

Standard Operating Procedure for Radiographic Investigations

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# **Clinical Governance**

Clinical Governance is about the quality and safety of patient care. It is everything we do as individual autonomous clinicians and as an organisation to achieve high standards of clinical care. This includes the management of resources, clinical, and self-governance.

The Department of Health defines clinical governance as:

"A framework through which NHS organisations are accountable for continually improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish." (Department of Health 1998).

Below are the seven areas of activity, often referred to as 'the seven pillars of clinical governance,' which are used to make sure we deliver the highest quality health care to service users.

- Clinical audit
- Risk management
- Education, training, continuing personal & professional development
- Clinical effectiveness
- Information management
- Client/service user and experience and involvement
- Staffing and staff management

## Introduction

Prosthetists and orthotists, working within the allied healthcare (i.e., non-medical) professions (AHPs) make an immense contribution to effective and efficient patient care pathways. Under the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) 2017<sup>(1, 2)</sup>, prosthetists and orthotists as registered healthcare professionals may be entitled to act as referrers.

For this to occur, there is an amount of extra work and oversight required for these departments to have in place robust processes to ensure compliance with IR(ME)R. Regular audits of practice will need to occur, as detailed later in this document.

While IR(ME)R does not specify a particular training requirement for non-medical referrers, the IR(ME)R regulators will expect to see a procedure in place for the entitlement of non-medical referrers which is likely to reflect registration standards and professional body guidance.

All prosthetic and orthotic clinicians who wish to request radiographic images must be able to demonstrate that they are each educated, trained, and competent in this aspect of practice, or working as part of a formal training and/or development programme with appropriate supervision to acquire competence in this area. It is up to the individual clinician and manager to ensure any initial training has been completed as required and ongoing locally required training to develop and maintain competence in this area is completed.

Entitlement is granted by the IR(ME)R employer to whom an individual is referring. The employer will need to be satisfied that the referrer is working within their scope of practice. They should also consider how this impacts service improvement measures. Although IR(ME)R does not distinguish between medical and non-medical referrers, in practice, each entitlement for non-medical referrers reflects a clearly defined (and usually limited) scope of practice. It is the employer's decision whether to entitle someone as a duty holder under IR(ME)R. This would usually occur at a Trust level within the NHS. For contracted services, extra lines of communication would need to be completed within the contract for the clinician to be registered within the specific Trust(s) or hospital(s) they are practising within.

Within the musculoskeletal context of practice, requests for diagnostic imaging form part of the comprehensive orthotic and prosthetic assessment of a patient's presenting condition and may be required to reach a differential diagnosis and/or to rule out serious medical pathology.

More complex imaging or ordering investigations outside the musculoskeletal context would need careful consideration in relation to professional scope. BAPO does not keep a list of techniques/modalities that fall within the profession's scope of practice, instead, we ask members to reflect critically on the scope and purpose of the prosthetic and orthotic management they are delivering. It is important to determine if you are working outside your professional scope as this can impact your insurance cover.

## Indemnity

To ensure an individual is insured to order radiological investigations, it must be made clear who is providing your indemnity for this task. If fully employed within the NHS, the employer provides indemnity for your work. If you are employed by a commercial/contracting company or are self-employed, prosthetic and orthotic clinicians must ensure there is appropriate indemnity in place for their work.

#### N.B.

- It is the responsibility of each prosthetic/orthotic clinician to ensure they each have the correct indemnity in place for their work. BAPO members' insurance only covers activities within the scope of standard professional practice (subject to the terms and conditions of the policy). Therefore, you must be clear that you are requesting investigations in the context of prosthetic/orthotic practice.
- It is important that the job description of the prosthetic/orthotic clinician wishing to request radiographic investigations accurately reflects their role and responsibilities as an extended scope practitioner and should specify if referring for radiological investigations is an expectation.

# **Training required**

Organisations may require non-medical referrers (NMRs) to undertake specific learning activities related to IR(ME)R (The Ionising Radiation [Medical Exposure] Regulations 2017), which may include online learning or self-directed activity in order to be given referral rights for radiological imaging.

Prosthetic and orthotic clinicians who would like to extend their role and be eligible to request radiographic investigations should liaise with your management and radiology leads to determine local requirements for learning and professional development.

In addition, IRMER regulations<sup>(1)</sup> require employers to ensure that written protocols are in place for every type of radiological imaging practice. All healthcare professionals who request diagnostic imaging tests using ionising radiation should follow the protocols in place within their organisation to ensure safe referral for imaging<sup>(5)</sup>.

## Additional governance arrangements required

Additional governance considerations include standard operating procedures (SOPs), NMR protocols or advanced clinical practice guidelines within the local Trust carrying out the imaging. Trust guidelines and protocols will sometimes include specific criteria on the appropriate imaging recommended for specific conditions.

