
A Data-Driven Approach to Improving the Care of In-Center Hemodialysis Patients

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Health care providers, patients, the end stage renal disease (ESRD) networks, and HCFA have developed the ESRD Health Care Quality Improvement Program (HCQIP) in an effort to assess and improve care provided to ESRD patients. Currently, the ESRD HCQIP focuses on collecting information on quality indicators (QIs) for treatment of anemia, delivery of adequate dialysis, nutritional status, and blood pressure control for adult in-center hemodialysis patients. QIs were measured in a national probability sample of ESRD patients, and interventions and evaluations of the interventions are beginning. The ESRD HCQIP illustrates a way to mobilize the strengths of the public and private sectors to achieve improved care for special populations.

INTRODUCTION

HCFA's HCQIP is designed to help Medicare providers use population-based data to identify opportunities for improving the quality of beneficiary care (Gagel, 1995). HCQIP was initially developed in 1992 for utilization and quality control peer review organizations (PROs) (Jencks, 1992; Hayes, 1994). HCQIP was extended to include the Medicare ESRD program in 1994, with the award of new 3-year con-

tracts to the ESRD network organizations. This article describes the development of the ESRD HCQIP and HCFA's data-driven HCQIP model in the Medicare ESRD program. In particular, it describes the multiple data sources used during the development of the 1994-97 ESRD HCQIP.

