Osteoporosis in the European Community:

Action Plan A report of the key next

A report of the key next steps towards a Europe free from fragility fractures

November 2003





"It is shocking that many Europeans at high risk of fragility fractures remain undetected, and are missing out on preventive therapies with proven efficacies. This Action Plan aims to address this by setting out practical, cost effective strategies to prevent fragility fractures."

Mel Read MEP, chair of the European Parliament Osteoporosis Interest Group



A Report of the European Union Osteoporosis Consultation Panel

Supported financially by the European Commission.



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The human cost of osteoporosis

Inger Lundegaardh of Sweden, shown here in a series of photos,

is just one of millions of Europeans with osteoporosis.

Mrs. Lundegaardh's life has changed drastically because of osteoporosis. She can only walk with the help of two canes, cannot bend down, is constantly in pain, and has lost much of her independence. Earlier diagnosis and treatment could have helped to prevent the multiple fractures which have caused Mrs. Lundegaardh untold suffering and loss of quality of life.



20 years of age



50 years of age



59 years of age

Foreword



Tutiet Capan

Dr. Juliet Compston, 'A Call to Osteoporosis Action' project leader and International Osteoporosis Foundation board member

Why does osteoporosis need to be a health care priority in the European Community?

Osteoporosis is characterised by bone fragility and increased risk of developing fractures. The occurrence of osteoporosis-related fractures rises steeply with age. With life expectancy in Europe increasing, the elderly population is increasing. Unless action is taken now, Europeans will face an epidemic of osteoporosis and a miserable future of fragility fractures, disability and premature death. The action required to combat this crisis is clearly outlined in this action plan.

The need to prioritise osteoporosis and to develop strategies for preventing fragility fractures in high-risk individuals is obvious. Among people over the age of 50 years, one in three women and one in eight men will suffer at least one osteoporotic fracture during their lifetime. Osteoporotic fractures of the hip, spine, and wrist are common, and have a profound effect on quality of life. Hip fractures are particularly serious, affecting the frail and elderly, with one in five patients who sustain a hip fracture dying within six months. Those who survive a hip fracture face only a one in three chance of returning to their previous level of independence. Fractures of the spine are also debilitating, causing pain, deformity and height loss, limiting physical activity and lowering self-confidence and self-esteem.

Managing osteoporosis-related fractures imposes huge costs on healthcare systems. In Europe, the total cost of caring for patients in the first year after a hip fracture is presently estimated to be a staggering Euro 14.7 billion. Since these patients very often require treatment for more than one year, this figure still underestimates the true costs. In women over 45 years of age, osteoporosis accounts for more days spent in hospital than many other diseases, including diabetes, myocardial infarction and breast cancer. It is therefore essential that we implement policies to prevent osteoporosis and its consequences. Since the occurrence of a first fracture can lead to the rapid development of further fractures (in a so-called 'fracture cascade'), it is especially important that policies should promote the detection of osteoporosis before the first fracture occurs. Currently, there is disturbing evidence that early detection of osteoporosis is not perceived as a healthcare priority, and action is now urgently needed to address this problem.

We offer our sincere thanks to the EU Osteoporosis Consultation Panel members for their commitment and work over the past year to improve policies for osteoporosis. We urge the Consultation Panel to continue to work with stakeholders at national and EU levels to implement the practical actions outlined in this report. Step by step, we are working towards preventing avoidable fractures, with the aim of making a difference to the lives of millions of Europeans.

Foreword



he dead

Mel Read MEP, chair of the European Parliament Osteoporosis Interest Group

Why was the European Parliament Osteoporosis Interest Group created?

The European Parliament Osteoporosis Interest Group (Table 1) was set up in response to an audit in 2001⁵, which revealed that little progress had been made in achieving the goals set out in 1998 by the 'Report on osteoporosis in the European Community – Action for prevention', which was published by the European Commission.⁶ To help stimulate much-needed policy developments, we recently issued a 'Call to Action' (Table 2). Over the past two years, we have been working with the EU, and member and accession states, to implement these actions.

I only have to talk with my colleagues to know that awareness of osteoporosis, and the debilitating fractures it causes, is still low. Many politicians remain unaware of the huge human and economic cost of this neglected disease. It is shocking that many Europeans at high risk of fragility fractures remain undetected, and are missing out on preventive therapies with proven efficacies. This Action Plan aims to address this by setting out practical, cost effective strategies to prevent fragility fractures.

My colleagues and I from the European Parliament Osteoporosis Interest Group are therefore delighted to host the launch of this much needed Action Plan at the European Parliament in Brussels on 12 November 2003. To further raise awareness of the human costs of osteoporosis, the launch event includes a moving photographic exhibition. In addition, participants have the opportunity to find out more about their own risk of osteoporosis.

As politicians – and particularly as members of the European Parliament Osteoporosis Interest Group – we will continue to keep a watchful eye on developments. We look forward to seeing real progress as the next key steps in this report are implemented. This should ensure that the burden of osteoporosis-related fractures in Europe is reduced over the coming years.

Thank you for your ongoing support.

Table 1

European Parliament Osteoporosis Interest Group Members

Mary Banotti MEP, Ireland John Bowis MEP, UK
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Concepcio Ferrer MEP, Spain
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Elly Plooij van Gorsel MEP, The Netherlands
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Proinsias de Rossa MEP, Ireland
Catherine Stihler MEP, UK
Astrid Thors MEP, Finland
Helle Throning-Schmidt MEP, Denmark
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Table 2

The European Parliament Osteoporosis Interest Group's Call to Action

At a press conference on 1 December 2001 the European Parliament Osteoporosis Interest Group issued a Call to Action to prevent unnecessary suffering and costs associated with osteoporotic fractures. National health authorities and health insurance agencies were urged to:

- Financially support and participate in educational and awareness-raising campaigns;
- Improve access to, and funding for, bone density scans for individuals at high risk of osteoporosis-related fractures;
- Fund proven therapies for individuals at high-risk of osteoporosis-related fractures.

Additionally, to help member and accession states develop best practices and to evaluate the results of their actions, this Call to Action urges the European Commission to work in partnership with the International Osteoporosis Foundation to:

- Bring together national and European policy makers, and osteoporosis experts and concerned groups, to produce practical, cost effective strategies to prevent osteoporosis-related fractures. These strategies should specify measurable, realistic, time-based targets;
- Create a co-ordinated data collection system to monitor osteoporosis-related fractures across Europe.

Members of the European Parliament Osteoporosis Interest Group act as ambassadors for those with osteoporosis and fractures in member and accession states, and at the EU in order to help implement this Call to Action. After three years an audit will be conducted to monitor progress.

European legal basis for action in the field of public health

Article 152 constitutes the legal basis for Community action in the area of public health. First introduced by the Maastricht Treaty in 1993, it was considerably reinforced by the Treaty of Amsterdam which entered into force in 1999. It now provides the Community with the necessary legal basis to adopt measures aimed at ensuring (rather than merely contributing to) a high level of human health protection. Most of the power in relation to public health remains in the hands of the Member States which are responsible for the delivery of public health services and medical treatment. However the Community has an important subsidiary role that mainly involves supporting the efforts of the Member States and helping them formulate and implement coordinated objectives and strategies. Article 152 encourages close co-operation between Member States in certain areas of public health. It covers the fight against the major threats to health, and the promotion of research into their causes, transmission and prevention, as well as health information, education and monitoring.

In line with its powers in the area of public health, in its action on osteoporosis the European Commission has concentrated on health promotion, prevention such as that of osteoporosis-related fractures, and on health monitoring issues. The action of the European Commission is reflected in the words of Commissioner David Byrne made at the launch of the European Parliament Osteoporosis Interest Group's Call to Action on 1 December 2001.



"We must continue our work together with national governments who are responsible for the organisation and delivery of health services and medical care."

European Health and Consumer Protection Commissioner David Byrne

Introduction

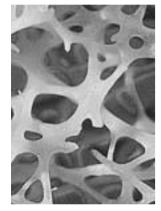
Why do we need a European Union Action Plan?

The reason is simple. Whilst osteoporosis is one of the most serious, debilitating and costly diseases in Europe (affecting one in three women, and one in eight men over the age of 50),¹ it is also one of the least recognised.

This action plan, produced with financial support from the European Commission, is a "call to action" to brighten the future for Europeans at high risk of fragility fractures by outlining key next steps towards a Europe without fragility fractures.

As well as detailing these key next steps, this report provides references, resources and examples of best practice to encourage member and applicant states to share policy success stories, to avoid reinventing the wheel, and to cost-effectively implement change.

Healthy bone



It also emphasises the need for accurate and current data on the rates of fragility fracture, collected on an ongoing basis in Europe. This is necessary in order to evaluate the impact of programmes designed to prevent fragility fractures, and to develop effective strategies to reduce the health-economic burden of osteoporosis.

Another related initiative funded by the European Commission is the 'European Bone and Joint Health Strategies' project, set up in 2001 to reduce the burden of bone and joint diseases within Europe. This project has a broad remit, covering osteoporosis, rheumatoid arthritis, osteoarthritis, back pain, and trauma, with the aim of examining the incidence, prevalence, risk-factors, prevention, treatment, and rehabilitation of these diseases. The final report will be published in December 2003, and should complement the more in-depth osteoporosis-focused work outlined in this action plan.



Osteoporotic bone

What is osteoporosis?

Osteoporosis is defined by the World Health Organization as a systemic disease characterized by low bone mass and microarchitectural deterioration of bone tissue, leading to enhanced bone fragility and increased fracture risk⁷. Fragility fractures are the consequence of osteoporosis and are particularly common in the spine, hip and forearm. These fractures show a steep age-related increase and are major causes of morbidity and mortality in elderly populations.

