



CREST-2 Update and Tactics to Improve StrokeNet Enrollment

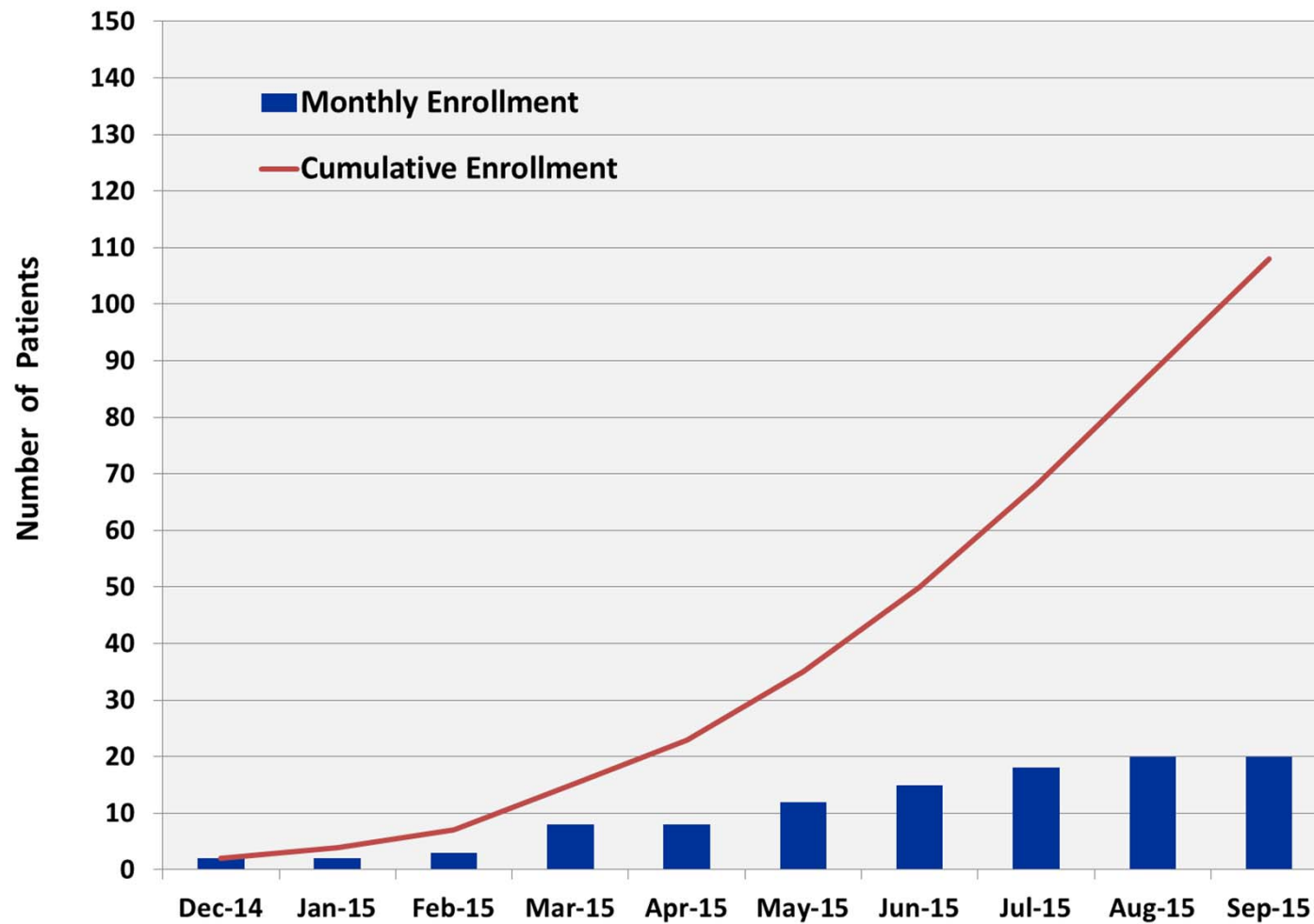
October 7, 2015 – Bethesda, MD

CREST-2 Enrollment Update



- **2,480 patients needed**
 - 40% women
 - 12% minorities
- **113 patients enrolled, 14 from StrokeNet sites**
 - 48 to CEA Trial
 - 65 to CAS Trial
- **32 StrokeNet Sites approved (18 are RCCs)**
- **17 sites are “Green Lighted” to randomize**
- **689 randomizations mandated by NINDS by October 2016**

CREST-2 Enrollment Update



First patient enrolled December 9, 2014.

