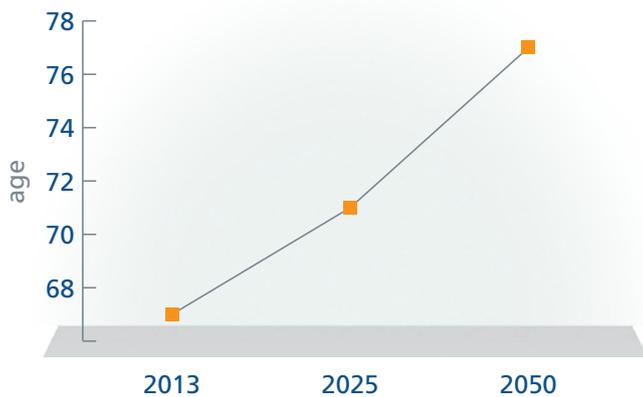


INDIA

COUNTRY OVERVIEW

India, with a population of 1.2 billion people, is the second largest emerging economy and second most populated country in the world. Life expectancy is 67 years and is expected to increase to 71 years by 2025 and to 77 years by 2050 (Figure 1)¹. Currently, approximately 10% of India's population (more than 100 million) is aged over 50 years. Based on current patterns of growth, India's population is expected to grow by 16% to reach 1.4 billion by 2025. From 2025 to 2050 the population will increase by a further 34%, reaching 1.88 billion (Figure 2)¹. Those above the age of 50 years will constitute 22% of the population in 2025 and 33% of the population in 2050. With estimates showing that approximately 80% of the urban Indian population is vitamin D deficient² and hip fractures occur about a decade earlier than in western nations³, osteoporosis is a major concern for this ageing population.

FIGURE 1 Life expectancy in India



State of osteoporosis/osteopenia

In the 2009 IOF Asian Audit, expert groups estimated that the number of osteoporosis patients in India was approximately 26 million in 2003, with projections indicating that this would rise to 36 million patients by



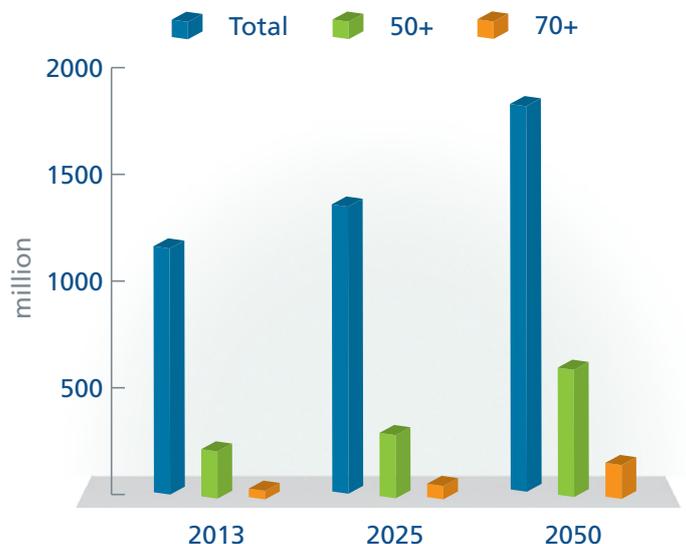
CURRENT

Population **1.2 billion**
 Aged over 50 years **10%**
 Life expectancy **67 years**
 Hip fracture incidence per year **163/100,000** (women)
 Cost per hip fracture **772–3,860 USD**
 Number of DXA per million population **0.26**
 Fracture liaison services **not implemented**

PROJECTED 2050

Population **1.88 billion** ↑
 Aged over 50 years **33%** ↑
 Life expectancy **77 years** ↑

FIGURE 2 Population projection for India until 2050



2013⁴. Now, in 2013, sources estimate that 50 million people in India are either osteoporotic (T-score lower than -2.5) or have low bone mass (T-score between -1.0 and -2.5)⁵.

In a study among Indian women aged 30–60 years from low-income groups, bone mineral density (BMD) at all skeletal sites was much lower than values reported from developed countries, with a high prevalence of osteopenia (52%) and osteoporosis (29%), thought to be due to inadequate nutrition⁶. In a more recent study from Delhi, 792 males and 808 postmenopausal females with a mean age of 57.67 ± 9.46 years were evaluated. Osteoporosis was present in 35.1% of subjects (M-24.6%, F-42.5%) and osteopenia in 49.5% (M-54.3%, F-44.9%)⁷. Both of these studies used the manufacturer's White Caucasian reference database.

