skills with acceptable success and complication rates as laid out in this guideline. Continued competence should depend on participation in a quality improvement program that monitors these rates.

Continuing Medical Education

The physician’s continuing education should be in accordance with the [ACR Practice Guideline on Continuing Medical Education \(CME\)](#).

B. Qualified Medical Physicist

A Qualified Medical Physicist should be responsible 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. Medical physicists assuming these responsibilities should meet the following qualifications:

A Qualified Medical Physicist is an individual who is competent to practice independently one or more of the subfields in medical physics. The American College of Radiology considers that certification in the appropriate subfield(s) and continuing education demonstrates the competence of the individual. The ACR recommends that the individual be certified in the appropriate subfield(s) by the ABR or for MRI, by the American Board of Medical Physics (ABMP) in magnetic resonance imaging physics.

The appropriate subfields of medical physics for this guideline are Diagnostic Radiological Physics and Radiological Physics.

The continuing education of a Qualified Medical Physicist should be in accordance with the [ACR Practice Guideline for Continuing Medical Education \(CME\)](#). (2006 - ACR Resolution 16g)

C. Registered Radiologist Assistant

A registered radiologist assistant is an advanced level radiographer who is certified and registered as a radiologist assistant by the American Registry of Radiologic Technologists (ARRT) after having successfully completed an advanced academic program encompassing an ACR/ASRT (American Society of Radiologic Technologists) radiologist assistant curriculum and a radiologist-directed clinical preceptorship. Under

radiologist supervision, the radiologist assistant may perform patient assessment, patient management and selected examinations as delineated in the Joint Policy Statement of the ACR and the ASRT titled “Radiologist Assistant: Roles and Responsibilities” and as allowed by state law. The radiologist assistant transmits to the supervising radiologists those observations that have a bearing on diagnosis. Performance of diagnostic interpretations remains outside the scope of practice of the radiologist assistant. (2006 - ACR Resolution 34)

D. Radiologic Technologist

The technologist, together with the physician and nursing personnel, should have responsibility for patient comfort and safety. The technologist should be able to prepare and position² the patient for the 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. If intravenous contrast material is to be administered, qualifications for technologists performing the intravenous injection should be in compliance with ACR policy statements³ and existing operating procedures or manuals at the interventional radiology facility and/or imaging facility. The technologist should also perform regular quality control testing of the equipment under the supervision of the physicist.

Technologists should be certified by the American Registry of Radiologic Technologists (ARRT) or have an unrestricted state license with documented training and experience in the imaging modality used for the percutaneous nephrostomy procedure.

E. Nursing Services

Nursing services, when deemed appropriate by the performing physician, are an integral part of the team for periprocedural and intraprocedural patient management

²The American College of Radiology approves of the practice of certified and/or licensed radiologic technologists performing fluoroscopy in a facility or department as a positioning or localizing procedure only, and then only if monitored by a supervising physician who is personally and immediately available*. There must be a written policy or process for the positioning or localizing procedure that is approved by the medical director of the facility or department/service and that includes written authority or policies and processes for designating radiologic technologists who may perform such procedures. (1987, 1997, 2007 - ACR Resolution 12-m)

*For the purposes of this guideline, “personally and immediately available” is defined in manner of the “personal supervision” provision of CMS—a physician must be in attendance in the room during the performance of the procedure. Program Memorandum Carriers, DHHS, HCFA, Transmittal B-01-28, April 19, 2001.

³See the [ACR Practice Guideline for the Use of Intravascular Contrast Media](#). (2007 - ACR Resolution 38)

and education and are recommended in monitoring the patient during the procedure.

V. SPECIFICATIONS AND PERFORMANCE OF THE PROCEDURE

Several technical requirements are necessary to ensure safe and successful PCNs. These include adequate imaging equipment and institutional facilities, physiologic monitoring equipment, and personnel.

A. Imaging Equipment and Facilities

The following are considered the minimum equipment requirements for performing PCN. In planning facilities for PCN, equipment and facilities more advanced than the minimum requirements outlined below may be desired to produce higher quality studies with reduced risk and time of study. In general, the facility should have the following:

1. A high-resolution image intensifier and television chain with adequate shielding and collimation. Ability to perform complex angle (e.g., anteroposterior [AP], lateral, or oblique) views may facilitate fluoroscopically guided procedures in ensuring proper needle placement. Overhead fluoroscopic tube suites are less desirable because of increased radiation exposure to personnel during this procedure.
2. Availability of ultrasound. Proper transducer frequency is required to direct and monitor needle placement. Ultrasound equipment should provide Doppler capabilities.
3. Computed tomography (CT) capability when appropriate to better demonstrate anatomy, particularly in:
 - a. Patients with lesions in unusual or difficult to access locations.
 - b. Locating the optimal access route to avoid, when possible, transgressing vital structures.
 - c. Patients with unusual anatomy.
4. A suite that is large enough to allow easy transfer of the patient from the bed to the table and to allow room for the procedure table, monitoring equipment, and other hardware such as intravenous pumps, respirators, anesthesia equipment, and oxygen tanks. Ideally, there should be adequate space for the operating team to work unencumbered on either side of the patient and for the circulation of other technical staff in the room without contaminating the sterile conditions.
5. An area within the institution appropriate for patient preparation prior to the procedure and for observation of them after the procedure. At this location, there should be personnel to provide care as outlined in Patient Care Section below,

and there should be immediate access to emergency resuscitation equipment.

