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EXPERT OPINION REPORT

Artificial intelligence-driven clinical decision support systems to assist healthcare professionals and people with diabetes in Europe at the point of care: a Delphi-based consensus roadmap

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Abstract

The use of artificial intelligence (AI) to improve the diagnosis, assessment and treatment of people with diabetes has the potential to drive a paradigm shift in diabetes care, both minimising treatment inertia and optimising clinical outcomes. This is a significant opportunity, given the predicted increase in the burden of diabetes over the next 20 years. However, there are concerns that regulatory processes for development and implementation of AI-driven technologies are not adequate for systems that may adapt to new data and change from their original performance characteristics as evaluated. The European Diabetes Forum (EUDF) convened a working group to review and investigate the unmet needs around implementation of AI technology in diabetes care. The working group developed the framework and focus of the accompanying analysis through a series of virtual and face-to-face meetings, including email conversations. The working group examined the key objectives for good diabetes care in the context of current and predicted AI-driven clinical decision support systems (AI-CDSS), including the outcomes for people with diabetes, the goals for personalised medicine and the implications for guideline-driven diabetes services and healthcare professionals. The process covered the needs of primary care healthcare professionals, who will shoulder the majority of diabetes care. The challenge of developing regulatory concepts and processes that are sufficiently robust to be AI inclusive was considered as central to the outcomes. Based on the available evidence, the EUDF working group believes that AI-CDSS will deliver benefits for people with diabetes, although there are clear challenges to moving AI-CDSS into the practical clinical space. To encourage debate on how this can be achieved safely and effectively, at the conclusion of the process a series of 14 recommendations was agreed using a nominal group technique and Delphi methodology, which are discussed in context in this article.

Keywords Artificial intelligence · Clinical decision support · Diabetes clinical practice · European Union · Regulatory process

Abbreviations

AI	Artificial intelligence
AI-CDSS	AI-driven clinical decision support systems
AID	Automated insulin delivery
CDSS	Clinical decision support systems
CGM	Continuous glucose monitoring
DSMES	Diabetes self-management education and support
EHR	Electronic health record
EMA	European Medicines Agency
EU	European Union
EUDF	European Diabetes Forum
FDA	US Food and Drug Administration
HCP	Healthcare professional
LLM	Large language model
LMIC	Low- and middle-income countries
ML	Machine learning
PCDE	Primary Care Diabetes Europe
PCP	Primary care physician

This consensus roadmap was reviewed and endorsed by the European Association for the Study of Diabetes (EASD) Committee on Clinical affairs (CCA) and approved by the EASD Board.

Extended author information available on the last page of the article

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Introduction

In 2024, diabetes prevalence in the adult population in Europe was estimated to be 9.8% [1], with more than 66 million individuals affected, a number that is predicted to rise to 72 million by 2050. The need to treat this number of people with diabetes creates a burden on healthcare services and healthcare professionals (HCPs) that may be unsustainable using current treatment modalities. For people with diabetes, there remain significant unmet needs related to monitoring and improving their glucose levels and cardiometabolic and mental health, as well as their overall wellbeing.

The treatment and management of people with diabetes is benefiting significantly from the application of technology, including continuous glucose monitoring (CGM) systems, digitally connected insulin pens, insulin pumps and automated insulin delivery (AID) systems. These technologies generate huge quantities of information on daily glucose control and treatment activities, largely self-managed by the people with diabetes. The use of artificial intelligence (AI) to improve the diagnosis, assessment and treatment of people with diabetes, and associated cardiometabolic complications, is a dynamic area of healthcare research that can drive a paradigm shift in the way that diabetes care is provided. This could meet the dual objectives of minimising treatment inertia and optimising clinical outcomes for people with diabetes, who are acknowledged to have higher risks for microvascular and macrovascular disease [2, 3]. For example, AI-driven retinal screening and bone scanning systems are already available, both as research applications [4] and for clinical use [5], and are able to send data directly to electronic health records (EHRs). In addition, data routinely collected through digitised EHRs and healthcare-directed information technology systems can support predictions around diagnosis, future health states and treatment requirements, all of which can aid clinicians. In this context, the use of routinely collected data from EHRs is the focus of AI-driven clinical decision support systems (AI-CDSS) for the prediction and diagnosis of type 2 diabetes [6, 7] and diabetes complications [8], which have been shown to outperform existing methods, albeit in limited application studies.

Working group composition and methodology

The aim of this European Diabetes Forum (EUDF) working group was to investigate the implementation of AI technology as it relates to diabetes, including understanding the possibilities whereby and predicting the scenarios in which AI can improve the detection of diabetes and the delivery of diabetes care. The members of the working group were nominated as representatives of not-for-profit diabetes associations and federations, physicians with expertise in diabetes care, experts from medical technology associations, stakeholders from industry operating within the EUDF and people living with diabetes. As such, the focus of the working group was to ascertain the perceptions of the diabetes community on the potential and feasibility of AI to improve outcomes for people with diabetes and increase the capabilities of diabetes services and HCPs in their daily clinical practice, rather than to review the current status of AI application for the diagnosis and management of diabetes. This included identifying the current limitations of AI technology and the hurdles that must be overcome to implement it in an effective manner.

The consensus process was designed to follow a nominal group technique methodology, combining brainstorming, discussion and refinement of ideas, to reach consensus [9]. A first step in this process was an attitudes survey among the 19 members of the EUDF working group using a Delphi methodology [10], the results of which are provided in the electronic supplementary material (ESM). Following the first Delphi survey and the discussions prompted by the outcomes, a second Delphi survey was conducted to identify recommendations that met the requirement for a minimum two-thirds majority in agreement or strong agreement. It is acknowledged that dissenting viewpoints are not discussed in this article and that the recommendations are not all actionable. Both surveys were run and reported such that each participant was blinded to the responses of other respondents. Neither of these Delphi survey steps was prospectively registered.

What is artificial intelligence?