In an attempt to generate an India-specific database, the Indian Council for Medical Research (ICMR) carried out a large multicentre study which confirmed data from smaller, single-centre studies, and showed that Indians have lower BMD than their North American counterparts⁸. A study involving more than 3,500 subjects carried out at a tertiary care center in South India to study the effect of the newly generated ICMR database (ICMRD) on the diagnosis of osteoporosis reported that a greater proportion were diagnosed as having osteoporosis with Hologic as compared to the ICMR database. Osteoporosis at the spine and hip was present in 42.7% and 11.4% subjects using the Hologic database and in 27.7% and 8.3% subjects using the ICMR database⁹.

Similarly in a study from North India where age-specified BMD reference ranges were established in females between 18–85 years, the prevalence of osteoporosis among women aged older than 50 years was significantly higher based on Caucasian T-scores as opposed to using peak BMD/standard deviation values from the population under review at lumbar spine. However, there was no major difference observed at femoral neck¹⁰.

Reasons ascribed for lower BMD in Indians include possible genetic differences, nutritional deficiency and smaller skeletal size¹¹.

Lifestyle

Widespread vitamin D deficiency has been shown unequivocally across all ages throughout India. More

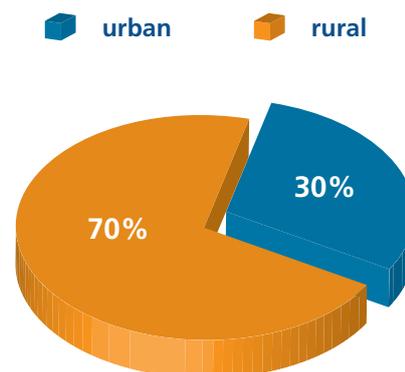
than 80% of urban Indians have serum 25(OH)D levels below 20 ng/mL. This includes pregnant women and their newborns, children and adolescents, young adults and the elderly. Vitamin D deficiency during childhood and adolescence decreases peak bone mass in adults and may increase the risk of developing osteoporosis¹¹. Studies indicate approximately 80–90% of hip fracture patients are vitamin D deficient^{12,13}. The high rate of vitamin D deficiency may be due to several causes such as low sun exposure, inadequate dietary vitamin D intake, lack of food fortification with vitamin D, pigmented skin, environmental pollution, and traditional dress code⁴. To combat the low levels of vitamin D a couple of states have recently initiated vitamin D fortification of edible oil and milk fortification which can be an effective means of delivering vitamin D¹⁴.

Nutritionally, the Indian population consumes much lower amounts of calcium (300–500 mg/day) than the ideal daily intake¹⁵. Additionally, tea is a popular beverage consumed by the Indian population; however, due to the high caffeine content, some studies have suggested that it may be associated with a greater risk of hip fracture¹⁶.

As in other Asian countries, urbanization also appears to be associated with an increase in prevalence of osteoporosis due to lifestyle changes, lower physical activity, increase in indoor living, and lower sun exposure (*Figure 3*)^{17,18}.

Glucocorticoids are taken on a long-term basis by an estimated 1% of the Indian adult population, especially the elderly. This is a contributing factor to osteoporosis in India¹⁹.

FIGURE 3 Urban versus rural population in India¹⁸



Expatriate Indians also show evidence of poorer bone health than their western counterparts. Experts have found that women from India who have migrated to western countries are at increased risk of accelerated age-related bone loss when compared to their counterparts living in the same geographic region due to their darker skin, dressing habits and lower bone mass²⁰.

Level of awareness

Awareness of osteoporosis is low in India with a number of small-scale surveys indicating that in the urban population approximately 10–15% are familiar with the disease. However, awareness varies widely according to the level of education and those with a family history of the disease. One study reveals that Indians find information about osteoporosis mostly through the television and radio (55%) when compared with family/friends, newspaper and doctors (approximately 20% each). Unfortunately, information from the media is not always accurate, and with only 20% of information coming from physicians there is a clear need for increased involvement of doctors in educating patients about osteoporosis²¹.

