

UNLOCKING ACCESS TO DIGITALLY ENABLED DIABETES CARE The case for a better Type 2 Diabetes ecosystem in Europe



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Unlocking Access to Digitally Enabled Diabetes Care

The case for a better type 2 diabetes ecosystem in Europe

This paper reflects the views of the MedTech Diabetes Sector Group with the input of a wide set of stakeholder experts. It has been written by Harwood Levitt Consulting.

The MedTech Europe Diabetes Group is committed to addressing the needs of people living with diabetes and their care teams to improve health outcomes and quality of life, while supporting healthcare systems in meeting the demands of this growing diabetes pandemic and improving their resilience.

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are European and multinational companies as well as a network of national medical technology associations that research, develop, manufacture, distribute and supply, health-related technologies, services and solutions.

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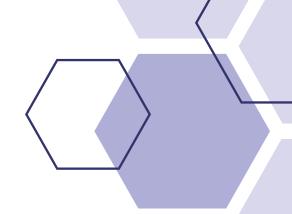








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Introduction

Diabetes is a 'silent' pandemic in Europe, and type 2 diabetes (T2D) accounts for the vast majority (around 90%) of all cases. Unlike type 1 diabetes (T1D)¹, which is an autoimmune condition, T2D is a chronic and progressive condition developed over time and linked to a combination of lifestyle, environmental, genetic, and other factors.

T2D leads to serious health emergencies if not effectively managed, including blindness, kidney failure, heart attacks, stroke and lower limb amputation^{2, 3}. This places a large burden first and foremost on those living with T2D, as well as their care teams, and is costly for health systems and society at large.

Diabetes-related complications can be postponed or avoided altogether if detected and managed early, by means of improving glucose management^{4, 5, 6}. While prevention is key in addressing the growing diabetes pandemic, it cannot alone solve this growing health challenge. Solutions are needed for the millions of people already living with the condition in order to improve health outcomes and quality of life, support HCPs, and unburden overstretched health systems.

Proper management of T2D involves several pillars, comprising lifestyle changes, medication, integrated care team support, and self-management tools and services such as medical technologies, apps, algorithms, and Al. **Together, this 'ecosystem of digitally enabled care' has the potential to support people living with T2D and their care teams in better managing their condition**, as reflected in evidence⁷⁻¹¹ and conveyed by expert interviewees.

However, there are significant barriers to accessing such devices and services in Europe for people living with T2D, with substantial consequences for thousands of individuals and healthcare systems.

The need for more effective diabetes management is clear. In 2021, more than 650,000 people died in the EU due to complications related to diabetes¹², while the high hospitalisation costs of secondary conditions linked to ineffective diabetes management – such as cardiovascular events, organ failure and amputations – placed significant strain on healthcare systems that are often equipped to address acute events rather than manage chronic illnesses. Traditional, sometimes **outdated healthcare interventions can under-deliver on outcomes and over-charge on costs: it is time to change them.**

Thankfully, there is a growing momentum around tackling diabetes in the European Union, with both national governments and EU institutions increasingly recognizing the urgent need to address these pressing health challenges.

The 2024-2029 EU institutional mandate is a unique opportunity to take concrete actions to signifi-



cantly improve the care and lives of millions of Europeans affected by diabetes. By placing diabetes at the heart of the EU's efforts to combat non-communicable diseases (NCDs), policymakers can drive meaningful progress in reducing the

burden of these conditions on individuals, healthcare systems, and society as a whole.

This paper explores the current challenges to efficient management of T2D and the main obstacles that prevent the opportunity presented by digitally enabled care from being fully realised. It also outlines six recommendations for policymakers, to move forward towards better, more sustainable and equitable access to quality care for all people living with T2D. These range from speeding up the digitalisation of healthcare systems and regulatory processes at EU level to improving interoperability and data-sharing within and between countries, to delivering value-based healthcare and improving digital literacy across Europe. It is also crucial to recognise, that while the focus of this paper is on T2D more specifically, there is also a long way to go for the challenges related to T1D to be resolved.







Summary of key recommendations

To address the growing pandemic of T2 diabetes in Europe, stakeholders must collaborate to find joint solutions. Decision-makers at national and EU level must urgently address the growing healthcare needs in this area, to ensure better access to digitally enabled care.

What is needed for T2D

Bolstered capacity for early diagnosis and appropriate monitoring of T2D to ensure quick access to adequate care

- Fostered efficiencies and better support for healthcare professionals (HCPs) through digitalised healthcare systems
- Advanced equity in T2D care access and outcomes in Europe, through better public health data
- **Strengthened** access by HCPs to health data through interoperability and data-sharing
- Appropriate reimbursement frameworks that recognise value-based diabetes care in all Member States
- 6 Increased awareness of digital health solutions and improved digital literacy

How to get there

- Establish targeted screening programmes for T2D, support novel diagnostics, adoption of own-initiative report on diabetes by the European Parliament
- Invest in robust digital infrastructure to integrate electronic patient records, monitoring role for the European Commission to track progress
- Develop national diabetes plans with national registries, support cross-border data collection
 - Draw up implementation plans for EHDS regulation in alignment with existing regulatory frameworks, avoid national standards and promote international convergence on interoperability
 - Promote reimbursement frameworks that recognise value-based healthcare (including bundled payment schemes and alternative frameworks), reimburse cost-effective digitally enabled diagnostics, treatments and therapies
 - Upskill HCPs on using digital tools and analysing patient data, promote digital health literacy through digital literacy programmes for HCPs and people with diabetes, and increased funding for related initiatives



Methodology and interviewees

This paper has been prepared on the basis of a literature review and desk research, in addition to interviews to gather the perspectives of expert stakeholders in the diabetes field. These discussions have informed the sections on barriers and recommendations in this report.

