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Cardiovascular Disease in Patients With Type 2 Diabetes

A Qualitative Analysis of Knowledge, Attitudes, and Beliefs of Health Care Professionals

Elizabeth L. Ciemins, PhD; Monette McKinnon; Carol Mahler Hamersky, PhD; Neeraj N. Iyer, PhD; Jill Powelson, DrPH

Abstract: Guidelines for the management of patients with type 2 diabetes mellitus (T2DM) recommend SGLT-2 (sodium-glucose cotransporter 2) inhibitors and GLP-1 RAs (glucagon-like peptide 1 receptor agonists) as second-line agents for patients with, or at risk for, cardiovascular disease. A better understanding of guideline implementation will further the provision of evidence-based health care to patients. Interviews and surveys of clinicians were conducted to understand providers' knowledge, attitudes, and beliefs related to the 2019 American Diabetes Association Standards of Care for T2DM. There was a lack of widespread knowledge of the guidelines and comfort with their use. Clinicians require additional training and education on the efficacy of the new medications and accompanying clinical guidelines. **Key words:** *cardiovascular disease, clinical guidelines, diabetes, evidence-based care*

ATHEROSCLEROTIC CARDIOVASCULAR DISEASE (ASCVD) is the leading cause of morbidity and mortality for individuals with diabetes (American Diabetes Association [ADA], 2017a; Raghavan et al., 2019). Patients with type 2 diabetes mellitus (T2DM) are also at increased risk for micro- and macrovascular complications (ADA, 2019). Vascular complications associated with T2DM can cause eye and kidney damage and result in major adverse cardiovascular events (MACE), that is, myocardial infarction, stroke, limb ischemia, and cardiovascular mortality (DeFronzo et al., 2015).

Cardiovascular disease (CVD) is mostly attributable to modifiable risk factors (Graham

Author Affiliations: *AMGA, Alexandria, Virginia (Drs Ciemins and Powelson and Ms McKinnon); and Novo Nordisk, Plainsboro, New Jersey (Drs Hamersky and Iyer).*

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Correspondence: *Elizabeth L. Ciemins, PhD, AMGA, One Prince St, Alexandria, VA 22314 (eciemins@amga.org).*

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et al., 2006), whose reduction in patients with T2DM is an essential focus of AMGA's Diabetes: Together 2 Goal® disease management campaign (AMGA, 2016). Together 2 Goal® has identified "assess and address risk of cardiovascular disease" as one of 11 evidence-based care processes to be implemented by participating AMGA member organizations. In a campaign survey, 73% of participating health care organizations (HCOs) have implemented or plan to adopt this care process (Penso, 2017).

In 2017, US and European consensus guidelines added use of 2 new classes of medications as second- or third-line agents for glycemic control (after metformin and lifestyle) for patients with uncontrolled T2DM and established ASCVD (ADA, 2017b; Cosentino et al., 2020). Additions were based on data obtained from several large-scale cardiovascular outcome trials (ie, CANVAS; EMPA-REG OUTCOME; LEADER; and SUSTAIN6) that showed 4 medications, empagliflozin and canagliflozin (sodium-glucose cotransporter 2 [SGLT-2] inhibitors), and liraglutide and semaglutide (glucagon-like peptide 1 receptor agonists [GLP-1 RAs]), had a cardioprotective benefit. These favorable cardiovascular outcomes were accompanied by reductions in hyperglycemia and body weight and a lower incidence of hypoglycemia (Marso et al., 2016a, 2016b; Neal et al., 2017; Zinman et al., 2015).

Revised clinical practice guidelines that followed these trials, if disseminated broadly across HCOs, have the potential to reduce modifiable CVD risk in patients with diabetes and improve overall health. Generally, guidelines are viewed as a foundational means to translate new evidence into practice, enhance health care quality, and improve patient outcomes (González et al., 2015). Guidelines inform decision making, particularly when clinicians may not be aware of, or are uncertain about, new and sometimes complex therapies. Adherence to guidelines can also be very important in complex diseases that can lead to premature mortality (eg, diabetes and CVD) (Fischer et al., 2016).