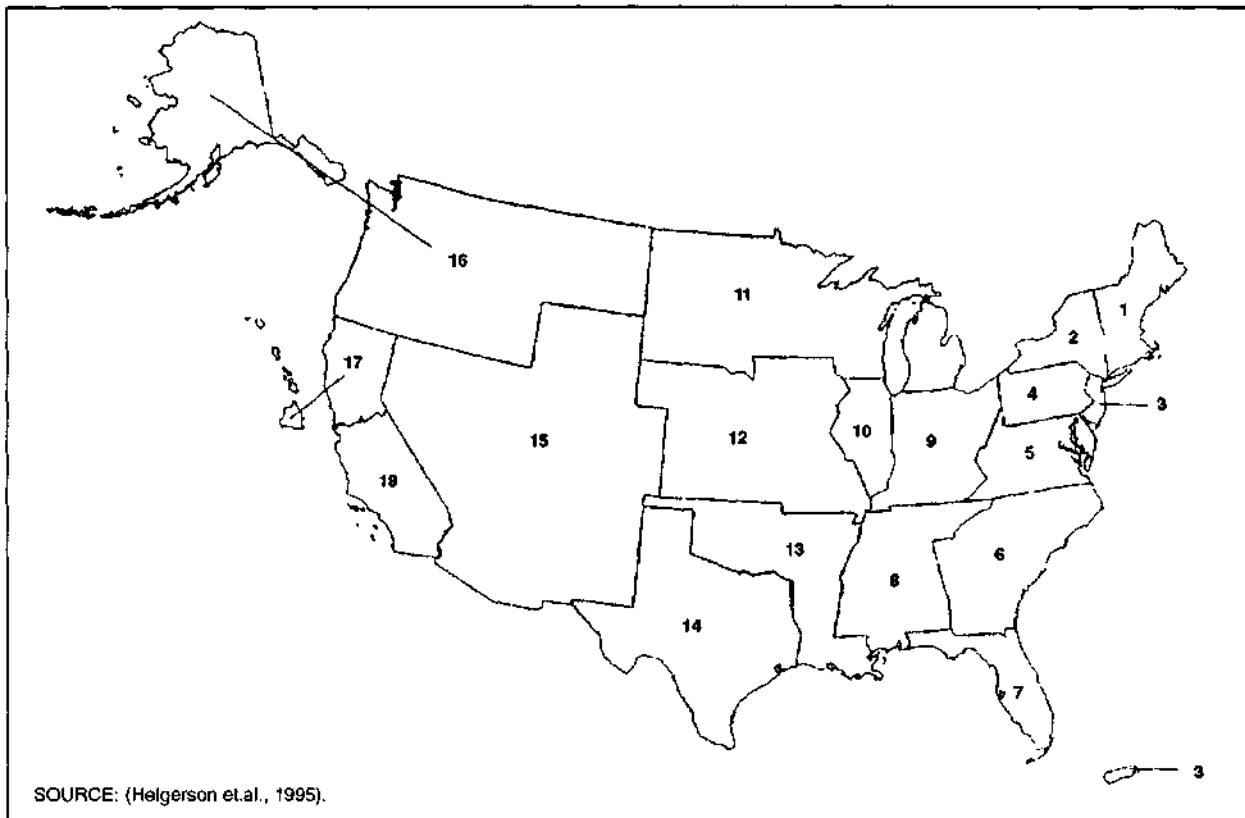
Applying HCQIP in ESRD: 1994-97

ESRD HCQIP outlined in the 1994-97 networks' contract scope of work is a collaborative effort of HCFA and national organizations concerned with the care of individuals with ESRD. The collaboration was initiated in 1992 when HCFA invited several organizations in the renal community¹ to meet and begin discussion on how to improve the quality of care for renal patients. This action was prompted by concerns with the quality of care provided Medicare beneficiaries in the ESRD program, including: the treatment of anemia; the adequacy of dialysis (a major determinate of risk of death); variations in transplantation outcomes; high mortality rates in the United States compared with the rates in ESRD populations in other countries; and continuing variations in case-mix-adjusted treatment center mortality (Rettig and Levinsky, 1991; Schrier et al., 1994; Eggers, Greer, and Jencks, 1994; Nissenson, 1994; McDonald and Aultman, 1994; U.S. Renal Data System, 1994;

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¹ Organizations participating in the 1994-97 ESRD HCQIP include: American Association of Kidney Patients; American Nephrology Nurses Association; Renal Physicians Association; National Renal Administrators Association; Forum of ESRD Networks; HCFA; and the National Institutes of Health—National Institute of Diabetes and Digestive and Kidney Diseases.

Figure 1
End Stage Renal Disease Networks in the United States



McClellan, Flanders, and Gutman, 1992; McClellan and Soucie, 1994; Held et al., 1991; Owen et al., 1993). In September 1993, HCFA convened a voluntary workgroup consisting of representatives from the organizations previously identified to begin the development of a quality-improvement program for ESRD.

The data necessary to evaluate these concerns were available, in part, from the ESRD network organizations (Figure 1). Eighteen ESRD networks covering the United States and its territories collect, validate, and analyze data on the occurrence and outcomes of treatment for ESRD Medicare beneficiaries. Network data are aggregated, analyzed, and reported by HCFA and by the U.S. Renal Data System (USRDS), so that both regional and national outcomes-of-care information is available (U.S. Renal Data System, 1994).

Selection of QIs

The first step in the development of the ESRD HCQIP involved selection of areas of dialysis patient care concerns where opportunity to improve care potentially existed. Information about patterns of care (i.e., pattern analysis) provided by HCFA and the individual ESRD networks was used to describe outcomes and trends observed for the treatment of anemia, transplantation, adequacy of dialysis, and mortality. While pattern analyses have limited ability to distinguish between variations in clinical processes which are remediable and patient characteristics (case mix) which contribute to observed outcomes, they are useful for identifying areas of care warranting further scrutiny (Jencks and Wilensky, 1992; Lohr, 1990; Rettig and Levinsky, 1991; Schrier et al., 1994). For

each aspect of care identified by pattern analysis, the work group considered the following criteria recommended by the Institute of Medicine (IOM):

- The frequency of the condition in the ESRD Medicare population (salience).
- Methods available to measure outcomes and risk factors (measurability).
- Substantial, clinically important, differences existing between clinical guidelines and current practice (significant variation).
- Well defined and widely accepted guidelines for care (available guidelines).
- Guideline conformity that can be accomplished with available skills and resources and that has been addressed by clinicians and allied health professionals in the area of concern, e.g., cardiovascular disease (practicability) (Lohr, 1990).

Pattern analyses were combined with a literature review conducted by clinicians and scientists in the work group to determine that anemia treatment and mortality were quality of care problems in the ESRD program that met the IOM criteria and therefore warranted further study (Table 1).

Based on the literature review, the workgroup chose adequacy of dialysis, treatment of anemia, nutritional status, and blood pressure control as QIs to describe the care received by dialysis patients. We will illustrate the development of these QIs with adequacy of dialysis and treatment of anemia.

The work group first had to decide which quality of care or clinical measures were to be collected to describe or measure the QIs. These decisions involved a separate set of information-based criteria. The workgroup used the IOM's general criteria for outcome indicators that:

- Account for case-mix differences in outcomes (adaptability).

- Reflect patient preferences and values (flexibility).
- Apply to large populations of patients (inclusiveness).
- Reflect a professional consensus (concordance).
- Are acceptable to practitioners (acceptability).
- Meet validity specifications for content, criterion, and construct (validity).
- Apply to the intended project (appropriateness).
- Are able to be documented empirically (documentation).
- Demonstrate appropriate test characteristics (sensitivity, specificity, and reliability).
- Allow for appeals to peer review (flexibility).
- Can be clearly communicated (clarity) (Lohr, 1990).

