

State Plan for Chronic Kidney Disease Treatment

As Required by

Texas Health and Safety Code, Section

83.006

Texas Chronic Kidney Disease Task Force

January 2023

This report was prepared by members of the Chronic Kidney Disease Task Force. The opinions and recommendations expressed in this report are the members' own and do not reflect the views of the Texas Health and Human Services Commission Executive Council or the Texas Health and Human Services Commission.

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Introduction

House Bill 1225 (also known as the Glenda Dawson Act), 86th Legislature, Regular Session, 2019, created Health and Safety Code, Chapter 83, reestablishing the Chronic Kidney Disease Task Force. The Task Force is composed of 24 members, 20 appointed by the Governor, two members of the senate appointed by the lieutenant governor, and two members of the house of representatives appointed by the speaker of the house of representatives.

The Task Force reorganized its committee into workgroups in July 2020 to ensure efficiency regarding the review and analysis of chronic kidney disease (CKD) in the state of Texas and appointed five workgroups: Education & Prevention, Legislative Issues, Treatment, Early Detection and Comorbidities, and Living Donation Transplantation.

The workgroups assembled leading Texas nephrologists, nurses, dietitians, educators, and other CKD experts to review the minimum practice standards data from state agency programs, health systems, and special studies that can be used to assess the effectiveness of CKD management in Texas.

Texas Health and Safety Code, Section 83.003, requires the Task Force to provide to the Governor findings and recommendations on developing and implementing a state plan for cost-effective plan for prevention, early screening, diagnosis, and management of chronic kidney disease for the state's population through national, state, and local partners; and educate health care professionals on the use of clinical practice guidelines for screening, detecting, diagnosing, treating, and managing chronic kidney disease, its comorbidities, and its complications. Per Texas Health and Safety Code, Section 83.006, the Task Force shall submit the state plan and its findings and recommendations to the governor, lieutenant governor, and speaker of the house of representatives, the presiding officers of the appropriate standing committees of the legislature with jurisdiction over health issues and does so no later than January 1 of each odd-numbered year.

The CKD Task Force will provide recommendations based on reviews and discussions of CKD prevention and self-management, cost-savings studies, and evidence-based research studies. Task Force members' professional experiences span decades and includes expertise in the treatment of CKD, education and

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training, nutrition education, and public health policy. Task Force meetings serve as opportunities to review and discuss topics, which assist in the identification of these priorities as outlined in the CKD Task Force Priorities and Recommendations. While being conscious of the federal executive order and ongoing pandemic, the Task Force priorities and recommendations are centered on the following themes:

- Education to the public regarding kidney disease and with an emphasis on preventing the onset of kidney disease.
- Early screening and diagnosis of kidney disease aimed at mitigating progression of disease including the management of co-morbidities such as diabetes, hypertension, and obesity as well as other risk factors.
- Optimizing treatments of Stages 1-4 of kidney disease including peritoneal and hemodialysis.
- Increasing donation through education of the public on both Living Donor and Deceased Donation.
- Legislation in support of the CKD community including those patients at risk of developing renal disease in the future or those living with renal disease now.

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Chronic Kidney Disease – A Brief Introduction

Chronic Kidney Disease is a significant health problem in Texas as noted in detail in this report. There are over 70,000 Texans on dialysis and over 8,000 waiting for a kidney transplant as well as a large, undefined number of patients with lesser stages of CKD. Governor Greg Abbott has appointed individuals with expertise and experience to the Texas CKD Task Force to make recommendations to benefit the health of Texans. It is hoped that this report will also be noted by non-expert readers. Hence this brief introduction to CKD.

Fifty years ago, CKD was a fatal diagnosis. Kidney dialysis or transplant was only available to a few hundred people a year in the US. Large public hospitals typically had a ward devoted to patients dying of kidney failure. This changed with the End-Stage Renal Disease Act of 1974 which made dialysis and transplant Medicare entitlements, saving thousands of lives. However, no funding was provided for early-stage kidney disease.

At birth, each kidney has about two million functional units called nephrons which are a lifetime supply; no new nephrons develop. About thirty percent of the blood circulation passes through the kidneys. Kidneys have a large reserve of function and must lose 80 to 90 percent of nephrons before significant symptoms occur. CKD is a silent disease until late in its course.

A nephron has three portions. The glomerulus is a small glob of specialized blood vessels and a membrane which filter fluid and substances from the blood. This filtrate passes into a renal tubular system which concentrates the fluid and retains desirable salts and other substances. The microscopic tubules converge to form a collecting system_that carries urine to the bladder.

Various causes of CKD can affect the nephron; some common examples follow. High blood pressure damages the blood vessels. Diabetes damages the glomerular membrane. Inflammation, drugs, and other factors can damage the tubules. The collecting system can be damaged by infection, kidney stones, or bladder dysfunction.

Kidney function is commonly measured by a blood test for serum creatinine. Creatinine is a substance produced by muscles which is excreted by the kidneys. Another measure is the creatinine clearance, which compares the amount of

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creatinine in a 24-hour urine collection with the serum creatinine level, giving a more accurate indication of function. Creatinine clearance does not depend on racial or ethnic factors.

CKD is classified into stages depending on the level of remaining kidney function. Stage I and II depend on laboratory diagnosis and are usually asymptomatic. Stage III CKD presents with symptoms requiring medical management. Stage IV disease implies impending need for dialysis or transplant, i.e., end-stage disease.

The recommendations of the Task Force are related to these stages of CKD. Individuals with normal kidney function who have risk factors such as high blood pressure, diabetes, or family history of CKD should be screened yearly for any indication of CKD. The goals in Stage I and II CKD are early diagnosis and treatment to reverse or prevent progression of disease. Patients and primary care providers should not regard early abnormalities of kidney function as something to just follow-up on but should refer patients for optimal management. The goal in Stage III disease is to preserve as much function as possible for as long as possible. New drugs are available which promise benefit in this regard. With Stage IV disease, preparation for dialysis and/or transplantation is required. The optimal goal would be transplant before dialysis or after as short a time on dialysis as possible.

In summary, recognition of risk factors, early diagnosis and intervention, and optimal care of more advanced CKD can save and improve lives, reduce health care costs, and benefit the entire state of Texas.

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Executive Summary

<u>Texas Health and Safety Code, Chapter 83</u>, established the Chronic Kidney Disease Task Force (Task Force) whose purpose is to apprise the Governor on matters as described below:

- A. Coordinate implementation of the state's cost-effective plan for prevention, early screening, diagnosis, and management of chronic kidney disease for the state's population through national, state, and local partners; and
- B. Educate health care professionals on the use of clinical practice guidelines for screening, detecting, diagnosing, treating, and managing chronic kidney disease, its comorbidities, and its complications based on the Kidney Disease Outcomes Quality Initiative Clinical Practice Guidelines for Chronic Kidney Disease.

Two events coincided with the launch of the Texas Chronic Kidney Disease Task Force in 2021 and remain pertinent to this 2023 report.

The first event being that the initial components of the Executive Order the president signed in July 2019 were being implemented for "Advancing American Kidney Health." This order outlined policy priorities centered on advancing three main goals:

- (1) preventing kidney failure whenever possible through better diagnosis, treatment, and incentives for preventive care;
- (2) increasing patient choice through affordable alternative treatments for end stage renal disease (ESRD) by encouraging higher value care, educating patients on treatment alternatives, and encouraging the development of artificial kidneys; and
- (3) increasing access to kidney transplantation by modernizing the organ recovery and transplantation systems and updating outmoded and counterproductive regulations.

