Prevalence and Medical Care Cost Associated with Chronic Kidney Disease in Texas

BACKGROUND

Chronic kidney disease (CKD) has been recognized as a major health problem in the US. According to the Center for Disease Control (CDC) 1999-2004 National Health and Nutrition Examination Study (NHANES) data, 16.8% of the U.S. adults (age 20 years and older) had CKD. As in other chronic diseases, the prevalence of CKD is much higher in older individuals, with 39.4% of persons aged 60+ years versus 12.6% and 8.5% of persons aged 40-59 years and 20-39 years respectively. The United States Renal Data System (USRDS) 2010 annual report indicated that the overall per person per year (PPPY) cost in 2008 reached $19,752 for Medicare CKD patients. In particular, Texas has the second highest CKD prevalence and expenditure among Medicare beneficiaries in the US. The end stage renal disease (ESRD) incidence rate is also higher than the national average.

To address the disease and economic burden of CKD and ESRD in Texas, the 80th state legislature passed House Bill 1373 in 2007 and established the Chronic Kidney Disease Task Force. The Task Force found that CKD was under-diagnosed and under-treated in Texas. Evidence-based guidelines were used by only a small proportion of healthcare providers. Diabetes mellitus (DM) and hypertension (HTN) were key precursors of CKD. In addition, CKD affected racial and ethnic minority groups more than non-Hispanic white, probably of the higher prevalence rates of DM and HTN in these groups. In particular, the Task Force established that the state lacked reliable prevalence and cost data for CKD.

Two classes of CKD identification have been used in previous studies. One uses biochemical/lab measures such as estimated Glomerular Filtration Rate (eGFR) and microalbuminuria levels. This definition of CKD is exemplified by studies using the NHANES data. Using this method, the prevalence of CKD was estimated to be about 16.8% in the US population. The CKD identification based on lab values provides more accurate estimates but the number of studies using this definition is very limited due to the cost of collecting patients' biochemical information, especially for a large sample. The other approach is based on clinical diagnoses of CKD, demonstrated by ICD-9 or DRG codes in claims data. Prevalence is likely to be underestimated if CKD is under-diagnosed in the population. The USRDS annual reports utilize this method and showed that the prevalence of CKD in the Medicare population was about 6.4% in 2006. The key advantage of using claims data is that they can provide additional information in regard to the economic burden and the utilization of service among CKD patients, which cannot be estimated using the NHANES data.

OBJECTIVES

The current study addresses two objectives using existing data from various sources:

A) To identify statistically significant subgroups who are at risk and recent patterns of change within these subgroups; and
B) To identify costs associated with kidney disease and its precursors, including projected costs over the next ten years.

RESEARCH METHODOLOGY

Data

Because of the short duration of the contract period (1.5 years), implementation of primary data collection of multiple years to address the objectives was impossible. Consequently, the research team focused on existing datasets, some of which were publicly available whereas others were purchased. After researching over numerous potential data sets, the research team identified three datasets that could provide Texas-specific estimates.

Behavioral Risk Factor Surveillance System (BRFSS), 1999-2008

The BRFSS data was collected by the CDC and National Center for Health Statistics (NCHS). It was a computer-assisted telephone interview conducted in each state. Self-reported disease status was used in the interviews. The questions for DM, HTN, hyperlipidemia and body mass index (BMI) to calculate obesity status were:

- Have you ever been told by a doctor that you have diabetes?
- Have you ever been told by a doctor, nurse, or other health professional that you have high blood pressure?
- Have you ever been told by a doctor, nurse, or other health professional that your blood cholesterol is high?
- About how much do you weigh without shoes? About how tall are you without shoes?

Data for DM and BMI were available from 1999 through 2008. Data for HTN and hyperlipidemia were available for only 1999, 2001, 2003, 2005 and 2007.

Medicare 5% sample CKD cohort, 2002-2007

The claims data were collected by Centers for Medicare & Medicaid Services (CMS) and compiled by the USRDS. The data were purchased from the USRDS following protocol. The Medicare 5% sample was selected each year from the beneficiary pool by selecting records with 05, 20, 45, 70 or 95 in positions 8 and 9 of the Health Insurance Claim (HIC) number. Information used in the CKD cohort included age, gender, race, diagnoses of DM and HTN, institutional care cost (Medicare Part A) and physician/supplier cost (Part B). The identification of CKD, DM and HTN was based on ICD-9 codes:

CKD 016.0, 095.4, 189.0, 189.9, 223.0, 236.91, 250.4, 271.4, 274.1 283.11 403.x1 404.x2 404.x3, 440.1, 42.1, 447.3, 572.4, 580-588, 591, 642.1, 646.2, 753.12-753.17, 753.19, 753.2, 794.4 (2008 USRDS Researcher's Guide)
DM 250.xx, 357.2, 362.0x, 366.41 (2008 USRDS Researcher's Guide)
HTN 401.xx-405.xx, 437.2 (The Medical Expenditure Panel Survey Medical Condition File, Agency for Healthcare Research and Quality)

Texas hospital discharge data, 2002-2007

The data were collected and managed by Texas Health Care Information Collection Center (THCIC) for Health Statistics, Department of State Health Services. In addition to the public use data, we purchased from THCIC a linking file of Patient Unique ID and Record ID to convert claim-level data in the Public Use Files to patient-level data. The Patient Unique ID was not available in years prior to 2002.

Texas hospital discharge data were used to provide information for both Medicare beneficiaries and non-Medicare patients. THCIC collected discharge data from all state licensed hospitals except those that were statutorily exempt. In 2008, there were over 500 reporting hospitals in Texas. The data captured the vast majority of hospital discharges that occurred in Texas. The exempt hospitals in Texas were those located in a county with a population less than 35,000, or those located in a county with a population more than 35,000 and with fewer than 100 licensed hospital beds and not located in an area that was delineated as an urbanized area by the US Census, and those that did not seek insurance payment or government reimbursement. CKD, DM and HTN were identified using the ICD-9 codes and DRGs described earlier.

The time frame and variables for data analyses were restricted by data availability. Age, gender and race were available in all three data sets. Consequently, subpopulations were generated based on these characteristics. Specifically, age was categorized into <45, 45-64, and 65+. The categorization was created based on previous analyses of CKD by the USRDS and the available age groups used in BRFSS. According to the US Census estimates of 2008, non-Hispanic whites constituted 47.4% of the Texas population, Hispanics, 36.5%, African Americans, 11.9%, and other races, 4.2%. Because less than 1% of Hispanics in Texas were not white, we did not further divide the Hispanic group by race; both Hispanic whites and Hispanics of other races were included in the Hispanic group. Consequently, race/ethnicity was grouped into non-Hispanic white, Hispanic, black, and other races. There were a total of 24 subpopulations, 3 (age) by 2 (gender) by 4 (race/ethnicity). In addition to using demographic characteristics, we also divided the patient sample into CKD only, CKD + HTN, CKD + DM, and CDK + HTN + DM subgroups.

<u>Definition of CKD</u>

As discussed earlier, the definition of CKD by lab values or diagnosis can produce different prevalence rates. For the current investigation, the CKD diagnosis was used to select CKD patients for the following reasons. One, cost was only available when there was a diagnosis using ICD-9 or DRG codes. Two, there were no Texas-specific data that had lab values to identify CKD. Three, previous research performed by USRDS showed that the prevalence of CKD estimated by lab values was roughly 2.6 times (16.8% for HNANES 1999-2004, MMWR) as much as that estimated by diagnosis (6.4% for Medicare beneficiaries, USRDS 2008 report). One could use this as a conversion factor to gauge the magnitude of prevalence should lab values be used to define CKD.

Objective 1: Prevalence and Trend

The BRFSS data were used to estimate state-level prevalence of DM, HTN, hyperlipidemia and obesity. To provide Texas-representative estimates, proper weighting was used as suggested by CDC to account for sampling design, non-response and households without a telephone. For each year of data, the prevalence rates for the state and subpopulations were estimated. Linear trends were estimated using Ordinary Least Squares (OLS) over time. Due to the limited number of observation points over time, the estimation of non-linear trends and multivariate adjustments were not pursued. Projections of prevalence within each subpopulation for 2010, 2015 and 2020 were made from the OLS parameters obtained. Based on the US Census' projection of each subpopulation in Texas for 2010, 2015, and 2020, the total numbers of patients for each condition in each projected year was calculated. Dividing these numbers by their corresponding total population projections by the Census yielded the overall prevalence rates. Aggregate prevalence projections for each age group, gender and race/ethnicity group were also calculated in a similar fashion.

There was no single data set that could provide Texas-specific prevalence of CKD. Consequently, we used Medicare 5% sample CKD cohort and Texas hospital discharge data to approximate the state-level prevalence. The total number of Medicare beneficiaries with CKD in each year, 2002-2007, could be calculated as the number of subjects in the CKD cohort times 20 (the inverse of 5%) because of the simple random sampling design used to collect the 5% samples. To determine whether the 5% Medicare sample and the Texas hospital discharge data were congruent, we estimated the total number of Medicare beneficiaries who incurred hospital stays in both data sets. In 2002-2007, the 5% Medicare sample underestimated the annual total number of Medicare beneficiaries who had inpatient stays by 13.31-25.04% as compared to the Texas hospital discharge data. Therefore, Texas hospital discharge data were used to calculate the prevalence.

Due to the complete lack of data for non-Medicare patients, the following steps were taken to obtain the total number of CKD patients in the non-Medicare population for each year. Using the Texas hospital discharge data and based on payment sources, non-Medicare patients with CKD diagnoses were selected as the counterpart of the Medicare 5% CDK cohort for each year. We then calculated the total number of hospitalized non-Medicare patients by CKD type, age, gender, race/ethnicity and year. In order to account for non-Medicare CKD patients who did not have hospital admissions, we assumed that the proportions of Medicare CKD patients using only hospitals, only ambulatory services and both, respectively, were similar to those of non-Medicare CKD patients. If X% of Medicare beneficiaries in the 5% Medicare sample had hospital stays (with or without additional ambulatory service use), and the number of non-Medicare CKD patients in the Texas hospital discharge data was Y, the total number of non-Medicare CKD patients could be calculated as Y/X%. This calculation was done for each subpopulation defined by CKD type and demographic characteristics.

In the preliminary data analyses, we found that dividing the sample by CKD type, age, gender, race/ethnicity and year in the 5% Medicare sample yielded numerous empty cells of hospital use that would lead to divisions by 0%. After further investigations, it was identified that the stratification by gender and race/ethnicity produced the empty cells. Consequently, only CKD type, age and year were used as the stratification variables. In addition, we found that all Medicare patients who had hospital stays incurred ambulatory services.

State-level prevalence for each year was calculated by the total number of CKD patients divided by the total state population estimated by the Census. Prevalence was also calculated for each subpopulation defined by age, gender, and race/ethnicity. Linear trends of the subpopulation-level prevalence rates were estimated using OLS over time. Aggregate prevalence projections for each age group, each gender and each race/ethnicity group were calculated in a similar fashion. To investigate geographic differences within Texas, we selected 8 cities: Austin, Dallas, El Paso, Houston, Lubbock, McAllen, San Antonio, and Tyler. An expanded metropolitan area in the current study was defined as the county in which the city is located plus all bordering counties. Data from 2007 were used to examine the cross-sectional differences in the prevalence of CKD in these areas.

Objective 2: Cost and Projection

The annual total cost of CKD in Texas equals cost per patient per year (PPPY) multiplied by the total number of CKD patients. More precise estimates can be obtained if the annual total cost for each subpopulation is obtained first and then aggregated to account for utilization variations between subpopulations. The variation in the payment for the same medical services due to various types of insurance can be a potential problem. To be consistent in our calculation of cost, we decided to use the actual amount paid out by Medicare as the approximation for cost for the following reasons. One, USRDS reports that about 80% of the CKD cost was inpatient cost; in the US, the inpatient DRG-based payment set by Medicare is the benchmark for the majority of private insurance. Two, the variation in private insurance payments and the unavailability of data from private insurance make the estimation of "true" cost impossible. Since many private insurance payments are higher than Medicare, the actual payment by Medicare can make a good approximation of the lower bound of the "true" cost. Three, the capture of out-of-pocket payment and deductible is inconsistent throughout the system, making the estimation of this portion of cost impossible. Consequently, we focused on using the actual payment made by Medicare to estimate the lower bound of the cost.

PPPY cost for each subpopulation was estimated first using the 5% Medicare sample from 2002 through 2007. Due to the lack of ethnicity information in the data and the scarcity of non-white Hispanics in Texas, PPPY cost for Hispanics was calculated the same as that for non-Hispanic white. Linear time trends of the subpopulation-level PPPY cost were estimated using OLS. Because of the limited number of observation points over time, the estimation of non-linear trends and multivariate adjustment was not pursued. Projections of the PPPY cost within each subpopulation for 2010, 2015 and 2020 were made based on the OLS parameters obtained. The total cost for each subpopulation and year was then calculated using the corresponding PPPY and total number of CKD patients. The PPPY cost at the state level was calculated using a weighted average, with the weight being the total number of CKD patients in each subpopulation.

Statistical Softwares

The majority of the statistical analyses were conducted using SAS (SAS® Corp, Cary, NC) and Stata (Stata® Corp, College Station, TX).

RESULTS

Prevalence and Projections

The results from our analyses are detailed in the Appendix. Between 2002 and 2007, the prevalence of CKD defined by diagnoses in Texas increased from 1.03% to 1.81%, a 75% increase over the 5-year period. In 2007, the prevalence in the 65+ group was 9.13%, whereas for <45 and 45-64 groups, the prevalence rates were 0.47% and 2.50%, respectively. No gender differences were observed. Between racial/ethnic groups, the prevalence was the highest among blacks, followed by other races. In terms of CKD and its co-morbidities, the proportions of patients with only CKD and CKD+DM, respectively, decreased over the years. In contrast, the proportions of patients with CKD+HTN, and patients with CKD+DM+HTN, respectively increased. Among expanded metropolitan areas, the highest prevalence rates were found in McAllen (2.22%), Tyler (2.04%), and Lubbock (1.91%).

Among subpopulations by demographic characteristics, the 5 groups that had the largest total number of CKD patients were 65+ female non-Hispanic white, 65+ male non-Hispanic white, 45-65 female non-Hispanic white, 45-64 male non-Hispanic white and 65+ male Hispanic. In terms of prevalence within a subpopulation, the top 5 were 65+ male black, 65+ male other races, 65+ female other races, 65+ male Hispanic and 65+ male non-Hispanic white. In examining the fastest growing prevalence, it was found that the top 5 were 65+ male black (1.91% annual growth in prevalence), 65+ male non-Hispanic white (1.05%), 65+ female black (0.88%), 65+ male Hispanic (0.85%) and 65+ female non-Hispanic white (0.80%).

Our projections show that the total number of CKD patients in Texas will be approximately 544,119 in 2010, 803,844 in 2015 and 1,125,583 in 2020, respectively, corresponding to the prevalence of 2.38%, 3.31% and 4.37%. In 2020, the prevalence in 65+, 45-64, and <45 age groups will grow to 20.85%, 4.68% and 0.53%, respectively. The prevalence by race/ethnicity will be 5.27%, 2.62%, 6.32% and 3.08% for non-Hispanic white, Hispanic, black and other races, respectively.

In analyzing the precursors of CKD, we found that the proportion of Texans who were obese increased by almost half between 1999 and 2008, from about 20% to nearly 30%. No gender differences were identified. The middle age group had the highest prevalence rate. In 2008, the prevalence of obesity for non-Hispanic white, Hispanic, black and other races were 26.6%, 32.83%, 38.79% and 16.15%, respectively. Among the subpopulations, the 5 groups with the highest prevalence were 65+ female black, 45-64 female black, <45 male black, 45-64 female Hispanic and 45-64 male black. The top 5 fastest growing prevalence were seen in 65+ male other races, <45 male other races, 45-64 male black, 65+ female black and 65+ female Hispanic. Based on the projections, the prevalence of obesity in Texas will be close to 40% in 2020. In blacks, the prevalence will reach approximately 50%.

The prevalence of HTN increased from about 24% in 1999 to over 27% in 2007. No gender differences were identified. The elderly group had the highest prevalence approaching 60% in 2007. In 2007, the prevalence of HTN for non-Hispanic white, Hispanic, black and other races were 29.0%, 21.7%, 41.2% and 25.4%, respectively. Among the subpopulations, the 5 groups with the highest prevalence were 65+ female other races, 65+ male black, 65+ female black, 65+ female white and 65+ male other races. The top 5 fastest growing prevalence were seen in 65+ female other races, 45-64 male other races, 65+male Hispanic, 65+ male black and 45-64 female other races. Based on the projections, the prevalence of HTN will be about one-third among all Texans and about two-thirds in the elderly population in 2020.

The prevalence of hyperlipidemia increased from about 30% in 1999 to about 38% in 2007. It was more prevalent in males. The elderly group had the highest prevalence, about 55% in 2007. In 2007, the prevalence of hyperlipidemia for non-Hispanic white, Hispanic, black and other races were 39.74%, 37.26%, 33.16%, and 41.16%, respectively. Among the subpopulations, the 5 groups with the highest prevalence were 65+ male other races, 65+ female non-Hispanic white, 65+ male non-Hispanic white, 65+ female other races, and 45-64 male black. The top 5 fastest growing prevalence were seen in 45-64 female other races, 45-64 male black, 65+ male Hispanic, <45 male Hispanic, and 65+ female other races. Based on the projections, the prevalence of hyperlipidemia will be about more than one-third among all Texans and over 60% in the elderly population in 2020.

The prevalence of DM increased from about 6% in 1999 to about 10% in 2008. No gender differences were identified. The elderly group had the highest prevalence approaching 23% in 2008. In 2008, the prevalence of DM for non-Hispanic white, Hispanic, black and other races were 8.29%, 11.15%, 13.06%, and 7.56%, respectively. Among the subpopulations, the 5 groups with the highest prevalence were 65+ male other races, 65+ male black, 65+ female Hispanic, 65+ female black and 65+ male Hispanic. The top 5 fastest growing prevalence were seen in 65+ male Hispanic, 65+ female black, 45-64 male other races, 65+ female Hispanic and 65+ male black. Based on the projections, the prevalence of DM will be about 15% in all Texans and over 22% in the elderly population in 2020.

<u>Cost and Projection</u>

The economic burden of CKD and its precursors is tremendous. As discussed earlier, the cost estimates are the lower bounds. Between 2002 and 2007, the cost of CKD in Texas more than doubled, from 6.9 to 15.1 billion dollars. Based on our analyses, CKD cost is expected to reach $33.7 billion in 2015 and $51.6 billion in 2020.

Consistent with the estimates obtained by USRDS using Medicare and private insurance data, the CKD cost among the elderly was lower than their younger counterparts. For example, in 2007, the per-patient-per-year (PPPY) cost estimates of CKD for <45, 45-64 and 65+ were $43,214, $40,389 and $29,007, respectively. Similar to the findings in prevalence, no significant gender differences were identified. Among racial/ethnic groups, the cost of CKD was the highest among blacks in 2002-2007.

Taking into account the sizes of various subpopulations, the total cost in 2002-2007 was the highest among the elderly ($6.3 billion in 2007) and the non-Hispanic white ($7.3 billion in 2007).

When the co-morbidities HTN and DM, were accounted for, the cost by CKD type varied greatly by age groups. For example, in 2007, for the group <45, CKD+DM had a PPPY of $48,062, CKD+HTN $35,210, CKD only $23,273, and CKD+DM+HTN $15,910. In contrast, in the same year for the 65+ group, the most costly subgroup was CKD only (PPPY=$40,266), followed by CKD+DM+HTN (PPPY=$34,620), CKD+DM (PPPY=$21,342) and CKD+HTN (PPPY=$14,508). Within a CKD type, patterns differed by age group. For CKD only, the PPPY was the highest in the 65+ group. For CKD+DM, the highest was in the <45 group. For CKD+HTN, the highest was in the 45-64 group. For CKD+DM+HTN, the highest PPPY occurred in the 65+ group.

In the examination of economic burden within specific subpopulations, we found that the PPPY cost was the highest among 45-64 female black ($57,673), 45-64 female other races ($54,805) and 45-64 male blacks ($48,193) in 2007. Total cost that took into consideration the number of CKD patients showed that the subpopulations that had the highest cost were 65+ female non-Hispanic white ($1.9 billion), 65+ male non-Hispanic white ($1.8 billion). 45-64 female non-Hispanic white ($1.3 billion) and 45-64 male non-Hispanic white ($1.0 billion). It is worth noting that the projections, taking into account the rate of changes in prevalence, showed that the two subpopulations, 45-64 female black and 65+ male black, would outpace female non-Hispanic whites in terms of total cost in 2020.