Prosthetic/orthotic clinicians and departments wishing to request radiographic images will therefore need to establish links with the local radiology department and follow the process to become registered with them as an NMR. This may require the agreement of a new pathway. If so, this should also be established in conjunction with your senior managers and involve the rehabilitation consultant where clinics are being delivered.

As with other investigations (e.g., blood tests), there will need to be robust governance to ensure results are acted upon even if the requesting prosthetic/orthotic clinician is absent through planned or unplanned leave. If you are a contracted or private practitioner, you will need support from your rehabilitation lead or GP to obtain referral rights within secondary care.

## Interpretation of radiographical investigation results

It should be noted and understood that if a non-medical referrer is expecting to make their own clinical evaluation of the images (rather than wait for the images to be read/interpreted and the resulting radiology report), they must first be trained and entitled as an IR(ME)R operator to do this. This training is detailed in schedule three of IR(ME)R<sup>(3)</sup> and would need to be evidenced relative to the individual's scope of practice. Making the referral and making the clinical evaluation are two different duties under IR(ME)R and require quite different training, education, and practical experience.

As with all areas of your practice, each prosthetic/orthotic clinician must be able to demonstrate they are appropriately and adequately educated, trained and competent in this aspect of practice, or are working as part of a formal training and/or development programme with appropriate supervision to acquire competence in this area.

Interpretation of investigations requires more specialist training. Investigations will normally be returned to primary care settings with a report provided by the radiology department. This is the same process for GPs. More information can be found in the Royal College of Radiologists standards for the interpretation and reporting of imaging investigations<sup>(6)</sup>.

# Guidelines for ordering radiographic investigations for prosthetic and orthotic services/practitioners

This guidance document is intended as a point of reference for prosthetic and orthotic services. This is an example and should be locally adapted to reflect service levels agreements and clinical indications within individual hospitals/Trusts for radiological investigations and should be reviewed within either the musculoskeletal (MSK) or rehabilitation pathways prior to implementation.

Clinical recommendations are made in line with the evidence and recommendations at the time of writing and should be updated accordingly, e.g., as part of an annual cycle.

The document includes the information generally required when establishing nonmedical referrers. The layout and information should be adapted to the format required locally to comply with local governance structures.

#### Suggested format:

- 1. Introduction
- 2. Indications for X-ray
  - 2.1.1 Red Flags
  - 2.1.2 Rheumatology
- 3. Referral procedure and acting on urgent results
- 4. Audit of practice
- 5. Staff authorised to act under this Standard Operating Procedure (SOP)
- 6. Reference of related policies

All sections will need amending/additional information, to reflect the local healthcare economy. Each area has been flagged with an asterisk and \* highlighted in red.

#### 1. Introduction \*(EXAMPLE)

This document is pertinent to prosthetists and orthotists working in an advanced practice role within a primary care setting and specifies the indications for requesting X-ray investigations (spinal and peripheral) when working as a Non-Medical Requestor. It also covers the potential red flags that may be identified when working within this setting.

#### 2. Indications for X-ray \*(EXAMPLE)

The National Institute of Clinical Excellence (NICE) recommend osteoarthritis (OA) can be diagnosed without X-ray in people > 45 years with activity-related joint pain with or without morning stiffness lasting < 30 minutes in the absence of signs and symptoms indicating possible alternative pathology e.g. trauma, infection, inflammatory arthropathy etc...

Spine	*EXAMPLE – re-write according to local requirements/latest evidence X-rays are generally not indicated for spinal pain.
	<ul> <li>Indications for X-ray for spinal pain are limited to:</li> <li>Significant trauma or suspected osteoporotic vertebral fracture</li> <li>Suspected atlanto-axial subluxation - lateral view in supervised comfortable flexion. More common in patients with rheumatoid arthritis (RA) or downs syndrome</li> <li>Red flags present* i.e., if suspected tumour, infection or fracture. <i>Note that "normal" plain films may be falsely reassuring</i></li> </ul>
Shoulder	<ul> <li>*EXAMPLE - re-write according to local requirements/latest evidence <ul> <li>If red flags are present*</li> </ul> </li> <li>After trauma to exclude fractures - dependent on mechanism of injury (MOI), range of movement (ROM) restriction/loss of function, bony tenderness</li> <li>X-rays are not initially indicated, as degenerative changes in the acromio-clavicular joints and rotator cuff are common and may be unrelated to the patient's symptoms.</li> <li>X-ray if there is no improvement after six months of conservative management</li> <li>If the following conditions are suspected clinically: <ul> <li>Calcific tendonitis - to confirm</li> <li>Frozen shoulder - to exclude glenohumeral OA and malignancy</li> <li>Glenohumeral and acromio-clavicular joint (ACJ), OA, available in anteroposterior (AP), lateral and axillary views</li> <li>Subacromial pain - if failure of conservative treatment for six months</li> </ul> </li> </ul>
Knee	<ul> <li>*EXAMPLE - re-write according to local requirements/latest evidence         <ul> <li>After trauma to exclude fractures (including stress fractures) - Ottawa knee rules.</li> <li>If locking, restricted movement or effusion is present and suspected loose body</li> </ul> </li> </ul>

