

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

"KNOW YOUR NUMBER" BROCHURE

PERSPECTIVES OF DIALYSIS PATIENTS



JUNE GIBBS BROWN
Inspector General

JANUARY 1997
OEI-06-95-00320

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EXECUTIVE SUMMARY

PURPOSE

This study describes the perspectives of end stage renal disease (ESRD) patients regarding the effectiveness of the Health Care Financing Administration's (HCFA) "Know Your Number" brochure in educating them about a way to monitor the adequacy of their dialysis.

BACKGROUND AND METHODOLOGY

By Medicare's definition, ESRD is "that stage of renal impairment that appears irreversible and permanent, and requires a regular course of dialysis or kidney transplantation to maintain life." Concern has grown over the adequacy of hemodialysis with the recent release of the ESRD Core Indicators Workgroup's report, conducted as part of HCFA's and the 18 contracting ESRD Network Organization's quality assurance and continuous improvement efforts. Their report found that only 43 percent of patients were receiving adequate hemodialysis.

The ESRD brochure "Know Your Number" was developed out of this concern. Its purpose is to educate the approximately 156,000 in-center hemodialysis patients so they may better determine the adequacy of their dialysis and become more proactive in the treatment process.

We surveyed two separate random samples of 800 hemodialysis patients in late October 1995 and mid-February 1996, to test both early and later dissemination of the brochure.

FINDINGS

Overall, we found the brochure was somewhat successful in increasing patient awareness of information about adequate dialysis, how it is measured, how patients know if they have achieved it, and what they can do to improve their dialysis. Additionally, it appears the brochure has helped to enhance the dialogue between facilities and patients about adequate dialysis and the use of URR or KT/V numbers to monitor adequacy of dialysis treatment.

Nevertheless, there were problems with dissemination of the brochure. The majority of patients did not receive it; and most of those who did were not familiar with their facility's use of URR or KT/V tests and had no idea what the appropriate target number for either of these tests should be.

Following are more specific findings.

DISSEMINATION. *Only one-third of ESRD hemodialysis patients reported receiving the brochure.*

GENERAL EFFECT. *Generally, patient awareness of URR or KT/V was low but improved somewhat over time.*

Less than half of surveyed patients reported the URR or KT/V test(s) as being used by their facility to measure adequacy, with about one-quarter of all patients saying they did not know which test(s) were used; nevertheless, patient awareness of URR and/or KT/V has increased somewhat over time.

However, only one-quarter of all patients, whether they received the brochure or not, could correctly identify either the target URR or KT/V number(s). Many patients who said the brochure was easy to understand and/or that it was very helpful still could not identify the correct URR or KT/V target number. Even among college educated patients, only 43 percent successfully identified the correct target URR or KT/V number.

SPECIFIC EFFECT. *Overall, patients receiving the brochure reported it easy to understand, very useful, and had a better understanding of adequate dialysis.*

Eighty-four percent of brochure recipients reported the brochure's content was very or somewhat easy to understand, and over two-thirds reported the brochure was very helpful.

Patients receiving the brochure were almost 1.5 times more likely to identify URR or KT/V as the test(s) used to measure adequacy in their dialysis facility, 2.3 times more likely to also know the correct target URR or KT/V number, and 1.3 times more likely to track this information over time, compared to those not receiving the brochure. Patients receiving the brochure were also more likely to have been told by the dialysis staff what they could do to improve the adequacy of their dialysis.

PATIENT/STAFF RELATIONSHIP. *The patient/staff relationship emerged as a most important element in patient understanding of adequate dialysis and the successful use of the brochure.*

Among patients receiving the brochure, less than half reported receiving an explanation of the brochure's content or having it read to them by dialysis staff. However, dialogue between patients and facility staff regarding the adequacy of patients' dialysis and/or their test results appears to have increased somewhat over time.

RECOMMENDATIONS

Overall, HCFA's strategy to educate patients and enlist them in monitoring the adequacy of their dialysis shows promise. The educational brochure has the potential to serve as an effective part of a broader strategy of improving patients' understanding and pursuit of adequate dialysis. However, the brochure's dissemination and its use by facilities need to be refined and improved before this can fully occur.

Based on our findings, we recommend that HCFA:

Assure future patient brochures are received by all Medicare dialysis patients.

Severe dissemination problems occurred with this patient brochure, either because facilities did not distribute the brochure to all patients, and/or patients received no staff explanation when receiving the brochure, and therefore did not recall receiving the brochure.

Build on the patient/staff relationship in order to improve patient understanding of URR and KT/V and the importance of achieving adequate dialysis.

It was also clear that the patient/staff relationship was critical in increasing patient understanding of the brochure's content and of dialysis adequacy. Facility staff should be encouraged to engage in two-way communication with patients about the adequacy of their dialysis, specifically, informing them about URR and KT/V and the appropriate target number. Additionally, facility staff should actively participate in the dissemination of future educational brochures by providing explanations about the brochure's content, along with stressing the importance of the material.

Additional Office of Inspector General Work

A companion report by the Inspector General's office (OEI-06-95-00321) provides information about how individual facilities disseminated the "Know Your Number" brochure to their patients. The report describes what adequacy information is being given to patients by facilities, such as patients' URR or KT/V numbers. Additionally, it highlights educational strategies used by facilities to better inform patients, and provides recommendations on the creation and distribution of future educational brochures, as well as facility activities to educate and involve patients in monitoring the adequacy of their dialysis.

AGENCY COMMENTS

The Health Care Financing Administration (HCFA) concurred with all the report's recommendations. We appreciate their responsiveness to our proposals. However, we have a new concern that has arisen since we issued our draft report.

We originally recommended that HCFA encourage facilities to calculate dialysis adequacy monthly and share these numbers with patients on a regular basis. HCFA informed us that they had no requirement for facilities to measure the adequacy of dialysis at prescribed intervals but that their revised ESRD Conditions for Coverage will require facilities to calculate the adequacy of dialysis quarterly. This is in marked contrast to the upcoming National Kidney Foundation's Dialysis Outcome Quality Initiative guidelines which recommend a standard practice guideline of a monthly URR or KT/V calculation, not quarterly calculations. We are concerned that facilities will interpret HCFA's Conditions for Coverage as the acceptable standard and conduct adequacy testing only quarterly.

In our view, this could pose a severe health risk for ESRD patients whose dialysis could go three months before needed corrections could be made to their treatment. We are convinced that facilities should be required to calculate adequacy numbers monthly and we urge HCFA to reconsider or amend the Conditions for Coverage accordingly.

TABLE OF CONTENTS

	PAGE
EXECUTIVE SUMMARY	i
INTRODUCTION	1
FINDINGS	5
Overview	5
Dissemination	5
General Effect	6
Specific Effect	13
Patient/Staff Relationship	18
RECOMMENDATIONS	22
AGENCY COMMENTS	23
ENDNOTES	24
APPENDICES	
A: Response Rates and Non-Respondent Analysis	A-1
B: Confidence Intervals and Tests for Significance	B-1
C: Text of Agency Comments	C-1

INTRODUCTION

PURPOSE

This report assesses the effectiveness of HCFA's "Know Your Number" brochure in reaching end stage renal disease (ESRD) patients by determining 1) if brochures were successfully disseminated, 2) if patients understood the content, and 3) the extent of interaction between patients and providers as a result of the brochure's distribution.

BACKGROUND

By Medicare's definition, ESRD is "that stage of renal impairment that appears irreversible and permanent, and requires a regular course of dialysis or kidney transplantation to maintain life."¹ Although some Americans with chronic kidney failure receive kidney transplants, the majority receive either hemodialysis or peritoneal dialysis treatment.^{2,3} Over 186,000 ESRD patients currently receive some form of dialysis therapy in the United States. Although dialysis is expensive and is not a cure, the treatments can greatly prolong an ESRD patient's life.

