



SOLUTIONS FOR FRACTURE PREVENTION



IN SPAIN



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Guidance for Policy Shaping

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Report compiled by the International Osteoporosis Foundation (IOF) under the umbrella of Capture the Fracture® initiative (CTF), in collaboration with Spanish bone health experts.



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SUMMARY

This document provides an assessment of the current policy and post-fracture care landscape in Spain, and provides recommendations which are aligned with the needs and opportunities identified by the Capture the Fracture Partnership in cooperation with a panel of Spanish experts.

This document aims to:

SECTION 1 - A Problem on the Rise

Summarize the increasing burden of fragility fractures in Spain

SECTION 2 - Successes and Failures Observed

Map out successful post-fracture care initiatives in Spain, and identify current areas for improvement

SECTION 3 - Solutions Exist: Policy Recommendations

Provide health policy recommendations to address the burden of osteoporosis and fragility fractures and drive their implementation

SECTION 4 - Build your Response

Support local stakeholders in prioritising osteoporosis and fragility fractures

SECTION 5 - Expected Benefit of FLS

Provide a detailed report on the benefits of Fracture Liaison Services (FLS) and improved patient outcomes

Key Messages

The increasing burden of osteoporosis, treatment gap and importance of secondary fracture prevention

- a. Fragility fractures are a major concern for public health in Spain** and are associated with a substantial (and escalating) health and financial burden. About 285,000 fragility fractures occurred in the year 2019 and the osteoporosis-related costs were estimated at €4.3 billion in the same year. With an ageing population and no change in policy, the number of fragility fractures is expected to increase by a third over the next 15 years.

- b. Osteoporosis remains largely underdiagnosed and undertreated.** Today, more than 1.1 million Spanish women at high risk of fracture remain untreated for osteoporosis, despite the existence of safe and effective medications. Poor treatment initiation is especially marked in high-risk patients with two-thirds of Spanish women (aged 50 years and above) not currently receiving effective secondary fracture prevention after an initial fragility fracture, despite this population being most likely to sustain a further fracture. Interestingly, a recent study assessing the 2-years follow-up of a novel fracture liaison service (FLS) revealed that the implementation of a FLS protocol was associated with an increase of anti-osteoporotic treatment, higher adherence, and greater survival in elderly fracture patients.

- c. The Spanish population is underserved with Post Fracture Care (PFC) services.** Despite the recognized benefits of FLS (a model of Post Fracture Care) in reducing the risk of fractures, only 10% (as described in the SCOPE 2021 report) Spanish hospitals have an FLS. This represents a substantial missed opportunity, as it is a well-known fact that those who have had one fracture are vastly more likely to have another, and that targeting treatment in this group through PFC is a viable, and high-yield place to start.

Key Recommendations

Although several initiatives are already in place and need to be reinforced, specific recommendations include:

- 1. The recognition of osteoporosis** as a chronic and progressive condition

- 2. The roll-out of a larger number of FLS** to increase post-fracture screening, diagnosis and treatment rates

- 3. Placing fragility fractures as a priority of healthcare management** and improving public awareness of osteoporosis

4. Data collection and audit of fractures with quality improvement

Expected outcomes from the Spain Benefits Calculator

Increased uptake of FLS will lead to:

About 3,560 subsequent fragility fractures prevented over the next 5 years leading to substantial improvements in patient health and outcomes. Concurrent reductions in hospitalisations and costs of treating osteoporosis will lead to far greater savings than interventions for other chronic diseases.

Highly beneficial solutions in a cost-effective way to reduce the increasing burden that osteoporosis poses on patients and society.

