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# STAKEHOLDER PERSPECTIVES IN DIABETES MANAGEMENT FOR PATIENTS WITH RENAL IMPAIRMENT

APRIL 2011 • PART 5 IN A SERIES

## Advisory Board Panel Discussion: Managing Patients with Type 2 Diabetes and Associated Complications

By Diana I. Brixner, PhD, RPh; Alan J. Garber, MD, PhD, FACE; Maria Lopes, MD, MS;  
Robert P. Navarro, PharmD; Adam Whaley-Connell, DO, MSPH  
Moderated by Robyn R. Graham, PharmD

### EDITOR'S NOTE

*American Health & Drug Benefits* is publishing a newsletter series designed to provide stakeholder insights on diabetes management, chronic kidney disease (CKD), and the effect available therapies may have overall. In light of the wealth of published information on diabetes, this newsletter series provides relevant, up-to-date information on diabetes and its related complications, specifically renal impairment, in a clear and concise manner to assist you in the development of innovative policies, practices, and benefit designs to appropriately and effectively manage this complex disease that is associated with exorbitant healthcare costs.

Each newsletter hosts a thought leader whose expert opinion is presented for review and consideration when evaluating diabetes management initiatives. The thought leaders selected for the Editorial Board for this series are respected experts in their respective areas of practice—endocrinology, benefit design, evidence-based medicine, pharmacoeconomics, and nephrology. They provide fair and balanced information to serve as guidance in the choice

of appropriate care for patients with diabetes to improve glycemic control; prevent disease progression, including the management of comorbidities, such as CKD; and decrease overall healthcare resource utilization and costs.

The first newsletter of the series (available at [www.AHDBonline.com](http://www.AHDBonline.com)) focused on the relevance of diabetes as a topic of substantial importance to the healthcare industry.

The second newsletter provided an overview of the pathophysiology of diabetes and the measurement and screening parameters related to successful screening, diagnosis, and management of diabetes and its related complications.

The third newsletter focused on the non-pharmacologic management of type 2 diabetes.

The fourth newsletter addressed adherence to therapy in patients with diabetes and those with the complications of type 2 diabetes, including CKD.

This fifth and last newsletter is a consolidation of a discussion by the Editorial Board in response to a set of questions regarding diabetes, CKD, and other topics pertinent to today's healthcare environment. ■

*The following discussion is based on expert opinions provided by members of the Editorial Advisory Board of this series.*

SUPPLEMENT TO  
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# Advisory Board Panel Discussion

**The first set of questions addressed by the panel concerns patients with diabetes and the primary challenges associated with managing this patient population.**

**Moderator:** *What do you see as the greatest obstacles to diabetes management?*

**Maria Lopes, MD, MS:** Lack of patient adherence to lifestyle modification, medication regimens, a lack of education, cultural disparities, clinician inertia in getting to goal, decision support tools, and alignment of incentives.

**Diana I. Brixner, PhD, RPh:** The greatest obstacles in managing the diabetes population are achieving and maintaining glycemic control, while also managing obesity and other cardiovascular-related comorbidities, such as hypertension and hyperlipidemia. Another obstacle is implementing risk education strategies.

**Robert P. Navarro, PharmD:** Obstacles are sometimes patient-specific and sometimes involve the healthcare delivery system. Some patients have a lack of personal responsibility and continue with poor lifestyle choices, remain obese, and are poorly adherent to their treatment regimen. Some delivery systems lack adequate education and individualized follow-up where necessary.

**Alan J. Garber, MD, PhD, FACE:** The fact is that patients don't realize that diabetes is a progressive disease, and they fear progressive therapy. The fact is that patients don't realize that diabetes is a progressive disease, and they fear progressive therapy—a greater number of drugs to deal with beta-cell failure, higher doses. This is a challenge for patients and providers. The lack of recognition that progressive beta-cell failure—the core defect in type 2 diabetes mellitus requires aggressive, anticipatory treatments.

**Moderator:** *It is evident that there is some agreement that patient nonadherence, lack of patient understanding, obesity, and comorbidities are significant obstacles in the management of patients with diabetes. What tools/mechanisms of communication do you think are necessary to improve adherence in patients with diabetes?*

**Dr Navarro:** First, improved access and distribution of patient educational material that may be customized for specific patient needs and their level of understanding. Second, more effective triage for identifying patients who are better educated about and are able to self-manage their disease versus patients who require greater one-on-one training and more frequent follow-up. Third, greater assignment of case managers and diabetes educators for high-risk individuals who require an intensive level of care, as well as greater involvement by pharmacists for monitoring poor adherence and expanding intervention strategies with patients, providers, and case managers.

**Dr Lopes:** Evaluation of issues driving nonadherence, such as lack of member education, cultural disparities and language barriers, and providing motivational assessments to help overcome these barriers.

**Dr Brixner:** Communication needs to be patient-centric to help improve adherence. This can be accomplished through a multidisciplinary approach to care using motivational interviewing and culturally competent strategies that educate patients on why it is important to take their medication as prescribed, as well as the consequences of not adhering to drug therapy. Patients should also be educated about other lifestyle and self-monitoring recommendations.