CONCLUSIONS

Our analyses show that in Texas, about 1.81% of the population had diagnoses of CKD in 2007, which was about half a million individuals. In particular, the prevalence in the elderly and blacks were much higher than other groups. Accounting for the possibility of underestimating using CKD diagnoses due to under-diagnosing in the population, the true prevalence could be 2-3 times higher. By 2015, the prevalence of CKD could reach 10% in the general population and 45% in the elderly subpopulation, posing a heavy burden on the patients and the health care system in Texas.

CKD is a costly condition. Coupled with persistent increase in overall medical care cost and higher inflation in the medical care industry as compared to other sectors of economy, the economic burden of CKD has been steadily increasing in the past years. The total economic burden of CKD is expected to double in the next 10 years, possibly reaching over $50 billion in 2020. Consistent with findings in previous studies of the US population, the average cost per patient is higher in the younger than the elderly populations. However, because of the much higher prevalence of CKD in the elderly population, the total CKD cost for the elderly population accounts for about 42% of the state total.

Equally alarming are the trends of the prevalence of the CKD precursors. By 2020, over one-third of Texans will be obese, have hypertension and have hyperlipidemia. Over 15% will be diagnosed with diabetes. Although no research has been done to show the exact pathways and probabilities of how these precursors transition to CKD over time, it is well known that these conditions greatly increase the risk of CKD. As expected, our analyses show that the elderly population has and will continue to have the highest prevalence in hypertension, hyperlipidemia and diabetes. Similar to the results found in the analyses of CKD, blacks have the highest prevalence of obesity, hypertension and diabetes. Perhaps the most alarming finding is that the prevalence of obesity is higher in the younger population than the elderly, especially in the black and Hispanic populations in Texas.

Appendix

Table 1 Total Number and Prevalence of CKD in Texas

Year	Total	Prevalence
2002	223,670	1.03%
2003	284,449	1.29%
2004	287,064	1.28%
2005	323,403	1.42%
2006	385,612	1.65%
2007	431,057	1.81%
2010	544,119	2.38%
2015	803,844	3.31%
2020	1,125,583	4.37%

Table 2 Total Number and Prevalence of CKD in Texas, by Age Group

Year	Total			Prevalence		
	<45	45-64	65+	<45	45-64	65+
2002	52,837	69,576	101,257	0.35%	1.52%	4.73%
2003	83,834	85,129	115,485	0.55%	1.80%	5.30%
2004	71,280	85,923	129,862	0.47%	1.75%	5.85%
2005	56,669	113,223	153,511	0.37%	2.23%	6.77%
2006	69,751	119,638	196,222	0.44%	2.26%	8.38%
2007	75,914	136,178	218,964	0.47%	2.50%	9.13%
2010	69,946	171,543	302,630	0.48%	3.08%	11.64%
2015	77,871	224,773	501,199	0.51%	3.89%	16.23%
2020	86,491	270,780	768,312	0.53%	4.68%	20.85%

Table 3 Total Number and Prevalence of CKD in Texas, by Gender

Year	Total Number		Prevalence	
	Male	Female	Male	Female
2002	114,385	109,285	1.06%	1.00%
2003	147,236	137,213	1.34%	1.24%
2004	148,785	138,280	1.33%	1.23%
2005	165,233	158,170	1.45%	1.38%
2006	197,038	188,573	1.69%	1.61%
2007	219,679	211,378	1.85%	1.77%
2010	276,013	268,106	2.46%	2.31%
2015	411,372	392,472	3.45%	3.18%
2020	582,669	542,914	4.61%	4.14%

Table 4 Total Number and Prevalence of CKD in Texas, by Race/Ethnicity

Year	Total Number				Prevalence			
	NH White	Hispanic	Black	Others	NH White	Hispanic	Black	Others
2002	110,013	63,052	36,423	14,182	0.99%	0.87%	1.48%	1.55%
2003	139,548	80,781	45,197	18,923	1.25%	1.08%	1.82%	1.99%
2004	146,262	75,181	46,553	19,068	1.31%	0.97%	1.85%	1.92%
2005	164,791	84,740	52,724	21,148	1.47%	1.06%	2.06%	2.05%
2006	200,481	98,112	65,215	21,804	1.77%	1.19%	2.43%	2.01%
2007	228,955	108,262	72,189	21,652	2.00%	1.27%	2.66%	1.90%
2010	310,777	119,428	96,889	17,025	2.62%	1.61%	3.42%	2.31%
2015	465,660	171,408	144,888	21,888	3.84%	2.07%	4.75%	2.68%
2020	650,536	241,437	205,869	27,741	5.27%	2.62%	6.32%	3.08%

Table 5 Total Number of Prevalence of CKD in Texas, by Co-mordities

Year	Total Number				Prevalence			
	CKD Only	CKD+ DM	CKD+ HTN	CKD+DM +HTN	CKD Only	CKD+ DM	CKD+ HTN	CKD+ DM+HTN
2002	88,683	35,454	51,289	48,244	39.65%	15.85%	22.93%	21.57%
2003	132,558	39,945	58,853	53,092	46.60%	14.04%	20.69%	18.66%
2004	126,646	33,295	68,687	58,437	44.12%	11.60%	23.93%	20.36%
2005	121,685	38,027	84,509	79,182	37.63%	11.76%	26.13%	24.48%
2006	121,360	45,392	112,119	106,740	31.47%	11.77%	29.08%	27.68%
2007	132,359	47,102	129,069	122,526	30.71%	10.93%	29.94%	28.42%

Table 6 Total Number of CKD Patients in Texas, By Age Group and Co-morbidity

		2002	2003	2004	2005	2006	2007
CKD Only	**<45**	36,155	69,747	55,815	36,645	43,055	52,576
	45-64	22,938	26,305	30,475	44,786	38,175	34,117
	65+	29,591	36,506	40,356	40,254	40,129	45,667
CKD+DM	**<45**	6,230	2,949	3,159	4,088	9,387	3,310
	45-64	14,868	24,222	16,566	19,298	15,886	24,998
	65+	14,356	12,774	13,570	14,641	20,119	18,795
CKD+HTN	**<45**	6,969	7,189	8,193	10,903	10,700	12,542
	45-64	12,786	13,803	16,624	20,346	26,626	33,414
	65+	31,535	37,861	43,870	53,260	74,794	83,113
CKD+DM+HTN	**<45**	3,484	3,949	4,113	5,032	6,609	7,487
	45-64	18,985	20,799	22,258	28,794	38,951	43,649
	65+	25,776	28,344	32,066	45,356	61,180	71,389

Table 7 Total Number and Prevalence of CKD in Texas in 2007, by Expanded Metropolitan Area

	Total Number	Prevalence
Austin	18,877	1.46%
Dallas	74,567	1.51%
El Paso	10,421	1.53%
Houston	74,612	1.63%
Lubbock	6,019	1.91%
McAllen	21,932	2.22%
San Antonio	28,608	1.88%
Tyler	11,718	2.04%

Table 8 Total Number of CKD Patients in Texas, by Subpopulation

			2002	2003	2004	2005	2006	2007	2010	2015	2020
< 45 yrs	Male	White	11,933	19,128	16,721	12,330	15,289	17,514	17,906	20,047	22,324
		Hispanic	9,758	15,871	13,138	11,173	13,499	15,099	11,782	13,515	15,550
		Black	5,112	7,668	6,738	6,224	7,674	7,713	8,710	10,656	12,810
		Others	1,883	3,481	2,867	2,092	2,321	2,238	1,095	605	20
	Female	White	9,436	15,189	12,802	9,276	11,512	12,702	12,248	12,828	13,501
		Hispanic	8,364	13,442	11,278	8,495	10,509	11,091	8,645	8,376	7,949
		Black	4,549	6,134	5,430	5,360	6,849	7,394	8,478	11,117	14,038
		Others	1,802	2,922	2,306	1,718	2,097	2,163	1,082	727	298
45-64 yrs	Male	White	13,886	17,701	18,900	24,520	25,164	28,979	38,373	48,942	56,983
		Hispanic	10,516	12,621	11,296	15,226	15,515	17,716	19,328	24,272	28,762
		Black	6,740	8,343	8,527	11,182	12,790	14,420	19,614	27,267	34,117
		Others	1,944	2,448	2,448	3,268	3,194	2,814	2,311	2,702	3,055
	Female	White	17,121	20,614	21,230	28,993	30,083	34,500	45,846	58,866	68,645
		Hispanic	10,652	12,678	12,190	15,639	16,607	19,088	22,433	29,522	37,082
		Black	6,405	7,831	8,631	10,593	12,702	14,953	20,598	29,509	37,761
		Others	2,313	2,895	2,700	3,803	3,584	3,708	3,039	3,694	4,374
> 64 yrs	Male	White	28,348	33,306	38,614	44,314	59,017	67,516	99,608	167,978	256,461
		Hispanic	12,858	14,063	14,792	18,187	22,255	23,756	29,222	48,992	78,522
		Black	8,191	9,068	10,322	11,459	14,890	16,416	23,704	40,091	65,368
		Others	3,229	3,642	4,436	5,251	5,386	5,444	4,359	6,305	8,696
	Female	White	29,288	33,609	37,996	45,385	59,428	67,776	96,798	156,999	232,621
		Hispanic	10,906	12,107	12,485	16,004	19,719	21,492	28,017	46,731	73,571
		Black	5,427	6,154	6,905	7,895	10,305	11,280	15,784	26,248	41,775
		Others	3,011	3,536	4,311	5,017	5,222	5,283	5,138	7,855	11,299

Table 9 Prevalence of CKD in Texas, by Subpopulation

			2002	2003	2004	2005	2006	2007	2010	2015	2020	Annual Growth
< 45 yrs	**Male**	**White**	0.35%	0.57%	0.50%	0.37%	0.46%	0.53%	0.53%	0.59%	0.65%	0.01%
		Hispanic	0.32%	0.51%	0.41%	0.34%	0.40%	0.43%	0.42%	0.44%	0.46%	0.00%
		Black	0.57%	0.85%	0.74%	0.68%	0.81%	0.81%	0.90%	1.04%	1.18%	0.03%
		Others	0.55%	0.98%	0.78%	0.55%	0.58%	0.54%	0.43%	0.22%	0.01%	-0.04%
	Female	**White**	0.29%	0.46%	0.39%	0.29%	0.36%	0.39%	0.37%	0.39%	0.41%	0.00%
		Hispanic	0.30%	0.47%	0.38%	0.28%	0.34%	0.35%	0.31%	0.28%	0.24%	-0.01%
		Black	0.50%	0.67%	0.59%	0.58%	0.71%	0.76%	0.86%	1.06%	1.26%	0.04%
		Others	0.53%	0.83%	0.64%	0.46%	0.53%	0.53%	0.41%	0.25%	0.09%	-0.03%
45-64 yrs	**Male**	**White**	0.98%	1.22%	1.27%	1.61%	1.61%	1.82%	2.31%	3.01%	3.70%	0.14%
		Hispanic	2.02%	2.29%	1.94%	2.46%	2.36%	2.55%	2.82%	3.10%	3.37%	0.05%
		Black	3.07%	3.63%	3.56%	4.48%	4.83%	5.26%	6.58%	8.51%	10.45%	0.39%
		Others	2.24%	2.66%	2.52%	3.19%	2.94%	2.46%	3.10%	3.25%	3.41%	0.03%
	Female	**White**	1.19%	1.39%	1.40%	1.86%	1.88%	2.11%	2.69%	3.50%	4.31%	0.16%
		Hispanic	1.97%	2.23%	2.04%	2.48%	2.50%	2.73%	3.14%	3.64%	4.14%	0.10%
		Black	2.56%	2.99%	3.15%	3.70%	4.14%	4.69%	5.87%	7.77%	9.67%	0.38%
		Others	2.41%	2.86%	2.52%	3.37%	3.00%	2.95%	3.50%	3.87%	4.24%	0.07%
> 64 yrs	**Male**	**White**	4.40%	5.10%	5.83%	6.57%	8.53%	9.55%	12.44%	17.69%	22.95%	1.05%
		Hispanic	7.95%	8.31%	8.38%	9.85%	11.48%	11.72%	14.30%	18.55%	22.80%	0.85%
		Black	11.83%	12.93%	14.47%	15.74%	19.52%	21.01%	26.43%	36.00%	45.56%	1.91%
		Others	15.15%	15.77%	17.72%	19.22%	17.92%	16.64%	19.49%	21.70%	23.90%	0.44%
	Female	**White**	3.31%	3.76%	4.22%	4.98%	6.39%	7.19%	9.39%	13.40%	17.40%	0.80%
		Hispanic	4.94%	5.26%	5.22%	6.42%	7.55%	7.90%	9.82%	13.08%	16.35%	0.65%
		Black	4.94%	5.53%	6.13%	6.87%	8.52%	9.16%	11.70%	16.10%	20.50%	0.88%
		Others	10.83%	11.86%	13.44%	14.52%	13.93%	13.05%	15.82%	18.45%	21.08%	0.53%

Table 10 Prevalence of Obesity in Texas

	Male	Female	18-44 yrs	45-64 yrs	65 yrs +	NH White	Hispanic	Black	Others
1999	21.89%	20.36%	19.27%	25.87%	19.06%	17.75%	26.23%	32.91%	15.48%
2000	23.70%	21.68%	21.60%	27.91%	16.63%	19.45%	30.60%	26.41%	11.36%
2001	24.51%	24.68%	22.91%	29.80%	20.47%	21.16%	30.52%	34.99%	16.60%
2002	26.40%	24.53%	23.63%	30.41%	22.52%	21.99%	30.14%	41.65%	14.39%
2003	24.10%	25.14%	22.37%	31.51%	18.73%	23.06%	25.92%	35.53%	18.88%
2004	26.49%	25.04%	23.45%	32.21%	20.87%	23.20%	29.24%	37.23%	16.09%
2005	27.75%	26.28%	25.69%	32.33%	20.44%	24.47%	31.92%	33.82%	21.32%
2006	26.50%	25.60%	24.54%	30.68%	21.56%	22.69%	29.29%	40.70%	28.25%
2007	28.61%	28.48%	27.93%	32.00%	23.15%	25.48%	32.70%	38.48%	16.95%
2008	29.28%	28.51%	27.87%	31.88%	26.07%	26.26%	32.83%	38.79%	16.15%
2010	31.32%	30.56%	29.87%	35.40%	24.78%	27.61%	33.69%	42.01%	22.17%
2015	34.51%	34.15%	34.05%	38.55%	27.19%	31.20%	36.03%	46.25%	25.49%
2020	37.37%	37.66%	38.15%	41.56%	29.57%	34.64%	38.32%	49.94%	28.97%
Projected Total Numbers									
2010	2,521,053	2,627,398	2,530,607	1,973,210	644,633	2,567,772	1,628,399	836,487	115,794
2015	2,960,052	3,133,118	3,024,094	2,229,266	839,809	2,980,475	1,967,968	995,758	148,969
2020	3,389,344	3,659,864	3,552,912	2,406,258	1,090,038	3,369,925	2,338,697	1,153,347	187,239

Table 11 Prevalence of Obesity in Texas, by Subpopulation

			1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2010	2015	2020	Annual Growth
< 45 yrs	M	**White**	15.80%	20.50%	22.68%	22.67%	19.71%	22.69%	24.87%	19.65%	26.51%	29.52%	28.77%	33.62%	38.46%	0.97%
		Hispanic	22.02%	32.86%	25.01%	26.26%	21.07%	27.03%	30.70%	28.02%	29.84%	25.76%	28.71%	30.14%	31.56%	0.28%
		Black	40.32%	16.45%	33.79%	41.93%	32.87%	25.38%	43.27%	38.37%	41.48%	37.56%	41.82%	46.97%	52.11%	1.03%
		Others	6.38%	7.99%	12.16%	8.82%	20.69%	15.91%	14.91%	32.87%	16.65%	20.64%	27.76%	37.03%	46.30%	1.85%
	F	**White**	13.55%	15.49%	14.81%	15.56%	18.63%	17.41%	21.17%	21.36%	22.40%	20.51%	24.37%	29.20%	34.03%	0.97%
		Hispanic	25.47%	22.96%	32.01%	28.91%	26.65%	26.53%	26.81%	25.27%	32.81%	36.00%	33.20%	36.95%	40.70%	0.75%
		Black	30.27%	25.98%	32.55%	38.53%	38.40%	36.48%	28.23%	40.16%	32.60%	40.77%	40.14%	44.57%	49.00%	0.89%
		Others	1.21%	14.03%	14.67%	8.29%	12.99%	12.08%	16.45%	17.08%	21.10%	8.30%	18.49%	23.01%	27.52%	0.90%
45-64 yrs	M	**White**	26.95%	25.66%	27.19%	28.33%	32.13%	30.79%	31.31%	30.22%	32.12%	34.09%	35.08%	39.09%	43.09%	0.80%
		Hispanic	33.98%	30.52%	31.06%	38.71%	30.96%	39.87%	39.64%	33.24%	33.74%	35.35%	36.96%	38.70%	40.44%	0.35%
		Black	13.99%	33.33%	32.88%	40.53%	18.36%	47.66%	33.00%	42.22%	39.03%	37.28%	45.75%	54.93%	64.11%	1.84%
		Others	44.32%	18.71%	22.58%	23.63%	27.27%	18.69%	33.29%	32.00%	7.95%	11.01%	11.82%	2.50%	-6.82%	-1.86%
	F	**White**	18.42%	24.08%	25.10%	25.13%	29.73%	27.58%	27.31%	24.84%	27.64%	25.70%	29.25%	32.08%	34.92%	0.57%
		Hispanic	32.30%	46.91%	45.30%	36.12%	35.60%	34.43%	46.51%	41.75%	40.35%	40.08%	41.36%	42.46%	43.56%	0.22%
		Black	42.80%	31.27%	46.31%	50.50%	54.60%	58.94%	35.25%	48.55%	45.24%	47.00%	50.21%	53.40%	56.59%	0.64%
		Others	31.53%	8.73%	37.68%	22.79%	20.27%	23.31%	27.77%	30.54%	22.70%	24.35%	25.57%	26.04%	26.50%	0.09%
> 64 yrs	M	**White**	16.78%	12.81%	20.20%	19.89%	20.03%	21.62%	15.66%	18.81%	19.93%	23.97%	22.77%	25.69%	28.62%	0.58%
		Hispanic	34.80%	21.15%	23.31%	34.81%	26.61%	17.73%	16.23%	33.37%	28.00%	29.73%	26.11%	25.74%	25.38%	-0.07%
		Black	39.81%	47.83%	33.33%	41.84%	17.42%	23.40%	14.79%	44.36%	24.14%	22.21%	17.35%	6.92%	-3.52%	-2.09%
		Others	N/A	9.09%	10.46%	23.32%	12.49%	18.36%	23.90%	43.87%	15.77%	34.14%	38.13%	52.18%	66.23%	2.81%
	F	**White**	17.84%	14.04%	17.40%	20.83%	16.33%	17.22%	21.11%	18.11%	18.95%	20.43%	20.71%	22.61%	24.52%	0.38%
		Hispanic	31.06%	29.93%	32.04%	29.57%	23.54%	40.78%	39.57%	29.22%	34.10%	43.39%	40.14%	45.40%	50.65%	1.05%
		Black	22.28%	32.08%	30.30%	34.03%	26.02%	22.63%	28.10%	27.45%	44.59%	36.78%	37.62%	43.16%	48.69%	1.11%
		Others	39.31%	11.11%	11.77%	24.09%	7.84%	N/A	26.63%	14.68%	18.76%	25.77%	18.64%	17.61%	16.58%	-0.21%