As a result of the Social Security Amendments of 1972 (P.L. 92-603), ESRD patients may qualify for Medicare under the renal disease provision which pays for 80 percent of the cost of the treatment no matter how old they are. To qualify for Medicare a person must: 1) have worked long enough to be insured under the Social Security program, or be the spouse/child of someone who has; or 2) already be receiving Social Security benefits. If a person isn't eligible for Medicare, they may qualify for Medicaid if their income is below a certain level.

As part of its oversight to assure the appropriateness of services for ESRD patients, Congress passed the ESRD Amendments of 1978 (P.L. 95-292) which authorized the establishment of ESRD Network Organizations. Currently, the Health Care Finance Administration contracts with 18 ESRD Network Organizations throughout the United States. In striving for quality assurance and continuous improvement, the ESRD Networks, together with HCFA and the renal community, worked to implement the ESRD Health Care Quality Improvement Program. This program allows the ESRD Networks and HCFA to track improvements in health care provided to renal Medicare beneficiaries through the development of quality indicators.

ESRD Core Indicators Project

In 1994 the ESRD Health Care Quality Improvement Program conducted the National/Network ESRD Core Indicators Project to assist providers of ESRD services in assessing and improving the care provided to ESRD patients. The first phase of this project targeted adult in-center hemodialysis patients receiving care in the last quarter of 1993. The project's focus was on establishing a consistent clinical database of key components of care. Such clinical measures included the determination of the adequacy of

dialysis using the pre- and post-dialysis blood urea nitrogen (BUN) levels to calculate the urea reduction ratios (URR).⁴ Baseline estimates were then used to identify opportunities for improvement in ESRD care across the United States.

The project's data was compared to standard medical levels of adequate hemodialysis developed by the Renal Physicians Association and a National Institute of Health (NIH) Consensus Development Conference Panel ($URR \geq 0.65$ or $KT/V \geq 1.2$).^{5,6,7} Only 43 percent of the study's patients met these new standards, with significant differences existing by gender, race, age, and region. The percent of patients in particular network areas who received adequate hemodialysis ranged from 29 to 57 percent, accounting for differences by race and gender.

The ESRD Core Indicators Workgroup produced a report in late 1994, along with an analysis of the project's results, and is currently conducting an evaluation of the impact of the Health Care Quality Improvement Program on patient care and outcomes. Networks will also prepare summary reports of their intervention and follow-up activities on an annual basis.

ESRD Brochure

The ESRD brochure "Know Your Number" was developed out of concern for the large percent of hemodialysis patients not receiving adequate treatment. With the development of a consensus medical standard for adequate hemodialysis, patients now have a benchmark against which to compare their own test results.

The brochure's purpose is to educate the approximately 156,000 in-center hemodialysis patients so they may better determine the adequacy of their treatment and become more proactive in the treatment process. The brochure focuses on heightening patients' awareness of the following: 1) there is a recommended level of dialysis associated with a number; 2) why achieving this level is important; and 3) how patients would know if the recommended level of dialysis was achieved. The brochure also seeks to inform patients on what they can do to track and improve their dialysis test results.

A total of 350,000 brochures were initially printed in English, with an additional 50,000 brochures printed in Spanish for a later distribution. The brochures were sent directly to approximately 2,500 dialysis facilities for dissemination to ESRD patients. Distribution of the brochure to patients at the facility-level is intended to improve communication between providers and patients, in addition to increasing patients' understanding of their treatment and progress.

SCOPE

Since the goal of the ESRD "Know Your Number" brochure is to increase patient awareness about the adequacy of their dialysis, this study examined whether patients received the brochure and understood its content and facilities' experience in using the brochure. In addition, we determined how brochures were disseminated and the extent of

interaction between patients and providers as a result of the brochure's distribution. We did not aim to measure any broad-based changes in patient behavior resulting from the brochure due to the difficulty of making such causal inferences.

METHODOLOGY

Sample selection

This study was comprised of three separate samples:

The first sample surveyed in-center hemodialysis patients about their familiarity with adequate dialysis, their relationship with facility provider(s), and whether or not they received the brochure. We randomly selected a sample of patients and administered a brief mail questionnaire the last week of October 1995, shortly after the brochure was disseminated to dialysis facilities.

Although we had originally hoped our surveys for the first sample would arrive prior to the brochure's distribution, thus serving as a baseline, this was not possible. Shipping of the brochures to facilities occurred early to mid-October by an independent contractor hired by HCFA. The results of our first sample indicated the brochure had already reached our sampled patients; therefore, we used this sample's findings to represent time period one.

- A total of 800 in-center hemodialysis patients out of an eligible universe of 113,475 patients were selected from HCFA's Medical Information System using simple random sampling. Eligible adult patients received hemodialysis between 1/94 and 6/95 from a staff facility. Anticipating less than a 50 percent response rate from this population, we oversampled to obtain a representative sample of 385 respondents. The actual response rate for this sample was 48 percent (see Appendix A).

The second sample randomly surveyed another group of in-center hemodialysis patients almost four months after the brochure's dissemination to dialysis facilities. Specifically, this survey was mailed during the second week of February 1996 and assessed in greater detail whether patients received the brochure and also measured the brochure's effectiveness. Patients were asked questions about the readability of the brochure, its usefulness, and whether they could identify URR or KT/V as a test of adequacy or knew the target levels for either of these tests. Additionally, patients were asked to recall what type of explanation they received regarding the brochure, and their interaction with the dialysis facility staff regarding the adequacy of information about their own dialysis.

- Using simple random sampling, another 800 in-center hemodialysis patients were selected from a universe of 119,311 eligible patients from the database. Eligible adult patients received hemodialysis between the 4/95 and 9/95 from a staff facility. Of the 800 patients randomly selected, seven patients were excluded from the sample because they were also surveyed in our first sample, leaving 793

eligible patients. Allowing for non-respondents, we expected to obtain a representative sample of 385 respondents. The actual response rate for this sample was 50 percent (see Appendix A).

A third sample mailed during the first week of April 1996, surveyed staff in randomly selected in-center facilities to further assess how well the brochure achieved its desired goals. We analyzed specific actions taken in using the brochure, such as: 1) how was the brochure distributed; 2) did they explain the brochure to patients; 3) did they put the information in a newsletter; and 4) how did/does the brochure fit into their broader educational outreach? The findings from this survey are included in a separate OIG report (OEI-06-95-00321).

- A total of 150 out of 2,847 dialysis facilities in operation prior to 10/1/95 were selected from HCFA's database using simple random sampling. Of the 150 dialysis facilities selected, we surveyed 132 facilities with hemodialysis patients in April 1996. Our response rate for this sample was 86 percent, with 113 facilities responding to our survey.

Non-Response Analysis

A complete analysis of non-response bias from our first and second sample, along with our findings from a separate survey of 60 non-respondents from our second sample are included in Appendix A.

Tests of Significance

Tests of significance for key survey questions were performed using either t-tests or Chi-square tests. For the majority of findings in this report we only highlight statistically significant differences between our first and second sample. Additionally, Chi-square tests were used to capture significant differences among those patients receiving the brochure vs. those not receiving it, along with those patients understanding URR and/or KT/V tests and the target number associated with them vs. those patients not understanding these tests of adequacy. Confidence intervals are also included for key survey findings in Appendix B.

This inspection was conducted in accordance with the *Quality Standards for Inspections* issued by the President's Council on Integrity and Efficiency.

