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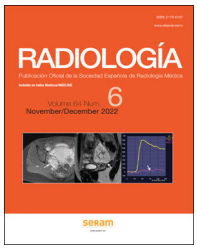

UPDATE IN RADIOLOGY

The legal regulation of artificial intelligence in the European Union: A practical guide for radiologists

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Abstract The European Union is taking the lead globally on the regulation of Artificial Intelligence (AI) and developing important legislation, namely the AI Act. The purpose of this article is to describe this regulation and examine three implications that will affect radiologists. In relation to the' risk approach', AI applications in radiology will be classified as high risk, thus necessitating compliance with a series of requirements and obligations. Secondly,' effective radiologist supervision' involves establishing supervision-automation levels, defining an appropriate degree of authority, and determining how AI recommendations will be documented in the radiological report. Finally, this article examines the different forms of' legal liability' that radiologists may incur in the event of a diagnostic error made by combined radiologist-artificial intelligence.

PALABRAS CLAVE
Radiología;
Diagnóstico por imagen;
Inteligencia artificial;
Algoritmos;
Unión Europea;
Responsabilidad legal;
Regulación gubernamental

La regulación legal de la inteligencia artificial en la Unión Europea: guía práctica para radiólogos

Resumen La Unión Europea, está liderando a nivel global la regulación legal de la Inteligencia Artificial (IA) y desarrollando una importante actividad legislativa; entre la que destaca la Ley de IA. El propósito de este artículo es dar a conocer esta normativa y analizar tres implicaciones prácticas que van a tener que gestionar los radiólogos. En relación al ''enfoque de riesgos'', las aplicaciones de IA en radiología van a ser clasificadas como de alto riesgo, lo cual conlleva el cumplimiento de una serie de requisitos y obligaciones. En segundo lugar, la ''supervisión efectiva del radiólogo'' implica establecer niveles de supervisión- automatización, su grado de autoridad y, definir cómo se van a documentar las recomendaciones de la IA en el informe

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radiológico. Por último, se examinan las formas de ''responsabilidad legal'' en las que puede incurrir el radiólogo en el supuesto de que el binomio radiólogo-inteligencia artificial cometa un error diagnóstico.

Introduction

The first article to feature an application of artificial intelligence (AI) in radiology was published in 1990, where it was used for the diagnosis of neonatal chest radiographs.[1] However, after four decades marked by long ''AI winters'',[2] we are now entering a period of rapid transition as we move away from the experimental research stage to practical implementation.[3] At present, there are 127 AI radiology products authorised across the European Union (EU) that bear the CE conformity mark.[4]

In the last five years, radiologists have found themselves, as described in *Alice behind the Looking Glass*, facing a new and surprising world,[5] in which they are learning and adding to dozens of new terms and concepts,[6] and incorporating AI not only for diagnostic purposes, but also for many non-diagnostic tasks and activities throughout the radiology process,[7] in radiomics[8] and in imaging biobanks.[9]

There is no doubt that AI is a disruptive technology that will unleash rapid and substantial changes throughout the radiology process and to the way that radiologists work. This will mean facing technical, training, professional, employment, social, ethical and legal challenges. The latter generate uncertainty for both patients and radiologists,[10] and the legal risks derived from the use of AI are a source of concern second only to those related to patient safety.[11] Regulation of AI systems is currently being debated and developed, no case law exists on the matter, and moreover, the impact of liability claims for harm caused to patients as a result of AI use is an issue that has not yet been resolved.[12]

The EU is taking the lead globally in the legal regulation of AI, following a strategy that is grounded in two major objectives.[13]

1 Achieve an 'ecosystem of excellence' that provides resources for research and innovation and that accelerates the adoption of AI-based solutions.
2 Establish a 'trust-based approach' that guarantees a safe, ethical process and respects the fundamental rights of individuals.

To this end, EU institutions are developing important legislation: the most relevant legislation[13–22] applied to radiology is presented in Table 1. The leading piece of legislation is the forthcoming 'Artificial Intelligence Act'.[14]

The main objective of this paper is to set out the basic principles and legal obligations as established in EU regulation. The other objectives are to examine the application of the concept of oversight in the radiologist's daily practice, to analyse the liability held by the radiologist in the diagnostic process and to learn how to manage the legal risks of AI.

Proposed regulation on artificial intelligence: the Artificial Intelligence Act

The EU AI Act[14] was presented by the European Commission (EC) in April 2021 and has a twofold objective: to guarantee that high safety requirements are met in the application of AI and to prevent harm and damage to users. In December 2022, the European Council set out its provisional position on the proposal, and laid the foundations for pre-negotiation talks with the European Parliament (EP).[15] On 14 June 2023, the EP approved the law, incorporating 779 amendments.[16]

The legislative process is currently in its final phase and is expected to be completed by December 2023. Until it is finalised and adopted, the text may be subject to changes. However, the essential practical elements that apply to radiology, and which are described below (risk-based approach, human oversight and liability) have not changed since 2021 and no substantial changes are expected.[23,24]

Legal definition of artificial intelligence

The EU AI Act defines an 'artificial intelligence system', as: 'a machine-based system that is designed to operate with varying levels of autonomy and that can, for explicit or implicit objectives, generate outputs such as predictions, recommendations, or decisions that influence physical or virtual environments'.[16]

General requirements for artificial intelligence systems (AIS) in radiology

The following general requirements are all of equal importance, are interrelated and should be implemented and evaluated throughout the AIS lifecycle (Fig.1).[16]

Human agency and oversight

AI systems should be developed and used as a 'tool' to serve patients, should respect patient dignity and personal autonomy, and should function in a way that can be appropriately controlled and overseen by radiologists.[16]

Table 1 Relevant European Union (EU) regulation.

