The KDIGO Diabetes Guidelines - Implications for the practicing nephrologist

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Diabetic kidney disease over time in the US

Prevalence of DKD in the US increased from 1988 to 2008 (2.2 to 3.3%)

Prevalence of DKD was stable despite increased use of glucose-lowering medications and renin-angiotensin-aldosterone system inhibitors

2009-2014 NHANES: 8.2 million adults with DKD
Contribution of Diabetes to CKD burden in the US

Diabetes and Chronic Kidney Disease in the US population, 2009-2014

METHODS
NHANES 2009-2014
N = 15,765

OUTCOME
Prevalence of CKD by Diabetes Status

<table>
<thead>
<tr>
<th>Diabetics</th>
<th>Any CKD</th>
<th>ACR ≥30</th>
<th>ACR ≥300</th>
<th>eGFR&lt;60</th>
<th>eGFR&lt;30</th>
</tr>
</thead>
<tbody>
<tr>
<td>N=2,279</td>
<td>25%</td>
<td>16%</td>
<td>4.6%</td>
<td>12%</td>
<td>2.4%</td>
</tr>
<tr>
<td>Non-diabetics</td>
<td>5.3%</td>
<td>3%</td>
<td>0.3%</td>
<td>2.5%</td>
<td>0.4%</td>
</tr>
<tr>
<td>N=13,396</td>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>

CONCLUSION
Diabetes is strongly associated with albuminuria and reduced eGFR, independent of demographics and hypertension, and contributes substantially to the burden of CKD in the US.

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# KDIGO - Description for rating guideline recommendations

<table>
<thead>
<tr>
<th>Grade</th>
<th>Implications</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Level 1</strong></td>
<td></td>
</tr>
<tr>
<td>“We recommend”</td>
<td>Most people in your situation would want the recommended course of action and only a small proportion would not.</td>
</tr>
<tr>
<td><strong>Level 2</strong></td>
<td></td>
</tr>
<tr>
<td>“We suggest”</td>
<td>The majority of people in your situation would want the recommended course of action, but many would not.</td>
</tr>
<tr>
<td>Grade</td>
<td>Quality of evidence</td>
</tr>
<tr>
<td>-------</td>
<td>---------------------</td>
</tr>
<tr>
<td>A</td>
<td>High</td>
</tr>
<tr>
<td>B</td>
<td>Moderate</td>
</tr>
<tr>
<td>C</td>
<td>Low</td>
</tr>
<tr>
<td>D</td>
<td>Very low</td>
</tr>
</tbody>
</table>
KDIGO guidelines continue to use the GRADE methodology, but we have strengthened the link between evidence and the recommendations themselves.

Guidelines now include a mix of recommendations and “Practice Points” to help clinicians better evaluate and implement the guidance from the expert Work Group.

All recommendations follow a consistent and structured format and are similar in style to previous KDIGO recommendations.

Practice Points are a new addition to KDIGO guidance, and may be formatted as a Table, a Figure, or an Algorithm to make them easier to use in clinical practice.

Guidelines will be published in print form and simultaneously posted online in MAGICapp; the online format will facilitate rapid updates as new evidence emerges.
How should I use Practice Points when caring for my patients?

- As noted, Practice Points are consensus statements about a specific aspect of care, and supplement recommendations for which a larger quality of evidence was identified.
- Note that Practice Points represent the expert judgment of the guideline Work Group, but may also be based on limited evidence.
- Unlike recommendations, Practice Points are not graded for strength of recommendation or quality of evidence.
- Users should consider the practice point as expert guidance, and use it as they see fit to inform the care of patients.
HbA1C measurement and target

- We recommend using hemoglobin A1c (HbA1c) to monitor glycemic control in patients with diabetes and CKD. (IC)
HbA1C target in DKD

We recommend an individualized HbA1c target ranging from 6.5% to <8.0% in patients with diabetes and non-dialysis dependent CKD (1C)

