



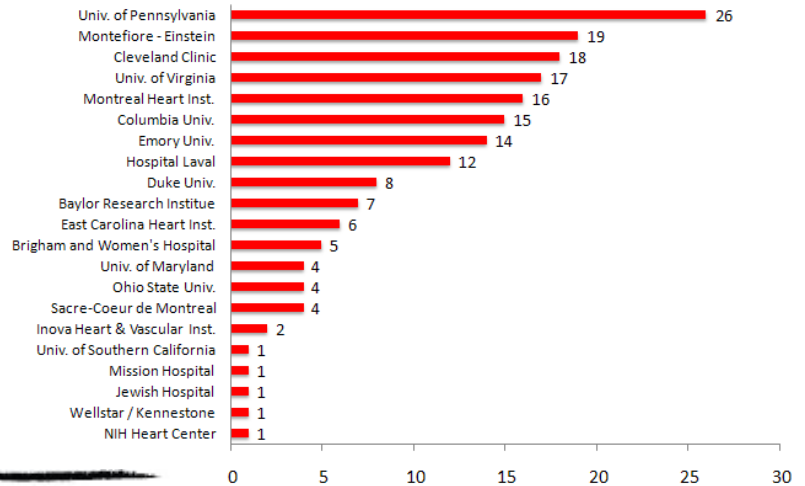
# THE NETWORK NEWS

April 2011

## Trials Update

### Enrollment in SMR Trial Nearly Completed

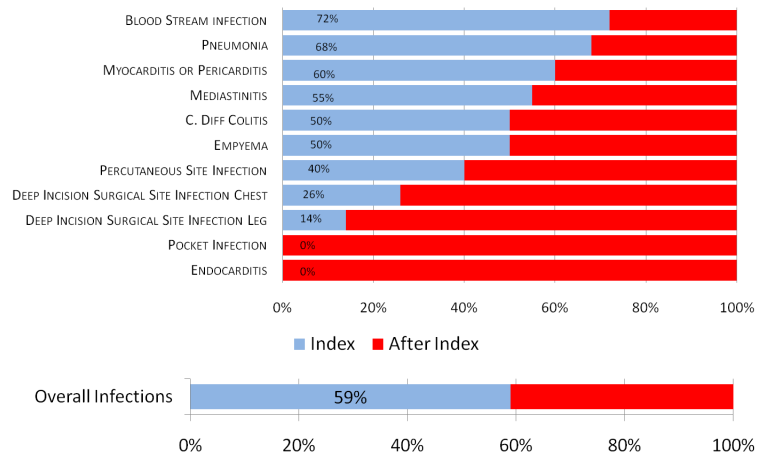
As of April 14<sup>th</sup>, the Network has randomized 182 patients in this trial that evaluates the effectiveness and safety of mitral valve repair and replacement in patients with severe ischemic mitral regurgitation (SMR). With 1-year mortality rates as high as 40%, recent practice guidelines recommend repair or replacement but there remains a lack of conclusive evidence supporting the long-term comparative benefits of these interventions. The choice between therapeutic options is characterized by the trade-off between reduced operative morbidity and mortality with repair versus a better long-term correction of mitral insufficiency with replacement. Investigators expect to complete enrollment (n=250) in the late summer of 2011.



### Infections Post-Cardiac Surgery Study Enrollment Completed

Hospital-acquired infections represent the main non-cardiac complication after heart surgery. They are associated with substantial morbidity, mortality and economic burden. CMS has recently announced that prevention of hospital acquired infections is one of their highest priorities. Thus, there is a crucial need to identify processes of care that might mitigate infections post cardiac surgery and help to develop effective preventive strategies. Prior studies examined the relationship between patient characteristics and infections post cardiac surgery. However, little is known about the relationship between routine practices (e.g., line and ventilator management, etc.) and postoperative infection risk. The CTSN enrolled over 5,187 patients in a study which seeks to better understand management practices that put patients at high risk for infections post-cardiac surgery. The first presentation of data was at the ISHLT meeting April 14, 2011 (by D. Goldstein, et al) regarding the heart transplant or VAD cohort.

