ACR–SAR–SPR PRACTICE PARAMETER FOR THE PERFORMANCE OF MAGNETIC RESONANCE IMAGING (MRI) OF THE LIVER

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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.

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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.*

I. INTRODUCTION

Magnetic resonance imaging (MRI) of the liver is a proven and useful tool for the evaluation, assessment of severity, and follow-up of diseases of the liver. Although liver MRI is one of the most sensitive diagnostic tests for detection and characterization of hepatic lesions, findings may be misleading if not closely correlated with the results of previous imaging studies, clinical history, physical examination, or laboratory tests. Adherence to the following parameters will enhance the probability of accurately assessing such abnormalities.

II. INDICATIONS

Indications for MRI of the liver include, but are not limited to, the following:

1. Detection of focal hepatic lesions
2. Focal hepatic lesion characterization (eg, cyst, focal fat, hemangiomas, and vascular malformations), hepatocellular carcinoma (HCC), hepatoblastoma, metastasis, intrahepatic cholangiocarcinoma, focal nodular hyperplasia, and hepatic adenoma
3. Evaluation for known or suspected metastases, including preoperative mapping for liver resection
4. Evaluation of vascular patency, including Budd-Chiari and portal vein thrombosis
5. Evaluation and noninvasive quantification of iron, fat, and fibrosis in chronic liver disease, such as hemochromatosis, hemosiderosis, nonalcoholic steatohepatitis, (NASH) and hepatitis in adults and pediatric patients
6. Evaluation of cirrhotic liver and HCC surveillance
7. Clarification of findings from other imaging studies, laboratory abnormalities, or alternative imaging for contraindications to CT scans
8. 8. Staging of liver and biliary cancers, including assessment of vascular and biliary invasion
9. Evaluation of infection
10. Potential liver donor evaluation, liver resection evaluation, liver transplant evaluation, and evaluation of postsurgical complications
11. Evaluation of tumor response to treatment, eg, image-guided liver interventions/tumor ablation, chemoembolization, radioembolization, chemotherapy, radiotherapy, or surgery
12. Evaluation of known or suspected congenital abnormalities
13. Informing or guiding clinical decision making and treatment planning

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

See the ACR Practice Parameter for Performing and Interpreting Magnetic Resonance Imaging (MRI) [1].

IV. SPECIFICATIONS OF THE EXAMINATION

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

Documentation that satisfies medical necessity includes 1) signs and symptoms and/or 2) relevant history (including known diagnoses). The provision of 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)

The supervising physician must have adequate understanding of the indications, risks, and benefits of the examination as well as alternative imaging procedures. The physician must be familiar with potential hazards associated with MRI, including potential adverse reactions to contrast media. The physician should be familiar with relevant prior ancillary studies. The physician performing MRI interpretation must have a clear understanding

and knowledge of the relevant anatomy and pathophysiology.

The supervising physician must also understand the pulse sequences to be used and their effect on the appearance of the images, including the potential generation of image artifacts. It is also critical to understand the different contrast agents used for liver MRI as well as the basis for choosing between them. Standard imaging protocols may be established and varied on a case-by-case basis when necessary. These protocols should be reviewed and updated periodically.

A. Patient Selection

The physician responsible for the examination should supervise patient selection and preparation and be available for consultation by direct communication. Patients must be screened and interviewed prior to the examination to exclude individuals who may have contraindications to MRI, in which the risks may outweigh the benefits (see the ACR Guidance Document on MR Safe Practices 2020 [2]).

Certain indications require administration of intravenous (IV) contrast media. IV contrast administration should be performed using appropriate injection protocols and in accordance with the institution's policy on IV contrast utilization (see the ACR–SPR Practice Parameter for the Use of Intravascular Contrast Media [3]).

Patients suffering from anxiety or claustrophobia or who are unable to cooperate or suspend respiration, such as children, may require sedation or additional assistance. Administration of sedation may be necessary to achieve a diagnostic examination. If sedation is necessary, refer to the ACR–SIR Practice Parameter for Sedation/Analgesia [4] and the American Academy of Pediatrics (AAP) - American Academy of Pediatric Dentistry(AAPD): Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic procedures [5].

B. Facility Requirements

Appropriate emergency equipment and medications must be immediately available to treat adverse reactions associated with administered medications. The equipment and medications should be monitored for inventory and 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.

C. Examination Technique

A phased array surface coil should be used [6] unless precluded by patient body habitus or scan indication. The field of view should be selected so that it includes the entire liver without introducing undesirable artifacts.

An adequate MRI examination of the liver is typically performed in the axial plane, and coronal plane images are added as necessary to improve the visualization of the liver dome, vasculature, and bile ducts and to facilitate interventional and surgical planning.

