AMGA

Advancing High Performance Health

AMGA Foundation

Chronic Care Roundtable

Medication Care Paths for Type 2 Diabetes and Advanced Complications

November 13, 2019

Meeting Summary

Launched in 2016, the Diabetes: Together 2 Goal® (T2G) campaign represents 61,000 FTE physicians treating 2 million patients with a diagnosis of Type 2 diabetes. To date, organizations participating in the campaign have collectively improved care for more than 1 million Americans with this chronic condition.

Patients with Type 2 diabetes often concurrently experience advanced complications like chronic kidney disease and cardiovascular disease. What medication care paths can improve care for these patients? On November 13, 2019, in Alexandria, Virginia, AMGA Foundation President and AMGA Chief Medical Officer John W. Kennedy, M.D., welcomed participants to talk about screening and diagnosis, care intensification, emerging medications and guidelines, and more.

Through an information-packed day of presentations, panel discussions, and workgroup breakout sessions, participants shared best practices, posed questions, and talked about research findings from AMGA Analytics and throughout the industry.

Keynote: *Medication Care Paths for Type 2 Diabetes and Chronic Kidney Disease*

Evan Norfolk, M.D., *Director of Nephrology, Geisinger*

Diabetes-related kidney disease is the leading cause of chronic kidney disease and contributor to half of end-stage renal disease cases, and half of patients with Type 2 diabetes are at risk of developing it. Fortunately, four sodium-glucose cotransporter-2 (SGLT-2) inhibitors, which are cardio-renal risk reduction agents that lower glucose as a side effect, have been approved for treating chronic kidney disease in people managing Type 2 diabetes. Furthermore, the American Diabetes Association (ADA) has developed guidelines for implementing an algorithm or care path.

Norfolk discussed the pros and cons of these SGLT-2 inhibitors. Benefits, in addition to decreased albuminuria and hyperfiltration, can include weight loss, enhanced b cell function, and decreased blood pressure, serum uric acid, insulin sensitivity, and activation of the sympathetic nervous system. Some SGLT-2 inhibitors have been shown to lower A1c readings. Adverse effects may include genital candida infections (in men and women), urinary infections,

> *"One out of every 16 patients who is treated with the latest evidence-based therapies to prevent end stage renal disease will not progress to the point where they need dialysis.[1] This is a tremendous advance in the prevention of renal disease. It's huge."*
>
> **— Evan Norfolk, M.D., Geisinger**

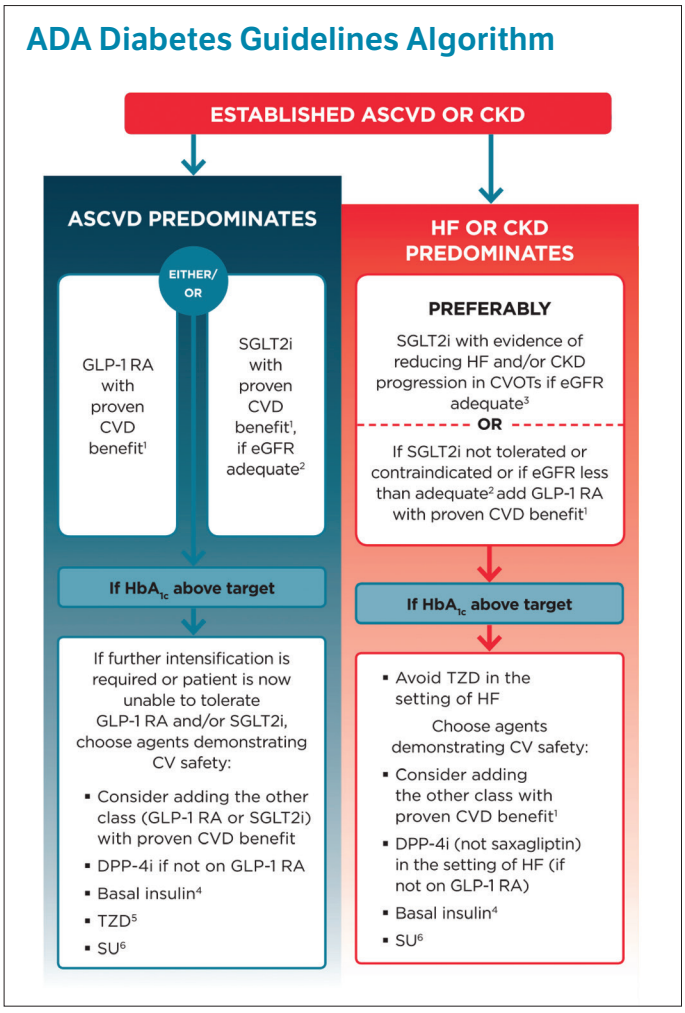
[1] G. Bakris. 2019. On the Renal Outcomes from the CREDENCE Trial: Regarding number needed to treat for renal replacement therapy, if you treated 16 people, you prevented one dialysis. Podcasts 360 July 5, 2019.

