Global Dialysis Perspective: United States
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Kidney failure, leading to end-stage renal disease (ESRD) is invariably an irreversible condition, which for survival, typically requires renal replacement therapy - either dialysis or a kidney transplant. ESRD is associated with high mortality, morbidity, lower quality of life, high resource utilization and cost, thereby posing a substantial burden primarily on patients but also on families and society at large. The focus of this mini-review is to summarize the state of dialysis management and changes in financing of dialysis in the US over the last decade. In addition we briefly highlight the recently announced federal executive order – ‘Advancing American Kidney Health’, that promises to raise awareness and improve kidney disease management in the United States.

**Epidemiology of dialysis patients**

Based on a survey of 79 countries, the United States has the second highest incidence of treated ESRD, which is attributed to age, race, genetic predisposition, high prevalence of risk factors such as obesity, diabetes and hypertension. Primordial risk factors such as inequities related to race, income, education, food security, recreational and routine physical activity, access to healthy food options, healthcare, and environmental factors, likely play a major role in the predisposition to disease and its complications; kidney disease is no exception. There were 746,557 prevalent patients with ESRD in the US at the end of 2017, of which 124,500 were new cases, translating to a crude incidence rate of 370.2/million/year (Figure 1a & 1b). The adjusted ESRD incidence rate, has stabilized, however and begun to decline slightly in recent years. About 29.9% of prevalent ESRD patients and 2.9% of incident ESRD patients had a functioning kidney transplant. For quite some time now, diabetes and hypertension have remained the leading assigned primary causes of ESRD in the United States (Table 1).

Thrice-weekly hemodialysis (HD) is the predominant form of renal replacement therapy. In 2017, a total of 1545.8 per million population were receiving dialysis treatment (Table1). There has been an increase in home dialysis since 2008, predominantly in the form of peritoneal dialysis (PD, Figure 2a & 2b). Patients receiving PD are on average younger, more likely to be White, non-Hispanic and or with glomerulonephritis or cystic kidney disease as the assigned primary cause of ESRD, compared with those on hemodialysis.

Kidney disease ranked as the 9th leading cause of death in the US, although the mortality rates among those with ESRD, similar to the general population, have steadily decreased from 2001 through 2017 (Table 1). While this trend could be attributed to increased pre-ESRD care, improved quality of care on dialysis and better management of comorbid conditions, it may also largely be a reflection of the improved life expectancy in the general population. Cardiovascular causes comprised 54% of known causes of death among dialysis patients. Dialysis patients remain at high risk of hospitalization, although like mortality, rates have declined over time from 2.0 to 1.7/patient/year (2007-2016). Accompanying a decline in hospitalization rates, an increase in emergency room and observation care stays has been observed. Readmission within 30 days of discharge occurs at a rate of 37.5% and 37.1% in HD and PD patients, respectively. Dialysis facility readmission rates are being tracked as a quality...
measure by the Centers for Medicaid and Medicare (CMS). Not surprisingly, the leading causes of hospitalization in dialysis patients are cardiovascular events and infections.

Pre-ESRD care
Early nephrology referral has been associated with lower risk of morbidity and mortality in ESRD patients. By 2017, about 32.6% of US patients had been seen by nephrologists at least 12-months ahead of initiation of dialysis, while in about 19% of patients there was no evidence of having been seen by nephrologists before declaration of ESRD (Table 1). Patients with earlier nephrology referral had better biochemical and care quality parameters (e.g. dietary care) than those without nephrology visits (Table 1).

Major improvements in vascular access practices, particularly at dialysis start, are urgently needed. In 2017, only 16.8% of incident ESRD patients received hemodialysis through autogenous arteriovenous (AV) fistula, the preferred mode of vascular access for hemodialysis, with 80% of incident cases documented as initiating HD using a central venous catheter (CVC), a circumstance fraught with higher risk of infection and death. In 2018, 62.9% of prevalent dialysis patients used an AV fistula, while 17.5% and 19.6% of patients were on AV graft and CVC, respectively. There are many possible contributors to this suboptimal vascular access practice pattern, including barriers to timely access to care and care coordination, suboptimal AV fistula maturation as a major impediment, and inadequate supply of providers with the necessary training, expertise and commitment to creating high quality AV fistulas.

