Management of Diabetes and Kidney Disease Through COVID-19
August 18, 2020

Support of the Diabetic Kidney Disease Collaborative is provided by Bayer, Boehringer Ingelheim and Lilly, AstraZeneca, and Janssen Pharmaceuticals, Inc.
Welcome & Opening Remarks

DEREK FORFANG
KHI PFPC, DKD Patient

Disclosures

Consultancy Agreements: University of North Carolina Kidney Center, CareDX, Ardelyx Inc
Scientific Advisory Board, ASN and Responsum, Bayer
Ownership Interest:
Research Funding:
Honoraria: National Kidney Foundation, ASN, HSAG ESRD Network #17
Patents and Inventions:
Scientific Advisor or Membership: HSAG ESRD Network #17 Board Member; National Forum of ESRD Networks, Board Member; National Forum of ESRD Networks, Kidney Patient Advisory Council, Chair; Kidney Health Initiative, Patient Advisory Committee; National Kidney Foundation, SONG Group, European Association for Dialysis, Arbor Research and Unity Health Toronto OPPUS, and Geisingers Institutes
Speakers Bureau:
Other Interests/Relationships: Volunteer for The Forum of ESRD Networks as Kidney Patient Advisory Council Chair and Board Member; Volunteer for ESRD Network #17 as Patient Advisory Committee Chair and Network Board Member; Volunteer for the NKF as a member of their Public Policy Committee; Volunteer for the NKF as a Regional Leader of their Kidney Advocacy Committee, KHI PFPC Member
MEETING SUMMARY

Conference 1 - “Implementing New Diabetic Kidney Disease Treatments - Time for Nephrologists to Act”

Date: January 14, 2020
Location: Washington, DC

Conference 1 - “Implementing New Diabetic Kidney Disease Treatments - Time for Nephrologists to Act”

• Focus: How to engage nephrologists to take on the responsibility to use innovative and powerful new drugs and other strategies to prevent chronic kidney disease or its progression in patients with diabetes
• Stakeholders
  • Nephrologists
  • Pharmaceutical
  • Healthcare Delivery
  • Patients
Project Objective

Develop, communicate, and enact ASN’s strategy concerning the role of the nephrologist, the provision of educational information, and the ideal focus of legislative and regulatory policy efforts to ensure that new therapies are used appropriately to provide high-quality care to people with diabetic kidney disease.

Project Goals

• Determine the role of the nephrologist in diagnosing and treating diabetic kidney disease
• Encourage nephrologists to interact proactively with primary care physicians and endocrinologists to ensure people with diabetic kidney disease receive the highest-quality care possible
• Provide educational information (through ASN’s education, media, communications, and publications channels)
• Address legislative and regulatory policy issues
New Therapies for Diabetic Kidney Disease: GLP-1 Receptor Agonists and Non-Glycemic Agents

Katherine R. Tuttle, MD, FASN, FACP, FNKF

Providence Health Care Nephrology Division, Kidney Research Institute, and Institute of Translational Health Sciences, University of Washington

SGLT2 inhibition and cardiorenal protection for patients with diabetes

David Cherney, MD CM, PhD, FRCP(C) Associate Professor of Medicine, University of Toronto Clinician Scientist, Division of Nephrology, UHN Director, Renal Physiology Laboratory, UHN Scientist, Toronto General Hospital Research Institute
State of DKD Care Implementation *Best Practices*

A Levin MD FRCPC CM
University of British Columbia
Vancouver, Canada

---

Diabetes and CKD in American Indian/Alaska Native People

*ANN BULLOCK, MD*

DIRECTOR
DIVISION OF DIABETES TREATMENT AND PREVENTION
INDIAN HEALTH SERVICE
Disclosures

**Employer:** Indian Health Service  
**Consultancy Agreements:** None  
**Ownership Interest:** None  
**Research Funding:** None  
**Honoraria:** None  
**Patents and Inventions:** None  
**Scientific Advisor or Membership:** only standard professional organization memberships  
**Speakers Bureau:** None  
**Other Interests/Relationships:** None

---

**Diabetes and CKD in American Indian/Alaska Native People**

Ann Bullock, MD  
Director  
Division of Diabetes Treatment and Prevention  
Indian Health Service
CDC National Diabetes Statistics Report, 2020

Figure 2. Age-adjusted estimated prevalence of diagnosed diabetes by race/ethnicity group and sex for adults aged 18 years or older, United States, 2017-2018.

