



COURAGE Chronicle

Courage Chronicle

September 1999

Hello! To all of the hard working coordinators and investigators of the COURAGE Trial!

By now we hope everyone has begun enrollment into this terrific trial. Since this project is very comprehensive and complex, I wanted to share some of my ideas, which I have found to be very successful. Also, I would like to share some comments from my patients who are in follow-up. Preparation and organization are a necessity to keeping your sanity!

Here are a few ideas:

- Prepare a folder of information for each patient: include AHA handouts, medications education sheets, low fat recipes, phone numbers of local chapters of ACS or ALA for smoking cessation classes, a glossary of common medical terms, a medication list, a goal-tracking sheet, and a list of contact persons on the study team. We purchased canvas tote bags saying "Making a Difference: Ann Arbor VA Cardiology Research" to give to each patient. This allows for ease in carrying their folder, medications, handouts, etc.
- Use progress note overlays to ease the documentation. I developed some, which I have forwarded to Karen Potter and Paul Casperson (if you are interested).
- Prepare a simple summary letter to provide to the referral or primary care provider. We have found this to be invaluable.
- Remember to pull out all of the tricks: Use of contracting with patients to change their behavior has been very successful. Setting a stop smoking date with them also helps. Or use the PACE worksheets as "homework" and review with patients briefly at their follow-up visit.

Patients have been **very** enthusiastic about participating. I have had several comments about the **FUN** patients had with the pentabret. They also enjoy the close follow-up with a consistent provider.



It seems that the patients actually feel accountable to make the necessary lifestyle changes. Lastly, my patients have made tremendous strides toward reaching goals. One patient has gone from 3 packs a day to 12 cigarettes per day! Another has dropped his MEDFICTS score from 109 to 45!

It has been our experience that patients welcome the goal-tracking sheet to monitor their progress and the comprehensive approach to their overall health.

Kendra Szymanski, RN, CS, ANP
Anita Bargardi, RN, CS, ACNP
Ann Arbor VA Medical Center

WAY TO GO!!

VASOSEAL

If you would like to use Vasoseal at your site, you need to contact your local Vasoseal representative. Datascope will replace Vasoseal free of charge for patients who are randomized in the COURAGE Trial. If you are unclear on how to contact your local representative, please call Karen Potter at 1-800-215-7330.

SITE AUDITS

Every participating site will be audited at least once during the trial by the Good Clinical Practice Auditing team from Albuquerque. The auditor will contact the study site prior to the visit to arrange a mutually agreeable time. The auditor will check the investigator's study records to ensure that they are complete and organized. Please refer to Section 10 of the Operations Manual for more details on what is expected in order to be in compliance with Good Clinical Practices.

RANDOMIZATION ENVELOPES

Randomization envelopes are to be completed at the time of randomization for EVERY patient. Usually this will occur when the coordinator makes the call to West Haven, but may also occur in the cath lab. Each completed envelope must be detached from the remainder and sent to West Haven along with completed CRF's for screening/baseline visits.



REMINDER: Be sure to use the latest CRF's. The new forms are dated "August 1999" and "September 1999" on the bottom left corner.

PATIENT ENROLLMENT

671 San Antonio – Audie Murphy VAMC	19
506 Ann Arbor VA Medical Center	11
580 Houston VA Medical Center	11
558 Durham VA Medical Center	7
598 Little Rock VA Medical Center	5
663 Seattle VA Medical Center	5
202 London Health Sciences Centre	4
308 Mid America Heart Institute	4
210 The Toronto Hospital	4
501 Albuquerque VA Medical Center	3
584 Iowa City VA Medical Center	3
596 Lexington VA Medical Center	3
626 Nashville VA Medical Center	3
508 Atlanta VA Medical Center	2
311 SUNY Health Science Center at Syracuse	2
302 Cleveland Clinic	1
200 Foothills Hospital	1
Total Patients Enrolled as of 9/17/99:	88

DRUG ISSUES



Welcome aboard to Carol Fye, R.Ph., M.S. who will be assuming Nancy Morgan's position as Assistant Director at the VA Cooperative Studies Program-Clinical Research Pharmacy Coordinating Center in Albuquerque, NM and Bill Gagne who will be the new Project Coordinator. Direct your questions regarding Serious Adverse Events to Carol and requests for drug supplies to Bill. Phone/Fax numbers remain the same. PH: (505) 248-3203, FAX: (505) 248-3205
 E-mail: carol.fye@CSP.RESEARCH.MED.VA.GOV, william.gagne@CSP.RESEARCH.MED.VA.GOV

DRUG INVENTORY REPORT

A COURAGE Drug Inventory Report form has been distributed to all sites that have received study drugs. The purpose of this report is to provide PCC with information that will enable us to automatically replenish supplies at each site in a timely manner. In order for PCC to be able to accomplish this, it is necessary that sites complete and fax these forms to PCC **AT LEAST EVERY TWO WEEKS**. This form can also be completed at any time that a site feels additional drug is required. Since all drug being provided for this study is open-labeled, it is essential that sites monitor their drug usage and inventory to ensure that a sufficient supply of study drug is available for study patients at all times.

INVESTIGATIONAL DRUG INFORMATION RECORD (VA-Form 10-9012)

The Investigational Drug Information Record (VA-Form 10-9012) is a VA form required to be completed for all investigational drugs used in clinical trials. An investigational drug for clinical use, as defined by M-3, Part I, Chapter 9, is a drug for which a sponsor has filed an Investigational New Drug (IND) application and received approval from the FDA. Since there is no US IND and the drugs being supplied to the participating VA centers in COURAGE are US marketed, commercially packaged, open-label drugs, it was decided these forms were not required and thus were not provided by PCC. However, if an individual VA's Research and Development (R&D) Committee requires completion of a form for each drug being supplied in the COURAGE trial, it will be the site's responsibility to comply. It may be prudent at the time these forms are requested to mention that there are a minimum of 12 different drugs that will be provided for COURAGE patients, thus 12 separate forms would be required to be developed, signed off, and placed in each patient's medical record. Unless locally mandated by the R&D Committee, auditors from the Good Clinical Practices Audit Unit will not verify the presence of these forms in the medical records.