Date	Body	Document	Comments
Artificial Intelligence (AI) Act (White paper, guidelines and standards)			
19-02-2020	European Commission	- White paper on AI: a European approach to excellence and trust[13]	- Develops the principles of excellence and trust - Forms the basis for the AI Act - First document in the world of this type
21-04-2021	European Commission	- Proposed regulation on AI. AI Act[14]	- First AI law in the world
06-12-2022	EU Council	- Proposed regulation on AI. AI Act. General guidance (6 December 2022)[15]	- Establishes the EU Council's provisional position on the AI Act proposal - - Constitutes the foundation for pre-negotiation talks with the European Parliament
14-06-2023	European Parliament	- Amendments approved by the European Parliament on 14 June 2023 on the proposal for a regulation of the European Parliament and Council, through which harmonised standards related to AI are established (AI Act).[16]	- European Parliament approved 779 amendments to the AI Act - Some of the amendments substantially modify the AI Act
08-04-2019	European Commission	- Guidelines for trustworthy AI from the high-level expert group on artificial intelligence: building trust in human-centric artificial intelligence[17]	- Concept of trustworthy AI, based on seven key requirements: 1. Human agency and oversight; 2. Technical robustness and safety; 3. Privacy and data governance; 4. Transparency; 5. Diversity, non-discrimination and fairness; 6. Societal and environmental; 7. Accountability.
17-07-2020	European Commission	- Guidelines for trustworthy AI from the high-level expert group on artificial intelligence. List to support self-assessment of trustworthy AI[18]	- Proposes a list to verify the seven key requirements from the document: 'Building trust in human-centric artificial intelligence'[17]
AI civil liability			
20-10-2020	European Parliament	- Resolution with recommendations to the Commission on a civil liability regime for AI[19]	- Analyses new forms of civil liability - Focuses on complaints made to the AI operator
28-9-2022	Parliament and European Council	- Proposal for a Directive on non-contractual civil liability in the context of artificial intelligence[20]	- Objective: establish standardised requirements for specific aspects of non-contractual civil liability for harm caused by AI - Especially in terms of 'evidence'

Table 1 (*Continued*)

Date	Body	Document	Comments
Liability for harm caused by AI defective products			
28-09-2022	Parliament and European Council	- Proposal for a Directive from the European Parliament and Council on liability for harm caused by defective products[21]	- Aim: to adapt defective products standards to account for AI
AI and data protection			
27-04-2016	Parliament and European Council	- EU General data protection regulation[22]	- Regulates the treatment of personal data of natural persons and guarantees its free circulation within the single market

Source: Treaty on the Functioning of the European Union.
- Regulations. These are binding legislative acts. They are broad in their scope, obligatory and directly applicable to Member States, and any individual can demand compliance before national courts.
- Directives. These are standards that are legally binding to all Member States. They establish objectives with which all EU countries must comply and each country is responsible for developing their own laws about how to achieve these aims (through their transposition).
- Recommendations. These are not binding. They allow the institutions to set out their perspectives and suggest a course of action without imposing legal obligations on those to whom the recommendations are aimed.

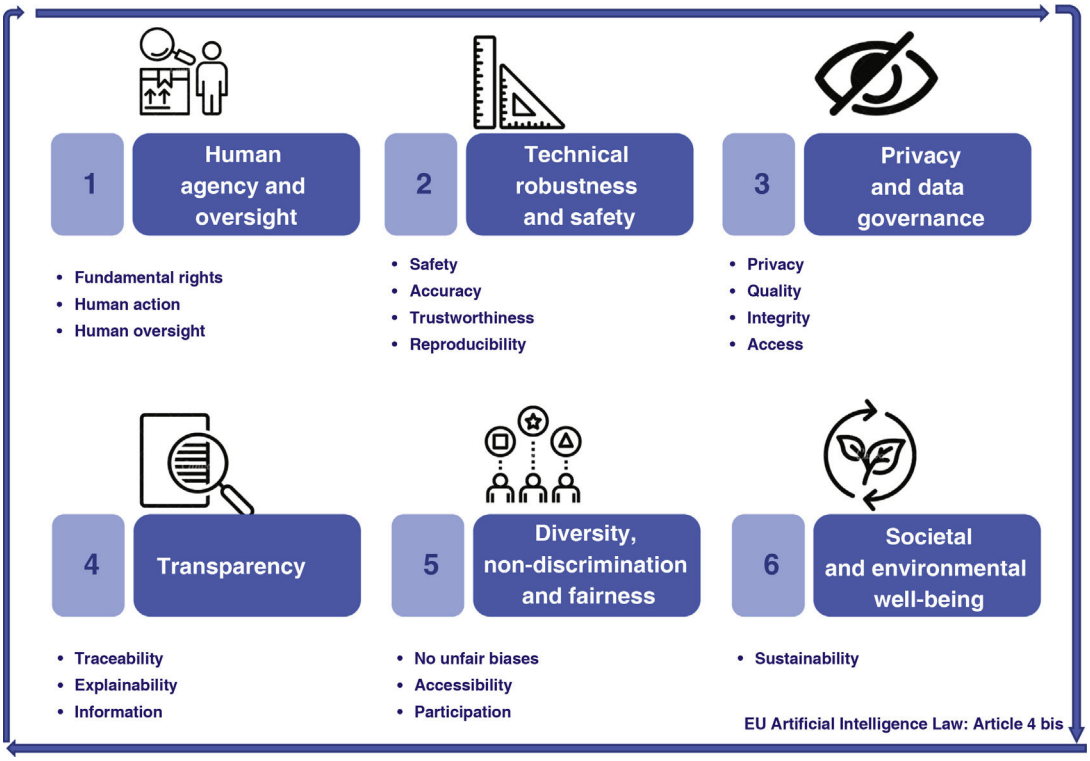

Figure 1 General requirements for AIS in the EU AI Act.

