

Standards for the provision of teleradiology within the United Kingdom



RCR Standards

The Royal College of Radiologists (RCR), a registered charity, exists to advance the science and practice of radiology and oncology.

It undertakes to produce standards documents to provide guidance to radiologists and others involved in the delivery of radiological services with the aim of defining good practice, advancing the practice of radiology and improving the service for the benefit of patients.

The standards documents cover a wide range of topics. All have undergone an extensive consultation process to ensure a broad consensus, underpinned by published evidence where applicable. Each is subject to review four years after publication or earlier if appropriate.

The standards are not regulations governing practice but attempt to define the aspects of radiological services and care which promote the provision of a high-quality service to patients.

Current standards documents

Standards for the recording of second opinions or reviews in radiology departments

Standards for a results acknowledgement system

Standards for iodinated intravascular contrast agent administration to adult patients, Second edition

Standards for radiofrequency ablation (RFA)

Standards for the introduction of new procedures and new devices

Standards for providing a 24-hour diagnostic radiology service

Standards for patient confidentiality and PACS

Standards for providing a 24-hour interventional radiology service

Standards for the communication of critical, urgent and unexpected significant radiological findings

Standards for Self-assessment of Performance

Standards for Radiology Discrepancy Meetings

Standards in Vascular Radiology

Standards for Ultrasound Equipment

Standards for Patient Consent Particular to Radiology

Standards for the Reporting and Interpretation of Imaging Investigations

Cancer Multidisciplinary Team Meetings – Standards for Clinical Radiologists

360° Appraisal – Good Practice for Radiologists

Individual Responsibilities – A Guide to Medical Practice for Radiologists

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Foreword

The main purpose of this document is to update previous guidance issued by The Royal College of Radiologists (RCR) *Teleradiology – A Guidance Document for Clinical Radiologists* – which is now withdrawn – in the light of the almost universal implementation of picture archiving and communication systems (PACS) across the UK and the development of technologies that enable the sharing of patients' image and report data among different healthcare organisations and across international boundaries.

This document sets out a set of standards for the sharing of such data and for outsourcing reporting of images outside the local healthcare organisation – commonly referred to as teleradiology. It is intended to inform potential commissioners of such services.

The complementary use of teleradiology to help develop and support local imaging services requires an adherence to standards which will ensure continued patient safety and confidentiality.

European legislation has yet to be completed but, at the time of writing, the RCR expects teleradiology to be included in the forthcoming telemedicine legislation. We also expect such legislation to be the subject of future revision as technology changes and European society matures in its understanding of the benefits and implications of e-health. The standards set in this document are those that the RCR believes best serve the population of the United Kingdom. Most are achievable now but all should be considered by UK healthcare providers and commissioners when considering outsourcing of image reporting to teleradiology companies.

This revised set of standards complements the guidance undertaken by the National Imaging Board of the Department of Health published in *The role of teleradiology in supporting the delivery of Diagnostic Imaging Services*.¹ The RCR is indebted to Dr Laurence Sutton for the work he has put into this important and difficult standard. Thanks also go to the members of the RCR IT Sub-committee, the Standards Sub-committee, its e-consultation panel and the Professional Support and Standards Board all of whom contributed. Finally, the RCR wishes to acknowledge the contribution made to this standard regarding European legislation by Dr Richard Fitzgerald.

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Definition of teleradiology

Teleradiology is the transmission of images and associated data between locations for the purpose of primary interpretation or consultation and clinical review. Teleradiology also encompasses the process of remote viewing of images via a web viewer. Such processes involve the sharing of patient-identifiable information, within and among organisations and potentially across international boundaries.

Introduction

Changing methods of delivering diagnostic imaging services and the increasing commercialisation of aspects of healthcare, including telemedicine and teleradiology, means that there will be increased fragmentation of where and how services are delivered. Increasingly, there will be a greater opportunity for radiologists from within and outside the European Union (EU) to report on images for United Kingdom (UK) patients.

The setting of standards for the sharing of patients' image data and reports via teleradiology is essential to maintain high-quality diagnostic imaging reporting within the UK in an ever-increasing commercially competitive environment.

