Review

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Enhancing patient safety and delineating professional liability in radiological procedures involving contrast medium administration

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Abstract

Radiological procedures requiring the administration of contrast medium are considered invasive procedures and require obtaining written consent from the patient. The risks of the procedure must be weighed against the risks of a potential missed diagnosis.

Understanding the clinical question of the exam is crucial. For evaluating the risks to which the patient is exposed, both in contrast procedures and in the case of magnetic field use, a thorough analysis of the patient's medical history is equally important. The radiologists' liability is intertwined with that of the prescribing physician. However, in the absence of a prescription, demonstrating that correct action was taken may be challenging. Therefore, our opinion is therefore that it is advisable to encourage both the radiologist and the prescribing physician to sign a form that includes the examination indication on one side and the execution technique of the radiological investigations on the other, especially when contrast medium injection is involved.
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Introduction

Every individual has the right to receive appropriate information regarding the nature and potential benefits of the diagnostic-therapeutic path they may undergo, as well as any alternative therapies, including the consequences of not continuing the diagnostic-therapeutic path. The information provided must be as comprehensive and clear as possible, to ensure the patient's free and informed choice, and thus their personal freedom, in accordance with Article 32, paragraph 2, and Article 13 of the Italian Republic Constitution. The medical profession, being legitimate as a profession regulated by Professional Registers and Orders, is lawful regardless of consent. However, in the absence of adequate consent from the patient, medical practice may violate the principle of self-determination, although it may not necessarily be harmful to health if the contested medical act, lacking valid consent, has not resulted in any negative effects on the person who underwent it. If, on the other hand, any service characterized by a defect of consent causes unjust harm, the person who committed the act will be obliged to compensate for the damage caused.

It is evident that the lawfulness of the medical act is perfected with the patient's consent; otherwise, its legitimacy, existing in theory, is not realized in the specific case. The lawfulness of the medical act is therefore subject to the requirement of obtaining consent from the patient, which must be expressed in writing or, in cases where pathology prevents obtaining written consent, stored digitally (Italian Law No. 219/2017 *Norms on informed consent and advance treatment directives*) (1)

Substantial jurisprudence now outlines the essential characteristics of consent to medical procedures:

a) **Simple and Personalized**: Information must be easily understandable, tailored to the patient's cultural background and level of comprehension, comprehensive enough to explain foreseeable risks, and truthful yet balanced.

b) **Explicit**: Consent must be clearly expressed, not implied, with written consent serving as solid proof and a useful reflection point for the patient.

c) **Free**: Consent must be given voluntarily, without coercion or deception.

d) **Personal**: Consent must be provided by the patient, except in exceptional circumstances.

e) **Informed and Expressed**: Consent must be based on complete information given to a patient capable of understanding and willing at the time it is given.

f) **Precautionary**: Consent should precede the medical intervention and can be revoked at any time.

g) **Specific**: Consent must pertain only to the proposed diagnostic or interventional procedure unless a state of necessity exists. For second-level radiological procedures involving hospitalized patients, the attending physician acts as a third party in the consent process.

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The aim of our paper is to evaluate the protocols and ethical considerations associated with radiological procedures involving the administration of contrast medium, which are deemed invasive and necessitate written patient consent. The research was conducted through a comprehensive review and analysis of existing guidelines, medical records, and literature pertaining to radiological practices, patient consent, and associated risks (2). The study aims to assess the effectiveness of the consent process, risk evaluation, and interdisciplinary collaboration between radiologists and prescribing physicians (3), through the clarification of the peculiarities and risks associated with radiological procedures (4).

Presentation of the Viewpoint

We propose that both the radiologist and the prescribing physician should be required to sign a consent form that details the indication for the examination and the technique of radiological investigation, particularly for procedures involving the administration of contrast medium. In fact, numerous studies have highlighted the risks associated with contrast medium administration, including allergic reactions, nephrotoxicity, and other adverse effects. Understanding the patient's medical history and the clinical question of the exam is crucial for mitigating these risks, and the role of informed consent is crucial for sharing responsibility for any potential harm among different specialists. According to the authors, clear documentation and shared responsibility could reduce medical errors and improve patient outcomes. A dual-signature consent form ensures that both the radiologist and the prescribing physician are fully aware of and agree on the necessity and safety of the procedure, promoting a collaborative approach to patient care.

