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Review

Integrated personalized diabetes management goes Europe: A multi-disciplinary approach to innovating type 2 diabetes care in Europe

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ABSTRACT

Type 2 diabetes mellitus represents a multi-dimensional challenge for European and global societies alike. Building on an iterative six-step disease management process that leverages feedback loops and utilizes commodity digital tools, the PDM-ProValue study program demonstrated that integrated personalized diabetes management, or iPDM, can improve the standard of care for persons living with diabetes in a sustainable way. The novel "iPDM Goes Europe" consortium strives to advance iPDM adoption by (1) implementing the concept in a value-based healthcare setting for the treatment of persons living with type 2 diabetes, (2) providing tools to assess the patient's physical and mental health status, and (3) exploring new avenues to take advantage of emerging big data resources.

Contents

Abbreviations: BMI, body mass index; CLOSE, automated glucose control at home for people with chronic disease; DTSQc, Diabetes Treatment Satisfaction Questionnaires for change; EIT, European Institute of Innovation and Technology; EU, European Union; ICHOM, International Consortium for Health Outcomes Measurement; IDF, International Diabetes Federation; HbA1c, hemoglobin A1c; iPDM, integrated personalized diabetes management; iPDM-GO, Integrated personalized diabetes management goes Europe; KIC, knowledge and innovation community; KORA, Kooperative Gesundheitsforschung in der Region Augsburg; PROM, patient reported outcome measure; SMBG, self-monitoring of blood glucose; T2DM, type 2 diabetes mellitus; VBHC, value-based healthcare.

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1. Integrated personalized diabetes management

In 2019, the International Diabetes Federation (IDF) estimated that worldwide approximately 463 million adults between 20 and 79 years of age were living with diabetes, (59 million in Europe), of whom roughly 90% had type 2 diabetes mellitus (T2DM) [1]. The IDF further estimated that in the same year diabetes resulted in a global healthcare expenditure exceeding 760 billion USD, comprising approximately 10% of the total healthcare expenditure for adults worldwide, again with a large proportion due to the burden of T2DM. One reason for the enormous costs associated with T2DM is that despite the availability of multiple therapeutic intervention strategies, many patients still fail to achieve their treatment targets [2–5]. This is at least partially due to a phenomenon known as clinical inertia, i.e. the ineffectiveness of treatment intensification to improve clinical outcomes among patients who do not achieve their treatment goals despite the availability of guideline compliant healthcare services [6–8]. Other barriers that undoubtedly also limit treatment success include insufficient therapy adherence and lack of patient empowerment, both of which are dependent on the applied approaches and therapies [9–12]. Together, these barriers point towards a need for the provision of evidence-based, patient-centered approaches to T2DM care if we want to improve outcomes for persons living with T2DM.

Integrated personalized diabetes management (iPDM) is an interventional approach consisting of a structured disease management process, which utilizes digital tools and aims at bringing together physicians and patients for collaborative, therapeutic decision-making. The process incorporates six defined steps that are repeated iteratively throughout the diabetes care process and are, ideally, adapted to an individual patient's unique circumstances (Fig. 1) [13]. Specifically, the six steps include:

(1) Structured assessment and training of each patient by the medical team;
(2) Structured and therapy-adapted self-management of blood glucose levels (and other parameters) in a manner that is adapted to the individual patient's therapy requirements and circumstances;
(3) Structured documentation of clinical information including blood glucose levels and other data using digital tools;
(4) Systematic analysis of patient generated data using digital tools in close collaboration between the patient and their treating healthcare professional on a regular basis;
(5) Shared decision making and commitment about personalized treatment strategies based on individual circumstances and abilities; and
(6) Regular treatment effectiveness assessments in which therapy is adjusted or adapted, if considered necessary.

Fig. 1. iPDM consists of six steps that are repeated iteratively throughout the continuum of care: (1) structured assessment and training; (2) structured and therapy-adapted self-management of blood glucose; (3) structured documentation of clinical information. (4) systematic analysis of patient generated data using digital tools; (5) joint decision making about personalized treatment strategies; and (6) regular treatment effectiveness assessments.

