

# Guidelines for the provision of a clinical bone densitometry service

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This guidance has been produced to support the development, implementation and operation of high-quality bone densitometry services. Although it is written from the viewpoint of the service provider, the guidance will also provide useful information for those seeking to commission a service. Indeed, the introduction of a densitometry service may well result from partnership between commissioner and provider. This guidance focuses on services using dual-energy X-ray absorptiometry (DXA) of the axial (central) skeleton as the current technique of choice. It aims to define best practice and will also be useful to commissioners and service providers when examining the quality of current service provision.

The guidance reflects current evidence and UK policy and should be read in conjunction with the following National Osteoporosis Society documents:

- Peripheral X-ray Absorptiometry in the Management of Osteoporosis
- Position Statement on the Use of Quantitative Ultrasound in the Management of Osteoporosis
- A Practical Guide to Bone Densitometry in Children
- Reporting Dual Energy X-ray Absorptiometry Scans in Adult Fracture Risk Assessment
- A Structure for Reporting Dual-Energy X-ray Absorptiometry Scans at the Hip and Spine in Adults

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Please send any comments on this practical guide to [policyissues@nos.org.uk](mailto:policyissues@nos.org.uk).

## Contents

Guidelines for the provision of a clinical bone densitometry service	2
Key recommendations	4
Background	4
The aim of bone densitometry services	4
The current context of bone densitometry using DXA	5
Identifying the need for a new bone densitometry service	6
Stakeholders in the provision of osteoporosis services	6
Development of the business case	6
Service delivery models	7
Operational considerations	8
Pathway	8
Clinical/operational governance	10
Staffing the DXA service	13
Environmental issues	16
Supporting documentation	17
Commissioning and acceptance testing of DXA equipment	17
References	18
Appendix 1: Outline of a business case for a bone densitometry service	20
Appendix 2: Sample referral proforma for DXA scanning	22
Appendix 3: Commissioning and acceptance testing of DXA equipment	24
Appendix 4: Sample information leaflet for patients and carers	26

### Key recommendations

- It is critical to identify key stakeholders and involve them in the development of a new clinical densitometry service.
- Ensure that the nature of the service that is best suited to the needs of the local population is identified.
- Consider how the densitometry service will embed within the complete patient pathway to ensure optimal management and establish appropriate clinical links within primary and secondary care.
- Ensure the service is supported by a robust healthcare governance framework and is compliant with relevant guidance and legislation.
- Consider the staffing required to support the service and ensure resources are identified to fulfil their continuing professional development.

### Background

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. Over 300,000 individuals present with fragility fractures each year in the UK [1]. Such fractures are associated with significant morbidity and mortality and the direct management cost of fractures to the UK health economy in 2000 was estimated to be £1.8 billion, which is projected to increase to £2.2 billion by 2025 [2].

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 expressed as T-scores in which the individual's BMD is compared to the average BMD in healthy young adults. 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 [3].

However, although the T-score definition of osteoporosis is well established, it is of limited value for clinical decision-making. BMD is an important

predictor of fracture risk, but there are many other independent risk factors. 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.

The ability to assess fracture risk accurately is key to optimal patient management. There is available a range of pharmacological treatments 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. Initial fracture risk assessment may be undertaken using risk calculators that need not involve measurement of BMD [4]. 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. Increasing awareness of rare adverse effects of long-term osteoporosis treatment has led to recommendations for periodic review of the risk-benefit balance in an individual patient [5]. BMD measurement is an important part of this review process even in patients in whom treatment was initiated on the basis of clinical risk factors alone.

The provision of DXA bone densitometry services has increased considerably across the UK over the past decade but access remains suboptimal as in some regions patients have to travel long distances for assessment. There is also marked variability in the nature of DXA service provision [6], which, in some cases, may be insufficient to support optimal patient management in primary care. 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.

### The aim of bone densitometry services

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

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 by GPs in accordance with the advice given in the 2006 joint document from the Royal College of Radiologists and the Royal College of General Practitioners, "Right Test, Right Time, Right Place – A Framework for Primary Care Access to Imaging" [7]. Furthermore, the output of the service should be accessible to non-specialist physicians and allow them to manage patients with osteoporosis confidently.

### 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 [4,8] 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. Access to bone densitometry is necessary for implementation of current UK guidance and compliance with the Quality and Outcomes Framework (QOF) [9]. Providers in England are regulated by the Care Quality Commission; guidance is available to enable compliance with requirements and advice is available on registration [10]. Figure 1 summarises the role of DXA within the osteoporosis care pathway.

