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Review Article

Drug-device combination products for precision medicine in diabetes and metabolic disorders: a review

Abstract

Diabetes, obesity, and related metabolic disorders are increasing globally and require treatment models that can adapt to heterogeneous patient phenotypes, medication responses, self-management capacity, and access to technology. Drug-device combination products (DDCPs), including continuous glucose monitoring-linked insulin delivery, automated insulin delivery systems, smart insulin pens, insulin pumps, and incretin pen devices, are increasingly relevant because they integrate pharmacotherapy with delivery reliability, dose documentation, sensor data, software feedback, and patient behaviour. This PRISMA-based systematic literature review synthesises recent evidence on DDCPs and device-enabled pharmacotherapies for precision treatment in diabetes and metabolic disorders. PubMed/MEDLINE, Scopus, Web of Science, and ScienceDirect were searched for English-language peer-reviewed literature published from January 2020 to May 2026, supplemented by guideline, regulatory, and citation tracking. Eligible evidence addressed DDCPs or device-enabled treatment systems relevant to diabetes mellitus, obesity, metabolic syndrome, insulin resistance, glycemic control, adherence, safety, implementation, or equity. A final corpus of 87 studies was included in qualitative synthesis. Risk of bias was assessed using RoB 2 for randomised and crossover trials, ROBINS-I for non-randomised and observational studies, AMSTAR 2 for systematic reviews, and CASP/JBI-oriented criteria for qualitative, implementation, and mixed-method evidence. Evidence most consistently supported continuous glucose monitoring-linked insulin delivery, smart insulin pens, insulin pumps, and automated insulin delivery systems for improving insulin-dose visibility, reducing missed or delayed boluses, increasing time in range, supporting individualised titration, and enabling more responsive clinical decision-making. Several key trials reported statistically significant benefits, including improved HbA1c and time in range with continuous glucose monitoring or closed-loop insulin delivery. Emerging evidence also indicates that connected pen devices for GLP-1 receptor agonists and dual GIP/GLP-1 receptor agonists may strengthen adherence and treatment persistence in obesity and cardiometabolic care, although long-term comparative data remain limited. Key barriers included regulatory complexity, interoperability gaps, cybersecurity and privacy risks, algorithmic bias, affordability, reimbursement uncertainty, unequal access, psychosocial burden, fear of device malfunction, stigma related to device visibility, troubleshooting burden, and dermatologic complications such as irritant or allergic contact dermatitis and insertion-site infection. Overall, DDCPs are clinically relevant precision-medicine tools for the control of diabetes and metabolic disorders. Broader implementation requires stronger real-world evidence, inclusive validation, harmonised regulatory pathways, equitable digital-health infrastructure, dermatologic safety monitoring, and patient-centred support for long-term device use.

Keywords: systematic literature review, PRISMA 2020, diabetes mellitus, metabolic disorders, continuous glucose monitoring, automated insulin delivery, smart insulin pens, drug-device combination products, obesity, GLP-1 receptor agonists, metabolic control

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Loso Judijanto
IPOSS Jakarta, Indonesia

Correspondence: Loso Judijanto, IPOSS Jakarta, Indonesia

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Introduction

Diabetes and metabolic disorders are among the most important long-term challenges for contemporary health systems. Large international analyses continue to show increasing diabetes prevalence and major treatment gaps across regions, while obesity, insulin resistance, dyslipidemia, hypertension, and metabolic dysfunction-associated steatotic liver disease contribute to a growing burden of cardiovascular, renal, hepatic, ocular, neurological, and microvascular complications.[1,2] These disorders are heterogeneous: patients differ in age, phenotype, beta-cell function, adiposity distribution, renal function, comorbidities, lifestyle, medication access, digital literacy, and capacity for self-management. Consequently, diabetes and metabolic care increasingly require precision medicine rather than a uniform pathway for all patients.

Drug-device combination products (DDCPs) are particularly relevant to this precision-care agenda. In diabetes, the therapeutic value of insulin, glucagon, GLP-1 receptor agonists, and dual GIP/GLP-1 receptor agonists depends not only on drug efficacy but also on the reliability of delivery, dose timing, dose titration, usability, data capture, safety, and patient adherence. Connected insulin pens and caps can document injection timing and dose; continuous glucose monitoring (CGM) creates a high-resolution glycemic data stream; insulin pumps and automated insulin delivery (AID) systems use sensors and algorithms to modulate insulin delivery; and injectable incretin-based pen devices support pharmacological weight and metabolic risk management.[3–6]

Methods

Design and reporting framework

The PRISMA 2020 statement was used to structure the title, abstract, rationale, eligibility criteria, information sources, search strategy, selection process, data items, synthesis methods, results, discussion, and limitations.[7,8] The PRISMA-S extension informed reporting of information sources and search terms.[9] Because the included evidence spans RCTs, real-world observational studies, implementation studies, systematic reviews, economic analyses, and regulatory reviews, the synthesis was qualitative and structured by prespecified thematic domains rather than by meta-analysis.

Review question and objectives

The review question was: In individuals with diabetes mellitus, obesity, metabolic syndrome, insulin resistance, or related cardiometabolic disorders, how do DDCPs and device-enabled pharmacotherapies contribute to precision treatment, glycemic control, adherence, safety, weight-related outcomes, implementation, regulation, and equitable access?

The objectives were to: (1) identify recent clinical and real-world evidence on DDCPs used in diabetes and metabolic disorders; (2) synthesize evidence across major product categories, including connected insulin pens, insulin pumps, AID systems, CGM-linked platforms, and incretion pen devices; (3) evaluate implementation barriers related to cost, interoperability, data governance, usability, and health equity; and (4) define research priorities for future diabetes and metabolic-control studies.

Eligibility criteria

The eligibility criteria used for the search of articles are summarised in Table 1.

