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Osteoporosis
Society**

Better bone health for everybody

Guidelines for the provision of a clinical bone densitometry service

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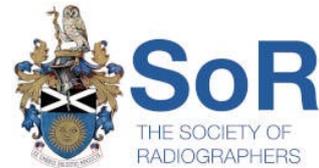
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Please send any comments on this practical guide to healthservices@theros.org.uk

Endorsements:



Contents

1. Introduction	5
1.1 Key practice points	6
1.2 Background - the clinical roles of bone densitometry	10
2.1 The current context of bone densitometry using DXA	12
2. The aim of Bone Densitometry Services	12
3.1 Stakeholders in the provision of osteoporosis services	14
3. Identifying the need for a new bone densitometry service	14
3.2 Development of the business case	15
3.3 Service delivery models	16
4.1 Regulatory framework	18
4. Operational considerations	18
4.2 Case-finding	19
4.3 Referral	20
4.4 Appointment	21
4.5 Scan visit	22
4.6 Reporting	24
4.7 Further investigation	26
4.8 Clinical/operational governance	27
4.9 Policies, protocols and standard operating procedures	27
4.10 Radiation protection	30
4.11 Healthcare governance	30
4.12 Workforce	30
4.13 Infection Control	30
4.14 Equal access	31
4.15 Information governance	31
5. Monitoring and reporting service data	32
5.1 Quality assurance	32
5.2 Maintenance	33
6. Staffing the DXA service	34
6.1 DXA operators	34
6.2 Nursing staff	35
6.3 Medical staff	36
6.4 Scientific support	37
6.5 Administrative and clerical staff	37

7. Environmental issues	38
7.1 Premises	38
7.2 Facilities	39
7.3 Equipment	39

8. Supporting documentation	40
8.1 Patient documentation	40
8.2 Other documentation	40

9. Clinical quality	40
9.1 Clinical quality	40
9.2 Clinical audit	41

Appendix 1: Outline of a business case for a bone densitometry service	42
1. Project goal and purpose	42
2. Background	42
3. Project-management team and beneficiaries	42
4. Methodology	43
5. Benefits realisation	43
6. References	43
7. Appendices and evidence	43

Appendix 2: DXA Patient Risk Questionnaire	44
---	-----------

Appendix 3: Commissioning and acceptance testing of DXA equipment	46
Commissioning	46
At installation	46
Acceptance and commissioning radiation safety testing	47
After installation and acceptance tests	47

Appendix 4A: Recommendations to improve understanding of DXA	48
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Appendix 4B: Sample information leaflet content for patients and carers	52
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Appendix 4C Template Report - Fracture risk and bone density assessment	54
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Bibliography	56
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1. Introduction

This document has been produced to support the development, implementation and operation of high-quality bone densitometry services. The purpose of this guideline is to define best practice for those seeking to commission or launch a new service or develop an existing one. The guideline focuses on services using dual-energy X-ray absorptiometry (DXA) of the axial (central) skeleton as the current technique of choice.

The guideline reflects current evidence and UK policy and should be read in conjunction with *Royal Osteoporosis Society: Reporting Dual Energy X-ray Absorptiometry Scans in Adult Fracture Risk Assessment: Standards for quality*.

1.1 Key practice points

The aim of bone densitometry services	<p>Osteoporosis is managed predominantly in primary care therefore bone densitometry services must be directly accessible to GPs and outputs (reports) must be accessible to non-specialist physicians and include a clinical interpretation, including advice on appropriate ongoing management of the patient.</p>
Identifying the need for a new bone densitometry service	<p>The establishment of a new bone densitometry service requires the involvement of a diverse range of stakeholders at the planning stages, including physicians, operators, radiographers, pharmacists, osteoporosis specialist nurses, radiation protection advisors, medical physics experts, radiation protection supervisors and patients.</p> <p>Consideration should be given to a one-stop service model where additional tests can be undertaken at the time of the scan appointment, providing the benefits of convenience to the patient and reduced time to treatment.</p> <p>A bone densitometry service pathway should preferably include access to an appropriately trained and staffed osteoporosis or metabolic bone clinic for complex patients who require specialist management.</p>
Operational considerations	<p>Bone densitometry services must comply fully with the existing regulatory framework to protect patients, carers, staff and the public from risk of harm from exposure to radiation.</p> <p>All sources of patient referrals must be included in the service model to ensure effective case finding and equitable access to the bone densitometry service.</p> <p>DXA bone densitometry service providers must establish locally agreed referral criteria and communicate the referral process clearly to entitled referrers. The criteria should reflect national recommendations and guidance and be reviewed and updated regularly.</p> <p>All referrals must be reviewed, justified and authorised by the IR(ME)R practitioner or delegated under protocol to a member of staff with appropriate entitlement and training. Appointments should be offered within six weeks of the referral being received.</p> <p>Written employer's procedures under IR(ME)R (Employers procedures) must be in place and adhered to for patient identification and possibility of pregnancy.</p>

Operational considerations

A fracture risk assessment should be conducted alongside measurement of bone density and risk factor questionnaires should be used to optimise the scan interpretation.

Informed consent must be obtained through explanation of the scan and benefits and risks of harm from radiation.

All patients should be sent a letter/leaflet on what to expect from their scan alongside their appointment invitation.

Clear information must be given to the patient advising how and when they will receive the results.

Reporting should be undertaken by a registered healthcare professional with appropriate training who is entitled to do so under IR(ME)R.

DXA bone densitometry providers should provide reports that are actionable by the referrer, who will often be a non-specialist physician.

DXA reports should be integrated into electronic patient health record systems.

Reports should include personalised information for the patient, a clear and understandable summary of results and an explanation, where relevant, of any factors that may affect the reliability of the results.

Reports should:

- use the Royal Osteoporosis Society standard template (Appendix 4C)
- include a clinical interpretation, written in lay language
- present the bone mineral density result and the fracture risk assessment together in an integrated statement or sentence
- include the patient's height, weight and risk factors used for fracture risk calculation and personalised sentence about potential over/under-estimation of fracture risk
- include a clear statement(s) of recommended actions to consider, in lay language, that are individualized and evidence based
- explain the limitations of T-scores and fracture risk scores for people from minority ethnic backgrounds, including relevant reference data used
- include signposting to relevant guidelines and patient resources to aid understanding
- define the technical validity of the scan and the measurements
- for a repeat DXA measurement, the report must explain whether any identified change is statistically or clinically significant
- provide a recommendation for an appropriate time interval to consider a follow-up DXA assessment

Operational considerations

The service must ensure that regular audits of reports are carried out for accuracy and appropriateness.

Recommendations for the ongoing management of the patient and any fracture risk assessment calculation should be included.

Vertebral fracture assessment should be conducted if there is a history of height loss in the patient or appearances in the DXA images or measurements that suggest the presence of a vertebral fracture.

Radiographs should be considered according to local protocols where there is a grade 1 (mild) vertebral fracture identified on VFA to exclude non-fracture deformity where this has not already been imaged or documented.

Every element of the pathway should be documented in detail through standard operating procedures (SOP) and protocols that are clear about what is undertaken, when, where and by whom. This ensures that the DXA measurements remain accurate, precise and reliable when undertaken by a range of trained operators.

A radiation protection adviser and medical physics expert should be involved early in the planning process to indicate when and where their input will be required to meet the requirements of radiation legislation and to inform the quality assurance framework for the equipment.

The bone densitometry service needs the workforce to have access to training, appropriate supervision (and defined lines of accountability) and should be subject to ongoing evaluation of their competency.

The bone densitometry service must comply with the Equality Act 2010 and make reasonable adjustments for the large proportion of patients who will have mobility problems and disabilities. Arrangements should be made at the planning stage to meet the needs of these patients to ensure that they can access the service, such as the use of a hoist for example.

Monitoring and reporting service data

Services require robust Quality Assurance (QA) procedures to ensure compliance with regulation, contractual obligations and local procedures, as well as to ensure the reliability of the quantitative outcomes from the DXA scanner.

All X-ray equipment used by the service must be maintained to enable safe and reliable functioning. Other equipment, such as weighing scales and stadiometers, should have regular calibration checks.

<p>Staffing the DXA service</p>	<p>At the planning stage, sufficient staffing must be put in place to deliver a consistent, high-quality densitometry service – with an additional allowance for annual, sick and study leave.</p> <p>A DXA bone densitometry service must contract a registered healthcare professional as the IR(ME)R practitioner who is trained, entitled and responsible for the justification of medical exposures.</p> <p>DXA bone densitometry reporters should be given appropriate time to undertake reporting with clinical interpretation.</p> <p>DXA operators must be trained and entitled, as defined by IR(ME)R. The operators must undergo additional training in bone densitometry (such as ROS bone densitometry training) and have the time and funding for continuing professional development.</p> <p>DXA operators must work within their defined scope of practice and be able to explain the purpose of tests, regardless of grade or professional background.</p> <p>The clinical leadership of a bone densitometry service requires skills and expertise in imaging, osteoporosis and bone health. Multi-disciplinary team working is essential (e.g. rheumatology, endocrinology and geriatric medicine).</p> <p>A bone densitometry service must have access to support functions that enable efficient administration of the service such as making appointments, fielding queries and greeting patients.</p>
<p>Environmental issues</p>	<p>At the planning stage, consideration must be given to the location of a service to allow for easy, affordable and practical access for <i>all</i> patients. In rural areas this may include consideration of a mobile DXA service.</p> <p>Consideration must be given at the planning stage for adequately sized facilities to house the scanner and reporting station, reception, toilets, changing, consultation and waiting areas.</p>
<p>Supporting documentation</p>	<p>At the planning stage, consideration should be given to a comprehensive package of documentation for patients, including information that supports self-management of osteoporosis.</p> <p>In line with IR(ME)R, services must establish general procedures, protocols and general assurance programmes.</p> <p>DXA service must establish clear definitions of required competencies, training programmes and up to date training and CPD records.</p> <p>A DXA service must make provision within employer’s procedures under IR(ME)R for establishment of a programme of audit and feedback including taking appropriate actions in relation to the results of such audit.</p>

1.2 Background - the clinical roles of bone densitometry

BMD measurements are used clinically to support the diagnosis and management of osteoporosis, and in the context of fragility fracture prevention.

The three main clinical roles are:

- **Diagnosis** of osteoporosis in accordance with WHO criteria.¹
- Informing **fracture risk assessments** with FRAX[®] tool.²
- **Monitoring changes in bone mass** to direct intervention or changes to treatment plans.

Osteoporosis is a condition characterised by low bone mass and structural deterioration of bone tissue with a consequent increase in bone fragility and susceptibility to fracture.

The cost of fractures to the UK health economy in 2019 was estimated at £4.5 billion.^{3,4} There were 527,000 fragility fractures in the UK in that year - this figure is expected to increase to 665,000 by 2034 because of the ageing population.

Diagnosis

Osteoporosis may be diagnosed by bone densitometry, the accepted method being dual-energy X-ray absorptiometry (DXA). This is a technique based on measurement of the attenuation (absorption) of low-dose X-ray beams to estimate bone mineral density (BMD). Measurements are usually made at the spine and hip (i.e. in the axial or central skeleton) and, in adults, expressed as T-scores in which the individual's BMD is compared to the average BMD in healthy young women of mostly white heritage. The World Health Organization (WHO) proposed a diagnostic threshold to define osteoporosis as a BMD T-score of less than or equal to -2.5 standard deviations (SD).^{1,5}

In the INDEX research study, clinical consensus was reached to use a clinical diagnosis of osteoporosis in people with clinical characteristics of bone fragility.⁶

In children, the definition of osteoporosis is limited to the presence of one or more vertebral compression fractures or the presence of a clinically significant fracture history and a low BMD Z-score.^{7,8} The diagnosis of osteoporosis in children and adolescents must not be made based on densitometric criteria alone.

Fracture risk assessment

BMD is an important predictor of fracture risk, but there are many other independent clinical risk factors with risk prediction tools such as FRAX[®] and QFracture[®].^{2,9} Therefore, it is important that BMD measurements are undertaken in the context of a comprehensive fracture risk assessment and that the results are integrated with these other factors to provide an estimate of absolute fracture risk for the individual. To that end, the DXA report can be considered a 'fracture risk and bone density assessment.'

The ability to assess fracture risk accurately is key to optimal patient management. A range of pharmacological treatments are available that are effective in reducing this risk, and treatment can be demonstrated to be cost effective when appropriately targeted at individuals with high risk of fracture.¹⁰⁻¹⁵ Initial fracture risk assessment may be undertaken using risk calculators that need not involve measurement of BMD.¹⁶ Estimation of fracture risk may then be refined in borderline cases using BMD measurement. Baseline BMD measurement prior to treatment should also be considered in high-risk cases to enable assessment of disease severity and subsequent response to treatment.

Monitoring changes in bone mass

BMD measurements are used to monitor changes in bone mass over time. The aim of monitoring bone mass change is to direct if, and when, bone strengthening medication should be commenced, paused or stopped.

Increasing awareness of rare adverse effects of long-term osteoporosis medication has led to recommendations for periodic review of the risk-benefit balance in an individual patient.¹⁷ BMD measurement is an important part of this review process even in patients in whom treatment was initiated based on clinical risk factors alone.