The term ‘AI’ refers to the field of computer science that focuses on developing models and algorithms capable of performing tasks that typically require human intelligence [11]. This can include, but is not limited to, understanding natural language, recognition of complex images and autonomous problem-solving. A conceptual schematic for AI is shown in Fig. 1. Machine learning (ML) refers to the subfield of AI that is focused on models that are capable of learning and making predictions or decisions, based on data, without being explicitly programmed to do so [11]. So-called ‘deep learning’ is a subset of ML that uses multi-layered ‘neural networks’, which mimic how neurons in the human brain signal each other. Connections within a neural network allow an AI system to adapt to new inputs and make decisions based on learned patterns, typically after training

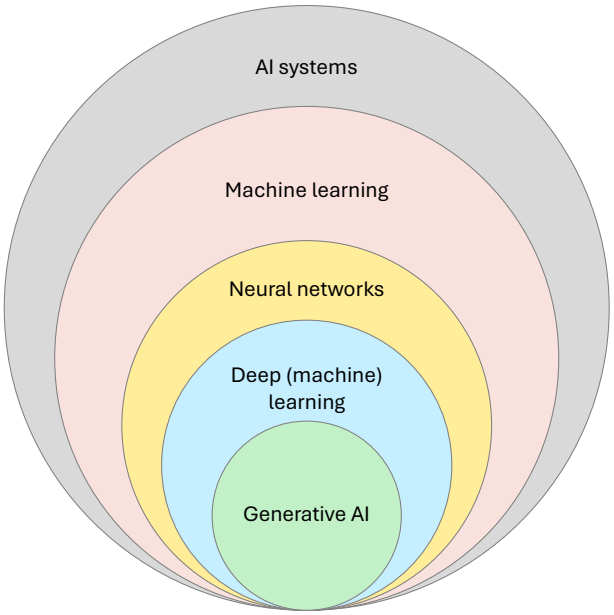

Fig. 1 The core elements underlining the development of AI systems. AI is a discipline within computer and information sciences. The goal of AI is to construct practical technologies that can simulate human intelligence by learning and adapting their processes and outputs to deliver improved results over time

on large datasets [12, 13]. Many of the beneficial AI applications in diabetes care, as discussed in this roadmap, involve clinical prediction models. Although it is beyond the scope of this article to discuss how the performance of such predictive models is assessed and reported, we refer the reader to expert discussions concerning the TRIPOD+AI checklist for AI-driven prediction models [11, 14].

Generative AI, a subset of deep learning (Fig. 1), is potentially able to create new and meaningful content based on learned patterns or data inputs, and has the potential to transform clinical decision-making and improve health outcomes [15]. Generative AI models can be trained on huge datasets of medical records, clinical measurements and imagery, to identify patterns related to disease pathology and progression. Recent developments in generative AI include the development of large language models (LLMs), which are massive neural networks capable of being trained with billions of parameters and suited to use as clinical predictive engines and for pattern recognition [16, 17]. One proposed application of this capability is the medication management of people with type 2 diabetes on polypharmacy [18] and at a scale that reduces the burden and cost of clinical administration. LLMs are intended to recognise and understand human language, classify text and voice-based information according to its purpose, and generate responses that are appropriate and understandable [19]. Once trained, LLMs do not learn from new interactions but are able to generate relevant and coherent responses when challenged. For example, LLMs can undertake personalised glucose forecasting for people with type 1 diabetes, including those on insulin pumps or multiple daily injections, when trained on large-scale CGM datasets and using individual glucose data profiles [20]. However, it is important to acknowledge the limitations of LLMs. For example, until 2022, LLMs trained on many billions of data points were unable to achieve a passing score on a US medical learning examination-style question set [21]. Although proficient at answering multiple choice questions, factual long-form questions proved problematic. Improvements to such LLMs, including medical domain-specific fine-tuning and strategies to improve reasoning, have resolved many of these issues, such that a few LLMs are now able to achieve passing scores [21, 22]. However, this improved performance does not exclude the possibility of wrong answers, which could occur in safety-critical situations. The phenomenon of 'hallucination', whereby an AI model produces factually incorrect or nonsensical responses, is an acknowledged issue with LLMs with clinical decision support capabilities [23]. Such considerations mean that, until AI-CDSS can be validated in real-world workflow situations without compromising patient safety, their deployment will be significantly limited.

AI tools based on LLMs have numerous potential applications in the diagnosis and therapeutic management of people with all forms of diabetes. However, the landscape of AI in CDSS is complex and requires that multiple intersecting needs are managed, with appropriate checks and balances in place, as discussed in the following section and illustrated in Fig. 2.

Challenges in using AI-CDSS in diabetes care

The working group recognises that successful clinical adoption of AI-CDSS in diabetes care can involve developing systems that are adaptive to specific challenges, including changes to clinical workflows, direct communication with EHRs, local availability of medications and prescribing systems, and cost and reimbursement criteria for any European healthcare sector. To achieve these objectives for a large population of people with diabetes, a single AI-CDSS would need to extract and report huge amounts of data, which may be challenging. In this context, the performance of generative AI systems, such as LLMs, in diabetes and CVD is considered problematic, as training datasets for LLMs specific to these clinical specialties do not yet have sufficient amounts of validated information to optimise the clinical performance of AI tools [24–26]. This highlights a wider issue in the development of applications of AI-CDSS with clinical predictive attributes. The TRIPOD+AI checklist has been developed to provide standardised guidance for reporting studies on