Over the age of 50, one in three women and one in eight men will experience at least one fragility fracture during their remaining life¹. The lifetime risk of a hip fracture in women is greater than the sum of the lifetime risks of breast, endometrial and ovarian cancers. In Europe, the total cost of caring for patients in the first year after a hip fracture is presently estimated to be a staggering Euro 14.7 billion. As the population of Europe ages, it is forecasted that the burden of osteoporosis will increase dramatically. Unless we act now, the annual incidence of hip fractures in the EU alone is expected to more than double, from 414,000 to 972,000, over the next 50 years.⁶

Hip fractures are the most serious type of fragility fracture. They are especially disabling and, together with vertebral fractures, are associated with a substantially increased death rate. The occurrence of a fragility fracture is the strongest indicator for a future fracture, with the risk of having any further fracture over the next year increasing by two-fold, and the risk of spinal fracture increasing by up to five-fold in cases where a spinal fracture has already occurred. Osteoporosis, often considered a slowly developing disease, may become rapidly progressive once a fracture occurs. For

this reason, prevention of the first fracture is crucial to prevent a cascade of fractures. However, this presents a significant challenge, since osteoporosis has no obvious symptoms before fractures occur, and because awareness in individuals at risk is poor. As Prof. Dr. Rita Süssmuth, former president of the Bundestag stated: "Osteoporosis is one of the worst chronic diseases in Europe but scarcely any woman in Germany knows her individual osteoporosis risk".

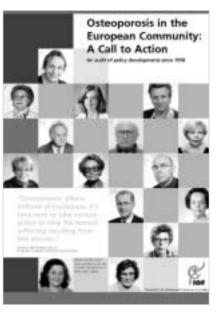
The vital role of the European Union and the European Parliament

In response to these worrying statistics, the European Parliament requested the European Commission to prepare recommendations aimed at making osteoporosis a healthcare priority. In 1998, the European Commission published eight recommendations in the Report on Osteoporosis in the European Community – Action for Prevention (Table 3). However, an audit in 2001 reported that disappointing progress had been made towards implementation of these eight recommendations. Far too many Europeans at high-risk of fragility fractures are still suffering unnecessarily and missing out on timely diagnosis and effective preventative therapies for fragility fractures.

In 2002, with financial support from the European Commission, more than 40 government health policy makers from member states, members of the European Parliament, osteoporosis experts and project partners formed an EU Osteoporosis Consultation Panel (Table 4). The aim of the panel's "call to action" is to increase the priority of osteoporosis at a governmental level, with particular emphasis on the development of effective strategies for the prevention of fragility fractures in high-risk individuals. This action plan is an important step in this process and has been produced as the result of formal meetings and individual consultations with EU Osteoporosis Consultation Panel members over the past year.



The 1998 "Report on Osteoporosis in the European Community – Action for Prevention" outlined the eight recommendations (Table 3) aimed at making osteoporosis a health care priority in Europe.



The 2001 "Osteoporosis in the European Community: A Call to Action" audited policy developments since 1998. The report showed that the annual hospital costs to treat osteoporotic fractures had increased by 33% in three years while very little progress had been made in acheiving the eight recommendations.



In April 2003 a new publication arising from the First EU Osteoporosis Consultation Panel Meeting held in September 2002, gave a report of the state of developments in each country. The new report reveals that although significant progress has been made in many countries, much remains to be done to fulfill the eight recommendations made in 1998.

Table 3

Recommendations from the 1998 "Report on Osteoporosis in the European Community – Action for Prevention" (European Commission)⁶

Recommendation 1

Osteoporosis is to be adopted as a major healthcare target by the EU and governments of the 15 member states.

Recommendation 2

More information is required about the incidence and prevalence of osteoporotic fractures.

Recommendation 3

Co-ordinate national systems throughout the EU to plan effectively for an increase in demand for healthcare and to institute appropriate resource allocation.

Recommendation 4

Develop and implement policies to advise the general public and health professionals about calcium and vitamin D nutrition.

Recommendation 5

Access to bone densitometry systems should be universal for people with accepted clinical indications and reimbursement should be available for such individuals.

Recommendation 6

Member states to use an evidence-based approach to determine which treatment should be advised. Reimbursement should be available for all patients receiving treatment according to accepted indications.

Recommendation 7

Governments should actively promote national patient and scientific societies, providing financial support and helping to publicise their cause. Appropriate training of healthcare professionals involved in the management of osteoporosis should also be an important priority.

Recommendation 8

Further research is urgently required in a number of areas, including:

- Modifiable determinants (such as exercise and calcium intake) of peak bone mass and how these might be used to achieve higher peak bone mass in the population.
- Identification of risk factors for falling and the effects of fall prevention strategies on fracture.
- Additional evaluation in different age groups of approaches to identify individuals at risk from fracture, for example the use of broadband ultrasound attenuation, biochemical markers of bone turnover and risk factors, either singly or in combination.
- Assessment of the cost/utility ratio of screening in older women.
- The causes and treatment of osteoporosis in men.



In recognition that something had to be done to stop the impending osteoporosis epidemic in Europe, the "Report on Osteoporosis in the European Community" was launched in June 1998 at the European Parliament in Brussels.

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Executive summary

Introduction: Why do we need an action plan now?

Osteoporosis is a serious, debilitating disease affecting one in three women and one in eight men over the age of 50 years. As well as having a major impact on peoples' health and quality of life, fractures due to osteoporosis place an enormous economic burden on healthcare systems in Europe. As life expectancy increases the number of Europeans suffering as a result of osteoporosis is expected to reach epidemic proportions unless action is taken now. The good news is that osteoporotic fractures can be prevented and, in 1998, a list of recommendations for the prevention of osteoporosis and associated fractures in Europe was published by the European Commission. However, an audit in 2001 showed that there has been very little uptake of these recommendations. In 2002, a group of more than 40 government health policy makers from EU countries, members of the European Parliament, osteoporosis experts and project partners formed the 'EU Osteoporosis Consultation Panel', calling for action to implement the 1998 recommendations using a step-by-step approach. Over the last 12 months, the Panel has met formally twice and in addition there have been ongoing individual consultations with Panel members to agree on the key next steps required. The recommended actions to lead us towards a Europe with better prevention of osteoporosis-related fractures are summarised below.

Step 1

Awareness-raising campaigns

To be optimally effective, awareness-raising campaigns should focus on those individuals at highest risk from osteoporosis, and those physicians who see most osteoporosis-related fractures. These fractures are most

common in post-menopausal women, but studies have shown that these individuals are very often unaware of their risk. One innovative campaign has been the 'one-minute risk test', in which individuals answer 'yes' or 'no' to a list of ten very simple questions. The risk test has been promoted through TV, print advertising, special events, and the International Osteoporosis Foundation (IOF) web pages. Other initiatives have been developed at local levels by IOF member societies.

Many specialists are in a position to contribute to the prevention of osteoporosis, particularly gynaecologists, but their awareness of the condition is often low. In addition, orthopaedic surgeons/traumatologists and radiologists play important roles in the diagnosis of osteoporotic fractures, but studies have shown that this opportunity is often missed. Key to improving the care provided by orthopaedic surgeons/traumatologists will be improved access to equipment for measuring bone mineral density. Other strategies have included the use of 'care pathways' to assure consistency of care for patients and 'fracture liaison nurses' to co-ordinate patient care. Radiologists are well placed to diagnose vertebral fractures using radiographic techniques, but unfortunately studies have shown that many of these fractures are not detected, and that existing fractures are often not recorded. Standards of care provided by radiologists can be raised by promoting better radiographic techniques (e.g. by using standardised procedures), and improving communications with other healthcare professionals (e.g. clearly writing "vertebral fracture patient" on letters and notes).

Finally, in order to audit the effectiveness of campaigns, it will be vital to improve the recording of data on osteoporotic fractures throughout Europe.

Action	Responsibility	Target date
Implement awareness-raising campaigns targeted at potentially high-risk individuals such as postmenopausal women	Osteoporosis patient organisations, with financial support and participation by each member and accession state's Ministry of Health	December 2005
Implement awareness-raising campaigns for healthcare professionals such as gynaecologists, orthopaedic surgeons/ traumatologists and radiologists	Specialists' associations (e.g. radiologists' association) in cooperation with osteoporosis and related non-profit organisations with financial support and participation by each member and accession state's Ministry of Health	December 2005

Preventive strategies: lifestyle considerations

Osteoporosis develops as a result of sub-optimal bone growth in child-hood and adolescence, and/or loss of bone mass later in life. Falls also play an important role in the development of osteoporotic fractures.

Preventative measures should therefore address these issues. Lifestyle adjustments include ensuring good nutrition throughout life (in particular, adequate calcium and vitamin D intake), adequate levels of physical activity, avoiding smoking, and avoiding alcohol abuse.

Although there is good evidence for the importance of calcium and vitamin D in osteoporosis prevention, there is little promotion of this at governmental level. In addition, not every European country has defined a recommended daily intake of these nutrients. Perhaps as a result, inadequate intake is very common (particularly in the elderly).

Weight-bearing exercise early in life is known to increase peak bone mass. Importantly for elderly individuals, as well as improving bone mineral density, exercise also increases muscle strength, thus improving co-ordination and helping to prevent falls.

Children and adolescents have been targeted in campaigns to improve nutrition and raise levels of physical activity. High-risk groups can also be targeted in campaigns to minimise osteoporosis-related lifestyle risk factors. Better promotional and educational programmes are required in order to persuade more people to make the right lifestyle choices.