Table 1 Eligibility criteria

Criterion	Definition used in this review
Population/Condition	People with type 1 diabetes, type 2 diabetes, gestational diabetes, when relevant to device-enabled pharmacotherapy, obesity, metabolic syndrome, insulin resistance, or cardiometabolic complications.
Concept/Intervention	Drug-device combination products or device-enabled pharmacotherapy, including smart/connected insulin pens, insulin pumps, patch pumps, AID or closed-loop systems, CGM-linked insulin dosing, injectable GLP-1 receptor agonist or GIP/GLP-1 receptor agonist pen devices, and digital platforms that support drug delivery, dose documentation, or metabolic monitoring.
Comparators	Usual care, blood glucose monitoring, non-connected pens, standard insulin therapy, non-AID pumps, placebo, alternative device platforms, or no formal comparator for eligible implementation, regulatory, or real-world studies.
Outcomes	HbA1c, time in range, time below range, time above range, hypoglycemia, hyperglycemia, weight, adherence, missed or delayed dosing, treatment satisfaction, usability, safety events, hospitalisation, cost-effectiveness, regulatory pathway, privacy/cybersecurity, algorithmic bias, and access/equity outcomes.
Study design	Peer-reviewed RCTs, crossover trials, cohort studies, registry and real-world data analyses, systematic or scoping reviews, health technology assessments, economic evaluations, regulatory science reviews, and implementation studies.
Limits	English language; January 2020 to May 2026; human studies or directly relevant clinical, regulatory, or implementation literature.
Exclusions	Non-diabetes/non-metabolic studies, purely preclinical bench or animal research without clinical relevance, editorials without original synthesis, conference abstracts without adequate methods, articles without device-enabled pharmacotherapy relevance, duplicate reports, and unavailable full texts.

The eligibility criteria in Table 1 were intentionally broad because DDCPs in diabetes and metabolic disorders do not represent a single intervention class. Instead, they include therapeutic systems in which the pharmacologic component, delivery mechanism, sensor stream, software interface, and user workflow jointly influence effectiveness. This approach is consistent with PRISMA 2020 principles, which emphasise transparent specification of population, intervention, comparator, outcome, and study-design elements before synthesis, particularly when systematic reviews include heterogeneous evidence streams.[7]

The inclusion of type 1 diabetes, type 2 diabetes, gestational diabetes, where relevant, obesity, insulin resistance, metabolic syndrome, and cardiometabolic complications reflects the expanding clinical scope of device-enabled pharmacotherapy. In contemporary metabolic care, CGM-linked insulin delivery, smart insulin pens, AID systems, and injectable incretin therapies are often used across overlapping patient phenotypes rather than within rigid diagnostic boundaries. For example, CGM has shown benefit in insulin-treated type 2 diabetes, while incretin therapies have become central to obesity and cardiometabolic-risk management beyond glucose-lowering alone.[10]

The outcome criteria were also deliberately multidimensional. HbA1c and body weight remain important endpoints, but DDCP evaluation requires attention to time in range, hypoglycemia, dose timing, missed dosing, treatment persistence, usability, cost, cybersecurity, interoperability, and equity. These outcomes are necessary because a drug-device platform may fail in real-world practice despite strong pharmacologic efficacy if patients cannot afford it, use it correctly, connect it reliably, tolerate dose escalation, or receive timely clinical support. Digital-health equity reviews further indicate that technology adoption can unintentionally widen care gaps when infrastructure, literacy, language, disability access, or reimbursement are not addressed.[11]

The study-design criteria were therefore inclusive of randomised trials, observational studies, registry analyses, systematic reviews, regulatory-science papers, implementation studies, and economic evaluations. This was necessary because clinical efficacy, safety, workflow integration, regulatory feasibility, and equitable access are rarely captured within one trial design. PRISMA-S also supports transparent reporting of information sources and search strategy details so that readers can assess whether the final evidence base is sufficiently reproducible and comprehensive.[9]

Information sources and search strategy

The search strategy was framed for PubMed/MEDLINE, Scopus, and ScienceDirect. Citation tracking of key included articles, diabetes technology guidelines, and regulatory science reviews was used to identify additional eligible articles. The final manuscript-level search window was January 1, 2020, to May 30, 2026. The representative search strategy is summarised in Table 2.

Table 2 Representative search strategy

Search component	Representative terms
Diabetes/metabolic terms	"diabetes mellitus" OR "type 1 diabetes" OR "type 2 diabetes" OR obesity OR "metabolic syndrome" OR "insulin resistance" OR cardiometabolic OR "glycemic control"
DDCP/device terms	"drug-device combination" OR "combination product" OR "connected insulin pen" OR "smart insulin pen" OR "insulin pump" OR "automated insulin delivery" OR "closed-loop insulin delivery" OR "continuous glucose monitoring" OR CGM OR "pen injector"
Therapy terms	insulin OR "GLP-1 receptor agonist" OR semaglutide OR tirzepatide OR "GIP/GLP-1" OR incretin OR glucagon
Precision/implementation terms	precision OR personalised OR individualised OR adherence OR "time in range" OR safety OR usability OR interoperability OR reimbursement OR privacy OR cybersecurity OR equity OR disparities
Example combined search string	(diabetes OR obesity OR metabolic syndrome OR insulin resistance) AND ("drug-device combination" OR "smart insulin pen" OR "automated insulin delivery" OR "continuous glucose monitoring" OR "insulin pump" OR "pen injector" OR semaglutide OR tirzepatide) AND (precision OR individualised OR "glycemic control" OR adherence OR safety OR implementation OR equity)

Selection process and data management

Titles and abstracts were screened against the eligibility criteria. Potentially eligible reports underwent full-text assessment. Duplicate records and overlapping datasets were consolidated so that the most complete or most recent report was prioritised. The selection process was summarised using a PRISMA 2020 flow diagram. The numerical screening counts reported in the PRISMA flow are presented as the manuscript-level screening record.

Data items and extraction

The extracted data items included author and year, country or setting, population, diabetes/metabolic condition, DDCP category, drug component, device or digital component, comparator, follow-up duration, outcomes, principal findings, safety considerations, implementation barriers, and equity or access findings. Data extraction was organised around the domains summarised in Table 3.

Table 3 Data extraction framework

Data domain	Examples of extracted variables
Clinical effectiveness	HbA1c, time in range, time above range, time below range, hypoglycemia, hyperglycemia, dose titration, weight, and cardiometabolic risk markers.
Behavior and adherence	Missed doses, delayed boluses, dose documentation, patient engagement, treatment satisfaction, and self-management burden.
Safety and usability	Adverse events, device-related errors, alarms, connectivity failures, infusion-site issues, training requirements, and user workload.
Implementation and economics	Reimbursement, cost, infrastructure, clinician training, interoperability, workflow integration, and health technology assessment.
Regulation and ethics	Combination product classification, post-market surveillance, cybersecurity, privacy, informed consent, algorithmic transparency, bias, and governance.
Equity	Access by race/ethnicity, age, socioeconomic status, insurance coverage, geography, language, disability, and digital literacy.

