

# **Osteoporosis and fragility fracture prevention in Bulgaria**

The Osteoporosis and Fragility Fracture Policy Network is a multi-stakeholder group aiming to raise awareness of osteoporosis and fragility fractures as a policy priority across Europe. The Network is independent and all work is non-promotional. The Expert Advisory Group and all other members provide their time for free. The Health Policy Partnership Ltd acts as secretariat to the Network, which is funded by Amgen (Europe) GmbH.

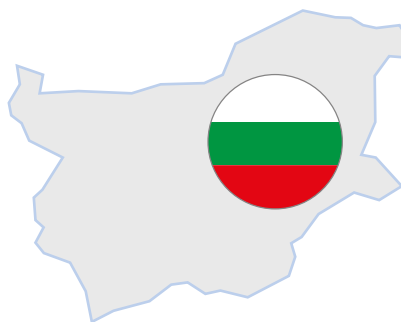
## Acknowledgements

Research, coordination and drafting of this country profile were undertaken by Taylor Morris, Jody Tate, Catherine Whicher and Madeleine Murphy of The Health Policy Partnership (HPP).

We are grateful to the individual who took the time to be interviewed for this country profile:

- **Mihail Boyanov**, Professor of Endocrinology, University Hospital Alexandrovska, Medical University Sofia; President, Bulgarian Society for Clinical Densitometry

# Introduction



**Osteoporosis is a chronic disease that weakens bones, leaving people at risk of painful and often life-changing fragility fractures.**<sup>1</sup> Bone mass naturally decreases as people age, but factors such as menopause, physical inactivity and certain medications can contribute to more rapid bone loss and the development of osteoporosis.<sup>2,3</sup> This usually does not cause any symptoms until a person sustains a fragility fracture – a fracture caused by a minor impact that would not usually be expected to break a bone.<sup>4,5</sup>

**The burden of osteoporosis and fragility fractures in the European Union is significant.** In 2010, it was estimated that 21% of women and 6% of men aged 50–84 in the EU were living with osteoporosis, contributing to nearly 10,000 fragility fractures each day.<sup>1</sup> In addition to the personal impact on patients and their families, these fractures represent a considerable cost for health systems.<sup>6</sup> They accounted for around 3% of healthcare spending in the EU in 2010,<sup>6</sup> which may be significantly higher than for many other chronic diseases, such as stroke or coronary heart disease.<sup>1,7</sup>

**Too often, the needs of people living with osteoporosis go unmet.** Osteoporosis frequently remains undetected until a serious fracture occurs and, even then, the vast majority of people do not receive treatment following a fracture.<sup>8</sup> In fact, medication use for osteoporosis is decreasing in one country in Europe<sup>9</sup> and access to evidence-based best-practice models of care is far from adequate.<sup>8</sup>

**This country profile aims to support policymakers and those advocating for change in Bulgaria by examining the prevention and management of osteoporosis and fragility fractures.** It is structured around five building blocks of an effective policy response which were first presented in *Osteoporosis and fragility fractures: a policy toolkit*.<sup>10</sup> The country profile aims to examine the policy and practice environments to identify effective strategies, examples of best practice and key areas for improvement. We hope this will support policymakers and clinicians at a national and local level to implement the required changes to ensure that best-practice care is available all those who need it so they can avoid fractures and maintain their quality of life, mobility and independence.

# Osteoporosis and fragility fractures in Bulgaria

## Burden and impact of osteoporosis and fragility fractures

**The burden of osteoporosis in Bulgaria is significant, although the amount spent on osteoporosis care is among the lowest in Europe.**<sup>1 11</sup> Based on European estimates, it is thought that approximately 21% of women and 6% of men aged 50 and over are estimated to be living with osteoporosis in Bulgaria.<sup>1 11</sup> This contributed to approximately 38,000 fragility fractures in 2010, a figure that is expected to increase to 40,000 by 2025.<sup>11</sup> In 2010, the health system spent around €42 million on osteoporosis, equating to €6 per capita – lower than every other country in the European Union except Romania.<sup>1 11</sup>

