

Operations Memo No. 13



VA COOPERATIVE STUDIES PROGRAM # 424

Clinical Outcomes Utilizing Revascularization and Aggressive DruG Evaluation

Date: October 20, 1999

From: Pamela Hartigan, PhD, Study Statistician for COURAGE

Subj: Reporting of Adverse Events

To: Study Personnel

Thru: Trial Leadership

Drug (device) related

Because all the medications and devices in this study are licensed products being used for labeled indications, side effects in this trial are not treated in the usual manner. If a patient has one of the more common adverse effects of the study medications or devices the occurrence, as well as action taken, if any, should be documented in the progress notes for the patient but does not need to be recorded by the coordinator on study forms. The symptom distress scale, completed by the patient, is the study form on which the occurrences of the more common adverse effects of the study medications are being recorded. There is no attempt to link the effect to a drug on this form.

If the adverse event is **SERIOUS AND REASONABLY ATTRIBUTABLE** to a study drug it should be recorded on Form 18 and the form faxed immediately to the Pharmacy Coordinating Center in Albuquerque. It may also be documented on other study forms, e.g. hospitalization.

Procedure related

If there is an adverse event, common or serious, related to a procedure, it is recorded on Form 10 – PCI. If this event is life-threatening or fatal the Study Cochairman's office should be informed as soon as possible. The event may also be documented on other study forms, e.g. report of death.

Events not related to drugs, devices, or procedures

Adverse events, such as hospitalization for unstable angina or the occurrence of an MI are documented on the hospitalization form. Death is documented on the Report Of Death – Form 19.