

Fracture Liaison Service (FLS) for secondary prevention of fragility fractures: the Italian IMPACT Project

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ABSTRACT

Osteoporosis and subsequent fragility fractures are an important public health issue since this is a common disease that leads to disability, and increased mortality, and therefore has a significant social and economic impact. Several studies have highlighted a dramatic diagnostic-therapeutic gap. A coordinated multidisciplinary system, known as the fracture liaison service (FLS) model, is the most appropriate approach for osteoporosis management and secondary prevention. Developed by the International Osteoporosis Foundation (IOF) through its Capture the Fracture campaign, the FLS model aims to avoid fragmentation of the care pathway by facilitating communication and coordination between primary care and medical specialists. The approach also involves patient identification and education, risk evaluation, the approval of treatments, and long-term follow up. The development of FLS programs has been strongly supported by the IOF. In Italy's case, the primary recommendations made by the IOF in order to improve the management of patients with fragility fractures, and reverse the expected increase in the number of such fractures and their relative cost over the next 10 years, include the development of dedicated multidisciplinary care pathways, based on the FLS model.

In order to make an effective contribution to the organizational needs in this regard, the primary objective of the IMPACT Project is to support the implementation and customization, in selected pilot centers in Italy, of an FLS model in line with the IOF recommendations and coherent with the Italian National Health Service (SNN), and to identify connection points with the territory, the activities of new healthcare professionals, and digital touchpoints in the care pathway.

KEYWORDS

FLS, fragility fractures, osteoporosis, bone specialist.

Introduction

Osteoporosis is a skeletal disease characterized by decreased bone density and microarchitectural changes, and therefore a deterioration in bone quality and consequent loss of bone strength. This leads to an increased risk of non-traumatic fractures, whose most frequent sites are the vertebral body, proximal femur, proximal humerus, and distal radius. Such fractures are called fragility fractures and, according to the WHO, they result from low-energy traumas, in other words mechanical forces that would not ordinarily cause a fracture^[1].

An Italian study^[2] explored the incidence of the most frequent fragility fractures, through analysis of hospital discharge forms, and analyzed changes over a three-year observation period. The results showed increases of 5.9% in hip (90000/year), 5.5% in humerus (56000/year), 3.9% in distal radius (97000/year), and 3.1% in vertebral body (61000/year) fractures. Regardless of the site, a strong correlation with age and sex has been observed: about 60% of these fractures affect women aged >75 years^[3].

The probability of occurrence of fragility fractures increases with age both in women and in men, being 47.3% and 23.8%, respectively, at the age of 45 in Western Europe^[4].

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A recent study has predicted a 22% increase in fragility fractures between 2017 and 2030^[5].

The impact of a fracture, especially one involving the proximal femur or vertebral body, is both physical and emotional, causing increased anxiety, depression and chronic fear. Being aware of the increased risk of further fractures (40% 10 years after the first fracture)^[6] can have a negative impact on the patient's attitude, leading them to modify their level of social interaction and avoid certain activities, thus compromising their general quality of life. Loss of quality-adjusted life years (QALYs) and of disability-adjusted life years (DALYs) has been reported to amount to 3.9/1000 inhabitants and 20/1000 inhabitants, respectively^[5].

For 40% of patients, hip fractures result in a significant

decrease in their functional level and loss of independence in walking. Moreover, they are associated with a 15-30% increase in mortality ^[7], especially during the first year following the fracture.

Vertebral fractures, in addition to causing acute and chronic spinal pain, can also cause deformities, such as dorsal hyperkyphosis and height loss with subsequent impairment of lung function and ventilation.

The risk of subsequent fractures is highest right after initial fractures: a quarter occur within 1 year, while one in two occur within 5 years ^[8].

As regards excess mortality after fractures, deaths often occur within the first year, gradually declining in number thereafter ^[9]. The risk is increased approximately twofold in women and two- to threefold in men ^[10].

The impact on mortality is higher for non-hip non-vertebral fractures, since these account for three-quarters of the total number of fractures in the population ^[11].