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

Figure 1. The osteoporosis care pathway.

### Identifying the need for a new bone densitometry service

The need for a new service to be established will be driven by a local decision based on the fact that patients are unwilling or unable to travel to the nearest existing service and/or a lack of capacity in that service. Although the development of an osteoporosis pathway is often initiated by a single clinical champion, for the project to flourish a strong partnership between relevant stakeholders across both primary and secondary care is required. Identifying the key stakeholders and bringing them together is fundamental to the development of an effective local strategy.

### 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, care of the elderly, endocrinology or orthogeriatrics
- a bone densitometry operator (may be a radiographer or technologist)
- a pharmacist
- an osteoporosis specialist nurse
- patient(s)
- representatives from
  - radiology and/or medical physics
  - management (both provider and commissioner)
  - a patient support group (e.g. the National Osteoporosis Society)
  - a falls prevention service
  - a fracture liaison service/orthopaedics.

This group will bring together the local information necessary to develop the optimal pathway and 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.

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.

### 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
- 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 <sup>[11]</sup> and does not need to be reproduced here. 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. An example outline business case is included in the appendices for reference.

### 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 on the basis of their fracture risk assessment. Some further investigations may be undertaken in the GP surgery but others, such as musculoskeletal radiography, are generally only available in a secondary care or diagnostic centre setting, and thus require a further appointment. 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 <sup>[12]</sup>.

A small 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
- bone biopsy and histomorphometry.

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.

<b>Case-finding</b>	<ul style="list-style-type: none"> <li>• Case-finding</li> <li>• In primary or secondary care</li> <li>• Systematic or opportunistic</li> </ul>
<b>Referral</b>	<ul style="list-style-type: none"> <li>• Local referral criteria (assessment of patient by registered healthcare practitioner)</li> <li>• Agreed mechanism of referral (by authorised referrer)</li> </ul>
<b>Appointment</b>	<ul style="list-style-type: none"> <li>• Receipt of referral</li> <li>• Justification and triage</li> <li>• Decision about appointment required (consider possible special needs of patient)</li> <li>• Inform patient and send all necessary documentation</li> </ul>
<b>Scan visit</b>	<ul style="list-style-type: none"> <li>• Greet patient and complete preparatory checks</li> <li>• Scan acquisition and analysis</li> <li>• Clinical risk factor collection</li> <li>• Obtain any additional investigations</li> </ul>
<b>Reporting</b>	<ul style="list-style-type: none"> <li>• Interpretation and clinical report by experienced clinician (written report to referrer and GP)</li> </ul>
<b>Further investigation</b>	<ul style="list-style-type: none"> <li>• One-stop assessment</li> <li>• Recall to clinic</li> <li>• Advice to referrer</li> </ul>

Figure 2. Key elements of the DXA pathway.

## Operational considerations

Factors that need to be considered during planning and implementation can be divided into the processes around the pathway, clinical/operational governance, staffing the DXA service, environmental issues and supporting documentation.

## Pathway

### Regulatory framework

The management of a patient is subject to compliance with a wide variety of legislation. In addition to that generally associated with patient care, bone densitometry by DXA is particularly subject to compliance with the Ionising Radiation (Medical Exposure) Regulations 2000 (IRMER) (as amended 2006 and 2011). These are intended to protect patients undergoing X-rays or similar exposure for medical purposes from inappropriate or unnecessary exposures. Since DXA is an X-ray-based technique (albeit the exposure is tiny), the service must comply with the IRMER. Compliance with the IRMER has an influence on the patient pathway involving DXA and on the responsibilities of particular individuals along it. In particular, legal obligations are placed on the employer<sup>1</sup>, the referrer, the practitioner and the operator. More detail on their specific duties is given at the appropriate point along the pathway.

### Case-finding

Detailed consideration of case-finding is outside the remit of this document but the identification of sources of patient referrals is an important part of the service model. DXA assessment should be accessible to referrers within both primary and secondary care. Streamlined and systematic referral pathways will facilitate implementation of fracture liaison services and support implementation of national guidance.

Likely sources of referral will include:

- GPs and specialist nurses working in primary care
- fracture liaison pathways<sup>[13,14]</sup>
- falls prevention pathways<sup>[15]</sup>
- secondary-care teams (e.g. rheumatology, endocrinology, care of the elderly)

- prescribers of medications known to have adverse effects on bone health, including glucocorticoids and aromatase inhibitors.

The referrer must be a registered healthcare professional who is entitled in accordance with the employer's procedures to refer individuals to the practitioner following locally agreed referral criteria (IRMER)<sup>[16]</sup>.

