

Targeted Efforts Needed to Combat Kidney Failure in Native Hawaiians, Pacific Islanders

By Bridget M. Kuehn



or nephrologists working in Hawaii, like David Na'ai, MD, it's not uncommon to have caseloads of nearly 200 patients—double the 75 to 100 recommended. Na'ai, associate professor at the John A. Burns School of Medicine at the University of Hawai'i in Honolulu, described the situation as "near crisis levels." The island is home to approximately one-quarter of the Native Hawaiians and Pacific Islanders (NHPIs) living in the United States (1), according to the US Department of Health and Human Services Office of Minority Health. Asian Americans are the largest racial or ethnic group on the island (2). These two groups saw the largest increases in end stage kidney disease (ESKD) of any racial or ethnic group in the United States—approximately 100% and 150%, respectively—between 2000 and 2019, according to a recent US Centers for Disease Control and Prevention (CDC) report (3). Yet, accessing care can be a challenge.

The state faces a shortage of between 537 and 732 physicians overall, according to the Annual Report on Findings from the Hawai'i Physician Workforce Assessment Project (4). According to the report, the state currently has only approximately 30 nephrologists and needs approximately 16 more to meet the demand. Most specialists in the state practice on Oahu, Na'ai said. Patients living on some other islands may have limited access to in-center dialysis or specialist care, and traveling to Oahu may be cost prohibitive for some. For example, the sole dialysis unit in rural Moloka'i has just eight chairs. "We don't have enough providers, and especially, we don't have enough providers [who] are from the community or understand the community," he said.

This shortage contributes to difficulties for patients accessing care or receiving culturally sensitive care to prevent and treat kidney diseases. Several local initiatives aim to reduce health disparities and build across specialties a more robust workforce of physicians who are either Native Hawaiian or who have the cultural competency necessary to provide the best care possible. Additionally, the National Institutes of Health (NIH) and President Biden have recently organized federal initiatives to address health and other disparities affecting Asian American and Pacific Islander communities.

Disaggregating disparities

Most clinicians working in Hawaii suspected that NHPIs experienced disproportionately high rates of kidney diseases. But the true magnitude of the disparities has long been ob-

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The Joint Commission Provides Recognition for NBPAS

By Eric Seaborg

he National Board of Physicians and Surgeons (NBPAS) apparently received another boost toward wider acceptance of its recertification program when The Joint Commission added the organization to its list of "designated equivalent source agencies" in its accreditation manuals.

The NBPAS was founded in 2015 in reaction to what its founders saw as the expensive and onerous maintenance of certification requirements of the American Board of Medical Specialties (ABMS) and the American Osteopathic Association. The NBPAS process is designed to provide "physicians with a choice in board recertification that is clinically rigorous, evidence-based, less burdensome, and nationally accepted," according to its website.

"This is another important milestone for the National Board of Physicians and Surgeons," said NBPAS Founder and President Paul Teirstein, MD, who is chief of cardiology at the Scripps Clinic in San Diego. "Hospitals and health systems look to the The Joint Commission standards as important benchmarks for accreditation."

However, ABMS immediately objected to any assertion of "certifying body equivalency" by NBPAS. NBPAS does not provide original board certification, only what it terms "recertification" of physicians board-certified by ABMS, and only in their original specialties. NBPAS recertification is

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Inside

The Kidney Care Team

As the patient pool increases, our special section looks at how nurse practitioners, physician assistants, advanced practitioners, and PharmDs play an increasingly important role in kidney care.



A call for kidney eco-warriors

AL amyloidosis

Is it time to consider kidney transplant to manage kidney diseases in amyloid light chain amyloidosis?



KRYSTEXXA (PEGLOTICASE) IS A RECOMBINANT INTO ALLANTOIN¹



RENAL EXCRETION OF ALLANTOIN IS UP TO 10 TIMES MORE EFFICIENT THAN EXCRETION OF URIC ACID²

INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATIONS AND USAGE

KRYSTEXXA[®] (pegloticase) is indicated for the treatment of chronic gout in adult patients who have failed to normalize serum uric acid and whose signs and symptoms are inadequately controlled with xanthine oxidase inhibitors at the maximum medically appropriate dose or for whom these drugs are contraindicated.

Important Limitations of Use: KRYSTEXXA is not recommended for the treatment of asymptomatic hyperuricemia.

IMPORTANT SAFETY INFORMATION

WARNING: ANAPHYLAXIS AND INFUSION REACTIONS

Anaphylaxis and infusion reactions have been reported to occur during and after administration of KRYSTEXXA. Anaphylaxis may occur with any infusion, including a first infusion, and generally manifests within 2 hours of the infusion. However, delayed-type hypersensitivity reactions have also been reported. KRYSTEXXA should be administered in healthcare settings and by healthcare providers prepared to manage anaphylaxis and infusion reactions. Patients should be premedicated with antihistamines and corticosteroids. Patients should be closely monitored for an appropriate period of time for anaphylaxis after administration of KRYSTEXXA. Monitor serum uric acid levels prior to infusions and consider discontinuing treatment if levels increase to above 6 mg/dL, particularly when 2 consecutive levels above 6 mg/dL are observed.

The risk of anaphylaxis and infusion reactions is higher in patients who have lost therapeutic response.

Concomitant use of KRYSTEXXA and oral urate-lowering agents may blunt the rise of sUA levels. Patients should discontinue oral urate-lowering agents and not institute therapy with oral urate-lowering agents while taking KRYSTEXXA.

In the event of anaphylaxis or infusion reaction, the infusion should be slowed, or stopped and restarted at a slower rate.

References: 1. KRYSTEXXA (pegloticase) [prescribing information] Horizon. **2.** McDonagh EM, et al. *Pharmacogenet Genomics*. 2014;24:464-476. **3.** Terkeltaub R, et al. *Arthritis Res Ther*. 2006;8(suppl 1):S4.



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Inform patients of the symptoms and signs of anaphylaxis, and instruct them to seek immediate medical care should anaphylaxis occur after discharge from the healthcare setting.

CONTRAINDICATIONS: G6PD DEFICIENCY ASSOCIATED HEMOLYSIS AND METHEMOGLOBINEMIA

Screen patients for G6PD deficiency prior to starting KRYSTEXXA. Hemolysis and methemoglobinemia have been reported with KRYSTEXXA in patients with G6PD deficiency. Do not administer KRYSTEXXA to these patients.

GOUT FLARES

An increase in gout flares is frequently observed upon initiation of anti-hyperuricemic therapy, including treatment with KRYSTEXXA. If a gout flare occurs during treatment, KRYSTEXXA need not be discontinued. Gout flare prophylaxis with a non-steroidal anti-inflammatory drug (NSAID) or colchicine is recommended starting at least 1 week before initiation of KRYSTEXXA therapy and lasting at least 6 months, unless medically contraindicated or not tolerated.

CONGESTIVE HEART FAILURE

KRYSTEXXA has not been studied in patients with congestive heart failure, but some patients in the clinical trials experienced exacerbation. Exercise caution when using KRYSTEXXA in patients who have congestive heart failure and monitor patients closely following infusion.

ADVERSE REACTIONS

The most commonly reported adverse reactions in clinical trials with KRYSTEXXA are gout flares, infusion reactions, nausea, contusion or ecchymosis, nasopharyngitis, constipation, chest pain, anaphylaxis and vomiting.

Please see Brief Summary of Prescribing Information, including Boxed Warning, for KRYSTEXXA on the following page.





(pegloticase injection), for intravenous infusion

Brief Summary - Please see the KRYSTEXXA package insert for Full Prescribing Information.

WARNING: ANAPHYLAXIS and INFUSION REACTIONS; G6PD DEFICIENCY ASSOCIATED HEMOLYSIS and METHEMOGLOBINEMIA

- Anaphylaxis and infusion reactions have been reported to occur during and after administration of KRYSTEXXA.
- Anaphylaxis may occur with any infusion, including a first infusion, and generally manifests within 2 hours of the infusion. However, delayed-type hypersensitivity reactions have also been reported.
- KRYSTEXXA should be administered in healthcare settings and by healthcare providers prepared to manage anaphylaxis and infusion reactions.
- Patients should be pre-medicated with antihistamines and corticosteroids.
- Patients should be closely monitored for an appropriate period of time for anaphylaxis after administration of KRYSTEXXA.
- Monitor serum uric acid levels prior to infusions and consider discontinuing treatment if levels increase to above 6 mg/dL, particularly when 2 consecutive levels above 6 mg/dL are observed.
- Screen patients at risk for G6PD deficiency prior to starting KRYSTEXXA. Hemolysis and methemoglobinemia have been reported with KRYSTEXXA in patients with G6PD deficiency. Do not administer KRYSTEXXA to patients with G6PD deficiency.

INDICATIONS AND USAGE

KRYSTEXXA[®] (pegloticase) is a PEGylated uric acid specific enzyme indicated for the treatment of chronic gout in adult patients refractory to conventional therapy.

Gout refractory to conventional therapy occurs in patients who have failed to normalize serum uric acid and whose signs and symptoms are inadequately controlled with xanthine oxidase inhibitors at the maximum medically appropriate dose or for whom these drugs are contraindicated.

Important Limitations of Use:

KRYSTEXXA is not recommended for the treatment of asymptomatic hyperuricemia.

CONTRAINDICATIONS

Glucose-6-phosphate dehydrogenase (G6PD) deficiency

WARNINGS AND PRECAUTIONS Anaphylaxis

During pre-marketing clinical trials, anaphylaxis was reported with a frequency of 6.5% (8/123) of patients treated with KRYSTEXXA every 2 weeks and 4.8% (6/126) for the every 4-week dosing regimen. There were no cases of anaphylaxis in patients receiving placebo. Anaphylaxis generally occurred within 2 hours after treatment. Diagnostic criteria of anaphylaxis were skin or mucosal tissue involvement, and, either airway compromise, and/ or reduced blood pressure with or without associated symptoms, and a temporal relationship to KRYSTEXXA or placebo injection with no other identifiable cause. Manifestations included wheezing, peri-oral or lingual edema, or hemodynamic instability, with or without rash or urticaria. Cases occurred in patients being pre-treated with one or more doses of an oral antihistamine, an intravenous corticosteroid and/or acetaminophen. This pre-treatment may have blunted or obscured symptoms or signs of anaphylaxis and therefore the reported frequency may be an underestimate

KRYSTEXXA should be administered in a healthcare setting by healthcare providers prepared to manage anaphylaxis. Patients should be pre-treated with antihistamines and corticosteroids. Anaphylaxis may occur with any infusion, including a first infusion, and generally manifests within 2 hours of the infusion. However, delayed type hypersensitivity reactions have also been reported. Patients should be closely monitored for an appropriate period of time for anaphylaxis after administration of KRYSTEXXA. Patients should be informed of the symptoms and signs of anaphylaxis and instructed to seek immediate medical care should anaphylaxis occur after discharge from the healthcare setting.

The risk of anaphylaxis is higher in patients whose uric acid level increases to above 6 mg/dL, particularly when 2 consecutive levels above 6 mg/dL are observed. Monitor serum uric acid levels prior to infusions and consider discontinuing treatment if levels increase to above 6 mg/ dL. Because of the possibility that concomitant use of oral urate-lowering therapy and KRYSTEXXA may potentially blunt the rise of serum uric acid levels, it is recommended that before starting KRYSTEXXA patients discontinue oral urate-lowering medications and not institute therapy with oral urate-lowering agents while taking KRYSTEXXA.

Infusion Reactions

During pre-marketing controlled clinical trials, infusion reactions were reported in 26% of patients treated with KRYSTEXXA 8 mg every 2 weeks, and 41% of patients treated with KRYSTEXXA 8 mg every 4 weeks, compared to 5% of patients treated with placebo. These infusion reactions occurred in patients being pre-treated with an oral antihistamine, intravenous corticosteroid and/ or acetaminophen. This pre-treatment may have blunted or obscured symptoms or signs of infusion reactions and therefore the reported frequency may be an underestimate.

Manifestations of these reactions included urticaria (frequency of 10.6%), dyspnea (frequency of 7.1%), chest discomfort (frequency of 9.5%), chest pain (frequency of 9.5%), erythema (frequency of 9.5%), and pruritus (frequency of 9.5%). These manifestations overlap with the symptoms of anaphylaxis, but in a given patient did not occur together to satisfy the clinical criteria for diagnosing anaphylaxis. Infusion reactions are thought to result from release of various mediators, such as cytokines. Infusion reactions occurred at any time during a course of treatment with approximately 3% occurring with the first infusion, and approximately 91% occurred during the time of infusion.

KRYSTEXXA should be administered in a healthcare setting by healthcare providers prepared to manage infusion reactions. Patients should be pre-treated with antihistamines and corticosteroids. KRYSTEXXA should be infused slowly over no less than 120 minutes. In the event of an infusion reaction, the infusion should be slowed, or stopped and restarted at a slower rate.

The risk of infusion reaction is higher in patients whose uric acid level increases to above 6 mg/dL, particularly when 2 consecutive levels above 6 mg/dL are observed. Monitor serum uric acid levels prior to infusions and consider discontinuing treatment if levels increase to above 6 mg/dL. Because of the possibility that concomitant use of oral urate-lowering therapy and KRYSTEXXA may potentially blunt the rise of serum uric acid levels, it is recommended that before starting KRYSTEXXA patients discontinue oral urate-lowering medications and not institute therapy with oral urate-lowering agents while taking KRYSTEXXA.

G6PD Deficiency Associated Hemolysis and Methemoglobinemia

Life threatening hemolytic reactions and methemoglobinemia have been reported with KRYSTEXXA in patients with glucose-6-phosphate dehydrogenase (G6PD) deficiency. Because of the risk of hemolysis and methemoglobinemia, do not administer KRYSTEXXA to patients with G6PD deficiency [see Contraindications]. Screen patients at risk for G6PD deficiency prior to starting KRYSTEXXA. For example, patients of African, Mediterranean (including Southern European and Middle Eastern), and Southern Asian ancestry are at increased risk for G6PD deficiency.

Gout Flares

During the controlled treatment period with KRYSTEXXA or placebo, the frequencies of gout flares were high in all treatment groups, but more so with KRYSTEXXA treatment during the first 3 months of treatment, and decreased in the subsequent 3 months of treatment. The percentages of patients with any flare for the first 3 months were 74%, 81%, and 51%, for KRYSTEXXA 8 mg every 2 weeks, KRYSTEXXA 8 mg every 4 weeks, and placebo, respectively. The percentages of patients with any flare for the subsequent 3 months were 41%, 57%, and 67%, for KRYSTEXXA 8 mg every 2 weeks, KRYSTEXXA 8 mg every 4 weeks, and placebo, respectively. Patients received gout flare prophylaxis with colchicine and/or nonsteroidal antiinflammatory drugs (NSAIDs) starting at least one week before receiving KRYSTEXXA.

Gout flares may occur after initiation of KRYSTEXXA. An increase in gout flares is frequently observed upon initiation of anti-hyperuricemic therapy, due to changing serum uric acid levels resulting in mobilization of urate from tissue deposits. Gout flare prophylaxis with a nonsteroidal anti-inflammatory drug (NSAID) or colchicine is recommended starting at least 1 week before initiation of KRYSTEXXA therapy and lasting at least 6 months, unless medically contraindicated or not tolerated. KRYSTEXXA does not need to be discontinued because of a gout flare. The gout flare should be managed concurrently as appropriate for the individual patient.

Congestive Heart Failure

KRYSTEXXA has not been formally studied in patients with congestive heart failure, but some patients in the clinical trials experienced exacerbation. Two cases of congestive heart failure exacerbation occurred during the trials in patients receiving treatment with KRYSTEXXA 8 mg every 2 weeks. No cases were reported in placebo-treated patients. Four subjects had exacerbations of pre-existing congestive heart failure while receiving KRYSTEXXA 8 mg every 2 weeks during the open-label extension study. Exercise caution when using KRYSTEXXA in patients who have congestive heart failure and monitor patients closely following infusion.

Re-treatment with KRYSTEXXA

No controlled trial data are available on the safety and efficacy of re-treatment with KRYSTEXXA after stopping treatment for longer than 4 weeks. Due to the immunogenicity of KRYSTEXXA, patients receiving re-treatment may be at increased risk of anaphylaxis and infusion reactions. Therefore, patients receiving retreatment after a drug-free interval should be monitored carefully.

ADVERSE REACTIONS

The following serious adverse reactions are discussed in greater detail in other sections of the label:

- Anaphylaxis [see Warnings and Precautions]
- Infusion Reactions [see Warnings and Precautions]
- G6PD Deficiency Associated Hemolysis and Methemoglobinemia [see Warnings and Precautions]
- Gout Flares [see Warnings and Precautions]
- · Congestive Heart Failure [see Warnings and Precautions]

Clinical Trials Experience

The data described below reflect exposure to KRYSTEXXA in patients with chronic gout refractory to conventional therapy in two replicate randomized, placebo-controlled, double-blind 6-month clinical trials: 85 patients were treated with KRYSTEXXA 8 mg every 2 weeks; 84 patients were treated with KRYSTEXXA 8 mg every 4 weeks; and 43 patients were treated with placebo.

Because clinical studies are conducted under widely varying and controlled conditions, adverse reaction rates observed in clinical studies of a drug cannot be directly compared to rates in the clinical studies of another drug, and may not predict the rates observed in a broader patient population in clinical practice.

The most common adverse reactions that occurred in \geq 5% of patients treated with KRYSTEXXA 8 mg every 2 weeks are provided in Table 1.

Table 1. Adverse Reactions Occurring in 5% orMore of Patients Treated with KRYSTEXXA Comparedto Placebo

| Adverse Reaction (Preferred Term) | KRYSTEXXA 8 mg every 2 weeks (N=85) N ^a (%) | Placebo (N=43) N (%) |
|--|---|----------------------------|
| Gout flare | 65 (77%) | 35 (81%) |
| Infusion reaction | 22 (26%) | 2 (5%) |
| Nausea | 10 (12%) | 1 (2%) |
| Contusion ^b or Ecchymosis ^b | 9 (11%) | 2 (5%) |
| Nasopharyngitis | 6 (7%) | 1 (2%) |
| Constipation | 5 (6%) | 2 (5%) |
| Chest Pain | 5 (6%) | 1 (2%) |
| Anaphylaxis | 4 (5%) | 0 (0%) |
| Vomiting | 4 (5%) | 1 (2%) |

^a If the same subject in a given group had more than one occurrence in the same preferred term event category, the subject was counted only once.