Provision of care
In the US, the majority of dialysis services are provided through private, for-profit, freestanding outpatient dialysis facilities. Fresenius and DaVita were the two dominant large dialysis organizations, owning 60% of all dialysis units comprising 63% of patients on dialysis in 2011. The supply of nephrologists varies across regions in the US, where some regions have less than 62 ESRD patients per nephrologist compared to regions have more than 105 ESRD patients per nephrologist. Nurse practitioners (NPs) and physician assistants (PAs) play an important role in provision of dialysis services. On average, 68% of facilities had their patients seen by nephrologists at least weekly during their dialysis sessions. The estimated average duration of dialysis session was 216.5±26.1 minutes among those receiving thrice weekly hemodialysis.

Financing of dialysis
Medicare is a national social insurance program (enacted in 1965), that provides health insurance coverage for adults aged 65 or order. Medicare has become the predominant payer for dialysis services since the enactment of the Medicare entitlement Act of 1972 when the coverage was expanded to cover even younger adults, and those with disabilities (including ESRD). Originally Medicare was on a fee-for-service basis that provided coverage for hospitalization under Medicare Part A and outpatient services or supplies under Part B. In 2006, with the launch of the Medicare Prescription program, ESRD patients began to receive medication coverage through Medicare Part D. The Medicare Advantage Plan, also known as
Part C is a prospective, capitated-fee coverage provided by Medicare that combines medical services and prescription drug coverage to those who have private health insurance coverage (typically following retirement) among those age 65 or older. ESRD patients are not eligible for Medicare Advantage Plan, unless they had enrolled in such a plan prior to the onset of ESRD.

While Medicare remains the dominant payer for treatment of kidney failure, the remaining costs are paid by Medicaid, the Department of Veterans Affairs, private insurers and other assistance programs\textsuperscript{17}. Overall Medicare spending for ESRD reached 46.6 billion in 2017, which is approximately 7% of all Medicare spending for 1% of its covered population\textsuperscript{4}. Patients’ out-of-pocket costs were an additional 3.5 billion in 2017, 1.3% more than in 2016\textsuperscript{4}. Outpatient services accounted for the largest share of Medicare spending for ESRD (33%), followed by inpatient services (32%) and physician and supplier billing claims (15%). The fastest-growth occurred in spending on outpatient prescriptions (5.1 billion), a 5% increase from 2016\textsuperscript{4}. Per person per year Medicare spending was far lower for transplant patients compared with those on dialysis\textsuperscript{4}.

**Federal Regulation and Policy**

Like for other medical conditions, CMS has implemented continuous regulations with a view to improving care quality, patient outcomes and patient experience, but also with an eye on reducing healthcare expenditures for ESRD patients (Table 1). CMS implemented the ESRD Prospective Payment System (PPS) since 2011 to improve the quality of dialysis care while reduce costs through financing reforms. Different from the traditional fee-for-service payment model, dialysis facilities receive bundled payment per dialysis treatment from this PPS for their dialysis services. The bundled payment is adjusted based on patient-level and facility-level factors, and covers supplies, equipment, laboratory services, oral medications, injectable drugs and biologicals\textsuperscript{18}. The ESRD PPS may pay an additional amount for high-cost patients based on medical necessity. Meanwhile, ESRD PPS provides training add-on payment to facilities for patients with home and self-dialysis modalities. The most current ESRD PPS base rate is $239.33 in 2020\textsuperscript{18}. Usually, patients pay 20% of the payment and insurance pays the rest\textsuperscript{18}.

The ESRD Quality Incentive Program (QIP) invokes the value-based purchasing concept to incentivize dialysis facilities to improve healthcare quality\textsuperscript{19}. The ESRD QIP evaluates facilities’ performance through quality measures and then links this to part of Medicare bundled PPS payments. Facilities receive payment penalty of up to 2% when their total performance score do not meet or exceed the minimum requirement set by CMS. Dialysis Facility Compare (DFC) program provides patients and their families a tool for comparing and selecting dialysis facilities based on their quality performance\textsuperscript{7}. Star ratings have, in recent years been applied to individual dialysis facilities, based on core quality measures