Action	Responsibility	Target date
Development of government-backed health education programmes for all age groups to inform the public about ways of reducing osteoporosis risk. Agree on education programmes and secure funding	Healthcare professionals and patient organisations acting in co-operation with policy makers and national co-ordinators for osteoporosis within government Ministries of Health	December 2005
Harmonisation of recommendations for calcium and vitamin D intake throughout Europe for all age groups	Healthcare professionals, policy makers and national co- ordinators for osteoporosis within government Ministries of Health	December 2005
Development of government-backed public health campaigns to increase calcium and vitamin D intake, to recommended daily intake, and to ensure appropriate levels of physical activity in all age groups	Healthcare professionals and patient organisations acting in co-operation with policy makers and national co-ordinators for osteoporosis within government Ministries of Health	Commence implementation by December 2006



"There is compelling evidence that adequate intake of calcium and vitamin D is essential for normal bone development and maintenance of bone health."

Prof. René Rizzoli, WHO Collaborating Centre Geneva, Switzerland and Chair of the IOF Committee of Scientific Advisors

Guidelines for the prevention of osteoporosis-related fractures Guidelines are effective tools for promoting evidence-based clinical practice. Since some aspects of osteoporosis management vary according to country (e.g. availability of resources), country-specific guidelines for

osteoporosis are required. Many countries do not have national evidence-based guidelines for osteoporosis management, and immediate action is required in these cases. The EU Osteoporosis Consultation Panel is currently in the process of collating all available member state osteoporosis guidelines. Guidelines from accession states will also be assessed in the near future. Available guidelines will be assessed using the AGREE instrument, which provides a framework for systematic quality assessment. Development of new guidelines requires co-operation between all relevant healthcare professional and lay organisations (especially those representing patients and their carers), and typically requires four to eight meetings over one to two years, followed by a consultation period. Recommendations should be based on systematic literature reviews, and explicitly linked to evidence. Financial support for development and dissemination of guidelines should come from national governments, which should also endorse the recommendations. Full implementation of guidelines usually requires additional resources and/or organisational changes, and health-economic analyses are a powerful means of justifying additional resource allocation. Once guidelines have been implemented, it is vital to audit their uptake, and audit criteria should be clearly defined in guidelines. Generally, two audits (separated by one to two years) are required to properly assess uptake. Finally, guidelines must be frequently updated to take into account new advances. Regular updates should be scheduled (e.g. at least every five years), but occasional unscheduled updates may be required as new evidence emerges.

Action	Responsibility	Target date
Improvement of accessibility of current evidence- based guidelines to member and accession states to enable sharing of best practice and to ensure optimal care	The EU Osteoporosis Consultation Panel	June 2004
Development of national, evidence-based guide- lines in all member and accession states and endorsement of existing evidence-based national guidelines by government agencies	National osteoporosis related scientific societies, osteoporosis patient organisations, policy makers and the national co-ordinators for osteoporosis within government Ministries of Health	December 2005
Provision of financial support from governments for the development, dissemination and implementa- tion of national guidelines	Policy makers and the national co-ordinators for osteoporosis within government Ministries of Health	January 2005
Development and application of audit tools to assess clinical impact of guidelines	Healthcare professionals and policy makers	December 2005



"It is essential that guidelines are appropriately disseminated to potential users, that their use is audited to define resulting changes in clinical practice, and that they are updated regularly."

Dr Juliet Compston, 'A Call to Osteoporosis Action' project leader and International Osteoporosis Foundation board member

Fracture care, rehabilitation and prevention of falls

Despite the fact that methods to identify individuals at risk of osteoporotic fractures, and effective preventive measures are available, their use is disappointingly low. The incidence of fractures remains high and

is expected to increase in the future. It is therefore important that all measures aimed at reducing morbidity and mortality are included in health programmes for older people. Unfortunately this rarely happens, due to a lack of co-ordination of the many disciplines involved in the care of such patients, and a lack of evidence-based guidelines. While many European countries lack evidence-based guidelines, this situation is starting to change. As an example of best clinical practice the Scottish Intercollegiate Guidelines Network produced comprehensive, evidence-based guidelines on the management of hip fractures in 2002.

For patients who have suffered a hip fracture, the co-ordination of professionals in the health services and social care sectors greatly facilitates the rehabilitation process. Evidence is available that the use of ortho-geriatric units reduces the length of hospital stay and mortality, and improves functionality; such units however are rare. Nutritional support can also help recovery by reducing postoperative complications, and therefore hospital stay. Supported discharge schemes may also reduce in-patient hospital stays, aiding the safe discharge of hip fracture patients by close liaison between the hospital and the community. Many osteoporotic fragility fractures are the result of a fall. There is evidence that multifaceted interventions reduce falls in older people, and that assessment of high-risk residents in nursing homes with relevant referral is also effective. In 2001 an action plan to improve the health and social services for older people was produced by the English government. Among the standards set out was action to prevent falls and so reduce fractures, indeed all localities in England will need to have a specialist falls service in place by 2005.

Action	Responsibility	Target date
Develop and recommend evidence-based fracture care programmes that encompass all aspects of management and are endorsed and supported by governments	National experts in osteoporosis including members of the EU Osteoporosis Consultation Panel, members of the IOF Fracture Working Group, policy makers and the national co-ordinator for osteoporosis within the government's Ministry of Health	June 2005
Develop multidisciplinary falls services with integrated care pathways that incorporate the diagnosis and management of osteoporosis	National experts, including members of the EU Osteoporosis Consultation Panel, members of the IOF Fracture Working Group, policy makers and the national co-ordinator for osteo- porosis within the government's Ministry of Health	June 2005

Step 5

Step 5: Economic data

It is estimated that 643,000 people are suffering from osteoporosis-related hip fractures in Europe today. The cost of treating these fractures in the first year post-fracture is estimated to be Euro 14.7 billion, and the

annual cost of treating all osteoporotic fractures in Europe is estimated to be Euro 25 billion. As the elderly population in Europe increases, this cost will rise to an estimated Euro 31.8 billion for all osteoporotic fractures by 2025. This figure is an underestimate, since it assumes there will be no increase in treatment costs per patient, and no increase in incidence. To reduce the costs associated with osteoporosis, it is vital to identify individuals at high risk, and take preventative measures. The measurement of bone mineral density using DXA is a cost-effective way of identifying those at high risk of fracture, but is often unavailable, or poorly reimbursed in Europe. It is estimated that measuring bone mineral density in patients with prior fractures would require 4 DXA units per million population. This would rise to 8 DXA units per million if measurements were extended to those with other strong risk factors.

Many interventions, such as bisphosphonates and raloxifene, are cost-effective if targeted at individuals at high-risk of osteoporotic fractures. It is estimated that, by targeting the 25% of women over the age of 65 years at greatest risk, it will be possible to prevent 23% of all osteoporotic fractures over a 10-year period. However, cost-effectiveness studies have only been conducted in a small number of European countries.

Action	Responsibility	Target date
Provision of adequate bone densitometry resources throughout Europe with a minimum of eight DXA systems per million population	Policy makers and the national co-ordinators for osteoporosis within government Ministries of Health	January 2005
Reimbursement of bone density measurements and intervention costs for individuals at high-risk of osteoporotic fractures	Policy makers and the national co-ordinators for osteoporosis within government Ministries of Health	January 2005
Analysis of cost-effectiveness of interventions should be extended to all member and accession states	Health professionals acting in co-operation with policy makers, including members of the EU Osteoporosis Consultation Panel and the national co-ordinators for osteoporosis within government Ministries of Health	December 2005

Step 6: Evaluation of actions and planning the allocation of future healthcare resources: the European fracture database

The availability of incidence and prevalence data for osteoporosis-related fractures on an ongoing basis is vital for developing strategies for dis-

ease prevention and management, and planning the allocation of resources. High quality data will allow the assessment of the economic burden of fractures, and changes in incidence over time. This will facilitate economic modelling and planning of resource allocation. By comparing hospital and rehabilitation requirements, any reallocation required between health and social sectors can also be determined. In addition, incidence and prevalence data will allow the impact of preventive strategies to be assessed.

The European Commission has an ongoing project to develop a general EU health information system (EUHIS), and, as a part of this effort, the EC Health Indicators (ECHI) project, initiated in 2001, identified a set of indicators for health monitoring. However, because of the broad remit of this project, the osteoporosis health indicator set is not in-depth, and does not define fracture type according to patient age and gender. Therefore it is now important to address this issue.

The first step should be to assess the comparability of data from member and accession states where information is available. These data will be analysed and reformatted for integration into the EUHIS database. This should also provide examples of best practice that can be repeated throughout Europe. The most accessible data relate to hip fractures, since these fractures always require hospital inpatient treatment and hospital record systems should therefore provide a rich source of high quality data.

