



COURAGE Chronicle

Courage Chronicle November 1999



CONGRATULATIONS TO THE FOLLOWING SITES!



Site	Pts. Enrolled	Site	Pts. Enrolled
200 Foothills Hospital	5	312 University of Michigan Medical Center	1
201 Hamilton General Hospital	1	313 University of Oklahoma Health Science Center	3
202 London Health Science Centre (Univ.)	10	501 Albuquerque VA Medical Center	5
Victoria Campus	1	506 Ann Arbor VA Medical Center	17
203 Montreal Heart Institute	3	508 Atlanta VA Medical Center	3
205 Queen Elizabeth II Health Sciences Centre	3	558 Durham VA Medical Center	13
210 The Toronto Hospital	6	580 Houston VA Medical Center	16
301 Boston Medical Center	1	584 Iowa City VAMC/ Univ. of Iowa Hospitals & Clinics	3
302 Cleveland Clinic	4	596 Lexington VA Medical Center	7
304 Emory University Hospital	5	598 Little Rock VA	8
306 Mayo Clinic Rochester	1	626 Nashville VA Medical Center/ Vanderbilt University	4
307 Christiana Care Health Systems	1	671 San Antonio-Audie Murphy VAMC	29
308 Mid America Heart Institute	11	663 Seattle Division-Puget Sound Health Care System	6
311 SUNY Health Science Center	5		

TOTAL AS OF 11/26/99: 171

Patient VISIT Schedules



- All Patient visits should be scheduled from his/her date of randomization, not date of consent or baseline. For example, if a patient is randomized Dec. 1, the 30-day visit should be scheduled between Dec. 18 and Jan. 15 (plus or minus two weeks of actual target date of Jan. 1). After the 3 month visit the window is 30 days. For example if the 1-year visit target date is March 1, the patient can be scheduled between Jan. 31 and March 31.
- Please use the scheduling system on the Pentablet to keep track of your patients' visits. It's easy and very useful. This will help avoid missed patient visits. An example of a patient schedule printout from the Pentablet is enclosed with this newsletter. If you need help with the scheduling system please call Tassos Kyriakides at 203-932-5711 Ext. 3771.

INVESTIGATORS/COORDINATORS ANNUAL MEETING



MARK IT ON YOUR CALENDAR

- The Annual COURAGE Update meeting will be held in San Diego, California on Jan. 24th to 26th. A reception will be held on Monday evening and a separate session for new coordinators is scheduled for 1PM to 5PM Jan. 24. New coordinators only need to bring their Pentablet with them. Please fax your invitation reply ASAP. For more information call Joan Smith at 203-932-5711 Ext. 3765 or Liz Jobses at 203-937-3440. Hope to see you there!



Important Reminders

- Please send all completed CRFs to West Haven as soon as possible and a copy to either Paul Casperson or Karen Potter. Also, please remember to send the following

to the appropriate places:

- Angiographic films, catheter tips, baseline and PCI procedures.
- Screening Logs.
- Baseline ECG. Be sure to enter the correct visit number on the label. Refer to Sec. 8-5 of the OP Manual for
- Schedule of Evaluations and Forms with corresponding visit numbers.
- Nuclear logs for Sestamibi reimbursement.
- Nuclear scans.
- Pentablot disk including log sheet.
- 30-day visit Lipid Core Lab Specimen.
- If you haven't already done so, please send your local lab normal ranges to Tassos Kyriakides or call him at 203-932-5711 Ext. 3771 to verify your local values.
- Please send your Drug Inventory Report, Form 28 to Albuquerque every two weeks to ensure adequate supply.

From Mid-America Heart Institute

At the Mid-America Heart Institute we hold a Cardiovascular Grand Rounds Conference every Thursday morning. We invite local and nationally recognized speakers to share new and cutting edge ideas and practices with our physicians, nurses, and staff. To encourage prompt attendance to Grand Rounds and to stimulate enrollment into COURAGE, we have begun the "COURAGE Case of the Week". The interventional fellows present a brief clinical vignette and review the cath films for COURAGE-eligible patients. Given that COURAGE is challenging the very foundation of clinical care for patients with CAD, this is a great opportunity to challenge and educate our medical staff.