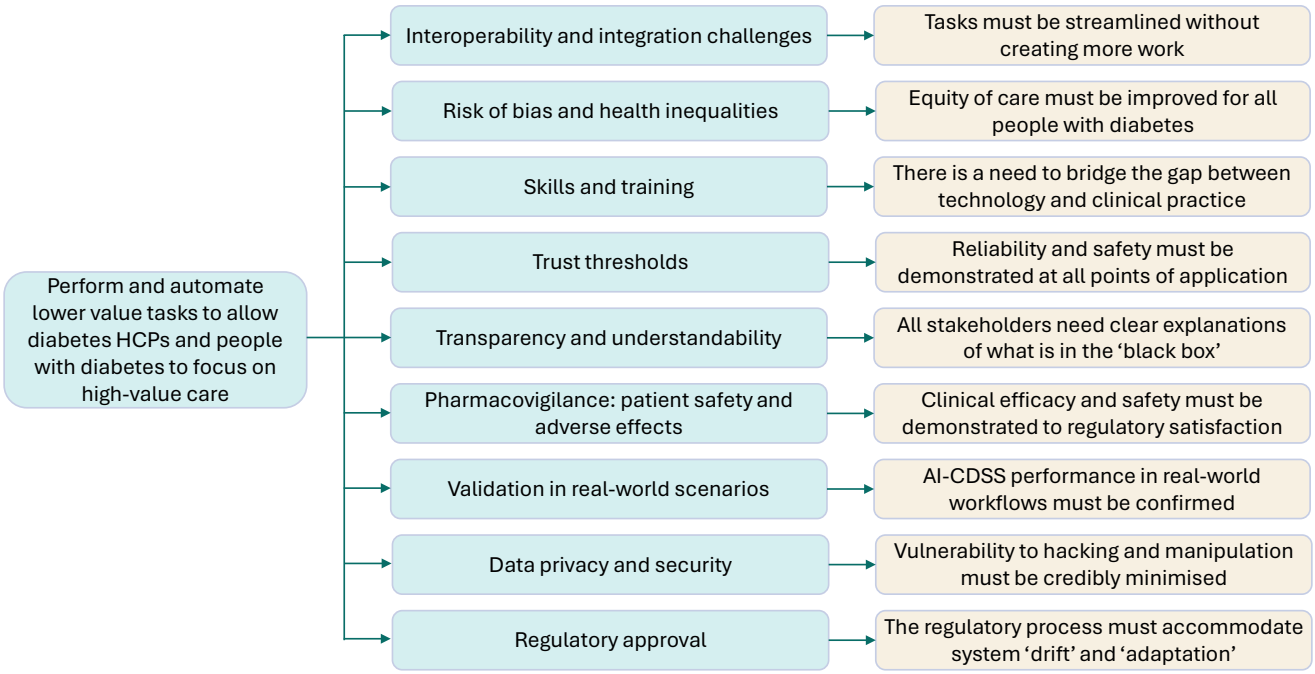

Fig. 2 The promise and challenges of diabetes AI-CDSS. The figure shows the many challenges in the implementation of AI-CDSS for optimising the care of people with diabetes and supporting HCPs to focus on high-value tasks in the delivery of diabetes care

prediction models, particularly in the domain of ML [11] and adherence to this guidance is a hallmark of accurate, interpretable and clinically actionable predictive models. However, although the TRIPOD+AI checklist has been used in ML studies on cancer diagnosis and treatment, in neurology and on postoperative complications, studies on predictive models in diabetes have not been quick to adopt this framework [27].

The challenge of interoperability Currently, a major unmet need in the clinical application of AI-CDSS in diabetes care is the limited adoption of open standards and interoperability of diabetes technologies, including those for standard EHR formats. This also impedes the seamless implementation of diabetes technology devices, such as CGM systems, insulin pumps, AID systems, ketone meters, smart insulin pens and retinal-scanning systems. A fundamental requirement for optimising the impact of AI-CDSS on clinical outcomes in people with diabetes is to enable data interoperability between different devices, using a standard application programming interface [28]. One of the most prominent initiatives to resolve this problem is the iCoDE project [29], which is centred on a data standard and workflow for integrating CGM data into EHRs for use in routine clinical care. Such a project is complex, requiring co-operation between multiple stakeholders, including device manufacturers, HCPs, payers and governmental bodies. The iCoDE 2 project aims to support data transfer from AID systems in EHRs.

The issue of interoperability extends beyond the need to distribute data. Initiatives such as Fast Healthcare Interoperability Resources (FHIR) [30] have tried to set standards for exchanging health data as reusable components that could work across different EHR systems. Naturally, access to information stored in an EHR system should routinely be restricted to people with diabetes and their HCPs. A key challenge therefore is that European stakeholders need to set appropriate legal guidelines to ensure that diabetes device manufacturers conform to a collaborative standard for sharing data that is necessary for patient care, with interoperability of devices and informed consent for data sharing.

The key role of primary care healthcare teams Changes to clinical workflows are perceived to be most challenging for primary care physicians (PCPs), given that they work across multiple disease areas and have a limited time with each patient. However, as PCPs must also manage multiple diabetes treatment indications (glucose levels, lipids, hypertension, etc.), AI-CDSS have the potential to deliver significant benefits for them. One small-scale survey (n=47) concluded that PCPs have a generally positive view of AI, dependent on the context in which it was adopted [31]. Among a larger survey of UK PCPs (n=720), the benefits of AI were perceived to be related to improved workflow and reduced administrative burdens [32]. This group felt strongly that clinician empathy and clinical judgement could not be emulated by AI tools. However, a much wider investigation of PCP attitudes is

warranted, and the working group felt that one way to achieve this would be to undertake a Delphi survey (or similar; see Khodyakov et al [10] for a description of the Delphi methodology) across members of Primary Care Diabetes Europe (PCDE) and/or the World Organization of National Colleges, Academies and Academic Associations of General Practitioners/Family Physicians (WONCA) Europe.

The application of predictive AI, based on LLMs, should be appropriate in the primary care setting, focusing on a subset of AI tools that supports training for PCPs to increase their knowledge and skills, streamlines clinical tasks and improves clinical decision-making by allowing PCPs to focus on diabetes management, for example by identifying prognostic biomarkers within individual patient data to help in the early detection of type 2 diabetes [33]. This would require continuing professional development for HCPs, in order to better implement AI-CDSS for people with diabetes and other conditions. Equally, the principles and practice of AI technologies and AI-CDSS in medicine should also be a core element of training for medical school students, with periodic recertification in this discipline after qualification.