### Referral

The service will need to establish locally agreed referral criteria and develop a referral pro forma. A sample referral pro forma is included in the appendices. Referral indications will reflect national guidance and local prioritisation. They should take into account recommendations made by a number of sources:

- the Royal College of Physicians
  - osteoporosis guidance, 1999<sup>[17]</sup> and 2000<sup>[18]</sup>
  - glucocorticoid-induced osteoporosis guidance<sup>[19]</sup>
- NICE
  - TA160/161/204<sup>[20-22]</sup>
  - CG146<sup>[2]</sup>
- the National Osteoporosis Guideline Group<sup>[23]</sup>
- the Scottish Intercollegiate Guidelines Network<sup>[8]</sup>
- disease-specific guidelines (e.g. for chronic liver disease, cystic fibrosis, inflammatory bowel disease and coeliac disease, breast cancer treatment<sup>[24-28]</sup>).

The method of referral must also be defined.

Depending on local circumstances, referrals may be received by one or more of the following methods:

- 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 clinically relevant information with the request to enable a practitioner to decide whether the exposure is justified. As such, irrespective of the means by which the request is made, it must be possible to identify that the referrer is entitled to make the request and has authorised it in a manner that confirms their responsibility for it (e.g. signature on paper or

electronic referral from their log-on account). There should be an appropriate system of management for referrals once received. Generally speaking, this implies use of a secure database system such as a hospital patient administration system (PAS) or radiology information system (RIS).

### Appointment

Each referral will need to be reviewed to ensure that a DXA scan is justified (i.e. 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 of a practitioner (IRMER), who 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 authorise requests or may delegate this task to an operator (IRMER) – for example, a member of the scanning team (the operator does not need to be a registered healthcare professional but must be adequately trained). In the latter case 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 particular circumstances.

Once a decision has been reached about the scans that are required, the patient should be offered an appointment. Local agreement should be reached about the maximum waiting time from receipt of referral to appointment, which is generally six weeks or less. 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 is 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 and what to expect at the appointment
- 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 policies.

### Scan visit

On arrival for the DXA bone densitometry scan, the patient should have their identity checked; be entered on a PAS, RIS or similar system; and, if appropriate, be shown to a waiting area and advised how long the waiting time might be. Some patients may require assistance at this stage with completion of the risk factor questionnaire and preparation for the scan if they need to change into a gown. Obtaining a list of the patient's medications is helpful for interpretation and reporting, in particular to identify any bone-modifying agents..

Females of child-bearing capacity must be asked whether they are or might be pregnant (IRMER) according to local procedures<sup>[29]</sup>.

It should also be confirmed 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.

Prior to scanning, height and weight should be measured accurately, the operator must check the patient's identity against the referral and all these details must then be entered into the DXA scanner database along with other patient details, as appropriate. The required DXA scans should be performed following

<sup>1</sup> The employer referred to in the IRMER is that employer responsible for the delivery of the medical imaging service (in this case DXA service).

local protocols based on guidance provided by the manufacturer. Even if scans are not analysed until later, the 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).

Depending on the service model, further investigations (such as radiographs and laboratory tests) may be undertaken at the same appointment (according to appropriate procedures for referral, justification and authorisation), with the decision being 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.

Once all investigations are complete and prior to the patient leaving, they should be advised of when and how to obtain the result.

### Reporting

Local agreement will determine who is responsible for reporting the scan results to the referrer. This is ultimately the responsibility of the lead clinician for the service (who will usually be a medical practitioner but may alternatively be another registered healthcare professional)<sup>[30]</sup>. Detailed advice about interpretation and reporting may be found in the National Osteoporosis Society guidance<sup>[31,32]</sup>. Agreement should be reached between the provider and commissioners of the service about the scope and content of the DXA report. It is insufficient to simply send an unannotated DXA scanner printout to non-specialist referrers. As a minimum, the report should define the technical validity of the measurement and include a summary of the results in an easily understood format and a guide to interpretation. Many referrers will require a more detailed report with 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 radiography background); experts in the medical management of osteoporosis (often specialist secondary-care consultants); and those who must manage individual patients (GPs and other primary and secondary healthcare practitioners).

Reports should be issued within an agreed period of time and may be made available electronically or sent in paper format. An 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 the IRMER that there is a written clinical (not necessarily medical) record 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.