An adequate MRI examination of the liver should include T2-weighted imaging, which may be performed with an accelerated fast spin-echo, single-shot accelerated fast spin-echo (FSE), or steady-state free precession sequence (in axial and/or coronal planes). T2-weighted images can be obtained using a breath-hold or non–breath-hold technique. When a non–breath-hold technique is used, every effort should be made to minimize the respiratory motion artifacts by using multiple signal averages and/or respiratory compensation or respiratory triggering, which could include bellows or navigator-triggered sequence. Other motion-correction strategies, including periodically rotated overlapping parallel lines, may be useful. For effective T2-weighting, an echo time (TE) between approximately 80 and 100 ms should be used at 1.5T and 70–100 ms at 3T. T2-weighted images are helpful to show abnormal increased fluid or inflammation in diseased tissue and fluid-containing lesions (eg, cysts, biliary hamartoma, hemangiomas, and vascular malformations) [7]. When using a 2-D technique, the slice thickness and interslice gap in one of the planes should not exceed 8 and 2 mm, respectively. Parallel MRI with suitable phased-array coils is often used to reduce scan time and increase spatial resolution. Fat suppression may be helpful to assess for fluid and inflammation and to improve image contrast dynamic range.

IV contrast enhancement with gadolinium chelates is critical for accurate diagnosis of various liver

pathologies [8]. Use of IV contrast should be strongly considered except when there is a) no IV access, b) history of prior allergic-type reaction to gadolinium chelates and the patient has not been premedicated prior to the study, c) contraindication to gadolinium chelates (such as pregnancy), d) known or suspected nephrogenic systemic fibrosis (NSF) or particular concerns regarding NSF risk that outweigh the benefits of a contrast-enhanced liver MR, or e) contrast is not felt to be necessary for the diagnosis in question [2,9,10]. In patients with a high risk of NSF in whom contrast is not used, an unenhanced MR could still be helpful. Long-term safety of gadolinium-based contrast agent (GBCA) administration is not yet established, especially in young infants. A cautious risk/benefit approach is desirable with avoidance of GBCA when feasible in young infants. When contrast administration is required, lower dosing and macrocyclic agents should be considered. Dynamic fat-suppressed MRI should be performed after bolus administration of a gadolinium chelate contrast agent. T1-weighted images should be acquired before gadolinium contrast injection as well as during late hepatic arterial, portal venous, and 2- to 5-minute delayed phases using a 2-D or 3-D technique [11,12]. The 3-D techniques are preferred. Methods to obtain late hepatic arterial phase include using a bolus timing technique, such as automated bolus detection algorithm or fluoroscopic triggering, or obtaining multiple consecutive arterial-phase data sets with higher temporal but lower spatial resolution. An optimal late arterial phase is characterized by the following:

- Hepatic artery and branches are fully enhanced
- Hepatic veins not yet enhanced by antegrade flow
- Portal vein is enhanced

Additional delayed images with delays greater than 2 to 5 minutes may help characterize certain lesions, such as HCC, hemangiomas, and vascular malformations, or intrahepatic cholangiocarcinomas [13-15]. Fat-suppressed 3-D T1-weighted gradient-echo images have quality comparable to that of conventional fat-suppressed 2-D gradient-echo images [16]. It is advantageous to acquire 3-D data sets using the smallest voxel dimensions possible to achieve the highest resolution practical in each axis. Minimizing slice thickness of a volumetric acquisition can reduce truncation artifacts in the axis of slice encoding, which can be a source of boundary artifacts at high-contrast borders. When using a 2-D technique, the slice thickness and interslice gap should not exceed 8 and 2 mm, respectively.

Hepatobiliary phase (HBP) images obtained between 45 minutes and 3 hours after the administration of gadobenate dimeglumine and approximately 20 minutes after the administration of gadoxetate disodium revealing retention of contrast within the lesion can confirm the diagnosis of focal nodular hyperplasia [18-20]. HBP images can also be used to detect and characterize malignant disease and assess its extent [21-23]. The use of hepatobiliary agents partially excreted in the biliary system, such as gadoxetate and gadobenate, can help delineate biliary anatomy [26-28]. When interpreting HBP images, it is important to ascertain the adequacy for diagnosis. For an adequate HBP image in patients without chronic liver disease, the liver parenchyma is unequivocally brighter than the intrahepatic blood vessels; otherwise, the HBP images are considered suboptimal. Poor enhancement of hepatic parenchyma may be seen in some patients with chronic liver disease. The use of hepatobiliary agents may not be advisable in patients with total bilirubin of greater than 2 mg/mL [24-26]. T2-weighted imaging of the biliary tree (Magnetic resonance cholangiopancreatography (MRCP) images) must be completed before contrast is excreted into bile ducts because gadolinium within the bile can shorten the T2 and result in the biliary tree not being visible on MRCP images. This can be prevented by obtaining MRCP images before or within 5 minutes after administration of gadoxetate or within several minutes after administering gadobenate dimeglumine. T2-weighted and diffusion-weighted images can be obtained after injection of gadoxetate disodium to improve time efficiency, and diffusion-weighted imaging (DWI) sequences may be delayed more than 5 minutes after HBP agents.