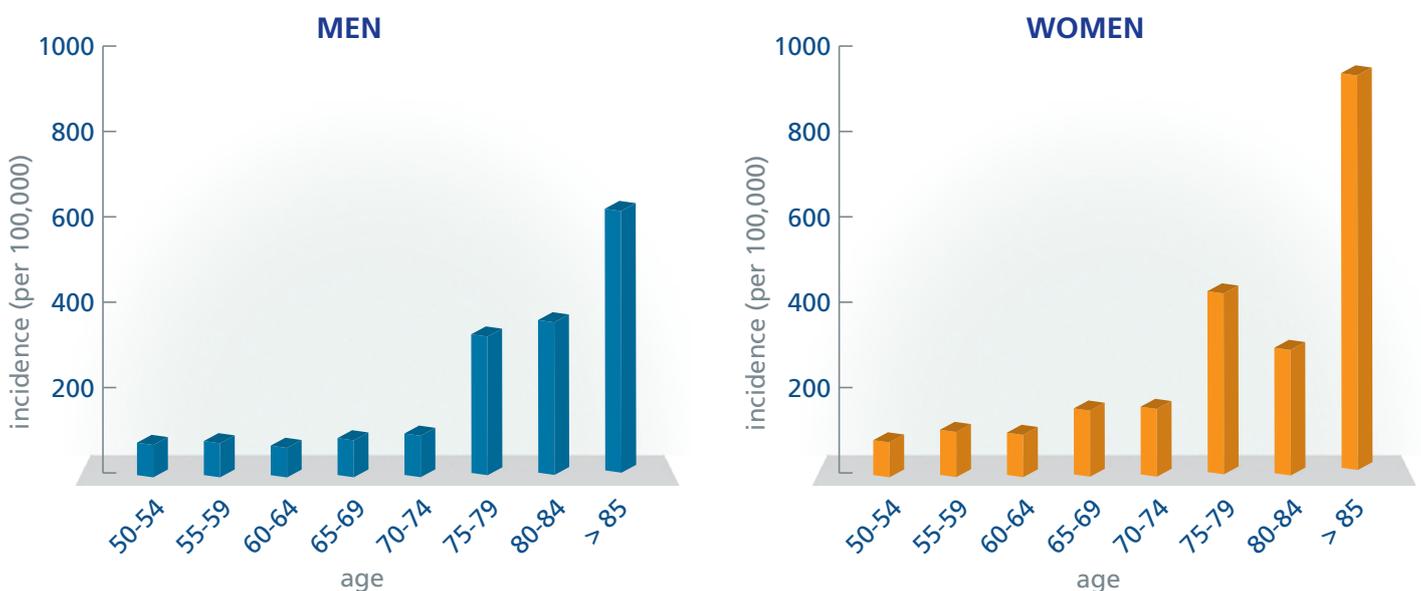
FRACTURE RATES

Hip fracture

Hospital-based studies suggest that hip fractures are common in India too²². A study on expatriate Indians in Singapore showed that hip fracture rates in Indians are somewhat lower than in the Chinese and higher than in Malays²³. This study has been used to develop the FRAX model for India. A recent study from Rohtak district in North India shows an annual incidence rate of 163 and 121 per 100,000 per year in women and men respectively above the age of 55 years (Figure 4)²⁴. However, with the rapid increase in the ageing population, an exponential rise is expected in the absolute numbers of fractures in the next decade¹.

The preponderance of hip fractures in females that is observed in Western populations is less striking in India^{3,24}. In Caucasians, hip fractures are twice as common in women, whereas in India the ratio of hip fractures in women to men is more in the order of 3:2²⁴. Additionally, it has been suggested that hip fractures occur at an earlier age in Indians in comparison with

FIGURE 4 The age- and sex-specific hip fracture incidence in Rohtak district, North India during 2009



SOURCE Dhanwal D.K. et al. (2013) Incidence of hip fracture in Rohtak district, North India.