After extensive review of the scientific literature, the work group chose a process indicator related to mortality, the urea reduction ratio (URR), which is used to measure the adequacy of a dialysis treatment, and an outcome indicator, hematocrit, which reflects the successful treatment of anemia. Information gathered from HCFA data bases and literature reviews demonstrated that the indicators met the criteria for targeting clinical areas in the ESRD HCQIP (Table 2) and were responsive to the concerns of the patient groups.

Table 1
Selection Criteria for Quality Indicators Used in the ESRD HCQIP

Selection Criteria	Quality Indicator	
	Adequacy	Hematocrit
Salience	High Mortality	Low
Measurability	Yes	Yes
Significant Variation	Yes	Yes
Available Guidelines	Yes	Developed
Practicability	Yes	Yes

NOTES: ESRD is end stage renal disease. HCQIP is Health Care Quality Improvement Program.

SOURCE: (Lohr, 1990).

Treatment of Anemia in ESRD

During the development of the ESRD HCQIP, Eggers, Greer, and Jencks (1994) used data from HCFA's ESRD Program Management and Medical Information System (PMMIS) to study patterns of anemia treatment and use of recombinant human erythropoietin (rHuEPO) in the program. rHuEPO is a substance made by the kidney which stimulates red blood cell production and is given to more than 90 percent of ESRD Medicare beneficiaries (Powe et al., 1993). Eggers, Greer, and Jencks found a steady increase in patient average rHuEPO dose over time after the introduction of the drug and reimbursement of its administration by Medicare. They also noted that, despite increasing use and dose of the drug, average hematocrits of beneficiaries had only increased from 27.5 percent in November 1989 to 29.6 percent in January 1993. Further, between 1989 and 1992, the proportion of patients with hematocrits below 25 percent had only declined from 28 percent to 18 percent. The proportion of patients with hematocrits above 30 per-

cent in June 1993 was less than 50 percent. These outcome measures are disturbing because hematocrit levels over 30 percent are easily achievable by following current treatment guidelines and are associated with increased quality of life and functional status (Powe et al., 1993; Biddle et al., 1994). These studies illustrate how administrative data obtained from HCFA can be used to identify trends in care patterns.

Adequacy of Dialysis of ESRD

The high death rate for ESRD patients was among the most worrisome of the quality-of-care issues raised in the review of data from the Medicare ESRD system. Analysis of aggregated national data and network-specific data revealed high mortality rates experienced by ESRD patients and indicated that variations across facilities in the process of care might be a contributing factor to this adverse outcome (Kusek, Agoda, and Jones, 1993; National Institutes of Health, 1993). Data collected by the networks from ESRD treatment centers and analyzed by the USRDS have consistently shown high mortality rates for ESRD Medicare beneficiaries (U.S. Renal Data System, 1994). For example, the USRDS 1994 Annual Report cites age, gender, race, and cause of renal-failure-adjusted mortality rates for the 1991 cohort of new patients at 1 year of 23 percent and at 2 years for the 1990 cohort of 38 percent (U.S. Renal Data System, 1994). Comparison of the U.S. mortality data with outcomes of ESRD treatment in other industrialized nations shows that the U.S. dialysis patients (virtually all of whom are Medicare beneficiaries) have a higher age- and gender-adjusted risk of death than patients treated in health care systems in other countries (Held et al., 1990).

Table 2
Attributes of a Quality Indicator Applied to the ESRD HCQIP

Criteria	Quality Indicator	
	Adequacy	Hematocrit
Adaptability	+	+
Flexibility	+	+
Inclusiveness	+	+
Concordance	+	+
Acceptability	+	+
Validity	+	NA
Appropriateness	+	+
Documentation	+	+
Test Characteristics:		
Sensitivity	-	+
Specificity	-	+
Reliability	+	+
Flexibility	+	+
Clarity	+	+

NOTES: ESRD is end stage renal disease. HCQIP is Health Care Quality Improvement Program. NA is not applicable.

SOURCE: (Lohr, 1990).

ESRD network data analyses of facility-specific mortality rates, adjusted for case-mix factors, demonstrate considerable unexplained variation in the risk of death at different treatment centers within the same geographic region (McClellan, Flanders, and Gutman, 1992; McClellan and Soucie, 1994). Among 161 dialysis facilities in ESRD Network 6, the risk of death for patients in the 75th percentile of facility mortality, after accounting for differences between facilities in the distribution of case-mix factors, was 1.7 times higher than that of patients in the 25th percentile of facilities. Further, there was a substantial gradient of risk among dialysis facility crude mortality rates that persisted after adjusting for case-mix factors.

