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Diabetes Device Interoperability for Improved Diabetes Management

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Abstract

Scientific and technological advancements have led to the increasing availability and use of sophisticated devices for diabetes management, with corresponding improvements in public health. These devices are often capable of sharing data with a few other specific devices but are generally not broadly interoperable; they cannot work together with a wide variety of other devices. As a result of limited interoperability, benefits of modern diabetes devices and potential for development of innovative new diabetes technologies are not being fully realized. Here we discuss diabetes device interoperability in general, then focus on 4 examples that show how diabetes management could benefit from enhanced interoperability: remote monitoring and data sharing, integrating data from multiple devices to better inform diabetes management strategies, device consolidation, and artificial pancreas development.

Keywords

artificial pancreas, continuous glucose monitor, diabetes, insulin pump, interoperability

Diabetes is a serious disease that affects almost 30 million Americans and is a major threat to public health.[1] Diabetes management is dependent in large part on the use of medical devices to monitor blood glucose levels and dose insulin; and continuous advancements in diabetes technology have made sophisticated glucose monitoring and insulin delivery devices increasingly available to Americans with diabetes. These innovative new devices—including advanced glucose meters, continuous glucose monitoring systems (CGMs) and insulin pumps—generate large amounts of data that can be used in ways that provide significant positive health benefits for patients.[2,3] In some cases, these devices are capable of transferring data to a few other specific devices, such as software systems for data analysis or display. However, most current diabetes devices are not broadly interoperable. Device interoperability refers to the ability of devices to communicate and exchange information and also to correctly interpret and use information that has been exchanged. In our definition of devices, we include physical components like insulin pumps and also software systems such as electronic health record systems, remote monitoring systems, and other visualization and analytic platforms. When we say that these diabetes devices are not "broadly" interoperable, we mean that they cannot work together (ie, share data in an understandable and useful way) with a wide variety of other devices. This lack of interoperability exists because proprietary protocols with undisclosed data interface specifications are used for data transmission, extraction, and viewing, and means that many modern diabetes devices interact in only a limited way with a few specific devices, if at all. Consequently, their potential utility and benefit to individual patients and the public health are not being fully realized. Lack of interoperability also likely limits the growth of the diabetes device marketplace, prevents expansion of device functionality, and slows innovation. The development of interoperability standards for diabetes devices (eg, within the IEEE 11073 health informatics family of standards)[4,5] has been a critical first step toward harnessing the benefits of enhanced interoperability for improved diabetes management. While these standards do not address safety or cybersecurity, widespread adoption of these standards, combined with the implementation of appropriate safety and cybersecurity measures, will allow patients and providers to maximize the value of existing technologies and contribute to the creation of innovative new diabetes devices. Here, we briefly discuss 4 examples of diabetes management where enhanced interoperability could provide significant benefits: remote monitoring and data sharing, integrating data from multiple devices to better inform diabetes management strategies, device consolidation, and artificial pancreas development.

Improving interoperability could allow more accessible and convenient remote/secondary monitoring of diabetes device data by ensuring robust and reliable data sharing. The potential impact of improved data sharing is significant

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because effective diabetes management depends in large part on blood glucose data produced by glucose meters and CGMs. Care for many people with diabetes comprises a broad support network of caregivers including friends, family members and health care providers. However, many caregivers are limited in their ability to assist in diabetes management because of limited access to blood glucose data. Enhanced interoperability will allow for more comprehensive and robust transmission of data between medical devices, or from medical devices to consumer electronics (eg, smartphones, smartwatches), and make these devices more readily available. For example, this will give parents of children with diabetes greater access to smartwatches that allow reliable overnight monitoring of their child's blood glucose levels. By providing a greater diversity of reliable data sharing options, interoperability will improve diabetes management by giving caregivers better access to device data and providing a stronger safety net for patients.

Enhanced interoperability also has an incredible potential to integrate the wealth of data produced by multiple devices and allow for the design of more informed diabetes management strategies. Currently, many people with diabetes use insulin pumps and CGMs, which produce large amounts of data that can be analyzed for insulin delivery and glycemic control patterns. Analysis of data from each of these devices independently can be extremely useful, but independent analysis does not exploit the relationship between insulin delivery and glycemic control. Integrated analysis has the capacity to provide a more holistic overview of an individual's diabetes management strategy. However, proprietary communication protocols mean that there are currently few options for integrating and analyzing data from insulin pumps, continuous glucose monitors, and blood glucose meters. Furthermore, the ability of third-party developers to create new data integration options is limited. Interoperability creates opportunities for patients and providers to access diabetes data from multiple devices in more open and user-friendly formats. By promoting the integrated analysis of insulin delivery and glycemic control data, interoperability allows data from existing technologies to better inform diabetes management decision making.