In-phase and out-of-phase chemical shift gradient-recalled echo T1-weighted imaging should be included for lesion characterization and for confirmation of hepatic steatosis and iron overload; these sequences should be obtained prior to the administration of IV contrast material [27]. Out-of-phase images can be helpful to assess for signal loss from fat in fat-containing lesions, such as hepatic adenomas and HCC. Every effort should be made to ensure that the out-of-phase TE is shorter than the in-phase TE. Note that in livers with simultaneous iron overload and steatosis, a potential pitfall exists in which in-phase and out-of-phase imaging may show no comparative signal loss (ie, signal loss due to steatosis on the out-of-phase image may be counterbalanced by signal loss due to iron overload on the in-phase image). Another pitfall may occur when in-phase images have a shorter TE than out-of-phase images. In these instances, signal loss on

the out-of-phase echo could be from iron overload, steatosis, or a combination of both. In addition, the TEs for the in-phase and out-of-phase images at 3T are half that at 1.5T, which needs to be accounted for when assessing for fat or iron. A number of techniques have been developed, tested, and validated for quantitative measurement of liver iron and fat content [28-32]. These methods have been commercialized by many MR vendors and are available clinically for quantitative measure of liver iron and fat. The current gold standard for fat quantification with MRI is proton density fat fraction (PDFF). PDFF is the proportion of mobile protons in liver tissue attributable to fat and thus is a noninvasive MR-based biomarker of liver triglyceride concentration.

3T imaging systems are more widely available. Potential advantages of 3T systems include an increased signal-to-noise ratio (SNR) [33] and an increased conspicuity of enhancement after administration of a gadolinium chelate contrast agent [34]. Potential disadvantages include decreased image contrast on T1-weighted images, increased predisposition to susceptibility artifact, increased chemical shift artifact, increased specific absorption rate, and signal inhomogeneity [35]. The latter can be partially compensated for by the use of radiofrequency (RF) cushions [36] and/or parallel transmit technology. In short, 3T imaging can offer substantial improvements in SNR and spatial resolution and/or decreases in imaging times, but sequence modifications are often required to maintain desired image contrast and reduce artifacts [37,38]. However, in patients with obesity or those with cirrhosis, 1.5T MRI may be considered because of the standing wave and dielectric artifacts seen on 3T MRI.

DWI has become commonly used for abdominal protocols [39-44]. The most common technique uses single-shot echo-planar imaging (SS-EPI). Breath-held, free breathing multiple-averaging, and respiratory-gated SS-EPI techniques can be used [45,46]. Parallel imaging can be used to decrease imaging time and has been shown to result in accurate apparent diffusion coefficient (ADC) values [47]. DWI has shown promising results in detection and characterization of focal liver lesions, in detection and staging of liver fibrosis, and appears to be at least a value-added adjunct sequence capable of revealing additional sites of disease in the abdomen [48,49]. The ability to depict areas of high cellularity can be helpful in hepatic lesion detection and in characterization in a noninvasive manner. DWI does not rely on IV gadolinium; therefore, its use is particularly attractive in patients who are unable to receive IV contrast agents. ADC maps can be generated to help differentiate between restricted diffusion and T2 shine-through. At least 2 b-values are obtained, including b = 20–50 s/mm^2 and b = 400 to 1,000 s/mm^2. However, overlap exists between ADC values of solid benign hepatocellular lesions, such as focal nodular hyperplasia (FNH) or hepatocellular adenoma (HCA) , and those of malignant lesions [40,43,50-56]. Thus, information provided by DWI needs to be interpreted in conjunction with lesion morphology and signal characteristics on other sequences. Moreover, ADC values are technique and scanner dependent; diagnostic cutoff values reported in the literature may not be applicable to other scanners. Techniques such as simultaneous multislice (SMS) technique may allow DWI to be performed in under one minute [57].

MR elastography (MRE) is a technique that enables measurement of liver stiffness. Published data over the last 5 years show that this method has high accuracy in discriminating different stages of liver fibrosis [58-62].

V. DOCUMENTATION

Reporting should be in accordance with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [63].

In patients at high risk for HCC, please refer to the Liver Imaging Reporting and Data System (LI-RADS) (http://www.acr.org/Quality-Safety/Resources/LIRADS) for additional guidance on reporting of MRI in this population.

Specific policies and procedures related to MRI safety should be in place with documentation that is updated annually and compiled under the supervision and direction of the supervising MRI physician. Guidelines should be provided that deal with potential hazards associated with MRI examination of the patient as well as to others in the immediate area [64-73]. Screening forms must also be provided to detect those patients who may be at risk for adverse events associated with the MRI examination [64-73].

VI. EQUIPMENT SPECIFICATIONS

Equipment monitoring should be in accordance with the ACR-AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Magnetic Resonance Imaging (MRI) Equipment [74].

The MRI equipment specifications and performance must meet all state and federal requirements. The requirements include, but are not limited to, specifications of maximum static magnetic strength, maximum rate of change of magnetic field strength (dB/dt), maximum RF power deposition (specific absorption rate), and maximum acoustic noise levels.

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 and 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).

Peer-reviewed literature pertaining to MR safety should be reviewed on a regular basis [4-13]

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*Parameters and standards are published annually with an effective date of October 1 in the year in which amended, revised, or approved by the ACR Council. For parameters and standards published before 1999, the effective date was January 1 following the year in which the parameter or standard was amended, revised, or approved by the ACR Council.

<u>Development Chronology for this Parameter</u>

2005 (Resolution 3)

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