



وزارة الصحة
Ministry of Health

National Plan for Osteoporosis Prevention and Management in the Kingdom of Saudi Arabia

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National Plan for Osteoporosis Prevention and Management in the Kingdom of Saudi Arabia 2018

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Executive Summary

Osteoporosis has attracted much attention in the last two decades all over the world. Being a silent disease, it goes undetected many a times. Due to its prevalence worldwide, osteoporosis is considered a serious public health concern. Per International Osteoporosis Foundation, osteoporosis affects an estimated 75 million people in Europe, USA and Japan and causes, world wide, more than 8.9 million fractures annually, resulting in an osteoporotic fracture every 3 seconds. Approximately 30% of all postmenopausal women have osteoporosis in the United States (USA) and in Europe. At least 40% of these women and 15-30% of men will sustain one or more fragility fractures in their remaining lifetime. Ageing of populations worldwide will be responsible for a major increase in the incidence of osteoporosis in postmenopausal women.

The prevalence of osteoporosis and osteopenia in Saudi Arabia (KSA) is 37.8% and 28.2% in men and women above the age of 50 years. Vitamin D deficiency remains the major risk factor of the disease in the country. In 2015, it was estimated that the overall incidence of osteoporosis related femoral fractures could be 7,528 (1,300,336 population 55years or older) with the direct cost of SR 564.75 million (\$150.60 million).

Over the next few decades, the %age of Saudi population in the 50+ segment of total Saudi population is expected to rise steeply – 21% (2020), 26% (2025) and 30% (2030). Life expectancy will increase too – from 63.1 years in 1980s to 74.5 in 2015 and is further expected to rise to 79.3 by 2050. Given, the demographic shift in population over the next few decades the Kingdom can expect a rise in osteoporosis. It is high time that action is taken against osteoporosis as it was predicted by Bubshait et al. (2007) that the lifetime cost of fragility femoral fractures in KSA is expected to be SR 35 billion (\$9.34 billion) by 2025.

Though ample information exists, globally, on osteoporosis and its prevention, diagnosis, treatment and management, this knowledge is not being translated into useful practice. The onus of reducing osteoporosis prevalence and managing the disease in KSA is not just on Health care Professionals (HCPs) or the Ministry of Health (MoH) but also on the the public. The public plays a crucial role in curbing its burden in the country just by being aware about the disease and its repercussions. Additionally, the public, patients, healthcare professionals (HCPs), health providers and the government need to work hand-

in-hand to bring the disease under control, indirectly reducing the cost burden of the same on the country.

Keeping these in mind, this action plan has been developed by leveraging multiple sources of information. Following are the key sources that have led to this plan coming to fruition:

- Extensive literature search on Pubmed for published literature about osteoporosis in KSA and search engines for reports, new articles etc. to drive local disease landscape development
- Inputs from National Action Plan Working Group members (MoH and SoS), in the form of one on one discussions, reports and publications, on local treatment, disease management and patient journey insights
- Published literature on the action plans of Ontario and Australia to be used a benchmarks
- Inputs from National Action Plan Working Group members – Dr. Khan and Dr. Kendler, in the form of one on one discussions, reports and publications, on execution of Ontario Osteoporosis Strategy and best practices to implement in KSA
- National Action Plan Working Group Meeting on the 20th of December 2017 in Riyadh, KSA, to discuss the first draft and finalize recommendations

Following is a brief summary of recommendations posited in this action plan to better manage and prevent osteoporosis in KSA.

A. Education and Health Promotion

Recent Knowledge Attitude and Practice (KAP) surveys among general Saudi population reveal that knowledge of osteoporosis is low and consequently the attitude and practices towards this disease are poor. Good knowledge and awareness of a disease are pre-requisites for the success of preventive measures, modifications in life styles and treatment adherence.

Recommendation 1:

Create materials and programs for the community focused on increasing public knowledge around:

- Education about the disease to minimize the risks for osteoporosis in low and high risk population
- Healthy dietary intake with fruits and vegetables, Vitamin D, Calcium and other vital elements to maintain bone health
- Importance of regular physical activity
- Disease management and bone health among children and adolescents

Recommendation 2:

Train and educate medical trainees and HCPs through college programs and "Continuous Medical Education" (CME) in order to:

- Promote importance of musculoskeletal health in all the fields
- Highlight their important role in the prevention, treatment and management of the disease

B. Screening, Diagnosis and Treatment

Early detection and consequently early treatment of osteoporosis are necessary in curbing the prevalence of the disease in the country as they will aid in the reduction of number of patients presenting with fractures and decrease the overall cost burden on an individual and the country.

Recommendation 3:

Enhance the role of General Physicians (GPs)/Primary Care Physicians (PCPs)/Family Physicians to diagnose and treat osteoporosis at early stages through:

- Evidence based modules to identify patients at risk and then have them investigated and treated for osteoporosis
- GP guidelines to address disease management
- Increased availability of Dual-energy X-ray absorptiometry (DEXA) in primary care centers clusters and ensure implementation of uniform guidelines

Recommendation 4:

Update local guideline and ensuring it is uniformly followed; nature of guideline to be more prescriptive rather than descriptive. Ensure guidelines are updated every 2 year.

Recommendation 5:

Instate a national level mandatory BMD reporting certification course and further develop:

- A local adaptation of the International Society for Clinical Densitometry (ISCD) certification course
- Guidelines and tools/algorithms at primary care level to outline everything HCPs need to know to deliver the highest quality densitometry

Recommendation 6:

Develop or improve on existing assessment tools for predicting the incidence of fractures in individuals

- Develop a clinically proven, government certified fracture risk calculator (FRAX) for the Saudi context
- Establish databases for diagnosed patients and standardize DEXA software used across KSA

C. Post-Fracture Care Management and Secondary Prevention

It has been noted in a study that the 1-year mortality rate associated with fragility femoral fractures was high and survivors exhibited significant functional disability. This indicates that post-fracture care in KSA is not as established as it should be.

Recommendation 7:

Establish fracture liaison services (FLS) and rehabilitation services to prevent further fractures and improve quality of life. This FLS service will be comprised of care/nurse coordinators and should be available in all large public sector medical hospital, providing treatment for osteoporosis and fragility fracture. Further, best practices from established rehabilitation centers should be disseminated and adopted across KSA.

D. Self-management and Falls Prevention

Recommendation 8:

Effective disease management ultimately lies in the hands of the individual patient, who must take responsibility for key health behaviors related to bone health. According to a study to identify the risks of falls in KSA, it was noted that low physical activity score, past-year history of falls, advancing age, presence of knee osteoarthritis (OA), poor handgrip strength, and poor performance on the 8-FW test (in decreasing order of impact) are the key reasons for falls. Hence

it is key to build support for people with or at high risk of osteoporosis and develop non-pharmacologic interventions directed at preventing falls.

E. Research and Evaluation

In order to know the impact of the national plan on the country's public health, an evaluation committee needs to be set up that overlooks the implementation and monitors the outcomes. Research into osteoporosis is much lesser in KSA as compared to that in western countries. As of 2012, Saudi Arabia ranked 45th globally with respect to scientific output related to osteoporosis.

Recommendation 9:

Generate credible disease data and real world evidence on osteoporosis in KSA

1. Conduct a prospective multi-center cohort study which will measure the incidence and prevalence of osteoporosis and fractures, and the effect of putative risk factors
2. Create a conducive regulatory and financial atmosphere which encourages industry or investigator driven real world studies in various hospitals (public and private)
3. Establish a committee to set up a National Fracture Registry and National Registry for Patients Diagnosed via BMD which ensure that necessary steps are taken to establish both registries over the next 2-3 years. Initially, the fracture registry can focus on a small population such as atypical femoral fractures and then scaled up.

Recommendation 10:

Form a committee that overlooks the implementation and outcome of the National Action Plan in Saudi Arabia in order to quantify and qualify the impact of the actions on the prevalence and incidence of the disease in the country and to ensure broader alignment to the KPIs set under the National Transformation Plan (NTP) 2020 in vision of 2030

Recommendation 11:

Ensure necessary long-term research and knowledge transfer in osteoporosis through activities, in collaboration with KACST, Universities, NGOs and Saudi Health Council.

Implementation of the action plan is entrenched in cross-stakeholder collaboration. While the Ministry of Health is responsible for the overall execution of the plan, following stakeholders will be key for the success of this plan and establishing KSA as the center of excellence for Osteoporosis prevention and management in the Middle East region.

- Public Health Units – National Guard (NGHA), Ministry of Defense (MODA), Ministry of Municipalities and Rural Affairs (MOMRA),

Ministry of Education (MoE), Security Forces Hospitals (SFH) etc.

- School students and Teachers
- Primary care patients
- Health care professionals
- Healthcare workers
- Researchers
- Professional Medical Associations
- Government Agencies
- Medical schools

Finally, short term and long terms goals will be set to measure and track the performance of actions taken by stakeholders to achieve each of the recommendations.

