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The Newsletter of the POINT Trial
Volume I, Issue II 1st Quarter 2011

2010 Recap

Looking Forward to 2011

Dear Colleagues,

POINT accomplished much in 2010, thanks to much hard work.

During the year, we finalized our protocol, built a solid system of Case Report Forms, prepared the Manual of Procedures, obtained Institutional Review Board approval at over 70 institutions, and recruited 149 subjects (as of January 31, 2011), 61 of whom have already completed their 90-day Follow-Up visit (Figure 1). Recruited subjects were racially diverse and included a good balance of TIAs and minor strokes, as well as of men and women.

Some sites have done an exceptional job of recruiting, including Guilford Neurological, Henry Ford, Hospital of UPenn and Hennepin County Medical Center, while others seem to be struggling to get their screening mechanisms in place.

Great Progress...

...but 2011 needs to be even more productive!

We are still 90 sites away from our target of 150 active sites, so we need those of you waiting in the wings to complete your paperwork (as painful as it may seem, it really doesn't take long) and get up and running. Those sites without a recruited subject really need to look at where subjects are being missed. All the sites have active emergency departments and clinics, and the great success at some centers shows the patients are out there. If you need help with strategies, please let us know.

So, then, thanks for a great 2010. We look forward to working together on an even better 2011!

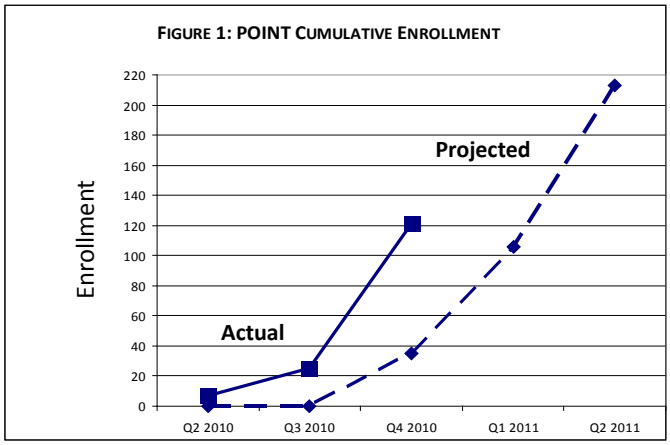
Sincerely,

Clay Johnston MD, PhD, POINT Trial Principal Investigator
Don Easton MD, POINT Trial co-Principal Investigator

Reminder

The POINT Investigator Reception is being held to coincide with the 2011 International Stroke Conference in Los Angeles. The Reception will be held at the Millennium Biltmore Hotel, on Tuesday, February 8th, 6-7:30 p.m.
To RSVP, or for more information, please contact your NETT-CCC or POINT CRC Site Manager.

Figure 1: POINT Cumulative Enrollment



POINT Enrollment Update: Total=149

Top Enrollers† (as of January 31, 2011)

Site (Hub)	City	State	#
Guilford Neurological (CRC)	Greensboro	NC	22
Henry Ford (HFHS)	Detroit	MI	11
Hospital of U. Penn (Penn)	Philadelphia	PA	9
Hennepin County Medical Ctr. (Minnesota)	Minneapolis	MN	7
Detroit Receiving (Wayne)	Detroit	MI	6
Abington (UPenn)	Abington	PA	5
Froedert Memorial Hospital (Wisconsin)	Milwaukee	WI	5
U. of Kentucky (Kentucky)	Lexington	KY	5
El Camino (Stanford)	Mt. View	CA	4
Temple U. Hospital (Temple)	Philadelphia	PA	4
University Hospital (Cincinnati)	Cincinnati	OH	4
Bon Secour (CRC)	Midlothian	VA	3
Diablo/Walnut Creek Campus (CRC)	Walnut Creek	CA	3
Memorial Hermann (Texas)	Houston	TX	3
OHSU-Oregon (OHSU)	Portland	OR	3
San Francisco General Hospital (UCSF)	San Francisco	CA	3
Sinai-Grace Hospital (Wayne)	Detroit	MI	3
UCSF Medical Center (UCSF)	San Francisco	CA	3
UMMC, Fairview (Minnesota)	Minneapolis	MN	3
U. of Maryland (Maryland)	Baltimore	MD	3
West Bloomfield (HFHS)	Detroit	MI	3

† Includes sites with at least 3 subjects enrolled.

In This Issue

Send your feedback and suggestions for future newsletters to Mary.Farrant@ucsfmedctr.org

POINT Frequently Asked Questions (FAQs)

Q. *One of our neurologists learned that a patient who was on aspirin and had a minor stroke was entered into POINT. The next day he became the patient's neurologist and insisted that the patient was "an aspirin failure" so he withdrew the patient from POINT and started him on clopidogrel. Is this okay?*

A. Aspirin for primary prevention of serious vascular events is of uncertain net value, as the reduction in occlusive events needs to be weighed against any increase in major bleeds (Lancet 2009; 373: 1849-60 & Stroke. 2011; 42: 227-276; page 249). Aspirin for secondary prevention reduces the risk of these events by about 20% compared to placebo. Thus the majority of stroke-prone patients on aspirin will have their stroke in spite of treatment. There is no evidence that modifying the aspirin treatment (to a different dose or drug) after brain ischemia is better than maintaining it. See the FAQ below addressing new AHA/ASA guidelines regarding this matter.