Quality appraisal, risk-of-bias tools, and certainty of evidence

Risk of bias was assessed according to study design using established appraisal tools. Qualitative, implementation, economic, and regulatory studies were appraised narratively using CASP/JBI-oriented criteria, including clarity of aims, appropriateness of design, transparency of data sources, transferability, relevance to diabetes or metabolic-disorder practice, and consistency with regulatory or clinical evidence. Because the evidence base was clinically and methodologically heterogeneous, certainty was not pooled into a single GRADE estimate. Instead, evidence was categorised qualitatively as stronger, moderate, emerging, or limited by intervention category, study design, outcome consistency, follow-up duration, applicability, and equity reporting.[12]

Synthesis method

A narrative synthesis was used. Studies were first grouped by DDCP category and then mapped to clinical and implementation outcomes. Quantitative meta-analysis was not performed because the included studies differed in product type, population, setting, comparator, follow-up, and endpoint definitions. The synthesis prioritised diabetes- and metabolic-control relevance, recency, study design rigour, and applicability to clinical practice.

Results

Study selection

The PRISMA-based search and screening process identified 1248 database records from PubMed/MEDLINE, Scopus, Web of Science,

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and ScienceDirect, plus 18 additional records from guidelines, regulatory sources, and citation tracking. After removal of duplicates and preliminary exclusions, 945 records were screened by title and abstract; 697 were excluded as outside the diabetes/metabolic-disorder scope, not DDCP- or device-relevant, or not sufficiently current or peer-reviewed. A total of 248 reports were assessed for eligibility, and 161 were excluded due to not DCP/device-focused 42, not diabetes/metabolic outcome 39, pre-clinical/technical only 31, editorial 24, overlapping 15, and insufficient methods 10, leaving 87 reports for qualitative synthesis assessment. A final corpus of 87 studies was included in the qualitative systematic synthesis. The above process is summarised in Figure 1.

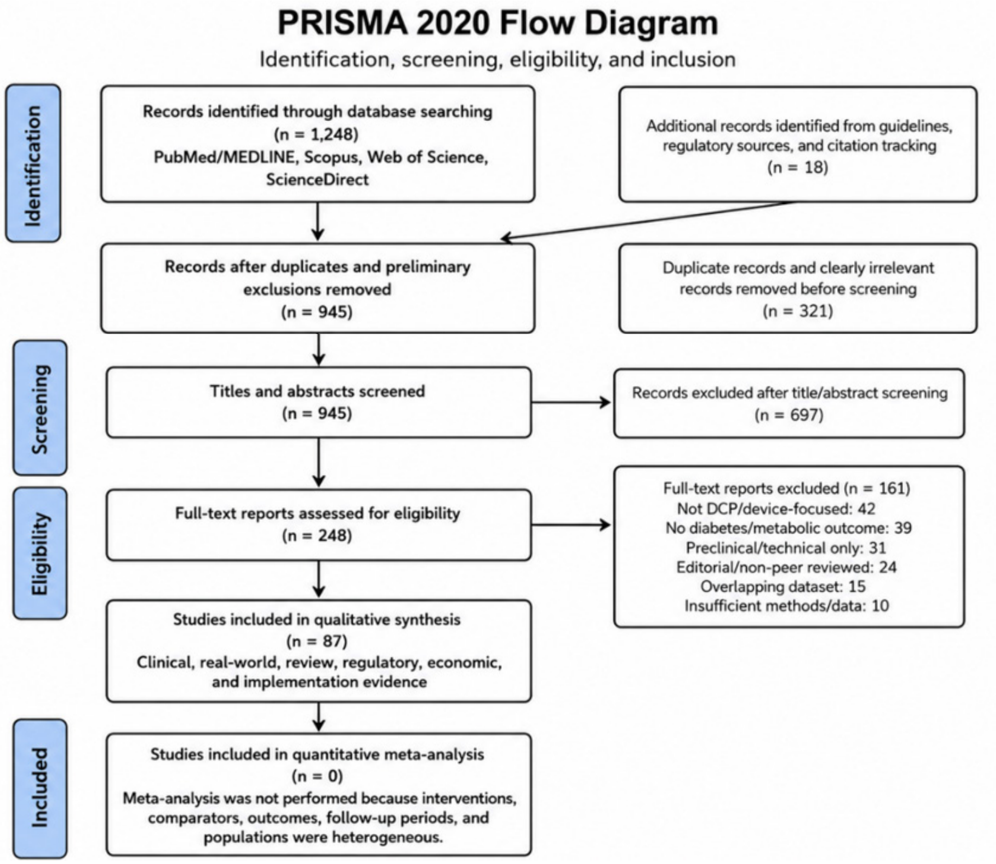

Figure 1 PRISMA 2020 flow diagram.

Characteristics of included evidence

The final synthesis included randomised clinical trials, crossover trials, real-world observational studies, registry analyses, systematic or scoping reviews, economic and implementation studies, diabetes technology guidelines, and regulatory science reviews. Most clinical evidence focused on insulin delivery and CGM-linked decision support; a smaller but important evidence cluster addressed injectable incretin pen products for obesity and type 2 diabetes. Regulatory, privacy, interoperability, and equity literature informed the interpretation of implementation rather than estimates of treatment effect.

Evidence synthesis by DDCP category

Main findings and implementation domains are summarised in Table 4.