A systematic review found that the general public and patients also feel positively about the use of AI in medicine, with some caveats [34]. As with PCPs, the preference was for provider supervision of AI tools, rather than for AI to replace clinician contact, and the general public expressed ambivalence towards the use of chatbots in healthcare. In another study, outside primary care, clinicians practising in imaging-based disciplines, such as radiology, ophthalmology, pathology and dermatology, where ML is clinically advanced, were generally positive about the impact of AI in their specialisms [35], even if they did not have experience in using AI technologies. However, practitioners of non-imaging specialties expressed more caution.

Regional diversity and equity in access to diabetes healthcare Individuals from communities with racial and ethnic minority backgrounds, with lower levels of socioeconomic resources or with other adverse social determinants of health, are known to bear a disproportionate burden of diabetes while also having reduced access to diabetes technologies [36, 37]. Changing this dynamic will require a multifaceted approach, including improved public and patient engagement, specific tools to identify risks for inequity, avoidance of bias in clinical research studies and improved capture of demographic data within trials [38]. The working group recognises the diversity of healthcare systems regionally and believes that AI-CDSS will need to be adaptable across regions, or that different AI-CDSS may be needed to accommodate different healthcare datasets and health status indicators, depending on the regional situation. For example, what works in the USA or Europe may be of limited or no value in low- and middle-income countries (LMICs). As well as HCPs in each region, additional stakeholders must also be compliant with the adoption of AI-CDSS, for example payers (insurance companies, governmental drug-prescribing agencies). Critically, it is important that implementation of AI-CDSS does not reinforce existing biases and inequity, particularly as a consequence of access to digital services [39, 40]. The European Union (EU) is potentially in a position to better facilitate the adoption of new AI technologies in diabetes, as it encompasses considerable regional diversity and can set common standards and manageable cost boundaries. Moreover, the EU has the size and reach to influence legal systems to ensure that open standards for data are followed by commercial diabetes technology manufacturers, rather than proprietary solutions that foster commercial objectives. The ability of AI-CDSS to deliver solutions for underserved communities has been assessed for retinal screening, indicating that the identification and grading of diabetic retinopathy is realistic in LMICs using AI-CDSS [41].

What should AI-CDSS deliver in diabetes care?

The primary focus of diabetes AI-CDSS should be on reducing the burden of the disease for people with diabetes and supporting the delivery of care by HCPs [42]. This can include risk assessment and diagnosis, disease management, prediction of disease progression, individualising intervention and optimising early measures of treatment response. Ultimately, this means improving clinical outcomes for a diverse range of people with diabetes, from paediatric to adult care, with the ultimate goal of delivering personalised care and ensuring access to high-quality care for this large group of individuals. At a fundamental level, AI-CDSS should empower HCPs to focus on human factors in the delivery of care and build improved relationships with people with diabetes. For example, the first US Food and Drug Administration (FDA)-approved AI-driven diagnostic system in any field of medicine was an autonomous system for the detection of diabetic retinopathy in 2018 [43], and AI-based retinal screening using pattern recognition algorithms is now routinely used in diabetes care [5, 44], reducing the task load related to negative screens and allowing HCPs to concentrate on individuals in need of expert care and intervention. The emphasis on human factors was agreed by the working group to be more important than the potential for AI-CDSS to reduce the costs of diabetes care. Equally, the working group emphasised the need for AI-CDSS that allow users to manage their diabetes remotely to have an inbuilt ‘red flag’ functionality that recognises and alerts users or their HCPs of an urgent need for in-clinic review, when indicated by available clinical data.

Personalised medicine The delivery of personalised medicine in diabetes care is a highly anticipated benefit of AI-CDSS. This means that treatment is tailored to the unique disease physiopathology for each person with diabetes, taking into account the factors that define disease heterogeneity in type 1 and type 2 diabetes, such as genetics, lifestyle and medical history. Increased application of personalised medicine is expected to drive treatment optimisation for people with diabetes. For example, a real-world case study tested an AI-CDSS that supports basal insulin titration and dosing decisions through smart speaker conversations, during which people with diabetes share their most recent insulin use and fasting plasma glucose values [45]. The voice-based conversational AI system provides insulin-dosing instructions based on these conversations. Participants using conversational AI were able to optimise their basal insulin doses and improve their glucose levels significantly faster than control participants receiving standard care from their diabetes HCP [45].

The capability of diabetes AI-CDSS to use very large datasets is important in the delivery of personalised medicine. This includes applying available clinical and scientific knowledge on drug–drug interactions to safely manage treatment decisions for people with diabetes on multiple drugs for glycaemic management as well as other comorbid conditions. This is exemplified by the use of AI-CDSS to improve treatment decisions through AI-assisted selection of glucose-lowering therapies in type 2 diabetes, using data available in EHRs [46]. This has led to the development of a five-drug-class model of optimised prescribing for individuals with type 2 diabetes [47] using nine routine clinical indicators to predict treatment response: age, sex, diabetes duration, baseline HbA_{1c}, BMI, eGFR and HDL-cholesterol, total cholesterol and alanine aminotransferase levels. This model of personalised treatment selection used more than 100,000 drug initiations from the UK Clinical Practice Research Datalink (CPRD) to accurately predict the optimal oral glucose-lowering therapy for people with type 2 diabetes, which resulted in clinically relevant reductions in HbA_{1c}.

Supporting self-management needs for people with diabetes The potential for a significant impact of AI-CDSS on self-management in people with diabetes is high; however, a large number of separate tools may be required to cover all aspects of lifestyle and nutritional needs. Meal planning, physical activity and wellness AI-CDSS must reflect the local landscape of patient care, including applicable clinical guidance, prescribing and reimbursement systems and any local socioeconomic realities. This concept is embodied by the use of low-risk digital health applications, which are reimbursed in Germany and commonly available for people with diabetes [48]. The interest in creating such local solutions is perceived to be limited among the current stable of large, commercial healthcare companies. However, apps that help people with diabetes to self-manage their dietary and activity goals are already seeing the incorporation of AI tools. A proof-of-concept study published in 2023 reported the efficacy of a behavioural intervention using a food-recognition smartphone app that was able to determine the energy content of meals with high accuracy from photographs taken by the user [49]. Adults with type 2 diabetes using the app to self-manage their meal planning were able to reduce their HbA_{1c} significantly over 48 weeks compared with a group with no access to the app. Further, a third group, using both the app and also provided with a CGM system for 1 week every 3 months, with remote text messaging from medical staff, achieved even greater improvements in glucose management. Similarly, in small-scale comparative studies, at least two commercially available smartphone apps have been shown to outperform the accuracy of unaided carbohydrate counting among adults with type 1 diabetes [50, 51].