FINDINGS

OVERVIEW

Overall, we found the brochure was somewhat successful in increasing patient awareness of information about adequate dialysis, how it is measured, how patients know if they have achieved it, and what they can do to improve their dialysis. Additionally, it appears the brochure has helped to enhance the dialogue between facilities and patients about adequate dialysis and the use of URR or KT/V numbers to monitor adequacy of dialysis treatment.

Nevertheless, there were severe problems with dissemination of the brochure, with the majority of patients not receiving it. Also, the majority of patients who did receive the brochure were not familiar with URR or KT/V as tests used by their dialysis facility to measure adequacy and had no idea what the appropriate target number for either of these tests should be.

DISSEMINATION

Only one-third of ESRD hemodialysis patients reported receiving the brochure.

The majority of patients in both samples stated they had not received or did not remember receiving the brochure (see table 1). In our first random sample conducted shortly after the brochure was mailed to facilities, only 33 percent of patients reported receiving the brochure, while 52 percent had not received it and another 15 percent did not remember. We found similar results in another random sample conducted several months after the brochure's dissemination. Thirty-two percent of our second sample reported receiving the brochure, 52 percent did not, and 16 percent did not remember. Seventy-six percent of patients in this sample reported receiving the brochure from their dialysis center, 19 percent thought they had received it in the mail, two percent received it some other way, and 3 percent did not remember.

Received brochure	First Sample	Second Sample
Yes	33 % (120)	32 % (126)
No	52 % (193)	52 % (202)
Don't Remember	15 % (54)	16 % (64)

No significant differences existed, among patients receiving the brochure compared to those not receiving it, based on patients' primary language or by their education level.

In a separate facility survey (OEI-06-95-00321), 76 percent of facilities reported receiving the brochure. However, only half of facilities said they distributed the brochure to every patient.

GENERAL EFFECT

In order to determine if the brochure led to an increased focus on adequacy of dialysis among facility staff and patients, we asked all patients surveyed a number of questions about adequate dialysis and the tests used to measure it. The majority of the results reported in this section reflect the responses from all respondents to our survey, not just those patients receiving the brochure.

Generally, patient awareness of URR or KT/V was low but improved modestly over time.

Patient familiarity with URR or KT/V tests.

Fewer patients identified the important URR or KT/V tests as being used by their facility to measure adequacy, than other tests, such as potassium and phosphorous. About one-quarter of all patients said they did not know which test(s) were used by their dialysis facility.

When queried about which tests were used by their dialysis facility to measure the adequacy of their dialysis, patients from both samples marked a wide-assortment of tests other than the URR or KT/V number (see table 2). The potassium test was most commonly identified, with 60 and 61 percent of patients selecting this test from a list of possibilities. The phosphorous test and BUN test were also frequently selected by patients. Fifty-five and 58 percent of patients in our first and second sample identified the phosphorous test, while 53 and 55 percent of patients selected the BUN test.

Forty-five percent of our first sample and only 35 percent of our second sample respondents identified the URR number as a test used by their dialysis facility to measure adequacy, while 37 and 36 percent of patients selected the KT/V number. Clearance, a term often used by facility staff, was selected by 32 and 29 percent of patients.

Significantly, about one-quarter of all patients sampled said they did not know which test(s) were used by their dialysis facility to measure adequacy. Several patients from both samples (11 and 9 percent) said other tests, besides the ones included on the survey, were used to measure adequacy in their dialysis facility. The most frequently identified additional tests included albumin (12 patients) and calcium (11 patients). A few patients mentioned cholesterol (4 patients), glucose (4 patients), and hematocrit (3 patients).

Table 2: TESTS IDENTIFIED BY PATIENTS AS THOSE USED BY THEIR DIALYSIS FACILITY TO MEASURE ADEQUATE DIALYSIS Comparison of first and second sample results		
	First Sample	Second Sample
Potassium test	60% (231)	61% (193)
Phosphorous test	55% (212)	58% (182)
BUN	53% (204)	55% (173)
Urea Reduction Ratio (URR)	45% (171)	35% (111)
KT/V	37% (143)	36% (113)
Clearance	32% (122)	29% (90)
Don't Know	23% (89)	26% (82)
Other	11% (42)	9% (29)

Most patients in both samples said they knew their own dialysis was adequate or were aware there was a recommended level of adequate dialysis, however, far fewer reported their facility used the URR or KT/V number to measure adequacy.

Seventy-three percent of all patients from our first sample reported knowing there was a recommended level of adequate dialysis. However, only 36 percent of these patients correctly identified the URR or KT/V number as the test(s) used in their dialysis facility to measure adequacy, even when these tests were included on a list of possible choices (see table 3).

Patients unaware of the recommended level of adequate dialysis were much less likely (13 percent vs. 36 percent) to identify the URR or KT/V number as a test used by their dialysis facility to measure adequate dialysis.

If all patients were given their URR or KT/V test results by facilities, we would have expected far more patients to have identified one of these tests as a measure of adequate dialysis. However, the lack of patient familiarity with the URR or KT/V tests suggests not all facilities are providing patients with this information as part of their test results.

Based on the results from our facility survey (OEI-06-95-00321), just over 50 percent of facilities surveyed said they give patients their URR or KT/V numbers all the time, while

27 percent give these numbers 75 percent of the time, 16 percent give them between 25-50 percent of the time, and four percent don't ever give patients their test results.

However, facilities giving patients URR or KT/V numbers all of the time were more likely to have distributed the brochure to every patient and to report a higher percent of patients are interested in the adequacy of their dialysis.

Table 3: PATIENTS KNOWING THERE WAS A RECOMMENDED LEVEL OF ADEQUATE DIALYSIS by those reporting URR or KT/V used at their dialysis facility First Sample		
	Reported URR or KT/V Used by their Dialysis Facility	Reported URR or KT/V <u>Not</u> Used by their Dialysis Facility
Yes	36% (97)	64% (171)
No	13% (13)	87% (84)

While 94 percent of patients in our second sample reported knowing their own dialysis was adequate, far fewer of these patients (52 percent) identified the URR or KT/V number as the test used by their dialysis facility to measure adequacy (see table 4).

Table 4: PATIENTS KNOWING THEIR DIALYSIS IS ADEQUATE by those identifying URR or KT/V test used at their dialysis facility Second Sample		
	Reported URR or KT/V Used by their Dialysis Facility	Reported URR or KT/V <u>Not</u> Used by their Dialysis Facility
Yes	52% (147)	48% (136)
No	24% (4)	76% (17)

Reasons for patients' lack of familiarity with their dialysis facility's use of URR or KT/V number(s) are unclear. However, this could suggest facility staff do not provide the URR or KT/V number on a regular basis to patients, but instead just inform them their dialysis is "good" or "adequate."

Awareness of the URR or KT/V number(s) among patients knowing there is a recommended level of adequate dialysis and those knowing their dialysis is adequate does

appear to have increased from 36 to 52 percent between the first and second sample (see tables 3 and 4).⁸

Although patients reported receiving test results about the adequacy of their dialysis from their facility, the majority of patients were unable to identify the URR or KT/V test as one used by their dialysis facility to measure adequacy.

Of patients who asked the dialysis staff for test results, 51 and 37 percent of patients from our first and second sample were unable to identify the URR or KT/V test as one used by their facility to measure adequacy (see table 5).

Additionally, 56 percent of patients who were told their test results by facility staff from our first sample and 47 percent from our second sample were also unable to identify the URR or KT/V test as one used by their dialysis facility to measure adequacy.

As previously discussed, to some extent, this inability of patients to identify the URR or KT/V tests reflects the fact that facilities are not giving adequacy numbers to patients all the time.