### Further investigation

Depending on the result of the DXA scan, further investigation may be indicated. For example, height loss or appearances on DXA or vertebral fracture assessment (VFA) images may suggest the presence of vertebral fracture, necessitating further imaging. Indications for further clinical assessment and/or laboratory investigation may include:

- presence of low-trauma vertebral fracture
- low BMD for age (e.g. Z-score less than -2)
- unexplained bone loss on serial measurement
- clinical suspicion of an underlying cause of osteoporosis or contra-indication to treatment.

In addition, baseline investigations (such as measurement of renal function or bone turnover markers) may be required prior to the introduction of treatment.

Unless there is provision for these to be undertaken in a one-stop assessment at the same time as the DXA scan, either the patient will need to be recalled to an out-patient clinic or the referrer may be asked to undertake the required tests and seek further clinical advice if necessary.

### 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.

### Standard operating procedures

It is good practice to document the detail of each element of the pathway to ensure it is implemented in a standardised manner. This is increasingly important with the involvement of more members of staff, for example if DXA scans are undertaken by a team of operators who rotate within a larger department and have other roles. Standard operating procedures are an important element of an induction process for new staff. Procedures must be clear about what is to be undertaken, by whom, and when and where if these latter parameters are relevant. Examples include:

- patient pathway within the DXA scanning department
  - detailing of the minutiae of the process
  - inclusion of agreed timescales to facilitate monitoring
- scan acquisition and analysis
- scan archiving
- reporting
- quality assurance (QA) procedures (see below).

### Radiation protection

Although the radiation dose from a DXA scanner is relatively low, the legislation in place to protect patients (IRMER) and that in place to protect staff and the public (the Ionising Radiations Regulations 1999 (IRR 99)) still apply. It is important to contact and obtain advice from a radiation protection adviser (RPA) and 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 will 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.

Note that if you intend to start work with ionising radiation for the first time the Health and Safety Executive (HSE) needs to be informed at least 28 days before commencement of work.

The HSE has published an overview of the regulatory requirements associated with medical exposures: "The Regulatory Requirements for Medical Exposure to Ionising Radiation: An Employer's Overview" (2001) (a free downloadable version is available from [www.hse.gov.uk/pubns/books/hsg223.htm](http://www.hse.gov.uk/pubns/books/hsg223.htm)).

### 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 particular consideration are highlighted here.

### Workforce

- Staff should possess appropriate qualifications and experience for their role and have up-to-date registration with appropriate professional bodies.
- As regards staff, the employer must ensure that:
  - there is adequate provision of training
  - competency is evaluated and maintained
  - there is adequate supervision.
- There must be defined lines of accountability.
- There must be access to support (e.g. occupational health service).

### Infection control

To reduce the risk of the spread of infection, standard operating procedures 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.

### Equal access

The service must be compliant with legislation relating to equal access and avoidance of unfair discrimination. Examples of the practical implications of equality of access include the availability of:

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

It is important to remember that many patients may be elderly and infirm and may have mobility problems. This has important implications for the design of the facility, provision of patient handling aids, and staffing.

### Information governance

All handling of personally identifiable data must be carried out in compliance with the Data Protection Act 1998 and local policies. According to the act, the service must comply with the principles of the Caldicott Guardians, particularly in defining methods of communication between referrers and the service.

DXA scans should be archived at the end of each working day, storing the image and data files. 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 to 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.

### 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).

### Quality assurance <sup>[33]</sup>

Services require robust QA procedures to ensure consistent compliance with regulation, contractual obligations and local procedures as well as to ensure the reliability of the quantitative outcomes from the DXA scanner itself. Checks on specific instruments should be undertaken in accordance with the DXA manufacturer's guidelines and all operators should understand the QA procedures and the action to be taken if a scanner fails a QA check.

- The choice and commissioning of new DXA equipment should be made with expert help and advice from suitably qualified individuals (e.g. MPE, RPA, bone densitometry operator and clinician).
- QA checks should be carried out daily prior to patient workload and a minimum of three times per week.
- 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 or non-standard scans being undertaken and reason for doing so).
- Service and repair records should be kept, including details of any faults discovered.

### Maintenance

All X-ray equipment used by the service must be maintained to enable safe and reliable functioning (IRR 99). 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 (IRR 99) to the service engineer as well as for receiving it back into clinical service.

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 about 10 years and certainly beyond that time period 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.

### Staffing the DXA service

Staffing requirements will depend on the service model chosen but there is a minimum requirement that is 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.

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 (IRMER 2000). Therefore, the service must always have at least one registered healthcare professional contracted to provide this function.