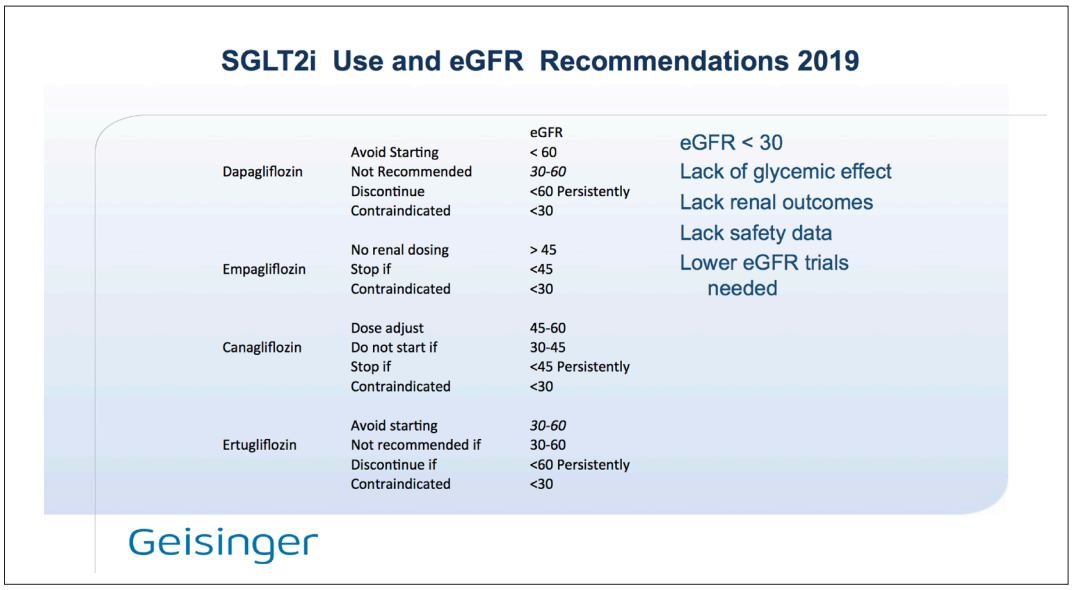
polyuria, postural hypotension, and Fournier gangrene. Increased bone fractures and leg/foot/toe amputations have been seen with canagliflozin.

Norfolk presented highlights from recent research, usage recommendations, and updated U.S. Food and Drug Administration (FDA) indications.

The chronic kidney disease care path also involves best practices in payments, products, and processes. To this end, the Center for Medicare and Medicaid Innovation (CMMI)—in conjunction with the White House's Advancing American Kidney Health Initiative—released the end-stage renal disease (ESRD) Treatment Choices payment model, which encourages in-home dialysis, plus four optional payment models to align provider incentives around more comprehensive, person-centered disease prevention and management.

What if a patient with chronic renal disease could "wear" a new kidney? Kidney X unites the Department of Health and Human Services (HHS), the Food and Drug Administration (FDA), and the Society of Nephrology in the development of wearable/implantable artificial kidneys, faster development of drugs and devices across the spectrum of kidney care, and a clearer and less expensive path to bringing such products to market.





For workflow, Norfolk said, Geisinger uses its Ask-A-Doc program (which has a 99+% completion rate) to route questions to specialists and has for over a decade enrolled all patients with a certain level of chronic kidney disease into its medication therapy management program. Pharmacists are responsible for obtaining insurance authorization, ensuring timely and appropriate labs and therapy adjustments, and discussing parameters that don't fit protocol. Particularly with SGLT-2 inhibitors, this frees up a physician to concentrate on other tasks.