Achieving guideline adherence is a slow and complex process (Fischer et al., 2016), and clinician use of guidelines remains inconsistent (Gagliardi et al., 2014). An estimated 30% to 40% of patients receive treatment not based on scientific evidence (Fischer et al., 2016). In the management of T2DM, approximately 70% of nonadherence to guidelines has been attributed to physicians' lack of knowledge or patients' lack of awareness (Fürthauer et al., 2013). Even when awareness is high, adoption and adherence are comparatively lower (Gagliardi et al., 2014). Sluggish adoption of evidence-based guidelines can lead to omission of recommended therapies, suboptimal patient outcomes, and inappropriate resource use (Pronovost, 2013). Furthermore, most implementation studies fail to provide evidence linking any proposed determinant to specific changes in practice (Flottorp et al., 2013) and guideline interventions have narrowly targeted physician specialties (Grimshaw et al., 2004). More research is needed to help users identify and select implementation strategies that are effective in addressing specific barriers and to raise awareness of the interplay of barriers (eg, cost) across stakeholders (patients and providers).

Evidence suggests that guidelines recommending specific medications for patients with T2DM and at high risk for MACE/mortality are not being followed. Administrative claims studies have found patients with T2DM and CVD less likely to be prescribed SGLT-2 inhibitors than other medications (McCoy et al., 2019; McGurnaghan et al., 2019). Studies are needed that address what clinicians/administrators know and believe about the diabetes guidelines, the newly recommended SGLT-2 inhibitor and GLP-1 RA medication classes, and the evidence behind the guideline changes. While costs of these new agents are higher than other second-line agents (ADA, 2019), from a value standpoint, the "greatest savings and waste arise from the clinical outcomes that result from the wise or poor prescribing of drugs, often dwarfing the costs of the drugs themselves" (Avorn, 2017, p. 362).

As the prevalence of diabetes grows, so will the prevalence of CVD and the co-occurrence in patients with T2DM. In 2017, an individual with diabetes was estimated to have direct medical expenditures 2.3 times higher than those of a similar person without diabetes (ADA, 2018). The United States spends $237 billion and $37.3 billion each year on diabetes and its CVD-related costs, respectively (ADA, 2018). With renewed emphasis on population health and value, HCOs may be inspired to proactively integrate these guidelines into routine management of CVD risk for patients with T2DM (Penso, 2017). However, more information is needed to identify knowledge gaps among physicians/administrators to address barriers and facilitate systematic translation and adoption of guidelines into routine practice.

The purpose of this study was to understand the knowledge, attitudes, and beliefs of physicians and administrators in 4 US health systems about guidelines and use of these new medication classes to inform dissemination and translation of the guidelines into US HCOs. A better understanding of how guidelines are adopted, and barriers and facilitators in the process, will further the timely provision of evidence-based health care to patients with chronic conditions such as diabetes.

METHODS

An exploratory, sequential study design included clinician surveys and interviews at 4 US HCOs. The purpose of the 30-question, structured, online survey instrument was to help understand to what extent HCOs are transitioning care for patients with T2DM and risk of CVD in light of the guidelines. Interviews were intended to collect more detailed, in-depth information.

HCOs were selected on the basis interest and willingness to participate. Participating clinicians included physicians, a nurse, and a pharmacist, in the disciplines of family medicine, internal medicine, endocrinology, cardiology, and nephrology. Clinician roles included quality directors/leaders, medical directors, specialty department chiefs, pharmacy leaders, population health leaders, and practicing primary and specialty care providers.

Exploratory interviews helped refine the surveys and interview guide. Saturation was reached after interviewing 20 clinicians for approximately 2 hours each. Interview questions were organized around the Consolidated Framework for Implementation Research (CFIR) (Damschroder et al., 2009) and included questions regarding treatment of patients with T2DM and with, or at risk for, CVD in the following domains: intervention characteristics, outer setting, inner setting, individual (clinician) characteristics, and processes (see Table S1, Supplemental Digital Content, available at: http://links.lww.com/JACM/A98). Interviewees were also asked to reflect on the survey findings.

Quantitative analysis of surveys included comparisons between the 4 organizations, as well as stratifications by specialty and years in practice. Qualitative data analysis used a constant comparison approach to identify themes, guided by the CFIR domains. Barriers and facilitators to adoption of guidelines were identified. Three qualitative investigators reviewed the data using grounded theory methodology (Strauss & Corbin, 1998) and contributed to the development of themes using a data reduction approach (Miles et al., 1994). This entailed selecting, simplifying, abstracting, and transforming the data from the transcripts by CFIR domain. Three investigators independently reviewed all transcripts from at least one organization and identified themes and supporting quotations. Once preliminary themes were identified, the 3 investigators met and discussed, combining or expanding themes as appropriate. Two investigators then sought additional support for themes by searching transcripts using key words. Themes were further refined and condensed. The principal investigator presented themes to the remaining authors for feedback and further refined and clarified themes.