Some key actions recommended on this action plan contribute to the achievement of a no. of KPIs set by the NTP for the MoH.

NTP KPI	Action Plan Recommendations
Increase number of resident Saudi physicians who are enrolled in training programs	Recommendations 2, 3 and 11
Increase number of qualified Saudis in the field of nursing and support staff for every 100,000 people	Recommendations 2, 3, 7, 8 and 11
Increase number of primary healthcare visits per capita	Recommendations 1, 2, 3, 7 and 8
Increase percentage of patients who get health care after critical care and long term hospitalization within 4 weeks	Recommendation 7

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INTRODUCTION

What is Osteoporosis?

Per the International Osteoporosis Foundation (IOF), osteoporosis, which literally means porous bone, is a disease in which the density and quality 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. Often there are no symptoms until the first fracture occurs.¹

Bones are living tissue and constantly changing. From the moment of birth until young adulthood, bones are developing and strengthening. Bones are at their most dense in the early 20s - called peak bone mass. With age, some of the bone cells begin to dissolve bone matrix (resorption), while new bone cells deposit osteoid (formation). This process is known as remodeling.¹ For people with osteoporosis, bone loss outpaces the growth of new bone. Bones become porous, brittle and prone to fracture.¹

Who is at Risk?

Osteoporosis is often referred to as the "silent disease" as bone loss is gradual and painless, and there are usually no symptoms to indicate a person is developing osteoporosis. Most commonly, osteoporotic fractures occur at the spine, the wrist or the hip, although osteoporotic fractures can occur in other bones as well. Since there are usually no outward signs of osteoporosis developing, doctors will often recommend diagnostic testing depending on age and existence of other risk factors for the disease.²

A risk factor is anything that increases the chance of getting a disease. Having a risk factor, or even several, does not mean an individual will develop osteoporosis. However, the more risk factors, the greater the chance of developing a disease and also, the greater the level of each risk factor, the greater the risk.³

There are different kinds of risk factors - fixed and modifiable. Fixed risks that cannot be changed include age, gender, family history of osteoporosis, ethnicity, menopause, long term glucocorticoid therapy, rheumatoid arthritis and primary/secondary hypogonadism in men.⁴⁻⁷ Modifiable risks directly impact bone biology and result in a decrease in bone mineral density (BMD), but some of them also increase the risk of fracture independently of their effect on bone itself, and they include alcohol, smoking, vitamin D deficiency, poor nutrition, insufficient exercise, low dietary calcium intake, frequent falls etc.^{8,9}

What is the global disease landscape?

Osteoporosis is estimated to affect 200 million women worldwide - approximately one-tenth of women aged 60, one-fifth of women aged 70, two-fifths of women aged 80 and two-thirds of women aged 90.¹⁰ Osteoporosis affects an estimated 75 million people in Europe, USA and Japan.¹¹ For the year 2000, there were an estimated 9 million new osteoporotic fractures, of which 1.6 million were at the hip, 1.7 million were at the forearm and 1.4 million were clinical vertebral fractures. Europe and the Americas accounted for 51% of all these fractures, while most of the remainder occurred in the Western Pacific region and Southeast Asia.¹² Worldwide, 1 in 3 women over age 50 will experience osteoporotic fractures, as will 1 in 5 men aged over 50.^{13,14,15} 80%, 75%, 70% and 58% of forearm, humerus, hip and spine fractures, respectively, occur in women. Overall, 61% of osteoporotic fractures occur in women, with a female-to-male ratio of 1.6.¹²

Nearly 75% of hip, spine and distal forearm fractures occur among patients 65 years old or over.¹⁶ A 10% loss of bone mass in the vertebrae can double the risk of vertebral fractures, and similarly, a 10% loss of bone mass in the hip can result in a 2.5 times greater risk of hip fracture.¹⁷ By 2050, the worldwide incidence of hip fracture in men and women is projected to increase by 310% and 240%, compared to rates in 1990.¹⁸ Osteoporosis takes a huge personal and economic toll. In Europe, the disability due to osteoporosis is greater than that caused by cancers (with the exception of lung cancer) and is comparable or greater than that lost to a variety of chronic non-communicable diseases, such as rheumatoid arthritis, asthma and high blood pressure related heart disease.¹²

KSA SITUATIONAL ANALYSIS

Disease landscape in Saudi Arabia

It is difficult to give a clear estimate of the prevalence of osteoporosis in KSA as the rate largely depends on the characteristics of the different population groups. However, the study by Ardawi et al. (2005) gives rates for two anatomical sites, using a Saudi and US/European reference. This study conducted among 1,980 healthy volunteers in Jeddah found a prevalence of either spine or femur osteoporosis of 28.2% and 37.8% among women and men above 50 years respectively (Saudi reference).¹⁹ In a recently published retrospective study on 371 men aged over 50 years old and referred for DEXA at a tertiary hospital in KSA, 59.8% were osteoporotic based on spinal T score.²⁰

According to Saudi General Authority for Statistics, the population of KSA, in mid-2017, was 32.6 Mn, of which 63% composed of Saudi Nationals.²¹ Individuals over 50 years of age comprise of 14% of the Saudi National population. Applying the prevalence rates estimated by Ardawi et al. (2005), one reaches a total osteoporotic population of ~940,000 in 2017 (~546,000 in men and ~394,000 in women).^{19,21}

Between 2007 and 2017, the proportion of Saudis >50 years of age grew from 10.5% to 13.9% of the total Saudi population.²¹ Consequently (in Figure 1), the estimated burden of osteoporosis in Saudi nationals >50 years old has increased by more than 1.5 times.^{19,21}

The most recent estimate of the incidence of fractures of the proximal femur comes from Sadat-Ali et al. (2015). The study provides data on all 780 proximal femur fractures collected from 24 of the 28 hospitals in the Eastern Province, in a population aged 55 years and older. The overall incidence found was 4,950/1,000,000 person-years and, in general, it increases with increasing age (Figure 2). In the older age groups (>70), incidence is higher among women compared to men.²²

Figure 1: >50 years old Saudi National population and estimated osteoporosis prevalence

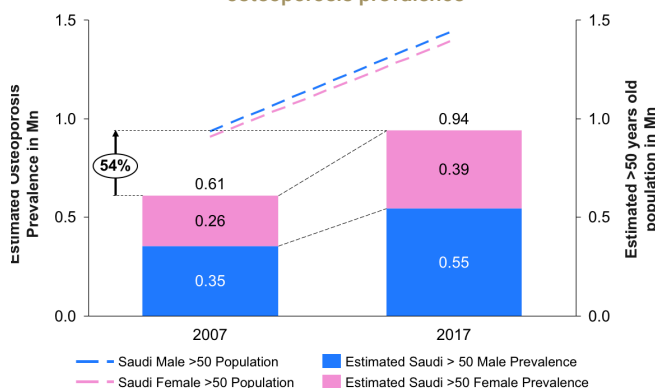
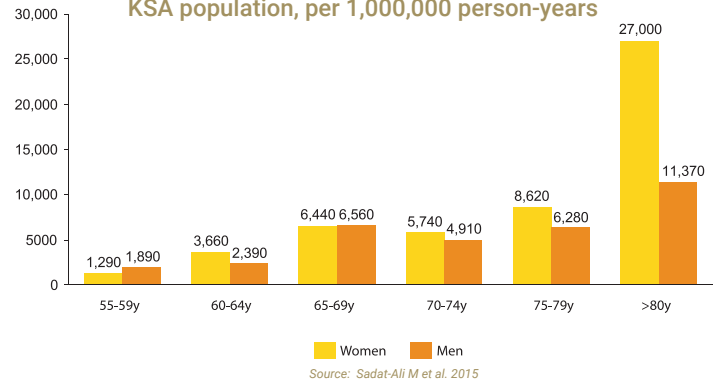


Figure 2: Annual femur fracture rate in the KSA population, per 1,000,000 person-years



The cost and consequences of osteoporosis

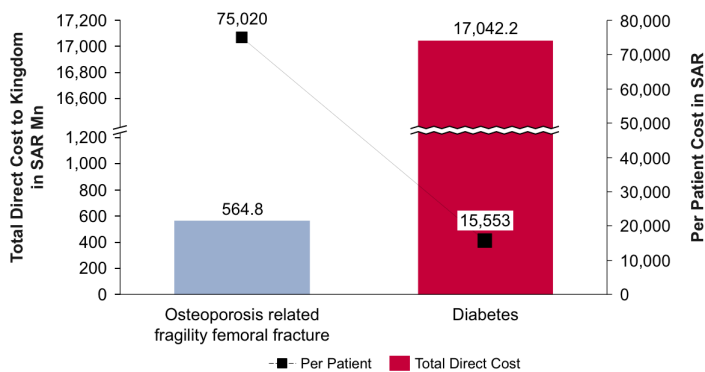
Osteoporosis causes painful breaks and fractures leading to reduced mobility, reduced health generally and reduced quality of life. Fractures due to osteoporosis, including at the hip and pelvis, spine, ribs, wrist, forearm and upper arm, and ankle and foot, can result in chronic pain, disability, loss of independence and premature death, especially from hip and spine fractures.