Table 5: PATIENTS ASKING OR BEING TOLD TEST RESULTS by those identifying the URR or KT/V as being used at their dialysis facility Comparison of first and second sample results.				
	First Sample		Second Sample	
	Reported URR or KT/V Used by Dialysis Facility		Reported URR or KT/V Used by Dialysis Facility	
	Yes	No	Yes	No
Patients asked dialysis staff for test results	49% (70)	51% (74)	63% (91)	37% (54)
Patients told test results by dialysis staff	44% (60)	56% (77)	53% (120)	47% (106)

Nevertheless, patient awareness of URR and/or KT/V has increased over time, with sizeable increases occurring in the percent of patients identifying these tests as a measure of adequate dialysis.

Among patients asking the dialysis staff for their test results, there were sizeable increases in patients identifying either the URR or KT/V as a test used by their dialysis facility to measure adequacy, with increases from 49 percent in our first sample to 63 percent in our second sample (see table 5). Additionally, among patients told their test results, the percent reporting their facility uses the URR or KT/V number to measure adequacy increased from 44 to 53 percent between the two samples. This increase in the number of patients familiar with URR or KT/V as a test(s) of dialysis adequacy suggests an overall

increase in patient inquiries and staff communication about patients' URR or KT/V numbers.

Patient familiarity with Target URR or KT/V numbers.

Only one-quarter of all patients, whether they received the brochure or not, could correctly identify either the target URR or KT/V number(s).

When patients from our second sample were asked to select how much the urea in their blood should go down after their treatment, only 25 percent of all patients were able to identify either a URR of at least 65 percent or a KT/V of 1.2, even when given a list including these as possible options. Regarding URR, 21 percent of all patients knew the correct URR target number, with four percent giving an incorrect number, and 75 percent saying they did not know.

As expected, even fewer patients (14 percent) knew the correct KT/V target number, while six percent gave an incorrect answer and 80 percent did not know this information.

Patients keeping track of their personal URR or KT/V numbers were somewhat more likely to know the correct URR or KT/V target number(s) than those not keeping such records.

Fifty-seven percent of patients from our second sample that reported keeping track of their personal URR or KT/V number(s) knew the correct target number for at least one of these tests (see table 6). However, a large number of patients (43 percent) personally recorded this information but still did not know the correct target range for either of these numbers. This suggests that even those patients who are actively involved in their dialysis care need further instruction on what level their URR or KT/V number should be for adequate dialysis.

Table 6: PATIENTS KEEPING TRACK OF PERSONAL URR OR KT/V NUMBER by those knowing URR or KT/V target number Second Sample		
	Knew URR or KT/V Target Number	Did Not Know Correct Target Number
Yes	57% (27)	43% (20)
No	48% (40)	52% (43)

Even among college educated patients or those with a professional degree, only 43 percent were able to correctly identify the URR or KT/V target number.

Although patients with a college degree were the most likely to know the correct URR or KT/V target number, still, a majority of this group (57 percent) did not know this information (see table 7). Additionally, only about one-quarter of patients with some college, a high school diploma, or less were able to correctly identify the target level for adequate dialysis.

Table 7: PATIENTS KNOWING URR or KT/V TARGET NUMBER by patient's education level Second Sample				
	Less than High School Diploma	High School Diploma	Some College	College Degree or Professional Degree
Knew correct target number	23% (31)	22% (24)	28% (17)	43% (16)
Did <u>not</u> know correct target number	77% (104)	78% (85)	72% (43)	57% (21)

Many patients who said the brochure was easy to understand and/or that it was very helpful still could not identify the correct URR or KT/V target number.

Of the patients finding the brochure easy to understand, only 55 percent knew the correct URR or KT/V target number, while 45 percent did not know (see table 8). This finding highlights the apparent difficulty patients had in really understanding the brochure's content, which focused on patients being able to track whether their URR or KT/V number(s) were at the appropriate level for adequate dialysis.

However, patients who reported the brochure easy to understand were more likely (55 percent) to know the correct URR or KT/V target number compared to those not finding the brochure easy to understand (31 percent). Similarly, 69 percent of patients not finding the brochure easy to understand could not correctly identify the target URR or KT/V number.

Table 8: PATIENTS RATING OF BROCHURE by those knowing URR or KT/V target number Second Sample		
	Knew Target URR or KT/V Number	Did Not Know Correct Target Number
Patients finding brochure easy to understand		
Yes	55% (33)	45% (27)
No	31% (15)	69% (33)
Patients finding brochure very useful		
Yes	52% (36)	48% (33)
No	28% (9)	72% (23)

Likewise, patients finding the brochure very helpful, more often (52 percent) correctly identified the URR or KT/V target number than those not finding the brochure helpful (28 percent, see table 8). Significantly, an even higher percent (72 percent) of those not rating the brochure as very useful could not correctly identify the correct URR or KT/V target number.

SPECIFIC EFFECT

Overall, patients receiving the brochure reported it easy to understand, very useful, and had a better understanding of adequate dialysis.

Patient rating of brochure

Eighty-four percent of brochure recipients reported the brochure's content was very or somewhat easy to understand.

Fifty-eight percent of patients from our second sample found the information in the brochure easy to understand, while another 26 percent found it somewhat easy to understand (see table 9). Only four percent thought it was somewhat or very hard to understand.

Very easy to understand	58 % (68)
Somewhat easy to understand	26 % (31)
Neither easy nor hard to understand	12 % (14)
Somewhat hard to understand	3 % (4)
Very hard to understand	1 % (1)

Over two-thirds of brochure recipients reported the brochure was very helpful.

Sixty-seven percent of patients receiving the brochure found it very helpful in increasing their understanding of the URR or KT/V number (see Table 10). The following comments illustrate their responses: 1) *"The pamphlet gave me a chance to ask questions about something I had no idea about;"* 2) *"They explained it (URR or KT/V number) to me before, so it was all information I had already heard, but it was useful to go over it again."*

Another 23 percent said the brochure was somewhat helpful, but 10 percent found it not helpful. The following comments are typical of patients finding the brochure less helpful: 1) "*(I) needed a practical application of it. Had there been a follow-up or encouragement to record the KT/V numbers, on the part of the nurses, the pamphlet would have been very helpful;*" 2) "*(The pamphlet was) over my head;*" 3) "*(I) don't understand how (the) number is obtained;*" 4) "*Our unit does not do urea reduction. Too much information is confusing.*"

Table 10: PATIENT RATINGS OF BROCHURE'S HELPFULNESS Second Sample	
Very Helpful	67% (77)
Somewhat Helpful	23% (26)
Not Helpful	10% (11)

Patient familiarity with URR or KT/V tests.

Patients receiving the brochure were more likely to identify URR or KT/V as the test(s) used to measure adequacy in their dialysis facility.

Fifty-eight percent of patients receiving the brochure from our first sample and 43 percent of patients from our second sample identified URR as a test used by their dialysis facility to measure adequacy, compared to 39 and 31 percent of patients not receiving the brochure (see table 11). Similar patterns were found with patients selecting the KT/V number as the test used to measure adequacy. Ten percent more patients receiving the brochure correctly identified KT/V from a list of possible test(s), compared with those not receiving it.

Only 13 and 23 percent of patients from our first and second sample who reported receiving the brochure said they did not know which tests were used by their facility, compared to 29 and 28 percent of patients who reported not receiving the brochure.