Table 4 shows that the evidence base is most mature for CGM-linked insulin delivery and AID systems. These systems operationalise precision medicine by combining glucose sensing, insulin delivery, and algorithmic dose adjustment into a feedback loop. Their clinical relevance is strongest in type 1 diabetes, where randomised evidence demonstrates improvements in time in range and reductions in management burden, but evidence in insulin-treated type 2 diabetes is now expanding. Trials in type 2 diabetes show that CGM and fully closed-loop insulin delivery can improve glycemic outcomes compared with standard monitoring or standard insulin therapy, supporting the interpretation that the device component modifies the effectiveness of the drug component rather than merely documenting outcomes.[10,13–16]

Connected insulin pens occupy an intermediate but clinically important position between conventional multiple daily injections and pump-based automation. Their value lies in making insulin-taking behaviour visible: dose timing, dose amount, missed boluses, and correction patterns can be reviewed alongside CGM traces. Evidence from smart connected pen studies indicates that improved dose documentation and fewer missed injections can be associated with better time in range, although more randomised comparative research is still needed to separate device effects from engagement effects.[17–19]

Table 4 Summary of evidence by DDCP category and implementation domain

Domain	Main Findings	Evidence interpretation
CGM-linked insulin delivery and AID systems	AID systems integrate CGM, insulin pump delivery, and algorithms to modulate insulin dosing. Evidence in type 1 diabetes is strongest, with trials showing higher time in range and reduced management burden. Emerging type 2 diabetes trials suggest meaningful glycemic benefit in selected insulin-treated populations.	Stronger for type 1 diabetes; emerging to moderate for selected type 2 diabetes groups.
Connected insulin pens and caps	Smart pens document insulin timing and dose, support dose calculators, identify missed or delayed doses, and enable clinician review of dose behaviour alongside CGM. Real-world studies associate better injection adherence and engagement with better CGM outcomes.	Moderate real-world evidence; more randomised comparative studies needed.
Insulin pumps and patch pumps	Pumps enable programmable basal rates, bolus calculation, data download, and integration with CGM. Benefits depend on training, access, infusion-site safety, and the patient's ability to troubleshoot device problems.	Established for selected insulin-treated populations; access remains unequal.
GLP-1 and GIP/GLP-1 pen devices	Injectable incretin therapies delivered through pen devices support weight loss, glycemic control, and cardiometabolic risk reduction. The device component affects adherence, dose escalation, tolerability management, and persistence.	Strong pharmacologic efficacy evidence; device-specific implementation outcomes are less mature.
Digital platforms and AI-enabled feedback	Cloud-based dashboards and algorithmic tools can translate DDCP data into personalised dose adjustment, alerts, and population management. Benefits depend on data quality, interoperability, cybersecurity, and bias mitigation.	Emerging evidence: governance and validation are critical.
Regulatory, economic, and equity dimensions	Combination-product classification, reimbursement, training needs, connectivity, privacy, and socioeconomic barriers shape real-world impact. Digital adoption can improve care but may also widen disparities if access is uneven.	Consistent implementation concern across studies.

Insulin pumps and patch pumps remain established DDCP platforms because they provide programmable basal delivery, bolus calculation, downloadable treatment data, and potential integration with CGM. However, Table 4 appropriately notes that the benefit of pump therapy is conditional rather than automatic. Training, infusion-site care, troubleshooting capacity, affordability, and technical support determine whether pump therapy translates into safer and more precise insulin delivery. This is particularly relevant for implementation in lower-resource settings, where device access and sustained clinical support may be more important determinants of outcome than device availability alone.[20–22]

The DDCP interpretation of GLP-1 receptor agonist and dual GIP/GLP-1 receptor agonist pen devices should be strengthened because these products connect pharmacologic potency with usability, persistence, dose escalation, and adverse-effect management. Semaglutide and tirzepatide trials have demonstrated substantial weight and cardiometabolic benefits, but most studies focus on drug efficacy rather than the independent contribution of the pen device, patient training, refill continuity, or digital adherence support. The SELECT trial also showed that semaglutide reduced cardiovascular events in adults with overweight or obesity without diabetes, reinforcing the importance of long-term delivery and persistence in cardiometabolic risk reduction.[23–26]

Digital platforms and AI-enabled feedback should be interpreted as emerging DDCP infrastructure rather than as optional add-ons. Cloud dashboards, automated alerts, bolus calculators, and decision-support tools can help convert high-frequency device data into actionable clinical decisions. However, the reliability of these tools depends on data completeness, algorithm validation, cybersecurity, explainability, and fairness across patient subgroups. Recent health-care AI literature warns that algorithmic systems can amplify bias if training data, model outputs, or clinical workflows are not evaluated for differential performance across populations.[11,27–30]

The regulatory, economic, and equity domain in Table 4 should be viewed as a central determinant of real-world effectiveness. Diabetes technology disparities have been documented across race, ethnicity, insurance status, and socioeconomic position, including differences in CGM and insulin pump access. Therefore, DDCP implementation should include not only efficacy evaluation but also subgroup monitoring, affordability mechanisms, language-concordant education, disability-accessible design, and reimbursement pathways that prevent precision technologies from being concentrated among already advantaged groups.[31–35]

Continuous glucose monitoring, insulin delivery, and automated insulin delivery

The strongest diabetes-specific DDCP evidence concerns CGM-linked insulin delivery. Modern diabetes technology includes glucose measurement, insulin administration, and automated therapy adjustment, and current standards recognise AID systems that use CGM-informed algorithms to modulate insulin delivery.[6] In type 1 diabetes, AID systems improve time in range and can reduce day-to-day treatment burden. The CREATE trial showed that an open-source AID system produced a significantly higher percentage of time in the target glucose range than sensor-augmented pump therapy in children and adults with type 1 diabetes over 24 weeks.[36]

Evidence is expanding in type 2 diabetes. In a randomised clinical trial of adults with poorly controlled type 2 diabetes treated with basal insulin, CGM improved HbA1c and CGM-derived time in range compared with traditional blood glucose monitoring.[37] The Steno2tech randomised trial similarly supported CGM over blood glucose monitoring in adults with inadequately controlled insulin-treated type 2 diabetes.[38] Fully closed-loop insulin delivery also improved time in target range and HbA1c in adults with type 2 diabetes in a crossover trial, without increasing hypoglycemia.[39] These results are clinically important because they show that the device component is not peripheral; it changes the pharmacologic behaviour of insulin therapy by improving measurement, timing, algorithmic adaptation, and user feedback.