Technical robustness and safety

Unexpected harm must be minimised, the robustness of the system must be ensured in case of unexpected problems, and systems must be resistant to attempts to modify their use or performance and prevent unlawful use by malicious third parties.[16]

In radiology, AI systems should be based on a clearly defined medical approach and should predict the main rel-

evant clinical endpoints, with the aim of making robust and trustworthy associations and inferences.[25]

Privacy and data governance

AI system use must comply with current privacy and data protection regulation[16] (General Data Protection Regulation [GDPR][22]) and data treatment must comply with strict quality and integrity standards. The EU has created the European Data Space with the aim of facilitating data availability and interoperability.[26]

When AI is used in radiology settings, it may be vulnerable and susceptible to both generalised[27] and targeted[28] cyberattacks. Deep learning systems may be compromised by malicious attacks on radiology images, which may cause diagnostic errors and harm patients.[28]

Transparency

AI systems should offer sufficient levels of traceability and 'explainability', and users (patients) should be informed of their rights, and the capabilities and limitations of the AI system.[16] An AIS is 'explainable' if its operational functionality can be presented in a non-technical manner to a non-specialist.[6] This concept contrasts with the 'black box' approach in which even the designers of the algorithm are unable to explain why the system arrived at a specific prediction.[6]

In radiology, explainability is a legal obligation and the end goal is to transform this 'black box' into a 'glass box'.[29] In the event that an error causes harm, 'transparency' dictates the system should be auditable should an injunction be issued.[30]

Diversity, non-discrimination and fairness

The development and use of AI systems should promote equal access, gender equality and cultural diversity, while avoiding discriminatory impacts and unfair biases that are prohibited by Spanish and/or EU law.[16]

In radiology, the protection of vulnerable and underrepresented populations must be guaranteed, and strategies to mitigate this type of bias must be implemented.[29]

Societal and environmental well-being

AIS must be used sustainably and in ways that respect the environment.[16] The use of AIS has a significant environmental impact: data centres consume between 1% and 1.5% of electricity worldwide, which is approximately 1% of global greenhouse gas emissions.[30]

The EU has published a checklist for these requirements.[17,18] A list of these requirements adapted to radiology is set out in Table 2.

Risk-based approach

This is the corner stone of the EU AI Act which, together with the GDPR[22] and the EU Regulation on Medical Devices,[31] forms the legislative triad that regulates the EU position on the topic.

General data protection regulation

When data processing involves new technologies (AI) that present a 'high risk' to the rights and freedoms of natural persons, the responsible party is obliged to carry out an impact assessment of operations.[22]

Regulation on medical devices

AIS in radiology influence clinical decision making (prevention, diagnosis, follow-up, prognosis and treatment), and therefore should be qualified as medical devices,[31,32] and as such are classified according to the level of risk: IIa, IIb and, in exceptional cases, III.[31,33] (Fig. 2)

As regards AIS in radiology, it is important to note:

1. They must carry the CE marking to be marketed in the EU. In Spain, this certification is issued by the National Certification Centre for Medical Devices,[34] under the Spanish Agency for Medicines and Medical Devices.
2. Once CE certification has been acquired, AIS—like all other health technologies—must be evaluated for their use in routine clinical practice, in order to be included in the Common Portfolio of Services of the National Health System.[35]
3. In the AI for Radiology database on the Grand Challenge platform, you can find radiology AIS that are CE-marked[4] and that are therefore in compliance with Medical Device Regulation (MDR), as laid down in the Medical Device Regulation.

The European Union Artificial Intelligence Act

Levels of risk

The Act[14,16] establishes four risk categories: unacceptable risk, high risk, limited risk and minimal risk (Fig. 3). The largest segment of AIS, which also contain the most important systems used throughout the radiological process (indication, diagnosis, etc.) will be classified as high risk, as they are deemed to be medical devices that may adversely affect the safety and/or fundamental rights of patients.

Requirements and obligations for high-risk artificial intelligence systems

Providers and deployers (hospitals, departments, radiologists) must meet mandatory requirements prior to market launch of high-risk artificial intelligence systems.[16] These are summarised in Fig. 4.

Requirements to manage risks arising from the use of artificial intelligence systems in radiology is a little explored and analysed topic; its implementation in breast cancer screening[11] is a suitable example of good practice and compliance.

Oversight in radiology

The EU AI Act establishes human oversight[14] as a cardinal principle, and in high-risk systems, a key requirement of their design and development is that they can be 'effectively overseen by natural persons'.[16]

Table 2 Checklist for the general requirements of the European Union Artificial Intelligence Act.

1. Human agency and oversight	- Have you informed your patients that the diagnosis is the result of an AIS recommendation? - Have you designed a protocol assigning tasks to the AIS and the radiologist? Does the protocol clearly establish the physician's levels of oversight and authority? - Is there a procedure for: for documenting any possible errors in the imaging report? - If necessary, is there a procedure to interrupt AIS interventions? - Does this procedure abort the process or delegate control to the radiologist?
2. Technical robustness and safety	- Have areas of potential harm been identified and analysed should the AIS make inaccurate predictions? - Have measures been proposed to prevent this harm?
3. Privacy and data governance	- Have the methods used to develop the AIS or to train the model been analysed to ensure they keep the use of potentially sensitive data to a minimum? - Does the system comply with EU and Spanish data protection legislation? - Is the system aligned with relevant standards (e.g. ISO, IEEE standards...) or with protocols generally adopted for daily data management and governance? - Does the AIS record when, where, how, who access data and for what reasons?
4. Transparency	- Have measures been adopted to guarantee traceability and documentation of the algorithm's training? - Has an assessment been carried to ascertain the degree to which the AIS's decisions, and therefore its outputs can be understood? - Have the characteristics, limitations and possible weaknesses of the AIS been clearly described to patients?
5. Diversity, non-discrimination and fairness	- Does the data account for patient diversity and are they adequately represented? - Have tests been performed on specific populations or cases that have proved problematic?
6. Societal and environmental well-being	- Have measures to reduce the environmental impact been introduced into the AIS lifecycle?