The CMS Innovation Center implemented the Comprehensive ESRD Care (CEC) Model from 2015 October-2020 December. The CEC Model tests whether the creation of ESRD Seamless Care Organizations (ESCOs), comprising of dialysis clinics, nephrologists, and other providers, can reduce Medicare expenditures while maintaining or improving the quality of care. ESCOs
who participate in the model agree to be accountable for care quality and cost of care for dialysis patients who are aligned to them. Dialysis organizations share in savings regardless of their size, but large dialysis organizations are responsible for shared losses. After 2 years (by 2017), the CEC Model reduced Medicare spending by $68 million, or 1.8%, compared to non-CEC beneficiaries. There was about 4% reduction in the number of hospitalizations, 8% decrease in catheter use and 1% increase in outpatient dialysis sessions. However, Medicare experienced an aggregate net loss of $46 million after taking into account shared savings payments made to ESCOs. The final results of the evaluation will be available after the program ends in December 2020.

**Advancing American Kidney Health**

In July 2019, the U.S. Department of Health and Human Services (HHS) launched a federal executive order—Advancing American Kidney Health Initiative (AAKH). HHS set three goals to improve kidney health in the United States: 1) reduce the number of Americans developing ESKD; 2) increase the number of new (incident) American patients on home dialysis or transplantation to 80% by 2025; and 3) double the number of organs available for transplantation by 2030. To achieve these ambitious goals, substantial changes will need to occur in the management of kidney disease at multiple levels, e.g., campaigns to raise societal awareness of kidney disease including the general public, health systems, providers, insurers and policy makers, earlier diagnosis and optimal management of all stages of the disease, enhancing quality of pre-ESRD care, increasing access to home dialysis options, and reforming the organ procurement and management system.

**Future Challenges**

Kidney failure represents a substantial health and financial burden for the United States. Based on current estimates, the burden of ESRD is projected to continue to grow at least until 2030. The Advancing American Kidney Health initiative has raised hope for those who suffer from kidney disease in this country. For this to be realized, raising societal awareness of kidney disease with increased focus on prevention through attention to social and environmental determinants of health and enhanced access to high quality care, should be among the top priorities. Once ESRD is imminent, greater access to home dialysis and kidney transplantation, continually enhancing the quality of patient-centered care, and increasing the supply of donor kidneys is vitally important.
Disclosures
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Author Contributions
Y Han: Conceptualization; Investigation; Writing - original draft; Writing - review and editing
R Saran: Conceptualization; Investigation; Validation; Writing - review and editing
References