	<ul> <li>Weight-bearing films needed to image degenerate joints - see above re-diagnosis of OA</li> <li>Post-operatively if implants are used or painful prosthesis</li> <li>If red flags present* / suspicion of serious pathology</li> <li>In knee pain/dysfunction not responding to conservative measures for three months</li> <li>Any patient over 45 yrs. with knee pain should have X-rays before considering further investigations such as Magnetic Resonance Imaging (MRI) in order to exclude degenerate changes in the absence of any other clear cause for symptoms e.g., trauma. Consider alternative views e.g., Rosenberg and Skyline if standard views are normal.</li> </ul>
Elbow,	*Add according to local requirements/latest evidence
Hand and Wrist	<ul> <li>After trauma to exclude fractures - dependent on mechanism of injury (MOI), range of movement (ROM) restriction/loss of function, bony tenderness</li> <li>X-rays are not initially indicated, as degenerative changes in some joints (e.g., subtalar and talocrural) are common and may be unrelated to the patient's symptoms</li> <li>If locking, restricted movement or effusion is present and suspected loose body</li> <li>Post-operatively if implants are used or painful prosthesis</li> <li>If red flags present* / suspicion of serious pathology</li> <li>In pain/dysfunction not responding to conservative measures for three months</li> <li>Any patient over 45 yrs. with foot and ankle pain should have X-rays before considering further investigations such as MRI in order to exclude degenerate changes in the absence of any other clear cause for symptoms e.g., trauma. Consider alternative views if standard views are normal</li> <li>Red flags present* i.e., if suspected infection, tumour or fracture. <i>Note that "normal" plain films may be falsely reassuring</i></li> </ul>
Hip	*Add according to local requirements/latest evidence
	<ul> <li>Add according to local requirements/latest evidence</li> <li>After trauma to exclude fractures - dependent on mechanism of injury (MOI), range of movement (ROM) restriction/loss of function, bony tenderness</li> <li>X-rays are not initially indicated, as degenerative changes in some joints (e.g., subtalar and talocrural) are common and may be unrelated to the patient's symptoms</li> <li>If locking, restricted movement or effusion is present and suspected loose body</li> <li>Weight-bearing films needed to image degenerate joints - see above re-diagnosis of OA</li> <li>Post-operatively if implants are used or painful prosthesis</li> <li>If red flags present* / suspicion of serious pathology</li> <li>If hip pain/dysfunction not responding to conservative measures for three months</li> <li>Any patient over 45 yrs. with foot and ankle pain should have X-rays before considering further investigations such as MRI in order to</li> </ul>

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	<ul> <li>exclude degenerate changes in the absence of any other clear cause for symptoms e.g., trauma. Consider alternative views if standard views are normal</li> <li>Red flags present* i.e., if suspected infection, tumour or fracture. <i>Note</i></li> </ul>
	that "normal" plain films may be falsely reassuring
Foot and	*Add according to local requirements/latest evidence
Ankle	<ul> <li>After trauma to exclude fractures - dependent on mechanism of injury (MOI), range of movement (ROM) restriction/loss of function, bony tenderness</li> </ul>
	• X-rays are not initially indicated, as degenerative changes in some joints (e.g., subtalar and talocrural) are common and may be unrelated to the patient's symptoms
	<ul> <li>If locking, restricted movement or effusion is present and suspected loose body</li> </ul>
	<ul> <li>Weight-bearing films needed to image degenerate joints - see above re-diagnosis of OA</li> </ul>
	<ul> <li>Post-operatively if implants are used or painful prosthesis</li> </ul>
	<ul> <li>If red flags present* / suspicion of serious pathology</li> </ul>
	<ul> <li>In foot and ankle pain/dysfunction not responding to conservative measures for three months</li> </ul>
	<ul> <li>Any patient over 45 yrs. with foot and ankle pain should have X-rays before considering further investigations such as MRI in order to</li> </ul>
	exclude degenerate changes in the absence of any other clear cause for symptoms e.g., trauma. Consider alternative views if standard views are normal
	Red flags present* i.e., if suspected infection, tumour or fracture. <i>Note that "normal" plain films may be falsely reassuring</i>

#### 2.1 Red Flags \*EXAMPLE – EDIT WITH LOCAL INFORMATION/LATEST EVIDENCE

These are signs of suspected serious pathology and can include any of the following:

- Presentation age (1st episode) < 20 or > 55
- Progressive, unremitting pain which does not improve or gets worse with rest
- Past history of carcinoma, steroids, HIV
- Unwell, unexplained weight loss
- Widespread and progressive neurological symptoms and signs
- Structural deformity
- Thoracic pain
- Possible infection

#### 2.2 Rheumatology

\*The threshold for radiological investigations should be agreed upon collaboratively with local rheumatology secondary care services.

