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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.

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ACR–ACNM–SNMMI–SPR PRACTICE PARAMETER FOR THE PERFORMANCE OF HEPATOBILIARY SCINTIGRAPHY

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 care¹. 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 in light of 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 the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document 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 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 sole purpose of this document is to assist practitioners in achieving this objective.

I. INTRODUCTION

This practice parameter has been revised collaboratively by the American College of Radiology (ACR), the American College of Nuclear Medicine (ACNM), the Society of Nuclear Medicine and Molecular Imaging (SNMMI), and the Society for Pediatric Radiology (SPR) to guide physicians performing hepatobiliary scintigraphy

¹ Iowa 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.

in adult and pediatric patients. Hepatobiliary scintigraphy involves the intravenous administration of a technetium-99m (Tc-99m)-labeled iminodiacetic acid (IDA)-related radiopharmaceutical and imaging with a gamma camera.

The goal of hepatobiliary scintigraphy is to identify abnormalities of the hepatobiliary system under defined physiologic conditions and, when indicated, with pharmacologic intervention. Tc-99m IDA compounds are extracted from the circulation by hepatocytes and are secreted into the biliary tree without conjugation. This uptake mechanism of Tc-99m-IDA compounds is useful in evaluation of bile formation and secretion, observation of the passage of bile through the biliary tree, gallbladder, and small intestine, as well as illustration of functioning hepatic tissue.

Hepatobiliary scintigraphy is a sensitive method for detecting a variety of conditions involving the liver and biliary system. Although certain patterns may suggest specific diseases (eg, nonvisualization of the gallbladder in patients with acute cholecystitis), correlation of abnormal patterns with clinical information, physiologic state of the patient, and other imaging techniques is imperative for the specific diagnosis. Adjunctive pharmaceuticals and quantitative assessment may enhance diagnostic performance.

Application of this practice parameter should be in accordance with the [ACR–SPR Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals](#) [1].

II. INDICATIONS

Clinical indications include, but are not limited to [2-4]:

1. Diagnosis of acute cholecystitis
2. Evaluation of functional gallbladder disorders (eg, gallbladder biliary dyskinesia and chronic acalculous cholecystitis) by calculation of stimulated gallbladder ejection fraction (GBEF)
3. Diagnosis of common bile duct obstruction versus hepatocellular dysfunction with cholestasis
4. Differential diagnosis of neonatal cholestasis (biliary atresia versus neonatal hepatitis)
5. Evaluation of biliary malformations, such as choledochal cysts [5]
6. Demonstration of postoperative or posttraumatic bile leak and biliary fistula
7. Evaluation of liver allograft function and complications
8. Assessment of patency of biliary-enteric bypass (eg, Kasai procedure)
9. Evaluation of postoperative abdominal syndromes (postcholecystectomy syndrome, sphincter of Oddi dysfunction, afferent loop syndrome)
10. Quantitative evaluation of hepatocellular function prior to partial hepatectomy
11. Differentiation of focal nodular hyperplasia from other hepatic neoplasms

The [ACR–SPR Practice Parameter for Imaging Pregnant or Potentially Pregnant Adolescents and Women with Ionizing Radiation](#) provides useful information on radiation risks to the fetus regardless of source. Information on managing pregnant or potentially pregnant patients undergoing nuclear medicine procedures is available from the International Commission on Radiological Protection [6-8].

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

See the [ACR–SPR Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals](#) [1].

IV. SPECIFICATIONS OF THE EXAMINATION

The written or electronic request for hepatobiliary scintigraphy 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. (ACR Resolution 35 adopted in 2006 – revised in 2016, Resolution 12-b)

A. Radiopharmaceutical

Tc-99m–labeled IDA analogues (mebrofenin or disofenin) are administered intravenously in activities of 3 to 5 mCi (111-185 MBq) for adults. A higher administered activity may be needed if the patient's bilirubin is elevated or hepatic function is compromised. In such instances, mebrofenin is preferred because of a higher hepatic extraction. Administered activity for children should be determined based on body weight and should be as low as reasonably achievable (ALARA) while maintaining diagnostic image quality. For children, the recommended administered activity is 0.05 mCi/kg (1.85 MBq/kg), with a minimum of 0.5 mCi (18.5 MBq). In evaluating neonates with hyperbilirubinemia, a minimum administered activity of 1.0 mCi (37 MBq) may be considered due to the need for delayed imaging for up to 24 hours.