<table>
<thead>
<tr>
<th>CKD stages</th>
<th>HbA1c</th>
<th>Microvascular complications/comorbidities</th>
<th>Age</th>
<th>Life expectancy</th>
<th>Resources for hypoglycemia management</th>
<th>Hypoglycemia awareness</th>
<th>Propensity of treatment to cause hypoglycemia</th>
</tr>
</thead>
<tbody>
<tr>
<td>CKD1</td>
<td>6.5%</td>
<td>Yes</td>
<td>Yes</td>
<td>Short</td>
<td>Absent</td>
<td>No</td>
<td>Low</td>
</tr>
<tr>
<td>CKD5</td>
<td>8.0%</td>
<td>No</td>
<td>Old</td>
<td>Long</td>
<td>Present</td>
<td>Yes</td>
<td>Low</td>
</tr>
</tbody>
</table>
Individual patient data meta-analysis

- Four trials (ACCORD, ADVANCE, UKPDS, and VADT) with 27,049 participants comparing intensive vs less intensive glucose control

- Composite of end-stage kidney disease, renal death, development of an estimated glomerular filtration rate <30 mL/min per 1·73m², or development of overt diabetic nephropathy

- 1626 kidney events, 795 eye events, and 7598 nerve events were recorded during the follow-up period

- More intensive glucose control: -0·90% (95% CI -1·22 to -0·58) lower mean HbA₁c and 20% lower risk for kidney events (HR 0·80, 95% CI 0·72 to 0·88)

Intense glucose control increases the risk of death in CKD

- ACCORD trial data- 6,506 were free of CKD at baseline and 3,636 had CKD

- In CKD, compared with standard therapy, intensive glucose lowering was significantly associated with both 31% higher all-cause mortality (1.306: 1.065–1.600) and 41% higher cardiovascular mortality (1.412: 1.052–1.892)
Practice points (selected)

• Monitoring long-term glycemic control by HbA1c twice per year is reasonable for patients with diabetes. HbA1c may be measured as often as four times per year if the glycemic target is not met or after change in anti-hyperglycemic therapy.

• Accuracy and precision of HbA1c measurement declines with advanced CKD, particularly among patients treated by dialysis, in whom HbA1c measurements have low reliability.

• A continuous glucose management indicator (CGMI) can be used to index glycemia for individuals in whom HbA1c is not concordant with directly measured blood glucose levels or clinical symptoms.
We recommend that treatment with an angiotensin-converting enzyme inhibitor (ACEi) or an angiotensin II receptor blocker (ARB) be initiated in patients with diabetes mellitus, hypertension, and albuminuria, and titrated to the highest approved dose that is well tolerated. *(1B)*
Trends in Angiotensin Converting Enzyme Inhibitor and Angiotensin II Receptor Blocker Use among Those with Impaired Kidney Function in the United States

METHODS
U.S. adult population according to the National Health and Nutrition Examination Survey, years 1999-2014, by level of kidney function (normal, ACR ≥ 30 mg/g regardless of eGFR, or eGFR < 60 mL/min/1.73m² with ACR < 30 mg/g)

OUTCOME Prevalence of ACE/ARB use

ACE/ARB use (%) by era in those with ACR ≥ 30 mg/g regardless of eGFR

<table>
<thead>
<tr>
<th></th>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>2000</td>
<td>21</td>
<td>30</td>
<td>34</td>
<td>29</td>
</tr>
</tbody>
</table>

P < 0.001

ACE/ARB use (%) by era in those with eGFR < 60 mL/min/1.73m² and ACR < 30 mg/g

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>2000</td>
<td>21</td>
<td>34</td>
<td>50</td>
<td>69</td>
</tr>
</tbody>
</table>

P < 0.001

ACE/ARB use in those with any CKD: 26% in 1999-2002, 33% in 2003-2006, 39% in 2007-2010, and 40% in 2011-2014; P < 0.001

CONCLUSION ACE/ARB use has increased over time in the population with chronic kidney disease, including those with albuminuria and those with reduced eGFR without albuminuria, though progress has slowed since 2003-2006.