Note: Error bars represent upper and lower bounds of the 95% confidence interval.
Data sources: 2017-2018 National Health Interview Survey, 2017 Indian Health Service National Data Warehouse (for American Indian/Alaska Native group only).

<table>
<thead>
<tr>
<th>Intervention</th>
<th>1997</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes clinical teams</td>
<td>30%</td>
<td>95%</td>
</tr>
<tr>
<td>Diabetes patient registries</td>
<td>34%</td>
<td>96%</td>
</tr>
<tr>
<td>Nutrition services for adults</td>
<td>39%</td>
<td>94%</td>
</tr>
<tr>
<td>Access to registered dietitians</td>
<td>37%</td>
<td>85%</td>
</tr>
<tr>
<td>Access to physical activity specialists</td>
<td>8%</td>
<td>84%</td>
</tr>
<tr>
<td>Access to culturally tailored diabetes education materials</td>
<td>36%</td>
<td>96%</td>
</tr>
<tr>
<td>Adult weight management programs</td>
<td>19%</td>
<td>76%</td>
</tr>
<tr>
<td>Nutrition services for children and youth</td>
<td>65%</td>
<td>90%</td>
</tr>
<tr>
<td>Community-based physical activity programs for children and youth</td>
<td>13%</td>
<td>85%</td>
</tr>
<tr>
<td>Physical activity programs for school-age youth</td>
<td>9%</td>
<td>83%</td>
</tr>
</tbody>
</table>

Source: Evaluation of the IHS Special Diabetes Program for Indians
Mean A1C 1997-2019

Source: IHS Diabetes Care and Outcomes Audit

Mean Blood Pressure 1997-2019

Source: IHS Diabetes Care and Outcomes Audit
Mean LDL Cholesterol
1998-2019

Audit Year

Mean LDL Cholesterol (mg/dl)

Source: IHS Diabetes Care and Outcomes Audit

CKD Testing and Diagnosis (Age ≥18 Years)
2010-2019

Audit Year

% Patients

Source: IHS Diabetes Care and Outcomes Audit
ACE Inhibitor/ARB Use
1997-2019

% Patients Using Ace Inhibitor/ARB

Audit Year

- All Patients
- Patients with Known Hypertension
- Patients with Elevated Urine Albumin/CKD

Source: IHS Diabetes Care and Outcomes Audit

Progress in Diabetes and Kidney Failure Outcomes

Indian Health Service
Division of Diabetes Treatment and Prevention
**Diabetes Prevalence**

- New study published by IHS and CDC authors
- Prevalence of diabetes in AI/AN people decreased from 15.4% in 2013 to 14.6% in 2017
  - First known decrease in AI/AN population
    - Decreases occurred in all age groups
    - Geographic regions: decreases or leveling off of prevalence
  - Happened at the same time that diabetes-related mortality also decreased in AI/AN people

- Full text article available at: [https://drc.bmj.com/content/bmjdc/8/1/e001218.full.pdf](https://drc.bmj.com/content/bmjdc/8/1/e001218.full.pdf)

---

**Diabetic Eye Disease**

- IHS Joslin Vision Network Tele-retinal Program (JVN)
  - Telemedicine program, established in 2000
- Data analysis of 54,000 AI/AN people with diabetes who participated in the JVN program 2011-2016
- Compared with studies done in the 1980s and 1990s, the prevalence of diabetic eye disease decreased by over 50%

  *PLoS ONE 2018;13(6):e0198551*
Uncontrolled Diabetes

AHRQ Data Spotlight:
“Hospital Admissions for Uncontrolled Diabetes Improving Among American Indians and Alaska Natives”

• Decreased 84% from 2000 to 2015

Agency for Healthcare Research and Quality (AHRQ)
AHRQ Publication No. 18(19)-0033-7-EF, December 2018

Diabetes-related Kidney Failure

• CDC Vital Signs
  • “Native Americans with Diabetes: Better diabetes care can reduce kidney failure”
    • *MMWR*, January 10, 2017

• Used data from the U.S. Renal Data System, U.S. Census, and IHS Diabetes Audit
Kidney failure from diabetes among AI/AN adults decreased by 54% (1996-2013)

*Rate per 100,000 population and age-adjusted based on the 2000 US standard population.
American Indians and Alaska Natives. Racial groups include persons of Hispanic and non-Hispanic origin; Hispanics may be of any race.
Source: Data from the US Renal Data System and the US Census.