#### INFECTION DURING INDEX HOSPITALIZATION



#### Core Clinical Centers

- Cleveland Clinical Foundation (E. Blackstone, M. Gillinov)
- Columbia University Medical Center (M. Argenziano)
- Duke University (P. Smith)
- East Carolina Heart Institute (B. Ferguson)
- Emory University (J. Puskas)
- Montefiore Medical Center - Albert Einstein College of Medicine (R. Michler)
- Montreal Heart Institute (L. Perrault)
- NIH Heart Center at Suburban Hospital (K. Horvath)
- University of Pennsylvania (M. Acker)
- University of Virginia Health Systems (I. Kron)

#### Ancillary Clinical Centers

- Hôpital du Sacré-Cœur de Montréal (P. Pagé)
- Inova Heart & Vascular Institute (A. Speir)
- Institut Universitaire de Cardiologie de Québec (Hôpital Laval) (P. Voisine)
- Ohio State University Medical Center (S. Sudhakar)
- WellStar Health System, Kennestone Hospital (W. Cooper)

## FDA Approves 13 New Sites for AF Trial

Another critical area is the treatment of *atrial fibrillation* (AF), including surgical ablation, which the Institute of Medicine (IOM) recently ranked as among the first quartile of the 100 priorities for comparative effectiveness research. The CT Surgical Trials Network designed a comparative effectiveness randomized trial of surgical ablation with left atrial appendage (LAA) closure versus LAA closure alone in patients with (longstanding) persistent AF undergoing mitral valve surgery. Nested within this trial, is a further randomized comparison of 2 different lesions sets (pulmonary vein isolation and full Maze lesion set). Currently, 75 patients have been randomized in the AF trial. This trial began with the 10 core CTSN sites, all of whom were open to enrollment by May 2010. In December 2010, the FDA approved 3 additional sites. The University of Maryland, Baylor Research Institute and Laval Hospital were selected. In March, the FDA approved 10 additional sites, with selection of new sites to occur in May 2011.

## Translational Research

The Network has designed 2 proof-of-concept trials: (1) implanting mesenchymal cells in LVAD patients to improve cardiac function in collaboration with the Cardiovascular Cell Therapy Research Network; and (2) a safety study of cardiac stem cells in patients following transplant. Both protocols will be submitted to the FDA shortly.

## MMR Trial Has Hit the 50% Enrollment Mark

The Moderate MR (MMR) Trial is designed to evaluate the effectiveness and safety of mitral valve repair in addition to CABG compared to CABG alone. The presence of ischemic MR is a significant predictor of adverse short and long term outcome, particularly after acute MI. When treated with CABG alone, patients with ischemic moderate MR (IMR) experience a substantially higher mortality than those without pre-operative IMR. IMR is characterized by geometric alterations of the left ventricle that may respond to revascularization, but the degree to which revascularization alone can stabilize or reverse this abnormality and improve long-term survival is unknown. Investigators expect to complete enrollment (n=300) by the spring of 2012.

## What's New ?

Three trial design papers (MMR, SMR, AF) are in press by the *Journal of Thoracic and Cardiovascular Surgery*.

### Network Chairs

Timothy J. Gardner, MD (Chair)  
Patrick T. O'Gara, MD (Co-Chair)

### Data Coordinating Center (DCC)

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Ron Levitan, DipCompSci  
Karen O'Sullivan, MPH  
Alan Weinberg, MS  
Paula Williams, MS

### NHLBI

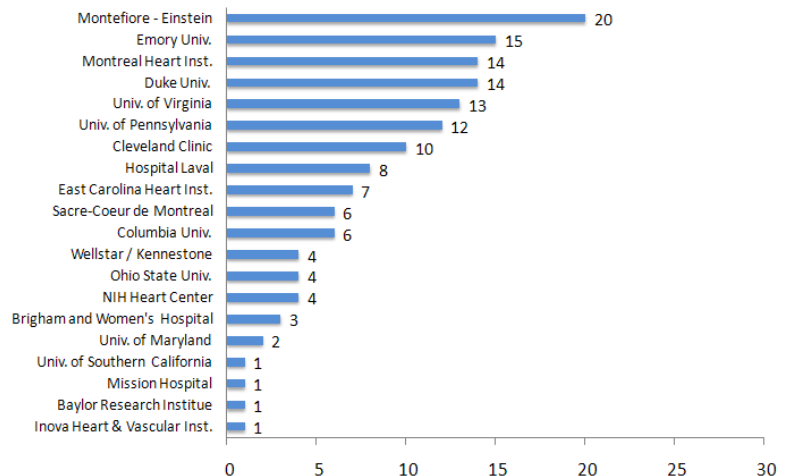
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### NINDS

Claudia Moy, PhD

### Canadian Institutes of Health Research (CIHR)

Ivana Kogan Gombos, PhD  
Jennifer Ralph



### Satellite Clinical Centers

Baylor Research Institute (M. Mack)  
Brigham and Women's Hospital (F. Chen)  
Jewish Hospital (M. Slaughter)  
Mission Hospital, Inc. (M. Groh)  
University of Maryland Medical Center (J. Gammie)  
University of Southern California (M. Bowdish)  
Washington University School of Medicine (R. Damiano)



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