IEEE: Institute of Electrical and Electronics Engineers; ISO: International Organization for Standardization; AIS: artificial intelligence system.

Preliminary remarks

'Oversight' is vague and ambiguous, both conceptually and terminologically.

Vagueness. From a legal perspective, there are two sides to the concept of 'oversight':

- On the one hand, it is legally determined in the EU AI Act.[14]
- On the other hand, it is a concept that cannot be technically determined. The regulatory challenge will be to establish what constitutes effective radiologist oversight for specific AIS applications and their different areas of use.

Ambiguity. In Spanish, the term 'oversight' has been translated in several ways. The Spanish version of the EU AI Act[14] translates human oversight as '*vigilancia humana*' [human surveillance] and modifies the translation of the EU White Paper on AI[13] where it is transcribed as '*supervisión humana*' [human oversight]. In addition, market surveillance[14] is translated as '*vigilancia del mercado*', which is a reiteration of the term *vigilancia* [surveillance] in different contexts.

We will use the term ''*supervisión*'' [oversight or supervision in English] as it is a well-known and legally applied term in radiology in two areas:

- In the 'supervision/oversight' of staff 'the radiologist must oversee the correct performance of the procedures'[36] and

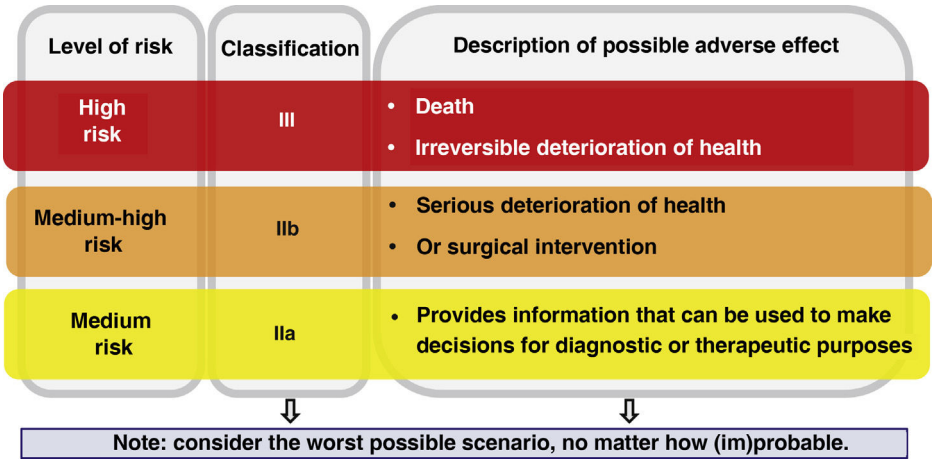

Figure 2 Classification of the levels of risk for AIS as medical devices.

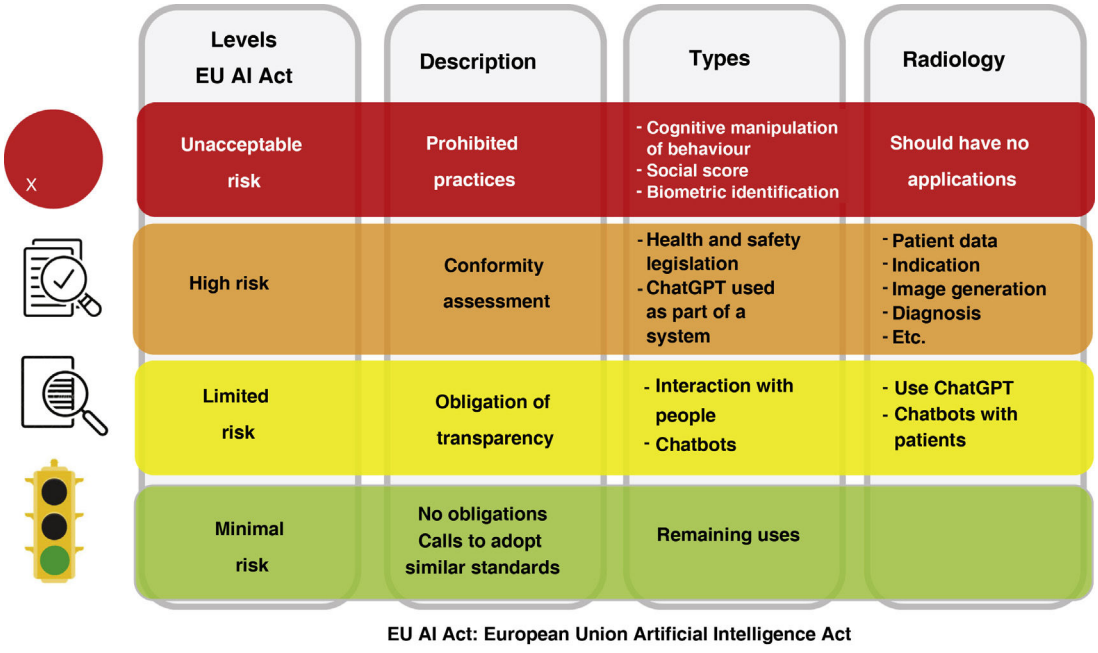

Figure 3 Levels of risk in the EU AI Act.

'the technicians perform their work under the supervision of the radiologist'.[37]

- In the 'supervision' of resident doctors: personal, indirect and on-demand level of supervision.[38]

Likewise, it is the term used in the Spanish scientific legal literature.[39–41]

At present, the EU AI Act does not provide for high-risk AIS to act autonomously. Therefore, failure to oversee the process on the part of the radiologist would constitute illegal conduct.[14,16,40]

The radiologist must provide oversight throughout the whole lifecycle[42]: training, validation, review, correction and verification of results.