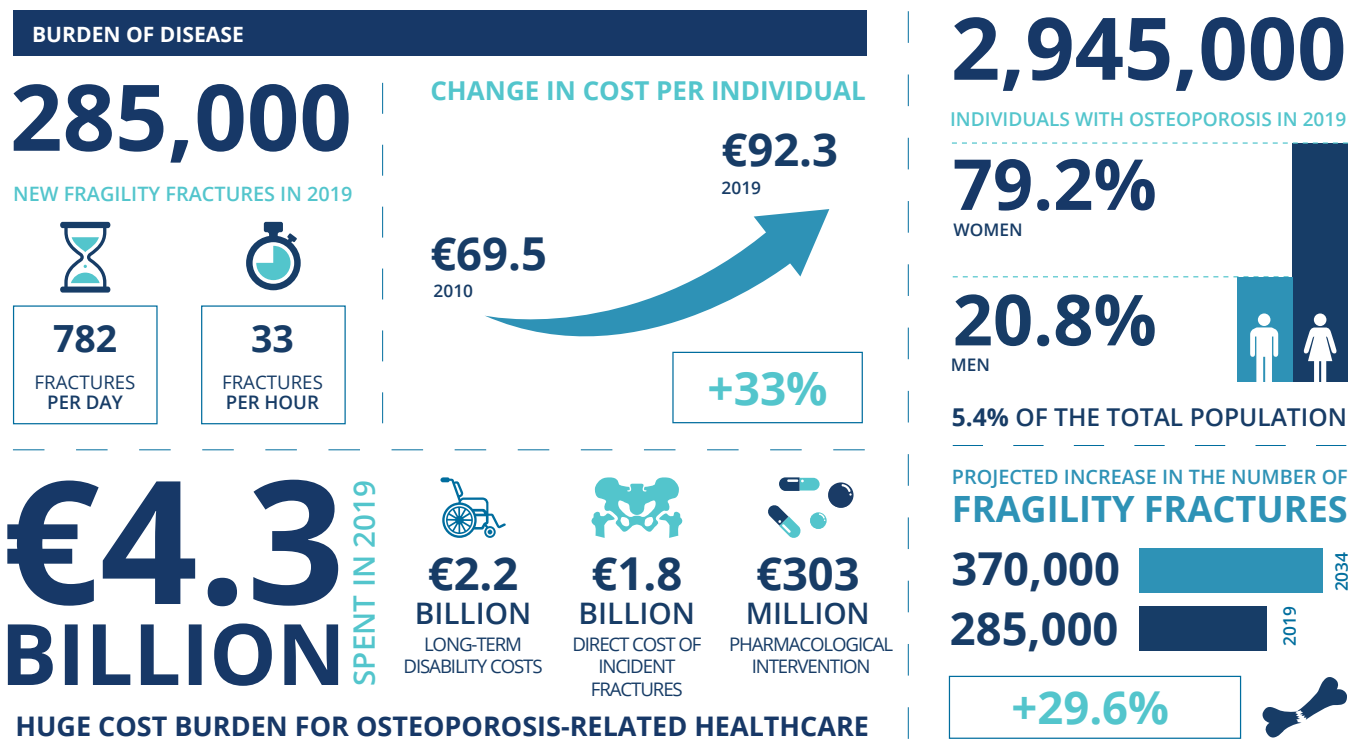


A PROBLEM ON THE RISE

Osteoporosis is a disease that makes bones weak and fragile. This greatly increases the risk of breaking a bone even after a minor fall. The disease has no obvious symptoms and so many people do not know they have osteoporosis until they suffer a fracture.

These, osteoporotic ‘fragility fractures’ are common, particularly in older adults, are increasing in prevalence, can be life-altering, causing pain, disability and loss of independence, and are associated with a substantial direct and indirect financial burden. Figure 1 summarizes key data regarding the burden of osteoporosis and fractures in Spain.

Figure 1:
Burden of osteoporosis-related fractures in Spain (ScoreCard for Osteoporosis in Europe, 2021)



Population ageing

An increasing ageing population proportion. Currently, in Spain, the average life expectancy is 84 years (86.7 years for women and 81.3 years for men). It is predicted that there will be a 24% decrease in the population size over the next 50 years, as Spain has one of the lowest birth-rates in the world. However, **the population will comprise the highest percentage of over 65s in any country.** Currently the over 65s make up 17% of the population, which will rise to 37% by 2050 and to 66% by 2100.

This shift in demographics **will markedly increase** the incidence and societal burden of fragility fractures occurring in the population.

Fractures are common with dramatic consequences for patients

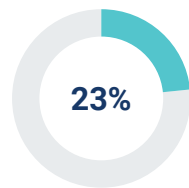
Fragility fractures are a substantial public health issue. In 2019, about 285,000 fractures occurred in Spain (approximately 33 fractures per hour) and there are currently estimated to be 3 million individuals living with osteoporosis (5.4% of the general population).

Fragility fractures affect numerous women and men. It has been reported that nearly 3 million individuals (including 2.3 million women) are living with osteoporosis in Spain. The prevalence of osteoporosis in the over 50s is 23% for women and 7% for men. Furthermore, the lifetime risk of hip fracture (the most serious fracture type) from age 50 is 12% in women and 4% in men.

WOMEN

+50

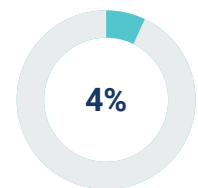
YEARS



MEN

+50

YEARS



Fragility fractures are on the rise. With life expectancy continuing to increase, fragility fracture incidence in Spain is predicted to increase by 30% in the next 15 years.

Re-fractures are also on the rise. Fragility fractures substantially increase (almost double) the risk of developing a new fracture, with even higher increased risk in the first 24 months following a fracture.

Fragility fractures increase are associated with increased death.

Mortality with hip fractures is particularly high with one in three patients dying within two years.