Not only is the integration of data from multiple devices a potential benefit of improved diabetes device interoperability, but so is the consolidation of diabetes devices themselves. In contemporary diabetes management strategies, glucose meters are often used with additional electronic diabetes devices (an insulin pump, CGM) to provide significant health benefits.[2,3] However, in some cases, the burden of managing multiple devices may contribute to patients choosing not to adopt new technologies.[6,7] For example, patients might choose to use an insulin pump or a CGM rather than both of these technologies. Increasing the availability and diversity of consolidated devices that perform multiple functions—for example, insulin pumps that also display CGM information—may encourage patients to take advantage of a broader array of beneficial technologies. Currently, proprietary communication protocols mean that there are only a limited number of available consolidated devices. Using standard open device communication protocols could lower the barrier to developing consolidated devices that perform multiple functions. This should give patients better access to consolidated devices that are best suited for them—for example, data from their preferred CGM displayed on their preferred insulin pump. The availability of multifunctional consolidated devices, enabled by interoperability, could expand the market for advanced diabetes devices, exposing more patients to advanced technologies that can improve diabetes management.

Finally, a wearable artificial pancreas (AP) is the ultimate goal of many ongoing diabetes technology development efforts. AP systems automate diabetes decision making and have the potential to significantly lower the burden of diabetes management. Currently, an AP must integrate data from a glucose meter, insulin pump and CGM with an insulin dosing algorithm. A major challenge in AP development is in bringing pump, CGM and algorithm components together into a coherent functional system. Traditionally, AP development models have been based on a single company using proprietary protocols to develop, integrate and market all the components of an AP device. While this proprietary model has produced important advances toward the development of a fully automated closed-loop AP system, enhanced diabetes device interoperability could further speed the pace of development by enabling an alternate development pathway. In this alternate pathway, different companies and third-party algorithm developers could produce interoperable components (CGM, pump, meter, algorithm, and algorithm controller) that would be integrated into a complete and functional AP system. This interoperability could result in systems which better cater to individual patient needs. For example, the creation of systems in which an algorithm housed on a smartphone or watch could be configured to interact with a selection of specific CGMs or insulin pumps. Interoperability-driven increases in the availability and diversity of AP systems could significantly improve the public health by easing the burden of diabetes management.

While there are benefits to interoperability-based AP development there are also technical and regulatory challenges. The technical challenges preventing reliable integration of distinct components into a safe and effective AP system could be significantly eased through the use of interoperability controls or standards. There would also be challenges associated with regulatory compliance of an AP device developed through the alternate pathway—including ensuring adequate postmarket surveillance and meeting adverse event reporting requirements, resolving device malfunctions appropriately and initiating necessary recalls, and maintaining compatibility of modifications, upgrades, or new versions of individual device components with the continued safety and effectiveness of the system as a whole. Interoperability standards could lay the foundation for technological solutions to these regulatory

challenges, but it will also be important to identify a responsible party or parties for devices developed in this way.

FDA believes that all stakeholders, including regulators, manufacturers, patients, and caregivers, have a role to play and will benefit from enhancing diabetes device interoperability. Achieving anticipated future benefits of broader interoperability requires all stakeholders to accept responsibility. FDA strongly supports medical device interoperability in general as a fundamental step toward providing enhanced patient care and improving the public health. The benefits of device interoperability depend on the adoption of open, standard communication protocols; and this depends in part on continued support for the development, recognition, and implementation of interoperability standards. To that end, FDA has recently recognized several diabetes device-specific interoperability standards (eg, IEEE 11073-10417, Glucose Meters,[4,5,8] and IEEE 11073-10425, Continuous Glucose Monitors)[4,5,8] and plans to review additional standards as they are finalized. Recognition of standards by FDA allows manufacturers who adopt these standards to certify conformance in premarket submissions, leading to more efficient and effective regulatory review and providing an incentive to focus on interoperability. Additional motivation for manufacturers to pursue interoperability can come from patients and health care providers, who continue to express their demands for interoperable devices. Moving beyond diabetes device-specific interoperability standards, manufacturers can also consider other existing communication protocols and specifications (eg, IP, Bluetooth, etc) during the development of diabetes devices. Increased communication between diabetes devices will require continued communication between all stakeholders as an important next step; and cooperation to create an environment of interoperable diabetes devices will benefit manufacturers and patients alike. Patients and health care providers will be able to make better use of existing data to inform disease management and access the products of innovation that can exist only in an interoperable device environment. Manufacturers will experience greater demand for existing technologies where interoperability-driven development broadens device functionality and appeal. Ultimately, realizing the use of fully interoperable diabetes devices will generate significant short and long-term benefits to patients, caregivers, and device manufacturers.

Abbreviations

AP, artificial pancreas; CGM, continuous glucose monitoring system; FDA, US Food and Drug Administration; IEEE, Institute of Electrical and Electronics Engineers.

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