**SOCIETÀ ITALIANA di RADIOLOGIA MEDICA**
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# THE SONOGRAPHIC MEDICAL ACT PERFORMED BY THE SPECIALIST IN DIAGNOSTIC IMAGING

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*Foreword*

*In 2007 SIRM published a statement on "The Radiological Medical Act" on the basis of legislation which is still in force (Decree of Law 26.5.2000).*

*While re-emphasising that our professional association does not engage in any union activity in favour of its members (SIRM Statute, www.sirm.org, art. 2), the Executive Committee of SIRM, under the chairmanship of Professor Rotondo, was prompted to issue a new statement on "The Sonographic Medical Act by the Specialist in Diagnostic Imaging" by several reasons. The widespread availability of ultrasonography, its low cost and lack of biological invasiveness combined with the mistaken belief that the technology is easy to use are just a few of the factors underlying the uncontrolled rise in requests for sonographic imaging services. It is important to note that the use of ultrasonography does not appear to be properly regulated in legal terms. Indeed, the practice of sonographic imaging is not limited and exclusive to the radiology specialist. However, sonographic imaging remains an exclusively medical act and a modality which, although at times by itself sufficient to complete the diagnostic process, is very often part of integrated imaging and therefore requires specific competencies in assessing radiographic, CT and MR images.*

*The interpretation of sonographic images for clinical purposes takes place during the examination itself, and is done by attributing clinical significance to the images being displayed in real time on the monitor. We therefore re-emphasise that the image documentation produced, a mere selection of the images visualised during the procedure, is by no means exhaustive and cannot allow any overall assessment of the examination nor, clearly, its reporting. The report therefore remains the exclusive competence and responsibility of the radiologist who carried out the examination.*

*SIRM therefore believes that, as an instrumental medical procedure which is performed dynamically and evaluated in real time, ultrasonography cannot be delegated to either non-physician health professionals or to physician specialists who have not personally performed the examination.*

*In order to obtain non-self-referential validation of the document, SIRM requested an evaluation by the Italian Society of Legal and Insurance Medicine (SIMLA). "The Sonographic Medical Act by the Specialist in Diagnostic Imaging", in the version published herein, was officially approved by the Executive Board of SIMLA on 29/9/2012.*

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**The Sonographic Medical Act Performed by the Specialist in Diagnostic Imaging**

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Ultrasound (US) examination is a real-time imaging modality. The present document discusses US performed for diagnostic and/or interventional purposes by physician specialists in diagnostic imaging who, thanks to the expertise acquired during postgraduate specialty training, rely on their knowledge of all the techniques and modalities available for identifying the patient's disease and use them according to their relative contribution.

In fact, since US is a dynamic real-time study, the clinical interpretation of US images occurs during the course of the examination, by attributing clinical significance to the images displayed on the screen. For this reason, the pictorial documentation produced with the report - only a selection of the images seen – can never be an exhaustive account of the US study, as it enables neither its complete visualization or its correct reporting. This is why the radiologist who has performed the US examination is the only person qualified to issue an accurate report for diagnostic and therapeutic purposes.

In diagnostic imaging, the sonographic medical act is no different from the radiological medical act, with the exception of issues related to radiation protection, which do not apply to US on account of its physical features.

Legal requirements of quality control of US equipment are similar to those in place for MRI devices as stated by Italian Law 542/1994, and for radiological devices as provided for by Law 187/2000. These requirements represent an essential component in the diagnostic imaging process and are needed to guarantee the quality of the medical services provided (ISTISAN 7-26, p. 31). Tests assessing the acceptance and condition of the equipment according to criteria stated in both the Italian and international associations' guidelines are carried out by technologists, who receive specific training during their studies to be able to perform all necessary procedures and tests. At the end of the quality control process, the radiologist must certify that the equipment is compliant (see Quality Control in Ultrasound, SIRM 2004).

The physician specialist in radiology is the person responsible for performing the medical procedure which can only be considered concluded when he or she considers it to be sufficiently exhaustive to produce a report, or requiring integration of a contrast-enhanced study or other imaging techniques.

Sonographic medical acts in diagnostic imaging consist of a series of interdependent steps characterized by the following operational and decisional features:

1) analysis of the prescribing physician's request with information on the clinical condition and/or direct assessment by the radiologist;
2) analysis of the patient's clinical presentation and medical history, with an assessment of any previous tests, in particular imaging tests;
3) justification for the proposed examination (or lack of justification, with possible suggestions for alternative investigations);
4) patient information regarding the procedure and purposes of the examination and formal acquisition of informed consent in the case of invasive US procedures and/or of use of a contrast agent;
5) performance of the examination following appropriateness criteria, which include:
    - assessment of suitability of the equipment
    - selection of the transducer (probes)
    - optimization of scanning parameters (emission frequency, amplification, focus, Doppler settings)
    - type of scans
    - adequate pictorial documentation;
6) interpretation/reporting;
7) communication/discussion with the referring physician.