Questions for a Chronic Kidney Disease Care Path

- **What problem do you want to solve?**
- **Is the solution evidence-based? How strong is the evidence?**
- **Do providers agree with your goals?**
- **Can you easily identify your patients?**
- **How are you tracking progress—through a registry or the patient's electronic records?**
- **If patients aren't meeting targets, why (e.g., providers are overwhelmed, they're getting too many alerts, they need financial incentives)?**

AMGA Analytics: *Patients with Type 2 Diabetes and Kidney Disease*

Nikita Stempniewicz, Sc.M., *Senior Population Health Analyst, AMGA Analytics*

Screening, diagnosis, and risk-stratification for chronic kidney disease is critical for treating patients with Type 2 diabetes today and predicting healthcare costs, utilization, and outcomes in the future. Stempniewicz shared research in this area by AMGA Foundation and AMGA Analytics.

Under current quality measures, a patient qualifies as getting medical attention if they've visited with a nephrologist, been diagnosed with nephropathy, received any urine protein test, or been prescribed an angiotensin-converting enzyme inhibitor (ACE-i) or angiotensin reception blocker (ARB). The National Kidney Foundation (NKF), the Physician Consortium for Performance Improvement (PCPI), and the National Committee for Quality Assurance (NCQA) are developing measures to improve chronic kidney disease testing. The proposed replacement, the kidney health evaluation, requires both an estimated glomerular filtration rate (eGFR) and a urinary albumin-creatinine ratio (uACR) measurement.

> *"Among 685,000 patients with Type 2 diabetes receiving care at 24 different healthcare organizations, only half the patients had documentation of a urinary albumin to creatinine ratio—one of two key measures endorsed by the National Kidney Foundation and the National Committee for Quality Assurance to improve chronic kidney disease testing."*
>
> **— Nikita Stempniewicz, Sc.M., AMGA Analytics**

Among 685,000 patients with Type 2 diabetes receiving care at 24 different healthcare organizations:

- 49% had an uACR measurement
- 15% had a urine protein test
- 6% had nephropathy diagnosis/treatment or a visit with a nephrologist
- 15% had ACE-i or ARB prescriptions

Results showed that the current measure engenders a false sense of optimism. For example, among patients with only ACE-i/ARB use as a measurement, less than 1% had a prescription for microalbuminuria, and roughly three quarters had a diagnosis for cardiovascular disease.

"Use of these medications does not obviate the need for a nephropathy screening in diabetics," research authors wrote in *Managed Care*. "Inclusion of these medications as numerator compliance leads to overreporting, and may contribute to underscreening of a population at risk."[1]

> *"The medical attention to nephropathy measure is too readily satisfied. Now is the time for healthcare providers to move to the evidence-based and guideline-recommended standard of measuring both urine albumin to creatinine ratio and estimated glomerular filtration rate (eGFR) to better risk stratify their population for progression to end stage renal disease."*
>
> **— Nikita Stempniewicz, Sc.M., AMGA Analytics**

Under the current nephropathy-based measure, patients and providers may be getting a false sense of optimal kidney care for people with Type 2 diabetes. The proposed kidney health evaluation, by contrast, may stimulate more accurate risk prediction and more consistent use of evidence-based therapy, reducing complications in this high-risk population.

Background

Clinical guidelines (ADA) recommend measuring urine albumin, [e.g., urine albumin to creatinine ratio (uACR)], and estimated glomerular filtration rate (eGFR) ***at least once per year in all patients with type 2 diabetes***

- Powerful predictors of future health-care costs and utilization, and cardio-vascular and kidney outcomes
- Allow providers to screen, diagnose, and risk stratify chronic kidney disease (with a known risk relationship)

Prognosis of CKD by GFR and albuminuria category

GFR categories (ml/min/ 1.73 m²) Description and range				Persistent albuminuria categories Description and range		
				A1	A2	A3
				Normal to mildly increased	Moderately increased	Severely increased
				<30 mg/g <3 mg/mmol	30-300 mg/g 3-30 mg/mmol	>300 mg/g >30 mg/mmol
	G1	Normal or high	≥90			
	G2	Mildly decreased	60-89			
	G3a	Mildly to moderately decreased	45-59			
	G3b	Moderately to severely decreased	30-44			
	G4	Severely decreased	15-29			
	G5	Kidney failure	<15			

Green: low risk (if no other markers of kidney disease, no CKD); Yellow: moderately increased risk; Orange: high risk; Red, very high risk. KDIGO 2012

For next steps, AMGA Analytics is working with NKF and NCQA to evaluate the kidney health evaluation measure. The organizations will be examining performance, disparities, and evidence-based interventions, such as the use of kidney protective drugs, nephrology consultations, statin therapies, and diabetes and blood pressure control. AMGA Analytics is also working with AMGA members to understand trends and barriers in measuring uACR and eGFR in patients with Type 2 diabetes.

