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## Part One of Two Episodes: How the Top Osteoporosis Research Is Advancing Care

### Announcer Introduction:

You're listening to "Boning Up on Osteoporosis" on ReachMD. This program is sponsored by the National Osteoporosis Foundation. Here's your host, Dr. Mimi Secor.

### Dr. Secor:

For the approximately 10 million Americans over the age of 50 who have osteoporosis, and for their healthcare providers, there is some good news to share. Research on osteoporosis from the past decade has brought about many advancements in care, which can help prevent 50% of repeat fractures. So, what are those advances? And what's the latest research behind them?

Welcome to Boning Up on Osteoporosis on ReachMD. I'm Dr. Mimi Secor, nurse practitioner, and joining me to discuss some of the top research in the field is Dr. Felicia Cosman, Coeditor in Chief of the Osteoporosis International journal and Professor of Clinical Medicine at Columbia University Medical Center in New York.

Dr. Cosman, welcome to the program.

### Dr. Cosman:

Thank you very much. It's my pleasure.

### Dr. Secor:

So, without further ado, Dr. Cosman, let's get started. Can you tell us about any of the highly cited papers from the Osteoporosis International journal that address the way we approach patients living with this bone disease? And is there any general guidance we can glean from them?

### Dr. Cosman:

Yes, I think one of the top papers of the last decade is the National Osteoporosis Foundation Clinician's Guide that was published in 2014. This paper covers all the key clinical aspects important to the management of osteoporosis beginning with the discussion of what osteoporosis is and how we define osteoporosis-related fractures. The guide stresses universal prevention measures that include reducing risk factors, stopping or reducing doses of medicines that have adverse effects on the skeleton, modifying behavior such as stopping smoking and moderating alcohol intake, and it also includes recommendations on nutrition and exercise to maximize bone health. This paper covers who should be tested for the risk of osteoporosis and what tests are used, most often a bone density test of the spine and hip.

One of the most important parts of the guide that is stressed is to identify patients who have had vertebral fractures. And although these are the most common fractures that occur with osteoporosis, they usually are undiagnosed for months, or sometimes even years. Height loss and change in posture can be important signs, but a single spine imaging test, often a lateral spine x-ray, for example, to screen for these fractures is recommended in individuals at risk, and the paper identifies who these at-risk patients are who should have the vertebral imaging. The guide reviews who should be treated with medicine and how patients should be monitored, and it's really a must-read for clinicians who take care of patients with osteoporosis.

Another highly cited paper that covers the general management of osteoporosis is the position paper from the International Osteoporosis Foundation, and an update of this guidance was published in 2019 by Kanis and colleagues.

### Dr. Secor:

And what about diagnosis? One important paper by Siris and colleagues came out in 2014?

Dr. Cosman:

That's correct. This is a really important paper by Siris and colleagues regarding how we diagnose osteoporosis, and it was a position statement from a large group of clinical scientists called the National Bone Health Alliance. Prior to the paper, we were defining osteoporosis solely by a bone density level of T-score in the spine or hip of -2.5 or below, but we've known for a long time that the majority of fractures actually occur in people who have low bone mass, not osteoporosis. In part, the large number of fractures that occur in patients with low bone mass are occurring because there are so many more people who have low bone mass than osteoporosis on bone density testing, but also because low bone mass can be associated with disordered architecture and other factors, qualitative factors, that it can increase the risk of fracture beyond bone density alone.

In the Siris paper, an alternate clinical definition of osteoporosis is proposed, and the paper suggests diagnosing osteoporosis when a hip fracture has occurred in the setting of low trauma, such as a fall from standing height or less, and for hip fractures, you make the diagnosis without regard to bone density. The paper also suggests making the diagnosis in patients who have had vertebral fractures or fractures of the upper arm—the humerus—or pelvis, and at least some wrist fractures with low trauma. And the consensus of the group also recommended diagnosing osteoporosis clinically in patients who had absolute fracture risk calculated to be 20% over 10 years for the major fracture category and at least 3% over 10 years for the hip fracture category.

This paper is really important because it focuses not just on BMD results but also on the fracture itself, and it provides a diagnostic framework for us to target these high-risk individuals for treatment and provides the rationale for diagnostic and therapeutic costs to be covered by insurance payers.

Dr. Secor:

So, if we focus on epidemiology of osteoporosis, what new research has been done on this front?

