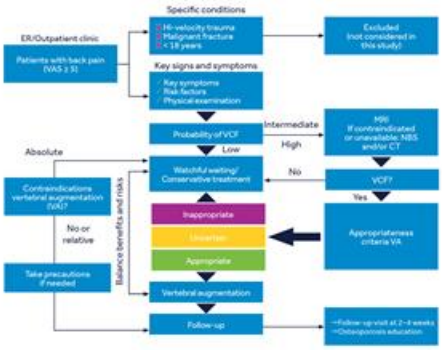
Medtronic News

National Osteoporosis Foundation Supports New Evidence-Based Care Pathway Designed to Optimize Care for Vertebral Compression Fractures (VCF)

Pathway Helps Physicians Better Identify Which Patients to Treat with Vertebral Augmentation, Which to Manage with Conservative Care

DUBLIN, Sept. 16, 2019 (GLOBE NEWSWIRE) -- Medtronic plc (NYSE:MDT), the global leader in medical technology, today announced that the National Osteoporosis Foundation (NOF) supports the VCF Care Pathway, a new evidence-based clinical care pathway developed by a multispecialty panel of experts to ensure osteoporotic vertebral compression fracture (VCF) patients receive timely and appropriate care. The VCF Care Pathway, published in *Spine Journal* in 20181and developed with grant support from Medtronic*, is an algorithm that has the potential to be integrated into a hospital's electronic medical record (EMR) system, ensuring patients who present with moderate or severe back pain as their primary or secondary complaint receive standardized treatment across all departments and healthcare providers, consisting of evidence-based care and follow-up.



BKP VFF Clinical Care Pathway

Osteoporosis is a common cause of VCF,2,[3]a debilitating and costly condition. In 2000, there were an estimated 9 million new osteoporotic fractures that came to medical attention, of which 1.4 million occurred in the spine (VCF).4The incidence of VCFs is likely to increase as the nation's population ages.5VCFs decrease mobility and can also cause severe pain, often leading to increased use of opioid pain medications and decreased quality of life.2, 3 Untreated VCFs can lead to a downward spiral that progresses from back pain, to deformed spines, reduced physical function, limited mobility and, finally, increased mortality.6-10Direct costs of VCFs in the United States are estimated to be $1 billion annually.5

The NOF believes that educating the healthcare community on appropriate patient care and working towards national standards are critical for advancing care of VCF patients. NOF has recently recorded and featured a discussion of the VCF Care Pathway on the NOF Bone Talk podcast.

"Our goal in working to integrate the VCF Care Pathway algorithm into commercially-available electronic medical records is to standardize and optimize care for VCF patients regardless of where in the care continuum they present." said Joshua Hirsch, M.D., vice chair, Procedural Services and chief of the neurointerventional spine service at Massachusetts General Hospital and the lead author on the *Spine Journal* publication. "We believe optimizing VCF patient care pathways on a macroscopic level will provide benefits at the patient level."

A lack of consensus within the medical community and different levels of familiarity with the literature have made it challenging for healthcare providers to identify those VCF patients who may benefit from vertebral augmentation (VA) and those who could

be appropriately managed with conservative care. The VCF Care Pathway is designed to systematically address this challenge.

The VCF Care Pathway was developed using the RAND™/UCLA Appropriateness Method (RAM), a highly-structured approach for developing patient-specific recommendations that combines best available clinical evidence with the collective judgments of a multispecialty panel of experts. To develop the VCF Care Pathway, the panel considered 576 potential clinical scenarios.

“The NOF supports the development and implementation of the VCF Care Pathway,” saidElizabeth Thompson, CEO ofthe National Osteoporosis Foundation. “Identifying, diagnosing, and treating VCF patients in a timely and appropriate manner will have a critical impact on patients across the country. One in two women and one in four men over the age of 50 depend on the NOF to educate physicians about osteoporosis-related conditions and treatments, such as VCF, and to continue advocating for appropriate treatments that provide patients with the greatest likelihood of positive outcomes. We believe that the VCF Care Pathway is an important tool that can help achieve that objective, and we encourage its adoption and implementation.”

