Revealing policy barriers in diabetes care: how we can improve outcomes

How local policies can compromise the ability to adhere to clinical guidelines, their impact and potential solutions

A study by PwC & EFPIA - **May 2023**

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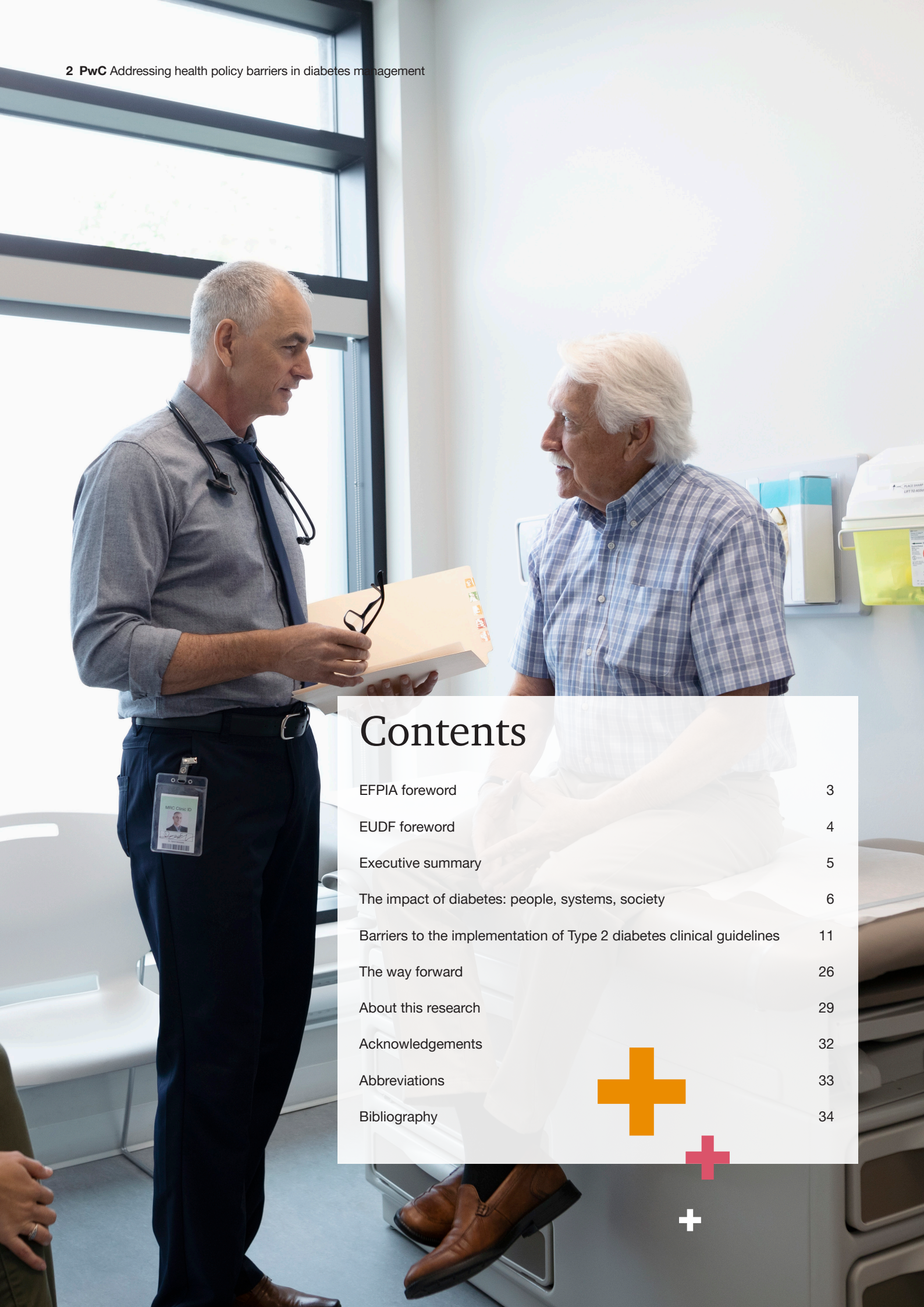

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European health systems face some worrying trends, including increased costs and the challenges of addressing ageing populations' long-term care needs, as a result of multiple morbidities and chronic diseases such as diabetes. These pressures exacerbate the already challenging post-COVID-19 environment and the uncertain economic climate.

To maximise health systems' resilience and efficiency, innovation is essential. This is certainly the case with diabetes, where it offers the chance to improve the health outcomes and quality of life for people with diabetes (PwD). However, there are large disparities across Europe in the time it takes for PwD to access new medicines after approval – from 182 to over 1,500 days, depending on the country. Delays in (and lack of) availability of innovative medicines have a number of interrelated causes, such as systems and processes for authorising medicines in EU Member States, the pace of pricing and reimbursement negotiations or healthcare system readiness.

Yet this is only part of the story. Even once a new medicine gains access to the national reimbursement list, patient access may be impaired, as in many countries there are other barriers to overcome after a medicine becomes 'available'. This latest report from PwC and EFPIA investigates these additional barriers and, crucially, makes some clear proposals about what can be done to overcome them.

EFPIA and its members work closely with all stakeholders to increase the availability of medicines and decrease the time people living with diabetes must wait for treatments that could improve their health outcomes. In line with this, in April 2022 EFPIA members committed to:

- filing for pricing and reimbursement in all EU countries no later than two years after EU market authorisation, provided that local systems allow it
- setting up and maintaining the European Access Portal to improve visibility of medicines access across the EU and the root-causes of unavailability and delays
- engaging in discussions with all stakeholders on an Equity-Based Tiered Pricing framework, to ensure that ability to pay across countries is considered in price negotiations
- supporting the implementation of novel payment and pricing models, to help payers manage clinical uncertainty and budget impact

This report adds to the industry's efforts to improve patients' access to new medicines, and thereby improve patient health as well as health system and societal resilience and sustainability.

EUDF foreword

Introductory remarks by the European Diabetes Forum (EUDF)

There are more than 60 million people with diabetes in Europe and this number is likely to continue rising. This poses a major challenge for both individuals and society. In recent decades, better methods for diagnosis, prevention, and treatment of the disease have become available. Some of the new pharmacologic approaches have offered unprecedented opportunities to reduce the risk of chronic complications, which still account for most of the excess costs associated with diabetes.

Despite many innovations, there are still variations in diabetes management across European countries. By revealing gaps and hurdles that create these discrepancies, it may be possible to identify ways to overcome them and achieve the ultimate aim of more uniform treatment of the disease throughout Europe.

EUDF welcomes this publication highlighting the importance of access to innovation. As experts in clinical day-to-day practice, we recognise some of the barriers to innovation access that are linked to guidelines, reimbursement and local processes.

As clinical researchers assessing the efficacy and safety of new forms of treatment, we expect beneficial innovations to reach the wider population. It is the EUDF's mission to "ensure the translation of research into policy actions towards better diabetes care at national level."

The following pages, therefore, should be seen as a starting point for exploring how diabetes is tackled by different health systems in order, hopefully, to foster a more systematic and analytic assessment of how diabetes is handled across Europe. This publication may serve as a catalyst for all diabetes stakeholders to put in place the necessary strategies to drive timelier adoption of innovation. Doing so will lead to faster diagnosis, more effective disease prevention, a significant reduction of the risk of microvascular and macrovascular complications and a more rational use of financial resources.

The EUDF strives for equal access to innovation and technology for all people in Europe with diabetes, regardless of their age or the type of diabetes they have. We are happy to contribute to the conversation that this publication starts, and we will continue our effort and collaboration with all diabetes stakeholders in finding solutions to improve the quality of life for people with diabetes.

