European Society of Radiology

Response of the

European Society of Radiology (ESR)

to the

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS

on telemedicine for the benefit of patients, healthcare systems and society COM(2008)689

Executive Summary

The European Society of Radiology (ESR) welcomes the Communication on Telemedicine issued by the European Commission as a document that brings to the attention of different stakeholders several important issues concerning telemedicine. As the European body representing the radiology profession, and with teleradiology being a major aspect of telemedicine, the ESR is eager to contribute to the consultation process, and looks forward to being considered among the stakeholders in any future discussion on the issues raised in the Communication on Telemedicine.

The ESR has published a White Paper on teleradiology[1], as well as a position paper on teleradiology[2], which can be downloaded at www.myesr.org: These documents clearly show that the ESR is convinced that:
- Teleradiology is a reality, is here to stay, and will expand.
- Teleradiology has several positive aspects for patient care.
- There are, however, legal and medical concerns that should be solved to safeguard quality of care, patient safety, and the legal certainty of patients' rights.

The e-health topics that are covered more in depth in the Communication on Telemedicine are telemonitoring on the one hand and teleradiology on the other. The ESR would like to point out some key differences between these two telemedical practices:
- **Telemonitoring** is a new technical procedure that provides otherwise previously unavailable biological parameters to a remote physician. When appropriately integrated within a tele-aid and tele-welfare project, telemonitoring could improve the quality of care provided to chronically ill patients and reduce hospital stays.
- **Teleradiology** is a well-established expansion of an already existing medical practice, i.e. radiology, and results in the acquisition of the most appropriate medical images (depending on the clinical history of the patient), their secure transmission on a telematic network and their remote interpretation. The quality of care to the patients, however, is improved only when teleradiology makes available a remote radiologist in cases when no local radiologist is easily available.

The ESR finds it particularly important to state that teleradiology is not equivalent to "telereporting radiological images" but it is a medical act in its own right, consisting of different phases:
- evaluation of examination requests to ensure appropriateness and avoid unnecessary exposure to ionising radiation
- selection of the most appropriate imaging strategy
- optimisation of examination performance
- customisation of imaging protocols to individual patients
- integration of clinical and imaging information into the radiological report.

Teleradiology, therefore, is not the provision of a healthcare service, but medicine through the use of ICT (with all deontological implications).

On the following pages the e-Health subcommittee of the ESR presents the ESR's views and comments as a response to the Communication on Telemedicine.

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[1] European Society of Radiology, Teleradiology in the European Union, White Paper, Nov. 2006
[2] European Society of Radiology, Teleradiology, Nov. 2006

The ESR strongly agrees with the statement given on page 9 (3.2. box):

"As a general principle, the classification of specific telemedicine services as medical acts should ensure that these meet the same level of requirements as equivalent non-telemedicine services (e.g. teleradiology vs. radiology). This principle ensures that adequately regulated health services are not replaced by less regulated telemedicine services."

The ESR fully supports the statement given on page 5 (2.1.):

"The most important challenge for teleradiology is to ensure that it develops in a manner that benefits patient care and ensures overall patient safety, and does not in any way reduce the quality of radiology services provided to the citizen."

The ESR is of the opinion that teleradiology applications should be distinguished as:
- business-to-consumer: when they are aimed at providing a patient with the service of acquisition of medical images and their remote interpretation thanks to the existence of a more-or-less explicit patient-doctor relationship
- business-to-business: when they are aimed at providing a second opinion, a remote expert consultation or – in short – a teleconsultation. In this instance, the relationship is between two professionals or institutions.

Despite requiring a similar technological implementation, nevertheless the legal implications of the two aforementioned applications (business-to-business and business-to-consumer) could be very different.

The ESR would like to point out that in a number of Member States teleradiology applications different from outsourced teleradiology are being developed at a regional level. Regional teleradiology is based on a network of multisite PACS systems (belonging to the same organisation or to a consortium of healthcare institutions), which are usually integrated with Electronic Patient Record, thereby ensuring the necessary access to clinical information. Moreover, the regional nature of these projects favours the contacts between radiologists and prescribers, who are more likely to have personal relationships and who share agreed protocols. This allows optimisation of resource allocation and homogenisation of quality throughout a region, without reducing the quality of radiology services provided to the citizen.

The ESR does not recommend encouraging teleradiology projects for the sole objective of cost containment: it is important to note that published studies proposing that telemedicine activity increases efficiency in terms of economics refer mainly to telemonitoring.

