ACR-SIR-SPR PRACTICE PARAMETER FOR THE PERFORMANCE OF PERCUTANEOUS NEPHROSTOMY

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The American College of Radiology will periodically define new practice parameters 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 parameters and technical standards will be reviewed for revision or renewal, as appropriate, on their fifth anniversary or sooner, if indicated.

Each practice parameter 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 and approval. The practice parameters 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 parameter and technical standard by those entities not providing these services is not authorized.

PREAMBLE

This document is an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. Practice Parameters and Technical Standards are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care 1. For these reasons and those set forth below, the American College of Radiology and our collaborating medical specialty societies caution against the use of these documents 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 practitioner considering all the circumstances presented. Thus, an approach that differs from the guidance in this document, 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 this document when, in the reasonable judgment of the practitioner, such course of action is indicated by variables such as the condition of the patient, limitations of available resources, or advances in knowledge or technology after publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document may consider documenting in the patient record information sufficient to explain the approach taken.

The practice of medicine involves the science, and 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 the guidance in this document 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 purpose of this document is to assist practitioners in achieving this objective.

1 lowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing, 831 N.W.2d 826 (Iowa 2013) Iowa Supreme Court refuses to find that the "ACR Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures (Revised 2008)" sets a national standard for who may perform fluoroscopic procedures in light of the standard's stated purpose that ACR standards are educational tools and not intended to establish a legal standard of care. See also, Stanley v. McCarver, 63 P.3d 1076 (Ariz. App. 2003) where in a concurring opinion the Court stated that "published standards or guidelines of specialty medical organizations are useful in determining the duty owed or the standard of care applicable in a given situation" even though ACR standards themselves do not establish the standard of care.

I. INTRODUCTION

This practice parameter was revised collaboratively by the American College of Radiology (ACR), the Society of Interventional Radiology (SIR), and the Society for Pediatric Radiology (SPR).

Percutaneous nephrostomy (PCN) is a well-established therapy for urinary drainage in patients with urinary tract obstruction; for urinary diversion, as in patients with urinary fistulae, leaks, or hemorrhagic cystitis; and for other indications [1-10]. The procedure is also performed to gain access to the urinary tract for ureteral stent placement, dilatation of ureteral stenosis, percutaneous stone removal, and other endoscopic procedures. The collecting system can be located with fluoroscopy, including intraprocedural intravenous pyelography (IVP), or by using cross-sectional techniques, such as ultrasonography (US), contrast US, or computed tomography (CT), and [11,12]. Fluoroscopic localization is especially useful if a radiopaque stone, indwelling ureteral stent, or contrast-opacified collecting system can serve as a target [13-27].

This practice parameter may be used in a quality improvement program that monitors PCNs [28].

The most important processes of care are 1) patient selection, 2) procedure performance, 3) monitoring, and 4) patient follow-up [29]. "The outcome measures [or indicators] for these processes are 1) indications, 2) success rates, and 3) complication rates. Outcome measures are assigned threshold levels" [29].

PCN: image-guided percutaneous placement of a catheter into the renal collecting system [29].

Technical success for PCN: 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 procedure can be successfully completed through the nephrostomy tract [29].

Endoscopic procedure: "procedure performed through the nephrostomy tract [under direct visualization], using rigid or flexible nephroscopes or ureteroscopes [29]. Flexible endoscopes require a 12- to 16-French tract, whereas rigid nephroscopes require a 24- to 30-French tract." Examples of such procedures are incision of a strictured ureteropelvic junction (endopyelotomy) and resection or fulguration of upper tract transitional cell carcinomas [29].

Percutaneous nephrostolithotomy: 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 endoscope so that large stones can be fragmented under direct vision before removal [29]. Smaller stones may be amenable to extraction without fragmentation. "The targeted stones should be successfully removed through the percutaneous access tract" [29]. The placement of multiple nephrostomy tracts and the use of flexible instruments may be necessary for complete removal of stone material [29].