Osteoporotic fractures have been associated with increased risk of subsequent fracture, morbidity and excess mortality. They therefore place a considerable burden, both medical and economic, on healthcare systems ^[12].

In 2017 the economic burden of fragility fractures in Italy was EUR 9.4 billion; the cost of hip fractures accounted for over 50% of this total, and it is destined to increase (+25% in the next 12 years) ^[3].

Treatment accounts for about 66% of the total cost of these fractures and long-term healthcare for 29%; pharmacological prevention absorbs just 5% ^[13]; there is therefore a clear imbalance in the distribution of financial resources.

There is also an important treatment gap that has worsened recently ^[14]: most patients do not receive treatment with anti-osteoporosis drugs after a fragility fracture, despite the availability of many effective pharmacological interventions, as well as strong guidelines, that would allow active management of osteoporosis and prevention of subsequent fractures ^[12]. This treatment gap, which varies from 25 to 95% in Europe ^[15], is ascribed to inadequate clinical management, which includes poor communication between physicians, absence of healthcare continuity, and lack of knowledge among both patients and physicians ^[16,17].

Fracture Liaison Service

In 2012, the International Osteoporosis Foundation (IOF) started a campaign called Capture the Fracture (CTF) to promote the introduction of models of care for secondary fracture prevention based on a coordinated multidisciplinary system: the fracture liaison service (FLS). The FLS approach is the most suitable for secondary prevention, involving patient identification and education, risk evaluation, treatment and long-term follow up.

The FLS is based in primary or secondary healthcare settings, and its purpose is to facilitate communication and coordination between primary care and medical specialists, and the approval of treatments for osteoporosis and fragility fractures, in order to avoid fragmentation of the care pathway, as this is a

factor that contributes to failure in secondary prevention.

A major issue is that compliance with osteoporosis treatment declines quickly in about half of these patients, and there is insufficient definition of the clinical responsibility for osteoporosis treatment ^[18]: orthopedic surgeons treat the acute phase of the fracture, but primary care physicians do not examine patients with recent fragility fractures unless there is a specific recommendation to do so from a hospital specialist.

Mitchell and Chem assessed the FLS model as a cost-effective means of eliminating the care gap ^[19].

According to the IOF, the FLS should be structured around a core group, comprising an orthopedic surgeon, FLS coordinator (bone specialist) and specialized bone nurse, who interact with other professionals (orthopedist, internist, endocrinologist, rheumatologist, geriatrist, radiologist, primary care physician). The coordinator, who should have a particular interest in secondary prevention of fractures, has an essential role in making sure all eligible patients are registered in the program, and in facilitating communication and collaboration within the multidisciplinary team. The coordinator should also provide educational material and schedule FLS activities together with the nurse manager. The latter has an important role in supporting the coordinator and the orthopedic surgeon, in order to achieve the purpose of the program, encouraging patient enrollment and family support. The nurse manager should also interact with other specialty services in the hospital, such as Physiotherapy, for gait training and fall prevention, as well as Internal Medicine, Endocrinology, Rheumatology, Geriatrics, Nutrition services and Radiology, promoting an integrated care pathway ^[20,21].

The orthopedic surgeon, being the first to take care of a patient with a fragility fracture, has an important role; indeed, the orthopedic surgeon has the opportunity to diagnose osteoporosis when admitting the patient following the trauma, thereby facilitating the initiation of a secondary prevention program.

This is crucial, because patients do not usually return to their primary care physician once they are healed, as they do not perceive the need for further investigations; as a result, they miss out on additional specific treatment for bone fragility and osteoporosis.

Diagnosis of fragility fracture, following patient admission, should involve a complete bone health consultation, including evaluation of their medical history, physical examination and laboratory exams. A DEXA examination should be performed to evaluate bone mineral density, together with dorsal and lumbar spine X-rays. Recommendations for fracture risk factor modifications should follow, which may involve both pharmacological and nonpharmacological strategies, together with physical therapy and fall prevention: calcium and vitamin D supplementation can be recommended, as well as lifestyle modifications. Afterwards, a bone health follow up is needed, and there must be clear communication with primary care providers concerning recommendations on dealing with bone fragility.