“As a leader in medical technology, Medtronic knows that VA procedures have provided clinical benefits to VCF patients,” said Jeff Cambra, vice president and general manager of the Pain Therapies Interventional business, which is part of the Restorative Therapies Group at Medtronic. “However, we also know that a critical challenge in appropriate use of VA is identifying those patients most likely to benefit from the procedure and those who can be effectively managed with non-surgical treatment options. Our goal is providing funding to experts in the field so they could develop the most simple and effective tool that allows healthcare providers to address patients with VCF who enter into the healthcare system. Broad implementation of the VCF Care Pathway should help increase awareness and access to careassociated with treating this common and debilitating condition.”

About the RAND™/UCLA Appropriateness Method and Development of the VCF Care Pathway

The RAND™/UCLA Appropriateness Method (RAM), is a highly structured approach for developing patient-specific recommendations that combines best available clinical evidence with the collective judgments of a multispecialty panel of experts (neurosurgery, interventional neurology, radiology, pain medicine, and orthopedic surgery).To develop the VCF Care Pathway, a 12-member panel of experts reviewed and evaluated the 83 studies related to the management of VCF. The VCF Clinical Care Pathway supports early diagnosis and appropriate treatment of VCF regardless of the patient’s entry point into the healthcare system by identifying patients most likely to benefit from non-surgical management (NSM) as well as those for whom vertebral augmentation (VA) may be most appropriate. The panel members reviewed 20 signs and symptoms associated with VCF and considered the relevance of five procedures, comprising 576 clinical scenarios.

About Balloon Kyphoplasty

Balloon Kyphoplasty is a minimally invasive procedure for the treatment of pathological fractures of the vertebral body due to osteoporosis, cancer, or benign lesion. The complication rate with BKP has been demonstrated to be low. There are risks associated with the procedure (e.g., cement extravasation), including serious complications, and though rare, some of which may be fatal. Risks of acrylic bone cements include cement leakage, which may cause tissue damage, nerve or circulatory problems, and other serious adverse events, such as: cardiac arrest, cerebrovascular accident, myocardial infarction, pulmonary embolism, or cardiac embolism. For complete information regarding indications for use, contraindications, warnings, precautions, adverse events, and methods of use, please reference the devices’ Instructions for Use included with the product.

About the National Osteoporosis Foundation

Established in 1984, the National Osteoporosis Foundation, a leading community-focused health organization, is dedicated to the prevention of osteoporosis and broken bones, the promotion of strong bones for life and the reduction of human suffering through programs of awareness, education, advocacy and research. For more information on the National Osteoporosis Foundation, visit www.nof.org.

About Medtronic

Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, is among the world's largest medical technology, services and solutions companies—alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 90,000 people worldwide, serving physicians, hospitals and patients in more than 150 countries. The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

*The VCF Pathway published in *Spine Journal*1In 20181was supported by a grant from Medtronic. However, Medtronic was not involved in the design or execution of the project, nor the preparation and review of this manuscript. Names of panel members were not disclosed to the sponsor, and panel members were not informed about the identity of the sponsor before submission of the manuscript. Limitation: Double-blinded doesn't mitigate that the panel process was subjective input. It included strict adherence by the multidisciplinary experts to adopt the RAND™ methodology process, based on published clinical evidence and expertise.

VCF Care Pathway image is reprinted from*Spine Journal* 2018, Hirsch JA, Beall DP, Chambers MR, et al.Management of vertebral fragility fractures: aclinical care pathway developed by a multispecialty panel using the RAND/UCLA Appropriateness Method.Nov;18(11):2152–2161 Copyright 2018, with permission from Elsevier.

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Attachment

- BKP VFF Clinical Care Pathway

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Source: Medtronic plc

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https://news.medtronic.com/2019-09-16-National-Osteoporosis-Foundation-Supports-New-Evidence-Based-Care-Pathway-Designed-to-Optimize-Care-for-Vertebral-Compression-Fractures-VCF