APPROXIMATELY

1/3
OF ELDERLY
PATIENTS



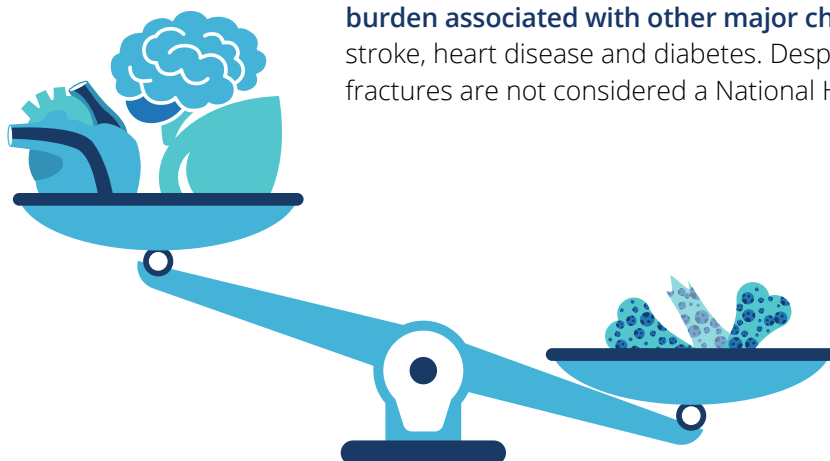
**WITH
HIP
FRACTURES**



**WILL DIE
WITHIN
2 YEARS**



Fragility fractures cause pain, disability, loss of independence, and have a significant impact on quality of life. In Spain, due to fragility fractures, per 1,000 individuals aged over 50 years, an estimated 12 years are lost due to disability (disability-adjusted life years, DALY). Another Spanish study estimated that osteoporosis leads to a loss due to **disability of 6.2 years** per individual. In the Global Burden of Disease study, osteoporosis (2.0 million DALY) accounted for **1.75% of the total DALY losses** for non-communicable diseases in Europe. Other chronic diseases including asthma (1.4 million DALY), migraine (1.2 million DALY), hypertensive heart disease (1.2 million DALY), and rheumatoid arthritis (1.0 million DALY) were outranked by DALY losses due to osteoporosis.



The Spanish burden of fragility fractures is higher than the national burden associated with other major chronic diseases of aging, such as stroke, heart disease and diabetes. Despite this, osteoporosis and fragility fractures are not considered a National Health Care priority.

HIGHER
BURDEN THAN
CARDIOVASCULAR
DISEASE
STROKE
DIABETES

Financial impact

Fragility fractures are costly to the healthcare system. In 2019, the total related burden for osteoporosis were estimated at €4.3 billion (almost €100 per inhabitant), including about €1.8 billion for direct costs of incidence fractures, €2.2 billion for long-term disability costs and €303 million for pharmacological treatment.

€4.3
BILLION

SPENT IN 2019



€2.2
BILLION

LONG-TERM
DISABILITY COSTS



€1.8
BILLION

DIRECT COST OF
INCIDENT FRACTURES



€303
MILLION

PHARMACOLOGICAL
INTERVENTION

Financial burden is on the rise. Due to the ageing population, the direct costs of incident fractures is predicted to increase by more than 25% in the next 15 years.

Fragility fractures do not just affect national finances directly, but also indirectly through fractures in the workforce and the additional care required from family and relatives of working age. Although the majority of fragility fractures affect those in later life, 20% of fractures occur prior to retirement. Spain has relatively low fracture costs compared to other European countries but has one of the highest burdens for caregivers. An estimation of 75,000 hours per year per 1000 individuals are attributed to indirect costs. In a Spanish study, a high burden was perceived by 46% of the caregivers in a hospital setting, by 50% of caregivers at 1-month, by 36% at 3-months and 26% at 1-year.

Fragility fractures in Spain generate a legacy of financial burden with 10% of patients aged 50 or above who suffer a hip fracture being admitted to long-term care within 12 months of the fracture (one of the highest proportions of any of the EU6 countries).



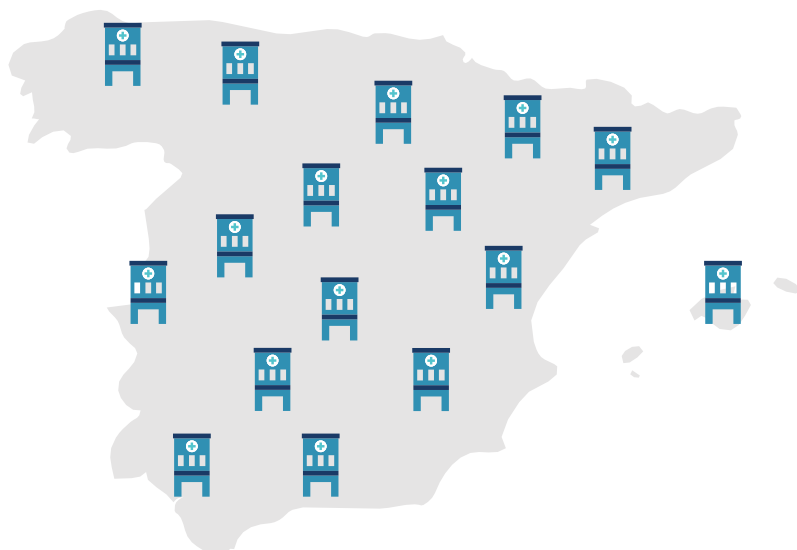
SUCCESSSES AND MISSED OPPORTUNITIES OBSERVED

We have identified positive initiatives for reinforcement and missed opportunities which need to be taken.