**Moderator:** *Improved patient communication strategies including consideration of cultural diversity and language barriers, in addition to motivational exercises appear to be critical components for addressing poor or lack*

*of adherence in the diabetes population. In your opinion, what needs to be done to accomplish diabetes prevention?*

**Dr Lopes:** Lifestyle modification to achieve reduction in obesity.

**Dr Whaley-Connell:** I'm unsure that diabetes prevention is possible without tackling the obesity epidemic. I think screening and detection are more appropriate.

**Dr Brixner:** To accomplish diabetes prevention, the obesity problem in the United States at an early age needs to be addressed. Healthcare providers should not wait until individuals become obese, or until obese youth make it to adulthood. Obesity awareness should focus on the benefits of healthy nutrition and physical activity strategies, as well as negative health consequences. Obese adults should be aggressively managed and monitored, and diet and exercise therapy should be implemented sooner and not put off until chronic conditions, such as diabetes, develop.

**Dr Navarro:** Nutrition and the seriousness of diabetes must be communicated at an early age, in elementary schools, with special emphasis and aggressive and emphatic education for high-risk student subgroups. Patient education through age-appropriate venues, such as public service announcements on television and radio emphasizing nutrition, obesity, exercise, and even diabetes, should help increase the awareness and urgency of the importance of screening and early intervention for the prevention of diabetes. Screening that reveals high-risk or prediabetes should result in intensive education to reverse the trend.

**Moderator:** *To summarize—screening, lifestyle modification, more powerful education, and a reduction in obesity in all age-groups needs to be accomplished to attain any level of prevention in the incidence*

# Managing Patients with Type 2 Diabetes

of diabetes. What should managed care organizations (MCOs) do, beyond creating disease management programs, to improve diabetes management outcomes?

**Dr Navarro:** Closed-model plans may be more effective in reducing practice variance. Many open-model plans have successfully used diabetes disease management programs to improve average glycemic control and HEDIS (Healthcare Effectiveness Data and Information Set) measures, all indicating a general improvement in management and supporting better outcomes. Pay-for-performance (P4P) may be effective. However, patient irresponsibility will sabotage the best-designed care plan. Identifying and improving patient irresponsible behavior—personal lifestyle or adherence—remains a challenge.

**Dr Brixner:** MCOs' diabetes prevention and care models should support a patient-centric proactive approach. Programs should not wait for a high level of disease severity to develop or for the onset of complications to occur before intervening; they should address all related comorbidities within the diabetes framework, including obesity and hypertension; reimburse health professionals for improving outcomes and not just delivering care; and recognize all healthcare team members, including pharmacists, dietitians, and certified diabetes educators for the unique knowledge they can contribute. Also, MCOs may want to consider using patient incentives (eg, decreased premiums, copays) to help achieve healthy outcomes.

**Dr Whaley-Connell:** Improve access at all levels; specialist referral as well as reimbursement for lifestyle and pharmacologic intervention.

**Dr Lopes:** Consider what the clinician needs to be successful in achieving better outcomes.

**Moderator:** Access to care and incentives on the provider and the patient levels should be incorporated into disease management programs for diabetes. What are your thoughts on disease management programs focusing on all stages of chronic kidney disease (CKD)?

**Dr Lopes:** Plans tend to focus on stage 4 or 5 CKD. The detection of nephropathy should be incorporated in diabetes, hypertension, or cardiovascular disease (CVD) management programs.

**Dr Whaley-Connell:** I think the point should really be on promoting awareness, which is incredibly low for CKD. Nephrology referral has been shown to improve outcomes, but awareness of CKD needs to be addressed first and foremost.

**Dr Brixner:** Disease management programs should focus on prevention strategies for CKD that are similar to those for diabetes. Clinicians should emphasize the correlation between CKD and diabetes-related retinopathy.

**Dr Navarro:** Screening for diabetes and annual physical examinations must include renal function tests, such as estimated glomerular filtration rate (eGFR). Patients with diabetes who have renal impairment or abnormal renal function tests must be monitored more carefully and drug therapy must be given greater consideration.

As suggested by Baxley, "Successful management of chronic diseases therefore necessitates that the MCO embrace the entire spectrum of a disease. For instance, CKD, as a component of a chronic disease state, should be included in any diabetes or hypertension program. Unfortunately, this long-term encompassing approach frequently is at odds with an MCO's short-term, compliance-driven data requirements."<sup>1</sup>

**Moderator:** Screening and interventions for CKD should be included in diabetes and hypertension disease management programs.

What role do case management and/or quality outcomes groups play in the management of type 2 diabetes, with or without CKD?

**Dr Navarro:** The National Kidney Foundation Kidney Disease Outcomes Quality Initiative (NKF KDOQI) has been in existence since 1997, and has guidelines (available at [www.kidney.org/professionals/kdoqi/guidelines\\_comments.cfm](http://www.kidney.org/professionals/kdoqi/guidelines_comments.cfm)) familiar to anyone caring for patients with CKD, including disease management companies.

**Dr Brixner:** Case management and quality outcomes groups play a role in strategies such as continuous quality improvement and persistent reassessment of patient outcomes, which may help identify and focus on patients who are outside target ranges for glucose, blood pressure (BP), and lipids.