Taken together, the iPDM approach leverages therapy-relevant data to inform treatment decisions while facilitating both shared decision-making and patient empowerment, all of which are important components of patient-centric care. Indeed, several aspects of the iPDM approach are in line with both the United States chronic care model, a structured approach to changing healthcare by involving communities in a primary care setting, and the European Association for the Study of Diabetes (EASD) and American Diabetes Association (ADA) consensus report for the management of hyperglycemia in T2DM [14,15].

In applying iPDM, the PDM-ProValue study program, which included 907 patients with insulin treated T2DM in Germany, demonstrated the impact iPDM can have upon outcome parameters including metabolic control and treatment satisfaction [16–18]. The iPDM intervention not only resulted in a greater reduction of haemoglobin A1c (HbA1c) from baseline compared to usual care, but also resulted in significantly higher patient treatment satisfaction, as measured by the Diabetes Treatment Satisfaction Questionnaires for change (DTSQc), and physician satisfaction after 12 months. A follow up report on the PDM-ProValue study program further demonstrated that both patients and physicians perceived a benefit in the utilization of digital tools in a structured manner [19]. In this respect, further personalization of each step encompassed within the iPDM cycle may have the potential to provide additional benefits as treatment is further tailored to the individual person living with T2DM's unique needs in the future.

2. Assembling an international consortium to implement and enhance iPDM

The PDM-ProValue study program served as the foundation and starting point for 'iPDM Goes Europe' (iPDM-GO), a three-year innovation project curated by the European Institute of Innovation and Technology (EIT) Health, a public private partnership backed by the European Union (EU). The consortium behind the project includes organizations with key capabilities in healthcare service provision as well as in the clinical development of healthcare technologies, products and services. These skills are complemented by competencies in the fields of healthcare research and economic modelling as well as in the conceptualization and implementation of training and education. The collaborating consortium partners include a global healthcare corporation, a clinical contract research organization, leading universities, an academic diabetes centre at a maximum care hospital, a municipal centre for diabetes care, and a model region exploring the possibilities of value-based healthcare (VBHC) remuneration schemes.

In brief, the project's overarching goal is to systematically explore options for implementing and enhancing iPDM in European healthcare systems by putting it into the context of VBHC. Specifically, the consortium aims to enhance the iPDM process by co-creating a novel digital, smartphone-based patient assessment tool that both captures persons with T2DM's physical and mental health and disease traits and helps them address specific health goals. The data collected from this smartphone-based tool will be available for healthcare providers in a cloud-based data management and analysis platform, which will provide them with an in-depth understanding of the patient's individual needs, barriers and circumstances. This may also enable healthcare providers to adapt a person-centric viewpoint and integrate diverse dimensions of the patients' individual life situations. In parallel, the consortium strives for a further enhancement of iPDM by developing novel algorithms for early prediction of individual disease traits and chances of treatment success. Robust health economic modelling will be an essential component of this endeavour in order to measure the impact iPDM enhancement has on some of the main drivers of diabetes-related costs, including hospitalisation and the occurrence of co-morbidities [20]. Importantly, the novel tools developed in the iPDM-GO project will be co-created with continuous and iterative input from all relevant stakeholder groups aiming to add real value for persons with T2DM, healthcare professionals and healthcare providers alike.

3. iPDM-GO: a personalized approach to increase value in diabetes care

There is substantial evidence indicating that digital tools and telemedicine approaches can improve outcomes for persons living with chronic diseases. Hu et al., for instance, analysed the impact of telemedicine on hypoglycaemia in diabetes across 14 randomized controlled trials published between 2006 and 2017. While the authors did not observe an effect on patients' body mass index (BMI), they did observe improvements in HbA1c and a reduced occurrence of moderate hypoglycaemia [21]. Similarly, the ValCrònic telemonitoring program, which focused on high-risk patients with at least one long-term condition including diabetes, high blood pressure, heart failure and chronic obstructive pulmonary disease treated in primary care, is also worth mentioning. Among other things, the telemedicine intervention applied in this study resulted in significant improvements in weight control, blood pressure and HbA1c levels, as well a decrease in primary care emergency service utilization after 12 months of intervention, providing further support for the potential of digital health solutions [22]. Despite the aforementioned promising results, however, it is important to note that sufficient clinical evidence is needed when developing digital healthcare solutions, given that several barriers need to be overcome for their broad and successful implementation. These barriers include challenges concerning long-term engagement of different patient groups, socioeconomic aspects and the so-called "digital divide", an aging society and varying levels of digital health literacy among different demographic groups [23–27].