### Table 1 Clinical dialysis practice and its financing in the United States

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<th>Measures</th>
<th>Statistics</th>
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<td><strong>Epidemiology of dialysis patients</strong></td>
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| Total ESRD patients in the United states in 2017                         | Incident case: 124,500 (370.2 per million/year)  
Prevalent case: 746,557 (2203.5 per million/year) | 2019 USRDS ADR  |
| Number of dialysis patients (per million people in the general population): Total (HD vs PD, 2017) | Incident cases: 359.3 (232.0 vs 37.4)  
Prevalent cases: 1545.8 (1381.6 vs 155.6) | 2019 USRDS ADR  |
| Percent of ESRD patients on home dialysis (2017)                         | Incident cases: 10.5%  
Prevalent cases: 8.3% | 2019 USRDS ADR  |
| Primary cause of ESRD in incident dialysis patients: Total (HD vs PD, 2017) | Diabetes: 47% (48% vs 44%)  
Hypertension: 29% (30% vs 28%)  
Glomerulonephritis: 7% (6% vs 13%)  
Cystic kidney: 3% (2% vs 6%)  
Other/Unknown: 14% (14% vs 8%) | 2019 USRDS ADR  |
| Standardized mortality rate: Total (HD vs PD vs Transplant, 2017)        | 134 (167 vs 156 vs 29) per 1,000 patient-year                                                | 2019 USRDS ADR  |
| Hospitalization: HD vs PD, 2016                                         | 1.7 vs 1.7 per patient-year                                                                  | 2018 USRDS ADR  |
| Proportion of readmission within 30 day of discharge: HD vs PD, 2016     | 37.5% vs 37.1%                                                                               | 2018 USRDS ADR  |
| Emergency department visit: HD vs PD, 2016                              | 3.0 vs 2.3 per patient-year                                                                   | 2018 USRDS ADR  |
| Observation stay: HD vs PD, 2016                                        | 0.4 vs 0.2 per patient-year                                                                   | 2018 USRDS ADR  |
| **Pre-ESRD care**                                                        |                                                                                               |                 |
| Proportion of receiving Pre-ESRD nephrology care                         | >12 months: 32.6%  
6-12 months 19.9%  
0-6 months :14.2  
None 19.2%  
Unknown/Missing:14.1% | 2019 USRDS ADR  |
| Clinical characteristics by pre-ESRD nephrology care: >12 months vs none | Dietary care: 13.3% vs 0.3%  
Erythropoiesis-stimulating agents use:  
21.7% vs 2.2%  
AV fistula: 24.4% vs 2.4%  
Central venous catheter: 51.7% vs 92.6%  
eGFR<5: 11.8% vs 19.7% | 2019 USRDS ADR  |
| Vascular access in HD patients (2018)                                   | AV fistula: 62.9%  
AV graft: 17.5%  
Central venous catheter 19.6% | 2019 USRDS ADR  |
| **Provision of care**                                                    |                                                                                               |                 |
| **Average full-time employee (FTE)** | Physician FTEs: 0.05±0.47  
Nursing FTEs: 4.24±3.59  
Technician FTEs: 6.01±4.68  
Other clinical FTEs: 0.70±1.81 | Shreay S et al. 2014 |
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<td><strong>Average length of a dialysis session</strong></td>
<td>216.5±26.1 minutes</td>
<td>Flythe JE et al. 2013</td>
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| **Frequency of seen by nephrologist during dialysis sessions** | <4 times per month: 32%  
4 times per month: 51%  
>4 times per month: 17% | Kawaguchi T et al. 2013 |
| **Type of dialysis units in 2020** | Profit: 89%  
Non-profit: 11% | 2020 Dialysis Facility Compare |
| **Distribution of patients by unit affiliation in 2011 (proportion)** | Hospital-based: 9% (13%)  
Large dialysis organizations: 63% (66%)  
Independent Units: 14% (13%)  
Small Dialysis organizations: 14% (12%) | 2014 USRDS ADR |
| **Financing of dialysis** | All ESRD patients are eligible to Medicare coverage | Rettig RA 2011 |
| | Dominant payer: Medicare, as a federal health insurance program  
Other payers: Medicaid, the Veterans Affairs, private insurers and other assistance programs | NIDDK Financial help for treatment of kidney failure |
| **Regulations in dialysis financing** | January 2011: Implementation of the ESRD Prospective Payment System (PPS)  
January 2012: Implementation of ESRD Quality Incentive Program (QIP)  
October 2015: Implementation of Dialysis Facility Compare program (star ratings)  
October 2015: Implementation of the Comprehensive ESRD Care (CEC) Model by the creation of ESRD Seamless Care Organizations (ESCOs)  
July 2019: Launch of a federal executive order-Advancing American Kidney Health Initiative (AAKH) | |
| **Reimbursement per dialysis session in $US** | Base rate: $239.33 | 2020 CMS Prospective Payment System |
| **Medicare expending** | Total: 46.6 billion | 2019 USRDS ADR |
Medicare fee-for-service Plan: 35.9 billion
Medicare Advantage Plan: 10.7 billion

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<th>Per person per year Medicare spending in 2017</th>
<th>HD: $91.795</th>
<th>2019 USRDS ADR</th>
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<tr>
<td></td>
<td>PD: $78,159</td>
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<td>Transplant: $35,817</td>
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Abbreviations: ESRD, end-stage renal disease; HD, hemodialysis; PD, peritoneal dialysis; USRDS, United States Renal Data System; ADR, Annual Data Report; CMS, Centers for Medicare & Medicaid Services; eGFR, estimated Glomerular filtration rate; AV, arteriovenous.
Figure 1. Trends in the annual number of ESRD incident cases and prevalent cases, by modality, in the US population, 1980-2017

(a) Incident

(b) Prevalent


Abbreviation: ESRD, end-stage renal disease. Persons with “Uncertain Dialysis” were included in the “All ESRD” total, but are not represented separately.
Figure 2. Trends in the number of incident and prevalent ESRD cases using home dialysis, by type of therapy, in the US population, 1996-2017

(a) Incident

(b) Prevalent


Abbreviation: ESRD, end-stage renal disease.