As described, the sonographic medical act takes on a "special significance" in diagnostic imaging, as it is not limited to performing and reporting on the examination.
In fact, as happens with the radiological medical act, US studies require the professional contribution of a radiologist throughout the examination, and specifically from the time preceding the examination, all the operations required for acquiring the images, generation of the pictorial documentation, assessment of diagnostic completeness and/or of the need to suggest further imaging investigations (even those using ionizing radiation), and reporting and communication of the results to the patient and the prescribing physician.

**1)** Analysis of the prescribing physician's request with information on the clinical condition and/or direct assessment by the radiologist.

The radiologist must examine the request for the examination formulated by the prescribing physician. The request is a form (paper-based or electronic) indicating the clinical question, the type of US examination believed to be most suitable, and the degree of urgency (elective, urgency, emergency).
It should be noted that the prescribing physician's request is to be considered a "suggestion" and not a "legally binding order".
It is ultimately up to the radiologist to perform the investigations using the best techniques and modalities to solve each case, provided that he or she justifies the change; in fact, a nonjustified failure to perform the examination might constitute a failure to comply with a public duty.

**2)** Analysis of the patient's clinical presentation and medical history, with an assessment of any previous tests, in particular diagnostic imaging.

As a general rule, the radiologist must be provided with all the information enabling, on the basis of his specialized knowledge and skills, production of the most accurate description for each clinical case. However, where the prescribing physician provides insufficient information the radiologist must collect at least the basic information himself.
This allows the radiologist to:

a. decide whether the requested US examination is really adequate to yield the information necessary to answer the clinical question or if other examinations are equally or better indicated;
b. proactively assess the likelihood of success of US in investigating the presence of suspected disease.

In clinical practice, this information can be obtained from the request, from the assessment of previous studies, from the clinical examination, from the patient, and from the treating physician.

**3**) Justification for the proposed examination (or lack of justification, with possible suggestions for alternative investigations.

US examinations do not involve the use of ionizing radiation and are not included among the studies requiring justification as provided for by Law 187/2000.
Any medical act is considered to be "justified" if it influences the following diagnostic and therapeutic course, and if it implies greater benefit than harm.

Given that the physical properties make US harmless, the likelihood of it yielding useful data for patient management becomes the only criterion required to justify its use.
As a consequence, justification of its use is closely related to knowledge of the patient's clinical condition.
In fact, as with other imaging techniques, justification comes after an initial evaluation based on validated medical data and shared guidelines (reported in the Official Gazette of the Italian Republic of 2 May 2005); the clinical situation is then assessed, taking into account not only the patient's clinical presentation and condition, but also the available technological equipment, the operator's experience and skill, and the organizational environment.

**4)** Patient information and formal acquisition of consent in the case of invasive US procedures.

The Decree of the Ministry of Health of 1 September 1995, the Legislative Decree 230/95, the Decree of the Ministry of Health of 15 July 1997, and the Decree of the Ministry of Health of 18 March 1998 (Guidelines for the Setting up and Running of Ethics Committees) contain precise regulations concerning the acquisition of informed consent, which have been repeated in the Code of Medical Ethics (Chapter IV – Information and Consent).
On the basis of the above regulations, it is not accurate to state that in routine clinical practice consent must always necessarily be provided in writing. The consent, however, must always be adequately informed, that is, based on information provided by the physician.
In US imaging, informed consent may be:
- implicit or tacit consent, in cases routinely occurring in clinical practice, after adequate information has been provided;
- explicit, informed and documented consent (art. 32 of Chapter IV of the Code of Medical Ethics) in the case that the diagnostic and/or therapeutic act is associated with foreseeable risks (e.g., endocavitary or interventional US) or when the examination is performed with non-standard technique (e.g., contrast-enhanced US studies).

Acquisition of consent is the responsibility of the physician specialist who performs the examination.
It is generally accepted that routine diagnostic US examinations require the first type of informed consent, whereas the US examinations associated with a foreseeable risk require explicit consent.
In fact, even examinations performed with endocavitary transducers, although they have become routine in clinical practice, require explicit information for the patient, who will have to be told in advance about the imaging procedure and the sensations (including unpleasant ones) and risks associated with the examination. Similarly, contrast-enhanced US studies, although not carrying the same risks as other intravenous contrast agents administered during angiography, CT or MR imaging, are, although validated by clinical and scientific experience, nonstandard examinations requiring the patient's explicit consent.