Action	Responsibility	Target date
Identification of health indicators for osteo- porosis to correct existing deficit in the devel- oping EU Health Information System	National experts in osteoporosis, including members of the EU Osteoporosis Consultation Panel, and members of the IOF Fracture Working Group	June 2004 (subject to funding from the European Commission)
Assessment of existing data and data collection methods in member and accession states	National experts and policy makers, including members of the EU Osteoporosis Consultation Panel, and members of the IOF Fracture Working Group	March 2005 (subject to funding from the European Commission)
Implementation of data collection in member and accession states, sharing best practice where applicable	National experts and policy makers, including members of the EU Osteoporosis Consultation Panel	December 2005 (subject to funding from the European Commission)
Use of data on fractures to plan future healthcare resource allocation and to study the impact of fracture-prevention strategies	National experts, policy makers and govern- mental agencies, including members of the EU Osteoporosis Consultation Panel	December 2005 (subject to funding from the European Commission)

The key next steps

Feedback from the Member States on osteoporosis policy developments since the 2001 audit – provided by the EU Osteoporosis Consultation Panel Members – show that policy makers and healthcare professionals in Europe are starting to work together to reduce suffering and unnecessary costs caused by osteoporosis-related fractures²⁰. However osteoporosis is still a neglected disease. The majority of Member States have still to make osteoporosis a government priority. Some governments have demonstrated that they are starting to adopt osteoporosis as a priority, with particularly encouraging progress in countries such as Austria, Finland, France, Italy, Luxembourg, Portugal and in parts of the UK, but much more needs to be done.

To move further towards making osteoporosis a government priority the following key next steps must be actioned:

Step 1: Awareness-raising campaigns

Step 2: Preventive strategies: lifestyle considerations

Step 3: Guidelines for the prevention of osteoporosis-related fractures

Step 4: Fracture care, rehabilitation and prevention of falls

Step 5: Economic data

Step 6: Evaluation of actions and planning the allocation of future

healthcare resources: the European fracture database

Working together to reduce the burden of osteoporosis

The Leiden meetings of the EU Consultation Panel Members brought together policy makers and osteoporosis experts who joined forces to contribute to this "Action

Plan". Below are photos from the 2nd Leiden meeting of the EU Consultation Panel in September 2003.

First row from left: Dr. Frederic Sicard, observer, European Commission, DG Public Health and Prof. Olof Johnell, WHO Working Group and vice-chair of the IOF Committee of Scientific Advisors; Dr. Benoit Lavallart, Directorate General of Health and Prof. Liana Euller-Ziegler, osteoporosis expert (France)

Second row from left: Dr. R. Schlogh, Federal Ministry of Health and Women and Dr. Gerold Holzer, osteoporosis expert (Austria) with Prof. David Marsh, International Society for Fracture Repair; Prof. Christel Lamberg-Allardt, Department of Applied Chemistry and Microbiology, University of Helsinki and Dr. Olli Simonen, Government Ministerial Advisor (Finland)









Step 1: Awareness-raising campaigns

Introduction

In order for osteoporosis to receive the attention it deserves it is vital that the governments of member and accession states view this disease as a major healthcare priority, and that they work effectively with the local patient organisations, and scientific and related non-profit organisations to plan and implement awareness-raising campaigns. To maximise impact on suffering and to minimise costs to national health authorities, campaigns should target segments of the general public at highest risk of osteoporosis-related fractures and the healthcare professionals who see most fracture patients.

Awareness-raising campaigns for individuals at high risk of osteoporosisrelated fractures

Postmenopausal women, the main 'at risk' segment of the population, are often unaware of their own risk of osteoporosis and related fractures. An IOF survey, conducted in 2000, revealed that less than half of the women interviewed in five European countries were aware of their risk prior to being diagnosed with osteoporosis. It is therefore vital that individuals at high risk of fragility fractures are made aware of their personal risk and options available for prevention of fractures.

Simple, self-administered One-Minute Risk Test

To help people understand their personal risk of developing fragility fractures and to encourage appropriate action, a simple, self-administered, 'One-Minute Risk Test' has been developed by the IOF (Table 5). ¹⁰ The test, now available in 16 languages, recommends that individuals who answer 'yes' to any of the ten questions should consult their doctor and their local osteoporosis society about possible lifestyle changes. The test clearly states that having risk factors does not necessarily imply that the person has osteoporosis – it simply means they should consult their doctor to find out more. In order to encourage people to take the One-Minute Risk Test, the IOF and its members have developed several interlinking programmes including:

Television and print advertising

The IOF has obtained the pro bono support of Torre Lazur McCann (an IOF member) to produce and place international advertising. Torre Lazur McCann is a member of the international McCann Erickson network, and their European offices are encouraged to work with local IOF member societies to adapt the advertising according to local needs and obtain placement on local television. The advertising advises people of their risks and specifically encourages them to take the One-Minute Risk Test. The advertising can be seen on the IOF website: www.osteofound.org

Website

The top banner of the IOF homepage encourages people to "Take the One-Minute Risk Test".

Special events

The IOF regularly develops special events to raise awareness and encourage people to complete the One-Minute Risk Test. A good example was the 'Osteo-Tour', which involved a touring 'Osteo-Truck', with bone density testing equipment, trained nurses, and appropriate information material. The Osteo-Tour was usually linked to a photo-

graphic exhibition entitled Osteoporosis: A Photographic Vision by Oliviero Toscani. For more information, please see the IOF website: www.osteofound.org

IOF also gives the Osteoporosis Media Award, which encourages journalists to write about osteoporosis and to include the One-Minute Risk Test in their articles.

World Osteoporosis Day

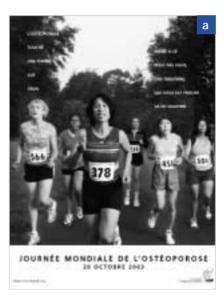
On World Osteoporosis Day, held each year on October 20th, IOF and its member societies highlight important themes. The theme for World Osteoporosis Day 2003 is 'quality of life', and the theme for 2004 will be 'osteoporosis in men'. All World Osteoporosis Day activities either include the One-Minute Risk Test or refer people to the IOF website, where the test is available.

Circulation of the One-Minute Risk Test by IOF member societies

IOF member societies also develop creative local actions to distribute the One-Minute Risk Test, such as distribution through pharmacies and public lectures.

Awareness raising campaigns

Print advertising was launched throughout Europe on World Osteoporosis Day, October 20, 2003 (a). Both print and television advertising directs viewers to the IOF website (b) where The One Minute Risk Test (c) is available in over 17 languages. Special events, such as the touring "Osteo-truck" (d) and "Osteoporosis: A Photographic Vision" by Oliviero Toscani, also support national and international awareness raising efforts. Television advertising was launched in January 2003 and has appeared, on a pro bono basis, on several European channels including CNN, Discover, Eurosport CNBC and many national stations (e).

















Awareness-raising campaigns for healthcare professionals who see fracture patients: preventing new fractures

The diagnosis, prevention, and treatment of fragility fractures involve a wide range of healthcare professionals including general practitioners, rheumatologists, geriatricians, gynaecologists, endocrinologists, orthopaedic surgeons/traumatologists, and radiologists.

The development of a fragility fracture is the strongest risk indicator for future fractures, increasing the risk of a further fracture within one year by two- to five-fold. Therefore priority must be given to education of those healthcare professionals who commonly see fracture patients. These include:

- Orthopaedic surgeons/traumatologists. Orthopaedic surgeons/traumatologists are the physicians who see fracture patients and are therefore uniquely placed to identify undiagnosed cases of osteoporosis.
- Radiologists. Radiographic diagnosis is considered the best way to identify and/or confirm the presence of vertebral fractures in clinical practice, and therefore radiologists have a central role in the diagnosis of such fractures.¹¹

Orthopaedic surgeons/traumatologists must do more than fix the fracture Despite the mounting evidence in support of evaluating and treating patients for osteoporosis after they have sustained a fragility fracture, up to 95% of these patients are discharged without adequate investigation for osteoporosis, and very few patients are prescribed medication to help prevent future fractures.

A recent international survey of orthopaedic surgeons/traumatologists revealed that these specialists often failed to recognise osteoporosis as a cause of fracture, and are inconsistent in providing appropriate treatment or referral. Approximately half of the respondents commented that they had received little or no training in osteoporosis management. However, the majority felt they had a responsibility to identify and evaluate patients with fragility fractures, and most wanted to learn more about diagnosis and management.

Implementing a simple care pathway to prevent new fragility fractures International guidelines developed by the World Orthopaedic Osteoporosis Organisation ('Recommendations for care of the osteoporotic fracture patient to reduce the risk of future fracture')¹³ describe a care pathway for optimal management of patients with fragility fractures. This is a useful resource for member and accession states to adapt and implement locally.

A multidisciplinary team approach co-ordinated by 'fracture liaison nurses' The concept of 'fracture liaison nurses' has been explored in several countries, including Finland and the UK, with encouraging initial results. ¹⁴ Playing a co-ordinating role using agreed protocols, these nurses are able to develop productive relationships with diverse teams of healthcare professionals, ensuring that fragility fracture patients are diagnosed and receive appropriate advice, treatment, or preventive therapy. Dr. Liisa Hyssälä DSc, MsocSc, Finnish Minister of Health, recently stated that "The Finnish Ministry of Health is actively supporting the training of healthcare professionals to improve the care of patients with fragility fractures. In addition we recommend that every hospital and health centre have a trained nurse dedicated to the diagnosis and management of patients with fragility fractures".

Ensuring adequate resources are in place

Access to bone densitometry systems is fundamental for the diagnosis of osteoporosis, yet in many member states, access is still inadequate and/or not appropriately reimbursed by the government.

Radiologists play a central role in the recognition and reporting of vertebral fractures

Vertebral fractures are the most common of all osteoporotic fracture, causing back pain, limited spinal mobility, height loss, deformity, disability and premature death. The presence of a vertebral fracture increases the risk of developing a future fracture within the next year by two- to five-fold. Since radiographic diagnosis is considered the best way of identifying vertebral fractures, radiologists play a central role in the recognition and reporting of these fractures. However, the majority of vertebral fractures remain undiagnosed. A large international study recently demonstrated that existing vertebral fractures are frequently not recorded in radiographic reports of postmenopausal women with osteoporosis. 15

Improved recognition of vertebral fractures using radiography imaging techniques

Radiographic assessment of vertebral fractures is not common, and when undertaken it is often poorly standardised and misinterpreted. However, a standardised radiographic methodology and a semi-quantitative grading scheme are now available. This procedure is accurate and reliable, and can be simply performed by any trained radiologist, requiring no specialised equipment.

