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

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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.

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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 for evaluating those patients who have abnormal digital rectal examinations or an abnormal serum prostatic-specific antigen (PSA) level, azoospermia, a low ejaculatory volume, and those in whom tissue diagnosis is needed for further management.

Ultrasound findings may be used to guide systematic biopsy of the prostate or guide a targeted biopsy approach, which is performed to supplement the standard systematic biopsy protocol in order to improve the positive cancer yield of prostate biopsy [2,3]. Conventional ultrasound techniques using grayscale Doppler, color Doppler, and power Doppler imaging are not sufficient to confirm or exclude the presence of prostate cancer and should not be used to preclude the performance of prostate biopsy [4-6]. Although newer techniques using elastography and contrast-enhanced ultrasound may provide superior detection of prostate cancer, these techniques are not sufficiently established to be included as routine imaging 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. In some cases, an additional and/or specialized examination may be necessary. Although it is not possible to detect every abnormality, following this practice parameter will maximize the detection of abnormalities of the prostate.

II. INDICATIONS

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

1. Guidance for biopsy in the presence of an abnormal digital rectal examination or elevated PSA [7] or a suspicious prostatic lesion detected on MR. This includes use of transrectal ultrasound (TRUS) biopsy as part of the TRUS/MRI fusion technique [6]
2. Assessment of prostate volume prior to medical, surgical, or radiation therapy [8,9] and to calculate PSA density [10]
3. Real-time guidance for the placement of brachytherapy seeds [11]
4. Real-time guidance for the placement of peri-prostatic spacer material
5. Assessment of lower urinary tract symptoms [12]
6. Assessment of congenital anomalies [13]
7. Infertility including azoospermia and a low ejaculatory volume
8. Hematospermia
9. Evaluation for suspected recurrence in the prostatectomy bed in patients who have undergone prostatectomy
10. 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 abdominal aorta 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.

A. Prostate

The transrectal approach to ultrasound of the prostate is the method of choice because the resulting image quality is superior to transabdominal or 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 be useful to obtain an estimate of 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 volume can be calculated using prostate planimetry, which allows greater accuracy by accommodating individual variations in prostate shape [18].

The gland should be evaluated for focal mass, echogenicity, symmetry, and continuity of margins. Color and power Doppler sonography may be helpful in detecting areas of increased vascularity that can be used to select potential sites for biopsy [19]. A cine loop survey scan, taken in both longitudinal and transverse projections, can be obtained and stored with the rest of the study. The periprostatic fat and neurovascular bundle should 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 for evaluation of periprostatic spread of cancer. The course of the prostatic urethra should be documented when possible, and asymmetry between left and right periurethral tissues as well as any effect on the base of the bladder should be noted.

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 normal 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 prior relevant imaging studies may prove helpful. Images of all appropriate areas, both normal and abnormal, 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.

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

The transrectal probe, after ultrasound gel application, must be covered by a disposable sheath prior to its insertion. Additional gel should be applied after covering the probe with a disposable sheath to aid in comfort with probe insertion and optimizing transducer to target interface. Following the examination and disposal of the sheath, the probe must be disinfected. 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

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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Collaborative Committee

Members represent their societies in the initial and final revision of this practice parameter.

ACR	AIUM	SRU
Vikram Dogra, MD, Chair	Pat Fulgham, MD, FACS	Carol B. Benson, MD, FACR
Christopher Fung, MD	Bruce Gilbert, MD, PhD, FACS	Ulrike M. Hamper, MD, MBA, FACR
Subramaniyan Ramanathan, MD	Harvey Nisenbaum, MD	
Marjorie W. Stein, MD, FACR		
Sadhna Verma, MD		

Committee on Practice Parameters – Ultrasound

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

Sheila Sheth, MD, FACR, Chair	Jamie Hui, MD
Marcela Böhm-Velez, MD, FACR	Stephen I. Johnson, MD
Kaleigh Burke, MD	David U. Kim, MD
Nirvikar Dahiya, MD, MBBS, FAIUM	Harriet J. Paltiel, MD
Christopher Fung, MD	Henrietta K. Rosenberg, MD, FACR
Helena Gabriel, MD	Jason M. Wagner, MD

Beverly G. Coleman, MD, FACR, Chair, Commission on Ultrasound

Jacqueline A. Bello, MD, FACR, Chair, Commission on Quality and Safety

Mary S. Newell, MD, FACR, Chair, Committee on Practice Parameters and Technical Standards

Comments Reconciliation Committee

Timothy Crummy, MD, FACR– Chair

Catherine Everett, MD, MBA, FACR– Vice Chair

Richard A. Barth, MD, FACR

Jacqueline Anne Bello, MD

Carol B. Benson, MD, FACR

Beverley Coleman, MD, FACR

Vikram S. Dogra, MD

Richard Duszak, Jr., MD

Pat Fulgham, MD

Christopher Fung, MD

Bruce Gilbert, MD

Ethan Halpern, MD

Ulrike M. Hamper, MD, MBA, FACR

Paul A. Hill, MD

Amy L. Kotsenas, MD

Mary S. Newell, MD

Harvey Nisenbaum, MD

Subramaniyan Ramanathan, MD

Erick M. Remer, MD

Sheila Sheth, MD, FACR

James Shwayder, MD

Marjorie W. Stein, MD, FACR

Sadhna Verma, MD

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