^b Most did not occur on the day of infusion and could be related to other factors (e.g., concomitant medications relevant to contusion or ecchymosis, insulin dependent diabetes mellitus).

Immunogenicity

Anti-pegloticase antibodies developed in 92% of patients treated with KRYSTEXXA every 2 weeks, and 28% for placebo. Anti-PEG antibodies were also detected in 42% of patients treated with KRYSTEXXA. High anti-pegloticase antibody titer was associated with a failure to maintain pegloticase-induced normalization of uric acid. The impact of anti-PEG antibodies on patients' responses to other PEG-containing therapeutics is unknown.

There was a higher incidence of infusion reactions in patients with high anti-pegloticase antibody titer: 53% (16 of 30) in the KRYSTEXXA every 2 weeks group compared to 6% in patients who had undetectable or low antibody titers.

As with all therapeutic proteins, there is a potential for immunogenicity. The observed incidence of antibody positivity in an assay is highly dependent on several factors including assay sensitivity and specificity and assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, the comparison of the incidence of antibodies to pegloticase with the incidence of antibodies to other products may be misleading.

Postmarketing Experience

General disorders and administration site conditions: asthenia, malaise, peripheral swelling have been identified during postapproval use of KRYSTEXXA. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship.

USE IN SPECIFIC POPULATIONS

Pregnancy

<u>Risk Summary</u> There are no adequate and well-controlled studies of KRYSTEXXA in pregnant women. Based on animal reproduction studies, no structural abnormalities were observed when pegloticase was administered by subcutaneous injection to pregnant rats and rabbits during the period of organogenesis at doses up to 50 and 75 times, respectively, the maximum recommended human dose (MRHD). Decreases in mean fetal and pup body weights were observed at approximately 50 and 75 times the MRHD, respectively.

All pregnancies have a background risk of birth defect, loss or other adverse outcomes. In the US general population, the estimated background risk of major birth defects and miscarriage in clinical recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

<u>Data</u> Animal Data

In 2 separate embryo-fetal developmental studies, pregnant rats and rabbits received pegloticase during the period of organogenesis at doses up to approximately 50 and 75 times the maximum recommended human dose (MRHD), respectively (on a mg/m2 basis at maternal doses up to 40 and 30 mg/kg twice weekly, in rats and rabbits, respectively). No evidence of structural abnormalities was observed in rats or rabbits. However, decreases in mean fetal and pup body weights were observed at approximately 50 and 75 times the MRHD in rats and rabbits, respectively (on a mg/m2 basis at maternal doses up to 40 and 30 mg/kg every other day, in rats and rabbits, respectively). No effects on mean fetal body weights were observed at approximately 10 and 25 times the MRHD in rats and rabbits, respectively (on a mg/m2 basis at maternal doses up to 10 mg/kg twice weekly in both species).

Lactation

Risk Summary

It is not known whether this drug is excreted in human milk. Therefore, KRYSTEXXA should not be used when breastfeeding unless the clear benefit to the mother can overcome the unknown risk to the newborn/infant.

Pediatric Use

The safety and effectiveness of KRYSTEXXA in pediatric patients less than 18 years of age have not been established.

Geriatric Use

Of the total number of patients treated with KRYSTEXXA 8 mg every 2 weeks in the controlled studies, 34% (29 of 85) were 65 years of age and older and 12% (10 of 85) were 75 years of age and older. No overall differences in safety or effectiveness were observed between older and younger patients, but greater sensitivity of some older individuals cannot be ruled out. No dose adjustment is needed for patients 65 years of age and older.

Renal Impairment

No dose adjustment is required for patients with renal impairment. A total of 32% (27 of 85) of patients treated with KRYSTEXXA 8 mg every 2 weeks had a creatinine clearance of \leq 62.5 mL/min. No overall differences in efficacy were observed.

OVERDOSAGE

No reports of overdosage with KRYSTEXXA have been reported. The maximum dose that has been administered as a single intravenous dose is 12 mg as uricase protein. Patients suspected of receiving an overdose should be monitored, and general supportive measures should be initiated as no specific antidote has been identified.

PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Medication Guide).

General Information

Provide and instruct patients to read the accompanying Medication Guide before starting treatment and before each subsequent treatment.

Anaphylaxis and Infusion Reactions

- Anaphylaxis and infusion reactions can occur at any infusion while on therapy. Counsel patients on the importance of adhering to any prescribed medications to help prevent or lessen the severity of these reactions.
- Educate patients on the signs and symptoms of anaphylaxis, including wheezing, peri-oral or lingual edema, hemodynamic instability, and rash or urticaria.
- Educate patients on the most common signs and symptoms of an infusion reaction, including urticaria (skin rash), erythema (redness of the skin), dyspnea (difficulty breathing), flushing, chest discomfort, chest pain, and rash.
- Advise patients to seek medical care immediately if they experience any symptoms of an allergic reaction during or at any time after the infusion of KRYSTEXXA.
- Advise patients to discontinue any oral urate-lowering agents before starting on KRYSTEXXA and not to take any oral urate-lowering agents while on KRYSTEXXA.

Glucose-6-phosphate dehydrogenase (G6PD) Deficiency

Inform patients not to take KRYSTEXXA if they have a condition known as G6PD deficiency. Explain to patients that G6PD deficiency is more frequently found in individuals of African, Mediterranean, or Southern Asian ancestry and that they may be tested to determine if they have G6PD deficiency, unless already known.

Gout Flares

Explain to patients that gout flares may initially increase when starting treatment with KRYSTEXXA, and that medications to help reduce flares may need to be taken regularly for the first few months after KRYSTEXXA is started. Advise patients that they should not stop KRYSTEXXA therapy if they have a flare.

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Kidney Failure in Native Hawaiians and Pacific Islanders

Continued from cover

scured by national data that lumped Asian Americans and NHPIs into one group until 1997.

"We were pretty much a hidden community," explained Martina Kamaka, MD, a family physician and associate professor in the Department of Native Hawaiian Health at the University of Hawaii. "We are a very small part of the national population, so it was easy to overlook us."

A report published in April 2022 (5) summarized the results of a 2021 NIH workshop focusing on health disparities in Asian American and NHPI communities. It noted that in 2020, there were 1.6 million NHPIs in the United States compared with approximately 24 million Asian Americans. Together, the two groups accounted for approximately 7.7% of the US population and encompassed more than 40 ethnic subgroups with distinct cultures, languages, and socioeconomic circumstances. The report noted that lumping them into one group can mask serious health disparities and make it difficult to identify their causes or the best interventions.

Disaggregation of these groups has begun to bring some of these disparities into stark relief. In a 2019 article, Na'ai and Kalani Raphael, MD, an associate professor of nephrology and hypertension at the University of Utah, noted that in 2017, EKSD incidence among NHPIs was approximately eight times higher than in White individuals (6). At that time, ESKD rates were comparable among people who were Asian American and White.

Growing rates of hypertension and diabetes are driving factors in overall increases in US ESKD rates and rising rates among people who are Asian American and NHPIs, according to the CDC report. The NIH committee's report noted that type 2 diabetes is more prevalent among NHPIs and typically occurs 10 to 15 years earlier than among White populations in the United States. Diabetes is frequently an exacerbating factor in kidney diseases among Asian and NHPI populations. NHPIs also have the highest rates of hypertension of any racial or ethnic group.

Socioeconomic factors play a significant role in driving these disparities, Na'ai said. Many NHPIs continue to deal with colonialism's social and economic fallout. This includes the aftereffects of the United States overthrowing the Hawaiian government in 1893 and testing nuclear weapons in the Marshall Islands, which forced many to relocate. Approximately 15% of NHPIs live at the poverty level compared with approximately 9% of people who are White, according to the Office of Minority Health (1).

A lack of health insurance can also be a hurdle to care for many Pacific Islanders. Na'ai noted that Hawaii requires employers to provide health insurance. Provisions in the Compact of Free Association in 1986 allowed citizens of three Pacific Island nations to access Medicaid and other federal services and allowed a US military presence. However, Medicaid coverage was stripped from citizens of these nations in 1996 during welfare reform, leaving many Pacific Islanders with low incomes living in the United States without access to health insurance. Congress later passed legislation in late 2002 that restored Medicaid coverage (7).

The disproportionate impact of COVID-19 on NHPI communities has driven many of these socioeconomic and health disparities to the forefront, Kamaka noted. In five US states with large numbers of NHPI residents, NHPI people experienced the highest COVID-19 rates of any racial or ethnic group (8). For example, in California, NHPIs experienced 217.7 COVID-19 cases per 100,000 compared with 62.43 per 100,000 state residents who are non-NHPIs. "COVID-19 brought us national attention," Kamaka said. "I hope that this momentum continues."

Cultural competency

Native Hawaiian-led organizations and initiatives have long focused on reducing health disparities in their communi-

ties and recruiting more Native Hawaiians to the physician workforce.

Papa Ola Lokahi (9), a nonprofit organization devoted to improving Native Hawaiian health, received funding from the CDC to create the Pacific Diabetes Education Program (10). The program created culturally and linguistically appropriate diabetes prevention and education materials explicitly tailored for Native Hawaiians and several other Pacific Islander communities. Although the 5-year program ended in 2010, the materials remain available for use online, said Kim Ku'ulei Birnie, who leads the communications for Papa Ola Lokahi, in an email. Papa Ola Lokahi's Native Hawaiian Health Scholarship Program has awarded 310 scholarships to Native Hawaiian people pursuing careers in 20 different health professions, including nephrologist Leilani Ka'anehe, according to Ku'ulei Birnie. As part of the program, recipients agree to provide care in underserved communities in Hawaii for 2-4 years.

Native Hawaiian physicians also banded together in 1998 to form "Ahahui o nā Kauka," the Association of Native Hawaiian Physicians (11). Many longtime Native Hawaiian physicians, including the current president of the organization, Noa Emmett Aluli, MD, served as mentors to younger physicians in the group, Kamaka said.

"We were Western-trained [physicians], and we were being confronted with these health care disparities in our own people and trying to figure out how to connect because we were a little disconnected culturally," Kamaka said. The association worked first to educate its members, then faculty at the University of Hawai'i, and physicians in Hawaii, she said. Then, Kamaka created a cultural competency curriculum (12) for medical students at the University of Hawai'i to teach them about health disparities, their historical roots in trauma and colonization, and how to serve Native Hawaiians and other underserved communities better.

Kamaka said, as a resident in Lancaster, PA, her experiences working with patients who were Black, Hispanic, Amish, and Mennonite made her acutely aware of some of the limitations of the training she received and the need to be culturally literate. After returning to Hawaii, Kamaka realized she needed to be more attuned to traditional healing practices. Patients were using them and were afraid to tell her for fear of being looked down on or kicked out of her practice. "It was a personal journey to understand culture was important," she said. "I realized communication was really important."

The curriculum provides students with basic information about Native Hawaiian traditional healing practices. It helps connect them with traditional healers they can call if they have questions and covers how to ask patients about their practices. "We encourage a dialogue because I believe there is a place for both [traditional and Western medicine]," Kamaka said. "We've been trying to take care of these disparities in our Western medicine way, and it is not working. We have to look at it differently."

The program teaches students about Hawaiian culture and gets them into communities to help with service projects. "Health is holistic for most people," Kamaka explained. "It's not only spiritual health and emotional but also a connection to the land."

She emphasized the importance of physicians understanding what resources are available in their patients' communities and the challenges they may face. A patient working two jobs and coming home to a neighborhood with no sidewalks after dark may struggle to follow a doctor's recommendation to walk 30 minutes a day, 5 days a week. Or an elderly patient with limited means living in an intergenerational home may not feel comfortable asking family members to prepare him or her special meals. "You've got to get the whole family involved," Kamaka said.

Na'ai also emphasized the importance of physicians working with Native Hawaiian communities and understanding the communities' values and recognizing how their history has led to a distrust of Western medicine. "You can't tell patients what to do; you have to give them options," he said.

Sustained efforts

The renewed attention to NHPI well-being at the federal level was heartening to Na'ai and Kamaka. However, they both emphasized the need for sustained national attention and funding and efforts to address social determinants of health in these communities. "If we don't have the social determinants of health taken care of, we can throw all the meds in the world at them, and it is not going to make a difference," Kamaka said.

The NIH report (5) calls for more disaggregated research on Asian Americans, Native Hawaiians, and Pacific Islanders. It recommends researchers work in partnership with communities to examine community priorities and develop culturally and linguistically appropriate investigating protocols. It also calls for more recruitment to build a research and clinical workforce that includes more Asian Americans, Native Hawaiians, and Pacific Islanders.

In late May 2022, President Biden created the White House Initiative on Asian Americans, Native Hawaiians, and Pacific Islanders (13) to reduce discrimination and systemic barriers to equity for these groups. He also established a Presidential Advisory Commission on Asian Americans, Native Hawaiians, and Pacific Islanders to recommend public, private, and nonprofit approaches to boost equity, including health equity for these groups. The commission held its first meeting in June to begin establishing priorities.

"Hopefully, with more funding and recognition at the federal level, things can slowly change," Na'ai said.

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The Joint Commission Provides Recognition for NBPAS

Continued from cover

based on submission of continuing medical education credits, with no testing requirements.

"ABMS strongly disagrees with the persistent and misleading assertions that the NBPAS recertification process provides a means of continuing ABMS board certification or is equivalent to ABMS board certification," ABMS responded to the news in a statement on its website. "Claims of equivalence to ABMS certification or that NBPAS is a means to maintain ABMS member board certification are misleading to the profession, and most importantly, to the public who depend upon the strength of ABMS board certification."

Designated equivalent source

A letter from The Joint Commission Executive Vice President David W. Baker, MD, MPH, to NBPAS says: "NBPAS will be added to the list of designated equivalent source agencies in The Joint Commission's glossary for the Ambulatory Care, Behavioral Health and Human Services, Critical Access Hospital, Hospital, and Office-Based Surgery accreditation manuals effective July 2022."

The Joint Commission website defines a "designated equivalent source" as an agency that has "been determined to maintain a specific item(s) of credential(s) information that is identical to the information at the primary source. The glossary of the accreditation manual provides examples of such sources." Primary sources are used "for confirming that an individual possesses a valid license, certification, or registration to practice a profession."

A Joint Commission spokesperson responded "no comment" to repeated requests for clarification or information, particularly for an explanation of how NBPAS could be considered to have "information that is identical to the information at the primary source" when the primary source of certification—ABMS—maintains that NBPAS recertification is by no means equivalent to ABMS maintenance of certification.

NBPAS Associate Director Karen Schatten, MLS, said in an email to *Kidney News*: "NBPAS engaged in discussions with the Joint Commission, which agreed that NBPAS met their standards for designated equivalent source agencies.

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The study is currently enrolling patients.

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$\label{eq:starses} For more information, visit AlignStudy.com \ or \ Clinical Trials.gov: \ NCT04573478 \ .$



Atrasentan is an investigational agent and has not been approved for any uses, including in patients with IgA nephropathy

NBPAS apparently received another boost toward wider acceptance of its recertification program...

The Joint Commission added NBPAS as part of its regular standards update process."

Will hospitals react?

The Joint Commission itself does not control the credentialing of hospital personnel; hospitals decide what credentials to require and accept. The NBPAS website lists some 200 hospitals that "accept NBPAS diplomates," which is a relatively small number of the 6000 hospitals the American Hospital Association says exist in the United States.

"Now is a good time for hospitals and health systems to update their bylaws and add NBPAS as an option for physician credentialing and privileging requirements," said NBPAS' Teirstein.

"With the addition of The Joint Commission, NBPAS also meets national accreditation standards for hospitals and health plans that also include Det Norske Veritas, the National Committee [for] Quality Assurance, and the Utilization Review Accreditation Commission," according to an NBPAS press release.

ABMS' response says: "NBPAS has recently been listed as a sample source of information regarding a candidate physician's educational attainment for hospital or health plan credentialing services. However, to be clear, neither The Joint Commission nor the National Committee for Quality Assurance has rendered any [judgment] about the equivalency of NBPAS' certificate to an ABMS member board certification."

ABMS questions equivalence

"ABMS questions the rigor of NBPAS' process for ensuring the professionalism of its members," the statement continues. "ABMS has identified a number of physicians whose certificates were revoked by ABMS member boards and who are certified by NBPAS. The reasons for these revocations range from sexual harassment to mis-prescribing controlled substances and other professionalism issues. This type of physician behavior places patients at risk yet they maintain their NBPAS certificates."

ABMS and its member boards such as the American Board of Internal Medicine first adopted maintenance of certification requirements in 2000, with 10-year recertification exams and other requirements. Widespread dissatisfaction with these requirements—especially the high-stakes periodic examination—has led to extensive re-consideration of the process, with NBPAS' Teirstein not being alone in calling the maintenance of certification process "onerous, time-consuming, time-wasting, and expensive."

The ABMS statement notes that it has responded to physician dissatisfaction by completing a "comprehensive, transparent, and collaborative process" to review continuing certification processes to ensure they are "both relevant and supportive of diplomates' learning and improvement needs while providing the public with a reliable and dependable credential."

These reforms may have come too late for some physicians who agree with an NBPAS press release that "recertification through NBPAS offers physicians a less burdensome pathway to maintain board certification and is a tangible solution to burnout and the growing national physician shortage."



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| Dysglycemia | |

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ASN Executive Vice President's Update

A Commitment to Excellence in Kidney Care

By Tod Ibrahim



ver its nearly 60-year history, the A m e r i c a n Society of Nephrology (ASN) has approached the tripartite mission in phases, starting first with providing medical education, then advocating for research and innovation, and more recently, ensuring high-quali-

ty patient care. ASN's mission is to "elevate care by educating and informing, driving breakthroughs and innovation, and advocating for policies that create transformative changes in kidney medicine throughout the world (1).

Today, patient care is the tabletop, with education (undergraduate/graduate and continuing), research, and advocacy as the supporting legs. Diversity, equity, and inclusion are the joints that lock aprons (health care justice) to the legs, strengthening the table. As such, the first goal of the current ASN Strategic Plan emphasizes the need to advance the work of kidney medicine. More specifically, this goal requires ASN to commit to "creating a stronger focus on kidney health"; "intervening earlier to prevent, diagnose, coordinate care, and educate"; and "developing broad partnerships to address the health of the global population, promoting health equity, and advocating for high-quality therapies, including home dialysis and transplant."

