



# COURAGE Chronicle

September, 2000

## Economic and Quality of Life Data Collection

The Quality of Life data collected on Forms 20 through 27 are important pieces of information for the COURAGE Trial that are time sensitive. Therefore, it's important to collect and send it as quickly as possible to Emory Center for Outcomes Research (ECOR). The Pentabket is the preferred method of completion; use the paper versions only if absolutely necessary.

All of these forms, except for Forms 20-B, 20-F and 26 are found on the Pentabket. Form 26 – Standard Gamble/Trader is on the Pentabket only and is NOT available in the paper version.

The Patient Economic Questionnaire (PEQ), Form 20B–Baseline and Form 20F–Follow-up, are used to request information on patients' economic status and should be collected at baseline, 3, 6, 12, 24, 36 month visits according to Table 5: Schedule of Evaluations and Forms. PEQ forms are NOT on the Pentabket. Each site should have hard copies of these to administer accordingly. Please do not use the forms from the manual stamped "copy". If you need either of these forms contact Cheryl Lewis, BSN at ECOR.

On the Pentabket, the patient should be entered using the quality of life (QOL) Patient ID. For Patient ID, enter the first three letters of the last name, first letter of the first name, and the last two digits of the year of birth. (e.g. Joe Smith, Jan. 1, 1940, the QOL ID would be SMIJ40).

**Download  
Now**

Data should be downloaded to disk and submitted AT LEAST every two weeks.

A missing data report was sent to each site in August. Please submit all outstanding data as soon as possible. When using the paper forms, please take the time to briefly review the subjects' responses to be sure that ALL questions are answered.

On Form 20-F, coordinators are asked to provide the previous PEQ completion date (#9, page 3). Most are being returned blank.

If you have any questions about Forms 20-27 or need additional forms (available in Spanish and French) please contact Cheryl Lewis at (404) 712-1655 (EST).

### Screening Patients

- ◆ If you discover that a patient is participating in another long-term trial besides COURAGE after the patient has been randomized: first, call Karen Potter, BSN, then notify the Chairman's office of both trials in writing, (refer COURAGE correspondence to the Syracuse Chairman's office - Attn: Karen Potter, BSN), and finally, notify your IRB. A determination will then be made as to whether the patient needs to be withdrawn from the COURAGE Trial.
- ◆ Patients who require a PCI by a surgeon prior to a planned surgery should NOT be randomized into the COURAGE Trial.



## West Haven Data Clarification

Baseline Form 4, Section VI asks about "Duration of Angina (months from first diagnosis)". This should be the duration from the **VERY FIRST** time of diagnosis, not the most recent one.

If the patient has an "Outpatient PCI" please complete Form 10. The fact that it is an outpatient PCI is indicated by the last question on the first page. There is no need to complete a Hospitalization Form (Form 11) if the PCI is done as an outpatient.

If your site receives an "Alternate EF Measurement" Form, the method of measurement of the EF should be clearly specified. If "3 –other" is checked for the question "How was EF measured?" An "Estimated" EF is NOT acceptable. A reminder, if PVCs are present on the angiogram, the Angiographic Core Lab will not be able to accurately record the EF and you are required to obtain an alternate EF, preferably before the patient is discharged to home.

Forms 6 and 7 as required by Form 2 to document ischemia must be at visit 00 (not as visit 01).

If a patient has missed a visit and you will not be sending in the required forms, please fill out Form 16 for that visit.



## PATIENT ENROLLMENT UPDATE

|     | <b>To Date</b> |
|-----|----------------|
| 671 | 73             |
| 202 | 53             |
| 580 | 39             |
| 203 | 36             |
| 506 | 32             |
| 558 | 27             |
| 205 | 26             |
| 209 | 26             |
| 598 | 26             |
| 630 | 23             |
| 306 | 22             |
| 596 | 22             |
| 200 | 22             |
| 663 | 21             |
| 501 | 19             |
| 308 | 17             |
| 312 | 17             |
| 304 | 16             |
| 584 | 16             |
| 210 | 15             |
| 313 | 15             |
| 212 | 12             |
| 626 | 12             |
| 207 | 12             |
| 301 | 9              |
| 211 | 9              |
| 204 | 9              |
| 201 | 8              |
| 208 | 7              |
| 314 | 6              |
| 648 | 5              |
| 300 | 3              |
| 626 | 3              |
| 316 | 2              |
| 315 | 1              |
| *** | 18             |

**Total Patients as of 09/22/00**

**679**

## The Sky Wasn't the Limit!!!



One enterprising and inventive PI recently decided that "the sky wasn't the limit" for one of his patients. While flying at 30,000 feet, Dr. Robert O'Rourke, on a flight from Chicago to San Antonio, randomized a patient in his cath lab back in Texas.

While we can't expect this "above and beyond" attitude from everyone, it sure does give us a goal to shoot for.

**Good Job, Dr. O'Rourke!**

By the way, was the patient a Navy Pilot???