Wrist and forearm fractures may affect the ability to write or type, prepare meals, perform personal care tasks like eating, dressing or going to the toilet, or manage household chores. Fractures of the spine and hip can affect mobility, making activities such as walking, climbing stairs, bending, lifting, pulling or pushing difficult. Hip fractures, in particular, often lead to a marked loss of independence and reduced wellbeing.

Bubshait et al. (2007) estimated that the total costs of a hospital stay after a fragility femoral fracture was around 50,000 Saudi Riyals (SAR) between 2001 and 2006.²³ Further, on a national basis, with a population of 1,461,401 Saudis aged 50 years or more, 8,768 would suffer femoral fractures yearly at a cost of SAR 4.27 billion (US\$1.14 billion).²³ Sadat-Ali et al. (2015) extrapolated that the overall incidence of osteoporosis related femoral fractures could be 7,528 (1,300,336 population 55 years or older) with the direct cost of SAR 564.75 million (\$150.60 million).²² This translates to approximately SAR 75,000 per fragility femoral fracture. Indirect costs - Costs due to productivity losses - were assumed to be three times the direct costs. The yearly indirect costs were assessed at SAR 1,693,800,000, making the total costs to treat fragility femoral fractures for the first year SAR 2,358,550,000 (\$USD 628.95 million).²² Even though the overall direct cost of osteoporosis related femoral fragility fractures to the Kingdom are estimated to be much lower than the total direct cost of diabetes (in Figure 3), the per patient direct cost is almost 4 fold. Hence, it is

very important to detect and treat osteoporosis early in order to avoid the high cost burden when patients present at much later stages with a fragility fracture.

Figure 3: Direct cost comparison of osteoporosis related fragility femoral fracture v/s diabetes

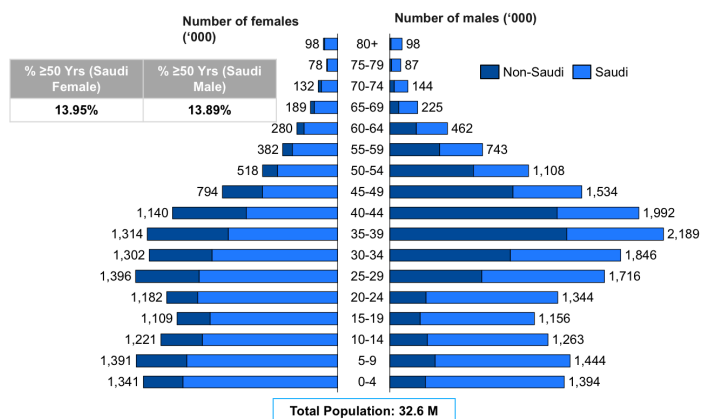


Source: Osteoporosis related fragility femoral fracture from Sadat-Ali M et al. 2015 and diabetes costs from Mokdad AH, et al. (2015) Cost of Diabetes in the Kingdom of Saudi Arabia, 2014. J Diabetes Metab 6: 575

Osteoporosis – A National Health Priority

Saudi Arabia's current population demographic is young and skewed towards the age group of 20-50, which makes ~47% of the population. The 50+ Saudi demographic constitute ~14% of the total Saudi population (Figure 4).²¹

Figure 4: Saudi Arabia Population Age Pyramid 2017



Source: Saudi General Authority for Statistics

Over the next few decades, the %age of Saudi population in the 50+ years old segment of total Saudi population is expected to rise steeply – 21% (2020), 26% (2025) and 30% (2030).²⁴ Life expectancy will increase too – from 63.1 years in 1980s to 74.5 in 2015 and is further expected to rise to 79.4 by 2050.²⁵ Given the impending demographic shift in population over the next few decades, KSA can expect a steep rise in Osteoporosis. Unless action is taken now, things can only get worse. By 2030, it is estimated, there will be 2.5 million Saudis aged 50 years or older with osteoporosis^{19,24} – a 76% increase from 2017 and it was projected that, by 2025, the lifetime cost of fragility femoral fractures is

expected to be SAR 35 billion (\$9.34 billion).²³ But if interventions are made now, it would be more likely to reduce this impending financial burden and shift focus to early detection and prevention. These would be aligned with many of the strategic objectives of the NTP for MoH dictating the “increase in efficient utilization of available resources”.²⁶

Steps taken till now

Many steps have been taken till, most of which are credited to the diligence of the MoH and the Saudi Osteoporosis Society (SoS)

- In July 2004, local recommendations and guidelines for the diagnosis and management of osteoporosis were made by the King Faisal Specialist Hospital and Research Center (KFSHRC). These were later updated in 2011.²⁷
- Proceeding from the MoH's keen interest in raising health awareness, and in an endeavor to overcome the silent disease, a National Osteoporosis Awareness Campaign under the name “Immunize Your Bones!” was launched on the World Osteoporosis Day, 2006. It was projected to last for 6 months to target the Saudi population, mostly women. Information that was given during the campaign related to risks of the disease, importance of getting screened, its treatment and most importantly, its prevention.²⁸
- To further create awareness of osteoporosis in KSA, the society “Osteo-Club”, under SoS held scientific activities in 2010 in the format of presentations and discussions in Riyadh. The topics of discussion ranged from epidemiology of osteoporosis to its treatment. In addition, workshops funded by the SoS entitled “Bone Builders” and “Osteo-Strong” were designed to reach different parts of the Kingdom.²⁷
- In the same year, several bone health experts from KSA participated in an Osteoporosis prevention awareness event held at a private hospital in Riyadh. The event was held with the support of a private fast-moving consumer goods company. The event aimed at promoting awareness of the importance of preventing Osteoporosis through a combination of healthy nutrition, physical activity and a generally balanced lifestyle.²⁹
- 2011 was a year that saw many activities from the SoS. It signed an agreement with Prince Miteb Chair for Biomarkers Research on Osteoporosis (PMCO) at King Saud University in Riyadh. The agreement covered various aspects of collaboration like sharing symposia, workshops, seminars, various research projects, public and professional education. In addition, it published its first bulletin on osteoporosis to provide education and updates to the doctors.³⁰
- In 2011, local recommendations and guidelines for the diagnosis and management of osteoporosis (from 2004) were updated by the Working Group of KFSHRC.²⁷

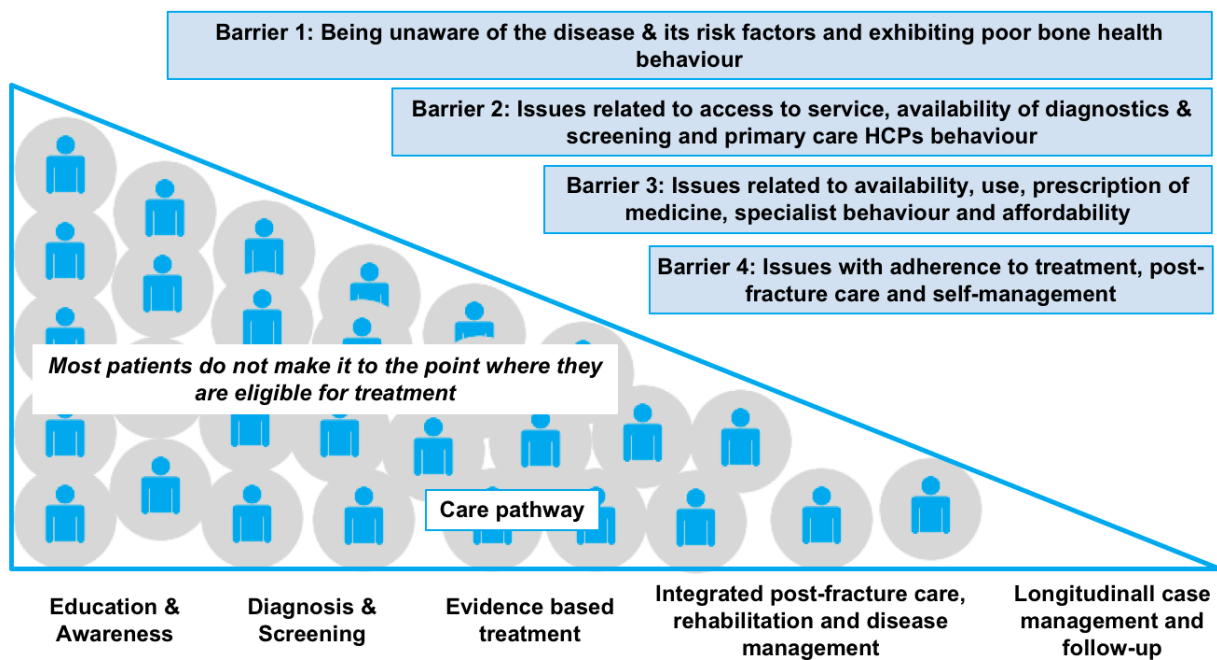
- 2012 saw the first international osteoporosis symposium held in KSA and an osteoporosis workshop in Jeddah, both held by the SoS. Additionally, it signed a collaboration agreement with King Saud University (KSU) to advance osteoporosis research.³¹
- 2015 saw a major step taken by the SoS: Guidelines for medical professionals in KSA regarding osteoporosis were published, with the help of a panel of 14 local experts in osteoporosis who assembled to provide consensus based on the strength of evidence and expert opinions on osteoporosis treatment.³² In the following year, a third international conference on osteoporosis was held by SoS in Jeddah, featuring international speakers.
- In 2017, the National Guard Minister signed a Memorandum of Understanding (MoU) with PMCO at KSU for collaboration in osteoporosis

research advancement. Prince Miteb was also informed about PMCO's participation in the recently concluded World Congress on Osteoporosis and Osteoarthritis (WCO) in Florence, Italy.³³

Gaps in Osteoporosis patient care pathway – Need for an Osteoporosis Action Plan

Even with multiple previous interventions, there still exists a no. of gaps and unmet needs on the osteoporosis care pathway in KSA. Figure 5, represent a conceptual care pathway for Osteoporosis and the barriers affecting the movement of patients across the care pathway, inevitably reducing the no. of patients receiving effective treatment.

