Medtronic News

Medtronic Announces First Patient Enrollment in Clinical Trial Assessing Guideline-Based Heart Failure Management in Primary Care Setting

IMPROVE HF Bridge Study Will Examine Specific Gaps in Implementation of Guideline-Recommended Treatment in Heart Failure Patients Post-Hospital Discharge

MINNEAPOLIS--(BUSINESS WIRE)--Feb. 1, 2012--Medtronic, Inc. (NYSE: MDT) today announced the initiation and first patient enrollment in a clinical study that will evaluate gaps in the implementation of evidence-based treatment guidelines among chronic heart failure patients post-hospital discharge. The IMPROVE HF Bridge Study will analyze approximately 120 patients from four different centers in the United States for a period of six months following their initial hospital stay. Patients will be cared for in the outpatient setting by either a primary care physician alone, or by both a heart failure specialist and primary care physician throughout the study.

“With primary care physicians managing the ongoing follow-up and treatment of heart failure patients once they are discharged from the hospital, this study will provide new insight on what is happening from a treatment perspective once this care is transferred,” said Mihai Gheorghiade, M.D., principal investigator and professor of medicine and surgery, Feinberg School of Medicine at Northwestern University, Chicago. “It is our hope that through ongoing collaboration between cardiologists and primary care physicians, we can increase adherence to treatment guidelines and ultimately enhance the quality of care and reduce hospital readmission rates among heart failure patients.”

The prospective, randomized study will also explore the feasibility of implementing Class I, Level A guideline recommendations set forth by the American College of Cardiology and American Heart Association. These include drug therapy (ACE inhibitors, beta-blockers), device therapy (implantable cardiac defibrillators, cardiac resynchronization therapy), heart failure education and anticoagulation for atrial fibrillation. Findings from this study will inform whether a larger trial to bridge the gap between guideline recommendations and actual practice will be initiated.

Each year more than 1 million patients are admitted to the hospital due to heart failure1, and many of these patients are readmitted within 30 days due to the complex nature of managing their disease.2 While numerous evidence-based, life-prolonging drug and device therapies have been developed and are now widely available to reduce morbidity and mortality and improve quality of life for heart failure patients, these innovative therapies continue to be underutilized in both the inpatient and outpatient settings.3 For instance, cardiac resynchronization therapy is broadly underused in indicated patients despite a growing body of clinical evidence showing its benefits in reducing heart failure hospitalization and death.4 IMPROVE HF, the first-of-its-kind, prospective study involving approximately 35,000 heart failure patients from 167 U.S. cardiology practices, was designed to quantify and improve quality of care for heart failure patients by promoting the use of these evidence-based, guideline-recommended therapies.

“The commencement of the IMPROVE HF Bridge Study underscores our commitment to ensuring that all heart failure patients receive the best possible care through clinically-validated treatment options based on the individual’s specific disease-state,” said Pat Mackin, president of the Cardiac Rhythm Disease Management business and senior vice president at Medtronic.

About the IMPROVE HF Bridge Study

Heart failure patients in the study will be randomized post-hospital discharge to standard of care by a primary care physician (observational arm) or care directed by a heart failure specialist (assessment arm). The heart failure specialist will perform a comprehensive assessment of patients in the assessment arm within one week of discharge, which will include a health care utilization review and a full physical exam, and may also include specific diagnostic testing as determined by the study investigators. While heart failure specialists will not manage patients directly, they will collaborate with primary care physicians

after the one week visit is complete to make recommendations for care, including medication needs and potential device therapy indications.

Patients in the assessment arm will be followed by the heart failure specialist at 30 days, three months and six months for re-evaluation. The enrollment period is expected to take approximately 15 months from first enrollment, with total study duration of approximately 22 months.

In collaboration with leading clinicians, researchers and scientists worldwide,Medtronic offers the broadest range of innovative medical technology for the interventional and surgical treatment of cardiovascular disease and cardiac arrhythmias.

About Medtronic
Medtronic, Inc. (www.medtronic.com), headquartered in Minneapolis, is the global leader in medical technology – alleviating pain, restoring health, and extending life for millions of people around the world.

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.

1Centers for Disease Control and Prevention [CDC], 2006.
2 Jencks, S, et al. Rehospitalizations among Patients in the Medicare Fee-for-Service Program. N Engl J Med 2009; 360:1418-1428.
3 Fonarow GC. Rev Cardiovasc Med. 2002;3:S2-S10.
4 Anand, I, et al. Cardiac Resynchronization Therapy Reduces the Risk of Hospitalizations in Patients With Advanced Heart Failure. Circulation. 2009; 119: 969-977.

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