The list of interviewees includes clinicians, researchers, patient representatives, policymakers, and payers active at EU, national and regional levels.

The interviews were conducted from February to April 2024 with expert stakeholders, some of whom include:

- Stefano Del Prato, Chairman of the European Diabetes
 Forum (EUDF), Medical Doctor, Professor of Endocrinology and Metabolism at the University of Pisa School of
 Medicine and Chief of the Section of Diabetes, University of Pisa
- Enrique Terol, Counsellor for Health at the Permanent Representation of Spain to the EU
- Dr. Francesc Xavier Cos Claramunt, Chairman of Primary
 Care Diabetes Europe (PCDE), Board member of the European Diabetes Forum (EUDF), Director of Sant Martí
 Primary Health Centres (Catalonia's National Health Service), GP
- Prof. Dr. Freimut Schliess, Independent consultant in the EIT Health Mentoring & Coaching network, Head of the CLOSE EIT Health Innovation Project
- Dr. Luk Buyse, Medical Doctor, GP, President of Diabetes Liga (Flemish organisation caring for people with diabetes)
- Dr. Aurora Ursula Joala, Policy Officer (Seconded National Expert) at DG SANTE

- Dr. Niti Pall, Managing Partner at Health4All Advisory Ltd., Senior Digital Health Advisor at AXA EC, Board member of the European Diabetes Forum (EUDF), former Chair of the International Diabetes Federation Europe Region
- Maya Victorova, President of the Bulgarian Diabetes
 Association, Board member of the European Regional Board of the International Diabetes Federation (IDF Europe)
- Simon O'Neill, Director of Health Intelligence and Professional Liaison at Diabetes UK, registered nurse

NB: The views expressed in this paper are the responsibility of the MedTech Europe Diabetes Sector Group, do not necessarily reflect the collective views of the contributing interviewees.

Abbreviations

AI: artificial intelligence

T1D: type 1 diabetes **T2D:** type 2 diabetes

PwT2D: people with type 2 diabetes

HCPs: healthcare professionals

Type 2 diabetes is a growing health challenge for Europe

T2D is a chronic condition affecting millions of Europeans. Often described as a 'silent pandemic', it is one of the major health challenges of our generation. Globally, more than one in 10 adults are currently affected with diabetes overall (T1 or T2), with an increasing number of countries seeing as many as one in five or more of the adult population living with diabetes¹³. Over the past two decades, the estimated prevalence of diabetes among adults aged 20-79 has more than tripled, from around 151 million individuals in 2000, or

4.6% of the global population, to 537 million individuals, or 10.5% of the world's population today¹⁴.

In Europe, over 61 million people live with diabetes – equivalent to the entire population of Italy¹³. By 2045, that number is expected to rise to 70 million people. Globally, if current trends persist, by then this number is expected to rise to a staggering 783 million – around 12% of the global population¹⁴.

T2D accounts for around 90 to 95% of all cases^{15, 2}. This means that at least 55 million people in Europe currently live with T2D, and that an estimated 63 million will have the condition in 2045. Globally, 713 million people are expected to have the condition by 2045.

What is Type 2 Diabetes?

When we eat, food is broken down into glucose, a type of sugar which enters the bloodstream to act as a source of energy for the human body. Insulin, a hormone produced by the pancreas, helps glucose enter the body's cells to be used for energy. For people living with T2 diabetes, cells become resistant to the effects of insulin, and the pancreas eventually becomes unable to produce enough insulin to move glucose and meet the body's needs. As a result, glucose remains in the bloodstream, leading to high glucose levels (hyperglycemia). In response, the pancreas produces more insulin to compensate, but over time, it may not be able to keep up with the demand^{19, 20, 21}.

If left untreated, high glucose levels can cause a range of health problems, including nerve damage, kidney damage, vision loss, and cardiovascular disease². The symptoms of T2 diabetes can be mild or absent in the early stages, which is why it is often referred to as a "silent" disease¹⁶.

The impact of diabetes on an individual's quality of life is all-encompassing. People living with T1 or T2 diabetes must continuously make



decisions through the day to effectively manage their health: diligently monitoring and responding to fluctuating glucose levels, persisting with medical regimens, carefully considering their dietary choices in terms of timing and composition, ensuring adequate hydration, and making informed decisions regarding physical activity¹⁷. The emotional burden of constantly managing their condition can significantly affect their physical and mental well-being¹⁸.



Key facts

- Diabetes ranks among the top 10 causes of mortality in the EU²², as well as globally¹³.
- In 2021 it was estimated that diabetes was responsible for 6.7 million deaths worldwide, equivalent to one death every 5 seconds²³.
- In 2021, the EU recorded more than 650,000 deaths related to diabetes among adults aged 20 to 79 years¹² roughly 34 times the number of people killed in road accidents the same year²⁴.
- One out of 3 people (36%) living with T2D in Europe are undiagnosed¹².

The cost and complications of type 2 diabetes

T2D can bring serious complications for people with diabetes and their families

T2D is a progressive condition that can **give rise to serious complications** if not effectively managed. These include:

- A 1 in 3 chance of cardiovascular disease (CVD), which
 can include coronary artery disease and stroke²⁵. Someone with diabetes has an 80% risk of dying from cardiovascular disease²⁶. Diabetes therefore significantly
 contributes to the economic burden of CVD, amounting
 to an estimated €282 billion annually in the EU.
- A risk of limb amputations 15 times greater for those with diabetes³ – it is the leading cause of lower limb amputations.
- 50% risk of having diabetic neuropathy (nerve damage)²⁷.
- Diabetic foot disease (DFD) is a frequently encountered complication in advanced stages of diabetes and one of the most severe and costly long-term diabetes-related complications.
 - Treatments have a substantial impact on healthcare expenses and burdens, and they often lead to increased hospital admissions, emergency room visits, and frequent outpatient appointments³⁴.
 - On average, diabetes is linked to a 1 in 4 chance to develop foot ulcers, with a resulting 50% risk of infection and 20% risk of amputation³⁵.