Positive initiatives that need to be built upon

Strength in collaboration. Organisations such as the Spanish Association for Osteoporosis and Arthritis (Asociación Española con la Osteoporosis y la Artrosis; AECOSAR), Hispanic Foundation for Osteoporosis and Metabolic Bone Disease (Fundación Hispana de Osteoporosis y Enfermedades Metabólicas Oseas; FHOEMO) and the Spanish Society for Bone Research (Sociedad Española de Investigación Ósea y del Metabolismo Mineral; SEIOMM) produce educational materials and run public awareness campaigns. In 2018, they launched a campaign to raise awareness of osteoporosis and fragility fractures called “Your Bones. Tomorrow and Always” (Tus Huesos. Mañana y siempre). This excellent initiative included a multimedia approach and incorporated a short film of a patient with osteoporosis which emphasised the huge, individual level impact of the disease.

Spain has a strong foundation of FLS. As of March 2022, there are 76 centres following IOF/CTF guidelines, including 13 gold star, 13 silver star, and 33 bronze star services. This is an impressive starting point from which to build.



76  **CENTERS** AS OF MARCH 2022



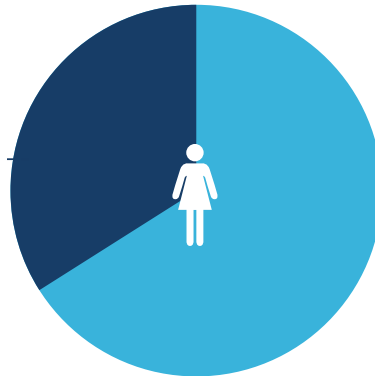
Gaps and missed opportunities

656,000

WOMEN TREATED FOR OSTEOPOROSIS

1,827,000

WOMEN ELIGIBLE FOR OSTEOPOROSIS TREATMENT



1,171,000

WOMEN REMAIN UNTREATED FOR OSTEOPOROSIS

64%
TREATMENT GAP

Figure 2
Treatment gap in Spanish women
(ScoreCard for Osteoporosis in Europe, 2021)

More than 1.1 million Spanish women who are at high risk of fracture remain untreated for osteoporosis, despite effective and safe medications.

The percentage of patients monitored after an initial fracture was further shown to decrease in the majority of health centers. Despite this, an estimated 64% of Spanish women (aged 50 years and above) eligible for osteoporosis treatment do not currently receive preventative treatment after an initial fragility fracture. The percentage of treated patients monitored after an initial fractures was further shown to decrease in most health centers.

Poor medication adherence, even after previous fragility fracture. After a fragility fracture, only 35% of Spanish patients are on anti-osteoporosis treatment 2 years after the fracture.

Fragility fractures may not be categorised as part of a chronic condition. In Spain, osteoporosis is not categorised as a chronic disease and so there has never been a coalition between bodies such as the IOF and the Spanish health service to formulate policies and drive changes. Classification of fractures in the elderly may therefore be overlooked and not reported as fragility fractures.

Too few FLS initiatives are currently operational. Despite the **benefits of FLS in reducing the risk of fractures and leading in cost-saving in most cases**, FLS were only reported for 1-10% (as described in the SCOPE 2021 report) of hospitals in Spain.

FLS highly cost-effective in Spain. A recent cost-effectiveness study in Spain revealed that FLS would provide better osteoporosis treatment initiation and adherence, leading to greater clinical benefits in life years and QALYs, in a cost-effective way (from an SNS perspective) and considering Spanish willingness-to-pay thresholds (cost per QALY gained of €6,855 over a 10-year time horizon).

SOLUTIONS EXIST: POLICY RECOMMENDATIONS

Specific recommendations for policy include:

- 1 Recognition of osteoporosis as chronic and progressive condition which must be addressed.**
 - Osteoporosis and resulting fractures are not considered as an ongoing chronic disease which can be managed. Both are perceived as having a negative image by both payers and policy makers and there is a belief that previous resource allocations have not delivered cost-effective improvements. Historically there has been an excessive push on primary prevention and diagnosis, but this has not been effective in the eyes of the Spanish health care system. There seems to be an underlying stigma attached to osteoporosis and fracture treatment which has affected credibility.
 - This needs to be actioned with buy-in from all stakeholders including policy-makers, clinicians and, most importantly, patients.
 - Include the diagnosis of fragility fracture in the databases of health centres.

- 2 Facilitate greater FLS uptake to increase post-fracture screening, diagnosis and treatment rates**
 - Look to the success stories of efficient FLS in Spain. For example, a recent study reported that FLS in Spain are able to maintain 73% of patients on antiresorptive, fracture preventing therapy 2 years after the fracture (compared to 35% without FLS).
 - More data on the efficiency of FLS within Spanish policy would inform future practice.
 - Emphasising the need to expand FLS (for example with the implementation of FLS among health systems by the public administrations) and changing organizational incentives to make it possible.

- 3 Fragility fractures should be a priority for healthcare management and public awareness of osteoporosis should be increased.**
 - Hospital managers have not been actively involved in FLS implementation and are key to effective development of FLS in the healthcare system at large.