The setting and acceptance of such standards should be seen as part of the patient safety and quality, innovation, productivity and prevention (QIPP) agenda.²⁻⁴

Attention to the guidelines and standards outlined in this document will maintain high-quality standards of reporting, thereby preserving patient safety and confidentiality.

Implementation of PACS in England and Scotland has been successfully achieved by national programme initiatives.⁵ Challenges remain with regard to the sharing and exchange of data between healthcare organisations (HCOs), either within a local healthcare community (HCC) – an example might be the sharing of data between a secondary centre and a more specialist referral centre – or on a larger geographical scale such as the remote reporting of images outside the UK.

Other current clinical examples of image data sharing include:

- Transfer of images to obtain a second opinion
- Transfer of images to a clinician at home to support an emergency referral (eg, head injury) or as part of a job-planned home reporting session
- Transfer of images to obtain out-of-hours specialist opinion either within a hospital trust (transfer of images to the on-call radiologist at home) or between hospital trusts
- Transfer of images to support a multidisciplinary team (MDT) meeting
- Transfer of images via linking of remote HCOs, for example, the remote Scottish Islands
- Transfer of images between linked HCOs in a particular geographical location to improve the overall reporting capacity for the participating organisations (reporting grid workflow)
- Transfer of images to a contracted third-party reporting service provider (outsourced teleradiology service)
- Transfer of images to and from independent sector diagnostic imaging service providers as part of, or separate from, NHS negotiated contracts.

Methods of data transfer

There are various technical methods for transferring images and reports as part of, or independent from, national implementation programmes for PACS. Examples are as follows:

- Several organisations are part of the same PACS and radiology information system (RIS) with common governance arrangements, ie, data sharing effectively within a single healthcare entity
- Direct 'push' of data to another organisation's PACS
- Direct viewing of data from another organisation via a web browser
- Sending data on a CD to another organisation
- Transfer of data from one organisation to another via an image router
- Direct 'pull' (retrieval) of data from another organisation's PACS
- Future data sharing (images and reports) across organisations using a set of international standards such as those defined by the Integrating the Healthcare Enterprise (IHE) framework⁶
- Sharing of images through the use of nationally deployed patient databases.

Changing the way diagnostic imaging services are delivered

The synopsis above suggests that clinical requirements are shaping the solutions for the sharing of images and reports. Further drivers for change include government initiatives, local HCOs where there is a need to address reporting capacity deficiencies and the requirement to maintain local specialist expertise in some areas of diagnostic imaging.

The benefits of teleradiology in maintaining services locally as much as possible were highlighted in the NHS Report *High Quality Care for All – NHS Next Stage Review Final Report*⁴ which is focused firmly on the highest quality of care for patients and the public that is locally led, patient-centred and clinically driven.

The potential opportunities to use the benefits of teleradiology are therefore twofold:

1. Data sharing across several HCOs to utilise any underused reporting capacity
2. 'Outsourcing' to an independent reporting service outside the main framework of the NHS.

Such opportunities are only fully realised when clinically useful reports are issued. This is most likely when the radiologists issuing reports have access to previous imaging and other diagnostic and clinical data, and are available for consultation with referrers.

Part 1. Standards for the provision of teleradiology

It is the view of the RCR that teleradiology should enhance and complement local diagnostic services and that there must be no overall detriment to the quality of UK diagnostic imaging services in general.

As a general working principle, the use of teleradiology should not undermine the normal clinical workflows within the radiology department or the hospital trust. The use of teleradiology *for outsourcing images* should also not undermine the normal clinical workflows within the radiology department or the hospital trust.

These standards are applicable to the safe sharing of data in general. There should be an uninterrupted flow of data from the point of request for imaging to the acknowledgement of receipt of the imaging report by the requesting clinician.

Standards can be divided into the following areas:

- Standards to ensure patient safety
- Standards applicable to image and report sharing in general
- Standards applicable to a radiologist providing a reporting service through a teleradiology service provider
- Standards applicable to a teleradiology service provider
- Standards specific to a healthcare organisation using a teleradiology service
- Standards applicable to the provision of image viewing at home for the on-call radiologist.