Stefano Del Prato
Chair EUDF

Chantal Mathieu
Vice-chair EUDF

Executive summary

Diabetes has a significant impact on European population health. It also incurs substantial healthcare costs, causes lost economic productivity and leads to premature mortality. Complications arising from the disease also have a profound effect on health systems' resilience and costs throughout Europe. Gaining control of diabetes is therefore a Europe-wide public health imperative.

In the past century, there have been continuous and impressive strides forward in diabetes treatment and management. Consequently, updated clinical guidelines for the treatment of diabetes, reflecting the latest scientific evidence, have regularly been released. Despite this, the evidence suggests that - for a large proportion of people with diabetes - the disease remains uncontrolled.

Thus the challenges facing Europe are not due to the lack of innovations proven to have significant benefits for people with diabetes, nor to the availability of clinical guidance. Instead, it is the incomplete and uneven implementation of these across European countries that drives poor outcomes.

This report explores the reasons for this variability in the therapeutic management of diabetes in different European countries, focusing on how policies at the national and local levels are creating barriers to more consistent, effective and equitable treatment of diabetes and improved health outcomes for all people living in Europe. These barriers include:

- guideline-related policies: how local and national policies can impair the ability to adapt and adhere to the best clinical standards as per international guidelines
- access-related policies: reimbursement delays and restrictions; prescription limitations and affordability concerns
- process-related policies: bureaucratic pathways, prescription processes and quotas, and limited HCP time and knowledge.

Taken together, these barriers can create 'therapeutic inertia'; in other words, people with diabetes do not always receive the treatment they need when they need it. This leads to worsening health outcomes and rising healthcare costs.

However, these persistently poor outcomes are not inevitable. This report offers clear principles and a series of actions that European and national policymakers can use to guide their future activities. Their collective aim is to ensure that all people with diabetes in Europe can receive the best possible treatments to improve their health and quality of life.

The impact of diabetes: people, systems, society

The burden of disease: health outcomes and costs

1.1m

Deaths caused by diabetes in Europe in 2021

Why it's essential to get control of diabetes

Diabetes is a chronic, metabolic disease characterised by elevated levels of glucose in the blood. Over time, this state can lead to complications and serious damage to the heart and blood vessels, as well as neuropathy (i.e. nerve damage) to eyes, kidneys and limbs.

Type-1 diabetes is a genetically driven condition in which endogenous insulin is lacking. It typically starts early in life and requires affected individuals to monitor their glucose levels and dietary intake very closely. Glycemic levels can then be managed with timely injections of insulin.

Type 2 diabetes **(T2D)**, on the other hand, arises from multiple factors, including genetic, environmental and metabolic, and is characterised by issues around insulin production and/or bodily response. The most recent burden of disease data show that high body mass index (BMI), pollution and smoking habits are the main contributors to T2D development.1 However, while T2D pathophysiology is well understood, its therapeutic management still poses challenges. This is because underlying glucose levels depend on a fine balance between drug administration, patient response to therapy (including physiological, behavioural and emotional factors), the actions doctors take and system-related factors. All of these, taken together, make disease control hard to achieve.[2]

According to the International Diabetes Federation (IDF), 61 million people in Europe (a population size that - were it a country - would be the third largest in Europe) are living with diabetes. In 2021, more than 1.1 million people in Europe died because of diabetes, while 1 in 3 adult people with diabetes (PwD) are undiagnosed.[3]

The global burden of diabetes has increased steadily over the past 20 years, with a 34% increase in terms of disability-adjusted life years in Europe from 2000 to 2019.[4] In Europe, T2D is the second highest cause of loss of healthy life among individuals aged 50-69 years.[a] Overall, one diabetes-related death is recorded every five seconds worldwide.[3]

a Measured as YLDs, years of healthy life lost to disability. In 2019, the rate was 1241 YLDs per 100 000 population (or 2.7 million YLDs in total). The first cause of healthy life lost among 50-69 years old is back pain, with more than 4 million YLDs lost across Europe (IHME, GBD Compare, 2019, link).

Rising trends

38%

Cost increase for diabetes management in Europe by 2045

Besides the impact on people's daily lives, T2D significantly contributes to the overall health spend. Estimates suggest that the average cost of each PwD in Europe amounts to USD 3,086[b] each year. At the population level, direct costs relating to diabetes in 2019 exceeded USD 189 billion[c], i.e. approximately 9% of total EU health expenditure.[5]

Finally, T2D results in indirect costs due to absenteeism, reduced productivity and reduced labour force participation. For example, a recent paper from Germany found that a person of working age with T2D loses 2.6 years of productive life compared to a peer without diabetes.[6]

While the burden of type 1 diabetes has remained constant over the past 35 years, the T2D burden has increased significantly and is expected to keep rising, with Europe predicted to have 69 million PwD by 2045. And the increase in the number of Europeans adults living with pre-obsity and obesity is only likely to reinforce this worrying trend.[7-9]

Overall, costs in Europe are projected to increase by 38%, even in the unlikely event that global burden goals[d] are met. Globally, costs are projected to rise by 61%, reaching a staggering estimated spend of USD 2.1-2.5 trillion.[10]

In addition, because in most people T2D occurs concomitantly with other chronic conditions, long-term patient management is expected to become increasingly complex and resource intensive for healthcare systems.[11] This creates a massive complication in times of crisis, as was seen during the recent COVID-19 pandemic.[12]

In summary, worrying trends and long-term effects make T2D a slow-burning crisis that requires immediate mitigation. This is even more so in the aftermath of the COVID-19 crisis, which showed how poor population health complicates the response to an emergency, as well as the resilience of healthcare systems.[13]

A united front for action

We have the tools to fight diabetes

European policymakers are starting to focus on diabetes as a priority public health topic. A key driver for this has been the gathering of virtually all actors involved in the fight against diabetes within the European Diabetes Forum (EUDF). This establishes a joint vision and strategy for the management of diabetes in Europe.[14] In addition, initiatives by both the European Parliament and Commission are making positive contributions to the lives of people living with diabetes. These include:

- 'Healthier Together', with diabetes being one of the five strands of this initiative addressing non-communicable diseases
- the Joint Action on Diabetes and Cardiovascular diseases
- the European Parliament's landmark Diabetes Resolution adopted in November 2022
- MEPs Mobilising for Diabetes 'Blueprint for Action on Diabetes in the EU by 2030'

The combined impact of these public health initiatives is a comprehensive call for action to fight diabetes across several fronts. These range from better health promotion and prevention to integrated and coordinated patient-centric care, along with calls for legislative action and effective policymaking.

b Roughly corresponding to EUR 2,700 (based on November 2021 average exchange rate).

c Roughly corresponding to EUR 165 billion (based on November 2021 average exchange rate).

d Target scenario defined as SDG 3.4 achievement, i.e. of a one-third reduction in premature mortality due to NCDs (here limited to diabetes) compared to 2015, and achievement of the voluntary target to halt the rise in the age-standardised prevalence of diabetes by 2025 compared to 2010 (as per WHO Global Action Plan for the Prevention and Control of NCDs 2013–2020).

Innovation and technology to fight diabetes

These initiatives complement the already robust action being taken by European countries. In the last decade, many have increasingly expressed commitment to, or taken steps towards, comprehensive policy responses to diabetes.[15] However, the implementation of strategic plans to date has been partial and fragmented.[e]

There has been significant technological progress since the first injection of insulin was given to a PwD 101 years ago. The standard approach to insulin delivery, for example, has evolved from multiple finger pricks per day to non-invasive and continuous glucose monitoring. Insulin pumps have freed PwD from the need for daily injections, and 'artificial pancreas' technologies for people living with Type 1 diabetes are slowly but steadily becoming a reality.[16]

Smart wearable technologies have also developed in line with the rise of integrated digital health solutions, remote consultations and support ecosystems. These are improving both the care and the quality of life that PwD are able to enjoy.

