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REVIEW ARTICLE

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Opportunities to overcome underutilization of enhanced insulin delivery technologies in people with type 2 diabetes: a narrative review

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ABSTRACT

Use of innovative technologies such as continuous glucose monitoring (CGM) and insulin delivery systems have been shown to be safe and effective in helping patients with diabetes achieve significantly improved glycemic outcomes compared to their previous therapies. However, these technologies are underutilized in many primary care practices. This narrative review discusses some of the clinical and economic benefits of tubeless insulin delivery devices and discusses how this technology can overcome the main obstacles inherent to use of conventional insulin delivery devices.

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Type 2 diabetes; insulin delivery; disparities; adherence

1. Introduction

Despite the availability of innovative technologies such as continuous glucose monitoring (CGM) and insulin delivery systems (conventional and tubeless devices), these technologies are mostly underutilized in primary care settings, where the majority of individuals with T2D receive their diabetes care [1]. In a recent online survey of 100 US endocrinologists and 102 primary care physicians (PCPs), 87.0% of endocrinologists reported using CGM compared with only 28.4% of PCPs with their T2D patients [2]. Although use of conventional insulin pumps among endocrinologists and PCPs was fairly similar (83.0% vs. 73.5%, respectively), whether these PCPs actually started patients with diabetes (PwD) on an insulin pump or are simply providing care for PwD who were started by an endocrinologist was not reported. However, use of tubeless insulin delivery devices was lower among both endocrinologists and PCPs, with significantly lower utilization in primary care (56.0% vs. 22.6%, respectively).

This narrative review discusses some of the clinical and economic benefits of tubeless insulin delivery devices and discusses how this technology can overcome the main obstacles inherent to use of conventional insulin delivery devices.

2. Rationale for efforts to improve medication taking behaviors

An estimated 537 million people, worldwide, have diabetes [3]. This includes more than 30 million people with insulin-treated type 2 diabetes (T2D) [4]. Although achieving and maintaining established glycemic targets is necessary to reduce the incidence of acute glycemic events and the development of long-term microvascular and macrovascular complications [5,6]. a substantial proportion of people with diabetes are not achieving their glycemic goals.

The most recent US data show that the percentage of people with T2D with HbA1c <7.0% declined from 57.4% to 50.5% from 2010 through 2014 [7].

The major driver to the prevalence of suboptimal glycemic control is failure to intensify therapy when clinically indicated, a phenomenon that is referred to as *therapeutic inertia* [8]. The causes of therapeutic inertia are multifactorial and significantly impact glycemic management among insulin-treated PwD. Delays in initiating and intensifying diabetes treatment, especially insulin therapy, have been well documented [9]. However, delays in transitioning from basal only therapy to multiple daily insulin injections (MDI) when needed are most concerning [9]. In a recent analysis of 225,135 T2D patients with insurance claims for an oral antidiabetes medication (OAD) ($n = 188,230$), basal insulin ($n = 23,724$), or MDI ($n = 13,181$), Brixner et al. reported notably higher HbA1c levels among MDI users (8.7%) compared with those treated with OAD (7.0%) and basal insulin (8.4%) [10]. Among PwD with HbA1c ≥9.0% the percentage of those treated with MDI was higher than PwD treated with basal insulin only and OAD (40%, 32%, and 8%, respectively). Among PwD with HbA1c levels 8.0% to <9.0%, the percentage of those treated with MDI (45%) was also notably higher compared with individuals treated with OAD (29%) but similar to those treated with basal insulin (46%). Within the full cohort, the differences in treatment modalities were reflected in the total direct medical costs and diabetes-related medical

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costs for outpatient care, emergency department services, and inpatient hospitalizations. The total and diabetes-related per annum costs were notably higher for MDI users ($17,185 and $8,278, respectively) versus OAD ($7,217 and $3,005, respectively) and basal insulin ($9,820 and $4,713, respectively).