**Dr Lopes:** Case management addresses the sickest, highest-cost members with multiple comorbid conditions, in which the best we can do is keep the patients out of the hospital. The focus of disease management is on less-severe disease, where there is an opportunity to modify outcomes and reduce costs.

**Moderator:** Case management and quality outcomes groups play a role in management strategy development and assessment of outcomes. Do patients with type 2 diabetes and comorbid CKD (any stage) automatically invoke case management or other interventions?

**Dr Lopes:** Yes, if the patient has high resource utilization such as frequent hospitalizations, multiple emergency department visits, or high cost.

**Dr Brixner:** Although automatic case management is ideal, case management is not always automatically invoked. In these cases, MCOs should be proactive and vigilant to ensure that patients with CKD are not falling out of target clinical end points and are provided with

# Advisory Board Panel Discussion

targeted educational interventions, such as disease and treatment expectations, monitoring renal function to assess appropriate dosing strategies, or, if receiving dialysis, appropriate times to take medications.

**Moderator:** *Health plans do not automatically enroll patients with comorbid disease states into case management programs; however, MCOs should be proactive and vigilant about assessing this patient population. What should MCOs do to enhance the efforts to reduce the incidence of prediabetes and diabetes?*

**Dr Brixner:** MCOs should promote obesity awareness and prevention programs in youth and young adults. Risk awareness of type 2 diabetes should be raised at an early age, while also increasing the awareness of the benefits of a healthy lifestyle.

**Dr Whaley-Connell:** Improving obesity lifestyle programs and improving reimbursement of screening and detection.

**Dr Lopes:** Improve member education and work with employers on lifestyle modification, exercise, and weight-loss awareness and initiatives.

**Dr Navarro:** Lifestyle modification and screening to identify prediabetes and high-risk individuals.

**Moderator:** *Lifestyle modification, primarily weight loss, and screening programs should be implemented and reimbursed to reduce the incidence of prediabetes and diabetes. Do certain methods of communication work better with this population than other methods?*

**Dr Navarro:** Effective patient communication depends on the patient. That is, patients respond to different forms of media and different messages. Certain patients respond to one-on-one training, some prefer classes, and the option of

incoming and outbound phone calls with a pharmacist, case manager, or diabetes educator should also be available.

**Dr Lopes:** Patient communication is not one size fits all. Communications need to motivate the patient and empower them to change their behavior.

**Dr Brixner:** Although each patient learns differently, multimedia and social networks work well with a younger population of patients who may benefit from education and prevention interventions.

**The second set of questions addresses the future of diabetes management.**

**Moderator:** *Thinking of the pathophysiology of diabetes, what drug classes do you see being the most beneficial—all-encompassing in terms of safety, efficacy, comorbid state considerations, other organ complications—microvascular and macrovascular therapy?*

**Dr Garber:** Because of the need for aggressive compensation of beta-cell function failure—drugs not associated with hypoglycemia and weight gain are favorable over those known to frequently produce hypoglycemia. If today a patient's glucose levels are not bad, but you know that in 6 months they will be, using a higher medication dose that you know will be needed later results in unsafe hypoglycemia at the present time.

This is the heart of what is wrong with diabetes treatment today, and where treatment will focus in the future. Using newer, more costly treatments—to get value for money spent—helps to avoid adverse effects while optimizing therapy and outcomes.

**Dr Whaley-Connell:** Drugs with renin-angiotensin-aldosterone system (RAAS) inhibition.

**Dr Navarro:** Drug therapy must be individualized for the patient based on

type of disease, severity of disease, comorbidities, hepatic and renal function, as well as the ability and willingness of the patient to use insulin, another injectable, or an oral medication. A major limitation I see is the unwillingness of patients and physicians to use insulin earlier and more effectively.

**Moderator:** *There are many considerations when selecting therapy for patients with diabetes. Indeed therapy must be individualized. Perhaps the best option for healthcare providers is to follow expert-developed and -recognized guidelines for the management of diabetes. Regarding adherence to therapy, what drug classes do you think provide the greatest potential?*

**Dr Garber:** Adherence is a critical component in the management of diabetes. Until patients are willing to take ownership of their disease management and accept diabetes as a progressive disease that requires adherence to therapeutic regimens, healthcare providers are not going to be able to change nonadherent behaviors.

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**Many patients will be motivated to remain adherent to products that quickly demonstrate improvements in glucose control.**

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**Dr Brixner:** Characteristics that provide potential for adherence to therapy include drug efficacy, adverse effect profile, effect on other organ systems, ease of administration, and ability to delay insulin. Many patients will be motivated to remain adherent to products that quickly demonstrate improvements in glucose control. Drug classes with few adverse events, including low risk of hypoglycemia, may be associated with improved adherence.

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Drugs that have a protective effect on other organ systems may facilitate adherence if treatment is supported with patient education as to importance of protecting other organ systems. Inconvenient administration (eg, injection, multiple daily doses) may reduce compliance.

Finally, the message that treatment with oral agents may delay the need for insulin could be motivating and help some patients remain adherent. However, an important strategy is for all clinicians to have an early discussion with patients on the benefits of insulin treatment as the most effective medication and increasing ease of use with new administration techniques, such as insulin pens.