The second event being that the Coronavirus (COVID-19) pandemic was sweeping the globe. In the short run, COVID-19 has disrupted access to preventative health screenings, transplantation, living donation, and resulted in a rise of Acute

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Kidney Injury. The long-term impact on our populations' health, including those of us practicing in the chronic kidney disease community is unknown. As the pandemic has progressed data is revealing the need for a long-term plan that addresses the fissures in our health care system. As access has come back online for the population a new normal is being carved out by medical professionals and their non-profit counterparts. The long-term impact on our populations' health, including those of us practicing in the chronic kidney disease community is unclear.

The CKD Task Force offers the following priority recommendations.

- Establish the comprehensive Centralized Resource Center
- Emphasize early detection, prevention and education efforts to empower patients to take control of their health
- Promote the early adoption of multiple new treatment options, and/or medications
- The Texas Kidney Health Care program should be supported and expanded
- Improving processes for referral and evaluation for transplant patients
- Increasing transplant activity and living and deceased kidney donation

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Background

The data tells a poignant story. An estimated 37 million adults in the United States have chronic kidney disease (CKD), many of whom are unaware that they have kidney illness. In fact, data shows that more than 90% of these individuals are unaware that they have any type of kidney dysfunction. Moreover, research shows that 48% of individuals with severely reduced kidney function are not aware they have significant kidney disease and are progressing to end stage renal disease (ESRD).1

Particularly distressing is the fact that diabetes and hypertension are significant risk factors for the development of renal insufficiency, and these are diseases that can in large part be prevented or medically managed to mitigate the onset of kidney disease. Yet, on average 29% of patients who are 65 years of age or older with Type II Diabetes Mellitus and 16% of patients of similar age with hypertension will develop CKD. Data shows the prevalence of hypertension in adults in the United States has increased significantly between 1999 and 2014. In 2014, 41% of adults in the US reported having hypertension or a having a measured blood pressure of greater than or equal to 140/90 mmHg (Figure B1).

The number of new cases of CKD and patients on dialysis continues to increase, but many Texans are not aware that they are at risk. Early detection and treatment of CKD and associated comorbidities (i.e., diabetes and hypertension) can reduce disease progression and improve overall health and wellness. The reported awareness of disease, among individuals with CKD stages 3 and 4, was 12.4% in 2013-2014.2

Over the past 16 years, no distinct increasing or decreasing trends have been noted. In 2015-2016, 14%-15% of adult National Health and Nutrition Examination Survey (NHANES) participants, representing ~31-34 million noninstitutionalized

¹ Chronic Kidney Disease in the United States, 2021. Centers for Disease Control and Prevention. https://www.cdc.gov/kidneydisease/publications-resources/ckd-nationalfacts.html

² US Renal Data System 2019 Annual Data Report: Epidemiology of Kidney Disease in the United States. https://www.usrds.org/media/2371/2019-executive-summary.pdf

U.S. civilian residents aged 20 years or older, had evidence of CKD stages 1-4; of these, \sim 15-18 million had evidence of CKD stage 3 or 4 (Figure B2).

Early detection and intervention are critically needed. Patients who progress to stage 3 kidney disease are ten times more likely to die from any cause than to progress to dialysis. The ten-year mortality of a patient with diabetes, albuminuria and impaired glomerular filtration rate is 47%.³ Kidney transplantation prior to the onset of dialysis not only diminishes the ten-year mortality from ESRD but substantially decreases total health expenditures. Thus, expanding the education of patients about kidney transplantation and the benefits of living donor kidney transplantation is also an important strategy to improve the well-being of patients with ESRD. Therefore, early detection of chronic kidney disease and management of comorbidities such as hypertension and diabetes are key to reducing progression of CKD into End Stage Renal Disease. Additional factors such as the impact of social determinants of health, behavioral health issues, and obesity must be addressed concurrently.

Texas unfortunately holds the distinction of having the largest percentage of dialysis patients in the entire United States. The impact of dialysis on patients, their families and their communities is devastating. In 2016, 124,675 patients initiated treatment for End Stage Renal Disease, 121,209 of whom started on dialysis (3,466 started with a kidney transplant). According to the End Stage Renal Disease Network of Texas (ESRD Network 14), in 2019, an additional 13,001 began dialysis.

The data in Texas demonstrates a pressing opportunity for improvement. In 2019, there were 71, 996 total end stage renal disease patients in Texas either on dialysis or having received a transplant.⁴ Texas's ESRD incidence rate exceeds the national rate, and we represent 10.3 percent of the nation's total ESRD patient population. The annual incidence is 379.1 per million population as compared to an average of 346.9 per million population.²

Health Care Disparities

Health care disparities have long been a problem within the medical community. In recent months social justice matters have shed new light on the problem. The social

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³ Data from End Stage Renal Disease Network of Texas which described a survey examining the all-cause mortality of patients with CKD and/or Type 2 Diabetes Mellitus in the US (n=15,046)

⁴ Data from End Stage Renal Disease Network of Texas. Network 14: Count of Prevalent ESRD Patients by Treatment/Setting 2019

determinants of health that influence the complex issues remain among the top influences, including the CKD community. African Americans and Hispanics have high incidences of diabetes and hypertension, so it is not surprising that they are also disproportionately affected by CKD and ESRD.²

African Americans make up the largest group of minorities in need of an organ transplant, yet the number of organ transplants performed on African Americans in 2019 was only 25.8 percent of the number of African Americans currently waiting for a transplant. The number of transplants performed on white Americans was 47.6 percent of the number currently waiting. While 28.7 percent of the total candidates currently waiting for transplants are African Americans, they comprised 12.5 percent of organ donors in 2019.

In 2019, 74.5 percent of donor organs from African Americans were from deceased donors. The total number of white Americans on organ transplant waiting lists for all organs is about 1.4 times greater than that of African Americans, and the number of candidates waiting for a kidney transplant is 31.8% for African American candidates as compared to 35.7% for white candidates.

The Cost Burden of End Stage Renal Disease

Chronic kidney disease is an expensive disease and a public health burden. Nondialysis CKD patients account for 18.2% of total Medicare expenditures, which is approximately \$45.5 billion. This amount does not account for individuals with ESRD or dialysis patients. CKD patients incur approximately \$22,348/person/year in medical expenditures, which is almost three times as much as non-CKD patients. ESRD costs about \$34.3 billion, with an annual growth of 6–12%.5

To approximate the cost of chronic kidney disease management and CKD complications, data from the Optum claims database was used to study 52,599 adults with CKD and Type 2 Diabetes from 2014 to 2019. CKD management costs ranged from \$7,725 for stage I to II kidney disease to \$11,879 for stage V kidney disease (without Renal Replacement Therapy), with high additional costs for dialysis and kidney transplantation (\$87,538 and \$124,271, respectively). Chronic kidney disease can cause other complications in a person's body, including heart failure, stroke, myocardial infarction, and hyperkalemia.

⁵ Trend in healthcare expenditure in United State adults with chronic kidney disease: 2002-2011. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5441091/

Costs for complications associated with CKD were \$31,063 for heart failure, \$21,087 for stroke, and \$21,016 for myocardial infarction in the first 4 months after a person gets chronic kidney disease. The acute event costs of atrial fibrillation and hyperkalemia were \$30,500 and \$31,212 with hospitalization, and \$5,162 and \$1,782 without hospitalization.⁶ The costs associated with cardiovascular-related death, renal-related death, and death from other causes were \$17,031, \$12,605, and \$9,900, respectively. Early detection of kidney disease is imperative.