One factor that contributes heavily to therapeutic inertia is suboptimal adherence to prescribed medication and self-management, particularly among PwD who are treated with MDI [11]. Although PwD are often thought to lack motivation when glucose is poorly controlled, several factors must be considered, such as 'psychological insulin resistance' [12]. Resistance to initiating or intensifying insulin therapy is often affected by the attitudes and beliefs held by PwD, including fear of hypoglycemia, potential harm (e.g. blindness), belief that taking insulin means their diabetes is getting worse, anticipated pain of injections, low confidence in their ability to safely use insulin, and that insulin therapy will be too restrictive [12]. None of these factors suggest lack of motivation. Other factors often out of the patient's control, such as psychological conditions (e.g. depression, distress, anxiety) [13], absence of social support [14], cognitive impairment due to advanced age [15], and even trypanophobia (fear of needles), which is common in children and adults [16], create barriers to adherence.

Another factor is the array of clinician-related barriers. Main barriers include insufficient time, work overload, lack of awareness of clinical guidelines, unfamiliarity with basal-bolus therapy, potential implicit biases, uncertainty about patient adherence, and concern about hypoglycemia [17]. In a global survey of 1,250 clinicians, 75.5% reported that they would treat more aggressively were it not for the risk of hypoglycemia with insulin therapy [17].

The availability of glucagon-like peptide-1 receptor agonist (GLP-1 RA) formulations has reduced some of this burden. Treatment with these medications has low hypoglycemia risk and is now the preferred initial approach to lowering HbA1c if injectable therapy is needed [18]. Moreover, when addition of basal insulin is required, GLP-1 therapy often results in lower basal insulin dosages [19]. However, this option may not be appropriate or acceptable for a minority of PwD. Some PwD may not be willing to tolerate the side effects (e.g. gastrointestinal) [20], whereas others may not be able to afford these medications due to coverage issues or socioeconomic status. Moreover, in real-world use, discontinuation rates are much higher than reported in randomized trials [21].

3. Barriers to conventional insulin pump adoption

Use of insulin pump therapy in individuals with T2D has been shown to lower HbA1c [22], reduce bodyweight [22], increase treatment satisfaction [22], and improve quality of life [23], all of which are important predictors of adherence to treatment [24]. Although the benefits of conventional insulin pump use in this population have been clearly demonstrated, the most recent data estimates that only approximately 35,000 T2D patients were using conventional insulin pump therapy in 2016 [25]. The underutilization of conventional insulin pump therapy can be linked to several factors.

3.1. PwD perceptions

In a survey of 1,503 T1D, investigators identified barriers associated with use of various diabetes devices [26]. Among the 73 insulin pump users, the most common barriers reported were: dislike having a device on their bodies (45.8%) followed by 'discomfort/pain' (20.8%), cost of supplies (20.8%), 'did not trust the device' (20.8%), 'difficulty in getting the device to work correctly' (16.7%), 'cost of the device' (13.9%), and 'caused other people to ask too many questions about their diabetes' (12.5%). It is reasonable to assume that these barriers may also be issues of concern for individuals with T2D [27].

3.2. Clinician perceptions of patient acceptance

Endocrinologists/diabetes specialists are the main prescribers of most diabetes technologies and play a primary role in encouraging use of diabetes devices. As such, their perceptions of the necessity and feasibility of using insulin pumps for PwD with T2D is highly influential. In a study by Tanenbaum et al., investigators surveyed 209 healthcare professionals to obtain their opinions regarding the main barriers in their T1D PwD' use of insulin pumps and other devices [28]. Apart from cost and lack of insurance coverage, which were considered to be unmodifiable, the most common barriers cited by respondents were their perceptions that PwD do not like to wear a device (73%), PwD do not like the number of pump alarms (40.7%), and PwD lack understanding of how to use the pump features and/or what to do with the information (42%). Again, we assume that healthcare providers likely have the same perceptions regarding their T2D PwDs.

