

The Changing Landscape of Diabetes Technology: Incorporating Existing and Emerging Tools into the Clinic

TARGET AUDIENCE

- Cardiologists
- Primary care physicians (PCPs)
- Nurse practitioners
- Physician assistants
- Diabetes educators
- Other healthcare professionals caring for patients at risk for CVD

PROBLEM STATEMENT

Technological advances are rapidly changing the landscape of diabetes treatment. Glucose monitors, smart insulin pens and pumps, sensors, applications, and patient management systems can dramatically improve the lives of patients. Some of the newest diabetes technologies reduce the need for injections and finger pricking and allow patients to live more active and confident lifestyles.¹ As a result, more patients are beginning to incorporate diabetes technologies into their treatment plans. For example, in 2002, there were approximately 130,000 type 1 diabetic patients using insulin pumps. However, by 2007, this number had more than doubled.² Today, more than 400,000 people are thought to use insulin pumps in their treatment plans.³ Additional innovations are only expected to further increase the number of patients using diabetes technologies over the next decade.² It is essential that clinicians and their practices be prepared to handle this increasing demand and understand how to incorporate the latest technologies into their practices.

However, the diabetes technology field is rapidly growing and clinicians may not know about some of the latest advances. For example, there are new updates for the only continuous glucose monitoring (CGM) device on the market,⁴⁻⁶ which could help clinicians and their patients understand patterns in blood sugar and make better lifestyle management decisions. Sensors that detect glucose in sweat, tears, or through disposable patches can also make life with diabetes easier and inform patient decisions.¹ Additional sensors, like those that monitor ketones or those that sense diabetic neuropathy, can even help prevent the occurrence of complications commonly associated with diabetes.^{1,7}

Insulin delivery technologies like smart pens and caps,⁸⁻⁹ pumps,^{1,10-12} and new close-loop systems¹³⁻¹⁵ can dramatically improve patient adherence to medication regimens and overall patient health in addition to noninsulin pumps.¹⁶⁻¹⁸ Finally, smart applications¹⁹⁻²⁰ and diabetes management systems²¹ can streamline patient healthcare and make treatment regimens more manageable. Other applications also aim to target more specific populations, like pediatric or older patients.¹⁹ Educating clinicians about both existing and emerging technologies could help improve the effective adoption of technological tools.

Clinicians also may not utilize available diabetes technologies to their full extent. Knowledge of the benefits associated with diabetes technologies and some of the most common hurdles to incorporating these tools in the clinic could help inform patient management decisions. Several recent studies demonstrate that effective incorporation of new technologies can lead to improved overall patient health and satisfaction.²²⁻²⁵ However, full adoption of technologies may be prohibited by high costs²⁶⁻²⁸ and a disconnection between clinicians and their patients.^{17, 29-30}

Finally, clinicians may not be aware of some of the latest guidelines and recommendations associated with diabetes technologies. In fact, there is still no standard of care for technology use,³¹⁻³² forcing patients to draw from scattered guidelines and consensus statements that are often outdated. Education about these collective resources could help inform clinician decisions and improve overall patient care. For example, new recommendations from the Endocrine Society on CGM devices could dramatically improve the care of type 1 diabetic adults while clinicians that treat pediatric patients can consult various guidelines for younger populations.³³⁻³⁵ Education about how to incorporate diabetes technologies into the clinic could improve patient satisfaction, adherence to medication, and overall patient health in both type 1 and type 2 diabetic patients.

STATEMENT OF NEEDS

Clinical Practice Gap #1: The landscape of diabetes technology is rapidly changing and clinicians may not be aware of new advances. In a recent survey of clinicians that referred patients to a diabetes technology clinic, respondents expressed a strong desire for better education about the latest technologies and what patients are best suited for them.³² Another recent study of respected medical centers that regularly treat patients who utilize diabetes technologies found that centers were not regularly staffed with clinicians who were knowledgeable about the latest devices.²

Educational Need #1: Clinicians need to be familiar with available and emerging diabetes technologies. Available diabetes technologies can be divided into different classes depending on their function. Some particularly popular classes of technology include glucose monitors, other types of sensors, devices for insulin therapy, and applications and diabetes management systems.^{1,7} Clinician education about recent innovations in these areas may help increase the adoption of diabetes technologies and improve overall patient care.