### DXA operators

The DXA operator is the person carrying out the authorised procedure (IRMER 2000). DXA operators should be adequately trained healthcare professionals, generally radiographers, nurses or clinical technologists. The IRMER states that "no practitioner or operator shall carry out a medical exposure ... without having been adequately trained".

This means that "practitioners and operators shall have successfully completed training, including theoretical knowledge and practical experience in ... radiation production, radiation protection and statutory obligations relating to ionising radiation".

Equipment-specific training should be provided by the company supplying the scanner. Further training is desirable and available through courses such as those organised by the National 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 continuing professional development.

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 99. 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 (IRR 99).

### Nursing staff

It is highly desirable for the densitometry service to incorporate nursing staff with specific training and skills relating to osteoporosis. This may not always be possible, for example if the DXA scanner is sited within an imaging or medical physics department. Healthcare assistants may be used to support the DXA operators and improve efficiency of patient

throughput by preparing patients for their scan and making measurements of height and weight. They may also be required to act as chaperones for some patients.

Qualified nursing support is desirable. A nurse with knowledge and experience in the diagnosis, prevention and treatment of osteoporosis can offer support and advice to patients attending for DXA or following diagnosis of osteoporosis. Providing a clear understanding of the condition and its treatment is a vital component in ensuring good compliance with medication and lifestyle advice. Nursing staff frequently provide the link between the DXA service and related pathways, such as falls prevention and fracture clinics.

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

- telephone helpline for patients and carers
- education of patients and healthcare professionals
- clinical governance.

### 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 are included within the training programmes for general practice and trainees in several medical specialties. Key skills and expertise are discussed in the National Osteoporosis Society guidance on reporting<sup>[31,32]</sup> 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:
  - 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
- current clinical guidance, and understanding of cost-effectiveness and local and national strategies
- clinical governance in relation to DXA reporting
- commitment to continuing professional development and clinical audit
- working within a clinical network to provide an optimal service
- education of health professions and the public
- membership of appropriate professional organisations such as the National 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
- seeking to develop the knowledge and experience of existing staff.

### Scientific support

To address the requirements of IRMER 2000, the service requires involvement of a suitably qualified MPE. Suitable qualification implies:

- a science degree
- experience in the application of physics to the diagnostic uses of ionising radiation
- membership of a recognised professional body.

Professional membership of the National Osteoporosis Society is also recommended.

An MPE should be available, as required, for consultation on optimisation, including patient dosimetry and QA, and to give advice on matters relating to radiation protection concerning medical exposure. Given the low radiation doses involved and the very 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, there must always be the opportunity to consult with one should it prove necessary.

A suitably qualified scientist may undertake other tasks outside the statutory role of the MPE:

- supervision and analysis of quality-control data
- advice on possible errors in individual scans arising from physical limitations 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.

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.

If the organisation has not appointed an RPA already because it does not use ionising radiation, the HSE holds a list of certified RPAs who have agreed to have their names published. Alternatively, a local district general or teaching hospital may be able to provide a contact.

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

- The RPA will advise the organisation on compliance with IRR 99.
- The RPA will review proposed plans for the scanner installation to ensure that there is adequate planned radiation protection for staff and members of the public and will provide advice on any requirement for a designated area, or someone acting under their guidance may inspect and test radiation-protection aspects of the new facility. Alternatively, the installer may appoint their own RPA to carry out this work. In either instance the employer should ensure that they receive a report confirming that the installation meets the protection specification agreed by their own RPA at the planning stage
- The RPA will advise on radiation safety procedures and the ongoing testing of equipment for radiation safety.

### Administrative and clerical staff

The service will require a receptionist to greet patients, make appointments and maintain the diary, generally using an electronic system.

Secretarial support will be required for the generation of letters and reports. There is a range of semi-automated reporting software that may be used to reduce the amount of secretarial time required. However, the additional physician or DXA operator time required to generate high-quality individualised reports using such software needs to be considered when making this choice.

### Environmental issues

#### 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 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<sup>[34]</sup>. 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.

### Facilities

The manufacturer's specification will define the minimum space required for the DXA scanner room and, depending on the space available, the RPA may suggest 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

- 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.