doi: 10.1681/ASN.20181000971
Suggested approach to manage adverse events with RAASi use

- Initiate ACEi or ARB
- Increase dose of ACEi or ARB
- Continue on maximally tolerated dose

- Monitor serum creatinine (within 2–4 weeks after starting or changing dose)
- Monitor serum potassium (within 2–4 weeks after starting or changing dose)

- < 30% increase
- > 30% increase
- Normokalemia
- Hyperkalemia

- Review for causes of AKI
  - Avoid dehydration and diuretics
  - Evaluate for renal artery stenosis
- Low potassium diet
  - Review concurrent drugs
  - Consider diuretics
  - Sodium bicarbonate
  - Consider Gl cation exchangers

- Persistent elevation in serum creatinine and/or potassium

- Reduce dose or stop ACEi or ARB as last resort
Oral hypoglycemic agent use in CKD

• In patients with Type 2 diabetes, CKD, and eGFR ≥30 mL/min/1.73m², we recommend that metformin be used as the first-line treatment for hyperglycemia. *(1B)*

• In patients with Type 2 diabetes, CKD, and eGFR ≥30 mL/min/1.73m², we recommend including an SGLT2i in the antihyperglycemic treatment regimen. *(1A)*

• In patients with Type 2 diabetes and CKD who have not achieved individualized glycemic targets despite use of metformin and SGLT2i, or who are unable to use those medications, we recommend using a long acting GLP-1 RA. *(1B)*
**Association of Treatment With Metformin vs Sulfonylurea With Major Adverse Cardiovascular Events Among Patients With Diabetes and Reduced Kidney Function**

Christianne L. Roumie, MD, MPH; Jonathan Chipman, PhD; Jea Young Min, PharmD, MPH, PhD; Amber J. Hackstadt, PhD; Adriana M. Hung, MD, MPH; Robert A. Greevy Jr, PhD; Carlos G. Grijalva, MD, MPH; Tom Elasy, MD, MPH; Marie R. Griffin, MD, MPH

<table>
<thead>
<tr>
<th></th>
<th>Metformin</th>
<th>Sulfonylureas</th>
<th>Adjusted Hazard Ratio (95% CI)</th>
<th>Favors Metformin</th>
<th>Favors Sulfonylureas</th>
<th>P for Interaction</th>
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</thead>
<tbody>
<tr>
<td><strong>Full matched-weighted cohort</strong></td>
<td>1048/24679</td>
<td>1394/24799</td>
<td>0.80 (0.75-0.86)</td>
<td></td>
<td></td>
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<tr>
<td><strong>Cardiovascular disease history</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>511/7797</td>
<td>671/7868</td>
<td>0.83 (0.75-0.92)</td>
<td></td>
<td></td>
<td>.34</td>
</tr>
<tr>
<td>No</td>
<td>537/16882</td>
<td>723/16931</td>
<td>0.78 (0.70-0.86)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Age, y</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥55</td>
<td>870/16796</td>
<td>136/16764</td>
<td>0.81 (0.75-0.88)</td>
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<td>.53</td>
</tr>
<tr>
<td>&lt;55</td>
<td>178/7883</td>
<td>258/8034</td>
<td>0.78 (0.66-0.92)</td>
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<tr>
<td><strong>Race</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Black</td>
<td>107/4035</td>
<td>154/4047</td>
<td>0.84 (0.87-1.06)</td>
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<td>.69</td>
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<tr>
<td>Nonblack</td>
<td>941/20644</td>
<td>1240/20752</td>
<td>0.80 (0.74-0.86)</td>
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<td></td>
<td></td>
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<tr>
<td><strong>Estimated glomerular filtration rate (eGFR)</strong></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;30 mL/min/1.73 m²</td>
<td>10/332</td>
<td>17/334</td>
<td>0.82 (0.51-2.72)</td>
<td></td>
<td></td>
<td>.38 and .54</td>
</tr>
<tr>
<td>30-45 mL/min/1.73 m²</td>
<td>65/1903</td>
<td>115/1886</td>
<td>0.70 (0.59-1.04)</td>
<td></td>
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</tr>
<tr>
<td>&gt;45 mL/min/1.73 m²</td>
<td>973/22444</td>
<td>1262/22578</td>
<td>0.80 (0.74-0.86)</td>
<td></td>
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<tr>
<td><strong>Consort entry criteria</strong></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Creatinine ≥ FDA threshold</td>
<td>125/5733</td>
<td>229/7779</td>
<td>0.74 (0.61-0.90)</td>
<td></td>
<td></td>
<td>.46</td>
</tr>
<tr>
<td>eGFR &lt;60 mL/min/1.73 m² + creatinine &lt; FDA threshold</td>
<td>923/39809</td>
<td>1164/29983</td>
<td>0.81 (0.75-0.88)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
# Kidney outcomes with SGLT2i based on baseline kidney function