Ethics approval and consent to participate

The study was determined exempt by the New England Independent Review Board (NEIRB# 1-5968-1) and one participating HCO's institutional review board.

RESULTS

Survey: Physician characteristics

A total of 443 clinicians from 4 HCOs received surveys with a 44% response rate (HCO range, 34%-84%). Five surveys were removed because they were completed by specialists outside the study scope (eg, neurologists, pediatricians), leaving 190 surveys for analysis. Most respondents were primary care providers (45% family medicine; 30% internal medicine). Cardiologists, endocrinologists, and nephrologists represented 14%, 9%, and 2% of respondents, respectively (Table 1). Participating organizations varied in geographic location, representing 3 US states, and organization size (75-1000 full-time equivalent physicians).

Survey: Guidelines and research

Table S2, Supplementary Digital Content (Survey Results: Clinician Knowledge, Attitudes, Behaviors, and Beliefs About Agents to Reduce MACE or CV Mortality for Patients With Type 2 Diabetes) (available at: http://links.lww.com/JACM/A99), summarizes the following survey results.

Most clinicians (74%) reported following clinical guidelines to reduce MACE/mortality in patients with diabetes. Reported guideline use decreased by years in practice, that is, the longer in practice, the less likely to report following a specific guideline. Most (60%-66%) followed ADA or American College of Cardiology (ACC)/American Heart Association (AHA) guidelines. Ninety percent (range, 84%–100%) were at least somewhat familiar with these guidelines; 20% were extremely familiar. Survey respondents were less familiar with clinical trials related to the latest diabetes medications (range, 60%–85% at least slightly familiar). Clinicians generally agreed that trials affect treatment decisions at least sometimes (range, 58%–80%).

Table 1. Participant Characteristics (N = 190)[a]

	Internal Medicine	Family Medicine	Cardiologists	Endocrinologists	Nephrologists
Total respondents, %	30	45	14	9	2
Years in practice, %					
<5	16	27	23	17	0
5-9	7	14	15	11	0
10-14	9	12	12	44	67
15-19	16	15	15	17	33
20+	53	33	35	11	0
Patients with T2DM seen per week, %					
<10	12	12	4	0	0
11-30	58	61	58	6	67
31-49	25	27	31	50	33
50+	5	1	8	44	0
Primary practice site, %					
Urban	21	12	8	17	0
Rural	11	20	15	11	0
Suburban	68	69	77	72	100

Abbreviation: T2DM, type 2 diabetes mellitus.

[a]Numbers may not add up due to rounding.

Survey: External factors

Overall, 54% of clinicians reported they hear concerns from patients about taking one of these new medications, with endocrinologists reporting the highest rates (82%). Cost to the patient was the concern heard most (88%), followed by fear of side effects (35%). The remaining concerns heard by clinicians, in order of frequency, included *reluctance to add another medication, fear of adverse events, discomfort/injection, feeling overwhelmed by disease, and denial.*

Most clinicians (81%) identified statins as the most common medication class prescribed to reduce MACE/mortality. Most (92%) reported insurance companies as restricting their ability to prescribe the newer medications through requirements of prior authorization (93%); requirements of trying a less expensive medication first (89%); and placing these medications in a higher tier on the formulary (85%).

Survey: Organizational and clinic factors

Only 5% of clinicians reported the duration and availability of appointments are never adequate (range, 0%-13%). Nurses were reported as most likely to educate patients in the self-administration of injectable medications (51%). Endocrinologists were most likely to report themselves as the educator. Almost one-third (29%) of respondents reported they sometimes or never educate patients with T2DM about risk of CVD. Finally, when they have questions about new medications or guidelines, 64% and 39% of clinicians ask physician colleagues and pharmacists, respectively.

Survey: Treatment

The most common reasons reported for not prescribing these medications were barriers of insurance formularies (74%), limited visit duration (74%), and patient concerns related to side effects, discomfort, cost, or other reasons (73%). Other reasons reported for not prescribing included time, diabetes not being a disease they treated, and their employer not allowing samples.