Table 12 Prevalence of Diabetes in Texas

	Male	Female	18-44 yrs	45-64 yrs	65 yrs +	NH White	Hispanic	Black	Others
1999	6.26%	6.20%	1.92%	10.79%	13.70%	5.56%	7.14%	7.84%	5.57%
2000	6.25%	6.13%	1.90%	11.49%	11.87%	5.67%	6.44%	9.04%	7.83%
2001	7.00%	7.16%	2.59%	10.72%	16.41%	6.14%	8.26%	10.08%	5.29%
2002	6.62%	7.34%	1.84%	12.32%	17.02%	6.46%	6.68%	10.86%	7.25%
2003	7.88%	8.24%	3.18%	13.21%	16.36%	7.73%	7.79%	10.88%	6.75%
2004	7.70%	7.62%	2.59%	11.86%	18.86%	6.96%	7.85%	11.49%	6.82%
2005	7.39%	8.44%	2.13%	13.96%	17.61%	7.43%	8.05%	13.05%	5.66%
2006	7.99%	7.91%	2.38%	12.62%	19.49%	7.76%	7.96%	10.27%	5.89%
2007	9.92%	10.76%	4.60%	14.47%	23.21%	8.29%	12.28%	12.64%	12.88%
2008	9.76%	9.67%	3.43%	14.65%	22.67%	8.29%	11.15%	13.06%	7.56%
2010	10.84%	11.06%	3.86%	15.57%	24.16%	9.33%	13.21%	13.57%	9.04%
2015	13.12%	13.37%	4.79%	17.87%	28.93%	11.28%	16.04%	15.79%	10.02%
2020	15.57%	15.88%	5.72%	20.26%	33.89%	13.39%	19.05%	18.22%	10.80%
Projected Total Numbers									
2010	872,942	950,702	327,217	868,018	628,411	867,540	638,682	270,212	47,210
2015	1,125,237	1,227,106	425,346	1,033,418	893,579	1,077,566	876,300	339,950	58,528
2020	1,412,165	1,543,419	533,044	1,173,358	1,249,182	1,302,491	1,162,382	420,893	69,818

Table 13 **Prevalence of Diabetes in Texas, by Subpopulation**

			1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2010	2015	2020	Annual Growth
< 45 yrs	**M**	**White**	1.49%	1.61%	1.86%	1.08%	2.26%	1.70%	2.00%	2.19%	2.58%	3.44%	3.13%	3.98%	4.84%	0.17%
		Hispanic	3.21%	1.47%	3.15%	2.48%	2.52%	2.95%	1.64%	3.29%	6.08%	4.62%	4.85%	6.17%	7.49%	0.26%
		Black	4.88%	2.20%	5.49%	1.39%	5.32%	0.83%	5.54%	4.82%	2.05%	2.41%	2.76%	2.19%	1.63%	-0.11%
		Others	N/A	3.03%	2.02%	0.52%	2.53%	4.67%	2.25%	0.82%	4.80%	2.56%	3.25%	3.82%	4.39%	0.11%
	F	**White**	0.94%	1.29%	1.30%	1.78%	2.62%	1.71%	2.54%	2.30%	3.14%	2.46%	3.31%	4.32%	5.32%	0.20%
		Hispanic	1.94%	3.31%	2.87%	1.95%	3.76%	3.65%	1.61%	2.19%	7.66%	3.98%	5.03%	6.37%	7.71%	0.27%
		Black	2.47%	2.08%	8.08%	5.27%	7.74%	5.64%	3.65%	1.76%	4.67%	3.91%	4.24%	4.01%	3.79%	-0.05%
		Others	N/A	2.37%	1.49%	0.45%	3.09%	1.97%	1.67%	0.78%	4.89%	N/A	3.39%	4.38%	5.37%	0.20%
45-64 yrs	**M**	**White**	8.44%	10.17%	8.23%	11.22%	12.51%	9.72%	9.45%	9.71%	12.10%	12.27%	12.24%	13.67%	15.11%	0.29%
		Hispanic	17.34%	17.69%	17.89%	11.18%	19.95%	20.69%	25.99%	17.59%	17.17%	20.17%	21.15%	23.13%	25.12%	0.40%
		Black	7.01%	21.21%	12.30%	21.45%	10.42%	19.80%	16.41%	17.31%	16.16%	21.76%	20.99%	24.52%	28.06%	0.71%
		Others	7.39%	6.05%	2.80%	13.75%	21.60%	13.00%	12.23%	25.26%	17.89%	9.45%	20.84%	26.92%	33.00%	1.22%
	F	**White**	8.07%	8.33%	7.29%	8.80%	10.12%	8.60%	10.64%	11.18%	9.59%	8.77%	10.65%	11.82%	12.99%	0.23%
		Hispanic	18.32%	14.89%	19.38%	15.89%	14.56%	14.31%	23.29%	21.51%	22.39%	21.80%	23.22%	26.75%	30.28%	0.71%
		Black	14.79%	18.28%	12.59%	26.30%	20.41%	19.46%	25.21%	15.46%	19.78%	24.55%	23.96%	27.25%	30.54%	0.66%
		Others	19.23%	19.57%	15.92%	14.99%	10.85%	8.41%	9.22%	2.72%	22.95%	18.95%	11.73%	9.78%	7.82%	-0.39%
> 64 yrs	**M**	**White**	12.18%	12.60%	17.43%	16.36%	15.57%	19.27%	15.13%	21.34%	20.11%	18.93%	22.12%	26.14%	30.17%	0.80%
		Hispanic	21.23%	20.37%	21.79%	15.93%	30.76%	22.79%	27.92%	31.13%	31.41%	35.62%	36.98%	45.51%	54.04%	1.71%
		Black	54.00%	17.39%	13.64%	25.47%	31.30%	36.31%	32.96%	39.59%	40.33%	35.84%	38.77%	43.44%	48.12%	0.94%
		Others	51.20%	27.27%	27.91%	38.57%	4.16%	21.09%	18.76%	28.30%	46.41%	14.95%	18.68%	11.63%	4.57%	-1.41%
	F	**White**	10.58%	7.31%	11.65%	11.61%	12.43%	13.10%	14.61%	12.49%	14.72%	15.71%	16.82%	20.22%	23.61%	0.68%
		Hispanic	22.13%	18.18%	32.23%	36.17%	31.81%	33.24%	27.31%	27.62%	36.64%	34.24%	37.43%	43.19%	48.94%	1.15%
		Black	16.68%	24.07%	26.17%	22.54%	18.50%	28.56%	31.66%	28.37%	34.43%	32.19%	36.58%	44.48%	52.37%	1.58%
		Others	N/A	33.33%	22.22%	19.58%	3.58%	N/A	13.31%	13.84%	30.01%	30.73%	21.94%	22.87%	23.81%	0.19%

Table 14 Prevalence of Hypertension in Texas

	Male	Female	18-44 yrs	45-64 yrs	65 yrs +	NH White	Hispanic	Black	Others
1999	23.80%	24.52%	12.24%	33.39%	50.19%	25.57%	18.74%	34.18%	19.99%
2001	23.75%	27.31%	11.95%	35.92%	55.06%	28.13%	18.94%	35.67%	17.93%
2003	25.20%	23.96%	10.45%	37.30%	53.17%	27.43%	16.23%	35.27%	21.07%
2005	23.93%	24.62%	10.22%	35.81%	54.86%	27.76%	16.59%	33.51%	21.28%
2007	27.71%	27.96%	13.56%	38.86%	58.07%	29.00%	21.73%	41.24%	25.43%
2010	29.34%	28.79%	12.49%	39.83%	59.94%	30.54%	22.67%	38.03%	27.53%
2015	32.03%	30.45%	12.66%	42.12%	64.15%	33.15%	24.33%	39.60%	32.97%
2020	34.97%	32.09%	12.79%	44.43%	68.56%	35.87%	26.10%	41.49%	38.48%
Projected Total Numbers									
2010	2,361,811	2,475,397	1,057,951	2,220,343	1,558,914	2,840,339	1,095,865	757,247	143,756
2015	2,747,230	2,794,063	1,124,176	2,435,595	1,981,522	3,166,921	1,329,035	852,696	192,642
2020	3,171,618	3,118,734	1,190,737	2,572,735	2,526,880	3,490,378	1,593,076	958,173	248,725

Table 15 Prevalence of Hypertension in Texas, by Subpopulation

			1999	2001	2003	2005	2007	2010	2015	2020	Annual Growth
< 45 yrs	**M**	**White**	12.34%	14.98%	12.88%	15.09%	14.37%	15.39%	16.43%	17.47%	0.21%
		Hispanic	9.62%	7.52%	10.47%	8.71%	13.23%	12.85%	14.95%	17.06%	0.42%
		Black	28.54%	17.84%	14.81%	17.61%	23.79%	17.11%	14.68%	12.25%	-0.49%
		Others	22.85%	10.62%	5.85%	10.48%	13.46%	6.03%	1.30%	-3.43%	-0.95%
	F	**White**	7.91%	11.42%	7.30%	7.79%	10.88%	9.87%	10.44%	11.02%	0.12%
		Hispanic	14.29%	11.76%	7.22%	7.31%	10.84%	6.31%	3.47%	0.64%	-0.57%
		Black	17.48%	17.95%	24.19%	15.67%	24.76%	24.31%	27.38%	30.45%	0.61%
		Others	4.81%	7.36%	11.20%	6.74%	8.18%	9.80%	11.32%	12.85%	0.31%
45-64 yrs	**M**	**White**	34.98%	35.13%	39.45%	33.68%	38.24%	38.06%	39.33%	40.59%	0.25%
		Hispanic	29.97%	31.99%	30.94%	31.90%	38.93%	38.98%	43.44%	47.89%	0.89%
		Black	56.93%	44.87%	51.77%	44.85%	53.73%	48.19%	46.58%	44.98%	-0.32%
		Others	15.40%	33.46%	51.20%	52.48%	40.00%	62.39%	79.44%	96.50%	3.41%
	F	**White**	29.74%	31.56%	32.03%	34.60%	33.78%	36.24%	39.02%	41.80%	0.56%
		Hispanic	32.63%	42.53%	34.63%	37.43%	36.62%	37.78%	38.50%	39.22%	0.14%
		Black	54.49%	62.10%	64.82%	55.35%	57.76%	58.83%	58.78%	58.73%	-0.01%
		Others	26.13%	30.99%	30.24%	30.47%	41.74%	42.66%	50.34%	58.01%	1.54%
> 64 yrs	**M**	**White**	47.61%	49.94%	54.99%	53.18%	53.80%	57.37%	61.27%	65.18%	0.78%
		Hispanic	29.82%	45.25%	48.51%	47.52%	50.31%	59.42%	70.23%	81.04%	2.16%
		Black	51.95%	75.00%	84.51%	62.46%	74.54%	81.12%	89.29%	97.45%	1.63%
		Others	35.50%	51.16%	43.77%	39.00%	56.02%	55.20%	62.42%	69.64%	1.44%
	F	**White**	51.65%	56.47%	52.04%	55.43%	58.64%	59.38%	62.61%	65.85%	0.65%
		Hispanic	57.26%	59.24%	42.33%	60.70%	55.93%	54.67%	54.37%	54.07%	-0.06%
		Black	56.89%	83.18%	60.67%	71.06%	72.11%	75.19%	79.77%	84.35%	0.92%
		Others	N/A	44.44%	47.44%	28.25%	76.26%	71.97%	91.03%	N/A	3.81%

Table 16 Prevalence of Hyperlipidemia

	Male	Female	18-44 yrs	45-64 yrs	65 yrs +	NH White	Hispanic	Black	Others
1999	29.51%	32.02%	16.57%	38.98%	50.07%	32.21%	27.29%	27.36%	38.77%
2001	32.23%	31.37%	18.73%	40.43%	46.46%	35.20%	24.50%	29.18%	25.76%
2003	35.69%	32.99%	19.49%	44.84%	49.63%	38.09%	24.99%	30.37%	30.60%
2005	32.81%	35.08%	19.90%	42.96%	48.99%	36.66%	28.18%	30.26%	29.83%
2007	40.68%	36.53%	24.87%	47.49%	54.56%	39.74%	37.26%	33.16%	41.16%
2010	40.41%	35.87%	25.25%	49.99%	54.24%	41.04%	36.09%	29.76%	35.07%
2015	46.61%	38.96%	29.23%	55.14%	57.88%	45.80%	42.22%	31.07%	38.10%
2020	52.79%	41.87%	33.23%	60.30%	61.64%	50.41%	48.38%	31.80%	41.14%
Projected Total Numbers									
2010	3,253,088	3,083,813	2,139,077	2,787,064	1,410,761	3,817,161	1,744,080	592,514	183,146
2015	3,998,330	3,574,722	2,596,363	3,188,849	1,787,840	4,375,393	2,306,033	668,992	222,634
2020	4,788,361	4,069,044	3,094,398	3,491,139	2,271,867	4,904,587	2,952,393	734,459	265,966

Table 17 **Prevalence of Hyperlipidemia, by Subpopulation**

			1999	2001	2003	2005	2007	2010	2015	2020	Annual Growth
< 45 yrs	**M**	**White**	14.22%	23.95%	22.28%	23.44%	28.42%	32.23%	39.20%	46.18%	1.39%
		Hispanic	16.37%	16.46%	17.86%	17.24%	33.47%	32.52%	41.26%	50.01%	1.75%
		Black	25.55%	9.36%	16.71%	15.30%	18.18%	13.94%	11.74%	9.54%	-0.44%
		Others	24.47%	25.04%	24.51%	27.59%	38.11%	38.38%	45.83%	53.29%	1.49%
	F	**White**	15.48%	17.75%	19.63%	21.57%	19.21%	22.68%	25.50%	28.32%	0.56%
		Hispanic	17.77%	17.09%	13.39%	16.01%	24.40%	22.00%	25.04%	28.09%	0.61%
		Black	17.20%	17.13%	23.62%	11.96%	10.64%	9.71%	5.13%	0.56%	-0.91%
		Others	30.64%	11.25%	24.07%	10.86%	22.05%	13.63%	9.24%	4.86%	-0.88%
45-64 yrs	**M**	**White**	39.31%	43.59%	50.57%	41.02%	48.44%	50.08%	54.00%	57.92%	0.78%
		Hispanic	34.31%	34.14%	40.25%	44.12%	44.84%	50.39%	58.15%	65.91%	1.55%
		Black	25.86%	41.79%	39.32%	29.15%	53.51%	52.85%	63.52%	74.18%	2.13%
		Others	56.21%	48.96%	46.98%	43.41%	50.21%	43.01%	38.63%	34.24%	-0.88%
	F	**White**	36.31%	41.63%	42.29%	45.23%	44.89%	49.33%	54.52%	59.71%	1.04%
		Hispanic	50.77%	34.82%	40.65%	43.39%	50.14%	46.51%	48.34%	50.16%	0.37%
		Black	42.46%	40.10%	46.50%	55.14%	49.85%	57.25%	64.70%	72.16%	1.49%
		Others	32.54%	25.55%	28.52%	38.53%	52.27%	53.83%	66.94%	80.05%	2.62%
> 64 yrs	**M**	**White**	48.81%	44.59%	50.21%	48.16%	55.97%	55.81%	60.28%	64.76%	0.89%
		Hispanic	41.75%	33.81%	33.16%	49.72%	52.25%	55.06%	64.28%	73.51%	1.85%
		Black	30.11%	60.98%	52.36%	55.96%	35.76%	49.23%	50.80%	52.37%	0.31%
		Others	64.09%	26.74%	55.22%	33.19%	58.02%	45.47%	44.04%	42.62%	-0.28%
	F	**White**	52.68%	50.15%	53.00%	49.70%	56.89%	55.27%	57.26%	59.24%	0.40%
		Hispanic	42.26%	36.46%	39.85%	51.34%	48.72%	53.46%	60.42%	67.37%	1.39%
		Black	52.85%	56.34%	36.25%	43.18%	52.57%	43.43%	40.00%	36.56%	-0.69%
		Others	N/A	46.67%	26.22%	32.95%	54.77%	49.46%	57.22%	64.97%	1.55%

Table 18 **Total Medical Care Cost of CKD Patients in Texas (in million dollars)**

	All	<45 yrs	45-64 yrs	65+ yrs	Male	Female	NH White	Hispanic	Black	Others
2002	6,933	1,933	2,521	2,479	3,404	3,529	3,182	1,927	1,388	436
2003	9,065	2,829	3,219	3,017	4,514	4,551	4,123	2,469	1,836	636
2004	10,026	2,970	3,547	3,509	5,098	4,928	4,711	2,584	2,057	675
2005	11,748	2,667	4,752	4,329	6,184	5,564	5,492	3,034	2,410	813
2006	13,284	2,801	4,853	5,631	6,862	6,422	6,243	3,222	2,942	878
2007	15,132	3,281	5,500	6,351	7,527	7,605	7,344	3,717	3,210	861
2010	20,750	3,430	7,602	9,718	10,665	10,085	10,677	4,347	4,932	794
2015	33,706	4,348	10,984	18,374	17,593	16,113	17,354	6,711	8,438	1,202
2020	51,609	5,358	14,515	31,736	27,293	24,316	26,319	10,138	13,415	1,737

Table 19 Average Annual Medical Care Cost of CKD Patients in Texas (in dollars)

	All	<45 yrs	45-64 yrs	65+ yrs	Male	Female	NH White	Hispanic	Black	Others
2002	30,998	36,588	36,232	24,484	29,758	32,296	28,927	30,567	38,108	30,715
2003	31,869	33,746	37,816	26,122	30,661	33,167	29,546	30,566	40,629	33,635
2004	34,926	41,671	41,281	27,019	34,267	35,636	32,206	34,369	44,187	35,376
2005	36,326	47,064	41,972	28,199	37,428	35,175	33,327	35,798	45,707	38,441
2006	34,449	40,150	40,564	28,695	34,825	34,057	31,139	32,836	45,105	40,282
2007	35,105	43,214	40,389	29,007	34,266	35,976	32,077	34,333	44,474	39,749
2010	38,135	49,042	44,313	32,112	38,638	37,617	34,355	36,402	50,899	46,651
2015	41,931	55,834	48,867	36,660	42,766	41,055	37,268	39,155	58,239	54,912
2020	45,851	61,946	53,604	41,307	46,841	44,788	40,458	41,990	65,162	62,616

Table 20 Total Medical Care Cost of CKD Patients in Texas, by Subpopulation (in million dollars)

			2002	2003	2004	2005	2006	2007	2010	2015	2020
< 45 yrs	Male	White	401.7	557.7	640.2	586.7	646.8	764.6	978.0	1,377.7	1,849.1
		Hispanic	328.5	462.7	503.0	531.6	571.1	659.2	643.5	928.8	1,288.0
		Black	177.6	346.2	385.2	355.9	348.5	333.7	470.2	641.4	850.5
		Others	57.2	115.9	88.5	62.5	90.6	84.3	45.8	29.8	1.1
	Female	White	349.2	491.4	513.6	386.4	392.5	548.6	538.8	633.4	739.3
		Hispanic	309.5	434.9	452.4	353.9	358.3	479.1	380.3	413.6	435.3
		Black	254.2	316.1	285.3	289.8	295.8	320.8	310.1	270.0	168.3
		Others	55.3	104.1	102.0	100.3	96.9	90.2	63.5	53.2	26.1
45-64 yrs	Male	White	448.8	587.1	714.0	1,062.1	907.4	1,022.1	1,568.3	2,202.6	2,800.2
		Hispanic	339.9	418.6	426.7	659.5	559.5	624.9	789.9	1,092.3	1,413.4
		Black	313.6	382.7	420.1	542.4	700.9	694.9	1,064.3	1,613.4	2,186.2
		Others	60.6	83.2	93.9	123.7	147.5	111.0	115.6	165.0	220.3
	Female	White	631.5	810.0	872.5	1,069.0	1,069.2	1,275.8	1,623.8	1,958.7	2,136.9
		Hispanic	392.9	498.2	501.0	576.6	590.3	705.8	794.6	982.3	1,154.3
		Black	249.7	334.8	383.0	525.9	720.9	862.4	1,451.7	2,673.0	4,179.6
		Others	83.9	104.6	135.9	192.9	157.4	203.2	193.5	296.6	423.9
> 64 yrs	Male	White	658.2	817.8	978.0	1,194.3	1,576.9	1,820.2	2,972.0	5,655.7	9,617.5
		Hispanic	298.6	345.3	374.6	490.2	594.6	640.5	871.9	1,649.5	2,944.6
		Black	223.6	276.7	347.9	396.3	509.9	583.0	971.6	1,947.3	3,670.9
		Others	95.9	123.6	126.7	178.9	206.6	187.3	173.5	289.1	451.1
	Female	White	692.9	859.0	992.5	1,194.2	1,650.4	1,914.0	2,995.9	5,526.2	9,176.2
		Hispanic	258.0	309.5	326.1	421.1	547.6	606.9	867.2	1,644.9	2,902.2
		Black	169.4	179.7	235.5	299.1	365.4	415.1	663.7	1,293.0	2,359.3
		Others	82.6	105.1	127.5	154.7	179.1	184.5	202.3	368.3	614.5