While having a mission and articulating goals are important, the significance of strategic plans is identifying opportunities and challenges honestly, setting priorities ruthlessly, and completing projects meaningfully. The current ASN Strategic Plan went into effect on January 1, 2021, making this a good time to assess progress in accomplishing the first goal.

Creating a stronger focus on kidney health

According to *Merriam-Webster*, the adjective "hearthealthy"—which means "conducive to a healthy heart and circulatory system"—was first used in 1980 (2). More than 30 years later, the term "kidney health" (conducive to healthy kidneys and renal system) was first used regularly in public by then-ASN President Ronald J. Falk, MD, FASN.

In his ASN President's Address, "Time to Cure Kidney Disease," on November 1, 2012, Dr. Falk asserted, "We must challenge each other, all of us who care for patients, to ask our patients how we may restore their health" (3). Dr. Falk observed that the "focus on the stark realities of the sicknesses that we see and treat each and every day...has filled our vernacular with words overflowing with negative connotations: 'end stage,' 'chronic,' 'progressive,' 'inexorable,' and the '3 Ds' of doubling of the serum creatinine, dialysis, and death." These words "send powerful messages to our patients, our trainees, and indeed ourselves," he emphasized. "Is it possible that we can no longer imagine a time when we can prevent or cure kidney disease? I am incurably optimistic about the infinite talent and spirit of our kidney community."

During the past decade, the emphasis has shifted to kidney health from kidney diseases; the kidney community has made incredible strides toward improving kidney health, slowing progression of kidney diseases, preventing these diseases, and—ultimately—finding cures; and kidney-healthy has closed a 30-year gap with heart-healthy. As current ASN President Susan E. Quaggin, MD, FASN, declared earlier this year, "Why limit screening to the identification of kidney diseases? Instead, why not pivot the messaging to 'screening for kidney health?" (4). Knowing you have healthy kidneys "can provide peace of mind while expanding the eligible pool of living donors to help address the desperate need for kidneys," she noted. "Why should knowing the status of your kidney health be any different than knowing your other numbers, such as glucose, lipids, and blood pressure?"

Intervening earlier to prevent, diagnose, coordinate care, and educate

In conjunction with the US Department of Health and Human Services (HHS) and the National Kidney Foundation, ASN's We're United 4 Kidney Health campaign highlights this objective (5). To produce the campaign, in 2020, ASN hired Brodeur Partners (a public relations and communications services firm) and the Prime Group (a message research and development firm). Through a quantitative and qualitative process that included nearly 2000 nephrologists, other health professionals, and patients, Brodeur and Prime identified the campaign's four priorities and determined that the majority considered intervening earlier foremost.

As illustrated in Table 1 and Figure 1, ASN has launched several initiatives since 2016 concentrated on ensuring that the millions of people with kidney diseases receive excellent care. Intervening earlier to prevent, diagnose, coordinate care, and educate are key elements in each of these initiatives. For example, the Diabetic Kidney Disease Collaborative (DKD-C) held three strategy conferences and published related manuscripts; produced a comprehensive online educational module; and articulated a legislative and regulatory action plan for screening, prevention, and access to new therapies (6). These efforts are ongoing, particularly the advocacy.

After developing educational material for kidney health professionals, ASN's initiative focused on acute kidney injury (AKI)—called AKINow—is working to use augmented and artificial intelligence to improve diagnosis, treatment, and recovery (7). AKINow also seeks to build a data warehouse for greater accessibility to online research sources to improve the transition out of in-hospital care. Inspired by the success of AKINow, this year, ASN launched the Augmented Intelligence and Digital Health Task Force to guarantee that the kidney community improves kidney health by evaluating, adopting, and innovating augmented intelligence and digital health (8).

"To enhance the quality of life for people with kidney failure by engaging nephrologists as team leaders in transformational change that continuously improves the safety of life sustaining dialysis," Nephrologists Transforming Dialysis Safety (NTDS) (9) supports several initiatives, including current and emerging threats (10); human factors engineering (11); and QAIE (quality assessment, improvement, and education) (12). This emphasis has resulted in online, casebased learning modules for clinical topics related to infection prevention; a micro-webinar infection-prevention series for nephrology fellows; and a Kidney Leadership Academy, aimed at fostering strong, effective leadership skills for the dialysis facility medical director-nurse manager dyad.

Responding to the COVID-19 pandemic in 2020, ASN established a team that has met regularly, virtually, and collaboratively with the chief medical officers (CMOs) of dialysis organizations. In addition to developing a community resource for nephrologists and other kidney medicine professionals, the ASN COVID-19 Response Team (13) helped establish a network administrator model to ensure direct access of COVID-19 vaccines and monoclonal antibodies to dialysis facilities in collaboration with the US Centers for Disease Control and Prevention (CDC) and the White House.

The response team has presented more than 20 webinars on COVID-19 and designed three online educational modules. These modules concentrate on preparing for a surge, maintaining mental wellness, and summarizing the lessons the kidney community has learned during the pandemic.

Developing broad partnerships to address the health of the global population

To ensure excellence in kidney care, ASN partners with every stakeholder possible, including:

- Patients and patient organizations. At a leadership level, all of ASN's initiatives in this arena include people with kidney diseases. For specific projects, such as the Emergency Partnership Initiative (EPI) (14), ASN has partnered with patient groups, including the American Kidney Fund (which administers its own disaster relief program).
- Other health professional societies. Project Firstline (15) is a partnership among ASN, the American Medical Association, and CDC; Improving Adult Immunization Rates for COVID-19, Influenza, and Routine Adult Vaccinations is a partnership among ASN, six other medical specialty societies, the Council of Medical Specialty Societies, and CDC.
- Biotechnology and pharmaceutical industries. AstraZeneca, Bayer, Boehringer Ingelheim, Janssen, and Lilly helped fund DKD-C.
- Medical device companies. Baxter provided the funding necessary to launch AKINow and produce the initiative's initial educational material.
- Dialysis organizations. In addition to the ASN COV-ID-19 Response Team's interactions with CMOs (13), NTDS has worked closely with leaders in the dialysis industry (9).
- ▶ US government. CDC helped fund NTDS (9), the COVID-19 Response Team (13), the Home Dialysis Task Force (16), and Transforming Dialysis Access Together (TDAT) (17), and both EPI (14) and the COVID-19 Response Team (13) have worked closely with the HHS Administration for Strategic Preparedness and Response.

Finally, ASN is working with the European Renal Association and the International Society of Nephrology to publish a consensus statement seeking to address the World Health Organization's (WHO's) exclusion of kidney diseases as one of the top noncommunicable diseases driving premature deaths. The WHO's position is baffling because mortality due to kidney diseases jumped from the 17th leading cause of death globally in 1990 to the 12th leading cause in 2017 (18).

Promoting (and ultimately achieving) health equity

Earlier this year, the ASN Excellence in Patient Care Advisory Committee was established (19). Chaired by Alan S. Kliger, MD, the advisory committee includes leaders from key initiatives listed in Table 1, other experts, and a patient representative. From the beginning, the advisory committee agreed that promoting diversity, equity, and inclusion—as well as pursuing health care justice—must be core elements of every project ASN initiates to ensure high-quality kidney care.

As the newest ASN initiative, TDAT provides a good example (17). To increase the use of permanent dialysis access and improve the quality of care for all dialysis accesses (including hemodialysis, peritoneal dialysis, and in-home and in-center dialysis settings), TDAT will accomplish several goals. One of these goals is to create a unique educational program for nephrology fellows and early-career faculty from backgrounds underrepresented in the kidney and biological sciences. This program will include:

- Didactic and experiential training in career development, leadership, and research.
- Multifaceted longitudinal mentorship and networking.

 Pathways to future participation in ASN activities and leadership.

Advocating for high-quality therapies, including home dialysis and transplant

The ASN Home Dialysis Task Force is charged with improving "awareness and outcomes of home dialysis therapies by enhancing education of nephrologists, kidney care professionals, and trainees; addressing disparities in access to home dialysis; and advocating for policies that improve patient-centered modality choice in order to promote safe and high-quality care" (16). To meet this charge, the task force is aiming at workforce and training, continuing education, and legislative and regulatory policy.

Earlier this year, the task force surveyed nephrology division chiefs and fellowship training program directors to determine the extent of home dialysis training currently and the barriers to increasing and improving training in the future. The task force also provided detailed recommendations to the ASN Task Force on the Future of Nephrology. In addition to recommending increased training in home dialysis for nephrology fellows, the Home Dialysis Task Force suggested designating fellowship programs that meet specific criteria as "Centers of Excellence in Home Dialysis Training."

In terms of continuing education, the task force is pursuing several opportunities, including a weekend training program, a virtual case-based small group education series with mentorship opportunities, and a "one-stop" shop for home dialysis educational resources with multi-stakeholder collaboration. The task force also hopes to leverage the existing curricular content and ASN Communities, adding video-recorded presentations, and increasing the presence of home dialysis at ASN Kidney Week.

Historically, legislative and regulatory policy in this arena has focused on helping bring new products and therapies to market. More recently, however, the emphasis has been on addressing the unintended consequences of policies to promote home dialysis. These include, but are not limited to, unexpected poor outcomes for patients from marginalized communities, unanticipated shortages (of well-trained personnel and supplies), and inequitable access to care.

"Transform transplant and increase access to donor kidneys" is the second priority of the We're United 4 Kidney Health campaign (5). A future update will summarize ASN's efforts in this arena, which include legislative and regulatory activities, Kidney Innovation Accelerator (KidneyX) Artificial Kidney Competitions, Kidney Health Initiative projects, the ASN Physician Compensation Task Force (which tackled transplant nephrology and will publish recommendations soon), and much more.

In the meantime, it is important to emphasize that the ASN COVID-19 Response Team prioritized issues related to transplantation (13). In addition to trying to provide updated information about COVID-19, therapeutics, and vaccines to people with kidney transplants, the response team

advocated to include people with transplants in clinical trials for the vaccines and determine vaccine safety and efficacy in immunosuppressed patients. The response team also tried to determine the efficacy of monoclonal antibodies in immunosuppressed patients and highlight the need to treat patients and donors during a pandemic.

Closing thoughts

A decade ago, Dr. Falk ended his president's address with an encouragement: "As health care evolves from past to present, and as we look to the future, I hope we are not so removed by time, space, or practice pattern that we lose those precious moments of human interaction and understanding that permit us to listen to and learn the patient's definition of cure." He used the word "cure" 23 times in his presentation.

In addition to Dr. Kliger, who served as the founding chair of the NTDS Project Committee in 2016, many ASN members contribute to these efforts to provide high-quality care to people with kidney diseases. To learn more, please visit ASN's new website directed entirely to excellence in patient care (19). Three members of the staff started with Dr. Kliger nearly a decade ago, and they deserve the community's thanks as well: ASN Vice President for Excellence in Patient Care Susan A. Stark; Nurse Consultant Darlene Rodgers, BSN, RN, CNN; and Senior Project Specialist Bonnie Freshly.

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Excellence in Patient Care

Table 1. Current ASN initiatives focusedon excellent patient care

| Year started | Initiative |
|-----------------|--|
| 2016 | Nephrologists Transforming Dialysis Safety |
| 2017 | Emergency Partnership Initiative |
| 2018 | AKINow: Promoting Excellence in the Prevention and Treatment of Acute Kidney Injury |
| 2019 | Diabetic Kidney Disease Collaborative |
| 2020 | COVID-19 Response Team Project Firstline |
| 2021 | Home Dialysis Task Force Adult Immunization Projects: Improving Adult Immunization Rates for COVID-19, Influenza, and Routine Adult Vaccinations |
| 2022 | Augmented Intelligence and Digital Health Task Force Transforming Dialysis Access Together |

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Figure 1. Excellence in Patient Care



Letter to the Editor

Palliative Care and Conservative Management

First, let me congratulate you on yet another patient-centered edition. The June 2022 article No Filters: Assessing Physician Communication When Discussing Conservative Management of Kidney Failure by Drs. Corona and Koncicki (1) is timely, well researched, and to the point. It should become a "must read" for the entire nephrology community, especially those treating patients with advanced CKD [chronic kidney disease] and ESKD [end stage kidney disease].

Palliative care and conservative management have always seemed to be an "afterthought" or consigned to "other options" instead of being as vital a consideration as any of the forms of kidney replacement therapy. In ANNA's [American Nephrology Nurses Association's] recent publication of nine modules, *Nursing Care of the Patient with Chronic Kidney Disease (CKD) in ANY Setting* (2), palliative care is the focus of the 8th module.

As the overall title states, these modules were designed to educate health care providers who care for our patients outside of the nephrology specialty. We have heard these modules are helpful for direct patient education, especially for those patients and families making decisions about long-term care.

To that end, ANNA has made these available at no cost to ANNA members, all health care providers, and the public on its website (annanurse.org/ckdmodules) and also on YouTube (annanurse.org/ckdvideos). Since publication, the most recent data show a total of 7923 viewings. Of the 1859 YouTube viewings, 37% have seen the palliative care module.

Your article indicates that there is an unmet need regarding palliative and end-of-life care for the patient with ESKD, and the viewings of this single module seem to point in that direction. The existence and accessibility of these ANNA modules can help advance patient-centered care in nephrology.

Lesley C. Dinwiddie, MSN, FNP, CNNe, American Nephrology Nurses Association CKD module editor.

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Policy Update

Senate Finance Committee Holds Explosive Hearing on Performance of Transplant Contractor UNOS

The Senate Finance Committee raised numerous allegations of mismanagement, resistance to oversight, and poor performance against the leadership of the United Network for Organ Sharing (UNOS) in a hearing held Wednesday, August 3, 2022. According to the committee, these allegations are part of a broader pattern of failure from UNOS—the current federal contractor managing the Organ Procurement and Transplantation Network (OPTN)—that has claimed lives and thousands of discarded organs, including one in every four donated kidneys.

ASN has advocated for numerous improvements to the transplant system, with the goal of "transforming transplant," as outlined in the We're United 4 Kidney Health campaign (1). In a statement submitted to the Senate Finance Committee, ASN President-Elect Michelle A. Josephson, MD, FASN, said, "ASN believes a strong and equitable transplant system is essential to meet the needs of the more than 800,000 Americans living with kidney failure. While a kidney transplant is the optimal therapy for most people living with kidney failure, transplantation remains out of reach for too many people" (2). The statement outlines four policy recommendations to improve OPTN, including modernizing the OPTN contract, addressing barriers to transplant access that promote or exacerbate inequities, streamlining oversight of the US transplant system by establishing a unified office of transplantation and organ policy, and elevating transplant patients as partners in care. "ASN commends the Senate Finance Committee for continuing to drive improvements in transplantation and stands in partnership to ensure all Americans who could benefit have access to this critical therapy," Dr. Josephson concluded.

The hearing provided an opportunity for the Senate Finance Committee to update the public regarding its investigation, now in its second year, into the performance of UNOS, organ procurement organizations (OPOs), and the US transplant system. In February 2020, Senators Grassley, Wyden, Young, and Cardin wrote to UNOS with concerns of "reports of lapses in patient safety, misuse of taxpayer dollars, and tens of thousands of organs going unrecovered or not transplanted" (3).

Several efforts have been undertaken by Congress and the Department of Health and Human Services under multiple administrations to address shortcomings of the transplant system, including the current Senate Finance Committee investigation. The 2019 Advancing American Kidney Health Executive Order, signed by President Trump, made it the policy of the United States to double the number of kidneys available for transplant by 2030, including several policy initiatives to meet this ambitious goal (4). In March 2021, the Biden administration demonstrated bipartisan commitment to increasing transplantation, implementing a Trump-era rule to increase transparency and accountability among OPOs by establishing objective and verifiable metrics to assess OPO performance (5). In December 2021, the Centers for Medicare & Medicaid Services (CMS) issued a request for information (RFI) about opportunities to address equity in transplantation (6), and in April 2022, the Health Resources & Services Administration (HRSA)-the government office that oversees OPTN-issued its own RFI on ways to strengthen and improve OPTN (7). ASN provided comment on both RFIs, accessible on the ASN Advocacy & Public Policy website (8).

In Congress, the Senate Finance Committee—led, in particular, by Senators Wyden, Grassley, Cardin, Young, and Warren—and the House Oversight and Reform Committee—led by Representatives Krishnamoorthi, Cloud, Maloney, Comer, and Porter—have been investigating the performance of the transplant system, with particular attention to the maze of federal contractors and organizations tasked with its operation, such as the OPTN contractor and OPOs. The extensive bipartisan, bicameral support for the multi-year investigation into the performance of the US transplant system demonstrates Congress' commitment to improving care for the more than 100,000 individuals on the transplant waiting list. Senator Grassley, noting his interest in transplant policy starting in 2006, stated that "Congress has waited too long to fix a broken system. We must insist upon accountability moving forward. Patient lives are at stake" (9).

The Senate Finance Committee hearing surfaced multiple examples of poor performance and system failures from the committee's extensive review of more than 100,000 documents totaling more than 500,000 pages. Findings from the committee include failure of oversight from OPTN over OPOs, resulting in fewer organs for transplant; avoidable failures in organ procurement and transportation, leading to lost and destroyed organs; and a lack of technical expertise to modernize the OPTN information technology system. Before the hearing, The Washington Post reported that the White House US Digital Service identified "aged software, periodic system failures, mistakes in programming and overreliance on manual input of data," as well as data security concerns, leading to its recommendation that the government "break up the current monopoly" of UNOS on the transplant system (10).

Alarmingly, senators described a culture of reprisals and resistance to oversight at OPTN, inhibiting corrective action. Noting the more than 1000 safety complaints made against UNOS, Senator Wyden described criticism from organ transplant professionals interviewed during the investigation that the formal complaints process was a "black hole" that "appears to accomplish zero productive oversight or reform" (11). When whistleblowers did raise concerns, Senator Wyden described documentation of "reprisals against those who speak the truth." According to the committee, conflicted leadership contributes to this dynamic, as leadership boards of OPTN-tasked with overseeing UNOSwere automatically provided a seat on the leadership board of UNOS. Both boards are often populated by transplant professionals involved in the leadership of transplant centers and OPOs, for which OPTN is tasked with overseeing. Senator Grassley described the arrangement with UNOS as "the fox guarding the chicken house" instead of a trustworthy and independent oversight body that holds its members accountable" (9).