II. INDICATIONS AND CONTRAINDICATIONS

A. Indications include, but are not limited to:

- 1. Relief of urinary obstruction [29]
 - a. Urosepsis or suspected infection
 - b. Acute renal failure
 - c. Intractable pain
- 2. Urinary diversion [29]
 - a. Hemorrhagic cystitis
 - b. Traumatic or iatrogenic ureteral injury
 - c. Inflammatory or malignant urinary fistula
- 3. Access for endourologic procedure [29]
 - a. Stone removal
 - b. Dilatation or stenting of a ureteral stricture
 - c. Endopyelotomy
 - d. Foreign body retrieval (eg, fractured or malpositioned stent)
 - e. Ureteral occlusion for urinary fistula

- f. Tumor fulguration
- g. Delivery of medications
- h. Biopsy of a urothelial lesion
- i. Cooling and warming pyeloperfusion
- 4. Diagnostic testing
 - a. Antegrade pyelography
 - b. Ureteral perfusion (Whitaker test)

The indications for percutaneous nephrostomy in renal transplants are largely the same as in native kidneys [29,30]. Occasionally, percutaneous nephrostomy drainage may be performed as a therapeutic trial to differentiate renal failures due to urinary obstruction from those related to rejection [29].

The threshold for these indications is 95%. "When <95% of procedures are performed for one of these indications, the department will review the process of patient selection" [29].

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 or bleeding diathesis (eg, thrombocytopenia, patient with liver or multisystem failure) [29]. Patients on oral anticoagulant therapy can safely undergo the procedure after correction of coagulation factors without increased risk of bleeding complications [31-33].
- 2. Severe uncorrectable hypertension. Patients with severe hypertension are at increased risk of bleeding complications [34,35].
- 3. Patients with severe hyperkalemia are at increased risk of complications related to moderate sedation or general anesthesia [34,35].
- 4. Terminally ill patient for whom death is imminent [29]. The mean life expectancy in patients with end-stage malignancies is rather short. In these patients, nephrostomy may not contribute to an enhanced quality of life, and it often necessitates multiple hospital admissions for complications related to the nephrostomy drain or ureteral stents [5,6,9].
- 5. Fluoroscopically guided procedures are best avoided in pregnancy, particularly in the first trimester. US-guided procedures are preferred in such patients, but limited fluoroscopy may be needed [36,37].

For the pregnant or potentially pregnant patient, see the <u>ACR-SPR Practice Parameter for Imaging Pregnant or Potentially Pregnant Patients with Ionizing Radiation</u> [38].

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

Core Privileging: This procedure is considered part of or amenable to image-guided core privileging.

A. Physician

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

 Certification in Interventional Radiology or Diagnostic Radiology by the American Board of Radiology (ABR), the American Osteopathic Board of Radiology (AOBR), the Royal College of Physicians and Surgeons of Canada, or the Collège des Médecins du Québec and has performed (with supervision) a sufficient number of PCN procedures to demonstrate competency as attested by the supervising physician(s).

C-

2. Completion of a residency program approved by the Accreditation Council for Graduate Medical Education (ACGME), the Royal College of Physicians and Surgeons of Canada (RCPSC), the Collège des Médecins du Québec, or the American Osteopathic Association (AOA) and has performed (with

supervision) a sufficient number of PCN procedures to demonstrate competency as attested by the supervising physician(s).

or

3. Physicians whose residency or fellowship training did not include the above may still be considered qualified to perform PCN procedures provided that the physician can demonstrate having performed (with supervision) a sufficient number of PCN procedures to demonstrate competency as attested by the supervising physician(s). 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 provided the following can be demonstrated. The physician must have supervised procedural experience and perform PCNs as primary operator with outcomes within the quality improvement thresholds of this practice parameter. Procedural experience should comply with state law, institutional policy, departmental policy, and local community practice.

and

- 4. Physicians meeting any of the qualifications in 1, 2, or 3 above must also have written substantiation that they are 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-sedation medications (if using moderate sedation), as well as recognition and treatment of adverse reactions and complications
 - d. Appropriate use and operation of 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, and radiation monitoring requirements as they apply to both patients and personnel
 - f. Pharmacology of contrast agents and intraprocedural medications, as well as 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
 The written substantiation should come from the chief of interventional radiology, the chair of
 the department of radiology, or designee at the institution in which the physician will be
 providing these services[1]. Substantiation could also come from a prior institution in which
 the physician provided the services, but only at the discretion of the chair of the department
 of radiology or designee who solicits the additional input.

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 practice parameter. Continued competence should depend on participation in a quality improvement program that monitors these rates. Consideration should be given to the physician's lifetime practice experience.

Continuing Medical Education

The physician's continuing education should be in accordance with the <u>ACR Practice</u> <u>Parameter for Continuing Medical Education (CME)</u> [39].