Table 21 Average Annual Medical Care Cost of CKD Patients in Texas, by Subpopulation (in dollars)

			2002	2003	2004	2005	2006	2007	2010	2015	2020	Annual Growth
< 45 yrs	**Male**	**White**	33,663	29,155	38,285	47,580	42,307	43,658	54,621	68,724	82,828	2,821
		Hispanic	33,663	29,155	38,285	47,580	42,307	43,658	54,621	68,724	82,828	2,821
		Black	34,743	45,146	57,170	57,181	45,418	43,265	53,980	60,185	66,390	1,241
		Others	30,371	33,302	30,888	29,881	39,034	37,673	41,805	49,334	56,862	1,506
	Female	**White**	37,004	32,355	40,116	41,657	34,091	43,192	43,992	49,376	54,761	1,077
		Hispanic	37,004	32,355	40,116	41,657	34,091	43,192	43,992	49,376	54,761	1,077
		Black	55,889	51,537	52,553	54,056	43,181	43,391	36,579	24,285	11,992	-2,459
		Others	30,710	35,633	44,227	58,390	46,230	41,719	58,691	73,120	87,549	2,886
45-64 yrs	**Male**	**White**	32,323	33,169	37,776	43,318	36,059	35,271	40,869	45,005	49,141	827
		Hispanic	32,323	33,169	37,776	43,318	36,059	35,271	40,869	45,005	49,141	827
		Black	46,523	45,874	49,272	48,506	54,801	48,193	54,262	59,171	64,080	982
		Others	31,179	33,973	38,345	37,847	46,198	39,435	50,000	61,066	72,131	2,213
	Female	**White**	36,884	39,295	41,094	36,872	35,541	36,978	35,419	33,274	31,130	-429
		Hispanic	36,884	39,295	41,094	36,872	35,541	36,978	35,419	33,274	31,130	-429
		Black	38,978	42,759	44,368	49,641	56,754	57,673	70,478	90,582	110,687	4,021
		Others	36,284	36,128	50,340	50,722	43,928	54,805	63,658	80,284	96,910	3,325
> 64 yrs	**Male**	**White**	23,220	24,553	25,326	26,951	26,719	26,959	29,837	33,669	37,501	766
		Hispanic	23,220	24,553	25,326	26,951	26,719	26,959	29,837	33,669	37,501	766
		Black	27,301	30,520	33,709	34,587	34,241	35,511	40,988	48,573	56,158	1,517
		Others	29,710	33,945	28,563	34,066	38,361	34,405	39,812	45,845	51,877	1,207
	Female	**White**	23,657	25,560	26,120	26,314	27,771	28,239	30,950	35,199	39,447	850
		Hispanic	23,657	25,560	26,120	26,314	27,771	28,239	30,950	35,199	39,447	850
		Black	31,210	29,202	34,097	37,889	35,454	36,802	42,046	49,261	56,477	1,443
		Others	27,433	29,717	29,580	30,834	34,309	34,927	39,383	46,884	54,385	1,500

Table 22 Average Annual Medical Care Cost of CKD Patients in Texas, by Age and Co-morbidity (in dollars)

		2002	2003	2004	2005	2006	2007
CKD Only	**<45**	20,374	21,085	30,972	32,054	28,540	23,273
	45-64	18,008	26,988	33,226	37,173	29,857	23,393
	65+	38,588	39,418	45,731	42,079	38,440	40,266
CKD+DM	**<45**	44,278	44,571	48,653	59,097	47,169	48,062
	45-64	15,041	20,308	18,881	20,588	20,533	21,943
	65+	26,096	23,090	26,547	21,319	18,064	21,342
CKD+HTN	**<45**	34,056	33,170	32,568	35,921	35,473	35,210
	45-64	41,303	42,486	47,457	48,319	47,890	46,490
	65+	14,925	14,404	12,988	15,135	15,345	14,508
CKD+DM+HTN	**<45**	12,282	16,950	15,452	17,301	17,949	15,910
	45-64	20,441	20,367	21,510	22,405	22,611	23,526
	65+	29,821	32,420	32,769	34,580	35,031	34,620

