



ESR statement on the European Commission Staff Working Document on the applicability of the existing EU legal framework to telemedicine services (SWD 2012/413).

The European Society of Radiology (ESR) is an apolitical, non-profit organisation, dedicated to promoting and coordinating the scientific, philanthropic, intellectual and professional activities of Radiology in all European countries. The Society's mission at all times is to serve the healthcare needs of the general public through the support of science, teaching and research and the quality of service in the field of radiology. The ESR is the European body representing the radiology profession with close to 54,000 individual members and acts as the umbrella organisation of all national radiological societies in Europe as well as Europe's subspecialty organisations in the field of radiology.

Introduction:

Health services fall within the scope of the freedom to provide services (Art 56 TFEU) and neither the special nature of health services nor the way in which they are organised or financed removes them from the ambit of this fundamental freedom. (ECJ)

Teleradiology is the responsibility of National governments when undertaken within the borders of an individual country and is subject to the legal constraints within that country. Most Member States do not have legal instruments dealing specifically with teleradiology and only a few have regulations or guidelines.

European legal involvement is only relevant when cross border teleradiology is utilised and increases the complexity of the delivery of the service. Indeed the EU citizens Report 2010 revealed that fragmented legal rules on essential aspects of healthcare across Member States hamper patients' rights to receive healthcare in other Member States and caused concern for healthcare professionals.

Under European law teleradiology is both a health service and an information society service.

- Health service: freedom for citizens to seek and receive healthcare services from another Member State regardless of how that service is delivered.
- Information society service: a service normally provided for remuneration, remotely, by electronic means at the individual request of a recipient of the service.

Teleradiology as a health service is there to provide EU citizens with cross border interpretation of images, diagnosis and recommendations for further investigation and advice, usually through another clinician. From the citizens' point of view it is primarily covered by the Cross Border Healthcare directive 2011/24/EU.

This directive requires that teleradiology is provided in accordance with the legislation of the teleradiologist's Member State of establishment and not with the legislation of the Member State where the citizen (patient) accessed and underwent the imaging.

1. Licensing, authorization and registration of the teleradiologist

Directive 2005/36/EC on the recognition of professional qualifications does not apply to healthcare professionals providing cross border teleradiology as it is only applicable to situations where the service provider moves to another host state. As a result, the teleradiologist is responsible to the professional registration authorities of the Member State where he/she performs the interpretation and they are not required to register with the patient's Member State authorities.

It is assumed that the teleradiologist complies with the authorisation and registration requirements of the Member State of establishment. They do not have to comply with the registration requirements of the Member State of the patient. Therefore unless the patient is informed prior to the imaging procedure the name, qualifications and experience of the interpreting radiologist they will have no idea of the standard of the interpretation.

Art 10 (4) states that Member States of treatment shall ensure that information on the right to practise of health professionals listed on national or local registers established on their territory is made available, upon request, to the authorities of the other Member States for the purpose of cross border healthcare via the internal market information 2008/49/EC.

A revision of the Professional Qualifications directive (2005/36/EC) is being formulated to simplify recognition procedures.

2. Teleradiology as a Medical Act

In some Member States teleradiology is not designated as a medical act and it is therefore conceivable that the patient may have their images interpreted by an individual who is not specialist, and who may even lack a medical qualification. However it is important to underline that telemedicine is not a new medical act and it is not intended to replace traditional methods of care delivery, such as face-to-face consultations. It rather represents an innovative way of providing healthcare services, which can complement and potentially increase the quality and efficiency of traditional healthcare delivery. Such potential was recently acknowledged in Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, due to be transposed by 25 October 2013. This Directive classifies the European Court of Justice jurisprudence on EU patients' rights to be reimbursed for medical treatment in other EU Member States, including through eHealth and telemedicine.

3. Patients' rights when receiving cross border healthcare including Teleradiology

a. Patients' rights when receiving cross border healthcare including Teleradiology are enshrined in the cross border healthcare directive (Art 4 and 6) and include:

- The possibility to receive treatment (i.e. radiological interpretation and diagnosis in teleradiology) in another Member State and be reimbursed under certain conditions.
- Patients who have received treatment are entitled to a written or electronic medical record of such treatment (Art 4.2(f)). This should be sent directly to the patient from the teleradiology service as well as to the referring doctor, and should include the details of the investigation and the name of the individual who interpreted and reported on the examination.
- Upon request relevant information on the standards and guidelines on quality and safety in that Member State should be made available from the national contact point of the Member State of treatment (teleradiology provider).
- The Member State of treatment must ensure that teleradiology providers provide relevant information, including on the availability, quality and safety of the service that is used, and that they also provide the interpretation and clinical advice in teleradiology (healthcare) as well as information on their authorisation or registration status (Art4 2(b)).
- There are transparent complaints procedures and mechanisms for patients to seek remedies in accordance with the legislation of the Member State of treatment if they suffer harm from the treatment they receive (Art 4 2(c)).
- Systems of professional liability insurance or a guarantee of similar arrangement are in place (Art 4 2(d)).

b. Informed Consent:

It is the view of the ESR that informed consent can only be achieved if the patient is informed at the site of imaging that their images may be interpreted through a teleradiology service. In addition, the patient should be informed of all the above provisions, including the reporting radiologist's qualifications, prior to their agreement to accept the service.

c. Processing of Health Data

The processing of personal data related to health is regulated under Directive 1995/46/EU on general data protection, currently under review. The Commission proposal for a regulation on data protection will, among other things, clarify the rules applicable to personal data related to health including for the purpose of research.