The high mortality rates and international and regional differences in risk of death among ESRD patients in the United States may be due to differences in the amount of dialysis U.S. patients receive (Held et al., 1992). Held et al. used data collected by the ESRD networks for a USRDS special study to estimate the dose of dialysis delivered to U.S. patients. They found that European patients were treated 23.5 percent longer; had dialyzer surface areas (a measure of toxin-removal capacity) that were 20 percent larger; and total urea clearances per week that were 29 percent higher than U.S. Medicare beneficiaries (Held et al., 1992). Both multicenter and USRDS studies have clearly established the high incidence of inadequate dialysis dosage in the U.S. ESRD program and the troubling relationship between inadequate dialysis and increased mortality risk (Parker, 1994; Parker et al., 1994). National adequacy of treatment guidelines have been published by the NIH and other organizations in an effort to redress this phenomenon (National Institutes of Health, 1993; Hornberger, 1993a, 1993b).

Fostering Consensus

Once a consensus was established within the workgroup to develop an ESRD HCQIP focusing on anemia and adequacy of dialysis, it was extended the leadership of the ESRD networks and to the renal community. The data discussed previously were reported to the networks and their medical review boards (MRB) and to renal community organizations. Courses and educational seminars were conducted nationally and regionally to prepare the networks to implement the ESRD HCQIP.

A survey conducted just prior to the inception of the ESRD HCQIP in July 1994 suggested that the efforts had been successful. There were 64 responses from 17 networks; 18 (28 percent) of these responses were from MRB and board of director members. Among the respondents, 72 percent of MRB and board members and 78 percent of network staff reported that they had been trained in the quality-improvement concepts to be employed on the project. Eighty-three percent of MRB and board members and 80 percent of staff reported that they could use the data to focus network problem solving and quality-improvement activities. Seventy-two percent and 56 percent of the respective groups were prepared to provide data feedback reports to dialysis facilities and assist them in fostering quality-improvement techniques and understanding the use of available data in those efforts. Eighty-nine percent and 84 percent, respectively, felt that the network would successfully implement the quality-improvement activities (Health Care Financing Administration, 1994).

Stimulating Regional and Local HCQIP

ESRD HCQIP has been translated by the networks into regional and facility-based programs to improve the care of Medicare

beneficiaries. Three data-driven components of the ESRD HCQIP were designed by the work group in collaboration with the ESRD networks and the renal community: the National ESRD Core Indicators Project, the Facility-Specific Intervention Project, and the National Anemia Cooperative Project.

National ESRD Core Indicators Project

The National ESRD Core Indicators Project is an ongoing collection of data about patterns of care identified by the adequacy of dialysis and anemia indicators (as well as indicators for blood pressure control and nutritional status) in the 18 regional networks. Two networks were administratively unable to participate in the 1994 segment of the National Core Indicators Project, but will participate in subsequent years. Patterns of URR and anemia treatment derived from the project are being used by network MRBs to plan and evaluate efforts to improve treatment of anemia and adequacy of dialysis in regional populations of Medicare beneficiaries (Health Care Financing Administration, 1994).

In the first year of the project, data for a random probability sample ($n = 6,358$) of adult in-center hemodialysis patients for the fourth quarter of 1993 were collected. This sample was large enough to ensure statistically meaningful estimates for practice outcomes in the networks and nationally. Completed survey forms were submitted by treatment facility staff for 6,141 patients (97 percent) from 1,728 treatment centers. Results from the project were used to describe the prevalence of important clinical characteristics of adult in-center hemodialysis patients in the United States and in each network. Results were reported to the network and to individual treatment centers as comparative rates (Helgeson, 1995).