The ESR is convinced that the success of teleradiology will ultimately depend on the quality of care provided to the patients, and therefore stresses the importance of establishing accreditation criteria for teleradiology providers that are homogeneous throughout the EU and also mandatory for providers from outside of Europe.

1. INTRODUCTION

(…) Telemedicine can improve access to specialised care in areas suffering from a shortage of expertise, or in areas where access to healthcare is difficult. Telemonitoring can improve the quality of life of chronically ill patients and reduce hospital stays. Services such as teleradiology and teleconsultation can help to shorten waiting lists, optimise the use of resources and enable productivity gains.

The ESR agrees that a timely radiological diagnosis provided by a remote radiologist would be better than no radiological diagnosis at all. Thus, while it could well be considered as a temporary solution in areas where access to healthcare is difficult, or in areas suffering from a shortage of expertise, nevertheless the ESR does not agree on the fact that teleradiology should be the solution for the shortage of radiologists.

As a matter of fact, the ESR suggests that the only long-term solution to the problem of access to specialised care in areas suffering from a shortage of radiological expertise would be to increase the number of doctors with specialty training in radiology.

The ESR also maintains that teleradiology will not necessarily have a positive impact on shortening waiting lists. The best way to keep waiting lists under control is to carefully watch the appropriateness of each requested exam, as so often in healthcare-delivering organisations there is paradoxical application of the economic law of supply and demand, that being particularly true for public-type

healthcare systems: if supply is increased, the demand will increase as well.

The facilitation of access to radiological procedures on the basis of an uncontrolled demand, may lead to more examinations being performed and consequently to an inappropriate use of resources, and finally to increased costs.

The benefits go beyond improving patient care and healthcare system efficiency.
Telemedicine can also make a significant contribution to the EU economy. This sector, where European industry - including thousands of small and medium-sized enterprises (SMEs) — is well placed, has been expanding rapidly in the past decade and is expected to continue to grow at a fast pace.

Well conscious of the importance attributed by the Commission within this Communication to the strategic use of telemedicine in order to achieve optimisation of resources and productivity gain, the ESR would like to make its clinical and professional representation on how productivity has to be regarded: the ideal radiological department is not the one that produces the highest number of imaging procedures with a given amount of human and technological resources, but, notably, the one that produces correct diagnoses with the least number of exams.

The ESR maintains that teleradiology should not be identified solely as producing management and resource gains. The main emphasis should be on the importance of delivering high-quality healthcare to the patient e.g. emergency service while after-hours and consultation of specialists.

Despite the potential of telemedicine, its benefits and the technical maturity of the applications, the use of telemedicine services is still limited, and the market remains highly fragmented. Although Member States have expressed their commitment to wider deployment of telemedicine, most telemedicine initiatives are no more than one-off, small-scale projects that are not integrated into healthcare systems.

The potential benefits of teleradiology to the EU economy are true, but from the point of view of patient care, it should be equally emphasised that not all circumstances are equally favourable for teleradiology.

Concerning the remarks on technical maturity and on the scale of the projects, these are truer for telemonitoring than for teleradiology. In fact, there are many large-scale regional teleradiology projects that have been successfully running for years and the industrial teleradiology market is mature, with a rich industrial offering based on widely accepted standards (DICOM) and initiatives for the integration and interoperability (the worldwide IHE initiative) of clinical information systems.

It is recognised that integrating these new types of services in healthcare systems is a challenging task. The aim of this Communication is to support and encourage Member States in this endeavour, by identifying and helping to address the main barriers hindering the wider use of telemedicine and by providing evidence to build trust and acceptance. The Communication defines a set of actions to be taken by Member States, the Commission and the broader stakeholders' community. It focuses in particular on:
- Building confidence in and acceptance of telemedicine services
- Bringing legal clarity

The ESR welcomes any initiative that will help to bring legal clarity to the issues of teleradiology.

- Solving technical issues and facilitating market development

Regardless of the efforts in which the Commission and other stakeholders are willing to engage, it is the Member States' health authorities, primarily responsible for the organisation, financing and delivery of healthcare, that remain the principal actors with the ability to make telemedicine a reality in the life of European patients - in full respect of the subsidiarity principle. (…)

The ESR believes that the objective of making teleradiology a reality in the life of European patients should be carefully evaluated, since it has not been proved (and it does not seem) that all situations are equally favourable for teleradiology applications.

Different countries, different regions, and different medical domains may show vastly different outcomes, following the introduction of teleradiology.

