Outcome and Recommendations of the Working Group on Reimbursement of Diagnostic Measures - Recommendations and Prioritisation

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EC Recommendation 5 on osteoporosis states that DEXA bone density measurements should be accessible and reimbursable for all high risk individuals.

There are several definitions for Osteoporosis: The WHO 1994 definition of osteoporosis is that osteoporosis is present when the bone mineral density or bone mineral content is over 2.5 standard deviations below the young adult mean (–2.5 T score) as measured by DEXA or an osteoporotic fracture.

Another definition is that osteoporosis is a disease characterized by a decrease in bone mass and a deterioration in bone microarchitecture, which leads to an enhanced fragility of the skeleton and, therefore, to a greater risk of fracture.

Osteoporosis is a silent disease and is the commonest bone disease worldwide. Osteoporotic fractures impose a huge social and financial burden in Europe, especially unnecessarily blocking acute hospital beds. It is also a preventable and treatable disease in the majority of cases. It is mandatory to have a multidisciplinary approach, otherwise patients could get lost in the system and it will result in an increased risk of fractures, poor quality of life and significant increases in the cost of healthcare. Unfortunately, the first sign is often a low trauma fracture or loss of height. One in 3 postmenopausal women and one in 5 men will develop an osteoporotic fracture during their lifetime. Osteoporosis affects all age groups including children; it is not just an “old lady’s disease”. Osteoporosis is a complication of many medical and surgical specialties, either the disease itself or medications used to treat these conditions. See appendix 1.

The most common cause in females is oestrogen deficiency and in males, it is testosterone deficiency. Some of the common risk factors include: age, family history of osteoporosis or hip fracture, inadequate calcium and vitamin D intake, excessive fibre, caffeine or alcohol intake, smoking or severe psychological stress. A previous low trauma fracture and low bone mass are the most important predisposing factors for an osteoporotic fracture. Once a person has had a low trauma fracture, research has shown that they will develop a second fracture within six months to one year, which could be prevented.

Most osteoporotic low trauma fractures are seen at A and E Departments, not at a general practice surgery. Osteoporotic fractures should be identified in a Fracture Clinic to prevent further fractures and to reduce both the financial cost and the devastating effect on the quality of life to the patient and their families. The majority of patients are sent home, without osteoporosis even being discussed or diagnosed. All low trauma fractures should be screened, as it is not normal at any age to break a bone from a trip and fall. More DEXA units should be available in hospitals to detect osteoporosis earlier and therefore reduce the amount of fractures and increased medical costs attributed to them. DEXA scan-
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...ing is the WHO Gold Standard to diagnose osteoporosis.

All DEXA units should have the patient fill out a detailed questionnaire, which should include the risk factors (see Appendix 1) as it is essential to try and determine the cause of the osteopenia or osteoporosis. The cause of osteoporosis is essential as this will help to decide which investigations should be carried out. All those at risk should be scanned, to ensure that they change their life-style and are prescribed appropriate treatment.

**Diagnostic procedures include:**

- X-ray may demonstrate low trauma or vertebral fractures
- Gold Standard is Dual Energy X-ray Absorptiometry (DEXA)
- Peripheral DEXAs
- MRI
- Ultrasound
- QCT or PQCT
- Bone Markers
- Biochemical and other investigations to determine the cause of osteoporosis or osteopenia

**Dual Energy X-ray Absorptiometry (DEXA) is the gold standard for diagnosis of osteoporosis:** it scans the hip and spine, the areas most at risk of fractures. The same machine must be used to monitor treatment. Calibration is essential. Daily quality control using a spine and hip phantom or a block phantom monthly. Radiation from a DEXA scan is less than a chest X-ray.

The procedure and the results should be explained to the patient, that it is painless, there are no injections, and they do not have to take their clothes off. The patient must not be pregnant or have metal in the area to be scanned. They should be informed about the cost of the scan and consultation if there is one.

**DEXA Scan Analysis: Correct positioning is vital.** Always use the region of interest (ROI) width, center the spine within the global ROI, include equal amounts of soft tissue on either side; always analyse L1–L4. If possible, you need at least two vertebrae.

Label vertebrae correctly: Report on size of each vertebra, the T-Score of total vertebrae and each individual vertebra. Note any bony abnormalities, osteophytes vertebral fractures, scoliosis, marked kyphosis. Is there uniform density or is it patchy? Secondaries check history. Calcification in abdominal aorta or in abdomen may affect results.

