



SOLUTIONS FOR FRACTURE PREVENTION

 IN ITALY



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



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SUMMARY

This document provides an assessment of the current policy and post-fracture care landscape in Italy and provides recommendations identified by the Capture the Fracture® Partnership (CTF-P) in cooperation with a panel of Italian experts.

This document aims to:

SECTION 1 - A Problem on the Rise

Summarize the increasing burden of fragility fractures in Italy

SECTION 2 - Successes and missed opportunities

Map out successful post-fracture care initiatives in Italy, and identify 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 to prioritise osteoporosis and fragility fractures

SECTION 5 - Expected Benefit of FLS

Provide a detailed report on the benefits of Fracture Liaison Services (FLS) for 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 Italy** and are associated with a substantial (and escalating) health and financial burden. About 570,000 fragility fractures occurred in the year 2019 and the osteoporosis-related costs were estimated at €9.5 billion in the same year. With an ageing population and no change in policy, the number of fragility fractures is expected to increase by 25% over the next 15 years.
- b. Osteoporosis remains largely underdiagnosed and undertreated.** Today, more than 2 million Italian 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 three-quarters of Italian women (aged 50 years and above) not currently receiving effective secondary fracture prevention after an initial fragility fracture (despite this being the population which is most likely to sustain a further fracture).
- c. The Italian population is under-served 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) Italian 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:

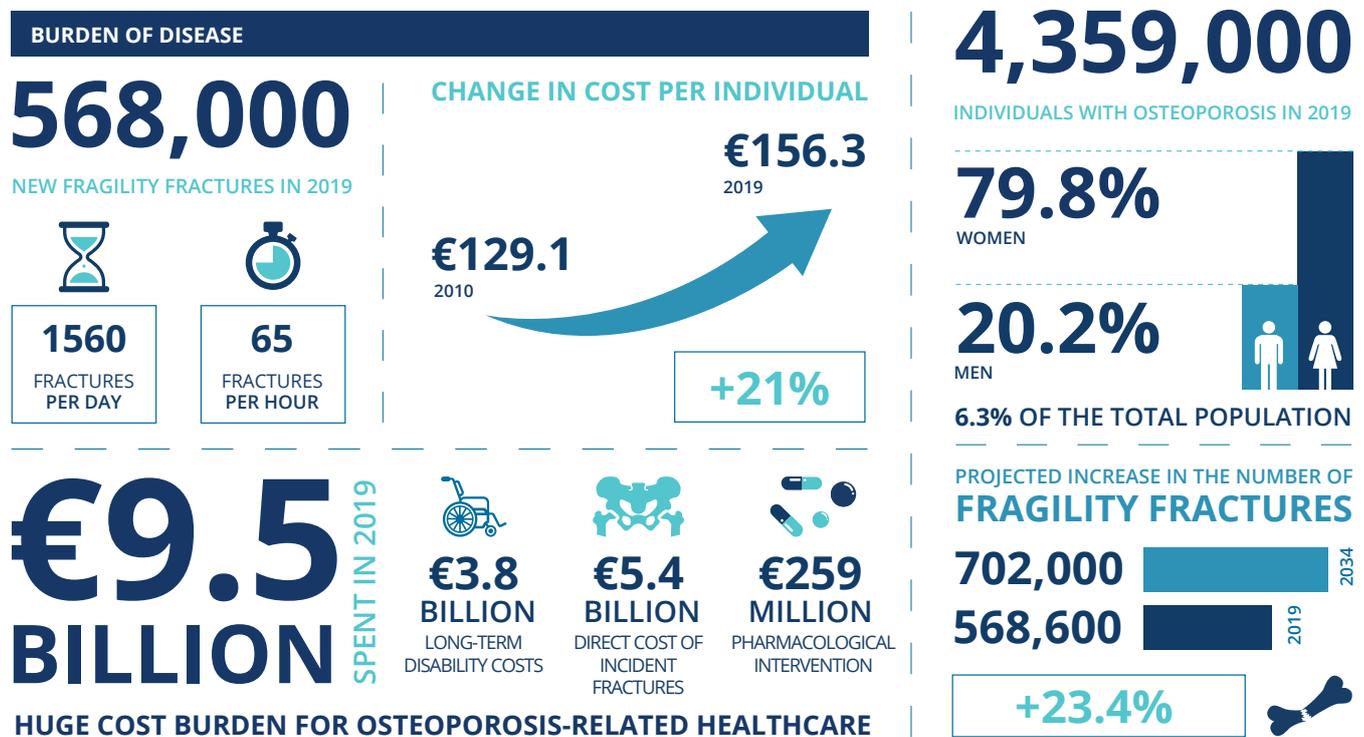
- 1. Develop a common voice** for osteoporosis stakeholders and integrate bone fragility in national policies
- 2. Continue to identify and share best practices** at a local level leading to the publication of an optimal patient pathway
- 3. Facilitate greater FLS uptake** to increase post-fracture screening, diagnosis and treatment rates