- 25% risk of diabetic retinopathy, an eye disease that can lead to vision impairment and blindness²⁸.
- 48% risk of developing kidney disease, which can lead to kidney failure²⁹.
- 2-3x increased risk of depression compared to those without diabetes^{30, 31}.
- 1.5-2x increased risk of dementia, compared to the general population²³.
- A decrease in the life expectancy of 5-10 years on average, compared to people without diabetes²⁶.

For people with T2D, these complications often cause a reduction in quality of life and mental well-being, as well as pain and discomfort, and may lead to disability and premature death³². Mental health issues can also further worsen diabetes management and care, creating a vicious cycle that ultimately impacts quality of life and longevity³³.



High collective costs of T2D for society at large

For health systems, addressing T2D and its complications is costly. The total expenditure in the European region (including non-EU countries) on the treatment of advanced diabetes and its complications amounted to \$189 billion (20% of global expenditure) in 2021¹². In the EU alone, direct expenditure on diabetes added up to €104bn in the same year.

Of the total T2D-related healthcare costs in Europe, half are due to hospitalisations for health emergencies³⁶ which arise when the condition is **not effectively managed**³⁷. In the EU, the median cost of health expenditure per person living with diabetes (T1 and T2) amounts to €2,482¹², which varies significantly by country.

Because in most cases, T2D occurs in parallel with other chronic conditions, long-term patient management is expected to become increasingly complex and resource-intensive for healthcare systems. This creates a massive strain in times of crisis, as was seen during the recent COVID-19 pandemic³⁸. Over the next 20 years, **diabetes-related health expenditure per person** in Europe is expected **to increase by almost 80%**, from around €2,900 in 2021 to over €5,200 in 2045³⁹.

At the same time, **healthcare budgets are under pressure:** the 2023 OECD Health at a Glance report on Member State Health Systems⁴⁰ finds that balancing health budgets with other competing priorities such as education, defence, and housing for resources is a key challenge. High inflation, coupled with stagnant or declining wages for HCPs in countries such as Finland, Portugal, Italy and Spain have recently led to regular strikes and increasing staff shortages. In light of this, it is urgent to adopt solutions that ease the burden on HCPs and lower costs to health systems.

For wider society, T2D brings a host of hidden costs. Diabetes-related productivity losses and disability can lead to reduced workforce participation, affecting the overall economy⁴¹.

Additionally, it contributes to more absences from work, as well as and presenteeism, where employees are present at work but less productive due to health issues⁴². It can also be physically and emotionally difficult to work while experiencing symptoms of high or low blood glucose (hyperglycemia and hypoglycemia, respectively).



In Belgium the yearly costs for diabetes draw near to 6 billion EUR, of which only 6% is medication – all the rest is spent on managing complications.

A healthcare professional that we interviewed





Several national studies have illustrated the costs of diabetes in the workplace, as well as the additional burden for people living with this condition:

- A study conducted in Germany found that, compared with a person without T2D, the mean productivity-adjusted life years lost per person with T2D in 2020 was 2.6 years⁴³.
- A Danish research study examining the yearly occurrence of work absenteeism caused by complications related to diabetes revealed that many of these complications resulted in an absence from work exceeding three months for the typical individual with diabetes. Cardiovascular problems were the most common complications⁴⁴.
- A survey on prejudice in the workplace for people with diabetes conducted in the United Kingdom found that⁴⁵:
 - 19% of people with diabetes were disciplined for needing time off
 - 25% were questioned about their time off
 - 12% were not allowed time off at all
 - 31% of workers with diabetes reported fear of diabetes impairing their careers
 - 16% lied when calling in sick, saying they had a cold rather than admitting their absence was due to their diabetes

Key facts

- The cost of primary care has been reported to increase almost sixfold when complications are present, with the majority (40-60%) of the costs of managing complications being through in-patient care³⁷
- Overall costs of complication management have led to an increased annual spend of up to EUR 4,051 in France and EUR 5,725 in Germany, respectively. End-stage renal disease, amputation, and fatal ischemic heart disease are among the most costly complications⁴⁶.
- Europe has the third largest diabetes-related ed expenditure globally, comprising more than 8% of global expenditure⁴⁷.
- Direct expenditure of EU member states on diabetes was €104bn in 2021¹².
- In 2021, diabetes represented almost 9% of the total yearly health expenditure in Portugal ^{48, 49}, about 8% in Finland⁵⁰ and 7% in Italy⁵¹.
- In Sweden, the health system expenditure for each person living with diabetes amounts to €7,200. In Belgium the average is €6,000⁵².
- A Swedish study revealed that, in some settings, the cost of managing complications in Sweden represents up to 75% of total hospital expenditure for people with T2D⁵³.