3.3. Potential for implicit bias

Studies have revealed notably lower utilization of insulin pumps and other diabetes technologies adolescent and adult T1D populations [29–32]. In an observational study of 300 young T1D PwD (age 18–28 years), Agarwal et al. observed that insulin pump use was notably higher among White PwD (72%) compared with Black PwD (18%) [30]. Similar findings were reported by Fantasia et al. in a cohort of 227 adult T2D PwD who received care at an urban safety-net endocrinology clinic. Investigators found a higher percentage of White PwD (55%) used insulin pumps and/or CGM compared with Black PwD (21%) and Hispanic PwD (28%) [29].

In an analysis of the 5,145 T2D adults who participated in the Look AHEAD trial [33], race/ethnicity was significantly associated with use of newer diabetes medications ($p = .019$) over the median follow-up of 8.3 years. Among the 2,211 PwD, a higher percentage of White PwD (48.0%) initiated therapy with a newer medication compared with Black (44.2%) and Hispanic (41.4%) PwD. Gender disparities in prescription of medications have also been reported by Zhang

et al., who found that a significantly lower percentage of women were prescribed a lipid-lowering medication than men (38.1% vs. 48.2%, $p < 0.001$) [34].

3.4. Access to specialists

Because insulin pumps are prescribed mostly by endocrinologists [2,35], the majority of individuals with T2D may not have ready access to this technology. The most recent data show that there are only approximately 8,500 practicing endocrinologists in the US, and many of these clinicians focus on other diseases (e.g. thyroid, pituitary) [36]. As recently reported by Oser et al., more than 75% of US counties have no endocrinologists; whereas 96% of US counties have at least one primary care physician [37]. Moreover, the shortage of endocrinologists is an increasing concern nationwide will make it increasingly difficult for PwD to receive care from an endocrinologist. It has been predicted that the shortage of adult endocrinologists will increase to ~ 2700 by 2025 [38]. Access to specialists and newer diabetes medications can also by impacted by socioeconomic status. In interviews with 28 T1D patients and six healthcare providers, Scott et al. found that PwD from lower socioeconomic areas were unable to access hospital-based services because they lacked the ability to navigate the healthcare system [39].

3.5. Cost

The cost of insulin pump therapy remains a major barrier for many individuals with diabetes [26], particularly in those of lower socioeconomic status or on fixed incomes. This is particularly relevant to those enrolled in Medicare, the US federal health insurance program that covers primarily people 65 years of age or older. As reported in a recent article by Aleppo et al., Medicare coverage eligibility criteria for insulin conventional pumps are also restrictive, creating barriers to beneficiaries who could benefit [40]. However, unlike conventional insulin pumps, which are covered by Medicare Part B as durable medical equipment, disposable tubeless insulin delivery devices are covered by Medicare Part D.

Coverage policies for insulin pumps under Medicaid, the US joint federal and state health care program for low-income individuals, vary by state [41]. According to a 2022 report, among the 40 US States and the District of Columbia that provide coverage, 20 cover CGMs as a durable medical equipment (DME) benefit and 21 cover CGMs as a pharmacy benefit [41]. Although commercial healthcare coverage of diabetes technologies, in general, is more prevalent than with public insurers, many commercial insurers follow the same eligibility criteria as Medicare.

3.6. Time/resource constraints

Incorporating devices such as insulin pumps into clinical practices requires practices to establish a multidisciplinary team of diabetes specialists who are trained in the functionality and limitation of all current insulin pump systems and can deliver comprehensive training/education to PwD. Importantly, team members must have expertise in interpreting the data and making appropriate treatment adjustments [42]. While many endocrinology practices are staffed to provide this level of care and expertise, most primary care practices are not.

In a survey by Grunberger et al., 202 clinicians (primary care, $n = 102$; endocrinology, $n = 100$) ranked the major barriers to using insulin pumps in their patients with T2D [2]. Investigators administered a 7-item questionnaire that queried participants about their current practices, comfort level, and perspectives on use of diabetes technologies. The possible weighted rank score ranged from 4.04 to 48.48. Identified barriers with the highest weighted-rank scores were complexity of the device (16.12), extra office time requirement (14.27), difficulty in training/monitoring PwD (14.24), patient acceptance (13.79), and extra resources requirement (13.19).