Table 11: TESTS IDENTIFIED BY PATIENTS AS THOSE USED BY THEIR DIALYSIS FACILITY TO MEASURE ADEQUATE DIALYSIS Comparison of first and second sample results by brochure receipt				
	First Sample		Second Sample	
	No Brochure	Brochure	No Brochure	Brochure
Potassium test	58% (144)	63% (75)	64% (128)	54% (60)
Phosphorous test	54% (134)	56% (67)	62% (124)	48% (53)
BUN	55% (135)	50% (60)	57% (114)	51% (56)
Urea Reduction Ratio (URR)	39% (95)	58% (69)	31% (62)	43% (48)
KT/V	34% (84)	44% (53)	32% (63)	43% (48)
Clearance	32% (79)	31% (10.1)	29% (57)	26% (29)
Don't Know	29% (72)	13% (16)	28% (56)	23% (26)
Other	9% (23)	13% (16)	8% (15)	12% (13)

Patient familiarity with target URR or KT/V numbers.

Although the majority of patients receiving the brochure did not know the correct URR or KT/V target number, patients who received the brochure were much more likely to know this information than those not receiving the brochure.

Fifty-seven percent of patients receiving the brochure from the second sample were unable to correctly identify either the target URR number of at least 65 percent or KT/V number of 1.2 (see table 12), even when given a list including the target numbers as possible options from which to choose.

Table 12: PATIENTS RECEIVING BROCHURE by those knowing URR or KT/V target number Second Sample		
Received Brochure	Knew Target URR or KT/V Number	Did Not know Correct Target Number
Yes	43 % (47)	57 % (62)
No	19 % (34)	81 % (147)
Don't Remember	9 % (5)	91 % (51)

Specifically, 35 percent of patients receiving a brochure in our second sample knew the correct URR target number, compared to only 15 percent of those not receiving the brochure (see table 13). Patients receiving the brochure were also less likely (56 percent) to say they did not know the correct URR target number than those not receiving it (84 percent).

Fewer patients were expected to be familiar with the KT/V target number since KT/V is used less frequently in dialysis facilities. Thirty-one percent of patients receiving the brochure selected the correct KT/V target number, compared with only 7 percent of those not receiving the brochure. Eighty-nine percent of patients not receiving the brochure told us they did not know the correct KT/V target number, contrasted with 57 percent of those receiving it.

Table 13: PATIENTS RECEIVING BROCHURE by those knowing URR or KT/V target number Second Sample						
Received Brochure	URR Number			KT/V Number		
	Selected Correct URR Target #	Selected Incorrect URR Target #	Didn't Know Target #	Selected Correct KT/V Target #	Selected Incorrect KT/V Target #	Didn't Know Target #
Yes	35 % (38)	9 % (10)	56 % (60)	31 % (32)	12 % (13)	57 % (59)
No or Didn't Remember	15 % (35)	1 % (4)	84 % (200)	7 % (16)	4 % (9)	89 % (215)

Patient tracking of personal URR or KT/V numbers.

Although only 35 percent of patients, overall, tracked their personal URR or KT/V number, patients who received the brochure were more likely to keep such records than those not receiving it.

Although not statistically significant, of patients from our second sample who kept track of their URR or KT/V number, 56 percent received the brochure compared to only 44% of patients who did not (see table 14). However, we cannot tell whether patients started tracking their URR or KT/V numbers as a result of receiving the brochure.

Table 14: PATIENTS KEEPING TRACK OF PERSONAL URR OR KT/V NUMBER			
by brochure receipt			
Second Sample			
	Overall	No Brochure	Brochure
Yes	35 % (48)	44 % (21)	56 % (27)
No	65 % (91)	46 % (42)	54 % (49)

Patient receipt of information about improving dialysis.

Patients receiving the brochure were also more likely to have been told by the dialysis staff what they could do to improve the adequacy of their dialysis.

Ninety-one and 95 percent of patients from our first and second sample receiving the brochure were given advice on improving their dialysis, contrasted with only 81 and 75 percent of patients not receiving the brochure (see table 15).

Table 15: DIALYSIS STAFF TOLD PATIENTS WHAT THEY COULD DO TO MAKE DIALYSIS WORK BETTER Comparison of first and second sample results by brochure receipt				
	First Sample		Second Sample	
	No Brochure	Brochure	No Brochure	Brochure
Yes	81 % (198)	91 % (106)	75 % (184)	95 % (111)
No	19 % (47)	9 % (11)	25 % (63)	5 % (6)

PATIENT/STAFF RELATIONSHIP

The patient/staff relationship emerged as an important element in patient understanding of adequate dialysis and the successful use of the brochure.

Staff discussions of adequate dialysis.

Most patients learn whether their own dialysis is adequate by the dialysis staff telling them it is adequate or by being told their test results.

Regardless of whether patients received the brochure or not, 73 percent of all patients from our first sample reported knowing there was a recommended level of adequate dialysis. Eighty-one percent of patients from the second sample said they knew their dialysis was adequate.

Sixty-three percent of patients from our first sample and 72 percent of patients from our second sample were told their dialysis was adequate by facility staff (see table 16). Fifty-three and 76 percent of patients from our first and second sample reported learning about the adequacy of their dialysis from test results given to them by the facility staff.

Over the four month period between our first and second sample, noteworthy increases, from 63 to 72 percent, occurred in patients reporting the dialysis staff told them their dialysis was adequate. Similarly, the number of patients being told their test results increased from 53 to 76 percent from our first and second sample. Patients from the later sample were more likely to ask if their dialysis was adequate, suggesting patient and facility interest in improving understanding of dialysis adequacy and in releasing patient test results had increased over time.

Table 16: HOW PATIENTS KNOW IF THEIR DIALYSIS IS ADEQUATE Comparison of first and second sample results.		
	First Sample	Second Sample
Dialysis staff tell patients dialysis is adequate	63% (219)	72% (218)
Patients ask staff for test results	55% (189)	50% (152)
Dialysis staff tell patients test results	53% (181)	76% (232)
Patients ask staff if dialysis is adequate	48% (165)	55% (166)

Two-way communication exists between over half of patients and facility staff regarding patients' test results and the adequacy of their dialysis.

Patients learned about the adequacy of their dialysis or their individual test results through a variety of ways (see table 17). The majority (51 percent) of patients from our first sample and 57 percent from our second sample relied on both asking for and being told this information by facility staff, suggesting two-way communication exists between patients and facility staff.

However, 25 and 31 percent of patients from our first and second sample counted on the dialysis staff telling them this information and did not ask about it. Thirteen percent of patients from our first sample and 10 percent of patients from our second sample obtained this information by asking the dialysis staff, but were not provided this information unless they asked. A few patients from both our first sample (10 percent) and our second sample (2 percent) said they were neither asked nor were told about the adequacy of their dialysis or their test results by dialysis staff.

**Table 17: METHOD USED BY PATIENTS TO DETERMINE
IF DIALYSIS IS ADEQUATE OR LEARN THEIR TEST RESULTS.**
Comparison of first and second sample results.

METHOD USED IN DETERMINING ADEQUACY OR NUMBER	First Sample	Second Sample
Asked facility staff about information, but were <u>not</u> told.	13% (47)	10% (32)
Told information by facility staff, without asking.	25% (85)	31% (93)
Both asked for and told this information	51% (178)	57% (172)
None of the above occurred	11% (37)	2% (6)

Dialogue between patients and facility staff regarding the adequacy of patients' dialysis and/or their test results appears to have increased somewhat over time.

Patients were more likely to ask and be told information on whether their dialysis was adequate from facility staff in the later sample. An increase in patient inquiries and staff communication about adequacy information and/or patients' test results occurred between our first and second sample, increasing from 51 percent to 57 percent. Additionally, the percent of patients not asking or being told information about the adequacy of their dialysis and/or their test results decreased from 11 to two percent between the two samples.

Over 80 percent of patients reported receiving advice from facility staff about what they could do to make their dialysis work better.