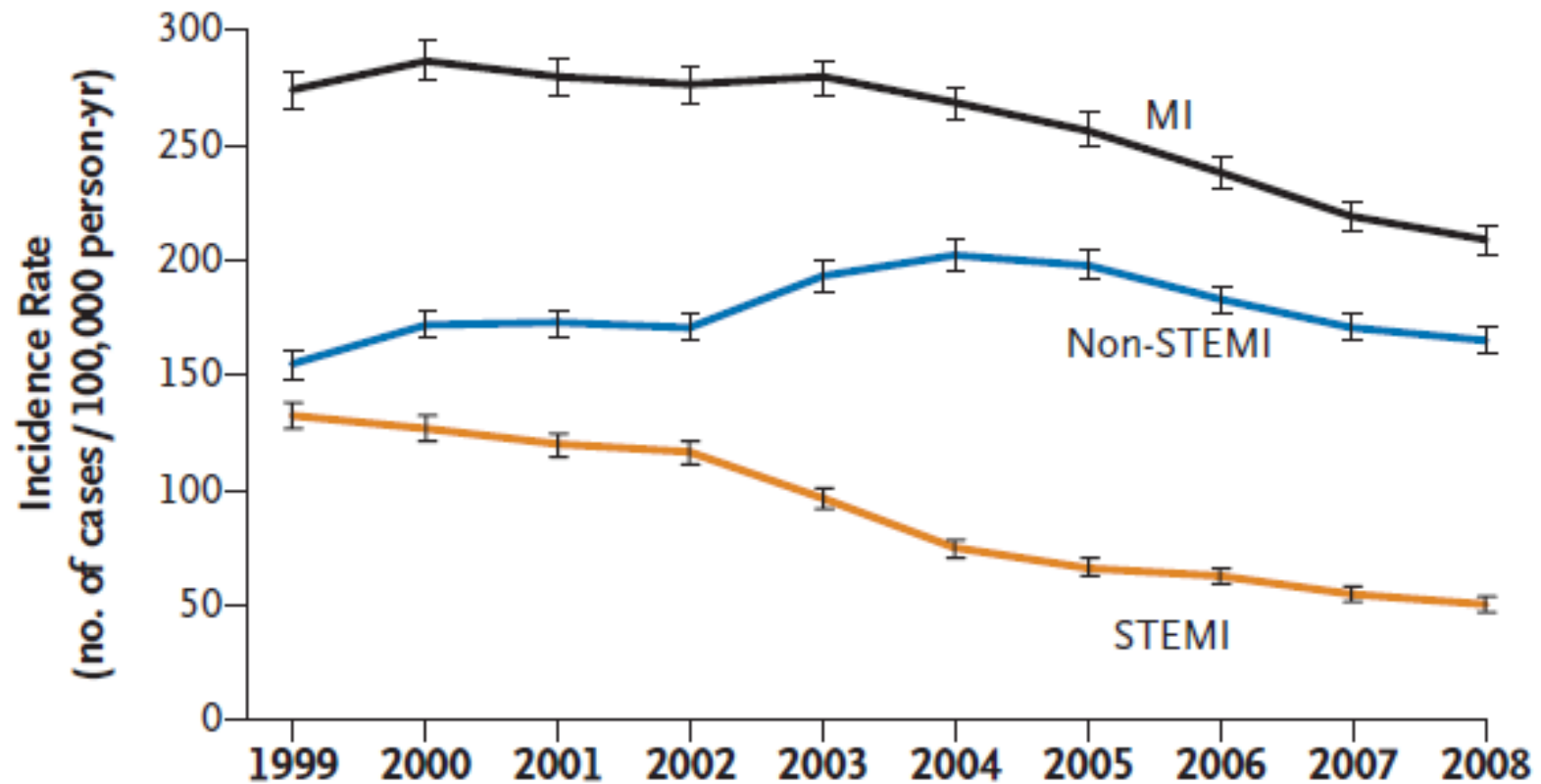


Figure 1. Age- and Sex-Adjusted Incidence Rates of Acute Myocardial Infarction, 1999 to 2008.

I bars represent 95% confidence intervals. MI denotes myocardial infarction, and STEMI ST-segment elevation myocardial infarction.