A total of 41% of respondents reported their organization had adopted a standardized diabetes treatment protocol that included CVD risk (HCO range, 28%-65%). Family medicine providers (50%) and those in practice for less than 5 years (48%) were most likely to report having protocols. Of those reporting existing protocols, 93% stated they usually or always followed them. Most (98%) agreed or strongly agreed it is important that patients with T2DM and at high risk of MACE/mortality take medications to reduce their risk.

Survey: Dissemination and implementation of guidelines

While 41% reported that they typically hear about new/revised diabetes mellitus guidelines from *UpToDate*, Medscape, or similar services, about one-third also reported hearing about guidelines from scientific journals, ACC/AHA, or ADA. Only 16% heard about guidelines from their employer/HCO. A total of 40% of respondents reported that their electronic health record (EHR) provided an alert about medications for patients with T2DM and at high risk for MACE/mortality (HCO range, 33%-49%). Less experienced providers were more likely to report these alerts (~50%) as were internists (48%).

In summary, respondents identified external factors, for example, cost, insurance, and patient fears/concerns, as the most important reasons for not prescribing medications shown to reduce MACE/mortality in patients with T2DM (69%). Second were treatment reasons, that is, physician judgment due to side effects or adverse events (30%). As free-text comments, cardiologists, nephrologists, and some primary care physicians reported that treating these patients was not their responsibility but instead was the role of endocrinologists and everyone is waiting for someone else to take the lead. Others suggested the need for an increased focus on diet and exercise and highlighted the importance of shared decision-making and motivational interviewing, but they feared patients were making poor decisions regardless. Physician champions were proposed to

help disseminate guidelines and implement best practices.

Integrative results: Themes

While each organization was unique and identified its own challenges, several themes emerged. The 2 drug classes recommended in the guidelines for the treatment of patients with T2DM and CVD were not broadly prescribed. There was a lack of widespread knowledge of the guidelines and comfort with their use and concerns with cost and insurance coverage. Moreover, these treatments lacked technology support (eg, best practice alerts) or physician or practice-level reporting of prescribing patterns and these treatments were not incentivized for impacting internal or external quality metrics.

Per the CFIR domains, *characteristics of the intervention* (ie, guidelines/medications) that impeded use included (1) lack of perceived relative advantage, that is, to available treatment alternatives such as metformin, statins, diet, and exercise; (2) complexity of intervention, that is, injection barrier; and (3) cost. Countering these impediments was the strength of the evidence, which resulted in a positive reaction to the guidelines by some clinicians.

Outer setting barriers included (1) insurance and cost, including medications not on formularies or in tiers discouraging broader use; (2) external policies and incentives around risk-based contracts, including lack of incentives to treat and cost concerns with capitated payments; (3) equity between patients, that is, high-risk and risk-based contract patients more likely to receive prescriptions and services (eg, care coordination); (4) lack of data, for example, from pharmacies on fills/refills, medication adherence; and (5) other patient factors, for example, polypharmacy burden and affordability. Outer setting facilitators included support from AMGA Collaboratives and the Together 2 Goal® campaign (AMGA, 2016) and insurance support, that is, data, incentives, and services. An apparent disconnect was observed between insurers (via risk-based contracts) providing more services, for example, care coordination, yet also imposing high costs and limiting patient coverage.

Inner setting barriers included (1) interdepartmental silos; (2) lack of education/communication around guidelines/treatments; (3) time/resources shortages and competing priorities; (4) lack of technology/data; and (5) cultures of provider autonomy, that is, lack of direction to treat based on specific guidelines. Some barriers were facilitators in other settings. For example, technology was noted as a facilitator including diagnostic assessment tools; an EHR guideline hub; best practice alerts; medication adherence; and options/costs at the point of care via EHRs. Many interviewees recognized the need for a care pathway, one that addressed CVD risk in particular. Other facilitators included the involvement of team-based multidisciplinary care, pharmacy team, value-based thinking, organizational culture of standardization, and various innovations, for example, group visits, high-impact huddles, e-consultations with endocrinology, dedicated diabetes centers, and positive deviance techniques to elicit behavior change.