**Moderator:** *Adherence to long-term therapy, as in diabetes, is a significant factor in the overall success of achieving glycemic control. Some factors that may influence patient behavior related to adherence are convenience and ease of use, adverse effect profiles, and patient/provider communication.*

**The third set of questions involves the relationship between and relevance of diabetes and CKD.**

**Moderator:** *How would you rate the significance of CKD in type 2 diabetes from the economic, resource utilization, and quality-of-life perspectives?*

**Dr Brixner:** Economic; very significant for the 5% to 10% of patients with type 2 diabetes who develop CKD; resource utilization, very significant and linked to above; quality of life, very significant.

**Dr Garber:** CKD is a very significant and major complication of diabetes.

**Dr Whaley-Connell:** Economic, critical. CKD augments CVD outcomes as well as healthcare expenditures; resource utilization, dialysis and real-time reverse transcriptase-polymerase chain reaction

are 2 of the Centers for Medicare & Medicaid Services' largest expenditures.

**Dr Lopes:** Economic, very high; resource utilization, high; quality of life, medium.

**Dr Navarro:** The American Diabetes Association (ADA) Standards of Medical Care in Diabetes—2010 states that diabetic nephropathy occurs in 20% to 40% of patients with diabetes and is the single leading cause of end-stage renal disease (ESRD).<sup>2</sup> The presence of renal disease presents challenges in the management of comorbid disease states, which often include hypertension and CVD. Such complicated patients with comorbidities require more intensive disease management to manage all diseases and minimize the consumption of medical resources. Comorbidities also increase the challenge of patient education, which must be done in an individualized manner, with frequent assessments to ensure patient understanding and adherence.

**Moderator:** *Laliberté and colleagues recently quantified the incremental direct all-cause healthcare costs associated with a diagnosis of CKD in patients with diabetes and/or hypertension.<sup>3</sup> Using healthcare claims and laboratory data from the Integrated Healthcare Information National Managed Care Benchmark Database, they found that the unadjusted annualized per-patient mean all-cause healthcare cost differences associated with CKD were significantly higher in the CKD groups compared with patients with no CKD (the cost in the diabetes cohort was \$18,444 for patients with CKD versus \$6631 for those with no renal impairment,  $P < .001$ ).<sup>3</sup> In patients who developed CKD, the post-CKD phase was also associated with a significant increase in healthcare costs—approximately 67% increase compared with the pre-CKD period for the diabetes cohort.<sup>3</sup> What are your thoughts on the onset of renal impairment and prevention of CKD in patients with diabetes?*

**Dr Navarro:** To prevent or try to slow the progression of CKD, patients must achieve glycemic and BP control as quickly as possible after a diagnosis of diabetes. Early screening of eGFR will help to evaluate the presence of CKD and guide practitioners when making overall disease management decision in patients with diabetes.

**Dr Lopes:** CKD risk factors include diabetes and hypertension, 2 prevalent conditions. To prevent CKD, patients with prediabetes need greater awareness of factors they can control, such as diet, exercise, and weight loss, and patients with diabetes should achieve glycemic and BP goals.

**Dr Whaley-Connell:** CKD can only be prevented or delayed if awareness is increased and screening is performed early. Patients with prediabetes must achieve glycemic control and systolic BP control to prevent the development of CKD.

**Dr Brixner:** Renal impairment probably begins before diagnosis, especially when patients go for years (on average up to 7 years) before being diagnosed with type 2 diabetes. As such, type 2 diabetes screening should be conducted for persons at risk (per ADA clinical practice guidelines). To prevent type 2 diabetes, patients with prediabetes should have regular screening for diabetes onset and microalbuminuria screening.

Patients with diabetes should receive education on managing glycemia, BP, and the importance of annual renal function testing, plus eGFR, because serum creatinine and albuminuria tests may not detect CKD.<sup>4</sup> Also, patients should have retinopathy screening, because CKD and retinopathy are highly correlated. If patients are smokers, this may damage vasculature not only in the heart but also in the kidneys and the eyes. Annual testing should be emphasized to patients and providers and initiated at the time of diagnosis.

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**Dr Garber:** The risk of CKD in the population of patients with diabetes needs to be emphasized, and CKD needs to be recognized at its earliest possible presence. Microalbuminuria needs to be addressed as early as possible. Antihypertensive medications should be initiated for aggressive BP control in addition to glucose management and control.

**Moderator:** *The NKF KDOQI guidelines provide specific recommendations for screening for CKD in patients with diabetes.<sup>5</sup> The guidelines state that patients with diabetes should be screened annually for diabetic kidney disease.<sup>5</sup> Initial screening should commence 5 years after the diagnosis of type 1 diabetes, or from the time of diagnosis of type 2 diabetes. Screening should include measurements of urinary albumin to creatinine ratio in a spot urine sample and measurement of serum creatinine and eGFR.<sup>5</sup> What resources do you think would be most beneficial for patients with diabetes and CKD?*

**Dr Brixner:** Education is definitely beneficial. This should begin with prediabetes or at-risk patients (eg, obese with family history). Healthcare providers need to help patients understand why they should avoid/delay the onset of diabetes, and the consequences of uncontrolled diabetes.