Radiologists must write "vertebral fracture patient" in the patient's report to avoid ambiguity

Radiologists can often use unclear terminology in the patient's report, and as a result, the referring physician may not follow up adequately. It is therefore fundamentally important that the diagnosis "vertebral fracture patient" is clearly written.

Evaluation of awareness raising campaigns

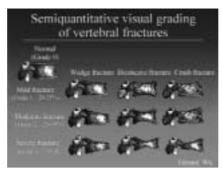
In order to evaluate the impact of such awareness-raising campaigns on the prevention of osteoporosis-related fractures, it is essential that accurate data on the rates of osteoporosis-related fractures are collected on an ongoing basis. Currently this is not the case in the vast majority of member and accession states, and this urgently needs to be addressed.

Next key steps

Action	Responsibility	Target date
Implement awareness-raising campaigns targeted at potentially high-risk individuals such as postmenopausal women	Osteoporosis patient organisations, with financial support and participation by each member and accession state's Ministry of Health	December 2005
Implement awareness-raising campaigns for healthcare professionals such as gynaecologists, orthopaedic surgeons/traumatologists and radiologists	Specialists' associations (e.g. radiologists' association) in co-operation with osteoporosis and related non-profit organisations with financial support and participation by each member and accession state's Ministry of Health	December 2005



Currently, up to 95% of patients suffering a fragility fracture are discharged without adequate investigation for osteoporosis.



Radiologists have a central role in confirming the presence of vertebral fractures. IOF and the European Society of Musculoskeletal Radiology have begun an osteoporosis education programme to improve the recognition and reporting of vertebral fractures by radiologists

Access to bone densitometry systems, such as DXA testing, is fundamental

for the diagnosis of osteoporosis. In many member states, access is still inadequate or not appropriately reimbursed by the government.



Table 5

The One-Minute Osteoporosis Risk Test

- 1. Have either of your parents broken a hip after a minor bump or fall?
- 2. Have you broken a bone after a minor bump or fall?
- 3. Have you taken corticosteroid tablets (cortisone, prednisone, etc) for more than 3 months?
- 4. Have you lost more than 3 cm (just over 1 inch) in height?
- **5.** Do you regularly drink heavily (in excess of safe drinking limits?)
- 6. Do you smoke more than 20 cigarettes a day?
- 7. Do you suffer frequently from diarrhoea (caused by problems such as celiac disease or Crohn's disease)?

For women:

- 8. Did you undergo menopause before the age of 45?
- **9.** Have your periods stopped for 12 months or more (other than because of pregnancy?)

For men:

10. Have you ever suffered from impotence, lack of libido or other symptoms related to low testosterone levels?

If you answered "yes" to any of these questions, you may be at risk of getting osteoporosis and we recommend that you consult your doctor, who will advise whether further tests are necessary. Bring this checklist with you. The good news is that osteoporosis can be diagnosed relatively easily and treated. Talk to your local osteoporosis society about what changes you might make in your lifestyle to reduce your osteoporosis risk. You can contact your national osteoporosis society via www.osteofound.org or the International Osteoporosis Foundation secretariat at tel: +33 4 72 91 41 77, fax: +33 4 72 36 90 52, info@osteofound.org

Step 2: Preventive strategies: Lifestyle considerations

Introduction

Osteoporosis occurs as the result of sub-optimal bone growth during childhood and adolescence and/or subsequent bone loss. Loss of bone mineral density begins in the fourth decade of life, and is accelerated in women in the years immediately after the menopause. In addition to increased bone fragility, falls also play a major role in osteoporotic fractures.

Preventive strategies should therefore be designed to optimise bone growth, to reduce the influence of risk factors for compromised bone integrity, and to reduce the risk and consequences of falls.

Development of health promotion strategies targeted at prevention of osteoporosis

A number of lifestyle changes can improve bone health and should therefore be a part of health promotion strategies for reducing osteoporotic fractures. These include nutritional improvements (particularly ensuring adequate intake of calcium and vitamin D), increased physical activity, avoiding smoking, and avoiding alcohol abuse. Addressing these issues will provide multiple benefits that extend beyond bone health (e.g. reduced risk of cardiovascular disease).

Specific preventive strategies can be aimed at different segments of the population. For example, improving diet and increasing levels of physical activity will promote bone growth during childhood and adolescence. This approach has been reviewed in an IOF booklet translated into more than 30 languages. In addition, information about a number of imaginative education programmes for young people (created by non-profit organisations in over 20 countries) is available at the IOF website. This approach could also be applied to other segments of the general population. These interventions are known to help prevent loss of bone mineral density in later life, although their efficacy in terms of fracture reduction remains to be established.

Another approach is to target preventive measures at high-risk populations; for example those people with a history of low energy fracture, low bone mineral density, or glucocorticoid therapy. For these individuals, advice on dietary intake, promotion of appropriate physical activity, and avoidance of smoking and alcohol abuse are important aspects of management.

State of current public health policies on nutritional intake and bone health Despite compelling evidence that adequate intake of calcium and vitamin D is essential for normal bone development and maintenance of bone health, 18,19 there are very few government-backed public health and education programmes that promote this. One such exception is the French 'Programme National Nutrition Santé', a five-year project initiated in 2001, which aims to reduce the number of people with insufficient calcium and vitamin D intake by 25% (www.sante.gouv.fr/htm/actu/34_010131.htm). The

impact on bone health and risk of osteoporotic fracture of this and the few other National programmes that exist²⁰ remains to be fully quantified. Furthermore, not all European countries have national guidelines for intake of these nutrients. Existing guidelines generally recommend a daily calcium intake of 700–800 mg for adults (\geq 800 mg daily for women aged 50–65 years), and a daily vitamin D intake of 0–400 IU for adults (400 IU daily for all adults aged 65 years and over). Policies on the fortification of food with calcium and vitamin D vary widely across Europe, and many people have an inadequate dietary intake of these nutrients, particularly the elderly population. ^{21, 22}

There is a strong case for individuals at high risk of low energy fracture to take supplements of both calcium and vitamin D. One study has shown that use of these supplements can reduce non-vertebral fractures (including hip fractures) in elderly institutionalised women. These benefits may extend to the older population in general. Although the effects of these supplements in fracture prevention are generally attributed to increases in bone mineral density, vitamin D may also increase muscular strength, thereby reducing the risk of falls. The important role of calcium and vitamin D in the management of osteoporosis is recognised by the European regulatory authorities, who require that all subjects participating in clinical trials of new osteoporosis drugs have adequate intakes of calcium and vitamin D.







Exercise and proper nutrition with adquate calcium and vitamn D is essential for normal bone development and the maintenance of bone health.

Many people have an inadequate dietary intake of calcium and vitamin D. A study has shown that these supplements in elderly institutionalised women can reduce non-vertebral fractures, including hip fractures.

The IOF publication "Invest in Your Bones: How diet, life styles and genetics effect bone development in young people", translated into more than 30 languages, reviewed how improving diet and increasing levels of physical activity promotes bone growth in youth.

Effects of physical activity on bone health

Regular physical exercise provides numerous benefits not only for bone mass accumulation and the prevention of age-related bone loss, but also for general health, including neuromuscular function, movement co-ordination, and cardiovascular health. Weight bearing physical activity early in life can contribute to the achievement of a higher peak bone mass.²⁸ In the elderly, exercise increases muscle strength and improves quality of life by protecting functional independence in this population. Regular exercise has a favourable influence on bone mineral density and on the risk of falling, although the impact of these measures on fracture incidence is not yet known.

Campaigns aimed at promoting behaviour changes in terms of physical activity have been launched in several countries (e.g. the French 'Bien Vieillir' programme launched in 2003, which aims to encourage physical exercise and good nutrition for a 'healthy ageing' population), but their impact on bone health remains to be fully evaluated.

Development of strategies for education about preventive measures to reduce osteoporosis risk

The education of the European population about ways to reduce the risk of osteoporosis is currently inadequate, and is rarely supported by government-backed public health campaigns. It is essential that such education should start early in life and should be available for all age groups. Better education of healthcare professionals involved in primary and secondary care is also urgently required.

Next key steps

Action	Responsibility	Target date
Development of government-backed health education programmes for all age-groups to inform the public about ways of reducing osteoporosis risk. Agree on education programmes and secure funding	Healthcare professionals and patient organisations acting in co-operation with policy makers and national co-ordinators for osteoporosis within government Ministries of Health	December 2005
Harmonisation of recommendations for calcium and vitamin D intake throughout Europe for all age groups	Healthcare professionals, policy makers and national co-ordinators for osteoporosis within government Ministries of Health	December 2005
Development of government-backed public health campaigns to increase calcium and vitamin D intake, to recommended daily intake, and to ensure appropriate levels of physical activity in all age groups	Healthcare professionals and patient organisations acting in co-operation with policy makers and national co-ordinators for osteoporosis within government Ministries of Health	Commence implementation by December 2006



"The EP Osteoporosis Interest Group's Call to Action urges national health authorities and health insurance agencies to make osteoporosis a healthcare priority"

Ms. Elly Plooij van Gorsel, Member of the European Parliament (The Netherlands)

Step 3: Guidelines for the prevention of osteoporosis-related fractures

Introduction

The importance of an evidence-based approach to clinical practice is now widely accepted, and the application of evidence-based guidelines provides a means by which best practice can be shared both within and between countries. In order to achieve their full potential, the development of guidelines for the prevention of osteoporosis-related fractures should be rigorous with respect to their evidence base, stakeholder involvement, objectivity and editorial independence. They must also be clearly presented so that key recommendations are unambiguous and can be easily identified, and should preferably include implementation tools such as a summary guide and patient information sheet. Finally, it is essential that guidelines are appropriately disseminated to potential users, that their use is audited to define resulting changes in clinical practice, and that they are updated regularly.

