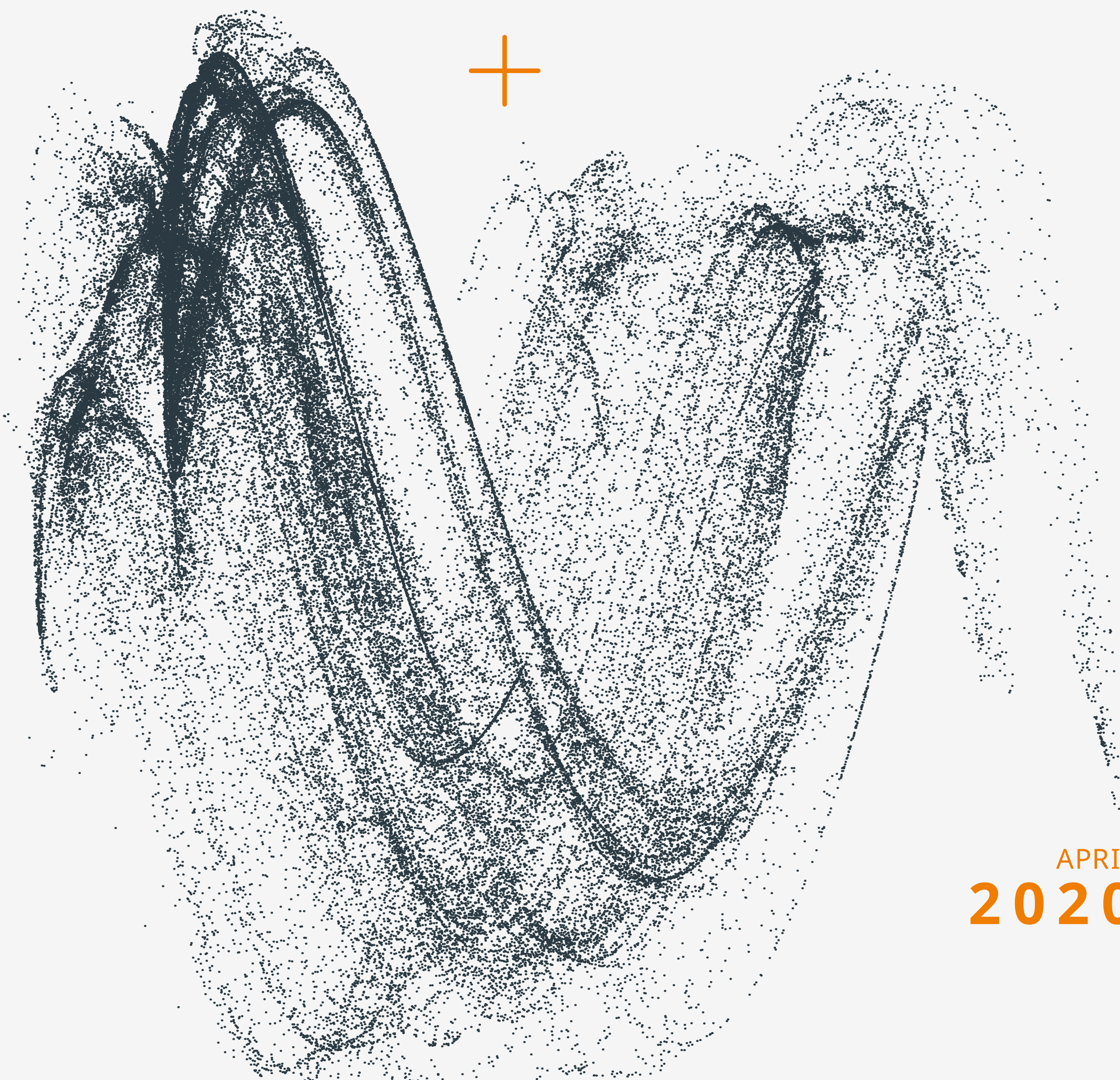
IQVIA INSTITUTE
FOR HUMAN DATA SCIENCE

Innovation in Diabetes Care Technology

KEY ISSUES IMPACTING ACCESS AND OPTIMAL USE



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Introduction

Since the 1920s, diabetes care has improved significantly, resulting in enhancements in diabetes management and outcomes. However, assessments of blood glucose control through metrics like HbA1c and Time-in-Range (TIR) indicate that many people with diabetes, and their care teams, still struggle to meet treatment targets. This suggests a need for further advances in diabetes care at a population level. Recent developments in digital medicine products offer the potential to overcome challenges in the current care paradigm and provide greater value for people with diabetes, the health system, payers, and healthcare professionals (HCPs) that collaborate in care management.

This report introduces recent advances across three main categories of diabetes digital healthcare technologies — connected devices, digital applications (which include mobile applications and software programs), and algorithms. It further examines the potential benefits and challenges offered by these recent innovations to people with diabetes and other stakeholders from a clinical, psychosocial, and economic perspective. Finally, this report explores key limitations that are likely to impact people with diabetes' access to and optimal use of these recent innovations in diabetes care.

This is the first in a series of short reports that will be published over the course of 2020 to examine these key issues in more detail, look at how they are evolving, and explore possible approaches to overcome challenges associated with these issues.

This study was produced by the IQVIA Institute for Human Data Science based on research and analysis undertaken by the IQVIA Real World & Analytics Solutions group with support and funding from Eli Lilly and Company.

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MURRAY AITKEN
Executive Director
IQVIA Institute for Human Data Science

Overview

Diabetes care and blood glucose management have advanced significantly over the last century, aided by developments in insulins, insulin delivery, glucose monitoring, and insulin dosing algorithms, along with recent movements towards more patient-centric models of care delivery and refined standards of care. However, significant gaps in blood glucose management and diabetes care still remain. For example, current HbA1c levels in the U.S. average around 8.4% for people with Type 1 Diabetes (T1D) where the consensus target is 7%, and conservative estimates of mean Time in Range (TIR) for people with T1D are between 42% and 58% where the consensus target is >70%. Such gaps in glucose management can have serious consequences. Poor glucose management is related to a host of microvascular and macrovascular complications that have substantial impacts for people with diabetes, HCPs, and the healthcare system alike.

The complexity of diabetes care has been widely recognized as a driver of current care gaps. In response, new diabetes digital tools and care technologies are being developed to address the complexity of care in a more holistic way. There has been substantial growth in companies offering new, digital approaches to the management of diabetes with a patient-centric view, which may suggest that we are entering a new era of care; one in which more seamless and remote chronic disease management is possible. Advances in diabetes digital medicine products (via connected devices, digital applications, and algorithms) offer the potential to provide more precise information and simplify diabetes management, leading to better outcomes.

Unlocking the value of these new approaches hinges on optimally understanding and harnessing new digital medicine products to advance healthcare delivery and healthcare policy. Therefore, there is substantial and growing interest in understanding and measuring the value of digital medicine products from a clinical, psychosocial, and economic perspective. While the majority of research is still at an early stage, initial findings suggest that digital medicine products offer value across all three of these dimensions.

From a clinical perspective, studies report that optimal use of connected devices may result in improved HbA1c and increases in TIR. For example, multiple studies looking into pump systems and hybrid closed-loop systems have reported an improvement in glycemic control. Additionally, studies on the use of digital applications have reported reductions in HbA1c amongst users.