Pharmaceutical innovations are especially benefitting people with T2D, as new, effective, and safe drugs help manage glucose levels. Between 2014 and 2020, 17 new drugs were made available to PwD in Europe,[17] with new molecules and formulations in the pipeline.

These drugs can lower glucose levels, offer protection against major cardiovascular disease for people with established atherosclerosis, reduce the risk of admission to hospital for heart failure, contain the need for other medications, and decrease cardiovascular- and all-cause mortality.[18, 19] Additional benefits include reducing blood pressure and addressing weight management, thus contributing to the management of T2D in a number of ways.[20, 21]

e Reported by experts.

Treatment guidelines for evidence-driven decision making

Sept '22

Release of the latest international guidelines for the management of T2D

The availability of several tools and approaches for managing the health of people affected by diabetes, and especially T2D, requires healthcare professionals (HCPs) to handle a vast amount of data and knowledge – which makes treatment guidelines fundamental to their practice.

Treatment guidelines[f] are defined as "statements that include recommendations intended to optimise patient care, [and] that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options".[22, 23] By definition, they are the tools upon which evidence-based medicine relies.

Independent clinical experts create guidelines using consensus-based and iterative processes, which make use of the best available scientific evidence to define actionable protocols and algorithms, allowing optimal clinical pathways to be defined and recommendations created. Protocols may go beyond therapeutic management to cover aspects related to disease prevention, early patient identification and long-term management, as well as lifestyle and behavioural strategies that have a demonstrated benefit on patient outcomes.

Clinical guidelines are crucial tools for today's HCPs, as they provide guidance while taking into account the growing number of treatment options, the complexity of clinical study design and the speed of clinical development.

In summary, guidelines encapsulate the scientific community's commitment to improving the quality of care delivered to patients by prioritising effective and safe interventions; they also enable the standardisation of care across practices and regions, and support public policy decisions to provide holistic, patient-centred treatments.

Importantly, guidelines are regularly updated based on newly emerging scientific evidence (see Figure 1). For T2D, authoritative guidelines include:

- the 2022 consensus paper published by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD) on the management of hyperglycaemia in T2D[21];
- the 2019 guidelines by the European Society of Cardiology (ESC) and EASD on the management and prevention of cardiovascular disease in PwD[24]; and
- the 2018 recommendations by the IDF for managing T2D in primary care settings.[25]

Once published, international guidelines are typically translated and adapted for use in individual countries by taking into account the local context, and in particular the existing access to treatments, practices and care settings.

Guidelines on managing diabetes are considered a fundamental tool in clinical practice by European HCPs. A recent survey conducted among a sample of physicians from Eastern and Southern Europe confirmed the key role that guidelines play: virtually all physicians say they consult guidelines in their practice, with 66% of them considering diabetes guidelines as 'fundamental' to their work.[26]

It should also be mentioned that the WHO European Observatory on Health Systems and Policies deems clinical practice guidelines to be one of the central strategies – together with health technology assessment, accreditation/certification strategies and audit processes, to name a few – for improving the quality of care provided by European health systems in the future.[23]

f Throughout this report, the term 'guideline' is used neutrally to indicate e.g. consensus papers, positions statements, best practices and similar evidence-based documents.

Figure 1: The evolution of ADA/EASD clinical guidelines for T2D over the last 20 years.

2006

The first consensus algorithm for the management of hyperglycaemia is published by ADA/EASD

The Standards of Medical Care in Diabetes are considered the gold standard for medical knowledge in diabetes, and include guidance on multiple aspects of diabetes management, e.g.:

- classification and diagnosis
- screening
- prevention/delay
- prevention and management of complications
- care, including care in specific populations and in specific settings
- third-party reimbursement of diabetes care, DSME and supplies

2006

Approval of the first GLP-1 receptor agonist by EMA

2009

Approval of the first DPP-4 inhibitor by EMA

2009

Updated guidelines

New drug classes are included in the treatment algorithm

Introduction of a grading system of therapies (tier 1 and tier 2) based on the strength of supporting data

2012

Updated guidelines

Stronger focus on patient centricity

Frequency of glycemia monitoring increased from 2-3 months to 3-6 months

Target level for HbA1c defined at 6.5% for some patients

2015

Approval of the first SGLT-2 inhibitor by EMA

2015

Addendum to the 2012 guidelines

New drug classes are included in the treatment algorithm

GLP-1s recommended as the optimal addition to basal insulin because of their efficacy and safety profile

2019

Updated guidelines

Identification of subpopulations that should be treated with antidiabetics, irrespectively of glycaemic levels

Identification of high-risk indicators suggesting that therapeutic treatment is required

2022

Approval of the first GIP/GLP-1 receptor co-agonist by EMA

2022

Updated guidelines

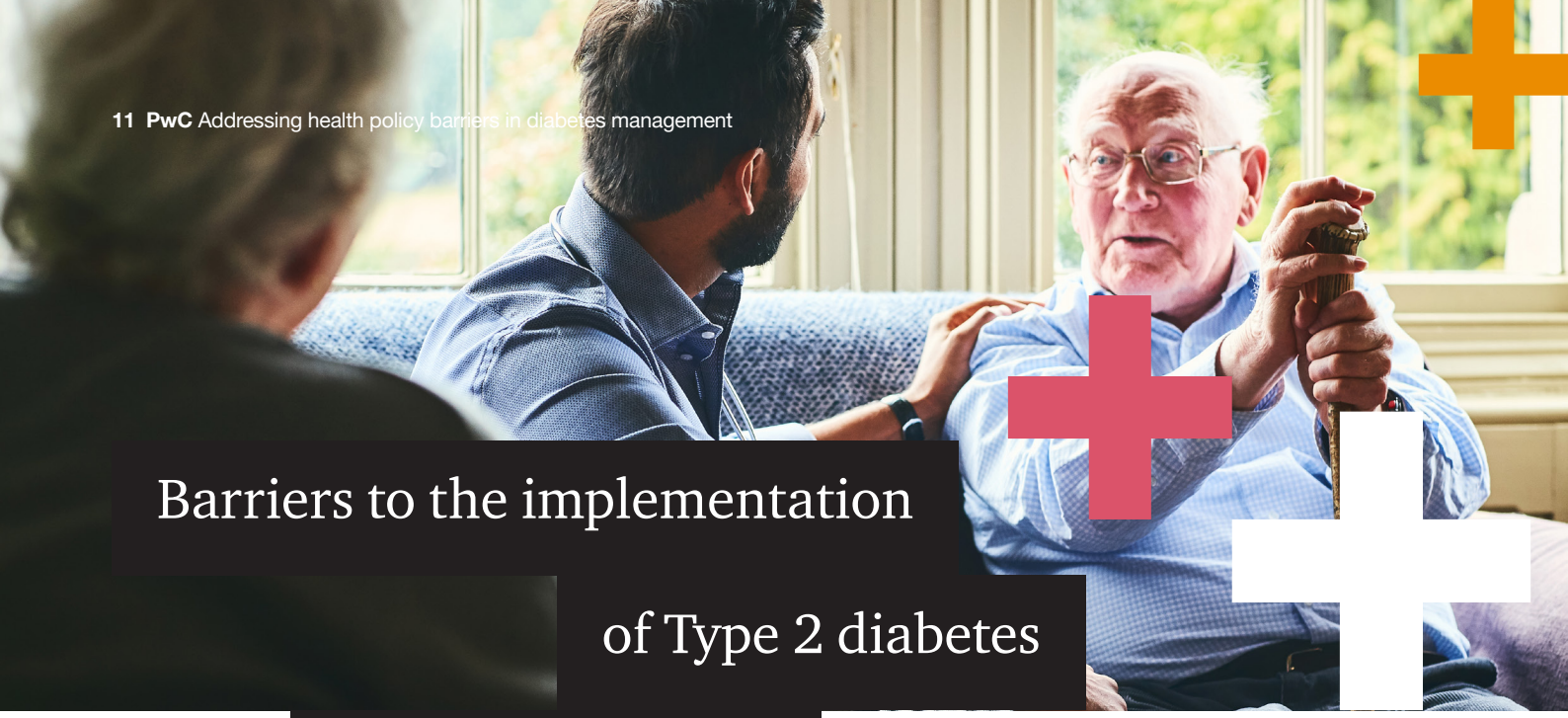
Higher importance placed on early intensification of treatment, including the use of multiple agents simultaneously, rather than a stepped approach