This role is important particularly in patients who are being treated with drugs known to cause bone loss such as aromatase inhibitors, androgen deprivation therapies and oral glucocorticoids. Where bone loss is detected over and above the normal rate for age and sex, appropriate bone protection can be provided at the appropriate point.¹⁸

The provision of DXA bone densitometry services has increased considerably across the UK over the past decade. However, access remains suboptimal in some regions where patients must travel long distances for assessment. There is also marked variability in DXA service provision, which, in some cases, may be insufficient to support optimal patient management in primary care.¹⁹⁻²¹ This document aims to support the development of existing and new services to enable all referrers to have access to a high-quality, local diagnostic service.

2. The aim of Bone Densitometry Services

The aim of establishing a bone densitometry service is to facilitate the prevention of osteoporosis-related fractures and their associated morbidity and mortality, and, therefore, to reduce attendance at emergency departments, emergency admissions to hospitals and the associated burden on social care.²²

However, this is a long-term goal. In the shorter term, access to bone densitometry should enable rapid, accurate clinical decision-making to optimise the prevention and management of osteoporosis.

Osteoporosis is predominantly managed in primary care and so bone densitometry should be directly accessible to general practitioners (GPs). Furthermore, the output of the service should be accessible to non-specialist physicians and allow them to manage patients with osteoporosis confidently.

Key practice point

Osteoporosis is managed predominantly in primary care therefore bone densitometry services must be directly accessible to GPs and outputs (reports) must be accessible to non-specialist physicians and include a clinical interpretation, including advice on appropriate ongoing management of the patient.

2.1 The current context of bone densitometry using DXA

Bone densitometry is an important component of a comprehensive fracture risk assessment and should be used when it will influence present or future patient-management decisions. Current guidance on fracture risk assessment and the recent development of clinical risk assessment tools such as FRAX[®] and QFracture[®] help to define the framework within which a DXA service should operate.^{16,23} Access to bone densitometry is necessary for implementation of current UK guidance and compliance with the Quality and Outcomes Framework (QOF).^{23,24} Providers in England are regulated by the Care Quality Commission (CQC); guidance is available to enable compliance with requirements and advice is available on registration.²⁵⁻²⁷ Figure 1 summarises the role of DXA within the osteoporosis care pathway.

<p>Case-finding</p>	<ul style="list-style-type: none"> • Identification of at-risk individuals in primary or secondary care <ul style="list-style-type: none"> - includes strategies such as fracture liaison services, medication reviews and application of NICE guidance
<p>Fracture risk assessment</p>	<ul style="list-style-type: none"> • Clinical risk assessment tool (FRAX®/Qfracture®) in accordance with NICE <ul style="list-style-type: none"> - DXA for individuals close to intervention threshold • Direct referral for DXA in specific clinical situations
<p>Management</p>	<ul style="list-style-type: none"> • Investigate for underlying causes of osteoporosis • Consider DXA prior to the introduction of therapy to facilitate future treatment decisions • Consider pharmacological and lifestyle approaches to reducing fracture risk • Manage independent risk factors including falls prevention
<p>Monitoring</p>	<ul style="list-style-type: none"> • Early clinical review of compliance • Consider repeat DXA after a minimum of 2 years to evaluate efficacy of treatment <ul style="list-style-type: none"> - Access to biochemical markers may provide an alternative approach to monitoring • Periodic reassessment of need for treatment using DXA e.g. every 5 years

Figure 1. The osteoporosis care pathway

3. Identifying the need for a new bone densitometry service

The need for a new service to be established will be based on the health needs of the local population, considering the accessibility and capacity of services that already exist. Although the development of an osteoporosis pathway is often initiated by a single clinical champion, identifying and working in partnership with the key stakeholders across both primary and secondary care is fundamental to the development of an effective local strategy.

3.1 Stakeholders in the provision of osteoporosis services

These will vary depending on local service configuration but will include some or all of the following:

- primary and secondary-care physicians (one of whom will usually lead the group); the secondary-care physician may have a background in rheumatology, geriatric medicine, endocrinology, radiology or orthogeriatrics
- a bone densitometry operator
- a DXA trained radiographer
- a pharmacist
- an osteoporosis specialist nurse
- patient(s) and carers
- representatives from:
 - radiology
 - medical physics
 - management (both provider and commissioner)
 - a patient support group (e.g. the Royal Osteoporosis Society)
 - a falls prevention service
 - a fracture liaison service/orthopaedics

The knowledge and expertise of these diverse stakeholders is necessary to develop the safe and optimal pathway and to evaluate existing elements of the service. The decision as to whether a new DXA bone densitometry service is required is likely to be relatively straightforward once the stakeholder group has been established. The next step is to define the configuration of the service and develop the business case. At this stage, the clinical stakeholder group will require input from additional sources including:

- finance
- estates
- IT services
- clinical and information governance
- human resources
- a radiation protection adviser and a medical physics expert

In the planning stage it may be useful to visit other clinical services and canvass opinion from a broader group of frontline staff to inform the formal appraisal of options.

Key practice point

The establishment of a new bone densitometry service requires the involvement of a diverse range of stakeholders at the planning stages, including physicians, operators, radiographers, pharmacists, osteoporosis specialist nurses, radiation protection advisors, medical physics experts, radiation protection supervisors and patients.

3.2 Development of the business case

There are three phases to the development of a successful business case:

- Scoping: development of the strategic case:
 - strategic context
 - case for change
 - identification of preferred way forward
 - indicative costs
- Planning: development of the outline business case
 - formal option appraisal
 - detailed costing – capital and revenue
 - suggested contract
 - procurement strategy plan
 - risk assessment²⁸
- Procurement and detailed project planning to support the full business case
 - details of procurement process
 - implementation plan
 - preparation of document for final investment decision
 - contract development

The generic process of developing a business case is described in detail elsewhere.²⁹ It is important to engage with the relevant service/business managers at an early stage to facilitate progress and to ensure adherence to local processes.

The remainder of this document will focus on operational considerations specific to the establishment of a bone densitometry service.

3.3 Service delivery models

There are many ways in which bone densitometry services can be delivered. These range from the availability of DXA as one of the standard diagnostic investigations within a medical imaging or medical physics service to a stand-alone static or mobile DXA unit. A common model is for the DXA scanner to be sited in proximity to the fracture clinic or osteoporosis clinic. The location of the DXA service will influence the choice of service delivery model and vice versa. In models where the DXA measurement occurs at a separate location from other components of the osteoporosis pathway, it is vital to ensure that all elements of the pathway are integrated.

Some patients will require further investigation and treatment based on their fracture risk assessment. Depending on the service model chosen, further management may be undertaken in the GP surgery, however this entails further appointments for the patient. In terms of patient convenience, reduction of patient transport costs and reduction of time to treatment, it is advantageous for additional tests to be performed at the DXA appointment. In this model it is necessary to ensure that sufficient time and appropriate expertise are available to analyse and interpret the DXA scans at the time of BMD measurement. The cost of further investigations also needs to be included within a locally agreed tariff for the fracture risk assessment. The greater cost of a one-stop model may be offset by reducing the need for onward referral.³⁰

Key practice point

Consideration should be given to a one-stop service model where additional tests can be undertaken at the time of the scan appointment providing the benefits of convenience to the patient and reduced time to treatment.

A proportion of patients will present with complex osteoporosis requiring specialist management. It is necessary to ensure this need can be met through the provision of an appropriately staffed osteoporosis or metabolic bone clinic. This will usually be in secondary care and should have access to specialised investigations, techniques and expertise including:

- specialist physiotherapy and occupational therapy
- musculoskeletal radiology
- orthopaedic surgery
- laboratory investigations including biochemical markers of bone turnover
- and possibly bone biopsy and histomorphometry.

Key practice point

A bone densitometry service pathway should preferably include access to an appropriately trained and staffed osteoporosis or metabolic bone clinic for complex patients who require specialist management.

Figure 2 defines the key elements of a generic DXA pathway and provides the basis for detailed consideration of the operational issues relating to each stage of the pathway.

Case-finding	<ul style="list-style-type: none"> • primary or secondary care • systematic or opportunistic
Referral	<ul style="list-style-type: none"> • local referral criteria <ul style="list-style-type: none"> - assessment of patient by Registered Healthcare Practitioner • agreed mechanism of referral <ul style="list-style-type: none"> - authorised referrer
Appointment	<ul style="list-style-type: none"> • receipt of referral • justification and triage • decision about appointment required <ul style="list-style-type: none"> - consider possible special needs of patient • inform patient and send all necessary documentation
Scan visit	<ul style="list-style-type: none"> • greet patient and complete preparatory checks • scan acquisition and analysis • clinical risk factor collection • obtain any additional investigations
Reporting	<ul style="list-style-type: none"> • interpretation and clinical report by qualified clinician <ul style="list-style-type: none"> - written report to referrer and GP where this is requested/commissioned
Further investigation	<ul style="list-style-type: none"> • one-stop assessment • recall to clinic • advice to referrer

Figure 2. Key elements of the DXA pathway.

4. Operational considerations

When healthcare providers plan and implement a DXA bone densitometry service they need to consider certain factors that will enable them to utilise the available resources in a safe, consistent and efficient way. These factors include:

- the clinical pathway
- development and maintenance of up-to-date protocols in line with the evidence base, which optimise scan processes and exposures
- clinical and operational governance matters
- service staffing
- environmental issues
 - service supporting documentation
 - reporting and investigating incidents including statutory requirements.³¹

4.1 Regulatory framework

The management of the service is subject to compliance with a wide variety of regulatory frameworks, including:

- the Ionising Radiations Regulations 2017^{32, 33} will be referred to as IRR. These regulations are enforced by the HSE and are essential for the protection of staff and the public.
- the Ionising Radiation (Medical Exposure) Regulations^{35, 36} and subsequent amendments to these^{31, 37} will be collectively be referred to as IR(ME)R in this document.

IR(ME)R regulations are enforced by the CQC, Healthcare Inspectorate Wales (HIW), Regulation and Quality Improvement Authority (RQIA) and Health Improvement Scotland (HIS).

These regulations are intended to protect patients and carers from the risk of harm when undergoing X-rays or similar exposures to ionising radiation in a healthcare setting. Compliance with the IR(ME)R is an essential element of the patient pathway and legal obligations are placed on the duty holders:

- the employer¹
- the referrer
- the practitioner
- the operator

It is also the legal obligation for the employer to adhere to IRR and IR(ME)R. IRR are the legal requirements put in place to protect staff and members of the public from exposure to ionising radiation in the workplace. It requires employers to keep exposure to ionising radiation as low as reasonably practicable (ALARP), and to ensure that exposures do not exceed clearly defined limits for both staff and members of the public.

Staff education and training is a key aspect of ensuring the service is operated by staff who are suitably skilled, qualified and have the expertise required to safely and effectively deliver the service. The CQC requires enough suitably qualified, competent, skilled and experienced persons to deliver the service.³⁸ The staff must receive support, training, professional development, supervision and appraisals necessary for them to carry out their role and responsibilities.

Key practice point

Bone densitometry services must comply fully with the existing regulatory framework to protect patients, carers, staff and the public from risk of harm from exposure to radiation.

1. The employer referred to in the IR(ME)R is that employer responsible for the delivery of the medical imaging service (in this case DXA service).

4.2 Case-finding

Details of all relevant clinical scenarios are beyond the scope of this guideline. Case-finding involves identifying the sources of patient referrals and is an important part of the service model. It must not involve the creation of barriers to patients who would benefit from the service or to healthcare providers who require DXA bone densitometry to inform their medical decisions. Healthcare providers who refer patients with clear indications for a DXA bone densitometry examination should have access to the service. Assessment of bone density with DXA needs to be accessible to referrers within all levels of care as needed. Having in place streamlined and systematic referral pathways supported by robust processes to entitle non-medical and medical referrers will facilitate implementation of fracture liaison services, support the implementation of national guidelines and encourage the application of international guidance.

Likely sources of referral include:

- GPs and entitled non-medical referrers such as specialist nurses and allied health professionals working in primary care.³⁵
- Fracture liaison pathways.^{39,40}
- Opportunistic case-finding including the use of artificial intelligence software.
- Falls prevention pathways.⁴¹
- Secondary-care teams (e.g. rheumatology, gynaecology, oncology, endocrinology, care of the elderly/geriatrics).
- Healthcare providers who prescribe medications known to have adverse effects on bone health, including glucocorticoids (e.g. neurologists) and aromatase inhibitors (e.g. oncologists).
- Specialised care teams caring for patients with diseases or receiving treatments that affect bone health.

The referrer must be a registered healthcare professional who is entitled, in accordance with the DXA providers employer's procedures under IR(ME)R, to refer individuals to the service following locally agreed referral criteria.⁴²

Key practice point

All sources of patient referrals must be included in the service model to ensure effective case finding and equitable access to the bone densitometry service.

4.3 Referral

The DXA bone densitometry service providers will need to establish locally agreed referral criteria, clearly communicate the referral process (e.g. required clinical information, available methods of referral), and develop a referral pro forma. A sample referral pro forma is included in the appendices.

