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Cardiac Device Infections Cost Money and Lives

TYRX, Sohail and Collaborators Present Findings of Medicare Study this Week at IDSA2011

Monmouth Junction, N.J. (October 20, 2011): Infections associated with the implantation or replacement of electronic cardiac devices result in incremental increases in mortality, both in the hospital and after discharge as well as substantially higher financial costs, compared to rates in uninfected patients. Increased costs in intensive care, routine care and pharmacy costs vary with the type of implanted device and account for the majority of the cost increase with infection, with almost half of the incremental hospital cost attributed to intensive care. These and other important findings from a large retrospective study of more than 200,000 Medicare beneficiaries undergoing cardiac device procedures, both with and without infection, are being presented this week at the 49th Annual Meeting of the Infectious Diseases Society of America being held from October 20 – 23 in Boston, MA.

"Cardiac implantable electronic devices (CIEDs) like pacemakers, implanted cardioverter-defibrillators (ICD), and cardiac resynchronization therapy/defibrillators (CRT-D) can reduce illness and extend life, but this benefit can be greatly reduced in terms of patient health, mortality and treatment costs if device implantation or replacement procedure is complicated by infection. Unfortunately, the rate of CIED infections today is increasing even faster than the rate of CIED implantation. The aim of this study was to better understand the mortality and costs associated with CIED infections, and the relationship of these outcomes to different CIED types," said Daniel Lerner, MD, chief medical officer of TYRX, Inc., which supported the study.

The study, conducted by M. Rizwan Sohail, MD, Mayo Clinic College of Medicine, and collaborators including Dr. Lerner, looked at 200,219 admissions of Medicare beneficiaries undergoing CIED procedures, 5,817 of whom were associated with device infection. The researchers found that the risk-adjusted length of hospital stay and costs were significantly higher for infected patients compared to the standard length of stay for individuals undergoing CIED procedures in the absence of infection. The risk-

adjusted incremental and total admission costs with infection were $14,360 - $16, 498 and $28,676 to $53,349, respectively, depending on CIED type. The largest incremental cost associated with infection was intensive care, which accounted for more than 40% of the difference. Infection was also associated with significant increases in adjusted admission mortality (rate ratios, 4.8-7.7; standardized rates, 4.6-11.3%) and long-term mortality (rate rations, 1.6-2.1; standardized rates, 26.5 – 35.1%, depending on CIED type). Importantly, about half of the incremental long-term mortality occurred after hospital discharge.

"The high cost of health care is a growing national concern, as is the increased rates of hospital-acquired infections that add significantly to those costs," commented Dr. Lerner. "This study found that increases in routine care, pharmacy cost, and especially intensive care costs accounted for the majority of the incremental cost associated with infection – areas that can be targeted to reduce costs associated with infection management. However, it is quite clear that the strategy that would have the greatest impact on costs associated with CIED infections, as well as patient mortality, is to prevent CIED infections in the first place."

About TYRX, Inc.

TYRX, Inc. commercializes innovative, implantable combination drug+device products focused on infection control, including the AIGISRx® Antibacterial Envelope & Flat Sheet technologies, designed to reduce surgical-site infections associated with Cardiac Implantable Electronic Devices (CIEDs). AIGISRx products contain antimicrobial agents, rifampin and minocycline, which have been shown to help 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, the AIGISRx Envelope has been implanted in over 20,000 patients nationwide. The company estimates that over 2% of all U.S. implantable pacemaker and defibrillator patients in 2011 will receive an AIGISRx product during their procedure. TYRX is preparing to commercialize its second AIGISRx technology, the AIGISRx ST, designed to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue. Current research & development projects are focusing on a fully-resorbable version of AIGISRx.

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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