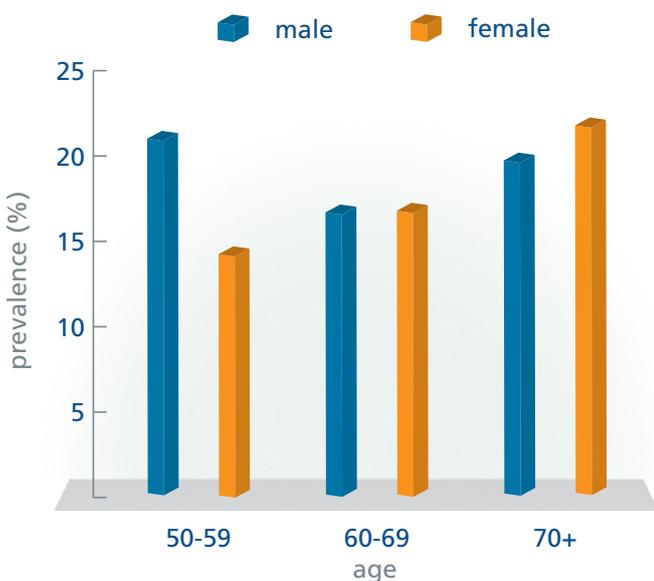
western counterparts with the peak age for hip fractures in Indians occurring in their sixties³. This may be a function of a shorter life span. Studies of osteoporotic, postmenopausal women in India found that on average, 34% were aged below 60 years²⁴. The 1-year mortality after hip fractures is high at over 30% in the public hospital setting²⁴.

India does not have standardized criteria for the management and treatment of hip fractures, and procedures vary by hospital setting. The Indian Society of Bone and Mineral Research (ISBMR) estimates that 90% or more of hip fractures are managed surgically in urban areas. While the average waiting time for hip surgery is less than 1 day in private hospitals, Indians often wait over 3 days for hip surgery in public hospitals where the majority of cases are seen. The proportion of patients undergoing surgery in rural areas is likely to be much lower.

Other fragility fractures

In a large questionnaire-based study involving 14,271 subjects, population incidence of low trauma fractures at hip, spine and wrist was 34.3/100,000 per year²⁵.

FIGURE 5 Prevalence of vertebral fractures in males and females according to age strata²⁶



SOURCE Marwaha R.K. et al. (2012). The prevalence of and risk factors for radiographic vertebral fractures in older Indian women and men: Delhi Vertebral Osteoporosis Study (DeVOS).

Vertebral fractures

Vertebral fractures are common in Indians, with 15–20% of older urban adults aged over 50 years showing evidence of at least one vertebral fracture. The prevalence of radiographic vertebral fractures in older adults in Delhi has been recently reported to be 17.9% (18.8% male and 17.1% female); indicating that vertebral fracture prevalence in India is similar to Western populations (*Figure 5*)²⁶.

COSTS OF FRACTURE

Costs vary according to town, bed type and whether or not the hospital is governmental, public or private. In private hospitals, the total cost of hip surgery is between 2,360–3,860 USD (150,000 to 250,000 Rs), and in public hospitals the cost is approximately 772 USD (50,000 Rs). Private hospitals generally report shorter bed days of 5–6 days than public hospitals, where the stay can often be 15 days (*Table 1*).

TABLE 1 Hip fracture in India

	HOSPITAL COSTS PER HIP FRACTURE (USD)	AVERAGE HOSPITAL BED DAYS	SURGICALLY TREATED
Private	\$2,360–3,860	5-6	90% (urban areas)
Public	\$772	15	

FRACTURE REGISTRIES

There are no official fracture registries in India, although there could possibly be some at the hospital level.

FRACTURE LIAISON SERVICES

India does not have any coordinator-based models of care, otherwise known as fracture liaison services (FLS) for secondary fracture prevention. However, at least two hospitals in New Delhi are in the early stages of developing a FLS.

SPECIALISTS RESPONSIBLE FOR OSTEOPOROSIS

The general management of osteoporosis is by orthopaedists and endocrinologists, but other specialities

also manage patients, including: family doctors, rheumatologists, gynaecologists, endocrinologists, geriatricians, rehabilitation specialists and internal medicine physicians.

There is little osteoporosis-related education at the medical undergraduate level. However, osteoporosis is a recognized component of speciality training for endocrinologists. Various aspects of osteoporosis are also a component of training for orthopaedic surgeons, gynaecologists, rheumatologists and rehabilitation medicine physicians.

GOVERNMENT POLICIES

Osteoporosis as a documented national health priority

Osteoporosis is not a national health priority (NHP) in India. Of the NHPs, the one that will most closely impact osteoporosis is the nutritional programme aimed at schoolchildren to provide vitamins and minerals including vitamin D and calcium. Although not formally recognized in health programmes, vitamin D deficiency is increasingly becoming an important public health issue, and there is a proposal currently under review for musculoskeletal diseases to be a NHP.