**5)** Performance of the examination.

Performance of a US examination is an elaborate process, which involves constant interaction between the examiner, the US scanner and the patient throughout the examination.
Only continuous analysis of the data in real time can prompt the decision to continue with the acquisition of further information or to consider the examination completed.
Overall, US studies are similar to clinical examinations, the results of which are constantly related to knowledge of the anatomy, physiology and pathology of the region being examined.
Performance of the examination requires compliance with a correct procedure:

a. assessment of the suitability of the equipment.
   Based on the clinical question and the patient's clinical condition, radiologists can and must decide whether the examination can be accurately performed using the equipment available. US scanners are subject to dramatic technological advances and relatively rapid technological obsolescence. Additionally, in order to study the different anatomic regions, they require a wide range of transducers with different shapes and frequencies.

b. selection of the appropriate transducer and optimization of the scan

parameters (depth, amplification, focus, emission frequency).
Before starting the examination, the radiologist has to select the transducer (or transducers) and adjust the scanning parameters to the tissue and anatomic region to be imaged, so as to ensure that the images have adequate contrast and detail.

c. selection of scanning planes.
US is a dynamic examination, in which the radiologist not only places the transducer on predefined anatomic planes to visualize the given structures but, depending on what he sees, he constantly changes the position of the transducer, so as to have a more extensive or in-depth study. This way, he can, for example, follow any abnormality or anatomic variation or clarify a finding to identify normal or pathological aspects.
In addition to changing the scanning planes, the radiologist acts on other parameters, such as focus adjustment, selective amplification, field of view; furthermore, he can use dedicated scanning algorithms, such as harmonic imaging and/or scan-line interpolation.
In practice, then, no single study exists which, on account of the examination technique (scans performed or scanner settings) and the results obtained (visibility of organs in relation to possible patient bowel gas and breath-holding), is completely identical to a previous study. The study starts with predefined scans based on the clinical question and the patient's condition, but it is constantly changed on the basis of what is seen during the examination and the information provided by the patient. For this reason, it is not possible to define a strict technical protocol for US imaging examinations.
Lastly, during the examination the radiologist simultaneously evaluates image quality and completeness of the study; both of these parameters are influenced not only by the scanner, but also by patient characteristics (body habitus, bowel gas, position of organs, breath-holding capability, surgical dressings and scars, etc.), which are crucial to the diagnostic yield of the examination.

d. pictorial documentation.
Pictorial documentation of a US examination must correspond to the scanning method and to the clinical purposes; this, together

with the written report, is fundamental to the correctness of the professional service.
Images should indicate patient data, the place, date and hour of examination, the side and plane of the scan (whenever possible).
Radiologists must adhere to the minimum technical requirements for pictorial documentation contained in the SIRM paper “Standardization and optimization of US examinations”, and which define completeness of the documentation even for the purposes of future re-evaluation.
These requirements apply to all situations, that is, not only to positive examinations identifying pathological findings, but also to negative examinations, which must include documentation of the most representative anatomic sections of interest.

**6)** Interpretation/reporting.

Reporting of US examinations is mandatory, and it qualifies the professional service provided by the radiologist.
In fact, written reports represent the most significant phase of the sonographic medical act in that they include the description and interpretation of the images.
It is important to remember that US is a “dynamic”, real-time examination, which means that the study is mostly interpreted during the examination itself by attaching clinical significance to the images displayed on the screen.
In the final conclusions of the report, the case may be indicated as “closed”, with a final answer being given to the clinical question, or else it may be “open”, with comments and suggestions for further investigation.
At this point, it should be emphasized that examination correctness and completeness are sufficient to identify a good-quality professional service. Therefore, all situations that limit the scope of the examination due to anatomy, physiology or pathology must be reported.
A separate case is the performance of US examinations in urgency/emergency settings: unlike what happens with elective imaging, the sequence of the different stages may change to some extent, with reporting and communication necessarily taking place immediately in some cases.
Nonetheless, in the case of both standard and non-standard situations (e.g., emergency), the radiologist should always make sure that his conclusions are

transmitted to the referring/treating physician in a timely, precise and clear manner, so that the most appropriate treatment can be promptly initiated.

7) Communication/discussion with the referring physician.

Communication of the findings of a US examination is the last stage of the specialist service, and involves firstly the patient, who is personally concerned about his/her health, and secondly the treating physician, who is usually also the referrer.
In the case of out-patient services, the patient is the first recipient of the report; on the other hand, given that there is constant interaction between the radiologist and the patient during the examination it is natural that the patient be informed of the results, in full respect of the well-established ethical conventions. The results will then have to be communicated to the treating physician, following the typical procedure of any specific out-patient service.
In the case of in-patient services, where the findings are transmitted to a hospital physician, it is also advisable to explain the findings to the patient at the end of the examination, similarly to what happens with out-patients.
Special attention must be paid to patients with complex problems, so as to provide effective and accurate communication, in full respect of the individual patient's sensibility. Being available for consultation and discussion of the case with the treating physician is a fundamental step of communication in complex cases.

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