<table>
<thead>
<tr>
<th>eGFR &lt;60 mL/min per m²</th>
<th>Patients</th>
<th>Events</th>
<th>Events per 1000 patient-years</th>
<th>Weight (%)</th>
<th>HR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment (n)</td>
<td>Placebo (n)</td>
<td>Treatment</td>
<td>Placebo</td>
<td>Treatment</td>
<td>Placebo</td>
</tr>
<tr>
<td>EMPA-REG OUTCOME</td>
<td>1196</td>
<td>605</td>
<td>NA</td>
<td>11.4</td>
<td>15.1</td>
</tr>
<tr>
<td>CANVAS Program</td>
<td>NA</td>
<td>NA</td>
<td>83</td>
<td>8.9</td>
<td>15.2</td>
</tr>
<tr>
<td>DECLARE-TIMI 58</td>
<td>606</td>
<td>659</td>
<td>59</td>
<td>8.9</td>
<td>15.2</td>
</tr>
<tr>
<td>Fixed effects model for eGFR &lt;60 (p&lt;0.0054)</td>
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<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>eGFR 60 to &lt;90 mL/min per m²</th>
<th>Patients</th>
<th>Events</th>
<th>Events per 1000 patient-years</th>
<th>Weight (%)</th>
<th>HR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment (n)</td>
<td>Placebo (n)</td>
<td>Treatment</td>
<td>Placebo</td>
<td>Treatment</td>
<td>Placebo</td>
</tr>
<tr>
<td>EMPA-REG OUTCOME</td>
<td>2406</td>
<td>1322</td>
<td>NA</td>
<td>4.6</td>
<td>7.4</td>
</tr>
<tr>
<td>CANVAS Program</td>
<td>NA</td>
<td>NA</td>
<td>118</td>
<td>4.2</td>
<td>7.8</td>
</tr>
<tr>
<td>DECLARE-TIMI 58</td>
<td>3838</td>
<td>3894</td>
<td>106</td>
<td>4.2</td>
<td>7.8</td>
</tr>
<tr>
<td>Fixed effects model for eGFR 60 to &lt;90 (p&lt;0.0001)</td>
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<td></td>
<td></td>
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<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>eGFR ≥90 mL/min per m²</th>
<th>Patients</th>
<th>Events</th>
<th>Events per 1000 patient-years</th>
<th>Weight (%)</th>
<th>HR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment (n)</td>
<td>Placebo (n)</td>
<td>Treatment</td>
<td>Placebo</td>
<td>Treatment</td>
<td>Placebo</td>
</tr>
<tr>
<td>EMPA-REG OUTCOME</td>
<td>1043</td>
<td>486</td>
<td>NA</td>
<td>3.8</td>
<td>8.1</td>
</tr>
<tr>
<td>CANVAS Program</td>
<td>NA</td>
<td>NA</td>
<td>48</td>
<td>3.8</td>
<td>8.1</td>
</tr>
<tr>
<td>DECLARE-TIMI 58</td>
<td>4137</td>
<td>4025</td>
<td>120</td>
<td>2.5</td>
<td>4.9</td>
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<tr>
<td>Fixed effects model for eGFR ≥90 (p&lt;0.0001)</td>
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<td></td>
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</tr>
</tbody>
</table>