From a psychosocial perspective, early research suggests the use of connected devices, including insulin pumps and CGM sensors, can result in reduced anxiety, improved sleep, improved confidence, and an increased sense of relief or “time-off” from diabetes demands. However, some studies also indicate an additional physical and mental burden due to the use of these devices. More research is needed to robustly understand the benefits and challenges associated with the uptake of digital medicine products to ensure that they are designed in a way that results in more seamless care.

From an economic perspective, studies report that the use of connected devices like continuous glucose monitors (CGMs) can significantly reduce overall medical costs, including inpatient and outpatient costs, while the use of digital coaching systems can also result in cost savings for both people with diabetes and payers.

There are several issues across the healthcare ecosystem that impact access to and optimal use of these digital medicine products. These include issues related to reimbursement, the adoption of new technologies, data privacy and security, and most importantly, the experience of people with diabetes using these digital medicine products.

Advances in Diabetes Care

+ **Diabetes care and glucose management have gone through multiple eras of advancement over time. Developments in insulins, insulin delivery, glucose monitoring, and insulin dosing algorithms along with more patient-centric models of care delivery and refined standards of care have contributed to improvements in diabetes management.**

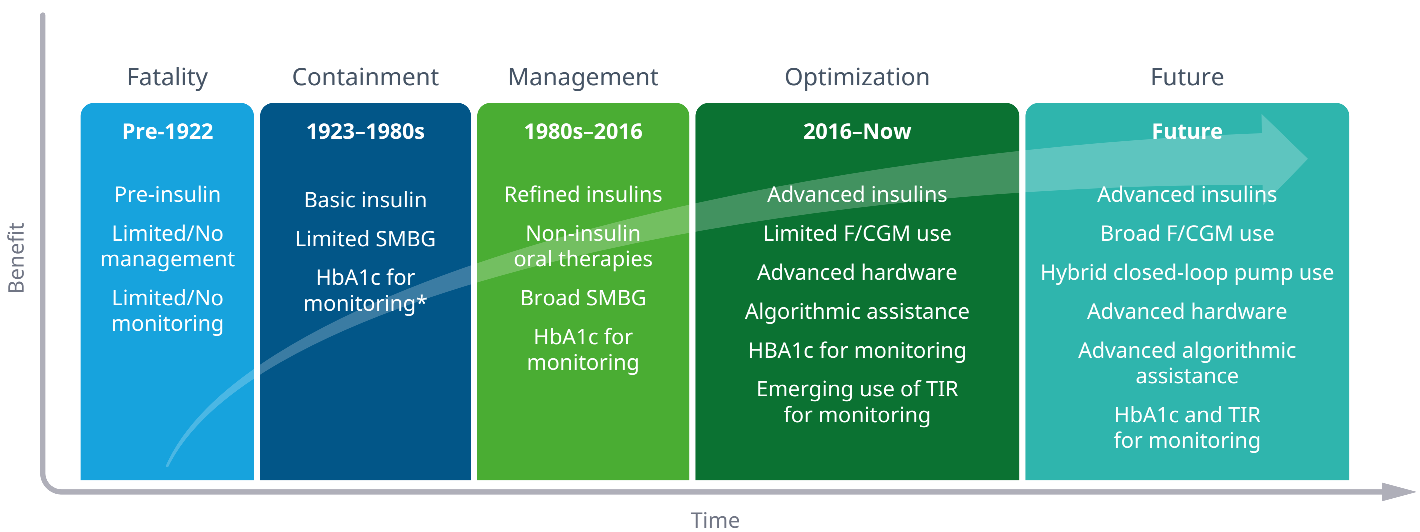
+ **The complexity of diabetes care is widely acknowledged and is recognized as a driver of gaps in optimal blood glucose attainment.**

+ **Innovations in diabetes care are being brought forth to address this complexity in a more holistic way, to ease the care burden for people with diabetes and help them achieve improved care outcomes more easily and consistently.**

+ **There has been a substantial growth in companies offering new digital medicine products aimed at providing more precise information on various blood glucose related metrics to people with diabetes and their caregivers to simplify diabetes management, suggesting that we are entering a new era of care that offers potential to improve patient outcomes.**

Over the last century, diabetes care with insulin has advanced through multiple eras, leading to substantial improvements in glucose management (see Exhibit 1). Most recently, developments in insulins, insulin delivery, glucose monitoring, and insulin dosing algorithms have further enhanced diabetes management.[1,2,3,4,5] These developments, combined with refined standards of care, more patient-centric models of care delivery, and the vast expansion of companies offering new, digital tools and platforms to manage diabetes (such as connected continuous glucose monitors, hybrid closed loops, and diabetes digital care providers) indicate a new era of care 'optimization' that can propel care towards a future state by offering further refinement of care and care outcomes.

Exhibit 1: Eras of Diabetes Care[6]



Source: IQVIA Institute for Human Data Science. Advancing Glycemic Management in People with Diabetes; New Approaches and Measures. Oct 2019

Notes: SMBG = Self-monitoring of blood glucose; F/CGM = Flash/continuous glucose monitoring; TIR = Time in Range; PPG = Postprandial glucose
*HbA1c measurements were available for monitoring in the latter part of this era. Fatality refers primarily to people with Type 1 diabetes. Advanced hardware includes various technologies such as smart insulin pens and hybrid closed loop pumps, which are an automatic insulin delivery system that regulates basal rate insulin levels and typically integrate a CGM data sensor, transmitter and insulin delivery system.

The era of optimization is witnessing the rise of important measures beyond traditional ones like glycated hemoglobin A1c (HbA1c), such as time-in-range (TIR), which can help in expanding the understanding of diabetes management. HbA1c is an important long-term and indirect measure of blood glucose management and is used by clinicians to determine the success of glucose management, as well as to understand the risk of developing diabetes-related complications.[6] TIR is defined as the amount of time spent within a clinically acceptable glucose range.[7,8]

Today, at the population level, outcomes measured by HbA1c and, increasingly, TIR indicate that significant care gaps exist and there is a need for improvement in blood glucose management. Current HbA1c levels in the U.S. average around 8.4% for people with Type 1 Diabetes (T1D) although the consensus target is 7%, while conservative estimates of mean TIR range are between 42% and 58% for people with T1D, though the consensus target is >70%.[10,11] This comparison to consensus targets indicates that there is still a long way to go before glycemic targets are more broadly and consistently achieved. Multiple studies have shown that only a small percentage of insulin-using people with diabetes achieve the American Diabetes Association (ADA) standards for HbA1c levels.[12] Recent data from T1D Exchange registries in the U.S. show that only 21% of adults with T1D achieve the ADA HbA1c goal of less than 7%. Additionally, only 17% of adolescents (<18 years old) achieve an HbA1c of less than 7.5%.[11,13,14] Not meeting these targets can result in severe consequences, as higher HbA1c levels have been directly linked to an increased risk of developing diabetes-related microvascular and macrovascular complications.[6,15]