Effective delivery of diabetes self-management education and support (DSMES) can significantly improve outcomes for people with type 1 diabetes [52] or type 2 diabetes [53]. In this context, speech-based dialogue AI systems are perceived to have potential for transforming access to DSMES information. Studies have assessed the ability of ChatGPT, a commercially available generative AI chatbot, to provide diabetes-specific support for diet and exercise, education for hypoglycaemia and hyperglycaemia management, and insulin dose management [54–56]. However, the outcomes revealed deficiencies in performance related to reliance on outdated information, poor interpretation of clinical data and instances of AI-generated misinformation.

A bespoke chatbot, the Artificial Intelligence Diabetes Assistant (AIDA), has been developed with the involvement of an expert diabetes panel to provide information specific to diagnosis, lifestyle and diet and the prevention of diabetes complications for individuals with type 1 or type 2 diabetes, as well as information for PCPs [57]. In testing, AIDA demonstrated the ability to answer with confidence 91% of the questions asked by users. Another chatbot, focused on type 2 diabetes [58], has shown promising results in a limited-scope 12 week trial, with users achieving a mean decrease in HbA_{1c} of 11.0 mmol/mol (1.0%). Overall, chatbots show some potential, but cannot currently substitute for diabetes educators in this context [59].

Digital interactive DSMES applications that can support self-management decision-making for people with diabetes are in development for use as web-based services or mobile apps [60, 61]. Their utility has been validated in small-scale studies, including their cost-effectiveness for people with type 2 diabetes not using insulin compared with usual care [62]. Wider use of these and other digital AI applications will confirm whether there is a significant long-term impact

of these technologies on rates of diabetes complications and healthcare resource use.

Drivers for the development of AI-CDSS

The need for different and more productive healthcare practices for the management of people with chronic diseases has never been greater. There is a growing expectation that AI-CDSS can change healthcare delivery by managing routine tasks within the treatment space, such as triaging people with diabetes for more or less frequent clinical review, and allowing qualified HCPs to focus on higher value clinical tasks. It is important to emphasise that, to meet these needs, it is not essential that treatment decisions made by AI-CDSS are superior to those made by HCPs; simply, that they are not inferior and that AI-CDSS can manage core tasks equally well, in partnership with people with diabetes. Both the ADVICE4U initiative in type 1 diabetes [63] and the PDM-ProValue initiative in type 2 diabetes [64] have demonstrated the reality of this. In delivering on these approaches, AI-CDSS can reduce the costs of diabetes healthcare, which is a significant driver for developing such tools.

It is widely accepted that use of AI-CDSS is crucial to meet the needs of the growing number of people with diabetes and the ever-decreasing number of HCPs tasked with their care. In addition to person-centred goals, a key driver for the involvement of pharmaceutical companies in developing and promoting AI-CDSS is improvements in the identification of people with diabetes for whom their medications are applicable. This is especially relevant for the management of individuals with type 2 diabetes, as at least one longitudinal screening study has estimated that approximately 50% of people with type 2 diabetes are undiagnosed [65] and any AI-CDSS that improves their detection and diagnosis will create a larger market for relevant glucose-lowering drugs. For example, glucagon-like peptide-1 receptor agonists are used for glucose-lowering treatment in people with type 2 diabetes and are also used off-label for weight reduction, but in several European healthcare services they are not currently reimbursed for people who are not diagnosed with dysglycaemia. An AI-driven diagnostic tool could change the business model for this segment of the market by identifying a greater proportion of individuals with type 2 diabetes who could benefit from this treatment approach.

The need to better manage clinical trials of disease-modifying treatments for people with diabetes may also be an important outcome of AI technologies. Multiple clinical trials targeting common aspects of diabetes treatment have generated huge datasets that can be used to train AI tools and to re-evaluate objective outcomes. By combining participant data across multiple clinical studies and RCTs, a dataset larger than that from any single RCT could be generated and tested in a comparatively short period, with the potential to identify benefits of drugs that, in clinical development, were not revealed in expensive and time-consuming stand-alone clinical trials. In this context, access to data from industry-sponsored clinical studies must be encouraged. Existing partnerships, such as INNODIA (www.innodia.eu) and C-Path (https://c-path.org), have shown that such paradigms can be successful and should be expanded. The struggle to recruit study participants in clinical trials of disease-modifying treatments further underscores the fundamental need for data sharing.

The use of AI-CDSS in diabetes diagnosis is expected to explode in the next 5–10 years and is a focus for smaller technology companies and academic–industry consortia, which can foster creativity and agility in contrast to established corporations. For example, a consortium of academic and commercial partners have developed GluFormer, an application based on neural network architecture, that can predict an individual's future glucose levels and how they respond to specific foods, based on past CGM data [66]. Similarly, AI for Sustainable Prevention of Autoimmunity in the Society (ASSET) is a multidisciplinary consortium of academic, healthcare and industry partners with the goal of applying AI to existing cohort studies in type 1 diabetes [67]. By using data from the TEDDY registry study on individuals at high risk of type 1 diabetes [68] as a training dataset for ML, ASSET is aiming to identify features that can be used in routine clinical practice to improve risk prediction for type 1 diabetes and to determine the optimal frequency of screening and follow-up.

Regulation of AI technologies in diabetes care

The working group perceives regulatory processes, focused on approving the marketing and use of AI-CDSS products in the clinical setting, as the most significant barrier associated with effective implementation of this technology over the next 5–10 years. AI systems used for medical purposes are not new to the regulatory process. More than 500 such systems, across a diverse range of healthcare specialties, have undergone regulatory evaluation and approval by the US FDA and/or the European Medicines Agency (EMA) [69, 70].