Figure 1 **Total Number and Prevalence of CKD in Texas**

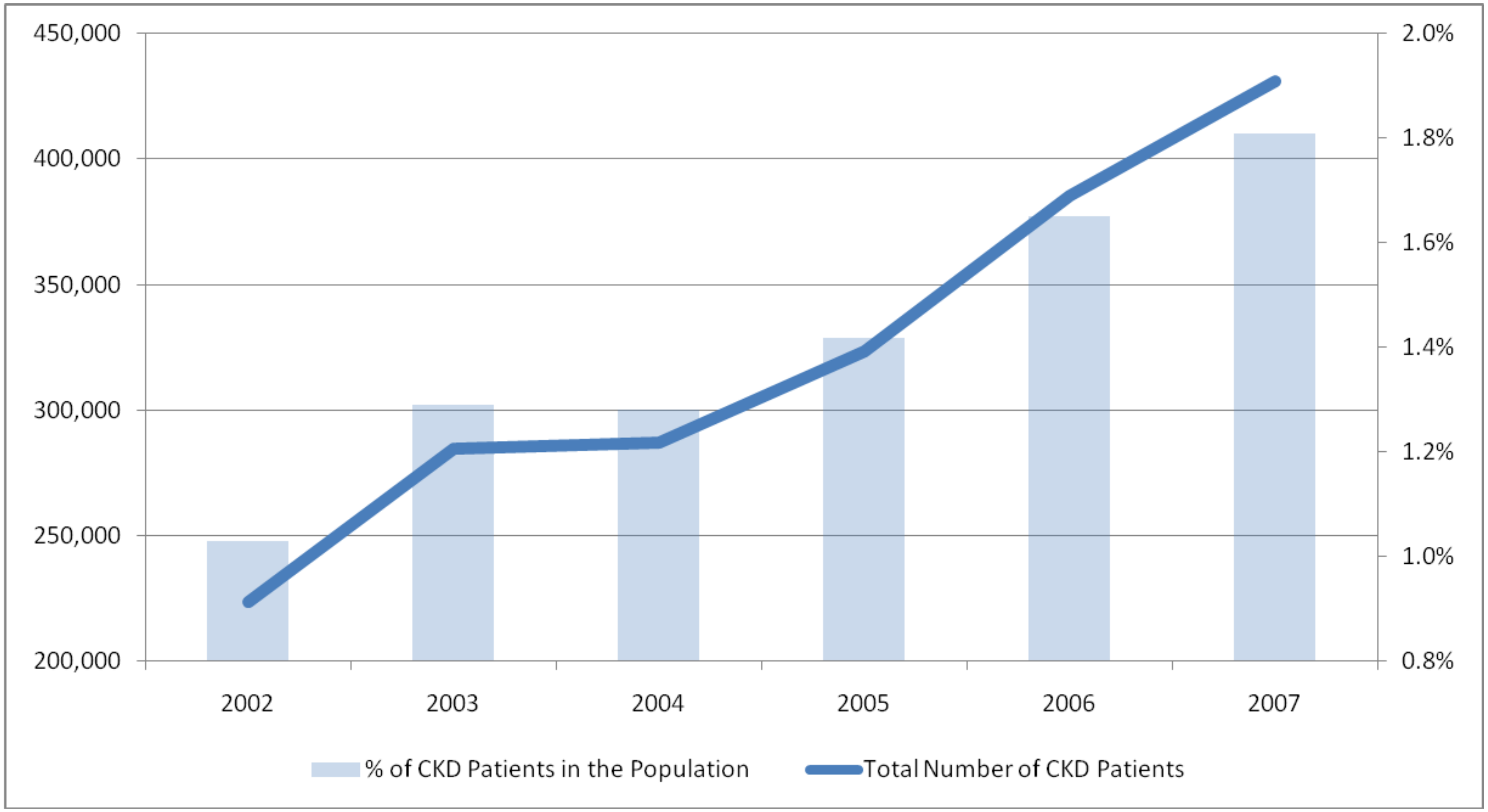


Figure 2 **Total Number and Prevalence of CKD in Texas, by Age Group**

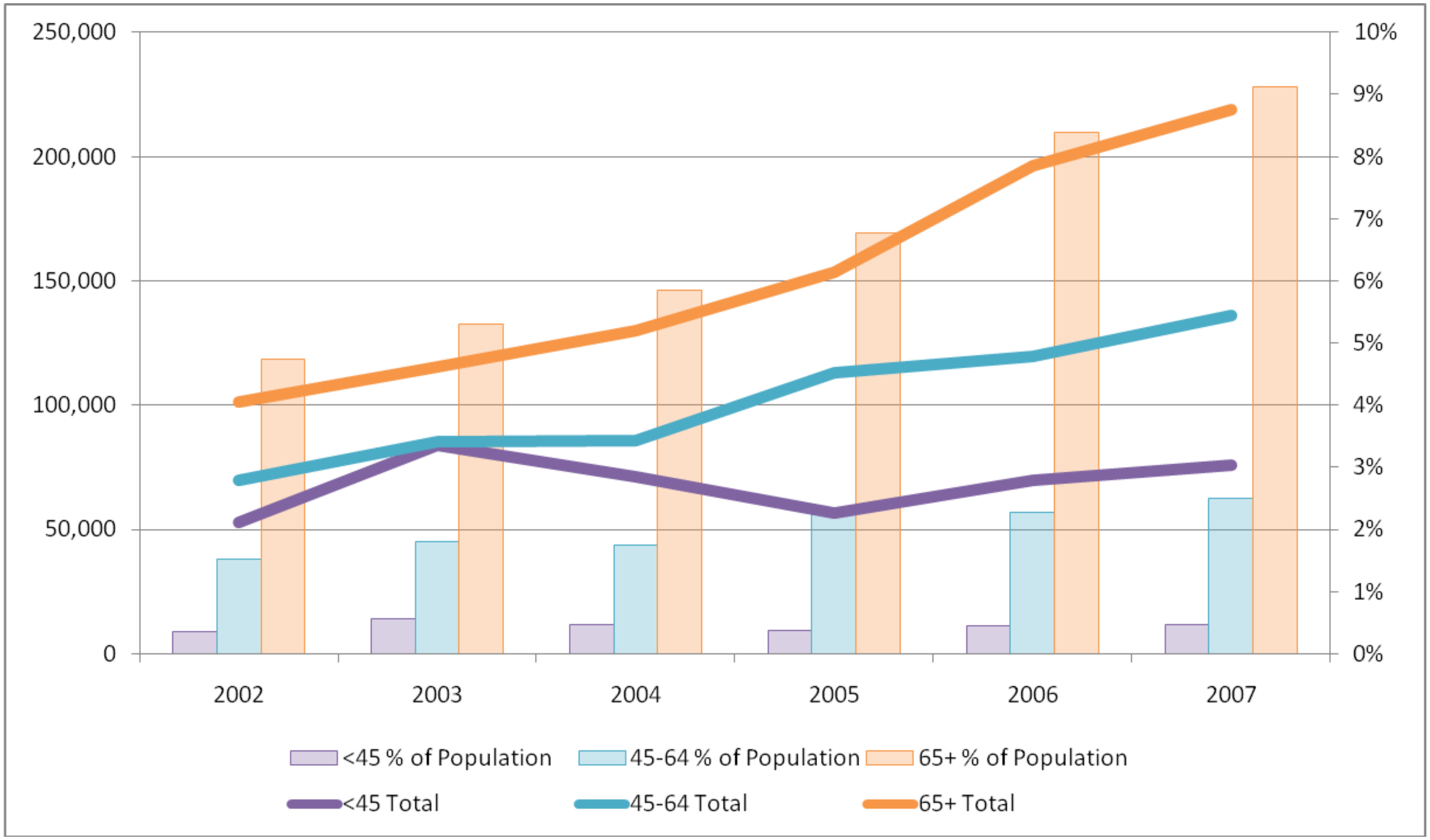


Figure 3 **Total Number and Prevalence of CKD in Texas, by Gender**

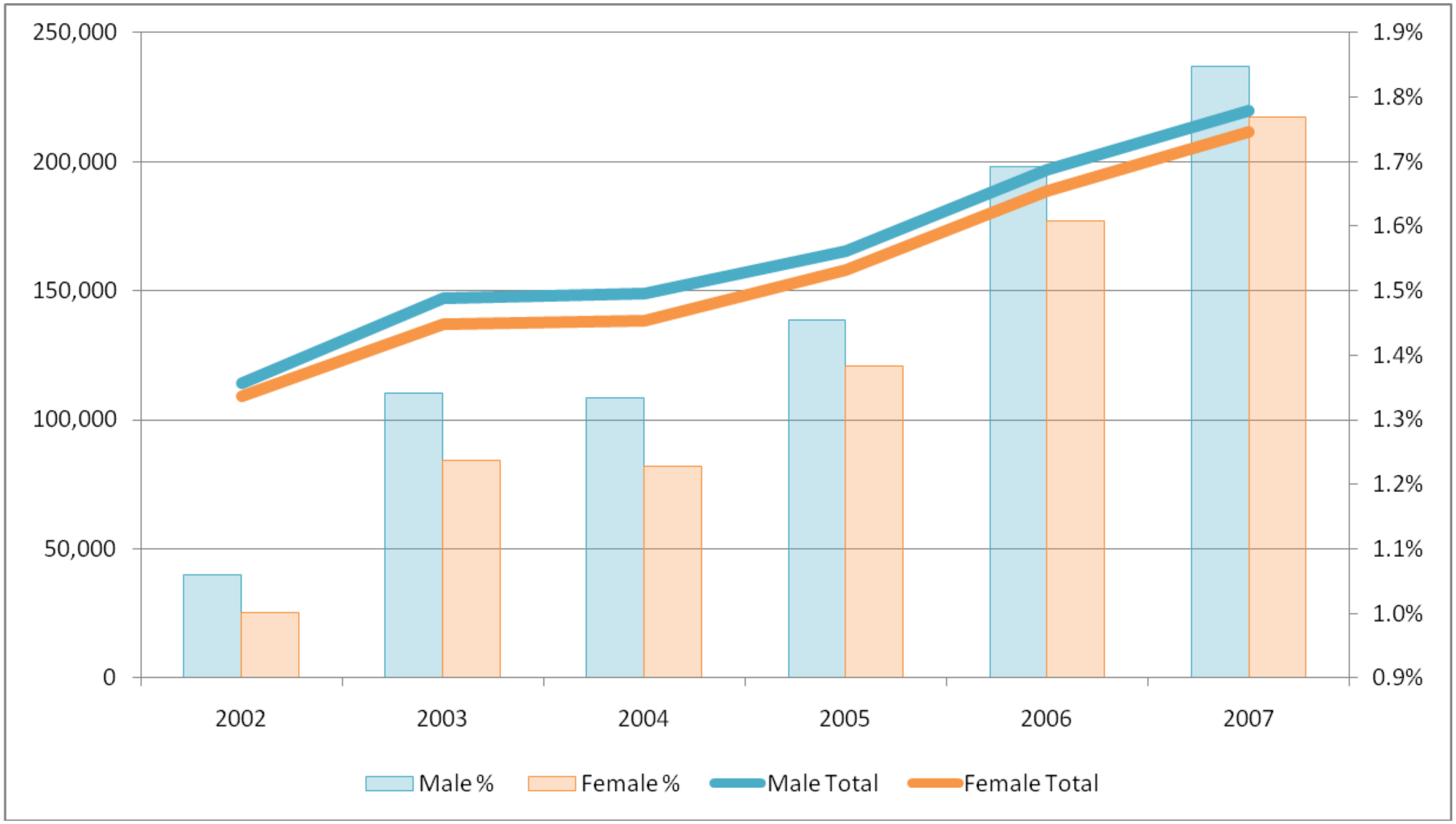


Figure 4 **Total Number and Prevalence of CKD in Texas, by Race and Ethnicity**

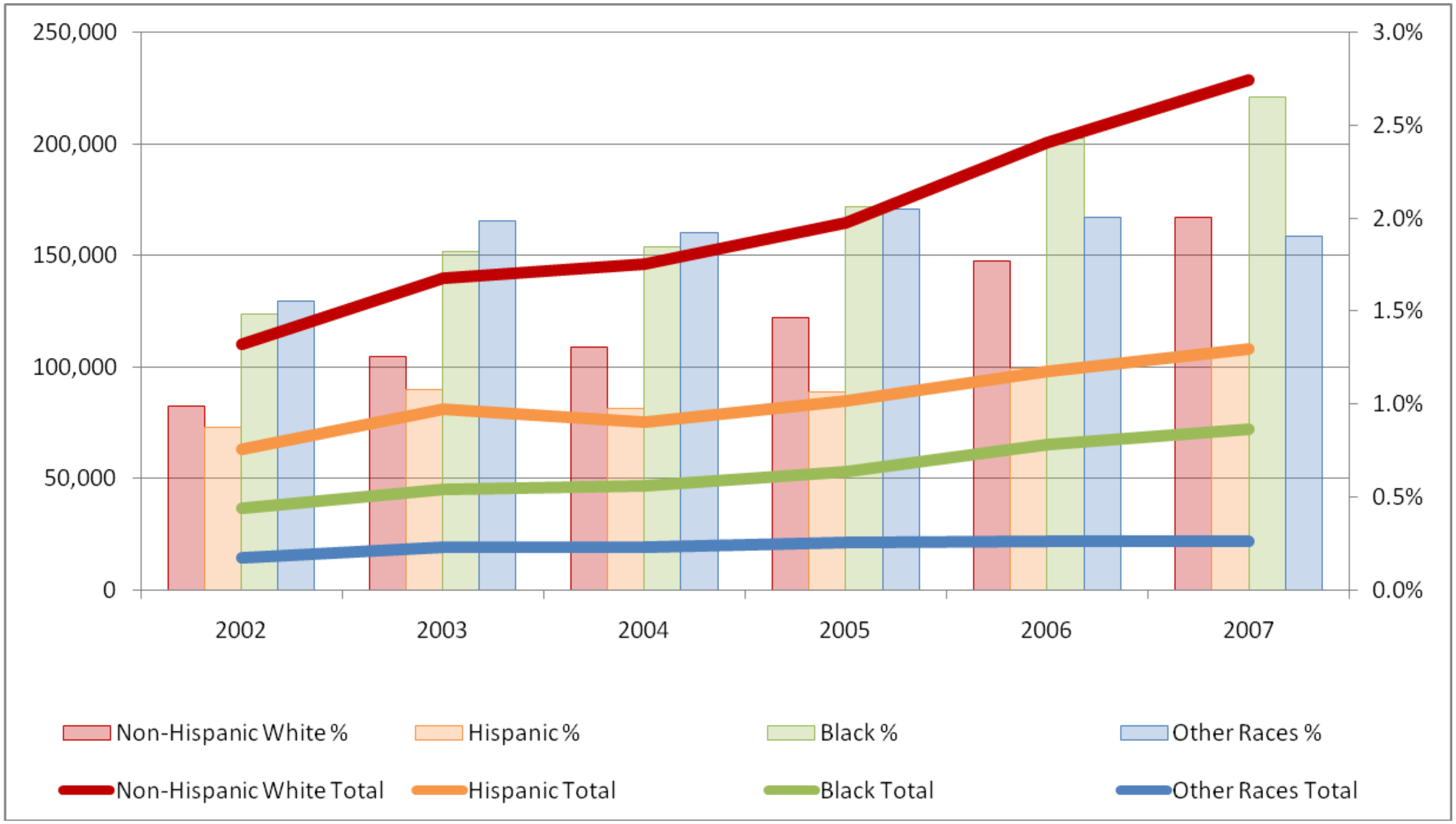


Figure 5 **Total Number of Prevalence of CKD in Texas, by Co-mordity**

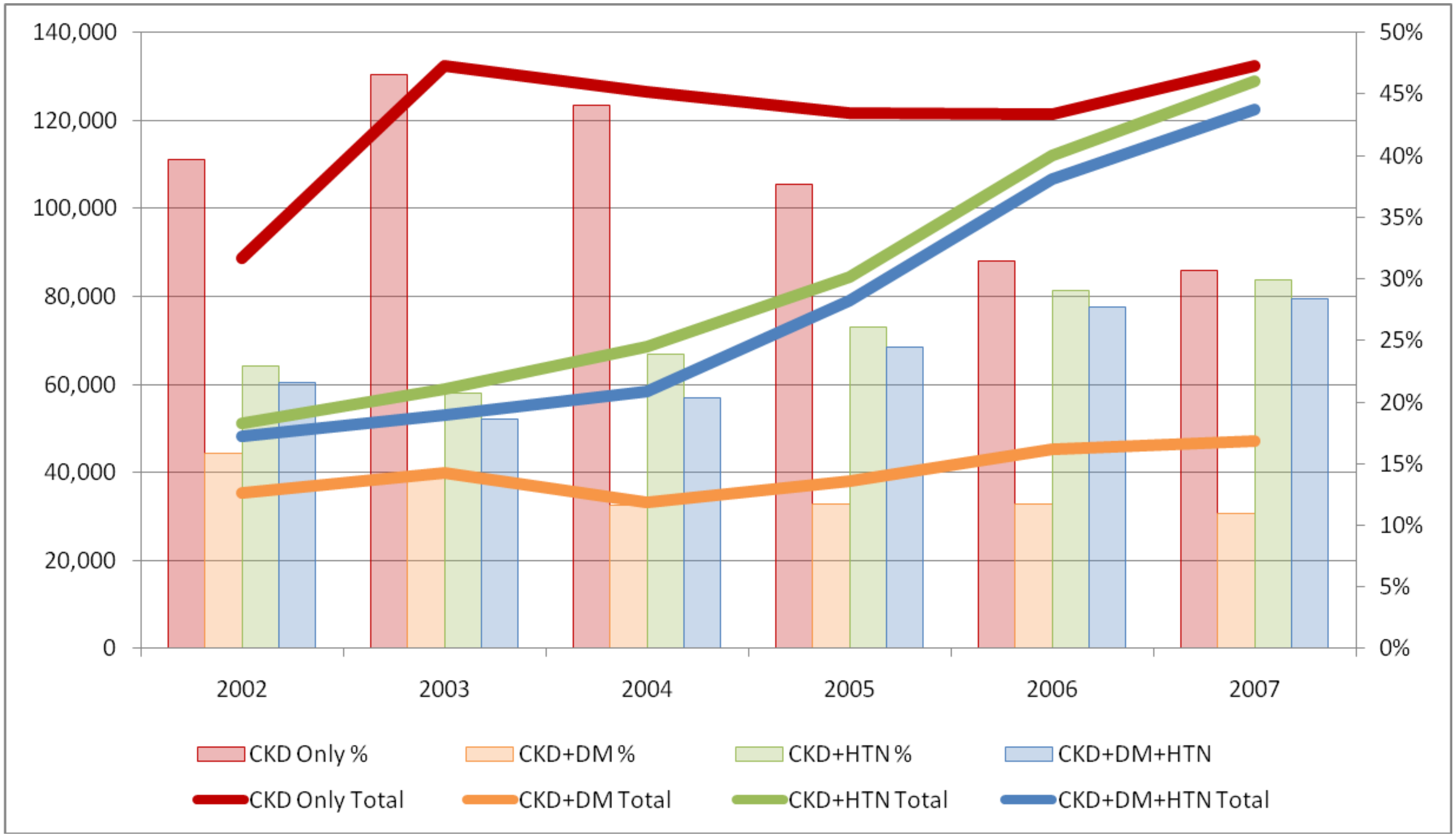
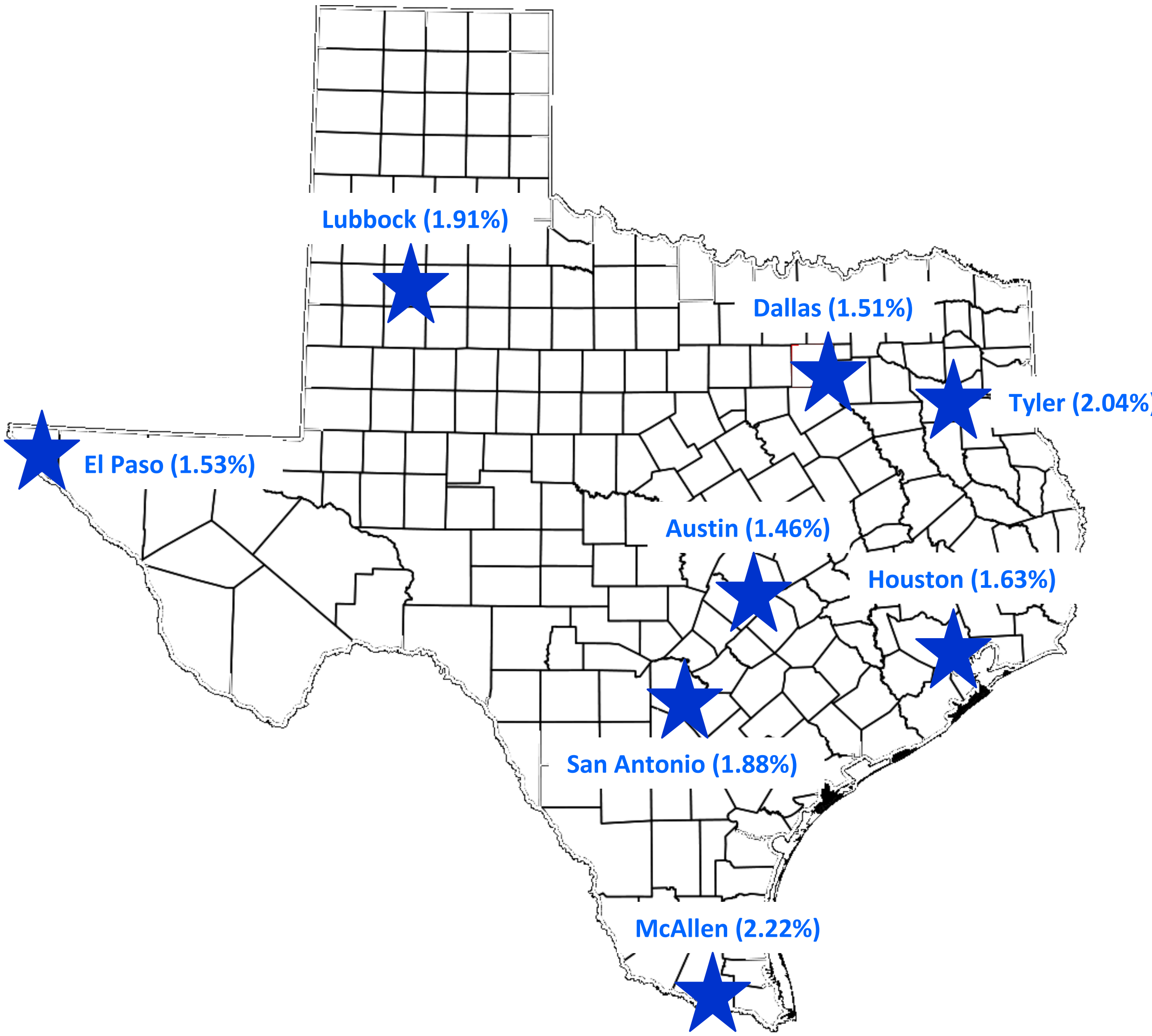


Figure 6 CKD Prevalence in Selected Expanded Metropolitan Area



Chronic Kidney Disease Demonstration Project

Texas Tech University Health Sciences Center
School of Medicine
Department of Internal Medicine
Division of Nephrology
3601 4th Street, STOP 9410
Lubbock, Texas 79430

Background/Significance:

Chronic kidney disease (CKD) is a growing healthcare problem. It is estimated that over twenty-six million people are affected with CKD in the US. In addition, about half a million patients have end stage renal disease (ESRD) and are on chronic dialysis. The direct healthcare costs associated with CKD exceeds $49 billion annually in the US, and care of ESRD costs another $35 billion a year. It is known that diabetes mellitus is the most common cause of ESRD. There are about two million Texans with diabetes mellitus and this warrants measures to prevent diabetic complications, such as renal disease. The state of Texas ranks second highest in the prevalence of CKD and costs associated with it in the nation. In 2007, the state of Texas passed a State Bill recognizing the public health significance of CKD and has established a CKD Task Force. The true prevalence of CKD is currently unknown, and there are no state-based statistics of CKD prevalence and its risk factors. Current knowledge of incidence and prevalence of CKD is based on sample studies from sources such as National Health and Nutrition Examination Surveys (NHANES).

Objectives:

The objectives at Texas Tech University Health Sciences Center (TTUHSC) Lubbock were to:

1. Organize a multi-campus demographic analysis to identify the characteristics of CKD followed in West Texas nephrology clinics, including the prevailing medical practice patterns and
2. Organize a multi-campus demonstration project (to be performed in West Texas primary care clinics) to:

   (i) Examine the prevalence of various CKD stages in the general patient population (as opposed to high risk patients) and

   (ii) Implement a simple intervention to prevent CKD. In this regard, we chose the angiotensin converting enzyme inhibitors (ACEi) / angiotensin receptor blockers (ARB) option in an at-risk group-diabetics, since this is a simple, evidence based preventive measure that is perhaps the most cost-effective in the prevention of CKD.

   Currently as per 2008 USRDS data, diabetes is the leading cause of CKD nationwide and much more so in Texas. Yet fewer than 20% of diabetics among Medicare patients are screened for CKD. Only 20-23% of CKD patients receive ACEi/ARB even as late as 12 months before end-stage renal disease (ESRD), (USRDS 2008).

   Furthermore, our strategy involves both screening and primary prevention for CKD at an early stage. Thus we anticipate this approach will effectively improve CKD diagnosis and prevention in the long term. We are supplementing the above screening with education of primary care physicians, whose involvement and commitment is critical, regarding vigorous screening of patients for CKD and early referral.

3. Randomly screen for CKD in a general adult population in a representative community of west texas.

Three separate studies are being carried out to address these objectives:

1. **Title: A Cross-Sectional, Demographic Analysis of Chronic Kidney Disease at Texas Tech University Health Sciences Center – CKD DEMOGRAPHICS STUDY**

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Co-Investigator(s): Melvin Laski, M.D., TTUHSC-Lubbock
Meryem Kara, M.D., TTUHSC-Lubbock
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Roger Smalligan, M.D., TTUHSC-Amarillo
Georges Maliha, M.D., TTUHSC-Amarillo
Ronald Gibbons, M.D., TTUHSC-Permian Basin
Craig Spellman, D.O., Ph.D., TTUHSC-Permian Basin

Specific Aims:

To identify the CKD prevalence within the West Texas region, a review of all chronic kidney disease patients currently being followed in nephrology clinics at Texas Tech University Health Sciences Center (TTUHSC), and select private nephrology clinics in Amarillo, Texas and Midland/Odessa, Texas, is being administered.
By assessing the prevalence of CKD, the study will be able to identify:

- The stages of CKD at which patients are referred to the nephrology clinics of TTUHSC and select private clinics in Amarillo, TX and Midland/Odessa, TX
- Initial and current CKD stages of patients in nephrology clinics at TTUHSC in Lubbock
- Current practice and referral patterns in West Texas
- Any potential preventive measures for CKD

A. Experimental Design & Methods

- This cross-sectional, demographic analysis is intended to indicate the demographics of the CKD population in West Texas, and also reflect the current practice patterns in CKD clinics and referrals.
- The project was being based on the CKD patient population of TTUHSC's nephrology clinics located in Lubbock, Midland/Odessa, and the select private nephrology clinics in Amarillo and Midland/Odessa, via chart review.

  - Population is being obtained via International Classification of Diseases-9 (ICD-9) codes for CKD through TTUHSC's medical records system.
- All data being collected was coming from visits that occurred from March 1, 2009 to March 17, 2010.
- All CKD patients who have been seen in TTUHSC nephrology clinics, and the select private nephrology clinics in Amarillo and Midland/Odessa within the given time frame are subject to be reviewed, with no identifiers being attached to any data collected.
- Data is being collected by research coordinators in all of the participating campuses of TTUHSC
  - Letters of support for this research study were collected from the private nephrology clinics in Amarillo and Midland/Odessa:
- After the CKD patient population was indentified, and Institutional Review Board (IRB) approval obtained, the patient's charts and medical records are being reviewed to collect the following data:
  - Age
  - Gender
  - Ethnicity
  - Etiology of CKD
  - Duration of CKD
  - Initial Stage of CKD
  - Current Stage of CKD
  - Co-morbidities
  - Serum Creatinine, eGFR, and Urine Protein excretion lab values
  - Hemoglobin, Hematocrit, and Iron studies if available
  - Lipid panel
  - Serum proteins
  - Hemoglobin A1c
  - Medication profile
  - Family History

- During the chart reviews, the patients initial CKD stage and current CKD stage were being noted
- Data collected at all three sites was entered by study coordinators into Sharepoint, a large-capacity, controlled, internet-based platform that allows users to log in and share data using common applications such as Microsoft Excel. Sharepoint automatically provides data encryption and frequent data back-up to the TTUHSC servers. The Sharepoint was being administered by research staff in Lubbock, TTUHSC's main campus, where all information was processed for demographic statistical analysis.

B. Subject Population

- All patients with CKD being followed in TTUHSC nephrology clinics at the Lubbock and Midland/Odessa campuses are being reviewed with no identifiers being attached.

- All patients with CKD being followed in the private nephrology clinics were reviewed with no identifiers being attached
- All patients with a CKD diagnosis that are not being followed in TTUHSC nephrology clinics at the Lubbock campus were reviewed with no identifiers being attached
- All subjects were between the age of 1-89
- Sample size will be approximately a thousand patients, and entire population will come from TTUHSC nephrology clinics at the Lubbock and Midland/Odessa campuses, TTUHS and the select private clinics for the Amarillo and Midland/Odessa Sites.
- Inclusion requirements are those with a diagnosis of CKD and being seen in TTUHSC nephrology clinics at the Lubbock and Midland/Odessa campuses, TTUHSC non-nephrology and the select private clinics for the Amarillo and Midland/Odessa sites
- Exclusion requirements are patients that do not have a diagnosis of CKD
- Subjects are not receiving any compensation for being included in this study

C. Risks

- There is less than minimal risk for the subjects being included in this study

D. Benefits

- Subjects included in this study are not receiving any direct benefit by being included in the study
- Any benefits gained are directly related to obtaining knowledge of current prevalence rates of CKD, and current clinical and referral practices within the West Texas regions

E. Privacy and Confidentiality

- All subject information gathered through chart reviews are free of any identifiers that could be associated with a given subject
- No identifiers such as name, initials, date of birth, zip code, phone numbers, mailing address, or institutional medical record number are used at any time during the study

F. Results/Conclusions

- To date, a total of **1,059** study subjects have been collected.
- 63% of the study population is either White or Hispanic.
- The most common etiology is diabetes, with hypertension being second.

- The majority of the subjects that were seen and classified in the nephrology clinics were initially diagnosed as a CKD stage III. Significant numbers of subjects were seen as an initial stage I, II, or IV also. Unfortunately, a large number of subjects did not have an initial CKD stage documented.
- With respect to current CKD stage, the great majority of the subjects have been classified as a stage III.

A pediatric subpopulation, totaling 31subjects to date, has also been collected.

- 68% of the subjects are White and 26% are Hispanic.
- Lupus is the most common etiology.
- The vast majority were classified as an initial CKD stage I.
- With regard to current CKD stage, the great majority of the subjects have also been classified as stage I.

2. A Screening Study on the Prevalence of Chronic Kidney Disease Found in the Patient Population of Texas Tech University Health Sciences Center Primary Care Clinics –PCC- CKD STUDY [STUDY STILL IN PROGRESS]

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Craig Spellman, D.O., Ph.D., TTUHSC-Permian Basin
Jamal Islam, MD, TTUHSC-Permian Basin

Sponsoring Agency: Texas Department of Health

Study Sites: TTUHSC campuses of Lubbock, Amarillo, and Permian Basin

A. Objectives/Specific Aims:
Estimate the glomerular filtration rate (eGFR) of patients that are ≥ 18 years of age and are attending primary care clinics of TTUHSC campuses in Lubbock, Amarillo, and the Permian Basin. Some private primary care clinics have also been added.

- Determine what percentage of at-risk diabetic patients are not screened for microalbuminuria/proteinuria
- Determine the percentage of diabetic patients that test positive for microalbuminuria but are not placed on an ACEi/ARB, and initiate a study to place those patients on an ACEi/ARB regimen and follow them longitudinally
- Initiate education of primary care physicians concurrently with the project, to promote CKD awareness and prompt referral for nephrology care.

B. Research Methods:

a. General Design

The study is a cross-sectional, screening study of patients that are ≥ 18 years of age being seen in the primary care clinics (Family Medicine and Internal Medicine) of TTUHSC campuses in Lubbock, Amarillo, and the Permian Basin.

- Institutional Review Board (IRB) approval has been obtained
- Expected duration of the study will be approximately one year, March 1, 2010 – April 1, 2011
- Informed consent process and HIPAA authorization is taken for every subject prior to any research activity taking place
- Chart reviews are being conducted to screen the subject populations of TTUHSC primary care clinics in Lubbock, Amarillo, and the Permian Basin.
- Subject identifiers (subject name/initials, date of birth, gender) are being utilized, but are being kept confidential by participating research staff
  - Identifiers are not being attached to any final study reports where subject's identification could be revealed
  - All identifiers are being solely utilized to ensure accurate follow-up if needed
- Target population is coming from the current general patient population of all participating primary care clinics; all current patients of participating TTUHSC Family Medicine and Internal Medicine clinics are being included for the study
- Lab values for a basic metabolic panel (BMP) and Urine Microalbumin/ Protein testing are needed for the study
  - BMP values taken within the past six months are being used for the study
  - Any prior testing for Microalbuminuria/Proteinuria within the past 12 months from the date of visit, is being used for the study
- If the subject does not have BMP lab values within the past six months available, a current BMP lab draw is being obtained via venipuncture
  - All costs associated with the BMP lab draw are being covered by the study

- If the subject does not have any prior testing for Microalbuminuria/Proteinuria, within the past 12 months from the date of visit, a current urine sample is being obtained and tested for any evidence of Microalbuminuria
    - All costs associated with the Microalbuminuria/Proteinuria testing are being covered by the study
- Once target population is selected, the research staff collect the following data:
    - Subject's name/initials
    - TTUHSC Medical Record number
    - Date of birth
    - Sex
    - Race
    - BMP values, which include eGFR and Serum Creatinine values
    - Microalbumin/Urine Protein lab values
    - Potential CKD risk factors (HTN, diabetes, retinopathy, CVD, obesity, smoking status, family history of kidney disease)
    - Medication profile
    - Primary care physician contact information
- eGFR, creatinine lab values taken from a BMP and Urine Microalbumin/ Protein lab values, are being examined by the research staff to determine any risk/prevalence of CKD
    - For any abnormal eGFR or serum creatinine lab values, a letter is being sent to the subject's PCP regarding concern for possible onset of CKD and any further recommendations
        - Normal serum creatinine: 0.5-1.2 mg/dL (range may vary slightly depending on lab)
        - Chronic Kidney Disease Stages based on eGFR:

eGFR (ml/min/1.73m^2)	CKD Stage
90-120	1
60-89	2
30-59	3
15-29	4
<15	5

    - For any abnormal Microalbumin/Urine Protein lab values, a letter is being sent to the subject's PCP regarding concern for possible onset of CKD and any further recommendations.
        - Normal urine microalbumin/protein: 20-200 mcg/mL or <30mg/g creatinine

- Subjects, who will have a letter sent to their respective PCP, are having their chart reviewed again in 3 months, by the research staff, to determine whether or not their PCP implemented any recommendations given by the study's physicians.

– Creatinine value, age, sex, and race data are also being entered into an algorithm (CKD-EPI formula) to calculate the eGFR
  - $eGFR_{CKD\text{-}EPI}$=141 X (minimum of standardized serum creatinine [mg/dL]/k or 1)$^{\alpha}$ X (maximum of standardized serum creatinine [mg/dL]/k or 1)$^{-1.209}$ X 0.993^{age} X (1.018 if female) X (1.159 if black)
    - k is 0.7 if female and 0.9 if male
    - α is -0.329 if female and -0.411 if male

– The *Diabetic population* is being selected from the overall target population, and analyzed separately
  - Population includes any subjects, ≥ 18 years of age, that have been diagnosed with diabetes mellitus (Type I or II)

– For the general target population, eGFR, creatinine, and Microalbumin/Urine Protein lab values are being evaluated for any evidence of possible CKD onset

– For the *diabetic population*, the research staff are collecting data on eGFR values and any previous testing for microalbuminuria/proteinuria
  - If the subject *has been previously tested* for microalbuminuria/proteinuria, within the past 12 months from the date of visit, and results were positive, data is being collected on whether the subject was placed on an ACEi/ARB by their respective PCP
    - If the subject was not placed on an ACEi/ARB, a letter is being sent to the subject's PCP, by the study's P.I., recommending the use of standard of care
  - If the subject *has not been previously tested* for microalbuminuria/proteinuria, within the past 12 months from the date of visit, the research staff is obtaining a urine sample from the subject for a urine analysis to test for microalbuminuria/proteinuria
    - Patient has the right to chose whether or not he/she will participate in study
  - If the patient tests positive, a letter is being sent to their PCP, recommending an additional urine analysis for confirmation, as per standard of care
  - Subjects, who have a letter sent to their respective PCP's, are having their chart reviewed again in 3 months, by the research staff, to determine whether or not their PCP implemented the recommended standard of care by the study's P.I.