The complexity of insulin-managed diabetes care has been widely recognized. The challenge for individuals to consistently achieve optimal glucose management is linked to a host of factors, including multiple rounds of decision-making on insulin dosing that requires a high-level of disease awareness, as well as a constant need to assess current blood glucose level, food type and quantity consumed, activity levels and stress levels, to name a few. This can be on top of the burden of managing other comorbidities. At the health system level, people with diabetes, and those who support them, are required to manage multiple interactions with healthcare professionals and insurers.[16,17,18,19,20] Each of these interactions and daily insulin-management decisions are complex and can contribute to sub-optimal results.[21] Furthermore, a person with diabetes may also experience challenges in accessing specialists and general practitioners, as a shortage in these types of professionals has been reported repeatedly.[22,23] Indeed, diabetes care management is multifaceted, and several dimensions of care may be out of an individual's control. Due to the complicated nature of diabetes care and management, all aspects cannot be fully addressed by any one individual. The 2020 ADA Standards of Medical Care in Diabetes recommends that healthcare systems utilize team-based care and use of patient registries, decision support tools, and community involvement to meet patient needs.[24]

The vast expansion of companies offering new, digital tools and platforms to manage diabetes... indicate a new era of care 'optimization'

New diabetes care technologies are being developed to address this complexity of care and aim to overcome the associated challenges in a more holistic way. Increasingly, there is a trend towards placing the person with diabetes at the center of the overall process of care and empowering them with appropriate tools and information to self-manage diabetes more consistently, simply, and independently outside of their appointments with HCPs. This is seen in the proliferation of tools for easier glucose monitoring, increasingly automated insulin delivery management, regular monitoring of key diabetes care metrics such as TIR, feedback based on this monitoring, and coaching or mentoring.[25]

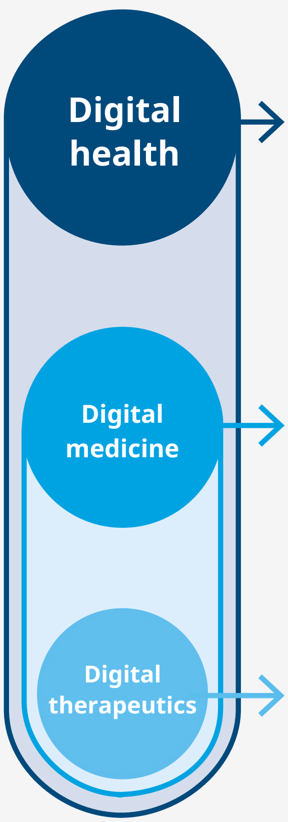
DEFINING DIGITAL TECHNOLOGIES: DIGITAL HEALTH PRODUCTS, DIGITAL MEDICINE PRODUCTS, AND DIGITAL THERAPEUTIC PRODUCTS[9]

Recent innovations across digital technologies in the overall diabetes ecosystem are part of a broader movement towards digital health taking place across multiple therapy areas, particularly for chronic conditions. In response to the variety and sheer number of diverse digital technologies that are emerging, terminology is being established to enable meaningful distinctions between digital categories.

Under the categorization established collaboratively by the Digital Medicine Society (DiMe), Digital Therapeutics Alliance (DTA), HealthXL, and NODE.Health, 'digital health' is a comprehensive category that encompasses 'digital medicine', which in turn includes 'digital therapeutics' (see Exhibit 2). While digital health products include "technologies and platforms that engage consumers for lifestyle, wellness, and health-related purposes," digital medicine products specifically refer to "evidence-based software and/or hardware products that measure and/or intervene in the service of human health." More narrowly still, digital therapeutic products "deliver evidence-based therapeutic interventions to prevent, manage, or treat a medical disorder or disease." As such, products in each of these categories have varying requirements for clinical evidence and regulatory oversight.

In this report, and the forthcoming series of reports on digital diabetes technologies that will be released throughout 2020, the focus will be on digital medicine products, which includes digital therapeutics, as they offer evidence-based approaches to improving diabetes care.

Exhibit 2: Definitions of Digital Health Products[9]



	Definition	Non-exhaustive product examples
Digital health	**Digital health products** include technologies, platforms, and systems that engage consumers for lifestyle, wellness, and health-related purposes; capture, store or transmit health data; and/or support life science and clinical operations.	• **User-facing technologies:** Lifestyle apps, fitness trackers, nutrition apps • **Health information technology (HIT):** Electronic medical record systems, electronic prescribing and order entry systems • **Consumer health information sources:** Online repositories, personal health records, patient portals, information databases
Digital medicine	**Digital medicine products** include evidence-based software and/or hardware products that measure and/or intervene in the service of human health.	• **Digital diagnostics:** Software-driven connected technologies that detect or confirm the presence of a disease or condition of interest or to identify individuals with a subtype of the disease • **Digital biomarkers:** Digital tools that measure patient characteristics that are objectively measured and evaluated as an indicator of normal biologic processes, pathologic processes, or biological responses to a therapeutic intervention. Includes all BEST biomarkers • **Electronic clinical outcome assessment technologies:** Digital measures of how patients feel, function, or survive
Digital therapeutics	**Digital therapeutic (DTx) products** deliver evidence-based therapeutic interventions to prevent, manage, or treat a medical disorder or disease.	• **Interventions that treat a disease:** DTx that deliver a medical intervention to treat a disease • **Interventions that manage a disease:** DTx that deliver a medical intervention to manage a disease • **Interventions that improve a health function:** DTx that deliver a medical intervention to improve a health function and/or prevent a disease.

Source: Digital Therapeutics Alliance, DiME, Node Health, HealthXL. Digital Health Industry Categorization. Available from: https://dtxalliance.org/wp-content/uploads/2019/11/DTA_Digital-Industry-Categorization_Nov19.pdf

Note: The product examples shown here are a small subset of the total possible examples for each category

Broadly, advances in diabetes care are taking place across several categories (see Exhibit 3) namely,

- **Connected Devices**, which encompass continuous glucose monitors, smart pens that automatically adjust basal insulin dosing to the amount currently needed for personal injection, and automated insulin delivery (AID) devices like hybrid closed-loop systems that deliver insulin in an automated fashion. All of these function alongside digital applications and programmed dosing algorithms. Insulin pumps and smart pens are increasingly being connected with CGMs to inform delivery of the right amount of insulin to people with diabetes.

- **Digital Applications**, which can assist people with diabetes and their caregivers in managing diabetes by tracking nutrition, physical activity, insulin titration or other holistic diabetes management components, as well as software programs that are able to analyze the large amounts of data generated to aid in care decisions. These platforms can also be linked to connected devices such as CGMs and can facilitate insulin delivery as well.[25] This category of digital medicine products also enables digital care providers like Livongo and Omada, which can be defined as a group of personalized care pathways that aim to deliver care in a manner similar to specialty medical clinics or hospitals.[26]

- **Artificial Intelligence or Machine Learning-based Algorithms**, which, at a high level, encompass two main categories. The first includes artificial intelligence (AI) — or machine learning (ML)-based algorithms that assess large databases, harnessing data and generating insights that may simplify and enhance care management for both people with diabetes and HCPs. The proliferation of large databases and algorithms that have the capacity to aggregate and assess large amounts of information using AI and ML offer the potential to develop and drive new insights regarding approaches to care from a health-system perspective. The second category of algorithms are those that analyze an individual's glucose data and compare it with large non-identified multi-patient datasets to predict future fluctuations and then either recommend an adjustment to dosing, or independently adjust dosing. This would allow for