The EASD and ADA have authored a joint consensus report including recommendations on how digital technology providers and regulators can adapt to unmet needs in the classification of digital health technologies in diabetes care, to ensure that adoption is based on the best evidence on safety and efficacy, such that diabetes digital health technology can meet its full potential [48]. A key concern regarding

the future development and implementation of AI-CDSS is the need for a regulatory process for systems that may change with input or use. Unlike the majority of medical technologies, which meet fixed definitions of their purpose and operation, AI-CDSS have the potential to introduce randomness (e.g. hallucinations) once they are used, such that they may exhibit characteristics that were not part of the original regulatory submission. Equally, RCTs, which represent the regulatory gold standard to evaluate the efficacy and safety of new therapies, typically report an average treatment effect that does not describe the individualised benefit for each unique patient profile, and which can negate the goal of personalised medicine using AI technologies. That said, a review of FDA approvals for AI medical devices between 2015 and 2020 found that at least 90% of regulatory evaluations used retrospective studies only, and that none of the so-called 'high-risk' AI devices were evaluated using prospective data [70].

In the USA, most AI-CDSS are regulated under the software as a medical device (SaMD) designation and are categorised as class I (low risk), class II (moderate risk) or class III (high risk). Class III devices undergo a more in-depth review process, but the device manufacturers do not necessarily have to provide prospective study data [70]. The EMA regulatory process in the EU is different, with the lowest-risk class I devices being the responsibility of the manufacturer and class II and class III devices being processed through so-called 'notified bodies', which are private companies. A concern is that, in the absence of agreed minimum standards for class II or class III devices, such as those specified by the International Organization for Standardization (ISO), device manufacturers and notified bodies in the EU can obtain a Conformité Européenne (CE) mark without disclosing the data on which a submission is based [71]. This can lead to a lack of rigour in the approvals process, potentially putting people with diabetes at risk of harm [71]. A scoping review of AI as a medical device for retinal image analysis [5] identified that 97% of such AI devices were approved in the EU, despite a significant number lacking published performance data. In contrast, only 22% of the same technologies were approved in Australia, with only 8% obtaining FDA approval in the USA.

However, the reality is that most AI-driven technologies to date have failed to translate into improved treatment outcomes for people with diabetes or better care by HCPs. There is an acknowledged gap between evidence generation in small-scale clinical trials and large-scale clinical implementation. Part of this paradox may be related to the current paradigm of AI implementation in medical devices, which is heavily reliant on existing data streams and learning sets that reflect established treatment practices and perpetuate systemic biases. An allied concern is how effective AI-CDSS will be when released into real-world application if they have been developed using highly curated learning datasets. Notable in this context is the need to understand and address racial bias in widely applied prediction algorithms. Using National Health and Nutrition Examination Survey (NHANES) data from 1999 and 2010, risk prediction models in diabetes were shown to be biased towards non-Hispanic White individuals [72]. Similarly, using data from individuals enrolled in risk-based contracts at a large academic hospital in the USA, for any given risk score, Black individuals were provided with less access to services than their White counterparts [73]. This frames the goal for AI-CDSS to be developed and trained on datasets that minimise or eliminate such biases, with similar needs to identify and exclude biases based on sex or indices of socioeconomic status.

Developing AI-inclusive regulatory concepts and frameworks in healthcare The FDA, Health Canada and the UK Medicines and Healthcare products Regulatory Agency (MHRA) have collaborated to develop ten guiding principles for good ML practice to ensure the safe and effective use of AI in healthcare [74]. These principles are defined in Table 1 and are intended to guide the development and deployment of AI in medical devices, emphasising safety, effectiveness and quality while fostering innovation. However, it is acknowledged that monitoring AI-CDSS is difficult once they are incorporated into clinical workflows and that post-market surveillance is very important. Separately, a number of multi-stakeholder groups have been created to establish principles for healthcare deployment of AI that follow a pragmatic pathway that ensures equity, transparency, usability and safety. These include the WHO Global Initiative on AI for Health (https://www.who.int/initiatives/global-initiative-on-ai-for-health), the Coalition for Health AI (CHAI; https://www.chai.org/) and the Artificial Intelligence Industry Innovation Coalition (AI3C) [75].

The EU Artificial Intelligence Act Among the first practical regulatory frameworks for AI devices is the EU AI Act (www.artificialintelligenceact.eu/), which came into force in 2024. In this, the EU has chosen to follow a risk-based regulatory framework, with AI devices assigned to one of four risk categories: minimal risk, limited risk, high risk and unacceptable risk. Any AI system intended for use in the healthcare arena will be designated as a high-risk device, although there are currently no objective criteria to support the risk categorisation assignment for any device. The expectation is that the EU AI Act will be accompanied by concrete tests, metrics and best practices that will improve confidence in AI-CDSS once approved for use. However, creating effective standards typically requires practical experience of the systems in question, which is currently limited for AI systems in healthcare.

The European Health Data Space regulation Coming into force in March 2025, the European Health Data Space (EHDS) regulation is a landmark initiative by the EU aimed

Table 1 Good machine learning practice for the development of AI-driven medical devices

Principle	Intent
1. Multidisciplinary expertise	Leverage diverse expertise to ensure that AI-enabled devices are integrated effectively into clinical workflows and address real clinical needs safely
2. Good software engineering and security practices	Use foundational software engineering practices focusing on data quality, management and robust cybersecurity
3. Representative clinical study participants and datasets	Ensure that data collection reflects the diversity of the intended patient population, to reduce or remove biases and achieve generalisable performance
4. Independence of training datasets from test datasets	Maintain strict separation between training and test datasets, to ensure that evaluation of an AI system is both unbiased and representative
5. Use of best available methods for reference datasets	Employ clinically relevant and well-characterised data for model training and testing to ensure robustness and applicability
6. Model design tailored to data and intended use	Design models that appropriately reflect the available data and intended use of a device, focusing on reducing known risks and enhancing clinical benefits
7. Performance of the human–AI team	Emphasise the combined performance of AI systems and their human operators, considering human factors and the interpretability of AI outputs
8. Transparency	Ensure a high level of transparency about the capabilities and limitations of AI technologies to facilitate trust and understanding among all stakeholders
9. Ethical responsibility	Ensure that the deployment of AI technologies adheres to ethical standards, protecting patient privacy and promoting fairness
10. Continuous learning and adaptation	Enable AI systems to adapt and improve through continuous learning from real-world use, while managing the risks associated with changes to AI/ML models