B. Non-Physician Radiology Provider (NPRP)

NPRPs are all Non-Physician Providers (eg, RRA, RPA, RA, PA, NP, ...) who assist with or participate in portions of the practice of a radiologist-led team (Radiologists = diagnostic, interventional, neurointerventional radiologists, radiation oncologists, and nuclear medicine physicians). The term "NPRP" does not include radiology, CT, US, NM MRI technologists, or radiation therapists who have specific training for radiology related tasks (eg, acquisition of images, operation of imaging and therapeutic equipment) that are not typically performed by radiologists.

The term 'radiologist-led team' is defined as a team supervised by a radiologist (ie, diagnostic, interventional, neurointerventional radiologist, radiation oncologist, and nuclear medicine physician) and consists of additional healthcare providers including RRAs, PAs, NPs, and other personnel critical to the provision of the highest quality of healthcare to patients. (ACR Resolution 8, adopted 2020).

Physician assistants and nurse practitioners can be valuable members of the interventional radiology team. These NPRPs can function as independent members of the team. See the <u>ACR-SIR-SNIS-SPR Practice</u> <u>Parameter for the Clinical Practice of Interventional Radiology</u> [40].

C. 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 (ACR) considers certification, continuing education, and experience to demonstrate that an individual is competent to practice one or more of the subfields in medical physics and to be a Qualified Medical Physicist. The ACR strongly recommends that the individual be certified in the appropriate subfield(s) by the American Board of Radiology (ABR), the Canadian College of Physics in Medicine, the American Board of Science in Nuclear Medicine (ABSNM), or the American Board of Medical Physics (ABMP).

A Qualified Medical Physicist should meet the <u>ACR Practice Parameter for Continuing Medical Education</u> (<u>CME</u>). [39]

The appropriate subfield of medical physics for this practice parameter is diagnostic medical physics (previous medical physics certification categories, including radiological physics, diagnostic radiological physics, and diagnostic imaging physics, are also available). (ACR Resolution 17, adopted in 1996 – revised in 2008, 2012, 2022, Resolution 41f)

D. Radiologic Technologist

The technologist, together with the physician and nursing personnel, should have responsibility for patient comfort, care, and safety. The technologist should be able to prepare and position[2] the patient for the percutaneous procedure. 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 statements[3] 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 PCN 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 and education and are recommended in monitoring the patient during the procedure.

[1]At institutions in which there is joint (dual) credentialing across departments doing like procedures, this substantiation of experience should be done by the chairs of both departments to ensure equity of experience among practitioners when their training backgrounds differ [43].

[2] The 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. (ACR Resolution 26, 1987 – revised in 2007, Resolution 12m)

*For the purposes of this parameter, "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.

[3] See the ACR-SPR Practice Parameter for the Use of Intravascular Contrast Media.

IV. SPECIFICATIONS AND PERFORMANCE OF THE PROCEUDRE

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 particular, children are at greater risk than adults of developing cancer associated with ionizing radiation because of longer life expectancy and radiosensitivity of organs and tissues [41]. In general, the facility should have the following:

- 1. A high-resolution flat panel detector or image intensifier and television chain with adequate shielding and collimation. Ability to perform complex angle (eg, 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. A proper transducer is required to direct and monitor needle placement. Ultrasound equipment ideally should provide Doppler capabilities to avoid vascular injury.
- 3. CT or flat detector cone-beam CT (CBCT) 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 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 the Patient Care section below, and there should be immediate access to emergency resuscitation equipment.
- 6. In accordance with "as low as reasonably possible" (ALARA) principles when treating children, the following should be available to further minimize radiation exposure:
 - a. Equipment with the ability to tightly collimate in concordance with the child's size and body habitus.
 - b. A radiation dose reduction package including pulsed fluoroscopy and last image hold capabilities is recommended.

B. Performance Guidelines

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

1. Tight collimation should be used.

- 2. Radiation dose should be minimized.
- 3. Radiation dose estimates should also be recorded in the patient's medical record [42]. In accordance with the ALARA principle, a radiation dose reduction package, including pulsed fluoroscopy and last image hold capabilities, is recommended.

C. Physiologic Monitoring and Resuscitation Equipment

- 1. Equipment should be present in the procedure suite to allow for monitoring the patient's heart rate, cardiac rhythm, and blood pressure. If the patient is to receive moderate sedation, the ACR-SIR
 Practice Parameter for Minimal and/or Moderate Sedation/Analgesia [43] should be followed.
- 2. Appropriate emergency equipment and medications must be immediately available to treat adverse reactions associated with administered medications and/or procedural complications. The equipment should be maintained and medications inventoried for drug expiration dates on a regular basis. The equipment, medications, and other emergency support must also be appropriate for the range of ages and sizes in the patient population.