Heart failure, which occurs when the heart muscle is unable to pump the required amount of blood the body needs for blood and oxygen, was associated with an incremental per-person per-year Medicare cost of \$19,944 among patients with CKD. Hyperkalemia, which occurs when there is too much potassium is in the blood and can lead to heart problems, is another complication that is common among patients with CKD, and it is associated with substantial health care costs. Specifically, hyperkalemia was associated with an increased 1-year cost of \$21,857 in patients with CKD and \$20,657 in patients with diabetes.⁷

Importantly, the incidence in Texas is rising as compared to a downward trend nationally. In 2016, Texas ranked in the top 20 states with a higher prevalence of ESRD. Although the total cost of kidney disease in Texas is unknown, as CMS does not publish cost analysis by state, a 2022 report states treating Medicare beneficiaries with CKD cost the United States over \$87 billion and treating patients with ESRD cost an additional \$37 billion resulting in total health care expenditures of \$124 billion towards kidney disease.⁸

The Task Force studied these statistics, best practices and focused on recommending a set of high impact priorities whose implementation will stand the test of time to deliver on the goals of the legislature in mitigating the adverse impacts of chronic kidney disease. These priorities encompass education of our citizens about kidney disease including transplantation, expanding health care literacy, implementing public health initiatives to diminish the sequelae of diabetes/hypertension including early detection of renal disease, enhancing access to culturally competent health care providers to decrease health care disparities,

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⁶ <u>Acute Kidney Injury in a National Cohort of Hospitalized US Veterans with COVID-19</u> | American Society of Nephrology (asnjournals.org)

⁷ U.S. Department of Health and Human Services. National Institute of Diabetes and Digestive and Kidney Diseases website. https://www.niddk.nih.gov/health-information/kidney-disease/chronic-kidney-disease-ckd/causes. Accessed Oct. 7, 2020.

⁸ Chronic Kidney Disease: Common - Serious - Costly (cdc.gov)

and the importance of expanding organ donation are critical to addressing kidney disease in our nation and in Texas as these efforts will save countless lives.

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CKD Task Force Subcommittee Reports and Recommendations

The Chronic Kidney Disease Task Force recommendations are centered on the following themes:

- Education to the public regarding kidney disease and with an emphasis to help prevent the onset of kidney disease.
- Early screening and diagnosis of kidney disease aimed at mitigating progression of disease including the management of co-morbidities such as diabetes, hypertension and obesity as well as other risk factors.
- Optimizing treatments of Stages 1-4 of kidney disease including peritoneal and hemodialysis.
- Increasing donation through education of the public on both Living Donor and Deceased Donation.
- Legislation in support of the CKD community including those patients at risk of developing renal disease in the future or those living with renal disease now.

The Task Force has proposed several recommendations and initiatives that addresses the following areas of need.

Education & Prevention

The Rita B. Littlefield Chronic Kidney Disease Centralized Resource Center

A key strategy of advancing these themes is for the Legislature to establish a CKD Centralized Resource Center (CRC). This Task Force recommends that a centralized resource center, sponsored by the State and brought forth by legislation, should receive and maintain funds for its creation and long-term maintenance. The center may also serve as a platform for several other initiatives recommended by the Task Force. The Task Force recommends that a methodology be established to track

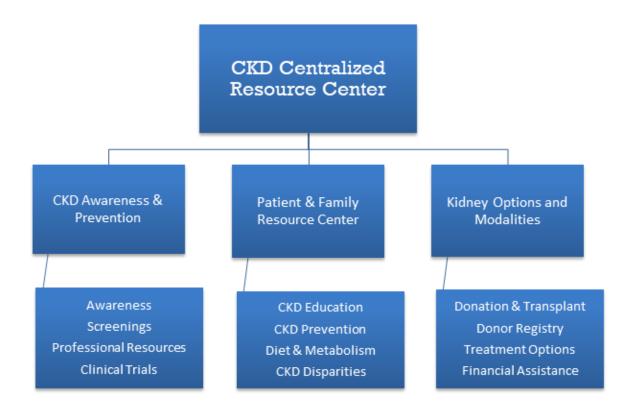
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progress in the implementation of any of the recommendations accepted by the Texas Legislature.

The CRC will be the center point for access and distribution of CKD information to citizens and health care providers. This CRC will be strategically designed to provide "real time" assistance and resources for patients and providers including CKD awareness, prevention, patient-family resources, and CKD treatment options. Ideally, the CRC will encompass a multilayered approach to provide awareness, education, and resources at every level of CKD for the general population as well as for health care professionals. The CRC will include information directly related to CKD, ESRD, and should be made available in English and Spanish. The online resource center will act as a centralized hub for content created based on recommendations from the CKD Task Force for use by CKD professionals, clients, and stakeholders. The center seeks to offer key points of engagement for persons in the CKD community including CKD Awareness, Patient and Family Resources and Kidney Options and Modalities.

The CKD CRC will also help address the lack of a standardized referral process for early detection, treatment, and kidney transplantation. The centralized system will support and provide resources for patients, family members, providers, and professionals all in one place (i.e. access to immunosuppressant assistance, assistance with other CKD/ESRD medications, transplant and home modalities navigators, peer mentoring, referral orientation, living donor resources, transportation, lodging, self-referrals to transplant and home dialysis, living donor registry, other related expenses for CKD preventive care, patient advocacy, research, data, free screenings, and home/self-care training). See CKD CRC flow chart below.

The Rita Littlefield CKD Resource Center Supported by the Health Human Services Commission



This flow chart depicts a multilayered approach to address CKD. This structure will be utilized as the backbone of the centralized resource center with the intention to continue to build and expand on each of these categories.

The CKD Centralized Resource Center should best reside within the appropriate state agency with the appropriate oversight and accountability.

The Texas Quality Improvement Network's (TMF) <u>"Improving Chronic Disease Self-Management – Chronic Kidney Disease Change Package"</u> stresses that *early detection is critical to slow down the progression of chronic kidney disease.*⁹

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⁹ TMF Quality Innovation Network (2020). Improving Chronic Disease Self-Management Chronic Kidney Disease Change Package, https://tmfnetworks.org/Networks/Community-Coalitions/Change-Packages/itg/CDCPCKD1. Accessed Oct. 1, 2020.

However, less than 10% of people with hypertension and less than 40% of people with diabetes receive screening for kidney impairment. A proactive population health model for CKD includes early screenings per the National Kidney Foundation (NKF) guidelines. These guidelines include prompt screening, diagnosis, and management of diabetes and high blood pressure with timely referrals to nephrologists. These guidelines are more critical for providers working in communities with a high percentage of under-represented minorities and socioeconomically disadvantaged citizens. The prevalence of both CKD and ESRD among these communities are disproportionally high. Kidney disease affects African Americans (16%) and Hispanics (14%) more than any other race or ethnicity. The prevalence of ESRD is three times greater for African Americans than non-Hispanic whites.

Utilizing the Rita Littlefield CKD CRC, the Task Force recommends promoting early detection of chronic kidney disease and aggressive treatment of comorbidities (hypertension, diabetes, obesity, cardiovascular disease) through education of health care providers including the offering of Continuing Medical Education Hours, Continuing Education Units, and provider toolkits. The Task Force recommends working with physician organizations such as the Texas Medical Association, Texas Academy of Family Physicians and similar groups to include the topics of early detection of CKD and management of comorbidities in their educational curriculum seminars. This change package was distributed to providers by the ESRD Network of Texas and its available on the TMF's website.

CKD can also be improved through addressing food insecurity, including lack of access to nutritious food, as this can result in the development of chronic illness or the worsening of existing diseases including chronic kidney disease and obesity.

Using the Rita Littlefield CKD CRC, provide education and information on resources to access to nutritious foods by working with organizations such as Feeding America and local food banks.

The Rita Littlefield CKD CRC will be linked to social media and will play a key role in promoting awareness, education, and early detection interventions. To maximize efficiency and availability of resources, the following interventions are recommended, and where applicable, will need to be made accessible through the Rita Littlefield CKD CRC:

• Reactivation of previous ESRD prevention campaigns, "Love Kidneys" and the "Save Their Kidneys" program to educate health care providers.