Definition

Human oversight in radiology is the sequence of activities through which the radiologist effectively controls and guides the results generated by high-risk AIS, guaranteeing their diagnostic accuracy, quality and safety, all in compliance with the requirements and obligations established by law.[14,16,40] These are summarised in Fig. 5.

Levels of oversight

The Society of Automotive Engineers (SAE) has defined five levels of automation.[43] In radiology, similar levels have been proposed for the diagnostic process.[44,45]

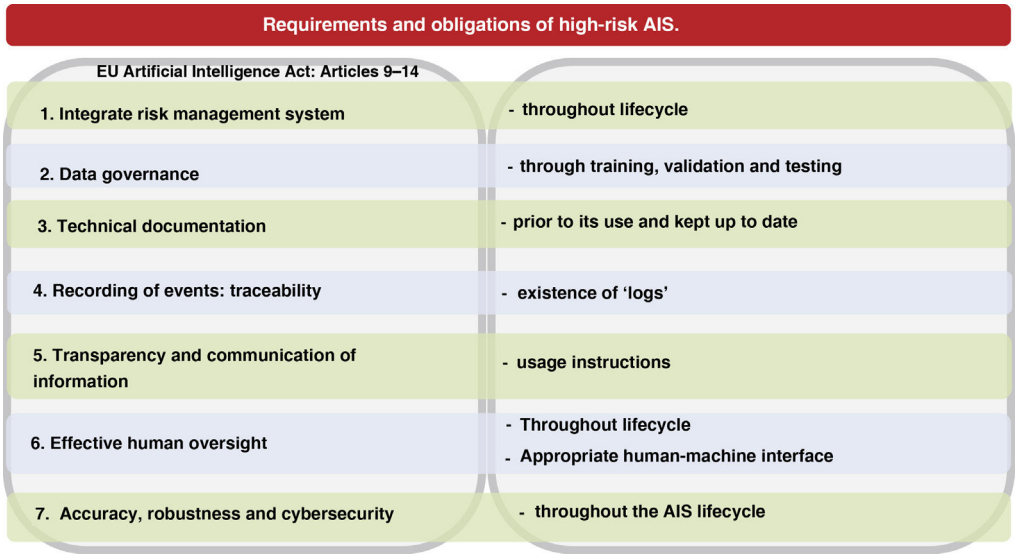

Figure 4 Requirements and obligations for high-risk AIS.

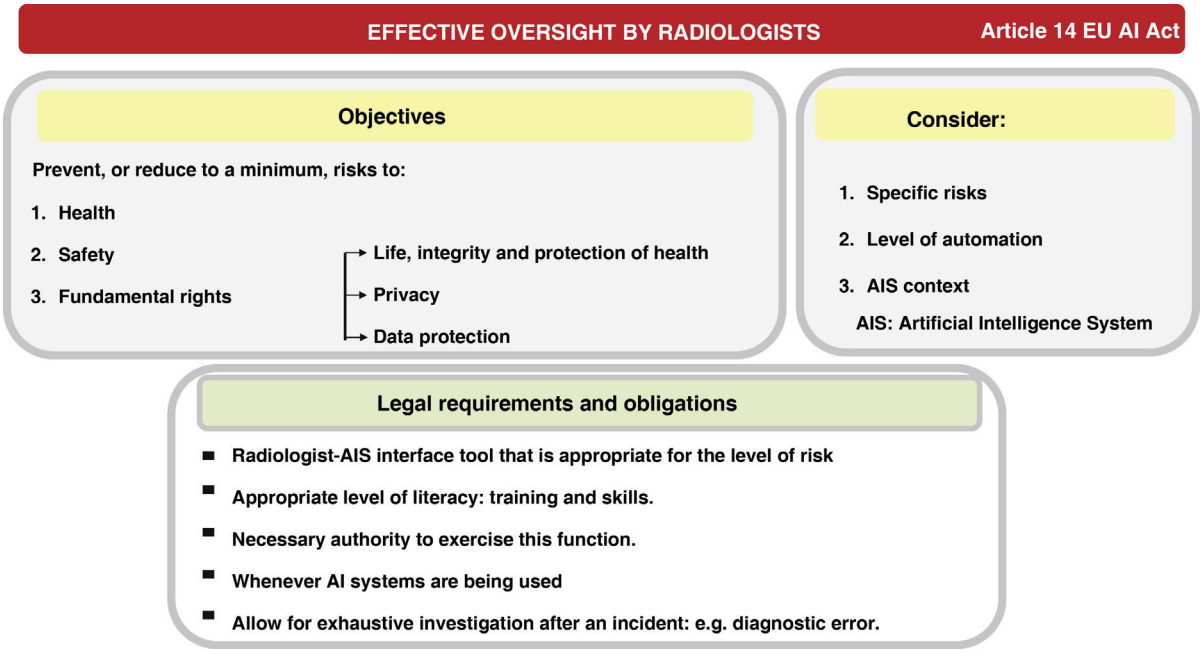

Figure 5 Legal requirements and obligations for effective radiologist oversight.

The levels proposed are the following:
Level 0. Traditional:

- There is no AIS, no oversight, and the radiologist is the only actor in control of all activities and tasks in the process.

Level 0.1. Assistance to radiologist using first generation computer-assisted diagnosis (CAD):

- The radiologist controls the traditional process with the help of CAD[9] used for automatic lesion detection.
- *Stricto sensu*, it is not possible to speak of an AIS here, and therefore the legal concept of oversight would not apply.

Level 1. Partial automation:

- AIS: performs the recommendation acting as an auxiliary tool.
- Radiologist: personally oversees all its recommendations.
- Diagnostic decision: requires final radiologist approval for all studies.

Level 2. Conditional automation:

- AIS: makes the recommendation for a specific indication and offers two proposals: suspicious-pathological versus normal image.