3.7. Experience with insulin pumps in primary care

Among many primary care providers, inexperience with insulin pumps and other diabetes devices is a key obstacle to adopting these technologies in their practices. A recent study by O'Donovan et al. assessed the willingness of primary care physicians to prescribe advanced diabetes technologies through a cross-sectional survey of 76 PCPs from 4 geographically diverse centers [43]. Participants included 45 (63%) physicians, 22 (31%) residents, 4 (6%) nurse practitioners, and 1 (1%) clinical pharmacist. The majority (88%) of respondents reported being uncomfortable initiating (88%) or adjusting (89%) conventional insulin pump therapy for PwD withT2D.

In a survey of 41 rural clinic healthcare providers in the northeast US is only 47.4% reported that they use any diabetes devices, citing the need for additional medical team expertise in order to adopt insulin pumps and/or CGMs [44]. Investigators concluded that lack of experience among providers and having PwD managed remotely by out-of-area specialists were the main reasons for not using diabetes devices.

4. Tubeless insulin delivery devices address the barriers inherent to conventional insulin pumps

4.1. Simpler technology

Because use of insulin pumps can mitigate many of the obstacles associated with MDI therapy while improving clinical and economic outcomes, an increasing number of individuals with T2D are using this technology, and the first pumps designed specifically for this population are now available [45]. Moreover, these new devices may be extremely valuable in transitioning PwD treated with basal insulin to basal-bolus therapy.

A key contributor to many T2D patients' dissatisfaction and frustration with conventional insulin pumps is the inclusion of advanced features that enable PwD to utilize multiple bolus insulin configurations and basal infusion rates. Although these features can be extremely useful for individuals with T1D, they add a level of complexity that is often unnecessary for effective management of T2D [46]. Many T2D patients can achieve good glycemic control with only one or two daily basal rates [47].

Tubeless insulin delivery devices represent a new generation of insulin delivery technologies. Currently there are three categories of these devices available in the US market: wearable patch (e.g. CeQur Simplicity™), once-daily wearable (e.g. V-GO®), and tubeless insulin pump devices (Omnipod DASH®, Omnipod® 5). These devices attach directly to the skin without external tubing; insulin is infused through a short canula into the interstitial tissue [48]. Some of these devices use prefilled insulin cartridges such as the battery-operated Sigi™ patch device (currently under development) [49]; however, most require users to manually fill the insulin reservoir.

The on-body tubeless devices are available with varying features and functionalities. Devices, such as the CeQur Simplicity (US) and PaQ (Europe) devices, are fully mechanical and used mainly as a replacement for insulin pen therapy. Users manually administer their insulin by using buttons located on the device to deliver rapid-acting analog for mealtime coverage and correction dosages; however, injections are still required for basal insulin coverage. The spring-operated V-Go delivery systems (Mannkind Corporation) are fully disposable and are available with pre-set 20 unit, 30 unit, and 40 unit basal dosing capability per day with an additional 36-unit reservoir on all 3 devices for manual, on-demand bolus dosing in 2-unit increments per 24-hour periods. The Omnipod Dash system is simply sensor augmented, whereas the Omnipod 5 Automated Insulin Delivery system (Insulet Corporation) automatically adjusts insulin infusion based on CGM data, residual insulin, and other inputs. Both systems enable users to program their bolus dosages and basal insulin infusion rates, utilizing a separate hand-held controller to deliver the insulin and provide information about 'insulin-on-board' to help users avoid unsafe correction bolusing. With the Omnipod 5, infusion of basal can be automatically delivered based on CGM data from the sensor. However, administration of both prandial and correction bolus doses must be programmed by the user. Similar to conventional insulin pumps, full set-up of infusion rates is required.

Among the key advantages to tubeless devices is that they eliminate potential risks of tubing kinks or dislocation, which can interrupt insulin delivery [50]. Another advantage is ease of use and simple handling [26], which, in turn, simplifies education and training [51]. Because the devices are smaller than conventional insulin pumps and can be worn under clothing [26], insulin administration is discreet. Moreover, tubeless devices are often less costly than conventional pumps [45,51].

