COMPARISON OF FACILITY-REPORTED, CALCULATED, AND PRESCRIBED DIALYSIS ADEQUACY VALUES: RESULTS FROM THE 2000 END-STAGE RENAL DISEASE (ESRD) CLINICAL PERFORMANCE MEASURES (CPM) PROJECT

Supplemental Report #3

2000 ESRD Clinical Performance Measures Project

The Centers for Medicare and Medicaid Services *June 2001*

INTRODUCTION

The purpose of the ESRD Clinical Performance Measures (CPM) Project is to assist providers of ESRD services in the assessment of care provided to ESRD patients and to stimulate improvement in that care. Annually, a national random sample of adult (aged ≥ 18 years) in-center hemodialysis (HD) patients is selected for inclusion in this Project. Patient demographic characteristics and clinical information related to the CPMs for dialysis adequacy, anemia management, and vascular access are collected for the last quarter prior to the sample year.

This supplemental report describes the comparison of facility-reported (reported) dialysis adequacy values (urea reduction ratio [URR] and Kt/V) to the dialysis adequacy values calculated by the Centers for Medicare and Medicaid Services (CMS), formerly the Health Care Financing Administration (HCFA), using individual datapoints from the ESRD CPM data collection form. Additionally, this report compares CMS-calculated (calculated) Kt/V values derived from the Daugirdas II formula[1] to predicted Kt/V values derived from the dialysis prescription[2] using the prescribed dialyzer, the delivered blood flow rate and the patient volume (V) as determined by the Watson formula.[3] The prescribed Kt/V could not be calculated as the prescribed time and blood flow rate were not available in the database. The predicted Kt/V value, however, should provide a closer estimate of the delivered Kt/V than the prescribed Kt/V.

This report describes some initial findings for the reader to consider. The information presented may raise many questions that are not addressed in this report. Additional analyses and publications are planned to further examine many of the issues raised in this report.

METHODS

The Sample

A national random sample, stratified by the 18 ESRD Networks, of adult in-center HD patients alive and dialyzing on December 31, 1999 was drawn. The sample included 8697 patients.

Data Collection

During May 2000, a three-page data collection form for each patient was sent to each facility that had one or more patients in the sample. Clinical information in the patient's medical records was abstracted for each patient who was receiving in-center HD during the months of October, November, and December, 1999. Patient characteristic information collected included: gender, age, race, Hispanic ethnicity, years on dialysis, and primary cause of ESRD. Clinical information collected related to dialysis adequacy included: patient height, the first monthly reported URR, the first monthly reported Kt/V and the method used to calculate this Kt/V value (urea kinetic modeling [UKM], Daugirdas II, an estimated Kt/V from URR only [Jindal or Basile equations,[4,5] referred to hereinafter as "URR, no patient weights"], or Other/Unknown), and the following information from the dialysis session at which the pre- and post-dialysis blood urea nitrogen (BUN) values were drawn: pre- and post- dialysis BUN values, pre- and post-dialysis body weight, delivered dialysis session length, delivered blood pump flow rate at 60 minutes into the dialysis session, and dialyzer code.

Completed forms were returned to the appropriate Network office where data were reviewed and entered into a computerized database (Visual FoxPro). The data were forwarded to CMS for aggregation and analysis.

Data Analysis

The sample for analysis included those patients with data for at least one of the study months for the following: paired pre- and post-dialysis BUN values, hemoglobin, and serum albumin. Information was not available on residual renal function; for purposes of the Kt/V calculation, residual renal function was considered to be zero. Reported URR and Kt/V values were matched to calculated URR and Kt/V values; if either the reported or the calculated value was missing, it could not be matched and that record was deleted from subsequent analyses. All remaining available values were utilized in calculating mean and median values. Associations by race were restricted to white and black races only due to the low numbers of patients in other racial categories.

Comparison of reported and calculated dialysis adequacy values was conducted using linear regression analysis and

deriving Pearson correlation coefficients. Risk factors for being in the top decile of difference between reported and calculated Kt/V values were determined using a forward-stepwise logistic regression procedure. A p-value < 0.05 was considered to be significant.