6. An appropriate range of devices to meet the needs that might be encountered during the procedure should be maintained.

B. Performance Guidelines

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

1. Fluoroscopic time should be minimized and recorded. In accordance with the ALARA principle, a radiation dose reduction package including pulsed fluoroscopy and last image hold capabilities is recommended.
2. Tight collimation and, when appropriate, shielding (e.g., thyroid, gonadal area) should be used.

C. 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. If the patient is to receive moderate sedation, a pulse oximeter or an end-tidal carbon dioxide monitor should be available (See the [ACR Practice Guideline for Adult Sedation/Analgesia](#) and the [ACR Practice Guideline for Pediatric Sedation/Analgesia](#)).
2. There should be ready access to emergency resuscitation equipment and drugs, including the following: an emergency defibrillator, oxygen supply and appropriate tubing and delivery systems, suction equipment, tubes for endotracheal intubation, laryngoscope, ventilation bag-mask-valve 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. Resuscitation equipment should be monitored on a routine basis in compliance with institutional policies.

D. Surgical Support

Although complications of PCN only rarely require urgent surgery, it should be performed in an environment where operative repair can be instituted promptly. Ideally, this would be an acute-care hospital with adequate surgical, anesthesia, and ancillary support. If PCN is performed in a freestanding center, rapid transport or admission of patients to an acute-care hospital should be available.

E. Patient Care

The written or electronic request for percutaneous nephrostomy should provide sufficient information to demonstrate the medical necessity of the examination and allow for its proper performance and interpretation.

Documentation that satisfies medical necessity includes 1) signs and symptoms and/or 2) relevant history (including known diagnoses). Additional information regarding the specific reason for the examination or a provisional diagnosis would be helpful and may at times be needed to allow for the proper performance and interpretation of the examination.

The request for the examination must be originated by a physician or other appropriately licensed health care provider. The accompanying clinical information should be provided by a physician or other appropriately licensed health care provider familiar with the patient's clinical problem or question and consistent with the state scope of practice requirements. (2006 - ACR Resolution 35)

Percutaneous nephrostomy can be performed on an outpatient basis in selected patients. Patients who live alone, or in whom the risk of complications is high, such as in those with staghorn calculi, uncorrected hypertension or a coagulopathy, are best treated in an inpatient setting or a short stay unit, so they can be appropriately monitored.

In patients with severe uncorrected metabolic imbalance such as hyperkalemia or metabolic acidosis, correction of these imbalances may be necessary prior to the PCN in order to decrease the risk of complications such as arrhythmias or cardioplegia related to the profound electrolyte abnormality.

1. Preprocedure Care

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

- a. Clinically significant history, including indications for the procedure.
- b. Clinically significant physical examination findings, including an awareness of clinical or medical conditions that may necessitate specific care such as administration of prophylactic antibiotics.
- c. Any preprocedure imaging studies or findings at cystoscopy.
- d. Possible alternative methods, such as surgical or medical treatments, to obtain the desired therapeutic result.

Informed consent must be in compliance with all state laws and the [ACR Practice Guideline on Informed Consent for Image-Guided Procedures](#).

2. Procedural Care

- a. Adherence to the Joint Commission's Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™ is required for procedures in non-operating room settings including bedside procedures. "Time out" must be conducted in the location where the procedure will be done, just before starting the procedure and must:

- Involve the entire operative team.
- Use active communication.
- Be briefly documented, such as in a checklist, and
- At the least, include:
 - Correct patient identity.
 - Correct side and site.
 - Agreement on the procedure to be done.
 - Correct patient position.
 - Availability of correct implants, and any special equipment or special requirements.

The organization should have processes and systems in place for reconciling differences in staff responses during the "time out."

- b. The physician performing fluoroscopy should have knowledge of exposure factors, including kVp, mA, magnification factor, and dose rate, and should consider additional parameters such as collimation, field of view, and last image hold.
- c. Nursing personnel, technologists, and those directly involved in the care of patients undergoing PCN should have protocols for use in standardizing care. These protocols 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. A procedure note should be written in the patient's chart summarizing the major findings of the study and any immediate complications. This note may be brief if an

official interpretation⁴ will be available within a few hours. However, if the official interpretation is not likely to be in the medical record the same day, a more detailed summary of the study should be written in the chart at the conclusion of the procedure. In all cases, pertinent findings should be communicated to the referring physician in a timely manner.

