ACR–AIUM–SRU PRACTICE PARAMETER FOR THE PERFORMANCE OF ULTRASOUND EVALUATION OF THE PROSTATE (AND SURROUNDING STRUCTURES)

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

The clinical aspects contained in specific sections of this practice parameter (Introduction, Indications, Specifications of the Examination, and Equipment Specifications) were developed collaboratively by the American College of Radiology (ACR), the American Institute of Ultrasound in Medicine (AIUM), and the Society of Radiologists in Ultrasound (SRU). Recommendations for Qualifications and Responsibilities of Personnel, Written Requests for the Examination, Documentation, and Quality Control and Improvement, Safety, Infection Control, and Patient Education vary among the three organizations and are addressed by each separately.

Ultrasound examination of the prostate and surrounding structures is used in the diagnosis of prostate cancer, benign prostatic enlargement, prostatitis, prostatic abscess, congenital anomalies, ejaculatory dysfunction, and male infertility as well as for the treatment of prostatic cancer, abscess, and benign prostatic enlargement [1]. Ultrasound-guided biopsy of the prostate is useful to evaluate patients with abnormal digital rectal examinations or an abnormal serum prostatic-specific antigen (PSA) level, azoospermia, low ejaculatory volume, and in patients requiring tissue diagnosis for further management.

Ultrasound findings may guide systematic biopsy of the prostate or guide a targeted biopsy approach, performed to supplement the standard systematic (nonlesion targeting) biopsy protocol to improve prostate biopsy cancer yield [2, 3]. Grayscale, color, spectral, and power Doppler imaging are insufficient to confirm or exclude the presence of prostate cancer and should not be used to obviate the need for prostate biopsy [4-6]. Although micro ultrasound elastography and contrast-enhanced ultrasound may provide superior detection of prostate cancer, these techniques are not sufficiently established to be considered routine at this time.

These practice parameters are intended to assist practitioners performing an ultrasound examination of the prostate. Ultrasound of the prostate and surrounding structures should be performed only when there is a valid medical reason, and the lowest possible ultrasonic exposure should be used to gain the necessary diagnostic information. Sometimes, an additional and/or specialized examination may be required. Although it is not possible to detect every abnormality, following this practice parameter will maximize the detection of prostate abnormalities.

II. INDICATIONS

Indications for prostate ultrasound include, but are not limited to, the following:

1. Guidance for biopsy for elevated PSA [7], after an abnormal digital rectal examination, following radiotherapy or other treatment to monitor patients with known prostate malignancy [8, 9], or for a suspicious prostate lesion detected on magnetic resonance imaging MRI. This includes the use of transrectal ultrasound (TRUS) biopsy as part of the TRUS/MRI fusion technique [6].
2. Assessment of prostate volume before medical, surgical, interventional radiology, or radiation therapy [8, 9] and calculations of PSA density [10]
3. Real-time guidance for the placement of brachytherapy seeds [11]
4. Real-time guidance for the placement of interstitial catheters for brachytherapy
5. Real-time guidance for the placement of periprostatic spacer material
6. Real-time guidance for the placement of fiducials for image-guided radiation therapy
7. Assessment of lower urinary tract symptoms [12]
8. Assessment of congenital anomalies [13]
9. Infertility including azoospermia and a low ejaculatory volume
10. Hematospermia
11. Evaluation for suspected recurrence in the prostatectomy bed in patients who have undergone prostatectomy
12. Ejaculatory dysfunction or painful ejaculation

III. QUALIFICATIONS AND RESPONSIBILITIES OF THE PHYSICIAN

See the ACR–SPR–SRU Practice Parameter for the Performance and Interpretation of Diagnostic Ultrasound Examinations [14].

IV. SPECIFICATIONS OF THE EXAMINATION

The written or electronic request for ultrasound of the prostate examination 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 following practice parameters describe the examination of the prostate and surrounding structures.

IV. SPECIFICATIONS OF THE EXAMINATION

A. Prostate

The transrectal approach to prostate ultrasound is the method of choice because the resulting image quality is superior to transabdominal and transperineal examinations. In patients for whom the transrectal approach is not possible, a transperineal ultrasound examination may be used to direct a biopsy procedure [15]. A transabdominal approach can estimate prostate size in some settings.