The predicted Kt/V value was calculated from dialysis prescription data using:
1) the dialyzer clearance "K", determined from the dialyzer KoA value, assuming a dialysate flow rate of 800 mL/minute, (The actual dialysate flow rate was not available as it was not collected as a part of the CPM data set. An assumed dialysate rate of 800 mL/minute yields a reasonable estimate of dialyzer clearance which does not minimize the calculated Kt/V.) and using the delivered blood flow rate at 60 minutes into the dialysis session. The resultant value for K was modified by the method of Daugirdas for a variety of factors as outlined in the Handbook of Dialysis, [6]
2) the actual dialysis treatment time, and
3) the patient volume "V" as calculated from the Watson equation.[3]

Predicted Kt/V values were matched to calculated Kt/V values; if either the predicted or the calculated value was missing, it could not be matched and that record was deleted from subsequent analyses. Patients were then characterized as having a mean calculated Kt/V value either greater than, or less than/equal to the mean predicted Kt/V value. The percent of patients with a mean calculated Kt/V greater than the mean predicted Kt/V was determined by calculated Kt/V category. Risk factors for receiving a mean calculated Kt/V greater than a mean predicted Kt/V were determined using a forward-stepwise logistic regression procedure. A p-value < 0.05 was considered to be significant.

RESULTS

Comparison of Reported and Calculated Dialysis Adequacy Values

8154/8697 (94%) of patients met inclusion criteria to remain in the sample for analysis. This sample was 53% male, 55% White, 36% Black, 12% Hispanic, with a mean (± SD) age of 61.2 (± 15.2) years (TABLE 1). Forty percent of patients had diabetes mellitus as the cause of ESRD. Over one- half of the patients had been dialyzing two years or more, with a mean (± SD) of 3.5 (± 3.8) years.

After matching reported and calculated values, 6818/8154 (84%) of patients had at least one matched Kt/V pair and 7841/8154 (96%) had at least one matched URR pair (TABLE 2). The methods reported by the facility to calculate Kt/V varied widely, with approximately 14% reporting using UKM, 36% Daugirdas II, 27% reporting an estimated Kt/V from URR, no patient weights, and 21% reporting other methods not further described.

Independent reliability testing of the item on the data collection form capturing the method reported by the facility to calculate Kt/V had a concurrence or agreement rate (facility abstraction v. Network abstraction) of only 64% and a kappa statistic of 0.54[7] The kappa statistic measures the agreement between two sources beyond what would be expected by chance alone. A kappa value of 1.0 would indicate complete agreement, values of 0.4-0.59 indicate moderate agreement, 0.6-0.79 substantial agreement, and 0.8-0.99 almost perfect agreement.[8]

The mean reported Kt/V values were significantly higher than the mean calculated Kt/V values (1.51 [± 0.28] v. 1.47 [± 0.27], respectively, p< 0.001). Mean reported URR values were not significantly different from mean calculated URR values (69.9% [± 6.9%] v. 69.9% [± 7.0%], respectively).

Table 1: *Patient Characteristics*

Characteristic	n	(%)
TOTAL	**8154**	**(100)**
Gender		
Male	4336	(53)
Female	3806	(47)
Race		
Black	2958	(36)
White	4444	(55)
Hispanic Ethnicity	980	(12)
Age group (years)		
18-44	1399	(17)
45-54	1401	(17)
55-64	1673	(21)
65-74	2065	(25)
75+	1616	(20)
mean (± SD)	60.8(± 15.5)	
median	62.9	
Primary cause of ESRD		
Diabetes mellitus	3258	(40)
Hypertension	2103	(26)
Glomerulonephritis	1006	(12)
Other/unknown	1787	(22)
Duration of dialysis (years)		
< 0.5	1080	(13)
0.5-0.9	1072	(13)
1.0-1.9	1617	(20)
2.0+	4380	(54)
mean (± SD)	3.5 (± 3.8)	
median	2.2	
Post-dialysis weight (kg)		
mean (± SD)	73.8(± 19.5)	
median	71.1	

Table 2: Numbers of matched (calculated and reported) adequacy values

	Oct	Nov	Dec	Mean
Kt/V (all)	5532	5774	5745	6818
UKM	771	812	813	770
Daugirdas II	2021	2120	2061	2000
URRs, no weights	1529	1548	1567	1480
OTHER method	1173	1245	1229	1172
URR	6689	7048	7187	7841

Table 3: Pearson correlation coefficients for calculated and reported adequacy values

	Oct	Nov	Dec	Mean
Kt/V (all)	0.852	0.858	0.852	0.857
Kt/V (UKM)	0.772	0.782	0.774	0.755
Kt/V (Daugirdas II)	0.852	0.865	0.860	0.858
Kt/V (URRs, no weights)	0.892	0.891	0.897	0.892
Kt/V (OTHER methods)	0.873	0.879	0.859	0.871
URR	0.954	0.952	0.948	0.967