Additional focus on social determinants of health, the healthcare system and healthy habits, including sleep

Increased importance placed on weight management as part of a holistic approach to diabetes management

Additional recommendations for cardiorenal protection due to emerging evidence

Source: PwC analysis.



Barriers to the implementation of Type 2 diabetes clinical guidelines

The prevalence of uncontrolled T2D

T2D clinical goals are not achieved

Despite the abundance of effective tools available for managing diabetes, population data collected over the years shows that the disease remains uncontrolled for a sizeable proportion of people with T2D[g]. For example, in a European cohort of people with T2D followed between 2009-2010, glycaemic levels were acceptable in just half of the individuals, with large variability across countries (ranging from 71% in the Netherlands to 36% in Italy). In addition, only 6% of PwD were able to achieve all three targets of glycaemia, blood pressure and cholesterol, while a worrying 85% of individuals had a BMI in the overweight range.[27]

Unfortunately, more recent measurements based on real-world data and surveys do not show improvements in disease control. Only 39% of PwD across the US and Europe are in a controlled state.[28] What's more, studies suggest that individuals' disease control worsens over time, and this is particularly the case for people with comorbidities.[29]

g Disease control is typically defined in terms of blood glucose levels (glycaemia), and specifically by measuring the concentration of glycated haemoglobins (HbA1c) in the blood. The target level is usually placed at 53 mmol/mol (7%) or below.

When clinical goals are not met, in addition to addressing health behaviours and referring to educational and support resources, the **intensification of glucose-lowering medications** should be pursued. This means combining drugs with complementary mechanisms of action.

Traditionally, a stepwise approach was advocated in guidelines for glycemic management in T2D, in which a new agent was progressively added to the existing regimen. However, evidence is growing to **support a more proactive approach** in many , by combining glucose-lowering agents from initial diagnosis.

Early use of combinations of agents allows **tighter glucose control** than monotherapy with the individual agents, and thus combinations of agents are indicated in those who have HbA1c levels above their target at diagnosis.

(Paraphrased from 2022 ADA/EASD guidelines)

Drivers of uncontrolled disease

Several reasons, including medical history and lifestyle, as well as an individual's response to treatment, may account for a lack of disease control. However, in addition to individual factors (and even when those factors are potentially favourable), suboptimal monitoring and delayed treatment intensification are major contributors to the inability to control diabetes in each individual – as critically highlighted by the latest ADA/EASD guidelines.[21]

Data show that delayed or absent therapy intensification, so-called 'therapeutic inertia', goes hand-in-hand with uncontrolled diabetes. In T2D, such a lag may last several years after excess glycaemia is measured.[28, 30] Conversely, adherence to guidelines is associated with reduced mortality and morbidity.[31] As explained below, there may be a number of reasons causing therapeutic inertia (Figure 2).[h]

First, the guidelines themselves might play a role. It could be that the guidelines are complex and hard for HCPs to use when compared with existing standards. Or, if not properly adapted to the local context, recommended protocols may not suit local needs and existing processes, or may simply represent too great a deviation from the usual clinical practice.

The second reason for inertia might be behavioural. Patients' lack of persistence with treatment may be attributable to poor health literacy, lack of trust in HCPs, low understanding of the therapy regimen or bothersome adverse reactions, as well as practical hurdles such as getting prescriptions refilled.[32, 33] For HCPs, lack of education and training, as well as low exposure to some of the therapeutic options, may limit confidence in new treatments. HCPs might also be unused to consulting guidelines consistently and instead rely on other management approaches, including their own experience and knowledge.[34]

The third reason, as explored in greater detail in the next section, is a range of system-related barriers, which may prevent full adherence to treatment guidelines and therefore optimal T2D management. In particular, systemic barriers include the way in which clinical guidelines are translated into processes and policies intended to make therapeutic interventions available to PwD. Furthermore, barriers might be related to care organisation and availability of resources.

In the literature addressing therapeutic inertia in diabetes management, policy and systemic barriers, such as reimbursement of therapies and constraints related to the use of local guidance, are the most frequently acknowledged reasons to for deviating from clinical guidance accounting for more than half of the cases. Less frequently, lack of adherence arises from HCPs relying on their own experience, use of other guidance for managing PwD, and lack of access to patient data.[26, 35]

In consequence, evidence shows that in some European countries less than 10% of medical professionals initiate PwD on insulin at the recommended time.[36] Moreover, a systematic analysis of the literature found that treatment intensification tends to occur well beyond one year – and even up to seven years! – after hyperglycaemia is first measured.[30] Lastly, the penetration of new non-insulin antidiabetics is considerably behind the expected rates based on patient population epidemiology, with large discrepancies measured across countries.[37]

h Frequently, the scientific literature distinguishes physician-related, patient-related and healthcare system-related factors that have the ability to cause therapeutic inertia. The classification used in this assessment deviates slightly from this approach, however the spectrum of identified barriers is similar to what is found in the literature relating to drivers of therapeutic inertia.

Figure 2: Factors that may act as barriers to the implementation of clinical guidelines

Evidence-related

Guideline-related factors: e.g. low-quality evidence, complexity, insufficient tailoring, lack of translation

Behavioural

Patient-related factors: e.g. low health literacy, poor adherence, lack of trust, disadvantaged socioeconomic status

HCP-related factors: e.g. insufficient training, lack of familiarity with guidelines, reliance on own experience, poor communication skills

Structural/systemic

Organisational factors: e.g. resource/personnel shortage, siloed settings and processes, administrative and bureaucratic hurdles

Systemic factors: e.g. suboptimal health policies and implementation, poor/inefficient governance, broader socioeconomic trends

Source: PwC analysis

3

Categories of policy barriers in T2D: related to Guideline implementation; related to Access to treatments and care; related to Processes and organisational matters

G.A.P. framework: a taxonomy of policy-related barriers

As mentioned above, the published literature, corroborated by expert opinion,[i] suggests that system-related barriers are some of the biggest impediments for HCPs in adhering to clinical guidelines in T2D – rather than factors related to individuals' decision-making and behaviour.[26, 35] It is therefore worth focusing on policy barriers and assessing how these translate into organisational and systemic limitations when it comes to managing PwD.

Despite being varied and fragmented, policy barriers that stand in the way of implementing scientific guidelines fall into three main policy categories: Guideline implementation; Access to treatments and care recommended by clinical guidelines, and Processes and organisational issues around the clinical management of T2D (Figure 3).