Exhibit 3: Advances in Diabetes Digital Medicine Products

	Connected devices	Digital applications	Algorithms
Advances	Includes continuous glucose monitors, insulin delivery devices like hybrid closed-loop systems, and smart pens used alongside digital applications and programmed dosing algorithms. Insulin pumps and smart pens are increasingly being connected with CGMs to inform delivery of the right amount of insulin to people with diabetes.	Includes applications for self-management that focus on nutrition, physical activity, insulin titration and holistic diabetes digital care provider programs. Mobile apps can also be linked to connected devices such as glucose monitors and can facilitate insulin delivery.	Encompasses two main categories: algorithms that assess large databases, harnessing data and generating insights that may simplify and enhance care management; and algorithms that analyze an individual's data and compare it with known datasets and then recommend or independently adjust dosing.
Examples (non-exhaustive)	• AID (automated insulin delivery) devices • Smart Pens • CGMs (continuous glucose monitors)	• Mobile applications that aggregate blood sugar information and insulin dosing, generating insights on patterns, providing real-time feedback • Other lifestyle programs that track food and activity levels	• AI-based algorithms that assess the data of individual people with diabetes as well as large databases to improve outcomes • Algorithms to allow for interoperability between devices

Source: IQVIA, Apr 2020

more precise and customizable use of diabetes device systems. For example, the FDA recently authorized marketing of algorithm technology that enables insulin pumps to automatically adjust insulin delivery for people with diabetes. It does this by digitally connecting an interoperable automated glycemic controller device with an alternate controller-enabled insulin pump ("ACE pump") and integrated CGM ("iCGM"), which allows the devices to continuously assess and administer drug dosing requirements as needed. This has the potential to enable those with diabetes to better personalize treatment to individual needs, and to relieve some of the psychosocial challenges to improve quality of life.[27]

With the emergence of new digital medicine products, different parts of the diabetes care landscape have the potential to be linked together more efficiently to provide optimal management across clinical, psychosocial, and economic dimensions, thereby forming a holistic ecosystem of care. Additionally, these products offer new modalities for diabetes management and treatment.

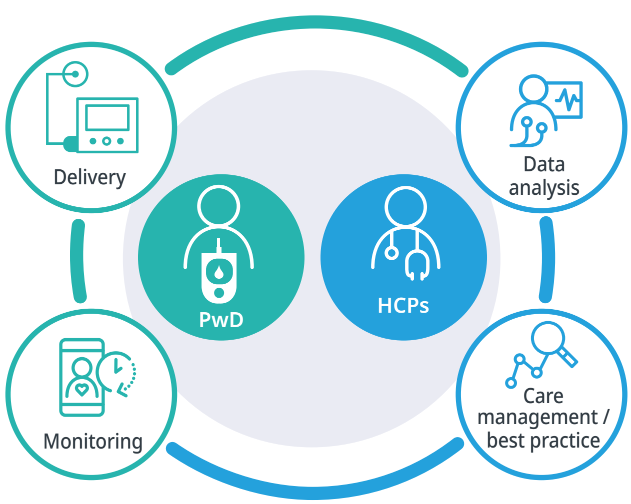
However, the digital medicine products discussed have traditionally evolved in a disjointed manner. A variety of companies have been independently working on different parts, and only recently have discussions begun to shift towards a more connected ecosystem that integrates them (see Exhibit 4).[18,25]

In the future, holistic digital medicine products may simplify life for people with diabetes and healthcare professionals and enable diabetes management to be handled more seamlessly. This is important as the key developments in diabetes care across digital medicine products present an opportunity to overcome several challenges within diabetes care (see Exhibit 5). This era also offers the potential to provide significant value for the health system, payers, HCPs, and people with diabetes, through improved care efficiency, lower overall cost, better health outcomes, and improved quality of life. Unlocking the value of this era of care hinges on optimally understanding and harnessing new digital medicine products, potentially through an integrated ecosystem, to advance healthcare delivery and healthcare policy.

Exhibit 4: Digital Ecosystem for Diabetes Care

Measurements of glucose by CGMs allows for automation of appropriate basal rate insulin delivery through **automated insulin delivery devices** and/or information to aid bolus dose decisions through smart pens leading to improved glucose control and TIR

CGMs allow PwD to monitor glucose levels regularly and can be linked to digital applications that can enable digital care providers to offer coaching, behavioral advice and feedback as well as allow for remote interactions with HCPs (including Endocrinologists, DCES)



Data generated on glucose levels through digital medicine products allows for remote monitoring and analysis of trends which can be used during patient visits. Measures such as TIR can be assessed more frequently, thereby enhancing understanding of the impact of blood glucose fluctuations and aiding to develop approaches to reduce HbA1c

Diabetes management decisions regarding approaches to manage glucose fluctuations can be positively influenced at a macro / policy-level using **algorithms** and data insights generated from the assessment of large non-identified patient databases that can be produced due to the increase in overall glucose monitoring

Other components can be integrated into the digital ecosystem such as telehealth support staff etc.

Source: IQVIA, Apr 2020

Note: This exhibit is a simplified, non-exhaustive representation of a digital diabetes care ecosystem. In reality, there are numerous possibilities for interactions across stakeholders and the various digital medicine products. PwD = Person with diabetes, CGM = Connected glucose monitor, TIR= Time in Range, DCES = diabetes care and education specialist, HCP = healthcare professional

Exhibit 5: Opportunities Presented by the Latest Digital Medicine Products[16–18, 21–25, 30–31, 37–41, 44, 46]

Current challenges		Opportunity presented by latest tools and technologies
• Not all people with diabetes (PwD) have access to a diabetes care and education specialist (DCES) and dietician services • HCP time to educate PwD in addition to conducting tests is limited during appointments • Access to specialists such as Endocrinologists may be limited • Reimbursement for HCP time reviewing PwD data remains limited	**Resources and time**	• Mobile health applications offer to provide coaching and behavioral advice for all PwD • Algorithms to analyze data and present therapeutic options to HCPs can reduce the burden of managing complex diabetes care • Remote monitoring and analysis of PwD data trends can increase the efficiency of time-limited PwD appointments and increase time focused on decision-making
• Current technologies are often not interconnected leading to the need for PwD to manage multiple, fragmented devices • Undiagnosed diabetes can go unnoticed for a long time as mild to moderately elevated blood sugar levels are often asymptomatic • Even if tests are conducted regularly, a clear set of steps to achieve target HbA1c levels is lacking • Semi-annual and once-every-12-week HbA1c testing will not capture daily fluctuations • Frequent monitoring through CGMs may not be feasible for all	**Clinical and technical**	• Interconnected devices can communicate with each other and adjust insulin dosing on a continuous basis (e.g., hybrid closed-loops), reducing PwD time and effort required to input data into multiple devices for insulin dosing • Measures such as time-in-range can be assessed more frequently with further CGM proliferation, This can promote understanding of blood glucose fluctuations, their impact and identify approaches to reduce HbA1c • Wider use of connected devices can result in more efficient, tailored, and personalized treatment discussions with HCPs, as the data can be directly transferred to them and they can provide direction based on historical trends in individual PwD data since the last appointment, rather than relying on the results of in-office blood tests