## Building a system that works: policies for scrutiny, accountability and investment

**Osteoporosis and fragility fractures are not currently prioritised at the policy level and there is no national registry to collect relevant data.** The National Osteoporosis Programme 2006–2010 was implemented to reduce the burden of osteoporosis and improve care,<sup>12</sup> but was terminated after the initial period of five years. Since then, there have been no further national efforts to address osteoporosis or fragility fractures, despite repeated calls for new programmes.<sup>13 14</sup> The current National Health Strategy action plan mentions the need to implement a new osteoporosis programme between 2016 and 2020,<sup>15</sup> and some proposals have been developed, but these were not adopted by the Ministry of Health.<sup>14</sup> In line with this seeming lack of national interest, there is no national registry to collect any data related to osteoporosis or fragility fractures.<sup>14</sup>

**Reimbursement policy in Bulgaria may restrict access to osteoporosis diagnosis and treatment.** Healthcare is provided through the public National Health Insurance Fund but out-of-pocket spending is relatively high, particularly for pharmaceuticals.<sup>16</sup> In 2014, 79% of pharmaceutical costs were paid out of pocket, leading to some concern over access to medications in Bulgaria.<sup>16</sup> Indeed, in 2010 it was estimated that 98% of men and 95% of women with osteoporosis were not being treated,<sup>11</sup> a problem reportedly related to the low level of reimbursement.<sup>13</sup> Osteoporosis medication is partially reimbursed for postmenopausal women but dual-energy X-ray absorptiometry (DXA) scans are not covered by the National Health Insurance Fund, restricting access for many people.<sup>14 17 18</sup>

## Catching it early: detection and management in primary care

**Assessment of fracture risk is recommended in clinical guidelines, but may not be routinely implemented.** Clinical guidelines published by the Bulgarian Society for Endocrinology recommend that fracture risk is assessed in all women aged 50 and over using medical history and the Fracture Risk Assessment Tool (FRAX®), followed by a DXA scan if necessary.<sup>19</sup> However, FRAX® is often not used in practice, reportedly due to the lack of a reliable country-specific model and the fact that it is not linked to reimbursement of treatment.<sup>14</sup> Given the lack of available data in the country, it is not clear how often osteoporosis is detected before a first fracture occurs.

**General practitioners (GPs) are usually responsible for the ongoing management of people with osteoporosis, but they often face significant barriers to providing best-practice care.** To initiate treatment, women at risk of osteoporosis should be referred by their GP to a specialist for an initial appointment, where they receive a prescription for osteoporosis medication if they are diagnosed with the disease.<sup>14</sup> After this appointment, the GP generally takes responsibility for further monitoring and the continued management of the patient.<sup>14</sup> However, it may be challenging for GPs to refer all eligible women to a specialist for osteoporosis as they are limited to a certain number of specialist referrals per month and other conditions are often prioritised.<sup>14</sup> In addition, the lack of reimbursement for DXA scans makes it difficult for clinicians to diagnose osteoporosis or monitor any changes in bone density and make informed decisions about stopping, continuing or changing medications in the medium to long term.<sup>14</sup>

### **Getting people back on track: facilitating multidisciplinary post-fracture care**

**Clinical practice and reimbursement policy may inhibit access to osteoporosis treatment for people who have sustained a fragility fracture.** Fragility fractures in Bulgaria are primarily treated by orthopaedic surgeons with little input from other specialists. While orthopaedic surgeons usually do not prescribe osteoporosis treatment, a person who has experienced a fragility fracture will frequently be referred to a rheumatologist or endocrinologist by the orthopaedic surgeon or the GP.<sup>14</sup> However, according to an expert interviewed for this country profile, fragility fractures are not part of the eligibility criteria for reimbursement of osteoporosis medication in Bulgaria, which is a significant barrier to appropriate post-fracture care and prevention of subsequent fractures.<sup>14</sup>

**Post-fracture follow-up care does not appear to be well-established in Bulgaria.** There do not seem to be any fracture liaison services (FLS) or similar programmes.<sup>14 20</sup> There have reportedly been some efforts to implement such services, but limited cooperation between specialists and a lack of national funding has restricted roll-out.<sup>14</sup>



**Prescribing osteoporosis medication after a hip fracture is a good common-sense measure. However, this strategy has not been adopted in Bulgaria.**