Cost Savings Estimate

- HHS ASPE released an Issue Brief on May 10, 2019 titled “The Special Diabetes Program for Indians: Estimates of Medicare Savings”

- ASPE estimated that the decrease in new cases of kidney failure due to diabetes in AI/AN people resulted in 2,200 to 2,600 fewer cases and $436 to $520 million of savings to Medicare over a ten-year period—with some part of that attributable to SDPI.

Office of the Assistant Secretary for Planning and Evaluation (ASPE)
Department of Health and Human Services (HHS)
ASPE Issue Brief, May 10, 2019
New Kidney Failure Paper

New study by CDC and IHS authors:

• Extended the previous study’s data to 2016
• Published online in Diabetes Care
  – Abstract available at: https://care.diabetesjournals.org/content/early/2020/06/29/dc20-0495

COVID-19 positive tests reported to IHS
33,417 positive (I/T/U) 8-3-2020
Key Points

• Efforts over many years to provide excellent diabetes services at Indian health sites across the country are paying off
  • Prevalence of diabetes in AI/AN adults has decreased for the first time
  • Tremendous progress has been achieved in reducing diabetes complications, including kidney failure
• The effect of COVID on this progress remains to be seen

Thank you
www.ihs.gov/diabetes
Diabetes and Kidney Disease During COVID-19

JENNIFER GREEN, MD
PROFESSOR OF MEDICINE
DIVISION OF ENDOCRINOLOGY, METABOLISM AND NUTRITION
DUKE UNIVERSITY MEDICAL CENTER
DUKE CLINICAL RESEARCH INSTITUTE
DURHAM, NORTH CAROLINA

Disclosures

Consultancy Agreements:
- Boehringer Ingelheim (BI)
- BI/Lilly Alliance
- NovoNordisk

Research Funding:
- Boehringer Ingelheim
- Sanofi/Lexicon
**ADA 2020: Choice of Diabetes Medication**

*(After Metformin)*

**NEW IN 2020:**
Add beneficial agent in high risk patients even if additional HbA1c lowering not necessary

---

**Glucose-Lowering Medications in Patients with T2DM and CKD**

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Hypoglycemia Risk?</th>
<th>Impact on CKD</th>
<th>Effect on MACE</th>
<th>Effect on HF</th>
<th>Use and Dosing Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biguanides (metformin)</td>
<td>No</td>
<td>Neutral</td>
<td>Possible long-term benefit</td>
<td>Neutral</td>
<td>Contraindicated if eGFR &lt;30 mL/min/1.73 m²</td>
</tr>
<tr>
<td>SGLT2 inhibitors</td>
<td>No</td>
<td>Beneficial</td>
<td>Beneficial (dipglagliflozin neutral)</td>
<td>Beneficial</td>
<td>Renal dose adjustment required (canagliflozin indicated for use to eGFR ≥30 mL/min/1.73 m²)</td>
</tr>
<tr>
<td>GLP-1 receptor agonists</td>
<td>No</td>
<td>Beneficial (primarily reduced progression of albuminuria)</td>
<td>Beneficial (liraglutide, exenatide neutral; oral semaglutide effect to be determined)</td>
<td>Neutral</td>
<td>Use with caution when initiating or up-titrating dose in patients with reduced eGFR; renal dose adjustment required for liraglutide and exenatide</td>
</tr>
<tr>
<td>DPP-4 inhibitors</td>
<td>No</td>
<td>Neutral</td>
<td>Neutral (exception: increased risk with saxagliptin)</td>
<td>Neutral</td>
<td>May be used in all stages of CKD; all agents except liaglutin require renal dose adjustment</td>
</tr>
<tr>
<td>TZDs</td>
<td>No</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Increased risk</td>
<td>No dose adjustment required; monitor for volume overload</td>
</tr>
<tr>
<td>Sulfonylureas</td>
<td>Yes</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Dose cautiously if used to reduce risk hypoglycemia; avoid use of glimepiride</td>
</tr>
<tr>
<td>Insulin</td>
<td>Yes</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Dose cautiously; lower doses needed with reduced eGFR</td>
</tr>
</tbody>
</table>
COVID-19 Illness in High-Risk Populations