2. TELEMEDICINE – DEFINITION AND EXAMPLES

Telemedicine is the provision of healthcare services, through use of ICT, in situations where the health professional and the patient (or two health professionals) are not in the same location. It involves secure transmission of medical data and information, through text, sound, images or other forms needed for the prevention, diagnosis, treatment and follow-up of patients.

The ESR believes that this is particularly important when the patients' clinical details and images are being electronically transferred from one EU country to another, or even to outside the EU.

Telemedicine encompasses a wide variety of services. Those most often mentioned in peer-reviews are teleradiology, telepathology, teledermatology, teleconsultation, telemonitoring, telesurgery and teleophthalmology. Other potential services include call centres/online information centres for patients, remote consultation/e-visits or videoconferences between health professionals. (…)

The ESR strongly believes that the potential of ICT to facilitate professional contacts (teleconsultation, remote consultations, video conferences between health professionals) should be emphasised. This is probably the best way to achieve a sustainable reduction of inequalities in healthcare delivery.

2.1. Telemonitoring: a major opportunity for chronic disease management

Telemonitoring is a telemedicine service aimed at monitoring the health status of patients at a distance. Data can be collected either automatically through personal health monitoring devices or through active patient collaboration (e.g. by entering weight or daily blood sugar level measurements into a web-based tool). Data, once processed and shared with relevant health professionals, may be used to optimise the patient's monitoring and treatment protocols. (…)

Telemonitoring is a valuable tool, provided it is linked to proper professional advice and integrated into a stable long-term care programme and not run as a separate commercial exercise with no clear line of communication to the clinicians.

2.2. Teleradiology: a way to optimise management of scarce resources

Teleradiology is a telemedicine service which involves the electronic transmission of radiographic images from one geographical location to another for the purposes of interpretation and consultation.
Teleradiology has developed alongside the gradual shift in medical imaging from film-based to digital-based technologies. Well structured professional organisations and early establishment of standards have supported this development.

Standards have been established (ESR, IRQN, ACR) but are not supported by a legal requirement for implementation.

Teleradiology can help healthcare facilities to cope with peak workloads, ensure round-the clock services, reduce waiting lists for specific examinations and, above all, cut costs.

Once again there is an emphasis on reducing waiting lists and cutting cost. However, there is currently no evidence that teleradiology activity reduces waiting lists. Waiting lists were reduced in the UK by investing large amounts of money into services that ended up being of suboptimal quality in some cases.

The ESR would like to reaffirm that cost savings must not come at the expense of quality or safety. Traditional ways of measuring quality shall be adapted to the new teleradiology environment. International standards for ensuring the competence of providers and institutions are needed to ensure the quality of care. This could be achieved by multinational speciality boards developing initiatives to establish borderless standards of quality and of certification. A careful monitoring of service providers including observation of the provision of care, information audits and performance review must be also developed.

Teleradiology has been chosen as an example for its specific features:
- It is currently the telemedicine service in the most advanced stage of deployment.
- It is usually carried out as an outsourced service, on a commercial contract basis.

This is not true in the EU, where most teleradiology projects are carried out on a regional scale, based on cooperation between consortia of hospitals, with minimal use of outsourcing.

- The service can be offered in a national or cross-border mode involving other EU countries or third countries.

The regulation of telemedicine and teleradiology should be the responsibility of the member state where the patient undergoes the imaging procedure or telemedical referral. All radiologists and other doctors practicing cross-border telemedicine must be subject to the regulatory requirements valid in the country in which the patient accesses healthcare. Details of the registered health professionals in the member state of treatment and any disciplinary proceedings against them shall be shared among member states.

The most important challenge for teleradiology is to ensure that it develops in a manner that benefits patient care and ensures overall patient safety, and does not in any way reduce the quality of radiology services provided to the citizen. Therefore, urgent action needs to be taken to obtain legal clarity, including assurance of high quality in patient care.

The ESR is in strong agreement with both points of this paragraph: that teleradiology shall "not in any way reduce the quality of radiology services provided to the citizen" and that legal clarity is needed.

3. TELEMEDICINE: MAKING IT HAPPEN!

3.1. Building confidence in and acceptance of telemedicine services

(…) It can be difficult to put a precise monetary value on the factors that are contributing to gains in effectiveness and cost savings, such as: fewer adverse health events; fewer prescriptions; more time s pent at work or better quality of life of patients. Savings on health costs may occur in a sector other than the sector where the investments have been made. For instance, investment in telemonitoring for chronic heart failure patients in the primary care sector may result in savings in hospitals through fewer or shorter hospital stays. The benefits of action, as well as the full consequences of inaction, can sometimes only be observed over long periods of time and in a broad context.