- Data collected at all three sites is being entered by study coordinators into Sharepoint, a large-capacity, controlled, internet-based platform that allows users to log in and share data using common applications such as Microsoft Excel. Sharepoint automatically provides data encryption and frequent data back-up to the TTUHSC servers. The Sharepoint is being administered by research staff in Lubbock, TTUHSC's main campus, where all information is being processed for statistical analysis.

b. Primary Endpoints
  - Once 1000 subjects have been reviewed, all data will be submitted to TTUHSC-Lubbock campus for statistical analysis

c. Selection/Withdrawal of Subjects
  - Inclusion Criteria:
    - Subjects have to be ≥ 18 years of age and attend a primary care clinic (Family Medicine or Internal Medicine) at any of the three participating TTUHSC campuses in Lubbock, Amarillo, or Permian Basin
    - For the *diabetic sub-population*:
      - All diagnosed diabetics ≥ 18 years of age attending a primary care clinic (Family Medicine or Internal Medicine) at any of the three participating TTUHSC campuses in Lubbock, Amarillo, and Permian Basin, and select private primary care clinics in the Permian Basin.
  - Exclusion Criteria:
    - Documentation of currently taking Bactrim and any Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) for a short course (≤ 10 days)
      - Those taking NSAIDs on a routine basis for management of a chronic illness, will be considered
    - Subjects who have received intravenous contrast for any radiological procedure within seven days of a qualifying BMP or urine microalbumin/protein
    - Subjects who have been diagnosed with CKD, and are currently undergoing hemodialysis treatment
  - Withdrawal Criteria:
    - Subjects who underwent the informed consent process, are able to withdraw themselves at any time during the duration of the study
  - Subject Recruitment:
    - All subjects are coming from primary care clinics (Family Medicine and Internal Medicine) of TTUHSC campuses in Lubbock, Amarillo, and Permian Basin

d. Safety Assessment

- Subject safety is at minimal risk for this study
- Risks are minimal, involved with the lab draw and include:
  - Excessive bleeding
  - Fainting or feeling light-headed
  - Bruising
  - Infection (a slight risk any time the skin is broken)
  - Pain

e. Statistical Analysis

- Data collected is being reviewed and calculated to obtain overall percentages on :
  - subjects who have risk factors for CKD but are not tested for microalbuminuria
  - subjects who have risk factors and are tested for microalbuminuria
  - subjects who test positive for microalbuminuria, but were not prescribed any ACEi/ARBs by their PCP
  - subjects who test positive for microalbuminuria and were prescribed an ACEi/ARB by their PCP
  - PCP's who initiated any recommended standard of care by the study's P.I.
    - Includes:
      - Recommended testing for microalbuminuria for those who have risk factors, but have not been tested
      - Prescribing of ACEi/ARBs for those who have a diagnosed microalbuminuria, but have not been placed on any treatment regimen

C. Anticipated Results:

Expectations are that the study will yield data that reflects:

- The prevalence of CKD in the general population that attend primary care clinics
- Percentage of patients with diabetes mellitus at risk, who have not been tested for microalbuminuria
- Percentage of patients who are not on ACEi/ARBs, despite indication
- Compliance of primary care physicians to recommended guidelines in CKD prevention

D. Results/Conclusions:

- To date, a total of **440** study subjects have been obtained.
- Of the common risk factors for CKD, hypertension was found to be the most common within our subject population. Diabetes is the second most common.
- Of the 440 subjects, 272 are of White ethnicity and 127 are of Hispanic ethnicity.

- Using eGFR only, 191 subjects were classified as CKD stage II, 156 were classified as stage I, and 82 were classified as stage III.
- Of the 102 total diabetic subjects in our study, 64 had undergone testing for microalbuminuria/proteinuria prior to the interview, and 26 were positive.
- Of the 26 subjects who were positive for microalbuminuria or proteinuria at the time of the interview, 18 were on either ACE inhibitor or ARB therapy.

3. PREVALENCE OF CHRONIC KIDNEY DISEASE IN A METROPOLITAN AREA AND ADJACENT RURAL COUNTIES IN TEXAS [STUDY STILL IN PROGRESS]

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Tom Xu, PhD, TTUHSC-Lubbock
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Study Sites: Lubbock County and bordering counties

A. Objectives:

To estimate the prevalence of Chronic Kidney Disease & risk factors in a representative population in general community of west Texas. The goal is to recruit 2000 subjects into the study.

B. Research Methods:

Target population: Target population is the general population of Lubbock and all bordering counties. Because the development of CKD is mostly among adults, we are including only subjects 21 years or older using the definition of adults by NIH. Therefore, the **inclusion criteria** are (1) ≥ 21 years of age, and (2) currently residing in Lubbock or bordering counties. There are **limited exclusion criteria** for this project to provide population-level estimates. The exclusion criteria are being applied to the following specified populations:

- Adults who are wards of the state or any other entity
- Pregnant Women
- Persons with cognitive impairments (comatose, developmentally disabled, thought process disorders, dementia, etc.)

- Prisoners (persons who are involuntarily confined in penal institutions)
- Persons who are terminally ill
- Texas Tech University System Employees

Sampling. Many sampling methods can produce population-representative estimates. In practice, however, the choices are limited by the scope, objectives, tolerance of errors, logistics, feasibility, efficiency and cost. In estimating prevalence in a large community-dwelling population, as in this study, the most widely used sampling method is the **Random Digit Dialing (RDD)**.

RDD is a method for selecting people for involvement in telephone statistical surveys by generating telephone numbers at random, which will be completed by a calling center. Its validity has been studied in the previous literature. Consequently, it is one of the methodologies for health data collection recommended by the Agency for Healthcare Research and Quality (AHRQ), a federal agency that specializes in clinical guideline development, epidemiology, and health services research.

Many national benchmark studies utilized this methodology, for example, the CDC's Behavioral Risk Factor Surveillance System (BRFSS). The BRFSS is the world's largest, on-going telephone health survey system, tracking health conditions and risk behaviors in the United States yearly since 1984, and is using the calling center of CDC to collect data monthly in all 50 states, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, and Guam. The BRFSS provided benchmark prevalence widely used by physicians, researchers, policy makers, and media for a variety of diseases, such as heart disease, stroke, asthma, diabetes, obesity, and visual impairment (**Prevalence of Heart Disease—United States, 2005** JAMA, March 28, 2007; 297: 1308 - 1309. **Prevalence of Stroke—United States, 2005** JAMA, July 18, 2007; 298: 279 - 281. **Asthma Prevalence and Control Characteristics by Race/Ethnicity—United States, 2002** JAMA, March 24/31, 2004; 291: 1435 - 1436. **Estimated County-Level Prevalence of Diabetes and Obesity—United States, 2007** JAMA, March 10, 2010; 303: 933 - 935. **Visual Impairment and Eye Care Among Older Adults—Five States, 2005** JAMA, February 14, 2007; 297: 582 - 583.). Other examples include National Immunization Survey by US Department of Health and Human Services, Community Tracking Survey conducted by Center for Studying Health System Change, and National Survey of American Families by the Urban Institute.

Using the same methodology as the above-mentioned studies, the subjects in this project consist of a random sample of directory-listed telephone numbers drawn from all area codes and telephone exchanges used in Lubbock and bordering counties served. Because of the highly specialized skills involved in the RDD method, we are contracting with University of North Texas Survey Research Center (UNT SRC), which has 18 years of experience in telephone surveys in Texas and has built a reputation as an organization that produces quality research for its clients. The sample is being generated from a software product licensed from Marketing Systems Group, MSG. MSG provides samples for a number of population studies including most of the BRFSS projects conducted in the United States. MSG will also provide the sample for the cell phone sampling frames. As cell phone frames are an emerging methodology, UNT SRC may also utilize the services of Survey Sampling International, a nationally recognized professional sampling firm. Preliminary calculations indicated that a sample of approximately 25,000 telephone numbers would be required to identify, obtain consent from and complete the project when approximately 2,000 residents of the study area agree to participate in the study. A couple of assumptions are made based on the survey company's suggestion and the investigators' prior experience with RDD:

- An estimated residential hit rate of 20% , i.e. 20% of the phone calls will be answered
- An estimated response rate of 40%, i.e. 40% of the people who answer the phone will agree to participate

Consequently, the initial sample size is calculated as:

2,000 completes ÷ .20 ÷ .40 ÷ .80 ÷ .80 = 25,000

Potential Risks and Human Subject Protection: There are very few risks associated with this project. The study includes no experimental drugs or other medical interventions. All participants are continuing their clinical care from their health care providers if there is any. Whenever an adverse event related to this project is identified, the PI, the directed health care provider of the patient, and IRB will be informed, and appropriate action will be taken accordingly. Throughout the study, IRB and HIPAA guidelines are being followed to ensure the privacy and integrity of the information we are collecting. Specifically, we are taking steps to maintain the confidentiality of any personally identifiable information. This includes keeping personal identifiers separate from the study information collected from subjects and the secure storage of all physical (hard copies) and electronic data. All patients are being assigned a unique study identification (ID) number, used to link identifying information to the study ID. This file is being maintained in password-protected folders, to which only the authorized study project personnel have access. Three years from the study's conclusion, all tracking files will be destroyed. All research results will be presented in aggregate form only (i.e. free of personal identifiers). Because this study involves RDD screening survey and in-person survey, we are addressing the consent issue accordingly.

Participation in surveys rarely puts respondents at more than the minimal risks of everyday of life. This fact is recognized explicitly in the Federal regulations which list surveys as examples of research that may be exempted by the IRB or handled with an expedited review process. As we are only conducting a brief survey (discussed in details below) via RDD to screen the eligible participants for our study, we believe the people who are being called are experiencing no more than minimal risks. We are seeking oral consent of the people to continue the screening. The key elements of consent can be provided to respondents in a concise way at the beginning of a survey in the brief introductory statements of a telephone interview. The main elements of consent are: an explanation of the purpose(s) of the study, the approximate amount of time it will take, a description of what the respondents will be asked to do, a description of any foreseeable risks or discomforts, a description of any benefits to the respondents or others, a statement describing the confidentiality of responses, and a statement of the voluntary nature of participation. In telephone surveys, research staff's contact information is also made available upon request for questions about the research and about respondent rights. In most surveys, respondents indicate their consent by agreeing to participate at the beginning of the interview, and/or by answering questions as they are asked. We are aware that significant numbers of people who are approached to participate in surveys will refuse to do so or refuse to answer individual questions. However, there is no evidence that people feel coerced to participate in survey research. Unlike much medical research, which requires "all or nothing" cooperation, surveys permit respondents to opt out easily of parts of the measurement process if they so desire. Federal regulations (CFR 46.117c) on human subjects protections recognize that written consent forms are not necessary or desirable in every research setting. The regulations provide that, while written consent is the norm in much research involving humans, IRBs may waive requirements for signed consent if they find that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. These conditions describe the vast majority of surveys. As noted above, few surveys pose risks greater than those that the respondent would confront in everyday life. Telephone surveys using random-digit dialing -- a very common approach in survey research -- cannot incorporate signed consent in the protocol prior to the initial contact since respondents' names and addresses are unknown to the researcher. Requiring signed consent prior to the beginning of an interview would, for all practical purposes, make many telephone surveys impossible. Thus, a waiver of documentation of consent is typically the most desirable approach for survey protocols – especially those utilizing telephone and electronic modes. Therefore, we requested TTUHSC IRB to grant a waiver of written consent for the RDD portion of the proposed project.

A written informed consent (Appendix 1) is being provided to the eligible participants who orally agreed to participate in the blood drawing and in-person survey when they come to the study site at TTUHSC. Only those who sign the informed consent are taking the blood drawing, urinary analysis, and in-person survey.

Procedure of RDD and recruiting:

The calling center that we are using to conduct RDD is the University of North Texas Survey Research Center (UNT SRC). The UNT SRC, housed in the College of Public Affairs and Community Service, conducts applied survey projects in many different areas of client need. It employs a professional staff team who has both formal training and practical experience in all aspects of survey research. All the interviewers are trained and monitored closely. They also complete NIH human subjects training and obtain a completion certificate.   This team is following the procedure below to conduct the RDD.

Conduct Household Screening

This task consists of administering a household screening instrument (Appendix 2) designed to determine whether households whose telephone numbers are included in the sample include one or more eligible adults (i.e. >21years old). UNT SRC is drawing a RDD sample of landlines and cell phones in enough quantity to yield 25,000 valid phone numbers, which is defined as a phone number that rings and is not disconnected, a business phone number, or a fax machine. UNT SRC is drawing 50% of the sample from landlines and 50% form cell phone sampling frames. To maximize the potential for contact with potential respondents and ensure equal sample coverage within and across sample replications, up to three to five contact attempts are made for each number included in each sample replication. In addition to the pre-designated calling sequence, this process is controlled by means of CATI (Computer Assisted Telephone Interview) sample management functions, whereby up to three standardized messages will be left on voice mail boxes and answering machines requesting a return call between the hours of 1:00 PM to 9:00 PM Monday through Friday, 12:00 PM to 3:30 PM Saturday and 5:30 PM to 9:00 PM Sunday.

For Spanish speaking subjects, the survey instrument is being translated into Spanish and programmed into the WinCATI system. When a Spanish-speaking interviewer encounters a Spanish-speaking respondent, the interviewer is selecting the code for the Spanish version of the instrument and proceeding with the interview. If the interviewer does not speak Spanish, he or she is reading a short, prepared statement in Spanish that informs the respondent to expect a callback in approximately 30 minutes. The interviewer then selects the code for a Spanish interview and the WinCATI software automatically sends that respondent to a Spanish-speaking interviewer within 30 minutes.

UNT SRC is inviting the eligible respondents to participate in the in-person interview at TTUHSC, and is making appointments for the in-person interview via a scheduling calendar provided by TTUHSC. Then UNT SRC is sending a map to TTUHSC and instructions to the eligible subjects. The contact information of the participating candidates is then being sent to the project coordinator at TTUHSC.

In-person interview and specimen collection

The project coordinator is making a reminder phone call one or two days prior to a subject's scheduled appointment. Informed consent process and HIPAA authorization are taking place for every subject at the appointment in TTUHSC. All questions regarding the study are being answered at this time. Subjects can chose whether or not he/she will participate in study. After the consent process, an in-person questionnaire is being conducted to obtain the information regarding the participant's health.

During the in-person questionnaire, TTUHSC research staff is collecting personal demographic information for each subject. The information includes name, date of birth, age, sex, race, home address, phone numbers (home, mobile), personal medical history/presence of CKD risk factors, family medical history, medication profile, height, weight, and blood pressure. Subjects are also being asked if they wish to have lab results sent to their respective primary care physician. Once the in-person interview is completed at TTUHSC, each subject is being directed to Covenant Medical Center's laboratory to provide the necessary blood and urine samples for the basic metabolic panel, microalbumin, and urine creatinine testing. Each subject is being given a lab requisition form with their unique study identification number as an identifier; this is ensuring that the subject's privacy is maintained by TTUHSC research staff. A map to Covenant Medical Center's laboratory is being provided, where the specified lab samples are being collected and analyzed for each participating subject. All cost associated with the lab draw and urinary analysis are being covered by the project budget. A $50 gift-card is being given to the participants who complete the survey and provide the blood and the urine samples. Once lab results are available, Covenant Medical Center is sending out results to TTUHSC research staff to be reviewed. Each participating subject is being given a copy of their lab results and suggestions regarding their follow up care by the research clinicians. A copy of the lab results is being mailed to the subject's respective primary care physician as well, if the subject requests that a copy be sent to them. Contact information is being collected for the subject's primary care physician if needed. If research investigators recommend that a follow up with a primary care physician is needed based on the subject's lab results, and the participating subject does not have a current primary care physician, the subjects are being recommended to make an appointment and follow up with one of primary care providers.

<u>Outcome Measures:</u>

The information being collected by the questionnaire that includes: demographics (subject's name, date of birth, age, sex, race, address, phone numbers), personal health status (e.g. height, weight, BP), Medical History, Family Medical History, and potential CKD risk factors (e.g. HTN, diabetes, retinopathy, CVD, obesity, smoking status) and medication profile.

Lab specimens are being collected as well via blood draw (serum creatinine) and urine collection (microalbumin and urine creatinine).

The primary indicators of CKD status are eGFR and urine microalbumin. Creatinine, age, sex, and race data are being entered into an algorithm (CKD-EPI formula) to calculate the eGFR.

eGFR CKD-EPI=141 X (minimum of standardized serum creatinine [mg/dL]/k or 1)α X (maximum of standardized serum creatinine [mg/dL]/k or 1)-1.209 X 0.993age X (1.018 if female) X (1.159 if black)

- k is 0.7 if female and 0.9 if male
- α is -0.329 if female and -0.411 if male

<u>Data management and quality control.</u> Data collected is being entered by study coordinators into Sharepoint, a large-capacity, controlled, internet-based platform that allows users to log in and share data using common applications such as Microsoft Excel. Sharepoint automatically

provides data encryption and frequent data back-up to the TTUHSC servers. The Sharepoint is being administered by research staff in Lubbock, where all information is being processed for statistical analysis.