D. Acute Care Support

If this procedure is performed in a freestanding center or similar setting, rapid transport or admission of patients to an acute care hospital should be available.

E. Surgical Support

Although complications of PCN only rarely require urgent surgery, it should be performed in an environment in which operative repair can be instituted promptly. Ideally, this would be an acute care hospital with adequate surgical, anesthesia, and ancillary support. Procedures done in low-volume hospitals and/or by inexperienced operators may be associated with higher complication rates [44-46].

F. Anesthesia Support

Although indications for general anesthesia during PCN are uncommon, certain patients may not tolerate the procedure with only moderate sedation. These patients may benefit from an anesthesia consult. These patients include, but are not limited to [43]:

- 1. Patients with chronic pain
- 2. Severe anxiety
- 3. Severe urosepsis requiring hemodynamic support
- 4. Patients treated by the anesthesiology or critical care service
- 5. Patients on mechanical ventilation
- 6. Patients who are ASA class IV and V
- 7. Pediatric patients

G. Patient Care

For additional information, see the <u>ACR-SIR-SNIS-SPR Practice Parameter for the Clinical Practice of Interventional Radiology</u> [40].

PCN can be performed on an outpatient basis in select patients. Patients who live alone or in whom the risk of complications is high (such as in those with urinary tract infection, 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 [47-49].

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 cardiac arrest related to the profound electrolyte abnormality.

1. Preprocedural 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 relevant 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 <u>ACR-SIR-SPR Practice Parameter on Informed Consent for Image-Guided Procedures</u> [50].

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 nonoperating room settings, including bedside procedures.
 - The organization should have processes and systems in place for reconciling differences in staff responses during the "time-out."
- a. 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.
- b. 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:
- c. Equipment needed for the procedure
- d. Patient monitoring

Protocols should be reviewed and updated periodically.

3. Postprocedural Care

- a. The operating physician or a qualified designee should evaluate the patient after the procedure, and these findings should be summarized in a progress note. If moderate sedation was administered prior to and during the procedure, complete recovery from sedation must be documented. The physician or designee should be available for continuing care during hospitalization and after discharge. The designee may be another physician, a physician's assistant, or a nurse (see the ACR-SIR Practice Parameter for Minimal and/or Moderate Sedation/Analgesia [43]). Postprocedural documentation should be in accordance with the ACR-SIR-SPR Practice Parameter for the Reporting and Archiving of Interventional Radiology Procedures [51].
- 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. Routine tube care, including follow-up evaluation at coordinated intervals, is recommended.

V. DOCUMENTATION

Reporting should be in accordance with the <u>ACR–SIR–SPR Practice Parameter for the Reporting and Archiving of Interventional Radiology Procedures</u> [51].

VI. RADIATION SAFETY IN IMAGING

Radiologists, medical physicists, non-physician radiology providers, radiologic technologists, and all supervising physicians have a responsibility for safety in the workplace by keeping radiation exposure to staff, and to society as a whole, "as low as reasonably achievable" (ALARA) and to assure that radiation doses to individual patients are appropriate, taking into account the possible risk from radiation exposure and the diagnostic image quality necessary to achieve the clinical objective. All personnel who work with ionizing radiation must understand the key principles of occupational and public radiation protection (justification, optimization of protection, application of dose constraints and limits) and the principles of proper management of radiation dose to patients (justification, optimization including the use of dose reference levels).

https://www-pub.iaea.org/MTCD/Publications/PDF/PUB1775 web.pdf

Nationally developed guidelines, such as the <u>ACR's Appropriateness Criteria</u>®, should be used to help choose the most appropriate imaging procedures to prevent unnecessary radiation exposure.

Facilities should have and adhere to policies and procedures that require ionizing radiation examination protocols (radiography, fluoroscopy, interventional radiology, CT) to vary according to diagnostic requirements and patient body habitus to optimize the relationship between appropriate radiation dose and adequate image quality. Automated dose reduction technologies available on imaging equipment should be used, except when inappropriate for a specific exam. If such technology is not available, appropriate manual techniques should be used.

Additional information regarding patient radiation safety in imaging is available from the following websites – Image Gently® for children (www.imagegently.org) and Image Wisely® for adults (www.imagewisely.org). These advocacy and awareness campaigns provide free educational materials for all stakeholders involved in imaging (patients, technologists, referring providers, medical physicists, and radiologists).