• PwD face a number of challenges self-managing their condition, such as:
  • Difficulty navigating complex self-dosing equations
  • Limited access to blood glucose data to monitor daily fluctuations
  • Anxiety that they may be mis-dosing
  • Fear of hypoglycemia
• HCPs are unable to monitor PwD compliance outside of appointments
	Psychosocial and behavioral	• Mobile health applications and digital care providers offer support and coaching programs to relieve PwD anxiety and stress around self-management while providing clear information on dosing derived from connected device data
		• Fear of hypoglycemia can be reduced through better dosing software, which offers guidance to PwD, and predictive hybrid closed-loop and open-loop systems
		• Diabetes management decisions, as well as policy, can be positively influenced using data insights generated from connected devices data and the pooling of this data into large databases
		• Additional research is needed to assess the burden of operating multiple wearable or connected devices and learning how to operate new technologies

• Not all PwD have access to reimbursement • Not all PwD have reimbursement coverage for specialist visits and tests • Additional costs sometimes associated with specialist visits may not be affordable for all PwD • Regular visits with multiple specialists is time consuming and has opportunity costs • Lack of reimbursement for lifestyle management and support programs • Poor PwD compliance and failure to reach target HbA1c levels drives complications and annual costs to the U.S. healthcare system	**Economic**	• PwD remote visits with specialists using mobile health software can reduce costs • Further analysis is needed to confirm and expand on initial research suggesting economic benefits

Source: Garcia-Perez et al, 2013; Cypress et al, 2013; AACE 2020; Young-Hyman et al, 2016; Vigersky et al, 2014; Levine et al, 2020; ADA, 2020; Fleming et al, 2019; Sierra et al, 2018; Adolfsson et al, 2018; Case Study, Livongo Demonstrates Cost Savings, Medical Claims Analysis for two self-insured employers, 2017; Gill et al, 2018; Reynolds et al, 2017; Zhu et al, 2017; Kubiak et al, 2016; Patton et al, 2016; Farrington et al, 2018.

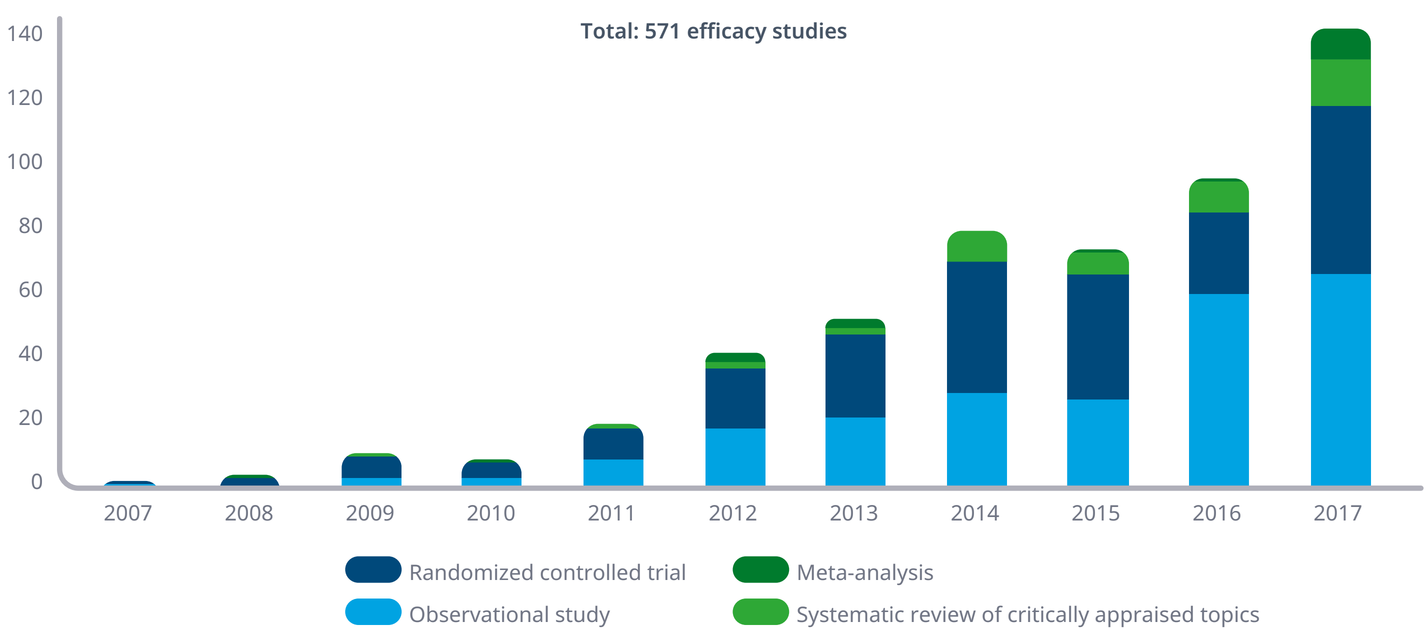
Notes: *Integration of the latest technologies into a holistic system of care can make diabetes care more efficient. The opportunities shown above represent the value being proposed by these technologies. While evidence is being generated to showcase these values, additional research is needed to robustly assess whether these opportunities are being achieved in a real world setting.

The promise of digital medicine products

- **There is substantial interest in understanding and measuring the value of digital medicine products from a clinical, psychosocial, and economic perspective. While the majority of research is still at an early stage, initial findings suggest they offer value across multiple dimensions.**
- **From a clinical perspective, studies report that optimal use of connected devices, digital applications, and algorithms can be linked to clinical improvements such as improvements in HbA1c, increases in TIR, and reduced hypoglycemia.**
- **From a psychosocial perspective, early research suggests that use of devices like CGMs can result in reduced anxiety, improved sleep, improved confidence, and an increased sense of relief or "time-off" from diabetes demands.**
- **From an economic perspective, studies report that the use of connected devices like CGMs can significantly reduce overall medical costs, including inpatient and outpatient costs, while the use of digital care providers can also result in cost savings for both people with diabetes as well as payers.**
- **As some studies also indicate additional physical and mental burden due to the use of these devices, more research is needed to understand potential challenges and ensure they are designed to provide more seamless care coordination.**

Overall, digital medicine products can address complexities in the current healthcare system by providing enhanced access to information, enhancing precision of information, and improving person with diabetes engagement and self-management, thereby leading to better outcomes. However, whether these

Exhibit 6: Number of Published Digital Health Efficacy Studies 2007–2017* [28]



Source: IQVIA Institute for Human Data Science. The Growing Value of Digital Health: Evidence and Impact on Human Health and the Healthcare System. Nov 2017
Notes: Analyses excludes accuracy studies. Only includes studies with hard outcomes. 'Observational study' includes all trials examining interventional value or impact of an app excluded from the other three categories regardless of design. *Data collected through August 2017.

aims can be achieved is still being understood. Given the increasing focus on, and importance of, such digital medicine products in diabetes, there is a need to understand their overall value to the health system, payers, HCPs, and people with diabetes, across various dimensions. Between 2012 and 2017, the number of efficacy studies for digital health increased by approximately 225% (see Exhibit 6).[28]

Within the diabetes care space, evidence is beginning to be generated that showcases the promise of digital medicine products. Given the complexity and challenges within this space, there is a need to understand the value of these digital medicine products across multiple dimensions — clinical, psychosocial and economic. A subset of the studies across these dimensions is summarized below.