Figure 5: Four barriers across the care pathway stop most patients from accessing effective disease management



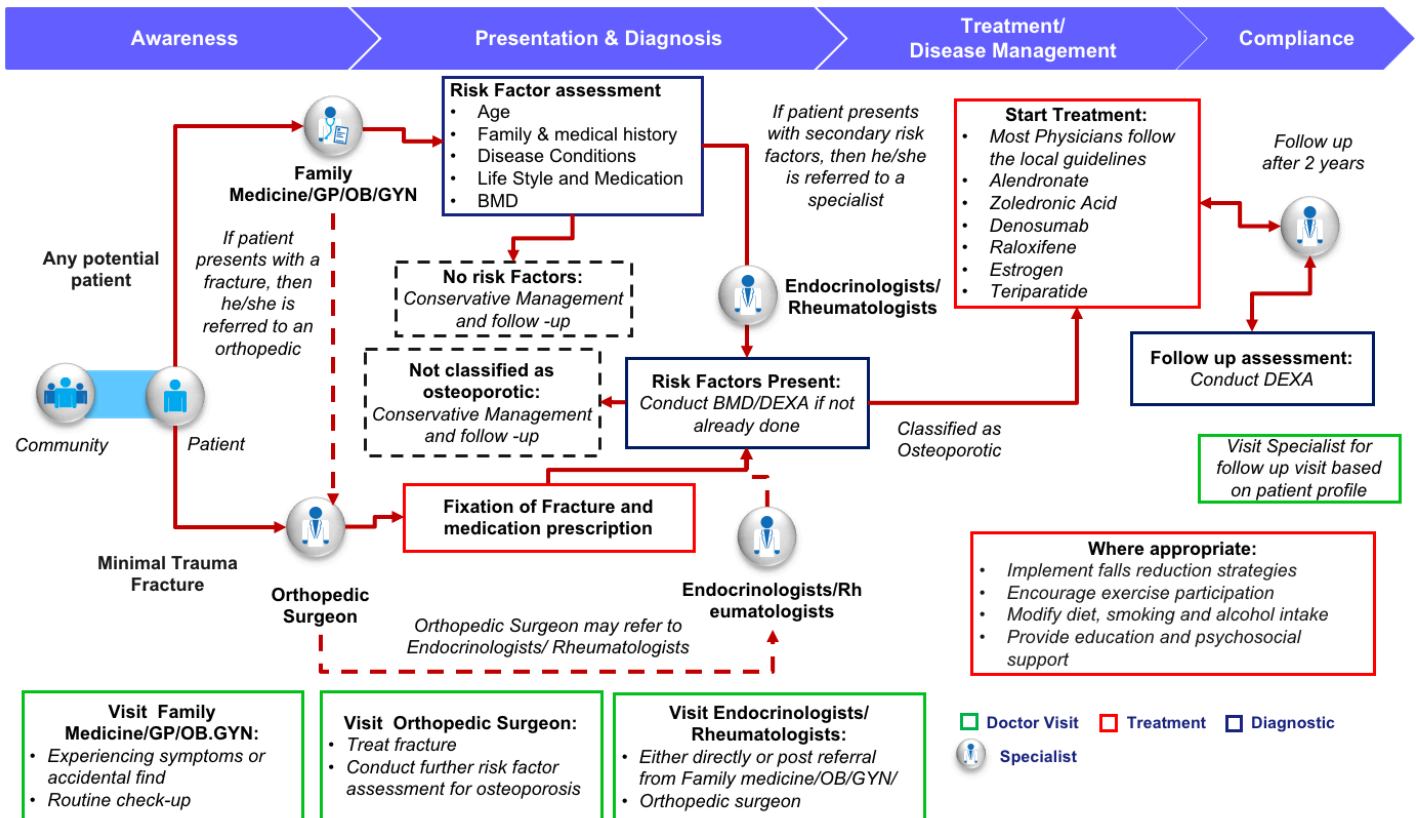
Source: IQVIA Analysis

Further in Figure 6, based on inputs from the members of the National Action Plan Working Group, the osteoporosis patient journey, in KSA, is highlighted. The journey starts when a patient approaches a family medicine physician/ GP/obstetrician-gynecologist/endocrinologist/rheumatologist/orthopedist as a non-fracture or a fragility fracture patient and ends in chronic treatment/ follow-up. Certain aspects stressed by the members of the National Action Plan Working Group on the osteoporosis journey of a Saudi Patient are:

a. While patients should be always referred from primary care physicians, they often approach specialists directly

- In certain hospitals or healthcare clusters (frequently in rural areas), there are no treating specialists (endocrinologists/rheumatologists). In such cases, GPs or family medicine physicians may manage the patient
- Role of the primary care health care professionals has to be enhanced to funnel in more patients on the care pathway
- Local FRAX is not yet available to calculate fracture risk

Figure 6: Osteoporosis Patient Journey in KSA



Source: Inputs from National Action Plan Working Group

Table 1 reflects on the gaps in the care pathway in KSA based on local evidence on osteoporosis and how it is managed in KSA.