The ESR agrees that studies on teleradiology are mainly biased audits performed by teleradiology providers. Proper research is needed and implementation of services that significantly modify current practices should be prudently carried out until such research has shown supportive results.

(…) Healthcare systems focus on meeting the needs of patients. Achieving telemedicine's potential, therefore, depends on patients being convinced of its ability to satisfy their healthcare needs. Acceptance by patients depends crucially on acceptance by the health professionals treating them, given the high degree of trust the former place in the latter.

The ESR would like to point out that patients are easily convinced that teleradiology may satisfy their healthcare needs if teleradiology is perceived by them as a medical act. It is possible that patients may be concerned when their clinical details and images are being electronically transferred from one EU country to another and being reported or consulted by individuals who have had no direct contact with them.

This emphasises the importance of proper information to the patient about the quality of teleradiology in particular when it is provided across two EU countries.

The ESR believes that the patient should be fully informed about the teleradiology workflow, with particular reference to where their images are going to be reported and to the qualification and certification of the remote professionals.

The ESR is of the opinion that teleradiology should not be performed without the patient giving informed consent at the site of imaging prior to the images being sent to another EU country.

(…) The wider deployment of telemedicine, and telemonitoring in particular, raises new ethical concerns, in particular because of the way in which the patient-doctor relationship is affected.

The ESR is concerned about the possible impact on the patient-doctor relationship that may be caused by outsourced teleradiology solutions. Without the integration of the remote radiologists into the local health provisioning environment, patients may be unaware of the role and presence of the radiologist.

Health professionals and patient organisations have signalled their intention to work on European-wide guidelines to address these issues. The Commission will welcome any initiative in this area driven by users' needs and aimed at enhancing trust and acceptance of telemedicine among patients and health professionals in the best interests of safety and care.

Privacy and security related aspects are also major components of building trust and confidence in telemedicine systems. The respect of rights and fundamental freedoms, like the fundamental rights to private life and to the protection of personal data, must be guaranteed during the collection and processing of personal data, in particular when relating to health. As any other transmission of personal health-related data, telemedicine can pose a risk to data protection right (in the sense that disclosure of a medical condition or diagnosis could adversely affect an individual's personal and professional life). Data privacy aspects should be systematically assessed whenever telemedicine services are provided. In all cases it is essential that the Member States' and Community provisions on the protection of personal data are complied with. (…)

Information privacy remains one of the main sources of concern in teleradiology.

The risk of breach of privacy in teleradiology stems from both the way information is transferred (i.e. transmission secured protocols) and the reliance on third parties. Many of the involved third parties (even domestic ones), although contractually bound to maintain confidentiality, operate beyond the scope of direct supervision.

Whether foreign cross-border teleradiology is inherently more risky than domestic teleradiology needs to be evaluated. In any case Europe urgently needs to develop HIPAA-like guidelines for privacy in teleradiology, including information audits.

3.2. Bringing legal clarity

Although telemedicine may be an interesting option for many healthcare facilities, the lack of legal clarity has been repeatedly mentioned in the stakeholders' consultation as an obstacle to its wider use.

The paramount objective in providing legal clarity in this area is to guarantee that telemedicine develops in such a manner that it benefits patient care while ensuring privacy and the highest standards of patient safety.
The lack of legal clarity – in particular with regard to licensing, accreditation and registration of telemedicine services and professionals, liability, reimbursement, jurisdiction – is a major challenge for telemedicine and, in particular, for teleradiology. Cross border provision of telemedicine services also require legal clarification with regard to privacy.

Where and against whom claims can be brought in, and insurers' policies regarding practices that are covered and those that are excluded still remain critical issues. There must be legal clarity on whether a domestic healthcare service can be found liable for the acts of its foreign teleradiology providers. For example, the American College of Radiology has established standards governing how

entities engage and supervise telemedicine providers. These standards create definable duties of care engaging the entity towards the remote provider. This raises the question of definition of a standard of care at the European level as well as to what extent the country readily enforces others' national court decrees. This is a complex issue in the field of foreign jurisdiction recognition between countries not only within Europe but also worldwide. Finally, insurers' policies must also be analysed in order to verify whether they clearly define the risks linked to teleradiology.