Continuous glucose monitoring (CGM) devices are able to measure glucose concentrations to assist both type 1 and 2 diabetes patients.^{23,36} There are four related CGM devices on the market,⁴ and they can communicate with other technologies, including smartphones, tablets, smart wrist-watches, or computers to remotely share data with physicians, spouses, and caretakers.³⁶ Traditionally, CGM devices have been utilized in a more adjunctive manner by providing supplemental information that can enhance patient care and diabetes management. However, the Food and Drug Administration (FDA) recently expanded approval for the only available stand-alone device, for informing treatment decisions without a finger stick blood test.⁵ This expanded FDA approval enabled Medicare to cover a CGM device for type 1 and some type 2 diabetes patients for the first time.⁵⁻⁶ Other existing CGM devices are integrated with insulin pumps.⁴ Clinician education about CGM devices, their benefits, and how some patients can overcome prohibitive costs through health insurance or other incentives could increase the incorporation of this useful diabetes technology in the clinic.

Other available and upcoming sensors monitor glucose levels in even more unique ways, including through human tears with contact lenses, with disposable smart patches, or even through sweat.¹ Conversely, some sensors help identify potential complications associated with diabetes. Sensors that measure ketone levels can help prevent life-threatening complications by warning patients when ketone bodies build up in the bloodstream.⁷ There are even socks in development with embedded sensors that can help prevent diabetic neuropathy which can result in limb amputation.¹

There have also been recent advancements in diabetes technologies that facilitate insulin delivery, including smart insulin pens, pumps, and artificial pancreases. Both the American Diabetes

Association and the European Association for the Study of Diabetes emphasize the benefits of insulin use in combination with oral medications like metformin and sulfonylureas.³⁷ However, both patients and clinicians have a tendency to resist insulin therapy, due in part to misconceptions.³⁷⁻³⁸ Clinicians tend to believe that therapy is ineffective, inconvenient, can have a wealth of negative side effects, and will result in patient dissatisfaction.³⁷⁻³⁸ However, technology has advanced significantly and there are now many more convenient insulin delivery systems than the traditional vial and syringe. Some of these systems can help negate the problems associated with insulin therapy.³⁷⁻³⁸ Clinician education about these technological innovations could improve the rate of insulin therapy and adherence to therapeutic regimens.³⁷⁻³⁹

Insulin smart pens are one such convenient delivery method. Insulin pens are already more common than vial and syringe in many countries,³⁷⁻³⁸ but their use in the United States remains less widespread despite being available for some time.³⁷ Smart insulin pens add even more convenience to regular insulin pens. Many can connect to other devices to transmit data to smartphones, tablets, and computers to offer a range of analytical tools.⁷ Some track time since the last insulin injection to help avoid accidental double doses or missed treatments. Smart pens can be stand-alone and use insulin cartridges.^{8,40-41} Others are pen caps which fit over the injection needle of most standard insulin pens.^{9,42} Recent studies suggest that how clinicians present and recommend insulin pens plays a major role in whether or not patients use insulin pens and how well they adhere to treatment,³⁷⁻³⁸ highlighting the importance of clinician education about insulin pens and by extension smart insulin pen technologies.