Discussion

It is well know that the consent document for a radiological procedure includes the patient's personal data, medical history, diagnosis, clinical question, the proposed examination, and a concise yet detailed description of the procedure's risks. It also outlines the potential need for contrast medium and associated risks, adhering to data privacy regulations. Healthcare providers must ensure compliance with data protection laws. The facility is responsible for archiving the consent document: the head of the Clinical Unit oversees outpatient documents, while inpatient documents become part of the medical record (5). The medical history, diagnosis, and clinical question must be cited per Legislative Decree No. 101 of 2020, which implements Directive 2013/59/Euratom on ionizing radiation safety. Expected diagnostic benefits and risks must comply with Law No. 219/2017. Procedure indications must follow relevant guidelines (Law No. 21/2017). The decision to use contrast medium is based on diagnostic suspicion and expected benefits. Risks and benefits must be expressed according to Laws No. 219/2017 and Legislative Decree No. 101/2020, emphasizing safety and professional liability.

Radiological risk

Radiological procedures pose dual risks: exposure to ionizing radiation or magnetic fields and interaction with contrast media. Let us now analyze both elements.

1. Radiation exposure risk

The agreement, pursuant to Article 4 of Legislative Decree No. 281/1997, between the Minister of Health and the Regions and Autonomous Provinces of Trento and Bolzano on "Guidelines for Diagnostic Imaging" (Act No. 2113/2004), provides guidelines for radiological investigations. It emphasizes that ionizing radiation causes biological damage by affecting cellular DNA, with effects appearing shortly or long after exposure, depending on the dose and method. There are two types of effects: deterministic (e.g., erythema, skin ulcers, leukopenia, lens damage, fetal malformations) which occur above a threshold, and stochastic (e.g., neoplasms, hereditary effects) which are probabilistic and increase in likelihood with dose. Understanding these risks necessitates justifying radiological exams and optimizing their performance.

2. Contrast exposure risk

According to the Italian Ministry of Health (2018), a medicine includes substances with therapeutic or diagnostic properties that affect physiological functions. Contrast media, classified as medicines, can cause allergic and nephrotoxic effects. The Italian Society of Medical Radiology (SIRM) (6) states that contrast-enhanced exams are invasive and risky, requiring informed consent. Historically, guidelines recommended having an anesthesiologist present, pre-procedure tests, and emergency drugs ready [Ministry of Health Circular prot.900 VI/AA.AG/642 of 17.09.97]. The radiologist's responsibility has since increased, particularly in managing contrast media injections and adverse reactions. The primary contraindication for contrast use is the lack of clinical justification, as per the 2009 SIRM-SIAARTI-SIN-AINR document.

In contrast to other medical fields, where the physician performing an invasive procedure obtains patient consent based on their diagnosis (7), the radiologist's role is different. The radiologist makes the diagnosis based on a procedure requested due to diagnostic suspicion. They are not responsible for, nor do they share, the diagnostic suspicion formulated by another healthcare professional, as this is outside their expertise(8). Once the diagnostic question is posed, the radiologist uses the most appropriate method to make a diagnosis, possibly analyzing anamnestic elements (Legislative Decree 101/2020). This must be done with suitable technical precautions. The justification for the investigation is the responsibility of the prescribing physician, who collaborates with the radiologist on the diagnostic question. The radiologist is responsible for selecting the appropriate methodology and conducting the examination, thus being accountable for risks associated with the chosen method, such as exposure to ionizing radiation or magnetic fields. Risk analysis in medicine is tied to the risk/benefit ratio, emphasizing the crucial role of the prescribing physician.

They must weigh the procedure's risks against the risk of missing a diagnosis based on the clinical suspicion.

Consequently, the figures involved in the process leading to a valid informed consent for the radiological procedure are three:

- the Patient, holder of the right to self-determination in the context of healthcare treatments, except in specific cases;
- the treating physician, responsible for formulating the diagnostic question based on the clinical suspicion;
- the Radiologist, responsible for conducting the radiological investigation.

The requesting physician formulates the diagnostic hypothesis and orders the appropriate investigation. The radiologist collaborates with the physician to select the best diagnostic approach while minimizing radiation dose. The radiologist assesses the request based on clinical data and expertise, and may suggest modifications or alternative methods as needed (9-11).

The radiologist is responsible for optimizing the investigation and managing radiation exposure. They also decide on the use of contrast media, considering risks and benefits according to Article 159 of Legislative Decree 101/2020. This decision involves evaluating potential adverse effects like allergic reactions or nephrotoxicity.

