New Paradigms of Collaborative Infrastructure: Impact of the “Fabric” Supporting Safety Registry Efforts

NHLBI view

Yves Rosenberg, M.D, M.P.H.

Program Director
Atherothrombosis and coronary Artery Disease Branch
Division of Cardiovascular Diseases
National Heart, Lung, and Blood Institute
NHLBI and CV Registries
A Long History

NHLBI-sponsored CV Registries

- **Completed**
  - Catheter Ablation Registry (1986 -1991)

- **On-going**
  - Dynamic Registry
  - Interagency Registry for Mechanically Assisted circulatory support (INTERMACS)
  - Pediatric Cardiomyopathy Registry
**Background**

Is a Safety Registry of AF Ablation Part of NHLBI Mission?

**NHLBI Mission:** Provide global leadership through research and education to enhance the health of all individuals so that they can live longer and more fulfilling lives. (E. Nabel, Feb, 2007)

**NHLBI Strategic Plan** (“a scientific blueprint for the next Decade”)

**Goal:** What are the “best practices” for the medicine of today and tomorrow?

**Challenge:** To enhance the evidence available to guide the practice of medicine, and improve public health

**Goal:** To translate research into practice for the benefit of personal and public health

**Challenge:** Evaluate the risks, benefits and costs of diagnostic test and treatments in representative populations and settings
Creating a Collaborative Infrastructure
NHLBI Strategies to Address Challenges

- Establish National standards for nomenclature
- Establish and expend collaborative resources for clinical research
- Extend the infrastructure for clinical research
- Support multidisciplinary teams
NHLBI and CV Registries
Criteria for Participation

• Important Public Health Problem
  ▪ Early clinical trials results often not confirmed: need on going evaluation in a “real life” clinical setting
    ▪ Different practices
    ▪ Different populations
  ▪ Relevant to patient care: safety, efficacy, cost

• Relevant Research Questions
  ▪ Scientific research rigor
  ▪ Using common methodologies and definitions from an early stage on
  ▪ Identify questions that need to be answered by an RCT
Creating a Collaborative Infrastructure
NHLBI Experience
Creating a Collaborative Infrastructure

NHLBI Approach

Our Approach
Work in partnership in an ever evolving environment.