Workgroup Breakouts

Affordability, Implementation, and Ownership of Medication Care Paths for Type 2 Diabetes and Chronic Kidney Disease

Group 1 Facilitator: Evan Norfolk, M.D., Director of Nephrology, Geisinger

Despite SGLT-2 inhibitors being a great class of drugs for managing Type 2 diabetes and chronic kidney disease, inertia on several fronts can hinder medication care paths. Primary care providers have a limited time frame for seeing patients, and specialists don't want to "own" diabetes.

Meanwhile, these factors are further impeded by a knowledge gap. Patients might not realize why they need ACE inhibitors. Population health alerts may not be sophisticated enough to assess risk for renal failure. And physicians outside of nephrology may not be aware of SGLT-2 inhibitors.

Participants discussed ways to address inertia, including:

- Data-based education/re-education, such as Extension for Community Healthcare Outcomes (ECHO) model or e-consultations for primary care providers and updated guidelines for specialists
- Education on the patient side as well, so they're aware of nephrology and the need for a more costly drug
- Reduced/removed deductibles to address cost barriers and pass cost savings to the patient
- Benchmarking and incentives to get providers' attention and encourage prescriptions—with an understanding that incentives may turn into a "double-edged sword"

Group 2 Facilitator: John Cuddeback, M.D., Ph.D., Chief Medical Informatics Officer, AMGA

Healthcare providers face a confluence of challenges in their treatment of chronic conditions like diabetes. Organizations that go public must report to Wall Street every 90 days; meanwhile, diabetes treatment is a lifetime endeavor. Organizations and their infrastructure face a Medicare population with 2% of patients consuming 18% of the dollars. Predictive modeling and longer-term planning (one to three years) can help. So can collaboration.

To co-manage Type 2 diabetes and chronic kidney disease, for example, care teams can increase collaboration between nephrologists and primary care physicians and educate patients about chronic kidney disease to reduce their need to see a nephrologist.

"Industry needs to be part of the solution, but they need to fit the workflow of the primary care provider," said Paula LeClair of Healthy.io. And all parties will need to take ownership. "From a financial perspective, the value dollars on the line will help how we manage people with chronic conditions," said Donna Montalto of CareMount.

Another important component is patient education—going beyond handing them a 2,500-calorie diet sheet to meet patients where they're at and move them from denial to activation. "If you ask the provider to choose between the best medication, the best device, or an engaged patient, they will choose an engaged patient every time," said Bruce Taylor of Dexcom.

> *"When it comes to diabetes, it can't be 'the diabetes,' it has to be 'my diabetes.' We need to move the patient from denial to activation."*
>
> **— Bruce Taylor, Dexcom**

Angela Zachery of Pfizer emphasized that one size may not fit all: "If you've seen one healthcare system, you've seen one healthcare system."

Group 3 Facilitator: Kevin Pantalone, D.O., ECNU, FACE, Director of Diabetes Initiatives, Department of Endrocrinology and Metabolism Institute, Cleveland Clinic

Many barriers can impede a medication care path: recognizing a patient with chronic kidney disease, navigating the complexity of technology and reimbursement, and engaging pharmacists and patients more effectively in care, to name a few.

"Healthcare systems and medical groups have implemented sophisticated electronic medical records, drawing physician attention to the computer and away from the patient. It's time we reverse that dynamic," said Barbara Kaplan Machlis, Pharm.D., Pfizer.

"The primary care physician knows the patient and prescriptions, but the U.S. healthcare system has become so complex and costly that access to care is difficult for many patients. At Sutter, we focus on improving both the affordability and access to the best care for our patients, but we have given them a mess," said Theresa M. Frei, M.B.A., R.N., Sutter Medical Foundation.

"Prior authorization is just one more obstacle for patients to manage in the healthcare landscape. Unfortunately, some patients and their providers simply stop trying to obtain the recommended therapies in the face of these challenges. Cleveland Clinic is working to overcome these and other barriers and deliver the right treatment to the right patient at every visit." said Kevin Pantalone, D.O., ECNU, FACE, Cleveland Clinic.