At present the processing of personal data related to health is prohibited unless certain conditions are fulfilled, in particular if processing is *required* for specified medical and healthcare purposes. The general prohibition of processing such personal data does not apply when:

- the patient has given his explicit consent to the processing;
- processing is necessary to protect the vital interests of the patient or of another person when the patient is physically or legally incapable of giving his consent;
- processing of the data is required for the purposes of medical diagnosis or treatment, and when those data are processed by a health professional (or other individual) who is subject under national law, or rules established by national competent bodies, to the obligation of professional secrecy.

It is essential that there is clarity about where the data controllers are situated on behalf of the patient in teleradiology, whether in the Member State where the service is provided, as with the cross border directive, or in the state of affiliation of the patient, or both. It is also essential that there is a robust tracking process so that the patient may know who has accessed their data in the teleradiology service.

d. Reimbursement:

Directive 2011/24/EU on the application of patients' rights in cross-border healthcare states that the costs incurred by the patient for cross-border healthcare, such as teleradiology should be reimbursed if the healthcare in question is among the benefits to which the insured person (i.e. patient) is entitled in his Member State of affiliation.

e. Liability:

Liability can be of a professional nature (medical) or of a defective product. EU legislation only harmonises rules related to liability for defective products. The mechanism of litigation is also dependent on whether or not a contractual relationship exists between the damaged person and the person responsible for the damage.

The professional liability regime of teleradiologists varies from one Member State to another. The legislation of the Member State in which the teleradiological provider is established should apply as a rule to the provision of cross-border teleradiology services to patients (Art 4 (1)).

Member States have the duty to put in place systems of professional liability insurance or a guarantee or similar arrangement that is equivalent, or essentially comparable as regards its purpose, and which is appropriate to the nature and the extent of the risk for treatment provided on their territory, including cross-border healthcare (Article 4(2)(d) of the Directive).

The lack of information as delineated above could play a significant role in determining possible liability.

A patient who attends a hospital or a doctor working in the country of their affiliation may take legal action in their own courts against that hospital or doctor for an error that results from the hospital's or doctor's use of a teleradiology service in another Member State.

As there is no contract binding the patient and the teleradiologist, the patient will have the option of taking legal action in the Member State of the teleradiologist or in the patient's Member State of residence where the harm took place i.e. where the erroneous diagnosis was acted upon inappropriately.

If the hospital or doctor has a contractual relationship with the teleradiology service or the teleradiologist they may, in certain circumstances, designate in writing which jurisdiction should be competent to resolve a possible conflict between them. If it is not contractually defined then it is the Member State where the teleradiologist or service is domiciled.

In essence in a cross border teleradiology scenario it can be assumed that the competent courts are:

- The place where the act causing the damage occurs i.e. the report is located in the Member State where the professional is when delivering the service.
- The place where the damage arises is located in the state where the patient was when the harm occurred i.e. erroneous treatment arising due to the report occurred.

If the patient themselves refers to a teleradiology service it may be deemed that a contract exists and if so the patient would have to take legal action in the Member State of the teleradiologist. If however the patient was attracted directly to the service by a teleradiologist or teleradiological service which was directed to the patient's Member State then it may be possible for the patient to take legal action in their own country.

4. Teleradiology Providers and the information society service

Teleradiology is an information society service as it fulfils the requirements which are a service normally provided for remuneration, remotely, by electronic means, at the individual request of a recipient of the service. A recipient of the service may be an individual patient but is more likely to be another doctor, a primary care practice, a hospital or an imaging company.

The eCommerce directive (2003/31/EC) creates a legal framework for information society services, i.e. teleradiology providers, setting out information requirements, rules on commercial communications, on contracts concluded by electronic means and on liability of intermediary service providers.

The main legal provisions are

- Country of origin principle: the law applicable to an ecommerce activity will be the law of the Member State where the service provider is established.

- Duty of information: Providers must provide information to the recipient, such as their identity, contact details, and for regulated professions including professional body or registered institution, professional title and the Member State where granted.
- Commercial communications: Member States must ensure that registered professions must comply with such professional rules governing the independence, honour and dignity of the profession.

Liability

Where a contract exists either between professionals in one country and the teleradiologists in another Member State or between imaging centres or hospitals and the teleradiology service in another Member State, the general rule is the applicable law to the contract will be the one which will be expressly chosen by the parties. In the absence of choice of applicable law in the contract, the contract of provision of services shall be governed by the law of the Member State where the service provider has his habitual residence.

Conclusion

The legal position of cross border teleradiology needs to be further clarified but it is clear that if a patient suffers harm he/she may take legal action in their own Member State of domicile.

The patient must be told that their images may or will be reported via a cross border teleradiology service.

They must be given full information regarding the quality and standards of the Member State and of the teleradiology service itself.

They must be given a full report including the name and qualifications and current status of the reporting radiologist also be given full information concerning where their examination will be reported.

If a contract exists between a professional or hospital and the cross border teleradiology service, which does not specify the Member State of jurisdiction, then the law is governed by the Member State of the teleradiology service.

In all cases where cross border teleradiology occurs informed consent should be obtained from the patient prior to imaging in order to allow the patient to make an informed choice and to give them the opportunity to alter their arrangements.

The referring clinician should also be aware that any therapeutic advice is based on a cross border teleradiological report.

All Member States that do not make teleradiology a medical act should be pressured to do so.

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