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New Study of Medicare Beneficiaries Reveals Significant Cost Burden, High Mortality Associated with Patient Infections Following Cardiac Device Implantation

New Orleans, LA (April 4, 2011): Surgical infections associated with pacemakers and defibrillators led to 3-fold increases in hospital stay, 55-118% higher hospitalization costs, 8 to 11 fold increase in mortality rates, and double the mortality after 1 year compared to pacemaker and defibrillator implantations where no infection occurred. Surprisingly, more than one-third of the excess mortality occurred after hospital discharge. These findings, from a new study in Medicare beneficiaries of more than 200,000 pacemaker and defibrillator implantations with and without infection, were presented today at a poster session at the American College of Cardiology 60th Annual Scientific Session by researchers from the Mayo Clinic, The Johns Hopkins School of Medicine, and TYRX, Inc.

“Rising health care costs are at the center of the political and economic debate this year,” said M. Rizwan Sohail, M.D., Assistant Professor of Medicine, Mayo Clinic College of Medicine, Rochester, MN, lead author of the new study. “However, efforts at cost reduction must begin by identifying the major driving forces behind the cost of patient care. In this study, we have tried to do just that for patients with cardiac device infections.”

Key findings from the study included:

- The in-hospital mortality rate for pacemaker and defibrillator implantation admissions, with an infection, was 8- to 11-fold the rate for non-infected admissions, depending on the device type.
- The longer-term mortality rate (death during the admission quarter and following year) was 27-36%, about 2-fold the rate without infection, depending on the device type.
- The mean hospital length of stay (LOS) with infection was 3-fold the length of stay without infection. Moreover it was substantially longer than the mean LOS for Medicare beneficiary admissions for the five leading principal diagnostic classifications: heart disease, pneumonia, malignant neoplasm, cerebrovascular disease, and fractures at all sites.

- Mean total hospitalization cost for pacemaker and defibrillator patients with infection was 55-118% higher than for those without infection, depending on the type of device. The incremental costs related to the treatment of the infection ranged from an average of \$17,000 for pacemaker infections to \$25,600 for certain types of defibrillators. The Medicare analysis revealed that the cost of managing the most extreme situations exceeded \$1 million.

“The ‘2010 American Heart Association/Heart Rhythm Society Scientific Statement on Cardiac Implantable Electronic Device (CIED) Infections and their Management’ identified a need for more precise data on the impact and economic burden of pacemaker and defibrillator infections,” commented Daniel Lerner, M.D., Chief Medical Officer of TYRX Inc. “This large population study in a broad spectrum of patients provides important information on the significant impact that cardiac device infections have on morbidity, mortality and health care costs. These findings further underscore the need for infection prevention as a key component of medical cost control.”

The new study was conducted with financial support from TYRX , Inc.

About TYRX, Inc.

TYRX, Inc. commercializes innovative, implantable combination drug/device products focused on infection control, including the AIGISRx® Antibacterial Envelope and AIGISRx® Flat Sheet products. AIGISRx products contain antimicrobial agents, rifampin and minocycline, which have been shown to reduce infection by organisms representing a majority of the infections reported in implantable pacemaker and defibrillator related endocarditis, including “superbugs” or MRSA*. Following commercial release in 2008, the AIGISRx Envelope has been implanted in over 17,000 patients nationwide.

TYRX, Inc. is an ISO 13485:2003 certified medical device manufacturer and its products utilize technology licensed exclusively from Rutgers, Baylor College of Medicine, and The University of Texas M. D. Anderson Cancer Center. For more information, please visit <http://www.tyrx.com>.

* Based upon preclinical *in vitro* and *in vivo* data. Data on file at TYRX and published in *PACE* 2009; 32(7) 898-907.

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