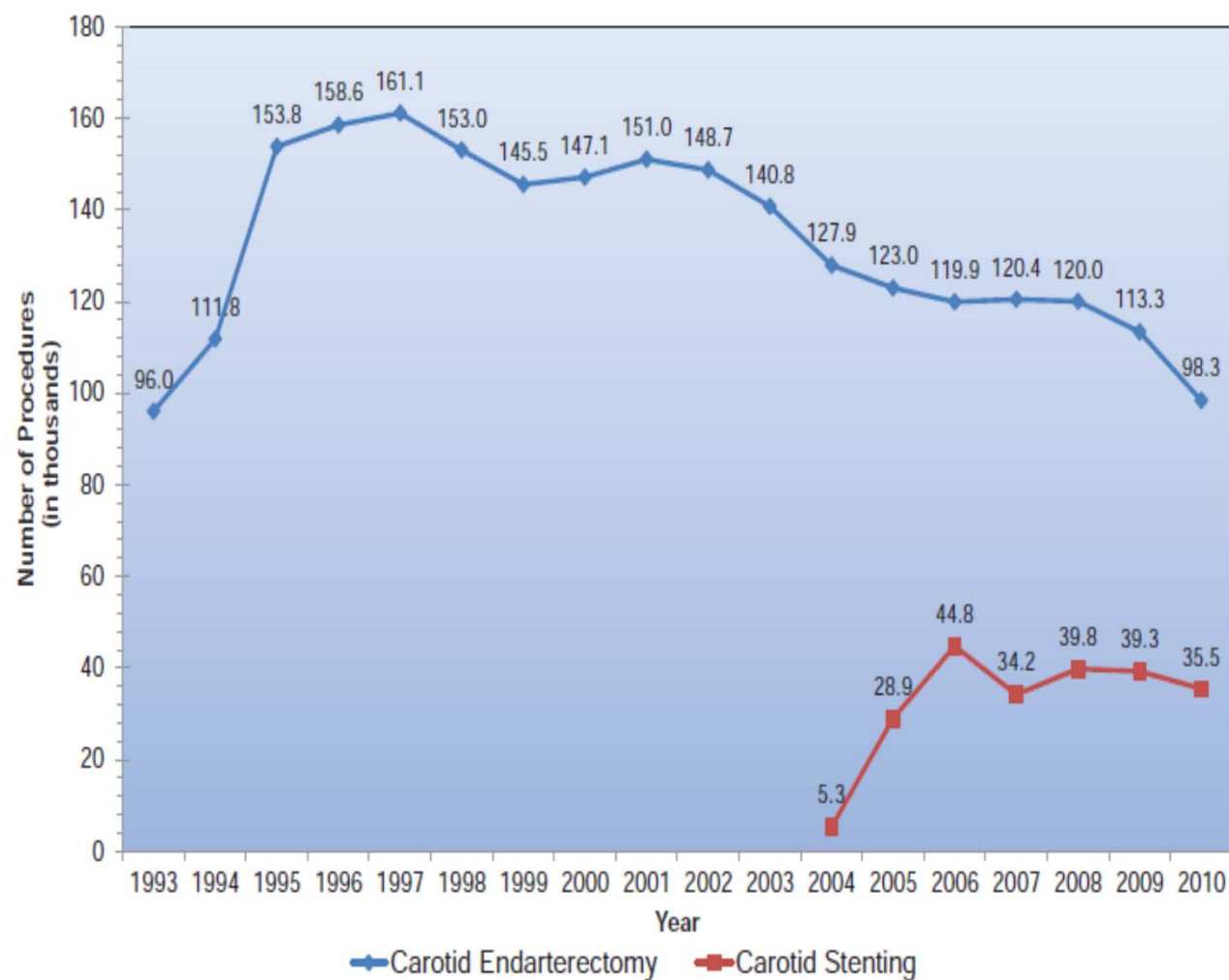


Chart 14-12. Trends in carotid endarterectomy and carotid stenting procedures (United States: 1980–2010). Source: Nationwide Inpatient Sample, Healthcare Cost and Utilization Project, Agency for Healthcare Research and Quality.



CEAS REIMBURSED BY CMS AT STROKENE^T HOSPITALS IN THE US

> 200 CEAs performed over a 4-year period	StrokeNet Site
943	Huntsville Hospital, Huntsville, AL
628	Christiana Care Health Services, INC. Wilmington, DE
391	Cleveland Clinic, Cleveland OH
377	Greenville Memorial Medical Center, Greenville, SC
358	Cedars-Sinai Medical Center, Los Angeles, CA
288	MUSC Medical Center, Charleston, SC
239	Cooper University Hospital, Camden, NJ
232	Northwestern Memorial Hospital, Chicago, IL
226	Summa Health Systems Hospitals, Akron, OH
224	Long Beach Memorial Medical Center, Los Angeles, CA
203	Hospital of University of Pennsylvania, Philadelphia, PA

Need every RCC and every Satellite

- All 25 RCCs have been sent Invitation Packets
- 23 have completed the Packet
- Several RCCs are on the brink of the “green light”
- 14 Satellites and Clinical Performance sites are approved, so > 100 could be candidates to be CREST-2 sites