Data Analysis:

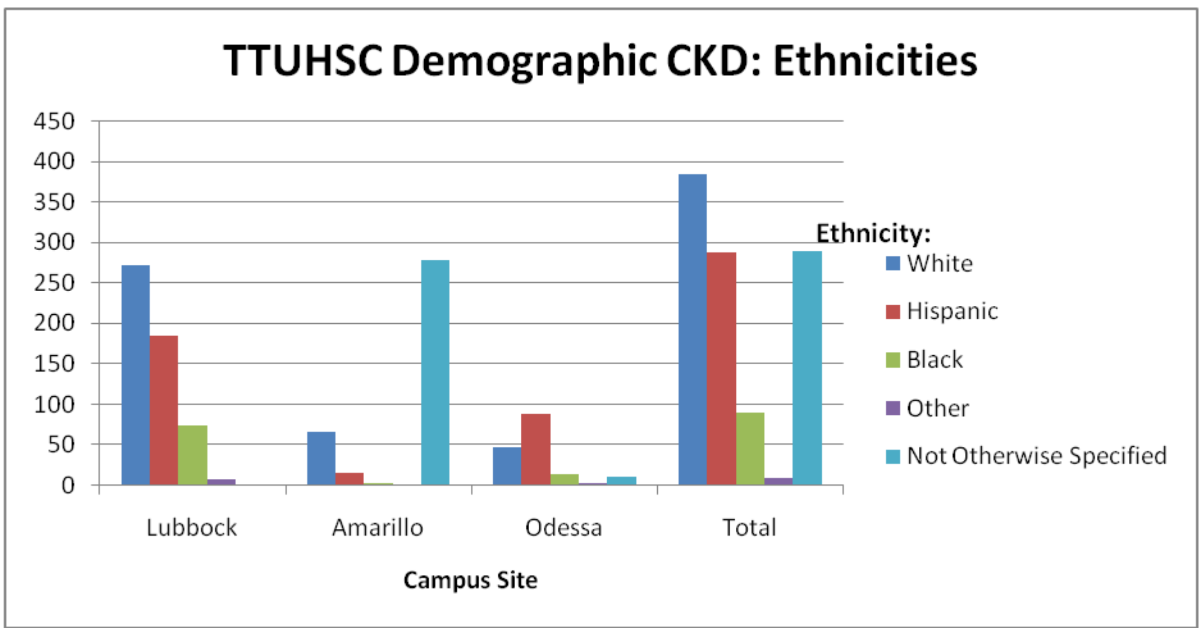
Anticipated Results:

Expectations are that the study will yield data that reflects:

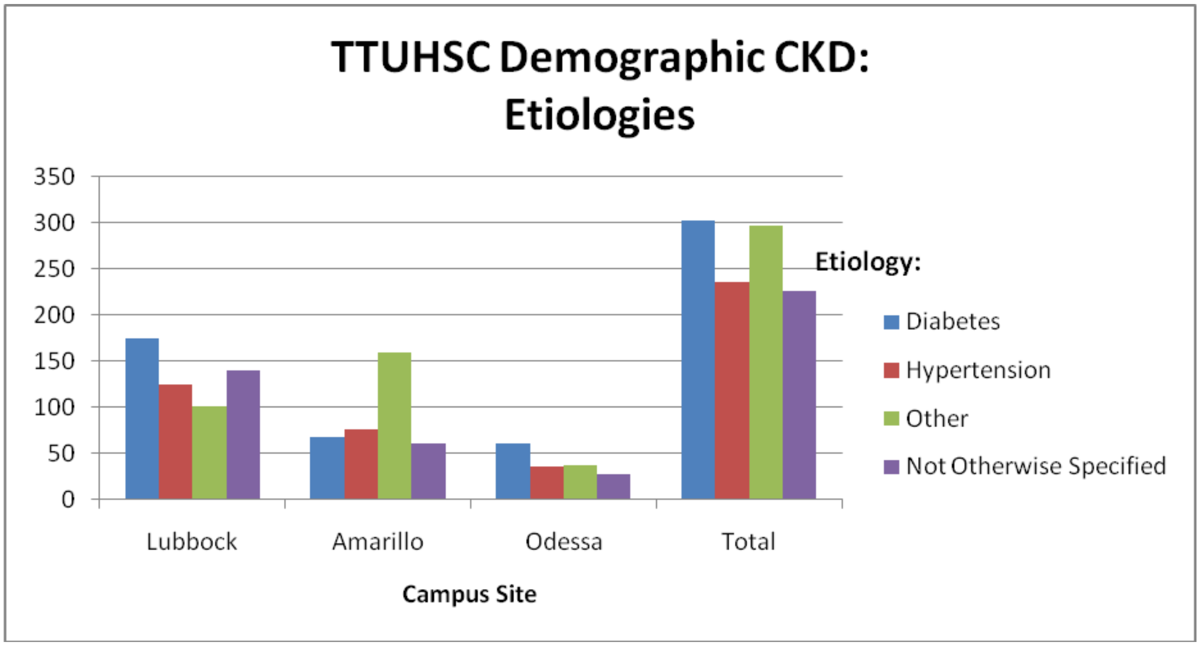
- The prevalence of CKD in the general population found within Lubbock and bordering counties
- Descriptive data
- Demographic composition and clinic data summary

C. Results/Conclusions

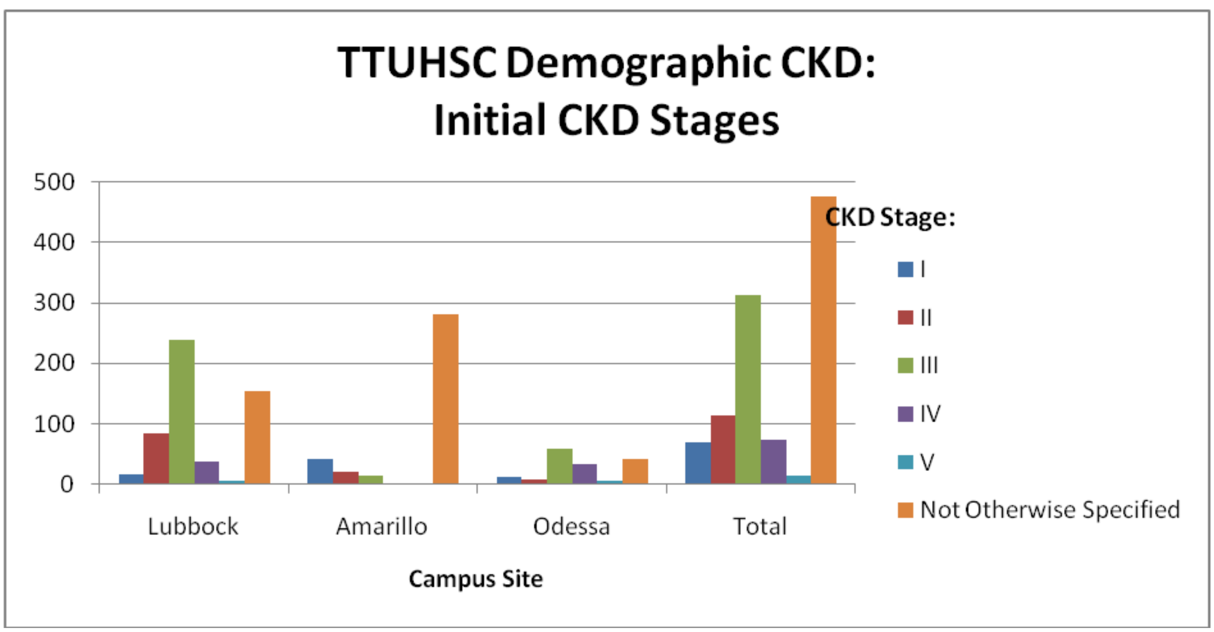
- To date, a total of 135 subjects have been screened and the data on **63** study subjects have been completed.
- Whites make up the great majority of the subjects.
- 30% of the subjects are between the ages of 60 and 69. 21% are between the ages of 50 and 59, and 17% are between the ages of 70 and 79.
- Of the common risk factors for CKD, hypertension has shown to be most common.
- We calculated eGFR using the CKD-EPI equation. Of the 63 total subjects, 22 were classified as CKD stage II and 10 were classified as stage III. 31 were classified as stage I.
- 9 out of the 63 subjects tested (+) for microalbuminuria.



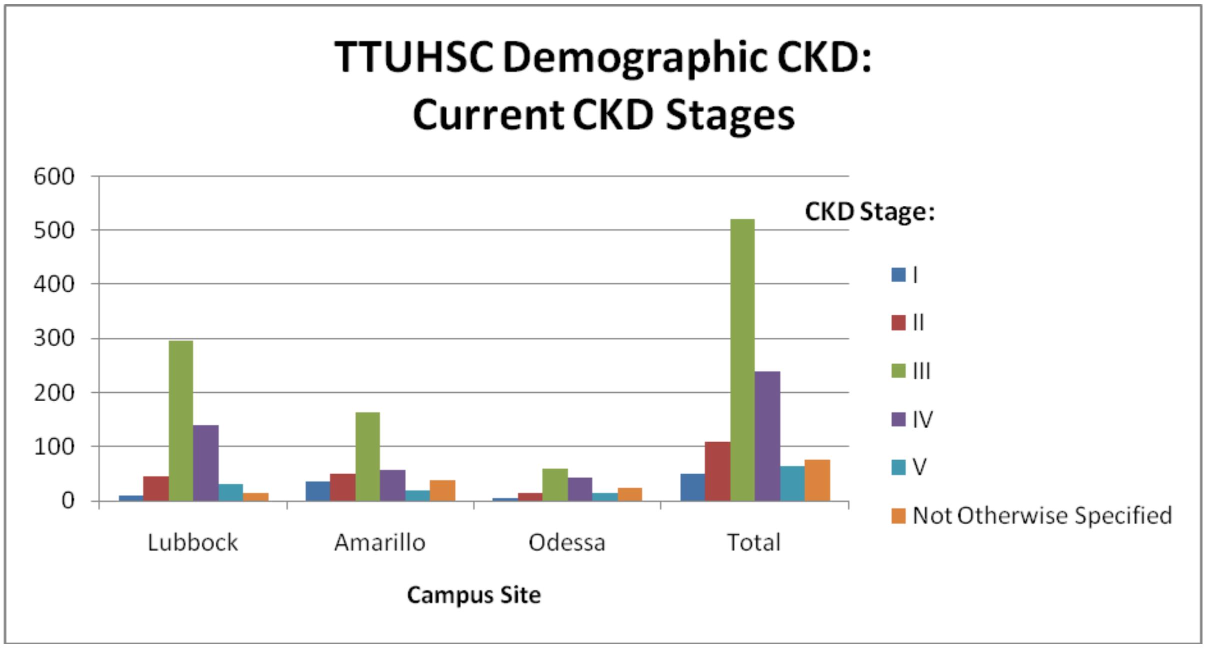
The chart above provides an ethnicity analysis for the three campuses to date. We have collected data on **1,059** subjects, where about 63% of the population is labled as either *White* or *Hispanic*. Unfortunately, race/ethnicity was not otherwise specified in 21% of the records.



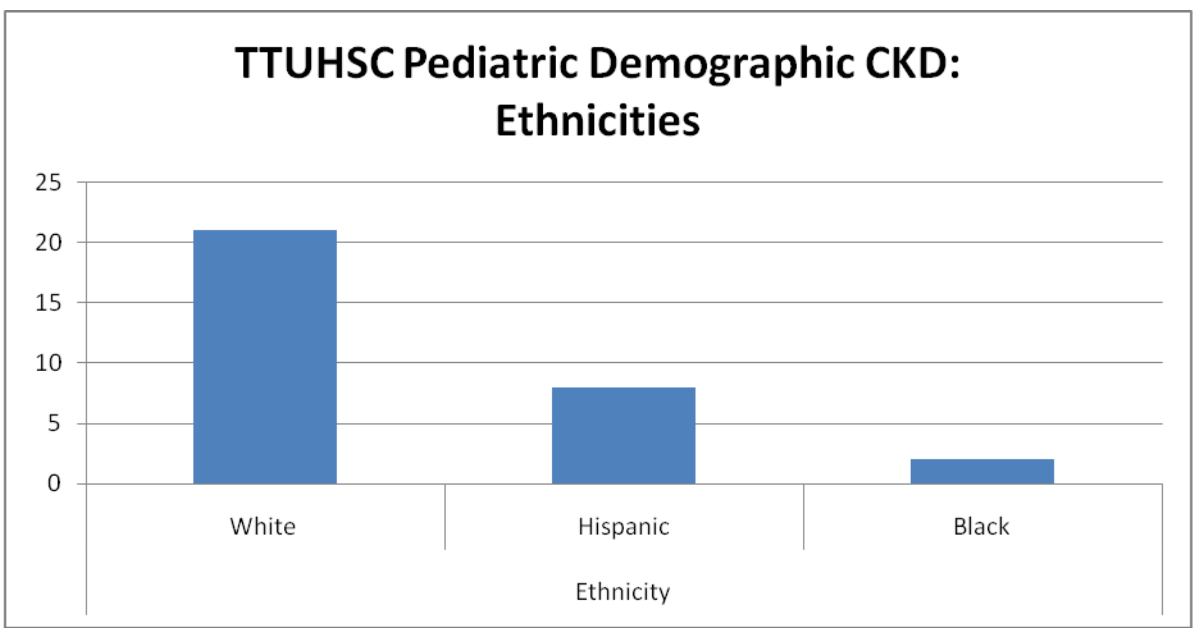
The two most common known etiologies within our clinics are *diabetes and hypertension.* We have grouped all other known etiologies under the label *Other (ex: age, drug toxicity, lupus, cancer, etc)*.



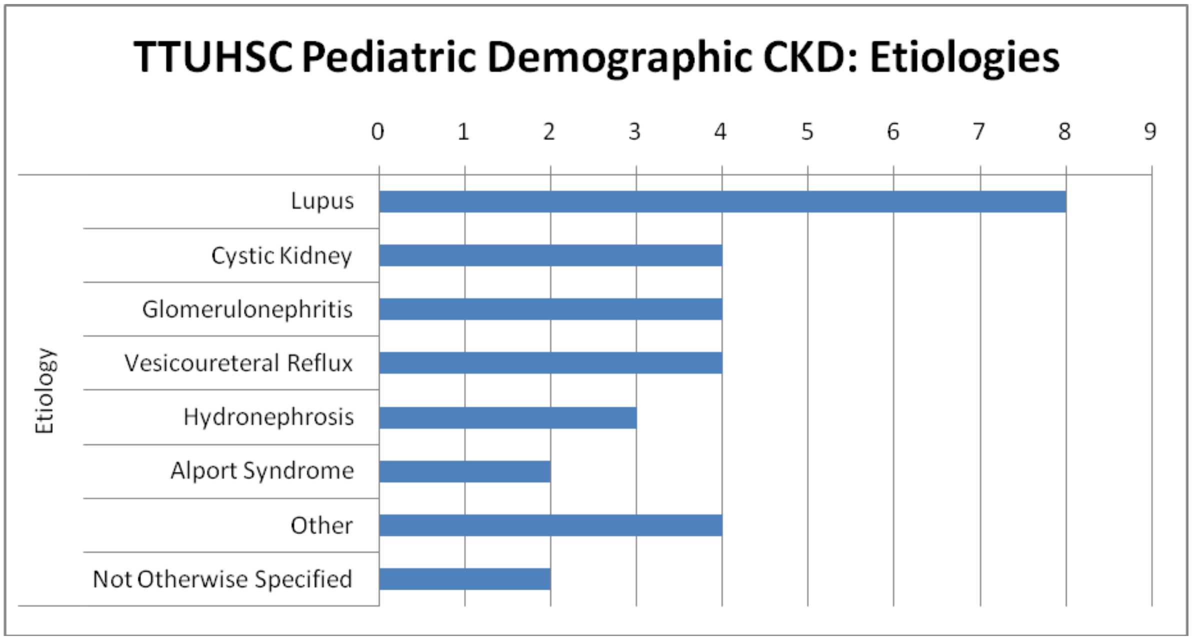
For the current data set, the majority of patients that were seen and classified within the CKD clinics were initially diagnosed as a *Stage III*. Significant numbers of patients were seen as an initial *Stage I, II or IV* also. Unfortunately, a significant number of patients did not have an initial CKD stage documented.



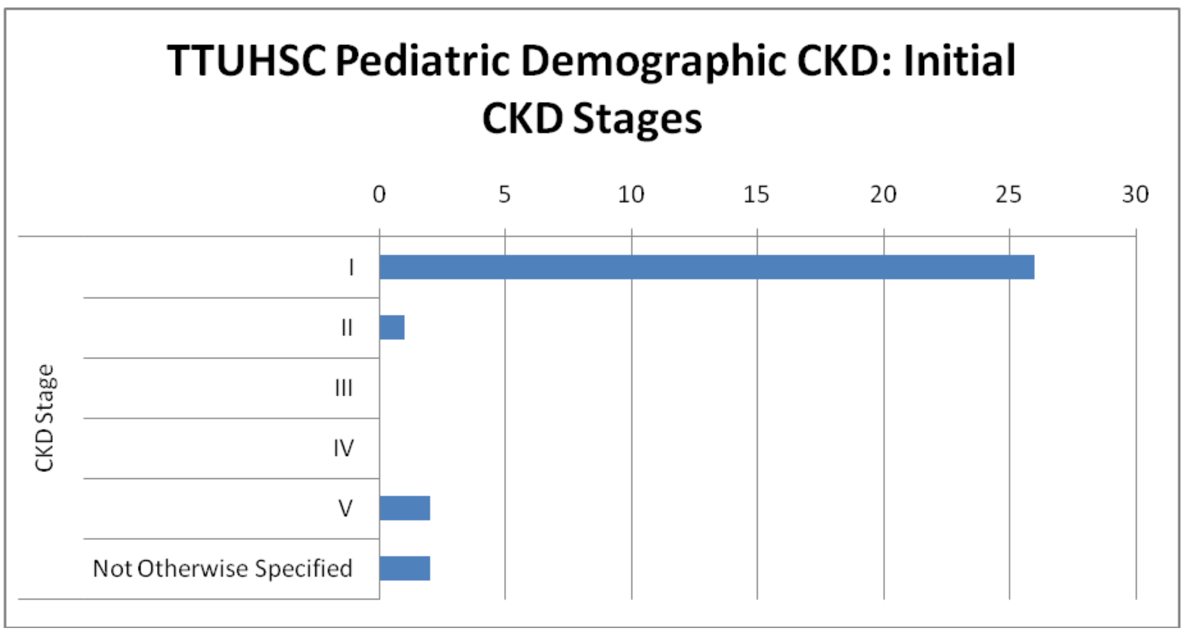
With respect to current CKD stage, the great majority of the subjects have been classified as a *Stage III*.



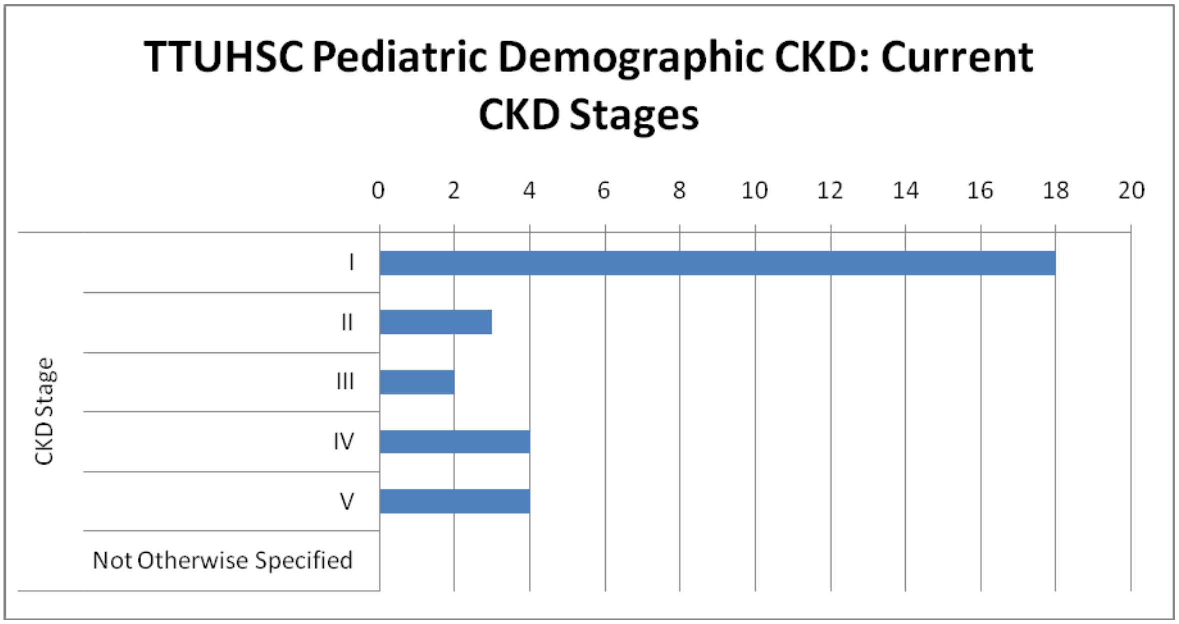
A pediatric subpopulation within the Demographic CKD Study is being evaluated at the Amarillo campus site. We have collected data on a total of **31** subjects to date. This graph shows the ethnicity breakdown. 68% of the subjects are white and 26% are Hispanic.



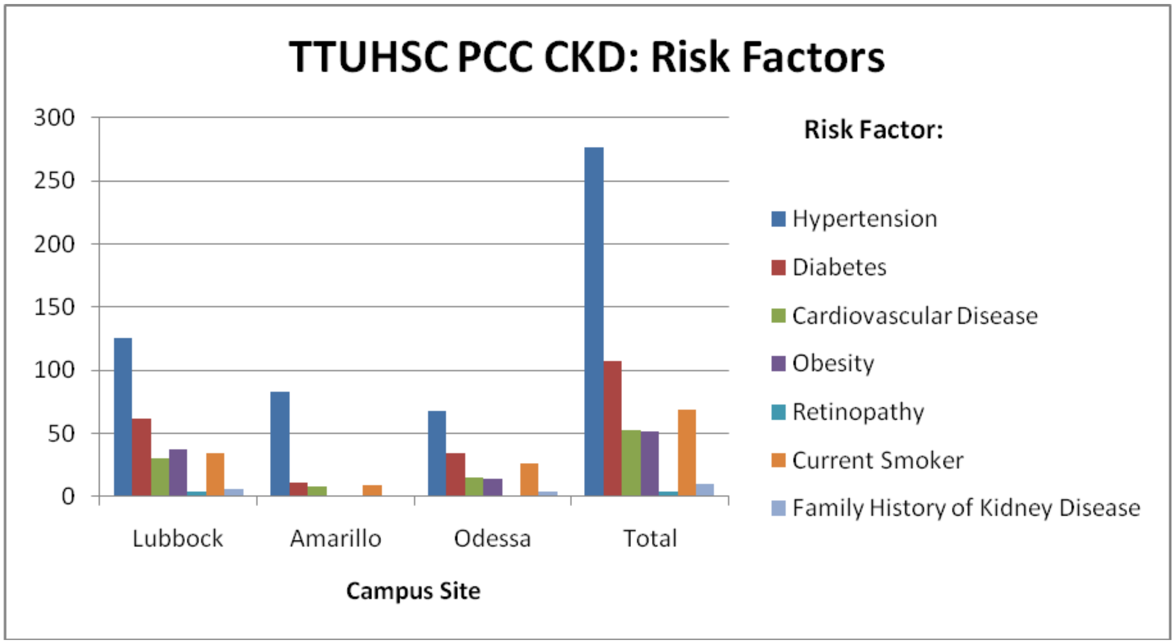
This graph reveals the etiologies in the pediatric subpopulation of the Demographic CKD Study. Of the various etiologies for the 31 total subjects, Lupus accounted for 8. Cystic kidney, glomerulonephritis and vesicoureteral reflux accounted for 4 each.



