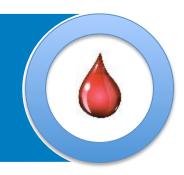
Focus on Diabetes

CMI/Compas - Endocrine Today Collaboration

May 2015



The diabetes journey touches many people in many ways, from patient to caregiver to healthcare professional. In a new whitepaper collaboration by CMI/Compas and Endocrine Today, that journey is explored through the eyes of practicing HCPs and patient advocates, with insights on how pharma can provide their support throughout the voyage.

From diagnosis to management, the diabetes journey is complex for both patients and physicians

With 21 million people currently diagnosed with Type 2 Diabetes — and an additional 8 million undiagnosed — diabetes is reaching epidemic status in the U.S. The discovery of an elevated hemoglobin A1C level — a test which tracks average blood glucose levels over 3 months — as well as a diagnosis of prediabetes or diabetes initiates a great number of patient and physician choices. The "pathway back to health" in patients with diabetes often begins with active lifestyle changes such as diet and exercise, but may also be supported by oral and injectable pharmacological interventions.

The varied range of treatment choices differs widely based on physician preferences between established treatments and newer, innovative regimens. Myriad options exist to control the progression of the disease, and physicians face complex decisions when choosing the practices best suited for their patients.

"We are continually looking for educational resources to help our patients..."



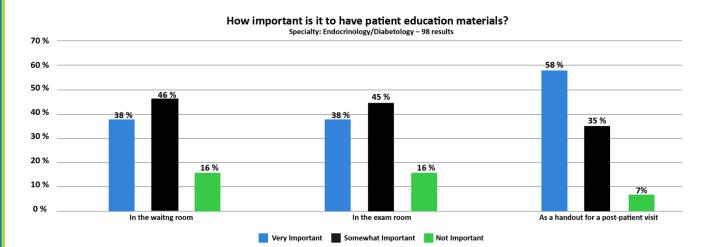
A Community of Care

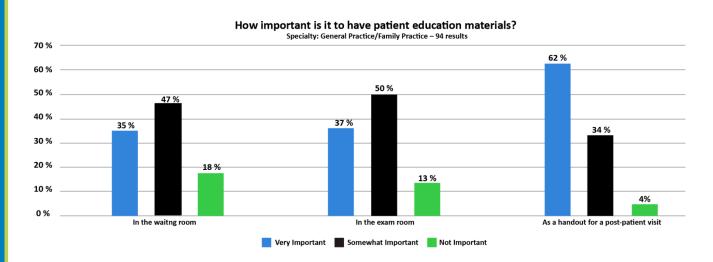
In the quest to keep blood glucose levels under control, patients often consult primary care physicians (PCPs), endocrinologists, dieticians, registered nutritionists, diabetes educators, and even mental health professionals. Care may also include ophthalmologists, podiatrists and cardiologists when or if the patient's disease progresses to include other comorbidities. Despite this large health care team — and the collaboration that must exist among them — Type 2 Diabetes providers agree that the key to long-term health is patient self-care.





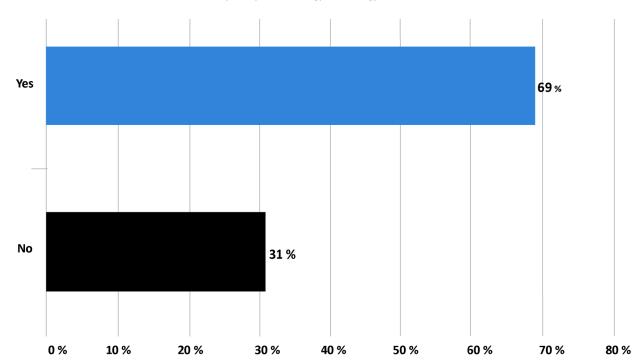
"Diabetes care, regardless of medical prescription choice, is self-care," said **Bennet Dunlap**, patient advocate. "At best a patient will see a health care provider a few times a year, for a few minutes." With proper guidance, said Dunlap, "the rest of the year the patient is managing their diabetes themselves." Medicare covers 10 hours of diabetes education the first year after diagnosis to equip patients with the tools and knowledge to better understand and care for their disease. Thereafter, patients typically visit these providers on a yearly basis in addition to their visits with a PCP or endocrinologist a few times a year. However, since this type of coverage is typically not available to patients with prediabetes, or when the patient is not yet Medicare-eligible, education and lifestyle changes are often the responsibility of the primary care practice.