CLINICAL

Studies have reported that people with T1D using continuous glucose monitors (CGMs) obtained lower HbA1c levels and improvements in TIR, compared to those utilizing other methods such as self-monitoring of blood glucose (SMBG), even when either methodology was combined with multiple daily injections (MDI) or continuous subcutaneous insulin infusion therapy (CSII). At three years, a nonrandomized, prospective, real-world, clinical trial demonstrated that groups of people with diabetes using CGMs (which includes both CGM+MDI and CGM+CSII) had significantly lower HbA1c (7.0% and 6.9% respectively), compared with SMBG groups, with HbA1c levels of 7.7% for SMBG+CSII and 8.0% for SMBG+MDI.

Within the diabetes care space, evidence is beginning to be generated that showcases the promise of digital medicine products... across multiple dimensions — clinical, psychosocial, economic.

There was no significant difference between the CGM groups on HbA1c levels.[29] Additionally, based on a study of healthcare claims and a large laboratory dataset from the United States, people with type 2 diabetes (T2D) who used CGMs also saw an improvement in their HbA1c levels.[30] Overall, regular CGM use has also been shown to reduce hypoglycemia, which is noted as a "significant health concern and a primary obstacle to optimal adherence to prescribed diabetes treatment."[31]

Multiple studies looking into pump systems and hybrid closed-loop systems have reported an improvement in glycemic control.[32,33] A hybrid closed-loop system is composed of an algorithm-enabled insulin pump that can be wirelessly connected to a CGM for the purpose of automatically or manually controlling the basal rate of insulin for a person with diabetes. When in automatic mode, the system uses the algorithm to check CGM responses every five minutes and adjusts basal rate of insulin delivery as needed. In manual mode, insulin delivery is not automated, and the basal rate of insulin can instead be pre-programmed throughout the day. The system is considered a "hybrid" closed-loop system because it automates basal rate of insulin delivery only. People with diabetes must still manually deliver bolus doses to cover meals or correct for residual hyperglycemia.[34]

Additionally, a recent randomized controlled trial assessed the impact of a technology associated with an insulin pump that suspends insulin prior to the occurrence of a hypoglycemic event. It found that this technology significantly reduced the number of hypoglycemic events compared to the control group, with 4 of the 76 (5%) participants in the intervention group reporting hypoglycemia over the course of six months compared with 10 out of 77 (13%) participants in the control group.[35] Another study, which looked at the impact of a predictive low-glucose suspend (PLGS) insulin delivery system algorithm on maintenance of glucose control and prevention of hypoglycemic events in people with insulin-dependent diabetes, demonstrated reductions in the mean frequency of hypoglycemic events from one every 9 days to one every 30 days.[36]

Digital care providers have also reported reductions in HbA1c levels with consistent use of their apps and programs. Livongo reported a reduction in HbA1c of 0.9% in their members over a one-year timeframe.[37] While many other digital applications exist with design features geared towards improving HbA1c levels, improving self-efficacy, changing self-monitoring frequency, and reducing the number of hypoglycemic episodes, many of these programs lack published outcome studies in peer-reviewed medical journals. While the impact of using these applications is promising, more research is needed to further define the clinical impacts of the broader range of digital applications.[20]

Further, digital medicine products are beginning to show improvements in measures beyond HbA1c such as TIR. Preliminary studies using the IQVIA Core Diabetes model suggested that increases in TIR to consensus targets were linked with reductions in the risk of developing diabetes-related complications, with the incidence of eye diseases, renal diseases, ulcer/amputation, and cardiovascular diseases reduced by -24%, -26%, -19% and -10%, respectively.[6,38] Digital medicine products offer the potential achieve these consensus targets.

PSYCHOSOCIAL

Understanding the links between psychological and behavioral aspects of diabetes digital medicine products is still at an early stage. Some studies have shown that there is an improvement in quality of life for people with diabetes using CGMs while others have shown no change on this measure. Overall, the results on the quality of life benefit have been mixed and there is benefit in conducting further studies.[39,40] Similarly, studies assessing reduction in fear of hypoglycemia, anxiety, and depression associated with CGM use have also reported mixed results.

Current research suggests that new advances across connected devices, including insulin pumps and CGM sensors may offer numerous psychosocial benefits including increased reassurance, reduced anxiety, improved sleep, improved confidence, and an increased sense of relief or “time off” from diabetes demands.[41] Outside of the United States, a prospective observational multicenter real world study investigating the impact of unrestricted reimbursement of intermittently scanned continuous glucose monitors for people living with type 1 diabetes in Belgium found that increased use of this type of CGM resulted in higher treatment satisfaction, less severe hypoglycemia, and less work absenteeism, while maintaining quality of life and HbA1c.[42] However, these benefits are enjoyed with some additional user burden associated with technological advances across insulin pumps and CGM sensors, including variable levels of trust in digital medicine products, increased physical and mental effort as a result of operating multiple devices, concerns around technical glitches, and the need to manage incorporating systems into daily life.[42]

Additionally, initial research focused on the psychosocial impact of digital applications and their corresponding digital care providers like Livongo — which offers access to Diabetes Care and Education Specialists (formerly known as Certified Diabetes Educators) for real-time support and goal-setting support — suggests significant reductions in distress and improvements in feelings of empowerment in real world outcomes settings.[43] However, research assessing the impact of such digital care provider programs as a whole are still at a nascent stage, and their use and access are limited to small populations. In addition, a greater understanding of the impact of a closer-knit community due to the digital medicine is important. Overall, there is a need to continue evaluating the psychosocial dimensions associated with digital medicine products in more detail as they form a core component of the overall management of diabetes.[40]

ECONOMIC

A U.S.-based retrospective, cross-sectional analysis used a large repository of health plan administrative data to compare average healthcare costs (excluding durable medical equipment), hospital admissions, and HbA1c levels for those using CGMs versus those not using CGMs. The study found that people with diabetes using CGMs spent an average of approximately $4,200 less in healthcare costs (excluding durable medical equipment) when compared to those who were not using CGMs.[44] The majority of this cost difference was in medical costs (more so than pharmacy costs) of which about $2,200 lower costs were seen in the “outpatient other facility” category which includes outpatient hospital, outpatient psychiatry, outpatient rehabilitation, and surgical center costs, likely driven by a reduction in the level of complications seen in outpatient settings, resulting in reduced costs for outpatient procedures.[44] Additionally, almost $2,000 lower costs, on average, were seen in the “inpatient hospital” category, driven by fewer hospital admissions and shorter lengths of stay.[44,45] A separate analysis of a large healthcare claims and laboratory dataset from the United States found that people with diabetes using CGMs saw an improvement in HbA1C, which resulted in annual diabetes costs being reduced by $3,376. People with diabetes who used CGMs while also changing their diabetes treatment regimen also reduced total costs by $3,327.[30]

One study reported that people with T1D on MDI therapy incur higher inpatient and insulin costs compared to people with T1D using digital medicine products like CSII.[46] This retrospective study used Truven Health MarketScan® Commercial Database (2010 to 2014) to assess annual inpatient and insulin costs from a private payer’s perspective for T1D patients in the United States, treated with MDI vs CSII. Results showed that the CSII treatment group had approximately 32% lower inpatient costs ($2,541 vs. $1,725) and 30% lower insulin costs ($4,898 vs. $3,406) relative to MDI treatment. MDI treatment was also associated with an increased risk for inpatient utilization.[46]