B. Patient Preparation

Adults with a gallbladder should fast for a minimum of 4 hours and no more than 24 hours before radiopharmaceutical administration. Patients who are on tube feeds should have these held for 4 hours. Patients who are on total parenteral nutrition (TPN) may benefit from pretreatment with sincalide or a fatty meal to aid in gallbladder emptying before imaging. Patients without a gallbladder need not fast.

Opioid administration may have a profound effect on the gallbladder that must be considered. When scheduling the patient, the time and dosage of these medications should be noted. Delaying the examination for 4 half-lives (of the opioid) or more after the last opioid dose may be helpful. Administration of opioid (narcotic) analgesics before imaging does not preclude the examination but may delay the transit of radiopharmaceutical into the small bowel. Severe pain requiring control with frequent opiate administration may prevent optimal evaluation with hepatobiliary scintigraphy.

Children with a gallbladder should fast for 2 to 4 hours before radiopharmaceutical administration. Infants need not fast because the usual clinical indication is differentiating biliary atresia from neonatal hepatitis and visualization of the gallbladder is not critical for the diagnosis [9-11]. Clear liquids are permissible, only if necessary.

C. Pharmacologic Enhancement

A variety of pharmacologic or physiologic interventions may enhance the diagnostic utility of the examination. Appropriate precautions should be taken to detect and treat any adverse reactions promptly.

1. Pretreatment

a. Sincalide (cholecystokinin analogue)

In patients who have been fasting for longer than 24 hours or who are on TPN, filling of the gallbladder with viscous bile may cause nonvisualization of the gallbladder in a patient without acute cholecystitis. Sincalide (0.02 µg/kg up to 2.5 µg maximum) may be given 30 minutes before radiopharmaceutical administration to induce emptying of the gallbladder to facilitate subsequent visualization during imaging. It is infused over a minimum of 15 minutes to avoid untoward side effects, including flushing, vomiting, and acute abdominal pain. In patients who can take nothing by mouth, IV erythromycin may contract the gallbladder, but data on dose and reference values are limited.

b. Phenobarbital

In neonates with hyperbilirubinemia, oral administration of phenobarbital, a total dosage of 5 mg/kg/d (2 divided dosages) for a minimum of 3, preferably 5, days before the examination stimulates bile flow and improves the specificity for the diagnosis of biliary atresia. With this regimen, an optimal serum

phenobarbital level of 14 to 15 µg/mL should be achieved; checking the blood level before the examination is suggested.

Pretreatment with ursodeoxycholic acid is an alternative to phenobarbital. Unlike phenobarbital, ursodeoxycholic acid does not cause sedation and allows for shorter premedication. Recommended dose is 20 µg/kg/d every 12 hours for 2 to 3 days before the scan and continuing through completion of imaging in whom biliary atresia is suspected, pretreatment with ursodeoxycholic acid is an alternative to phenobarbital.

2. During Imaging

a. Morphine sulfate

When acute cholecystitis is suspected and the gallbladder is not visualized within 60 minutes after radiopharmaceutical administration despite visualization of the activity in small intestine, morphine sulfate (0.04 mg/kg, maximum of 4 mg) may be administered intravenously followed by additional imaging for at least 30 minutes [12]. Morphine sulfate increases sphincter of Oddi tone, raises common bile duct pressure, and, in the presence of a patent cystic duct, promotes gallbladder visualization. Before administration of morphine sulfate, it may be necessary to administer more radiopharmaceutical (half of the original administered activity) to ensure an adequate amount of hepatobiliary activity to divert into the gallbladder. An expedited protocol in which morphine sulfate administration is performed simultaneously with the radiopharmaceutical has also been used and could shorten the duration of the test [13]. Increased intracranial pressure in children, severe respiratory depression in patients who are not ventilated, and allergy are absolute contraindications to morphine sulfate. Documented acute pancreatitis is a relative contraindication.

b. Sincalide

GBEF may be calculated as part of the evaluation of functional acalculous biliary disorders (eg, functional biliary pain syndromes and gallbladder dyskinesia) using intravenous sincalide (0.01-0.04 µg/kg up to a maximum of 2.5 µg) infused over 30 to 60 minutes [14]. The infusion is usually performed after 60 minutes of dynamic or static imaging [4]. The examination requires activity in the gallbladder but not in the small intestine. Shorter infusions have been associated with greater variability in ejection fractions in normal patients, potentially resulting in more false-positives [15]; a higher frequency of side effects has been reported with infusions shorter than 3 minutes. Although various protocols exist, the 60-minute infusion results in the most consistent ejection fraction measurement [4,16]. A sincalide-stimulated gallbladder ejection of >38% is considered to be within normal range [16]

c. Fatty meal

In instances in which sincalide is not available, standardized fatty meals with established reference values that contain more than 10 g of fat may be used in those patients without gastroparesis [17-21]. In patients being evaluated for functional gallbladder disorders, a fatty meal should be administered only after the gallbladder is identified. A GBEF of <33% is considered abnormal following ingestion of 237 mL (8 oz) of a standardized fatty meal, and <44% is considered abnormal following ingestion of 250 mL of milk [22].