Another popular class of diabetes technology associated with insulin delivery is insulin pumps. Many patients find insulin pumps easier and more discreet and convenient than insulin pens or syringe and vial insulin delivery.³ The pumps offer a more flexible treatment option and also have the added benefit of delivering insulin at a more controlled rate than insulin pens, which may help patients experience less drastic changes in their blood sugar.^{3,7} Recent studies also suggest that insulin pump therapy can be more effective than multiple daily injections in type 1 and 2 diabetes patients continuing to struggle to control their blood sugar.^{3,43} Indeed, an open-label randomized study found that over 70% of type 1 diabetes participants preferred insulin pumps over daily injections.^{3,44} However, other studies stress that clinicians should carefully weigh the benefits of pumps against the sometimes prohibitive costs when presenting treatment options to patients.^{26,33,45-46} Improved clinician education about insulin pumps, their benefits, and what patient populations are best suited for the devices could help improve management of diabetes patients.

New advances in insulin pump technology allow some devices to link to glucose sensors that provide patients with an increased awareness of fluctuating blood sugar patterns.^{7,47} Pumps augmented with sensors can communicate with tablets, smartphones, and computers to provide detailed information about glucose levels to patients, their caregivers, and even clinicians.⁴⁷ Some pumps are also equipped with additional features, like threshold sensors that can suspend the dispensing of insulin at a preset level to reduce the risk of hypoglycemia.¹¹⁻¹² Another prospective pump integrates with CGM technology to allow patients to continually monitor their blood sugar and share their information with clinicians and caretakers. The combined system recently received FDA approval for the treatment of patients for age two and older and is the only integrated system approved for some of the youngest diabetes patients.¹⁰ Conversely, other pumps are available that are water resistant and have less invasive or even no tubing, which may be especially worthwhile for patients with active lifestyles.^{1,12} Additional features incorporated into pumps include wireless Bluetooth capabilities, separate remotes, dosage calculators, and custom alarms.¹²

Perhaps the most recent innovation trend in insulin delivery diabetes technologies is the nearly closed-loop system.^{13,48} The time of day, composition of meals, physical activity, and even menstrual cycles can have a significant impact a patient's insulin requirement.^{13,48} The "artificial pancreas" helps compensate for this frequent, natural variability in insulin levels. The FDA recently approved a hybrid closed-loop system. The system combines CGM and pump technologies to provide tailored and automatic insulin delivery for type 1 diabetes patients and also allows for manual bolus insulin delivery after meals.^{13,15} Another system is currently in trials for delivery of both insulin alone as well as in combination with glucagon.¹³⁻¹⁴ Although the dual-hormone system may more closely imitate a healthy pancreas, the addition of glucagon complicates the delivery system by requiring a second pump and previous glucagon formulations have been unstable.¹³⁻¹⁴ However, a new partnership could allow the use of a more stable liquid glucagon analog that could improve the dual-delivery system.¹⁴

There have also been recent advances in noninsulin pump devices. One prospective pump provides a continuous subcutaneous delivery of the drug exenatide in type 2 diabetes patients and is currently awaiting FDA approval. The device is inserted under the skin in a short outpatient procedure and would be replaced once or twice a year. Treatment with the device would be more convenient and discreet than the current globally marketed twice-daily and once-weekly exenatide self-injection therapies for type 2 diabetes and could vastly improve treatment adherence of patients.¹⁶⁻¹⁸ Clinician education for both current and future closed-loop systems and noninsulin pump devices is particularly important because these types of devices are very new and have not been extensively evaluated in real-world settings.¹⁷ Clinicians need to understand how the devices work and the importance of patient training and compliance with the recommendations for each device.¹⁷

Additional technology advancements include the use of smart technology applications to manage diabetes care. Applications can educate patients about their condition, help them live healthier lifestyles and adhere to their treatment regimens, and communicate with healthcare professionals to assist with clinical decision making.¹⁹ The multitude of options can be overwhelming for both clinicians and patients. Careful education about the changing options could help ensure applications are effectively incorporated into clinical practices.