The role of digitally enabled care in effective T2D management

Self-management as part of the care pathway in T2D

While there is no one-size-fits-all approach, the care pathway for people living with T2D involves several stages, including diagnosis, initial assessment, and ongoing management – most frequently self-management:

- The diagnosis of T2D is typically made based on blood glucose levels and symptoms.
- Once diagnosed, people with diabetes undergo an initial assessment to determine the severity of their condition and develop a treatment plan.
- Treatment plans may include lifestyle modifications, such as changes to diet and exercise habits, as well as medication. If oral medication alone proves insufficient in managing blood glucose levels, insulin injections may be needed⁵⁴.
- In the longer term, ongoing management of T2D involves regular monitoring of blood glucose levels, check-ups with HCPs, and adjusting treatment as necessary.
- Individuals may also receive education and support to help them manage their condition, including information about healthy eating, physical activity, and medication management.
- A key fact to recognise is that management needs for T2D evolve as the condition progresses.

Self-management is a core component of an individual's T2D management plan. This refers to the active engagement of people with diabetes in self-care activities aimed at improving their behaviours and managing their condition. It includes blood glucose monitoring, taking diabetes medications, meal planning, physical activity, and managing episodes of illness and low and high blood glucose. Self-management in T2D is often challenging for individuals, as many struggle with the complexities of diet, exercise, medication, and monitoring blood sugar levels. The pain and psychological burden of blood glucose monitoring can also lead to individuals ignoring fluctuations in blood glucose until they cause physical discomfort.

Key facts

- Recent data from real-world observations and surveys show lack of progress in T2D management outcomes; among people with T2D in Europe and the US, only 39% effectively managed their condition⁵⁵.
- A Finnish study indicates T2D management shows a concerning trend of worsening over time, particularly for people living with other diseases at the same time (comorbidities)⁵⁶.



Digitally enabled care in daily T2D management

Digital tools and solutions can play a role in the care pathway for people with T2D by providing additional support to people with diabetes and their carers when it comes to the daily management of the condition. Digitally enabled care (see Table 1) consists of an ecosystem of devices and services that leverages data and digital connectivity to facilitate better self-management, strengthen interactions with care teams, and improve outcomes and quality of life for people with diabetes. The different medical technology elements of this ecosystem include connected glucose monitoring systems, smart insulin delivery systems, health apps and algorithms, and telehealth solutions, among others. These tools also enable services such as e-prescriptions and e-health records⁵⁷.

This ecosystem of digital devices, apps, systems and solutions present significant advantages for people living with T2D, their healthcare providers and carers:

- Digital devices empower people with T2D and their care teams to have a better understanding of their condition

 of the impact of stress, physical activity, and nutrition
 which ultimately contributes to better monitoring and self-management of glucose levels.
- Digital enabled medical technology allows individuals to more easily communicate with HCPs, and enable providers throughout the care pathway to coordinate and tailor their interventions to the needs of people with T2D. The data provided to HCPs by digital tools enables remote monitoring in a personalised way. Technology and connectivity also facilitate practical services such as e-prescriptions, through which algorithms can predict and prompt insulin refills via an automatic service. As a result, digital solutions enable people to receive the support required in difficult situations where they otherwise would not have been able to be assisted.



Technology, remote monitoring and alert systems can allow carers and patients to be proactive in managing the condition – rather than running after treatment failures and critical situations.

Stefano Del Prato, Chairman of EUDF, Medical Doctor, Professor of Endocrinology and Metabolism

- Digitally enabled devices and digital solutions enhance
 the ability of peole living with diabetes to self-manage
 their condition through better collection and analysis of
 data⁷. By greatly facilitating the constant evaluation and
 monitoring of glucose levels, digitally enabled diabetes
 medtech allows for informed decision-making by providing them with clear and objective information.
- The use of digital tools makes it possible to fully integrate
 the homes of people living with diabetes into the
 healthcare pathway to provide new services without disrupting daily life. Most individuals with
 diabetes are lacking this
 support and experience
 a tremendous burden
 when managing diabetes treatments,
 despite the mounting evidence of the
 effectiveness of digital

medtech in



improving several components of quality diabetes care, such as education, coaching psychotherapy, social support, physical activity promotion, medication adherence, and nutrition management^{58,59,60}.

People living with T2 diabetes confirm that digitally enabled care contributes to an improved quality of life, higher satisfaction levels, and higher levels of confidence in their ability to manage their diabetes⁸⁻¹¹. A 2020 study found that "through the use of digital interventions, participants felt like they had more control over their diabetes and felt more in control generally. Being "more informed" about diabetes in general and having personalised information created a feeling of greater agency to affect their diabetic bodies, behaviour, and health care"⁶¹.

In addition, these digitally enabled devices and services can result in cost savings and efficiencies for hospitals as better health data leads to better monitoring of glucose levels and informed decision-making, improving clinical – and reducing the likelihood of unplanned hospitalisations and complications⁶². This leads to a reduction in healthcare expenses and eases the burden on healthcare systems, ultimately limiting the burden on care teams, health systems and society⁶³.

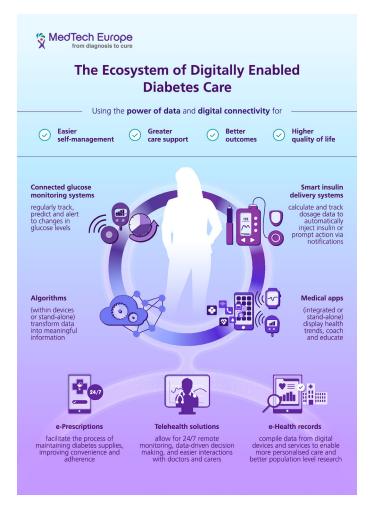


Table 1: The Ecosystem of Digitally Enabled Diabetes Care – Infographic

Value of digitally enabled diabetes care

Ultimately, the value of digitally enabled diabetes care for the individual and collective management of T2D is clear:

- Better health outcomes for people with diabetes⁶⁴, from the reduction of both acute health emergencies and long-term progression and comorbidities^{65, 66}
- Greater quality of life, peace of mind and autonomy for people with T2D and their loved ones^{64, 65}
- Greater secondary prevention and a reduction in the need for hospitalisations⁶⁷ and emergency services⁶⁸, more effective management and the prevention of comorbidity for people with T2D

- Lower demand for in-person care, allowing HCPs and care teams to focus time on individuals in need (an estimated 80% of routine care could be handled fully via telemedicine)⁶⁹
- Lower geographical barriers for people with diabetes to connect with HCPs (although this must be accompanied by an effort to reduce the digital divide)⁶⁷
- Cost-savings and more efficient resource allocation by health systems by keeping costs under control (including regular check-ups or management of co-morbidities)⁶⁷



• Improved knowledge and data sharing, including via Electronic Health Records and outcome-focused diabetes registries, to coordinate care and support clinical research⁶⁷ to better understand the diabetes pandemic and foster innovation

Improved outcomes for society, as people with diabetes and their care teams (including family members)
 benefit from a lightened burden linked to the demands of day-to-day diabetes management⁷⁰

However, despite these many benefits and the numerous efficient tools available for diabetes management, a significant proportion of people with type 2 diabetes still struggle to manage their condition.

Therefore, to identify ways forward with the T2D community and stakeholders, it is important to better understand and shed light on the major barriers and drivers impacting access to better T2D care.



Barriers to accessing digitally enabled care

Throughout the listening exercise with stakeholders in the diabetes community in Europe, several key themes emerged related to the range of barriers to equal and effective access to digitally enabled care for people living with T2D.

These can be broken down into three main areas:

- Systemic factors, such as ageing populations and workforce shortages, are challenges that go far beyond the single issue of access to digitally enabled care and tend to negatively impact the performance of health systems across the whole scope of services they provide.
- Policy barriers are institutionally established rules and legislations which, for a variety of reasons, prevent efficient tools, medical devices and other digitally enabled instruments from reaching the people that would benefit from them.
- Educational barriers are societal factors around a lack of knowledge or information, which hamper the uptake of digitally enabled tools and devices by the healthcare system, even when available.



Systemic Factors

Healthcare systems in Europe are affected by a multitude of developments which negatively impact their effectiveness and financial sustainability, which are particularly pronounced in the context of T2D. These include a rapidly growing patient population, an overburdened and strained workforce, and system-wide inefficiencies in the delivery of care.

- According to interviewees, the first major challenge relates to the growing number of people with T2D in Europe. It is estimated that 63 million Europeans will have T2D by 2045 around double the number of people living today with this condition. This booming number of people with T2D, together with the trend of an increasingly ageing population, will lead to significant resourcing needs.
- The increasing T2D population is an additional strain on the healthcare workforce. There is also shortage of specialists across all departments, including diabetology and endocrinology. In addition to the difficulty of accessing medical services in rural areas across Europe, these circumstances show that healthcare systems will not have the capacity to provide the time, resources and care required for people with T2D in the future with the current methods and tools.
- A third systemic challenge is the **fragment- ed nature of care delivery** in many European countries. There is a rising consensus that
 the way health systems organise diabetes care is
 siloed and inefficient. An example of this is the systemic
 lack of coordination between HCPs in the case of T2D,
 between primary care physicians, nurses, diabetologists,
 nutritionists and dietitians, and other professionals potentially involved in the management of the condition.
 Patient organisations and charities are also often not
 integrated into this ecosystem. The outcome of this is
 inadequate or delayed care for people with T2D.
- Another challenge in Europe is the **significant inequalities in access to quality diabetes care and patient outcomes**, between as well as within countries. For example, there are large disparities across Europe in the time it takes for people with diabetes to access medicines after approval⁷¹, as well as the medical services that would allow for better management of the condition in the long term⁷². This is acknowledged in the 2022 European Parliament Resolution on the "Prevention, management and better care of diabetes in the EU", which stressed that "many inequalities still exist […] among and within Member States regarding access to care, education, au
 - tonomy, medicines, tools to monitor blood sugar levels, supplies and technologies and health outcomes" ⁷³. Often, these disparities lead to higher-risk groups having less access to optimal treatments, in particular in the case of T2D⁷⁴.
 - These inequalities are further exacerbated in the realm of digitally enabled care^{75, 76}. Several studies^{77, 78} have highlighted that digital health technologies are



There is a shortage of healthcare providers which, if left unchecked, will result in an even greater and heavier burden on the remaining HCPs.

Stefano Del Prato, Chairman of EUDF, Medical Doctor, Professor of Endocrinology and Metabolism



not equally accessible to all communities and areas in Europe, with disparities in access first and foremost based on the urban versus rural areas divide and age, but also on factors such as ethnicity, language barriers, education levels and economic status. They also underline that inequalities in access, use, and engagement with digital technology can widen existing health inequities if not addressed. As a result, these disparities lead to significant inequalities in health outcomes in Europe⁷⁹.

Taken together, these challenges indicate that if the challenges are not addressed in the systemic management of the pandemic that is diabetes, the sustainability of health-care systems will be threatened across the whole of Europe.

Policy barriers

From a policy perspective, the European legislative framework presents challenges that, if resolved, could pave the way for better and more equal assimilation of digitally enabled care by healthcare services and people with diabetes. Barriers remain in terms of regulatory frameworks, the possibility of sharing, accessing and using data, as well as reimbursement schemes – with detrimental implications on access to digitally enabled care for people with type 2 diabetes if not resolved.

