



# COURAGE Chronicle

June/July 2000

## Happy Anniversary!!

Our first COURAGE patient was enrolled one year ago on June 28, 1999. We would like to take this opportunity to congratulate and thank all of you for your hard work, dedication and determination to make the COURAGE Trial a success. As we begin our second year, we want to review some recent developments:

- ◆ Amendment 2 was initiated May 17, 2000 that allows patients who present to the hospital with an acute coronary syndrome (ACS) without diagnostic ECG changes, abnormal biologic markers **or objective evidence of myocardial ischemia** to be randomized into the COURAGE trial if the ACS can be stabilized with intensive medical therapy. Patients must have a COURAGE -eligible coronary lesion that is  $\geq 80\%$  diameter stenosed and be off all **IV** nitroglycerine and anti-ischemic medications for 48 hours to be eligible to be randomized.

Please submit this amendment change to your IRB, and send a copy of the approval to Dr. Pamela Hartigan at the West Haven Coordinating Center and a copy or fax to Karen Potter at the Co-Chairman's office in Syracuse, NY.

- ◆ In order to minimize the need to obtain repeat stress tests to document objective evidence of myocardial ischemia, the window has been broadened to **six months** instead of three months.

These changes should decrease delays in the screening process and facilitate enrollment of patients into the trial.



## Successful Risk Factor Modification in the COURAGE

The hallmark of the COURAGE Trial is that **all patients receive intensive medical therapy in accordance with AHA Treatment Guidelines**. A measure of the successful implementation of this intensive medical therapy is the ability of each individual site, and of the trial as a whole, to help all patients reach the goals for specific risk factors as set out in the COURAGE Protocol. The critical period for modifying these individual risk factors occurs during the first three months that a patient is in the Trial. Current medical therapy, properly used, is able to bring these risk factors into the acceptable ranges for most patients during this period.

At three months, the anginal symptoms of enrolled patients were lowered on average to below CCS Class I. The COURAGE Trial has also been successful in moving the trial-wide average values of the targeted risk factors into the appropriate ranges. (See Table; underlined values are in the targeted range). An initial premise of the COURAGE Trial was that intensive medical therapy could help control the major risk factors for CAD. These results demonstrate that our target goals can be achieved at centers where a concerted effort is made to practice intensive medical therapy to modify their patients' risk factors.

### Average Risk Factor Values (Baseline/Three-Months)

	Diseased Vessels	CCS Class	SBP ( $< 130$ mmHg)	DBP ( $< 85$ mmHg)	LDL ( $60-85$ mg/dL)	HDL ( $> 35$ mg/dL)	TRIGLY. ( $< 200$ mg/dL)
COURAGE (N=187)	2.1	2.0/ <u>0.9</u>	134/ <u>129</u> [60%]	<u>73</u> / <u>73</u> [89%]	110/ <u>90</u> [50%]	<u>40</u> / <u>41</u> [38%]	<u>191</u> / <u>185</u> [71%]

## PENTABLET SECURITY

Recently, a theft of a Pentablet occurred at one of our sites. While this is unfortunate, it gives us the opportunity to review some basic security measures each site is responsible for:



1. Identifying and protecting all assets within their assigned area of management control from theft, damage and unauthorized access.
2. Protecting sensitive information generated or used by their offices from disclosure to and/or modification by unauthorized individuals.
3. Ensuring that sensitive information is secured when the work area is unattended.
4. Briefing new personnel regarding the rules on the protection of sensitive data from disclosure and misuse and protection of property.
5. Protecting their assigned user IDs, passwords, electronic signatures and other access codes from disclosure.
6. Logging off systems before leaving workstation unattended.

Each site is responsible for the replacement cost of \$3400 if a Pentablet is stolen. Don't let this happen to you! Your Hospital's insurance policy **MAY** cover the replacement cost. Please ensure that your equipment is registered with your equipment officer per the memo sent with the equipment from the West Haven Coordinating Center. Thank-you!

### Let's Welcome Our New Sites!

- ◆ Portland VA Medical Center—  
PI: Edward Murphy, M.D.  
Coordinator: Kathy Avalos, M.A.
- ◆ Southern CA Kaiser Permanente Medical Group (Los Angeles)-  
PI: Peter Mahrer, M.D.  
Coordinator: Phyllis Scutella, RN
- ◆ Hopital du Sacre Coeur (Montreal)-  
PI: Donald Palisaitis, M.D.  
Coordinator: Chantale Mercure, RN

### Spanish and French QOL CRFs Available

Economic and QOL Forms 20 through 27 are available in French and Spanish. Please contact Cheryl Lewis, BSN at ECOR Ph: 404-712-1655. to obtain copies if you need them. Cheryl Lewis has assumed responsibility as the QOL data coordinator. Please direct questions about the Pentablet to Cheryl and scheduling system to Tassos Kyriakides.

## PATIENT ENROLLMENT UPDATE

		To	Date
671	Audie L. Murphy VAMC – San Antonio	58	
202	London Health Sciences Centre	41	
203	Montreal Heart Institute	35	
580	Houston VA Medical Center	33	
506	Ann Arbor VA Medical Center	28	
598	John C. McClellan VA – Little Rock	24	
558	Durham VA Medical Center	24	
205	Queen Elizabeth II HSC	23	
306	Mayo Clinic—Rochester	21	
209	Sunnybrook & Women's College HSC	20	
200	Foothills Hospital	19	
630	New York VA Medical Center	19	
308	Mid America Heart Institute/Shawnee Mission	17	
663	Seattle VA Medical Center	17	
596	Lexington VA Medical Center	17	
304	Emory University Hospital	14	
584	Iowa City VAMC/Univ. of Iowa Hospital	13	
585	The Toronto Hospital	12	
501	Albuquerque VA Medical Center	12	
626	Nashville VA Medical Center	11	
312	University of Michigan Medical Center	11	
313	University of Oklahoma	11	
211	University of Alberta Hospital	9	
301	Boston Medical Center	8	
508	Atlanta VA Medical Center	8	
204	St. Michael's Hospital	7	
201	Hamilton General Hospital, McMaster Clinic	6	
207	St. Paul's Hospital	6	
212	Vancouver Hospital and HSC	6	
314	MIMA Century Research Associates	5	
311	SUNY Health Science Center at Syracuse	5	
208	Sudbury Memorial Hospital	4	
302	Cleveland Clinic	4	
300	Barnes-Jewish Hospital	3	
626	Vanderbilt University Medical Center	3	
307	Christiana Care Health Systems	1	

## Randomization Phone Numbers

To randomize a patient, please call the following numbers in the order listed:

1. Ray Kilstrom (203) 932-5711 x3767
2. Liz Petrokaitis (203) 932-5711 x3760  
or 888-803-5560
3. Joan Smith (203) 932-5711 x3765
4. Tassos Kyriakides (203) 932-5711 x3771
5. Pam Hartigan (203) 932-5711 x3773  
VA FTS #: 8-700-428-(ext. #)



If you are unable to reach one of these people, please use the pager at 1-888-473-4427. If you use an envelope to randomize a patient, please notify the West Haven Coordinating Center at one of these numbers