Eighty-four percent of patients in our first sample and 81 percent of patients from our second sample reported they were told what they could do to make their dialysis better. Seventy-seven percent of patients from our second sample were told this information by the dietician, 74 percent by the nurse, 62 percent by the doctor, 18 percent by another member of the dialysis staff; and 5 percent of patients by someone else; such as the social worker.

Explanations of the brochure by facility staff.

Nevertheless, among patients receiving the brochure, less than half of patients who received the brochure reported receiving an explanation of the brochure's content or having it read to them by dialysis staff.

Of the patients receiving the brochure, 49 percent of the first sample reported receiving an explanation of the brochure's content from the dialysis staff. Forty-two percent of the second sample who received the brochure reported the brochure was either read or explained to them by someone; such as the dialysis staff, a family member or friend. Specifically, 23 percent of patients received an explanation of the brochure, 11 percent reported it was read to them, and eight percent said it was both explained and read to them.

Fifty-two percent of the patients in our second sample reported they read the brochure themselves, but received no explanation from the facility staff or anyone else. Another six percent admitted throwing the brochure away without reading it.

When explanations of the brochure's content did occur, they most commonly came from the dialysis facility nurse or dietician.

When the dialysis facility staff provided explanations of the brochure or at least read it to patients, this was most commonly done by the facility nurse (47 percent). The dietician provided an explanation of the brochure for 24 percent of patients and the doctor for six percent of patients. Other members of the dialysis staff, such as the social worker, provided an explanation for 14 percent of patients. Another 13 percent of patients received an explanation from a friend or someone else.

The following describes the experiences of those patients receiving an explanation from the dialysis facility staff:

- 54 percent reported the staff answered questions.
- 52 percent reported the staff spent enough time with them.
- 49 percent reported they understood the staff's explanation.
- 43 percent reported the staff just explained the brochure.
- 6 percent reported they did not understand the staff's explanation.

RECOMMENDATIONS

Overall, we found the HCFA strategy to educate patients and enlist them in monitoring the adequacy of their dialysis shows promise. The educational brochure has the potential to serve as an effective part of a broader strategy of improving patients' understanding and pursuit of adequate dialysis. However, the brochure's dissemination and its use by facilities need to be refined and improved before this can fully occur.

Clearly, the brochure achieved some impact on patients' understanding of adequate dialysis, and more specifically, about URR and KT/V and the target numbers associated with these tests. Additionally, the brochure appears also to have influenced dialysis facility staffs by increasing their discussion with patients of URR and/or KT/V, and dialysis adequacy, in general. An increase in such discussions should result in more patients knowing about adequate dialysis and how to measure and monitor it, which, in turn, should lead to healthier patient outcomes.

Based on our findings, we recommend that HCFA:

Assure future patient brochures are received by all Medicare dialysis patients.

Severe dissemination problems occurred with this patient brochure, either because facilities did not distribute the brochure to all patients, and/or patients received no staff explanation when receiving the brochure, and therefore did not recall receiving the brochure.

Build on the patient/staff relationship in order to improve patient understanding of URR and KT/V and the importance of achieving adequate dialysis.

It was also clear that the patient/staff relationship was critical in increasing patient understanding of the brochure's content and of dialysis adequacy. Facility staff should be encouraged to engage in two-way communication with patients about the adequacy of their dialysis, specifically, informing them about URR and KT/V and the appropriate target number. Additionally, facility staff should actively participate in the dissemination of future educational brochures by providing explanations about the brochure's content, along with stressing the importance of the material.

AGENCY COMMENTS

The Health Care Financing Administration (HCFA) concurred with all the report's recommendations. We appreciate their responsiveness to our proposals. However, we have a new concern that has arisen since we issued our draft report.

We originally recommended that HCFA encourage facilities to calculate dialysis adequacy monthly and share these numbers with patients on a regular basis. HCFA informed us that they had no requirement for facilities to measure the adequacy of dialysis at prescribed intervals but that their revised ESRD Conditions for Coverage will require facilities to calculate the adequacy of dialysis quarterly. This is in marked contrast to the upcoming National Kidney Foundation's Dialysis Outcome Quality Initiative guidelines which recommend a standard practice guideline of a monthly URR or KT/V calculation, not quarterly calculations. We are concerned that facilities will interpret HCFA's Conditions for Coverage as the acceptable standard and conduct adequacy testing only quarterly.

In our view, this could pose a severe health risk for ESRD patients whose dialysis could go three months before needed corrections could be made to their treatment. We are convinced that facilities should be required to calculate adequacy numbers monthly and we urge HCFA to reconsider or amend the Conditions for Coverage accordingly.

Discussion of Technical Comments

HCFA suggested we assess whether some of the comprehension issues might be attributed to a lack of cultural sensitivity in the brochure. We did analyses looking at both a patient's race and primary language. However, we found no statistically significant differences on key questions related to comprehension based on these two variables.

Additionally, HCFA called attention to the Spanish version of the brochure. We were happy to mention that 50,000 brochures would be printed for later distribution in the background section of both reports. Of course this study examined only the English version; at the time of our facility survey the Spanish version had not been distributed.

See Appendix C for a full text of HCFA's comments.

ENDNOTES

1. Title 42 CFR 405.2102, Conditions for Coverage of Suppliers of ESRD Services, October 1993; pg. 127.
2. Hemodialysis therapy cleans and filters a patient's blood with a dialyzer. This procedure can be done at home or in-center by nurses or trained technicians. Hemodialysis is usually performed about three times a week, with treatments lasting 2 to 4 hours each. Through this treatment and a proper diet, ESRD patients can greatly reduce the amount of wastes building up in their blood.
3. Peritoneal Dialysis replaces the work of the kidneys by removing extra water, wastes, and chemicals from the body. A cleansing solution, called dialysate, helps facilitate a patient's peritoneal membrane of the abdomen to filter their blood, requiring a catheter to be permanently placed into their abdomen. Wastes are filtered from a patient's body once the dialysate is drained. There are three types of peritoneal dialysis, with Continuous Ambulatory Peritoneal Dialysis (CAPD) being the most common.
4. The Urea Reduction Ratio (URR) informs patients how well hemodialysis is working by telling them the percentage of urea (waste products) removed from their body during their treatment. Baseline estimates were then used to identify opportunities for improvement in ESRD care across the United States.
5. Some dialysis facilities calculate a KT/V ratio instead of URR. This urea kinetic model or index is defined as the dialyzer urea clearance (K) multiplied by the patients' treatment time (T) divided by the volume of urea distribution (V).
6. Consensus Development Conference Panel. Morbidity and mortality of renal dialysis: An NIH consensus conference statement. *Ann Intern Med*, 1994; 121: 62-70.
7. Renal Physicians Association. Clinical practice guideline on adequacy of hemodialysis: Clinical practice guideline, number 1. December, 1993
8. Although our first sample surveyed the extent patients knew there was a recommended level of dialysis and our second sample inquired whether patients knew their dialysis was adequate, both samples asked patients to identify which test(s) are used by their dialysis unit to measure if their dialysis is adequate.

APPENDIX A

RESPONSE RATES AND NON-RESPONDENT ANALYSIS

Our first sample resulted in an overall response rate of 48 percent, with 386 of 800 patients responding. Of the non-respondents, 25 surveys were mailed back to us but were unusable for a variety of reasons. Fifteen patients either moved or had incorrect addresses, seven patients were deceased, and three patients were not physically competent to complete the survey.