Table 3 Levels of automation and oversight in radiology.

Level	Description	AIS role	Radiologist role	Radiologist oversight	AIS function	Radiologist function	Diagnostic report
1	Partial automation	Auxiliary tool	Total	Yes	- Issue recommendations for cases assessed previously	- Personally supervise all studies	- All tests require final approval by radiologist
2	Conditional automation	Specific indications	Partial	Yes	- Performs automated triage of normal cases	- Monitors only positive or indeterminate results - But not negative results	- Positive results: require final approval by radiologist - An imaging report of normal findings is issued, based on the AIS prediction
3	High automation	Specific indications	Residual	Yes	- Performs automated triage of normal and pathological cases	- Only supervises on complex cases where the AIS requests	- Complex cases require final approval from the radiologist - Reports detailing both normal and pathological findings are issued, according to the AIS recommendation
4	Total automation	Generally indicated	None	No	- Autonomous diagnosis for all indications	- None	- AIS autonomously

AIS: artificial intelligence system.

- Radiologist: oversees only positive or indeterminate results, but not negative results (automated triage of normal cases).
- Diagnostic decision: positive cases require final approval by the radiologist, and in non-pathological cases a report describing the normal findings is issued, based on the AIS prediction.

Level 3. High automation:

- AIS: provides a recommendation for a specific indication, for which it can autonomously arrive at a differential diagnosis and recommend a diagnosis.
- Radiologist: only supervises complex cases in which the AIS asks for support or is unable to act.
- Diagnostic decision: complex cases require final approval by the radiologist, and for other cases a report is issued describing both pathological and normal findings, based on the AIS prediction.

Level 4. Total automation:

- AIS: performs a general interpretation for all indications that are expected from radiologists. It is able to arrive at both a differential diagnosis and a final diagnosis and recommend further imaging studies.
- Radiologist: in this scenario, radiologist oversight is expendable.
- Diagnostic decision: is definitive, with no final approval from the radiologist, and a comprehensive final report would be issued automatically to the electronic medical record, in a structured format, through a generative pre-trained transformer natural language generator.[46]

Currently there are no fully automated radiology AIS that operate without the oversight of human radiologists. At this

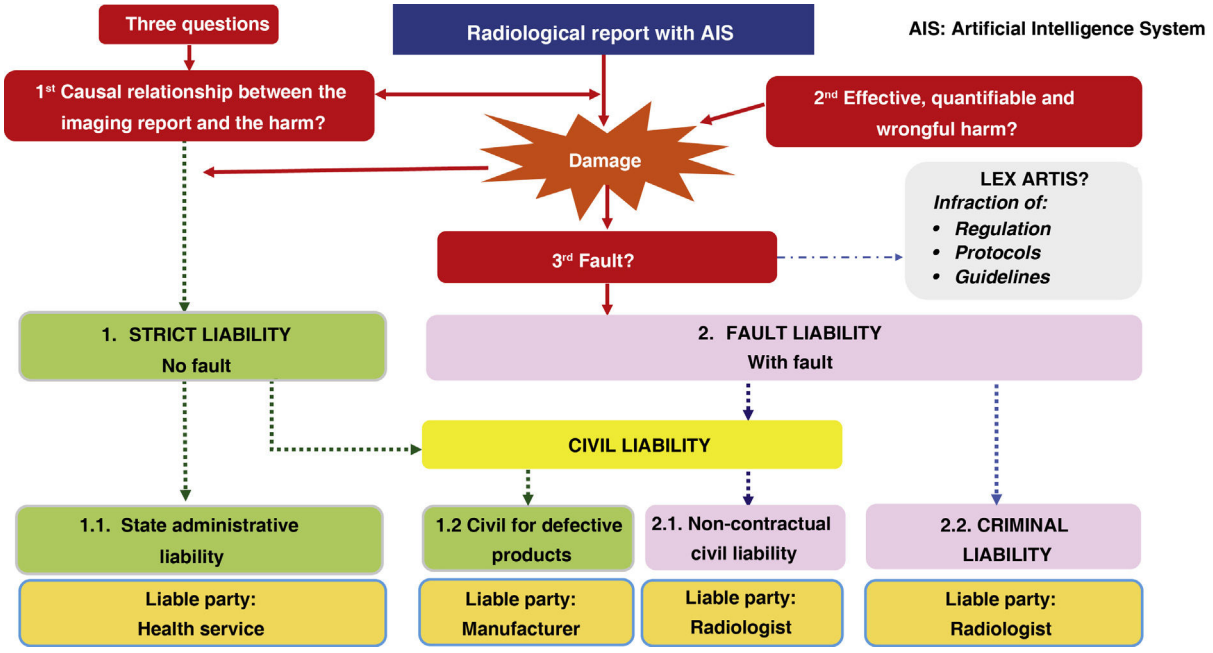

Figure 6 Algorithm for the types of liability when radiologists work together with AIS.

level, their role would not be oversight and we would be facing situations akin to those of 'validation'[47] in blood testing. Levels 1–4 are summarised in Table 3.

Legal liability when radiologists work in combination with AIS

European Union Legislation

The EP[19] and the expert group on Civil Liability and AI have recommended legal adjustments to the rules on civil liability.[48] From this, the EU has presented two closely linked directive proposals:

a Directive on non-contractual civil liability in the context of artificial intelligence.[20] Its aim is to improve access to information and facilitate the burden of proof in relation to harm caused by AIS.
b Directive on liability for harm caused by defective products.[21] Its aim is to introduce standards that provide guarantees in case of harm caused by AIS. To do this, the current directive on defective products from 1985[49] is revised to expressly contemplate liability for harm derived from AI use.

These legislative acts, together with the EU AI Act, complement each other; they are applied at different times and reinforce each other,[50] comprising the legislative triad that regulates the EU position on the matter.