Referral indications will reflect national recommendations and guidance, current best practice, and prioritisation according to individual patient risk assessment and available resources. In exceptional circumstances the DXA providers may need to consult national prioritisation criteria. Under IR(ME)R services must include in their employer's procedures provision for cancelling referrals and for informing referrers when exposures are not justified.

DXA providers should consider recommendations made by several sources, need to be mindful that national and international guidance and recommendations change with time, and must be reviewed regularly and remain updated. Relevant guidance includes:

- the National Osteoporosis Guideline Group UK clinical guideline.²²
- the Scottish Intercollegiate Guidelines Network.²³
- NICE
 - TA160¹⁵/161¹³/204¹¹/464¹⁰/791¹⁴
 - CG146⁴³
 - QS149⁴⁴
- disease-specific guidelines (e.g. for chronic liver disease, liver transplantation, cystic fibrosis, inflammatory bowel disease and coeliac disease, breast cancer treatment, glucocorticoid treatment in patients with thrombocytopenia and in patients with chronic obstructive pulmonary disease etc).^{22, 45–51}
- additional guidance (e.g. NICE CG124, international guidelines).^{18, 22, 53–54}

DXA providers should explain the referral process, including the minimum required clinical information that needs to be in the referral form, and the method of referral (e.g. secure electronic, paper via post, etc) The available methods of referral depend on local circumstances, and may include:

- post
- electronic means
 - encrypted email accounts such as @nhs.net
 - 'Choose and Book'
 - electronic "order-coms" integrated into radiology information systems.

The referrer has a legal obligation to provide sufficient clinical information in the referral to enable the IR(ME)R Practitioner within the DXA service to decide whether the requested examination is appropriate and feasible, and the radiation exposure is justified. Irrespective of how the referral is made, it must have adequate information that allows the healthcare provider (who receives and reviews the examination request) to identify that:

- the referrer is entitled within the employer's procedures under IR(ME)R to make the DXA referral and has confirmed it in a manner that confirms their responsibility for it (e.g. signature on paper or electronic referral from their log-on account).

The referral must include adequate information to identify that either:

- the referred patient fulfils the set criteria for referral and therefore, the requested examination is appropriate

or

- in cases where the referred patient does not fulfil any of the set referral criteria, the referring healthcare provider has provided adequate and clear information in the request that clinically justifies the examination (the requested examination is appropriate).

Patient referrals are part of the patient's healthcare record and there is an obligation to handle these in line with the principles set in the relevant professional and national management codes of practice.⁵⁴⁻⁵⁸ There should be an appropriate system of management for referrals once received. This implies use of a secure database system such as a hospital patient administration system (PAS) or radiology information system (RIS). Referrals received in a hard-copy format should be digitised and included in the patient's electronic record (PAS, RIS, etc), and then the hard copy can be securely discarded.

Key practice point

DXA bone densitometry service providers must establish locally agreed referral criteria and communicate the referral process clearly to entitled referrers. The criteria should reflect national recommendations and guidance and be reviewed and updated regularly.

4.4 Appointment

Each referral needs to be reviewed by the IR(ME)R Practitioner to ensure that a DXA scan is justified or authorised by the operator under guidelines issued by the practitioner according to the employer's procedures. This ensures that it is an appropriate investigation given the information provided and clinical question to be answered. If a scan is justified, then the request must be authorised by recording a signature (physical or electronic).

Justification is the responsibility the IR(ME)R Practitioner who is a duty holder under these regulations. They must be a registered healthcare professional with appropriate training and entitled to undertake the role according to the employer's procedures. The Practitioner may also delegate this task to an operator under IR(ME)R – for example, a member of the scanning team. The operator does not need to be a registered healthcare professional but must be adequately trained and named as entitled to act as operator within the employer's procedures under IR(ME)R. The Practitioner must provide written criteria to the operator describing the circumstances under which a scan would be justified and the types of scans to be undertaken in each circumstance.

Once the referral has been through the correct authorising processes, the patient will be offered an appointment within six weeks of the referral being received.^{59,60} In England, DXA imaging is reportable to the DM01 NHSE monthly diagnostics waiting times and activity data provision notice used to measure performance against the operational standard, that less than 1% of patients should wait six weeks or more for a diagnostics test.⁶¹

Key practice point

All referrals must be reviewed, justified and authorised by the IR(ME)R practitioner or delegated under protocol to a member of staff with appropriate entitlement and training. Appointments should be offered within six weeks of the referral being received.

The mechanism of appointment may involve the use of one of the following systems: Choose and Book, fixed booking or invitation to the patient to telephone for a booking. Using Choose and Book for DXA services can be cumbersome as referrals that are not justified have to be rejected in a timely manner and if a service operates more than one scanner it is important that patients referred for a follow-up measurement are booked onto the correct machine. Patients should be provided with clear written confirmation of the booking and contact details to enable their appointment to be altered if it is unsuitable. Additional information given to the patient prior to appointment may include:

- a leaflet about the DXA scan, the benefits and (very small) risks of ionising radiation and what to expect at the appointment (See [ROS DXA information](#) and [NHS DXA-Scan](#))
- what clothes to wear and what to do if the patient has recently undergone a nuclear medicine scan or another test using contrast medium, or may be pregnant
- a risk factor questionnaire for the patient to complete and bring to the appointment
- directions to the location of the DXA scanner and details of transportation and car parking
- contact details for the bone densitometry service
- a request that the patient contacts the bone densitometry service at the earliest opportunity if they are unable or do not wish to attend their appointment.

It may be helpful to issue a reminder shortly prior to the appointment to reduce the incidence of non-attendance. This may be via letter, text message or telephone, depending on local capabilities.

4.5 Scan visit

On arrival for the DXA bone densitometry scan the service should perform the following checks:

- Patient details confirmed, to always include 4-point ID. The identification procedure should include name, including family name and first name, date of birth, address and the correct examination being performed/ previous examinations taken place in the last 7 days.
- 'Attendance' of patient-on-patient administration systems, radiology systems or similar.
- Completion of risk factor questionnaire, which should be made available to the operator.
- Including list of past or current bone protection medication or medications that can affect bone health. This is particularly useful for the interpretation of reports especially if oral medication has not been tolerated or duration of medication.

To obtain an informed patient consent and comply with regulatory elements the operator will (according to local protocols):

- introduce themselves to the patient
- confirm patient ID
- enquire about the possibility of patient pregnancy (see advice below regarding transgender, non-binary and intersex patients)
- explain the reason for the visit
- what the scan is going to involve
- if not already explained in the patient's scan leaflet, the radiation risks arising from the DXA scan.

It is an IR(ME)R requirement to identify any pregnancy risk to individuals of child-bearing capacity. The operator must ask whether they are or might be pregnant according to local employer's procedures.⁶² This will need to be documented within the radiology system and a signature obtained as per local policy.

The requirement to identify any risk of pregnancy applies to all patients including transgender, non-binary and intersex patients. This must be done sensitively and with compassion. Services should consult the Inclusive Pregnancy Status Guidelines for

Ionising Radiation (2021) for how best to accommodate all patients regardless of age and gender, facilitate effective communication with transgender, non-binary and intersex patients and ensure patient safety.⁶³⁻⁶⁵

At this stage it should be determined that there are no contraindications or circumstances that might influence the scan outcome, such as recent nuclear medicine scans, investigations involving X-ray contrast or in-situ metalwork.

The patient's height and weight should be measured accurately and entered into the scanner database. Any changes in height and weight should be recorded on the questionnaire for the attention of the reporter.

The required DXA scans should be performed following local protocols and standard operating procedures (SOPs) and local rules. These will be based on guidance provided by the manufacturer; and approved through local governance structures.

All images must be checked while the patient is still present in case any need to be repeated or additional scans are required (e.g. a forearm scan if either the spine or hip result is unreliable). This will ensure that the images obtained, are of optimal diagnostic quality, are accurate according to current best practice and are optimised to reduce precision error.

IR(ME)R schedule 2 requires employers to have a written procedure for 'the carrying out and recording of an evaluation for each exposure including, where appropriate, factors relevant to patient dose and processes to record this are essential within a service.

Depending on the service model (such as a fracture liaison service) further investigations (such as radiographs and laboratory tests) may be undertaken at the same appointment (according to appropriate procedures for referral, justification and authorisation). This decision should be made based on the initial BMD measurements, information in the referral pro forma and patient history. The patient may need to spend time with a nurse or practitioner at this point if there are any questions or concerns.

At the end of the appointment the patient should be advised on how they will receive the results and the expected timescale. Any additional information can also be given to the patient at this point, to include information leaflets promoting bone health or signposting to information on the Royal Osteoporosis Society website.

Key practice point

Written employer's procedures must be in place and adhered to for patient identification and possibility of pregnancy.

A fracture risk assessment should be conducted alongside measurement of bone density and risk factor questionnaires should be used to optimise the scan interpretation.

Informed consent must be obtained through explanation of the scan and benefits and risks of harm from radiation.

All patients should be sent a letter/ leaflet on what to expect from their scan alongside their appointment invitation.

Clear information must be given to the patient regarding any factors affecting the reliability of the result.

4.6 Reporting

Reporting DXA scans is a clinical act and is considered a practical aspect of the examination under IR(ME)R. Therefore, those reporting DXA scans must be entitled to do so in the Employer's Procedures under IR(ME)R. It needs to be carried out by registered healthcare professionals who have the necessary skills, education and qualifications to make clinical decisions. There is a range of registered healthcare professionals who satisfy these principles. Irrespective of one's professional background, it is essential for any healthcare professional undertaking reporting DXA bone densitometry examinations to have relevant education and training.⁶⁶ They should be entitled as operators within a clearly defined and written scope of practice. Those undertaking DXA reporting should undergo regular audit to ensure that their reports remain accurate, appropriate and in line with the reporting standard operating procedures (SOPs) within the department as required by regulation 7 of IR(ME)R 2017, and outlined in guidance from both the RCR and Society and College of Radiographers.^{18,31,67,68} Local agreement will determine who is responsible for reporting the scan results to the referrer. This is ultimately the responsibility of the lead clinician who oversees the service. The lead clinician will usually be a medical practitioner, but it may be another registered healthcare professional such as a radiographer.

To avoid clinical risk associated with partial or unclear reports, they should:

- be integrated into the patient electronic healthcare record, and not stand-alone documents
- use the ROS standard reporting template
- if formatting is limited, use capitals and line breaks to delineate different sections.

Detailed advice about interpretation and reporting may be found in the guidance by the Royal Osteoporosis Society and the International Society for Bone Densitometry.^{18,67,69} The DXA bone densitometry providers, the referrers and the commissioners of the service should reach an agreement about the scope and content of the DXA report. Reports should only be sent to a GP

where this is requested or where the service is commissioned to do so. IR(ME)R schedule 2 requires employers to have a written employer's procedure for 'the carrying out and recording of an evaluation for each exposure including, where appropriate, factors relevant to patient dose.' It is insufficient and inappropriate therefore to send an unevaluated or uninterpreted DXA scanner printout to referrers because the data included in the DXA scanner printouts do not include clinical interpretation that can be used and/or verified by the referrer. Clinical evaluation is particularly important for non-specialist referrers and patients to understand the measurements and recommendations.

Reports should:

- Use the Royal Osteoporosis Society standard template.
- Include a clinical interpretation, written in lay language.
- Present the bone mineral density result and the fracture risk assessment together in an integrated statement or sentence, emphasising that bone density only represents part of a person's fracture risk and needs to be considered in context of other fracture risk factors and that treatment decisions should not be based on bone density alone.
 - Present only one bone density WHO classification result. For example, in a report of a patient with a lumbar spine measurement that falls in the range of "low bone density (osteopenia)" and a left hip measurement that falls in the range of "osteoporosis", only one term should be used in the report; in this example it would be the term "osteoporosis."
 - The fracture risk assessment should include the patient's height, weight and risk factors used, to support replication if needed, and personalised sentence about potential over/under-estimation of fracture risk.
 - Use appropriate terminology including using 'low bone density (osteopenia)' instead of 'osteopenia' in isolation. Do not describe osteopenia as a diagnosis or diagnostic classification. Use increased (high/very high) fracture risk instead of high/very high fracture risk alone to reduce fear and avoidance behaviours.

- Include a clear statement(s) of recommended actions to consider, in lay language, that are individualized and evidence based. For example, this can be a recommendation for management, a follow up scan, additional investigations, specialist referral, etc. Individualisation should be specific for the patient scanned and the referrer. For example, recommending a specialist referral to a patient referred by a specialist would not be relevant. It is important to refer to transgender, non-binary or intersex patients using their pronouns of choice rather than pronouns denoting their gender at birth which would be inappropriate and harmful.
- Explain the limitations of T-scores and fracture risk scores for people from minority ethnic backgrounds, including relevant reference data used.
- Include signposting to relevant guidelines and patient resources to aid understanding. For example, transgender patients can be referred to the ROS guidance on transgender people and osteoporosis.⁶⁵
- Be specific stating information relevant to the patient, the examination and the clinical question raised in the referral.
- Include information about the scanner manufacturer and software version used, if not already on the report.
- Define the technical validity of the scan and of the measurements. The report should explain any factors that may affect the quality and reliability of the data acquired and their analysis and make a recommendation about the suitability of the modality, when relevant. For example, in a patient with bilateral hip arthroplasty and severe lumbar scoliosis identified at scanning, DXA of the spine and hip would not be appropriate.
- Explain the site scanned and analysed. For example, lumbar spine, right hip, etc.
- Describe in a clear, accurate and easy to understand way whether there has been a comparison with previous DXA measurements and whether any identified difference is statistically, or clinically, significant or not. For example, describing measurements acquired from different scanners would not be reliable and should not be used to guide clinical decisions; and use of specialised language to describe the degree of significant change can be confusing.
- Provide a recommendation for appropriate time interval to consider follow-up DXA assessment.