#### 3. Referral Procedure and acting on urgent results \*EXAMPLE – EDIT WITH LOCAL INFORMATION/LATEST EVIDENCE

- An X-ray request will be made within the hospital/Trust in which you are employed
- The referral must comply with Ionising Radiation (Medical Exposure) Regulations (IRMER) and contain accurate patient identifiable information (three patient identifiers), relevant clinical information (including previous investigations) and a clinical question. Nuclear Magnetic Resonance (NMR) Imaging should be written within the clinical information.
- The patient will be provided with a printed copy of the X-ray request to take with them to their local X-ray department. Relevant information regarding access to the X-ray department will be provided to the patient.
- If an urgent finding is reported and the referring clinician is not available, the duty GP or rehabilitation consultant will take the necessary steps to make any necessary/urgent referrals. This will ensure that there is no delay in patient care.

#### 4. Audit of practice \*EXAMPLE – EDIT WITH LOCAL INFORMATION/LATEST EVIDENCE

A record of all X-ray requests made by the prosthetic/orthotic practitioner must be kept and include the patient's identifiable information, the clinical question/reason for referral, the result of the X-ray and the outcome.

- This will allow prosthetic and orthotic clinicians to:
  - Review their own practice
  - Determine whether the clinical question was answered/relevant information obtained
  - Ensure that no red flags/sinister pathologies are missed
  - Evaluate whether the X-ray was the most appropriate investigation/the initial suspected diagnosis was confirmed or refuted and whether it changed the outcome for the patient.

#### 5. Staff authorised to act under this SoP \*EXAMPLE – EDIT WITH LOCAL INFORMATION

- All clinicians working as prosthetists/orthotists within...
- An appendix of dated signatories may be required.

#### 6. Reference of related policies \*EXAMPLE – EDIT WITH LOCAL INFORMATION

\*Link to local policies and competencies- insert here

# **References:**

- 1. Legislation.gov.uk. The Ionising Radiation (Medical Exposure) Regulations, 2017. Available at: <a href="https://www.legislation.gov.uk/uksi/2017/1322/contents/made">www.legislation.gov.uk/uksi/2017/1322/contents/made</a>
- Gov.uk. National diagnostic reference levels (NDRLs) from 13 October 2022. Updated 24 November 2022. Available at: <u>https://www.gov.uk/government/publications/diagnostic-radiology-national-diagnostic-reference-levels-ndrls/ndrl</u>
- Legislation.gov.uk. The ionising radiation (medical exposure) regulations 2017, Schedule 3. Available at: www.legislation.gov.uk/uksi/2017/1322/schedule/3/made
- 4. Royal College of Nursing. Clinical imaging requests from non-medically qualified professionals. April 2021 (updated September 2021). Available at: <u>www.rcn.org.uk/professional-development/publications/rcn-clinical-imaging-requests-uk-pub-009-108</u>
- Royal College of Radiologists. iRefer: Making the best use of clinical radiology. 8<sup>th</sup> edition. Available at: <u>www.rcr.ac.uk/publication/irefer-makingbest-use-clinical-radiology-eighth-edition</u>
- The Royal College of Radiologists. Standards for interpretation and reporting of imaging investigations, Second Edition. 2018. Available at: <u>www.rcr.ac.uk/publication/standards-interpretation-and-reporting-imaginginvestigations-second-edition</u>

# **Further information about training recommendations:**

- British Institute of Radiology: guidance for non-medical referrers to radiology. Available at: <u>www.bir.org.uk/media-centre/position-statements-and-</u> <u>responses/guidance-for-non-medical-referrers-to-radiology/</u>
- Royal College of Radiologists: a guide to understanding the implications of the lonising Radiation (Medical Exposure) Regulations in diagnostic and interventional radiology. Available at: <u>www.rcr.ac.uk/sites/default/files/bfcr152\_irmer.pdf</u>

# Examples of online training modules:

- Royal College of Radiologists: iRefer: <u>www.irefer.org.uk/about</u>
- Health Education England e-learning for healthcare: Ionising Radiation (Medical Exposure) Regulations programme: <u>www.e-</u> <u>lfh.org.uk/programmes/ionising-radiation-medical-exposure-regulations/</u>