European legislation

The standards set out below reflect the considered view of the RCR that best supports patient care and safety. Some standards, highlighted in orange italics, are currently not supported by the current European legislative framework and commissioners of teleradiology services should be aware of this when considering such service provision. However, they should also consider whether such legislation is in the best interests of UK patients. It is likely that in the ensuing months and years, European regulation and legislative frameworks will be reviewed in the light of further experience with teleradiology. Any updates to these current standards will be updated through the usual RCR communication channels.

Standard 1. Ensure patient safety when sharing images and reports

- Patient data, imaging and all relevant clinical data should be available for review in any hospital the patient attends irrespective of its type. This will reduce the need to repeat studies.
- It is essential that a teleradiology reporting service has access to as much as required of the patient's previous imaging history and associated reports to enable safe clinical practice and to enable the production of accurate and relevant reports.
- It is essential that a teleradiology reporting service has the full clinical details of the patient before providing a report. The written details of which are always linked to the relevant report and images and displayed concurrently with them.
- It is preferable that the clinical details of the referral are included as part of the imaging report.
- It is essential that all organisations are able to display images and view reports obtained from other organisations alongside their own images irrespective of the vendor origin of the images.
- It is essential that any changes made to a report by one organisation should only be achieved by means of addenda to the original report, and the change flagged on the altered report. Furthermore, notification of the change to the original report should be propagated to all other organisations involved in the diagnosis and management of the patient, including the original requester of the imaging study, as well as the original reporter, if different from the individual adding to the report.
- To ensure effective delivery of reports to the referring clinician, the service should endeavour to provide a 'report acknowledgement system' to enable the referring clinician to view a work list of their unacknowledged reports. The service must enable the referring clinician to 'acknowledge' the report electronically. The report acknowledgement system should preferably support an audit trail to enable service providers to monitor that all reports are acknowledged in line with current clinical guidelines.^{7,8} It is essential that the

service provides the facility for the reporting clinician to flag a report as 'urgent' at the time of reporting. This flag must be communicated to the referring clinician and must highlight the report as 'urgent' in the report acknowledgement system work list.

- It is essential that there is a clearly defined pathway for an urgent unexpected finding to be rapidly conveyed to the requesting clinician.⁸
- It is essential that at all times and locations the identification of the requesting organisation, the requesting clinician, the provider of the imaging service, the original reporter and the identification of any subsequent reviewer should be clearly stated, with the relevant contact information available to enable clinical discussion as required.
- The reporting radiologist should be easily contactable on the telephone to discuss reports.

Standard 2. Image, data and report sharing

- The sharing of patient-identifiable data between healthcare organisations should be conducted in accordance with clear business processes and in accordance with agreed image-sharing protocols. The establishment of clear processes will ensure that the information-sharing agreements are transparent with regard to the method of data transfer, and how the data is managed and stored in the receiving organisation. This is necessary to provide reassurance to patients regarding patient confidentiality.
- The whole end-to-end process of image data sharing between organisations should be audited and all agreed access protocols to confidential patient data should be implemented, monitored and enforced.
- There should be agreement between the key stakeholders of each participating organisation and involvement of the organisation's Caldicott Guardian or equivalent. There should be compliance with the duty of confidentiality.⁹
- Legal advice should be sought on the most up-to-date requirements on patient consent for image data transfer to another organisation for the purposes of diagnosis and reporting and potential storage. Legal advice will draw upon the provisions of the Data Protection Act with regard to the transfer of images for diagnostic purposes.¹⁰
- It is a requirement of the Data Protection Act that patients are provided with all the information regarding the subsequent management of their images as part of the diagnostic process. An information leaflet should be provided at the time of agreeing to the diagnostic test.¹⁰ Information notices within radiology departments are also useful means of appropriate alternative communication.¹¹

Standard 3. Radiologists providing reporting services through a teleradiology service provider

