Advisory Statement A18/03

Clarification of consent requirements for transvaginal and transrectal ultrasound procedures

Purpose

To provide advice about the consent requirements for transvaginal and transrectal ultrasound procedures, through *Standard 2.2, Consumer Consent and Information Standard* of the Diagnostic Imaging Accreditation Scheme (DIAS).

Issue

The DIAS Advisory Committee has reviewed the requirements of Standard 2.2 with regard to the consent requirements for transvaginal and transrectal ultrasound procedures.

Standard 2.2 requires practices to obtain informed consent (verbal or written) from a patient, or substitute decision maker, prior to each diagnostic imaging procedure being performed. It is the responsibility of the practice to determine the level of risk associated with each diagnostic imaging procedure, for the individual patient, and to take this into account when deciding the appropriate form of consent for that patient.

For high risk and invasive procedures it is expected that written consent is obtained prior to the procedure being performed. However the DIAS Advisory Committee has considered whether transvaginal and transrectal ultrasound procedures should be considered invasive under Standard 2.2, thus requiring written consent regardless of the level of risk which applies for the procedure and the individual patient.

Requirements

Through Standard 2.2, prior to any diagnostic imaging procedure being performed (including transvaginal and transrectal ultrasound), patients must have access to information about the procedure and informed consent must be obtained from the patient, or substitute decision maker, with evidence of this consent recorded. For transvaginal and transrectal procedures, the DIAS Advisory Committee has further confirmed that

- Verbal informed consent is sufficient for low risk transvaginal and transrectal ultrasound procedures. However, practices may choose to obtain written consent for these procedures.
- Written consent must be obtained for all high risk procedures, such as those which use transvaginal or transrectal scanning as imaging guidance (e.g. for biopsies) or are otherwise determined by the practice to be high risk for the individual patient.

As evidence of compliance for the purposes of accreditation, practices must include in their Consumer Consent and Information Policy information about how individual patient risk is assessed and how informed consent is obtained and documented (for both verbal and written consent).

For more information

Practices should refer to the DIAS information resources for clarifying information about the evidentiary requirements for Standard 2.2, and contact their accreditor for further information and advice.

Diagnostic Imaging Accreditation Scheme Advisory Statement A18/03

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Information in this statement applies to	DIAS Accreditors Providers of Medicare-funded ultrasound services
Relevant standard	Standard 2.2, Consumer Information and Consent
Prepared by	Secretariat, Diagnostic Imaging Accreditation Scheme Advisory Committee
Contact details	Phone: 02 6289 8859 Email: dias@health.gov.au
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