- Tremendous progress made in addressing CV, renal risks in T2DM
- COVID-19 poses direct and indirect risks to health
  - Infection
  - Interruption of care

Management of the Outpatient with T2DM and COVID-19

**Metformin**
- Dehydration and lactic acidosis will probably occur if patients are dehydrated, so patients should stop taking the drug and follow sick day rules
- During illness, renal function should be carefully monitored because of the high risk of chronic kidney disease or acute kidney injury

**Sodium-glucose-co-transporter 2 inhibitors**
- These include canagliflozin, dapagliflozin, and empagliflozin
- Risk of dehydration and diabetic ketoacidosis during illness, so patients should stop taking the drugs and follow sick day rules
- Patients should avoid initiating therapy during respiratory illness
- Renal function should be carefully monitored for acute kidney injury

**Glucagon-like peptide-1 receptor agonists**
- These include albiglutide, dulaglutide, exenatide-extended release, liraglutide, lixisenatide, and semaglutide
- Dehydration is likely to lead to a serious illness so patients should be closely monitored
- Adequate fluid intake and regular meals should be encouraged

*Use with caution, or not at all, in acute illness*
Management of the Outpatient with T2DM and COVID-19

Dipeptidyl peptidase-4 inhibitors
- These include alogliptin, linagliptin, saxagliptin, and sitagliptin
- These drugs are generally well tolerated and can be continued

Insulin
- Insulin therapy should not be stopped
- Regular self-monitoring of blood-glucose every 2–4 hours should be encouraged, or continuous glucose monitoring
- Carefully adjust regular therapy if appropriate to reach therapeutic goals according to diabetes type, comorbidities, and health status

Connected Health models and Telemedicine should be used to continue regular reviews and self-management education programmes virtually and ensure patients are adherent to therapy.

Severe COVID-19 Illness

Hospitalized patients with diabetes
- Have longer LOS
- More likely to
  - Require ICU care
  - Receive invasive mechanical ventilation
  - Experience acute kidney injury
  - Receive renal replacement therapy
- Have higher risk mortality
Diabetes and COVID: Inpatient or ICU Care

Increased risk DKA, HHS in patients with diabetes
Use insulin to meet inpatient BG targets
Likely need for IV insulin with dexamethasone
Watch for new-onset diabetes, or stress-induced hyperglycemia

COV]ID-19 Disruption of Care

Impact to Inpatient and Outpatient Encounters

<table>
<thead>
<tr>
<th>Condition</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cataracts</td>
<td>-97%</td>
</tr>
<tr>
<td>Chronic Otitis Media and Sinusitis (ear infection/sinus)</td>
<td>-75%</td>
</tr>
<tr>
<td>Asthma</td>
<td>-62%</td>
</tr>
<tr>
<td>Sleep Apnea (often a harbinger of cardiac disorders)</td>
<td>-91%</td>
</tr>
<tr>
<td>Hypertension</td>
<td>-74%</td>
</tr>
<tr>
<td>Ischemic Stroke</td>
<td>-56%</td>
</tr>
<tr>
<td>Glaucoma</td>
<td>-88%</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>-74%</td>
</tr>
<tr>
<td>Congestive Heart Failure</td>
<td>-55%</td>
</tr>
<tr>
<td>Osteoarthritis</td>
<td>-88%</td>
</tr>
<tr>
<td>Neuro Pain and Neuropathy</td>
<td>-71%</td>
</tr>
<tr>
<td>Chest Pain (non-cardiac)</td>
<td>-44%</td>
</tr>
<tr>
<td>Coronary Heart Disease</td>
<td>-75%</td>
</tr>
<tr>
<td>Care for Diabetes</td>
<td>-67%</td>
</tr>
<tr>
<td>Prostate Cancer</td>
<td>-44%</td>
</tr>
</tbody>
</table>

Model examined YoY comparison for a 2 week period (March 24 - April 6, 2019 and March 22 - April 4, 2020)
Care Family definition per Sg3 Care Cluster™

COVID-19 Disruption of Care

- Only half the excess deaths in Italy were directly linked to COVID
- In NYC, 6 to 8 fold increase in deaths at home