Questions and answers

What types of liability must be applied?
For the radiological act to generate liability[51,52] three requirements must be fulfilled: harm to the patient, a 'causal link' between the radiological act and the harm, and the presence of 'fault'. Depending on the fulfilment of these requirements, two types of liability are distinguished: strict—without fault—and fault-based liability, and subordinate to this classification are the following cases (Fig. 6):

a a. Strict—no-fault—liability: state-administrative liability for the public authorities[51] and civil liability for defective medical devices.[21]
b b. Fault-based liability: non-contractual civil liability[20,51] and criminal liability.[53]

Non-contractual civil liability regulates the obligations arising from an action or omission that causes harm to the patient when there is fault or negligence (Article 1902 et seq. of the Spanish civil code).

In criminal liability, the radiologist must commit an offence or misdemeanour that is defined in the criminal code (e.g. crimes of manslaughter or reckless injury).

How is the causal link determined?
'Opacity'[52,54] may make it difficult or even impossible for stakeholders (patient, radiologist, etc.) to understand and explain the internal process that led to a concrete decision, and therefore to obtain the evidence to determine who is liable. It may be caused by black-box models,[5] biased data or unexplained changes derived from the system's capacity to learn ('plasticity').[55]

Opacity hinders compliance with the legal principles of 'transparency', 'explainability'[56] and 'auditability'.[57] The latter is a quality that means an AIS can be audited upon legal request.

Procedural changes in the proposal for a directive on non-contractual civil liability in AI[20] seek to minimise the issue of opacity, establishing an assumption of causality in the case of fault and facilitating the right of access to evidence.

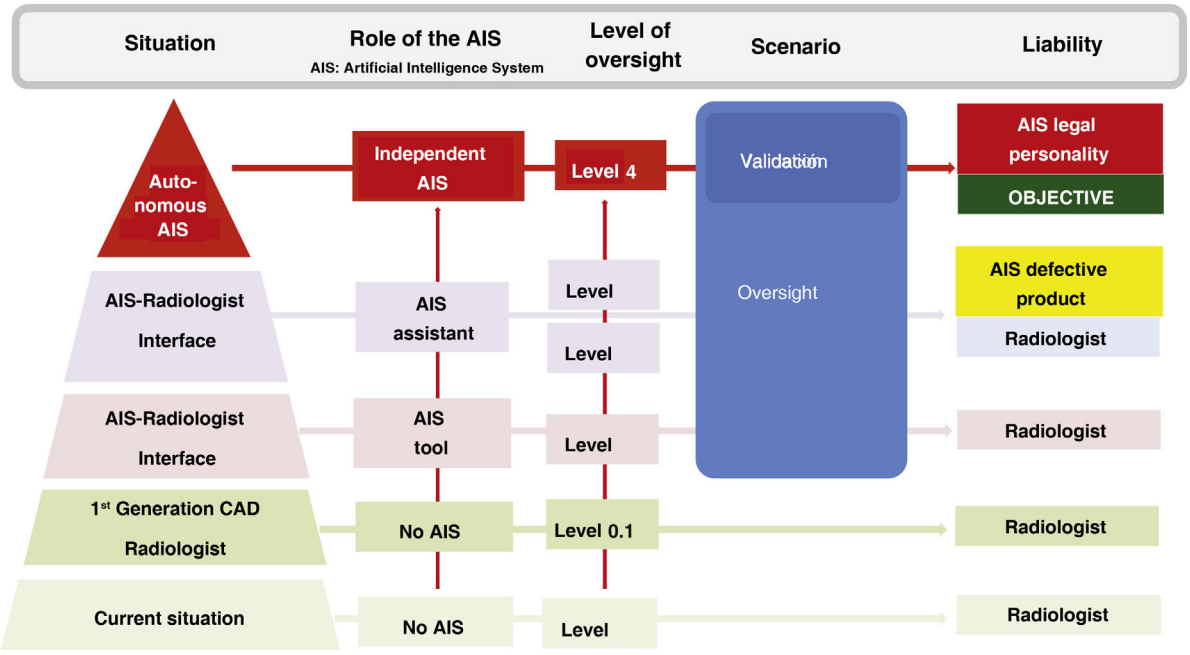

Figure 7 Connection between levels of oversight and types of liability.

Who is liable for harm?
There are various possibilities:

a AIS autonomously liable. Although there is an interesting legal doctrine on the subject and the suggestion to bestow AI with legal personality has arisen,[58] currently the EU legal system does not provide for this possibility.[59]
b The radiologist. The radiologist will always be presumed liable, not only because of their current legal obligations,[51] but also because of the obligations inherent to AIS usage.[60]
c Medical establishments. In the event that a radiologist followed the erroneous instructions of the AIS, the hospital radiology department could also be vicariously liable for the errors made by radiologists.[61]
d The developer-manufacturer. According to the proposed Product Liability Directive, they would be liable if it is proved that the AIS is defective.[21]

Radiologist oversight and types of liability

When analysing the connection between levels of radiologist oversight and types of liability, we will focus on their role in the diagnostic process, which includes: diagnostic inference, decision making, reporting and communication of results. In this role, their main function is to ensure the diagnostic accuracy and safety of imaging reports.

Analysing the connections of the other phases of the lifecycle is beyond the scope of this publication.

Levels of automation and oversight

How the AIS is to be used in the diagnostic process workflow must be clearly defined: as a recommendation (where 100% of the studies are reviewed), as an automated triage of normal cases (only pathological cases are reviewed) or as a fully automated diagnosis.[62] These are illustrated in Fig. 7.