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- The Department of State Health Services (DSHS) to offer presentations on CKD for its Grand Rounds Series at least once a year and made available through the Rita Littlefield CKD CRC.
- Assigned DSHS/HHS staff will contact the Texas Board of Nursing to partner and include educational and awareness information for CKD (recommended by Task Force subject matter experts) in the Texas Board of Nursing Newsletter. A permanent link to the newsletter would be accessible through the Rita Littlefield CKD CRC.
- Focus on social determinants of health by addressing issues of food insecurity, transportation to appointments, and access to affordable medications to improve overall health outcomes. Resources to mitigate these barriers can be housed and accessed through the Rita Littlefield CKD CRC such as links, education, and information to access to nutritious foods such as Feeding America, local food banks and programs like Texas A&M AgriLife Extension and the VIVA SA Healthy Corner Stores project
- Utilize available resources through Federal Agencies such as the Centers for Disease Control and Prevention (CDC), Centers for Medicare & Medicaid Services (CMS), National Institutes of Health (NIH), the Indian Health Service, Department of Veteran Affairs, and the Department of Defense, all of which support direct care systems that serve populations with a high prevalence of, or at high risk for, CKD (i.e., Kidney Interagency Coordinating Committee (KICC) and Federal Chronic Kidney Disease (CKD) Matrix). Links to access these resources will be made available through the Rita Littlefield CKD CRC.
- COVID-19 has demonstrated to health care workers the importance of telemedicine/telehealth as a means of expanding access to health care for Texans and should be considered as a permanent means of delivering care and an accepted means by national payors. The ESRD Network advocated and suggested integration of telemedicine as part of the new revised ESRD Rules and Regulations in Texas (not published yet). Open comment period information was provided to Task Force members to submit comments and recommendations for telemedicine by November 14, 2022.

Task Force recommends the utilization of data driven approaches to identify communities within the state for CKD screenings such as:

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The Behavioral Risk Factor Surveillance System (BRFSS) conducted by the
 <u>National Center for Chronic Disease Prevention and Health Promotion</u> that
 collects data on physical activity levels, tobacco or alcohol use and health
 care access. Participants are asked to provide basic demographic
 information, such as age, race and ethnicity, income, and education level.

The survey is conducted by telephone and includes questions about health risk behaviors related to nutrition, physical activity, tobacco and alcohol use, diabetes, heart disease, immunizations, injuries, health care access and use of health care services. BRFSS has been conducted annually since 1984.

Therefore, the data can be utilized to identify trends and develop public health strategies. Questions about income, educational level, and health care access are included in the survey and factor into the social determinants of health.

 Texas Kidney Foundation (TKF) and South Plains Kidney Foundation data to determine where annual return(s) to certain communities is advantageous to follow up with individuals that were screened and counseled to determine the extent adoption of recommended lifestyle changes and the impact

Early identification and engagement are critical in managing CKD. The Task Force strongly recommends leveraging upstream relationships and developing community coalitions that can increase collaboration between public and private organizations to address factors which can decrease the progression of CKD to ESRD. These coalitions will assist and support interventions and promote strategies to address issues impacting communities. Taking a community-based approach will allow for the development of strategies that can address gaps in health services and ensures alignment of goals that are identified as community needs.

Recommended partnerships		
Texas Medical Association	They provide CME and are respected educators. They should be enlisted to educate primary care physicians about kidney diseases and how to manage them within their practices.	
Texas Primary Care Office	The Texas Primary Care Office (TPCO) works with health care providers and communities to improve access to care for the underserved. This office should be utilized to coordinate education of primary care physicians and their staff.	

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	Recommended partnerships	
DSHS Community Health Workers (CHW)	DHSH CHW may work with their advisory committee to develop and promote a CKD outreach plan throughout the state.	
Texas Education Agency (TEA)	Work with TEA approved Coordinated School Health Programs to promote education in school systems through programs such as the Coordinated Approach to Child Health (CATCH).	
Texas Association of Community Health Centers	Coordination of care pathway should be created between free clinics and trusted nonprofits like the example that TKF has created.	
Wesley Nurses	They span 80 sites throughout South Texas and they are dedicated to service of the underserved	
American Nurses Association	Utilize the Texas primary care office to educate them about kidney diseases.	
Texas Quality Improvement Network (TMF)	TMF may assist working with hospitals and the CKD CMS improvement goals and activities.	
Nurses in the American Nephrology Nurses Association (ANNA)	ANNA may assist with outreach and screenings utilizing their network and chapters throughout the state.	

Forge and leverage partnerships with medical professionals who are working in patient populations that are at risk for kidney disease. Diabetes professionals, primary care professionals, cardiovascular professionals, obesity professionals and others should be utilized as they have the potential to encounter CKD in its early stages. Enlist community health workers, established non-profits, public health programs and service organizations as trusted community partners to coordinate

resources to assist in CKD testing during non-profit, community, or state sponsored events.

Building community trust between patients and testers is reliant upon having information disseminated by upstream organizations that are well educated in the importance of prevention, education, and early detection. Serving the underserved requires earning and building trust.

Leverage the existing community engagement of Quality Improvement Organizations (QIOs) such as TMF Quality Innovation Network. TMF is currently contracted with CMS to assist patients and families, providers, and communities to make care safer, support active engagement and self- management of chronic conditions such as CKD, eliminate health disparities, promote best practices for healthy living, improve access to care, and make care affordable.

The Task Force recommends the appropriate agency or department within the state government to contact TMF and TKF to discuss a collaborative effort that aligns with the goals stated above.

Early Detection & Co-Morbidities

One in three adult Texans who have diabetes are at risk for kidney disease, and one in five adult Texans with high blood pressure are at risk for kidney disease. Texas has 10 percent of the United States end stage renal disease population.

Early detection efforts have been sparse and inconsistent. The Texas Kidney Foundation (TKF) is a non-profit organization whose mission is to stop the progression of kidney diseases. The organization focusers on utilizing innovative testing methods to provide health care access to the underserved residents of Texas.

The first step in achieving their mission is early identification of chronic kidney disease (CKD). Community coalitions are necessary to stop the progression of chronic disease. Texas Kidney Foundation addresses CKD-related health inequity and disparities through collaboration with hospitals, counties, health departments, civic leaders, businesses, and other key community stakeholders.

Evident gaps in the health care continuum include but are not limited to:

 Health care access – The timely use of personal health services to achieve the best possible health outcomes⁴

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- Social determinants of health Conditions in the places where people live, learn, work, and play that affect a wide range of health and quality-of-liferisks and outcomes⁵
- Health care inequity Differences in health status or in the distribution of health resources between different population groups, arising from the social conditions in which people are born, grow, live, work, and age⁶

TKF addresses all the above through the Silent but Deadly (SBD) Movement The foundation serves the underserved, underrepresented, disadvantaged and vulnerable populations of Texas. They address inequity in CKD diagnosis by applying a precision health-focused approach (versus traditional race correction) and coordinating health care access through early detection screenings. Through collaborative public/private partnerships, TKF efficiently pools local and state resources to facilitate disease identification, management, and mitigation.

Disease Background

Through the SBD initiative, TKF has discovered methodologies and tactics to improve patient health care access and coordinate care to begin to address outcomes. Texas residents suffer from chronic kidney disease at disproportionate levels, ranking fourth in the nation for having the highest rates of kidney disease. A case study of testing rates in Texas was performed to demonstrate how Healthy.io and the State of Texas Kidney Foundation engaged untested, at-risk Texas residents with smartphone-powered home testing kits. Healhty.io developed a novel, in-home test kit for early detection of CKD that transforms the smartphone into a clinical grade medical device allowing at-risk patients to test their kidney function at home and receive instant results. Minuteful Kidney is the first and only smartphone powered home kidney test to receive FDA clearance across all current and Android devices (Appendix C).