However, there are disadvantages that should be considered. Unlike conventional insulin pumps, simplified tubeless devices might not be able to track insulin-on-board, which can lead to 'stacking' of correction insulin doses and the potential for hypoglycemia [45]. Also, because some simplified devices require users to push one or two buttons to administer their bolus doses, there is the possibility that they could lose track of the amount of insulin being delivered [52]. Inaccuracies in insulin delivery have been reported in some full feature tubeless devices, particularly at low insulin doses [53]. Because the infusion site is not visible, users are not able to see if the cannula has dislodged and infection may not be readily detected [54]. Unlike conventional insulin pumps, the tubeless devices can be worn when exercising, swimming or showering. However, if they are removed for any reason, they must be replaced with a fresh device, and any remaining insulin is wasted whenever the device is changed [55]. Also, as with conventional insulin pumps, there is the possibility the device can become dislocated from the infusion site, and skin problems such as inflammation or allergic contact dermatitis due to either the insertion or the adhesive fixing of the device can occur. Many PwD use protective tapes or glues under the device to prevent skin reactions [56].

4.2. Significant advantages over MDI

Studies have consistently shown significant advantages of tubeless insulin delivery devices over MDI therapy, including improved glycemic control [57–66], reductions in total daily insulin doses (TDD) [56–60,65], reductions in frequency and severity of hypoglycemia [64], greater treatment satisfaction and reduced diabetes burden [57,64,67,68], and cost savings [57–59,65,68] (Table 1).

Both single-arm and comparative studies demonstrated that use of tubeless devices resulted in significant improvements in HbA1c, ranging from −0.64% [60] to −1.98% [59], with significant reductions in TDD [57,59,65,66,71] Although some studies have concluded that the cost of tubeless devices tends to be higher than MDI therapy [45,72], use of some devices (e.g. the V-Go device) were associated with significant cost-savings [59,66].

In a prospective, pragmatic trial that evaluated use of the V-Go device in 169 T2D adults, Cziraky et al. reported reductions in cost per day (p=0.006) among V-Go users ($30.59) compared with PwD treated with MDI ($32.20) [70]. V-Go use also show greater cost-effectiveness per 1.0% reduction in HbA1c ($24.02 vs. $58.86, respectively).

Importantly, notable improvements in treatment satisfaction and PwD acceptance of tubeless devices were observed in many of the studies [61,68,71]. Survey results associated with the CeQur Simplicity tubeless insulin delivery device showed significant increases in respondents' overall treatment satisfaction, less diabetes burden, and improvements in psychological well-being compared with their prior insulin delivery method [68].

Additionally, results from a retrospective study of 3,592 T2D adults revealed distinct differences between prior MDI and conventional pump users regarding their reasons for switching to a tubeless device (Omnipod/Omnipod DASH) [71]. Among the most common reasons from switching to the tubeless device reported by participants were 'better glycemic control' (25%), 'did not want to be tethered to tubing' (24%), 'replace the discomfort and hassle of injecting' 16%), and 'replace MDI and provide greater flexibility in eating and exercise' (12%). Clinicians may find these findings useful when discussing use of this technology with their PwD.

5. Summary

Although use of MDI is the most common insulin delivery method in T2D patients who are treated with basal-bolus therapy, adherence and persistency to therapy is often

Table 1. Recent studies of on body insulin delivery device and tubeless insulin pump therapy in T2D.