D. Imaging

In evaluating a liver allograft, an initial 60-second radionuclide angiogram centered anteriorly over the upper abdomen can help to assess perfusion to the allograft.

For all other indications, dynamic or serial static (60 seconds per frame) anterior or left anterior oblique projections are acquired over a period of 60 minutes or until both the gallbladder (if present) and the proximal small intestine are clearly identified. Left anterior oblique, right lateral, and posterior planar views can aid in problem solving. Ingestion of water with delayed dynamic or static acquisition may help distinguish duodenal from gallbladder activity. Dynamic imaging in the left anterior oblique (35° to 40°) projection during infusion of sincalide will typically facilitate separation of gallbladder from the duodenal activity in the majority of patients, providing the

most accurate gallbladder counts for GBEF calculation, but the angle may need to be adjusted in cases with atypical gallbladder position. Additional images may be acquired up to 24 hours for delayed gallbladder visualization (eg, chronic cholecystitis) or small intestinal activity (eg, cholestasis or neonatal hepatitis) or for detecting bile leaks (may include imaging of peritoneal drains). In patients in whom planar imaging is indeterminate, single-photon emission CT (SPECT) or SPECT/CT may differentiate small intestinal activity superimposed on the gallbladder versus nonvisualized gallbladder or a dilated cystic duct (cystic duct sign) due to cystic duct obstruction in acute cholecystitis. Furthermore, obtaining SPECT or SPECT/CT may obviate the need for delayed imaging and may increase diagnostic certainty [17,18]. SPECT or SPECT/CT could prove useful in imaging of a suspected bile leak by clarifying ambiguous findings, which may occur in patients with surgically altered anatomy [23,24].

Quantitative Assessment

To calculate GBEF, a time-activity curve using a region-of-interest drawn around the gallbladder is generated, and the GBEF is calculated using the following formula:

$$\text{GBEF} = \frac{\text{GB counts max} - \text{GB counts min}}{\text{GB counts max}} \times 100\%$$

All counts are corrected by the background

V. EQUIPMENT

A low-energy all-purpose, general all-purpose, or higher-resolution collimator should be used. Images should be obtained for 500,000 to 1,000,000 counts in a 256 or 512 matrix. Dynamic acquisition is obtained in a 128 or 256 matrix. When imaging children, an appropriate electronic acquisition zoom should be considered.

When SPECT or SPECT/CT is performed, the SPECT component should have adequate angular and count sampling; 360° of rotation with at least 32 stops for 2 detectors or 64 stops for a single detector at 20 seconds per stop are usually adequate. It is desirable to use the lowest possible dose for the CT component, especially in children.

Equipment performance monitoring should be in accordance with the [ACR–AAPM Technical Standard for Nuclear Medical Physics Performance Monitoring of Gamma Cameras](#) and the [ACR–AAPM Technical Standard for Medical Physics Performance Monitoring of SPECT-CT Equipment](#) [25,26].

VI. DOCUMENTATION

Reporting should be in accordance with the [ACR Practice Parameter for Communication of Diagnostic Imaging Findings](#) [27].

VII. RADIATION SAFETY

Radiologists, medical physicists, registered radiologist assistants, 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 that work with ionizing radiation must understand the key principles of occupational and public radiation protection (justification, optimization of protection and application of dose limits) and the principles of proper management of radiation dose to patients (justification, optimization and the use of dose reference levels)

http://www-pub.iaea.org/MTCD/Publications/PDF/Pub1578_web-57265295.pdf

Facilities and their responsible staff should consult with the radiation safety officer to ensure that there are policies and procedures for the safe handling and administration of radiopharmaceuticals and that they are adhered to in accordance with ALARA. These policies and procedures must comply with all applicable radiation safety regulations and conditions of licensure imposed by the Nuclear Regulatory Commission (NRC) and by state and/or

other regulatory agencies. Quantities of radiopharmaceuticals should be tailored to the individual patient by prescription or protocol

Nationally developed guidelines, such as the ACR's [Appropriateness Criteria®](#), should be used to help choose the most appropriate imaging procedures to prevent unwarranted radiation exposure.