Further recommendations about the content of the report can be found in Appendix 4C ([Template Report - Fracture risk and bone density assessment](#)).

Referrers may require a more detailed report that provides details of the acquired data at each anatomical site and individualised management advice. The highest quality service will be achieved by close collaboration between those with a detailed understanding of the technical basis for DXA and the quantitative nature of the immediate outcome, often from a medical physics or clinical imaging background; experts in the medical management of osteoporosis, often specialist secondary-care physicians; and those who must manage individual patients, for example, GPs and other primary and secondary healthcare practitioners.

Reports should be issued within an agreed period and be integrated into clinical imaging health record systems. The electronic version should be archived. This will frequently be stored in association with the DXA images using a PACS (Picture Archiving and Communication System) record. It is a requirement of IR(ME)R that there is a written clinical evaluation of the outcome of any medical exposure (scan).

Consideration should be given to quality control and undertaking audit and/or peer review of the reports. Feedback from referrers is also important to ensure that the report meets the requirements of the clinician who will be managing the patient.

Ideally services will share the DXA report with the patient. Patients are also increasingly able to access their DXA scan reports (e.g. via the NHS app) independently from a health professional. This practice follows the principles of patient empowerment and health data (patient) ownership. This highlights the need for the DXA report to be written in lay language that considers the patient needs and health literacy, relevant codes of practice, and local standard operating procedures (SOPs).

Key practice points

Reporting should be undertaken by a registered healthcare professional with appropriate training who is entitled to do so under IR(ME)R.

DXA bone densitometry providers should provide reports that are actionable by the referrer, who will often be a non-specialist physician.

DXA reports should be integrated into electronic patient health record systems.

Reports should include personalised information for the patient, a clear and understandable summary of results and information about the reliability of data acquired where relevant.

Reports should:

- include a clinical interpretation, written in lay language
- use the Royal Osteoporosis Society standard template
- present the bone mineral density result and the fracture risk assessment together in an integrated statement or sentence
- include a clear statement(s) of recommended actions to consider, in lay language, that are individualized and evidence based
- include the patient's height, weight and risk factors used for fracture risk calculation and personalised sentence about potential over/under-estimation of fracture risk.
- explain the limitations of T-scores and fracture risk scores for people from minority ethnic backgrounds, including relevant reference data used.
- include signposting to relevant guidelines and patient resources to aid understanding.

For a repeat DXA measurement, the report must explain whether any identified change is statistically or clinically significant.

The service must ensure that regular audits of reports are carried out for accuracy and appropriateness.

Recommendations for the ongoing management of the patient and any fracture risk assessment calculation should be included.

4.7 Further investigation

Depending on the result of the DXA scan and the clinical information available from the patient's history, referral and other relevant healthcare records, further investigation may be indicated.

Height loss or appearances on DXA images and areal measurements, may suggest the presence of vertebral fracture(s), necessitating further imaging. Further imaging could include vertebral fracture assessment (VFA) at the time of the DXA if there is resource availability (appropriate scanner, skills, time, etc) and the patient agrees, or referral for radiographs according to local referral arrangements.

Indications for further investigations may include:

- Presence of low-trauma vertebral fracture. This can be a new finding incidentally seen during scanning or a previous known vertebral fracture that has progressed in severity.
- Loss of height greater than 4cm.
- Increased thoracic kyphosis, particularly when symptomatic (for example, dyspnoea, imbalance, difficulties sleeping, etc).
- Any of the indications for DXA vertebral fracture assessment examination (for example, a T-score below -1.0 in a woman older than 70 years or a man older than 80 years).⁶⁹
- Low BMD for age (e.g. Z-score less than -2.0).
- Unexplained bone loss on a serial measurement.

- Clinical suspicion of an underlying cause of osteoporosis (secondary osteoporosis).
- Known contra-indication to treatment.
- Any appearance at any of the visualised anatomical structures that raise the suspicion of an underlying pathology, and which cannot be verified as known/old by the patient and/or the available patient records.
- Radiographs should be considered according to local protocols where there is a grade 1 (mild) vertebral fracture identified on VFA to exclude non-fracture deformity where this has not already been imaged or documented.

In addition, baseline investigations may be required prior to the introduction of treatment. These will depend on the indication for which patients undergo assessment for osteoporosis, should follow the national recommendations and need to be locally agreed with the referring and specialised healthcare providers. Recommendation about blood tests and further investigations is beyond the scope of this document and further recommendations are available in the National Osteoporosis Guideline Group UK clinical guideline.²²

Wherever possible, provisions should be made so that any baseline investigations that are required may be obtained at the same time as the DXA scan. In case of incidental imaging findings and/or identification of clinical indication for further assessment at the time of scanning, the DXA provider may either refer/recall the patient to an out-patient clinic or guide the referring healthcare provider to request the required tests and seek further clinical advice if necessary.

Key practice points

Vertebral fracture assessment should be conducted if there is a history of height loss in the patient or appearances in the DXA images or measurements that suggest the presence of a vertebral fracture- where this has not already been imaged or documented.

Radiographs should be considered according to local protocols where there is a grade 1 (mild) vertebral fracture identified on VFA to exclude non-fracture deformity where this has not already been imaged or documented.

4.8 Clinical/operational governance

There will be many operational considerations to define and implement the DXA pathway. While these need to be defined at the outset they will also need to be reviewed and developed over time. A process of formal pathway-mapping involving the whole team can be an effective means to streamline pathways and reduce clinical risk.

4.9 Policies, protocols and standard operating procedures

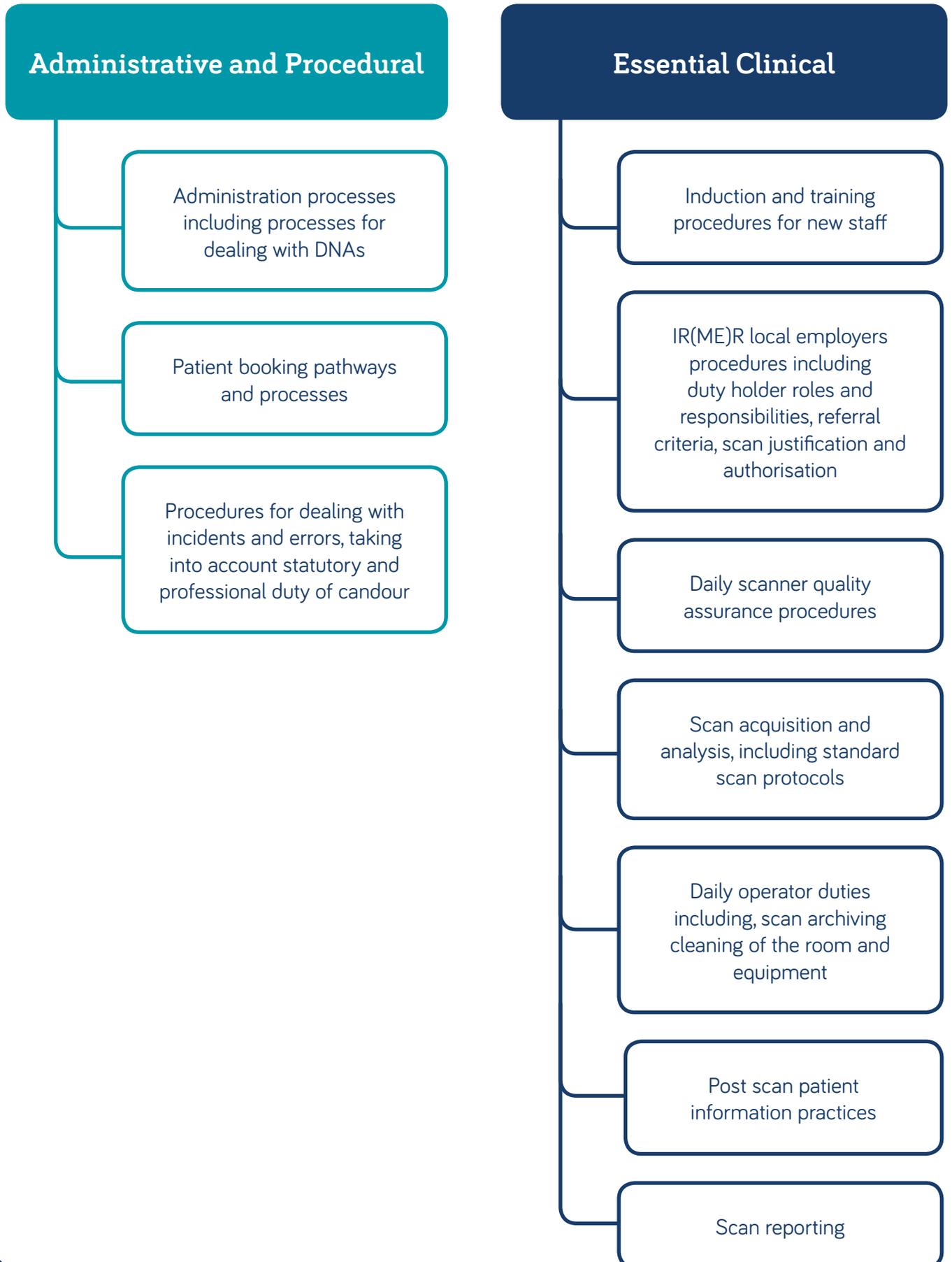
It is essential to document the detail of each element of the pathway through standard operating procedures (SOPs) and protocols so that the DXA measurements made are accurate, precise and reliable to best inform the clinical decisions based upon them.

This is increasingly important with the involvement of a more diverse range of operators both professionally registered and technical or support roles, and in teams where many operators may scan patients e.g. if DXA scans are undertaken by a team of operators who rotate within a larger department and have other roles. This must include establishment of minimum competencies and their review.

SOPs are an important element of an induction process for new staff; maintaining competence of more experienced staff; and setting the standard by which quality may be routinely monitored.

Procedures must be clear about what is to be undertaken, by whom, and when and where (if these latter parameters are relevant). Procedures should consider national guidelines and legislation relevant to the service and should detail how these are to be implemented locally.

Examples of procedures which will need to be considered include:



Some policies and procedures are mandated under IR(ME)R and must be provided and audited against, others are best practice and support clinical governance and quality assurance. Together they make up the service specifications for a quality bone densitometry service.

Essential policies, procedures and protocols include:

1. Patient referral policy
 - indications for DXA
 - exclusions
 - follow-up measurement and timing
 - procedure for justification and authorisation
 - protocols for delegation
 - entitlement of referrers
2. Management of patients who do not attend appointments
 - rebook or discharge
 - clinical review or clerical decision
 - communication with patient and referrer/GP
3. Use of telephone, letter text or other reminder service
4. Clinical DXA scanning
 - Daily Scanner QC procedures
 - Clinical scanner operation
 - Patient identification
 - Pregnancy checks
 - Skeletal sites scanned including scan mode selection
 - Scan positioning
 - Scan analysis including checking for presence of artefacts
 - Reporting including:
 - recommendations for intervals between sequential scans,
 - T and Z-score management thresholds,
 - definition of least significant change
 - archiving
5. Radiation-protection documentation (in consultation with the Radiation Protection Advisor and Radiation Protection Supervisor):
 - local rules for all work areas involving ionising radiation to define controlled areas and set out responsibilities of staff (IRR 2017)
 - written systems of work setting out safe methods of working
6. Quality assurance framework including:
 - Clinical audits for scan technique and reporting
 - IR(ME)R procedure audit
 - Scanner QC procedures
7. Complaints
8. Incident reporting
9. Equipment inventory
10. Operator training, competency and record of training.

Key practice point

Every element of the pathway should be documented in detail through standard operating procedures (SOP) and protocols that are clear about what is undertaken, when, where and by whom. This ensures that the DXA measurements remain accurate, precise and reliable when undertaken by a range of trained operators.

4.10 Radiation protection

Although the radiation dose from a DXA scanner is relatively low, the legislation in place to protect patients and carers (IR(ME)R), staff and the public (IRR) still apply.⁷⁰ It is important to contact and obtain advice from a radiation protection adviser (RPA) and a medical physics expert (MPE) early in the planning process so that they can indicate when and where their input will be required.

If the DXA service is to be part of an organisation that already carries out medical X-ray investigations, then it must have appointed an RPA and MPE and these people should be contacted. Otherwise, the employer setting up the new DXA service will need to obtain the services of suitably qualified experts.