Waves of Care Disruption in High CV Risk Patients

1st WAVE
Acute COVID morbidity/mortality

2nd WAVE
Deferred/delayed urgent CVD interventions

3rd WAVE
Interrupted outpatient CVD and preventive care

Mitigating Risk in Patients with Diabetes, CKD, CVD

Outpatient preventive care is critical

• Maximize health at home
  • Multifactorial guideline-based risk reduction
  • Continue delivery of routine and acute care
  • Address disparities in care

Key Points

• People with diabetes who develop COVID-19 are at high risk for complications and mortality
• Precautions to prevent infection are critical for people with diabetes and their families.
• Quarantine is challenging!
  • Good dietary practices, safe physical activities and regular glucose monitoring should be encouraged
  • Telemedicine services and home drug delivery can reduce exposure

COVID-19 and DKD Management: A Personal Journey

PATRICK O. GEE, SR., PHD, JLC
HEALTHCARE CONSULTANT
CONSUMER ADVOCATE
FOUNDER AND CEHD, iADVOCATE, INC.

Disclosures

Leadership Positions/Membership/Affiliations:
- Quality Insights UDS Network 1 Patient Advisory Committee Chair.
- Founder & CEO, Advocate, Inc.
- Quality Insights EUR Network 3 Medical Review BDO.
- Patient Family Centered Care Partners (PVCP) Partners Advisory Board.
- Longterm Kidney Disease Patient Centered Care Collaborative.
- Otsuka Pharmaceutical Advisory Board Member for their Autosomal Dominant Polycystic Kidney Disease campaign.
- Chronic Disease Coalition Southeast Region Co-Chair.
- Center for Diabetic Innovation (CDI) Patient Advisory Board.
- Physician Leadership for Health Care Networks.
- American Society of Nephrology (ASN) Diabetic Kidney Disease Collaborative Task Force.
- BMJ Rapid Recommendation on STI/12 Inhibitors Research Patient Representative.
- PCORI Comparative Effectiveness of Home-Based Strategies to Control Blood Pressure for Patients with High Cardiovascular Risk during the COVID-19 Pandemic Workgroup.
- P4A Network Advisor member.
- PVCP Partners Diversity, Equity, and Inclusion Workgroup.
- National Kidney Foundation (NKF) KAC member.
- Donate Life OC Ambassador.
- NYEE-LAN Legacy SME member.

Financial Disclosure: Honorariums:
- Otsuka Pharmaceutical Advisory Board Member for their Autosomal Dominant Polycystic Kidney Disease Campaign. Honorarium-$130.00.
- Center for Diabetic Innovation Patient Advisory Board/Kidney Research Institute Board Member. Two Years of research Development on a Portable/Wearable Dialysis Unit. Honorarium-$1,500.00.
- Patient Family Advisors Network Guest Speaker for three Webinars on Kidney Disease, Hypertension, and Antibiotic Stewardship. Honorarium-$200.00 each. Total-$600.00.
- APOLO APOH Long-Term Kidney Transplantation Outcomes Consortium Community Advisory Council (CAC), representing the Cleveland Clinic. Honorarium-$400.00 per year for attending two in-person yearly meetings.
- CareDX Patient Ambassador Panelist on Kidney Transplantation, and Surviving COVID-19. Honorarium-$200.00 each. Total honorarium-$400.00.

Organizational Affiliation and Travel Reimbursements:
- American Association of Kidney Patients for attendance at National Patient’s Meeting and any other events representing the organization as a Board of Director member, SME, or other position.
- American Kidney Fund Ambassador and Advocacy Day meeting of Capitol Hill.
- CareDX Ambassador Ambassador Meeting.
- Quality Insights EUR Network 1 PAC Chair/ Quality Conference Meetings and Medical Review Board Meeting.
- American Society of Nephrology’s Diabetic Kidney Disease Collaborative Task Force Member and in-person meeting.
- Kidney Health Initiative Patient Family Partnership Council Member and in person meetings and KHI Stakeholders Annual Conference and attendance to ASN Annual Meeting in person.
- National Coordinating Center National Patient and Family Engagement Learning and Action Network Legacy Member and attendance to the CMS Quality Conferences.
- Global Cardiovascular Clinical Trials Forum International Faculty Member and attendance to the Annual CVT Forums.
- Patient Centered-Outcomes Research Institute Ambassador and attendance to the Annual PCORI meetings.
- Patient Family Advisor Network events.