The complexity of the **EU Medical Devices Regulation** (MDR) leads to delays in many innovative technologies and instruments for T2D reaching individuals. Indeed, with current regulations, obtaining a certification for a medical device takes 12-18 months – a long time for people to wait. The way it is currently implemented, the EU MDR does not allow for innovations to be swiftly approved and made accessible due to an intricate and slow regulatory pathway, unnecessary bureaucratic and costly hurdles and structural inefficiencies.

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With current regulations, obtaining a certification for a medical device requires between 12 and 18 months. Policymakers have a huge duty to their communities to make sure the regulatory processes are sped up.

An interviewed patient representative

- hinder people with diabetes from fully benefiting from the potential of digitally enabled devices and tools. The current restrictions on which data can be collected and how they can be shared with healthcare practitioners, as well as the lack of unified systems for professionals to access these data either at EU or national level, prevent the whole healthcare ecosystem from people with diabetes to HCPs and healthcare systems from benefiting from the cost-saving and condition management gains mentioned above.
- Current reimbursement frameworks do not take a sufficiently value-based approach when it comes to digitally enabled care. That means that they do not reward better health outcomes on a systemic level, prioritising short-term services (acute treatment and care) rather than taking a long-term perspective. The implication for people with T2D is that many do not benefit from reimbursement for the tools they need to manage their con-

dition as frameworks do not allow digitally enabled care to be fully integrated into care pathways even if the long-term manage-



ment benefits significantly outweigh the upfront costs. People with T2D thus often do not benefit from digital devices and applications that could significantly empower them – and prevent costly complications.

Educational barriers

From an educational standpoint, many European countries are affected by a lack of digital skills, a hesitant and sceptical mindset towards digital health technology and, at times, improper clinical guidelines. These factors hinder the extent to which digitally enabled care reaches and is used by individuals.

- Digital literacy, or illiteracy, is a substantial challenge for the uptake of digitally enabled healthcare in the case of T2D. As of now, many people living with T2D but also healthcare providers in Europe lack the skills, knowledge and access to technology required to appropriately integrate digitally enabled tools, services and solutions into their daily management of their condition.
- Supporting educational efforts and diabetes awareness
 is important both for the general population, as well as
 for people living with all types of diabetes. In the case of
 T2D which is usually diagnosed later in life, it is particularly important to ensure awareness of lifestyle choices
 and how to best manage the condition.



The challenge is to achieve a higher level of education and training about digital solutions – to think less in terms of risks and much more in terms of opportunities.

Prof. Dr. Freimut Schliess, Head of the CLOSE EIT Health Innovation Project, consultant in the EIT Health Mentoring & Coaching network



The adoption of innovations in health and specifically digitisation is a clear current challenge for the health authorities. Although financially beneficial in the long term, investments in digital tools are seen as too high costs at the same time – no one wants to be responsible for these expenses in their tenure.

Dr. Francesc Xavier Cos Claramunt, Chairman of Primary Care Diabetes Europe (PCDE)

- Another impediment to digitally enabled care regards
 the perception of some people with diabetes and practitioners. A lack of trust in digital devices, applications
 and their algorithms, can lead to an overfocus on perceived risks rather than on the opportunities such tools
 present.
- Many European countries are burdened with **inade- quate clinical guidelines** which often solely focus on prevention (rather than looking across the entire pathway to management) and insufficiently integrate digital solutions into healthcare practices. This issue is further complicated by the heterogeneous playing field existing between countries in Europe, in which digital solutions are not appropriately and uniformly recognised for their benefits.

These obstacles to faster, better and more comprehensive uptake of digitally enabled care in the treatment and management of T2D constitute major challenges for the people living with this condition. By preventing them from accessing and utilising these digital solutions as needed, regulatory hurdles and skills limitations hinder the ability of people with type 2 diabetes to effectively manage their condition, with serious consequences on their health, as well as on healthcare systems' finances and capacity to provide high-standard care to all.

Six recommendations to optimise digitally enabled diabetes care in Europe

Action is needed to mitigate and overcome the barriers to accessing digitally enabled T2 diabetes care in Europe as outlined above. In this section, we include **six recommendations for policy action on diabetes** which we believe will help improve access to digitally enabled diabetes care and thereby improve the lives of people with T2D across Europe. Some of these measures can already be adopted in the short and medium term, others will take time to develop the right European and national frameworks to leverage the full potential of data and technologies for healthcare systems.

While our recommendations are specific to T2D, there are broader regulatory challenges that affect all medical devices. Without being exclusive to diabetes, regulatory frameworks must enable access to care for people living with diabetes. Ultimately, better regulatory processes at EU-level contribute to ensuring access to digitally enabled care for people living with diabetes. Ensuring the proper implementation of the EU MDR and that it does not delay innovations from reaching those in need⁸⁰ and, looking forward, guaranteeing that the EU HTA regulation⁸¹ avoids additional ambiguity, complexities and duplications with existing legislations, will be essential to secure timely access and availability of relevant digitally enabled solutions to people living with T2D.

Translating policy ideas to action requires coordination and alignment across multiple health system stakeholders including policymakers, industry, healthcare providers and people living with diabetes. We call on European decision makers at both the EU and national level to work with the stakeholder community to properly consider and implement these recommendations.