CV outcomes with SGLT2i based on baseline kidney function

**CREDENCE trial**

- Canagliflozin 100 mg daily vs placebo among those with eGFR 30-90 ml/min/1.73 m²
- N= 4401; >1300 with eGFR 30-45 ml/min
- No differences based on baseline kidney function and severity of proteinuria

Pooled data-SGLT2 inhibitors reduced the risk of dialysis, transplantation, or death

<table>
<thead>
<tr>
<th>Study</th>
<th>Events</th>
<th>Patients</th>
<th>RR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CREDEENCE</td>
<td>183</td>
<td>4401</td>
<td>0.72 (0.54–0.97)</td>
</tr>
<tr>
<td>DECLARE-TIMI 58</td>
<td>34</td>
<td>17160</td>
<td>0.42 (0.20–0.87)</td>
</tr>
<tr>
<td>CANVAS Program</td>
<td>21</td>
<td>10142</td>
<td>0.56 (0.23–1.32)</td>
</tr>
<tr>
<td>EMPA-REG OUTCOME</td>
<td>14</td>
<td>7020</td>
<td>0.90 (0.30–2.67)</td>
</tr>
<tr>
<td>Overall</td>
<td></td>
<td></td>
<td>0.67 (0.52–0.86; p=0.0019)</td>
</tr>
</tbody>
</table>

\( I^2 = 0.0\% \); \( P_{\text{heterogeneity}} = 0.53 \)

Favours SGLT2 inhibitor

Favours placebo

Neuen et al. Lancet Diabetes Endocrinol 2019 Sep 5
No increased Risk of Acute Kidney Injury in Patients on SGLT2 Inhibitors

Cohort study from two health systems in the US

>1500 SGLT2i users and >1500 non-users

Median f/u: 14 months

Similar data reported from Israel- >6000 news users of SGLT2-i

Adverse effects

- Urinary frequency/GU infections
- Fractures (canagliflozin)
- Lower limb (toe, mid-foot) amputations (canagliflozin)
- Euglycemic DKA
- Fourniers gangrene
SGLT2i practice points (selected)

- For patients in which additional glucose lowering may increase risk for hypoglycemia (e.g., those treated with insulin or sulfonylureas and currently meeting glycemic targets), it may be necessary to stop or reduce the dose of an antihyperglycemic drug other than metformin to facilitate addition of an SGLT2i.

- It is reasonable to withhold SGLT2i during times of prolonged fasting or critical medical illness (when patients may be at greater risk for ketosis).

- If a patient is at risk for hypovolemia, consider decreasing thiazide or loop diuretic dosages before commencement of SGLT2i and advising patients about symptoms of dehydration and low blood pressure, and follow up volume status after drug initiation.

- A reversible decrease in eGFR with commencement of SGLT2i may occur and is generally not an indication to discontinue therapy.

- Once an SGLT2i is initiated, it is reasonable to continue an SGLT2i even if eGFR falls below 30 ml/min/1.73 m2, unless reversible changes in eGFR are precipitating uremic symptoms or other complications of CKD.
Suggested approach for those with DM and CKD

- Lifestyle therapy
- Base drug therapy
- Additional drug therapy as needed for glycemic control, guided by patient preferences, comorbidities, eGFR, and cost

Physical activity
Nutrition
Weight loss

Metformin
- eGFR ≥ 30 mL/min/1.73m²: dose per eGFR
- eGFR < 30 mL/min/1.73m²: discontinue
- Dialysis: discontinue

SGLT-2 inhibitor
- eGFR ≥ 30 mL/min/1.73m²
- eGFR < 30 mL/min/1.73m²: do not initiate
- Dialysis: discontinue

GLP-1R agonist (preferred)
DPP-4 inhibitor
Insulins
Sulfonylurea
TZD
Alpha-glucosidase inhibitors