- All radiologists who provide image reporting services for UK patients should meet the same standards of professional practice.
- *All radiology practitioners providing a teleradiology service should be registered with the General Medical Council (GMC) and be on the specialist register of the GMC. The RCR urges commissioners of healthcare and hospital trusts to consider this when negotiating outsourced radiology.*
- *All radiologists reporting on UK patients should be subject to the same regulatory requirements as UK radiologists. Such specific national medical regulatory requirements will include processes such as recertification and relicensing.^{12,13}*
- Radiologists who work for private telemedicine providers on a part-time basis must ensure there is no conflict of interest with their main employer regarding on call or provision of emergency services during working hours.
- Radiologists who work for private telemedicine providers on a part-time basis should ensure that they comply with the European Working Time Directive¹⁴ in respect of their total weekly working commitment.
- Radiologists working for European or non-European teleradiology organisations and reporting on UK patients will have a full working knowledge of the English language and should have completed an accredited assessment of English proficiency when English is not their first language.¹⁵

Standard 4. Teleradiology service providers

- *All teleradiology service providers should be registered with the appropriate regulatory body (for example, the Care Quality Commission) and be subject to its regulations and standards.*
- The teleradiology service provider should establish a clear communication link with the organisations it is supporting such that clinicians and radiologists can discuss reports and cases with the original reporter.
- The teleradiology service provider will ensure and demonstrate compliance with the standards on image and report sharing and patient safety.¹⁶
- The teleradiology service provider should audit and provide information, when requested to do so, of all instances of access to the patients' data.

- It is recommended that organisations that provide teleradiology services establish and publish the results of a continuous audit process reviewing the quality and accuracy of the radiology reports through regular sampling of reports.
- *The teleradiology service provider must demonstrate that their radiologists are registered with UK national regulatory authorities (GMC) and provide evidence of the radiologists' competence to work in the country for which the practitioner provides a service.*
- *The teleradiology service provider must demonstrate that their radiologists have undertaken annual continuing professional development and annual appraisal to the same standard as that of UK-based radiologists.*
- The teleradiology service provider must ensure that the radiologists have individual insurance and indemnity and the provider should also have adequate medico-legal and insurance cover.
- The teleradiology provider should provide evidence of compliance with the requirements of the EU EURATOM 97/43 Directive including justification and optimisation of imaging technique.¹⁷
- The teleradiology provider should ensure that the employed radiologists comply with the European Working Time Directive¹⁴ with regard to their overall weekly employment commitment.

Standard 5. Healthcare organisations using teleradiology services

- The commissioning HCO must be fully conversant with the medico-legal requirements inherent in the contract between the teleradiology service provider and the recipient of the service (see below). It is likely that the HCO responsible for outsourcing imaging to a teleradiology provider would be held responsible in law if sufficient steps have not been taken to ensure both patient safety and quality of the service.
- The HCO must ensure that the clinical details on the imaging request are clear and unambiguous (preferably typed), and avoid the use of idiomatic English and abbreviations. The reason for the request and the questions that require answering must be clearly stated. This will enable the reporter to provide a relevant report that addresses the clinical problem.
- An audit of the teleradiology service provider's imaging reports to monitor the report structure, content, accuracy and quality of any advice given in the report, for instance, with regard to further imaging requirements, is essential.
- There should be a process for reviewing all externally generated reports to the organisation, especially those which are unlikely to be reviewed at a multidisciplinary team (MDT) meeting. It is important to monitor these reports, especially those that may be read solely by non-radiologists.
- Appropriate steps must be taken to ensure that the provision of a teleradiology service does not undermine local opportunities for education and training. Trainees should not be deprived of opportunities for reporting and gaining the necessary experience in a wide range of common and less common examinations in specialist areas.
- Teleradiology should be harnessed as an aid to learning through the establishment of links to centres where specialist imaging reporting is performed, and a resource created of teaching files to be accessed locally.