Bolster the capacity for early diagnosis and appropriate monitoring of T2D to ensure quick access to adequate care. In addition to prevention, early detection and diagnosis of T2D is crucial to manage diabetes

in Europe, given the progressive nature of the condition and the significant and costly long term complications stemming from inappropriate care. Screening people for diabetes and pre-diabetes could be considered, especially for those at high risk, to delay or reduce the risk of developing the condition. Those diagnosed should have a swift referral to appropriate care. While more evidence should be collected to assess their effectiveness to diagnose T2D, digital technologies can play a role in boosting diagnostics in all member states, for example with the increasing use of promising Al-based diagnostics with high classification accuracy⁸². Boosting the use of such technologies for monitoring purposes will also be key to ensure that people living with diabetes are referred and supported as necessary.

Recommended actions

- National and European policymakers should consider a holistic and integrated approach to early diagnosis of T2D and monitoring of individuals' health using novel diagnostics. This should include supporting the collection of data on novel diagnostics (such as apps or Albased systems) for diagnosing T2D.
- National policymakers should establish targeted screening programmes for T2D and diabetes-related complications for groups at high-risk, e.g. adults with overweight, obesity, high blood pressure, high cholesterol, and cardiovascular diseases. Such screenings could be integrated with existing testing programmes for high blood pressure and hypercholesterolemia within primary care. This should be part of a defined patient pathway with appropriate follow on care where needed.
- At the European level, the Commission should support the use of digital devices and tools that allow the compiling of data from screenings from across Europe to foster data exchanges. Such an avenue of action could reside in research & innovation programmes.
- Aligned with the target of diagnosing at least 80% of people living with diabetes in the EU by 2030⁷³, the European Parliament should adopt an own-initiative report on diabetes to address the silent pandemic, highlighting the need to boost diagnostics and health monitoring capacities, the role of novel diagnostics to achieve this objective and measures to adopt to foster efficiencies and innovation in the area.

Accelerate the digitalisation of healthcare systems in the management of T2D to foster efficiencies and support HCPs. Effective uptake of digitally-enabled T2D care is dependent on boosting the digitalisation of the processes, methods and procedures guiding the delivery of care. More digitalised systems will enhance coordination between the members of interdisciplinary diabetes care teams⁸³ and contribute to safeguarding their health and mental well-being – as shown in several studies validated by the WHO^{84, 85}. The further digitalisation of healthcare systems will strengthen the ability of our medical services to effectively support people with T2D. As European countries perform very differently on this issue (see Table 2), an indication of the reform needed can be found in Germany's Law for Accelerating the Digitalisation of the Healthcare System (Digital Act - DigiG)^{75, 86}.



Recommended actions

• In close cooperation with health-care providers, national policy-makers must invest in robust digital infrastructure that allows for electronic patient records to be seamlessly integrated into treatment plans and complex medical processes. This digitalisation must also facilitate remote monitoring, telehealth, and self-management tools to empower people with diabetes and reduce the strain on overburdened health systems.

3

• The European Commission, in line with its promotion of and support to the digital transformation of health and care across the EU, should monitor progress made by member states in digitalising their healthcare systems and make recommendations on the steps necessary to advance this objective.

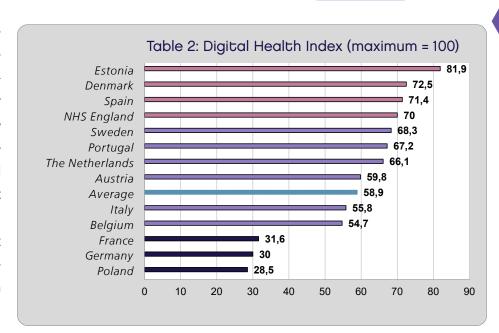


Table 2: Digital Health Index (maximum = 100) This table assesses the extent to which digitisation has been adopted within national healthcare systems and digital technologies integrated in practices and clinics.⁸⁷

Tackle disparities in T2D care access and outcomes in Europe by leveraging better public health data.

Health authorities throughout Europe need to recognise the scale of the current and growing T2D chal-

lenge. Inequalities in access can act as an amplifier for other problems, such as the lack of diagnostics capacity or workforce shortages. In order to address these disparities, Member States should develop databases to track and compare diabetes care metrics, as well as measure progress. One approach would be ensuring the wide adoption of diabetes registries, as part of national diabetes plans, to understand and address disparities in access to care access – including digitally enabled care – between and within countries. Registries are key components to drive and measure the outcomes of undertaken actions, as previously recognised by European policymakers^{73, 79}. There is also scope to explore how EU-level coordination in other disease areas such as the European Cancer Information System can support Member States in setting up registries and ensuring data can be collected across borders. Further work is needed for both T1 and T2 diabetes to achieve a more consistent and comprehensive coverage of data captured through registries.

Recommended actions

- National policymakers must commit to developing and implementing well-funded national diabetes plans that include national registries to map and tackle disparities in access to T2D care.
- European policymakers must consider how an EU-level initiative similar to the European Cancer Information System could support cross-border data collection and comparison of best practice.



Ensure doctors and care teams have uninterrupted access to relevant health data by improving interoperability and enhancing data-sharing within and between EU countries. The multicausal nature of T2D

requires healthcare systems that can effectively leverage data, helping ensure early diagnosis, better self-management, and improved personalised and integrated care delivery. Developing an interoperable system for health data is a prerequisite for people with diabetes, care teams and health systems to streamline care and effectively manage the condition. While the European Health Data Space (EHDS) is a step in the right direction, ensuring that people with T2D benefit from it will require national governments to develop tangible plans to operationalise new systems. The case of Germany and its recently adopted Health Data Utilisation Act (GDNG) illustrates the actions needed at national level, although tackling interoperability issues in a harmonised fashion across countries will be needed to ensure a smooth digital transition. The case of the USA could be looked at, given the proactiveness of the federal government in advancing interoperability by requiring specific standards to improve patient access, foster portability, and promote safety and transparency⁸⁸.