The first year results showed that only 43 percent of the patients sampled received an

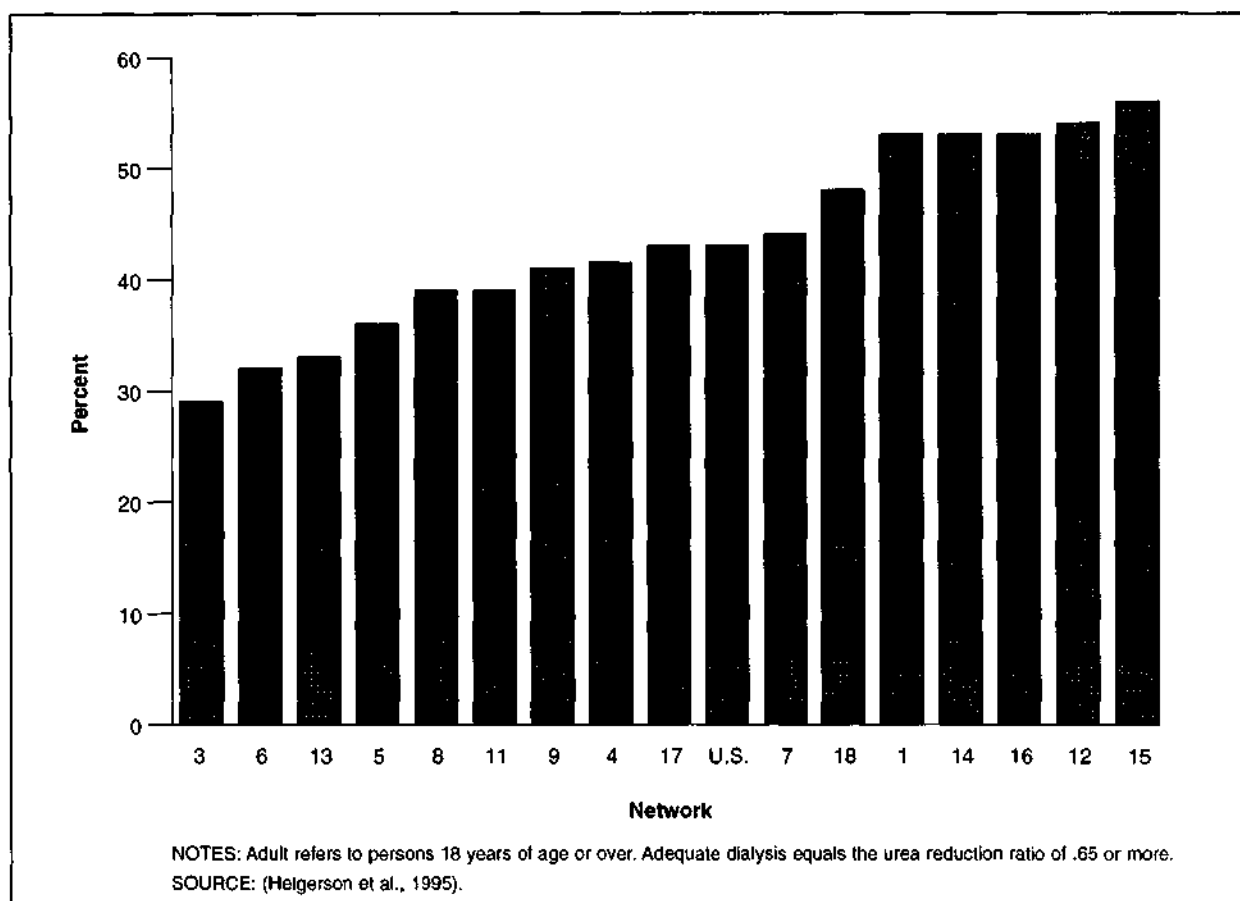
adequate dialysis in the last quarter of 1993 as defined by a URR of 65 percent or greater, an adequacy of dialysis measure recommended by the Renal Physicians Association (RPA) and a National Institutes of Health Consensus Conference (National Institutes of Health, 1993). Network means for the proportion of patients with URR of 0.65 or greater ranged from 29-57 percent of patients (Figure 2). The mean hematocrit for the patients sampled was 30 percent; 8 percent of all patients had hematocrit values of 25 percent or less. The range for hematocrit levels of 25 percent or less ranged among the networks from 3 percent to 13 percent of patients (Figure 3). The compilation of the results of the first year of the ESRD Core Indicators Project were disseminated to the networks and their MRBs and to all ESRD treatment centers within the United States in March 1995 (Health Care Financing Administration, 1994).

Facility-Specific Intervention Project

The Facility-Specific Intervention project is designed to link national and regional quality-improvement goals to individual treatment centers. The project commenced after the collection of the first core indicators data (October 1994) and involves an annual sample of 10 percent or more of the centers in each network. The network MRB will use the core indicators data and other data collected by the network to identify opportunities to improve care at individual treatment centers. The networks will develop intervention strategies to assist the centers in examining their care processes and identifying opportunities to improve treatment. Network staff and their MRBs are also prepared to provide education and technical assistance in interpreting and using the ESRD core indicators data to any treatment center.