Table 1: Gaps in osteoporosis management and prevention in KSA

	Gap	Evidence
Education	Osteoporosis and dietary awareness in children	<ul style="list-style-type: none"> %age of girls was significantly higher who thought that fruits and vegetables are not rich sources of vitamin D (24.7% girls vs. 15.4% boys and 29.6% girls vs. 20.9%), respectively.³⁵ Vitamin D deficiency was significantly higher in girls than boys (47.0% versus 19.4%) and Vitamin D status in boys was significantly higher than girls.³⁵
	Osteoporosis awareness in adults	<ul style="list-style-type: none"> In a cross sectional study including 505 participants, conducted in several malls of Riyadh city during March 2012, 86% of the participants had heard of osteoporosis.³⁶ Media was the main source for Participants' knowledge; mean knowledge score was 56.6% of the maximum achievable score.³⁶
	Vitamin D levels, calcium intake and dietary sufficiency	<ul style="list-style-type: none"> A systematic review on the prevalence studies (2011 to 2016) revealed that the prevalence of vitamin D deficiency (<50 nmol/l) in KSA among different populations (adults, children and adolescents, newborns and pregnant/lactating women) is 81.0%.³⁷ In a study conducted on 100 Saudi women above 40 years of age who were outpatients in Arar Central Hospital (Northern Saudi Arabia) during a period of four months, 82% had vitamin D deficiency.³⁸
Diagnosis	Adequate access to and frequency of BMD testing for high risk population	<ul style="list-style-type: none"> In a retrospective cross-sectional study conducted in the orthopedic surgery clinics at a university medical city in Riyadh – 951 >=70 years in males and >=65 years females attended the orthopedic surgery clinic over 15 months.³⁹ Only 487 patients (51.21%) had received BMD testing – among them 430 were females (64.66%) and 57 were males (19.93%) 172 had osteopenia (35%) and 190 had osteoporosis (39%).³⁹
	Family physicians and GPs usage and attitude towards BMD testing	<ul style="list-style-type: none"> In a study assessing the levels of Knowledge, Attitude and Practice towards osteoporosis among 364 PCPs across KSA, around 60% of the respondents reported that they examine their patients for kyphosis, loss of height and loss of weight.⁴⁰ For the main tools of investigations; only 13% of respondents declared that they have access to perform BMD and only 20% can ask for biochemical marking testing for their patients.⁴⁰
	Poor BMD testing rates linked to low treatment rates in at-risk population	<ul style="list-style-type: none"> In a study analyzing the chest radiographs of consecutive Saudi Arabian men ≥ 50 years and who visited the emergency room in a secondary hospital, 876 radiographs could be analyzed.⁴¹ 115 patients (13.1%) had 157 fractures.⁴¹ 22.6% of patients had a report by a radiologist that indicated a vertebral fracture, but the physicians still failed to take notice.⁴¹ Eight patients (6.9%) had a bone mineral density scan was ordered and none of the men who had spinal fracture were on antiresorptive therapy.⁴¹
Post-Fracture Care	Osteoporosis testing for post fragility fracture patient and reporting of BMD in such patients	<ul style="list-style-type: none"> In a retrospective analysis of all admission and discharge; medical and pharmacy records database of patients over ≥ 50 years with fragility fracture between January 2001 and December 2011.⁴² 207 patients were admitted with a fragility fracture; DEXA scan was ordered in 49 (23.6%). There were 20 males and 29 females with the mean age of 68.8 (11.9) years.⁴² It was found that only 22.7% of the admitted patients with fragility fracture got the recommended treatment for the condition which is calcium, vitamin D, antiresorptive/anabolic agent.⁴² The number of untreated patients who got at least vitamin D and calcium dropped from over 76% in 2001 to 30% in 2011.⁴²
	Physicians follow up on osteoporosis treatment of post fragility fracture patients	<ul style="list-style-type: none"> In a study aimed to determine hospital-based prevalence of vertebral fractures in postmenopausal Saudi Arabian women. Chest radiographs from consecutive Saudi women over the age of 50 years visiting the emergency room at secondary hospital were assessed.⁴³ Of 785 radiographs analyzed 159 (20.3%) patients had 198 vertebral fractures. The mean age of the women was 65.7 years.⁴³ In only 37.8% of the radiographs with fractures was a vertebral fracture highlighted in the radiologist's report, and only 13.2% of the women with vertebral fractures were on antiresorptive therapy for osteoporosis.⁴³
	Post-fracture patients starting on osteoporosis treatment	
Others	Credible epidemiology data and osteoporosis scientific output	<ul style="list-style-type: none"> With respect to scientific output related to osteoporosis till 2012, Saudi ranked 45th in the work. Research about osteoporosis from Arab countries was very low until 2002 and then increased steadily. A total of 426 documents about "osteoporosis" were published from Arab countries which represents 0.98% of the global research output; Saudi Arabia with 97 publications behind Egypt with 117. Thirty (7.04%) documents published from Arab countries about osteoporosis were published in Saudi Medical Journal.⁴⁴
	At-risk population at high pre-disposition to fall and adhere to medication	<ul style="list-style-type: none"> In a study to identify the risk factors for falls in Saudi postmenopausal (>50 years) , a prospective cohort study of 707 women was followed. During the mean follow-up of 5.2 years, 164 women (23.2%) reported at least one fall, of whom 73 women (10.3%) reported multiple falls. Six independent predictors of all falls were identified: poor physical activity score, past-year history of falls, age 65 years or older, presence of knee OA, poor handgrip strength, and prolonged time on the 8-ft walk test.⁴⁵

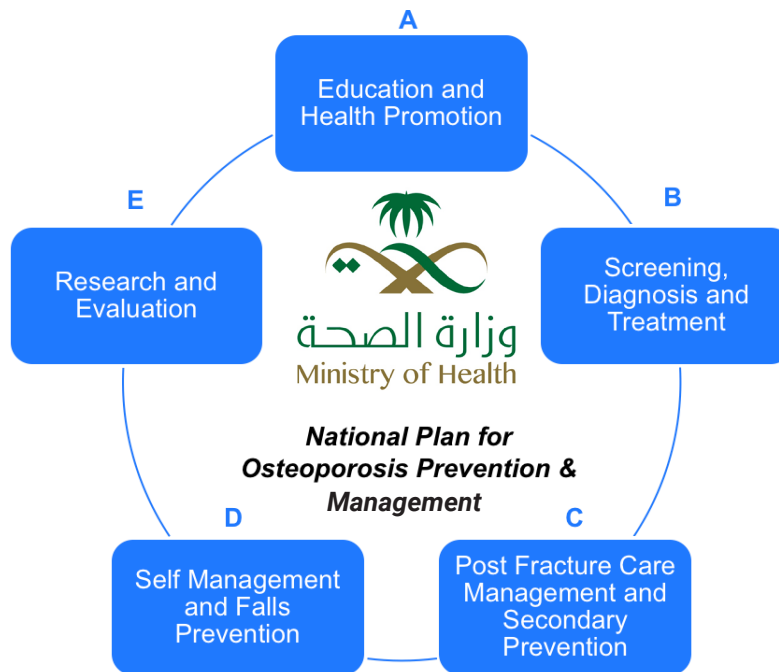
Consequences of these gaps can be severe in terms of overall health of the Saudi population, can reduce productivity of the society and may lead to economic strain on the healthcare system as patient eventually present themselves at much later stage of fragility fracture/re-fracture instead of at early low/medium-risk conditions. **Key consequences include:**

1. The peak rate of bone mass development occurs around age 13 for girls and age 14.5 for boys.⁴⁶ People with a high peak bone mass in early life have a lower risk of bone thinning in later life.^{47,48} Hence poor dietary habits, low level of physical activity and insufficient levels of calcium/vitamin-D may lead to an increased predisposition to developing bone-related issues such as osteopenia and osteoporosis in later life.
2. Poor awareness about the disease and low vitamin-D levels among senior and high-risk populations may manifest themselves as fragility fractures.
3. Limited role of family physicians and GPs from the osteoporosis care pathway compounds the problems of poor diagnosis rates and consequent low treatment initiation/persistence.

4. Insufficient post-fracture BMD testing, inadequate anti-resorptive therapy initiation and lack of fall prevention support reveal as re-fractures which not only cause trauma to senior citizens but also leads to expenditure that could have been avoid to begin with.

A comprehensive strategy (Figure 7) will help to raise public awareness, change the knowledge, attitudes and behaviors of both the public and health professionals, and improve prevention and treatment of the disease. KSA must act quickly to keep pace with international standards for osteoporosis prevention, diagnosis and management. Many jurisdictions around the world, such as Canada and Australia, have already developed evidence-based recommendations for all levels of care for osteoporosis.

Figure 7: Key areas of focus for the KSA Osteoporosis Plan for Prevention and Management



RECOMMENDATIONS FOR ACTION PLAN

A. Education and Health Promotion

Recommendation 1: Create educational materials and programs for the community

Maintaining strong, healthy bones is a lifelong process, which begins at birth and continues throughout life. Individuals, families and HCPs play a critical role in understanding and promoting bone health for children, middle-aged and aging adults and at-risk seniors.

Sub-optimal bone growth in childhood or adolescence and/or loss of bone mass later in life are some of the pre-disposing factors to the development of osteoporosis. Hence, preventative measures like bone health education should be addressed early in life through activities that focus on health promotion and primary prevention.

Through effective bone health promotion activities, bone fractures will be reduced, quality of life will be enhanced, osteoporosis-related healthcare costs will be reduced and overall, the public will be better equipped to reduce the risks predisposing to osteoporosis.

1.1. Increase awareness of disease and its risk factors among community members

Increasing general awareness of the disease is the step towards primary prevention, which has a potential to contribute to early detection and diagnosis of osteoporosis, effective treatment, better compliance to medication, falls/fracture prevention and ultimately patient and physician satisfaction to overall bone health care. Public knowledge needs to be enhanced to prevent the condition more effectively and to render positive outcomes via:

- Campaigns tailored to the needs of each age group and gender (owing to cultural beliefs and customs), addressing topics on osteoporosis, its risk factors and how it can be avoided.
- Programs at primary health care levels, sponsored by public health authorities, to upraise the awareness of the community.
- Patient education materials (booklets, brochures and posters) should be developed for use in the primary care setting and/or disseminated by physicians and community pharmacists.
- Secondary sources like social media (SMS and short videos) as to spread awareness of the disease as 70% of the population of KSA has access to internet.⁴⁹

Performance measures for recommendation 1.1

1. No. of proactive visits, by 50-64 years old, at primary care due to osteoporosis in control and test communities pre- and post-intervention (risk assessment).
2. No. of BMD tests, in >65 year old, in control and test communities pre- and post-intervention
3. No. of chronic disease prevention and health promotion campaigns integrating bone health messages per year
5. Biennial evaluation of the process and impact of health promotion / communication strategies by surveilling the public (knowledge of disease, risk factors, GP counselling about disease) and documenting program frequency and reach

1.2. Promote healthy eating and regular physical activity

A healthy diet, rich in essential elements, help in reducing bone loss in the elderly.

Two elements, Calcium and Vitamin D are critical to good bone health, in addition to other elements like phosphorous and magnesium which are essential in its maintenance.

Calcium comes mainly from food, particularly milk, yoghurt and other dairy products. Consumption of the fortified milk for 24 months significantly increased serum 25(OH)D and effectively reduced bone loss at the lumbar spine and hip.⁵⁰ Although Vitamin D can be obtained from some foods, as much as 80% to 90% of Vitamin D requirements come from exposure to sunlight.