Additionally, employer's procedures for optimisation of exposures and the use of diagnostic reference levels, required under IR(ME)R, must be considered. Using a supplier's default protocols may not represent the most optimised exposures for the clinical patient cohort and therefore must be considered.

Employer's Procedures regarding optimisation under IR(ME)R will include:

- Entitlement of referrers in line with scope of practice
- Appropriate referrals using referral guidelines
- Justification and optimisation of exposures
- Adequate training for operators undertaking exposures and making the clinical evaluation.

Note that if you intend to start work for the first time with ionising radiation in the category referred to by IRR as 'radiation generators', you will need to register with the HSE.

The HSE provides guidance on the regulatory requirements associated with medical exposures.⁷¹

Key practice point

A radiation protection adviser and medical physics expert should be involved early in the planning process to indicate when and where their input will be required to meet the requirements of radiation legislation and to inform the quality assurance framework for the equipment.

4.11 Healthcare governance

The service must operate within a robust healthcare governance framework. It must be able to demonstrate written evidence of compliance with national and local standards of safety relating to radiation exposure, electrical safety, fire risk, moving and handling, and health and safety legislation. Some areas for consideration are highlighted here.

4.12 Workforce

Staff should possess appropriate qualifications and experience for their role and have up-to-date registration with appropriate healthcare regulators.

As regards staff, the employer must ensure that:

- there is adequate provision of continuing education and training
- competency is evaluated and maintained
- there is adequate supervision
- there are defined lines of accountability
- there is access to support (e.g. occupational health service).

Key practice point

The bone densitometry service needs the workforce to have access to training, appropriate supervision (and defined lines of accountability) and should be subject to ongoing evaluation of their competency.

4.13 Infection Control

To prevent infection and reduce the risk of the spread, SOPs should be in place to cover routine cleaning and decontamination of the DXA scanner and management of patients known to carry infections such as MRSA. Vaccination of staff against hepatitis B and influenza should be considered.

4.14 Equal access

The service must be compliant with the Equality Act 2010 relating to equal access and avoidance of unfair discrimination.⁷²⁻⁷⁴ The Equality Act 2010 protects several characteristics including disability, gender reassignment and ethnicity; services that have not made reasonable adjustments for these patients would be in contravention of this legislation.

Examples of the practical implications of equality of access include the availability of:

- a language-interpretation service (in person or by telephone)
- a hearing loop
- patient literature in:
 - languages relevant to the locality
 - large script
 - braille
 - easily accessible format for those with a learning disability and cognitive impairment

It is important to remember that a DXA scanning service has a large proportion of older adults attending and many patients will have mobility problems and disabilities that may make it difficult to access the department and scanning table. This has important implications for the design of the facility, provision of patient handling aids and staffing.

By way of example, patients who require a hoist to transfer to the scanner can sometimes have difficulty accessing bone densitometry services, highlighting the importance of considering their needs. When planning a new service or reconfiguration of an existing scanning room, it is important to consult with local manual handling leads when considering how to safely transfer patients with mobility difficulties to the scanner and to plan for these accordingly, e.g. provision of an overhead hoist.

Key practice point

The bone densitometry service must comply with the Equality Act 2010 and make reasonable adjustments for the large proportion of patients who will have mobility problems and disabilities. Arrangements should be made at the planning stage to meet the needs of these patients to ensure that they can access the service, such as the use of a hoist for example.

4.15 Information governance

All handling of personally identifiable data must be carried out in compliance with the Data Protection Act 2018 and local policies.⁷⁵ The service must comply with the principles of the Caldicott Guardians, particularly in defining methods of communication between referrers and the service.⁷⁶

DXA scans should be archived at the end of each working day, storing the image and, importantly, data files in a secure system external to the scanning equipment. In addition, the database should be archived at appropriate intervals (usually weekly) onto digital media. During the database archiving process, automatic deletion of images can be selected to optimise disc space. The digital database archive should be a separate medium and stored in a different location from the scanner to protect against loss (e.g. by fire or theft). It is advisable to have two sets of database archive media in case an archive becomes corrupted. If the DXA scanner is linked to an NHS network and/or PACS, there is likely to be an automatic daily backup to a central server. However, PACS stores only images and a limited dataset so this will not obviate the need for local archiving of the full dataset, which is required to enable serial measurements to be performed optimally. All patient identifiable data must be encrypted if data is to be transmitted electronically.

5. Monitoring and reporting service data

Records should be maintained to enable service review and audit. The information recorded may be agreed with commissioners, but additional data collection may be useful internally. Outcomes will include:

- referral data (number of referrals, referral indication, source of referral)
- DNA (did not attend) and cancellation rates (analysed to evaluate strategies to maximise use of capacity)
- waiting times for scans and time to issue of report
- record of all training undertaken by staff
- scanner service and maintenance records and a repair log
- safety data, clinical incidents/near misses with evidence of root cause analysis and outcomes
- clinical outcomes:
 - proportion of patients in WHO diagnostic categories
 - proportion of patients requiring onward referral (to an osteoporosis clinic or to other services, e.g. falls prevention).

5.1 Quality assurance

Services require robust quality assurance (QA) procedures, to ensure consistent compliance with regulation, contractual obligations and local procedures outlined in the IR(M)ER employer's procedures, as well as to ensure the reliability of the quantitative outcomes from the DXA scanner itself. This may be supported through local quality assurance programmes or national schemes such as the Quality Standard for Imaging or ISO accreditation.^{77,78}

Checks on specific instruments should be undertaken in accordance with the DXA manufacturer's guidelines and all operators should understand the QA procedures, the action to be taken if a scanner fails a check and their responsibility in performing and reviewing the results of QA procedures.

Routine QA processes must include as a minimum:

- daily quality control (QC) and calibration scans
 - Daily QC and calibration should be undertaken according to the manufacturer's recommendations and procedures, before any patient scanning commences. If a machine fails its daily QC check then scanning should be halted and local procedures followed to investigate the cause, and scanning should only be resumed when it has been resolved.
- regular independent phantom quality assurance (QA) scans
 - Independent QA checks using an appropriate phantom should be carried out a minimum of once per week, and preferably daily, prior to patient scanning commencing.

A record of any issues that could potentially affect the reliability of the DXA scan should be provided to the person reporting the scan for reference at subsequent scan appointments. These issues may be:

- scanner-related
- patient-related (e.g. difficulty with positioning, a 10kg change in patient weight or non-standard scans being undertaken and reason for doing so).

Service and repair records should be kept, including details of any faults discovered.

Key practice point

Services require robust quality assurance procedures to ensure compliance with regulation, contractual obligations and local procedures, as well as to ensure the reliability of the quantitative outcomes from the DXA scanner.

5.2 Maintenance

All X-ray equipment used by the service must be maintained and performance tested regularly to enable safe and reliable functioning.³² Servicing must be undertaken by qualified personnel; in the case of the DXA scanner, this will usually be provided within a servicing and repair contract with the manufacturer or distributor of the device. DXA operators should maintain a daily equipment log to record any problems encountered with the DXA scanner for reference at maintenance visits.

There must be a handover procedure transferring responsibility for the scanner and any “controlled” area around it to the service engineer as well as for receiving it back into clinical service.³² The industry standard ‘AXREM’ form may be used.⁷⁹

It must not be forgotten that other items of equipment will also require regular maintenance. This will include weighing scales and stadiometers (both requiring regular calibration checks), and hoists.

A planned equipment-replacement programme should be established, which may include cross-calibration between equipment. It is generally stated that the useful lifetime of a DXA scanner is around 10 years. Certainly, beyond that time it may become difficult to obtain replacement parts for repair or the scanner may be designated as “end of life” by the manufacturer, which may no longer guarantee repair in the event of a breakdown.

Key practice point

All X-ray equipment used by the service must be maintained to enable safe and reliable functioning. Other equipment such as weighing scales and stadiometers should have regular calibration checks

6. Staffing the DXA service

Staffing requirements will depend on the service model chosen but there is a minimum requirement necessary to deliver a high-quality densitometry service and generic recommendations can be made about the staff configuration. An additional allowance of approximately 20% for annual, sick and study leave needs to be incorporated at the planning stage. The staffing structure within the organisation should be defined indicating clear lines of management and accountability. All staff should have access to appropriate training and continuing professional development (CPD).

At the heart of the DXA service is a medical exposure. This must be justified by a practitioner who, by regulation, must be a registered healthcare professional.³⁵ Therefore, the service must always have at least one registered healthcare professional contracted to provide this function.

Reporters need to be given sufficient time to undertake reports with clinical interpretation.

Key practice points

At the planning stage, sufficient staffing must be put in place to deliver a consistent, high-quality densitometry service – with an additional allowance for annual, sick and study leave.

A DXA bone densitometry service must always have a registered healthcare professional contracted who is trained entitled and responsible for the justification of medical exposures.

DXA bone densitometry reporters should be given appropriate time to undertake reporting with clinical interpretation.

6.1 DXA operators

The DXA operator is the person carrying out the authorised procedure under IR(ME)R.³⁵ DXA operators should be adequately trained healthcare professionals, typically radiographers, nurses, or clinical technologists. Accredited assistant practitioners working within an appropriate scope of practice can be a valuable addition to a DXA service.⁸⁰ IR(ME)R states that the “practitioner or operator must not carry out any exposure or any practical aspect without having been adequately trained.” This means that “Practitioners and operators must have successfully completed training, including theoretical knowledge and practical experience in - a) such of the subjects detailed in Table 1 as are relevant to their functions as practitioner or operator; and b) such of the subjects detailed in Table 2 as are relevant to their specific area of practice.”

Equipment-specific training should be provided by the company supplying the scanner. Further training is desirable and available through courses such as those provided by the Royal Osteoporosis Society and the International Society for Clinical Densitometry (ISCD). Operators must continue to maintain their skills and knowledge. Time and funding need to be allocated to enable CPD.

Operators must have sufficient grounding in the field of osteoporosis to be able to explain the purpose and nature of the test to the patient. However, they need to recognise the limits of their knowledge and, unless they are clinically trained, they should not give clinical advice to patients. Operators must be familiar with the importance of good positioning and be able to consistently acquire, analyse and archive studies in accordance with the manufacturer’s guidance and local procedures. They must also be able to recognise artefacts, be able to perform routine QA scans with a suitable phantom prior to scanning patients and be aware of the procedures to be followed when devices are not working correctly.

The employer is required to appoint a radiation protection supervisor (RPS) under IRR 2017. The RPS should have had appropriate training for the role. They should be in a line-management position but also routinely involved with the work. The role of the RPS is to oversee working practices and to ensure compliance with the legislation, including local rules that govern the use of equipment.

Key practice points

DXA operators must be trained and entitled, as defined by IR(ME)R. The operators must undergo additional training in bone densitometry (such as ROS bone densitometry training) and have the time and funding for CPD.

DXA operators must work within their defined scope of practice and be able to explain the purpose of tests, regardless of grade or professional background.

6.2 Nursing staff

The employment of nursing staff within a DXA service is becoming more desirable, particularly with the introduction of fracture liaison services and in support of multi-disciplinary team working. This depends on whether the DXA scanner is sited within secondary or primary care or sited within an imaging or medical physics department.

Qualified nursing staff must possess the necessary knowledge and experience in the diagnosis, prevention and treatment of osteoporosis to offer support and advice to patients attending for DXA or following diagnosis of osteoporosis. It is also important to have the theoretical knowledge and practical experience in radiation production, radiation protection and statutory obligations relating to ionising radiation under the IR(ME)R regulations if nurses⁵⁶ are going to be involved in DXA scanning as well as patient guidance, treatment and care.

Nursing staff should ensure that patients have a clear understanding of the condition and its treatment. This is vital to support good compliance with medication and lifestyle advice. Pathways can be developed to provide the link between the DXA service, falls prevention and fracture clinics and fracture liaison services. The ROS have developed guidelines for FLS, 'Effective Secondary Prevention of Fragility Fractures: Clinical Standards for Fracture Liaison Service' (2019).⁸¹ Use of these standards may assist and support nursing staff to achieve the standards required and provide a comprehensive service.

Healthcare assistants may support the DXA operators and improve efficiency of patient throughput by preparing patients for their scan and making measurements of height and weight. For services where patients are required to change into a gown, healthcare assistants can support this requirement. They may also be required to act as chaperones for some patients.

In many cases, the DXA service will integrate with the osteoporosis clinics and facilities for intravenous treatments to be administered. Nursing staff are a key component of a comprehensive service model like this and may have additional roles and responsibilities such as:

- Telephone helpline for patients and carers.
- Education of patients and healthcare professionals.
- Clinical governance
- Identifying patients over the age of 50 who have recently sustained a low-trauma fracture through FLS pathways. This may include entering the data into a national audit such as the FLS-DB.
- Telephone clinics.