**MIHAIL BOYANOV, UNIVERSITY HOSPITAL ALEXANDROVSKA, MEDICAL UNIVERSITY SOFIA**

## Supporting quality of life as part of healthy and active ageing: prevention of falls and fractures in later life

**There is some national interest in healthy ageing, but little attention seems to have been paid to falls prevention in Bulgaria.** The Ministry of Labour and Social Policy has published a national ageing strategy, which focuses on supporting older people to remain socially and economically active and includes some references to health.<sup>21</sup> The National Health Strategy 2020 also discusses the importance of supporting healthy ageing and increasing life expectancy through improving lifestyle factors.<sup>21</sup> However, neither of these documents discusses preventing falls or fractures, and there does not currently seem to be any significant governmental interest in such initiatives.<sup>14</sup>

## Engaging patients and public: awareness, activation and self-management

**There has been some public education activity at a local level, but national organisations are primarily oriented towards professionals rather than the public.** Some local campaigns have been implemented in recent years, often focused on providing free or reduced-price DXA scans.<sup>18 23-25</sup> These campaigns have been linked to World Osteoporosis Day and International Women's Day.<sup>18 23-25</sup> In 2019, a city-wide World Osteoporosis Day awareness campaign was implemented in Burgas, which included risk assessments and a range of educational materials.<sup>26</sup> Civil society organisations, including the Bulgarian Rheumatology Society,<sup>27</sup> the Bulgarian Endocrinology Society<sup>28</sup> and the Bulgarian Society for Clinical Densitometry,<sup>29</sup> are engaged in improving osteoporosis care but focus primarily on professionals.

**Most people who are prescribed osteoporosis medication continue taking it for at least the first year.** While the type of medication and the frequency with which it is taken affect adherence,<sup>30</sup> a study looking at one particular drug found that the proportion of people still on medication after two years was 58.9%.<sup>31</sup>

## Conclusion

**There is an urgent need for policymakers to prioritise and invest in initiatives to better prevent and manage osteoporosis and fragility fractures in Bulgaria.** While osteoporosis was a policy priority until 2010, more recent efforts to raise its profile at national level have not been successful. Accordingly, programmes to improve prevention and treatment of osteoporosis, fragility fractures and falls have not been developed in the last decade. A shortage of national data makes it difficult to assess the scale of the problem, and the lack of reimbursement is a significant barrier to appropriate care.