Metformin but not SGLT2i are recommended for kidney transplant recipients according to eGFR.
Adding SGLT-2i to current regimen

*Particularly for patients who are not experiencing hypoglycemia and those using only medications with low risk of hypoglycemia, i.e. metformin, GLP-1 RA, DPP4i, thiazolidinedione, and acarbose*
### Recommended dosing in CKD

<table>
<thead>
<tr>
<th>SGLT-2 inhibitor</th>
<th>Dose</th>
<th>Kidney function eligible for inclusion in pivotal randomized trials</th>
</tr>
</thead>
</table>
| Dapagliflozin    | 5–10 mg once daily    | No dose adjustment if eGFR ≥ 45 mL/min/1.73m²  
Not recommended with eGFR < 45 mL/min/1.73m²  
Contraindicated with eGFR < 30 mL/min/1.73m² |
| Empagliflozin    | 10–25 mg once daily   | No dose adjustment if eGFR ≥ 45 mL/min/1.73m²  
Avoid use, discontinue with eGFR persistently < 45 mL/min/1.73m²                                                      |
| Canagliflozin    | 100–300 mg once daily | No dose adjustment if eGFR > 60 mL/min/1.73m²  
100 mg daily if eGFR 30–59 mL/min/1.73m²  
Avoid use, discontinue with eGFR persistently < 30 mL/min/1.73m²                                                      |
Special considerations
Lifestyle modifications

- We suggest maintaining protein intake of 0.8 g/kg/day for those with diabetes and non-dialysis CKD. (2C)

- We suggest reducing sodium intake to 1,500 mg of sodium per day (or 65 mmol of sodium per day, or 3,750 g of sodium chloride per day) in patients with diabetes and CKD. (2C)

- We recommend patients with diabetes and CKD who use tobacco quit using tobacco products. (1D)

- We recommend that patients with diabetes and CKD should undertake moderate-intensity physical activity for a cumulative duration of at least 150 minutes per week, or to a level compatible with their cardiovascular and physical tolerance. (1D)
Kidney healthy diet
Physical activity in CKD

- Assess baseline physical activity level
  - Sedentary
  - Assess fall risk and comorbidity burden
    - **Low risk** Recommend low intensity activity and increase intensity as tolerated
    - **High risk** Referral to exercise specialists
  - Physically active for < 150 minutes per week
    - Recommend to increase physical activity level to achieve > 150 min/week
  - Physically active for > 150 minutes per week
    - Achieves recommended physical activity level
    - Assess and recommend muscle-strengthening activities
Self-management and team-based approach

• We recommend a structured self-management educational program be implemented for care of people with diabetes and CKD (1C)

• We suggest policy-makers and institutional decision-makers to support practitioners in implementing team-based, data-driven, integrated care focused on risk evaluation and patient empowerment to treat to multiple targets in patients with diabetes and CKD (2B)
Patients with diabetes and CKD

Multicomponent, integrated and team-based care

Non-physician care

Information technology to promote communication and feedback

Physician care

Special education and counselling:
- e.g. nutrition, weight reduction, foot care, stress management

Ongoing psychosocial support:
- Peers, community workers, expert patients, families and friends

Regular structured assessment:
- Risk factors, complications, lifestyles, psychological stress, nutrition, exercise, tobacco, alcohol, self-monitoring, drug adherence

Structured patient education and empowerment:
- Improve self-management
- Provide regular feedback to engage both patients and physicians

Multidisciplinary care:
- Individualize goals and treatment strategies
- Monitor clinical progress
- Assess risks and benefits
Combating DKD: Multidisciplinary effort

Experience from Indian Health Service

54% reduction in incidence of diabetes related to ESRD among American Indian and Alaskan Native people with Diabetes

Narva A. Am J Kidney Dis. 71(3):407-411
Improvement in RAASI use
Summary

• Final KDIGO guidelines on DM and CKD will be released in 2020
• Several aspects of management addressed- HbA1C, medication use, and lifestyle modifications
• Introduction of practice points
• Guideline will be updated as new trial results come out
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• KDIGO team