### 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 3)
- 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.

## Supporting documentation

### Local policies and procedures

These should include:

- patient referral policy
  - indications for DXA
  - exclusions
  - follow-up measurement and timing
  - procedure for justification and authorisation
  - protocols for delegation
- management of patients who do not attend appointments
  - rebook or discharge
  - clinical review or clerical decision
  - communication with patient and referrer/GP
- use of telephone, letter text or other reminder service
- DXA scanning
  - scanner operation
  - pregnancy testing
  - checking for presence of artefacts
  - patient identification
  - skeletal sites scanned
  - repeat scanning
  - archiving
  - reporting
- radiation-protection documentation (in consultation with the RPA):
  - local rules for all work areas involving ionising radiation to define controlled areas and set out responsibilities of staff (IRR 1999)
  - written systems of work setting out safe methods of working
- QA
- complaints
- incident reporting
- equipment inventory
- record of training.

### 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. a sample patient information leaflet is available as Appendix 4

- information about osteoporosis and bone health (e.g. published by the National Osteoporosis Society)
- information about related services and how these can be accessed
  - falls prevention
  - social services
  - exercise classes
  - patient support groups.

### 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
  - DNA
  - 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), advice about suitable clothing, contact numbers and how to change/confirm the appointment
- report template
- patient and referrer satisfaction survey/feedback channel.

## Commissioning and acceptance testing of DXA equipment

The practicalities of installing a new DXA scanner are detailed in Appendix 3, which covers considerations for preparation, installation and acceptance testing that need to be undertaken prior to operation.

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# 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 vDXA 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.

### REQUEST FORM FOR FRACTURE RISK ASSESSMENT

Appointment enquiries:  
Secretaries:  
Fax :

Patient	GP
Name: _____	Name: _____
DOB: _____	Address: _____
Address: _____	_____
Telephone: _____ mobile _____	_____
NHS number: _____	Telephone: _____
Can the patient attend at short notice using own/public transport? <input type="checkbox"/> 24-48 hours <input type="checkbox"/> 1 week Can the patient attend using own/public transport? <input type="checkbox"/> at 8.30 am <input type="checkbox"/> after 4pm	

For hospital referrals: Consultant \_\_\_\_\_ Department and Hospital \_\_\_\_\_

#### Reason for referral (please refer to guidelines overleaf)

1. Patient with a history of low trauma fracture   
For vertebral fractures please give details (eg level, date if known) \_\_\_\_\_
2. Patient on, or commencing, systemic glucocorticoid treatment
3. Osteopenia (or low bone density) reported on x-ray by radiologist
4. Patient with disease or medication known to cause osteoporosis
5. Fracture probability by FRAX<sup>®</sup> indicating need for BMD measurement or treatment 
  - NOGG amber zone
  - NOGG red zone
6. Follow-up scan to assess change in BMD   
Please specify where and year of scan: \_\_\_\_\_

Other relevant clinical details including current bone-active treatment: \_\_\_\_\_

- **Please indicate any special needs**, eg hearing/visual impairment, need for interpreter, disability
- BMD at the spine and hip cannot be measured accurately in patients over 120 kg or with high abdominal girth. In this situation we may be able to measure peripheral BMD only Patient's weight \_\_\_\_\_ kg

**Please note that referrals which do not give a valid reason for referral or without a signature will be returned for clarification/completion before the referral can be processed**

Signature of authorised referrer: \_\_\_\_\_

Name \_\_\_\_\_ Date \_\_\_\_\_

#### 1. Fracture

Postmenopausal women and men >50 with history of one or more fractures after age 40

- a. Postmenopausal women over age 75 may be considered for treatment without prior BMD (NICE HTA 161, [www.nice.org.uk](http://www.nice.org.uk))

#### 2. Steroids (RCP guidance, available at [www.nos.org.uk](http://www.nos.org.uk))

- a. All patients <65 years taking, or likely to be taking, steroids for >3 months
- b. Refer at initiation if high dose steroids (eg prednisolone ≥15 mg daily)
- c. Patients >65 years may be considered for osteoporosis prophylaxis without BMD

*Inhaled steroids without intermittent oral treatment or other risk factors are not an indication for BMD scan*

#### 3. Radiological osteopenia - appearance of low bone mineral density reported by a radiologist

#### 4. Disease/medication associated with bone loss - examples include:

- a. **Inflammatory conditions** – inflammatory arthritis; inflammatory bowel disease ([www.bsg.org.uk](http://www.bsg.org.uk)); liver disease (Gut 2002;50:i1-19)
- b. **Malabsorption**, eg coeliac (Gut 2000;46:i1-18)
- c. **Cystic fibrosis** ([www.cftrust.org.uk](http://www.cftrust.org.uk))
- d. **Endocrine disease**, eg primary hyperparathyroidism (JCEM 2009;94:335-339); thyrotoxicosis; Cushing's; premenopausal amenorrhoea; hypogonadism
- e. **Use of Depo-Provera** with amenorrhoea (local guidance intranet link)
- f. **Aromatase inhibitor** therapy (guidance available at [www.nos.org.uk](http://www.nos.org.uk)) or GnRH analogues
- g. **Androgen deprivation** therapy
- h. **Eating disorder/over-exercise with amenorrhoea**