Many of the aforementioned technologies come equipped with tailored applications that can be downloaded on multiple devices, like smartphones, tablets, and computers. In addition to these technologies, some more general applications already exist or are in development. For example, one application aggregates information from multiple devices, like glucose monitors and fitness trackers, to provide an overview of patient health and progress that can be shared with clinicians.¹⁹ Meanwhile, a prospective line of future phone applications could help patients with type 2 diabetes using basal insulin better manage their condition and communicate with clinicians. Pilot programs for the phone applications have already received FDA approval.²⁰ There are also applications and management systems specific to pediatric patients and other patient populations.¹⁹

In addition to phone applications, there are also more comprehensive patient management systems. For example, one management program offers monthly subscriptions to patients without a prescription. The system includes a blood glucose monitor and delivers test strips straight to the patient's home. The included application can help the patient analyze their glucose levels, select healthy foods, and share their data with clinicians.²¹ Conversely, another management system offers a prescription only option for type 2 diabetes patents that use basal insulin. Clinicians enter a treatment plan on the device tailored to the patient, and the device then provides personalized recommendations, educational material, and coaching messages related to measured glucose

levels. All data can be remotely shared with clinicians to improve overall patient health and management.²¹

In addition to the aforementioned devices, applications, and management systems, a number of interdisciplinary partnerships between pharmaceutical companies, technology companies, startup organizations, and other groups could dramatically change the landscape of diabetes technologies in the coming years. Partnerships promise to release miniature CGM devices,^{1,49} disposable and affordable glucose monitors the size of a Band Aid^{1,49} and technologies specific to the management of type 2 diabetes patients.⁵⁰ Many of these partnerships and their upcoming devices may help to negate the prohibitive costs often attributed to the poor adoption of many diabetes technologies. Improved clinician education about these upcoming technologies could help keep clinicians keep abreast of the rapidly changing technology landscape.

Clinical Practice Gap #2: Clinicians may under-utilize available technologies. Accumulating evidence suggests that clinicians may avoid the use of technology because of fear²⁹ or even simply because of a stable pre-disposition against early adoption of innovations.^{37,51} This tendency to resist adopting new innovations is especially prominent in smaller practices, possibly due in part to a lack of community support and education.⁵² Clinician awareness of the many benefits of diabetes technologies along with the common barriers associated with their adoption could improve effective incorporation of technology into the clinic.

Educational Need #2: Clinicians need to be aware of the many benefits associated with diabetes technologies and how these advancements can increase the effectiveness of their practices. Practices that regularly incorporate new technologies frequently report improved overall patient health and satisfaction. For example, a practice in the United Kingdom that regularly treats pediatric diabetic patients recently reported great success in combining a few simple diabetes management technologies. Within two years, the practice observed a statistically significant increase in patients achieving glycated hemoglobin (HbA_{1c}) levels below 7.5%. They also observed fewer hospital admissions and reduced length of stays.²² Furthermore, over 80% of both patients and caregivers in the same study said that they benefited from the technology and that it enhanced their management decisions.²² Patients and caregivers also said the technology made it easier to see trends and made them less likely to provide false data to clinicians. Finally, both patients and caregivers found that the use of the management systems made appointments more informative and less judgmental.²²

Another recent study that reviewed over 30 clinical trials determined that clinician use of diabetes technology was associated with a significant improvement in patient HbA_{1c} levels.⁵³ This finding was further supported by a recent clinical trial that suggested CGM devices may significantly reduce patient HbA_{1c} levels without the typical increase in risk of hypoglycemic events.²³⁻²⁴ Another clinical trial that randomly assigned diabetic patients to receive either their usual care or one with a technology support system also supported this finding. The trial found that patients on the support system experienced an improvement in care and better clinical markers, including blood pressure and HbA_{1c} levels.²⁵

One possible reason for the success of diabetes technologies in the clinic could be that diabetes care is particularly well suited to technological innovations. Diabetes management is easily quantified and technology can allow members of a patient's interdisciplinary team to quickly communicate and share information. It could even be a starting point to study the incorporation of technologies in the care of other chronic diseases⁵⁴

Educational Need #3: Clinicians need to be familiar with common barriers to successful technology adoption. A number of barriers exist to the incorporation of technology into clinical practice, including prohibitive costs and a disconnection between the desires and goals of clinicians and their patients.