This effort should be coordinated with providers and large employers to target at-risk patients. Wellness and disease management efforts are also important. The focus should be to prevent diabetes onset, but once developed, the focus should be placed on patient-provider partnerships for achieving diabetes control.

Services provided should include access to certified diabetes educators, dietitians, as well as pharmacists for pharmacotherapy monitoring and disease state management.

**Dr Whaley-Connell:** Education. Promoting awareness in the early stages of diabetes and not only screening for CKD,

but once CKD is diagnosed, providing education regarding complications unique to CKD and providing measures to engage patients in managing CKD.

**Dr Lopes:** Continued support for member engagement for achievement of long-term sustainability of adherence and outcomes.

**Dr Navarro:** Patient education must be individualized and embellished to include self-management of renal disease, as well as diabetes and hypertension.

**Dr Garber:** Case management is a necessary component of overall diabetes management. Patients need someone to speak with, someone who will provide guidance and encouragement to help achieve adherence and persistence.

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## Healthcare providers need to help patients understand why they should avoid/delay the onset of diabetes, and the consequences of uncontrolled diabetes.

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**Moderator:** *Case management is a valuable service offered to patients with diabetes and CKD and may help improve outcomes through encouragement and monitoring of the achievement of glycemic goals. Which drug classes or treatment regimens do you believe have the most potential benefit in patients with diabetes and CKD?*

**Dr Brixner:** Antihypertensive agents have the potential to benefit patients with diabetic renal impairment. Glucose-lowering agents are beneficial to ensure appropriate glucose targets. Also, it is important to consider renal dosing guidelines.

**Dr Whaley-Connell:** Therapies that provide RAAS inhibition and aggressive systolic BP control are the most important, although other measures like lipid control have been shown to improve CKD progression.

**Moderator:** *It is evident that there are many critical components in the diabetes management decision-making process, and the presence of CKD adds to this plethora of considerations. In patients with diabetes and CKD, therapy must be determined on an individual level based on the aforementioned considerations, and the clinical examination by the treating healthcare provider.*

**The fourth set of questions relates to benefit design.**

**Moderator:** *How can MCOs provide better benefits for patients with diabetes and CKD?*

**Dr Garber:** There is no one solution. This issue is all-encompassing, with the need to address multiple variables and challenges: BP control, glycemic control, and dietary modification. The current healthcare system is dysfunctional when it comes to patient self-sufficiency. Patients need to take an aggressive role in their own healthcare, not relying on practitioners or the government to make their decisions for them.

As a healthcare system in crisis, we need something to motivate patients to adhere to therapy and care about themselves and the outcomes of their disease. The major issue of a lack of adherence and persistence needs to be addressed by all involved in healthcare—payers, providers, pharmacists, case managers, and patients. Instead of throwing treatment options away by prescribing them to patients who aren't going to adhere to therapy, we need to incentivize the patient, then work with patients to determine the appropriate therapeutic options that will not only treat the disease but work for the patients' lifestyle, needs, and willingness to

participate in the management of their disease.

Health savings accounts work. Patients can be paid, in essence, for being adherent to therapies prescribed, for taking control of their disease, and for conducting self-management to effectively manage the outcomes of their disease.

**Dr Whaley-Connell:** Incentive programs are an excellent idea to promote control of certain disease states. Maybe incentives should be provided for those who achieve systolic BP and glycemic control and improve lifestyle measures. Case management services are also necessary for continuous management, interaction, and measurement of patient self-management and adherence.

**Dr Brixner:** Incentive programs can be beneficial. For instance, reducing patient out-of-pocket (OOP) expenses for antidiabetic and antihypertensive agents may improve adherence. However, clinical outcomes related to benefit changes in diabetes have not been reported. Mandatory monitoring may be a better component of a P4P program.

Charging no copayment for laboratory work or offering free or substantially discounted supplies may be beneficial to reducing patient OOP expenses, and is probably a worthwhile investment, but it may be hard to show return on investment. Frequent medical visits and education appointments may help to ensure that appropriate targets are being met. Furthermore, covering medication therapy management programs with early, automatic enrollment on diagnosis of prediabetes/diabetes may be beneficial if the copays for medication therapy management and medical nutrition management/certified diabetes educator visits were waived.

MCO partnerships with healthcare providers such as P4P may be beneficial, particularly the degree that incentives are aligned to promote good outcomes. In addition, joint MCO/employer programs

have a good opportunity to promote healthy lifestyle choices, to give easy access to routine care and monitoring, and to identify high-risk patients for screening and education.

**Dr Lopes:** Incentive programs should be tied to disease management initiatives and benefit design. Incentive programs will best succeed when employers work

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## Incentive programs will best succeed when employers work with MCOs on early screening and detection.

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with MCOs on early screening and detection. This can include partnerships with local pharmacies to provide better education for members, which may help improve adherence and outcomes.