Radiation exposures or other dose indices should be periodically measured by a Qualified Medical Physicist in accordance with the applicable ACR Technical Standards. Monitoring or regular review of dose indices from patient imaging should be performed by comparing the facility's dose information with national benchmarks, such as the ACR Dose Index Registry and relevant publications relying on its data, applicable ACR Practice Parameters, NCRP Report No. 172, Reference Levels and Achievable Doses in Medical and Dental Imaging: Recommendations for the United States or the Conference of Radiation Control Program Director's National Evaluation of X-ray Trends; 2006, 2009, amended 2013, revised 2023 (Res. 2d).

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

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 appearing under the heading ACR Position Statement on Quality Control & Improvement, Safety, Infection Control, and Patient Education on the ACR website (https://www.acr.org/Advocacy-and-Economics/ACR-Position-Statements/Quality-Control-and-Improvement).

VIII. QUALITY IMPROVEMENT

Although practicing physicians should strive to achieve perfect outcomes (ie, 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 parameters, a threshold is a specific level of an indicator that should prompt a review [29].

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. There are relatively few reports of success rates and complication rates in children. The thresholds given below apply to adults [29].

A. Success Rates and Threshold[1]

The technical success rates for PCN may vary depending on the clinical scenario, as follows [29]:

Clinical Scenario Reported Success Threshold

Obstructed dilated system 96% to 100% 96%

(with or without small stones)

Obstructed system in renal transplant [54] 98% to 100% 98%

Nondilated collecting system [23,55-57] 82% to 96% 80%

(with or without small stones)

Complex stone disease, staghorn calculi 82% to 85% 80%

Overall, "the ability to render a patient stone-free depends on factors beyond the placement of an optimal PCN tract" [29]. 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, patient body habitus, 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 [29,46,58-60], 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" [29].

B. Complication Rates and Threshold[2] [29]

Complications can be stratified on the basis of outcome. "When minor and major complications are considered together, they occur in approximately 10% of patients" [29]. The specific complications and their thresholds are given below [29]. The departmental thresholds apply to all complications that occur in the department. "The individual thresholds apply to all the complications that each practitioner encounters" [29]. For the purposes of this document, the following thresholds are for major complications only. For further information, see the Proposal of a New Adverse Event Classification by the Society of Interventional Radiology Standards of Practice Committee.

Complication Reported Rate Threshold

Septic shock (fever, chills with 1% to 10% 4%

hypotension, requiring major

increase in level of care)

[1,25,29,45,55,57,61-65]

Septic shock (in setting of pyonephrosis) 7% to 9% 10%

[7-10,29]

Hemorrhage (requiring transfusion)

PCN alone 1% to 4% 4%

[1,4,23,25,28,29,44,55-57,62,65-68]

With PCNL 12% to 14% 15%

[14-17,29,69,70]

Vascular injury requiring embolization 0.1% to 1% 1%

or nephrectomy [25,29,55,56,64,65,71,72]

Bowel transgression [29,55,57,73] 0.2% to 0.5% 1%

Pleural complications (pneumothorax,

empyema, hydrothorax, hemothorax)

PCN alone [1,28,29,64,65] 0.1% to 0.6% 1%

with PCNL or endopyelotomy 8.7% to 12% 15%

(intercostal puncture or upper pole

access for endoscopic procedures) [29,74,75]

Individual threshold* complications that 1% to 7% 5%

result in unexpected transfer to intensive

care unit, emergency surgery, or delayed

discharge from hospital [1,25,29,45,56,57,64,66-68,76]

*Complications that result in unexpected transfer to an intensive care unit, emergency surgery, or delayed discharge from the hospital

Note: PCN = percutaneous nephrostomy

PCNL = percutaneous nephrostolithotomy

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 [29]. 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, for example, early in a quality improvement program [29].

[1] Reprinted with modifications from Journal of Vascular Interventional Radiology, Pabon-Ramos WM, Dariushnia SR, Walker TG, et al., Quality Improvement Guidelines for Percutaneous Nephrostomy, 410-414, 2016, with permission from Elsevier.

[2] Reprinted with modifications from Journal of Vascular Interventional Radiology, Pabon-Ramos WM, Dariushnia SR, Walker TG, et al., Quality Improvement Guidelines for Percutaneous Nephrostomy, 410-414, 2016, with permission from Elsevier.

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<u>Development Chronology for This Practice Parameter</u>

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