+ Guideline-related policies

At the national and local levels, the way in which guidelines are taken up can have an impact on the ability to adhere to the best clinical standards in international guidelines. There are a number of factors here.

The first of these are **discrepancies between national and the latest international guidelines.** Obviously, local decision criteria and consideration of the context mean that national/regional guidelines and protocols are expected to divert - to some extent - from international guidelines. Occasionally, however, local considerations lead to:

- differences in the choice of preferred molecules, the sequence of drug administration in the algorithm and the approaches to therapeutic management, mainly due to the use of different evaluation criteria. For example, the UK's NICE placed GLP-1 drugs as fourth-line treatments,[38] diverging from the early-initiation approach recommended by recent guidelines.[21]

- Adaptations of protocols to reflect the absence or delayed availability of some recommended therapeutic options in local formularies,[j] due to existing procedures for formulary inclusion, e.g. internal price referencing, budget ceilings and/or procurement agreements.

- Delays may occur owing to local processes that need to be followed to validate and adapt international guidelines to a local context. For example, in Italy, the National Institute of Health translates and validates all national clinical protocols, a process that was introduced in 2017 to increase patient safety,[k] but inevitably leads to some delays in updated guideline availability. In France, the National Authority for Health's guidance on diabetes was last updated in 2013.

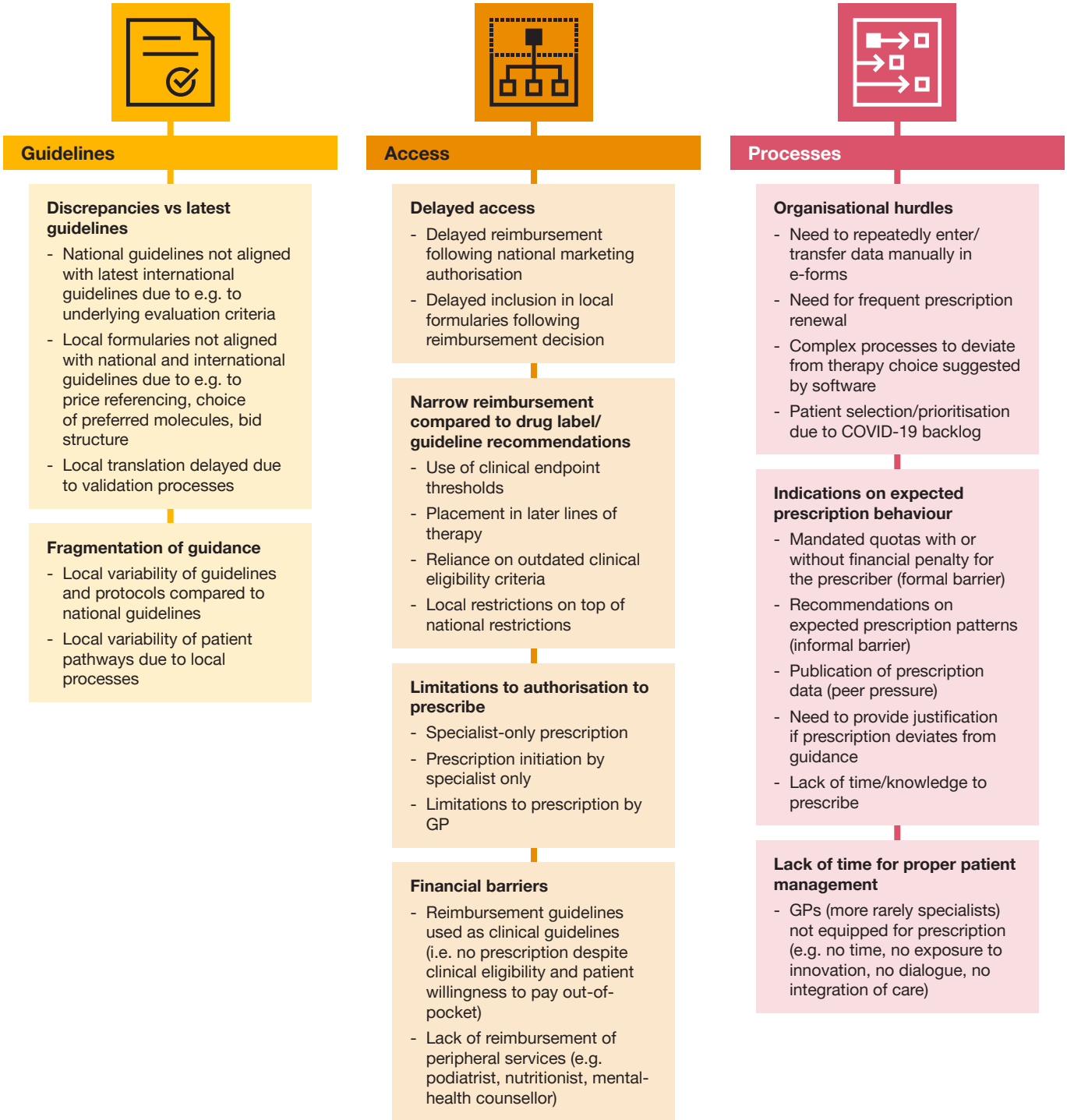
G Guidelines

A Access

P Processes

i See 'About this research', page 29.