Patch Pump System (Author & Publication Year)	Study Design (Type, Duration, Comparison Groups)	Study Population (n, Mean Baseline Demographics)	Outcome Measures	Results
V-Go Lajara 2015 [57]	Retrospective 27 weeks T2D Switched to Tubeless pump from MDI	n = 204 HbA1c 9.63% TDD 78 ± 46	HbA1c TDD	−1.53% HbA1c change at 14 weeks, $p < 0.001$ −1.79% HbA1c change at 27 weeks, $p < 0.001$ −28 U to −41 U TDD change at 27 weeks
V-Go Lajara 2016 [59]	Retrospective (medical records) 27 weeks T2D Tubeless pump vs. MDI	n = 116 HbA1c: 10.51%	HbA1c TDD Cost (PPPM, PPPQ)	Greater HbA1c reduction: V-Go vs. MDI: • -1.98% vs −1.34%, $p = 020$ Less TDD: V-Go vs. MDI: • 56 ± 17 U vs 78 ± 40 U, $p<0.001$ Lower diabetes-related direct pharmacy costs and cost inferential per 1% HbA1c reduction: V-Go vs. MDI $118.84±$158.55 PPPM vs $217.16±$251.66 PPPM
V-Go Sutton 2016 [66]	Retrospective 14 months T2D Switched to Tubeless pump from MDI	*n*=103 HbA1c 8.6%	HbA1c TDD Cost (PPPM)	−1.67% HbA1c change, $p<0.001$ −30 U TDD change, $p<0.001$ Direct pharmacy wholesale acquisition costs for diabetes therapeutics reduced by $25.00/PwD/month
V-Go Wahlqvist 2018 [69]	Simulation model analysis T1D V-Go vs. MDI Over 40 years	*n*= 331 HbA1c 8.0% to 12.0%	QALY Life-time, per-PwD costs	0.17 QALYs gained per PwD compared with MDI $66,883 lifetime cost-savings
V-Go Cziraky 2019 [70]	Prospective pragmatic clinical trial T2D V-Go vs. Standard Care (SC) Up to 4 months	*n*=415 HbA1c 9.6%	HbA1c Cost of therapy	V-Go: −1.0%, $p<.001$ SC: −0.5%, $p<.001$ V-Go had significantly larger decrease ($p=.002$) Cost per day: V-Go vs. SC ($30.59 vs. $32.20 Cost effectiveness per 1.0% HbA1c: V-Go vs. SC ($24.02 vs. $58.86)
V-Go Grunberger 2020 [61]	Prospective, open-label, multicenter 12 months T2D Switched to Tubeless pump from: OADs; OADs+non-insulin injectable; Premix insulins injections± OADs/non-insulin injectable; or MDI	*n*=112 HbA1c 8.88%	HbA1c Hypoglycemia Tx Satisfaction	−0.64% HbA1c change, $p=0.003$ 22 PwD reported a hypoglycemic event (≤70 mg/dL); hypoglycemic event rate: 1.51 events/year Treatment satisfaction (1=low, 10=high): • Comfort − 7.9 • Discreet − 8.4 • Physical Well-being − 7.8 • Mental Well-being − 8.1 • Ease of use compared to previous therapy − 8.7
CeQur Mader 2018 [64]	Prospective, open-label, non-controlled 12 weeks T2D Switched to Tubeless pump from MDI (bolus dosing)	*n*=28 HbA1c 8.6%	HbA1c Hypoglycemia (≤70 mg/dL) Tx Satisfaction (DTSQ)	−1.4% HbA1c change, $p<0.0001$ Hypoglycemia rate (episodes per 30 days) increased from 1.1 to 2.1 DTSQ total score increased from 29.18 to 33.30, $p=0.0051$

(*Continued*)

Table 1. (Continued).