To overcome affordability obstacles, providers need to be able to navigate electronic medical records to understand what is covered and not covered. Meanwhile, education can help physicians become aware of entrenched behaviors and become more innovative.

Throughout, participants cited ownership as vital. In addition to making medical prescriptions a trackable metric, they suggested a team approach guided by an expert "voice." Participants mentioned Geisinger's Ask-A-Doc—"in that

moment, a patient gets the information and leaves the office with what they need." They also suggested moving care to the patient via a "kitchen table" clinic. Yet virtual visits may not be reimbursed, and a subset of patients does not even engage with health care or the issues with their disease in the first place.

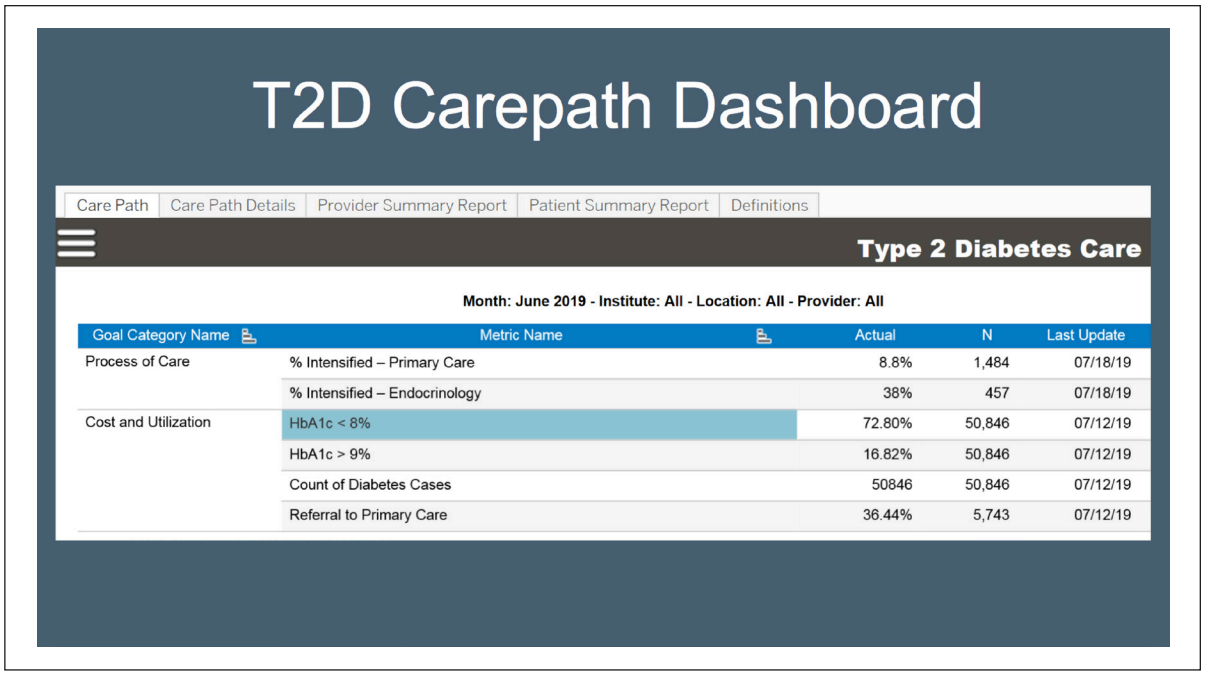
Panel Discussion

Moderator: John W. Kennedy, M.D., President, AMGA Foundation, Chief Medical Officer, AMGA

T2D Management: Therapeutic Inertia, Newer Therapies, and Intensification Tools, Oh My!

Panelist: Kevin Pantalone, D.O., ECNU, FACE, Director of Diabetes Initiatives, Department of Endrocrinology and Metabolism Institute, Cleveland Clinic