Report on hip: comment on each area. Look at neck of femur, trochanteric, intertrochanteric and total hip. A person’s total hip may be normal; however they may have osteoporosis of the neck or other areas of the femur. The majority of fractures tend to occur with a T score between –1.5 and –2.5, which is osteopenia, therefore early detection is essential. Ideally only 2 people should operate the same DEXA machine for accuracy purposes.

Consultation: Ideally the Questionnaire is checked, DEXA scan results explained and the print out given to the patient.

**T-Score compares the patient to young adult (20–30) mean bone mineral density (BMD) for same race and gender**

- 0 to –1.0 SD = Normal
- –1 to –2.49 SD = Osteopenia, Osteopenia can be subdivided into:
  - Mild –1 to –1.49 SD
  - Moderate –1.5 to –1.9 SD
  - Marked –2 to –2.49 SD
- More than –2.5 SD = Osteoporosis or Low Trauma Fracture = Osteoporosis

**Z-score compares patients’ BMD with the average BMD for their same age group.** Use Z-scores for children. However it is necessary to determine whether their bone age is the same as their chronological age, (X-ray of left hand) to determine osteopenia and/or osteoporosis.

Lifestyle advice should be given to all. Treatment advice must be individualised and should be based on questionnaire and DEXA result, which ideally should be interpreted in the context of history of fracture risk assessment. The presence of a prevalent low trauma fracture, despite a normal or osteopenic DEXA result is considered a diagnosis of osteoporosis and should be treated.

Patients should be monitored on the same machine whenever possible for reliable comparison results, usually every 2 years, if marked loss, query if quality control on machine has altered or operator error. Question if patient has developed another problem e.g., diarrhoea, are they on new medication or if they have ever taken or have stopped taking anti-osteoporotic medication.

**Bone markers**

Measuring markers of bone resorption and/or bone formation is useful for the diagnosis and follow-up of osteoporosis because it provides information which is different, yet complimentary to BMD measurements. Bone markers are associated with an increased risk of osteoporotic fractures independently of BMD [1–3] and only bone marker measurements provide information about the current bone turnover.

The benefits of monitoring therapeutic effectiveness are also well documented [4–8] in a meta-analysis of 18 individual studies [9]. Moreover, patient monitoring during the early stages of treatment has the potential to encourage continued treatment compliance and identify individuals who are not responding to treatment.

Serum markers respond much earlier to therapy than can be recognized by BMD reassessment. Resorption markers have fully responded after 3–6 months, however the effect on formation markers may take up to 6 months. Difficulties in the inter-
Interpretation of bone markers values are related to the sources of biological and analytical variability of their measurements. Bone markers exhibit substantial short and long term fluctuations related to the time of day, season of the year, exercise, diet and other factors known to influence bone remodeling. Defining the least significant change for a bone marker, i.e. the minimal change that is significant when taking the existing variability into account, allows to differentiate clinically relevant changes from random fluctuations.

Controlled conditions for sample taking, understanding and taking into account the problems that may be encountered in the analysis – due to the variability and stability of the analyte – are necessary to minimize the least significant change and for the correct interpretation of results. Preanalysis requirements depend on the type of analysis, the specifics of the assay and the type of specimen. These have to be discussed with the respective laboratory to realize the benefit from the measurement of bone markers.

Since a critical study in 2001 [10], the difficulties in the routine measurement of bone markers have been understood and addressed [11]. But there is still a lack of easily accessible external quality control schemes, that are necessary to ensure adequate performance and comparability of results. Algorithms for the interpretation of bone marker measurements have not yet been validated and would greatly expand the beneficial incorporation of bone markers into the diagnosis and follow up of osteoporosis.

Clinical chemists have to demonstrate that their application of these methods meets acceptable proficiency standards. And sceptical clinician will need to critically review published data concerning what biochemical markers of bone turnover can and cannot do when measured with proper standardization, accuracy, and precision.

**EU-Survey**

Questionnaires were sent out to the National Osteoporosis Societies in the European Union; Key Topic II: Diagnosis of Osteoporosis

1. **DEXA:**
   - Number of devices, number per million, cost, reimbursement, waiting time
   - X-Ray: Reimbursement
   - Blood Analysis (general):
     - yes
     - no
   - Bone specific Markers:
     - yes
     - no
   - TSH:
     - yes
     - no
   - Sex Steroids:
     - yes
     - no

**Results:** see Table 1.

Number of DEXAs varied from 3 per million to 20 per million. Cost is free in some countries and up to € 280. Reimbursement varies from 100% in some, partial or none in three countries. Waiting time varies from 3 days to 9 months. No question of whether there was a consultation to explain the scan was included, as without explanation – since it is silent disease – compliance can be an issue.