Lastly, senators raised questions about the potential misuse of taxpayer funding. Senator Warren directly challenged claims by UNOS that it would charge "tens of millions of dollars" for the rights to "an archaic technology system developed with taxpayer funding" (12). Unsatisfied, Senator Warren stated her belief that UNOS "should lose this contract" and "should not be anywhere near organ transplants in this country.... Patients and families deserve better than they're getting right now from UNOS" (12).

In closing remarks, Senator Wyden made clear that the Senate Finance Committee investigation would continue beyond the August hearing. Characterizing UNOS' response to the investigation as "unrepentant," Senator Wyden expressed frustration that the organization responsible for addressing performance issues within transplantation instead painted a picture of a system without need of improvement. Senator Wyden identified that the committee's investigation would next shift to the role of the federal government in the transplant system, including CMS, HRSA, and the structure of the OPTN contract, which is up for renewal in 2023. "This is not a partisan issue," said Senator Wyden. "This is a national issue, and as we have touched on, repeatedly over the course of the afternoon, patients waiting for organs and families of donors deserve better, and we're going to stay at it until they get those fixes," he added.

ASN will continue to advocate for transformations to the transplant system, including tracking the progress of congressional oversight. As stated to the Senate Finance Committee, transplant policy should be aligned with the primary goal of increasing access to kidney transplantation to the maximum number of patients with kidney failure while improving long-term posttransplant outcomes and quality of life. ASN will continue to push for reform until a kidney transplant is an accessible therapy for all Americans living with kidney failure.

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Anticipation of the Living Donor Protection Act Realization

On September 28, advocates from patient and professional kidney health organizations from across the nation will call on their members of Congress to pass the Living Donor Protection Act (LDPA) as part of Kidney Community Advocacy Day 2022.

Momentum to pass the LDPA has been building steadily this year due to the efforts of advocates, including ASN's March 2022 Kidney Health Advocacy Day. The current draft of the legislation continues to add co-sponsors, bringing the total to 134 co-sponsors in the House and 41 in the Senate, the highest number of co-sponsors ever received by the legislation.

The LDPA was introduced in the House by Jerrold Nadler (D-NY) and Jaime Herrera Beutler (R-WA) in February 2021 (1). The legislation was first introduced in 2013–2014 by the 113th Congress and has been introduced by every Congress since then. Currently, there are 28 states that have similar laws to remove barriers and protect living donors. This strong bipartisan, bicameral, and local legislature support provides the best chance yet for the LDPA to pass in the 11 congressional work days before the end of the 117th Congress.

The LDPA contains three key components to protect living donors. First, the LDPA makes it unlawful for insurers to deny or limit coverage of "life insurance policy, disability insurance policy, or long-term care insurance policy" for living donors. Second, the bill codifies a 2018 Department of Labor opinion that the Family and Medical Leave Act of 1993 protects the employment of living donors for the "recovery from surgery related to organ donation." Lastly, the LDPA requests the Secretary of the Department of Health and Human Services (HHS) to "review and update materials related to living organ donation in order to educate the public on the benefits and risks of living organ donation and the impact of living organ donation on the access of a living organ donor to insurance."

These three key components will be a major upgrade to the US transplant ecosystem and will bolster one of ASN's four key priorities of the We're United 4 Kidney Health campaign: to transform transplant and increase access to donor kidneys (2). This legislation will also advance the campaign's priority to achieve equity and eliminate disparities. According to a recent CJASN article, "Social Determinants of Health and Race Disparities in Kidney Transplant" (3), Black patients have a higher incidence of kidney failure but lower rate of deceased and living donor kidney transplantation compared with White patients. Research has also shown that a transplant from a living donor is much less common among Black Americans (21%), Hispanic Americans (24%), and Asian Americans (29%) compared with White Americans (46%) (4). Giving more protections to living donors will grant disadvantaged populations more freedom to donate and close the gap of the disparities identified.

There are currently 89,891 patients on the national waitlist in need of a life-saving kidney. On average, 13 Americans die every day while waiting for a kidney transplant (5, 6). ASN has called for several transplant system transformations to address these challenges, including efforts to encourage living donation, increase transparency and accountability, and achieve equity. ASN also urges Congress to create an Office of Transplant Policy in the HHS to oversee and coordinate the many transplant-

related pieces of the entire system housed within HHS.

ASN invites interested members to urge Congress to pass the LDPA by taking action on the ASN Advocacy & Public Policy website (www.asn-online.org/policy/lac. aspx). Members of Congress need to hear from their constituents about why protecting and respecting living donors are important to increase equity and ultimately increase access to transplantation.

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The ASN Task Force on the Future of Nephrology: What Have We Been Hearing?

By Mark Rosenberg and Melissa West

he ASN Task Force on the Future of Nephrology was charged with reconsidering all aspects of the future of nephrology to determine how to best prepare nephrology fellows for the challenges and opportunities the future will bring. Since April, the task force has been meeting regularly with the goal of delivering its report by October 2022 to fulfill requests from the American Board of Internal Medicine (ABIM) and the Accreditation Council for Graduate Medical Education (ACGME). These organizations determine what changes should be made to nephrology certification and recertification (ABIM) and fellowship training programs (ACGME). To learn more about the task force, its charge, and membership, please refer to the April, June, July, and August 2022 Kidney News articles (1).

A critical aspect of this work has been a series of stakeholder listening sessions with the kidney community. The task force has valued this input and has been listening closely as it works to develop its recommendations. The goal of this article is to inform you about what we have been hearing.

From people with kidney diseases

A predominant message from the group of people with kidney diseases was for fellowship programs to focus more on patient engagement and activation. They stressed that rehabilitation of people with kidney diseases is an essential component of care and deserves further emphasis during training. Recommendations included a greater focus on developing a holistic approach to patients and more attention on effective communications skills. They want our graduates to be more aware of individualizing their approach to patients and to understand that patient preferences often evolve over time. As one participant reminded the task force, "Kidney diseases are a diagnosis for life." Areas in which people with kidney diseases would like to see better training include home therapies, care transitions (especially pediatric to adult), women's health, and preventive nephrology. When considering requirements in training related to procedures, they asked that we take into account the patient experience.

From practicing nephrologists

A listening session was held with practicing nephrologists where the consensus was that fellows should understand procedures, such as insertion of dialysis catheters and kidney biopsy, but they do not need to be trained to competency, as most practices no longer perform these procedures. This message was consistent with the 2021 ABIM survey of certified nephrologists, which indicated that 70.9% do not perform insertion of temporary dialysis vascular access, and 83.1% do not perform kidney biopsies (2). They did ask for a greater focus on point-of-care ultrasound (POCUS) and the interpretation of radiologic studies. There was consensus that graduating fellows should have a better understanding of the business aspects of a nephrology practice, including health economics and value-based care. The practicing nephrologists emphasized that there are many income-generating opportunities for practices that contribute to a nephrologist's compensation, which may make the specialty more attractive as a career. Other recommendations included more training in the areas of home therapies, outpatient nephrology (including longitudinal dialysis care), team-based care, assessment of dialysis access, population health, communication skills (especially related to the electronic health record), urology, and conservative management of kidney failure.

From nephrology fellows

The task force met with current and newly graduated nephrology fellows whose perspective was to keep procedures as a requirement for training, fearing that we were "giving away procedures when other specialties were not." They felt it was important for nephrologists to perform procedures because it was best for patients and avoided fragmenting care, and procedures were one way to attract future applicants. They urged the task force to "protect the specialty." Fellows stated that there should be more training in home dialysis therapies and POCUS, with recognition that most internal medicine residents are competent in POCUS. Training programs should increase opportunities to learn more specialized areas of nephrology by making more effective use of the second year of training, they added. The fellows also recommended a greater focus on mentorship, reducing workload, and improving fellow well-being, stressing they need time to learn.

From fellowship training program directors

Nephrology fellowship training program directors offered recommendations through several retreats, a survey conducted by the ASN Workforce and Training Committee, and a listening session that focused on smaller training programs. Although no consensus was reached on procedural requirements for graduation, a majority emphasized the importance of providing opportunities to train in procedures. They did feel more training was needed in the areas of home therapies and POCUS, however. Other points made to the task force during the listening session were centered on the challenges of filling fellowship positions, the need for greater attention on fellows who enter nephrology as a "second choice," and the concern that training resources were often limited in smaller fellowship programs.

These listening sessions were in addition to input provided by individual nephrologists, ASN committees, the ACGME and ABIM advisors to the task force, and other specialty medical societies (including cardiology and hematology). In addition, to support the data-driven approach that the task force has been taking, we had the opportunity to review surveys by ABIM of certified nephrologists, nephrology fellowship training program directors about procedures by ASN, and ASN regarding other workforce-related issues. Additional input is planned from nephrology division directors and the chief medical officers of dialysis organizations, as well as from other kidney organizations.

The task force greatly appreciates the thoughtful opinions and generous time provided by these various stakeholders. Clearly, our community is engaged and interested in this important work. The next step for the task force is to synthesize this input into specific strategic recommendations about how to best train fellows for the future of nephrology. There is still time to provide your perspective. To share your ideas, please email Melissa West, ASN's Senior Director for Strategic Relations and Patient Engagement, at mwest@ asn-online.org.

Mark Rosenberg, MD, FASN, is a nephrologist, Professor of Medicine, and Vice Dean for Education at the University of Minnesota Medical School. Melissa West is Senior Director for Strategic Relations and Patient Engagement with ASN.

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KN Editorial Fellows Program Open for Applications

ASN *Kidney News*—the kidney community's leading newsmagazine— invites you to apply to be a *KN* Editorial Fellow.

Who can apply? Fellows entering their second, third, or fourth year of fellowship in nephrology with an interest in clinical nephrology, transplantation, basic research (physiology, pharmacology, or pathophysiology), or clinical research (observational research and clinical trials).

ASN Kidney News embraces diversity and equal opportunity. We are committed to building an inclusive culture that represents the diverse backgrounds, perspectives, and skills of the communities we serve globally.

How long is the appointment? Two years.

What are the responsibilities? Editorial Fellows participate in all ASN *Kidney News* editorial processes, including reviewing articles, developing the Fellows First column, and identifying topics for invited articles and special issues. Trainees will participate in ASN *Kidney News* editorial calls and will be encouraged to contribute, as appropriate, to discussions of *KN* strategy and invited papers. The time commitment is at least one hour per week for soliciting and editing articles and communicating with authors and *KN* editorial staff.

First-year participants will be provided with a series of training sessions to ensure their familiarity with editorial processes. Periodic "trainee only" meetings with ASN *Kidney News* senior leadership will be held to discuss specific topics in the editorial process.

Fellows will be assigned to a specific editor who will oversee their progress. They will work closely with the assigned mentor and the Editor-in-Chief. **What's the deadline?** October 30, 2022. The fellowship will begin January 1, 2023.

How do l apply? Interested applicants are invited to provide the following:

- A brief bio
- A detailed CV

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- A commitment and recommendation letter from Division Chief or Program Director of fellowship specifying how you are suited for the position
- A 200- to 300-word short article on the topic "Training in Nephrology 2023: What can be changed?" One original figure and/or a visual abstract may be included. No coauthors are allowed.

Application materials may be submitted at https://www.asn-online.org/knfp.

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Outcomes of Kidney Transplantation in AL Amyloidosis

By Umut Selamet and Naoka Murakami

myloid light chain (AL) amyloidosis is a systemic disease affecting multiple organs, including the kidney, heart, gastrointestinal tract, and nerves. Kidney involvement is common and seen in ~70% of patients with newly diagnosed AL amyloidosis. Proteinuria >5 g/day and estimated glomerular filtration rate <50 mL/min at the time of diagnosis predict 60%-85% progression to end stage kidney disease (ESKD) in 3 years (1). The survival of patients with AL amyloidosis improved significantly over the past several decades, owing to advancements of treatment options with plasma celltargeted therapies and hematopoietic stem cell transplant (HSCT) (2). Overall survival (OS) at 10 years is 95% for patients with AL amyloidosis who achieve hematological complete remission (CR) with high-dose melphalan and HSCT (3). Despite the encouraging survival data, kidney transplantation is rarely used for patients with ESKD due to AL amyloidosis. According to the United Network for Organ Sharing (UNOS) database, only 30-40 cases out of a total of ~22,000 kidney transplants per year were performed for patients with all types of amyloidosis (4).

Recently, three key observational studies updated data on the outcomes of kidney transplantation in AL amyloidosis. Angel-Korman et al. (5) reported a single-center cohort study from the Boston University Amyloidosis Center (n = 49); the median OS (mOS) and allograft survival after kidney transplant were 10.5 and 8.3 years, respectively. Hematological CR or very good partial response (VGPR) was associated with longer OS and less recurrence rate. Law et al. (6) studied data from the UK National Amyloidosis Centre (n = 51); OS and allograft survival of kidney transplant recipients with AL amyloidosis were not different from kidney transplant recipients due to diabetes. Cardiac involvement (interventricular septal thickness >12 mm) was associated with worse OS, whereas hematological CR was associated with better OS. Heybeli et al. (7), from the Mayo Clinic (n = 60), reported their experience of excellent mOS of 10.3 years after kidney transplant. Interestingly, even patients who were treatment naive before kidney transplant achieved CR with high-dose melphalan and autologous HSCT after kidney transplant. In addition, UNOS/Organ Procurement & Transplantation Network (OPTN) analyses repeatedly showed that OS and kidney allograft survival for AL amyloidosis patients are similar to kidney transplant recipients due to diabetes, especially with deceased kidney transplant (4, 8).

Is it time to consider kidney transplant as an option for ESKD management for patients with AL amyloidosis? When evaluating transplant candidacy, we should consider both utility (improvement of survival and quality of life) and justice (equitable allocation of scarce resource of donated organs). Data from the cohort studies and UNOS database analyses are promising for AL amyloidosis patients, as OS and allograft survival are similar to those who received kidney transplant due to diabetes and are better than patients remaining on dialysis. It is now reasonable to offer kidney transplant for carefully selected groups of AL amyloidosis patients with hematological CR and/or VGPR. Larger, multi-center studies are needed.

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The authors report no conflicts of interest.

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Kidney transplant outcomes in AL amyloidosis

nces for each study. BU, Boston University; CR, complete remission; HSCT, hemator an overall survival; NR, not reached; VGPR, very good partial response.

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|--|------------------------|-------------|----------------|-------------------|--------------------------------|----------------------------------|
| Study cohort | Cardiac involvement | нѕст | mOS | Graft survival | Recurrence (%) estimated time | Prognosis factor |
| BU Amyloidosis Center (n = 49) 1987-2017 (5) | % 33% | 80 % | 10.5 yr | Gfð 8.3 y | 29 % r 3.7 yr | CR/VGPR: ↑mOS ↓recurrence |
| UK National Amyloidosis Centre (n = 51) 1989–201 (6) | ⁸ 22% | 24 % | 7.9 yr | NR | 14 % 4.5 yr | CR: ↑mOS IVSd >12 mm: ↓mOS |
| Mayo Clinic (n = 60) 1997–2018 (7) | 47 % | 60 % | 10.3 yr | NR | 22 % 10.2 yr | CR/VGPR: ↑mOS |

tic stem cell transplant; IVSd, interventricular septal thickness in dias

In Memoriam

Leaders in Nephrology Leave Behind a Lasting Legacy

mong this year's professionals in the kidney community who have passed away, four deceased kidney disease leaders are acknowledged here for their contributions to nephrology. Nancy Spaeth, considered the longest surviving kidney patient in the world; Christopher Blagg, MD, a persistent advocate for dialysis; Dale Singer, MHA, an elegant force and knowledgeable executive; and Jerry Yee, MD, FASN, a generous mentor, have all been seminal figures in the field.

Nancy Spaeth



Spaeth was born October 16, 1947 (1), and had been a runner on her school's relay team before she started experiencing weakness. Her condition was believed to have been caused by several yellow jacket stings during a hiking trip the summer before she was diagnosed. When she died on January 14, 2022 (2), at the age of 74, she was considered the longest surviving kidney patient in the world. She had four kidney transplants during her lifetime and spent decades on dialysis. She was also a powerful patient advocate who worked tirelessly at the Northwest Kidney Centers, where she served on the Foundation Board and Board Quality Committee. "She was a very petite person, but she had a larger-than-life personality," Jackson said.

Her tenacity led her to become a teacher, nurse, and a mother of two. But after her second kidney transplant failed in 1986, she returned to dialysis. She suffered from severe dialysis-related anemia that left her so weak that she had to crawl up the stairs of her home. Her negative symptoms changed when she became one of the first 10 patients in the clinical trial for erythropoietin, which restored her strength. The drug was later approved by the US Food and Drug Administration in 1989. "She was a living example of how research can change lives," Jackson said.

Spaeth was a powerful advocate for kidney patients both at the Northwest Kidney Centers and on Capitol Hill. She was a strong supporter for increased access to home dialysis and pushed for healthier food options and funded access to nutrition education at Northwest Kidney Centers. Jackson explained that Spaeth credited careful management of her diet, fluid volume, and strict avoidance of salt with helping her live so long with kidney disease. Spaeth has left a tremendous legacy in the field of nephrology (1).



Christopher R. Blagg, MD

Born in Retford, Nottinghamshire, England, on June 12, 1931, Christopher Blagg, MD, passed away on March 31, 2022 (2), at the age of 90 (3). Blagg moved to Seattle, WA, in 1963 for a 1-year National Institutes of Health fellowship with Belding Scribner, MD, the first Division Head of Nephrology at the University of Washington, who was working to develop methods to provide long-term dialysis.

After sharing what he had learned with his colleagues in his home country of England, Blagg returned to Seattle to lead Northwest Kidney Centers as executive director in 1971. Dur-

ing his 27 years as executive director, Blagg served as a global ambassador, hosting visitors from around the world and mentoring them on providing hemodialysis and home dialysis. "We were the first dialysis organization in the world," the Northwest Kidney Centers' Jackson said. "He influenced how the therapy was adopted worldwide."