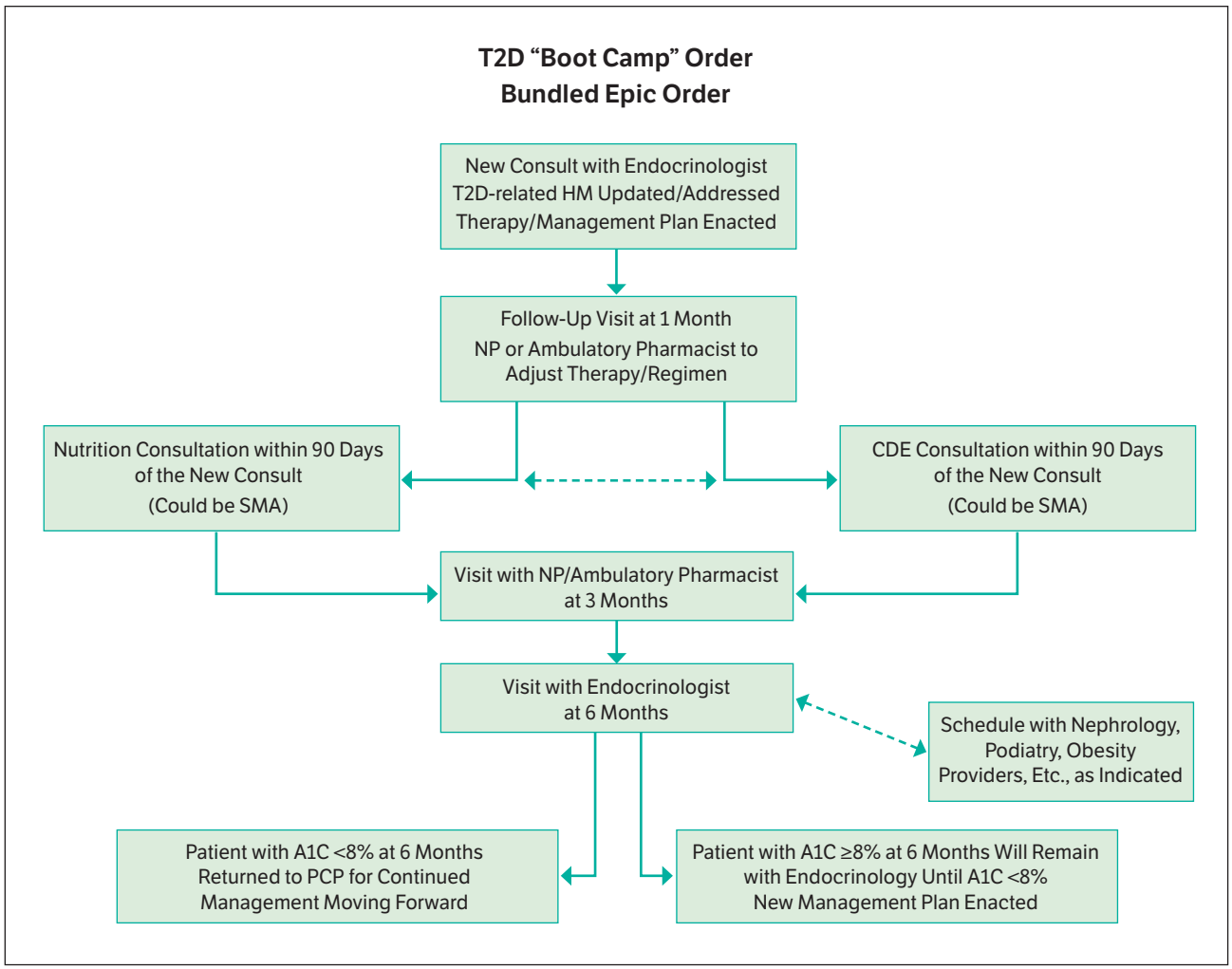
Pantalone talked about how Cleveland Clinic has been "changing the paradigm" of its diabetes care path through leveraging missed opportunities and intensifying care, particularly for patients not improving while on metformin therapy. Care teams are addressing lifestyle modifications, such as referring newly diagnosed Type 2 diabetes patients to nutritionists and diabetes educators. Additionally, they are referring patients with an A1c over 9 to an endocrinologist earlier on. "After a heart attack, you do not see the cardiologist 20 years later," Pantalone pointed out. "However, diabetes patients are not referred to the endocrinologist until years have passed."



Medication had been underprescribed at Cleveland Clinic, Pantalone said, noting that the patients most likely to benefit from these drugs have the lowest chance of receiving them.

Cleveland Clinic has also been engaging ambulatory pharmacists in its care for Type 2 diabetes and advanced conditions. One reason involves comorbidities; hypertension is the second-most common reason for referral to ambulatory pharmacists. Furthermore, ambulatory pharmacists understand the complexities of the many medications and have been incorporated in the "T2D Boot Camp" the clinic is designing for Epic. The "T2D Boot Camp" will ease information overload and obstacles to getting the right medication to the right patients.