Figure 3: The G.A.P. framework

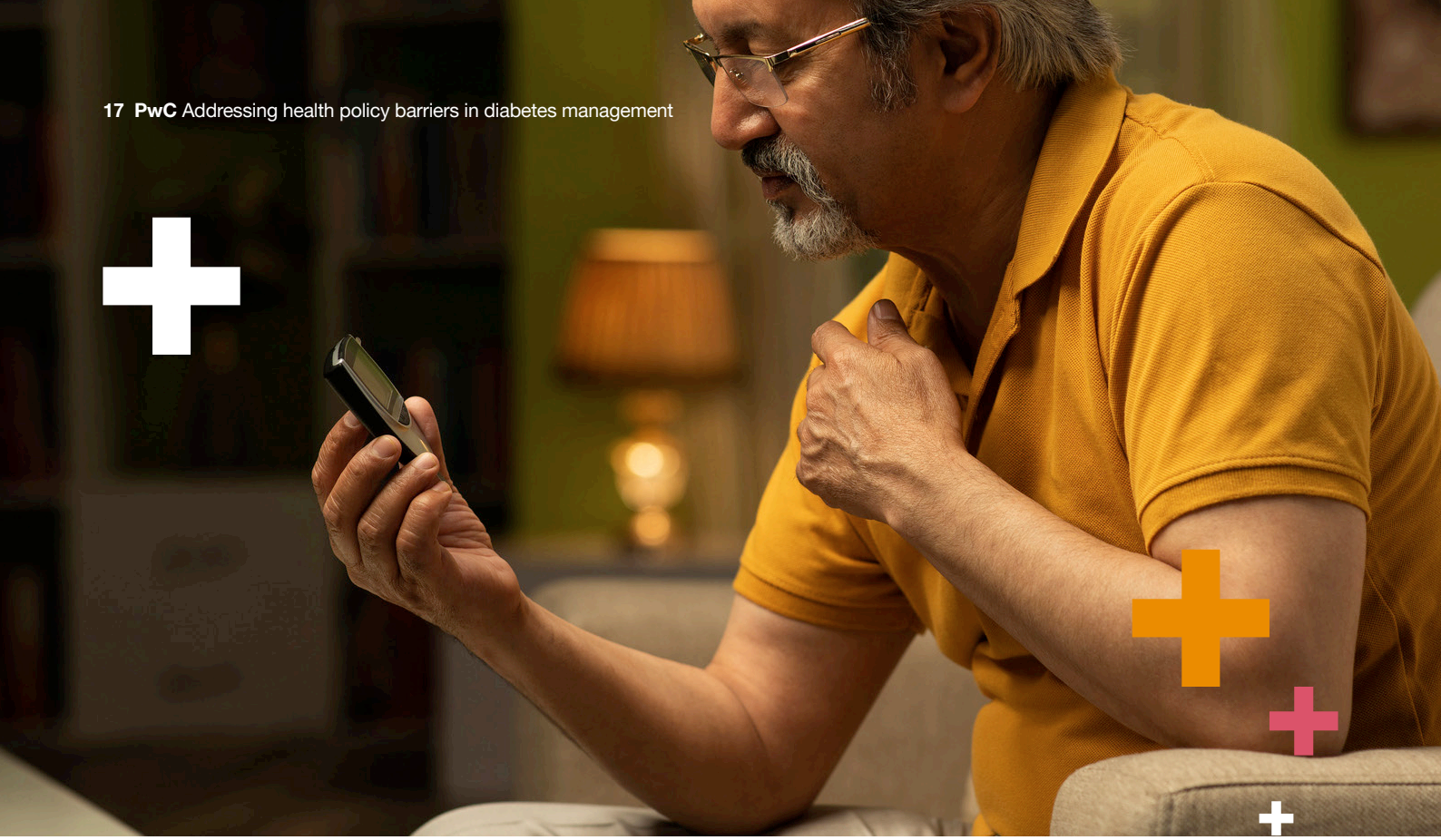


Source: PwC analysis

Note: See 'About this research' for detailed methodology and notes.

j Generally speaking, a formulary is an official list of medicines authorised and reimbursed for use in specific settings (e.g. hospital, local healthcare unit, region).

k Gelli-Bianco Law on Patient Safety and Medical Liability (N. 64/2017).



Access-related policies

647 days

Average time that people with diabetes are waiting to have access to new diabetes drugs in Europe (W.A.I.T. survey, Diabetes, 2021)

The other considerable driver of discrepancies is the **fragmentation of clinical guidance,** leading to redundant and/or contrasting protocols, guidelines and pathways within the same system. This is particularly common in countries with regionalised healthcare. There is often variation of formularies in these countries in terms of preferred treatments, eligibility criteria and even GPs' ability to prescribe certain therapies. In essence, even within the same country, the treatment that one person receives may differ from the treatment that another would receive in a different part of the country. This creates confusion for both patients and HCPs, and may deter some of the latter from prescribing certain therapeutic options.

The second main category of policy barriers, perhaps the most visible and discussed by the diabetes community, includes those related to access to the treatments indicated in guidelines. There are at least four types of barriers that obstruct optimal guideline implementation.

Delayed access to treatment is one. This happens, for example, when, following European Medicine Agency (EMA) and national marketing authorisation, considerable time elapses before the therapy is reimbursed for PwD. The EFPIA Patient W.A.I.T. Indicator for diabetes shows that this phenomenon is far from uncommon, and multiple root causes interact to cause drug unavailability and access delays. For example, it takes on average from 182 days (Sweden) to over 1,500 days (Poland) following EMA approval for a new antidiabetic to become available for PwD [17,39]

In addition to national delays, there can be delayed inclusion in local/hospital or regional formularies following a centralised reimbursement decision. As a result, certain regions might make a drug available later than others, resulting in unequal healthcare provision within the same country.

The second type of access barrier is **narrow reimbursement** compared to the drug label and/or guideline recommendation. This is one of the most prominent barriers to guideline implementation from the prescriber perspective (see for example Banach et al. 2021), and can occur in different ways, including:

- by using clinical thresholds to define the patient population eligible for therapy reimbursement. These restrictions, typically defined based on budget impact or cost-effectiveness considerations rather than efficacy and safety alone, are used by most systems to manage pharmaceutical spend. For example, in the UK, GLP-1s can only be prescribed to PwD with BMI>35.

- by positioning innovative therapies as later lines of treatment, another measure frequently used to contain spend. While EMA and nationally approved labels are typically broad for antidiabetics drugs, most in reality are not available as first or second-line therapies, but tend to be allowed only as last therapeutic resorts, sometimes accompanied by additional clinical thresholds to further narrow eligibility.

- by relying on 'outdated' eligibility criteria, in light of the fact that, as the body of evidence grows, clinical guidelines might evolve their overall approach to disease management. For example, the EASD/ADA Consensus Report published in October 2022 suggests considering the use of a combination of antidiabetic treatments early on, based on their complementary protective effects on the heart, kidneys and weight control, in addition to their glucose-lowering effects.[21] However, most of the countries reviewed in this study are aligned with older guidance, and still define glycaemic levels as a key eligibility criterion for the prescription of non-insulin antidiabetics and/or a step therapy approach.

- Regional and local guidance might add additional restrictions on top of national ones, and further narrow the eligible patient population as a result.

The third type of barrier to access is the **limitations** placed **on the HCP's ability to prescribe** some classes of antidiabetics, based on specialty and/or work setting. These restrictions can take several forms:

- In some countries, innovative therapies can only be prescribed by specialists, and often only when they are practising at authorised treatment centres. This is common practice in Europe, even though several countries (Poland, Italy, Spain, Greece, to name a few) are attempting to shift from hospital-centric care towards primary settings, and therefore increasingly allowing general practitioners (GPs) to prescribe specialty drugs.

- Even when GPs – who have a central role in the management of chronic health conditions – are allowed to prescribe speciality drugs, it may be that they cannot initiate PwD on such treatments, this task being reserved for specialists, while GPs can only assess/renew patients' prescription plans.

- Lastly, access limitations may arise from GPs' inability to prescribe a combination of treatments. In Italy, for example, GPs are not allowed to prescribe combination therapies, while specialists can.

Fourth, there is a tendency to **use reimbursement guidelines as prescription guidelines.** This is a way to mitigate the risk of financial insecurity that people suffering from chronic conditions, including T2D, may face in the long run. It is quite common for doctors to privilege the prescription of medications whose costs are reimbursed to the patient rather than drugs and therapies that patients pay for

themselves.[l] The downside of this approach is that some patients might be eligible for innovative and effective therapies recommended by international guidelines, but are unlikely to receive the medication, even when they are willing to pay directly for it. This observation also applies to peripheral services for successful diabetes management, such as nutritional therapy, mental health support, etc. When such services are not covered, they tend to be overlooked by both HCPs and PwD, with a consequent impact on health outcomes.

Processes & policy implementation

The third category of barriers related to health policies concerns processes, organisational issues, and the general way in which policies are implemented for care delivery. These barriers are the least visible, as they are deeply rooted in the way healthcare systems are organised – and might well affect the management of other chronic conditions. There are at least three ways that processes can get in the way of adherence to clinical guidelines.

First of all, HCPs and patients may face **organisational and bureaucratic hurdles** to prescribing, or being prescribed, a chosen therapy. These include:

- the need to complete lengthy electronic forms, where data has to be inserted manually and repeatedly. This is at odds with the already low amount of time that GPs and specialists working in public settings often have to manage PwD.
- the necessity for PwD to renew prescriptions regularly, typically requiring in-person presence for lab exams and GP appointments. Occasionally, referrals also need to be repeated. This is what happens in France when, a PwD moves from one region to the other, despite having an existing diagnosis.
- complex processes to deviate from the default and predefined therapeutic choices set up in electronic systems. In Spain, for example, prescribers need to manually browse several electronic form pages to be able to tailor treatments for a specific individual.[m]
- the COVID-19 backlog of care that has deprioritised non-severe cases, with the consequent risk of therapeutic inertia and increased risk of complications.

l Reported by experts
m Reported by experts

Secondly, process-related barriers are related to the **expected prescription behaviour.** Often health systems have a need to plan pharmaceutical spend ahead, and for this reason strategies are in place to ensure that actual spend adheres as closely as possible to the forecast. However, some of these strategies can limit HCPs in their ability to personalise treatments for some patient risk profiles. Such approaches might include:

- formal prescription quotas, i.e. mandated prescription patterns for HCPs to respect. These may carry financial penalties for prescribers that exceed their allocated quotas or budget. In some countries, a small fraction of a physician's salary depends on their quota adherence.