In deciding which cases to discuss, we generally try to pick a patient that will evoke much discussion and bring up interesting views. Some cases are patients actually enrolled whereas others are those that went straight to revascularization. Occasionally we find cases where some feel that it is unethical to randomize patients – despite the absence of evidence in the medical literature. These often provide the most exciting dialogue.

Case of the Month

Mr. Patient, an 85 year old WM presents to the ER with palpitations and an ECG confirms a-fib at 140 bpm with ST segment elevation of 3mm in leads V2-V5. His past history is notable for HTN and unstable angina in 1988. At that time he was found to have a high grade lesion in the RCA with a completely occluded proximal LAD and an 80% stenosis in the diagonal branch. The RCA was dilated and the other occlusions were not. On the present admission, an adenosine thallium revealed severe inferior and inferolateral ischemia and an EF of 45% at rest. Cardiac Cath showed an occluded LAD, an occluded large OM, and sequential high grade lesions in the RCA. The OM filled via left-to-left collaterals and the distal LAD filled via right-to-left collaterals.

Mr. Patient was not interested in CABG surgery, which left him with the options of PCI vs. medical therapy. In light of his lesions, we felt that he was certainly at high risk for angioplasty, yet nobody felt comfortable without some form of intervention. Thus, he was a perfect candidate for COURAGE! He was ultimately randomized to angioplasty and the procedure went without complications.

Mr. Patient is alive and doing well today. Although he was classified low risk, he was *clinically* high risk with the extent of his lesions and reduced ejection fraction. This case evoked much discussion and different physicians would have gone with different treatments. The conclusion is that we just were not sure which therapy was the best option, which will hopefully be revealed with the COURAGE Trial.

John Spertus, MD, MPH, FACC



\$\$ Enrollment = Reimbursement \$\$

Canadian and Non-VA US sites cover their expenses by successfully recruiting and randomizing patients, and subsequently submitting the completed data forms to the West Haven Coordinating Center (WH) and the Core Labs. The reimbursements for each patient are distributed throughout the length of the trial, and the total paid for each patient depends on the patient's risk classification at the time of randomization (see page 8-16 in Operations Manual) and the length of follow-up time. Payments for a high-risk patient randomized in June, 1999 would total \$7,500, while total payments for a low-risk patient randomized in June, 2002 would equal \$3,700. Quarterly payments are scheduled as follows:

Initial Payment (Low Risk: \$1,000; Intermediate Risk: \$1,500; High Risk: \$2,000) – Requires all Baseline data and ECGs sent to WH, angiographic data and QOL data submitted to their respective Core Labs.

Follow-Up Payments: (\$300/follow-up visit) – Requires all Follow-Up data sent to WH including data for any hospitalizations that have occurred since the last visit and any other procedure such as ECG, ETT and QOL data sent to ECOR.

- Payments are expected to be made within one to two months after the end of each quarter.
- Payments for Sestamibi will be sent by the second week of December.
- Payments for randomized patients with completed forms sent will be sent by the second week of December.

Sestamibi Reimbursement

- To be reimbursed for sestamibi, the patient must also be listed on the screening log form. This will be reevaluated at the end of December, 1999.
- Please write Joan Smith a memo stating the name, where you want the reimbursement check sent, hospital name, address, account # and Tax ID if necessary.

Q & A

- Q.** When do I need to complete CRFs 6 and 7?
- A.** This depends on how ischemia was documented (question #1 on CRF 2).
If ischemia was documented by 'ECG changes alone' or by '24 Hour Holter', CRFs 6 and 7 are NOT required.
If documented by ETT alone, only CRF 6 is required.
And for all other methods, BOTH CRFs 6 and 7 are required.

IRB Renewal

- Please submit the protocol and amendment on the increased window for qualifying angiograms for reapproval to your IRB if it is due. Also submit any Ops Memos to your local IRB if required. Remember to file a copy of the renewal in your regulatory binder and forward a copy to West Haven.