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Several pivotal studies provided inferential evidence supporting the clinical significance of device-enabled insulin management. In adults with type 2 diabetes treated with basal insulin, continuous glucose monitoring produced a greater reduction in HbA1c than blood glucose monitoring at 8 months, with an adjusted between-group HbA1c difference of −0.4 percentage points, 95% CI −0.8 to −0.1, P =.02. CGM also improved time in the target range of 70–180 mg/dL, 59% versus 43%, adjusted difference 15 percentage points, 95% CI 8 to 23, P <.001, and reduced time above 250 mg/dL, adjusted difference −16 percentage points, 95% CI −21 to −11, P <.001.[37] In adults with type 2 diabetes, fully closed-loop insulin delivery increased time in the target glucose range compared with standard insulin therapy, 66.3% versus 32.3%, mean difference 35.3 percentage points, 95% CI 28.0 to 42.6, P <.001, and lowered HbA1c by −1.4 percentage points, 95% CI −1.8 to −1.0, P <.001, without a significant increase in time below range. These inferential findings support the conclusion that DDCPs can produce statistically and clinically meaningful improvements in glycemic control when sensing, delivery, and feedback systems are integrated into insulin therapy.[39]

Connected insulin pens and multiple daily injection precision

Connected insulin pens address a common gap in diabetes care: the invisibility of insulin dosing behaviour outside clinic visits. Dose timing and missed boluses are major contributors to hyperglycemia, yet conventional pens do not automatically capture this information. Smart pens and connected caps can store dose and timing, link with CGM, support bolus calculators, and provide reminders. It has been reported that there is increased time in range and fewer missed bolus injections after the introduction of a smart-connected insulin pen.[3] A large real-world study across 16 countries found that adherence to basal-bolus insulin treatment and engagement with smart pens were associated with CGM outcomes in adults with diabetes.[5] Reviews of precision insulin management similarly highlight smart pens as a lower-burden alternative or complement to pumps for people using multiple daily injections.[4]

From a DDCP perspective, the smart pen is more than a container. It becomes a data-generating delivery system that links drug administration, patient behaviour, glucose response, and clinical review. This is especially relevant for type 2 diabetes, where many people require insulin but may not be candidates for pump therapy because of cost, preference, complexity, or resource constraints.[40–42]

Injectable incretin pen devices, obesity, and metabolic control

The DDCP framework should also include injectable incretin-based therapies delivered by pen devices. Semaglutide 2.4 mg produced substantial weight loss in adults with overweight or obesity in the STEP 1 trial.[43] Tirzepatide produced substantial weight reduction in SURMOUNT-1 among adults with obesity[44] and in SURMOUNT-2 among adults with obesity and type 2 diabetes.[45] In diabetes and metabolic disorder practice, the pen device contributes to dose escalation, weekly administration, user training, adherence, tolerability management, and safe disposal. Current diabetes standards also emphasise individualised obesity pharmacotherapy and pharmacologic approaches that consider weight, cardiovascular-kidney-metabolic benefits, hypoglycemia risk, treatment burden, cost, and patient preference.[46,47]

Compared with insulin delivery technologies, the literature on incretin pen devices focuses more heavily on drug efficacy than on device-specific adherence and usability. This is a gap. Future DDCP research should evaluate whether device design, training, refill systems, dose-escalation support, reminder systems, and digital follow-up affect persistence, weight outcomes, glycemic response, adverse-event management, and equitable access to anti-obesity pharmacotherapy.[48–51]

Regulatory pathways, interoperability, and cybersecurity

Regulatory evidence consistently shows that DDCPs are complex because their clinical performance depends on interactions between drug, device, software, human factors, and data systems. Regulatory frameworks differ across jurisdictions, including classification, primary mode of action, evidence requirements, post-market surveillance, and software validation.[52,53] Recent regulatory science literature emphasises that combination products require integrated safety and efficacy assessment rather than isolated evaluation of drug and device components.[54]

Interoperability is central to diabetes DDCPs because clinical value often depends on data moving between CGM, insulin pens, pumps, apps, cloud platforms, electronic health records, and clinician dashboards. Lack of interoperability can create workflow burden, incomplete records, and patient frustration. Cybersecurity and privacy are equally important because DDCPs generate high-frequency, identifiable health data. AI-enabled dosing support and decision feedback must be validated for safety, transparency, data quality, and bias mitigation.[11,55]

Recent 2025 regulatory developments in digital diabetes interventions

The 2025 regulatory landscape shows continued expansion of software-enabled and sensor-enabled diabetes technologies. In the United States, the FDA cleared Tandem Diabetes Care's Control-IQ+ technology in February 2025 as a software-only interoperable automated glycemic controller intended for use with compatible integrated continuous glucose monitors and alternate controller-enabled pumps. The system automatically increases, decreases, and suspends basal insulin delivery based on CGM readings and predicted glucose values, and the FDA clearance expanded the intended use to include type 2 diabetes in adults. In March 2025, the FDA also cleared the Signos Glucose Monitoring System, an over-the-counter mobile application paired with an integrated continuous glucose monitor for adults not using insulin; the system displays glucose values and trends and supports user understanding of lifestyle-related glucose excursions. These examples demonstrate the increasing regulatory relevance of software, mobile applications, interoperability, and user-facing digital feedback in metabolic care.[35,56]

For Europe, the wording should distinguish EMA involvement from CE marking. Medical devices are regulated primarily through EU medical-device legislation and national/notified-body conformity assessment, whereas the European Medicines Agency is involved in selected medicine-device and regulatory consultation processes rather than directly "approving" most stand-alone medical devices. Therefore, European updates should be described as CE-mark or EU regulatory developments rather than as direct EMA approvals unless a specific EMA medicine-device consultation is being discussed. In 2025, for example, the MiniMed 780G system received an expanded CE mark in Europe for broader indications, including insulin-requiring type 2 diabetes, pregnancy, and children as young as two years. This supports the manuscript's argument that AID systems are moving from specialised type 1 diabetes use toward broader metabolic-care populations.[57,58]

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Equity, access, and implementation

Equitable implementation is a recurring concern. Digital health technologies can improve access and personalisation, but they can also worsen inequities when cost, insurance coverage, smartphone access, broadband, language, disability, clinician bias, or digital literacy limit adoption.[59] Diabetes technology literature shows persistent racial, ethnic, socioeconomic, and insurance-related disparities in CGM and insulin pump use.[31,60] Large pediatric and young adult cohorts have also demonstrated differences in insulin pump utilisation by insurance type and race/ethnicity, even as pump use has increased over time.[61]

For JDMDC-relevant readers, the implication is that DDCPs should be evaluated not only by efficacy under trial conditions but also by access, affordability, training, cultural appropriateness, data costs, language support, and post-market safety monitoring. A device-enabled pharmacotherapy that improves time in range in early adopters may have limited population impact if it is inaccessible to the communities with the greatest diabetes burden.[62–64]

Risk-of-bias and evidence certainty summary

Risk of bias and applicability considerations are summarised in Table 5.