A large number of women aged 50+ are aware of osteoporosis, but do not consider themselves at risk, and a significant amount live active and independent lifestyles. However, these women neglect to take simple steps to protect their bone health and lifestyle by failing to consult their physicians and by not having their bone density tested.

**Reimbursement:** see Table 2.

**Recommendations**

- Quality assurance for diagnostic measures are not standardised in all countries.
- Implement uniform standardisation of DXA protocols and procedures to diagnose osteoporosis.
- Implement external quality assurance schemes for bone markers.

<table>
<thead>
<tr>
<th>DEXA</th>
<th>N0/million</th>
<th>Cost</th>
<th>Reimbursement</th>
<th>Waiting time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Netherlands</td>
<td>1 or 2 in major hospitals</td>
<td>€ 100–200</td>
<td>yes</td>
<td>Varies av. 2 weeks</td>
</tr>
<tr>
<td>Finland</td>
<td>81 DEXA</td>
<td>Free in public</td>
<td></td>
<td>0–3 days</td>
</tr>
<tr>
<td>Lithuania</td>
<td>10; 3.5/m</td>
<td>€ 10–25</td>
<td>no</td>
<td>short</td>
</tr>
<tr>
<td>Poland</td>
<td>4/million</td>
<td>€ 10–15</td>
<td>no</td>
<td>1–2 weeks</td>
</tr>
<tr>
<td>Slovak</td>
<td>7/million</td>
<td>€ 40</td>
<td>100 %</td>
<td>3–4 weeks</td>
</tr>
<tr>
<td>Slovenia</td>
<td>33; 15.5/million</td>
<td>€ 23–50</td>
<td>Not on 1st</td>
<td>1–7 days</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>50; 5/million</td>
<td>€ 1 per site</td>
<td>full</td>
<td>14 days</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>241; 4.1/million</td>
<td>£ 75–280</td>
<td>Yes if NHS</td>
<td>17 days av.</td>
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<tr>
<td>Malta</td>
<td>8; 20/million</td>
<td>€ 195</td>
<td>Free NHS</td>
<td>6–8 months</td>
</tr>
<tr>
<td>Switzerland</td>
<td>70; &gt; 10/million</td>
<td>€ 47</td>
<td>yes</td>
<td>No waiting</td>
</tr>
<tr>
<td>Spain</td>
<td>4–500; 10/million</td>
<td>€ 30–50 full</td>
<td>full</td>
<td>6–12 months</td>
</tr>
<tr>
<td>Ireland</td>
<td>47; 4.5/million</td>
<td>€ 100, free</td>
<td>% to some to GMS</td>
<td>2 weeks to 9 months</td>
</tr>
<tr>
<td>Austria</td>
<td>22/million</td>
<td>€ 85</td>
<td>In accredited centres yes</td>
<td>3 days to 3 months</td>
</tr>
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</table>
Each patient should be assessed as an individual. There must be a holistic approach to diagnosis and treatment. Patients with risk factors must be identified as early as possible. Link reimbursement to qualification and standardisation of all diagnostic measures. There must be a holistic approach to diagnosis and treatment. Each patient should be assessed as an individual.

Access to diagnostic measures are inadequate and varies from country to country. Use evidence based medicine principles to evaluate diagnostic measures (bone density, biomarkers, risk assessment, family history, genetics). Preventative measures must start in childhood. Daily physical activity (weight bearing) should be part of every primary and secondary school’s curriculum. Weight bearing activities can help prevent not only osteoporosis but obesity, heart disease, diabetes, strokes and depression. Prevention includes physical exercise, fall prevention and adequate nutrition.

Information and education about osteoporosis is urgently needed. The role of patient societies should be recognised, appreciated and financially supported.

Drugs with proven anti-fracture efficacy should be available and reimbursed in those who need them, in all countries. Reimbursement of generic drugs should not be allowed, until safety and bioequivalence to the original formulation is proven.

Treatment of high-risk patients is cost effective. Each member state is advised to determine the cost-effectiveness for all available drugs, in order to inform decision making on reimbursement of effective treatments.

Create an awareness of gender based medicine. Create an awareness of severity of male osteoporosis and osteoporosis in the young. Address early prevention of osteoporosis in both genders. Encourage the setting up of accurate fragility fracture registers. Invest in EU clinical trials in the prevention and treatment of osteoporosis and fractures. Address the social aspects of the disease.

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References

Table 2. Reimbursement in EU and Switzerland

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<tr>
<th>Country</th>
<th>X-Ray</th>
<th>Blood Analysis</th>
<th>Bone Specific</th>
<th>TSH</th>
<th>Sex Steroids</th>
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<td>Slovakia</td>
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