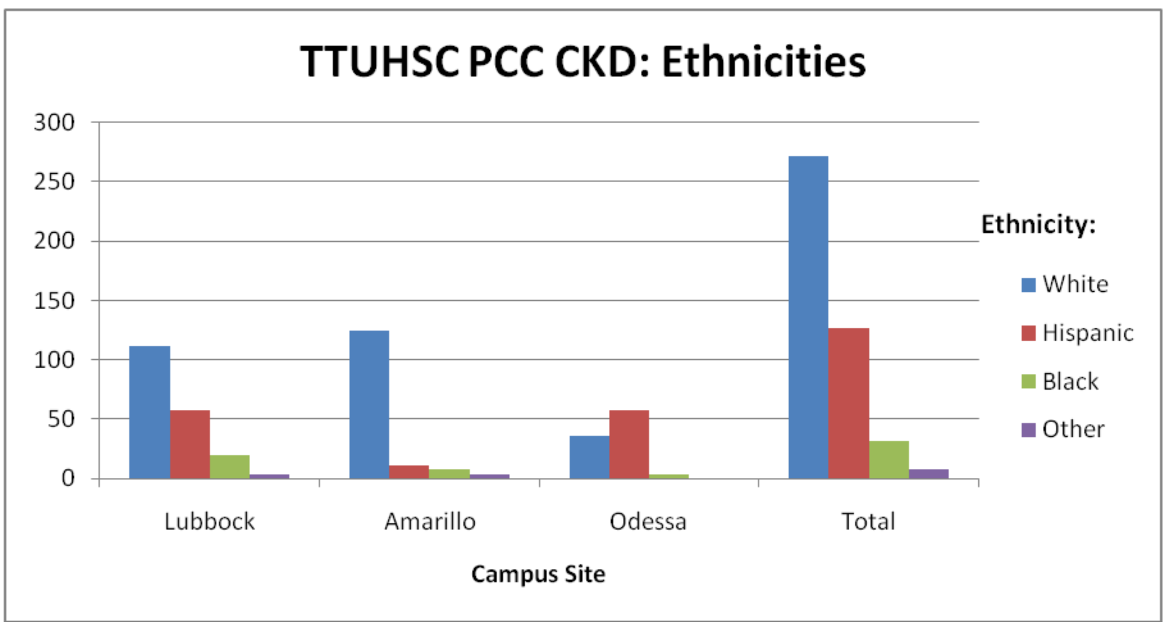
For the current data set, the vast majority of patients that were seen and classified within the pediatric Demographic CKD Study were initially diagnosed as a *Stage I*.



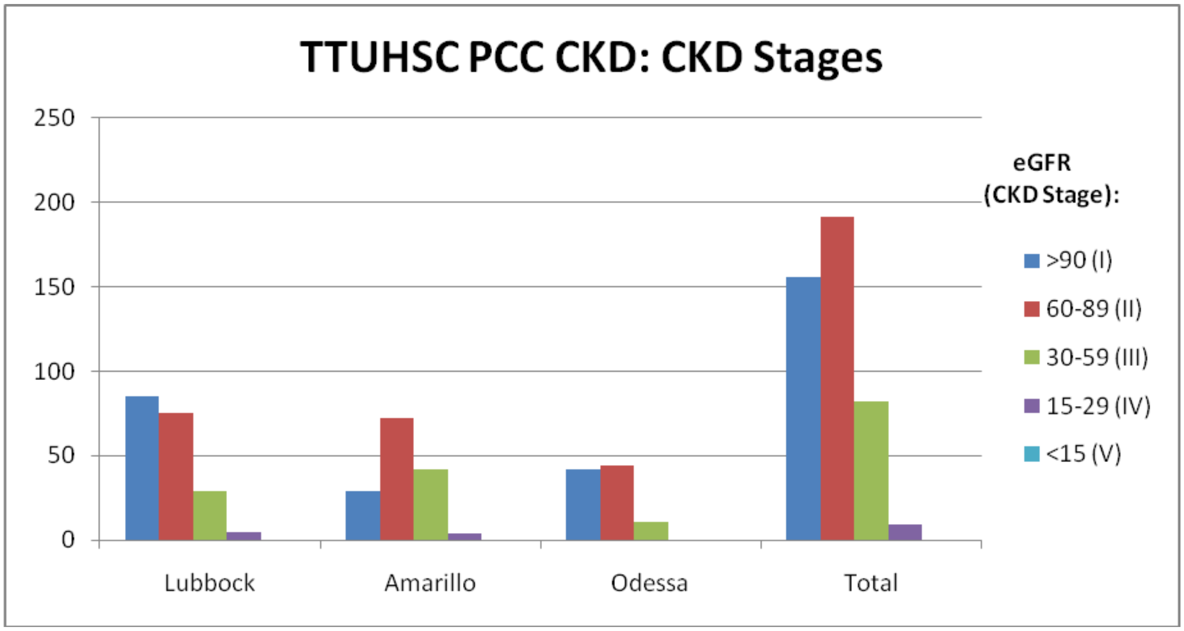
With respect to current CKD stage in the pediatric subpopulation of the Demographic CKD Study, the great majority of the subjects have been classified as a *Stage I*. Significantly smaller numbers of subjects comprise *Stages II, III, IV and V*.



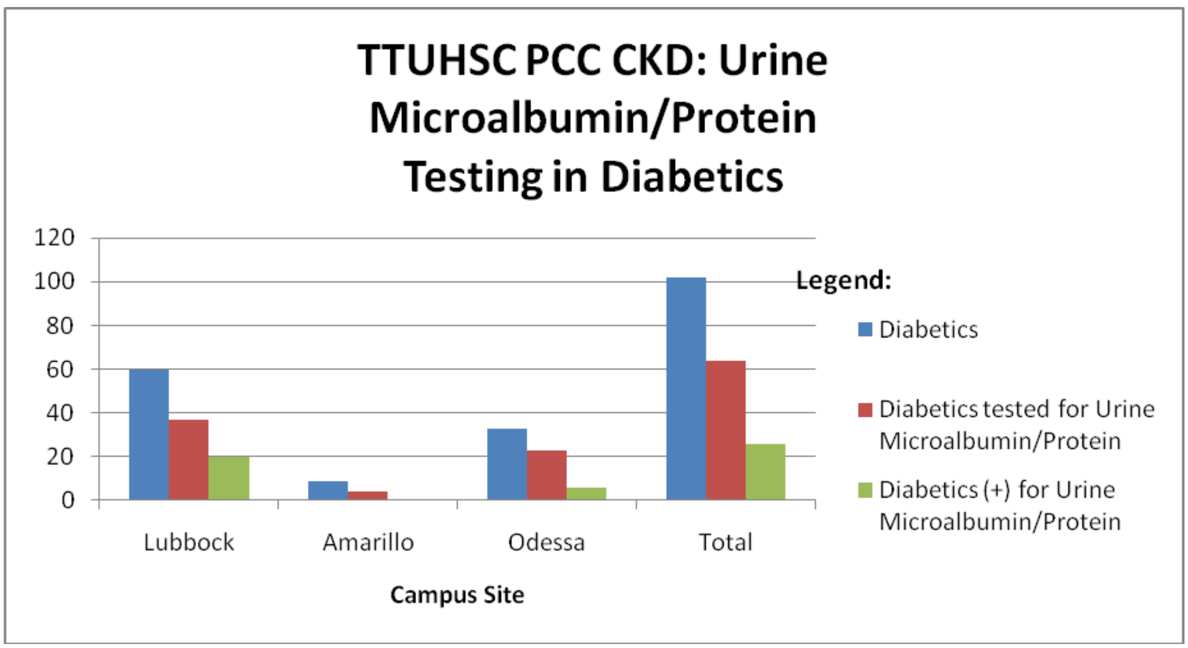
Within our primary care clinic study, we have been able to collect data on **440** subjects between the Lubbock, Amarillo and Odessa campuses. Of the common risk factors for CKD, *Hypertension* has shown to be most common within our current subject population. *Diabetes* is the second most common.



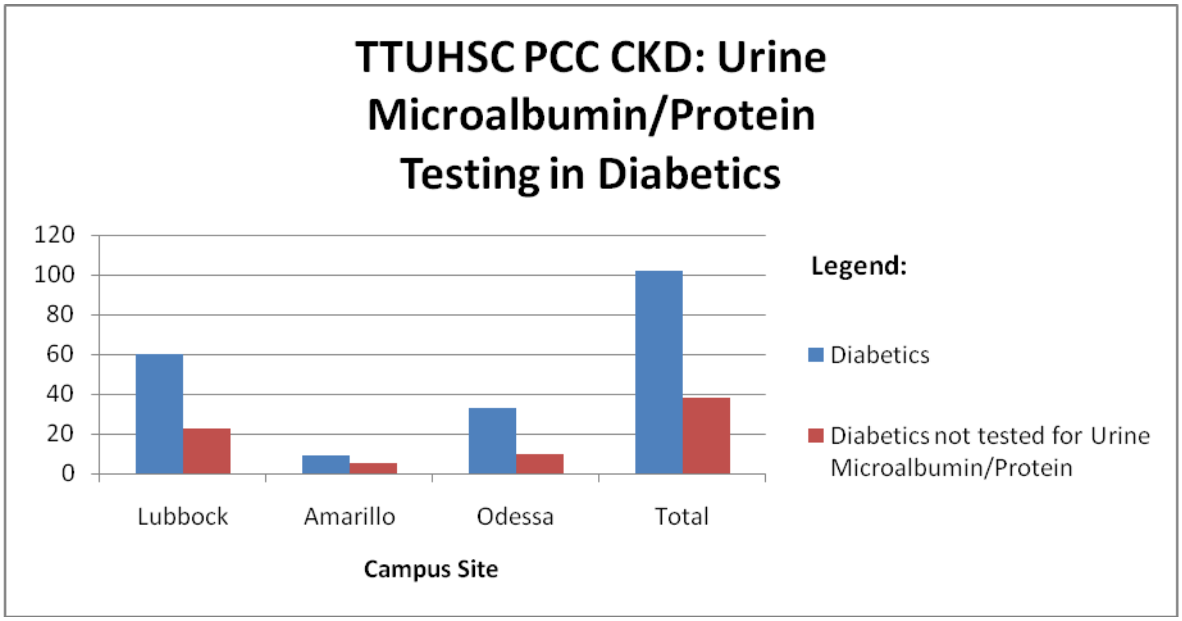
Of the 440 subjects, 272 are of white ethnicity and 127 are of Hispanic ethnicity.



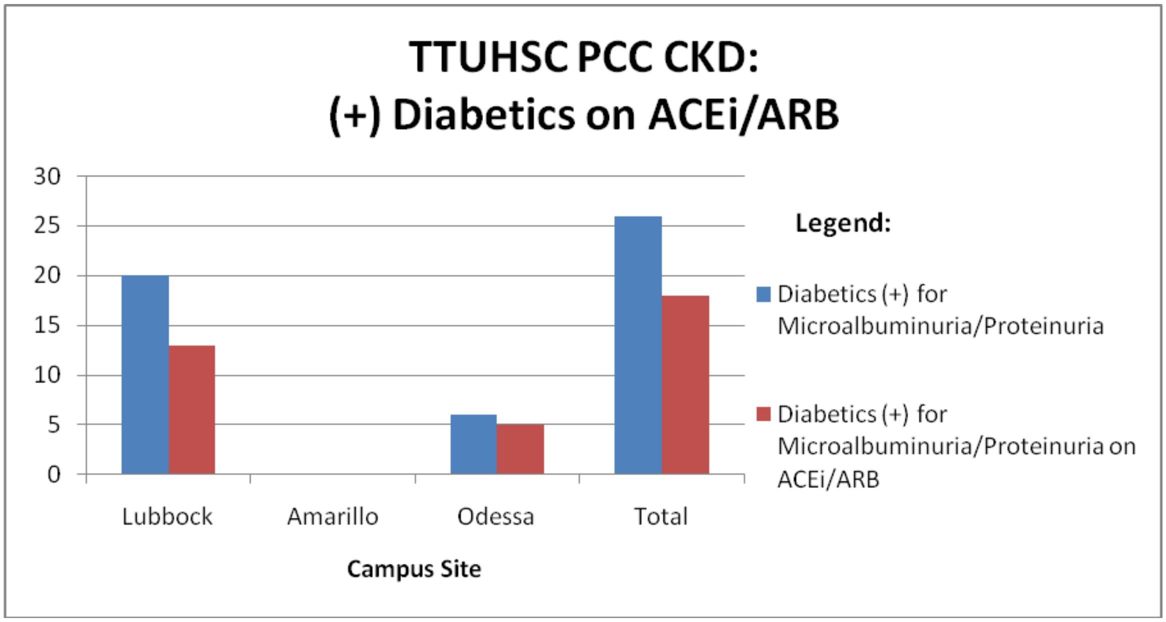
We calculated eGFR using the CKD-EPI equation on all of our primary care clinic subjects to date. Of the **440** total, *only* **156** were classified as CKD Stage I, whereas **191** were classified as Stage II & **82** were classified as Stage III. This classification uses calculated eGFR only.



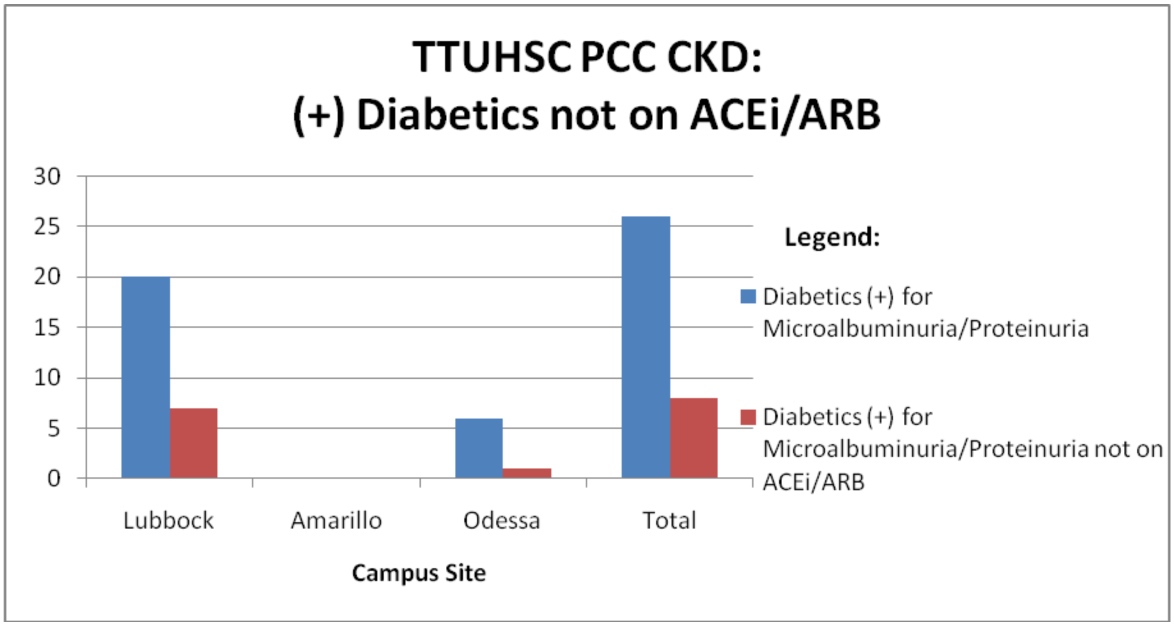
Of the 102 total diabetic subjects in our CKD Primary Care Clinics Study, 64 had undergone testing for microalbuminuria/proteinuria prior to the interview, and 26 were positive.



Of the **102** total diabetic subjects in our CKD PCC Study, **38** had ***not*** undergone testing for microalbuminuria/proteinuria within the 12 months prior to the interview.



Of the 26 total subjects who were positive for microalbuminuria or proteinuria at the time of the interview, 18 were on either angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) therapy.



Of the 26 total subjects who were positive for microalbuminuria or proteinuria at the time of the interview, 8 were ***not*** on either angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) therapy.

PUBLIC POLCY HYPOTHESIS

Chronic kidney disease (CKD) is becoming increasingly prevalent throughout the United States and even worldwide. While Texas ranks second in the prevalence and healthcare costs of end stage renal disease in the country. However there is no data so far on the true incidence and prevalence of chronic kidney disease. Our report from this study based on 5% Medicare cohort and indicates that the prevalence is high and is bound to increase based on the analysis and from the expected increase in the risk factors. However there is still a need for more organized and extensive studies to document the true prevalence of CKD so preventive measures be optimally implemented to decrease the burden of ESRD. This is particularly true since the disease and economic burden of ESRD has been escalating and impinging on the State healthcare budgets as well. The prevalence analysis of our study demonstrates that there may be over two fold increase in the occurrence of CKD in Texas in the next ten years increasing from 544,119 (2010) to 1,125,583 (2020). Similarly that the costs associated with the care of patients with CKD will increase from the current 20,750 million dollars (2010) to 51,609 million dollars (2020). Since these numbers are based on disease detection in Texas hospitals and 5% Medicare data rather than based on estimation of renal function in the population, the true prevalence and hence the Medical care costs are very likely going to be 2-3 times higher than stated here. These facts underscore the VERY URGENT need to implement large scale screening of the population, early detection and implementation of effective strategies for prevention of treatment of CKD.

The demographic analysis in the CKD clinic as reflected by the available published data and our study clearly demonstrate the higher percentage of CKD prevalence in ethnic minorities. Since a large segment of minorities are underinsured or uninsured, one of the direct public healthcare implications of these observations is that the screening and preventive tools be effectively implemented in those areas of the state with heavy minority population. Another important observation is that majority of the patients referred to nephrologists are in Stage III or more advanced CKD. While this trend has been known for years, our study clearly underscores this problem occurring even in tertiary care academic institutions implying that it is much more widespread in medical community. Early referral of CKD patients should be mandated through new practice guidelines so that the care of these patients is better streamlined and thereby costs of care are decreased.

The observations in the primary care clinics in this study demonstrate that up to 70% patients visiting providers for various reasons had risk factors for CKD and a large number of them when screened had CKD. CKD screening is currently not the universal practice in such clinics. It is important from public health perspective that legislation be introduced to incorporate into routine practice such screening in all the primary health clinics by measuring eGFR and screening for microalbuminuria. As reflected in the State DSHS data as well as in this study, the screening for microalbuminuria is suboptimal. Similarly upto 25% patients who needed to be on ACE inhibitors were not placed on such agents. These findings provide opportunities to effectively contain the development and progression of CKD. Such practice guidelines need to be rigorously implanted and mechanisms to monitor these practices be introduced.

Another important finding in our study was that only about less than a third of the patients diagnosed with CKD in primary and specialty clinics were referred to nephrology clinics. The patients not referred included a large number with advanced CKD. While the reasons for such non referral are many, an important factor was the fewer low physician: patient ratio implying major shortage of nephrologists. In Texas about 126 counties have no nephrologists. While this is a nationwide problem, the problem is more acute in Texas where population in general and CKD patients in particular are increasing year after year. The government should consider seriously facilitating training of more nephrologists and opening more training programs.

All the above described issues cannot be addressed without increasing the awareness of CKD not only in the general community, patient population and even healthcare providers including physicians. While a number such activities have been initiated, there is an URGENT NEED to boost such activities through federal and state funded programs. In summary this study clearly exposed several problems related to CKD prevalence costs and loopholes in the management and prevention and clearly delineated the need for the State to establish and fund statewide programs to curtail the epidemic of CKD. Engaging in such mechanisms proactively is crucial to diminish the morbidity, mortality and equally important, financial burden of the disease.

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