Q. *Will the new AHA/ASA guidelines on stroke prevention in TIA and stroke patients affect the POINT Trial?*

A. No. The new guidelines published January 1, 2011 state: **Recommendation 2**. "Aspirin (50 mg/d to 325 mg/d) monotherapy, the combination of aspirin 25 mg and extended-release dipyridamole 200 mg twice daily, and clopidogrel 75 mg monotherapy are all acceptable options for initial therapy." **Recommendation 5**. "For patients who have an ischemic stroke while taking aspirin, there is no evidence that increasing the dose of aspirin provides additional benefit. Although alternative antiplatelet agents are often considered, no single agent or combination has been studied in patients having an event while receiving aspirin." (Stroke. 2011; 42: 227-276; p. 249)

August-January Completed Readiness Calls* *(listed alphabetically)*

Site (Hub)	City	State
Advanced Neurology Specialists (CRC)‡	Great Falls	MT
Beaumont Royal Oak (Wayne)‡	Royal Oak	MI
Boston University (CRC)‡	Boston	MA
CPMC, Davies Campus (UCSF)	San Francisco	CA
CPMC, Pacific Campus (UCSF)	San Francisco	CA
Desert Neuroscience Inst. (CRC)‡	Rancho Mirage	CA
Emory (Emory)‡	Atlanta	GA
Harper University (Wayne)‡	Detroit	MI
Hershey (CRC)	Hershey	PA
Intercoastal Medical (CRC)‡	Sarasota	FL
Jewish Kenwood (Cincinnati)	Cincinnati	OH
Johns Hopkins (Maryland)‡	Baltimore	MD
Loyola (CRC)‡	Maywood	IL
Mayo Arizona	Phoenix	AZ
Medical College of Georgia (CRC)‡	Augusta	GA
Mercy Franciscan/Mt. Airy(Cincinnati)	Cincinnati	OH
Mercy Franciscan/Western Hills (Cincinnati)‡	Cincinnati	OH
Neuro-North Orange County (CRC)‡	Fullerton	CA
Northwestern University (CRC)‡	Chicago	IL
NYP Columbia (NYP)	New York	NY
NYP Methodist (NYP)	Brooklyn	NY
Palmetto Health Richland (CRC)‡	Columbia	SC
St. John Mercy (CRC)‡	St. Louis	MO
Salem Veterans Affairs (CRC)	Salem	VA
San Francisco General (UCSF)‡	San Francisco	CA
Shanti San Antonio (CRC)‡	Colton	CA
Sinai-Grace Hospital (Wayne)‡	Detroit	MI
UCLA Stroke Network (CRC)	Los Angeles	CA
UCSF Medical Center (UCSF)‡	San Francisco	CA
U. of Louisville (CRC) ‡	Louisville	KY
York (UPenn)‡	York	PA

‡ Has 1 or more enrollment as of January 31, 2011

**** Completed Readiness Calls after August 31, 2010.***

COORDINATOR'S CORNER—8 *Steps to Prevent Heparin Use in POINT Subjects*

by Andrace De Yampert, Project Monitor, University of Michigan NETT-CCC

The administration of heparin to POINT subjects, especially within the first 48 hours of enrollment, is a frequently noted violation during monitoring visits. Most of the time, the occurrence is discovered in retrospect: the study team was not aware of the order. In some institutions, *heparin prophylaxis* (also known as a preventative measure) is a well-established standard of care for patients at risk of developing blood clots. Given POINT's subject pool and the prevalence of standard initial orders for stroke and TIA, you may discover after the fact that a heparin order has been written and the drug already administered to one of your subjects. Consequently, it may be too late to stop what has already been ordered, or administered. Following recent POINT monitoring visits I've conducted, I noted that this scenario occurred at ALL sites for at least one of their enrolled subjects.

Despite our best efforts, violations may still occur. So it's important to develop, discuss and execute a strategy with your study team and clinical staff to help prevent them from occurring. The following steps are measures that study teams can take to prevent heparin from being ordered and/or administered to POINT enrollments, particularly in the first 48 hours following the qualifying event, thereby avoiding or minimizing protocol violations.

Scenario: *A subject is enrolled within 30 minutes of the 12-hour window.*

STEP 1: Discuss the enrollment as soon as possible with the physician/team treating the subject, and let them know heparin is one of the prohibited medications for the study.

STEP 2: Provide a copy of the ***Prohibited Medications*** sheet (see CRF 18, page 2)and point out the anticoagulants, including heparin, and other prohibited medications to the Attending and treating teams.

STEP 3: Talk to the physicians working with the subject. It may help to show the ordering physician and/or charge nurse the POINT consent signed by the subject, including the section where they consent to *not* receive anticoagulants.

STEP 4: Hang a ***Prohibited Medications*** sign (use bright color paper and large font) in the subject's room and/or at the head of the bed.

STEP 5: Establish a rapport with the clinical staff. Kindness and familiarity can go a long way.

STEP 6: Maintain frequent contact with your subject. Remind the subject which medications should not be administered—the subject may become a huge help!

STEP 7: Check the POINT FAQs (https://sitemaker.umich.edu/nett/point_faqs) frequently to be sure your are up-to-date on any changes to the listings for prohibited and discouraged medications.

STEP 8: Talk POINT, POINT, and more of POINT to be sure the clinical staff are aware of the basic protocol guidelines.