The Facility-Specific Intervention Project is in its first year; national data are not yet

Figure 2
Percent of Adult In-Center Hemodialysis Patients Receiving Adequate Dialysis



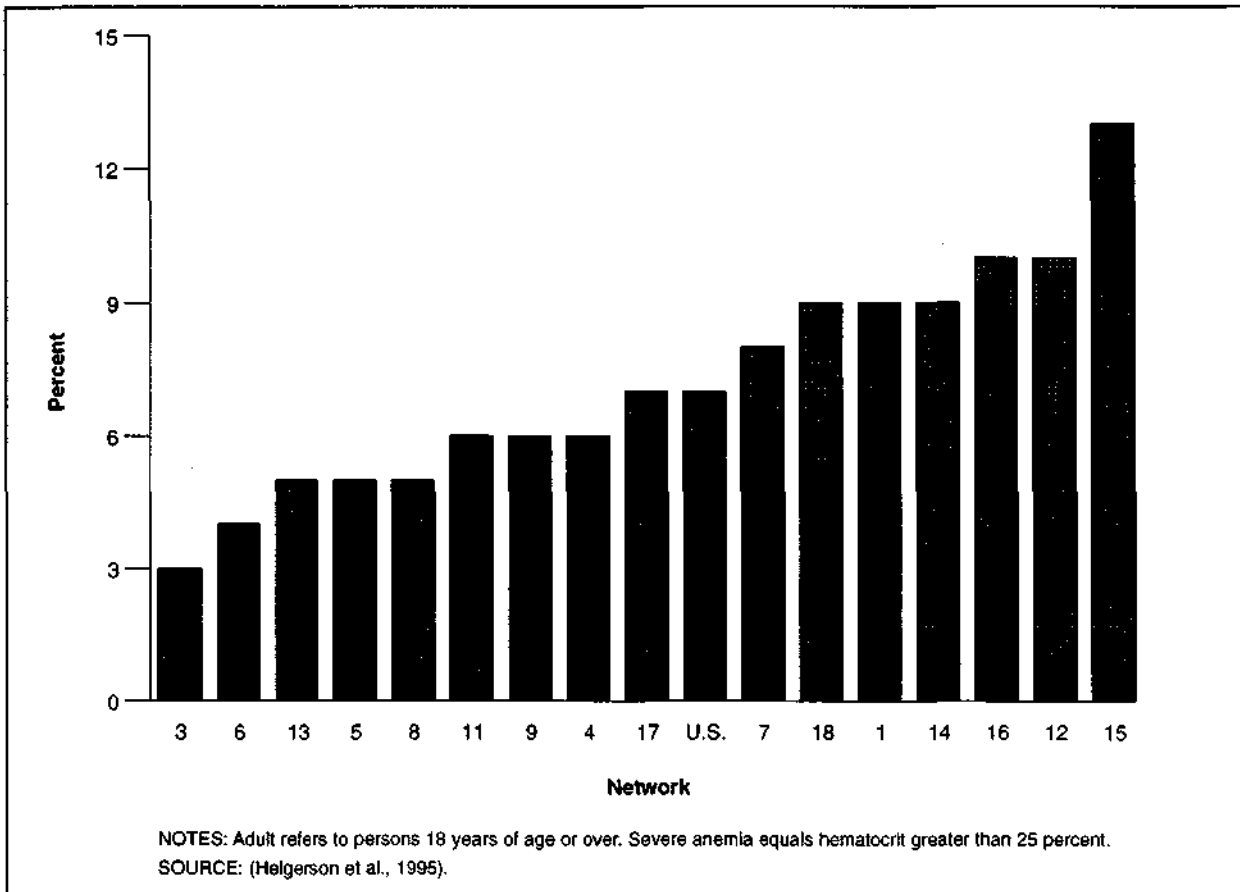
available. Initial data from one network's project are shown in Figure 4. The network MRB selected a random sample of treatment center patients ($n = 30$) from all of the region facilities ($n = 216$). Facility staff provided URR data for each patient during the month of October 1994 and facility-specific means were calculated (Figure 4). Based on these analyses, facilities with 50 percent or more of their patients with a URR of less than 0.60 (approximately 10 percent of facilities) were identified by the MRB and collaborative quality-improvement projects were initiated.