Table 5 Narrative risk-of-bias and applicability considerations

Evidence type	Main appraisal considerations
RCTs and crossover trials	Generally stronger internal validity, but many device trials are open-label because masking is impractical. Common concerns include small samples, short follow-up, selected participants, and industry sponsorship.
Real-world and registry studies	High external relevance but more vulnerable to confounding, missing data, selection bias, engagement bias, and device-affordability bias.
Systematic/scoping reviews	Useful for mapping fields and implementation issues, but quality varies by search transparency, appraisal rigour, and synthesis method.
Regulatory/economic/implementation studies	Essential for translation, but findings are context-dependent and may not generalise across payer systems, countries, or device ecosystems.

Table 5 appropriately distinguishes internal validity from real-world applicability. Randomised and crossover trials generally provide stronger evidence for causal effects, but many diabetes-device trials cannot be fully blinded because patients and clinicians know whether a CGM, pump, pen, or closed-loop system is being used. This introduces potential performance and expectation bias, particularly for patient-reported outcomes such as treatment satisfaction, usability, perceived burden, and confidence in self-management. Nevertheless, objective endpoints such as CGM-derived time in range, time below range, and HbA1c reduce some measurement concerns when data capture is complete and follow-up is adequate.[65,66]

For RCTs and crossover trials, the certainty of evidence is strongest when randomisation is clearly described, baseline characteristics are balanced, attrition is low, analysis follows the intention-to-treat principle, and outcomes are prespecified. However, the generalisability of device trials may be limited when participants are recruited from specialist centres, have high digital literacy, receive intensive training, or can afford devices and supplies. These factors may produce outcomes that are better than those achievable in routine primary care, rural clinics, or under-resourced health systems.[67]

Real-world and registry studies provide essential evidence on DDCP performance after implementation, but Table 5 correctly identifies their greater vulnerability to confounding and selection bias. Patients who adopt CGM, smart pens, pumps, or AID systems may differ systematically from non-users in income, insurance coverage, education, motivation, access to specialist care, and baseline health literacy. These differences can exaggerate apparent device benefit unless analyses adjust for socioeconomic and clinical confounders and examine nonadoption, discontinuation, and missing-data patterns.[68–71]

Engagement bias is particularly important for DDCP evidence. Device-generated data are most complete among users who wear sensors consistently, sync devices, respond to alerts, refill prescriptions, and attend follow-up visits. Consequently, studies based only on active users may overestimate effectiveness and underestimate barriers. This is especially relevant for smart pens, CGM-linked platforms, and incretin pen therapies, where persistence and correct use are part of the therapeutic mechanism rather than merely measures of compliance.[5,18,49,72,73]

Systematic and scoping reviews in this field are useful for mapping technologies, outcomes, and implementation barriers, but their certainty depends on search transparency, eligibility criteria, appraisal rigour, and synthesis methods. PRISMA 2020 and PRISMA-S provide relevant reporting standards because DDCP reviews must make clear how databases, search strings, grey literature, regulatory sources, and citation tracking were handled. Without transparent search reporting, readers cannot determine whether important evidence was missed or whether conclusions are overly influenced by a small number of commercial device studies.[7,74,75]

Regulatory, economic, and implementation studies should be interpreted as context-sensitive evidence. Their findings may differ across jurisdictions because device approval, reimbursement, privacy regulation, cybersecurity expectations, data-sharing infrastructure, and clinical staffing models vary substantially. Therefore, certainty for these domains should be described in terms of transferability rather than only methodological quality. A cost-effective or clinically feasible DDCP pathway in a high-income, digitally integrated health system may not be feasible in settings with fragmented reimbursement, limited broadband, scarce diabetes educators, or high out-of-pocket device costs.[76–81]

Overall, the certainty of evidence should be considered strongest for CGM-linked insulin delivery and AID systems in type 1 diabetes, moderate and expanding for selected insulin-treated type 2 diabetes populations, moderate but still developing for connected insulin pens, strong for the pharmacologic efficacy of incretin therapies, and limited for device-specific implementation outcomes related to incretin pen use. Across all categories, certainty is reduced when follow-up is short, samples are highly selected, industry sponsorship is prominent, missing data are substantial, or equity outcomes are not reported. This graded interpretation is more appropriate than a single pooled certainty rating because the review combines clinical trials,

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real-world studies, device usability evidence, regulatory literature, and implementation research.[15,16,82–85]

Discussion

Principal findings

This PRISMA-based systematic review shows that DDCPs are highly relevant to precision medicine in diabetes and metabolic disorders. The most clinically mature evidence concerns CGM-linked insulin therapy, connected insulin pens, insulin pumps, and AID systems. These technologies improve the visibility of glucose trajectories, insulin timing, titration opportunities, and time in range while enabling clinicians to identify behavioural and physiological patterns that remain invisible in conventional episodic care. The evidence base is strongest in type 1 diabetes and is increasingly supportive in selected insulin-treated type 2 diabetes populations, especially where CGM-derived data are used to adjust treatment rather than simply document hyperglycemia.[37–39]

A key contribution of device-enabled pharmacotherapy is that it changes insulin from a static prescription into an adaptive therapeutic system. CGM provides high-frequency glycemic information, pumps and pens document delivery behaviour, and algorithms or dashboards transform those inputs into actionable dose decisions. This matters because HbA1c alone cannot show hypoglycemia exposure, postprandial excursions, nocturnal patterns, glycemic variability, or missed boluses. Contemporary trials of automated or closed-loop insulin delivery therefore support a broader precision-medicine interpretation: the device component creates the measurement and feedback architecture required for safer individualisation of insulin therapy.[36,39,86]

The clinical meaning of smart insulin pens is also strengthened by this review. For many patients, especially adults with type 2 diabetes using multiple daily injections, pump therapy may be unacceptable, unaffordable, or operationally difficult. Connected pens and caps provide a lower-burden precision pathway by capturing dose timing, missed or delayed injections, and bolus behaviour alongside CGM profiles. This creates a practical bridge between standard injection therapy and highly automated pump-based systems, and it may be particularly valuable in primary care or resource-constrained endocrinology settings where clinicians need concise, interpretable dosing data.[3–5]

The review also broadens the DDCP concept beyond insulin. Incretin pen devices for semaglutide and tirzepatide connect pharmacologic efficacy with weekly delivery, user training, dose-escalation behaviour, tolerability management, and persistence. Since 2020, high-quality trials have shown that incretin-based therapies can produce clinically meaningful weight loss and glycemic improvement in obesity and type 2 diabetes, while newer outcome trials have extended the relevance of these agents to cardiovascular and heart-failure phenotypes.[23,43–45,87–89] From a DDCP perspective, these data indicate that the delivery platform should be evaluated not only for technical reliability but also for whether it supports long-term persistence and safe escalation in real-world metabolic care.