(…) The e-Commerce Directive defines rules for the provision of Information Society Services both within and between Member States. It also applies to telemedicine. For business-to-business (professional-to-professional) telemedicine services, such as teleradiology, the country of origin principle applies: the service offered by the professional must comply with the rules of the Member State of establishment. In the case of business-to-consumer activities (which might be relevant to telemonitoring services) the contractual obligations are exempted from the country of origin principle: the service might need to comply with the rules of the recipient's country. (…)

The ESR believes that teleradiology should be considered a business-to-consumer situation when it is aimed at providing primary interpretation (notably in this case the relationship is between physician and patient).
In contrast, teleradiology is comparable to a business-to-business situation when it is aimed at providing a second opinion (the relationship in this case is between two professionals or institutions).

3.3. Solving technical issues and facilitating market development

Although some telemedicine services have existed for a long time and most of the ICT has been in place for a while, there are still areas where technical issues need to be addressed.

Broadband access and the ability of providers to enable full connectivity is a prerequisite for the deployment of telemedicine. With broadband for all, telemedicine can eventually become a public good, accessible to all. Connectivity with all geographical areas in the EU, including rural and ultra-peripheral regions, is a precondition for telemedicine deployment and for universal access of all individuals to healthcare. The EU's cohesion policy supports both the broadband accessibility and the development of content, services and applications for citizens.

The ESR agrees that broadband connectivity is a relevant aspect, since geographical areas that may be more in need of teleradiology (scarcely populated areas) may have more difficult or limited access to the high-performance connections that are needed for high-quality teleradiology. These are the preconditions that may ensure that teleradiology becomes a "public good, accessible to all".

Interoperability and standardisation in telemonitoring are crucial to allow widespread use of the technologies, to enable them to benefit from the single market and to contribute to its completion. Use of existing standards and adoption of new standards and standardised approaches to achieve interoperability should be supported by standards development organisations, with the active participation of industry. Coordinated community action is necessary, and indeed has been explicitly called for in the proposal for a Directive on patients' rights in cross-border healthcare. (…)

The ESR stresses the importance of interoperability and standardisation. In Radiology there has been formidable progress in this area with the development of DICOM and IHE. However, fine tuning of existing standards is still needed to cope with the specific issues that are relevant to teleradiology. For example, EU wide consensus on specifications for transfer protocols, encryption, digital signatures and providing a Public Key Infrastructure (PKI) service would improve the practical access to teleradiology and the interoperability between different partners in healthcare.
The ESR maintains that interoperability has to include all information systems in which the remote radiologist may find the complete clinical information (images and data) that is necessary for the diagnosis. Therefore, access to prior imaging examinations as well as to the Electronic Patient Record must be available in teleradiology applications in order to ensure the same quality of radiological diagnosis that is obtainable in the HIS-PACS environment at the hospital level.

4. CONCLUSIONS

(…) The Commission will give its full support to ideas and initiatives to turn this goal into a reality and is ready to work with Member States and all stakeholders to achieve this objective. It proposes a concrete set of actions for this specific area. Other issues not specifically targeted in this communication, such as the availability of broadband for all and consistent attention to the implementation of measures aimed at ensuring respect for the right to protection of personal data, are also instrumental in the full beneficial deployment of telemedicine. (…)

In light of what has been analysed in this response to the Communication from the Commission, the ESR maintains that any initiative to help the development of teleradiology should go through an assessment of the following main aspects:

- LEGAL: this is one of the main areas in which the ESR stresses the importance of bringing clarity. A legal framework related to teleradiology and common to all Member States would pave the way to the trusted development of teleradiology as a medical practice;
- ORGANISATION: the introduction of teleradiology into clinical practice requires re-engineering of clinical pathways, medical protocols and management of human resources, with a noticeable impact on the overall healthcare-delivering system (both public and private). The ESR agrees that all stakeholders (including patient associations) should be alerted to the potential as well as the pitfalls of teleradiology, in order to ensure beneficial deployment of technology;
- TECHNOLOGY: having the relevant ICT infrastructures (e.g. broadband availability for all) with consistent attention to the implementation of measures aimed at ensuring respect for the right to protection of personal data.

Even if current *state-of-the-art* technology has reached a mature stage when it can really help to fulfill the aim of realising teleradiology, a true and serious deployment programme will never be possible unless the other two development points are tackled and fixed.
The ESR is ultimately convinced that the success of teleradiology will depend on the quality of care provided to the patients.

The preparation of this official ESR statement was coordinated by Professor Davide Caramella in his role as ESR eHealth Subcommittee Chairman. The eHealth Subcommittee is a subcommittee of the ESR National Societies Committee, chaired by Professor Guy Frija.

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