National Cooperative Anemia Project

The National Cooperative Anemia Project is an innovative aspect of the ESRD HCQIP developed to promote the rapid adoption of

national quality goals and quality-improvement techniques. The anemia project is designed to help network staff teach dialysis center personnel how to use statistical quality control tools to design and implement a quality-improvement program in the facility (Messana, 1994; Van Valkenberg and Snyder, 1994; Capelli, 1994; Deoreo, 1994). The project includes the distribution to all dialysis units in the United States of an anemia quality-improvement project guide which provides step-by-step instructions on how to conduct an improvement project and information on various quality-improvement tools and techniques, as well as a facility-specific data feedback report based on HCFA billing data displaying hematocrit levels and rHuEPO usage. The dissemination of comparative rate information to treatment cen-

Figure 3
Percent of Adult In-Center Hemodialysis Patients With Severe Anemia



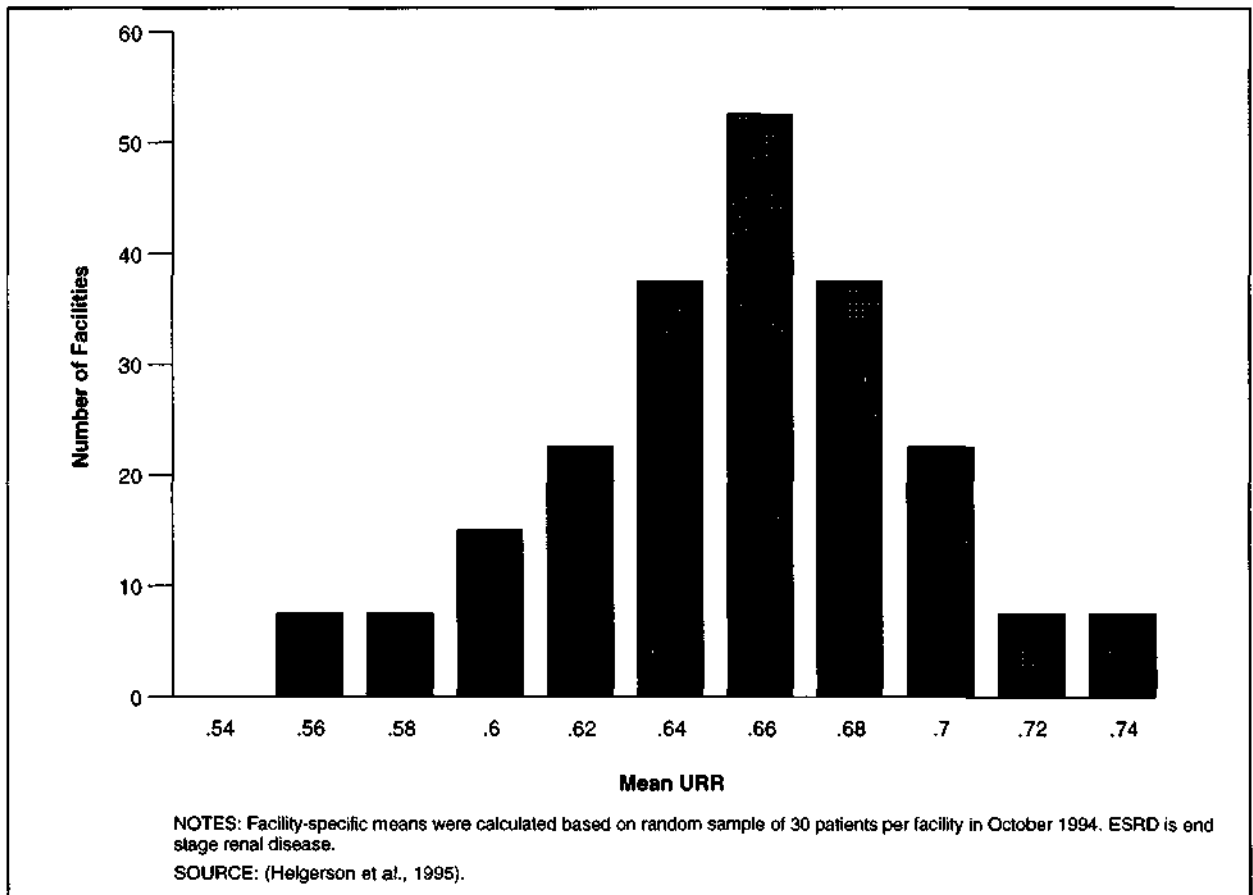
ters is intended to stimulate the development of quality-improvement programs. It is possible, however, that individual treatment facilities, particularly smaller ones, might lack the necessary technical background and skills to respond to quality problems (Biddle et al., 1994). Further, it has been documented that simple feedback of performance information has limited effects on physician behavior. In the absence of means to enhance the ability of individual clinician and allied health professionals to master new skills, the failure to provide continuing feedback, and the lack of suitable reinforcement, it was felt that the linkage between information and behavioral change would be weak (Hayes, Lundberg, and Ballard, 1994; Hayes and Ballard, in press).