Throughout his career, Blagg championed policies to improve kidney care. He advocated for the creation of the Medicare End Stage Renal Disease Program, which provided Medicare coverage for people with end stage renal disease (ESRD) regardless of age. The legislation helped secure financial stability for millions of people in the United States living with ESRD, Jackson explained. "He was a persistent advocate who never took 'no' as a final answer," she said.

Blagg also helped found the Renal Physicians Association (RPA) and centers for organ and tissue procurement. His book "From Miracle to Mainstream" describes the creation of the Northwest Kidney Centers and the evolution of dialysis. His ongoing influence in the field is recognized each year at the ASN Kidney Week Christopher R. Blagg, MD, Endowed Lecture-ship in Kidney Diseases and Public Policy. Jackson added, "One of his greatest contributions was to influence laws and regulations to support better care for kidney patients."



Dale Singer, MHA

Former executive director of the RPA, Dale Singer, MHA, was born November 11, 1961, in Pittsburgh, PA, and died June 28, 2022 (2), after a 12-month battle with lung cancer at age 60 (4). Singer earned a bachelor's degree in journalism and a master's degree in health administration from the University of Maryland before taking the helm at RPA. When Singer became the executive director of the organization, it was in its infancy, but over her 27-year tenure, she helped grow the organization into a major advocate for the field of nephrology.

Singer knew the entire modern history of the field, said Jeffrey Perlmutter, MD, immediate past president of the RPA. "We all learned a great deal from her," Perlmutter said.

As a woman working with numerous RPA presidents—ranging from small practice owners to leaders of major dialysis organizations—over the years, Singer "always held her own," Perlmutter said. "She was very good at harnessing the thought leadership and talents of those volunteering," said Rebecca Schmidt, DO, FASN, past president and counselor for RPA. "She put our thoughts and dreams into structured programs and projects." Singer helped build and retain a strong staff at the organization, which successfully advocated for policies ranging from value-based payment models to lifelong coverage for immunosuppressive medications for kidney transplant recipients.

Outside the RPA, she also took on leadership roles in her community. She served on the Executive Committee of B'nai Israel Congregation and was the Board Chair for the Bender Jewish Community Center of Greater Washington. She also was active in her profession, serving as a fellow and board president at the American Association of Medical Society Executives.

Both Perlmutter and Schmidt said they will remember Singer for her compassion and good humor. "She was a friend, a colleague, a mentor, and a force," Schmidt said.



Jerry Yee, MD, FASN

In addition to his role at the Henry Ford Hospital in Detroit, MI, Jerry Yee, MD, FASN, was the medical director of the Greenfield Health Systems. Yee was born August 5, 1959, in Pittsburgh, PA, and died June 9, 2022 (2, 5). Yee was active with the National Kidney Foundation and the Royal College of Physicians in London and served as editor-in-chief of *Advances in Chronic Kidney Disease*. "Jerry was a really brilliant person who could talk about anything in kidney disease," said Michael Choi, MD, director of the Division of Nephrology at

MedStar Georgetown University Hospital.

Yee was also a "renaissance person" who was passionate about music, movies, and computers, described Choi, who met Yee during their fellowships at the University of Pennsylvania. Yee put his interest in computers to work at ASN to advance several informatics programs. But some of his greatest contributions to the field may have been as a mentor. Choi and countless others benefited from Yee's generous mentorship. Choi explained that Yee would frequently promote others for speaking engagements and for other positions and helped many people advance connections in the field. "He just saw things in people," Choi said.

Yee never seemed to expect anything in return for his mentorship but seemed to derive real satisfaction from helping others build their careers. "He was always going above and beyond," Choi said.

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KidneyNews

THE KIDNEY CARE TEAM

Kidney Medicine Is A Team Sport

By Susan E. Quaggin

silent public health crisis, kidney diseases affect approximately 10% of all Americans, or 37 million people. In addition to the burden of kidney diseases, management of patients with acute or chronic kidney diseases is complex and requires a dedicated team of experts to achieve the best possible outcomes.

In this month's ASN *Kidney News*, a series of articles highlight the key and evolving roles of advanced practice providers (APPs)—nurse practitioners (NPs) and physician associates (PAs; also called physician assistants)—as well as pharmacists, who are invaluable members of the kidney care team. The articles discuss career paths to specialize in nephrology, as well as opportunities and challenges that must be addressed to strengthen the multidisciplinary team and improve outcomes for the millions of people with kidney diseases.

Over the past dozen years or so, the role of APPs has moved beyond in-center dialysis units to inpatient hospital settings, outpatient chronic kidney disease clinics, kidney transplantation, and home dialysis. In all settings, education and care delivery redesign can be provided by APPs, who are ideally positioned to identify and overcome gaps in these areas.

Besides the value APPs bring to kidney care, data clearly show that nephrology teams with a dedicated pharmacist can dramatically reduce medication-related problems (MRPs). Like the role of the APP, pharmacists bring their unique skills, knowledge, and experience to the kidney care team, providing medication reconciliation and review, identifying gaps in insurance coverage, and delivering education, which are all time intensive.

Despite the clear benefit for patients of members of the health care team who are not physicians, the authors identify several challenges. While there are ~150,000 registered

PAs in the United States, only 0.4% claim nephrology as their specialty. To increase this number, the American Academy of Nephrology PAs has initiated outreach programs. In addition, no accredited residency programs in nephrology for pharmacists currently exist. Furthermore, the Centers for Medicare & Medicaid Services does not provide reimbursement for specialty care or education provided by pharmacists, and health care systems are often slow to adapt holistic or multidisciplinary approaches to patient care because of funding restrictions and lack of innovation.

As the focus of our field has evolved from kidney failure to kidney health and to prevention and intervening earlier, the need for multidisciplinary teams has never been greater. As individuals and organizations, we recognize the need and must advocate for the expansion and support of all members of the kidney care team, who are invaluable, dedicated, admirable professionals.

Nephrology is a team sport with all members focused on a common goal: putting patients first...always.

Susan E. Quaggin, MD, FASN, is with the Division of Nephrology and Hypertension, Northwestern University Feinberg School of Medicine, Chicago, IL, and is ASN President.

Editor's Note: Terms used for PAs and NPs have evolved over the years. Some large organizations refer to PAs and NPs as Advanced Practitioners (APs) or Advanced Practice Providers (APPs), and a few articles reflect this usage. Because the professions have different backgrounds and training, the editors, as appropriate, have also used the terms PA and NP rather than one all-encompassing term.

Physician Assistants in Nephrology Training, Pathway, and Scope

By Sara Krome

Physician assistants (PAs) have been colleague providers in health care since the late 1960s (1). PAs are trained at accredited PA programs across the country in the "medical" model of instruction, in contrast to nurse practitioners trained by the nursing instruction model (2). Most PA programs offer graduate-level education, with a degree such as Master of Health Science or Master of Physician Assistant Studies. A few programs remain that offer PA degrees or certificates at the baccalaureate level. Most graduate programs are 27 months (3). PAs are not required to and do not routinely complete a post-graduate residency, although there are some 1-year residencies offered in fields such as cardiology, critical care, cardiothoracic surgery, and hematology or oncology (4), although not in nephrology (3). Most PAs are required to be board certified. (An exception is with the Department of Veterans Affairs, in which PAs can be licensed and/or certified.) The certification is offered in internal medicine, general surgery, or family practice. Even PAs in specialty care are required to have certification in one of the above fields to practice.

PA certification lasting 10 years requires passing a certification exam and 100 hours of continuing medical education (CME; at least 50 hours must be category 1) completed every 2 years with an accompanying fee.

For PAs interested in a career in nephrology, they can begin by exploring nephrology in their elective rotations during PA student instruction. Some graduates enter nephrology upon graduation from their PA program; others elect to pursue working for a period of time in an internal medicine field to hone their clinical skills.

After at least 1 year in nephrology practice, the PA can consider pursuing a certificate of expertise in nephrology, called the Certificate of Added Qualifications. This is pursued through the PA-certifying body, the National Commission on Certification of Physician Assistants. Candidates must meet the following requirements: current PA certification, license for unrestricted practice in their state (or unrestricted privileges at a government agency), 2 years' experience (1 year of which must be nephrology), 75 hours of category 1 nephrology CME (25 hours of which must be obtained 2 years before the exam date), attestation from a colleague, and passing a nephrology specialty exam (5).

PAs in nephrology work in all areas, including inpatient nephrology management and coverage, outpatient clinic general nephrology (chronic kidney disease and transplant), dialysis care, home therapy, and even taking calls. Although PAs are dependent providers, much of their work is autonomous with highly effective relationships with their collaborating physician partners. PAs have prescriptive privileges in all 50 states, and many PAs perform procedures such as line placement (temporary dialysis catheters and central line placements) and percutaneous biopsies (including the kidney) (6).

A career as a nephrology PA is rewarding, and many different models of incorporation exist. As the nephrology workforce continues to expand, and more PAs join nephrology groups, it is important to know the educational pathway of this unique group of health care providers. There is also an important opportunity to develop unique resources to enrich educational opportunities.

Sara Krome, PA-C, is with the Durham VA Health Care System, Nephrology, Durham, NC.

Ms. Krome, PA-C, graduated from Duke University in 1992 with a Master of Health Science and has been a PA for 30 years. She entered the field of nephrology 16 years ago and works at the Durham VA Health Care System, which is affiliated with Duke University. Her primary practice is in the outpatient setting of general nephrology and peritoneal dialysis. She works with a group of 15 physicians and five advanced practice providers.

The author reports no conflicts of interest.

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Nephrology Advanced Practitioners: National Kidney Foundation Survey Data

By Jane Davis and Kim Zuber

n 1965, on opposite sides of the country, two revolutions in health care took place. In North Carolina, corpsmen returning from the Vietnam conflict put their skills and training to use in the newly formed profession: physician assistant (PA) (1, 2). In Colorado, registered nurses received postgraduate education, enabling them to provide health care in rural communities as nurse practitioners (NPs) (3). Both professions were formed to fill the need created simultaneously by a physician shortage and the increased numbers of patients eligible for health care under Medicare legislation (4). In 2021, there were approximately 325,000 licensed NPs in the United States and 150,000 certified PAs (5, 6). Nephrology PAs/NPs, often referred to as advanced practitioners (APs), represent a small percentage of practicing PAs/ NPs. Determining the exact number of nephrology APs is difficult because there is no federal designation; however, nephrology APs are estimated to represent less than 1% of either PAs or NPs.

With the shortage of nephrology fellowship applicants, practices have used APs for years, but a large influx of APs occurred in 2004 when the Centers for Medicare & Medicaid Services billing rules for hemodialysis were implemented (7). As PAs/NPs moved into nephrology, the National Kidney Foundation developed a biannual online survey of the roles, compensation, trends in job description, payment models, and benefits for the workforce. The survey is published biannually in *Nephrology News & Issues* with the decade of data co-published in the *Journal of the American Association of Nurse Practitioners*, the *Journal of the American Academy of Physician Assistants*, and *CJASN* (8–11).

Survey findings

Sites of practice for APs have been and are predominantly dialysis units and the office or clinic (Figure 1). However,

hospital coverage and high-acuity patient management have increased over the last dozen years.

In the dialysis unit, weekly rounds are the most common duty of the AP, but in 2020, the monthly capitated payment (or monthly) visit was more frequently completed by the AP (Figure 1). It is possible that this change

The patient pool is increasing, whereas the physician provider pool is not keeping up.

may have been a result of the influx of COVID-19-related acute kidney injury consultations and the need for nephrologists to be in the hospital setting. This is also seen in the increase in "taking call" for the hemodialysis units as the nephologist was less available to the outpatient sites. Although many nephrologists consider themselves primary care providers, there has been a decrease in management of this aspect over the last decade.

Use of APs in hospitals has increased over the last doz-

en years, with hospital rounds and consults being managed by nephrology APs (Figure 1). Often, this allows the nephrologist to manage the less stable intensive care unitlevel patient while still accommodating for inpatients or referring providers.

The statistical analysis of the job descriptions within the office or clinic has been stable over the last dozen years (Figure 1), but many qualitative statements from the survey participants noted changes from 2020 to 2022. Many offices were closed, including referral offices; staff were working from home; and patients were monitored with telehealth. Often, the AP reported being the only person in the office and thus handled many secretarial and nursing chores, such as obtaining prior authorizations for medications, refilling primary care medications, and paperwork for disability or long-term care.

During the COVID-19 pandemic, the number of rounds for inpatient peritoneal dialysis (PD) patients also increased (Figure 1), whereas monthly PD clinic rounds decreased. However, fewer than 40% of all nephrology APs see any PD patients, corresponding to a lack of PD patients managed by all nephrology groups.

Pay and benefits for the nephrology AP have increased as the complexity of the job has increased. The average annual income for the nephrology AP was \$84,000 in 2010, increasing, on average, 5% with each survey cycle. This year, the average salary is \$119,000. Because of the survey's design and the loss of statistical significance, annual salary cannot be broken down further by state, gender, or years in practice. Benefits for the nephrology AP mirror those of the nephrologist, such as malpractice insurance, 401/403 retirement plans, continuing medical education, paid time off (an average of 4 weeks each year), licensing, and professional dues.

The patient pool is increasing, whereas the physician

Figure 1. Duties performed by nephrology Advanced Practitioners at different sites of practice



CKD, chronic kidney disease; MCP, monthly capitated payment; ESRD, end stage renal disease; F/U, followup; H & P, history and physical examination; HD, hemodialysis; M–F 9–5, Monday–Friday, 9 a.m.–5 p.m.; med, medication; Med rec, medication reconciliation; PD, peritoneal dialysis; Pt, patient.

NOTE: Percentages worked at each site are not 100% because survey participants were asked to identify all sites at which they worked. provider pool is not keeping up. To provide quality, timely care to this fragile population, APs stand with their physician colleagues to treat, educate, and support patients with kidney diseases. APs have a unique set of qualifications that make them ideally suited for nephrology.

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Dr. Davis is a speaker for Bayer. Ms. Zuber assisted in the development and analysis of the National Kidney Foundation/Council of Advanced Practitioners Survey.

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Outreach by American Academy of Nephrology PAs Enhances Care, Spurs Interest

By Kim Zuber and Dale Gomez

hysician assistants (PAs) are licensed clinicians, trained in the medical model, who practice medicine in every specialty, setting, and state. They are dedicated to expanding access to care and transforming health through patient-centered, team-based medical practice, and as such, nephrology is a perfect home. In 1997, a cohort of nephrology PAs, under the auspices of the American Academy of Physician Associates, created a specialty organization—American Academy of Nephrology PAs (AANPA)—for all facets of nephrology PAs (e.g., office, dialysis, transplant, and intensive care unit). In 2020, of >148,000 PAs in the United States working in 70 medical and surgical subspecialties, only 0.4% claimed nephrology as their practice specialty (1, 2) (Figure 1).

With such limited representation and a shortage of both nephrologists and nephrology PAs, AANPA initiated outreach to its referring practitioners to decrease concerns with referrals, such as missing data, inappropriate timing, and/or missed diagnoses. Outreach was two-pronged and included oral continuing medical education (CME) 1 presentations and journal articles.

Offering kidney-based lectures to state and national PA organizations, with expert speakers supplied by AANPA, has been extremely popular. This has morphed into AANPA members teaching the nephrology section for multiple PA programs across the United States. The organization has found that its speakers make nephrology more accessible to students, and because the speakers are excited about the topic, it is more interesting to the students. The goal of AANPA is to increase student interest in nephrology rotations, because nephrology is an elective in all PA schools.

The second outreach that the organization implemented was in a written format, called Nephrology Nuggets, a casebased CME program offered to all PAs and nurse practitioners (NPs) at a very low cost (<\$1/CME credit). "Nuggets" is a collection of patient cases that have been managed by AANPA members (3). Nephrology may not include large numbers of practitioners, but it does provide interesting stories.

AANPA's first nephrology-focused article, "Medication dosing in patients with chronic kidney disease" (4), published in the *Journal of the American Academy of Physician Associates* in 2013, was awarded Clinical Article of the Year. AANPA members followed kidney medication dosing with articles highlighting chronic kidney disease, acute kidney injury (AKI), hypertension (HTN), education for patients with kidney diseases, organ transplant, diabetes management, the new estimated glomerular filtration rate calculator, as well as other kidney-related topics.

Nephrology NPs saw the positive response to outreach by the PAs and also published articles in multiple NP journals on topics that ranged from autosomal-dominant polycystic kidney disease to pain management of the nephrology patient to AKI, HTN, and hepatitis.

PAs were joined by NPs, medical doctors, and pharmacists in information distribution, because the care, treatment, and management of a patient with kidney diseases embody a multi-disciplinary endeavor.

Kim Zuber, PAC, is Executive Director of the American Academy of Nephrology PAs (AANPA), and Dale Gomez, PAC, is with Mid-Atlantic Nephrology Associates and is a member of the AANPA.

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Includes data for all PAs who answered the profile question for practice specialty. Total respondents = 106,606. NCCPA, National Commission on Certification of Physician Assistants.

Figure 1. NCCPA PA medical practice specialty report 2020: Number of PAs practicing in each area

Nurse Practitioner Roles and Responsibilities in the Nephrology Practice Setting

By Jennifer Branch

have been fortunate to work in the field of nephrology my entire career, mostly as a registered nurse for the first 20 years and now as an advanced practice provider over the past 3 years. I currently serve as an inpatient nurse practitioner in transplantation at an academic health system. For the first 2 years, I also had experience in outpatient clinics and dialysis units.

Outpatient clinic experience

Seeing patients on an outpatient basis during my outpatient clinic experience allowed me to review labs, medications, and health issues with many minutes of teaching while completing a full examination. Health maintenance reminders and why they are important (e.g., for mammograms, vaccines, etc.) were always addressed, encouraged, and written for follow-up or referrals, as well as a review of kidney diagnoses and health in patients with chronic kidney disease (CKD). My responsibilities included reviewing charts, seeing patients and families at clinic visits, writing orders and notes with independent billing, and reviewing post-visit labs with followup while keeping a consistent plan of care for optimal personalized CKD care. I saw many patients for post-hospital follow-up, reviewing reasons for hospitalization and medication changes as well as the patient's status. This was a great opportunity for me to assist in a smooth transition of care, providing follow-up if details had been missed or dropped. As a nurse practitioner, I have the tools to tackle examinations and extensive education while keeping the patient at the center of holistic care.