Taken together, the evidence suggests that precision medicine in diabetes and metabolic disorders should be interpreted as a system-level model rather than only a molecular or pharmacogenomic approach. Drug selection remains essential, but optimal outcomes increasingly depend on whether the therapeutic product can sense, deliver, record, interpret, and adapt to the patient's changing metabolic state. This is particularly important for people with multimorbidity, variable insulin sensitivity, food insecurity, irregular work schedules, renal impairment, or fluctuating body weight, where treatment requirements may change over short intervals and where static treatment plans may be insufficient.[90–95]

Implications for clinical practice

DDCPs directly affect the prevention, treatment, and control of diabetes, obesity, insulin resistance, and metabolic complications. Clinically, DDCPs should be considered when they reduce treatment burden, improve measurable glycemic or weight-related outcomes, increase adherence, enhance safety, and enable data-driven self-management. For insulin-treated diabetes, CGM and connected delivery can shift care from retrospective HbA1c-only decisions toward dynamic treatment adjustment. For obesity and type 2 diabetes, injectable incretin pen devices represent drug-device platforms whose success depends on sustained access, persistence, patient education, and tolerability management.[20,49,96–99]

A practical implication is that device selection should be matched to the patient's therapeutic intensity, self-management capacity, and clinical risk. AID systems may be most appropriate for individuals with type 1 diabetes or insulin-treated type 2 diabetes who experience glycemic variability, nocturnal dysglycemia, high treatment burden, or recurrent dose-adjustment needs. Smart pens may be more suitable for patients who use multiple daily injections but need structured dose documentation, reminders, and clinician review. Incretin pen therapies may be prioritised when obesity, type 2 diabetes, cardiovascular risk, kidney risk, or heart-failure symptoms coexist, provided that cost, contraindications, gastrointestinal tolerability, and long-term adherence are addressed.[46,47,87]

Clinicians should also recognise that DDCP data require deliberate workflow design. CGM traces, insulin delivery logs, and app-based adherence information can improve care only if they are reviewed, interpreted, and converted into treatment decisions. Without structured data review, the same technologies may generate alarm fatigue, information overload, or frustration for both patients and clinicians. Therefore, implementation should include onboarding protocols, follow-up intervals, roles for diabetes educators and pharmacists, and concise data summaries that can be integrated into routine visits.[100–104]

The findings further support a team-based model of metabolic care. Nurses, diabetes educators, pharmacists, dietitians, behavioural-health professionals, and primary-care clinicians can all contribute to safe DDCP use by reinforcing injection technique, troubleshooting sensors or infusion sets, explaining dose escalation, monitoring adverse effects, and identifying financial or literacy barriers. This is especially important for incretin-based therapies, where early nausea, delayed dose escalation, medication interruptions, or lack of refill support can undermine otherwise strong pharmacologic efficacy.[105–110]

Psychosocial and patient-experience considerations

The psychosocial effects of DDCPs should be considered alongside glycemic and weight-related outcomes. Although CGM, smart pens, pumps, and AID systems can reduce uncertainty and support self-management, they may also create emotional and social burdens. Patients may experience fear of imminent malfunction, anxiety about alarms or interrupted insulin delivery, mistrust of automated decisions, frustration with connectivity failures, and distress when troubleshooting becomes frequent or poorly supported. Device visibility can also produce stigma, unwanted disclosure of diabetes status, body-image concerns, or avoidance of social and occupational situations where sensors, infusion sets, or pumps are noticed. These concerns are clinically relevant because psychosocial burden can reduce wear time, data completeness, adherence, and willingness to escalate to more effective technology. Device onboarding should therefore include expectation-setting, alarm optimisation, backup plans for malfunction, training in troubleshooting, discussion of body placement and visibility preferences, and access to behavioural-health or peer-support resources when technology-related distress is present.[111]

Dermatologic complications: contact dermatitis and infection risk

Dermatologic adverse events are an important safety and persistence issue for DDCPs that remain attached to the skin, including CGM sensors, infusion sets, patch pumps, and adhesive-supported wearables. Reported reactions include irritant contact dermatitis, allergic contact dermatitis, pruritus, erythema, vesiculation, skin breakdown, lipohypertrophy or lipoatrophy at repeated sites, and local infection related to insertion sites or disrupted skin barriers. Adhesives, acrylates, colophonium-related compounds, device plastics, occlusion, sweating, friction, and prolonged wear can contribute to these reactions. These complications may cause premature device removal, reduced CGM data capture, discontinuation of pump or sensor therapy, and lower satisfaction even when glycemic outcomes improve. Clinical implementation should include inspection of device sites, rotation of sensor and infusion locations, patient education on skin preparation and removal techniques, early treatment of dermatitis, consideration of barrier films or alternative adhesives where appropriate, patch testing for suspected allergic contact dermatitis, and clear escalation pathways for suspected cellulitis, abscess, or persistent inflammatory reactions. Future trials and registries should report dermatologic events separately from general device adverse events so that tolerability and long-term persistence can be assessed more accurately.[112]

Regulatory and implementation implications

DDCPs require evidence models that evaluate the product as an integrated system. Regulatory and reimbursement decisions should consider not only drug efficacy and device accuracy but also human factors, software performance, cybersecurity, interoperability, post-market surveillance, and real-world usability. Harmonised regulatory expectations would help developers generate evidence that can be interpreted across countries and reduce unnecessary delays in access. Health systems should develop implementation pathways that include clinician training, device onboarding, data review workflows, technical support, privacy safeguards, and mechanisms to prevent algorithmic and access-related inequities.[113–118]

The regulatory challenge is intensified by the speed at which device software, algorithms, sensors, and companion applications evolve. A drug component may remain unchanged while the software interface, connectivity architecture, or decision-support logic is updated repeatedly. This creates a need for lifecycle-based oversight, transparent version control, human-factors testing, and post-market monitoring that can detect dosing errors, cybersecurity vulnerabilities, biased algorithmic performance, and usability failures before they cause widespread harm.[11,52–55]