Availability of evidence-based guidelines in EU member states

In collaboration with the EU Osteoporosis Consultation Panel, guidelines from most EU member states have recently been collated and evaluated. The guidelines assessed to date range from consensus statements produced by expert groups (Table 6), to fully evidence-based guidelines developed in accordance with the latest guideline methodology. Denmark, France Germany, Italy, the Netherlands, Spain and parts of the United Kingdom have all developed fully evidence-based guidelines for osteoporosis (Table 7). The majority of these guidelines focus on osteoporosis in postmenopausal women although others, for example, for the management of hip fracture and glucocorticoid-induced osteoporosis have also been produced. Portugal, Greece, and Luxembourg are in the process of developing guidelines and these guidelines will be evaluated once available. In addition, a similar procedure is planned for accession states and will be included as part of the key next steps.

Need for guidelines in all EU member and accession states

Because some aspects of the prevention of osteoporotic fractures are country-specific (e.g. as a result of variations in diagnostic resources and the availability of different therapeutic options), development of individual evidence-based guidelines for each member and accession state is an important target for the future. The lack of such guidelines in many existing member states emphasizes the need for immediate action in this area. This should be regarded as a priority in the next few years in order that optimal care and uniform standards are provided to people with osteoporosis throughout the European Union.

Development of guidelines

The process for developing evidence-based guidelines is well defined.²⁹ It requires the co-operation of groups of experts from relevant professional groups together with representatives from appropriate lay organisations, and it is particularly important that patients and their carers are adequately represented. Guidelines should be based on a comprehensive systematic review of the literature and recommendations should be explicitly linked to the supporting evidence. In general, between four and eight meetings are required over a one- to two-year period, followed by a consultation period in which the draft guidelines are circulated for peer review.

Financial support and endorsement

The development and dissemination of guidelines requires financial support, which should be provided by government agencies. This should be accompanied by explicit endorsement of the guidelines by these agencies in order to promote and prioritise their use in clinical practice. Unless guidelines are adequately disseminated they cannot impact significantly on standards of care.

Implications for resource allocation and health care planning

Full implementation of guidelines is usually not possible without provision of additional resources and changes in the organisation of services. In this case it may involve setting up specialist osteoporosis units and explicit links between primary and secondary care, providing adequate bone densitometry resources, and ensuring appropriate reimbursement for both diagnostic and therapeutic interventions. Health-economic analyses are useful for defining the expansion of healthcare resources and financial investment required.

Audit

The ultimate aim of guidelines is to improve standards of clinical care. It is therefore essential to audit the use of guidelines and to demonstrate how their implementation results in changes in clinical practice. Guidelines should contain clearly defined audit criteria based on key recommendations. Ideally, an audit tool, which is easy to use and has clearly identified outcome measures, should be provided with the guidelines. Two audits, separated by an appropriate period of time (usually one to two years) are required to properly assess changes in clinical practice resulting from use of guidelines.

Updating guidelines

It is important that guidelines are regularly updated to accommodate new evidence and knowledge, and the original guidelines should contain some mechanism to prompt this updating procedure. Generally, an update will be required within five years, but the introduction of new interventions may necessitate an even earlier update.

Appraisal of guidelines

The AGREE instrument (Appraisal of Guidelines for Research and Evaluation) was developed in 2001 as the result of an international collaboration (website at www.agreecollaboration.org). Its purpose is to provide a framework for assessing the quality of clinical practice guidelines. There are six domains in this assessment, each of which addresses a separate aspect of guideline quality:

- Scope and purpose
- Stakeholder involvement
- Rigour of development
- Clarity and presentation
- Applicability
- Editorial independence

Within each domain there are a variable number of items, each of which is scored on a four point scale to provide a semi-quantitative assessment of the guidelines. This instrument is published in the English language and approved non-English language versions are being prepared. A user guide is also provided with the instrument.

This appraisal tool is internationally recognised and is the only available instrument of its kind. It is currently being used to evaluate evidence-based guidelines provided by the EU Consultation Panel in the member states.

Key next steps

Action	Responsibility	Target date
Improvement of accessibility of current evidence-based guidelines to member and accession states to enable sharing of best practice and to ensure optimal care	The EU Osteoporosis Consultation Panel	June 2004
Development of national, evidence-based guidelines in all member and accession states and endorsement of existing evidence-based national guidelines by government agencies	National osteoporosis related scientific societies, osteoporosis patient organisations, policy makers and the national co-ordinators for osteoporosis within government Ministries of Health	December 2005
Provision of financial support from governments for the development, dissemination and implementation of national guidelines	Policy makers and the national co-ordinators for osteoporosis within government Ministries of Health	January 2005
Development and application of audit tools to assess clinical impact of guidelines	Healthcare professionals and policy makers	December 2005

Working together to reduce the burden of osteoporosis

The EU Consultation Panel also comprises project partners from European organisations and non governmental organisations who have made important contributions to the drafting of this Action Plan.

First row from left: Prof. Socrates Papapoulos, project senior advisor, University of Leiden; board member International Osteoporosis Foundation; Ms. Mary Anderson, pharmacist, board member International Osteoporosis Foundation; Dr. Daniel Navid, CEO International Osteoporosis Foundation

Second row from left: Ms. Peggy Maguire, project partner, European Institute of Women's Health; Dr. Hermann Stamm, European Commission Joint Research Centre; head of unit

'Biomedical Materials and Systems' Institute for Health and Consumer Protection; Prof. David Marsh, project partner, International Society for Fracture Repair; Prof. Kristina Akesson, project partner, Bone & Joint Decade 2000-2010













Table 6

Consensus guidelines currently available in the European Union Country Year Title of guideline Osteoporose-Prävention und- Therapie 30 Austria 2003 1997 Diagnostiek van Osteoporose 31 Belgium 1999 Involutie-osteoporose bij de vrouw: behandelingsstrategie 32 Osteoporoosi 33 Finland 2000 L'ostéoporose chez les femmes ménopausées et chez les sujets traités France 2001 par corticoïdes: méthodes diagnostiques et indications 34 Sweden 2002 Svenska Osteoporossällskapets Rekommendationer ³⁵

Table 7

Evidence-based guidelines currently available in the European Union that have been appraised using the AGREE instrument

Country	Year	Title of guideline	Government endorsement
Denmark	2000	Osteoporosis, Klaringsrapport ³⁶	No
France	2000	Les indications des measures quantitatives du tissu osseux: actualisation ³⁷	Yes
Germany	2003	Osteoporose bei Frauen nach der Menopause und im hoheren Lebensalter, Prophylaxe, Diagnose, Therapie – Emfehlungen des Dachverbandes der deutschsprachigen osteologischen Fachgesellschaften (DVO) ³⁸	No
Italy	2001	Percorsi diagnostici e terapeutici condivisi sull'osteoporosis ³⁹	No
Netherlands	2002	Osteoporose. Tweede herziene richtlijn ⁴⁰	Yes
Spain	2001	Sociedad Espanola de Investigaciones Óseas Y Metabolismo Mineral - SEIOMM. Osteoporosis Postmenopáusica. Guia de Práctica Clinica ⁴¹	No
United Kingdom	1999/2000	Prevention and treatment of osteoporosis 42	Yes
	2002	Prevention and treatment of glucocorticoid- induced osteoporosis ⁴³	No
Scotland	2002	Prevention and management of hip fracture in older people 44	Yes*
	2003	Management of osteoporosis ⁴⁵	Yes*
			* Process andorsed

* Process endorsed

Step 4: Fracture care, rehabilitation and prevention of falls

Introduction

The burden of osteoporosis lies in its clinical consequence, the fracture. Although methods to identify individuals at risk and effective preventive measures are available, their use is disappointingly low and the incidence of fractures not only remains high but is expected to increase in the future. Therefore, measures aimed at reducing the morbidity and mortality associated with fractures, particularly of the hip, are essential and should be part of every health programme for older people. This, however, has been largely overlooked due mainly to lack of co-ordination of the multiple disciplines involved in the care of patients with fractures, and the lack, until recently, of evidence-based guidelines.

Care of patients with fracture

The care of patients who have suffered fracture involves many disciplines and cooperation between the different agencies involved is essential for optimal management. Thus the care of fractures may involve the emergency services, Accident and Emergency departments, hospital in-patient and out-patient departments, and rehabilitation and social services. Particularly in the case of hip fractures, which affect the frail older population, high and consistent standards are required in all aspects of care in order to minimise suffering and reduce subsequent dependency. For example, in one study it was shown that delaying surgery for hip fracture significantly reduced the chance of successful fixation, increased mortality and, in those who survived, reduced the likelihood of successful rehabilitation.

At present the majority of European countries do not have evidence-based guidelines for the management of hip fracture that encompass the disciplines outlined above. In 2002 the Scottish Intercollegiate Guidelines Network produced comprehensive and evidence-based guidelines on the management of hip fracture⁴⁴ and these provide an example of best clinical practice that should be shared between countries. However, it is also important that each country develops its own national guidelines, which are endorsed and supported financially by their government.