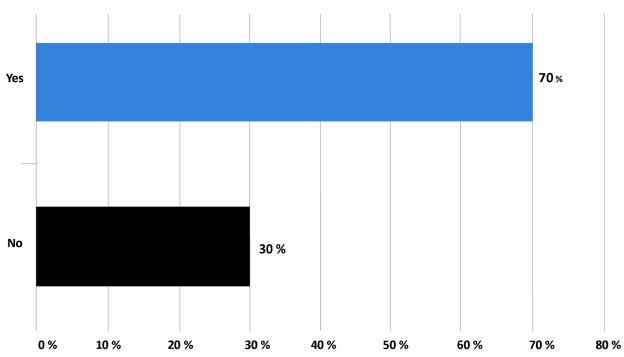
Have you ever referred a patient to a website for medical information?

Specialty: Endocrinology/Diabetology-100 results



Have you ever referred a patient to a website for medical information?

Specialty: General Practice/Family Practice-98 results



Source: CMI/Compas Media Vitals™ 2014

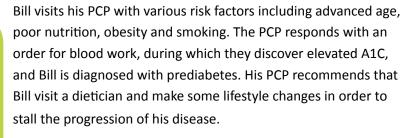


A Look at the Patient Community: Profiles of Those Living with Diabetes

Patient Profile:
Bill**— age 63 years

Diagnosis: Prediabetes

Pathway to Health: Primary Care Provider to Dietician



At this point, nutritionists and diabetes educators can assist Bill in learning key strategies to make behavior modifications such as making smarter food choices and incorporating exercise regimens. Yet, the key to the success of self-care, even with these resources, starts with how the diagnosis of prediabetes is conveyed.

"If the diagnosis is given with a message of 'this is not such a big deal,' then the patient will more likely approach their self-management approach in the same way and not provide the attention the diagnosis requires," said **Kellie Rodriguez, MSN, CDE,** Director of Diabetes Education and Community Engagement at UT Southwestern. "At the other extreme, fear tactics can result in the patient becoming too afraid to learn. A happy medium in the delivery of the message is essential."

Challenges also exist in this setting because, despite the fact that Bill presented with risk factors, he had no other obvious symptoms. "Patients often assume incorrectly that if they 'feel well' they must 'be well,'" Rodriguez said. "It is essential that providers and educators explain that the key to long-term health and well-being is taking a proactive approach to self-care."

"Bill's age may also present a challenge to care providers," **Tami Ross, RD, LD, CDE,** former president of the American

Association of Diabetes Educators and director of the Diabetes

Center for Excellence in Richmond, Kentucky, said in an interview.

"The patient has a lifetime of habits and behaviors, that now suddenly he has to think about changing," Ross said. "Building a relationship and trust level with their dietician and diabetes educator is absolutely key."



^{**} Monique is the pseudonym of a real patient. Others are composites of patients based on interviews with practicing primary care providers, endocrinologists, patient advocates and diabetes educators.

A Look at the Patient Community: continued

Patient Profile:

Monique**— age 51 years Diagnosis: Type 2 Diabetes

Pathway to Health:

Emergency Room Physician to Primary Care Provider



After a visit to the ER with symptoms of weight gain, fatigue and increased urination, Monique learns she has elevated A1C levels as well as a blood glucose of 400 mg/dL. Many patients with diabetes are prescribed metformin as first-line therapy; while this was the case with Monique, the PCP she was assigned to from the ER changed her regimen during a follow-up visit a few days later.