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.

Osteoporotic 'fragility fractures' are very common especially in older adults and their prevalence is progressively increasing. They can be life-altering, causing pain, disability and loss of independence, and lead to substantial direct and indirect financial burdens. Figure 1 summarizes key data regarding the burden of osteoporosis and fractures in Italy.

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



Population ageing

An expanding ageing population. Italy has one of the world's highest life expectancies, currently estimated at 85 years for women and 81 years for men. The population of Italy is 60 million but is forecast to decrease to 54 million by 2050 with an expected higher proportion of elderly persons in future. Nearly one in four (23.3%) Italian is already aged 65 or older and that is expected to grow to 35 percent by 2050, according to the Italian National Institute of Statistics.

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

Fractures are common

Fragility fractures are a substantial public health issue. In 2019, 570,000 fractures (including 20% hip, 15% vertebral) occurred in Italy (more than 1 fracture per minute).

Fragility fractures affect numerous women and men. It has been reported that 4.36 million individuals are living with osteoporosis in Italy (6.3% of the general population, somewhat higher than the EU27+2 average (5.6%)). The prevalence of osteoporosis in the over 50s is 23% for women and 7% for men.



Lifetime risk of fractures is higher than stroke. The lifetime risk of a major fracture at age 50 is higher than the lifetime risk of stroke in Europe for both women (34% fracture, 20% stroke) and men (16% fracture, 14% stroke). The lifetime risks of hip fracture (the most serious fracture type) at the age of 50 years are 19% in women and 7% in men.

Fragility fractures are on the rise. An Italian study reported that the number of hip fractures has increased by 29% between 2000 and 2014 in people ≥ 65 years old and even more in those over 75 years old. Furthermore, with life expectancy continuing to increase, fragility fracture incidence in Italy is predicted to increase by 23% 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 are associated with increased death. Mortality is high with about one in three Italian patients dying within two years of hip fracture.



Fragility fractures cause pain, disability, loss of independence, and have a significant impact on quality of life. In Italy, due to fragility fractures, per 1,000 individuals aged over 50 years, an estimated 20 years are lost due to disability (disability-adjusted life years, DALY). In 2017, the total health burden due to fragility fractures in Italy was just under 230,000 QALYs (quality-adjusted life-years), 70% of which were attributable to fractures occurring among women.

Fragility fractures and falls are common and burdensome to the Italian hospital system. Falls and fractures are in the top 5 causes of hospitalisation (also including ischaemic heart disease, dementia and lung cancer).

Hip fractures have long-term burden. An Italian study in 2017 showed that 35% of patients aged 90 years or more were admitted to long-term care after hip fracture. As their quality of life decreased, other ailments came to the fore and the risk of subsequent secondary fracture increased. Even at younger ages, fractures impair a person's ability to live independently and can be life-threatening. Several comorbid conditions (hypertension, iron deficiency anaemia, sleep disorders, chronic kidney disease, intestinal disorders) can develop, ensuing higher costs.