A key deliverable of the iPDM-GO project will be the delivery of a clinically tested adaptive, smartphone-based patient assessment tool to help monitor, tailor and prioritize individual patients' T2DM management plans, remotely as well as in the physician's practice. The tool, designed according to the Personal Health Technology Model, will create individual profiles based on a psychosocial assessment process, self-reported data on well-being and physical and mental health, automatic collection of biomedical health information, and real-world contextual information [28]. In doing so, the tool aims to enable persons with T2DM, and their treating healthcare professionals to focus their limited clinical interaction time on the most effective personalized diabetes management plans. The objective is that the results of the longitudinal psychosocial assessments will continuously improve the communication between patients and their treating physicians and pinpoint relevant areas of concern in order to improve outcomes for individual persons with T2DM, for example via specified behavior change measures. By synchronously collecting the most relevant patient reported outcome measures (PROM) over time, including those proposed by the International Consortium for Health Outcomes Measurement (ICHOM), the patient assessment tool will also provide an infrastructure to help inform the design and execution of outcomes-based contracts while enhancing different aspects of the iPDM cycle.

Beyond the aforementioned psychosocial assessment tool, the iPDM-GO consortium is also working towards leveraging the potential of population data in combination with robust health economic modelling to enhance iPDM effectiveness and scalability. By applying several machine learning approaches to multi-level "omics" data from the 'Cooperative Health Research in the Region of Augsburg' (KORA) cohort we aim to provide both diagnostic and predictive algorithms assessing the individual risk for co-morbidities in the area of diabetes [29]. In the future, such algorithms may support an accurate assessment of each patient's unique health and disease signatures and refine the prognosis of iPDM responsiveness and corresponding disease course scenarios. This again would inform renewed shared decision-making and contribute to gearing iPDM expansion towards diabetic complications.

Finally, to support an effective rollout of iPDM in Europe, the iPDM-GO consortium is exploring concepts for value-based business creation in different European healthcare systems starting in a Danish community setting. In this regard, we believe, that a concerted effort by academic, administrative and industry partners to co-create impactful new business models holds great potential for changing the way healthcare is delivered and moving from volume to VBHC. These efforts will be informed by economic modelling approaches and an analysis of existing programs and best practices compiled from a policy and operational perspective and supported by multiple international experts in European healthcare [30].

4. EIT Health: an enabler of innovation

The EIT Health public-private partnership is one of the EIT's eight knowledge and innovation communities (KICs). It comprises approximately 150 partner organizations from multiple sectors and countries across Europe with the common ambition of tackling some of Europe's most pressing healthcare challenges while delivering innovative products and services where they are needed the most. In this respect, the EIT Health network connects a vast number of renowned European organizations and stakeholder associations from the fields of business, research and education with the overarching goals of (1) strengthening healthcare systems in Europe, (2) promoting better health of citizens, and (3) contributing to a sustainable health economy.

Placing iPDM-GO within the EIT Health innovation project portfolio is thus an important lever supporting VBHC and the sustainable enhancement of iPDM in Europe. Traditional funding schemes often focus on the research and development of individual products aimed at specific markets. In iPDM-GO, however, we strive to implement a new and innovative healthcare model that requires a holistic vision on processes, technology, and markets. To support this, EIT Health provides easy access to co-creation communities, living labs, test beds and multiple stakeholder organizations. Moreover, the EIT Health KIC exposes projects like iPDM-GO to the global start-up scenes, competitions for product and service ideas and innovative business models. The connection with EIT Health also facilitates the consistent integration of market-oriented research, education, and business creation, a concept that is referred to as the EIT "knowledge triangle" [31]. This triangle matches well with the iPDM-GO strategy of achieving a high market acceptance by connecting iPDM to VBHC remuneration principles. The iPDM-GO consortium will greatly benefit from an interactive feedback culture, matchmaking opportunities as well as the combined forces to tackle the implementation barriers to digital health solutions in Europe. Indeed, the European Commission has recognized that, if it is to overcome these barriers, future healthcare will require (1) secure access and exchange of health data, (2) pooling of health data for research and personalized medicine, and (3) digital tools and data for citizen empowerment and person-centered healthcare, all of which are aspects addressed in the EIT Health's strategic agenda and the iPDM-GO initiative. Other EIT Health funded innovation projects in the area of chronic disease management include the pan-European consortium CLOSE (Automated Glucose Control at Home for People with Chronic Disease), which aims to develop artificial pancreas solutions for persons with T2DM dependent on homecare [32].