**The fifth question is in regard to measurements and monitoring for patients with diabetes and CKD.**

**Moderator:** *What are your recommendations for evaluating and monitoring patients with diabetes and CKD?*

**Dr Brixner:** Diagnosis should be based on plasma glucose levels and hemoglobin (Hb) A<sub>1c</sub> levels suggested by the ADA.<sup>2</sup> The ADA recommends an HbA<sub>1c</sub> of <7%, because this has been shown to reduce microvascular and neuropathic complications. These guidelines do not recommend reducing HbA<sub>1c</sub> below this point until more evidence suggesting better outcomes to justify the greater risk of hypoglycemia becomes available.<sup>2</sup> However, the American Association of Clinical Endocrinologists (AACE) recommends an HbA<sub>1c</sub> goal of ≤6.5% in patients,

because early and aggressive glycemic management can prevent or delay the development of diabetic complications.<sup>6</sup> To protect renal function, glucose control and BP control should be optimized, and to help reduce CVD risk, blood glucose, BP, and lipid levels should be tightly managed per treatment guidelines.<sup>2</sup>

Frequency for monitoring depends on the measurement being monitored and should be individualized based on patient characteristics and therapeutic regimens.<sup>2</sup> Patients with multiple daily insulin injections or those using a continuous insulin pump should check their blood glucose at least 3 times daily.<sup>2</sup> HbA<sub>1c</sub> should be monitored twice annually in patients who meet their glycemic goals and have stable glycemic control.<sup>2</sup> In patients not meeting glycemic goals, HbA<sub>1c</sub> levels should be monitored every 3 months.<sup>2</sup>

BP should be checked at every diabetes visit. A fasting lipid profile should be obtained annually.<sup>2</sup> In low-risk patients, a fasting lipid profile can be obtained once every 2 years.<sup>2</sup> Urine albumin excretion should be checked annually, as should creatinine clearance.<sup>2</sup> Patients should receive an eye examination annually; those with 1 or more normal eye examination can be screened every 2 to 3 years.<sup>2</sup> Patients should be screened for neuropathy annually.<sup>2</sup>

**Dr Whaley-Connell:** I think it is critical to assess eGFR and proteinuria when screening for and monitoring renal impairment.

**Dr Navarro:** I defer to the ADA Standards of Medical Care—2010<sup>2</sup> and the AACE/American College of Endocrinology (ACE) Consensus Panel on type 2 diabetes mellitus<sup>6</sup> guidelines for all inclusive recommendations.

**The sixth question addresses the published guidelines and consensus statements.**

# Advisory Board Panel Discussion

**Moderator:** *Is there a published guideline for the management of diabetes that you recommend, or, in your opinion, are there benefits that can be identified among each guideline?*

**Dr Navarro:** I like the AACE/ACE guidelines because the A<sub>1c</sub> target is 0.5% less, which may lead to better outcomes, if achievable. It may be wise to individualize

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**There are many well-recognized guidelines for the management of type 2 diabetes, and each has a place for a given provider-patient partnership.**

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targets based on what is attainable, and move the target down over time for positive reinforcement, thinking long-term. The ADA/European Association for the Study of Diabetes (EASD) consensus algorithm is a simplified stepwise approach to drug use in diabetes.<sup>7</sup> The NKF KDOQI clinical practice guidelines focus on CKD and hypertension comorbidity.<sup>5</sup>

**Dr Garber:** I think it is critical that providers follow the expert-developed and published guidelines. Patients with diabetes and CKD need extensive evaluation and care. This patient population cannot be cared for in the average 7 to 8 minutes allotted for general office visits. More time is necessary to fully evaluate and care for this patient population.

The current system is built on untruths that quality care can be accomplished in a matter of minutes. The consideration that patients with diabetes and CKD can be effectively managed by only rarely providing comprehensive care is laughable. A thorough, head-to-toe evaluation of this patient population is

necessary every visit to fully evaluate the patient and the myriad complications and issues that are present.

**Dr Whaley-Connell:** In my opinion, the NKF KDOQI guidelines should be used as a reference and consideration when determining management strategies or developing disease state management programs for patients with diabetes to ensure the appropriate screening, monitoring, and management of CKD.

**Dr Brixner:** There are many well-recognized guidelines for the management of type 2 diabetes, and each has a place for a given provider-patient partnership. For example, the ADA recommendation of HbA<sub>1c</sub> <7% is reasonable for many patients,<sup>2</sup> whereas the more aggressive AACE recommendation of HbA<sub>1c</sub> ≤6.5% is more difficult to achieve.<sup>6</sup> The EASD/ADA consensus algorithm provides a reasonable, simple algorithm for providers to implement,<sup>7</sup> and the International Diabetes Center also has a very reasonable algorithm.<sup>8</sup> The NKF KDOQI guideline evaluates renal outcomes/guidelines in a very detailed manner.<sup>5</sup>

**The seventh set emphasizes renal impairment and diabetes.**

**Moderator:** *What percent of patients with diabetes have any degree of renal impairment, not ESRD?*

**Dr Brixner:** Per the literature, 35% have CKD.<sup>9</sup>

**Dr Navarro:** In the United States, microalbuminuria is found in 43%, and macroalbuminuria is found in 8% of patients with a history of diabetes.<sup>5</sup> Moreover, diabetes accounts for 45% of prevalent kidney failure, up from 18% in 1980.<sup>5</sup>

**Moderator:** *What is the economic impact of renal impairment on your population of patients with diabetes?*

**Dr Brixner:** The economic impact is significant. Many patients use multiple drugs with complicated regimens and dosing strategies, and have comorbid eye disease or require dialysis, among other things.