Table 4: Linear regression r2 values for calculated and reported adequacy values

	Oct	Nov	Dec	Mean
Kt/V (all)	0.726	0.737	0.726	0.735
Kt/V (UKM)	0.597	0.611	0.599	0.571
Kt/V (Daugirdas II)	0.726	0.747	0.740	0.736
Kt/V (URRs, no weights)	0.796	0.794	0.804	0.796
Kt/V (OTHER methods)	0.762	0.772	0.737	0.758
URR	0.911	0.907	0.900	0.935

Pearson correlation coefficients for reported v. calculated Kt/V values and reported v. calculated URRs are shown in Table 3. Pearson correlation coefficients measure the strength of the linear relationship between two variables. A Pearson correlation coefficient of 1.0 would indicate an exact positive linear relationship between the two variables.[9] Table 4 lists the results of linear regressions of reported v. calculated Kt/V values and reported v. calculated URRs. It is possible that the higher correlations and r^2s seen for reported v. calculated URRs compared to reported v. calculated Kt/Vs is due, in part, to the smaller number of data points involved in calculating a URR compared to calculating a Kt/V.

Table 5: Significant predictors of being in the top decile of difference in Kt/V values (reported > calculated) in the final logistic regression model

	OR[a] (95% CI)	p-value
Female gender	1.6 (1.3, 1.9)	< 0.001
White race	1.4 (1.1, 1.6)	< 0.001
Increasing age (years)	1.013 (1.007, 1.020)	< 0.001
Absence of diabetes mellitus as cause of ESRD	1.4 (1.2, 1.7)	< 0.001
Increasing mean post-dialysis weight (kg)	0.9947 (0.9897, 0.9996)	< 0.05
Increasing years on dialysis	0.90 (0.88, 0.93)	< 0.001
Increasing mean calculated Kt/V	0.12 (0.08, 0.17)	< 0.001

[a] OR (95% CI) = Odds Ratio, 95% confidence intervals

Factors entered into the model but found to be NS included: Hispanic ethnicity

Predictors for being in the top decile of difference in mean Kt/V values (reported > calculated) in the final multivariable logistic regression model included female gender, white race, increasing age, absence of diabetes mellitus as the cause of ESRD, increasing mean post-dialysis weight (kg), fewer years on dialysis, and decreasing mean calculated Kt/V (TABLE 5).

KEY OBSERVATIONS

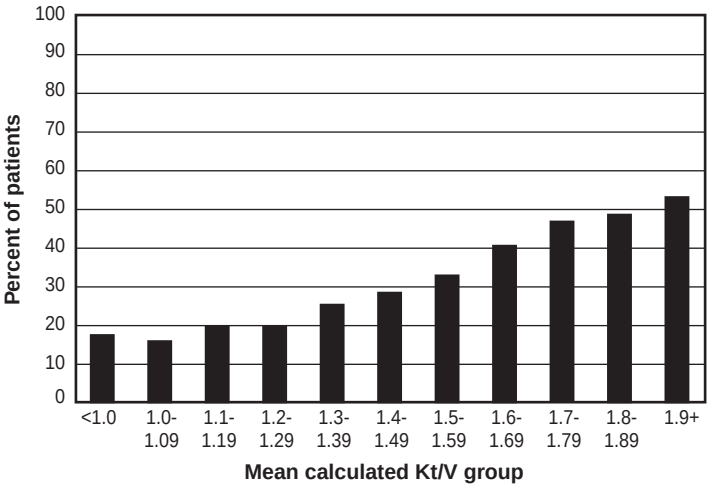
- There is a great amount of variability in the method used by the dialysis facilities (or laboratories) to report Kt/V.
- Reported Kt/V values are systematically higher than calculated Kt/V values.

Comparison of Predicted and Calculated (by Daugirdas II) mean Kt/V Values

There was sufficient information to derive a predicted mean Kt/V and match it to a calculated mean Kt/V for 6858/8154 (84%) patient records. 2164/6858 (32%) had a mean calculated Kt/V greater than the mean predicted Kt/V. As the calculated Kt/V increased, the percent of patients with a calculated Kt/V greater than a predicted Kt/V increased (FIGURE 1).

The initial multivariable logistic regression model demonstrated that the calculated Kt/V had a very significant effect

Figure 1: Percent of patients with mean calculated Kt/V greater than mean predicted Kt/V, by mean calculated Kt/V group



on this relationship (OR 38.0, 95% confidence interval 27.9-51.8). Therefore, the multivariable logistic regression model was modified to determine significant predictors of having a mean calculated Kt/V greater than the mean predicted Kt/V after adjusting for the calculated Kt/V value by examining this variable by quartiles.