AIS as a tool: level 1
If its primary use is simply to support the decision of the radiologist, who in all cases makes the final decision and issues the report, the answer is obvious: the radiologist always bears the risk of liability.[63] Preventing the AIS from being a primary actor and limiting its use to that of a tool that supports the radiologist's decision-making process, from a liability perspective, is the safest approach.[64]

AIS as assistant: levels 2 and 3
Here, AIS is used as an assistant rather than a tool, in which it acts independently only in pre-established and specified situations, under the regular and periodic oversight of the radiologist. In this case, liability in the first instance lies with the physician, and if they demonstrate that they have diligently overseen the process and that the error is attributable to the system, defective product liability could be pursued.[50]

Autonomous AIS: level 4
In this case, as AIS lack legal personality, they cannot be charged directly as liable[59] and we would be dealing with strict liability scenarios. Some authors argue that it is not necessary to grant AIS a legal personality, as the harm can and should be attributable to existing persons and bodies.[65]

Management of legal risk in diagnostic error

Errors may be made through the combined action of the radiologist and AI due to two factors: the correct or erroneous prediction by the AIS and the effective or ineffective over-

Error of commission-action

AIS issues a CORRECT recommendation of:	REAL FINDING	RADIOLOGIST	REPORTS	LIABILITY RADIOLOGIST	COMMENT ACTION TAKEN BY RADIOLOGIST
True +	Pathological	Accepts	Pathology	NO	√ Correct action
		Doesn't accept	Normal	Yes	■ Does not accept the recommendation, disagrees with the AIS. ■ Actively modifies the proposal. ■ Must justify the discrepancy in the report.
True -	Non-pathological	Doesn't accept	Pathology	Yes	■ Documentary evidence (AIS as expert witness)
		Accepts	Normal	NO	√ Correct action

Error of omission

AIS issues an INCORRECT recommendation of:	REAL FINDING	RADIOLOGIST	REPORTS	LIABILITY RADIOLOGIST	ACTION taken by RADIOLOGIST
False +	Non-pathological	Doesn't accept	Normal	NO	√ Correct action
		Accepts	Pathology	Yes	■ Does not correct the error - Oversees the study
False -	Pathological	Accepts	Normal	Yes	
		Doesn't accept	Pathology	NO	√ Correct action

ERROR of COMMISSION by OMISSION (may result in criminal liability)

AIS issues an INCORRECT recommendation of:	REAL FINDING	RADIOLOGIST	REPORTS	LIABILITY RADIOLOGIST	Comment
False -	Pathological	Accepts	Normal	Yes	■ Radiologist does not correct the error ■ No oversight ■ Violation of the legal obligation to oversee process

Figure 8 Legal risk scenarios in case of diagnostic error when radiologists work with AIS.

sight by the radiologist. Depending on their interaction we can foresee the following legal risk scenarios (Fig. 8).

Error of commission (action)

The AIS makes a correct recommendation and issues a true positive or true negative alert, the radiologist rejects it and makes a harmful error.[64,66,67] In this case the physician is responsible for the error and there is also evidence that he has gone against the recommendation. The AIS would metaphorically become an 'expert witness' against the radiologist.[68] *Stricto sensu*, this physician would have to justify in their report why they had ignored the alert, which would substantially increase their workload.[67]

Error of omission

The AIS issues an incorrect recommendation constituting a false positive or false negative alert. The radiologist follows this recommendation and fails to correct the error in their supervision.[60,64] They will be liable for the error and in their defence could claim that they have followed the system's recommendation.

Error of commission by omission

The AIS makes an incorrect false negative proposal, classifying an image as normal when it is pathological. The radiologist follows this recommendation and issues a report detailing normal findings without no oversight of the system. This scenario poses a high legal risk, as this professional could be criminally charged for the error, for the crime of commission by omission.[69]

Regardless of the type of error, studies indicate that when AIS propose incorrect data, radiologists make more errors than they would without its involvement, and false negative and false positive error rates increase.[70]

Proper legal management of these errors requires:

- Knowing about and avoiding authority bias,[70] automation bias[71] and confirmation bias.[72]
- Establishing guidelines on how to document both normal[70] and erroneous AIS recommendations in the imaging report.[73]

Codes of good practice

In this aspect, the role of scientific societies is paramount, as they must establish these codes throughout the AIS lifecycle (with special emphasis on the diagnostic process), recommending quality and safety indicators and standards. They should also determine best practice in basic and continuous training, both for trainees and specialists.[74]

To conclude

AIS are in their initial phase and we are aware that the issues we have analysed are subject to revision, updates and may become obsolete in the medium term. Despite these uncertainties, we are certain of two things:

1 Maximising its benefits and mitigating its risks requires an inherently multidisciplinary approach and the involvement of radiologists, engineers, mathematicians, data scientists, bioethicists and lawyers.

2 Radiologists are innovative professionals, and as such, will have to learn to live with more questions than answers and, most importantly, to enjoy it.[75]

Conclusion

Radiologists need to be trained on liability issues and the legal requirements with which AIS must comply in the EU. Prior to their implementation in clinical settings, it is their responsibility (together with other actors) to ensure that AIS implementation complies with obligations related to: reliability, technical robustness, safety, privacy and data governance, transparency, explainability, auditability, non-discrimination, fairness, reduction of environmental impact, oversight and CE marking.

They should also be aware that, due to opacity, they may validate the unknown ('black box') and that their diagnostic decisions may be affected by automation, authority and confirmation biases.

The legal classification of these systems as high risk requires adequate management (including legal) and effective oversight. Effective oversight is an essential requirement. To ensure legal certainty, protocols must be developed prior to implementation for the levels of oversight and automation, the degree of authority the physician has and how the AIS recommendations will be integrated and documented in the imaging report.

In the current scenario, where they are used as a tool (oversight level 1), the radiologist is always legally liable in case of error and lack of oversight carries a high legal risk. From oversight level 2 onwards, these systems require diagnostic accuracy assurance, validations and thorough evaluations before they can be reliably used in routine clinical practice.

Conflicts of interest

The authors declare that they have no conflicts of interest.

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