**Moderator:** *How can MCOs improve the identification of patients with prediabetes/diabetes-associated renal disease?*

**Dr Brixner:** MCOs can target education/disease awareness to patients and providers. When diagnosed, managed care knows who has diabetes or prediabetes (or considered at risk per impaired fasting glucose/impaired glucose testing). Organizations can pay for performance for all diabetes screening, including renal function tests, and educate/incent providers to calculate an eGFR annually.

**Dr Navarro:** On physical examination or when hyperglycemia is discovered (prediabetes), or diabetes mellitus, renal function tests must be ordered to check for evidence of renal insufficiency, or micro/macroalbuminuria, and other basics (blood/urinalysis).

**Moderator:** *What recommendations can you make as to how MCOs might improve the awareness of diabetes associated with any degree of renal impairment?*

**Dr Brixner:** Same as above. MCOs can target patients and providers based on claims data for diagnosis of any level of renal dysfunction. They should also promote yearly screenings for CKD and retinopathy.

**Dr Lopes:** Clinicians need better data and decision support tools, in addition to electronic medical records that link laboratory data and practice guidelines together.

**Dr Navarro:** Through screening campaigns. CKD is usually symptom-free early on, so healthcare providers must be

# Managing Patients with Type 2 Diabetes

reminded to screen for CKD on physical examination or as recommended by the NKF guidelines.

**Moderator:** *Early identification can only be accomplished through early screening. Thus screening programs are a must for patients at risk for diabetes and/or CKD. What interventions do you feel would best prevent any degree of renal impairment in patients with diabetes?*

**Dr Brixner:** Manage glycemia and hypertension with patient awareness of the consequences of unmanaged disease, because patients who perceive the consequences to be high have better compliance.<sup>10</sup> Promote yearly creatinine and GFR screenings.<sup>2</sup>

**Dr Whalley-Connell:** I strongly suggest aggressive systolic BP control, which is time tested—no question about it.

**Dr Navarro:** When identified, CKD management should be part of disease management classes/case management or other education (including print/online education). Material/classes/intervention must be individualized and embellished for patients with diabetes and CKD.

**The eighth series of questions is about comparative effectiveness research (CER).**

**Moderator:** *What data would be beneficial for the introduction of future diabetes drugs into the marketplace, such as head-to-head trials, which drug classes compare to which drug classes, or specific patient populations?*

**Dr Navarro:** I don't expect that CER will produce tactical, actionable guidance that will influence drug formulary decisions. Most formularies are generous regarding diabetes drug coverage, preferring to offer many options rather than managing these drugs tightly. Perhaps comparison of patient educational strategies, program components for specific subgroups, would

be beneficial. Perhaps drug category, but so much of drug performance rests with adherence to therapy, and adherence to lifestyle decisions. I have great skepticism in many patients being adherent or making proper lifestyle choices.

**Dr Garber:** The concerns I have with CER are that drugs are not the limiting factor. It is difficult to apply vast numbers of drugs to a population that is reluctant to take them.

**Dr Lopes:** I believe value-based algorithms, if followed, would help patients achieve and sustain glycemic goals. In addition, perhaps "at-risk" contracting with manufacturers would provide value for improving outcomes in patients taking specific oral antidiabetic drugs.

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**Real-world data that demonstrate product differentiation for achievement of glycemic goals would be very beneficial in the formulary review process.**

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**Dr Brixner:** New products should be compared with the treatment most likely to be considered an appropriate alternative (eg, same class or market leading alternative versus an older class of agents). Comparisons should first be based on the likely population of users with a high degree of external validity. Studies should then be conducted in subsets without randomized control trial data, such as children and the elderly, comorbid conditions, and off-label use.

**Moderator:** *What data do you deem necessary to guide prescribing and coverage decision-making processes?*

**Dr Navarro:** We already have a lot of guideline information. Perhaps a distillation

of essentials, including diagnostic criteria, targets, lifestyle, drug options, patient candidate recommendations, adverse event monitoring, and insulin-use monitoring.

**Dr Lopes:** Real-world data that demonstrate product differentiation for achievement of glycemic goals would be very beneficial in the formulary review process.

**Dr Brixner:** Randomized controlled trials, observational/real-world data, cost-effectiveness data versus active comparators, and humanistic outcomes, including patient satisfaction and medication adherence.

**The ninth set of questions assesses the risk evaluation and mitigation strategies (REMS) requirement,<sup>11</sup> which helps to ensure the safety of a new drug and educate providers and patients before the prescribing or administration of medications.**

**Moderator:** *What are your thoughts on REMS in relation to diabetes management?*

**Dr Navarro:** REMS seem to be best suited to help physicians prescribe and monitor drugs when a potentially serious risk/benefit tradeoff is considered, as perhaps with the thiazolidinediones. The US Food and Drug Administration requires a REMS program for any drug associated with a serious safety or misuse potential.