Accurate medical history from the treating physician and patient is essential for the radiologist's assessment. Both the radiologist and the referring physician must balance the diagnostic benefits against radiation and contrast medium risks (12,13). The radiologist makes the final decision on contrast medium administration, often consulting with the treating physician. The actual injection is performed by technical or nursing staff, with detailed documentation in the Radiology Information System (RIS) or the patient's medical chart. For hospitalized patients, formal consent procedures may involve the physician overseeing the hospitalization.

Specificity of access in MRI

Consent for MRI exams, similar to contrast-enhanced procedures, involves ensuring safety and accuracy. Patients must confirm the absence of pacemakers and metallic objects before entering the MRI room. Outpatients sign consent forms along with medical history questionnaires, indicating any intracorporeal devices. For hospitalized patients, their information is verified by both the patient and the attending physician, who also signs the consent form. Radiologists are responsible for assessing MRI safety based on the medical history questionnaires. Clarifying the roles of prescribing physicians and radiologists is crucial (14-16). The documentation of professional activities varies for inpatients and outpatients. For hospitalized patients, consent forms include signatures from the patient, the attending physician, the requesting ward physician, and the radiologist. Outpatient requests link the activities of prescribing physicians to the exam, although archival processes differ. Four combinations of responsibility division between prescribing physicians and radiologists can be identified:

a) Hospitalized patient: The prescribing physician formulates the clinical question. Both the clinical physician and the radiologist share responsibility for optimizing the examination. The radiologist conducts and reports the radiological examination, while the clinical physician is responsible for the medical history.
b) Hospitalized patient: The prescribing physician formulates the clinical question. The radiologist alone optimizes, conducts, and reports the examination. The clinical physician is responsible for the medical history.
c) Outpatient: The prescribing physician formulates the clinical question. Both the clinical physician and the radiologist share responsibility for optimizing the examination. The radiologist conducts and reports the radiological examination and is also responsible for the medical history.
d) Outpatient: The prescribing physician formulates the clinical question. The radiologist alone optimizes, conducts, and reports the examination, as well as handles the medical history.

The Laws in Europe

Italy

The legislative novelties introduced in the field of standardized radiological procedures, as outlined in the "Guidelines for procedures related to clinically tested radiological practices" (Article 6, Legislative Decree No. 187/2000) published in the Official Gazette No. 261 on November 9, 2015, define situations of autonomy for the clinical physician, even in the radiological domain, both in emergency conditions and in cases of standardized radiographic diagnostics: "If the service is provided urgently in a hospital emergency department located in a remote area or in a primary care facility where no radiologist is present, the attending physician in the emergency department or the specialist present in the facility shall, after collecting clinical history and consent, prescribe or perform the necessary and appropriate complementary imaging diagnostics. The absence of a radiological report, not provided for in the case of radiological activity complementary to specialist activity, requires the preservation of the examination record. Alternatively, if appropriate, the radiologist may be involved at the time of the request, reachable either physically or through telemedicine, to conduct the radiological investigation".

Furthermore, "The radiologist, in collaboration with the Medical Radiation Technologist (MRT) and the Medical Physicist, in agreement with the Health Directorate of the facility, shall preliminarily identify standardized radiological services (standard practices) that can be carried out at the same facility, for which only the evaluation of the individual justification made by the prescribing ward physician at the time of the request is deemed sufficient (17,18). These services can be conducted by the MRT without the need for the radiologist's presence in the radiology room, subject to verification by the MRT of the requester's request compliance with predetermined protocols approved by the Health Directorate of the facility". The professional relationship and respective professional responsibility of the radiologist

and prescribing physician may be evolving, particularly in those areas within the national territory where the presence of radiologists is scarce.

We can compare Italy with other European countries regarding informed consent collection for medical-radiological procedures; we aim to briefly cite France and Sweden as representatives of Central and Northern Europe.

France

In France, the collection of informed consent for medical-radiological procedures is regulated by the Public Health Code (Code de la Santé Publique). The main provisions are:

1. **Comprehensive Information**: According to Article L1111-2 of the Public Health Code, the patient must be clearly and comprehensively informed about the benefits, risks, alternatives, and consequences of the procedure (19).
2. **Written Consent**: For procedures that entail significant risks, written consent is required. Article L1111-4 stipulates that the consent must be free and informed, with the patient signing a consent form (20).
3. **Contraindications Verification**: It is confirmed that the patient has no contraindications, such as metallic devices incompatible with MRI.
4. **Roles of Professionals**: Consent is obtained by the prescribing physician, but the radiologist also has the responsibility to verify and confirm the patient's suitability for the procedure.