Financial impact

Fragility fractures, especially of the hip, are expensive to treat. The cost of a hip fracture is estimated at more than €10,000 per patient.

Fragility fractures are costly to the healthcare system. In 2019, the total related burden for osteoporosis was estimated at €9.5 billion (almost €100 per inhabitant), including about €3.75 billion due to direct costs, €5.44 billion for long-term disability costs and €259 million for pharmacological treatment.

The financial burden is on the rise. Between 2000 and 2014, the overall costs of hip fractures increased by 30%. With continuous expansion of the ageing population, the direct costs of incident fractures are predicted to increase by more than 25% over 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. In 2017 it was estimated that over 700,000 days were taken off work each year in the pre-retirement age group due to hip fractures. An average number of 21 sick days are taken per 1,000 people following any fragility fracture every year. Furthermore, Italy has the highest caregiver burden of the EU6 nations at over 882 hours each year per 1,000 people. This is almost twice the EU6 average (443 hours/year/1,000 individuals).



SUCCESSSES AND MISSED OPPORTUNITIES

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

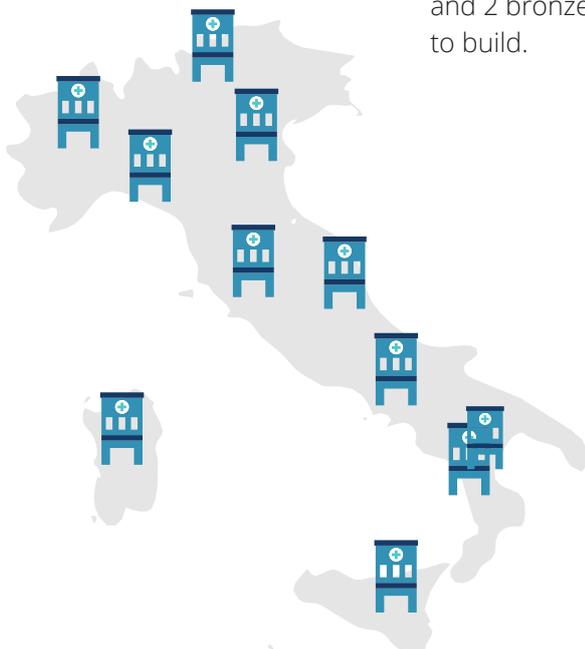
Positive foundations that need to be built upon

Clinical guideline for the prevention and treatment of osteoporosis.

The Italian Society for Orthopaedics and Traumatology, among others, produced guidelines primarily directed at Italian orthopaedic surgeons, but potentially also useful for other bone specialists and general practitioners to improve the diagnosis, prevention and treatment of osteoporosis and its consequences.

Adequate resource provision. There are approximately 15 DXA scanners per million persons which is adequate provision. In addition, Italy has scored 3/3 for access to medical intervention within the European Union.

Italy has a strong foundation of FLS. As of June 2022, there are 14 centres following IOF/CTF guidelines, including 2 gold star, 3 silver star and 2 bronze star services. This is an impressive starting point from which to build.



14  **CENTERS** AS OF JUNE 2022



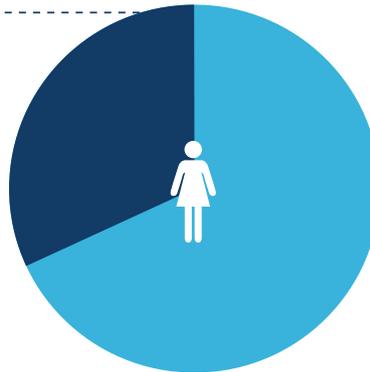
Gaps and missed opportunities

834,000

WOMEN TREATED FOR OSTEOPOROSIS

2,889,000

WOMEN ELIGIBLE FOR OSTEOPOROSIS TREATMENT



2,055,000

WOMEN REMAIN UNTREATED FOR OSTEOPOROSIS

71%
TREATMENT GAP

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

More than 2 million Italian women who are at high risk of fracture remain untreated for osteoporosis, despite effective and safe medications being available.