- Primary care managers should be involved in secondary fracture prevention plans within the healthcare system. Intermediate care, hospital at home and nurse care should also be involved in secondary fracture prevention initiatives.
- Guidelines for clinicians should be uniform for identification and therapy for individuals with low bone density and previous fracture.
- There appears to be a lack of empowered patients' associations to communicate the burden and chronicity of osteoporosis and fragility fractures.

4 Data collection and audit of fractures with improvement quality.

- To achieve this, national fracture registers need to coordinate and collect similar data. It has been suggested that the REFRA and mini-REFRA Database should expand, focusing on all types of fractures. However, the number of patients on the database is low at this time (approximately 4,000 patients at the end of March 2022). There are overlapping registers in some areas which may be duplicating data, and some registers only collect data on a patient for a finite time (e.g., the RNFC where data collection ceases 1 month after fracture) preventing measurement of long-term outcomes including refractures, treatment persistence and long-term mortality.

BUILD YOUR RESPONSE

Find and treat your fractures (through the increase of FLS)

Employ and improve the infrastructure already in place. Spain has an increasing number of FLS on the CTF map. Coalition of these facilities would strengthen the CTF message and improve patient outcomes. There should be a country-specific model of secondary fracture prevention and a formalised acceptance that PFC is a standard episode of care accredited by La Sociedad Española de Calidad Asistencial (SECA) and supported by scientific societies and patient groups.

Shift national and medical opinion of fragility fractures and osteoporosis among patients, clinicians and hospital managers and enforce the concept that it a disease which requires management and can be treated. This will require specific involvement from rheumatology, endocrinology, geriatrics, orthopaedics, nurses, physical medicine and rehabilitation and, of course, primary care physicians.

Facilitate and improve the development of FLS to improve diagnosis and treatment rates. Draw on the resources and guidance from the IOF/CTF to develop Spanish policies, foster coalition, improve mentorship, and utilize FLS databases (as described below).

Make use of available resources

The International Osteoporosis Foundation has developed several tools to facilitate and improve the development of Post Fracture Care/FLS including:

1. **The Policy Toolkit** which is a CTF-P Guidance for Policy Shaping generic narrative and associated resources (slide kit in several languages, Executive Summary, Infographic, webinar and Policy Toolkit. <https://www.capturethefracture.org/resource-center/advocating-for-pfc/policy-toolkits>)
2. **The Capture the Fracture® Resource Centre** (<https://www.capturethefracture.org/resource-center>) which provides tools to achieve the following:
 - Implementing an FLS
 - Improving an FLS
 - Advocating for the development of FLS



The Capture the Fracture® programme provides tools and resources to optimise post-fracture care:

1. **The Best Practice Framework**

- Provides guidance for institutions that are implementing FLS
- Sets benchmarking criteria to stimulate quality improvement of post-fracture care services at the organisational level

2. **The Mentorship Program** which partners experienced partners of FLS with newly formed services

3. **Lyosis®**: a software package for optimizing the national clinical management of FLS and post-fracture care services (www.lyosis.com)

4. **The Benefit Calculator**: a microsimulation tool to estimate the financial consequences of improving post-fracture care.

Reinforce your evidence base

- **Streamline electrical registries and resources.** In the past, a national ‘top-down’ approach has been unsuccessful. However, using a ‘bottom-up’ strategy by coalescing the regional databases until a full national registry can be formulated, may be more successful in gathering data. Development and implementation of technology should account for the needs of the national health system and be suitable for ‘scaling-up’. Any developed technology should receive official national recognition (accreditation) and the support of Spanish scientific societies and patient groups. By broadening the type of data collected and streamlining the existing registers, a more accurate picture of Spanish bone health and fracture incidence, treatment and outcome can be achieved. The cost of this exercise would help improve policies and treatment plans. The EPIC Study, performed with real-world data (Daniel Prieto Alhambra and Daniel

Martinez) which focused on fracture prediction in Spain acts as an encouragement for future collaborative, epidemiological endeavors.

- **Instigation of a fracture database developed at the regional, then national level.** Use regional databases and their guardians to instigate a plan for data collection, audit and research. Bench-mark all the available services with a view to scaling-up for national use.
- **Develop robust scientific research on fragility fractures** to provide epidemiological evidence and to standardize a series of quality and healthcare indicators.
- **Utilise the benefits calculator** to assess the expected financial impact of interventions to ensure you stay on track and utilise extensive resources available.

Form a policy team

- **Use renowned (inter)national mentors/collaborators** to educate and monitor the implementation of fragility fracture care pathways and FLS development. Inviting all the relevant key players in FLS to participate in events which would consolidate collaboration over the longer term.
- **Promote integrated care models;** specialist doctors, primary care doctors, nurses and community pharmacy that facilitate the evaluation and treatment of patients with bone fragility fractures.