- informal review of the expected individual/local patterns of prescription, as well as the publication of prescription data by, for example, healthcare unit (as is the case for some Italian regions), which may create peer pressure on spend outliers.

- the need for justification, meaning that in some countries, HCPs are able to deviate from recommended patterns of prescription but, need to justify their non-conformity, adding an administrative burden to an already considerable workload.

1 in 6

People with diabetes have not had contact with their diabetes medical team since before COVID-19

Last, and among the most prominent issues for HCPs, is the **limited availability of time and knowledge** to manage PwD. In Germany, for example, GPs are able to dedicate an average of eight minutes to each patient.[40] That's a challenging timeframe in which to formulate an appropriate treatment plan, and generally to manage patients, especially those affected by chronic conditions. This trend manifests across the board in Europe, and has been significantly exacerbated by the COVID-19-induced backlog. A UK report capturing the state of PwD up to April 2022 revealed that 1 out of 6 individuals had had no contact with their diabetes healthcare team since before the pandemic.[41]

Moreover, the scarcity of integration and collaboration across care settings and disciplines contributes to the suboptimal adherence to guidelines, as GPs (and more rarely specialists) might lack opportunities to exchange information with other health professionals (diabetologists, cardiologists, endocrinologists, as well aspharmacists) on PwD management, innovation and lessons learnt.

The impact of therapeutic inertia

As discussed above, policy barriers, and especially those triggering access restrictions and time-consuming tasks, are among the biggest limiting factors to clinical guideline adherence, and are likely to drive therapeutic inertia.[26] While this inertia can influence decision-making around 'person-centred glycaemic management' in many ways, it has a particularly high impact in terms of therapy choice, ongoing monitoring and treatment intensification (Figure 4).[42]

Therapeutic inertia in diabetes management is widely described in the literature, and has multifaceted consequences, as summarised below.

Figure 4: Potential impact of policy-related barriers on clinical decision-making

Barrier		1 Assess key characteristics	2 Consider factors that impact choice of treatment	3 Utilise shared decision-making to create a mgmt plan	4 Agree on mgmt plan	5 Implement mgmt plan	6 Provide ongoing support and monitoring	7 Review and agree on mgmt plan
Guidelines-related	Discrepancies vs latest guidelines	✓	✓					✓
	Fragmentation of guidance		✓	✓	✓			✓
Access-related	Delayed access		✓					✓
	Narrow reimbursement vs drug label		✓	✓				✓
	Limitations to authorisation to prescribe	✓	✓			✓	✓	✓
	Financial barriers		✓	✓	✓	✓		✓
Process-related	Indications on expected prescription behaviour	✓	✓	✓				✓
	Organisational hurdles	✓	✓		✓	✓	✓	✓
	Lack of knowledge/ time to prescribe	✓	✓	✓			✓	✓

Source: PwCs analysis.

Note: The 7 steps of clinical decision-making for glycaemic management in T2D are taken from Davies et al., 2018. Mgmt: management

Rise in complications and comorbidities

First and foremost, therapeutic inertia in T2D determines prolonged hyperglycaemia, which in turn increases the chance of micro- and macrovascular complications. Microvascular complications include retinopathy, macular oedema, neuropathy (such as gastroparesis and bladder dysfunction) and nephropathies with related proteinuria and macro-/microalbuminuria.[43, 44] Clinical inertia can significantly increase the incidence and progression of diabetic retinopathy.[45]

n E.g. in individuals with HbA1c >1.5% higher than target levels, and in young individuals with T2D

Macrovascular complications can also be triggered by prolonged hyperglycaemia.[21] For example, evidence shows that a one-year delay to treatment intensification leads to a significant increase in cardiovascular events, such as myocardial infarction (67% increase), heart failure (+64%) and stroke (+51%).[46] In addition, recent updates to guidelines recommend early intensive therapy in newly-diagnosed T2D, especially in high-risk individuals[n], as beingmore effective than conventional add-on therapy in controlling glycaemic levels.[47] This consideration makes the impact of delayed, or missed, management even clearer.

Decline in quality of life

For PwD, quality of life[o] also starts to decrease when complications occur. This decline takes place in several crucial ways, including physically, in the form of concomitant obesity, coronary arterial disease, renal failure, neuropathy and retinopathy; neurologically, if dementia presents; mentally, especially in younger individuals due to coexisting depression; and socially, due to isolation and stigma.[48]

Increased costs and missed savings opportunities

Finally, suboptimal adherence to guidelines has financial consequences, as demonstrated in some recent studies. A retrospective analysis conducted on 2014-15 Medicare data in the US assessed how T2D outcomes related resource utilisation (i.e. spend on pharmaceuticals and outpatient care) correlates to guideline adherence. The study shows that, while low adherence to guidelines consistently leads to smaller pharmacy spend (i.e. drugs and monitoring) in the short term, these savings are offset by significantly higher outpatient costs. In addition, the cost of low adherence to guidelines tends to increase over time.[49]

75%

Hospital care costs attributable to T2D complications when a PwD is hospitalised.

A recent modelling study based on UK primary care data estimated the incremental costs incurred by health systems when glycaemic levels are uncontrolled for several years. Overall, the excess costs of managing complications summed with the loss of workplace productivity over lifetime amounts to an additional economic burden of GBP 3,331 million at the population level.[50]

Another study reviewed economic evidence of the costs triggered by diabetes-specific treatment vs the overall costs generated by complication management. The latter was reported as generating an increased spend of up to EUR 4,051/5,725 per PwD each year in France and Germany respectively. The most expensive late complications include end-stage renal disease, amputation and fatal ischemic heart disease.[51]

In an attempt to tie all the evidence together, a review of health economic evaluations conducted for Europe reveals,[52] that the majority of the costs of managing complications related to T2D are driven by in-patient care (40-60% of the total costs), while pharmaceutical costs of managing glycaemia are identified as the smallest element of spend, ranging from between 6% to 18% on average.[51-53] In some settings, the cost of managing complications represents 75% of total hospital care spend for people with T2D.[54] In addition, the cost of primary care is reported to increase almost sixfold when complications are present.[52] The economic evaluation review concludes that early treatment intensification approaches are generally deemed cost-effective.

Overall, the body of evidence suggests that i. the incremental treatments costs due to early treatment are acceptable due to the health benefits they determine; and ii. the early spend is offset by the complication management costs averted down the line.[49, 52]

o Measured as health-related quality of life (HR-QoL) index

Key learnings from the GAP framework assessment

Some of the barriers discussed in the previous section are purposely designed by healthcare systems to optimise their short-term spend management, and especially their pharmaceutical spend. The intention is to generate the greatest value from the resources available to address local needs. Because limited resources require careful allocation, criteria other than efficacy and safety often come into play, such as cost-effectiveness, budget impact and equity.

However, this study reveals that some of the policies in place might be self-defeating by not supporting the goal of 'maximising the benefits' for the population. Reviewing the entire body of policy barriers that exist in Europe reveals some key insights.