"Usually there is a step approach to how we apply medications," Nancy Beggs, MD, FACP, attending physician of internal medicine at Cooper University Health Care, said in an interview. "Some medications, like metformin, are good but take longer to work. I saw this patient needed a quicker intervention, so I started her on an oral hyperglycemic to get her glucose down."

Whether patients are initially prescribed an oral or injectable agent hinges on the patient's presenting condition and glucose control. Their PCP will follow up in 3 to 4 weeks to evaluate how A1C levels are responding to the treatment, and if levels are persistent or higher, the PCP will typically move to a second-line oral or injectable medication.

"Although Monique's case was severe, because she had not yet been treated with an oral agent, it was likely that she would respond with one," Beggs said. "If someone has not used the pills before, they usually work effectively. However, in severe cases, such as when a patient has diabetic ketoacidosis, which is rare for a type 2 diabetic, I would go right to insulin."

A Look at the Patient Community: continued

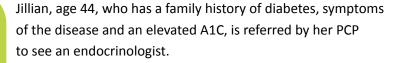
Patient Profile:

Jillian**— age 44 years

Diagnosis: Type 2 Diabetes

Pathway to Health:

Primary Care Provider to Endocrinologist to Diabetes Educator



Elizabeth Seaquist, MD, endocrinologist and professor of medicine at the University of Minnesota, said the key to choosing an oral agent for Jillian would be to look at her target A1C, which can vary with age.

"At the time of diagnosis, people who haven't thought about exercise and portion control often do become very successful in both of those areas, so with a combination of medicine, like metformin, and these lifestyle changes, they can often get to target," Seaquist said. "Even though medicine itself won't do it, the lifestyle really is important, especially in the beginning, in really getting that A1C down."

After metformin fails, it may be difficult to choose which oral medication the patient is likely to benefit from. Patients usually are treated on several oral medications before the progression to insulin, said David R. Sutton, MD, an endocrinologist at the Northeast Florida Endocrine & Diabetes Association.

"We see patients 2 to 3 months after the initiation of an agent to reevaluate the effectiveness and for possible side effects and to make sure the patient is progressing in the right direction," Sutton said. "If not, we add other drugs. Patients usually take one drug for several years, and then start two medications, and several years after that we move to three medications or to insulin therapy. That is the typical timeline for diabetics."





A Look at the Patient Community: continued

Patient Profile:
Peter**— age 57 years

Diagnosis: Type 2 Diabetes

Pathway to Health: Primary Care Provider to Endocrinologist to Diabetes Educator



Peter has had diabetes for a few years, but has uncontrolled glucose levels and high cholesterol. After he fails to respond to multiple oral agents prescribed by his PCP, he is referred to an endocrinologist, who prescribes insulin and recommends meeting with an onsite diabetes educator in the practice.

"Once a patient is prescribed an injectable they have to be educated on the risk for hyperglycemia, or high blood sugar," Seaquist said. This common side effect, and the many other responsibilities associated with injectable agents, usually requires the help of a diabetes educator. Patients must decide which blood glucose meter to use and how to use it, when to monitor their blood glucose, what their targets should be and how these relate to their A1C levels. Patients are also given an overview of insulin and how to store it, as well as when and where insulin should be injected.

"Most patients will require insulin therapy if they have the disease long enough," Sutton said. "They can slow that process by losing significant weight. However, eventually if they have diabetes for 15 or 20 years, they probably are all going to require insulin." Initiation of insulin therapy can be an overwhelming and frightening process, and many patients may feel that this progression means they have failed to enact lifestyle changes properly or are at risk for an untimely death.

"We want to remove blame from the discussion, which can negatively impact self-care desire, and channel the conversation into a pro-active 'what you can do now' discussion," diabetes educator Kelli Rodriguez said. "Many people are unaware that insulin therapy is a likely requirement in about 60% of people living with Type 2 Diabetes. We need patients to understand that they did not 'fail' with the introduction of insulin; instead, we are replacing the levels of a deficient hormone, essential for maintaining glucose control and health."