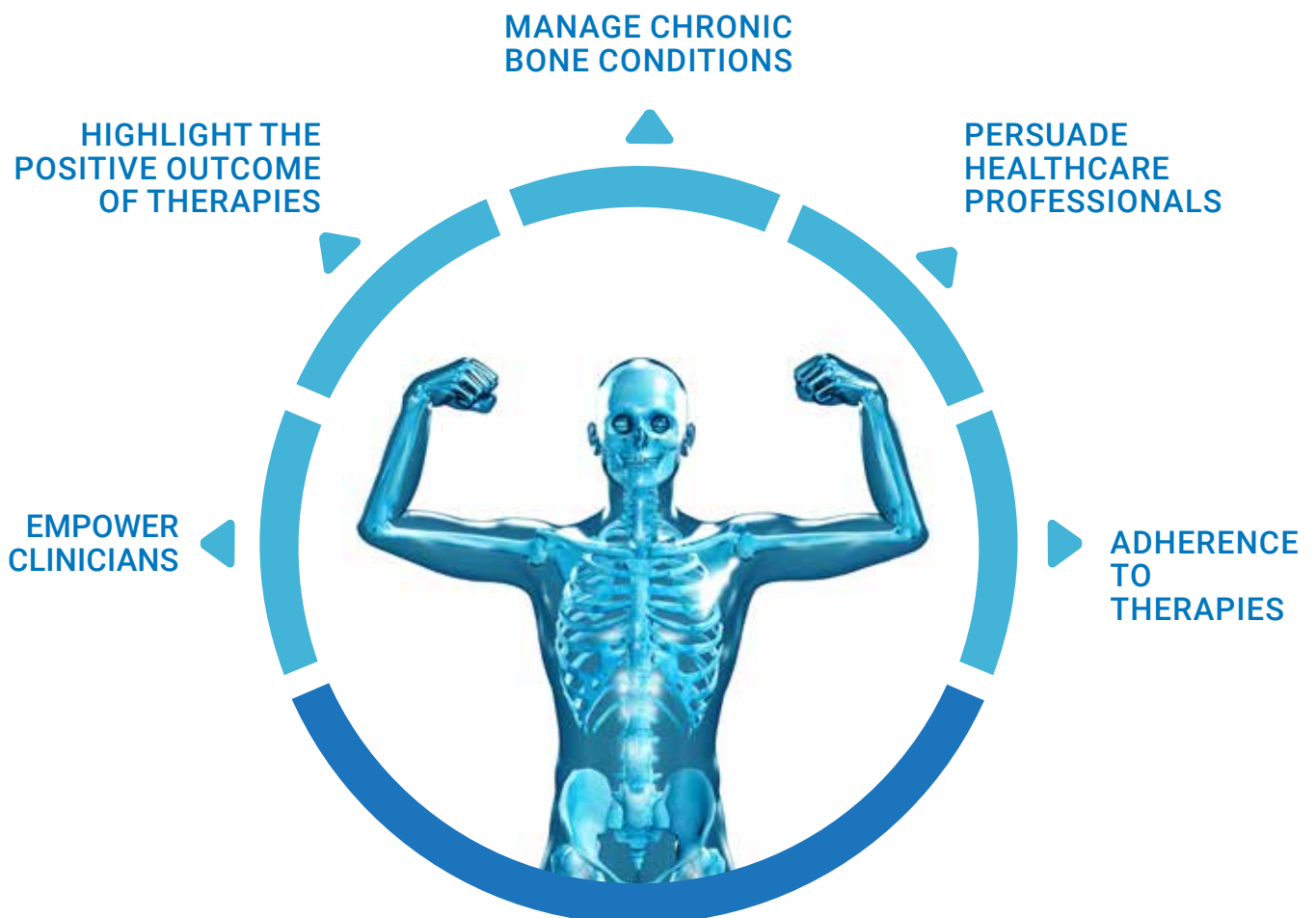
- **Policy recommendations for sustainable PFC services should involve approaching key funding stakeholders** including the Regional Authorities, General State Civil Servant Mutual Society (MUFACE), Spanish Association of Insurers and Reinsurers (UNESPA), Investigación Cooperativa entre Entidades Aseguradoras y Fondos de Pensiones (ICEA), Mutuality General Judicial (MUGEJU), Instituto Social de las Fuerzas Armadas (ISFAS).
- **Involve 'key players' for advocacy** including the Spanish Society of Osteoporotic Fractures (SEFRAOS), all societies related to fracture (SEIOMM, Spanish Society of Geriatrics and Gerontology (SEGG), Spanish Society for Rheumatology (SER), Spanish Society of Rehabilitation and Physical Medicine (SERMEF), the La Sociedad Española de Calidad Asistencial (SECA), La Sociedad Española de Directivos de la Salud (SEDISA), Spanish Society of Primary Care Physicians (SEMERGEN), Spanish Society of General and Family Medicine (SEMG) and the pharmaceutical partners in new initiatives.