6.3 Medical staff

The clinical responsibility for the service is frequently taken by a medical practitioner, although depending on the service model, it may be the role of another registered healthcare professional. Osteoporosis is relevant to many medical specialties and the background of the lead clinician may be within general practice but is more usually within one of the imaging specialties (i.e. radiology or medical physics) or within one of several medical sub-specialties including rheumatology, endocrinology and care of the elderly. The specific skills and expertise required for the role will span this range and good collaboration with colleagues is important. Management of osteoporosis and metabolic bone disease is included within the training programmes for general practice and trainees in several medical specialties. Key skills and expertise are discussed in the Royal Osteoporosis Society guidance on reporting¹⁸ and may be summarised as follows:

- Working knowledge of:
 - DXA technology
 - ionising radiation legislation
 - principles of scan acquisition and analysis
 - evaluation of the validity of DXA measurements including identification of anomalies, artefacts and confounding pathology
 - normative databases and their limitations
 - basic statistics.
- Detailed knowledge of osteoporosis including normal bone physiology, aetiology, epidemiology and clinical presentation; in particular:
 - the relationship between BMD, clinical risk factors and fracture risk
 - underlying causes of osteoporosis and relevant investigation
 - use of therapeutic agents in the management of osteoporosis.
- Working knowledge of:
 - current clinical guidance, and understanding of cost-effectiveness and local and national strategies
 - clinical governance in relation to DXA reporting.

- A commitment to:
 - CPD and clinical audit
 - working within a local multi-disciplinary team and available clinical networks to provide an optimal service
 - the education of health professions and the public
 - maintaining membership of appropriate professional organisations such as the Royal Osteoporosis Society.

The lead clinician will be responsible for providing leadership to the service and ensuring there is an appropriate managerial framework by:

- maintaining and extending their own knowledge and experience in relevant areas
- appointing sufficient, appropriately experienced and qualified individuals to safely deliver the service
- ensuring a framework of policies and procedures is implemented to deliver compliance with statutory obligations, best-practice guidance and the employer's own policies and procedures
- liaising with stakeholders including patients, carers and referrers
- seeking to develop the knowledge and experience of existing staff

Key practice point

The clinical leadership of a bone densitometry service requires skills and expertise in imaging, osteoporosis and bone health. Multi-disciplinary team working is essential (e.g. rheumatology, endocrinology and geriatric medicine).

6.4 Scientific support

To address the requirements of IR(ME)R, the service requires involvement of a suitably qualified MPE. Refer to chapter 4 (regulatory framework and radiation protection).

Given the low radiation doses involved in DXA and the limited opportunity the operator has to modify the radiation exposure, involvement of an MPE may be quite limited once the service is set up and running. However, if a significant accidental or unintended exposure occurs, this must be reported to the appropriate regulatory body (HSE or CQC/ HIW/RQIA/HIS), and input and advice from the MPE will form an essential part of this process.

Advice also needs to be sought from the RPA appointed for the organisation concerned. The RPA must hold a valid certificate of competence from an organisation recognised by the HSE as an Assessing Body for the certification of individual RPAs. (see Chapter 4)

An employer using a source of X-rays such as a DXA scanner is legally obliged to consult an RPA on specific issues. In general, the RPA will:

- advise the organisation on compliance with IRR, working to a minimum of the Approved Code of Practice³⁴
- review proposed plans for the scanner installation to ensure that there is adequate radiation protection for staff and members of the public and provide advice on any requirements for a designated area
- produce a report confirming that the installation meets the protection specification agreed by their own RPA at the planning stage
- advise on radiation safety procedures and the ongoing testing of equipment for radiation safety.

A suitably qualified scientist may undertake other tasks outside the statutory roles of the MPE and RPA. They will typically be a registered clinical scientist, preferably with professional membership of the Royal Osteoporosis Society.

A Clinical Scientist is regulated by the Health and Care Professions Council (HCPC) and a list of current registrants is published.

They may provide guidance on the following tasks:

- supervision and analysis of quality-control data
- advice on possible errors in individual scans arising from physical limitation or technical issues
- troubleshooting of faults
- training of operators
- cross-calibration of scanners
- support for the introduction of new techniques
- assistance with selection of a new scanner.

6.5 Administrative and clerical staff

The service will require an administrator to make appointments and be a first point of contact for queries. A receptionist to greet patients is preferred and they may be shared with a wider imaging department.

There is a range of semi-automated reporting software that may be used to reduce the amount of administrator time required and many hospitals are moving to fully electronic systems for reporting and report distribution.

Key practice point

A bone densitometry service must have access to support functions that enable efficient administration of the service, such as making appointments, fielding queries and greeting patients.

7. Environmental issues

7.1 Premises

The geographical location of the service is important. There are many factors that influence the choice of location and these need to be prioritised for the locality, as the final decision is likely to require compromise. The factors include:

- accessibility for patients
- central location within the referral catchment area
- public transport links
- car parking, including for the disabled
- access to related facilities
- imaging department
- clinical laboratory
- out-patient clinic.

If an additional scanner is required within an existing service, the relative merits of co-locating the scanners or siting them separately need to be considered. Co-location will facilitate economies of scale, especially in relation to staffing requirements, whereas separate sites may improve access for patients. Whichever option is selected, it will be important for the service to function in a unified manner to ensure equity of access and clinical experience.

In rural areas it may be advisable to consider the use of a mobile DXA unit. While this may appear an attractive option to provide a service that caters predominantly for older individuals, the advantages and disadvantages need to be carefully appraised.^{82,83} The mobile option may prove to be less cost-effective when consideration is given to factors such as travel costs and time and the reduction in patient throughput due to limited space within the unit. Sites to be used for the mobile unit will require an appropriate power supply and access to toilet facilities and a waiting area. These may already be available where other mobile services such as breast screening or retinal screening are provided, but power-point compatibility will need to be confirmed. Introduction of a mobile service is best achieved through careful planning involving all stakeholders. The procedure for referral to the mobile service may differ from that for a static site, especially where diagnostic waiting times apply. In such cases, the referrers for the catchment area covered by a mobile site may, over a period of time identify patients to be offered an appointment when the mobile unit is due on site.

Key practice point

At the planning stage, consideration must be given to the location of a service to allow for easy, affordable and practical access for all patients. In rural areas this may include consideration of a mobile DXA service.

7.2 Facilities

The manufacturer's specification will define the minimum space required for the DXA scanner room and, depending on the space available, the RPA must advise on the need for radiation shielding. Within the scan room there needs to be:

- a power supply, preferably with emergency backup, including adequate and appropriately positioned power sockets
- air conditioning (climate control)
- emergency call facility
- telephone and internet connectivity
- possibly a ceiling-mounted patient hoist (note that if a mobile hoist is to be used, not all types are compatible with all scanner mountings)
- networking to PACS and RIS; it is often desirable to have a networked PC separate from the scanner controller that also has PACS and RIS installed.

Further minimum requirements, which may be shared with other services, include:

- a waiting area
- a reception offering a suitable degree of privacy
- a changing area (patients may change within the DXA room, but this will reduce efficiency and may not provide sufficient privacy)
- toilets (including facilities suitable for the disabled)
- a private consulting area for patients to speak to nursing staff away from the DXA scanner
- space and facilities for staff (offices, kitchen facilities, staff room)
- depending on the operational model, a separate office with an independent reporting station (dual-screen PC) networked to the scanner database may be desirable.

Key practice point

Consideration must be given at the planning stage for adequately sized facilities to house the scanner and reporting station, reception, toilets, changing, consultation and waiting areas.

7.3 Equipment

The equipment required will be influenced by the service model, but the following are considered essential components:

- a DXA scanner (the choice of scanner may be influenced by equipment used in neighbouring services, particularly if these will operate in a "hub and spoke" or clinical network; advice on commissioning and acceptance testing of a new DXA scanner is provided in Appendix 1)
- an accurately calibrated stadiometer
- accurately calibrated weighing scales (where a predominantly elderly population is envisaged, "sit-on" scales are an advantage)
- computers connected to the organisation's network to facilitate safe data transfer, storage and management of appointments; computers must also have a link to PACS and RIS
- a hoist and/or other moving and handling equipment
- resuscitation equipment.

See also Appendix 3: Commissioning and acceptance testing of DXA equipment.

8. Supporting documentation

8.1 Patient documentation

This should include:

- risk factor questionnaire
- information leaflet about DXA and what will happen at the appointment, how and when to obtain the results, etc.
- information about osteoporosis and bone health (e.g. published by the Royal Osteoporosis Society)
- information about related services and how these can be accessed, including:
 - falls prevention
 - social services
 - exercise classes
 - patient support groups.

Key practice point

At the planning stage, consideration should be given to a comprehensive package of documentation for patients, including information that supports self-management of osteoporosis.

8.2 Other documentation

This might include:

- directory-of-service description
- guidelines to referrers (depending on the service's configuration, these may include locally agreed treatment guidance, especially if reporting is undertaken by non-medical staff)
- referral form
- template letters
- Did not attend (DNA) letters
- return of referral for reasons such as inadequate clinical information, inappropriate indication, unsigned
- appointment letter including directions, explanation of appointment/test (include patient information leaflet - see [Appendix 4B](#) and [ROS DXA information](#)), advice about suitable clothing, contact numbers and how to change/confirm the appointment
- report template
- patient and referrer satisfaction survey/feedback channel.

9. Clinical quality

9.1 Clinical quality

Accurate and consistent positioning and analysis of DXA scans is essential to reduce the precision error of measurements. This is important so that clinical decisions are made based on reliable clinical information. This reduces the risk of misdiagnosis and subsequent inappropriate treatment and maximises the ability of serial scans to detect small changes in BMD over time.

Maximise clinical quality

1. Ensure staff are adequately trained and competency is maintained by:
 - implementing a structured training program for new staff,
 - defining essential competencies to undertake scanning, analysis, interpretation and reporting of measurements
 - ensuring staff maintain their own CPD in line with their professional responsibilities. Access to training, such as the National Training Scheme for Bone Densitometry, or courses provided by the International Society for Clinical Densitometry may be useful as an addition to local training, leadership development and opportunities for research.
 - reviewing competency against departmental standards.
2. Ensure operators are scanning to clearly defined written protocols, as described in section 5.2.1.
3. Establish a program of clinical audit against the standards set in the competency and scanning protocols.

Key practice point

In line with IR(ME)R, services must establish general procedures, protocols and general assurance programmes.

The DXA service must establish clear definitions of required competencies, training programmes and up to date training and CPD records.

9.2 Clinical audit

Clinical audit is mandated under IR(ME)R. It is an important strategy to improve quality in healthcare settings and forms an essential component of clinical governance procedures within a department. Audit programmes are continual improvement cycles and should be embedded within the service and staff.

A program of audit and feedback has been shown to be most effective at achieving improvements in performance when: performance is poor to begin with; the person responsible for feedback is a supervisor or colleague; feedback is received at regular intervals, both in writing and verbally; and the program includes clear targets and an action plan.⁸⁴ It is likely to be beneficial to involve the whole team in the quality improvement program to encourage a shared ownership of quality within the service. In DXA, a program of audit and regular feedback has previously been shown to result in significant improvements in the consistency of scan positioning.⁸⁵

There are a range of more involved quality improvement methods which are not described in this guideline, such as the PDSA (Plan, Do, Study, Act) method, a common approach which aims to test changes to practice on a small scale and rigorously evaluate these changes prior to them being implemented more widely, if shown to be effective.⁸⁶ These methods could be applied to a range of measures of quality across the bone densitometry service, including:

- service audit
- patient satisfaction (local family and friends test)
- referrer satisfaction
- IR(ME)R-mandated audits:
 - referrer entitlement
 - referral justification
 - patient identification
 - patient pregnancy
 - patient dose audit and management of diagnostic reference levels
 - clinical evaluation/reporting

- clinical quality audits including:
 - scan technique: accuracy and consistency of scan acquisition and analysis⁸⁷
 - scan value
 - time from appointment to scan (indicative target: 6 weeks)^{18,22,60}
 - time from scan to report (indicative target: 3 weeks)¹⁸
 - DNA rates⁸⁸
 - adherence with infection control policies (e.g. hand washing)
 - compliance of reports with national standards.¹⁸

In all cases it is recommended that 10% of referrals and scans are audited annually, which can be broken down into monthly audits for practicality.

Key practice point

A DXA service must make provision within employer's procedures under IR(ME)R for establishment of a programme of audit and feedback including taking appropriate actions in relation to the results of such audit.

Appendix 1: Outline of a business case for a bone densitometry service

1. Project goal and purpose

Goal: broad goal outline – for example, to provide access to bone densitometry to enable rapid, accurate clinical decision-making to optimise the prevention and management of osteoporosis.

Purpose: what this service is designed to do – for example, to develop clinical pathways and provide a quality bone densitometry service for people at risk of osteoporosis and fragility fracture, and to provide advice and treatment for the primary and secondary prevention of fragility fractures for people who need it.