Individual clinician characteristics emerged as factors influencing uptake of guidelines and these medications. Characteristics included (1) skepticism and negative experience with pharmaceutical companies; (2) knowledge gaps; (3) lack of financial incentives and prioritization; (4) lack of self-efficacy or fear of the unknown; (5) therapeutic inertia; and (6) concerns regarding patient adherence due to cost.

Finally, challenges and opportunities in *system processes* were identified, for example, systemic processes to disseminate new guidelines and standardize care pathways. A disconnect was observed between leadership and practicing providers in knowledge and awareness of new guidelines and system-specific treatment algorithms. Clinicians reported disengagement with these new guidelines, evidenced by the lack of inclusion on quality metric dashboards and in transparent reporting. Quality committees were sometimes successful in raising awareness

and spreading innovation/ideas across departments by encouraging collaborative patient care. Table 2 provides commonly identified themes and supporting quotes from study participants.

DISCUSSION

This qualitative study sought to better understand the adoption of clinical guidelines and resulting provision of best practices using the 2019 ADA Standards of Medical Care in Diabetes, and the specific recommendation for treatment of patients with T2DM at high risk for MACE/mortality, as an example. Using the CFIR as an organizing guide, participants revealed a lack of awareness of the guidelines and low prescribing of the recommended medications. Reasons provided centered on patient and other external factors such as cost, insurance, and patient fear of side effects. Respondents cited clinician judgment regarding the most appropriate medication, considering potential side effects/adverse events, as a critical factor. Through stakeholder interviews, it was also discovered that health systems play an important role in the uptake of guidelines and a lack of effective communication strategies, clear direction, and technological solutions were potentially serious barriers. For example, there was little monitoring or tracking of provider prescribing patterns for patients who would most benefit, and provider incentives to use best practices and follow clinical guidelines were lacking. Finally, a significant disparity existed between administrators' understanding of the information being disseminated to practicing providers and what those providers reported receiving.

Supported by previous studies that found guideline interventions were typically targeted at physicians, often within a single specialty (Grimshaw et al., 2004), our results suggest that change at many levels will be important to influence provider and patient behaviors. In addition, while previous studies attributed 70% of nonadherence to physicians' lack of knowledge, (Fürthauer et al., 2013), our findings support a broader array of factors influencing adherence. This study suggested that providers lack education about treatment guidelines, including the details about the potential efficacy of various treatments for specific patient populations and side effects such as hypoglycemia and weight gain. At the system level, technological adaptations to EHRs, potentially including best practice alerts, and improving transparent data monitoring and tracking may improve use of best practices by making the right choice the easy choice and assisting providers at the point of care, as well as with regular prescribing pattern updates. Among actionable external factors, affordable pharmaceutical pricing as well as evidence-based formularies may ensure optimal patient access to medications. Payer system value-based risk contracts could enable demonstration of the real-world impact of these medications on outcomes, determining the cost-benefit of paying for costlier, but potentially more effective, medications. Even when awareness of guidelines is high, adoption is low (Gagliardi & Alhabib, 2015; Gagliardi et al., 2014), further underscoring the need for a multifaceted, multidisciplinary approach.

Study limitations included the type of health systems included, which were all AMGA member organizations. Because these organizations tend to be high-performing health systems that are focused on moving from volume- to value-based care, they may not be representative of the US population of HCOs, especially safety-net systems, federally qualified health centers, and other public institutions providing care to the most vulnerable and underserved patients. Another limitation was the number of HCOs participating in the study. Although we were limited by funding and expected that saturation could be reached by interviewing 20 providers at 4 HCOs, it is possible that we did not reach saturation and that interviewing different clinicians from other HCOs may have yielded dissimilar results. However, experiences from other related AMGA projects, such as the Together 2 Goal® campaign (AMGA, 2016), suggest that these findings