Development of a multidisciplinary approach for rehabilitation

The period following a hip fracture is universally recognised as crucial for the quality of life and independence of the patient. A multidisciplinary approach, involving professionals from both the health service and social care sectors, facilitates the rehabilitation process. Thus there is evidence that the use of ortho-geriatric units, in which gerontologists are responsible for the medical care and early rehabilitation of hip fracture patients, reduces the length of hospital stay, reduces mortality and improves functionality. However, such units are rare at present and many hip fracture patients are discharged without further assessment or treatment of their osteoporosis.

Nutritional support with nutrients containing high-energy protein, minerals and vitamins significantly reduces the frequency of postoperative complications and hence reduces the length of hospital stay. ⁴⁹ Finally, supported discharge schemes, with close liaison between the hospital and community facilitate the safe discharge of hip fracture patients, and reduce in-patient hospital stay. ⁴⁴

Prevention of falls

The majority of fragility fractures occur after falling. The frequency of falls is increased in older people and is particularly high in residents of long-term care institutions. There is increasing recognition of the importance of falls in the causation of fractures, since many risk factors for falling can be modified, for example environmental hazards, poor vision, or inappropriate footwear. It has been shown that multifaceted interventions reduce falls in older people (those aged over 65 years) and that assessment of high-risk residents in nursing homes with relevant referral is also effective; whether this results in a reduction in fractures is currently unproven and remains an important area for future research.

In 2001 a National Service Framework on Older People was produced by the English government⁵¹ as an action plan to improve health and social services for older people. Among the standards set out in this framework was action to prevent falls and reduce resultant fractures in older people. Attention was drawn to the importance of falls in the causation of osteoporotic fractures and a compulsory standard was set by which all localities must have a specialist falls service in place by 2005, with access to bone density measurements and an osteoporosis service. This is currently being implemented in England and provides an opportunity for sharing of best practice amongst European countries. Scotland also has a policy document that addresses falls and fracture prevention ('Adding life to years: report of the expert group on healthcare of older people').⁵² This document states that "osteoporosis management should be an important part of any falls assessment".

In contrast to measures aimed at reducing the frequency of falls, those measures aimed at reducing the impact of falls on the hip may also be effective. Thus, some studies indicate that hip protectors are effective in reducing hip fractures in residents of nursing homes⁵¹ although currently compliance is poor.

Key next steps

Action	Responsibility	Target date
Develop and recommend evidence-based fracture care programmes that encompass all aspects of management and are endorsed and supported by governments	National experts in osteoporosis including members of the EU Osteoporosis Consultation Panel, members of the IOF Fracture Working Group, policy makers and the national co-ordinator for osteoporosis within the government's Ministry of Health	June 2005
Develop multidisciplinary falls services with integrated care pathways that incorporate the diagnosis and management of osteoporosis	National experts, including members of the EU Osteoporosis Consultation Panel, members of the IOF Fracture Working Group, policy makers and the national co-ordinator for osteo- porosis within the government's Ministry of Health	June 2005

Step 5: Economic data

Introduction

Fractures and their sequelae are devastating consequences of osteoporosis, with the hip, spine, forearm and shoulder the most common sites of osteoporotic fracture. The probability of sustaining osteoporotic fractures varies markedly in different regions of the world. In Europe, the highest risks of hip fracture are seen in Norway, Sweden, Iceland and Denmark, whilst Germany, Switzerland, Finland, Greece, the Netherlands, Hungary, Italy, the UK and Portugal have been described as 'high risk' countries (defined as 50 to 75% of the risk seen in Sweden). Over the whole of Europe, one in three women and one in eight men over the age of 50 will sustain an osteoporotic fracture in their lifetime. In Sweden the incidence is even higher (Table 8) and places significant burden on the hospital system, with hip fractures accounting for 63% and 72% of hospital admissions for fracture in men and women over the age of 50 years and for 69% and 73% of hospital bed occupancy due to fractures. When all osteoporotic fractures are considered, they account for 84% and 93% of hospital bed occupancy due to fractures in men and women aged 50 years and over.

Current economic burden of osteoporosis compared with other chronic diseases

Although all osteoporotic fractures are serious, hip fractures impose the greatest economic burden since they require prolonged hospitalisation, and result in loss of independence for at least one-third of sufferers. It is estimated that in Europe as a whole in 2003, 140,000 men and 503,000 women will suffer hip fractures.^{56,57} The first year total direct cost of these fractures is estimated to be Euro 14.7 billion, and when all osteoporotic fractures are taken into account⁵⁸ these costs rise to Euro 25 billion. In addition, since the costs attributable to osteoporosis often extend beyond one year, this underestimates the true figure. In Sweden, the hospital costs of osteoporotic fractures exceed those for breast cancer and prostate cancer combined.⁵⁵

Projected costs over next 25 years

In Europe, the number of people aged 65 years or more is predicted to increase. This will lead to an increase in the number of osteoporotic fractures, and expand the annual total cost of care to an estimated Euro 31.8 billion by 2025. This is a conservative estimate, as it assumes that there will be no future increases in either the age-adjusted incidence of osteoporotic fractures, or the costs of treating a fracture.

Identification of resource needs, particularly the need for bone densitometry systems

Identification of individuals at high risk of osteoporotic fracture will be of key importance in any strategy to reduce the burden of such fractures. Measurement of bone mineral density currently provides the best means of predicting fracture risk, and dual energy X-ray absorptiometry (DXA) is acknowledged as the gold standard for the measurement of this parameter. The available evidence indicates that it is cost-effective to incorporate DXA measurements into case-finding strategies that are widely advocated in Europe, ^{6, 4} though less commonly practised.

If the diagnostic use of DXA is confined to individuals with a prior fragility fracture, the number of dedicated DXA units required would be approximately four per million head of general population. If its use was expanded to those with other strong risk factors (e.g. prolonged corticosteroid treatment, a family history of hip fracture, early menopause, low body mass, a history of falling) this requirement would double in the short and medium term. The availability of DXA varies widely across Europe, and is inadequate in many countries, with limited or no access for potential osteo-

porosis patients. Furthermore, even when available, bone densitometry is often not adequately reimbursed. There is therefore an urgent need to improve diagnostic resources, both in terms of the availability of DXA and its reimbursement.

Cost-effectiveness of targeted interventions

Recent assessments of the cost-effectiveness of preventing osteoporotic fractures have shown that certain treatments are cost-effective in particular populations. Assuming a threshold for cost-effectiveness of approximately Euro 45,000 per quality-adjusted life year gained, treatment of high-risk women with bisphosphonates is cost-effective and raloxifene treatment is also cost-effective, partly due to its protective effect against breast cancer. In older women (i.e. those aged 80 years or over) treatment of the population at average risk may be cost-effective. In general, interventions are cost-effective in men and women with osteoporosis defined using the WHO criteria, and even more cost-effective in such patients with a prior fragility fracture or other strong risk factors that are independent of bone mineral density. Examples include the use of oral glucocorticoids and a family history of hip fracture. There is thus increasing evidence for the cost-effectiveness of targeted intervention for osteoporosis; however, at present these analyses have only been conducted in a minority of European countries.

Economic justification for reimbursement of diagnostic procedures and interventions

It has been estimated that screening of women aged 65 years or older, using a combination of bone density measurement and clinical risk factors, could save over 23% of all fractures in women over a 10-year period by targeting 25% of that population for intervention. ⁶² The inclusion of bone mineral density tests in case-finding strategies has been shown to be cost-effective. ⁵⁹ Furthermore, the costs of bone density measurement have been included in the cost-effectiveness analyses of treatment outlined in the previous paragraph.

Key next steps

Action	Responsibility	Target date
Provision of adequate bone densitometry resources throughout Europe with a minimum of eight DXA systems per million population	Policy makers and the national co-ordinators for osteoporosis within government Ministries of Health	January 2005
Reimbursement of bone density measurements and intervention costs for individuals at high-risk of osteoporotic fractures	Policy makers and the national co-ordinators for osteoporosis within government Ministries of Health	January 2005
Analysis of cost-effectiveness of interventions should be extended to all member and accession states	Health professionals acting in co-operation with policy makers, including members of the EU Osteoporosis Consultation Panel and the national co-ordinators for osteoporosis within government Ministries of Health	December 2005



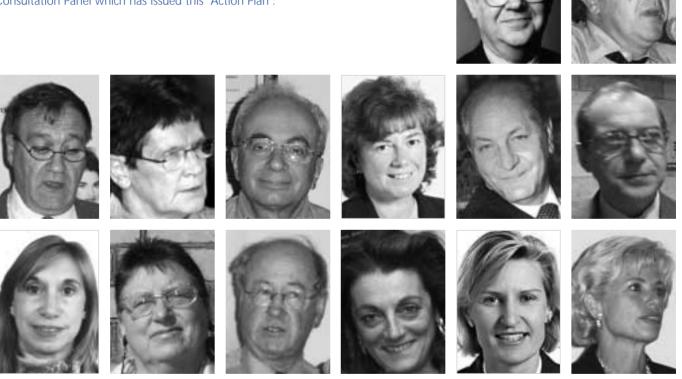
"There is an urgent need to improve diagnostic resources, both in terms of the availability of bone densitometry and its reimbursement"

Prof. Olof Johnell, WHO Working Group and vice-chairmain IOF Committee of Scientific Advisors

Table 8

Working together to reduce the burden of osteoporosis

Policy makers from the member states and the European Parliament Osteoporosis Interest Group are important members of the EU Osteoporosis Consultation Panel which has issued this 'Action Plan':