"Anything that interrupts a provider's flow is a challenge," Pantalone said. To this end, Cleveland Clinic is also partnering with Merck to create EMR alerts for situations like high A1c readings and possible medication problems and "SmartSets" for every diabetes drug.



Diabetes and Cardiovascular Risk: A Change in Paradigm and Call to Arms

Panelist: Paula Pinell-Salles, M.D., FACC, Cardiologist, Virginia Heart

Atherosclerotic cardiovascular disease is the leading cause of morbidity and mortality among people living with diabetes in the United States. According to Pinell-Salles, care teams have been navigating evolving guidelines, with those by the ADA as "more definitive," and emerging options for SGLT-2 inhibitors. How have these medications been performing? Recent studies have shown:

- **Empagliflozin** reducing all-cause and cardiovascular death
- **Canagliflozin** reducing the primary composite for cardiovascular death, nonfatal myocardial infarction, and cardiovascular accidents. Among diabetics with chronic kidney disease, it also reduced major adverse cardiovascular events and hospitalization for heart failure.
- **Dapagliflozin** reducing hospitalization for congestive heart failure

Yet cost and coverage present barriers to these medications. Furthermore, Pinell-Salles said, the health community needs more license to prescribe this drug class more broadly. She also emphasized the need for more data, collaboration, and follow-up.

Pinell-Salles then joined an impromptu mini-panel with Norfolk and Pantalone, moderated by Kennedy. From the perspectives of their respective specialties—nephrology, endocrinology, and cardiology—panelists shared suggestions for what specialties can do to more effectively integrate this class of drugs into primary care. Ideas included:

- Developing local solutions
- Expanding the pharmacist's role
- Incorporating medications into specialty guidelines

For targeting and prioritizing patients, Virginia Heart goes by the guidelines, with two additional factors for diabetes patients, Pinell-Salles said. Care teams can incorporate a cardiovascular disease calculator into their processes as well.

> *"As a cardiologist, I fear for my patients' well-being when they are having frequent, severe or symptomatic hypoglycemia, so I reach out to the endocrinologist to make sure the patient will receive follow-up."*
>
> **— Paula Pinell-Salles, M.D., FACC, Virginia Heart**

Participants asked about the mechanics of coordinating care and passing it along to endocrinology or nephrology. Is cardiology the driver? The answer varies. At Cleveland Clinic, patients hospitalized for heart failure are seen by an endocrinologist a week after discharge. In another example, Lilly just announced a "significant" trial of SGLT-2 inhibitors in hospitalized cardiovascular patients, in which case "we would not allow the handoff," Pinell-Salles said. Whatever the situation, the key is to have a plan.

Participants also wondered when more coordinated, public-facing guidance might emerge. In response to the need for a more unified program and playbook, groups have been starting to coalesce. This includes a new coalition by the American Diabetes Association, American Heart Association, and AMGA that will have a patient-facing arm.

Workgroup Breakouts

Implementing Medication Care Paths for Type 2 Diabetes and Cardiovascular Risk

Facilitator: Beth Averbeck, M.D., Senior Medical Director, Primary Care, HealthPartners Care Group

As emerging treatments and precision medicine offer promising possibilities, they bring challenges as well, from identifying the patients most likely to benefit to educating all parties on the benefits and risks. Participants discussed a variety of potential solutions, including:

- Using technology to identify patients most likely to benefit
- Delivering medication recommendations in electronic medical records
- Conducting e-consults with specialists
- Having payers cover costs for stronger medication adherence

Implementing Medication Care Paths for Type 2 Diabetes and Congestive Heart Failure

Facilitator: Paula Pinell-Salles, M.D., FACC, Cardiologist, Virginia Heart

What are the biggest obstacles in treating congestive heart failure? Participants cited diagnosing and classifying the condition, using drugs in an inpatient setting, and covering the costs. They're addressing these challenges through:

- Educating primary care providers on treatment benefits and new guidelines
- Reframing drugs, such as considering them in the same categories as ACE, ARB, and beta blockers
- Implementing programs like "beds to meds" at Jefferson Hospital to ensure drug coverage after discharge
- Using outpatient coordinators to manage transitions of care
- Aligning the entire health system under one formulary
- Helping patients access and apply for financial assistance
- Demonstrating, through benchmarking and clinical trials, that these medication paths prevent readmissions