There was no response bias among patients with just ESRD, as compared with aged or disabled ESRD patients. There was also no bias by gender in our first sample. However, response bias existed by race for the first sample. Black respondents were over two times more likely not to respond to our survey compared to white respondents, with only 36 percent of blacks patients responding as compared to 59 percent of white patients. Only a few statistically significant differences existed by race among our respondents in the first sample. White respondents were 1.4 times more likely to list the URR test and 1.3 times more likely to list the KT/V test as ones used by their dialysis facility to measure adequacy, compared to black respondents. Nevertheless, no statistically significant racial differences existed by education level or for other key questions, such as those receiving the brochure or an explanation of it.

Our second sample resulted in an overall response rate of 50 percent, with 395 of 793 patients responding. Of the non-respondents, 46 surveys were mailed back to us but were unusable for the following reasons: 22 patients had invalid addresses; ten patients were deceased; nine patients refused/or just didn't complete the survey; three patients were incompetent; and two patients were off dialysis.

No response bias existed by age or among patients with just ESRD vs. aged or disabled ESRD patients. However, response bias also existed by race for our second sample, with only 42 percent of Blacks responding to our survey compared to 56 percent of Whites. Although no response bias existed by race for key survey questions, such as; understanding of the brochure's concept, differences did exist in the educational levels of respondents. Sixty-seven percent of White respondents had a high school diploma or less, compared to 74 percent of Blacks and 87 percent of non-Black, non-White respondents. White respondents were two times more likely to have a college or professional degree compared to Black respondents.

The implications of the response bias by race are unclear. However, our greatest concern is the potential bias created by non-respondents not receiving the brochure. We anticipated those not receiving the brochure would be less likely to respond to our survey. Although we have no information about the educational level of our non-respondents, it is also likely our respondents had higher education levels and/or better reading abilities than our non-respondents. If bias by education does exist, our estimates will be more

conservative estimates of the true population, resulting in higher percentages of patients understanding the brochure's content compared to the actual population.

Non-response survey

Addressing concerns about potential bias because of the low response rates from our two samples, we conducted a separate phone survey of non-respondents from our second sample. Of the 398 non-respondents from our survey, we randomly selected 60 patients from the remaining 350 patients not completing our survey or having it mailed back to us as undeliverable. Patients selected for our non-response analysis were surveyed briefly by telephone in May 1996. Since we originally had no phone numbers for our sampled patients, phone numbers were obtained through directory assistance. Of the 60 patients sampled for this analysis, current phone numbers were not available for 24 patients. Of the 36 patients with valid phone numbers, we successfully surveyed 28 patients via the telephone. Patients contacted were asked if they had received our original mail survey, knew about adequate dialysis, got the "Know Your Number" brochure, and why they had not completed our mail survey.

Findings from non-response analysis:

Sixty-four percent (18) of patients we telephoned had received our mail survey, while 29 percent (eight patients) reported they had not received it and another seven percent (two patients) did not remember receiving it. It is unclear why these patients did not recall getting the survey since their mailed survey was not returned to us marked undeliverable by the mail service. However, it is possible these patients disregarded our survey without even opening the envelope to determine its' contents.

Ninety-six percent (27) of patients stated that they knew about adequate dialysis, while just one patient admitted they did not.

Only 15 percent (four) of patients reported they had received the brochure; 63 percent (17 patients) did not receive it, and 22 percent (six patients) did not remember receiving it.

Patients' reasons for not returning our survey included the following: 1) six patients had been very ill and had been in the hospital, thus they were either unsure they had even received our survey in the mail or were unable to complete it due to health problems; 2) six patients were blind and said they were unable to complete our survey by themselves; 3) ten patients admitted they just hadn't gotten around to completing the mail survey; and 4) four patients didn't complete our survey because they had not received the brochure and thought they didn't need to complete the survey.

Conclusions:

The results from our non-response analysis of patients receiving the brochure, compared to our respondents, suggest our sample over-estimates the number of patients really receiving the brochure. Almost one-third of respondents from our second sample stated that they received the brochure, compared to only 15 percent of our non-respondents.

APPENDIX B

ESTIMATES AND CONFIDENCE INTERVALS

The chart below summarizes the estimated proportions and the 95 confidence intervals for key statistics presented in this report based on this simple random sample.

Table 1: FIRST SAMPLE		
QUESTION	POINT ESTIMATE	95% CONFIDENCE INTERVAL
Proportion of patients receiving the brochure.		
	33 %	28.1% - 37.9%
Proportion of patients who knew about the URR test.		
	45 %	40.1% - 49.9%
Proportion of patients who knew about the KT/V test.		
	37 %	32.1% - 41.9%
Proportion of patients who knew there was a recommended level of dialysis.		
<u>By Patients who:</u> Knew URR or KT/V used	36 %	30.3% - 41.7%
Proportion of Patients who knew about URR or KT/V test.		
<u>By patients who:</u> • Asked dialysis staff about about adequacy.	49 %	40.8% - 57.2%
• Told about adequacy by dialysis staff.	44 %	35.6% - 52.4%
Proportion of patients receiving the brochure.		
<u>By patients who:</u> • Knew URR used	58 %	49.2% - 66.8%
• Knew KT/V used	44 %	39.5% - 48.5%
• Told what they could do to improve their dialysis.	91 %	85.9% - 96.1%

Table 2: SECOND SAMPLE		
QUESTION	POINT ESTIMATE	95% CONFIDENCE INTERVAL
Proportion of patients receiving the brochure.		
	32%	27.3% - 36.7%
Proportion of patients who knew about the URR test.		
	35%	29.7% - 40.3%
Proportion of patients who knew about the KT/V test.		
	36%	30.7% - 41.3%
Proportion of patients who knew their dialysis was adequate.		
<u>By patients who:</u>		
• Knew URR or KT/V used	52%	46.1% - 57.9%
• Didn't know tests used	24%	19.1% - 28.9%
Proportion of Patients who knew either their target URR or KT/V number.		
Overall	25%	20.5% - 29.5%
<u>By patients who:</u>		
• Kept track of their number	57%	47.6% - 66.4%
• Found brochure useful	52%	40.2% - 63.8%
• Found brochure easy to understand	55%	42.5% - 67.5%
Proportion of patients who found the brochure.		
• Very easy to understand	58%	49.2% - 66.8%
• Very helpful	67%	58.4% - 75.6%
Proportion of patients who received the brochure.		
<u>By patients who:</u>		
• Were told how they could make their dialysis better	95%	91.1% - 98.9%
• Knew their URR or KT/V target number	35%	26.0% - 44.0%
• Kept track of their number	56%	41.9% - 70.1%
Proportion of patients who reported that the URR or KT/V test was used.		
<u>By patients who:</u>		
• Asked or were told their test results	63%	55.2% - 70.8%

TESTS FOR SIGNIFICANCE

Differences between the first and second sample of patients were tested for significance for several questions. The table below shows the difference between the two groups and the resulting value when a t-test was performed.

Table 3: DIFFERENCES BETWEEN FIRST & SECOND SAMPLE FOR KEY QUESTIONS.			
QUESTION	FIRST SAMPLE	SECOND SAMPLE	T VALUE
	Reported URR or KT/V Used by Dialysis Facility		
Patients asked dialysis staff for test results	49%	63%	-2.42 ^{***}
Patients told test results by dialysis staff	44%	53%	-1.72 [*]
Did Not Receive Brochure			
Dialysis staff told patients what they could do to make dialysis work better	81%	75%	1.68 [*]
How Patients Know if Their Dialysis is Adequate			
Dialysis staff tell patients test results	53%	76%	-6.18 ^{***}

* Indicates significance at the 90% confidence level.