Engage the public

- **Engage patient support groups and the public** at large and with education resources and high-quality literature. Consider liaison with Care Home Groups such as “Edad y vida” / Fundación Edad y Vida, Ballesol / Sanitas Residencial, Centros Fundación La Caixa (Obra Social), Spanish Federation of Residences and Services for the Elderly-Solidarity Sector (LARES), AMAVIR (retirement home company) and DomusVi (elder home care company).

Foster healthy ageing

- **Empower clinicians and persuade health care managers and professionals that healthy bone ageing is possible**, and that chronic bone conditions can be managed, to prevent future fracture.
- **The vital importance of adherence to prolonged drug therapy should be highlighted** and the positive outcome for therapy adherence emphasized.



EXPECTED BENEFITS OF FLS

This section reports on the expected benefits of improved post fracture care through FLS compared to current practice in Spain. Additional recommendations and suggestions provided above will reinforce osteoporosis care leading to additional benefits.

The expected benefits summarised here were estimated by employing a microsimulation model (reviewed and validated by Spanish experts) that takes simulated individuals through a care pathway as they would experience it today in Spain, and compare its expected results to those if FLS were broadly operational throughout the country. Results are reported in terms of incidence of subsequent fractures, quality-adjusted life years (QALYs), use of health and social care resources, and FLS costs over the first five years. FLS are modelled according to their expected performance in terms of patient identification, assessment, treatment, and monitoring as reported by current FLS already operating in Spain and the judgement of expert local key opinion leaders.

The simulation was conducted for the expected number of people expected to experience a fragility fracture in Spain during a given year. Through a realistic implementation of FLS in Spain, we expect to see:

Figure 3
Expected benefits of a realistic implementation of FLS in Spain

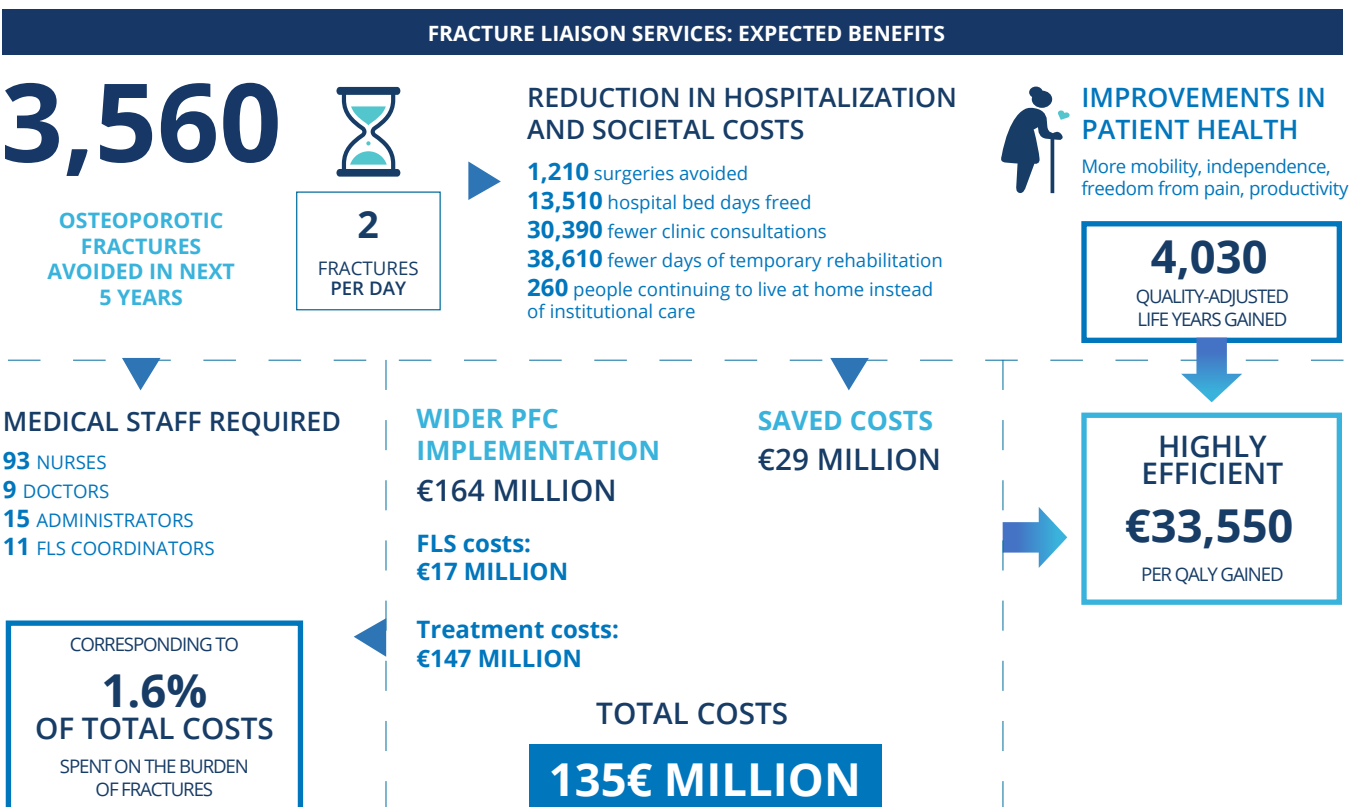


Figure 4 (right)
Yearly extra costs and QALYs gained by FLS within 5 years in Spain