Interoperability should be treated as a clinical safety issue rather than only a convenience feature. Fragmented data ecosystems can prevent clinicians from seeing complete dose histories, glucose trends, medication refills, or adverse-event signals. Conversely, interoperable platforms can support population-level dashboards, remote titration, early identification of nonadherence, and proactive outreach. Standards for secure data exchange among CGM systems, insulin pens, pumps, electronic health records, pharmacy databases, and payer systems are therefore central to realising the public-health value of DDCPs.[119–124]

Equity must remain a primary implementation endpoint. Evidence from diabetes technology adoption shows that racial, ethnic, socioeconomic, insurance, and geographic disparities can persist even after technologies become clinically effective [31], [60], [61]. DDCP programmes should therefore include affordability strategies, language-concordant education, disability-accessible design, culturally appropriate training, data-plan support, and monitoring of uptake and outcomes across population subgroups. Otherwise, precision technologies may preferentially benefit already-resourced patients and widen the very treatment gaps they are intended to reduce.[125–127]

Limitations

The main limitation is that the review is methodologically heterogeneous and therefore unsuitable for a single pooled effect estimate. Device categories, populations, outcomes, and follow-up durations differed substantially. Many technology studies were open-label, short-term, industry-associated, or conducted in specialised centres. Real-world studies were vulnerable to selection bias, confounding, missing data, engagement bias, and device-affordability bias.

Another limitation is that the available literature remains uneven across DDCP categories. Insulin delivery technologies and CGM-linked systems are supported by a larger body of device-specific evidence than incretin pen products, where the strongest evidence often concerns drug efficacy rather than the independent contribution of the device, training system, refill pathway, or digital support. In addition, many studies report glycemic or weight outcomes but provide less detail on digital literacy, language access, disability, long-term persistence, cybersecurity incidents, data-sharing failures, or implementation costs. These gaps limit the ability to estimate how DDCPs will perform when deployed at scale in diverse health systems.

Future research directions

I. Conduct longer pragmatic trials of connected insulin pens, CGM-linked MDI care, insulin pumps, and AID systems in diverse type 2 diabetes populations, including older adults, people with multimorbidity, pregnancy-relevant populations where appropriate, and low-resource settings.

II. Evaluate device-specific adherence, usability, persistence, dose-escalation support, and medication-interruption effects for GLP-1 receptor agonist and GIP/GLP-1 receptor agonist pen products used for obesity and type 2 diabetes.

III. Develop interoperable standards that allow secure data exchange among CGM, smart pens, pumps, electronic health records, pharmacy systems, payer systems, and clinician dashboards.

IV. Include equity outcomes in DDCP trials and registries, including race/ethnicity, language, insurance status, geography, disability, digital literacy, socioeconomic position, and access to smartphones or broadband.

V. Strengthen post-market surveillance for cybersecurity, algorithmic performance, device malfunctions, dosing errors, infusion-site complications, medication shortages, and adverse-event reporting.

VI. Assess cost-effectiveness, reimbursement, and implementation models for low- and middle-income countries, rural communities, and underinsured populations.

VII. Compare patient-facing education models, remote-monitoring workflows, and clinician-dashboard designs to identify which implementation strategies convert DDCP data into sustained improvements in metabolic outcomes.

VIII. Evaluate integrated strategies that combine incretin-based pharmacotherapy with device-enabled care, including GLP-1 receptor agonist or dual GIP/GLP-1 receptor agonist pen devices linked to reminders, refill support, dose-escalation tracking, adverse-effect monitoring, CGM feedback, weight trajectories, dietary counselling, and remote clinician review.

IX. Conduct pragmatic trials comparing incretin pen therapy alone versus incretin pen therapy plus digital adherence support, CGM-guided metabolic feedback, or connected injection systems, with outcomes including persistence, weight loss, HbA1c, cardiometabolic markers, gastrointestinal tolerability, discontinuation, cost, and equity.

X. Study patient-centred mitigation strategies for psychosocial burden, including fear of malfunction, alarm fatigue, device visibility stigma, troubleshooting burden, and trust in automated insulin delivery algorithms.

XI. Systematically capture dermatologic safety outcomes, including irritant contact dermatitis, allergic contact dermatitis, adhesive intolerance, infusion-site infection, premature device removal, and device discontinuation due to skin complications.

Conclusion

DDCPs are central to the future of precision medicine in diabetes and metabolic disorders because they join pharmacotherapy with delivery, sensing, algorithms, patient behaviour, and real-world data. Evidence supports CGM-linked insulin delivery, smart insulin pens, insulin pumps, and AID systems as tools for improving glycemic visibility, dose adherence, and individualised insulin management. Injectable incretin pen devices extend the DDCP framework to obesity, type 2 diabetes, and broader cardiometabolic risk reduction.

The central conclusion of this review is that the therapeutic value of DDCPs cannot be separated from the systems in which they are used. A highly effective drug or accurate device may have a limited impact if patients cannot afford it, understand it, tolerate it, refill it, connect it, or obtain clinical support for its data. Conversely, when DDCPs are embedded within accessible care pathways, they can transform diabetes and metabolic management from intermittent, clinic-centred decision-making into continuous, patient-centred, data-informed care.

For insulin-treated diabetes, the strongest near-term opportunity is to expand safe and equitable access to CGM-linked therapy, smart injection support, and automated insulin delivery while ensuring that clinicians have the time and tools to act on device-generated data. For obesity and type 2 diabetes, incretin pen devices should be studied and implemented as long-term metabolic platforms, not merely as drug containers. Their effectiveness will depend on persistence, dose escalation, side-effect management, supply continuity, affordability, and integration with cardiovascular, kidney, liver, and behavioural-health care.

The clinical promise of DDCPs will be realised only if regulatory pathways, interoperability, cybersecurity, affordability, training, and health equity are addressed in parallel with efficacy. Future studies should move beyond efficacy in early adopters toward inclusive, long-term, real-world evaluations that measure metabolic control, safety, usability, cost, persistence, patient experience, and equitable access. With these conditions in place, DDCPs can become practical precision-medicine tools for reducing the burden of diabetes, obesity, and related cardiometabolic disorders across diverse populations.

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Conflict of interest

The authors declare that there are no conflicts of interest.

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