Standard 6. The provision of image viewing at home for the on-call radiologist

- The employing organisation of the on-call radiologist must provide a secure link between the radiologist's home and the organisation's PACS network enabling the secure transfer of patients' data.
- The employing organisation of the on-call radiologist must provide a viewing facility for home use that is clearly separate from other computing facilities for home use and personal functions, thus preventing dissemination and storage of patients' data beyond the healthcare domain.
- It is essential that the on-call radiologist is provided with a viewing monitor of acceptable diagnostic quality commensurate with current available guidelines, and is trained in the appropriate use of the image tools on the image viewer, and benefits from the correct environmental conditions required for optimal image interpretation.¹⁸
- It is essential that, wherever possible, the on-call radiologist has access to all previous images and reports.
- It is essential that the speed and quality of the network connection permits image viewing which approaches that normally achievable within the radiology department.
- Where possible, an audit trail of access to patient identifiable data is kept in order to comply with national requirements to ensure appropriate access to patients' data.

Part 2. Medico-legal considerations and European regulatory requirements

Worldwide consensus on teleradiology regulation^{12,13} and legislation across innumerable jurisdictions is unlikely to occur. At the time of writing this standard, the European Commission's proposed *Directive on the application of patients' rights in cross-border healthcare*,¹⁹ has completed its First Reading, and is still being discussed. The RCR will continue to lobby at UK and EU level for legislation to adapt medical regulation to the telemedicine era in order that the safety of UK patients is best provided for.²⁰

The European Society of Radiology and the Union of European Medical Specialists' Section of Radiology Joint Position on this Directive contains three key principles.

1. Regulation of telemedicine and teleradiology should be the responsibility of the member state where the patient undergoes the medical imaging or medical referral.¹³
2. Patients should be provided with information regarding the outsourcing of image interpretation and ideally give informed consent for this to occur.¹³
3. Member states should ensure for the safety of the patient that doctors undertaking cross-border telemedicine and teleradiology have fulfilled the equivalent regulatory requirements to those of the country where the patient accesses healthcare.¹³

The European Commission's *Communication on telemedicine for the benefit of patients, healthcare systems and society*²¹ published in November 2008 includes, '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 (eg, teleradiology versus radiology). This principle ensures that adequately regulated health services are not replaced by less regulated telemedicine services and it avoids discrimination between providers of the same service which would be incompatible with the e-Commerce Directive [2000/31/EC]'.

In the interim, the medico-legal responsibilities of the referring hospital and those of the reporting teleradiology service must be clearly defined. The individual reporting radiologist has a personal, professional and medico-legal responsibility.

Liability is likely to reside with the purchasers of the teleradiology service and/or the employers of the radiologist. It must be explicit who retains responsibility for the care of the patient, and if the patient establishes a legal relationship with the radiologist, how liability will be apportioned, as it is unlikely that Crown indemnity will apply.

Teleradiology providers will need to comply with any statutory duty of candour to inform patients when they become aware of a negligent act or omission.

Mandatory professional indemnity/insurance

Currently, there is no legal obligation for doctors providing services for British patients to have individual insurance/indemnity cover. This needs to be rectified and also made explicitly applicable to radiologists providing teleradiology services, wherever their location, who report imaging of UK patients. It is the position of the RCR that radiologists should have individual insurance and indemnity cover for each of the member states for which they are providing the service. The teleradiology provider should also have adequate medico-legal and insurance cover.

Conclusion

The future of diagnostic imaging service provision is increasingly likely to involve the use of data sharing across organisations and some splitting of the image acquisition process from the reporting function within and outside the UK. Thus the establishment of standards is imperative in order to maintain high-quality and safe patient care, especially when such services are being provided in a more competitive commercial environment.

Attention to the guidelines and standards outlined in the forgoing document will ensure the sustainability of local diagnostic imaging services and maintain high-quality standards of reporting, ensuring patient safety and confidentiality.

Approved by the Board of the Faculty of Clinical Radiology: 19 February 2010

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Citation details:

The Royal College of Radiologists. *Standards for the provision of teleradiology within the United Kingdom*. London: The Royal College of Radiologists, 2010.

ISBN: 978-1-905034-46-8 Ref No. BFCR(10)7 © The Royal College of Radiologists, May 2010

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Design by [innov8 graphic design: www.innov8gd.com](http://www.innov8gd.com). Printed by Gallpen Colour Print.