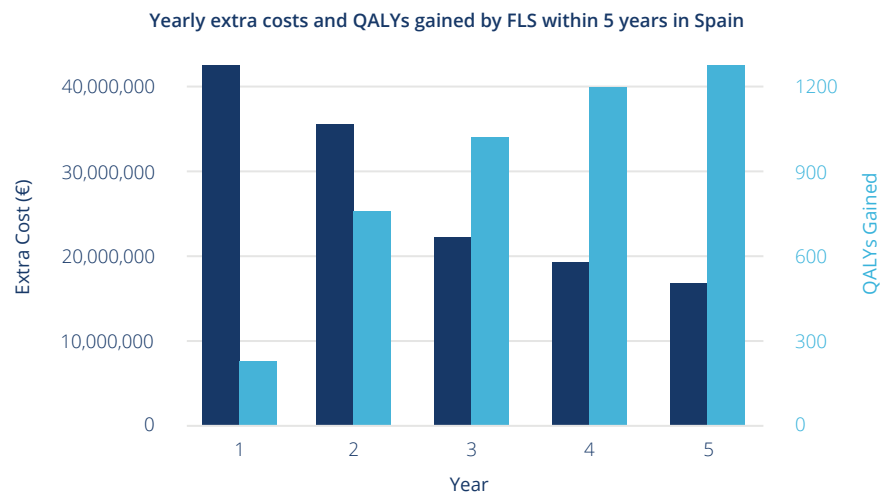


Figure 5 (below)
Cost per QALY gained by FLS over 5 years

Over Year	Cost per QALY gained
1	€250,000
2	€91,000
3	€57,000
4	€42,000
5	€34,000

- **Improvements in quality of care.** There are now clear data to support the notion that the introduction of post-fracture care initiatives, such as FLS, lead to improvements in the quality of care offered to fragility fracture patients.
- **Reductions in fragility fractures.** The Benefits Calculator suggests that FLS implementation would reduce the number of subsequent osteoporotic fractures by more than 3,560 (7.7% of the 36,340 expected with current practice) during the first five years of its implementation, with this figure due to substantially increase with continued PFC operation.

Leading to:

- **Reductions in hospitalization and societal costs.** Benefits of FLS implementation on one year of fracture patients followed for 5 years would include:
 - 1,210 surgeries avoided
 - 13,510 hospital bed days freed, and 121,590 hours of patient care released
 - 30,390 fewer clinic consultations
 - 38,610 fewer days of temporary rehabilitation
 - long-term institutional care cut by 590 person years
 - 260 people continuing to live at home who would have otherwise gone into institutional care
- **Improvements in patient health.** Every avoided fracture keeps people from losing mobility, and allows them to maintain independence, freedom from pain, productivity, and so much more! Over its first five years, the PFC programme would lead to a gain in quality of life equivalent to 4,030 years in perfect health (QALYs).
- **In a highly cost-effective way.** Although the extension of FLS would only amount to a net increase of 1.6% of current total costs, FLS offer clear cost-effectiveness (cost per QALY gained estimated at €33,550 during the first five years only, well below cost-effectiveness thresholds used in Spain, and expected to be even lower yet over longer periods of analysis), as well as the possibility of improved care for the Spanish population
- **With immediate short-term economic benefits.** From year 3, the extension of FLS leads to cost-effectiveness (see figure 4)

Glossary

FRACTURE – a broken bone

FRAGILITY FRACTURE - A broken bone which occurs due to minor force, such as a fall from standing height. The risk of fragility fractures can be reduced by lifestyle modifications, supplementation of calcium and vitamin D, falls prevention programmes and anti-osteoporosis medication.

FRACTURE LIAISON SERVICE (FLS) - See Post-Fracture Care Coordination Programme. A model of care which seeks to rehabilitate individuals after they have had a fracture and reduce the risk of them fracturing again in the future. The term is interchangeable with **POST-FRACTURE CARE (PFC) COORDINATION PROGRAMME**.

OSTEOPOROSIS - Osteoporosis is a disease in which the mass, density and strength of bone are reduced. As bones become more porous and fragile, the risk of fracture is greatly increased. The loss of bone occurs silently and progressively. It primarily affects the elderly and is more common in women than in men.

PRIMARY PREVENTION OF FRACTURES - Initiatives to prevent a first/sentinel/initial fracture occurring.

SECONDARY PREVENTION OF FRACTURES - Initiatives to prevent second/subsequent/further fractures occurring after the first fracture has occurred.

QALY (QUALITY ADJUSTED LIFE YEARS) - a generic outcome measure commonly used in economic evaluations that account both quantity and the quality of life. One QALY corresponds to one year of perfect health.

DALY (DISABILITY ADJUSTED LIFE YEARS) - a measure of overall disease burden expressed as the number of years lost due to disability or early death. One DALY represents the loss of the equivalent of one year of full health.

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