Additional information regarding patient radiation safety in imaging is available at the Image Gently® for children (www.imagegently.org) and Image Wisely® for adults (www.imagewisely.org) websites. 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 measured and patient radiation dose estimated for representative examinations and types of patients by a Qualified Medical Physicist in accordance with the applicable ACR technical standards. Regular auditing of patient dose indices should be performed by comparing the facility's dose information with national benchmarks, such as the ACR Dose Index Registry, the 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. (ACR Resolution 17 adopted in 2006 – revised in 2009, 2013, Resolution 52).

VIII. 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>).

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Writing Committee – members represent their societies in the initial and final revision of this practice parameter

ACR

Esma A. Akin, MD, FACR, Chair
Justin G. Peacock, MD, PhD
Andrew T. Trout, MD

ACNM

Yang Lu, MD, PhD, FACNM
Mark Tulchinsky, MD, FACNM, FSNMMI, CCD
Hongming Zhuang, MD, PhD, FACNM

SNMMI

Gary L Dillehay, MD, FACNM, FACR, FSNMMI

SPR

Adina L. Alazraki, MD
Deepa R. Biyyam, MBBS
Neha Kwatra, MD

Committee on Practice Parameters and Technical Standards – Nuclear Medicine and Molecular Imaging
(ACR Committee responsible for sponsoring the draft through the process)

Munir V. Ghesani, MD, FACR, Co-Chair

Andrew Kaiser, MD

Committee on Practice Parameters and Technical Standards – Nuclear Medicine and Molecular Imaging
(ACR Committee responsible for sponsoring the draft through the process)

Rathan M. Subramaniam, MD, PhD, MPH, Co-Chair
Esma A. Akin, MD, FACR
Alexandru C. Bageac, MD, MBA
Twyla B. Bartel, DO, MBA
Elizabeth H. Dibble, MD
K. Elizabeth Hawk, MD, MS, PhD
Eric Hu, MD

Jeffrey S. Kempf, MD, FACR
Justin G. Peacock, MD, PhD
Syam P. Reddy, MD
Eric M. Rohren, MD, PhD
Levi Sokol, MD
Andrew T. Trout, MD

Committee on Practice Parameters – Pediatric Radiology

(ACR Committee responsible for sponsoring the draft through the process)

Terry L. Levin, MD, FACR, Chair
John B. Amodio, MD, FACR
Jesse Berman, MD
Tara M. Catanzano, MB, BCh
Harris L. Cohen, MD, FACR
Kassa Darge, MD, PhD
Dorothy L. Gilbertson-Dahdal, MD
Lauren P. Golding, MD
Safwan S. Halabi, MD
Jason Higgins, DO

Jane Sun Kim, MD
Jennifer A Knight, MD
Jessica Kurian, MD
Matthew P. Lungren, MD, MPH
Helen R. Nadel, MD
Erica Poletto, MD
Richard B. Towbin, MD, FACR
Andrew T. Trout, MD
Esben S. Vogelius, MD

Don C. Yoo, MD, FACR, Chair of the Commission Nuclear Medicine and Nuclear Medicine
Richard A. Barth, MD, FACR, Chair, Commission on Pediatric Radiology
David B. Larson, MD, MBA, Chair, Commission on Quality and Safety
Mary S. Newell, MD, FACR, Chair, Committee on Practice Parameters and Technical Standards

Comment Reconciliation Committee

Kurt A. Schoppe, MD, Chair
Jamaal Benjamin, MD, PhD, Co-Chair
Esma A. Akin, MD, FACR
Adina L. Alazraki, MD
Helena R. Balon, MD
Richard A. Barth, MD, FACR
Deepa R. Biyyam, MBBS
Gary L Dillehay, MD, FACNM, FACR, FSNMMI
Richard Duszak Jr., MD, FACR
Saeed Elojeimy, MD
James Galt, MD
Munir V. Ghesani, MD, FACR
Arnold Jacobson, MD
Ran Klein, MD

Amy Kotsenas, MD, FACR
Neha Kwatra, MD
David B. Larson, MD, MBA
Terry L. Levin, MD, FACR
Yang Lu, MD, PhD, FACNM
Mary S. Newell, MD, FACR
Justin G. Peacock, MD, PhD
Victor Seghers, MD
Rathan M. Subramaniam, MD, PhD, MPH
Andrew T. Trout, MD
Mark Tulchinsky, MD, FACNM, FSNMMI, CCD
Don C. Yoo, MD, FACR
Hongming Zhuang, MD, PhD, FACNM

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