First row from left: Dr. Hubert Hrabcik, director general of public health, Federal Ministry of Health and Women (Austria); Dr. René Snacken, senior advisor to the Minister of Health (Belgium)

Second row from left: Dr. Olli Simonen, government ministerial advisor (Finland); Prof. Dr. Rita Süssmuth, former president of the Bundestag, head of the Parliamentary Assembly Delegation of the Organisation for Security and Cooperation in Europe (Germany); Dr. Costas Phenekos, designated representative of the Ministry of Health and Welfare; director, Red Cross Hospital (Greece); Hon. Rossana Boldi, member of the Senate Commission for Health; co-ordinator of the National Survey on Osteoporosis (Italy); Hon. Antonio Tommasini, chair of the Senate Commission for Health (Italy); Dr. Alexandre Diniz, health ministry consultant (Portugal)

Third row from left: Dr. Sagrario Mateu Sanchis, chief Mother and Child Health, Ministry of Health (Spain); Ms. Lena Ohrsvik, former Member of Parliament (Sweden); Mr. Tony McWalter Esq, Member of Parliament (UK); Ms. Minerva Malliori, Member of the European Parliament (Greece); Ms. Angelika Niebler, Member of the European Parliament (Germany); Ms. Elly Plooij van Gorsel, Member of the European Parliament (The Netherlands)

Step 6: Evaluation of actions and planning the allocation of future healthcare resources: the European fracture database

Introduction

Having accurate and current data on the prevalence and incidence of osteoporotic fractures is essential for planning the allocation of healthcare resources, and for developing effective strategies for the prevention and management of this disease. The 1998 'Report on Osteoporosis in the European Community' recommended that such information should be collected on an ongoing basis at both national and European levels. However, an audit published in 2001, and a follow-up survey by the EU Osteoporosis Consultation Panel revealed that reliable data on fragility fracture rates were lacking for the majority of member states. Since this information is essential for the development of effective strategies for reducing the health and economic burden of osteoporosis, it is important that these issues are addressed as quickly as possible. This need was recently endorsed by the WHO in their 'Burden of Musculoskeletal Conditions at the Start of the New Millennium' technical report, which recommended that data on the prevalence of musculoskeletal conditions (including osteoporosis) should be collected.

Current deficit in health indicators for osteoporosis in the European Union Health Information System (EUHIS)

A number of projects have been funded by the European Commission's Health Monitoring Programme with the aim of developing a comprehensive European Union Health Information System (EUHIS). The European Community Health Indicators (ECHI) Project, initiated in 2001, identified a set of 'indicators' for the purposes of health monitoring in Europe. Health European Community Health Indicators (ECHI) Project, initiated in 2001, identified a set of 'indicators' for the purposes of health monitoring in Europe. Health indicators in the 'Eurostat' database structure, but the osteoporosis data is not in-depth, and does not describe fracture types according to age and gender, making the extraction of much useful information impossible. Furthermore, a report of the EC-funded project 'Indicators for Monitoring Musculoskeletal Conditions' revealed that health indicators for osteoporosis were only briefly considered. There is therefore now an urgent need to correct the deficit in health indicator data for osteoporosis in European Union member and accession states.

Survey of existing data

The 2001 audit,⁵ and ongoing work of the EU Osteoporosis Consultation Panel, reveal that few member states have any systematic method for collecting data on fracture rates, and details of data availability and collection methodology are not currently

readily available in many countries. It is therefore important to first ascertain where this information is available, and then to assess methods used for collecting osteoporosis health indicator data in those countries. Building on the work of the Euro-Med-Data project, the comparability of these data will be assessed in terms of fracture prevalence, risk factors and management strategies.

Hip fractures cause the greatest morbidity, mortality and economic burden of all osteoporotic fractures. Collection of hip fracture data will therefore be a primary aim of this project, but methods for collection of accurate information on other osteoporotic fractures (e.g. wrist, vertebral, and pelvic fractures) will also be developed. Since hip fractures always require hospital in-patient treatment, accurate records should be available from standardised hospital disease coding systems.

Development of data collection methods

Member states in which national systems are available for the collection of fragility fracture data may provide examples of best practice that can be shared across other member and accession states (e.g. The Netherlands has a well co-ordinated system for collecting fragility fracture data, and in Denmark a national registry for hip fractures is coordinated by orthopaedic surgeons, although no information about osteoporosis is registered). In all member and accession states, data on the prevalence of osteoporosis and its risk factors, and the management of osteoporosis, needs to be collated, analysed, and reformatted for integration into the EUHIS database in collaboration with Eurostat. This will enable completion of existing osteoporosis health indicator sets in Europe, and provide essential information for policy makers.

Economic modelling and plans for allocation of healthcare resources

Widespread data collection will enable assessment of the current economic and social burden of osteoporotic fractures in Europe. In addition, these data will allow characterisation of changes in the incidence of these fractures according to age and gender. This information, together with data on demographic changes, will facilitate the modelling of costs associated with osteoporosis, and the planning of healthcare resource allocation in the future. The aim is to assess both direct hospital costs, and those associated with rehabilitation, and use this information to address any required reallocation of resources between health and social care sectors. In addition, the ongoing collection of fracture data in Europe will enable the impact of fracture prevention strategies to be measured.

Key next steps

Action	Responsibility	Target date
Identification of health indicators for osteoporosis to correct existing deficit in the developing EU Health Information System	National experts in osteoporosis, including members of the EU Osteoporosis Consultation Panel, and members of the IOF Fracture Working Group	June 2004 (subject to funding from the European Commission)
Assessment of existing data and data collection methods in member and accession states	National experts and policy makers, including members of the EU Osteoporosis Consultation Panel, and members of the IOF Fracture Working Group	March 2005 (subject to funding from the European Commission)
Implementation of data collection in member and accession states, sharing best practice where applicable	National experts and policy makers, including members of the EU Osteoporosis Consultation Panel	December 2005 (subject to funding from the European Commission)
Use of data on fractures to plan future healthcare resource allocation and to study the impact of fracture-prevention strategies	National experts, policy makers and governmental agencies, including members of the EU Osteoporosis Consultation Panel	December 2005 (subject to funding from the European Commission)

Conclusions

The actions described in this document represent the next key steps towards a Europe free from avoidable osteoporotic fractures. For maximum impact in the short- and medium-term, these strategies mainly target those individuals at highest risk of fractures. The approaches described are cost-effective, and supported by high-quality clinical evidence. Addressing osteoporosis in the longer term, for example by promoting better nutrition and exercise in childhood, may also provide other health benefits (e.g. reduced risk of cardiovascular disease).

As policy is developed, it will need to be supported by adequate resources, and it is important that the European Union and national governments face up to this challenge. It is vital that the necessary changes are made at the earliest possible time, otherwise, as the elderly population of Europe expands, we can expect to face numbers of osteoporotic fractures approaching epidemic proportions. Apart from the obvious human suffering that this would cause, the economic consequences would be enormous.

This document is therefore a "call to action" to policy makers, specialists, patients and other stakeholders to take these necessary key next steps to avoid a future of osteoporotic fractures and the ensuing physical, social and financial costs.

Full details of the key next steps, those responsible and target dates are described in the main body of this document. The key next steps can be summarised as:

- Step 1. Awareness-raising campaigns
 Implementation of awareness-raising campaigns amongst the at risk population and health care professionals
- Step 2. Preventive strategies: lifestyle considerations
 Public health campaigns for education on lifestyle measures to reduce risk of osteoporosis
- Step 3. Guidelines for the prevention of osteoporosis-related fractures
 Development of evidence-based guidelines in all member and accession states, with
 governmental endorsement and financial support
- Step 4. Fracture care, rehabilitation and prevention of falls
 Development of multidisciplinary programmes for fracture care, rehabilitation and
 falls prevention
- Step 5. Economic evaluation Adequate access to and reimbursement of diagnostic and therapeutic interventions, based on health economic analyses
- Step 6. Evaluation of actions and planning the allocation of future healthcare resources: the European fracture database
 Collation of fracture data in member and accession states to enable economic modelling and planning of health care resources for the future

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The International Osteoporosis Foundation (IOF) is a non-governmental organisation with 155 member societies in over 70 countries, including the European Union member and accession states. IOF's scientific work is directed by 65 of the world's leading osteoporosis researchers who are elected members of IOF's Scientific Advisory Committee. IOF was founded in 1998 after the European Foundation for Osteoporosis (EFFO), created in 1987, merged with the International Federation of Societies on Skeletal Diseases (IFSSD), established in 1995. IOF and its member societies work to increase awareness, education, and research on osteoporosis in order to reduce the enormous human cost and socio-economic burden imposed by osteoporosis.





This publication outlines the six important next steps which will help reduce the burden of osteoporosis in the European Community. It is the result of discussions and meetings of the European Union Osteoporosis Consultation Panel members, comprising over 40 policy makers and osteoporosis experts from the member countries. Photos left: meetings held in Leiden in September 2002 and 2003.



"Step by step, we are working towards preventing avoidable fractures, with the aim of making a difference to the lives of millions of Europeans."

Dr Juliet Compston, 'A Call to Osteoporosis Action' project leader and International Osteoporosis Foundation board member







This report was produced by a contractor for Health & Consumer Protection Directorate General and represents the views of the contractor or author. These views have not been adopted or in any way approved by the Commission and do not necessarily represent the view of the Commission or the Directorate General for Health and Consumer Protection. The European Commission does not guarantee the accuracy of the data included in this study, nor does it accept responsibility for any use made thereof.