Other Interest/Disclosures

Nothing further to disclose in the realm of kidney disease/medical innovation/pheramaceutical at this time.
Patient Access to New Therapies

GLENDA V. ROBERTS
KIDNEY RESEARCH INSTITUTE

Disclosures

Employment:
- Kidney Research Institute, Director – External Relations and Patient Engagement
- Center for Disease Innovation, Director – External Relations and Patient Engagement

Consultancy Agreements:

Research Funding:
- Center for Disease Innovation, AKTIV Human Factors Project, funded by Veterans Administration

Honors:
- Kidney Research Institute (KRI) Patient Advisory Committee (PAC)
- Kidney Precision Medicine Project Community Engagement Committee
- International Nephrology Society (ISN), Research Collaborative Meeting and 1st International Consensus Meeting on Defining Kidney Failure in Clinical Trials (Honorarium)
- APOLO Long-term Kidney Transplantation Outcomes Consortium Community Advisory Council (CAC), funded by NIDDK (Honorarium)

Scientific Advisor or Membership:
- American Association of Kidney Patients (AAKP) Ambassador
- American Association of Kidney Patients (AAKP), Speakers Bureau
- Center for Dialysis Innovation (CDI) Patient Advisory Board (PAB)

Other Interests/Relationships:
- Kidney Health Initiative (KHI) Patient Family Partnership Council
- American Society of Nephrology (ASN) COVID-19 Response Team
- American Society of Nephrology (ASN) COVID-19 Response Team, Transplant Subcommittee
- APOLO Long-term Kidney Transplantation Outcomes Consortium, Recruitment Committee
- International Nephrology Society (ISN), Global Trials Focus – Accessible to Patients
- International Nephrology Society (ISN), Patient Group
- Can-SOLVE CKD International Research Advisory Committee
- Home Dialyzer United Advisory Committee
- Kidney Precision Medicine Project, Member of Collaboration Committee
- Kidney Precision Medicine Project, Member of Return-of-Results Committee
- Kidney Precision Medicine Project, Director of Communications
- Founder & CEO, OUI Works

Financial Disclosure - Financial Support
- American Society of Nephrology (ASN), Kidney Week speaker (T&L Support)
- "The Role of the Kidney and SGLT2 in Glucose Homeostasis and Kidney Disease" Workshop, sponsored by the National Kidney Foundation (T&L Support)
- APOLO Delphi Consensus Meeting, funded by AstraZeneca (T&L Support)
- Microsoft stock ownership

Intellectual Property:
- Water-Conserving Kidney Dialysis System Incorporating Urea Photo-Oxidation, Center for Disease Innovation
- "DaGuardian: The Internet of Things" software application, Options Unlimited International, LLC
**Type 2 Diabetics with Kidney Disease**

- **SGLT2i** (sodium-glucose co-transporter-2 inhibitors)
  - Inhibit reabsorption of glucose in the kidney -> lower blood sugar
  - Farxiga, Jardiance, Invokana
- **GLP1RA** (glucagon-like peptide 1 receptor agonists)
  - Tells your body it needs to make insulin -> reduces blood sugar
  - Trulicity, Byetta, Bydureon, Tanzeum,
- **CGM** (continuous glucose monitoring)
  - Active/real-time management and control of diabetes
  - No finger sticks
  - Dexcom G6, Guardian Connect System, And Eversense CGM System
Human Subjects Research Trials

• Purpose
  • Determine if treatment works and is safe
  • Important to guide therapy options
• Eligibility criteria vary across trials
  • No standard eGFR threshold
  • Limiting to eGFR >30 is fairly common
• Consider IRB-approved national and international trials
• Industry trials are available

Randomized Clinical Trials Lags Behind Other Medical Disciplines

• Higher-than-average adverse event rates
• Limited number of known/validated disease mechanisms (KPMP)
• Small accessible patient population
• Innovative approaches are needed
  • to facilitate new trials in patients, and
  • to improve the therapeutic tool for doctors
ClinicalTrials.Gov

ClinicalTrials.gov is a database of privately and publicly funded clinical studies conducted around the world.