Adapted from Medicines and Healthcare products Regulatory Agency [74] under the terms of the Open Government Licence (https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/)

at transforming how health data are accessed, shared and reused across member states [76, 77]. The EHDS is a core component of the European Health Union and establishes a common framework for the secure exchange and secondary use of electronic health data across the EU. The EHDS is intended to underpin citizens' rights to access, control and share their electronic health data across EU borders, including medical records, prescriptions and imaging and clinical test results. Within this context, there are provisions for health data to be used for research and innovation and to inform public health policy and regulatory processes. The EU General Data Protection Regulation (GDPR) already lists 'explainability' as a requisite for any medical AI application, that is, the extent to which the inner workings of an AI-CDSS can be explained such that a human can understand why an AI-driven technology made a specific prediction or recommendation [78]. Both regulations will face challenges in that national healthcare data across the European Health Union lacks standardisation and reporting structures, with different countries having diverse national health systems.

Inclusion of people with diabetes

The proliferation of healthcare data and metrics of health status is increasing, with the anticipation of improved outcomes for people with diabetes. For example, the reliance on infrequent HbA_{1c} testing is being replaced with a raft of CGM-derived glycaemic indicators that support the timely adjustment of therapy and help to refine daily self-management behaviours for people with diabetes. This also comes with a responsibility to ensure that new AI-driven technologies using these datasets maintain a clear focus on the needs of the people with diabetes. How people with diabetes perceive AI-CDSS has been investigated in only a limited manner. A survey of 8420 people with or without diabetes in Denmark [79] reported that 46% of respondents agreed that the advantages of AI outweighed the risks, whereas fewer than 5% felt that the risks outweighed the benefits. Among survey respondents with type 1 diabetes (n=572), 89% were accepting of the use of AI technology for medical imaging of retinopathy. In addition, 66% felt that HCP involvement was still important in retinopathy screening, whereas 23% felt that technology could replace HCPs. For CGM use, 92% of people with type 1 diabetes were comfortable with this aspect of AI, of whom 30% felt that this did not require HCP supervision. Notably, only 62% of respondents with type 1 diabetes were accepting of chatbots as part of diabetes care, and only 10% felt that chatbots could provide support without HCP supervision.

Overall, and in line with previous proposals, the needs of people with diabetes may be categorised into four core objectives, illustrated in . 3. These are equity, personalisation, integration with healthcare services, and evaluation

[80]. Equity emphasises that all people with diabetes can access specific devices and applications, and is a fundamental design principle from start to finish in the development of diabetes-related AI-CDSS. This also encompasses the avoidance of bias in system development, for example through the use of non-inclusive datasets or the design of systems that are not accessible to people with diabetes with impairment or disability. The final element in ensuring equity is the need for digital literacy and straightforward education on the use of a system, both for people with diabetes and for HCPs.

Personalisation implies that development of AI-CDSS includes features that enable all people with diabetes to participate in defining their own needs for daily care and support. This may relate to the frequency of messaging and alerting, the collection of data from integrated health-monitoring systems, and supporting behaviour change that is achievable for each person with diabetes in the context of their own circumstances. All of this must be culturally and environmentally sensitive, as defined by the people with diabetes.

Integration with health services reflects the ability of AI-CDSS to deliver data, as needed, to diabetes teams and systems in a way that improves treatment decisions and actions for each person with diabetes, reducing the burden of diabetes management. This is most clearly exemplified by the ability of CGM and AID systems to upload patient-level glucose and insulin-dosing data 24 h a day for remote review by HCPs (and by the AI-CDSS) and to facilitate remote clinical review with the people with diabetes, particularly those in locations distant from their treatment centre. This also frames the ethical concept of autonomy and ownership of data, such that people with diabetes can decide who they share their data with and for what purpose. In at least one survey of people with chronic conditions [81], although not specifically people with diabetes, significant concerns over data sharing and misuse were reported. The blanket expectation that the benefits of sharing data for improved health management can be a green light for healthcare companies to monetise more widely the data they collect from people with diabetes must become a thing of the past.

Evaluation is the fundamental principle that should underpin regulatory approval of AI-CDSS (see above), such that the functional purpose of any AI-CDSS can be achieved in a safe, effective and consistent manner, across diverse diabetes populations in any healthcare practice setting. Rigorous evaluation also incorporates the need to evaluate a system against the needs for equity, personalisation and integration.

Consensus recommendations

Based on the potential opportunities and challenges presented by the use of AI-CDSS in diabetes care, a series of recommendations was developed on which the working group members were able to independently express their agreement or disagreement. Only statements on which there was a two-thirds majority in favour of adoption are provided here. The statements have been grouped into the following five categories: facilitating patient-centred care; empowering HCPs; fostering robust regulation and privacy safeguards; encouraging data standards and data sharing; and optimising clinical data capture.

Facilitating patient-centred care

1. The primary focus of AI-CDSS should be on reducing the burden of disease for people with diabetes, supporting delivery of care by HCPs, and rationalising and optimising resource use.