People at risk for CKD should complete an annual albumin-to-creatinine ratio test to assess their kidney health, yet 80 percent do not. As a result, most individuals are unaware they have CKD and remain at an increased risk of end-stage renal disease, cardiovascular disease, and stroke.

Nearly 2,000 kits were distributed. There was a 40 percent test completion rate. The results were 38 percent of those who took the test had abnormal to high abnormal results. TKF brought this test to Texas because it is through convenient, accurate early detection methods that we will beat CKD. The underserved seek

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better health as is proven by the high adherence rate. Health care providers must build trust to engage patients in new health care access options.

One of the ways legislators can begin to impact the cost of kidney diseases is by implementing upstream measures like at home test kits. This committee assesses that test kits and effective early identification programs will have an impact on patient outcomes and disease mitigation if coupled with SGLT2 inhibitors and other ESRD preventative measures.

Early detection of CKD in stages I, II, and III a or b is ideal because the costs are lower, and the disease is manageable. The patients and the state need relief from the burden of CKD as soon as possible. This test provides the innovative change that is needed to begin to address to numbers of people going into renal failure each year.

The Task Force recommends the appropriate agency or department within the state government to contact TKF to discuss a collaborative effort that aligns with supporting the dissemination of early detection test kits to the underserved.

CKD has five stages. Currently, medical professionals are not required to notify a patient about the status of their kidneys in the beginning stages of kidney disease. Industry best practices are that patients are made aware of their kidney decline in Stage 3a. The reality is that patients are routinely notified as late as stage four.

The information is present in many patients' files. Unfortunately, it is not communicated to the patient by medical professionals until the disease progresses to its latter stages.

Proposed Early Detection Solutions

National Medicare spending for all beneficiaries who had CKD exceeded \$120 billion in 2017, representing 33.8% of total Medicare fee-for-service spending. On an individual level, annual Medicare spending was \$16,112 per patient for those with CKD and increased to \$19,739 per patient for those with CKD and diabetes. In addition to general CKD management, addressing cardiovascular (CV) complications can be costly. Approximately 29% of the total inpatient hospitalization spending for those with CKD resulted from admissions to treat CV complications.

Chronic kidney disease management poses a substantial economic burden.

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To address this economic burden and improve the quality of life of our citizens the state of Texas should require medical professionals to test for CKD during the yearly check-up performed on patients with risk factors that increase the individual's susceptibility to CKD.

Patients with the following have a high prevalence for CKD:

- Those with a history of CKD in their families
- Those with a diagnosis of diabetes,
- Those with a diagnosis of high blood pressure,
- Those with a diagnosis of cardiovascular disease and/or
- Those with a diagnosis of obesity.

The Task Force recommends medical professionals should be required to report all stages of kidney diseases to the patients. Once the disease stage is identified the patient's continuum of care should be clearly communicated to the patient. If a person is found to have some stage of CKD medical professionals should be required to inform the patient of their status and their options. The tests are being conducted in some cases, but the results are not being conveyed to the patients.

The Taskforce recommends that Texas create such a requirement, it would have federal implications because of the number of Medicaid and Medicare patients here in Texas and beyond.

Transplantation Testing Requirements

As a part of the routine testing that is done during the work-up process for transplantation, patients should be tested for rare kidney diseases. Currently there is no standardized process around this matter. It is left to the hospitals to determine when to administer the tests. Patients with rare kidney diseases like APOL1 should be made aware of the genetic allele. Family members who are donating to one another need to know if there are genetic factors that should be considered during the organ donation process.

Treatment

Clinical Trial Network

The Task Force recommends the formation of a voluntary Kidney Health Clinical Listing and Trial Network for the state of Texas. This statewide clinical network would register patients and extended family members with end stage kidney disease or chronic kidney disease. The network would cover over 1 million Texan residents and support the infrastructure for new approaches to arrest kidney disease and improve the quality of life of our citizens. This kidney registry could be included with the proposed centralized resource center or an existing clinical network (National Kidney Registry | Facilitating Living Kidney Donation).

Texas has 10.3% of the national ESRD patient population and has a faster rate of progression from CKD to ESRD than most states in the country. CKD not only increases the risk of developing ESRD but also dramatically increases the risk of cardiovascular disease and overall mortality. The numbers of patients with CKD is likely to increase further with the recognition that COVID-19 affects the kidney to result in acute kidney injury and CKD. There is therefore a critical unmet need to identify patients in all stages of kidney disease in Texas and provide innovative treatments to arrest progression of CKD.

The registry and trial network will identify all patients with CKD in Texas and provide opportunities to provide clinical research options for these patients. With new available and upcoming treatments for CKD, which include new medications as well as diet and lifestyle changes, an organized approach to confronting the problem of CKD in Texas will have benefits to everyone with CKD, a reduction in financial costs to Texas and an overall improvement in the health of the state.

The Texas Kidney Listing will include:

- Identification of all patients with CKD stages 1-5 on a voluntary basis
- Identification of all patients who require any type of dialysis (CKD Stage 5-6) on a voluntary basis
- Identification of all patients with a successful or failed kidney transplant on a voluntary basis

The registry will be updated monthly and be part of a secure website. Educational information will be provided to all patients in the registry that is modified based on their CKD stage, with patient empowerment as a theme for both the registry and the trials.

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The Texas Kidney Registry will include:

- Identification of all patients with CKD stages 1-5
- Identification of all patients who require any type of dialysis (CKD Stage 5-6)
- Identification of all patients with a successful or failed kidney transplant

The registry will be updated daily and be part of a secure website. Educational information will be provided to all patients in the registry that is modified based on their CKD stage, with patient empowerment as a theme for both the registry and the trials.

The Texas Clinical Trial network will include:

- COVID-19 impact on acute and chronic kidney failure
- CKD-Clinical trials on
 - i. diet, lifestyle, exercise,
 - ii. telemedicine,
 - iii. therapeutics
- HD- Clinical trials to focus on
 - i. Training and coaching-home HD in center
 - ii. Quality hemodialysis, Transplant awareness
 - iii. Self-care in center dialysis
- PD- clinical trials on
 - i. Dextrose effect in PD
 - ii. Quality of life PD
- Transplant awareness
 - i. Implantable artificial kidneys
- Patient empowerment training for

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- i. Self-care in-center dialysis
- ii. CKD 1-5 for nephrology practice
- iii. CKD 1-5 for Primary Care Practice Team
- iv. Addressing social determinants of health
- v. Addressing Systemic issues of social injustice
- Primary Care Practice coaching and training for CKD management

Some examples of specific recommendations and clinical trial opportunities are described below.

- 1. Telemedicine: the emergence of telehealth-related technologies and their integration into health care delivery systems present exciting opportunities to enhance value-based clinical care, health promotion and safe access to clinical care. The senate bill 1107 amended the Texas state law definition of a telemedicine service to allow for caring of patients at different locations from where the physician is situated. Expansion of telemedicine and its impact on quality metrics for CKD outcomes presents an exciting, low-cost opportunity for a clinical trial. Empowering patients and providers for kidney care.
- 2. New opportunities developed in Texas have resulted in reduced mortality of patients with ESRD on dialysis. Implementing these models in different regions across Texas presents an amazing opportunity to reduce the hospital admission rate for patients on dialysis and reduce the rate of progression. Patients and providers will be provided resources to have lowest costs for coverage of medications and value for continuing the medications.¹⁰
- 3. New treatment interventions. New therapies such as the SGLT2 inhibitor medications reduce the need for dialysis, admissions for heart failure and overall mortality in patients with diabetic and non-diabetic kidney disease. New diets and exercise programs may also have major benefits for our CKD patients. These interventions could be quickly applied across Texas to find the best fit for specific treatment options for patients.