*** Indicates significance at the 95% confidence level.

**** Indicates significance at the 99% confidence level.

APPENDIX C

TEXT OF AGENCY COMMENTS



The Administrator
Washington, D.C. 20201

IG	_____
EAIG	_____
SAIG	_____
PDIG	_____
DIG-AS	_____
DIG-EC	_____ /
DIG-EI	_____ /
DIG-OI	_____
DIG-MP	_____
AD-LC	_____
OGC/IG	_____ /
ExecSec	_____ /
Date Sent	12-30

DATE: DEC 22 1996

TO: June Gibbs Brown
Inspector General

FROM: Bruce C. Vladeck
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Reports: "Know Your Number"
Brochure - Perspectives of Dialysis Patients (OEI-06-95-00320) and
"Know Your Number" Brochure - Experiences of Dialysis Facilities
(OEI-06-95-00321)

We reviewed the above-referenced reports which examine the effectiveness of the Health Care Financing Administration's End Stage Renal Disease program.

Our detailed comments on the report recommendations are attached for your consideration. Thank you for the opportunity to review and comment on these reports.

Attachment

Comments of the Health Care Financing Administration (HCFA) on
Office of Inspector General (OIG) Draft Reports:
"Know Your Number" Brochure - Perspectives of
Dialysis Patients, (OEI-06-95-00320) and "Know Your Number" Brochure -
Experiences of Dialysis Facilities, (OEI-06-95-00321)

"Know Your Number" Brochure - Perspectives of Dialysis Patients, (OEI-06-95-00320)

OIG Recommendation 1

HCFA should ensure future patient brochures are received by all Medicare dialysis patients.

HCFA Response

We concur. Direct mailing of brochures to patients was considered for our initial brochure distribution. However, the American Association of Kidney Patients recommended that the brochure be distributed through facilities where questions can be asked and explanations provided. If possible, future distributions will be a combination of direct mailing to patients and bulk mailing to facilities.

OIG Recommendation 2

HCFA should build on the patient/staff relationship in order to improve patient understanding of urea reduction ratios and the urea kinetic model and the importance of achieving adequate dialysis.

HCFA Response

We concur. The patient/staff relationship is critical to the improvement of a patient's understanding of end-stage renal disease (ESRD). Most patients rely on their care givers for necessary information and encouragement in order to be active participants in the health care decisions that involve them. Facility guidelines that provide the staff with additional background materials and suggestions on successful ways to use the brochure in patient education would support patient/staff dialogue as well as patient empowerment. However, it will not guarantee that the brochure will be distributed or that dialogue will occur.

"Know Your Number" Brochure - Experiences of Dialysis Facilities, (OEI-06-95-00321)

OIG Recommendation 1 (Dissemination)

HCFA should ensure that all facilities receive an ample supply of brochures and encourage them to distribute a brochure to every patient. HCFA might also consider providing guidelines to facilities on effective dissemination approaches.

HCFA Response

We concur. The initial distribution was intended to provide all ESRD dialysis facilities with enough brochures for 100-percent patient distribution plus extra brochures for anticipated new patients. The mailing labels and distribution amounts were provided long before the brochures were actually mailed. Consequently, some new facilities were not on the list. To the extent possible, future mailings will be done from the most current roster of facilities. Additional brochures will be sent to the Networks with a request that they send an ample supply to all facilities added to their Network rolls after the mailing list was created.

HCFA worked closely with the renal community (Renal Physicians' Association, American Association of Kidney Patients, National Kidney Foundation, American Nephrology Nurses Association, National Renal Administrators' Association, ESRD Network Forum and National Association of Nephrology Technicians) in the development and distribution of the brochure, as well as alerting the renal community to the brochure distribution. The national associations were most helpful in promoting the brochure at their national meetings and in their newsletters, as well as distributing brochures to their membership. The initial bulk mailing to facilities was accompanied by a letter of introduction that described the brochure development and encouraged facilities to use the brochures for patient education. We realize that continued and additional facility support are needed and that facilities which need the most support with the utilization of the brochure do not belong to or attend the various national meetings provided by the renal community. We will consider developing facility guidelines describing brochure distribution to patients and staff for patient education. The guidelines, if developed, will be included in future brochure bulk mailings to dialysis facilities.

OIG Recommendation 2 (Brochure Content and Format)

HCFA should simplify the language and concepts as much as possible in any subsequent or revised patient brochures. Consideration might be given to developing alternate versions of the brochure for different reading levels and to add greater use of color and graphics to gain interest and promote patient understanding.

HCFA Response

We concur. We appreciate the concern expressed regarding the language and concepts presented in the brochure. The National Renal Physicians' Association has a professional level brochure. There is also a high school level brochure on the topic. It is important for staff/patient dialogue to occur if a patient has difficulty understanding this brochure and needs the concepts explained further. Consideration can also be given to developing alternate versions of the brochure for different reading levels if needed and resources permit. Development of numerous versions of the brochure does not guarantee that all patients will get a copy, that the facility will educate their patients, or that all patients will be interested in learning about ESRD. Careful distribution plans would need to be developed to enable a variety of versions of the brochure to be effectively distributed so that the brochure supply and the need would coincide.

In considering reaching renal patients with information about adequacy of dialysis, the need for a Spanish version of the brochure became apparent. We have, therefore, had the brochure translated into Spanish and distributed to facilities with Spanish-speaking patients. Since all facilities were supposed to receive copies of the English version of the brochure with the introduction letter, we included information about the availability of the Spanish translation in the letter. As a result, we have had a number of requests for the Spanish version from facilities who were not on the original Spanish brochure distribution list.

We originally designed the brochure to have larger print and brighter, more varied colors. However, the Government Printing Office only allows a two-color process for printing brochures, and budgetary considerations reduced the size of the brochure. Future printings of the brochure will be more sensitive to the visually-impaired and more visually stimulating if at all possible.

OIG Recommendation 3 (Continuing Patient Education)

HCFA should encourage continuing efforts by facilities to educate patients and reinforce the importance of patient understanding and monitoring of the adequacy of their dialysis. A training video to introduce and/or reinforce the brochure concepts might also prove effective, based on the suggestions and experiences of some facilities.

HCFA Response

We concur. If funding permits, a training video to educate patients and reinforce the brochure concepts would probably be very helpful and well received. Having the brochure information on video would allow the visually-impaired to either better see the concepts or at least hear the concepts. Supporting patient/staff dialogue would still be needed.

In addition, since facility staff, in conjunction with the patient, are required to periodically review and update the patient's care plan, perhaps staff can be encouraged to take this opportunity to explain the information to patients and answer questions or address any concerns about the information in the brochure.

OIG Recommendation 4 (Use of Adequacy Measures)

HCFA should encourage facilities to calculate dialysis adequacy measures on a monthly basis and share these numbers with patients on a regular basis in order for the brochure to achieve its intended impact on patients and facilities.

HCFA Response

We concur. At this time there is no requirement for facilities to measure the adequacy of dialysis at prescribed intervals. Although the revised ESRD Conditions for Coverage, scheduled for release in early 1997, will require dialysis facilities to calculate the adequacy of dialysis quarterly, we encourage more frequent calculations as part of the facilities continuous quality improvement program.

The Facilities of Achievement Initiative will demonstrate, in volunteer ESRD dialysis facilities with existing computer capacity, the possibility of collecting medical indicators on 100 percent patient sample, then collating and analyzing the data and returning it to the participating facility for use in developing quality improvement interventions. The clinical indicators of the care received will be submitted to HCFA on a quarterly basis.

Technical Comments

The report should assess whether some of comprehension issues of the beneficiaries might be attributed to a lack of cultural sensitivity in the presentation. Not only is there the relatively large number of Hispanics in the ESRD program, but also American Indians and African-Americans are represented in the population disproportionately.

We also note that the report failed to mention that there was a Spanish edition of this publication. This is particularly important considering the large Hispanic community affected by ESRD.