5. Limitations

Despite their potential to improve outcomes in diabetes care, as became particularly evident during the Covid-19 outbreak that disproportionally affected persons with diabetes [33,34], there remain several barriers still limiting the effective use of digital tools in diabetes care. Smartphone utilization and access to digital solutions, for example, are heavily dependent on age, socioeconomic status and the respective healthcare system. Even if access to the respective technology is achieved, long-term engagement and health literacy are among the challenges, which can be difficult to overcome [23–25]. User-centered design represents a promising approach to address some of these barriers by identifying the users' preferences early on and tailoring solutions accordingly. To be most effective, however, co-creation should involve all relevant target groups, including elderly patients with their unique needs in managing T2DM [27]. Furthermore, evidence of sufficient quality is needed to assess the real-world effectiveness of any novel digital solution. Such broader investigations will be required to evaluate the viability of the digital, smartphone-based patient assessment tool during and beyond the iPDM-GO project phase, preferably in different cultural scenarios. Complimentary approaches to assess potential users' health technology readiness and enablement may also help identify the patient segments that will benefit most from a given healthcare intervention like the one developed in iPDM-GO [35].

Regarding the implementation of VBHC, it is important to note that while there is willingness to embark on VBHC solutions within many European healthcare systems, there are also several barriers that need to be overcome in order to be successful. The healthcare sector has largely not been able to translate and scale local VBHC pilots to national or regional VBHC programs. Even if individual payment initiatives have demonstrated improved healthcare value, it is not simple to integrate them with a comprehensive and coherent system-wide care delivery and payment regime. A major unresolved issue is how to design payment schemes that support VBHC across multiple providers and organizational levels. In order to be successful, there is a need for a systematic collection of PROM data to support the clinical effect measures. It has proven to be particularly resource heavy to collect and maintain information on cost. At the administrative level, VBHC projects have been used to identify departments with improvement potential, where the clinical departments request individual data to make proper use of the VBHC solutions (Vrangbæk K. & Starr L., Working Paper).

While in iPDM-GO we have the ambition to design models of how VBHC solutions can be co-created locally and demonstrate the impact they can have on healthcare, the broader implementation of such solutions will require the continuous engagement and commitment of diverse stakeholders over many years, thus going beyond the scope of this project. Nevertheless, we believe that multi-stakeholder approaches like those facilitated by the EIT Health High Value Health Care Forum play an important part if we are to move towards a sustainable provision of high value healthcare [36].

6. Conclusion

In summary, by realizing and further enhancing iPDM in Europe, the iPDM-GO EIT Health innovation project strives to deliver a community-based care model that aims to improve outcomes that matter to persons with T2DM. In turn, this approach may contribute to the broader overarching goal of further reducing the rates of avoidable hospitalization for ambulatory care sensitive conditions and thus help save healthcare and societal costs, while also potentially offering additional opportunities in the area of prevention. Ultimately, iPDM-GO hopes to contribute to enabling persons with T2DM to live longer and healthier lives. In this respect, continuous and collaborative exchange across the various projects in the EIT Health portfolio holds the potential to recognize and exploit synergies to mutually drive innovation in European healthcare.

Ethics

Work with human subjects or data derived from human subjects, will be carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki). Informed consent will be ensured and the privacy rights of human subjects will be observed.

Conflict of interest

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: AJ and DK are full-time employees of Roche Diabetes Care GmbH. FS is a full-time employees at Profil GmbH. TH and LH are shareholders of Profil GmbH.

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