Recommended actions

- National policymakers must draw concrete implementation plans for the EHDS regulation and work with industry and HCPs to ensure that the enforcement of the new systems is in alignment with existing regulatory frameworks at EU (MDR, AI Act) and national level, and does not create extra layers of regulatory complexity.
- To enable and enhance access to health data for HCPs, national policymakers should rely on the best current European and international practices in terms of interoperability and avoid developing their own national standards that might affect the availability of medical devices for T2D.

large, through cost-effective management of this chronic condition.



It would be desirable that decision-making processes in health take account of cost-effectiveness and the monitoring and evaluation of its adoption. The existence of a consensual national strategic health plan that includes mid- and long-term goals should not condition making relevant decisions on the basis of 4-year political mandates.

An interviewed patient representative

Adopt reimbursement frameworks that take a value-based approach to T2D innovation in in all Member

States. The increasing prevalence of T2D and other chronic conditions in Europe highlights the necessity of moving health systems away from incentives and reimbursement frameworks based on individual healthcare interventions, such as hospital visits, towards a broader value-based approach based on health outcomes over time and their wider societal and population benefits. Options to ensure the establishment of such systems could include the involvement of health economics experts and exploring bundled payments schemes. The evidence standards framework (ESF) for digital health technologies⁸⁹, introduced by the UK's National Institute for Health and Care Excellence (NICE) service, also constitutes a tentative prototype of a system based on health outcomes. Given how digitally enabled care can allow for better management of T2D which averts costly complications down the road, this not only serves people living with T2D but also care teams, health systems and society at



Recommended actions

 National policymakers should promote reimbursement frameworks that recognise value-based healthcare, including bundled payments schemes and alternative frameworks (e.g., NICE's ESF) to better recognise the value of all the components of digitally enabled care in T2D. To enable people with diabetes to receive the most appropriate care available, digitally enabled diagnostics, treatments and therapies proven to be cost-effective should be reimbursed and covered in national healthcare systems.

NICE Evidence Standards Framework (ESF)

The NICE Evidence Standards Framework (ESF) for digital health technologies is a comprehensive set of evidence standards developed by NICE to guide the evaluation and commissioning of digital health technologies (DHTs) in the UK. It outlines standards for evidence related to effectiveness and economic impact, helping technology developers plan their evidence development and aiding decision-makers in assessing whether to commission a digital health technology.

The ESF is innovative in its focus on ensuring that DHTs are clinically effective, offer value,

and meet specific criteria for evidence quality, user involvement, and equality considerations. It classifies technologies into different tiers based on their functions and provides clear standards for information content, user satisfaction, data accuracy, and transmission reliability. The framework has been updated to include specific considerations for data-driven technologies, adaptive algorithms, and high-quality data practices, reflecting the evolving landscape of digital health innovations.

Launch digital literacy programmes to bridge the digital divide in healthcare and promote best practice-sharing involving technological solutions. Digital literacy programmes should target both people living with diabetes and HCPs (in particular nurses), to address confusions or doubts, and to best clarify the advantages and components of digitally enabled services and devices. As demonstrated by studies, digital literacy and awareness-raising on the benefits of digitally enabled care heightens HCPs' confidence in using digital health tools are critical for people living with diabetes to feel empowered to self-manage their condition, and support doctor-patient decision-making^{90, 91}. Enhanced best-practice sharing between European countries will go hand in hand with such programmes, as collaboration on clinical guidelines is needed to foster research initiatives and enable the development of evidence-based practices and innovative solutions for managing T2D effectively.

Recommended actions

In partnership with hospitals, practitioners, and technology companies, national policymakers must develop training programmes to upskill HCPs on using digital tools and analysing patient data to optimize treatment

plans and develop more **personalised, proactive care** for people with type 2 diabetes.



National policymakers must launch digital literacy programmes for HCPs and for those living with diabetes.
 These programmes should provide training on using digital health tools, educate on data privacy and security, and build confidence in engaging with the different components of digitally enabled care.



- European policymakers must promote digital health literacy through increased funding for related initiatives such as Horizon Europe, the Digital Europe Programme, Erasmus+, EU4Health, Recovery and Resilience Plans, and the Digital Education Plan⁹².
- Working with practitioners and healthcare infrastructure (hospitals, clinics), national and European policymakers should enable cross-border platforms to allow HCPs to share best practices on the use of digital technologies in T2D. Such platforms could be envisioned under the EU "Healthier Together" NCD Initiative⁹³, or expanding existing initiatives like the Best Practices Portal⁹⁴ to better support the sharing of innovative solutions in T2D.

Conclusions

The benefits of digitally enabled care as part of the solution to the T2D pandemic are clear – for people living with diabetes first and foremost but also practitioners, healthcare providers and society at large.

On the other hand, political will and proactivity is key for any real change to take place. Thankfully, the urgency to act has been collectively recognised. A major European party has put health, non-communicable diseases (NCDs), and cardiovascular diseases (CVDs) at the heart of its manifesto and priorities for the 2024-2029 European legislative mandate⁹⁵. The diabetes community is also calling for political action, as reflected by the Diabetes Community Pledge developed by the European Diabetes Forum (EUDF)⁹⁶.

This momentum creates a unique window of opportunity to raise awareness on the challenges caused by diabetes and T2D specifically and, crucially, generates the imperative to address them through tangible initiatives and decisions. We sincerely hope that European and national policymakers will move from words to action in the following months on the basis of the above recommendations, for the benefits of the 55 million Europeans living with T2D today.

Time for action is now: let's work together for better, equal access to diabetes care for all.



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