In terms of digital application supported systems, a study by the digital care provider Livongo reported that their digital diabetes coaching system led to gross medical savings of $1,908 per participant per year. Livongo also reported saving two large self-insured employers $83.06 per member per month on healthcare costs.[37] Additionally, a retrospective analysis of a different digital health diabetes management program reported that use was associated with a 21.9% decrease in medical spending at one year, which translated to $88 in savings per program member per month. Those with access to the digital health program experienced a 10.7% reduction in diabetes-related medical spending and a 24.6% reduction in spending on office-based services.[47]

Due to the fact that digital medicine products can improve the time spent in target glucose ranges, a conservative estimate suggests a reduction of $6.7–9.7 billion in costs over a 10-year period is achievable if people in the United States are able to better utilize these technologies to reach the minimum consensus target levels for TIR (i.e., >70%).[6]

The studies being conducted across all three of the dimensions do vary in their robustness but from an economic and clinical perspective, evidence is beginning to showcase the value of these digital medicine products. However, the reach and use of these digital medicine products is still limited, with only 30% of people with T1D in the United States using CGMs.[11] Other digital medicine products such as hybrid closed-loop pumps, digital application and software-based programs, and algorithms are still at an early stage. Over time, as these digital medicine products become more integrated and fit into an overall diabetes care ecosystem, it is important to understand factors which may limit their access, use, and potential impact on health outcomes.

Key issues impacting access to and use of diabetes digital medicine products

+ **There are issues across multiple dimensions of the healthcare ecosystem that will impact access to and optimal use of digital medicine products going forward, including reimbursement for healthcare provider expertise, user experience and data privacy and security, among others.**

+ **These issues will be examined in greater detail through a series of upcoming short reports to assess how these issues impact the uptake of diabetes digital medicine products, how they are evolving and identify possible approaches to overcome associated challenges.**

The innovations provided by digital medicine products are moving diabetes care towards a new care paradigm; one in which more seamless and remote chronic disease management is possible. The availability of diabetes digital medicines is increasing rapidly, and a growing body of evidence suggests that they offer value across clinical, psychosocial, and economic dimensions to further enhance diabetes care. However, various issues across multiple dimensions of the healthcare ecosystem will ultimately impact the adoption of these digital medicine products (see Exhibit 7). It is crucial that such issues — including those impacting access to and optimal use of these digital medicine products — are identified. It is also important to recognize that the arrival of these digital medicine products will not be enough to optimize glucose management on its own. Rather, supportive aspects of the healthcare system will be needed to optimize their use.

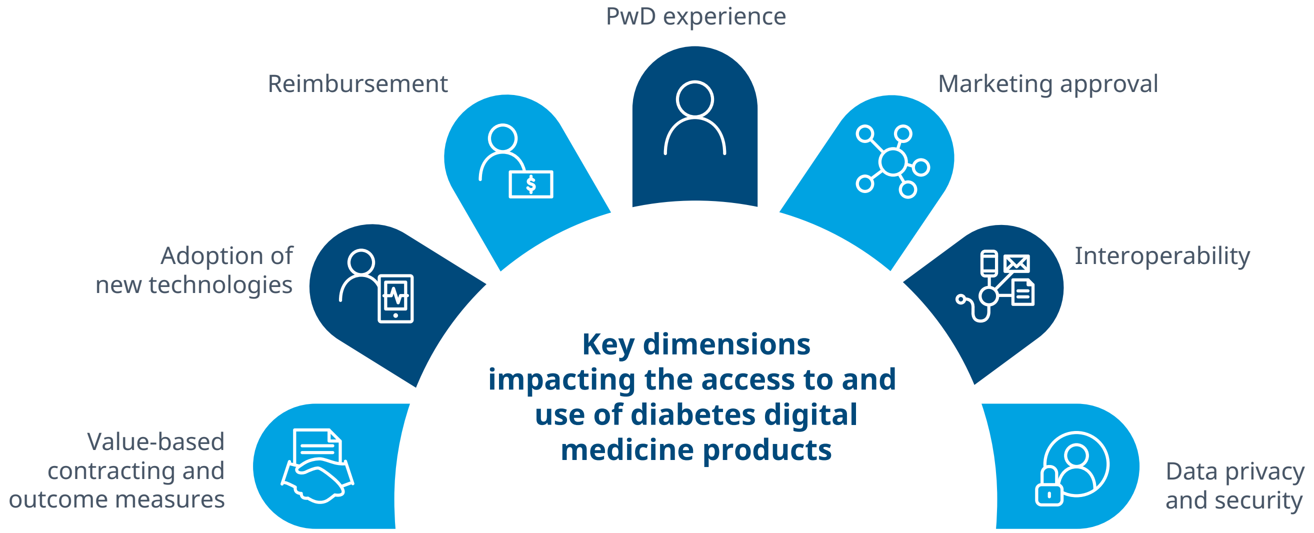
An evaluation of the overall healthcare ecosystem is, therefore needed to understand what must change and ensure that new digital medicine products, as they begin to showcase their value, can be appropriately assessed and accessed to lead to optimal diabetes care. These issues that can impact access to and optimal use of digital medicine products (and will be explored in subsequent reports in this series) span the following dimensions,

- **People with Diabetes' experience**: As discussed in the previous sections, the experience of those with diabetes is at the center of optimal diabetes management. Current digital medicine products have been reported to add some burden for those with diabetes that can impact their day-to-day lives. Understanding the quality of life improvements these products offer and their implications for the person with diabetes experience are crucial for sustained use of these digital medicine products.[48]

- **Adoption of new technologies**: Healthcare professionals across the board, and primary care physicians (PCPs) in particular, are overburdened within the current system due to the high number of patients they are required to see in a day and cumbersome administrative work. If a new technology does not integrate seamlessly into the physicians' workflow, then uptake can be severely limited. Several operational elements and lack of financial and human resources can also impact uptake by HCPs.

- **Reimbursement**: The willingness of payers to cover new diabetes digital medicine products and compensate HCPs for their time spent consulting with people using the new technology and remotely monitoring data can be limited. While payers have begun to take initial steps towards compensating HCPs for the set up of CGMs' and 'data interpretation associated with CGMs', the amounts remain insufficient for the time and effort involved. A well-constructed and flexible reimbursement paradigm for these digital medicine products and the overall ecosystem will be crucial for widespread coverage and use of all connectable care devices and related care tools.

Exhibit 7: Key Dimensions Impacting Access and Optimal Use of Digital Medicine Products



Source: IQVIA, Apr 2020

- **Value-based contracting (VBC) and new outcome measures**: Within the current reimbursement paradigm, value-based contracting is beginning to be utilized as a way of accounting for uncertainties around outcomes in the digital medicine space. Value-based contracting is a financially-based healthcare incentive model whereby purchasers of products or services agree to quality, outcomes and/or cost-of-care contract terms with payers (both public and private). An example of this innovative payment model occurs between manufacturers and payers, in which both groups agree to link coverage and reimbursement levels to a drug's effectiveness and/or a patient's adherence to using the medicine. As new digital medicine products and metrics are developed rapidly in the diabetes space, such VBC arrangements may become particularly relevant as they offer an approach to increase access to these digital medicine products by allowing for risk-sharing across stakeholders. However, such contracts can also limit PwD choices due to restrictions on the types of digital medicine products that are reimbursed.