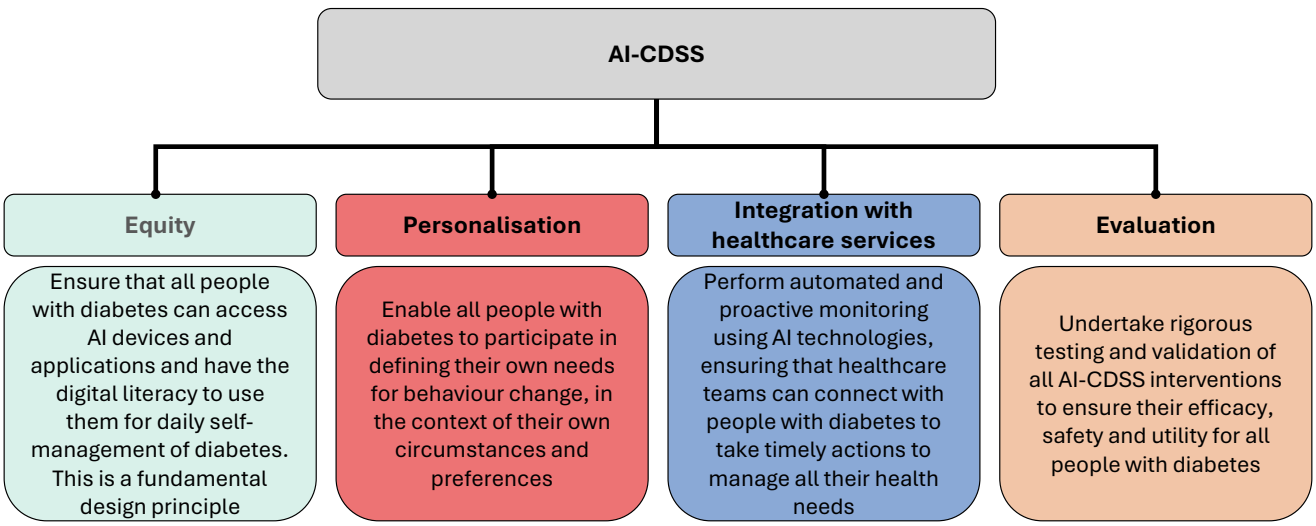

Fig. 3 The four person-centred priorities for diabetes AI-CDSS [80]

2. During the use of AI-CDSS tools, the frequency of patient–HCP contact (physical or remote) can be determined by the person with diabetes and their HCP and based on metabolic or psychosocial health status indicators.
3. The development of AI-driven technologies for any aspect of diabetes care must acknowledge the person-centred objectives of equity, personalisation, integration with healthcare services and evaluation.
4. The availability of AI-CDSS tools should not supersede the needs for patient–HCP interaction.
5. The development of AI-CDSS should include 'red flag' functionality to indicate the urgent need for in-clinic reviews.

Empowering HCPs

6. PCPs must be included as key stakeholders in the development and implementation of AI-CDSS.
7. Understanding the principles and practice of AI-CDSS must be a core competency for medical school students and a focus for continuous professional development after qualification, with periodic recertification in this discipline.

Fostering robust regulation and privacy safeguards

8. Regulatory processes for certification and marketing of AI-CDSS must be sufficiently agile to evaluate systems that may learn and change with each input or use.
9. Objective criteria must be developed to support the risk categorisation assignment for any AI-CDSS introduced under the governance of the EU AI Act. The data on which European market authorisation is based must be available for public scrutiny and should account for the diversity of the intended-use population of people with diabetes, including age, sex and ethnic background.
10. Legal safeguards must be sufficiently robust to protect the rights of people with diabetes to the same degree as for commercial developers of AI-CDSS and healthcare service stakeholders, including regarding data privacy and misuse.

Encouraging data standards and data sharing

11. Developers of AI-CDSS should adopt open standards for exchanging health data and enable data interoperability between different devices, using standard application programming interfaces.
12. AI-CDSS should be adaptable across geographical regions and be transparent to all relevant stakeholders and decision makers on whom adoption is dependent.

Optimising clinical data capture

13. RCTs should adopt study protocols consistent with data collection and reporting of individualised treatment effects for each patient profile, in addition to average treatment effects.
14. While the need to protect individual data privacy rights for people with diabetes is paramount, within these guardrails the development of AI-CDSS should aim to capture the maximum amount of data related to individual characteristics of people with diabetes, including diabetes health status indicators, phenotypic traits, cardiovascular and other risk scores, lifestyle metrics, nutritional needs and habits, and treatment adherence. This includes the need to ensure that bias is excluded based on ethnic, sex or socioeconomic status.

Strengths and limitations

A limitation of this consensus panel is that the selection of the contributors (see methodology) was not systematised in any way; rather, it reflected established experience in the emerging application of AI systems in diabetes care, from a diverse set of perspectives. The European complexion is also a potential limitation, as it may add bias to the focus and content of the recommendations. A strength of the consensus recommendations is that they are the outcomes of an acknowledged consensus methodology (nominal group technique and Delphi surveys), involving brainstorming, discussion and managed feedback among individuals with recognised expertise in diabetes technology, including diabetes HCPs, diabetes technology experts in the AI space, diabetes policy stakeholders and people living with type 1 diabetes.

Conclusions

Based on currently available data and outcomes for AI-CDSS, the EUDF working group believes that AI-CDSS will deliver benefits for people with diabetes and HCPs, but that there are significant challenges in moving AI-CDSS into the practical clinical space. The working group also acknowledge many unmet needs for improved development of AI-CDSS that are founded in optimising outcomes for people with diabetes, streamlining the delivery of healthcare with AI-CDSS and the exclusion of bias in data-driven healthcare that may discriminate against individuals on the basis of race, sex or socioeconomic status. It is acknowledged that this working group is a self-defined proactive group, which introduces a certain amount of bias in the recommendations made. From the perspective of healthcare systems, diabetes

care is underpinned by guidelines, metrics and targets that allow HCPs to understand the health status of people with diabetes in their care and support shared treatment decisions. However, this process is currently inefficient, particularly in the primary care setting, where HCPs have multiple non-diabetes responsibilities and lack the time and resources to fully understand treatment options in the context of the glycaemic status of each person with diabetes. The use of the multiple data sources that apply to people with diabetes, along with the associated guidelines and targets, makes diabetes care a healthcare discipline that is ready to exploit AI-CDSS tools.

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Data availability Any data generated during and/or analysed in the current document are available from the corresponding author on reasonable request.

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