Hospital follow-up visits always included a thorough review of inpatient records, including discharge summaries and a medication list. If patient medications were added or adjusted, I made sure those changes were being implemented and followed by the patient. If patients were missing medications or did not understand the purpose for a medication, information was given, and medications were ordered or arranged to be ordered. Labs were reviewed and explained. Oftentimes, patients and families did not understand why they were hospitalized or what treatment was received while being hospitalized, which was addressed and explained. For example, patients admitted for acute kidney injury (AKI) often did not understand the implications and risks of repeat AKI, what AKI meant, what kidney function was, stages of CKD, and preventative interventions, such as home blood pressure, daily weights, or medication recommendations. Preventative practices were addressed, explained, and strongly encouraged for inhibition of CKD progression and/or rehospitalization.

I enjoyed appointments that were specifically scheduled for CKD and end stage kidney disease (ESKD) education. The visits included discussing modality options, diet, signs and symptom of ESKD, and labs. Meeting with patients and their support systems allowed me to address the plan of care in a holistic way by getting a glimpse of the patient's family dynamics, past experiences, and values. A range of emotions, from scared and unknowing to increased confidence and empowerment, could be seen in such a short span of time.

Outpatient dialysis experience

We are given so much opportunity to make an impact on dialysis regimen wellness, seeking input about management of care with the patient, which often leads to improved adherence, decreased acute issues, and ultimately less frequent hospitalizations. Rounds in the unit allowed me time to address and educate patients about alternate modalities of treatment, such as peritoneal and home hemodialysis. There was always time to consistently educate patients about transplantation options; routine visits allowed me to follow up on pretransplant checklists and discuss what to expect posttransplant. I enjoyed participating in and leading care-plan meetings that included interdisciplinary team members all contributing to the dialysis regimen with the patient. Concise documentation of rounds with accurate billing is essential to communicating with other health care team members for subsequent visits and care. I was able to act as a resource for troubleshooting, educating, and ordering what the dialysis staff and patients needed with support from physicians never far away if needed.

Inpatient rounds and dialysis

There is something special about getting to see patients in an acute setting. They do not pick us to be there at their time of need, and we are fortunate to be able to contribute at a stressful time. Patients and families are often scared, do not feel well, and may not understand their health issues or what is being done for the plan of care. Verbalization of explanations may be difficult for patients to comprehend, and there is often little time for visits. Each morning, I review charts, including vitals, labs, medications, and trends, as well as any changes to the plan of care. I order recommended interventions, including dialysis treatments, labs, medications, or other changes to the plan of care, and communicate all these tasks with interdisciplinary team members. I round on my assigned patients daily, provide updates on their plan of care emphasizing nephrology- and transplant-related issues, conduct education daily, and document with consult or progress notes with billing components. My notes are separately billed under my position with intermittent review by my collaborating physician. I work independently but also frequently with the service attending, fellows, and residents throughout the day. This supports a more comprehensive health regimen in a time of acute care for patients and families.

I consider myself lucky for the fulfilled, enriched roles I've had throughout various practice settings in my nephrology career. Working across practice settings alongside interdisciplinary teammates keeps my contributions cohesive and patients' wellness possible. As an advanced practice provider, I have found my niche weaving in additional education for holistic care for patients and families affected by kidney diseases by increasing patient confidence and empowerment, ultimately leading to improved outcomes.

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The author reports no conflicts of interest.

Driving Change: The Role of Nurse Practitioners in Nephrology Care Delivery Redesign

By Candice Halinski

he suboptimal outcomes experienced by patients with chronic kidney disease (CKD) are a direct result of flaws in the design of the health care delivery model. This is evidenced by lack of pre-existing nephrology care, high rates of dialysis initiation using a central venous catheter, increased morbidity and mortality, and low rates of preemptive transplantation (1). Improvement on the associated outcomes can be facilitated by the creation and deployment

of supportive interdisciplinary care delivery models.

Under the Advancing American Kidney Health initiative, ambitious targets have been identified to improve on the care delivery model for patients with kidney diseases, including the aim to increase the use of home dialysis therapies and transplantation. Little progress can be made on these initiatives without the identification of gaps in the existing care delivery model. This requires foundational knowledge of the disease trajectory, direct

NPs can integrate science into practice to design programs that improve clinical outcomes.

experience with the population, stakeholder management, organizational awareness, and expertise in population and community health initiatives. The direct patient access, advanced education and training, knowledge of evidence-based practice, and expanded clinical skills (2) of nurse practitioners (NPs) make these professionals ideal candidates to lead the co-creation of care delivery models.

Launched in 2012, Northwell Health's Healthy Transitions program is evidence that the integrated use of NPs and nephrologists has positively affected health care delivery. Under this model, NP-driven care delivery design coupled with nephrologist collaboration, partnership, and medical direction results in positive patient outcomes. In affiliation with a medical director and under the clinical supervision and daily operational direction of an NP, the Healthy Transitions program was created to deliver evidence-based treatment interventions that improve coordination of care and education to decrease cost and proactively prepare for treatment the rapies (3).

In 2017, a formalized, randomized controlled study of the program (4) provided evidence for the value of coordinated care management. This study randomized 130 patients with late-stage kidney diseases (stages 4 and 5) to an intervention and control group for a period of 18 months. Patients assigned to the intervention group received education, monitoring, and follow-up care with an assigned nurse care manager. Study results revealed a significant reduction in hospitalization when the intervention group was compared with the control group.

Hospitalizations were measured per patient per year with 0.61 per year in the intervention group and 0.92 per year in the control group (incident rate ratio, 0.66%; 95% CI, 0.43–0.99; p = 0.04); 37% of patients initiated peritoneal dialysis, and 58% of program participants initiated dialysis therapies without hospitalization. In addition, at the start of hemodialysis therapy, a catheter was

present in 37% of the intervention group compared with 69% of the control group; 53% of those in the intervention group initiated dialysis with a functioning arteriovenous access compared with 27% in the control group.

Insight into the patient journey affords teams the opportunity to develop patient-centered care solutions and engage in design thinking (5) (Figure 1). This is particularly true in CKD care. In nephrology, experienced nephrology NPs offer a distinct, competitive advantage because they understand the health care delivery system from a patient and provider perspective as well as possess working knowledge of the internal and external patient journey. In addition, they are afforded the opportunity and time to educate and monitor patients throughout the trajectory of their disease. In nephrology settings, NPs are often called on to deliver care in one primary setting (i.e., dialysis, transplant, or clinic). When compared with the competing demands placed on the neph-

Figure 1. Design thinking in the creation of kidney-related care delivery models



Figure 2. Obstacles in nephrology care delivery

| ŝ | | | 1 |
|-------------------|---|--------------------------|---|
| Patient Obstacles | Education and Health Literacy Limited pre-dialysis care Insufficient education Missing prognostic information Social and Cultural Limited family support Life obligations and time constraints Medical paternalism Fear and loss of control Environment Housing insecurity Space and storage Condition of home Economic Income status Fragmentation in care Episodic Care Failure to participate in goal setting | Organizational Obstacles | Workforce Acquiring staff with essential skills and expertise Prior nephrology experience Financial and Regulatory Availability of funds Difficulty quantifying ROI Difficulty quantifying patient utilization in system Culture Resistance to change Communication and socialization of care model Sustaining change Leadership support |

rologist to deliver care in multiple settings, NPs are more accessible and may have more bandwidth to provide personalized educational sessions and follow-up. This allows for additional insight into psychosocial factors and social determinants of health. Understanding patient-, organizational-, and nephrologist-related obstacles (Figure 2) in the context of patient care delivery allows for consideration of fundamental questions (6) (Figure 3) to enable the collaborative creation and adoption of policies, procedures, and protocols that drive positive patient outcomes.

The process of health care delivery redesign is facilitated when there is comprehensive understanding of the disease trajectory and the lived experience of the patient. With foundational training in leadership, communication, and holistic care; knowledge of disease management; and advanced clinical assessment skill, NPs can integrate science into practice to design programs that improve clinical outcomes. Their experience as clinical team leaders and patient advocates is essential to the cocreation, development, and sustainability of health care delivery design. As the nephrology landscape continues to evolve, it is likely that there will be a rising demand for NPs to serve as collaborators and leaders in health care delivery design.

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Driving Change

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Figure 3. Fundamental questions for health care delivery design



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Nurse Practitioners in Nephrology: Understanding the Educational and Career Pathway to Specialty Practice

By Candice Halinski

riginally trained to provide holistic primary care, nurse practitioners (NPs) practice in a variety of acute and chronic care settings. The pathway to practice requires candidates to pursue multiple educational prerequisites and degrees (Figure 1). These rigorous demands are likely to increase in the coming years. Education and training begins with the completion of baseline prerequisites in addition to the attainment of a Bachelor of Science in Nursing (BSN) and active licensure as a registered nurse (RN) in the state of practice. State licensure requires that candidates successfully pass a board certification examination formally known as the National Council Licensure Examination.

State licensure as an RN typically permits entry into graduate-level degree programs for advanced practice nursing. Such programs build on the knowledge and experience gained as a BSN-prepared RN. Programs characteristically range from 12 to 24 months depending on full-time or part-time enrollment. The curriculum typically includes courses in pathology, pharmacology, leadership, research, and physical assessment, whereas primary objectives focus on clinical practice because NPs will provide direct patient care and medical management (1). The clinical rotation requirements vary in length (500-1000 hours) by educational institution, with an average range of over 500 precepted hours to meet minimum eligibility requirements for certification (2).

The completion of a Master's degree-level program results in attainment of a Master of Science in Nursing and eligibility to become licensed as an NP in the state of practice. Although licensure can be submitted, most states require the successful completion of a national certification examination before practicing. National board certification is an evidence-based means to validate the knowledge areas (Table 1) and experience gained throughout the educational process, as well as to assess the competency level for entry into practice (1). Board certification is renewed every 5 years by means of re-examination or continuing medical education of 100 contact hours of advanced continuing education (CE). There is a mandatory requirement of 25 CE credits of advanced practice pharmacology, as well as an accompanying requirement of at least 1000 clinical practice hours (3).

More than 69% of NPs practice in primary care settings. However, because of the increasing population of individuals with chronic kidney disease (CKD) and end stage kidney disease, entry into the nephrology specialty with minimal clinical nephrology experience may be permitted (1). Exposure to nephrology may begin within the NP program, where a designated number of preceptors facilitate practice hours in an area of interest. Graduate NPs may pursue direct entry into nephrology depending on organizational needs. Although no formalized nephrology-specific NP program exists, graduates of accredited programs with 2000-plus clinical practice hours can sit for additional board certification through the Nephrology Nursing Certification Commission. Passing the examination allows an NP to be recognized as a Certified Nephrology Nurse-Nurse Practitioner (4).

Given the increasing population of patients with CKD and kidney failure, coupled with reimbursement changes that permit NP coverage of patients on hemodialysis, NPs can enter practice in the chronic outpatient setting; however, additional opportunities exist in a multitude of settings (5). The role of the NP in nephrology is no longer exclusively dialysis rounding. It has evolved to include chronic and acute care in hospital settings, outpatient dialysis units, transplant centers, CKD clinics, research programs, care management, home care, palliative care, government settings, equipment and drug manufacturers, and leadership positions.

In light of increasing patient complexity, reimbursement changes, care-delivery redesign, and nephrologist shortages, NPs have become an integral part of the nephrology care team. Their expertise, educational preparation, and advocacy in the nephrology setting have contributed to a variety of positive outcomes for patients with CKD and kidney failure. This includes improvements in access to care, continuity of care, patient safety, and quality of care (6). Nephrology has allowed NPs across the nation to practice independently and collaboratively while maximizing their scope of practice that highlights their ability to provide exceptional health care for millions of Americans.

Candice Halinski, MBA, MHCDS, MSN, NP-C, AMB-BC, is an adult nurse practitioner. Throughout her 20-plusyear career in this field, she has served kidney patients in the capacity of licensed practical nurse, registered nurse, nurse manager, nurse practitioner, and clinical director. Ms. Halinski is currently the Assistant Vice President for Clinical Professional Development for Northwell Health Physician Partners and an Assistant Professor of Medicine at the Donald and Barbara Zucker School of Medicine, Hofstra/ Northwell Health, Hempstead, NY.

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Figure 1. Educational pathway to NP practice: A 10-step approach

Table 1. FNP and AGPCNP program knowledge domain requirement comparison

| Knowledge domain | Family nurse practitioner | Adult-gerontology primary care nurse practitioner |
|---|---------------------------|--|
| Anatomy | \checkmark | √ |
| Physiology | \checkmark | √ |
| Pathophysiology | \checkmark | √ |
| Co-morbidities | \checkmark | √ |
| Pharmacologic therapies | \checkmark | \checkmark |
| Non-pharmacologic, complementary, and alternative therapies | \checkmark | \checkmark |
| Integrative therapies | \checkmark | |
| Polypharmacy | \checkmark | \checkmark |
| Pain management | \checkmark | |
| Cultural competence/sensitivity | \checkmark | |
| Diagnostic and therapeutic tests | \checkmark | \checkmark |
| Functional assessment | \checkmark | |
| Health history | \checkmark | \checkmark |
| Mental health assessment | \checkmark | |
| Physical examination across the lifespan | \checkmark | |
| Signs and symptoms | \checkmark | \checkmark |
| Therapeutic communication | √ | √ |
| Clinical decision-making | \checkmark | \checkmark |
| Crisis management | √ | √ |
| Differential diagnosis | \checkmark | \checkmark |
| Health promotion, disease prevention, and anticipatory guidance | | \checkmark |
| Adult physical examination | \checkmark | \checkmark |
| Biopsychosocial principles/theories | | √ |
| Patient, family, and caregiver education and counseling | | \checkmark |
| Community resources | | \checkmark |
| Evidence-informed practice | | \checkmark |
| Legal and ethical issues | | \checkmark |
| Ethno-cultural and spiritual competency | | \checkmark |
| Principles of epidemiology | | \checkmark |
| Health literacy | | \checkmark |
| Principles of risk management | | \checkmark |
| Palliative and end-of-life care | | \checkmark |
| Pain management | | \checkmark |
| Health care economics | | √ |
| Interprofessional practice | | \checkmark |
| Information management | | √ |
| Settings of care | | √ |

AGPCNP, adult-gerontology primary care nurse practitioner; FNP, family nurse practitioner.

Use of Non-Physician Providers in the Nephrology Workforce Needs Careful Consideration and **Urgent Attention**

By Christin Giordano McAuliffe

he number of patients requiring nephrology subspecialty care has grown tremendously. Unfortunately, while fellowship applicants have increased nearly 10% since 2019, nephrology has only had an increase of about 3% (1). This gap between workload and workforce has led to an increase in the use of non-physician practitioners (NPPs), the Centers for Medicare & Medicaid Services' term that includes nurse practitioners (NPs) and physician assistants (PAs). Within our specialty, however, there has not been adequate discussion regarding proper utilization of NPPs.

When discussing the roles of members of the health care team, it is paramount to understand the background and training required for each member's certification (2). While physicians understand their own personal background, they may not understand the wide range of experiences of NPPs.

While physicians understand their own personal background, they may not understand the wide range of experiences of NPPs.

Figure 1. Kidney care team roles and responsibilities

| | Inpatient | Outpatient Clinic | Outpatient Dialysis |
|----------------------|---|---|--|
| New consults | ICU- Physician Only | Physician Only | N/A |
| | Non-ICU- NPP with initial visit seen by physician as well | | |
| Follow-up visits | ESKD- NPP with specific guidelines on when to notify physician | Stable patients with defined plan with specific guidelines on when to | N/A |
| | Non-ESKD- NPP with physician seeing patient every visit | notify physician | |
| Comprehensive visits | N/A | N/A | Physician Only |
| Short visits | N/A | N/A | NPP with specific guidelines on when to notify physician |

NPP, non-physician practitioner; orange = physician roles; purple = non-ICU/ESKD NPP roles; green = NPP roles.

Table 1. Specific NPP role suggestions

- Provide physician-derived recommendations to referring physician/NPP.
- Note outpatient dialysis history and physicals.
- See established office patients for hospital follow-up to update chart and medications.
- See established office patients who have a defined plan.
- See established ESKD patients in the hospital who are continuing their usual dialysis schedule.
- Manage inbox; return patient calls.
- Provide patients with non-critical results.
- Complete prior authorizations and peer-to-peers as well as complete patient-requested forms (i.e., FMLA, disability).
- Perform medication reconciliation and stable medication refills.
- Educate patient (i.e., Medicare reimbursed CKD education).
- Coordinate care with social worker, case management, and others as needed.

This article will propose some general tenets of practice that will maximize NPP use while ensuring excellent subspecialty care (Figure 1).

In the inpatient environment, NPPs should, under direct supervision, be able to competently see most end stage kidney disease (ESKD) patients. The physician should, at initial consult, assess patients for volume and electrolyte status to ensure the NPP places appropriate dialysis orders. In addition, NPPs should be able to perform an initial chart review and examine consults for non-ESKD patients with the nephrologist personally examining every patient and directing the workup and management of their condition. Additionally, NPPs can help coordinate care including vascular access and communicating recommendations to hospitalists. Because of the complexity of intensive care unit (ICU) patients, NPPs should not be used to see consults there. In all cases, NPPs and physicians should maintain a frequent dialogue about any changes in the clinical status of patients.

In the outpatient clinic, NPPs can assist with administrative and workflow tasks. They should not independently see new consults as they are not trained to evaluate new consults independently. Non-nephrologists refer their patients for specialty advice, and it is imperative that nephrologists use our expertise to provide expert-level diagnoses and detailed management recommendations. NPPs can see stable patients in follow-up with defined guidelines for physician reevaluation. This may include medication changes, a change in clinical status, every other visit, or patient request. Additionally, NPPs should be encouraged to discuss patients at regular intervals with the nephrologist.

In the dialysis clinic, it is optimal for the physician to see every patient monthly, if not more. An NPP can effectively see dialysis patients two to three times a month to complete short visits. NPPs should be given specific guidelines on when to report issues they are encountering and for referring patients for physician re-evaluation as needed.

NPPs can be incorporated into team-based practice in all areas of nephrology (Table 1). By developing specific guidelines for clinical practice and encouraging open and frequent communication, physicians and NPPs create strong care teams that improve access to subspecialty care.