**Dr Brixner:** The REMS program is very relevant to diabetes, given the elevated cardiovascular risk of this population and the increasing prevalence of diabetes. Also, REMS are highly pertinent regarding the risk of hypoglycemia with secretagogues or insulin. It is imperative to develop action plans so that patients know how to deal with adverse consequences.

**Moderator:** *Do you see any advantages*

# Advisory Board Panel Discussion

of REMS for prescribers and patients?

**Dr Brixner:** REMS help to reduce uncertainty regarding product safety. Medications may be more likely to be prescribed and used appropriately, and patient medication persistence may be improved if safety issues are addressed proactively and with less speculation.

**Dr Navarro:** REMS may be a valuable source of potential information to help prevent a serious adverse event.

**Moderator:** *Have you participated in a healthcare provider training? Do you believe it will provide value, and if so, for which practitioners do you feel it is most appropriate?*

**Dr Brixner:** Training is most appropriate for primary care providers and pharmacists, as well as other clinicians involved with disease state management.

**Dr Navarro:** REMS training may be helpful for healthcare professionals involved in prescribing or monitoring any drug with a potential for producing a serious adverse event.

**Moderator:** *Are medication guides for specific hypoglycemic agents of value to patients? Do you believe the diabetes patient population will read and follow the instructions/information in the medication guides? How can the guides be made to better inform the patient of the safety and use of the medications?*

**Dr Brixner:** These are valuable only if an educator specifically discusses information with the patient and provides adequate follow-up and a method for patients to ask questions. Agent-specific patient education/guides will likely be more effective. Patient education should not just be written, and it may be beneficial to introduce a multimedia approach (eg, video). A “push” technique to send medication education on a

scheduled basis reinforcing key messages and introducing other messages at select times may enhance patient recall. This approach is very feasible using Internet-based technology and will also be an effective technique for reaching young, obese patients at risk for type 2 diabetes, hypertension, and eventually CKD.

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**Patient education should not just be written, and it may be beneficial to introduce a multimedia approach (eg, video). A “push” technique to send medication education on a scheduled basis reinforcing key messages and introducing other messages at select times may enhance patient recall.**

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**Dr Navarro:** They are probably of value, but they need to be simple yet complete. Those provided with prescriptions by community pharmacies may be fine for most patients who read them, but some are too complicated.

**The tenth question asked panel members to present any known “best practice” diabetes management programs.**

**Moderator:** *Please describe any diabetes management programs that you feel can be classified as a “best practice” example to help other healthcare providers or organizations better serve their patients and/or members.*

**Dr Navarro:** Based on communications with colleagues at Aetna and United-Healthcare, it appears that both organizations have comprehensive and effective programs with demonstrated glycemic goal achievement.

**Dr Brixner:** Many articles describe diabetes management programs, including several that have demonstrated the value of clinical pharmacy services. A recent study evaluating the impact of clinical pharmacy services showed improvement in metabolic parameters, as well as a reduction in costs.<sup>12</sup> Two review articles have also described diabetes management programs.<sup>13,14</sup> Both reviews mention a study conducted to evaluate the outcomes of providing comprehensive pharmacy services to underserved patients in community health centers, which serve many high-risk patients.<sup>15</sup>

## Conclusion

A substantial number of patients with diabetes are at various stages of CKD.<sup>16</sup> In a study aimed at estimating the prevalence of CKD among people with diagnosed diabetes, undiagnosed diabetes, prediabetes, or no diabetes, Plantinga and colleagues found that CKD is prevalent in all of these patient populations.<sup>16</sup> The prevalence of CKD identified in the different patient populations includes<sup>16</sup>:

- Undiagnosed diabetes, 41.7%
- Diagnosed diabetes, 39.6%
- Prediabetes, 17.7%
- No diabetes, 10.6%

These figures indicate a strong association between diabetes and CKD. It is therefore pertinent that healthcare providers, MCOs, and pharmacists work together to implement and adhere to early screening and early intervention initiatives to decrease the incidence and severity of CKD and its related complications.

Plantinga and colleagues further found in the population of patients with diabetes the following prevalence rates of CKD, by stage<sup>16</sup>:

- Stage 1–10.4%
- Stage 2–13.4%
- Stage 3–4.1%
- Stage 4–1.1%.

As indicated by these percentages, a significant number of patients with diabetes have early stages of CKD.<sup>16</sup>

This confirms the importance of recognizing CKD with diabetes as a significant health issue to ensure that early screening and intervention is emphasized in this population. Early screening, identification, and intervention may help to prevent CKD from progressing to ESRD. As stated by the editorial board members throughout this and the previous articles in this series, diabetes and CKD are significant public health concerns and should be forefront when determining areas of focus for disease management, health and wellness, cost-effective strategies, and quality initiatives. Providing education to providers, as well as to this patient population, has the potential to help reduce the overall disease burden and improve outcomes. ■

## Disclosure Statement

All participants—including Diana I. Brixner, PhD, RPh; Alan J. Garber, MD, PhD, FACE; Robyn R. Graham, PharmD; Maria Lopes, MD, MS; Robert P. Navarro, PharmD; Adam Whaley-Connell, Do, MSPH—received fair market value compensation for taking part in this activity.

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