Dr. Cosman:

A key paper by Lewiecki and colleagues published in 2018 evaluated hip fracture rates through Medicare claims data from 2002–2015. They found age-specific hip fracture rates were declining from 2002–2012, consistent with the modern diagnostic technology and osteoporosis medication. That was good news. But in 2013–2015, the hip fracture incidence plateaued, and this appeared to be related to reduced testing and treatment of at-risk patients. It provided evidence to suggest that we have got a huge diagnosis and treatment gap in this disease. And the implications of this study are that thousands of additional hip fractures are occurring each year with associated impact on quality and quantity of life, as well as cost of course.

Another really important epidemiology study by Ballane and colleagues in 2017 looked at all the published literature around the world to determine the prevalence of vertebral fracture. As I said earlier, most of these vertebral fractures don't produce back pain when they first occur, so it's very difficult to diagnose them at the time. Even though these fractures don't produce acute back pain though, these so-called radiologic fractures have the same clinical significance as painful fractures in terms of ultimate clinical consequences. Ultimately, they are associated with height loss and kyphosis, which impacts mobility and balance. They can produce restrictive lung disease symptoms, abdominal distension and discomfort, and they often lead to chronic back pain. Very importantly, these fractures are major predictors of more fractures to come. Vertebral fracture prevalence is usually determined by getting spine x-rays in large, unselected populations, and techniques for diagnosing them by x-ray criteria vary across the world and in different periods of time. Most studies use the semiquantitative method of Genant, who's the major radiologic expert in the osteoporosis field. In the Ballane review, large cohorts across Europe, Scandinavia, the Mediterranean area, Asia, Latin America, Canada and the US were all evaluated, and although there was some variability, the fracture prevalence across all of these regions in the world was very high; 15-26% of the people who participated in these studies had vertebral fractures across the world..

Another key companion paper that was published by me and my colleagues in 2017 was an NHANES working group where we were trying to identify vertebral fracture prevalence in women and men 40 years of age and above. We used a technique on modern bone density equipment called the VFA, or Vertebral Fracture Assessment. Using really strict criteria, we found vertebral fractures in more than 10% of people in their 70s and almost 20% of people in their 80s with no real gender differences. But what was really surprising about our findings was that fewer than 10% of the people who had these fractures knew that they had them. We also compared patients who met the National Osteoporosis Foundation criteria for who should have vertebral imaging tests versus people who did not meet this criteria, and we found, as we predicted, that vertebral fracture prevalence was much higher in people who did meet criteria—15% of those tested—compared to fewer than 5% in those who did not meet the NOF criteria.

We know that most of the patients who have vertebral fractures should be treated with medication, but if we don't recognize that they have occurred, we can't take the opportunity to treat the patients and prevent more fractures, so this is a really important area to focus on currently and over the next decade.

Dr. Secor:

Absolutely. Thank you, Dr. Cosman. Were there any major advancements on risk assessment over the past decade as well?

Dr. Cosman:

There are some really important papers. One of the big themes in osteoporosis management right now is the severe treatment gap in patients who have already had fractures, as I implied earlier. The presence of a low trauma fracture is one of the most important predictors of subsequent risk of fracture events, and around the world we're treating fewer than 20% of these patients after a fracture occurs.

One of the most important papers looking at the fracture population is from Balasubramanian and colleagues published in 2019. In this paper, Medicare claims data were used to identify over 377,500 women who were 65 years of age and above who had had a clinical fracture already, and these women were followed in the database for up to 5 years to determine the risk of subsequent clinical fracture. Overall, the risk of subsequent fracture was 10% in the very first year after the first index fracture, 18% in the first 2 years, and 31% in the first 5 years. If you consider subsequent risk of hip fracture alone after the sentinel clinical fracture, 2.5% of patients had a hip fracture within the very next year, 5% had a hip fracture within the next 2 years, and 10% had a hip fracture within the next 5 years. These data confirm with a really large sample size that it's imperative that we treat patients quickly, within weeks or months after they have their first fracture, in order to prevent more fractures with their associated morbidity and impaired quality of life and mortality.

Another major advance in the area of risk assessment is the absolute fracture risk assessment tool called FRAX. The whole idea of FRAX is to allow an individual's 10-year risk of having a fracture to be calculated based not only on BMD, but based on other factors that we know contribute to the fracture risk. Those include gender, age, body mass index, prior fracture history, parental history of hip fracture, smoking history, heavy alcohol use, glucocorticoid treatment, and underlying diseases, such as rheumatoid arthritis and many others conditions. The tool can predict fracture risk even in patients who don't have BMD measurement. The FRAX calculator is used around the world with factors that are specific to each region incorporated to calculate fracture risk. It has really helped us target therapy to individuals, especially those who don't meet the obvious treatment criteria, and this is particularly true of many patients who are within that low bone mass category.

Dr. Secor:

Well, that's fascinating. Thank you, Dr. Cosman.

Announcer Close:

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