*“Fifty ways to find
CREST-2 patients.”*



Guiding Strategy: the *personalized approach* to clinical trial management

- Mayo Clinic in Florida
- UAB
- MUSC
- U of Maryland
- StrokeNet CCC and CIRB
- NINDS

Learn from the Masters



Michael Jones



Don Heck



Larry Wechsler

Tactics for StrokeNet Sites already in CREST-2

Teamwork

- **Principal Investigator**
- **Coordinator**
- **Medical Management Physician**
- **Surgeon**
- **Interventionist**

Tactics for StrokeNet Sites already in CREST-2

- **DEFINE TEAMWORK WITH SPECIFICS**
 - Meetings regularly with your CREST-2 team
 - *how would you define regularly?*
 - Each member with action items
- **Multiple avenues for referrals**
 - Angiogram Suites and Ultrasound Labs
 - Family and Internal Medicine
 - CREST-2 CIRB approved recruitment materials
 - Template referral letter
 - Flyer with QR code to YouTube video
 - CREST-2 website (crest2trial.org)

Tactics for StrokeNet Sites not in CREST-2



Start now:

- Implementation plan
- Multiple avenues to get patients
- Study kick off
- Organizational announcement
- Special Grand Rounds

Approach to Patients



Donald Heck, MD
CREST-2 Site PI
Novant Health
Winston-Salem, NC

“CREST-2 is an easy trial for me to recommend to our patients. **I emphasize the fact that there is no "placebo" arm** of the trial. All patients in the trial receive state of the art medical care, and that is likely to make patients in the trial healthier than they might otherwise be.”

Approach to Patients

TIPS, TACTICS, AND THINGS TO THINK ABOUT

CREST-2 RECRUITMENT



Kevin Barrett, MD
CREST-2 Co-Investigator
for Recruitment

CREST-2 is an opportunity for our patients with high-grade asymptomatic carotid stenosis. Recruitment blends many factors together to achieve success – collaboration and teamwork among site PI's and coordinators, maintaining equipoise between medical and surgical therapy, and establishing rapport and trust with our patients. Having the perspective that CREST-2 represents a unique opportunity can help frame the option of clinical trial participation with patients and their families. Keep these talking points in mind when discussing the opportunities that exist for patients enrolled in CREST-2:

- **EVERY patient in the trial will receive contemporary, intensive medical therapy** – the protocol-specified management algorithm has demonstrated early success in achieving blood pressure and lipid goals with 88% in target at 4 months for SBP and 64% in target for LDL as of September 28th. Follow-up visits every 4 months are likely more frequent than patients may receive through their primary care providers.
- **EVERY patient in the trial will receive personalized dietary and lifestyle coaching** – the INTERVENT program will be *provided at no cost to the patient* and addresses important aspects of stroke prevention.
- **EVERY patient in the trial will have baseline and follow-up cognitive assessments** – many older patients are concerned about their memory. Formal memory testing and follow-up may be perceived as reassuring to patients enrolled in the trial.
- **EVERY patient assigned to carotid revascularization will be treated by the most skilled operators** – CREST-2 provides access to the safest and most experienced operators based on the credentialing process used to select proceduralists.

Leverage the CREST Companion Registry

Leverage Internists and Family Medicine MDs

The SPRINT trial: A major advance in treating high blood pressure

POSTED SEPTEMBER 16, 2015, 11:53 AM

Deepak Bhatt, MD, MPH, Editor in Chief, *Harvard Heart Letter*



... includes more than 9,300 participants age 50 and older, recruited from about 100 medical centers and clinical practices...

Systolic Pressure Intervention Trial Factors Affecting Atherosclerosis Study (SPRINTFAST)

- **To examine**

1) whether the presence of Chronic Kidney Disease is associated with faster rate of progression of atherosclerosis as assessed by magnetic resonance imaging (MRI) of the carotid artery.

2) Whether there is a effect modification of the associations of blood pressure treatment groups with atherosclerosis progression by the presence or absence of Chronic Kidney Disease.

- 600 estimated enrollment.

Want to refer a patient?



crest2trial.org

844-956-1826

Where are the patients?

Who are the referring physicians?

Screening at your site

- **Number of carotid ultrasounds**
- **Number of neck MRAs**
- **Number of CTAs**
- **Number of CEA**
- **Number of CAS**

Who orders them, who receives them, and what do they show?



Incentives: *need your ideas*

- Enhancement of local leadership
- Publications – *in CREST, the site investigators were prominent in writing and authorship , but at the END*
- Presentations – *ditto, but also at the END*

What would incentivize your colleagues?

Thanks,
*please
send
ideas*