An evaluation of the overall healthcare ecosystem is needed to understand what must change and ensure that new digital medicine products, as they begin to showcase their value, can be appropriately assessed and accessed to lead to optimal diabetes care.

- **Marketing approval**: The FDA's rules and regulations surrounding various parts of the diabetes digital health ecosystem including CGMs, pump systems, treatment algorithms, and smart pens are still evolving. Coordination across centers (CDER and CDRH) at the FDA will be crucial for appropriate assessment of these digital medicine products.

- **Interoperability**: Interoperability generally refers to the connectivity between devices — e.g., connecting pumps, such as ACE pumps, with different CGMs. Another consideration is the connectivity of devices with the broader digital health ecosystem e.g., electronic health records (EHRs) — ensuring that data produced across different devices is compatible with and across software/analytics platforms. As new technology enters the market, it will be important that devices are able to work together seamlessly and with the overall healthcare ecosystem; the current limited interoperability can increase HCP burden and lack of data sharing can impact health outcomes.

- **Data privacy and device security**: Data privacy refers to the protection of health information and personal, identifiable data of the users of health devices, including the identities of device owners and how they are kept secure. Device security refers to the protection of digital systems from hacking or unwanted intrusion. As technology continues to advance, data security and privacy will remain relevant as HCPs and people with diabetes confident use of these devices will depend on it.

Over the course of 2020, the above issues will be discussed in greater detail through a series of short reports. These reports will contain further specifics on how a given issue impacts diabetes digital medicine products, how that issue is evolving, and possible approaches to overcome identified challenges. The next report in this series will focus on reimbursement. In particular, it will cover the current landscape surrounding the coverage of digital medicine products, the reimbursement of time for HCPs to assess and monitor data and associated challenges within the current system, along with possible solutions.

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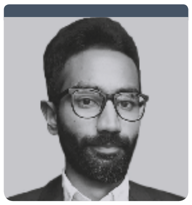
About the authors

MURRAY AITKEN
Executive Director, IQVIA Institute for Human Data Science

Murray Aitken is Executive Director, IQVIA Institute for Human Data Science, which provides policy setters and decisionmakers in the global health sector with objective insights into healthcare dynamics. He led the IMS Institute for Healthcare Informatics, now the IQVIA Institute, since its inception in January 2011. Murray previously was Senior Vice President, Healthcare Insight, leading IMS Health's thought leadership initiatives worldwide. Before that, he served as Senior Vice President, Corporate Strategy, from 2004 to 2007. Murray joined IMS Health in 2001 with responsibility for developing the company's consulting and services businesses. Prior to IMS Health, Murray had a 14-year career with McKinsey & Company, where he was a leader in the Pharmaceutical and Medical Products practice from 1997 to 2001. Murray writes and speaks regularly on the challenges facing the healthcare industry. He is editor of Health IQ, a publication focused on the value of information in advancing evidence-based healthcare, and also serves on the editorial advisory board of Pharmaceutical Executive. Murray holds a Master of Commerce degree from the University of Auckland in New Zealand, and received an M.B.A. degree with distinction from Harvard University.

PAUL VILLA
Senior Principal, IQVIA Global Consulting Services

Paul Villa is a Senior Principal at IQVIA Consulting Services, based in Philadelphia. Paul has 20+ years of pharmaceutical industry and healthcare consulting experience with interest and expertise in health policy, market access and pricing. His market access commercialization experience is based upon a 10-year foundation at AstraZeneca while holding a variety of payer leadership positions (e.g., brand, pricing and contracting strategy). He then transitioned into consulting where he developed pricing and market access practices at several small research-based consulting firms prior to joining IQVIA. Paul holds an MBA in Marketing from the Johnson Graduate School of Management at Cornell University as well as a BA in Psychology from Pomona College.



VIBHU TEWARY

Manager, IQVIA Global Consulting Services

Vibhu Tewary is a Manager within IQVIA Global Consulting Services based out of New York. His key areas of interest include global market access, healthcare policy and economic modeling. Vibhu has authored reports on global healthcare policy and market access. Prior to joining IQVIA, he worked as a researcher in a policy think tank in India. Vibhu did his undergraduate studies from the Indian Institute of Technology, Madras and holds an MBA from Duke University.

ALEXIS ANDERSON

Consultant, IQVIA Global Consulting Services

Alexis Anderson is a Consultant within IQVIA Global Consulting Services based out of Boston, USA. Her key areas of interest include digital health, strategic transformation, and healthcare policy. Prior to joining IQVIA, Alexis worked as a management consultant and assisted healthcare and life science organizations with designing and executing operational improvements. She holds an MPH from Boston University.

About the Institute

The IQVIA Institute for Human Data Science contributes to the advancement of human health globally through timely research, insightful analysis and scientific expertise applied to granular non-identified patient-level data.

Fulfilling an essential need within healthcare, the Institute delivers objective, relevant insights and research that accelerate understanding and innovation critical to sound decision making and improved human outcomes. With access to IQVIA's institutional knowledge, advanced analytics, technology and unparalleled data the Institute works in tandem with a broad set of healthcare stakeholders to drive a research agenda focused on Human Data Science including government agencies, academic institutions, the life sciences industry and payers.

Research Agenda

The research agenda for the Institute centers on 5 areas considered vital to contributing to the advancement of human health globally:

- Improving decision-making across health systems through the effective use of advanced analytics and methodologies applied to timely, relevant data.
- Addressing opportunities to improve clinical development productivity focused on innovative treatments that advance healthcare globally.
- Optimizing the performance of health systems by focusing on patient centricity, precision medicine and better understanding disease causes, treatment consequences and measures to improve quality and cost of healthcare delivered to patients.
- Understanding the future role for biopharmaceuticals in human health, market dynamics, and implications for manufacturers, public and private payers, providers, patients, pharmacists and distributors.
- Researching the role of technology in health system products, processes and delivery systems and the business and policy systems that drive innovation.

Guiding Principles

The Institute operates from a set of Guiding Principles:

- Healthcare solutions of the future require fact based scientific evidence, expert analysis of information, technology, ingenuity and a focus on individuals.
- Rigorous analysis must be applied to vast amounts of timely, high quality and relevant data to provide value and move healthcare forward.
- Collaboration across all stakeholders in the public and private sectors is critical to advancing healthcare solutions.
- Insights gained from information and analysis should be made widely available to healthcare stakeholders.
- Protecting individual privacy is essential, so research will be based on the use of non-identified patient information and provider information will be aggregated.
- Information will be used responsibly to advance research, inform discourse, achieve better healthcare and improve the health of all people.

The IQVIA Institute for Human Data Science is committed to using human data science to provide timely, fact-based perspectives on the dynamics of health systems and human health around the world. The cover artwork is a visual representation of this mission. Using algorithms and data from the report itself, the final image presents a new perspective on the complexity, beauty and mathematics of human data science and the insights within the pages.

The artwork on this report cover is created from information about digital health devices. The dataset includes information about the manufacturers of smart devices along with details about the devices themselves including; prices, weight, customer reviews, and review counts.

IQVIA™ INSTITUTE FOR HUMAN DATA SCIENCE

CONTACT US

100 IMS Drive

Parsippany, NJ 07054

United States

info@iqviainstitute.org

iqviainstitute.org