Substantial treatment gap. An estimated 71% of women (aged 50 years and above) eligible for osteoporosis treatment do not currently receive preventative treatment. This gap in treatment has increased since 2010 (when it was estimated at 59%) reflecting the low importance that continues to be given to the escalating issue of fragility fractures. Furthermore, there is still a high percentage of patients on steroid treatment and on hormone deprivation therapy not getting appropriate bone protection.

Missed opportunities to reduce fractures in those at high risk. Approximately 75% of elderly patients are discharged from Italian hospitals following a hip fracture without any pharmacological treatment for osteoporosis.

Poor medication adherence, even after fracture. Adherence to anti-osteoporosis medications at 6-month follow-up was estimated at 54%, and this constantly decreased over 1 year to 46%, and to 33% after 3 years. Even in the Italian Observational Study on Severe Osteoporosis (ISSO), overall treatment adherence at 24 months was suboptimal (66%) following vertebral fracture.

Importance of patients' education and disease awareness for improving adherence. An Italian study reported that education and disease awareness are associated with long-term alendronate adherence, while competing health problems negatively impact adherence.

More intensive post-fracture follow-up could improve therapy adherence. Studies show that post-fracture follow-up visits and contact with healthcare professionals encourage and improve treatment adherence.

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

LESS THAN
10%
OF ITALIAN
HOSPITALS



**HAVE A
FRACTURE
LIAISON
SERVICE**



Improve detection rate of vertebral fractures. In 2010, it was estimated that approximately one third of vertebral fractures were identified.

Good guidelines for PFC are not currently being implemented. Based on a survey sent to a number of PFCs across the EU6 enrolled in IOF's CTF network, it is estimated that only 3% of Italian hospitals and a maximum of 10% of general practitioners have an established referral system for fracture patients. This is significantly less than seen in the UK, where the National Osteoporosis Society estimates that 55% of the UK population has access to an FLS .

SOLUTIONS EXIST: POLICY RECOMMENDATIONS

Specific recommendations for policy include:

- 1** **Develop a common voice for osteoporosis stakeholders and integrate bone fragility in national policies.**
 - It is recommended that osteoporosis, fragility fractures and secondary fracture prevention are included in the health system's national policies.

- 2** **Continue to identify and share best practice at a local level leading to the publication of an optimal patient pathway and work at a regional level to improve osteoporosis management policy.** This can be achieved via:
 - Organisation of regional roundtables
 - Building a network of osteoporosis allies
 - We advise working at a regional level to improve osteoporosis management policy since the current national health policy and related budget are less effective in devising and implementing osteoporosis-dedicated measures.

The following associations will play a key role in facilitating this recommendation:

 - 1. Italian scientific societies** (such as the Italian Society for Orthopaedics and Traumatology)
 - 2. Patient associations** (such as the Italian Association of Osteoporosis Patients (AIPOS) that have a key role in raising awareness in both lay public and healthcare spheres

- 3** **Facilitate greater FLS uptake to increase post-fracture screening, diagnosis and treatment rates**
 - Emphasising the need to expand FLS and changing organizational incentives to make it possible.
 - An important challenge is to increase primary care physician awareness and involvement in PFC management. This could potentially be achieved via financial incentives.