The anemia project was pilot-tested in one volunteer treatment center in each network during July 1994-February 1995. After revisions based on the analysis of the pilot project experience, the anemia project will be implemented nationally during the summer of 1995. The tools and techniques in the project, although structured around anemia as an example, are intended to be broadly applicable to any quality-improvement effort identified by the dialysis facility (Biddle et al., 1994).

EVALUATION

ESRD HCQIP will be evaluated over the course of the 3-year network contracts. The evaluation will address the following issues:

Figure 4
Mean Urea Reduction Ratio (URR) for Hemodialysis Patients in ESRD Network 6



- Can ESRD networks collect, analyze, and disseminate information regarding national, regional, and center-specific treatment patterns of process and outcomes of care?
- Will dissemination of this information be associated with improved quality-indicator patterns, especially where networks and facilities have implemented quality-improvement activities?
- Will the dissemination of general ESRD information, national and regional feedback about practice patterns, and quality-improvement tools, such as computer software, to treatment centers improve their management of anemia and adequacy of dialysis?
- Will the implementation of the ESRD HCQIP be associated with improve-

ments in regional and national patterns of anemia care and adequacy of dialysis?

The above questions will be examined in part by a series of national ESRD core indicators studies. The second of these studies is currently being planned and data collection will begin during summer 1995.

DISCUSSION

ESRD HCQIP is an example of how health care providers and patients can initiate collaboration with HCFA to "shape the community" (Jencks, 1994). The process of developing the ESRD HCQIP was dependent at several crucial steps on data from diverse sources. First, carefully analyzed patient outcome data provided by

HCFA identified potential quality-of-care problems in the ESRD program that engendered concern within the provider community. This information prompted a request from the provider community for programmatic action and was essential in establishing a consensus on the need for collaborative work. Epidemiologic, basic, and clinical science studies identified by experts from the ESRD community were used to establish the basis for QI selection and intervention. The HCQIP ESRD project recognized patient concerns by involving patients in the project from its inception. The union of expert data management and analysis by HCFA, clinical and scientific perspective from the renal community, and guidance and assent from patients resulted in the formulation of a quality-improvement project that was able to elicit broad support prior to its implementation. The National ESRD Core Indicators Project, the Facility-Specific Intervention Project, and the Cooperative Anemia Project are also designed to use data to help providers translate quality-improvement goals into improved care. Collectively, these projects are intended to enhance the regional collection, analysis, and use of data relevant to quality-improvement goals for individual treatment centers. An innovative aspect of the ESRD HCQIP is the role of the networks in teaching providers basic data collection and analysis skills that can be applied to identify ways to improve the adequacy of dialysis and anemia treatment as well as other aspects of care.

An important aspect of the ESRD HCQIP that contributed to this process was the change in focus represented by the new model. The HCQIP model substitutes, in place of detailed review and regulation, consensus-based, broadly defined, quantitatively measured quality-improvement goals. It appeared that this focus was wel-

comed for several reasons. First, the process of problem identification, data gathering, intervention, and subsequent evaluation is quite congenial to the way medical scientists, clinicians, and allied health professionals are educated to think. Second, the use of operationally defined outcome measures with an unequivocal relevance to patient care to define the quality-improvement goals appealed to clinical audiences. Third, by focusing on aggregate, contemporaneous outcomes for groups of patients rather than isolated episodes of care often far removed in time, the ESRD HCQIP was perceived as pertinent to ongoing patient management. Finally, by emphasizing the role of outcome data as information used to evaluate local care and direct scarce facility resources, the HCQIP was perceived as an attempt to amplify efforts of clinicians and allied health professionals to improve care.

We have emphasized the centrality of data in the ESRD HCQIP for two reasons. First, the increasing availability of data from administrative and epidemiologic data sets like those maintained by the networks, the USRDS, and HCFA offers the opportunity to explore different quality of care issues with existing resources. While there are limitations to these data that must be recognized, their careful use in preliminary analyses was quite useful in the formulation of the ESRD HCQIP. Second, because these administrative data lack richness of detail, it is important to recognize that the additional collection of QIs will often be necessary to sufficiently diagnose potential problems and support meaningful interventions.

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