The prostate should be imaged in its entirety in at least two orthogonal planes, sagittal and axial or longitudinal and coronal, from the apex to the base of the gland. An estimated volume is determined from measurements in three orthogonal planes (volume = length × height × width × 0.52) [16, 17]. The volume of the prostate may be correlated with the PSA level. Alternatively, prostate planimetry, allows greater accuracy of prostate volume by accommodating individual variations in prostate shape [18].

The prostate gland should be evaluated for focal mass, echogenicity, symmetry, and continuity of margins. Color and power Doppler sonography may help detect areas of increased vascularity that can be used to select potential sites for biopsy [19]. Optionally, a cine loop survey scan obtained in longitudinal and transverse projections can be obtained and stored with the study. The periprostatic fat and neurovascular bundle can be evaluated for symmetry and echogenicity. Demonstration of any interruption in the normal fat plane along the anterior perirectal space may be particularly important to aid characterization of malignant lesions in the prostate and to evaluate periprostatic spread of cancer. The course of the prostatic urethra should be documented when possible, and asymmetry between left and right periurethral tissues and any effect on the base of the bladder should be noted.

IV. SPECIFICATIONS OF THE EXAMINATION

B. Seminal Vesicles, Vasa Deferentia, and Perirectal Space

The seminal vesicles should be evaluated for size, shape, position, symmetry, and echogenicity from their insertion into the prostate via the ejaculatory ducts to their cranial and lateral extents. Particular attention should be given to the expected tapering of the seminal vesicle as it joins the prostate. In patients being evaluated for infertility, the vasa deferentia must be evaluated. The presence and size of seminal vesicle, ejaculatory, Müllerian, or utricle cysts or evidence of seminal vesicle or ejaculatory duct obstruction should be noted.

V. DOCUMENTATION

Reporting should be in accordance with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [20].

Adequate documentation is essential for high-quality patient care. There should be a permanent record of the ultrasound examination and its interpretation. Comparison with previous relevant imaging studies may prove helpful. Images of all appropriate normal and abnormal areas should be recorded. The prostate should be measured in three planes. Any focal abnormality should also be measured. Images should be labeled with the patient identification, facility identification, examination date, and image orientation. An official interpretation (final report) of the ultrasound examination should be included in the patient's medical record. Retention of the ultrasound examination images should be consistent both with clinical need and with relevant legal and local health care facility requirements.

VI. EQUIPMENT SPECIFICATIONS

Equipment performance monitoring should be in accordance with the ACR-AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Real Time Ultrasound Equipment [21].

A. Equipment

Endorectal ultrasound of the prostate should be conducted with a transrectal (also termed endorectal) transducer using the highest clinically appropriate frequency (usually 6 MHz or higher), realizing that there is a trade-off between resolution and beam penetration. Both side-fire and end-fire transducers may be used. A lower-frequency transducer may be necessary for transabdominal and transperineal examinations, which may be performed with curvilinear or sector transducers.

An ultrasound-guided prostate biopsy can be performed with side-fire probe, end-fire probe, or biplanar or triplanar transducer configuration, acknowledging that transducer selection may vary with specific anatomic considerations [22].

B. Care of the Equipment

After ultrasound gel application, the transrectal probe must be covered by a disposable sheath before insertion. Additional gel should be applied after covering the probe with a disposable sheath to aid in comfort with probe insertion and optimizing the transducer to the target interface. The probe must be disinfected after examining and disposing of the sheath. The method of disinfection may vary by manufacturer recommendations and institutional practices. It is optimal to use a high-level disinfection protocol. Disposable accessory items used during the study must be discarded after each examination. Reusable accessory items should be processed or sterilized according to appropriate guidelines and procedures.

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

Transducers should be cleaned after each use [23].

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).

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*Practice parameters and technical 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 practice parameters and technical standards published before 1999, the effective date was January 1 following the year in which the practice parameter or technical standard was amended, revised, or approved by the ACR Council.

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