Workgroup: Using Technology to Improve Outcomes

Facilitator: Theresa M. Frei, M.B.A., R.N., President and Chief Executive Officer, Sutter Medical Foundation

From Cleveland Clinic's customized electronic medical records interface to Geisinger's alert for showing the A1c readings, organizations are leveraging technology for chronic conditions. Participants cited text messaging (particularly for physicians), smoking cessation apps, and a quality metric app that added money into a physician's account in real time. Recommendations included:

- Engaging patients with "surround sound" messaging aligned with their needs and recognizing their limitations
- Keeping point of care simple, one-click, and driven by primary care physicians
- Forging partnerships with retail pharmacies and community organizations
- Aligning policies with coverage

Together 2 Goal® Announcements

John Cuddeback, M.D., Ph.D., Chief Medical Informatics Officer, AMGA; Lisa Cornbrooks, Director, Campaign Marketing, National Health Campaigns, AMGA Foundation; Cori Rattelman, Senior Research Analyst, AMGA

In its third year, Together 2 Goal® exceeded its goal of improving care for 1 million people with Type 2 diabetes by 2019. Among 3.1 million patients with Type 2 diabetes, 1.082 million reported improved care and 336,000 sustained bundle control for over a year.

Extrapolating from the longitudinal data of collaborative participants and members using an Optum population health management tool:

- About one-third of patients with improved care were people with a new Type 2 diabetes diagnosis.
- Among new therapies and guidelines, SGLT-1 and SGLT-2 inhibitors were the preferred treatments.
- GLP 1 prescriptions increased from 8% to 13% from 2016 to 2019.
- Patients with cardiovascular disease were no more likely to be prescribed GLP-1 or SGLT-2 inhibitors than patients without cardiovascular disease—however, this is changing for patients with an A1c above 8.

Also in 2019, Together 2 Goal® welcomed four new partnerships (the American Heart Association, American Diabetes Association, Endocrine Society, and Know Diabetes by Heart™) and marked the conclusion of two 12-month cohorts.

The 12 groups of the cardiovascular cohort reached 4,000 full-time physicians and more than 190,000 patients, reporting:

- 1,700 additional tobacco-free patients
- 1,600 additional patients with documented aspirin therapy
- 2,675 additional patients with a statin prescription
- 1,640 additional patients with an LDL cholesterol measurement under 70 mg/dL

The eye care cohort noted 8,600 additional patients with documented screening, with absolute improvement of 2–21% and relative improvement of 5–45%.

What's next? According to participants, determining cost mitigation, advancing therapy, with a focus on initiating insulin, and identifying clinical inertia across all stages of chronic disease. Potential clinical inertia in adopting the new prescription guidelines has fallen nearly 8% since 2016—but still could be as high as 80%.

Screening was another priority: 75% of the population is available for screening, but not that many are getting screened.

For patients on the claim or "problem" list with no prior diagnosis, participants recommended reviewing clinical data for diagnostic or strongly suggestive evidence and conducting practice-based screening. For patients with a Type 2 diabetes diagnosis:

- Measure A1c—if over 8, bring it into control
- Measure blood pressure—if over 140/90, bring it into control
- Screen/diagnose for nephropathy or refer to a nephrologist
- If LDL is over 70 mg/dL, prescribe or re-try a statin

References

1. Krause, Ganduglia-Cazaban C, Finkel KW. Rates for HEDIS Screening for Diabetic Nephropathy Quality Measure May Be Overstated. *Manag Care*. 2018;27(8):45-49.

2019 National Day of Action

On November 7, more than 300 healthcare professionals from 32 groups nationwide participated in the fourth annual Together 2 Goal® National Day of Action. Over a healthy meal, Plank Mentors—individuals who have excelled at implementing a given campaign plank within their organization—shared best practices. Check out these healthcare teams across America taking action for diabetes care.

Utica Park Physician Group - Oklahoma

Sharp Rees-Stealy Medical Group - California

Henry Ford Medical Group - Michigan

Intermountain Medical Group - Utah

Summit Medical Group, P.A. - New Jersey

Premier Medical Associates, P.C. - Pennsylvania

Crystal Run Healthcare - New York

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AMGA Foundation serves as a catalyst, connector, and collaborator for translating the evidence of what works best in improving health and health care in everyday practice.

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