10.   Comorbidity Assessment

10.1   Introduction

The assessment of comorbidity is important to determine as the number and severity of non-renal medical conditions will vary from study patient to study patient. There are a number of comorbidity scales that have been developed. In the HEMO Study, the ICED was used to assess comorbidity; however, this assessment took 30 – 45 minutes to complete for each patient. The Charlson Index was developed in 1987 and has been used in numerous analyses of comorbidity in both non-dialysis and dialysis patients.

The FHN comorbidity assessment (Form 104) includes items from the Charlson Index. This index contains 19 categories of comorbidity, which are primarily defined using ICD-9-CM diagnoses codes (a few procedure codes are also employed). Each category has an associated weight, taken from the original Charlson paper [1], which is based on the adjusted risk of one-year mortality. The overall comorbidity score reflects the cumulative increased likelihood of one-year mortality; the higher the score, the more severe the burden of comorbidity. The original Charlson Index included points for the presence of kidney failure; a modified Charlson score for dialysis patients has been developed and will be used in the FHN trials.

10.2   Data Sources

It is important to have a number of different data sources in order to fully capture the comorbidites for each of the study patients. Key data sources include hospital discharge summaries, physician consultation notes, and the nephrologist's comprehensive clinical assessment of the patient that includes a past medical history. At least one of these documents must be present from within the past 6 months in order to complete the comorbidity profile. Other additional sources that may be used to assess comorbidity include physician progress notes at the dialysis unit, nurses progress notes at the dialysis unit, medical problem lists and the completed HCFA 2728 form that lists comorbidities at the initiation of chronic dialysis therapy.

As many of these data sources as possible should be collected PRIOR to the comorbidity review. Note that these records may be located at a hospital, the nephrologist's office, or the dialysis unit and that these records could be either paper records or stored electronically.

The study coordinator who is trained by the DCC to use Comorbidity Form 104 (which includes the Modified Charlson Index) will assess comorbidity of patients in the FHN Trials.

10.3   Frequency

The comorbidity assessment will be conducted on each patient at baseline in the Daily Study and Nocturnal Study.

Reference:

1. Charlson ME, Pompei P, Ales KL, McKenzie CR (1987). A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. <u>J Chron Dis, 40(5),</u> 373-383.