## References

1. Hernlund E, Svedbom A, Ivergard M, *et al.* 2013. Osteoporosis in the European Union: medical management, epidemiology and economic burden. A report prepared in collaboration with the International Osteoporosis Foundation (IOF) and the European Federation of Pharmaceutical Industry Associations (EFPIA). *Arch Osteoporos* 8: 136
2. Hannan MT, Felson DT, Dawson-Hughes B, *et al.* 2000. Risk Factors for Longitudinal Bone Loss in Elderly Men and Women: The Framingham Osteoporosis Study. *J Bone Miner Res* 15(4): 710-20
3. Alswat KA. 2017. Gender Disparities in Osteoporosis. *J Clin Med Res* 9(5): 382-87
4. National Institute for Health and Care Excellence. 2017. *Osteoporosis: Assessing the risk of fragility fracture*. London: NICE
5. McCloskey EV, Rathi J, Heijmans S, *et al.* 2019. *Osteoporosis (op) diagnosis and treatment of women aged  $\geq 70$  years in primary care: results from a large european cross-sectional study*. Breda: Amgen
6. Kanis JA, Borgstrom F, Compston J, *et al.* 2013. SCOPE: a scorecard for osteoporosis in Europe. *Arch Osteoporos* 8: 144
7. Wilkins E, Wilson L, Wickramasinghe K, *et al.* 2017. *European cardiovascular disease statistics 2017*. Brussels: European Heart Network
8. International Osteoporosis Foundation. 2018. *Broken bones, broken lives: A roadmap to solve the fragility fracture crisis in Europe*. Nyon: IOF
9. Hurtado-Navarro I, Garcia-Sempere A, Rodriguez-Bernal C, *et al.* 2019. Impact of Drug Safety Warnings and Cost-Sharing Policies on Osteoporosis Drug Utilization in Spain: A Major Reduction But With the Persistence of Over and Underuse. Data From the ESOSVAL Cohort From 2009 to 2015. *Front Pharmacol* 10: 768
10. Budig K, Harding E, Morris T, *et al.* 2019. *Osteoporosis and fragility fractures: A policy toolkit*. London: The Health Policy Partnership
11. Svedbom A, Hernlund E, Ivergard M, *et al.* 2013. Osteoporosis in the European Union: a compendium of country-specific reports. *Arch Osteoporos* 8: 137
12. Ministry of Health. The National Osteoporosis Program 2006-2010 will limit the risk of disease and cases of disability. [Updated 29/06/06]. Available from: <http://www.mh.government.bg/bg/novini/aktualno/natsionalnata-programa-za-borba-s-osteoporozata-20/> [Accessed 27/04/21]
13. National Assembly of the Republic of Bulgaria. A national program for limiting osteoporosis in Bulgaria for a new five-year period is needed, said Dr Nigar Jafer, Chairman of the Health Care Committee. [Updated 10/04/14]. Available from: <https://parliament.bg/bg/news/ID/3088> [Accessed 27/04/21]
14. Boyanov M. 2020. Interview with Taylor Morris at The Health Policy Partnership [telephone]. 28/05/20
15. Ministry of Health of the Republic of Bulgaria. 2016. *Action plan for the completion of the National Health Strategy 2020*. Sofia: Ministry of Health
16. Dimova A, Rohova M, Atanasova E, *et al.* 2017. Drug policy in Bulgaria. *Value Health Reg Issues* 13: 50-54
17. Dexa Medical. Center for osteoporosis and osteometry - Varna. Available from: <http://www.dexamedical.com/%d1%82%d0%b5%d1%81%d1%82/> [Accessed 27/04/21]
18. Bulgarian National Radio. Campaign for prevention of osteoporosis in Varna. [Updated 10/03/20]. Available from: <https://www.bnr.bg/varna/post/101238437/kampania-za-prevenia-na-osteoporozata-vav-varna> [Accessed 27/04/21]
19. Bulgarian Society of Endocrinology. 2019. *Recommendations for good practice in osteoporosis*. Sofia: Bulgarian Society for Endocrinology
20. Capture the Fracture. Map of Best Practice. Available from: <https://www.capturethefracture.org/map-of-best-practice> [Accessed 27/04/21]
21. Ministry of Labour and Social Policy. *National strategy for an active life of adults in Bulgaria (2019-2030)*. Sofia: Ministry of Labour and Social Policy
22. Ministry of Health. 2016. *National Health Strategy 2020*. Sofia, Bulgaria: Ministry of Health
23. Peycheva G. They measure bone density in an osteoporosis campaign. [Updated 07/10/19]. Available from: <https://dariknews.bg/regioni/stara-zagora/izmervat-kostna-plytnost-v-kampaniia-za-osteoporozata-2190930> [Accessed 27/04/21]
24. Darik News. They measure bone density in an osteoporosis campaign. [Updated 09/10/17]. Available from: <https://dariknews.bg/regioni/ruse/izmervat-kostna-plytnost-v-kampaniia-za-osteoporozata-2053209> [Accessed 27/04/21]

25. Vratsa D. Prophylactic free bone density tests in Montana. [Updated 30/11/18]. Available from: <https://dariknews.bg/regioni/vraca/profilaktichni-bezplatni-pregledi-za-kostna-plytnost-v-montana-2134516> [Accessed 27/04/21]
26. World Osteoporosis Day. World Osteoporosis Day in Burgas, Bulgaria. [Archived web content]
27. Georgiev T, Stoilov R. 2019. Bulgarian rheumatology: science and practice in a cost-constrained environment. *Rheumatol Int* 39(3): 417-29
28. Bulgarian Society of Endocrinology. Good practices. Available from: <http://endo-bg.com/dobri-praktiki/> [Accessed 27/04/21]
29. International Osteoporosis Foundation. Bulgarian Society for Clinical Densitometry. Available from: [http://www.osteofound.org/member\\_societies/society\\_id\\_19.html](http://www.osteofound.org/member_societies/society_id_19.html) [Accessed 27/04/21]
30. Petranova T, Boyanov M, Shinkov A, *et al.* 2017. Medication-taking behaviour in Bulgarian women with postmenopausal osteoporosis treated with denosumab or monthly oral bisphosphonates. *Arch Osteoporos* 13(1): 1
31. Kuzmanova SI, Solakov PC, Geneva-Popova MG. 2011. Adherence to bisphosphonate therapy in postmenopausal osteoporotic women. *Folia Med (Plovdiv)* 53(3): 25-31