Guidelines

The Indian guidelines on glucocorticoid-induced osteoporosis, 'Indian Rheumatology Association guidelines for management of glucocorticoid-induced osteoporosis (GIOP)' were published in 2011 as a collaboration between the Indian Rheumatology Association, the Endocrine Society of India, and the Indian Society of Bone & Mineral Research²⁷.

Postmenopausal Osteoporosis guidelines are in the process of development jointly by the Endocrine Society of India and ISBMR and are expected to be released in late 2013.

There are numerous initiatives and programmes hosted by ISBMR promoting osteoporosis awareness and education, such as:

- Education programmes and conferences for doctors
- Research grants for young investigators awarded annually
- Bone densitometry courses
- Web based education on osteoporosis
- Printed educational material produced

Additionally, there are numerous campaigns targeted toward healthcare providers:

- Orthopaedic & gynaecologic initiative
- IOF/ISCD courses
- Osteoporosis for students
- National Bone Health Quiz for medical students organized every few years
- Essay competition for nutritionists

Audit and quality indicator systems

Audit and quality indicator systems are not in place in India.

TREATMENT (REIMBURSEMENT OF MEDICATION)

In general, patients pay for treatment directly out-of-pocket. Health-care coverage is limited to less than

TABLE 2 Osteoporosis treatments and respective reimbursement in India

	YES	NO	IF YES, % REIMBURSED
Risedronate	x		<10
Alendronate	x		<10
Ibandronate	x		<10
Zoledronic acid	x		<10
Clodronate		x	
Pamidronate		x	
Raloxifene	x		<10
Bazedoxifene		x	
Denosumab		x*	
Strontium Ranelate	x		<10
Teriparatide	x		<10
PTH (1-84)		x	
Vitamin D/Ca supplements	x		<10
Calcitonin	x		<10
Hormone Replacement Therapy	x		<10
Testosterone	x		<10
Alfacalcidol	x		<10
Calcitriol	x		<10

*not available

10% of users. Those with health insurance (e.g. central government employees, state insurance or private coverage) are generally only reimbursed for hospital-based services. Outpatient services, including diagnostics and medications, are not commonly reimbursed. This is true for osteoporosis care as well with designated first-line treatments such as bisphosphonates, vitamin D and calcium, which are paid for by the patients (*Table 2*). In cases where reimbursement is available, it is based on the doctor's prescription without any strict regulations. However, 'cheaper' generic medications are available and are usually preferred in public/government systems. And, because only hospitalized patients are reimbursed by insurance companies, several doctors prefer to infuse zoledronic acid in the hospital setting. *Table 2* summarizes the treatments available to those who have health-care coverage.

DIAGNOSTICS

Most Indian women cannot afford dual-energy X-ray absorptiometry (DXA) due to the costs involved²⁸. Like medication treatments, reimbursement is also limited for the diagnoses of osteoporosis. In general, DXA and ultrasound are not reimbursed, and patients pay for scans out of pocket (*Table 3*). There are approximately 0.26 DXA machines per one million of the general population²⁹ and very few of these are based at the government hospitals, a fact which further limits access. In the private centres where DXA is available, there is no waiting time for DXA, but again a very small proportion of the population is reimbursed through the private sector.

Due to the limited reimbursement for DXA and ultrasound, cost is a barrier to access. In general DXA costs 27–67 USD. Ultrasound has no waiting time and costs between 25–40 USD.

RECOMMENDATIONS

While there has been considerable progress in research and epidemiology of osteoporosis in India since the last IOF Asian Audit in 2009, numerous gaps still exist. Some of the high-priority areas for action over the next three years are listed below.

Prevention

- Fortification of food with vitamin D needs to be introduced as a universal government programme.
- Greater emphasis is needed on attainment of peak bone mass/childhood adolescent bone health by nutrition and life style measures. Intensive, sustained, awareness and intervention programmes need to be initiated at the school level.

Treatment

- Establishment of reliable, accurate hip fracture registries is urgently needed and is a prerequisite to the improvement of hip fracture care and implementation of secondary prevention strategies.
- Introduction of fracture liaison services will considerably help secondary fracture prevention efforts.

