Quality Oversight of Dialysis in the United States

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In the United States, payment for the medical care of more than 95% of end-stage renal disease (ESRD) patients is provied, at least in part, by the federal government through the Health Care Financing Administration (HCFA). HCFA provides quality oversight to the ESRD program through two mechanisms: the State Departments of Health which ensure compliance by dialysis providers to minimal standards of care (conditions of participation), and the 18 regional ESRD Networks which promote quality improvement activities by providers through data collection and educational activities. The conditions of participation specify policies and procedures by which each dialysis provider should operate, and failure to adhere to these standards can jeopardize that the providers payment by HCFA. Each dialysis facility undergoes a site visit by agents of theat states Department of health to assure compliance with the conditions of participation at the time the facility opens and periodically (every 1-9 years, depending upon that states dialysis facility licensing laws) thereafter. If a facility fails to comply with the conditions of participation, the facility must submit a plan for corrective action and must demonstrate that the violations have been rectified within a specified period of time. It is extremely rare for a facility to lose HCFA funding because of failure to correct deficiencies. However, given the infrequency of state surveys of dialysis facilities in some states, it is not unusual for a facility to fall out of compliance between site visits.

The ESRD Networks are independent corporations that contract with HCFA to provide quality oversight activities to dialysis providers in their respective regions of the US. The contract with HCFA specifies activities in three major areas data collection and analysis, quality improvement, and community outreach. The Networks act as conduits for the collection from providers of demographic and some outcome data to the two major national ESRD database: The United States Renal Data System (USRDS) and the national ESRD Clinical Performance Measures Project. Each Network may also collect process and outcome data from facilities to support its own quality improvement projects (which are required by the HCFA contract). A national ESRD data infrastructure is currently evolving which links the Networks to HCFA and to each other (SIMS or standardized information management system) and will eventually link every dialysis provider with its respective Network (VISION or vital information system for improvement of outcomes in nephrology). Once the VISION system is completed (possibly by the end of 2001), every facility will be able to electronically download patient demographic and quality data to the Networks. This will allow the Networks to generate confidential facility-specific profiles with regional comparatives to drive facility internal quality improvement programs, it will allow for

the development of an improved national ESRD database, and it will support accountability as some facility outcomes will drive state survey activities and/or will be disclosed to the public to assist in consumer choice.

Currently, the USRDS database, which is primarily descriptive with a scholary focus, does not generate any facility-sepcific reports except for a standardized mortality ratio (SMR), a standardized hospitalization ratio (SHR), and a standardized transplant ratio (STR). The data which drive these reports come from HCFA billing data and certain standardized forms which every facility must complete when a patient starts ESRD therapy, changes modality (dialysis to transplant or vice versa), or dies. The standardized ratios take into account some of the facilitys case-mix, including patient age, race, gender, and cause of ESRD (diabetic or non-diabetic). These facility-specific standardized ratios allow facilities to compare their performance with other, and are being used as accountability tools to trigger state survey activities and public scrutiny.

The national ESRD Clinical Performance Measures Projects is the evolution of the national ESRD Core Indicators Project, which began in 1993. In 1997, following the publication of the Netional Kidney Foundations Dialysis Outcomes Quality Initiative (DOQI) clinical practice guidelines addressing hemodialysis and peritoneal dialysis adequacy, anemia management, and hemodialysis vascular access, HFCA contracted to have selected DOQI guidelines converted into evidence-based clinical performance measures to provide an annual snapshot of the quality of dialysis care provided in the US, based on a random sample of 400 hemodialysis patients from each of the 18 ESRD Networks and a national sample of 1500 peritoneal dialysis patients. Parameters such as percent of patients with hemoglobin >11gm/dl (previously hematocrit >31%) and percent of patients with Kt/V >1.2 (previously URR >65%) have shown continued annual improvement since 1993. Other performance measures such as serum albumin >3.5 gm/L and percent of dialysis patients with catheters have shown little improvement over the years. Once VISION is operational at the facility level, the national sample for the ESRD Clinical Performance Measures Project will be 100% of patients, and the generation of Network-specfic and facility-specific outcome reports will allow each of the ESRD Networks to target its quality improvement activities to the domain in which the greatest oppotunities for improvement exist (there are profound regional variations in processes and outcomes) and to target those facilities in greatest need of guidance.

The dual oversight mechanism of state surveyors conducting quality assurance activities and the ESRD Networks conducting quality improvement activities has recently come under increased scrutiny because of well publicized patient grievances and data which suggest that outcomes for dialysis patients in the US are poorer than for their counterparts in other parts of the world. However, this mechanism has succeeded in continuously improving certain dialysis patient outcomes over the past few years and in protecting patients from harm due to substandard care. It is anticipated that funding for increased frequency of state survey activities, increased public accountability of providers, implementation of the VISION data system, and increased leverage for Networks and state survey agencies to demand facility compliance with quality initiatives will further improve dialysis patient outcomes in the US, and allow for the rapid deployment of new evidence-based processes of care.