According to multiple studies, physical activity helps to prevent osteoporosis by promoting peak bone mass accumulation in early life, reducing bone loss in adulthood, and helping to reduce the likelihood of fracture. Long-term physical activities postpones disability and increases independent living in the elderly.

Interventions around the nutrition and physical activity to promote healthy eating may reduce /prevent disease occurrence and halt progression. To achieve this objective of promoting health eating, collaboration among the MoH, SoS, milk & dairy producing companies, fitness clubs/gymnasiums and care providers (hospitals and clinics) is imperative. Initiatives to include:

- Print, TV and social media campaigns highlighting
 - a) Adequate exposure to sunlight and time of the day most appropriate for sun exposure (before mid-day)
 - b) Consequences of vitamin-D and calcium deficiency and their link to chronic diseases
 - c) Benefits of vitamin-D and calcium supplementation on aspects of daily life functions and prevention of diseases, including osteoporosis, in the future

d) Health benefits of walking and regular mild to moderate physical exercise

e) Consequences of smoking on general health including bone health and benefits of smoking cessation

- Vitamin-D status correction campaign targeting children, pregnant/lactating women, post-menopausal women and the elderly (>50 years). Recommendations from "MoH's Clinical Practice Guideline on the Role of Vitamin D, Calcium and Exercise in Fracture Prevention in Elderly"⁵¹ and "Vitamin D status correction in Saudi Arabia: an experts' consensus under the auspices of the European Society for Clinical and Economic Aspects of Osteoporosis, Osteoarthritis, and Musculoskeletal Diseases (ESCEO)"⁵² should be followed in practice.
- Extend existing vitamin D fortified milk products policy to other food products such as orange juice and ensure all production companies (of milk and orange juice) adhere to a set threshold for vitamin-D concentration.
- Vitamin-D screening for all Saudis including high-risk groups to be carried out as a one-time mass initiative, by the public health authorities, at primary and secondary level, especially when the elderly make scheduled/regular visits to their physicians for other chronic diseases such as diabetes and hypertension.
- Workplace programs encompassing right nutrition and physical activity will help increase cognizance of young adults and low-risk population about the disease and clinical implications of sedentary lifestyle
- Routine assessments and counseling on physical activity, by primary care physicians, for high-risk population group. Exercise prescription tailored to patient types should be provided. ⁵³
- Aligned with the with the Vision 2030, opportunities for physical activity to be made available for a wide range of people, including the elderly, children and women.²⁶

Performance measures for recommendation 1.2

1. No. of print, social and TV campaigns promoting nutrition and physical activity per year
2. Vitamin-D status in the community, stratified by age, and among hospital visitors
3. Vitamin-D concentrations in milk and orange juices across brands
4. No. of community-based physical activity interventions for families and adults age >50 per year
5. No. of workplace program about physical activity interventions per year
6. No. of activities related to osteoporosis prevention

1.3. Promoting bone health and disease management in children and adolescents

Childhood and adolescence are the critical stages in life for bone growth and awareness and prevention programs during these critical years can have life-long benefits for many. Collaboration with the Ministry of Education and Ministry of Health could ensure that children receive consistent messages / activities and school policies promote bone health. As children and adolescents spend a significant amount of time in school, developing the following school-based initiatives would be the most prudent way of increasing behavior that promote bone health:

- Subjects on chronic diseases, encompassing bone health, to be included in the school subjects/ curriculum or as a separate topic to engage the interest of the children in primary schools. Curricula to include topics such as appropriate dietary intake, necessity to maintain requisite vitamin-D

levels and importance of minerals in the diet.

- Develop interactive programs such as holding contests, quizzes and activities to engage their interest in the topic of various lifestyle related issues and diseases.
- Encourage implementation of daily physical education for students from kindergarten to grade 12 to promote life-long physical activity among Saudis. Emphasis should be on quality curricula and instructions that help students develop the knowledge, attitudes, motor skills and confidence needed to adopt and maintain physically active lifestyles.⁵³

Performance measures for recommendation 1.3

1. Number of resources developed to address chronic diseases including bone health in schools per year
2. Number of extra-curricular activities targeted at chronic diseases including bone health in schools per year
3. Changes to curriculum, food service or opportunities for physical activity in schools
4. No. of schools that incorporated changes

Recommendation 2: Educate medical trainees and HCPs about bone health

It holds true that it is up to individuals to make health lifestyle decisions; however, HCPs also have a role to play in working with patients to understand bone health and engage in healthy lifestyles for the same, spanning over information about nutrition, treatment persistence and exercise to steps patients can take to prevent falls. Integrated osteoporosis care also involves general practitioners, family medicine practitioners, pharmacists, nurses, nutritionists, and physical and occupational therapists.

Education of medical trainees is essential while they are still in the learning phase is an important step in order to create awareness on the seriousness of bone health maintenance. Expand the competencies on musculoskeletal health in the education of medical trainees, especially those looking to specialize in family medicine, rheumatology, endocrinology, gynecology, geriatrics, rehabilitation and orthopedics, along with allied health professionals and nurses. Develop and execute programs, in partnership with medical associations such as Saudi Health Council (SHC) & Saudi Commission for Health Specialties (SCFHS), Ministry of Education and pharmaceutical manufacturers, to assist in educating health care professionals (GPs, family medicine physicians, radiologists, nurses, exercise physiologists, pharmacists, physiotherapists,

occupational therapists, etc) on the issues of bone health and osteoporosis prevention and management. Interventions to be considered are

- Support through curriculum and continuing education across all levels (graduate and post-graduate) with modules focusing on osteoporosis
- 'Continuing Medical Education' (CME) programs tailored to specific groups. For example, programs to encourage develop geriatric nurse specialists who not only disseminate osteoporosis information to patients but also ensures follow-up to treatment.
- Seminars, conferences and online forums which give them a platform to engage with multidisciplinary teams and get a feel of the current practices and treatments available, globally and nationally, in the field of osteoporosis
- E-Learning portals, which disseminate educational material and provide simple certification courses, could be developed to supplement in-hospital training and education

Effective interventions actively involve the learner in the educational process, are interactive rather than didactic, provide opportunities for practice and feedback, actively engage respected peers as part of the learning process, include assistance at the practice level.

Performance measures for recommendation 2

1. No. of medical and allied health science universities incorporating changes in curriculum
2. No. of graduate and postgraduates taking up courses on bone health and other chronic diseases
3. No. of CME programs for allied health professionals such as nurses, physiotherapists etc. in a period of 1-3 years
4. No. and type of allied health professionals attending CME courses
5. No. of seminars, conferences and online forums every year where primary care physicians and allied health professionals engage with specialists
6. E-health strategy for education
 - Development of portal for HCPs
 - No. of HCPs taking up and completing certification courses
 - type of HCPs completing certification courses

B. Screening, Diagnosis and Treatment

Recommendation 3: Enhance the role of GPs/PCPs/ Family Physicians to diagnose and treat osteoporosis at early stages

In western societies such as Canada and UK, GPs and Family Medicine Practitioners play a key role in osteoporosis management. Because they see patients over the entire life cycle, they can promote bone health during the stages of bone growth, consolidation and loss (primary prevention), detect people with osteoporosis and provide timely treatment (secondary prevention), and ensure that every patient who has had a fragility fracture receives integrated fracture care, rehabilitation and osteoporosis management (tertiary prevention).⁵⁴ For effective osteoporosis prevention and management, general /family medicine practitioners must have the knowledge and skills to⁵⁴:

1. Recognize that kyphosis (curvature of the spine), loss of height and fractures are not normal parts of aging but possible indicators of osteoporosis
2. Identify people who may be at risk of osteoporosis and should be referred for BMD testing
3. Interpret test results
4. Know how to appropriately manage those with osteoporosis or at increased risk (i.e., therapies, modifiable risk factors, pain management, psychosocial support)
5. Know when to refer patients for specialist care (e.g., to a endocrinologist or a rheumatologist) or to an allied health professional (e.g., nutritionist, nurse, pharmacist, physical or occupational therapist)
6. Identify those who have sustained fragility fractures and have them screened and treated for osteoporosis
7. Integrate osteoporosis, falls and fracture risk assessments into their practice

One of the main reason why a large part of the prevalent osteoporotic population goes undiagnosed and untreated for osteoporosis is due to the limited role of primary care level physicians from the care pathway. This bridge this gap an effective multiple-stakeholder driven strategy is needed. Key figures include specialists (endocrinologists, rheumatologists and orthopedics), Ministry of Health, SHC, SCFHS, MOMRA, SFH, Ministry of Education, Medical Universities and physician's societies such SoS, Saudi Society of Endocrinology and Metabolism, Saudi Society of Family and Community Medicine. Key actions to be taken:

- Develop guidelines that will specially be pertinent to prevention, diagnosis and management of osteoporosis at a primary care level and encourage primary care physicians to follow-up patients to monitor the adherence to treatment and assess patient's risks for falls and/or fracture
- Build and disseminate simple evidence-based modules and aids (one-page algorithms/flow charts and practice toolkits) to primary care physicians (PCPs) which enable them to identify patients at risk (over age of 50, male or female, post-menopausal, history of fragility fracture), counsel them and have them tested for BMD and future fracture risk and treated for osteoporosis
- Engage select primary care physicians on "preceptorship programs" where GPs and family medicine practitioners are mentored by a leading specialist (endocrinologist or orthopedic) on the management of the disease. Thereby creating "Osteoporosis Champions" at the primary care level who can further transfer knowledge to their peers
- Provide osteoporosis "Continuous Medical Education" programs to physicians led peer facilitators and treating specialists.
- Amplify the number of PCPs taking the course and using tools & aids by partnering with SHC to develop e-learning portal thus causing minimum disruption to their practice and work schedule.
- Identify key primary care clusters across KSA, which are receiving or have the potential to receive large volume of high-risk population

Performance measure for recommendation 3

1. Development of primary care guidelines and its periodic update, every 3 to 5 years
2. No. of evidence-based modules and aids (algorithms, tools, flow charts) prepared for primary care physicians
3. No. of peer or specialist led CME courses for primary care physicians in period of 3-5 years
4. No. of primary care physicians attending CME courses
5. No. of primary care physicians enrolled on the preceptorship programs
6. No. of specialists and tertiary centers engaged on the preceptorship programs
7. E-health strategy for primary care education
 - Development of portal for HCPs
 - No. of HCPs taking up and completing certification courses
8. No. of primary care physicians who have access (in their clusters) to BMD
9. No. of primary care centers clusters that have DEXA machine
10. No. of BMD tests in >50 years old visiting primary care clusters pre- and post-intervention (introduction and use of guidelines & aids, CME)
11. No. of patients referred to specialist by cluster primary care physicians pre- and post-intervention (introduction and use of guidelines & aids, CME)

Recommendation 4: Update local guidelines and ensuring it is uniformly followed

Last version of the local guideline were published in 2015 and should be revised to provide clear, up to date evidence-based recommendations to assist specialists and other health professionals in managing patients with osteoporosis. Key points to be considered when updating the guideline:

1. Nature of guideline to be more prescriptive rather than descriptive. Guidance to prevent and manage the disease for each type of healthcare professional, specialist or primary care, to be delineated.
2. Additionally create/update a one-page summary and flow chart for risk assessment and treatment initiation

Performance measures for recommendation 4

1. Development of evidence-based local treatment guidelines and best practice case studies
2. Periodic update to guidelines (every 2 years)
3. No. of high risk patients receiving antiresorptive therapies pre- and post- intervention (introduction of guidelines) at individual hospitals and assess difference across hospitals

Recommendation 5: Instate a national level mandatory BMD reporting certification course

At the core of osteoporosis treatment and management is receiving the correct diagnosis. Both treating physicians and radiologists are equally responsible. Radiologists play a vital role in the diagnosis and management of the disease through the identification of the early radiographic features, and the detection of fractures, which may be asymptomatic or undiagnosed.

But studies^{39,41,42,43} in KSA have indicated that there is a big knowledge-practice gap with respect to recommendation for BMD screening and actual testing, especially higher in men at-risk. Plausible explanations why a large number of the fractures are underdiagnosed in KSA have been posited

- Variations between different physician practices regarding osteoporosis screening recommendations³⁹
- Radiologists were concentrating on the organs in the chest cavity and they failed to recognize the skeletal structures⁴¹
- Radiographs were reviewed and reported on by staff with different levels of experience⁴¹
- Learning curve for semi-quantitative morphometry is very high⁴¹
- Osteoporosis and osteoporosis-related fractures in men were never on the agenda for the diagnosis⁴¹

In some cases radiologist reported was left unnoticed by the physicians. Hence, BMD testing and reporting related interventions need to be organized in partnership with International Society for Clinical Densitometry (ISCD), Radiological Society of Saudi Arabia (RSSA), public and private radiology diagnostic providers (hospitals or clinics). Recommended actions include:

- Instate a national level accreditation and certification program, a local adaptation of the ISCD certification course, and mandate that for any clinician involved in reporting of BMD tests in KSA, public or private sector, needs to be certified by this program to continue reporting BMDs
- Promoting and ensuring quality at not only radiologist level but also extending it to physicians (primary care and specialists) in guidelines and tools/algorithms to outline everything they need to know to deliver the highest quality densitometry

Performance measure for recommendation 5

1. Development of ICSD standardized training process
2. Development and testing of BMD and reporting algorithms
3. Number of professionals with ICSD BMD certification
4. Assessment of appropriate use of BMD testing and rate of change in practice of radiologists
5. Establishment of BMD database

Recommendation 6: Develop or improve on existing assessment tools for predicting the incidence of fractures in individual

Several clinical factors are associated with a fracture risk that is greater than what can be accounted for by bone mineral density alone.⁵⁵ Fracture risk assessment, therefore, should employ specific risk factors in addition to bone mineral density. On the basis of a series of meta-analyses undertaken to identify clinical risk factors for osteoporosis, the Fracture Risk Assessment Tool (FRAX) was developed and released in 2008 by the World Health Organization^{56,57,58}. FRAX calculates the ten-year probability of a major osteoporotic fracture (in the proximal part of the humerus, the wrist, or the hip or a clinical vertebral fracture) and of a hip fracture calibrated to the fracture and death hazards^{59,60}.

With a high incidence of femoral fractures in KSA and increasing costs of treating them, it becomes vital to collaborate with medical researchers, Medical Universities and physicians associations to enhance future risk assessment in KSA. Recommendations in this regard entail:

- Develop a clinically proven, government certified fracture risk calculator (FRAX) developed for the Saudi context. The 2015 guidelines by the Saudi Osteoporosis Society recommend using the USA (White) version of the FRAX tool in the absence of a local, country-specific FRAX tool for Saudi Arabia.
- Establish national guidelines should also explicitly highlight the process of using the FRAX tool, though its judgment of use entirely depends on clinical judgment

Performance Measure for recommendation 6

1. Development of local FRAX and guidelines for use
2. No. of high risk patients receiving FRAX assessment year on year after FRAX is rolled out across hospitals
3. No. of high risk patients receiving anti-resorptive therapy pre- and post-FRAX roll out
4. No. of fragility fracture cases received by hospitals in high risk group pre- and post-FRAX roll out
5. No. of re-fracture cases received by hospitals in control and test population pre- and post-FRAX roll out

C. Post-Fracture Care Management and Secondary Prevention

Recommendation 7: To establish fracture liaison services (FLS) and rehabilitation services

Individuals who have suffered a first fragility fracture are at considerably increased risk of second and subsequent fractures. In the absence of a systematic approach to delivery of secondary fracture prevention, the vast majority of fragility fracture patients do not receive the osteoporosis care that they need. Anyone who has experienced a fragility fracture should be managed within a formal integrated system of care that incorporates a Fracture Liaison Service (FLS). It is essential to intervene with a FLS service that identifies, investigates and initiates treatment.⁶¹

KSA will immensely benefit from a post-fracture service, at secondary/tertiary hospitals, that helps identify, investigate, and appropriately treat all orthopedic outpatients and inpatients who presented to the hospital with a fragility fracture

of the wrist, shoulder, hip, or vertebra. FLS/Nurse Coordinator/Osteoporosis Nurse Educator to guide timely assessment and management of medical conditions, including diagnostic imaging, pain assessment and cognitive assessment. FLS has already been successfully implemented in National Guard Health Affairs (NGHA) Hospital, Riyadh. Key learning should be assessed from NGHA and FLS should be implemented in all major hospitals treating osteoporosis and fragility fracture patients across KSA.

Goals of FLS should be –

- a) Develop awareness among hospital staff regarding the importance of identifying patients with a fragility fracture and their need for referral, evaluation, and possible treatment
- b) Increase identification and referral rates of patients with a fragility fracture
- c) Develop awareness among patients that the fracture may have been caused by an underlying bone disease
- d) Emphasize Vitamin D supplementation in fragility fracture patients as they

- have limited exposure to sunlight
- e) Ensure treatment initiation by specialist
- f) Enhance patient knowledge regarding osteoporosis and its management
- g) Ensure that before a patient with a fragility fracture leaves hospital, he/she should be offered a falls and bone health assessment, and a management plan based on this assessment to reduce the risk of another fracture.

Post-fracture, rehabilitation should be insisted upon by the treating physicians in order to re-gain functionality post-fracture. Currently, there are limited number of hospitals that provide rehabilitation services. Prince Sultan Hospital is a pioneer of rehabilitation service in KSA.