Table 2. Themes, Associated CFIR Construct, and Excerpts From Participants

CFIR Construct	Theme	Associated CFIR Construct	Participants Excerpts
Intervention characteristics	Lack of perceived relative advantage	Relative advantage	*Although the SGLT-2 data is pretty robust it's also short-term data compared to statins which have been around forever. . . . it's probably the most beneficial medication we have.*
	Complexity of intervention	Complexity	*I can't say as a cardiologist I'm comfortable knowing each and every drug. When it comes to diabetes it's just gotten so complicated . . . I wouldn't be able to keep up with all the different agents to say if it's the best drug for that person.*
	Cost	Cost	*So, you have an option to choose from the SGLT2 with a $300 to $500 cost per month compared to [another] for $20 a month.*
Outer setting	Insurance	External policy and incentives	*Insurance payer sources have too much influence and input on what meds the patient can take.*
	Lack of pharmacy or payer data	External policy and incentives	*. . . we do have some of our contracts that the Pop Health Dept has occasionally shown us some data on the uses of different agents. I mean, I used to get a report from [payer].*
Inner setting	Interdepartmental silos	Networks and communications	*It's been endocrinology only that is prescribing [SGLT-2s, GLP-1s]; I don't even see internal medicine prescribing those drugs. It's mostly endocrine.*
	Lack of time	Available resources	*We have to be cautious in how many things we ask providers to make sure that they're doing . . . because there's so much work to do.*
	Lack of communication	Networks and communications	*There's definitely a communication issue in our perception of who owns the guidelines, . . . we need to do a better job of disseminating it and having an owner to it . . . .*
	Lack of technology	Available resources	*There's not something [in EHR] while [the patient] is in the exam room that's telling [me],* "Okay. You should go to an SGLT-2 or GLP-1 here now." *It's in the algorithm. But the algorithm resides outside of the EHR.*

(*continues*)

Table 2. Themes, Associated CFIR Construct, and Excerpts From Participants (*Continued*)

CFIR Construct	Theme	Associated CFIR Construct	Participants Excerpts
	Competing priorities	Relative priority	*The downside of measuring metrics is that people feel pressured. So, they feel like,* " . . . if I don't get their diabetes under control right now, I'm going to get dinged for this on my metrics."
	Lack of incentives	Organizational incentives/rewards	*We're not able to measure adherence to algorithms or evidence-based practice. That's not in the incentive program yet. I would love to put it in.*
Clinician characteristics	Personal beliefs	Knowledge and beliefs about intervention	*What we don't want is to prescribe a medication that's so expensive and they never take it. They refill it but never really use it or they don't refill it.*
	Lack of self-efficacy	Self-efficacy	*I know some of the side effects, I know some of the risks, and I certainly know the benefits. But it would not be in my best interest or the patient's best interest for me to prescribe a drug that I'm not comfortable with.*
	Therapeutic inertia	Individual state of change	*Old habits are hard to break. I definitely could see, especially as . . . the guideline . . . becomes more generally accepted, I could see us creating a best practice advisory that would say, "*Your patient has diabetes and heart disease or diabetes and peripheral vascular disease. Please consider the use of one *of these two* agents."
Process	Disconnect between leadership and practice	Reflecting and evaluating	*I guess I was a little frustrated by comments that people didn't know what the guidelines were. Because . . . we've had lectures on them, we have links, we've sent them out by multiple e-mails. When I see that, I almost want to go bang my head against the wall.*

Abbreviations: CFIR, Consolidated Framework for Implementation Research; EHR, electronic health record; GLP-1, glucagon-like peptide 1; SGLT-2, sodium-glucose cotransporter 2.

are supported at least among AMGA member organizations.

The adoption of clinical guidelines and integration into practice are complex processes. Attention to the multifaceted factors influencing acceptance and ultimate embracement of guidelines is critical. The CFIR provides the necessary domains that require exploration, and the study findings provide specific factors to address to foment change in uptake of clinical guidelines. As the participants reported, the guidelines themselves should be simple, understandable, and translatable into practice and insurance and pharmaceutical company influence should be addressed. The study also found that the inner setting, that is, the health system and its silos, competing priorities, communication to providers, and degree of technological solutions, is paramount. Furthermore, the characteristics of clinicians, including clinical experiences with certain medications, concerns for patients, and therapeutic inertia, require recognition and better understanding. Finally, processes should be implemented to effectively disseminate guidelines and provide important feedback to clinicians.

This study demonstrated the lack of universal uptake of guidelines for the treatment of patients with T2DM and at high risk for MACE/mortality. The disconnect between practicing providers' and administrators' perceptions of the understanding and use of guidelines, as well as the awareness and use of treatment protocols, was striking. Perceived barriers and facilitators were highlighted, and their dissemination was found to be important in efforts to understand why guideline adherence was low and to ultimately increase adoption.

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