Sweden

In Sweden, the collection of informed consent is governed by the Health and Medical Services Act (Hälso- och sjukvårdslagen, HSL). The main provisions include:

1. **Transparent Information**: According to Chapter 3, § 1 of the HSL, patients must receive all relevant information regarding the risks, benefits, and alternatives of medical procedures.
2. **Verbal or Written Consent**: Consent must be obtained verbally for standard procedures, but for higher-risk procedures, such as radiological ones, written consent is preferred.
3. **Documentation and Archiving**: Informed consent must be carefully documented in the patient's medical records. Local laws may specify additional documentation requirements.
4. **Verification and Responsibility**: Before the radiological examination, medical staff verify that the patient has no contraindications. The physician performing the procedure is responsible for confirming that consent has been obtained and documented.

These guidelines ensure that patients are adequately informed and that their consent is obtained and documented in compliance with national regulations (21).

In both countries, France and Sweden, informed consent is not the sole responsibility of the prescribing physician. The radiologist plays a crucial role in verifying the information and the patient's suitability for the procedure, often also participating in signing the consent form.

Our question is therefore: Why shouldn't we implement a similar process in Italy?

Interdisciplinary Collaboration

Previously, we mentioned the importance of interdisciplinary collaboration. Therefore, let's outline some practical insights and recommendations on how this can be effectively implemented in clinical settings.

1. **Enhance Communication Channels**
   Regular Meetings: Schedule regular interdisciplinary meetings between radiologists and prescribing physicians to discuss complex cases and review ongoing investigations.
   Clear Documentation: Ensure that diagnostic suspicions and clinical questions are clearly documented in the patient's record. This documentation should be easily accessible to all relevant healthcare providers.
2. **Improve Medical History Collection**
   Thorough History Taking: Implement standardized protocols for collecting comprehensive medical histories from patients. Encourage treating physicians to include relevant details that could impact the radiological examination.
   Patient Interviews: Radiologists can occasionally conduct brief interviews with patients or consult the treating physician for clarification on ambiguous or incomplete medical histories.
3. **Collaborative Decision-Making**
   Consultation Process: Develop a structured process for radiologists to consult with prescribing physicians when there is uncertainty about the appropriateness of an investigation or the potential need for alternative tests.
   Case Review Systems: Use case review systems where complex cases are discussed in detail, enabling collaborative decision-making on the best investigative approach.
4. **Optimize Radiation and Contrast Use**
   Protocols and Guidelines: Establish and regularly update protocols and guidelines to minimize radiation exposure and optimize the use of contrast media. Ensure these guidelines are based on current best practices and evidence.
   Dose Management Tools: Implement advanced dose management tools and software that help radiologists select the appropriate dose based on the specific clinical scenario and patient characteristics.
5. **Training and Education**
   Joint Training: Offer joint training sessions for radiologists and prescribing physicians on the principles of diagnostic imaging, risk management, and dose optimization.
   Continuous Education: Encourage ongoing education for all staff involved in diagnostic imaging to keep up with the latest techniques and technologies that improve examination quality and safety.
6. **Feedback Mechanism**
   Quality Assurance Programs: Develop quality assurance programs that include regular audits of diagnostic investigations and their outcomes. Use feedback to continuously improve the process.
   Patient Outcome Tracking: Track patient outcomes related to diagnostic imaging to evaluate the effectiveness of the chosen investigation and adjust practices as needed.

By integrating these strategies into clinical practice, healthcare teams can enhance the effectiveness of diagnostic investigations, optimize patient safety, and ensure that examinations are both appropriate and well-justified.

Conclusions

Radiological medical procedure cannot be abstractly assessed in its entirety, but every evaluation must start from a specific case. In the specific case for which each person may be called upon to respond, the traceability of a valid informed consent form, along with its signature by a specialist physician or the attending physician, is encouraged both in inpatient and outpatient settings. Moreover, the implementation of a dual-signature consent form for radiological procedures involving contrast medium is a practical and effective measure to enhance patient safety and professional accountability. By ensuring that both the radiologist and the prescribing physician are fully engaged and accountable, this approach minimizes risks and promotes high standards of care in radiological practices. Future research should explore the impact of this practice on patient outcomes and procedural efficiency, and further refine guidelines to support its widespread adoption. In our opinion, the approach to radiological procedures could change radically. In this manuscript we did not consider how artificial intelligence (22- 26) could alter the way radiologists work and their responsibilities, nor how the presence of new technologies will influence the procedures for obtaining informed consent. Our work also aims to contribute to the discussion in this still little-known and utilized field in the medical context.

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