Some of the limitations to the rehabilitation services in KSA are, but not limited to lack of established patient safety standards, limited capacity, inexperience of staff or their qualifications, limited communication with other departments or treating physicians and limited research in the field of rehabilitation. Best practices from the service established at Prince Sultan Hospital should be documented and disseminated across KSA so that

- Rehabilitation for all Saudis over the age of 60 Years who sustain a fragility fracture or an osteoporotic fracture is adequately addressed
- All personnel in rehabilitation centers are trained to provide efficient care to patients post-fracture

Performance measure for recommendation 7

1. Identification – No. of fragility fracture patients identified or enrolled by FLS program from estimated no. of fragility fracture patients in hospital/catchment area
2. Investigate – No. of risk assessments completed (low, medium, high) from the total no. of fragility fracture patients identified by the FLS program
3. Initiate – No. of high risk patients initiating treatment from the number of high risk patients identified via FLS
4. No. of patients adherent to their treatment from total no. of patients initiated or recommended to remain on treatment
5. Identification, documentation and dissemination of rehab and FLS best practices
6. Development of recommendations for integrated osteoporosis rehabilitation care
7. Evaluation of initiatives, including quality of life measures
8. Number of facilities participating in rehabilitation services programs

D. Self-management and falls prevention

Recommendation 8: Build support for people with or at high risk of osteoporosis and develop non-pharmacologic interventions directed at preventing falls

In order to implement effective self-management, it is critical to acknowledge the patient's central role in their care, one that fosters a sense of responsibility for their own health. Some of the recommendations that could be put forward to ensure effective self-management and prevent falls in patients could be:

- Expand the screening (at primary or secondary care level) for risk factors for falls to appropriately targeting healthcare resources, attention, and preventive intervention, especially for populations who are at highest risk for injury or death caused by falling
- Develop osteoporosis/bone health home care services in the public and private sector to avoid long hospital stays
- Encourage medical universities and public/private providers to provide good quality training for elderly home care services
- Pilot exercise based self-management and fall prevention programs – community based professional led exercise program providing safe and gentle exercises for individuals with minimal previous exercise experience or home based program aimed especially at elderly frail women incorporating muscle strengthening and balance retraining
- Assess home hazards by occupational therapist (removing any obstacles that may result in falls) is an important intervention. These could include slippers with no grip, slippery floors, etc.
- Install hand-rail in homes with the elderly or those diagnosed with osteoporosis
- Create an online community for osteoporosis patients to share experience, coping with disease, exercise videos and dietary intake suggestions

Performance measures for recommendation 8

1. Evaluation of pilot programs
2. No. of fall prevention programs offered and no. of patients participating in fall prevention programs
3. Impact on participant's quality of life and level of knowledge
4. Reduction to falls & fractures and changes in behavior of elderly
5. Members of online community – traffic on website, video views and downloads
6. Increase in home health care professionals trained

E. Research and Evaluation

Recommendation 9: To generate credible disease data and real world evidence in osteoporosis in KSA

Real world evidence (RWE) has been defined simply as 'data used for decision-making that are not collected in conventional randomized clinical trials (RCTs).⁶²

RWE is especially important in the context of KSA as the presently younger population is expected to age over the next few decades, thus increasing the societal and economic burden of chronic diseases such as osteoporosis. RWE can help KSA payers to not only create an equilibrium between the available health resources and demands of the population but also develop optimum community prevention and patient sub-group treatment strategies.

Limited data exists on the epidemiological, clinical and economic burden of osteoporosis in KSA. Available literature that provides estimates of prevalence of osteoporosis in >50 years old population is now outdated. Evidence-based treatment and prevention strategies are deeply rooted in disease related data.

To put KSA on the map of one the preferred places for osteoporosis clinical and medical research, investment into interventions which generate credible local osteoporosis data have to be made via a collaboration among MoH, Saudi

Food and Drug Administration (SFDA), King Abdulaziz City for Science and Technology (KACST), Medical Universities and pharmaceutical manufacturers.

Initiatives to be considered are:

9.1 Conduct a prospective multi-center cohort study which will measure the incidence and prevalence of osteoporosis and fractures, and the effect of putative risk factors. Care should be taken that all regions and ethnicities of the Saudi population are well represented. An multi-disciplinary oversight committee to align research across KSA is essential. Overarching objectives of this study should be to:

- Examine the development and demographics of osteoporosis
- Identify risk factors for osteoporotic fractures (e.g. genetic risk factors, calcium and vitamin D intake and serum levels, age, physical activities) and their associations with BMD, fractures, and/or mortality
- Assess outcomes of osteoporosis and treatment – vitamin-D and anti-resorptive therapies
- Increase publication of data driven scientific articles quantifying the burden of disease

Performance measures for recommendation 9.1

1. Committee set-up, decision on in time line, cohort size, research centers and researchers identified
2. Patient recruitment and data capture
3. Analysis of data
4. Publication on analyzed data (epidemiology. Risk factor, BMD testing)
5. Periodic updates, new cohorts added

9.2 Create a conducive regulatory and financial atmosphere which **encourage industry or investigator driven real world studies** in various hospitals (public and private). RWE studies to encompass:

- Capture cost associated with testing and treatment of the disease

- Nuances of patient journey and clinical pathway management
- Effectiveness of various therapies in patient sub-groups and economic impact
- Osteoporosis patient quality of life assessment

Performance measures for recommendation 9.2

1. No. of RWE studies in Osteoporosis or bone health per year
2. Evidence-based revision to guidelines based on outcomes data
3. Publication on and sizing of cost of osteoporosis and osteoporosis related fractures on KSA health system
4. Forecast of expected disease and economic burden in the next 10 to 20 years
5. Publication on quantified gaps on care pathway – prevalent to diagnosed, diagnosed to treated

9.3 Establish a committee to set up a **National Fracture Registry and National Registry for Patients Diagnosed via BMD** which ensure that necessary steps are taken to establish both registries over the next 2-3 years. Initially, the fracture registry can focus on a small population such as atypical femoral fractures and then scaled up.

Performance measure for recommendation 9.3

1. Creation of committee and selection of centers for data input
2. Establishment of data capturing infrastructure
3. Longitudinal follow-up of patients and periodic publishing of data

Recommendation 10: To form a committee that overlooks the implementation and outcome of this Osteoporosis National Action Plan in Saudi Arabia

In order to quantify and qualify the impact of the actions on the prevalence and incidence of the disease in the country and to ensure broader alignment to the KPIs set under the National Transformation Plan 2020 in vision of 2030, a committee (comprising of MoH, SOS and Saudi Health Council) has to be formed that develops a monitoring and evaluation framework that outlines a core set of performance indicators, data elements, data collection methodology, and protocols for reporting. Committee will also be responsible for maintaining and encouraging stakeholder collaboration. Framework to encompass metrics which assess pre- and post- intervention:

- Vitamin-D levels and mineral intake among various low-, medium- and high risk-group

- Nutritional intake of children and behaviors that promote good bone health
- Increase in no. of medical trainees and HCPs enrolling on CME
- Success of educational programs to raise awareness of primary care physicians about disease diagnosis, management
- Effect of primary care physicians role on the osteoporosis patient care pathway
- Increase in no. of enrollees for the BMD certificate course and improve in diagnosis rates
- Success of FLS services (once implemented) in reducing re-fractures and initiating treatment
- Reduction in falls among elderly
- Proportion and geographic expanse of population covered when collecting osteoporosis data
- Increase in publications on osteoporosis related issues

Following are examples of how the action plan contributes to NTP KPIs

NTP KPI	Action Plan Recommendations
Increase number of resident Saudi physicians who are enrolled in training programs	Recommendations 2, 3 and 11
Increase number of qualified Saudis in the field of nursing and support staff for every 100,000 people	Recommendations 2, 3, 7, 8 and 11
Increase number of primary healthcare visits per capita	Recommendations 1, 2, 3, 7 and 8
Increase percentage of patients who get health care after critical care and long term hospitalization within 4 weeks	Recommendation 7

Performance measure for recommendation 10

1. Development of evaluation and monitoring strategy
2. List of KPIs and data elements to be capture
3. Data capture methodology
4. Annual reports on outcomes of various recommendation of the action plan
5. Liaison with stakeholders, responsiveness to Ministry's queries
6. Alignment with National Transformational Program and Vision 2030

Recommendation 11: To ensure necessary long-term research and knowledge transfer in osteoporosis through activities, in collaboration •

Forming research funds and grants for academic researcher. Research agendas should be tailored to the unique needs of KSA.

- Encouraging graduate and post-graduate students (pharmacy, medicine, nursing, allied health), through awards and recognition schemes, to select osteoporosis-related issues as their thesis topics.

- Developing scholarship programs for students who studying allied health field to pursue career that are strong related to management of osteoporosis such as densitometrist, BMD and radiology technicians, nurse coordinators and physiotherapist
- Raising levels of fund raising to support osteoporosis research

Performance measure for recommendation 11

1. No. of grants offered to academicians and researcher to develop knowledge on osteoporosis/bone health
2. No. of graduate/post-graduate thesis on osteoporosis/bone health related topics year on year
3. No. of scholarships given out to pursue allied health profession related to osteoporosis treatment/bone health
4. Increase in manpower in the allied health profession related to osteoporosis/bone health
5. Increase in no. of publications on osteoporosis in KSA

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