#### 5. Use FRAX<sup>®</sup> tool to triage any other patients over 40 years presenting with risk factors for osteoporosis/fracture ([www.sheffield.ac.uk/FRAX](http://www.sheffield.ac.uk/FRAX))

- a. Use linked National Osteoporosis Guideline Group (NOGG) guidance to aid decision to refer for detailed fracture risk assessment - We recommend referral of:
  - i. **All individuals with result in amber range**
  - ii. **Individuals with result in red range to facilitate:**
    1. uptake of treatment
    2. decision whether further investigation is indicated (eg severe osteoporosis, vertebral fractures)
    3. need to consider second line treatment in future

- FRAX<sup>®</sup> may not be used to assess fracture risk in patients who are currently taking or who have already been treated with osteoporosis treatment other than calcium and vitamin D
- FRAX<sup>®</sup> does not take account of dose of glucocorticoids or number (or site) of fractures and we advise direct referral for these categories

**Patients with non-osteoporosis bone disease can be referred directly to the Metabolic Bone Clinics. Any referrals and queries may be discussed with Metabolic Bone Centre staff**

## Appendix 3

### Commissioning and acceptance testing of DXA equipment

#### Commissioning

##### Prior to installation

- Contact the local RPA to ensure compliance with the Ionising Radiations Regulations 1999.
- As soon as the scanner is installed, arrange with the RPA a date and time for acceptance and commissioning radiation-safety tests to be carried out. These should include a measurement of radiation output in the X-ray beam and a measurement of scattered radiation at the operator's console.
- Discuss the need for a dedicated electrical supply to comply with electrical regulations and arrange for this to be installed.
- As soon as the scanner is installed, arrange with the Medical Physics/Electronics department a date and time for electrical safety checks to be carried out.
- 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 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.

- 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 scanner, investigate 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 99 to carry out the critical examination lies with the installer (usually the manufacturer's service engineer). The installer will consult an RPA, who may be appointed by the installing company; alternatively, this role could be covered by the employer's RPA by prior arrangement. 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.
- Make sure that your experienced DXA operators have received basic familiarisation with the new system.
- 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.
- Ensure that the critical examination report, the engineer's installation report and any other paperwork is signed.

#### Acceptance testing

Inform the local radiation protection service that a new scanner is ready for radiation safety tests. Ensure that an experienced person is there to help operate the scanner during the measurements. These usually consist of scanning an ionisation chamber using the various scan modes available to check the entrance surface dose. The scatter dose in the scanning room is measured by scanning an appropriate phantom. Once the equipment has passed the assessment tests, the medical physics 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 and check that the BMD measurements are within the specified quality control limits and that the in-vitro precision is acceptable. This forms 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 RPA to agree a suitable QA programme.
- Start a maintenance and faults recording book for the new scanner. Enter 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.
- Confirm the date of a visit 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.
- Carry out an in-vivo cross-calibration study if required <sup>[35]</sup>.
- Carry out an in-vivo precision study for the new system if required. The ISCD recommends scanning 30 patients twice or 15 patients three times each. Ethics approval should not be required for this but the process will require local governance approval and patients will need to give informed consent.
- Once documentation and training are complete, patient scanning may commence, but do not fully book the scanner for at least a week to allow for unforeseen problems.
- Take out a maintenance contract with the DXA supplier for when the warranty period expires.

If replacing an old scanner, the following should also be considered:

- Discuss with the DXA equipment supplier the procedures for transferring the existing patient database and scan archive onto the new scanner.
- If replacing a scanner used for research studies,

# Appendix 4

## Sample information leaflet for patients and carers

### SAMPLE Information Leaflet for patients and carers

#### Why have I been referred for a fracture risk assessment?

You have been referred because you may be at risk of osteoporosis.

#### What is osteoporosis?

Osteoporosis is a condition in which thinning of the bones makes them fragile. Broken bones (fractures) can happen more easily in people with osteoporosis.

#### How can you tell if I have osteoporosis?

The best test to identify osteoporosis is a Bone Mineral Density (BMD) measurement using a DXA scan. We usually measure the lower spine and one hip.

#### What is a DXA scan?

A DXA scan measures the density of the bone. This tells us about the strength of the bones and the risk of breaking bones in the future.