Healthcare cost is one of the biggest hurdles to the adoption of diabetes technologies.²⁶⁻²⁸ One recent study found that patients diagnosed with type 2 diabetes at age 40 have a discounted average of over \$120,000 in related medical expenses over their lifetime.²⁷ The calculations in the study did not fully take into account the growing popularity of some diabetes technologies and their higher costs. These significant medical expenses are further complicated by the fact that many diabetes patients already have a tendency to have lower incomes.²⁷

Some of the most recent technologies are not covered by insurance plans. For example, CGM devices have been around for a while, but Medicare did not cover the only stand-alone device until very recently because it was not FDA approved for non-adjunctive use. The approval of the device for a non-adjunctive use now allows patients under Medicare to receive coverage for a CGM device for the first time.⁵⁻⁶ A general awareness about the possible prohibitive costs for some technologies along with the possibility for coverage and other financial incentives could help clinicians improve effective incorporation of diabetes technology into their practices.

Another barrier to technology incorporation is a disconnection between the desires and goals of clinicians and their patients. A recent large survey of health care providers and consumers highlighted differing viewpoints between clinicians and their patients about technology use in healthcare settings. Clinicians overestimated patient anxiety about some technological tools by almost 50%.²⁹ The findings emphasize that patients may be more comfortable with new devices and tools than clinicians believe.

The disconnection between clinicians and their patients was also highlighted in a separate multi-center survey in Japan. In the study, clinicians underestimated patient concerns and embarrassment about injecting insulin in front of others or their desire to hide their diagnosis. Clinicians were more concerned about the clinical benefits of treatments and the medical outcomes as opposed to psychological benefits and tended to believe their patients felt the same way.³⁰ The study highlighted the importance of clinician education about the social and interpersonal fears patients have regarding insulin use. Advances in diabetes technology like smart pens, pumps, and closed-loop systems could be a good fit for patients with social anxiety and discomfort with syringe and vial insulin therapy. The use of diabetes technologies could help improve treatment adherence and overall health in these patient populations.^{17,30} This is especially important given that fewer than half of diabetes patients are currently at their treatment goals.¹⁷ In addition to a disconnection between clinicians and their patients, health literacy of patients and a lack of engagement with healthcare providers may also contribute to the poor rates of patient adherence to medication regimens.¹⁷

Clinical Practice Gap #3: Clinicians may not be aware of the latest guidelines, recommendations, and consensus statements concerning diabetes technologies. The landscape for diabetes technology is rapidly changing with the continual development of new devices, tools, and applications. Clinicians may have trouble navigating this rapidly changing field because there is still no standard for the care of patients that use diabetes technologies.³¹⁻³² This is further complicated by the fact that efforts to identify best practices for managing patients that use diabetes technologies have largely failed.^{2,32} Education about existing guidelines and recommendations along with how clinicians can incorporate newest technologies into their practice may help improve management of type 1 and type 2 diabetes patients.

Educational Need #4: Clinicians need to be up-to-date with the latest guidelines and recommendations for the use of diabetes technologies. There is no definitive and comprehensive guidelines on the use of diabetes technologies for type 1 and type 2 diabetes patients.³¹⁻³² Instead, clinicians must draw on scattered resources to make the best management decisions for their patients. Education about these guidelines and recommendations may help inform clinical decisions and improve overall patient care.