2. Background

Description of population served (with references):

Including:

- physical catchment area
- catchment population
- age profile
- population growth prediction
- hip fracture rates
- how the population and hip fracture rates compare nationally

Description of stakeholders (with references):

Including:

- the organisation proposing the service
- clinical commissioning groups
- primary-care users – number of GP practices
- local interested groups (researchers and private users)
- wider developments for the organisation (e.g. foundation trust or new specialist designations)

- corporate strategy and how the project might fit with it (e.g. long-term condition strategy)
- external care targets (e.g. National Hip Fracture Database, NICE QOF and fracture reduction)

Description of department/group presenting the case:

Including:

- the department applying for funding
- the directorate where it sits
- what services it already offers and whether this is a new service or a service enhancement or development

Description of the origin of the business case (with references):

Including:

- why the business case is being proposed
- the cost of not providing service – fracture costs, human costs
- theoretical demand by the population
- existing capacity/demand profile with backlog and trend

3. Project-management team and beneficiaries

Including:

- who will deliver
- how the management of the delivery will be organised (e.g. via a project group with a lead practitioner)
- who will benefit, including patients and stakeholders (e.g. via the QOF and national service frameworks)

4. Methodology

List of objectives and supporting details (examples):

Objective 1: Appoint a lead clinician to deliver the project

Including:

- who
- how
- what skills are required
- costing
- how long and how substantively financed
- what to deliver (e.g., develop and deliver pathways, procurement of equipment, project-manage infrastructure)

Objective 2: Design and deliver a fracture liaison pathway

Including:

- new pathway
- how deliverable
- costing – capital and revenue
- demand
- support

Objective 3: Procure and commission a DXA scanner and roll out the service

Including:

- demand
- projected capacity
- how delivered
- costing – capital and revenue
- timeframes

5. Benefits realisation

Detailing:

- performance indicators and risks
- clinical governance
- audit
- outcome measures.

6. References

7. Appendices and evidence

Including:

- local capacity and demand profiles
- costing profiles
- capital and revenue
- timeframe
- deliverables

Appendix 2: DXA Patient Risk Questionnaire

This is an example clinical questionnaire used in DXA services to gather information and history from the patient to support scanning protocols and inform recommendations at reporting. Services may wish to edit or amend questions to meet the needs of the service.

(Hospital contact information)

DXA Scan Questionnaire

(Please complete and bring with you on the day of your appointment, if you need help with this a member of staff will help you on the day). Please list your regular medications overleaf

Your surname		Your first name	
Your date of birth		Your hospital or NHS number	
What is your ethnic group?		Pronouns: he/him, she/her, they/them, other	

Scan information <i>(this information helps us to plan your DXA scan):</i>	Tick the boxes below		
	Yes	No	unsure
Have you had a Bone Density (DXA) scan before? If yes please tell us when and where:			
Have you had any operations on your spine or hips? If yes please tell us when and where:			
Have you had any x-ray, CT, or nuclear medicine scans or tests in the last 4 weeks? If yes please tell us what this was:			
Medical history <i>(this information helps us to understand your DXA scan measurements and risks of breaking a bone)</i>	Yes	No	unsure
Do you drink alcohol every day? Tell us how many units you drink regularly: (1 unit = 1 small glass of wine or ½ pint regular strength beer/cider)			
Have either of your parents ever broken or fractured a hip (top of femur)?			
Have you ever taken steroid tablets? (prednisolone)? If yes please tell us when and for how long:			

Medical history <i>(this information helps us to understand your DXA scan measurements and risks of breaking a bone)</i>	Yes	No	unsure
Have you been diagnosed with a long term medical condition? If yes please tell us what this is:			
Do you see a rheumatologist for rheumatoid arthritis? (auto-immune inflammatory condition of the joints)			
Are you current a tobacco smoker?			
Have you taken, or are taking medicines for osteoporosis or bone strengthening? If yes which one? How long have you/did you have it?			

People with childbearing capacity or internal reproductive organs (uterus/womb, ovaries) only	Yes	No	unsure
Is there any possibility you may be pregnant? <i>(this information is required by law because DXA uses x-rays which may be harmful to an unborn baby)</i>			
Have you had a hysterectomy? If yes were your ovaries removed?			
Are you going through/been through the menopause?			
Have you ever taken HRT?			

Radiographer use only			
LMP date:			cm
Pt signature (LMP)			kg
ID check by (initials):			date

Appendix 3: Commissioning and acceptance testing of DXA equipment

Commissioning

The choice and commissioning of new DXA equipment should be made with expert help and advice from suitably qualified individuals (e.g. Medical Physics Expert (MPE), Radiation Protection Adviser (RPA), bone densitometry operator and clinician).

Prior to installation

- Contact the local RPA for advice regarding the employer's responsibilities to comply with The Ionising Radiations Regulations 2017.
- Discuss the need for a dedicated electrical supply to comply with electrical regulations and arrange for this to be installed.
- If the new scanner is to be connected to the hospital network, discuss this with the IT department and Radiology if sited outside this area, and if necessary, arrange for the installation of a network point prior to the date of arrival of the scanner.
- Discuss the installation of anti-virus software compatible with both the IT network and the densitometer and arrange for installation after equipment commissioning.
- Arrange a date with the DXA equipment supplier and agree a process for staff to receive training on the use of the scanner from an applications specialist.
- In the case of a replacement scanner, once the date of installation is known, make sure that the appointments diary is cleared for the required period.
- Agree arrangements for ongoing servicing and software updates.
- Ensure a maintenance contract with the DXA supplier is taken out for when the warranty period expires.
- If replacing an old scanner, the following should also be considered:
- Discuss with local scientific experts and consult ISCD published guidance⁶⁹ about the specific cross calibration requirements for ongoing treatment monitoring in the existing clinical cohort of patients. This will be influenced by any change in manufacturer or model and may require additional scans of phantoms or an in-vivo cross-calibration study. Discuss with the DXA equipment supplier any additional advice or assistance they can give.

If replacing a scanner used for research studies, inform the relevant study QA centres and obtain copies of their procedures for cross-calibration.

- Discuss with the DXA equipment supplier the procedures for cross-calibration at installation and determine whether any additional measurements will be necessary – for example, additional scans of phantoms or an in-vivo cross-calibration study.
- If the old scanner is being removed at the time of installation of the new one, consider whether any cross-calibration scans of phantoms or patients need to be performed on the old scanner before its departure.
- If planning an in-vivo cross-calibration or precision study on the new scanner⁶⁹ (or as part of routine quality programmes), investigate compliance with IR(ME)R 2017 and local policies to determine whether this is classified as a service evaluation or whether ethics committee approval is required.

At installation

The equipment should undergo critical examination after installation. The duty under IRR 17 to carry out the critical examination lies with the installer (usually the manufacturer's service engineer) and the appointed RPA. Following satisfactory critical examination, the installer should provide a written report endorsed by the RPA to confirm this. The installer should also provide information on proper use, testing and maintenance of the equipment.

The manufacturer's engineer will carry out routine installation checks. Before the engineer leaves:

- Check against the specification that all facilities ordered are installed and working.
- Ensure all operators (including experienced DXA operators) are adequately trained and in the case of clinical use of new techniques, training related to those techniques and the relevant radiation protection requirements.
- Check that archive media are formatted and ready for use.
- Ensure that the software settings are those required and that they conform to other local systems.

- Arrange for installation of anti-virus software by the local IT department while the manufacturer's engineer is on site to assist and advise on compatibility.
- If the scanner is connected to the hospital network, check the status of the network connection.
- Check with the engineer what safety checks and cross-calibration procedures have been done.

Acceptance and commissioning radiation safety testing

Inform the appointed Medical Physics Expert (MPE) and local radiation protection service that a new scanner is ready for radiation safety tests. The MPE should be a trained and entitled operator. Ensure that an experienced person is there to help operate the scanner during the measurements. These should include a measurement of radiation output in the X-ray beam and a measurement of scattered radiation at the operator's console. Once the equipment has passed the assessment tests, the MPE staff who perform the assessment will provide a written report of the results of the tests and will sign to transfer responsibility for the use of the equipment to the department.

- Inform estates or whichever department is responsible in the locality that the new machine is ready for electrical safety checks.
- Perform at least 10 scans of the new scanner's spine phantom without repositioning the phantom to determine the baseline for routine performance monitoring. Calculate the mean value of BMD for L1-L4 and 1.5% and set tolerance limits using these data.⁶⁹ Check in-vitro precision is acceptable. This may form part of the installation checks that will have been carried out by the installation engineer.
- Carry out any further acceptance tests required using phantoms (e.g. scans of a resolution phantom).
- Test the archive and backup of patient scan data on the new scanner. If replacing an old scanner, make sure that patient details from the old system can be accessed and that old scans can be recovered to aid scan analysis for patient follow-up. This should ideally be undertaken at the installation stage to ensure any problems are resolved while the engineer is on site.
- If the scanner is connected to the hospital network, check that this is performing as required.

After installation and acceptance tests

- Make sure the new scanner is added to the hospital equipment inventory.
- Consult with the MPE to agree a suitable QA programme.
- Start a maintenance and faults recording file for the new scanner. Record the details of the system, the date installed, the installation engineer's report and the results of the acceptance tests. Engineer reports from subsequent maintenance visits should be kept with this book.
- Write or review the local rules and submit to the RPA for approval. Ensure all operators are familiar with the local rules and keep a record confirming who has read them.
- Write scanner-specific QA and scanning protocols for the new system and ensure exposures are optimised under IR(ME)R.
- Confirm the date(s) of a visit(s) by the DXA supplier application specialist to give all staff relevant training and compile a training log.
- Carry out further in-vitro cross-calibration measurements with phantoms if these are required, for example for research studies.
- In-vivo precision studies for individuals or units are not necessary and are unlikely to be compliant with regulatory requirements. Robust training, protocols and scan technique audit processes should be employed to assure precision in DXA teams. If precision studies are required for research reasons, then this requires Health Research Authority ethical approval.
- Once documentation and training are complete, patient scanning may commence. It is helpful to book fewer patients while orientation occurs to allow for unforeseen problems, familiarisation by the operators and embedding new scanning practices.

Appendix 4A: Recommendations to improve understanding of DXA

The INDEX study (Improving uNderstanding of bone DEnsity (dXa) scans), funded by the Royal Osteoporosis Society, worked closely with patients and health professionals to identify their unmet information needs about DXA scans and results. The INDEX study then developed recommendations to address **identified** information needs and supporting patient information resources (including template information leaflet, Appendix 4B) and standard report template (Appendix 4C).

Patients and health professionals rated the importance of each recommendation. This resulted

in 30 recommendations that have consensus among patients and health professionals as important to address unmet DXA information needs.

The recommendations are split into those relevant for DXA reporters/providers (Table 1) and DXA referrers (Table 2). Recommendations are further organised by topic area and ranked based on their scored importance out of 100.

Further information about the INDEX study is available on request.⁶

Table 1. INDEX recommendations for DXA reporters and providers

Recommendation statement	Rationale	Score*
1. Using a DXA scan reporting template		
Use the Royal Osteoporosis Society standard report template**	<i>The standard template is organised to make information easier to find for the referrer and reduce clinical risk associated with missing key information in reports.</i>	95.24
2. Diagnosis section of DXA scan reports		
Present the bone mineral density result and the fracture risk assessment together in an integrated statement or sentence.	<i>Bone mineral density in isolation is not a meaningful result and needs to be interpreted in context.</i>	93.33
Use a clinical diagnosis of osteoporosis, if appropriate in pre-agreed circumstances* (e.g. bone mineral density is not osteoporotic as per World Health Organisation (WHO) definition, but patient has clinical characteristics of bone fragility such as low trauma vertebral fractures).	<i>WHO diagnosis is restrictive and primary care healthcare professionals' express reluctance to treat people without an osteoporosis diagnosis. * = pre-agreed circumstances are to be defined</i>	92.86
Use 'low bone density (osteopenia)' instead of 'osteopenia' in isolation. Do not describe osteopenia as a diagnosis or diagnostic classification.	<i>Patients and healthcare professionals feel that 'osteopenia' required explanation and therefore the term alone was insufficient.</i>	88.57
Include primary care codes (e.g. SnoMed codes) in reports.	<i>Primary care professionals need to code scans and expressed the burden and challenges of manually assigning codes to text in reports.</i>	83.67

3. Clinical interpretation section of DXA scan reports		
Include a clinical interpretation in reports.	<i>Both patients and healthcare professionals want to know the 'punchline' which might include whether bone strengthening medicines should be considered or if follow up results are as expected or not.</i>	98.10
Write the clinical interpretation in lay language.	<i>Clinical reports are often read to patients or received by patient on the NHS app. Primary care professionals stated the importance of language in reports mirroring language they should use when explaining results to patients.</i>	87.62
Use 'increased (very high) fracture risk' or 'increased (high) fracture risk' instead of 'very high fracture risk' or 'high fracture risk' in isolation.	<i>Primary care professionals often read reports to patients and patients often perceive high risk as close to 100% leading to fear and avoidance behaviour. 'Increased risk' is a preferred term for communication as it is more accurately interpreted.</i>	81.63
4. Recommendations section of DXA scan reports		
Emphasize or include standard statement: Bone density only represents part of a person's fracture risk and needs to be considered in context of other fracture risk factors.	<i>Bone mineral density in isolation is not a meaningful result and needs to be interpreted in context.</i>	94.90
Emphasize or include standard statement: Treatment decisions should not be based on bone density alone.	<i>Primary care professionals report using bone mineral density alone to make treatment decisions.</i>	94.29
Include a clear statement(s) of recommended actions to consider, in lay language, that are individualized and evidence based.	<i>Using the word "consider" in the report aims to encourage shared decision-making and consideration of their full clinical picture and patient preferences.</i>	92.38
5. Technical Information section of DXA scan reports		
Explain the limitations of T-scores and fracture risk scores for people from minority ethnic backgrounds, including relevant reference data used.	<i>People from minority ethnic background are keen to know limitations of scores.</i>	90.48
Include patient height, weight and risk factors used for fracture risk calculation.	<i>Primary care professionals report additional work when trying to reproduce fracture risk assessments.</i>	90.48