BUILD YOUR RESPONSE

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

- **Upgrade the post-fracture care pathway, especially for vertebral fractures, wrist fractures, and hip fractures.** Build on the guidelines and current policy to initiate new post-fracture care services involving the relevant healthcare professionals and employ a care coordinator (e.g. nurse).
- **Employ and improve the infrastructure already in place.** Italy has an increasing number of FLS on the CTF map. Coalition of these facilities would strengthen the CTF message and improve patient outcomes.
- **Facilitate and improve the development of FLS to increase diagnosis and treatment rates.** Draw on the resources and guidance from the IOF/CTF to develop Italian policies, foster coalition, improve mentorship, and utilize FLS databases (as described below).
- **Ensure adequate remuneration and incentives to support best practice.** Adapt the remuneration model for these post-fracture care pathways. Put in place incentives linked to the detection of osteoporosis and fragility fractures in cases where patients have been hospitalized via emergency and orthopaedic surgery services.
- **Shift national and medical opinion of fragility fractures and osteoporosis among patients, clinicians and officers** to the idea of a disease that can be treated following proper guidelines. This will require specific involvement by all the involved specialists, namely rheumatologists, endocrinologists, geriatricians, orthopaedics, nurses, physiatrists and, of course, primary care physicians.

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, outline video

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 and resources 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**, linking 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

- **Establishment 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.

- **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. Invite all the relevant key players in FLS to participate in events which would consolidate collaboration over the longer term.
- **Promote integrated care models including** specialist doctors, primary care doctors, nurses and community pharmacy in order to facilitate the evaluation and treatment of patients with bone fragility fractures.
- **Many disciplines can assist.** Encourage osteoporosis training in a broad range of healthcare professionals: rheumatologists, endocrinologists, general physicians, gynaecologists, primary care physicians, pharmacists, physiotherapists and dentists.
- **Ensure buy-in from primary care.** This could include osteoporosis-centred consultations with decision-assisting digital tools or financial incentives with incorporation of osteoporosis assessments into primary care electronic health records and business software.

Engage the public

- **Engage patient support groups and the public** at large, with education resources and high-quality literature. Consider liaison with patient and professional organizations.
- **Focus on Fractures and capture 'osteoporosis'.** There are common misconceptions regarding osteoporosis including "osteoporosis treatments are not effective" or "losing height is normal". Targeting public health awareness campaigns at fractures will be more successful, for example "the first fracture must be the last!". Osteoporosis is a silent condition and primary prevention is also key.
- **Increase awareness of osteoporosis throughout the lifecourse:**
 1. Make 'World Osteoporosis Day' a substantial entity.
 2. Consider engaging initiatives such as free bone mineral density assessments (DXA) for women over 65 years.
 3. Incorporate osteoporosis screening into established health checks (e.g. retirement check).
 4. Start early with prevention campaigns in schools: how to build strong bones, encouraging physical activity, getting sufficient levels of protein.

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.
- **Encourage bone health throughout the lifecourse, starting early.** Carry out prevention campaigns at school: how to build strong bones (bone capital); why it is important to take in 1 g of calcium per day (e.g. one dairy product) and a sufficient amount of vitamin D, to do physical activity, to get sufficient levels of protein. Furthermore educational campaigns should be addressed to pregnant and breastfeeding women in order to raise awareness about the importance of vitamin D and calcium supplementation.
- **Consider the following systematic interventions for the elderly:**
 - a. Healthy Ageing consultations for early identification of chronic diseases – a report from the National Health Insurance Fund identified an alarming drop in the identification of chronic diseases. A routine Healthy Ageing consultation would provide a valuable opportunity to screen for these conditions and improve patient outcomes. A recommended target population is all women over the age of 65 years.
 - b. Annual height measurements to capture vertebral fracture related height loss.
 - c. Screening programmes for falls risk – this is supported by the governmental ‘No Fall Plan’ and should be actioned to reduce both falls and fractures.
 - d. Target additional osteoporosis screening resources at patients suffering from chronic diseases.



ANNUAL HEIGHT MEASUREMENTS



EARLY IDENTIFICATION OF CHRONIC DISEASES



FALLS RISK SCREENINGS

- **Promote falls prevention services and improve the physical capacity of older individuals**, in order to support their physical activities and autonomy.

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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*Our vision is a world without fragility fractures,
in which healthy mobility is a reality for all*



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