#### What does the DXA scan involve?

You will be asked to lie down for the scans. For the spine scan your legs will be supported on a box. For the hip scan one foot will be supported to keep your leg in position. You will need to keep still while the scan is being done (about 2 to 3 minutes each). The arm of the scanner will move during the scan but you will not be in an enclosed space at any time. You may also have a VFA scan.

#### What is a VFA scan?

A VFA (Vertebral Fracture Assessment) scan shows us the shape of the bones in your spine to see if they have become damaged due to osteoporosis.

#### How safe are DXA and VFA scans?

DXA and VFA use very small amounts of x-rays. The dose of x-rays is about the same as you will be exposed to naturally in 3 days and is much less than in other common tests such as a chest x-ray. They are therefore very safe tests. However, if there is any chance you could be pregnant you must tell us before your scan as it may not be safe for a developing baby.

#### Do I have to have the scan?

No. As with any investigation it is your choice whether you want to have the scan and any other tests. However, the doctor who referred you thinks you may be at risk of osteoporosis, and a DXA scan is the best way to investigate this. If you have any concerns or queries please contact us.

#### Do I have to prepare for the scan?

If you wear clothes without any metal in them you may not need to undress. Metal interferes with the DXA measurement, so you may be asked to take off any clothes containing metal (e.g. zips, corsets and underwired bras) and will be given a gown to wear.

The scan result may also be affected if you have recently had tests such as an isotope (NM) scan or barium x-ray. If this is the case please tell us as your scan may need to be re-arranged.

#### Why have I been asked to fill in a questionnaire?

The questionnaire gives us important extra information about your bone health. If you need treatment this information will also help us decide what the best treatment is for you.

#### Will any other tests be done?

Depending on the result of your scan, we may also arrange other tests on the same day. These may include x-rays, blood tests and a urine test. These will give us more information about your bone health.

#### How long will my appointment take?

Please allow at least 2 hours for your appointment as we do not know until you have had your scan what other tests may be needed. The scans will take 20 to 30 minutes in total. If you

need x-rays you will need to visit the x-ray department nearby and may have a wait. If you need blood tests these will take another 10 to 15 minutes. Please note that, whilst we try to see patients on time, delays can sometimes happen. If this happens we will keep you informed.

#### Can I bring someone with me?

You can bring someone with you to your appointment, however because we are using radiation they must wait outside the room while the scans are being done. If this is a problem for you please contact us so that we can make special arrangements.

#### How will I find out my results?

We will send a report to the doctor who referred you. If this was not your GP, your GP will also get a copy. The report will give the result of the scans and any other tests. The report will also give advice about treatment if this is needed. We will tell you how long this will take, but it is usually within 4 weeks of your appointment.

#### What if the scan shows I have osteoporosis?

If you have osteoporosis you may be advised to take treatment. This is usually tablets. You may be given an appointment to have further tests and discuss the results.

#### Who can I contact if I have any questions?

If you have any questions please contact us on \_\_\_\_\_.

#### Please remember

- **To bring your completed questionnaire**
- **To allow at least 2 hours for your appointment**
- **If possible, to wear clothes with no metal in them**
- **To let us know if you have had a recent barium x-ray or isotope scan**
- **To tell us if you could be pregnant**

## About us

The National Osteoporosis Society is the only UK-wide charity dedicated to improving the diagnosis, prevention and treatment of osteoporosis. The charity works to:

Influence government and campaign to improve and maintain essential services.

Provide a range of information resources including leaflets on all aspects of osteoporosis for you and your patients, some of which can be ordered in quantities for you to use in healthcare settings.

Provide a helpline staffed by nurses with specialist knowledge of osteoporosis and bone health.

Raise money to fund important research.

Host a major UK scientific conference on osteoporosis for health professionals

## Professional membership

Professional membership of the National Osteoporosis Society can make your job easier if you support people with osteoporosis or fractures, or are involved in research connected with osteoporosis.

Your professional membership will mean you can stay up-to-date with new treatments, care and the latest news on research. It means you'll have a deeper understanding of the condition.

You can also feel proud to be part of an organisation working hard to help those affected by osteoporosis.

To find out more about becoming a professional member, call our membership department on

01761 473287 or visit us at  
[www.nos.org.uk/professionals](http://www.nos.org.uk/professionals)

 **0845 130 3076** (General Enquiries)

 **0845 450 0230** (Helpline)

 **[www.nos.org.uk](http://www.nos.org.uk)**

 **Camerton, Bath BA2 0PJ**



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