Include personalised sentence about potential over/under-estimation of fracture risk.	<i>Healthcare professionals describe reports as being too standardised and patients are keen to know limitations of scores.</i>	89.52
Include relevant T-score and fracture risk thresholds and indicate whether fracture risk is above or below 'intervention threshold.'	<i>Referrers report having to do additional work to cross check fracture risk and patients felt this addition would aid understanding.</i>	89.52
6. Further information section of DXA scan reports		
Include signposting to relevant clinical guidelines.	<i>Healthcare professionals wish to be sign posted to the relevant clinical guidelines (e.g. National Osteoporosis Guideline Group, Scottish Intercollegiate Guidelines Network (SIGN) guidelines).</i>	93.33
Include signposting to patient resources to aid understanding and support visualisation of risk.	<i>Patients and healthcare professionals like to visualise risk as it helps to give meaning to results and supports result communication.</i>	91.43
7. Miscellaneous		
Inform patients at the time of scan about what to expect regarding receiving their result.	<i>Patients express a need for reassurance about what will happen next and primary care professionals report that patient queries could be minimised by giving patients clear expectations prior to receiving results.</i>	95.24
Integrate reports into clinical imaging health record systems.	<i>Primary care professionals report that scanned PDF reports (not integrated into primary or secondary care records) lead to issues with missing pages and clinical risk.</i>	94.29
Send all patients a letter/leaflet on what to expect from their scan alongside their appointment invitation.	<i>Various uncertainties are described by patients regarding expectations of scans, which were associated with anxiety in some cases.</i>	93.33
If report formatting is limited, use capitals/line breaks to indicate headings using the format of the standard report template, and bold/underline for key text.	<i>Patients and healthcare professionals find report format hard to read, time consuming and clinical risk was identified associated with missing key information in reports.</i>	90.82
Entitle the report 'Fracture risk and bone density assessment'.	<i>Emphasizes that bone mineral density in isolation is not a meaningful result and needs to be interpreted in context.</i>	90.48

*Importance score out of 100. Recommendations with less than 70% agreement were removed.

**See Appendix 4C.

Table 2. INDEX recommendations for DXA referrers

Recommendation statement	Rationale	Score*
1. DXA scan result delivery method		
Offer patients an opportunity to discuss their results using a method that suits their preference (telephone, face-to-face appointment) to encourage inclusion and equity.	<i>Most patients express preferences for verbal consultations due to having spoken explanation of their results. Public contributors express that face-to-face consultations encourage inclusion and equity.</i>	94.29
Give all patients the same options for receiving results regardless of the nature of result (osteoporosis, osteopenia or normal).	<i>Often, patients with normal or osteopenia results are given less information but had unmet needs.</i>	91.43
Offer all patients a copy of their result which includes signposting to further information.	<i>Majority of patients prefer to receive a copy of their scan result (paper or app). Important to offer patients choice, as preference for amount of details varied amongst patients.</i>	90.48
2. Communication of DXA scans and results		
When communicating results, emphasize that bone mineral density is only part of person's fracture risk, and it needs to be considered in context of other fracture risk factors.	<i>Patients report lack of understanding of the meaning of bone density scan results.</i>	95.24
Check patient understanding when giving information about bone density scan referrals and/or results.	<i>Recommended practice in healthcare communication and raised as important omission in care by public contributors.</i>	93.33
When communicating results, use 'low bone density' in preference to 'osteopenia' as it is not a diagnosis or clinically meaningful in isolation.	<i>Patients and healthcare professionals feel that osteopenia requires explanation and therefore the term alone was insufficient.</i>	88.57
When communicating results, avoid language which might be perceived as frightening and associated with avoidance behaviour, e.g. 'very high/high fracture risk'.	<i>Public contributors thought that 'high/very high risk' was alarming. Worry is associated with avoidance behaviour.</i>	81.90
3. Training about DXA scans and results		
Undertake training about how to understand and communicate scan results.	<i>Raised as need by public contributors and health professionals.</i>	94.29

Appendix 4B: Sample information leaflet content for patients and carers

Patient Information: Your Bone Density (DXA) Scan

Your healthcare professional would like you to have a bone density scan. A bone density scan will assess if you have osteoporosis (weak bones) and your chance of future broken bones (sometimes called 'fractures'). **This is important because bone health can be improved. Steps can be taken to strengthen bone and lower the chance of broken bones.**

You may have questions about the scan. The following information should help you to understand what is involved and what you need to do.

What is a bone density scan?

Bone density scans are sometimes called bone mineral densitometry or 'DXA' scans (which stands for **D**ual energy **X**-ray **A**bsorptiometry). The scan uses low dose x-rays to measure your 'bone density.' Bone density is how solid the inside of your bones are. Bone density is just one factor that helps us to understand the strength of your bone. This is like how cholesterol is one factor that affects your heart health. Other factors, such as your age, family history and medical history will be considered alongside your scan result. **This will help us to assess your bone health and your chance of future broken bones.**

A bone density scan does **not** provide any information about cancer, arthritis (including osteoarthritis) or causes of pain.

What is involved?

You may be asked to complete a simple questionnaire. This will include questions about your family history, medical history and the date/year of your last period, if appropriate. These questions are used to assess your chance of broken bones.

Your weight and height will be measured before the scan.

The bone density scan appointment is simple and takes about 20 minutes. You will be asked to lie on a scanner table where the slow moving 'arm' of the scanner will pass over your body and take some pictures of your bones. This type of scan measures the density of your bones at the lower back (lumbar spine) and hip. Sometimes we will also measure the density of the bone in your wrist. The scan is carried out by a radiographer or technician who has had training to perform these specialist scans.

You are not enclosed during the scan (NO TUNNELS) and there are no injections.

For your lower back measurement, we need you to rest your legs on a raised foam block. This helps to keep your back straight, and it also makes you more comfortable. For the scan of your hip, we move your feet so that they face slightly inwards. This gives us a clearer picture of your hip.

[include picture/link to animation here, if possible]

Do I need to prepare for the bone density scan?

It is important that **no metal objects** such as **zips, heavy buttons, fasteners, or belts** get in the way of the scan picture. Please try to wear clothes without these around the hips and waist, and underwired bras. A private space to change and a hospital gown is available, if needed.

You do not need to stop any medicine for this scan, please continue to take any medicine that your doctor has prescribed. **Please bring a list of your medicine with you.**

Can I bring someone with me?

Yes, you can bring someone with you to your appointment. They may be asked to wait outside the room while the scan is being done. This is because we are using radiation.

Is the x-ray radiation dose harmful?

The amount of radiation from a bone density scan is very low and much lower than most other x-rays or scans. The amount is about the same as you would be exposed to naturally in 3 days.

However, if you are **pregnant**, please let us know as soon as possible and we will re-schedule your scan.

How long can I expect to wait to hear the results of my scan?

The results of your scan will be sent to the healthcare professional who referred you for the scan. This normally is within 3 weeks, but this can vary. The department should tell you what waiting times to expect.

If you have not received your results within the expected time, you should contact the healthcare professional who referred you to ask if the results are available. For example, if your GP advised you to have a bone density scan, they would be the person who referred you. **If you are unsure who referred you for your scan, ask the health professional undertaking your scan.**

What will happen after I receive my bone density scan results?

Depending on the result of your bone density scan, you may be asked to have further tests, such as a blood test.

You may be offered bone strengthening medicine if you have an increased chance of broken bones. This will include some, but not all, people with:

- osteoporosis
- low bone density (sometimes called 'osteopenia').

You will only be offered bone strengthening medicines if you have an increased chance of broken bones. Other factors, such as your

age, family history, and medical history will be considered alongside your scan result.

You should also be told if you need a follow-up bone density scan and when. Follow-up scans are not usually repeated until a minimum of 2 years have passed; however, the interval can be longer. This is because bone density changes very slowly over time.

Help us to help you

1. If you are unable to attend your appointment, please contact us as soon as possible on [insert telephone number]. This helps us to offer it to someone else.
2. Please let us know before your appointment if you have any other scans booked on the same day or up to 2 weeks before your bone density scan. This is because some scans can interfere with bone density scans.
3. Please arrive on time and allow 30 minutes for the whole procedure.
4. If you have any accessibility requirements or require a language interpreter at your bone density scan appointment, please telephone us as soon you receive this appointment. This will enable us to discuss any requirements you may have.

How to find our department [Localised information inputted here]

Further information on Osteoporosis and Bone Health can be obtained from:

theros.org.uk/DXA/

Royal Osteoporosis Society
St. James House
Lower Bristol Road
Bath
BA2 3BH

Free nurse helpline: 0808 800 0035
(open Monday to Friday between
9am – 12.30pm and 1.30pm – 5.00pm)

Website: theros.org.uk

e-mail: nurses@theros.org.uk

Appendix 4C Template Report - Fracture risk and bone density assessment

Informed by the INDEX study⁶ to meet identified needs of referrers and patients

Introductory information	<p>Address of DXA Scanning Service</p> <p>Date of report/date of scan</p> <p>Referrer name/address</p> <p>Patient details: Name, address, date of birth, unique identifier, ethnicity, BMI, height, weight</p> <p>Scanner manufacturer and scanner ID number</p>
Reasons for referral:	<p>Indications, fractures, current osteoporosis treatments/relevant supplements.</p> <p>Clinical risk factors for fracture and falls.</p>
Diagnosis and results summary:	<p>Present fracture risk and BMD assessment together in integrated statement, using recommended terms/phrases</p> <p><i>e.g. Increased (high) fracture risk and osteoporotic bone density; no increased fracture risk and low bone density (osteopenia)</i></p> <p>Use a clinical diagnosis of osteoporosis if appropriate (e.g. low trauma hip or spinal fracture in older person)</p> <p>Relevant code for primary care e.g. SNOMED</p> <p>Fracture risk estimates (Ranges):</p> <p>VFA and blood test results if applicable</p>
Clinical Interpretation and recommendations:	<p>Lay statement of results in context (in lay language)</p> <p>Treatment/investigation/referral options</p> <ul style="list-style-type: none"> • State whether and which bone strengthening medicine options can be considered (are results over or under treatment threshold as per relevant local/national guidance). • Emphasize that bone density only represents part of a person's fracture risk and needs to be considered in context of other fracture risk factors. • Lifestyle modification. • Falls risk assessment/intervention. • Investigations. • Onward referrals. • If repeat and appropriate, whether results suggest positive response to treatment.

Follow up and monitoring:	<p>Provide a recommendation for appropriate time interval to consider repeat DXA assessment.</p> <p>When medication review might be indicated (if medications are being recommended).</p> <p>What to do if fracture on treatment.</p>
Technical information and limitations of bone density and fracture risk:	<p>Bone Mineral Density: Bone density only represents part of a person's fracture risk and needs to be considered in context of other fracture risk factors. Treatment decisions should not be based on bone density alone.</p> <ul style="list-style-type: none"> • T and Z scores in results table, if possible (with indication of which score to use for fracture risk assessment). • Commentary on rate of change and statistical and clinical significance. • Database for T-scores. <p>Fracture risk score</p> <ul style="list-style-type: none"> • Which risk factors used, and any adjustments made. • Personalised sentence about limitations of T-scores/fracture risk. • Commentary on reliability of BMD measurements. • Commentary of limitations in regard ethnicity. • Any potential over/under-estimation of fracture risk.
Further information:	<p>Link or signpost to:</p> <ul style="list-style-type: none"> • Royal Osteoporosis Society DXA jargon buster explainer. • Online tools to visualise results. • Any relevant guidelines cited (NOGG, SIGN). • Additional relevant info e.g.: Exercise, dietary calcium calculator. • Local advice line and/or email. • Circumstances in which the patient should contact the GP (e.g. if they have a fall or start taking regular steroid medication).
Reporter information	Name, title, signature, GMC/HCPC/NMC number, date.

Appendix example results table

Site	Area	Date of measurement	BMD g/cm ²	T-score (young adult)	Z-score or % (age matched)	Change since baseline or previous scan (%)
Spine	L1-L4					
Hip*	Total hip					
Femoral neck**						

* Either total hip or femoral neck may be used depending on local protocol.

** Include for use in FRAX calculations depending on local protocol.

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About us

The Royal Osteoporosis Society is the UK's largest national charity dedicated to improving bone health and beating osteoporosis.

We equip people with practical information and support to take action on their bone health. Working with healthcare professionals and policy-makers, we influence and shape policy and practice at every level and invest in research.

To find out more visit our website: theros.org.uk

Professional Membership

Join us as a professional member and help us to support more people with osteoporosis.

Call our membership team on **01761 473287** or visit theros.org.uk/healthcare-professionals to find out more about the benefits of professional membership.

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