There is scientific evidence that the FLS approach can prevent subsequent fragility fractures, promote adherence to osteoporosis treatment, and lower the overall costs of fracture treatment.

Senay *et al.* aimed to assess the cost-utility of FLS according to patients' follow-up compliance trajectories. The results, in their prospective cohort of women and men (≥ 40 years) with fragility fractures, suggest that a high-intensity FLS with a systematic 2-year follow-up can be cost-effective, especially when patients attend follow-up visits. Moreover, their study underlines the importance of understanding the behaviors and factors determining follow-up compliance^[22].

Miller *et al.*^[21] observed that the power of the FLS model is that it facilitates patient care, providing the appropriate treatment to help prevent avoidable fracture-related complications or readmission to hospital. With this approach, more patients can be treated, adherence to treatment is increased, while secondary fracture risk and mortality are reduced.

A multicenter study considering patients with recent fragility fractures observed that 88% of the patients enrolled in FLS programs in four Dutch hospitals were adherent with their osteoporosis treatment at the 1-year follow-up, and only 2% of them had a subsequent fracture^[23].

In a UK study, the presence of an FLS allowed osteoporosis to be diagnosed and treated in a high percentage of patients after a hip or proximal humeral fracture. In particular, 85% of patients with a proximal humeral fracture and 20% of those with a hip fracture underwent a DEXA scan^[24].

A recent systematic review and meta-analysis^[25] summarized the efficacy of FLS on subsequent fractures and/or mortality; only studies comparing the FLS model with no-FLS care were included. Studies compared outcomes before versus after implementation of FLS care, or outcomes of hospitals with versus without FLS; two studies included both types of comparison.

From the initial search, 16 articles fulfilled the inclusion criteria. The studies were all designed as cohort studies; most of them were conducted in Europe (the Netherlands, Sweden, Italy, UK, Ireland, and Spain), followed by Australia and Asia, and the remaining two studies were performed in Canada and the USA. Follow-up time varied from 6 months to 4 years.

The findings of this systematic review and meta-analysis suggest an association between FLS care and a lower probability of subsequent fractures. Mortality was lower only in studies comparing outcomes before and after the introduction of an FLS.

Another systematic review and meta-analysis regarding the impact of FLSs on clinical outcomes found that they improve rates of DXA scanning and antiresorptive therapy and decrease rates of new fractures and mortality following minimum trauma fractures across many time points^[26].

A recent study that investigated outcomes in patients over 50 years of age after the introduction of the FLS approach showed it to promote prompt surgery, earlier recovery, rehabilitation after surgery, and a decrease in the rate of medical complications together with earlier rehabilitation, improving patients' independence in performing daily activities. The FLS approach may also possibly decrease the rate of secondary hip fractures^[27].

Finally, evidence suggests that an FLS can optimize osteoporosis management and the prevention of secondary fragility fractures, but it has to be well structured and patients should en-

ter the program at their first admission to hospital for a fragility fracture. Advantages concern both patients' health and optimal management of financial resources.

A recent study (5) assessed the impact the FLS approach would have in Italy if access to the service were extended to the whole population aged over 50 years: 2868 prevented fractures/year, an annual saving of EUR 55.7 million in fracture management, a decrease of 1602 per year in QALYs lost.

The development of these programs has been strongly supported by the IOF, which has established specific guidelines on planning and improving FLSs, which need to be adapted to the characteristics of the local population and local health system.

Specific recommendations have been drawn up by the Italian National Institute of Health (Istituto Superiore di Sanità, ISS) using the SNLG-ISS (National Guidelines System) methodology, which entails synthesis of the best literature evidence, and evaluation and interpretation of the results by experts.

A systematic review has been performed, using the Medline, Embase and Cochrane CENTRAL databases. Critical outcomes (such as BMD, initiation of anti-osteoporosis treatment, adherence to anti-osteoporosis treatment, risk of refracture, mortality, quality of life) were evaluated in two groups of patients: patients in the first group were enrolled in a clinical governance model, whereas those in the second were not. As regards the risk of refracture, the outcome was found to be improved by interventions promoting continuity of care, as revealed by literature evidence; in fact, undesirable effects have not been reported.