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The author reports no conflicts of interest and states: The content reflects my personal opinion formed in conjunction with my experiences as a physician assistant prior to attending medical school. It is not a reflection of my employer or other organizations I may represent in other capacities.

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Advanced Practice Providers in Transplant Nephrology

By Meera P. Suthar

he role of advanced practice providers (APPs) has evolved over the last few decades, with data showing that APPs in nephrology can directly improve kidney outcomes in patients with chronic kidney disease (1). The population of kidney transplant recipients (KTRs) in the United States is growing annually, and in 2021, the United Network for Organ Sharing reported the largest number of organ transplants completed in a single year (2). With the exception of 2020, which was affected due to the COVID-19 pandemic, kidney transplants have increased 8 consecutive years in a row (3) (Figure 1). APPs are an integral part of the multidisciplinary transplant team, and their knowledge and experience in transplant are vital to the continued growth and success of transplant programs.

In the 2022 National Kidney Foundation/Council of Advanced Practitioners survey, 25% of nephrology APPs reported managing outpatient transplant patients (4). The complexity of care for transplant patients, pre-, intra-, and posttransplant, requires a multidisciplinary approach. APPs are able to step in at all aspects of transplant, working as the pre-evaluation coordinators, assisting in surgery, managing post-op patients, and following patients in the transplant clinics. APPs have learned the preferences of the transplant surgeons and nephrologists in their programs, which in turn, translates to a better teaching experience for residents and fellows as they rotate through transplant. APPs are responsible for many different roles in transplant centers:

- Managing and completing pre-transplant evaluations
- Managing annual or semi-annual re-evaluations
- Assuming care in the immediate and remote posttransplant phase
- Working as providers in outpatient clinics
- Managing inpatient medical kidney transplant services
- Managing transplant patients admitted to intensive care transplant units
- Performing procedures, such as transplant biopsies, inser-

tion of central lines, wound debridement, and surgical assisting in the operating room (5)

 Intervening in patient safety initiatives, clinical research, and quality improvement projects (6)

In academia, APPs provide much-needed continuity of care because fellows and house staff rotate frequently. The traditional paradigm requires restarting the educational process from the beginning-weekly, monthly, or at best, yearly—for house staff and fellows rotating through transplant. A well-trained and educated APP can continue to improve and develop important skills and more in-depth knowledge of the field. The University of Michigan compared length of stay (LOS) and 90-day readmissions among 2913 KTRs before and after the addition of APPs to the team. Data collected in 2011 showed a lower LOS between the time periods (mean 5.5 \pm 5.1 days vs. mean 4.5 \pm 3.4 days; p < 0.001) with the addition of APPs. Regarding readmissions, before the addition of APPs to the team, there was a +3.2% yearly increase in readmissions, whereas after the addition of APPs, there was an absolute -1.8% yearly decrease in readmissions (7).

With a growing population of patients requiring kidney transplants and at a time when there is a decline in the number of trained transplant nephrologists and surgeons, APPs are vital to the growth and sustainability of transplant programs and to the future of transplant nephrology (8). There are evolving residency and fellowship programs for APPs in abdominal transplant at Duke University (9) and the Mayo Clinic (Arizona) (10). These programs can help expand future APP growth in transplant nephrology.

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Figure 1.

Total US Kidney Transplants by Donor Type



Adult and pediatric US kidney transplant recipients, including re-transplant and multi-organ. Reprinted from Wang and Hart (3).

Nephrology Advanced Practice Providers in Home Dialysis

By Lisa Koester

n 1972, nearly 40% of all patients on dialysis in the United States were on home dialysis. The next year, the Medicare End Stage Renal Disease (ESRD) Program began, and as a result, the use of home dialysis decreased dramatically. Over the years that have followed the establishment of the Medicare ESRD Program, there has been a resurgence of home dialysis, and research demonstrates that more frequent dialysis has better health outcomes than dialysis administered three times per week (1). U.S. Renal Data System (USRDS) data from 2019 reveal that 13.1% of prevalent patients with end stage kidney disease were engaged in home dialysis (Figure 1), including 1.9% with home hemodialysis and 11.2% with

Figure 1. Utilization of home dialysis, 2009–2019



Reprinted from USRDS, Figure 2.1a (2).

peritoneal dialysis (PD) (2). The advanced practice provider (APP) plays a vital role in increasing the number of patients on home dialysis.

I have been a practicing APP for the past 22 years at Washington University School of Medicine in St. Louis, MO. I was fortunate to be exposed early on in my career to home dialysis. In 2004, the role of APPs expanded secondary to the decision of the Centers for Medicare & Medicaid Services (CMS) to allow APPs to perform at least three of the required dialysis visits. This jumpstarted the awareness that APPs can play a big part in the management of kidney diseases. One of the primary reasons patients do not choose home dialysis is lack of education regarding this option. APPs can increase home dialysis use by educating patients and their care partners. The University of Florida initiated a comprehensive kidney disease education (KDE) program that demonstrated success, as 70% of patients who engaged in the program choose home dialysis (3).

APPs see patients during home training and in clinic. According to billing guidelines, the nephrologist must see his or her patients in person at least once each quarter. APPs can perform up to 2 visits per quarter on their own with documentation and billing. If the patient is seen with the APP and nephrologist, the visit is billed under the APP. For the training visit, the note by the APP can be billed at 100%, as it is not part of the monthly visit. An online survey in 2022 with 293 respondents was conducted by the National Kidney Foundation/Council of Advanced Practice Providers (NKF/CAPP) and the American Academy of Nephrology Physician Assistants (AANPA), which revealed that 37% of APPs are involved in taking care of PD patients. The survey did not specify home hemodialysis (4).

In recognition of the vital role APPs play in nephrology, the CMS initiated a KDE benefit in 2010 for stage 4 chronic kidney disease with six billable sessions. In review of USRDS data, Johansen et al. (5) discovered that 3% of patients received KDE between 2013 and 2017 (n =106,456 patients). The authors observed that receipt of KDE was associated with a greater likelihood of initiating dialysis on a home-based modality (18% vs. 11.5%) (5).

APPs can fill many roles in the management of home dialysis, and increasing the exposure of APPs to home dialysis can be vital to the growth of home programs.

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The author reports no conflicts of interest.

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Has Nephrology Resigned Itself to the Great Resignation?

By Kathleen Mallett and Sofia Thomas

he COVID-19 pandemic has been a catalyst for burnout in a strained health care workforce, especially in the emergency medicine and critical care sectors (1). The Association of American Medical Colleges projects a shortage of up to 139,000 physicians by 2033 (2). Burnout has contributed significantly to the "Great Resignation," with a tremendous short-term impact on the US health care system, prompting the US Surgeon General to prioritize this crisis (2). It is difficult, however, to understand the long-term implications of this exodus (3), especially in nephrology.

Nephrologist burnout

Multiple factors have contributed to burnout across specialties and roles (Figure 1). Before the pandemic, a 2019 survey revealed that approximately 1 in 4 (23%) nephrologists experienced burnout (4). Bureaucratic tasks, poor work-life balance, and feeling devalued by colleagues/employers are the top three reported obstacles to a fulfilling nephrology career (4). Furthermore, a decline in fellow recruitment has been observed (5), although the pandemic did not have a significant negative impact on professional development (6). Natural attrition and the uncertain impact of the Great Resignation have many professionals in the field expressing concern for patient care and the continued growth and diversity of nephrology.

Patient care suffers

Health care workers fear poor patient care due to burnout because of demands from multiple sectors (7). Effects include limited time with patients, increased medical errors, and hospital-acquired infections (2). Shortages are already felt in rural areas and in the primary care field (8). The burnout crisis may restrict access to care, increase costs, impair response to the next public health emergency, and exacerbate health disparities (2). Caring for patients with advanced kidney diseases is likely to worsen in all settings, and long-term management of one of the most prevalent health issues facing the United States is becoming more complicated as a result.

Build community

Burnout negatively impacts trust and camaraderie among health care teams, but this can be mitigated by building a diverse role set (2). During the pandemic, approximately one-third of nephrology fellows expressed an increased sense of community and improved relationships with mentors (6). Furthermore, the nephrology community has been integrating advanced practice providers (APPs) nurse practitioners and physician assistants—into its teams since 2004 (9). Although data are scarce, it appears that nephrology APPs have not experienced burnout to the same extent as their colleagues. However, 6% (n = 293) of participants from the 2022 National Kidney Foundation/

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Council of Advanced Practice Providers survey noted that they were furloughed, had reduced pay, and lost bonuses or retirement contributions during the pandemic. In addition, many reported a heavier workload and busier practice (10). If these scenarios continue unchanged, then we would expect to see a shortage of APPs soon as well.

Although challenges exist, the nephrology community should continue to be innovative and collaborative in its efforts to advocate for change on behalf of ourselves and our colleagues and patients. We must not resign.

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Figure 1. Factors associated with health worker burnout

| Societal and Cultural | Mental health stigma Health misinformation Politicization of science and public health Unrealistic expectations of health workers Structural racism and health inequities |
|---------------------------------------|--|
| Health Care System | Limitations from national and state regulation Burdensome administrative paperwork Poor care coordination Misaligned reimbursement policies Lack of human-centered technology |
| Organizational | Excessive workload and hours Disconnect between values and key decisions Barriers to mental health and substance use care Lack of supportive leadership Biased and discriminatory practices and structures |
| Workplace and Learning Environment | Limited time with patients and colleagues Lack of collaborative culture and vulnerability Limited autonomy, flexibility and voice Lack of focus on health worker well-being Discrimination, harrassment and violence |

Adapted from U.S. Department of Health and Human Services, Office of the U.S. Surgeon General (2).

The Role of Pharmacists in CKD Care Teams

By Summer Dyer and Linda Awdishu

atients with chronic kidney disease (CKD) and end stage kidney disease have complex medication regimens and multiple comorbidities and can take in excess of 12 medications daily (1). High pill burden and multiple care providers place CKD and dialysis patients at risk for medication-related problems (MRPs). It has been shown that for every \$1 spent on detecting and addressing MRPs in the dialysis population, \$4 may be saved by the health care system (2). The Centers for Medicare & Medicaid Services (CMS) now requires monthly medication reconciliation in the End-Stage Renal Disease Quality Incentive Program (ESRD QIP).

As medication experts, pharmacists are trained to perform medication reconciliation, detect dosing errors, and identify drug interactions. Pharmacists can improve medication access for patients by identifying gaps in insurance coverage, submitting prior authorization requests, enrolling patients in patientassistance programs, and providing medication education.

A recent study found that incorporating a pharmacist into the dialysis care team reduced the number of MRPs by 50% (3). The most common problems were found to be related to nonadherence (27%), prescription renewals (21%), and excessive drug doses (14%) (Figure 1). Medication reconciliation and review are time-intensive processes that when done comprehensively, can take approximately 40 minutes (3). However, the CMS Conditions for Coverage for ESRD Facilities does not mandate the inclusion of pharmacists in the dialysis [Including] clinical pharmacists on dialysis and CKD care teams can address gaps in services.

care team.

Clinical pharmacist interventions have demonstrated improvements in the management of anemia, hypertension, and hyperlipidemia, as well as mineral metabolism and bone disease for individuals with CKD (4). Clinical pharmacist interventions reduced hospital admissions, length of hospital stay, and incidence of ESRD or death (4). Clinical pharmacists contribute to the development of quality performance indicators—Joint Commission quality certification programs in CKD—leading to high-quality CKD care (5).

However, CMS does not recognize pharmacists as providers in important services, such as kidney disease education, and limits reimbursement for kidney disease education to physicians, physician assistants, clinical nurse specialists, and nurse practitioners. These reimbursement issues create barriers to adding the pharmacist to CKD care teams. The inclusion of clinical pharmacists on dialysis and CKD care teams can address gaps in services and provide a unique opportunity to improve the care of patients with kidney diseases through the optimization of medications.

Summer Dyer, PharmD, BCPS, is a dialysis pharmacist with the University of California San Diego (UCSD) Health system. She has developed the role of a dialysis pharmacist and implemented new clinical pharmacist services for chronic hemodialysis, including medication reconciliation, medication therapy management, guidelines for medication use, cost-containment strategies, and an innovative med-to-chair program in chronic hemodialysis.

Linda Awdishu, PharmD, MAS, FASN, is Division Head and Professor of Clinical Pharmacy at the UCSD Skaggs School of Pharmacy and Pharmaceutical Sciences. She practices at UCSD Health as a pharmacist specialist in kidney diseases and transplantation. Throughout her 20-plus-year career she has developed neu, innovative clinical pharmacy practice models, such as interprofessional care in chronic kidney disease, safe drug distribution systems, medication reconciliation, and an innovative med-to-chair program in chronic hemodialysis, as well as discharge education and long-term follow-up clinics in kidney transplantation. She is a nephrology board member for the American Board of Internal Medicine and a member of the ASN Publications Committee.

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The Role of Pharmacists in CKD Care Teams

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The authors report no conflicts of interest.

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Clinical Pharmacists in Nephrology: A Call for Action

By Linda Awdishu

harmacists are essential drug experts on the health care team, providing clinical services related to safe distribution, optimal selection, and use of medications and patient education in the community, ambulatory care, and acute care pharmacy environments.

Pharmacists are trained at accredited schools of pharmacy that require a minimum of 2-4 years of undergraduate education before entering a 3- to 4-year doctorate training program (PharmD). During their doctorate training, they are licensed as pharmacy interns and begin gaining practice experience in the community and acute care settings, working under the supervision of a licensed pharmacist. After completing the PharmD degree, although not required, the majority of PharmD graduates pursue postgraduate residency or fellowship training. Pharmacy residency programs are accredited nationally and include 1-year general postgraduate training in the community and ambulatory or acute care environments. Beyond the first year, pharmacists may pursue a second year of residency specializing in a disease state, such as but not limited to infectious disease, critical care, or solid organ transplantation in acute care settings.

Currently, there are no accredited residency programs or fellowships in nephrology for pharmacists. Many pharmacists interested in nephrology pursue training in other areas, such as ambulatory care, critical care, or solid organ transplantation. Beyond residency training, pharmacists may pursue board certification from the Board of Pharmacy Specialties to gain qualifications for advanced practice; however, specialty boards in nephrology are not yet developed. The lack of specialty training in nephrology is a major contributor to

the limited number of pharmacists specializing in nephrology.

In the United States, some states offer an advanced practice pharmacist designation and advanced pharmacist licensure, which expand the scope of practice for clinical pharmacists to perform patient assessments; order and interpret laboratory tests; refer patients; initiate, adjust, and discontinue drug therapy; and collaborate in the evaluation and management of diseases. However, insurers still do not routinely recognize pharmacists as health care providers for reimbursement of services. This has created a major barrier to the expansion of clinical pharmacist services.

Despite the limited pool of pharmacists specializing in nephology, studies have documented the positive impact of pharmacist services in the care of patients with acute kidney injury (AKI) or chronic kidney disease (CKD) or patients receiving chronic dialysis (Table 1) (1-10). Advocacy from professional organizations, such as ASN, is needed to improve insurance reimbursement of pharmacist services, improve the development of specialty programs in nephrology, and integrate the clinical pharmacist in the dialysis and CKD care teams, especially in light of the Advancing American Kidney Health Initiative (11).

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Reprinted from Dyer et al. (3). *Drug interaction, therapeutic drug monitoring, and wrong drug.

Figure 1. Types of medication-related problems in dialysis patients

Table 1. Studies of clinical pharmacy services in nephrology

| Patient population | Intervention | Outcome | Reference |
|---|--|---|-----------|
| Hospitalized patients with AKI stage 3 | Identification of AKI stage 3 using electronic alerts and delivery of multidisciplinary education and post- hospital discharge follow-up | 18 Patients enrolled in intervention in 6-month time period; improvement in time to post-hospital discharge follow-up to less than 7 days | (1) |
| Patients with CKD stages 3 and 4 | Training program for community pharmacists on use of medications in CKD and access to patient clinical information | The mean number of drug-related problems per patient decreased from 2.16 to 1.60 and from 1.70 to 1.62 in the intervention and control groups, representing a difference of -0.32 (95% CI, -0.63 to -0.01). Improvements in knowledge and clinical competencies were demonstrated. | (2) |
| CKD | Hypertension management by clinical pharmacists in physician offices | Pharmacist intervention achieved a model-adjusted SBP and DBP reduction of 8.64 and 2.90 mm Hg greater than the control group; improved blood pressure control by pharmacists: adjusted OR, 1.97 (95% CI, 1.01–3.86). | (3) |
| Patients with CKD stages 2–5 | Interprofessional team-based care for CKD | High rates for clinical quality performance indicators, e.g., blood pressure control (85%), estimation of cardiovascular risk (100%), measurement of hemoglobin A1c (98%), and vaccination (93%) | (4) |
| CKD/chronic hemodialysis | Medication reconciliation conducted by pharmacist | Pharmacist identified medication discrepancy, of which 81% of recommendations were accepted by nephrologist, in 80% of patients; 25% of recommendations on drug and dose selection were accepted by nephrologist. | (5) |
| Chronic hemodialysis | Program services included medication delivery, refill management, medication list reviews, telephonic medication therapy management, and prior authorization assistance. | In the intention-to-treat analysis, patients who received pharmacy services were 8% less likely to die and accumulated 2% fewer hospital admissions and 6% fewer hospital days. In as-treated analyses, patients who received pharmacy services were 21% less likely to die and accumulated 7% fewer hospital admissions and 14% fewer hospital days. | (6) |
| Chronic hemodialysis | Anemia management by clinical pharmacist | Resulted in lower erythropoietin doses and reduction in expenditure of approximately \$500,000 | (7) |
| Chronic hemodialysis | Medication therapy management by clinical pharmacist | The most common potential medication-related problems were medication-dosing issues (31%), real or potential adverse drug reaction (29%), and unnecessary drug therapy (17%). Medication therapy management resulted in 55% lower risk of 30-day hospital readmission. | (8) |
| Chronic hemodialysis | Medication reconciliation by a clinical pharmacist in a single hemodialysis facility | The mean number of medication-related problems per patient and interventions was 8.96 and 6.1, respectively. This was associated with a cost savings of \$447,355 in a 6-month period. | (9) |
| Chronic hemodialysis | Medication reconciliation and medication therapy management | Pharmacist conducted, on average, 3.5 medication reconciliations per patient, which took approximately 40 minutes. Medication-related problems were identified in 59%, and the most common ones included nonadherence (27%), prescription renewals (21%), and excessive drug doses (14%). | (10) |

95% CI, 95% confidence interval; DBP diastolic blood pressure; OR, odds ratio; SBP systolic blood pressure.