Patch Pump System (Author & Publication Year)	Study Design (Type, Duration, Comparison Groups)	Study Population (n, Mean Baseline Demographics)	Outcome Measures	Results
CeQur Isaacs 2022 [68]	Online Survey T1D, T2D Switched to Tubeless pump from: Syringe; Pen; Pump; or Inhaler	*N*=106 (T1D, *n*=27; T2D, *n*=74; Not sure, *n*=2; Other, *n*=3)	Satisfaction (Insulin Delivery System Rating Questionnaire [IDSRQ])	Significant improvements in all IDSRQ subscales: • Insulin delivery method satisfaction: 1.32, $p<0.05$ • Interference with activities: −0.71, $p<0.05$ • Clinical outcomes: 1.38, $p<0.05$ • Diabetes-related worry: −0.91, $p<0.05$ Psychological well-being: 0.60, $p<0.05$
Omnipod Layne 2018 [65]	Multicenter, retrospective 3 months Switched to Tubeless pump from MDI	*n*=81 HbA1c 9.1±1.5% TDD 100.2 U	HbA1c TDD Hypoglycemia	−1.2% HbA1c change, $p<0.001$ −27.6 U TDD change. $p=0.001$ −42.2% change in weekly hypoglycemic events
Omnipod Carlson 2021 [71]	Retrospective, observational 3 months T2D Switched to Tubeless pump from: MDI; or Conventional Insulin Pump	*n*=3,592 HbA1c 9.2±2.0% TDD 104±71U	HbA1c TDD Hypoglycemia (<70 mg/dL) PRO (*n*=2,028)	−1.3% HbA1c change −33±52 U TDD change Reductions in Hypoglycemic Events: from 1.2±2.0 to 0.7±1.1, $p<0.0001$ PRO – Reasons for switching to Tubeless device: Prior MDI users (*n*=1,516): • 'Better glycemic control' – 25% • 'Did not want to be tethered to tubing' – 24% • 'Replace discomfort and hassle of injecting' – 16% • 'Replace MDI and provide greater flexibility in eating/exercise' – 12% Prior Convention Pump users (*n*=349): • 'Did not want to be tethered to tubing' – 32% • 'Ability to wear it in various places' – 16% • 'Wanted a waterproof pump' – 12%

DTSQ=Diabetes Treatment Satisfaction Questionnaire; IDSQR=Delivery System Rating Questionnaire; OADs=oral antihyperglycemic drugs; PPPM=per patient per month; PPPQ=per patient per quarter; PRO=person-reported outcomes; TDD=total daily insulin doses.

suboptimal and can result in poor outcomes, higher costs and increased healthcare resource utilization [73,74]. The complexity of MDI therapy has been shown to be a key contributor to poor adherence, which, in turn, correlates with PwD perceptions of regimen inflexibility and a burden on daily life [11]. While use of conventional insulin pumps in this T2D population provides significantly better glycemic control compared to MDI therapy [22–24]; many PwD and their healthcare providers are still reluctant to utilize this technology due to several factors, including an unwillingness to be tethered to a device, hinderance of daily activities, social stigma, device complexity, and training requirements [75].

The concept behind tubeless insulin delivery devices is to provide intensively treated T2D patients with a safe, effective, and easy to use alternative to MDI and conventional insulin pump therapy. Recent studies have clearly demonstrated statistically significant reductions in HbA1c and TDD [57,59,61,64,66,71], with increased treatment satisfaction and notable PwD acceptance [61,68,71]. Moreover, reductions in TDD [57,59,65,66,71] and reported cost-savings associated with tubeless devices [59,66] may support greater acceptance of this technology among payers.

Most commercial insurers are beginning to recognize the clinical and economic benefits of tubeless devices in the T2D population; however, Medicaid coverage remains suboptimal. It is well understood that lower socioeconomic status is a strong predictor for the development of diabetes, diabetes-related complications, and mortality [76]. Moreover, a recent US population-based analysis found that Black PwD had lower odds of achieving a composite diabetes quality score than White PwD [77], which further supports the impact of racial disparities in diabetes management. Therefore, it is important that Medicaid reconsider and standardize eligibility criteria for coverage of all insulin delivery technologies and make them available for all patients who would benefit.

However, expanding access and coverage is only part of the solution. Industry needs to focus its efforts on developing more insulin delivery devices that are even less-complex and more affordable to address the specific needs of individuals with T2D and their prescribers. Moreover, because one of the main obstacles to greater adoption of these diabetes technologies is lack of clinician training and education, industry needs to provide educational resources to make it easier for healthcare providers to learn about the advantages and limitations of these technologies, become proficient in their use, understand both the benefits and barriers, and how to effectively convey this information to PwD. Given the ever-increasing prevalence of diabetes and its associated costs, companies that are investing in the development of innovative diabetes technologies need to dedicate financial and human resources for making both healthcare providers and their PwD aware of the benefits of these technologies.

Declaration of financial/other relationships

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