This modified final multivariable logistic regression model had the following significant predictors of having a mean calculated Kt/V greater than the mean predicted Kt/V: male gender, white race, non-Hispanic ethnicity, increasing age, absence of diabetes mellitus as the cause of ESRD, fewer years on dialysis, increasing mean V, increasing quartile of mean calculated Kt/V, AV graft or catheter in lieu of an AV fistula as type of access, and Network (TABLE 6).

KEY OBSERVATIONS

- The calculated Kt/V value should not be greater than the predicted Kt/V value. Possible causes for this observation from this data set include data entry errors, a blood flow rate during dialysis substantially higher than the blood flow rate at 60 minutes, laboratory error, and/or improperly drawn post-dialysis BUN samples.

- More uniformity is needed in the method used by the laboratory or dialysis facility to calculate the reported Kt/V.

Table 6: Significant predictors of having a calculated mean Kt/V greater than a predicted mean Kt/V in the final logistic regression model

	OR[a] (95% CI)	**p-value**
Male gender	1.2 (1.1, 1.4)	< 0.05
White race	2.0 (1.7, 2.3)	< 0.001
Hispanic ethnicity	0.79 (0.64, 0.98)	< 0.05
Increasing age (years)	1.005 (1.001, 1.009)	< 0.05
Absence of diabetes mellitus as cause of ESRD	1.5 (1.3, 1.7)	< 0.001
Increasing years on dialysis	0.9797 (0.9631, 0.9965)	< 0.05
Increasing mean V (liters)	1.09 (1.08, 1.11)	< 0.001
Quartile of mean calculated Kt/V (lowest quartile = referent)		
Quartile 2	2.4 (1.9, 2.9)	< 0.001
Quartile 3	4.6 (3.8, 5.6)	< 0.001
Quartile 4 (highest)	10.5 (8.4, 13.1)	< 0.001
Access type (AV fistula = referent)		
AV graft	1.3 (1.1, 1.5)	< 0.001
Catheter	1.8 (1.5, 2.2)	< 0.001
Network (Network 1 = referent)		
6	0.64 (0.44, 0.94)	< 0.05
9	0.61 (0.41, 0.91)	< 0.05
10	0.49 (0.31, 0.78)	< 0.01
12	0.57 (0.39, 0.82)	< 0.01
14	0.62 (0.43, 0.90)	< 0.05
17	2.5 (1.7, 3.7)	< 0.001
18	1.5 (1.1, 2.2)	< 0.05

[a] OR (95% CI) = Odds Ratio, 95% confidence intervals

NEXT STEPS

- Further analyses are planned to examine the association of vascular access type and subsequent mortality with discrepant calculated and predicted Kt/V values.

- Facilities should routinely compare their patients' predicted and delivered Kt/V values. If the delivered Kt/V is greater than the predicted Kt/V, the facility should determine the source of error that explains the reason for this and take corrective action. If the delivered Kt/V is well below the predicted Kt/V, the facility should examine this problem also.

REFERENCES

1. Daugirdas JT. Second generation logarithmic estimates of single-pool variable volume Kt/V: an analysis of error. J Am Soc Nephrol 1993;4:1205-1213.

2. Daugirdas JT, Blake PG, Ing TS, Ed. Handbook of Dialysis, 3rd Edition. Lippincott, Williams and Wilkins, Philadelphia. 2001.

3. Watson PE, Watson ID, Batt RD. Total body water volumes for adult males and females estimated from simple anthropometric measurements. Am J Clin Nutr 1980;33:27-39.

4. Jindal KK, Manuel A, Goldstein MB. Percent reduction in blood urea concentration during hemodialysis (PRU): A simple and accurate way to estimate Kt/V urea. ASAIO Trans 1987;33:286-288.

5. Basile C, Casino F, Lopez T. Percent reduction in blood urea concentration during dialysis estimates Kt/V in a simple and accurate way. Am J Kidney Dis 1990;15:40-45.

6. Daugirdas JT. Estimating dialyzer blood water clearance from KoA, Qb and Qd, in Daugirdas JT, Blake PG, Ing TS, Ed. Handbook of Dialysis, 3rd Edition. Lippincott, Williams and Wilkins, Philadelphia. 2001, Table A-1, p 674.

7. 2000 Study of ESRD Clinical Performance Measures: Reliability Report. PRO-West. January 2001. (www.hcfa.gov/quality/qlty-3.htm).

8. Landis JR, Koch GG. The measurement of observer agreement for categorical data. Biometrics 1997;33:159-174.

9. Daniel WW. Biostatistics: A foundation for analyses in the health sciences. Fifth Edition. John Wiley and Sons, New York. 1987.