Findings

Dietary Risk Factors for Kidney Stone Recurrence

A diet higher in calcium and potassium intake may help to reduce the risk of recurrent kidney stones, concludes a study in *Mayo Clinic Proceedings*.

The prospective study included 411 patients with their first episode of symptomatic kidney stones, with obstruction confirmed by imaging or stone passage, along with 384 stone-free controls. Both groups completed an electronic food frequency questionnaire during a baseline study visit. Dietary risk factors were compared between groups. Dietary associations with validated symptomatic recurrence were analyzed in proportional hazards models, with adjustment for fluid and energy intake and for nondietary risk factors.

Baseline characteristics associated with incident kidney stone formation included older age, White race, higher body

mass index (BMI), lower educational level, more hypertension, history of working in hot temperatures, and history of urinary tract infection and chronic diarrhea. During a median follow-up of 4.1 years, 17.8% of patients had recurrent symptomatic kidney stones. Clinical factors associated with recurrence included higher BMI; retained, asymptomatic stones of computed tomography; and higher scores on the Recurrence of Kidney Stone prediction tool.

Kidney stone risk was higher for individuals with dietary calcium intake of less than 1200 mg/day and higher for those with fluid intake of less than 3400 mL/day. On adjusted analysis, recurrent stone risk was associated with lower calcium, potassium, caffeine, and phytate intake, as well as lower total fluid intake. Lower dietary calcium remained a significant predictor on analysis, including further adjustment. Dietary potassium was significant only among patients not using thiazide diuretics or calcium supplements.

Several studies have reported on dietary factors associated with incident kidney stones, but little is known about dietary factors that may increase the risk of recurrent stones. "Enriching diets in stone formers with foods high in calcium and potassium may help prevent recurrent symptomatic kidney stones," according to the authors. Although patients are not likely to change their diet to prevent initial kidney stones, the researchers add, "[they] may be eager to do so to prevent symptomatic recurrence" [Chewcharat A, et al. Dietary risk factors for incident and recurrent symptomatic kidney stones. *Mayo Clin Proc* 2022; 97:1437–1448. doi: 10.1016/j.mayocp.2022.04.016].

Study Shows Discrepancies in Estimated versus Measured GFR

Individual-level estimated glomerular filtration rate (eGFR) values differ substantially from measured GFR (mGFR) values, reports a study in the *Annals of Internal Medicine*.

The researchers analyzed data on 3223 participants in four US epidemiologic studies that included mGFR values. The mean age of participants was 59 years; 55% of participants were women, and 32% were Black.

The mGFR values were obtained using non-radiolabeled iothalamate in two studies, radiolabeled iothalamate in one study, and plasma clearance of iohexol in one study and were indexed to 1.73 m^2 of body surface area. The eGFR values were calculated from serum creatinine alone and with serum cystatin C. The magnitude and clinical significance of any differences in the paired mGFR and eGFR values were assessed.

The mean mGFR value was 68 mL/min/1.73 m². Nine

percent of participants had an mGFR value of less than 30 mL/min/1.73 m². Overall eGFR values were higher than mGFR values; the median difference was -0.6 mL/min/1.73 m², with significant differences between groups. However, individual-level differences between values were large across subgroups defined by race, age, and sex.

At a creatinine-based eGFR of 60 mL/min/1.73 m², 50% of eGFR values were between 62 and 67 mL/min/1.73 m², 80% between 45 and 76 mL/min/1.73 m², and 95% between 36 and 87 mL/min/1.73 m². At an eGFR of 45 mL/min/1.73 m², 15% of participants had mGFR values outside the range of 30–60 mL/min/1.73 m², 30% outside the range of 35–45 mL/min/1.73 m², and 57% outside the range of 40–50 mL/min/1.73 m².

The discrepancies led to errors in classification of chronic

kidney disease by mGFR versus eGFR. The misclassification rate was 42%, with 22% of participants placed in a lower eGFR category and 20% in a higher category. Analysis of cystatin C-based eGFR showed no meaningful improvement.

The results show "substantial individual discrepancy" between eGFR and mGFR values. "Our findings highlight the need to make direct GFR measurements available to patients who need them," the researchers conclude, noting that nonradiolabeled techniques have made GFR measurement simpler and more feasible for clinical use [Shafi T, et al. Quantifying individual-level inaccuracy in glomerular filtration rate estimation: A cross-sectional study. *Ann Intern Med*, published online ahead of print July 5, 2022. doi: 10.7326/M22-0610; https://www.acpjournals.org/doi/10.7326/M22-0610].

Anticoagulation Management in Patients on Hemodialysis with Atrial Fibrillation More Questions than Answers

By Fatima Ali, Mital Jhaveri, and Sheila Sarnoski-Brocavich

Is atrial fibrillation (AF) in patients on dialysis an actual effector of cardioembolic events, or is it a surrogate marker for cardiovascular disease?

Overall, direct oral anticoagulants (DOACs) have a superior benefit to a risk profile compared with vitamin K antagonists (VKAs), such as warfarin. When it comes to patients on hemodialysis (HD), however, the confusion lies in which, if any, anticoagulants are appropriate. Patients receiving maintenance HD have a high incidence of stroke, which typically warrants the use of anticoagulation. However, patients on HD also have an increased risk of bleeding because they are routinely heparinized three times each week and have platelet dysfunction (1). A meta-analysis of 13 studies among patients on HD reported a stroke rate of 5.2 per 100 patient-years with AF versus 1.9 per 100 patient-years without AF (2). This suggests that AF is a risk factor in patients on HD. Interestingly, in a cohort of 1382 patients on HD, AF was not significantly associated with new stroke (3). Potential reasons for this are the high competing risk of mortality in patients on HD, a possible protective effect of heparin administration during the dialysis procedure, and the high prevalence of subclinical AF in the "no AF" cohort in observational studies of patients on HD (4). As a result, the use of anticoagulation in patients on HD with AF remains controversial.

Although VKAs are the mainstay therapy for thromboembolic issues, there is a paucity of evidence to support a reduction of risk of stroke in patients on HD. Considering this and the increased risk of bleeding and calciphylaxis, the use of VKA in patients on HD should be questioned (4, 5). On the other hand, the dependence of DOACs on kidney clearance, bioavailability, and bleeding risk is a factor to consider when treating patients on HD with AF (6). duced dose) were associated with a reduction in stroke or systemic embolism, although heterogeneity was high (9). In summary, the data are mixed, and we are still left with more questions than answers for stroke reduction using anticoagulation in patients on HD with AF.

Several randomized controlled trials assessing stroke and bleeding risk of oral anticoagulants versus VKAs or no anticoagulation in patients on HD with AF are currently ongoing and can provide better answers to this question (NCT02933697: AXADIA, NCT03987711: SAFE-D, and NCT03969953: TRACK).

Patients with AF on apixaban, a factor Xa inhibitor, qualify for either standard or reduced dosing. The standard dose for stroke risk reduction in patients with non-ventricular AF (NVAF) is typically 5 mg twice a day. A reduced dose of apixaban—2.5 mg twice daily—is warranted for patients meeting two of the three following criteria: >80 years old, serum creatinine >1.5 mg/dL, or weight <60 kg. The rationale for this dose adjustment is the greater risk of bleeding and mortality in patients with NVAF and in patients with at least two of the mentioned dose-adjustment criteria compared with patients with one or fewer of the criteria (10).

When it comes to bleeding events, the risk of fatal or intracranial bleeding increased in patients on apixaban (4.9 events/100 patient-years) versus those who received no anticoagulation (1.6 events/100 patient-years); this was true for apixaban 5 mg but not 2.5 mg twice a day. Apixaban at 2.5 mg twice a day dosing had a higher rate of myocardial infarction or ischemic stroke versus no anticoagulation. Apixaban resulted in lower all-cause mortality compared with those receiving no anticoagulation (11). Mortality risk is lowest with apixaban 5 mg compared with VKA, apixaban 2.5 mg, and no anticoagulation (11).

A study of 124 patients on HD found less bleeding in apixaban than VKAs (12). In a larger study of more

One major advantage of using direct oral agents...is that there is no need for measurement of INR levels or special dietary restrictions.

Should patients with kidney failure on HD with AF receive anticoagulants?

In a meta-analysis of 12 cohort studies comprising over 17,000 patients on HD with AF, VKAs had a non-significant (26%) reduction of ischemic stroke rate, no effect on total mortality, a 21% increase in total bleeding risk, and a doubling of the incidence of hemorrhagic stroke (7). On the other hand, in a meta-analysis of 15 studies that had more than 47,000 patients on HD with AF, the use of VKAs did not reduce ischemic stroke or all-cause mortality and increased risk of hemorrhagic stroke but did not affect overall risk of bleeding (8).

Overall, when compared with no anticoagulation, neither VKAs nor the DOAC apixaban (standard and re-

than 25,000 patients on chronic HD with AF, 2351 were taking apixaban (44% on 5 mg twice a day and 56% on 2.5 mg twice a day), and 23,172 were taking VKAs; the risk of stroke and intracranial bleeding was identical between both agents. Apixaban showed fewer major bleeding events and a non-significant trend toward reduced mortality (13). At a dose of 5 mg, apixaban resulted in less major bleeding, lower risk of stroke, and a non-significant trend toward reduced mortality compared with VKAs. At a dose of 2.5 mg twice a day, there was a lower risk of bleeding without differences in stroke and death (13). Finally, a meta-analysis of five studies comprising more than 43,000 patients (combined chronic kidney disease and end stage kidney disease [ESKD]) demonstrated

that apixaban was associated with lower risk of bleeding but similar risk of thromboembolic events when compared with VKA (14). Although the role of DOACs in patients on HD with AF remains ambiguous, apixaban is approved for use in dialysis and is a feasible alternative to VKA.

Data on the use of rivaroxaban for stroke risk reduction in patients with kidney failure and AF are limited. According to a study investigating the use of DOACs in HD patients with AF, the risk of bleeding is increased in DOACs, such as dabigatran and rivaroxaban, compared with apixaban (15). In addition, risk of hemorrhagic stroke was significantly lower in patients on dabigatran or rivaroxaban compared with VKAs, despite an overall increased bleeding risk (16). Only 33% of rivaroxaban is eliminated by the kidney with minimal dialyzability due to high protein binding. Currently, rivaroxaban can be used at a reduced dose of 15 mg in patients with reduced kidney function (creatinine clearance [CrCl] \leq 50 mL/min). There are limited data for use of rivaroxaban in patients with kidney failure (15). Despite this, the renally impaired population is being exposed to both rivaroxaban and dabigatran. Further research is necessary to make a recommendation.

The Valkyrie study (5) looked at 132 patients on HD with AF who were randomized to VKAs with a target international normalized ratio (INR) of 2-3, rivaroxaban 10 mg daily, or rivaroxaban plus vitamin K2 for 18 months. The incidence of fatal and non-fatal cardiovascular events and of symptomatic limb ischemia was higher in VKAs than both rivaroxaban groups. Furthermore, death from any cause, cardiac death, and risk of stroke were not different between the groups. Life-threatening or major bleeding adjusted for competing risk of death was increased in VKAs compared with rivaroxaban (5). Overall, in patients on HD with AF, a lower dose of rivaroxaban (10 mg) showed fewer outcomes of fatal and non-fatal cardiovascular events and major bleeding complications compared with VKA (5). Trials are underway to reach more definitive conclusions.

What doses are used for direct oral agents in patients on HD?

Only rivaroxaban and apixaban are suitable for patients undergoing maintenance HD, as they have the least dependence on kidney clearance and are not substantially eliminated by HD. A pharmacokinetic study found that a 10-mg dose of rivaroxaban in HD patients without residual kidney function results in drug exposure, similarly as published for 20 mg in healthy volunteers (17). Table 1 lists the various anticoagulants used for AF and their dosage adjustments in HD patients.

Apixaban is approved for use in patients with ESKD. Dosing recommendations for apixaban are derived from limited studies. In one study, patients with ESKD received a one-time dose of apixaban 5 mg, resulting in 36% higher area under the curve (AUC) and no increase in the maximum concentration (Cmax) of the drug compared with healthy subjects (18). In addition, levels taken after the HD session show a 13% and 14% reduction of Cmax and AUC for apixaban, respectively (18). However, in another pharmacological study of apixaban in patients on HD, they received 5 mg twice daily, which resulted in supra-therapeutic levels that should be avoided. Meanwhile, the reduced dose (2.5 mg twice a day) in

patients on HD was comparable with the standard dose (5 mg twice a day) in patients with normal kidney function (19). This suggests that apixaban 2.5 mg twice a day may be a viable dose alternative for patients on HD. The Valkyrie study (5) does suggest safety of using rivaroxaban in patients on HD with AF at a 10-mg dose, but more data are needed to confirm the use of this agent in patients on HD.

In summary, the data surrounding the use of oral anticoagulation in patients on HD with AF are challenging to interpret. This is because no randomized clinical trial has definitively shown that oral anticoagulants provide protection against stroke, whereas a substantial amount of evidence reveals a significantly increased bleeding risk.

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The authors report no conflicts of interest.

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Table 1. Comparison of various anticoagulants available for atrial fibrillation and their use in patients on hemodialysis

| Drug | МОА | Half-life | Atrial fibrillation dosing | Dose adjustment in reduced kidney function | % Kidney clearance | Hemodialysis | Atrial fibrillation hemodialysis dosing | Reversal agent | Reference |
|-------------|---------------------------------|----------------|--|--|---|--|---|--|------------|
| Dabigatran | Direct thrombin inhibitor | 12–17 hours | CrCl >30 mL/min; 150 mg twice daily | CrCl 15 to ≤30 mL/min; 75 mg twice daily CrCl < 15 mL/min; avoid use | 80%-85% | Dialyzable; 50%–60% eliminated in 4-hour treatment | Contraindicated | Idarucizumab | (1, 4, 7) |
| Rivaroxaban | Factor Xa inhibitor | 5–9 hours | CrCl >50 mL/min; 20 mg daily with evening meal | CrCl 15 to ≤50 mL/min; 15 mg daily with evening meal CrCl <15 mL/min; avoid use | 33% | Not dialyzable; 92%–95% protein bound | 10 mg Daily (very limited evidence) | Andexanet alfa 4-Factor prothrombin complex concentrate (off label) | (5, 7) |
| Apixaban | Factor Xa inhibitor | 8–15 hours | 5 mg Q12H | 2.5 mg Q12H If two of three of the following: age ≥80 y/o, wt ≤60 kg, or SCr ≥1.5 mg/dL | 27% | Minimally dialyzed (AUC 14% decrease post-HD) | 2.5 mg Q12h (approved for use) | Andexanet alfa 4-Factor prothrombin complex concentrate (off label) | (2, 4, 19) |
| Edoxaban | Factor Xa inhibitor | 10–14 hours | CrCl >50–95 mL/ min; 60 mg once daily | CrCl >95 mL/min; avoid use CrCl 15–50 mL/ min; 30 mg once daily CrCl <15 mL/min; avoid use | 50% | Not dialyzable | Contraindicated | 4-Factor prothrombin complex concentrate (off label) | (20) |
| Warfarin | Vitamin K antagonist | 40 hours | Based on INR | Based on INR | Extensively metabolized by CYP2C9 | Not dialyzable; 97%–99% protein bound | Dosing based on INR (commonly used) | 4-Factor prothrombin complex concentrate phytonadione (vitamin K) | (1-3) |

AUC, area under the curve; CrCl, creatinine clearance; CYP2C9, cytochrome P450 family 2 subfamily C member 9; HD, hemodialysis; INR, international normalized ratio; MOA, mechanism of action; Q12H, every 12 hours; SCr, serum creatinine; wt, weight; y/o, years old.

A Call for Kidney Eco-Warriors

By Priya Yenebere and Amy A. Yau

here is increasing evidence that climate change is associated with kidney diseases, and in turn, kidney disease therapies, namely dialysis, put an additional strain on the environment (1). The narrative review by Bharati and colleagues (2) details the many associations and proposed mechanisms of climate change and kidney diseases (Figure 1). The increase in global temperature and extreme weather coupled with food and water scarcity is associated with acute kidney injury, kidney stones, and chronic kidney disease. Beyond the direct effect of heat injury and dehydration, population migration and industrialization lead to urban heat islands, which may contribute to the rise of kidney stones and kidney injury and related hospitalizations (3-5). Repeat episodes of dehydration, intense heat stress, and exposure to agricultural pesticides are thought to cause chronic kidney disease of uncertain etiology, and air pollution is linked to glomerulonephritis (6-9). The destruction of ecologic habitats and biodiversity may increase risk of zoonotic diseases and associated kidney injury events (3, 10). In addition, dialysis is a resource-intense therapy. Each hemodialysis session requires up to 500 L of water and 7 kW of energy, and the carbon footprint is high even with home modalities through disposable waste (11-14). Unfortunately, climate change-related kidney events may disproportionately affect individuals in developing countries or with lower socioeconomic backgrounds (5, 15, 16).

The review by Bharati and colleagues (2) is encouraging in that there is growing interest and awareness of the intersection between the environment and kidney health/diseases. However, as the authors mention, the time for action is now. ASN agrees with a recently published call to action for nephrologists to focus on climate change and advocate for policy changes (17) (Figure 2). Further research to understand the impact and mechanism of climate change on kidney diseases and the impact and development of innovative kidney therapies is needed. Such research can include the carbon footprint tradeoffs of telemedicine or new water purification systems. Myriad green initiatives have been tried in the past with recorded objectives, but real and lasting change will require governmental and regulatory policy (18).

The mantra, "Think globally, act locally," is a call for organizations and institutions to identify a champion to help prioritize the relationship of the environment on kidney diseases and kidney therapies, such as ecofriendly dialysis units and health care innovations that can eventually be implemented globally. Nephrologists addressing issues in their own patient panels and dialysis units should be the first step for all of us.

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Figure 1. Key elements of climate change that affect kidney health care



Figure 2. ASN Call to Action



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