Research

- There is a need for multicentre, large-scale hip fracture incidence studies for which attempts are being made by ISBMR. The validation of a FRAX tool specifically for India would enable better use of diagnostic facilities and improve selection of patients requiring treatment.

TABLE 3 Diagnostics access and cost in India

	DXA	ULTRASOUND
Waiting time (d)	0	0
Cost (USD)	27-67	25-40
Is it reimbursed?	limited to no reimbursement	limited to no reimbursement
Is reimbursement a barrier to access to treatment?	yes	yes

REFERENCES

1. Government of India: Ministry of Home Affairs 2011, Office of the Registrar General & Census Commissioner, India, <<http://censusindia.gov.in>>.
2. Beloyartseva, M, Mithal, A, Kaur, P, Kalra, S, Baruah, MP, Mukhopadhyay, S, Bantwal, G & Bandgar, TR 2012, 'Widespread vitamin D deficiency among Indian health care professionals', *Arch Osteoporos*, vol. 7, no. 1-2, pp. 187-192.
3. Malhotra, N & Mithal A 2008, 'Osteoporosis in Indians', *Indian J Med Res*, vol. 127, no. 3, pp. 263-268.
4. Ambrish, M, Dhingra, V & Lau, E 2009, 'The Asian Audit: Epidemiology, costs and burden of osteoporosis in Asia', *International Osteoporosis Foundation*, pp. 24-29.
5. 'Osteoporosis in Asia: a call to action' 2012, *Curr Osteoporos Rep*, vol. 10, no. 4, pp. 245-247.
6. Shatrugna, V, Kulkarni B, Kumar, PA, Rani, KU & Balakrishna, N 2005, 'Bone status of Indian women from a low-income group and its relationship to the nutritional status', *Osteoporos Int*, vol. 16, p. 1827.
7. Marwaha, RK, Tandon, N, Garg, MK, Kanwar, R, Narang, A, Sastry, A, Saberwal, A, Bhadra, K & Mithal, A 2011, 'Bone health in healthy Indian population aged 50 years and above', *Osteoporos Int*, vol. 22, no. 11, pp. 2829-2836.
8. 'Population based reference standards of peak bone mineral density of Indian males and females: An ICMR multi-center task force study' 2010, *New Delhi: ICMR Publication; Published by Director General*, pp. 1-24.
9. Paul, T, Asha, HS, Mahesh, DM, Naik, D, Rajaratnam, S, Thomas, N & Seshadri, MS 2012, 'The diagnosis of osteoporosis among subjects of southern Indian origin above 50 years of age – The impact of the Indian council of medical research versus Caucasian bone mineral density reference standards Department of Endocrinology, Diabetes & Metabolism, Christian Medical College, Vellore, India', *Indian J Endocrinol Metab*, vol. 16, no. 2, pp. S514-S524.
10. Marwaha, R, Tandon, N, Kaur, P & Mani, KJ 2012, 'Establishment of age-specified bone mineral density reference range for Indian females using dual-energy X-ray absorptiometry', *J of Clin Dens*, vol. 15, no. 2, p. 241.
11. Shivane, V, Sarathi, V, Lila, A, Bandgar, T, Joshi, S, Menon, P & Shah, N 2012, 'Peak Bone Mineral Density and Its Determinants in an Asian Indian Population', *J Clin Densitom: Assessment of Skeletal Health*, vol. 15, no. 2, pp. 152-158.
12. Dhanwal, DK, Sahoo, S, Gautam, VK & Saha, R 2013, 'Hip fracture patients in India have vitamin D deficiency and secondary hyperparathyroidism', *Osteoporos Int*, vol. 24, pp. 553-557.
13. Khadgawat, R, Brar, KS, Gahlo, M, Yadav, CS, Malhotra, R, Guptat, N & Tandon, N 2010, 'High Prevalence of Vitamin D Deficiency in Asian Indian patients with fragility hip fracture: A pilot study', *JAPI*, vol. 58, pp. 539-542.
14. Khadgawat, R, Marwaha, RK, Garg, MK, Ramot, R, Oberoi, AK, Sreenivas, V, Gahlot, M, Mehan, N, Mathur, P & Gupta N 2013, 'Impact of vitamin D fortified milk supplementation on vitamin D status of healthy school children', *Osteoporos Int*, [Epub ahead of print].