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¹⁰ Kidney Health Initiative. https://khi.asn-online.org/

All these therapeutic strategies would quickly move Texas to the top of the best quality care for CKD patients in the United States. They are feasible and our Task Force has the requisite expertise to help lead this effort.

The recommendation will form a nimble system to quickly understand the scope of the CKD problem in Texas and test new solutions. The Clinical Registry and Trial network will facilitate and organize the impact of new therapeutics, exercise regimens, dietary practices, and behavioral interventions to make rapid Go/No Go decision on what works and what doesn't. Each year will see improvements in reduction of the number of patients who will need dialysis. This will have a direct impact to save enormous funds for the state and improve health of families and communities.

Medications

Resources can be provided to facilitate patients and their providers to be aware of cost-saving insurance programs that deliver conventional and therapeutic kidney medications, as well as communicating to patients the importance of taking medications. The Task Force also encourages all insurance companies and local and Federal funding agencies to participate in cost-saving programs.

Kidney Transplantation & Donation

Kidney transplantation is the optimal treatment for end-stage renal disease providing superior patient survival, quality of life and cost savings. Donor organ availability is the principal limitation to transplant and there are opportunities to increase both deceased and living donation. There are disparities in access to transplantation related to race, ethnicity, geography and socioeconomics which can be reduced. Times for referral and evaluation for transplant can be shortened, reducing or avoiding the need for dialysis. There are also opportunities to improve long-term transplant success.

The previous CKD Task Force Report of January 2021 noted five areas affecting access to kidney transplantation by Texans which could be addressed:

- Education in the public, patient and professional arenas
- Process improvement for diagnosis, referral and evaluation

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- Increasing deceased kidney donation with voluntary donor registry opportunities
- Increasing living donation by removal of financial and social barriers
- Improving post-transplant and post-donation issues

There was also concern regarding the COVID-19 pandemic and its effect on patient care as well as potential long-term issues related to acute kidney injury in severe cases.

The subcommittee strongly endorsed the Task Force recommendation for legislative action to create a centralized base for kidney disease issues, the Rita Littlefield Chronic Kidney Disease Resource Center. This would provide opportunities to positively influence all these areas affecting kidney transplant care.

New Developments since 2021

- Donation and transplantation rates in Texas for 2021 increased and exceeded pre-pandemic numbers of 2018 and 2019. However, transplant numbers for 2022 suggest that transplants may be decreased, although complete data is not yet available.
- Over 8,400 people are on kidney transplant wait lists in Texas, a relatively small proportion of the 70,000 on dialysis
- The US Congress passed the Comprehensive Immunosuppressive Drug Coverage for Kidney Transplant Patients Act which will provide medication funding so that patients will be able to maintain transplant function if other drug coverage is lost
- The Texas Living Donor Support act was passed, complementing the national Living Donor Protection Act to prevent insurance discrimination against prior living donors, removing a dis-incentive to donation
- The National Living Donor Assistance Center received increased funding to assist living donors with travel, lodging and other donation related expenses helping to further decrease dis-incentives to donation.
- Donor Registries such as the Glenda Dawson Donate Life Texas Registry have been shown to increase deceased donation by allowing individuals to make a legal decision to donate during their lifetime.

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- New policies for the allocation of deceased donor kidneys have been initiated by the national Organ Procurement and Transplant Network (UNOS) to decrease geographic disparity in wait time to obtain a transplant. Previous policy used Organ Procurement Organization boundaries for allocation; this has been replaced by a concentric circle model based on the donor location which may overlap OPO and state boundaries. This will require increased shipment distances for organs, however.
- New policies are also being developed to reduce the non-use rate of deceased donor kidneys which cannot be placed for transplant. This is a priority for the transplant community in general. The current non-use rate of twenty-five percent should be able to be reduced considerably with improved logistics and better organ preservation techniques.
- Telemedicine use increased and became more important in transplant patient care. This has the potential for further use to improve referral and evaluation times and processes as well as post-transplant care. Travel has become more difficult and expensive, and telemedicine has been an effective resource in this setting. Steps should be taken to ensure appropriate reimbursement and availability of telemedicine in transplant and kidney disease care.

The Transplantation and Donation Subcommittee looks forward to a time when improved education, early diagnosis, and better treatment will reduce end-stage renal disease and the need for dialysis and when organ availability and transplant care will allow every Texan to have access to the best possible options for their life.

Recommendations for the January 2023 CKD Task Force Report

- The primary recommendation is to approve and initiate the Rita Littlefield CKD Resource Center. This would address all five action areas identified in the Task Force reports for transplantation and donation: education, process improvement, living and deceased organ donation, and post-transplant care.
- The use of the Donate Life Texas Registry should be encouraged and additional opportunities for expression of the desire to donate should be provided. These could include driver's license, hunting and fishing license,

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vehicle registration and other encounters that could provide a donation option. Failure to honor a legal donor registration should be a "sentinel event" in hospitals requiring corrective actions.

- The Texas Kidney Health Care program should be supported and expanded. As federal funding for transplant medications becomes available, this may free up resources in the program which can be used for expansion.
- Recommendations should be developed for appropriate referral points for transplant evaluation based on CKD status along with timelines for completion of recipient and donor evaluations. This would help insure a more uniform approach to patient care and reduce disparities related to transplant access.
- Telemedicine use should be facilitated, and regulatory issues addressed regarding reimbursement, documentation and ability to initiate care and evaluation remotely. Geographic issues may need clarification, e.g., a patient living in another state is being evaluated for transplant by a Texas center.
- The three federally designated Organ Procurement Organizations (OPO) in Texas should coordinate efforts to increase organ donation and share best practices. New organ allocation policies removing OPO boundaries should encourage cooperative efforts in Texas.

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Conclusion

Given the increase in CKD prevalence in Texas over the past decade, there is concern escalating health care costs resulting from complications of poorly controlled comorbidities and treatment costs will continue to inhibit affordability and sustainability of the health care delivery system. This poses a simultaneous threat at multiple levels: fiscally for the Legislature and Texas taxpayers, as well as to the health and quality of life for all Texans.

The Task Force is committed to identifying ways to simultaneously reduce overall health care expenditures related to kidney disease and associated co-morbidities while improving the delivery of evidence-based, cost effective, prevention and health care services that improve population health for Texans.

There are new opportunities to achieve these goals with new medications for kidney disease and policy changes, as well as collaboration with chronic kidney disease nonprofit organization to promote CKD education, screening, and treatment options.