For example, the Endocrine Society recently released clinical guidelines for the use of CGM devices in adults.⁵⁵⁻⁵⁶ The guidelines recommend CGM devices as the gold standard for type 1 diabetic adults. They also highlight that the devices can be used with type 2 diabetes patients struggling to maintain blood glucose levels on an intermittent and short-term basis.⁵⁵⁻⁵⁶ Also among the recommendations, the guidelines suggest that all clinicians be educated and trained on the use of CGM devices.⁵⁵⁻⁵⁶ However, a recent survey of clinics that regularly serve patients that use diabetes technologies found that centers were frequently staffed with clinicians not familiar with the latest devices.²

Similar consensus statements have also been released for the use of other devices. For example, the American Association of Clinical Endocrinologists and the American College of Endocrinology released a joint statement on the use of insulin pump therapies.^{2,31} One study consulted a panel of experts and used the Delphi consensus process to determine the best practices for the safe use of insulin pens, which carry a number of health risks not associated with other devices.⁵⁷ In addition, there are also consensus statements specific to certain patient populations, including pediatric patients.³³⁻³⁵

As the use of smart technology and applications increase, many practices are also relying more on social media for patient management. Physicians need to stay aware of the latest guidelines for the use of social media to ensure that the technology is used effectively without crossing boundaries.¹⁹ Many organizations have clear guidelines on social media use, including the American Medical Association and the Mayo Clinic.¹⁹ Education about these and other guidelines and recommendations may help clinicians make informed management decisions and improve overall care for type 1 and type 2 diabetes patients.

LEARNING OBJECTIVES

Upon completion of this activity, learners will:

- Recognize new and emerging trends in diabetes technologies, what patients are best suited for these technologies, and how these technologies can be incorporated into the clinic.
- Describe how diabetes technologies can benefit patient management and overall health.
- Recognize the largest barriers to widespread adoption of diabetes technology.
- Describe the latest published guidelines and recommendations for diabetes technology
- Implement new advances in diabetes technologies into their clinical practice.

Clinical/Practice Gap	Educational Need	Learning Objective That Will Address the Gap and Need	Result(s) that will be measured	Type of Gap That Will Be Met	ACGME Competencies That Will Be Met
Clinicians may struggle to keep up with the rapidly growing field of diabetes technology.	Clinicians need to be aware of available diabetes technologies along with technologies currently in development.	Recognize new and emerging trends in diabetes technologies. Recognize what patients are best-suited to diabetes technologies. Recognize how technologies can be incorporated into the clinic.	1) Ability to meet learning objectives as measured by post-activity evaluation 2) Intention to make practice changes as indicated on post-activity evaluation	Competence	Medical Knowledge
Clinicians do not use diabetes technologies to their full potential.	Clinicians need to be aware of the clinical and patient management benefits associated with diabetes technologies. Clinicians need to be aware of hurdles associated with the adoption of diabetes technologies.	Describe how diabetes technologies can help overall patient health and management. Describe the biggest hurdles to widespread incorporation of diabetes technologies.	1) Ability to meet learning objectives as measured by post-activity evaluation 2) Intention to make practice changes as indicated on post-activity evaluation	Competence	Medical Knowledge
Clinicians may not be aware of the most recent guidelines, recommendations, and consensus statements associated with diabetes technologies.	Clinicians need to be up-to-date with the latest guidelines for the utilization of diabetes technologies	Describe the newest guidelines and recommendations associated with diabetes technologies. Implement new advances in diabetes technologies in the clinic	1) Ability to meet learning objectives as measured by post activity evaluation 2) Changes in level of knowledge as measured by pre and post-assessment knowledge based questions	Competence	Medical Knowledge Problem based learning and improvement

AGENDA

- 5 minutes **Activity overview**
Pre-activity assessment
- 10 minutes **Introduction**
--The increasing popularity of diabetes technologies
--Benefits of diabetes technologies
- 20 minutes **Overview of Diabetes Technologies**
--Sensors and monitors
--Insulin delivery devices
--Applications and patient management systems
--Interdisciplinary collaborations for new advancements
- 10 minutes **The Hurdles for Technology Adoption**
--Prohibitive costs
--Disconnection between clinicians and patients
--Patient education
- 10 minutes **Incorporation of Technologies into the Clinic**
--Review of the latest guidelines
--Examples of practices that have successfully adopted technology
- 5 minutes **Activity summary**
Post-activity assessment

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