Stepping Stones of Treatment

Although a majority of patients with Type 2 Diabetes will start their treatment with metformin, researchers have many different classes of drugs, which include oral and injectable agents, from which they can choose. These decisions are made on a case-by-case basis based on patient characteristics and side-effect profiles.

With so many choices available, physicians must weigh the toxicity profile of an agent against each patient's current condition and comorbidities.

"Some patients, and many patients with Type 2 Diabetes, are struggling with their weight goals, and so that might make me want to choose a drug whose main side effect is weight-loss, such as the GLP-1 analogs and SGLT2s to a lesser With so many choices available, physicians must weigh the toxicity profile of an agent against each patient's current condition and comorbidities.

degree," Seaquist said. "This requires sitting down with the patient and understanding what they are willing to accept as a side-effect from a drug, what the cost implications are and how they feel about taking a pill vs. an injection."

Physicians and patients also must consider the dosing schedule.

"Two injectable agents in the GLP-1 class are only taken once a week," Sutton said. "For some patients, this would be an advantage, but other patients may prefer a daily routine. The choice of medication is individualized, and it is very difficult to have a blanket algorithm that fits all patients."

Diabetes Issues, Patient Solutions

Access to care

Large clinics comprising the range of diabetes providers are not available to patients everywhere. In some cases, providers have to take extra steps to confer with other providers who are outside of their practice. This may also create insurance, transportation and communication barriers for patients. Use of telemedicine and communication through electronic medical records can help ease these issues.

In southeastern Kentucky, in the heart of the diabetes belt, Tami Ross and her colleagues are launching a test version of "microclinics" to provide platforms for change for patients with diabetes and their personal care network. These groups — composed of two to five patients who live in the same area — will set health care and fitness goals together based on the information they learn from meetings first at hospitals then at community clinics. "Rural communities are often very transient, and taking the message to where the people are is really what we are focused on," says Ross.

Holidays, restaurants and travel

Most people eat around the same 100 foods routinely, and so understanding a patient's habits and perspectives of portions is key to encouraging lifestyle changes, Ross said.

Although the transition to diabetes self-care is a challenge, patients may face particular difficulties when they eat out at restaurants or with family and friends during the holidays. Providers should not wait to prepare patients for these situations, but rather provide them with details on how to cope in various settings on their very first visit to the dietician or diabetes educator.

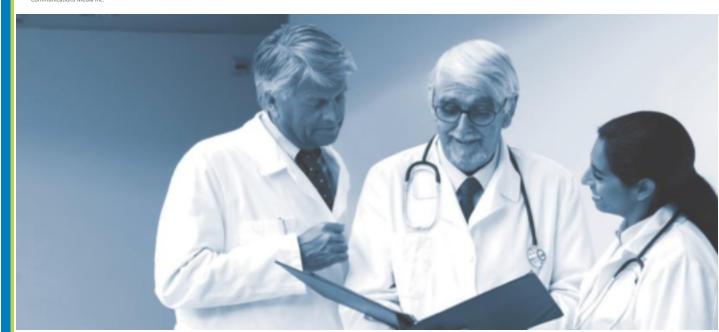
Smartphone apps can also be helpful in this setting, where providers and patients sit down and choose the foods they would normally eat at a given restaurant and evaluate its nutrition. This type of knowledge empowers the patient before they go back to eat in similar settings.

Incorporating fitness

No matter whether a patient is prescribed an oral or an injectable medication, lifestyle interventions will always play a role in their self-care. Smalls goals, help set by the patient according to their current exercise practices, are ways to encourage change, Beggs said.

"If a patient is a sedentary person who has never exercised in their life, I would tell them to try to walk for 15 minutes a day," Beggs said. "If they are already an active person, you can slightly increase their goal based on what they already do and what they feel comfortable doing."

Despite the many pharmaceutical interventions and helpful technologies that exist, only 15% of American diabetics are in control of their glucose, blood pressure and lipids, Rodriguez said. For this reason, ensuring appropriate and achievable self-care should be approached on a personal level.



How Pharmaceutical Partners Can Help Educate the Educators

Dieticians and diabetes educators are constantly looking for new and innovative ways to share information with patients on their diagnosis and ways to implement lifestyle changes.