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List of Acronyms

Acronym	Full Name	
ADA	Americans with Disabilities Act	
АНА	American Heart Association	
ANNA	American Nephrology Nurses Association	
BRFSS	Behavioral Risk Factor Surveillance System	
CATCH	Coordinated Approach to Child Health	
CDC	Centers for Disease Control and Prevention	
CKD	Chronic Kidney Disease	
CMS	Centers for Medicare and Medicaid	
CPL	Clinical Pathology Laboratories	
CRC	Centralized Resource Center	
DSHS	Department of State Health Services	
ESKD	End Stage Kidney Disease	
ESRD	End Stage Renal Disease	
HHSC	Health and Human Services Commission	
KICC	Kidney Interagency Coordinating Committee	

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NIH	National Institutes of Health	
NKF	National Kidney Foundation	
QIOs	Quality Improvement Organizations	
TKF	Texas Kidney Foundation	
TMF	Texas Quality Improvement Network	

Appendix

Appendix A: Chronic Kidney Disease Task Force Membership

Member	Positions Held	Task Force Membership
Francis H. Wright Jr., M.D.	CKD Task Force Chair, Education of Living & Deceased Donation Transplants Subcommittee Chair, Legislative Issues Subcommittee Member	Health Care System Representative
Ms. Mary E. Albin	Education & Prevention Subcommittee Member, Early Detection & Co-Morbidities Member	End Stage Renal Expert
Mr. Dany J. Anchia	Education & Prevention Subcommittee Chair, Education of Living & Deceased Donation Transplants Subcommittee Member, Legislative Issues Subcommittee Member	Nephrologist Nurse
Francisco G. Cigarroa M.D.	Education of Living & Deceased Donation Transplants Subcommittee Member	Kidney Transplant Surgeon
Roberto Collazo- Maldonado M.D.	Education of Living & Deceased Donation Transplants Subcommittee Member, Treatment Subcommittee Member	Primary Care Physician
Ms. Amie B.E. Duemer	Education & Prevention Subcommittee Member, Education of Living & Deceased Donation Transplants Subcommittee Member	South Plains Kidney Foundation Representative
Ahmed O. "Osama" Gaber M.D.	Education of Living & Deceased Donation Transplants Subcommittee Member, Legislative Issues Subcommittee Member	Kidney Transplant Surgeon

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Member	Positions Held	Task Force Membership
Richard L. Gibney M.D.	Education of Living & Deceased Donation Transplants Subcommittee Member, Treatment Subcommittee Member	Family Physician
Lisa Glenn, MD	Education & Prevention Subcommittee Member, Early Detection & Co-Morbidities Member	State Medicaid Program Representative
Ryan Guillen	CKD Task Force Member	House of Representatives
Ms. Anne K. Ishmael	Early Detection & Co-Morbidities Member, Legislative Issues Subcommittee Member	Renal Dietitian Representative
Ms. Nichole Jefferson	Education of Living & Deceased Donation Transplants Subcommittee Member, Treatment Subcommittee Member	National Kidney Foundation Representative
Ms. Tiffany N. Jones- Smith	Early Detection & Co-Morbidities Member, Treatment Subcommittee Member, Legislative Issues Subcommittee Member Education and Prevention Subcommittee	Texas Kidney Foundation Representative
Ms. Rita L. Littlefield	Legislative Issues Subcommittee Chair, Early Detection & Co-Morbidities Member	Texas Renal Coalition Representative
Ms. Benedicta Anikputa	Early Detection & Co-Morbidities Subcommittee Member	HHSC Kidney Health Care Program Representative
Mohammad R. "Hamed" Mizani M.D.	Education & Prevention Subcommittee Member, Treatment Subcommittee Member	Nephrologist Private Practice

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Member	Positions Held	Task Force Membership
Kumar Sharma M.D.	Treatment Subcommittee Chair , Legislative Issues Subcommittee Member	Pathologist
Phil Stephenson	CKD Task Force Member	House of Representatives
Leslie A. Weisberg M.D.	Early Detection & Co-Morbidities Chair, Education & Prevention Subcommittee Member	Preferred Provider or HMO

CKD Task Force Advisory Members

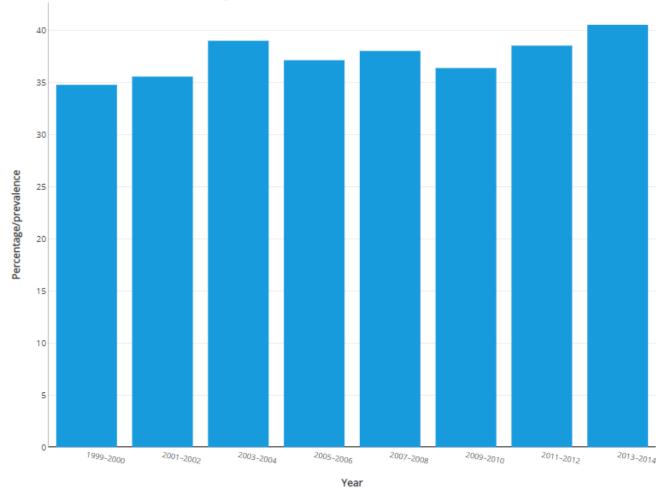
Ms. Jennifer Milton	Special Advisor to the Committee	Advisor and Project Manager
Mr. Alex Stivers	CKD Task Force Liaison	HHSC Specialty Health

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Appendix B: Chronic Kidney Disease Task Force Data

Figure B1

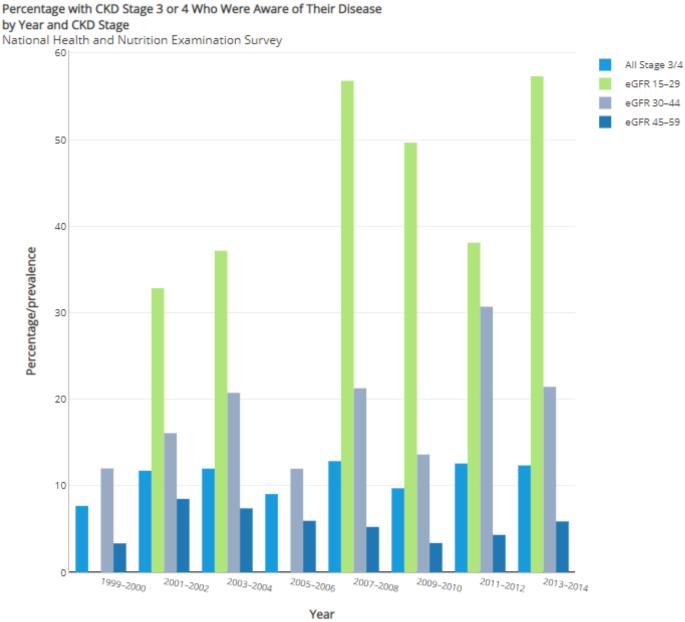




 $Centers for Disease Control \ and \ Prevention. Chronic \ Kidney \ Disease \ Surveillance \ System -- United \ States, \ website. \ https://nccd.cdc.gov/ckd$

Centers for Disease Control and Prevention. Chronic Kidney Disease Surveillance System—United States. website. http://www.cdc.gov/ckd

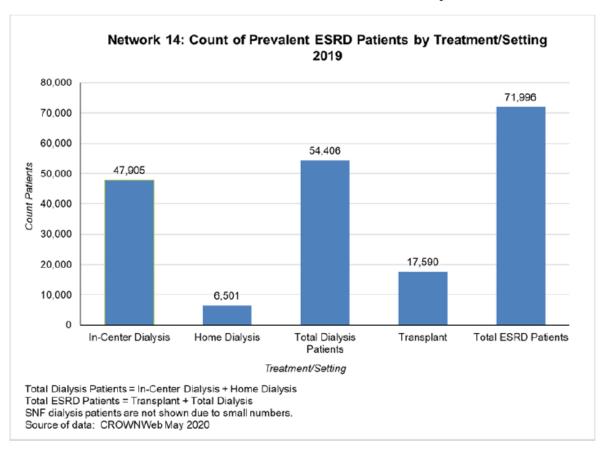
Figure B2



Centers for Disease Control and Prevention. Chronic Kidney Disease Surveillance System—United States. website. http://www.cdc.gov/ckd