15. Shatrugna, V, Kulkarni, B, Kumar, PA, Rani KU & Balakrishna, N 2005, 'Bone status of Indian women from a low-income group and its relationship to the nutritional status', *Osteoporos Int*, vol. 16, p. 1827.
16. Jha, R, Mithal, A, Malhotra, N & Brown, E 2010, 'Pilot case control investigation of risk factors for hip fractures in the urban Indian population', *BMC Musculoskelet Disord*, vol. 11, p. 49.
17. Harinarayan, CV, Ramalakshmi, T & Prasad, UV 2007, 'High Prevalence of low dietary calcium, high phytate consumption and vitamin D deficiency in healthy south indians', *Am J Clin Nutr*, vol. 85, pp. 1062-1067.
18. *Rural Population (% Of Total Population) In India*. 2013, Trading Economics, viewed 01 September 2013, <<http://www.tradingeconomics.com/india/rural-population-percent-of-total-population-wb-data.html>>.
19. Saigal, R, Mathur, V, Prashant, RK & Mittal, V 2006, 'Glucocorticoid induced osteoporosis', *Indian J Rheumatol*, vol. 1, no. 1, pp. 20-26.
20. Alekel, DL, Mortillaro, E, Hussain, EA, West, B, Ahmed, N, Peterson, CT, Werner, RK, Arjmandi, BH & Kukreja, SC 1999, 'Lifestyle and biologic contributors to proximal femur bone mineral density and hip axis length in two distinct ethnic groups of premenopausal women', *Osteoporos Int*, vol. 9, pp. 327-328.
21. Patil Sapna, S, Hasammis Ameya, A, Jena, SK, Rashid, AK & Narayan, KA 2010, 'Low Awareness of Osteoporosis Among Women Attending an Urban Health Centre in Mumbai, Western India', *Malaysian J Public Health Med*, vol. 10, no. 1, pp. 6-13.
22. Sankaran, B 2000, 'Clinical studies: Incidence of fracture neck of femur and intertrochanteric fractures in three Delhi hospitals', *New Delhi: South East Asia Regional Office, World Health Organization*, pp. 9-18.
23. Koh, LK, Saw, SM, Lee, JJ, Leong, KH & Lee, J 2001, 'Hip fracture Incidence rates in Singapore 1991-1998', *Osteoporos Int*, vol. 12, no. 4, pp. 311-318.
24. Dhanwal, DK, Siwach, R, Dixit, V, Mithal, A, Jameson, K & Cooper, C 2013, 'Incidence of hip fracture in Rohtak district, North India', *Arch Osteoporos*, vol. 8, pp. 135-139.
25. Tandon, N, Mithal, A, Anjana, RM, Pradeepa, R, Deepa, M, Mani, K & Mohan, V 2011, 'Population prevalence of fragility fractures in India based on a nationwide questionnaire based epidemiological study', *Abstract submitted in IOF regional-2nd Asia-Pacific Osteoporosis and Bone meeting to be conducted by ANZBMS and JSBMR*; September 4-8, 2011, Gold Coast Convention and Exhibition Center.
26. Marwaha, RK, Tandon, N, Gupta, Y, Bhadra, K, Narang, A, Mani, K, Mithal, A & Kukreja, S 2012, 'The prevalence of and risk factors for radiographic vertebral fractures in older Indian women and men: Delhi Vertebral Osteoporosis Study (DeVOS)', *Arch Osteoporos*, vol. 7, no. 1-2, pp. 201-207.
27. Krishnamurthy, V, Sharma, A, Aggarwal, A, Kumar, U, Amin, S, Rao, UR, Narsimulu, G, Handa, R, Mithal, A & Joshi, S 2011, 'Indian rheumatology association guidelines for management of glucocorticoid-induced osteoporosis', *Indian J Rheumatol*, vol. 6, no. 2, pp. 68-75.
28. Aggarwal, N, Raveendran, A, Khandelwal, N, Sen, RK, Thakur, RS, Dhaliwal, LK, Singla, V & Manoharan, SRR 2011, 'Prevalence and related risk factors of osteoporosis in peri- and postmenopausal Indian women', *J Midlife Health*, vol. 2, no. 2, pp. 81-85.
29. *Population Division of the Department of Economic and Social Affairs of the United Nations Secretariat, World Population Prospects: The 2008 Revision*, viewed March 28, 2011, <<http://esa.un.org/unpp>>; Kanis, JA, data on file.