"High-quality resources become very important services to those who do not have budgets to develop their own educational materials,"

Rodriguez said.

These tools can focus on the AADE 7 Self-Care Behaviors: healthy eating, being active, monitoring, taking medication, problem solving, reducing risks and healthy coping. "High-quality resources become very important services to those who do not have budgets to develop their own educational materials..."

"We are continually looking for educational resources to help our patients in those seven areas of diabetes self-care management," Ross said. "Any opportunity to help provide high-quality educational tools and resources is always appreciated so we can better inform our patients."

Support research.

Supporting association meetings also helps further knowledge about research advances. "There's a tremendous role for pharmaceutical companies to exhibit their new products at meetings so attendees can learn about them," Seaquist said. "Also, making certain that meetings are supported allows us to interact with pharmaceutical reps and help make certain that people get the information they need."



Make lasting connections with PCPs.

Educating PCPs is another way pharmaceutical partners can help endocrinologists.

Diabetes education is underrepresented in primary care residency programs, yet overrepresented

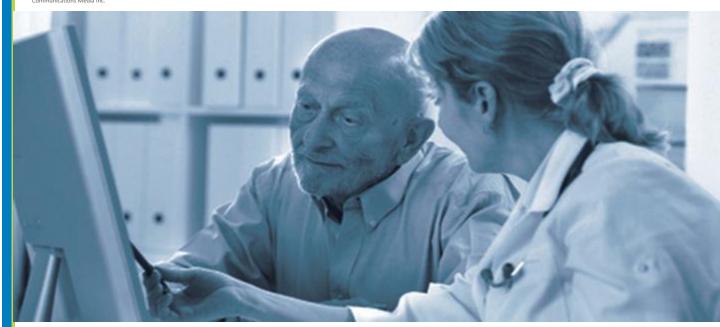
In their day-to-day practice, Sutton said.

"There has been an absolute explosion in diabetes knowledge and treatments, and it is very difficult for a PCP to be completely up to date of the risk, benefits and particular niches where each of the 12 drug classes play a role in Type 2 Diabetes," Sutton said. "Yet, there are not enough endocrinologists to treat these patients, and PCPs are going to have to do the front-line treatment for

"I believe that the pharmaceutical industry can become involved in a grass-roots education process teaching PCPs about the true pathophysiology of Type 2 Diabetes ..."

diabetics. I believe that the pharmaceutical industry can become involved in a grass-roots education process teaching PCPs about the true pathophysiology of Type 2 Diabetes and how each of these 12 classes of drugs fit into diabetes from a pathophysiological standpoint.

"In addition, making physicians aware of pharmaceutical access programs that are available can help patients receive the treatments they need and further improve patient outcomes."



The Impact of Technology

Whether PCP, endocrinologist or diabetes educator, Type 2 Diabetes providers recommend that their patients engage with online and mobile technological resources to better manage their disease. These resources help patients stay focused and motivated, and can include blood glucose trackers, calorie counters and fitness programs. Providers are widely introducing patients to and instructing them how to use these technologies, although they are not a fit for everyone.

"These technologies can be very sophisticated — measuring sugar, vitamin D, carbohydrates, etc. — so it is important to stick with what is simple so patients do not get overwhelmed," Beggs said.

Providers should be particular about the recommendations they make for their patients. "The younger generation is of course more tech savvy, but I am surprised once in a while," Ross said. "Amy, age 72, recently came into her appointment with her iPad. Age is not always a dividing factor for whether a patient is tech savvy; I see it across the spectrum."

Technology can also help providers stay current on all of the newest medications and research. "These programs were not utilized on a regular basis 5 or 7 years ago," Ross said. "It is definitely growing and will only be used more in the future to help improve health care."

Find out more at about valuable technology solutions for diabetes at: *Healio.com/Endocrinology*. Healio.com/Endocrinology is the companion website to *Endocrine Today*, a monthly newspaper that delivers timely and balanced reporting on clinical issues to physicians and health care professionals.

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