- b. The patient's vital signs and clinical status should be monitored until stable.
- c. The quality and quantity of tube drainage should be monitored at frequent intervals and charted by appropriately trained personnel.
- d. Care to prevent tube dislodgement or contamination must be exercised.
- e. The physician who performed the procedure or a qualified designee should assess the patient prior to discharge, and instructions for appropriate follow-up should be charted and reviewed with the patient or party responsible for the patient's care.

VI. DOCUMENTATION

Reporting should be in accordance with the [Practice Guideline for the Reporting and Archiving of Interventional Radiology Procedures](#).

VII. RADIATION SAFETY IN IMAGING

Radiologists, medical physicists, radiologic technologists, and all supervising physicians have a responsibility to minimize radiation dose to individual patients, to staff, and to society as a whole, while maintaining the necessary diagnostic image quality. This is the concept "As Low As Reasonably Achievable (ALARA)".

Facilities, in consultation with the medical physicist, should have in place and should adhere to policies and procedures, in accordance with ALARA, to vary examination protocols to take into account patient body habitus, such as height and/or weight, body mass index or lateral width. The dose reduction devices that are available on imaging equipment should be active or manual techniques should be used to moderate the exposure while maintaining the necessary diagnostic image quality. Patient radiation doses should be periodically measured by a medical physicist in accordance with the appropriate ACR Technical Standard. (2006 - ACR Resolution 17)

⁴The ACR Medical Legal Committee defines "official interpretation" as that written report (and any supplements thereto) that attach to the patient's permanent record. In healthcare facilities with a privilege delineation system, such a written report is prepared only by a qualified physician who has been granted specific delineated clinical privileges for that purpose by the facility's governing body upon the recommendation of the medical staff.

VIII. 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 in accordance with the ACR Policy on Quality Control and Improvement, Safety, Infection Control, and Patient Education Concerns appearing elsewhere in the ACR Practice Guidelines and Technical Standards book.

IX. QUALITY IMPROVEMENT

While practicing physicians should strive to achieve perfect outcomes (i.e., 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 purpose of these guidelines, a threshold is a specific level of an indicator that should prompt a review.

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. 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. Thus, setting universal 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.

A. Success Rates and Threshold

The technical success rates for percutaneous nephrostomy may vary depending on the clinical scenario, as follows:

<u>Clinical Scenario</u>	<u>Reported Success</u>	<u>Threshold</u>
Obstructed dilated system (with or without small stones)	98%	95%
Obstructed system in renal transplant	98%	95%
Nondilated collecting system (with or without stones)	85%	80%
Complex stone disease, staghorn calculi	85%	85%

Overall, the ability to render a patient stone free depends on factors beyond the placement of an optimal PCN tract. Variables such as the composition of the stones, whether the stone is a staghorn calculus or a solitary renal calculus, the anatomy of the patient, whether multiple access tracts are placed or not, whether flexible instruments are used or not, and whether extracorporeal shock wave lithotripsy is combined with the percutaneous methods for complete removal of stone material [8-11], all contribute to the stone-free rate. The success of other endoscopic procedures is similarly affected by factors other than the creation of an optimal nephrostomy tract.

B. Complication Rates and Threshold

Complications can be stratified on the basis of outcome. When minor and major complications are considered together, they occur in approximately 10% of patients. The specific complications and their thresholds are given below. The departmental thresholds apply to all complications that occur in the department. The individual thresholds apply to all the complications that each practitioner encounters. For the purposes of this document, the following thresholds are for major complications only (see Appendix A).

<u>Complication</u>	<u>Reported Rate</u>	<u>Threshold</u>
Septic shock (fever, chills with hypotension, requiring major increase in level of care)	1%-3%	4%
Septic shock (in setting of pyonephrosis)	7%-9%	10%
Hemorrhage (requiring transfusion)		
PCN alone	1%-4%	4%
With PCNL	12%-14%	15%
Vascular injury (requiring embolization or nephrectomy)	0.1%-1%	1%
Bowel transgression	0.2%	<1%
Pleural complications (pneumothorax, empyema, hydrothorax, hemothorax)		
PCN alone	0.1%-0.2%	<1%
With PCNL or endopyelotomy (intercostals puncture or upper pole puncture for endoscopic procedures)	8.7%-12%	15%

<u>Complication</u>	<u>Reported Rate</u>	<u>Threshold</u>
Individual threshold (complications that result in unexpected transfer to an intensive care unit, emergency surgery, or delayed discharge from the hospital)	4%-7%	5%

Note: PCN = percutaneous nephrostomy.
PCNL = percutaneous nephrolithotomy.

Published rates for individual types of complications are highly dependent on patient selection and are in some cases based on series comprising several hundred patients, which is a volume larger than most individual practitioners are likely to treat. 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, e.g., early in a quality improvement program.

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APPENDIX A

Society of Interventional Radiology Standards of Practice Committee

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.