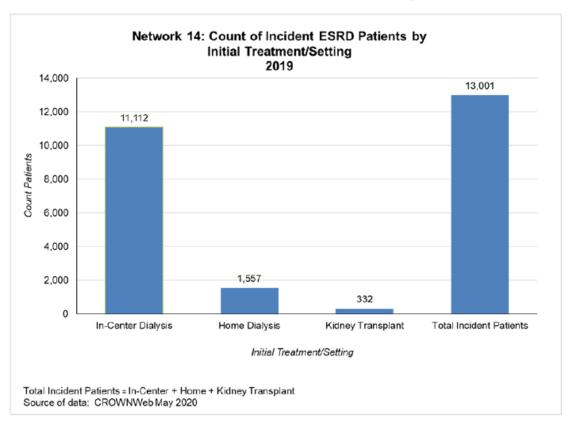
39

Chart 1: Count of Prevalent ESRD Patients by Treatment Setting



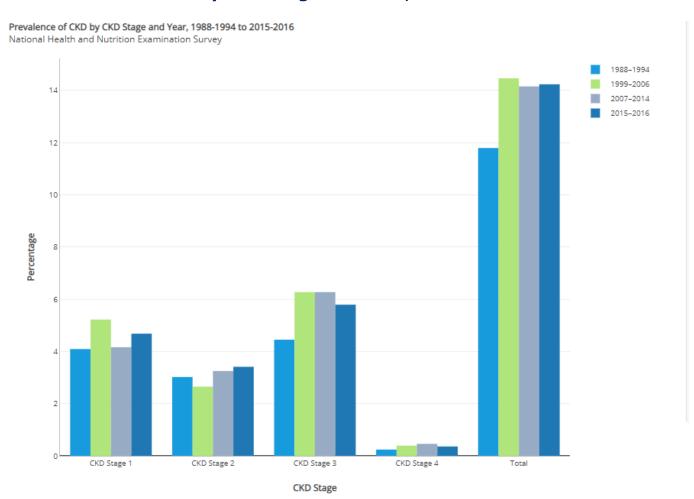
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Chart 2: Count of Incident ESRD Patients by Initial Treatment/Setting



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Prevalence of CKD by CKD Stage and Year, 1988-1994 to 2015-2016



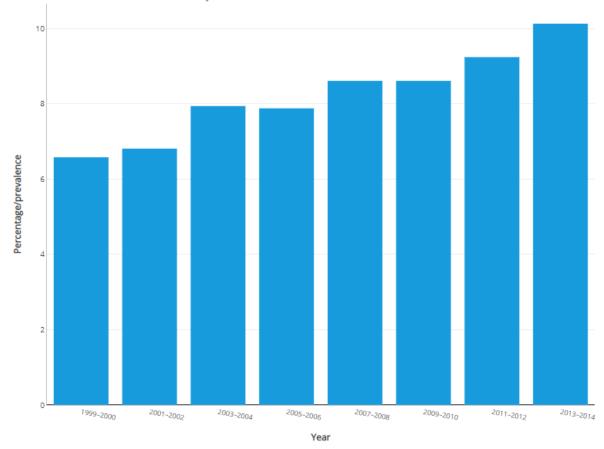
Centers for Disease Control and Prevention. Chronic Kidney Disease Surveillance System—United States, website, https://nccd.cdc.gov/ckd

Percentage with Diabetes by Year

Percentage with Diabetes

by Year

National Health and Nutrition Examination Survey



Centers for Disease Control and Prevention. Chronic Kidney Disease Surveillance System—United States. website. https://nccd.cdc.gov/ckd

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Table B1

U.S. Transplant Waiting List – Candidates by Race/Ethnicity					
Organ	All Candidates	# of Black Candidates	Black % of All Candidates	# of White Candidates	White % of All Candidates
All Organs	105,396	29,732	28.2	42,110	40.0
Kidney	89,800	27,736	30.9	32,163	35.8
Liver	10,871	740	6.8	7,204	66.3
Heart	3,345	920	27.5	1,861	55.6
Lung	977	131	13.3	652	66.7

Source: HRSA. U.S. Organ Procurement and Transplantation Network (OPTN). Based on OPTN data as of February 20, 2021.

https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/*

Table B-2

Transplants Performed in the U.S. by Recipient Ethnicity, 2021			
	Number	Percentage of Total 2021 Transplants	
Black	7,912	19.1	
White	18,064	43.5	
Total Transplants	41,356	100	

Source: HRSA. U.S. Organ Procurement and Transplantation Network (OPTN). Based on OPTN data as of February 20, 2022.

https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/

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Table B-3

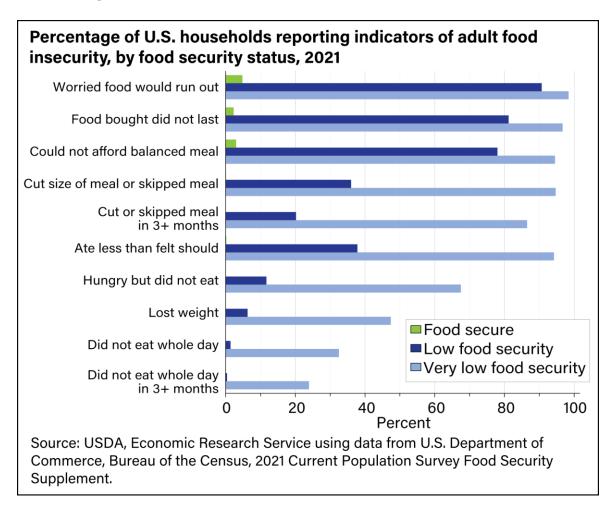
U.S. Organ Donors Recovered, 2021				
Donor Type	# of Black Donors	% of Black Donors	# of White Donors	% of White Donors
Living	484	18.7	4,631	33.6
Deceased	2,098	81.3	9,148	66.4
Total	2,582	100	13,779	100

Source: HRSA. U.S. Organ Procurement and Transplantation Network (OPTN). Based on OPTN data as of February 20, 2022.

https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/

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Percentage of U.S. households reporting indicators of adult food insecurity



Sept, 2021 USDA Economic Research Service

https://www.ers.usda.gov/topics/food-nutrition-assistance/food-security-in-the-us/definitions-of-food-security.aspx

Appendix C: Texas Kidney Foundation Case Study

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Improving Kidney Testing Rates in Texas

How Healthy, io and the State of Texas Kidney Foundation engaged untested, at-risk Texas residents with smartphonepowered home kidney testing



Overview

Texas residents suffer from chronic kidney disease (CKD) at disproportionate levels, ranking fourth in the nation for having the highest rates of kidney disease. Healthy, io has developed a novel, in-home solution for the early detection of CKD that transforms the smartphone into a clinical-grade medical device, allowing at-risk patients to test their kidney function at home and receive instant results. Minuteful Kidney is the first and only smartphone-powered home kidney test to receive FDA clearance across all current iOS and Android devices.

CKD and the Testing Problem

One in three Americans is at risk for CKD, including those with diabetes and hypertension. People at risk for CKD should complete an annual albumin-to-creatinine ratio (ACR) test to assess their kidney health, yet 80% do not. As a result, most individuals are unaware that they have CKD and remain at an increased risk of end-stage renal disease (ESRD), cardiovascular disease, and stroke.

Healthy.io's Minuteful Kidney service encourages kidney health testing by allowing patients to take their ACR test from home and receive instant results. By making tests available for anyone to take in their own home and on their own schedule, Minuteful Kidney can help reduce barriers to care for underserved populations.



Partnership Objective

Due to the high rates of CKD in Texas, Healthy.io partnered with the State of Texas Kidney Foundation (STKF) during their Silent but Deadly campaign with the following goals:

- Spread awareness about early detection of CKD
- Provide new and accessible screening options
- Engage underserved and hard-to-reach communities

Outcomes

Overall the partnership was a success with abnormal results demonstrating the necessity for early intervention.



Nearly 2,000 kits distributed



40% test completion rate



38% of those who took the test had abnormal to high abnormal results

Member Experience

98% found Minuteful Kidney easy or very easy to use

97% of users reported "no problems at all" using the kit

Everything was easily explained"

Minuteful Kidney user