USING CLINICALTRIALS.GOV IS EASY
Global Kidney Patient Trials Network

- New global kidney platform trials network (GKPTN)
  - Increase access to trials and interested patients worldwide
  - Building bio-sample repository
  - Improve patient outcomes with timely and efficient evidence
  - Long-term follow up of kidney disease treatment and outcomes
- Based out of Australia
- Contact US Lead: Dr. Ian DeBoer (ideboer@uw.edu)
- Registered on clinicaltrials.gov

Global Kidney Patient Trials Network Criteria

- Inclusion
  - Documented diagnosis of kidney disease
    - eGFR > 15 ml/min/1.73 m
    - Regular visits (at least 6 monthly) with a physician
  - Able to sign informed consent
  - Approachable about interventional research studies
- Exclusion Criteria: Life-expectancy < 6 months
Coordinating DKD Care: Who Takes Care of My Diabetes, and Who Takes Care of My Kidneys?

KEVIN J. FOWLER
KIDNEY HEALTH INITIATIVE, BOD PRINCIPAL, THE VOICE OF THE PATIENT
Disclosures

- ASN
- Bayer
- Gilead
- eGenesis
- Hansa BioPharma
- HHS: Technical Expert Panel
- Otsuka
- Palladio Biosciences
- Responsum
- Retrophin
- Talaris

OBJECTIVES:

- Selecting a Nephrologist
- Alignment of Care Plan
Timing of Nephrology Referral

- CKD Stage 3
  - Maximum benefit of early interventions
  - Care Coordination
  - Long Term Plan
  - Patient Choices

Selection of a Nephrologist
Selection Criteria

• Interpersonal Skills
  • Respect
  • Communication skills
  • Coach/Teacher
  • Encourages Self-Management Skills
  • Sets High Expectations

• Clinical Approach
  • Believes in value of early Intervention
  • Communicates value of delayed progression
  • Facilitator of care plan, services and care coordination

Holistic Approach

• Diet
  • Diabetic Educator
  • Low utilization of Renal Dietician
  • Slow down DKD?

• Exercise
  • Role of Nephrologist advocating for exercise
  • Peer Mentors
  • Sense of Control
  • Slow down DKD?
**Holistic Approach**

- Mental Health
  - Prevalence In DKD
  - Screening
  - Remove barrier to self-management
- Social Services
  - Prioritize Needs
  - Remove barriers to patient engagement
  - Foundation in Place

**SUMMARY**

**Final Thoughts**

- Assess the Foundation
- Think with the end in mind
- Remove barriers to self-management
- Nephrologist > Coach > Facilitator
- Invest in Communication Skills Training
Questions

Roundtable

PAUL T. CONWAY, MODERATOR
CHAIR POLICY & GLOBAL AFFAIRS, IMMEDIATE PAST PRESIDENT
AMERICAN ASSOCIATION OF KIDNEY PATIENTS (AAKP)
Disclosures

Consultancy Agreements: None
Ownership Interest: None
Research Funding: None
Honoraria: 2019: (Travel/lodging/nominal stipend), AZ ADVICE Collaborative, AZ Dept. of Health Services; 2018-2019: (Nominal Stipend), External Expert Panel, Kidney Precision Medicine Project, NIH/NIDDK; 2018-2019: (Nominal Stipend), Clinical Journal of American Society of Nephrology, (CJASN); 2018: (Nominal Stipend), Clinical Trials Transformation Initiative, (CTTI), Duke University; 2018: (Nominal Stipend), AMGEN, Global Summit; 2018: (Nominal Stipend), American Board of Internal Medicine
Patents and Inventions: None
Scientific Advisor or Membership: Chair, Policy & Global Affairs, Member of Executive Committee, American Association of Kidney Patients (AAKP); Chair, Patient Access to Pain Relief Coalition (PAPR); Board Member, Kidney Health Initiative (KHI); Member, Advisory Board, Center for Dialysis Innovation (CDI), Northwest Kidney Centers; Member, Transplant Roundtable, Patient Editor, Clinical Journal of the American Society of Nephrology (CJASN); Member, Nephrology Specialty Board, American Board of Internal Medicine (ABIM);
Speakers Bureau: American Association of Kidney Patients (AAKP), volunteer Board Member listed on patient speaker bureau.

Panelist Introductions

ANN BULLOCK, MD
DEREK FORFANG
KEVIN J. FOWLER

PATRICK O. GEE, SR., PHD, JLC
JENNIFER GREEN, MD
GLENDA V. ROBERTS
Roundtable Discussion

Please send questions to the panelists using the questions panel on your screen.

Closing Remarks

PAUL T. CONWAY
PRESIDENT
AMERICAN ASSOCIATION OF KIDNEY PATIENTS (AAKP)