It is strongly recommended that multidisciplinary health-care systems, such as FLSs, provide continuity of care between hospitals and territorial services, to ensure proper management of patients with fragility fracture [strong recommendation, moderate quality of evidence]^[28].

In a document called "Orthopedic Pathology in Frailty Conditions"^[29], the Italian Superior Health Council (Consiglio Superiore di Sanità, CSS) proposes to integrate the Italian Health Ministry document "A strategy of intervention for Osteoporosis" with national guidelines for a diagnostic and therapeutic care pathway (Percorso Diagnostico-Terapeutico, PDTA).

This project would involve the activation of FLSs to ensure properly coordinated multidisciplinary management of patients with fragility fracture, since management of these patients cannot be entrusted only to orthopedic specialists, but should involve all the other relevant specialists, as well as primary care physicians; furthermore, it should not be confined to hospitals, but assimilated into the territorial healthcare setting.

The Italian Impact Project

In Italy's case, the primary recommendations made by the IOF in order to improve the management of patients with fragility fractures, and reverse the estimated trend for the next 10 years — forecasts indicate a 22.4% increase in the number of fragility fractures and a 26.2% increase in the relative cost, exceeding EUR 11 billion — include the development of dedicated care pathways.

In line with the Italian National Health Service's aim to

reduce fragmentation in the provision of health services and improve the quality and efficacy of care, the decision-makers should encourage the development of integrated, multidisciplinary care pathways, based on the FLS model specifically developed for patients with fragility fractures.

In the Mission 6 (Healthcare) section of Italy's Recovery Plan, recently approved by the European Commission, enhancement of the community setting and extensive implementation of digital technologies/telemedicine, to allow management of chronicity outside the hospital and within the patient's home, are identified as primary and essential needs.

Therefore, it is necessary to address chronicity through hospital-territory organizational models and the implementation of digital health interventions.

At this stage, in order to make an effective contribution to the organizational needs in this regard, the IMPACT Project aims to implement the FLS multidisciplinary organizational model in 10 hospitals in Italy. These centers should represent virtuous organizational models that, through performance indicators collected as part of the project, will be able to show the respective health facilities and regions the value of the FLS model, thus promoting its implementation in other centers equipped with the necessary professional competences; at the same time, they will be able to define care models for patients with fragility fractures, exploiting local healthcare facilities and digital technologies.

With regard to the professional competences, the osteoporosis specialist, orthopedic specialist and properly trained specialist nurse are all crucial. The latter, known as the bone care nurse in the FLS model, has a fundamental role in the patient's management, being responsible for monitoring patients and referring them to the various experts in the FLS organizational model. The project will involve 10 pilot centers, whose

objectives will be first to perform an organizational gap analysis, with respect to the FLS model globally defined by the IOF, then to develop an operating plan for the implementation of the organizational model, and finally to support the collection of the performance indicators, starting from what the IOF has already proposed. The primary aim of this project is to support the effective implementation and customization, in selected pilot centers, of an FLS model that is in line with the IOF recommendations and coherent with the Italian National Health Service (SSN), and to identify connection points with the territory, the activities of new healthcare professionals, and digital touchpoints in the care pathway (Fig. 1).

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Figure 1 The objectives of the IMPACT Project.

IMPACT Project - The Objectives
Supporting the effective application and customization of the FLS model, set out by the IOF, in selected pilot centers

The objectives of this project are:

- ▶ To define an FLS model which is coherent with the Italian National Health Service (SSN), and aligned with the approach of the Recovery Plan, identifying connection points with the territory, the activities of the new healthcare professionals involved (such as nurses), and the digital touchpoints in the care pathway (such as telemedicine);
- ▶ To implement the model in 10 pilot centers and measure the process indicators, to evaluate the benefits for the patient;
- ▶ To create a network between the 10 pilot centers and communicate the results, so as to promote the adoption of the FLS by the SSN and by local health services, as well as its systemic diffusion.

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