First, some of the policies designed to allocate the available resources – especially Guideline- and Access-related – (Figure 3) may not necessarily manage to achieve their goals. For example, by delaying the use of effective pharmaceutical tools, the 'best weapons' may be used too late to grant a significant clinical benefit. Data also show that the overall cost of managing complications typically exceeds the budget saved by sparing the early use of pharmaceutical therapies.

Also related to this first observation, and one of the most prominent emerging barriers to guideline implementation is the widely used 'step reimbursement' approach (i.e. add-on therapies are reimbursed only when the previous line of therapy fails), which contrasts with the early, proactive intensification of treatment recommended by the most recent international guidelines. This approach to therapeutic management represents an evolution of the traditional step-therapy approach, and is based on a growing body of evidence,[21, 47] but it is hardly implementable at present considering the current access landscape.

Second, several examples exist of Processes related to T2D therapeutic management that are not designed to achieve cost/resource management goals, but simply 'get in the way' of effective disease management from both prescriber and PwD perspectives, without returning any real benefit for the healthcare system (Figure 3). In other words, some overly intricate and redundant processes may considerably impact on PwD ability to get the best treatment in a timely fashion, and therefore avoid complications further down the line.

The third finding is that primary care doctors are particularly affected by policy-related barriers that restrict their ability to prescribe, access the latest innovations, and exchange and coordinate with specialist care providers. This is at odds with ongoing attempts to enable integrated approaches and strengthen community and primary care.[55, 56]

Finally, and most importantly of all, the current European policy landscape creates and perpetuates deep inequities of care, largely based on geography/location and socioeconomic status, across and within countries (Figure 5). While this is not a new or surprising finding, it reinforces the understanding that people living in Europe are subject to a 'postcode lottery' when it comes to accessing innovation and quality care.[57] This unequal access has a decisive effect on clinical outcomes.[58] In addition, the socioeconomic status and related disparities also affect – for several reasons – health outcomes. One example among many: it has been measured that those individuals who are aware of their disease management goals, i.e. have a good level of 'health literacy', achieve slightly higher levels of adherence and are better monitored/treated than others;[28, 59] this, again, contributes to a self-reinforcing cycle of inequity of access to care.

Figure 5: Cross-country heatmap of system-related barriers

		France	Germany	Italy	Spain	Poland	United Kingdom
Guidelines-related	Discrepancies vs latest guidelines						
	Fragmentation of guidance						
Access-related	Delayed access						
	Narrow reimbursement vs drug label	*		*	*	*	*
	Limitations to authorization to prescribe			*			*
	Financial barriers						
Process-related	Indications on expected prescription behavior		*		*	*	
	Organisational hurdles						
	Lack of knowledge/ time to prescribe						

No PwD or HCPs affected/Minor impact
Some PwD or HCPs affected/Moderate impact
Most PwD or HCPs affected/Large impact
All PwD or HCPs affected/Guidelines not implementable

Note: Barriers that apply to a subpopulation only are indicated with an asterisk. See 'About this research' for detailed methodology and notes. **Source:** PwC analysis

Guiding principles for action

Experts consulted for this study converged on a set of principles that should guide future activities to improve policies around diabetes management in Europe.

1

Equitable access to quality care across Europe

The European Union defiines the reduction of social inequalities across the region as a fundamental principle to improve the control of non-communicable diseases and, more broadly, to promote social inclusiveness.[60] The fragmented pattern of diabetes management described in this study therefore represents a focal area of action to achieve equitable access to care delivery across Europe.

2

Evidence-driven approach to policy making

Health policy decisions should be guided by the scientific evidence included in clinical guidelines. These represent the 'gold standard' for disease management, and are transparently compiled by the scientific community for the benefit of HCPs, PwD and decision-makers.

3

Integrated and patient-centric care provision

To make sure that the available resources are used effectively and efficiently, transforming care provision towards integrated models is key. These models consider the patient holistically, and are able to capture, evaluate and improve outcomes for all people in need.

4

The right care at the right time, delivered by the right person, tailored to individual patient needs

The continued accumulation of knowledge about diabetes enables the scientific community to provide tailored recommendations for each individual profile. In future, health systems should ensure that they make use of these insights at scale.

The way forward

This study reviews how lack of adherence to clinical guidelines, and consequent therapeutic inertia, are driven by a wide range of barriers. In particular, policies and organisational barriers that can affect the ability to adhere to guidelines in multiple ways are described and summarised in the GAP framework (Figure 3). Finally, the consequences of not adhering to guidelines, in particular when caused by delayed or absent treatment intensification, are reviewed, and include the impact on clinical outcomes, comorbidities and health costs.

By reviewing these findings, stakeholders that are involved in the fight against diabetes at both national and European level have an opportunity to take action to improve the healthcare provided to PwD living in Europe.

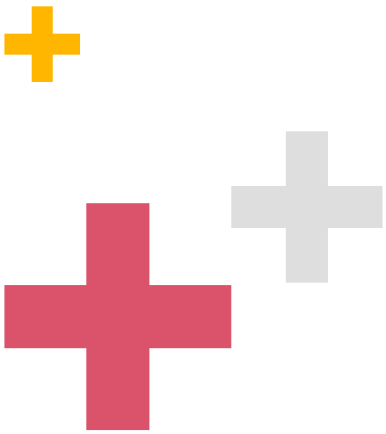
While the assessment focused on T2D due to considerable unmet needs, the key principles and recommendations discussed in this section might be relevant to the entire diabetes community – and even beyond, to the management of chronic non-communicable diseases in general.

Recommendations for national policy makers

Policy barriers exist at the national level, and as such should be discussed and addressed locally. That means taking into account specific resource availability, governance mechanisms, financing mechanisms and settings of care provision.

The experts consulted during this study, as well as the overall diabetes community, agree that to mitigate the impact of policy barriers, national policy makers should consider the following measures:

1. Review and optimise any complex processes that may impair doctors' ability to prescribe the best therapy for each patient, as well as the PwD ability to fill their prescriptions.
2. Regularly review guideline updates and the ever-growing body of health economic data concerning therapeutic approaches to T2D to make sure that existing resources are allocated as efficiently as possible, and the value delivered to PwD is maximised.
3. Update existing access and reimbursement policies to enable early therapy intensification (versus step approach) in diabetes management – as recommended by the most recent international guidelines.
4. Review eligibility criteria for non-insulin antidiabetics, in particular by making sure that other risk factors, in addition to uncontrolled glycaemia, are considered for initiating prescription – as recommended by the most recent international guidelines.



Enabling holistic T2D management across Europe

In addition to actions addressing punctual barriers related to the way T2D guidelines can be implemented technically, as identified in the GAP assessment, broader action can support a better life for PwD.

Fact-based, system-level, strategic directions around T2D management have already been put forward by the EUDF and, and by the diabetes community in general. Synergies may be created around these topics thanks to EU-wide action and initiatives. To achieve the greatest impact, multi-stakeholder coordinated action should be undertaken across Europe; dialogue on these strategic areas should be pursued and intensified in countries by designing and tailoring models to local needs.

Action may revolve around the following areas:

Data and outcomes

Investing in data collection and usage would make it possible to:

- connect guideline adherence to outcomes to support evidence-based decision-making
- identify gaps in guideline adherence, as well as excellence of care, to make sure inequity of care delivery is addressed
- understand risk patterns, and therefore enable targeted care approaches, potentially alleviating the occurrence of costly complications.

To ensure the optimal use of collected data, stakeholders should converge around standardisation of parameters, interoperability and, importantly, commit resources and willingness to act decisively on the collected data.

Innovation and health management

Making technology and innovation accessible to the widest population, and integrating such tools into care pathways, would make it possible to:

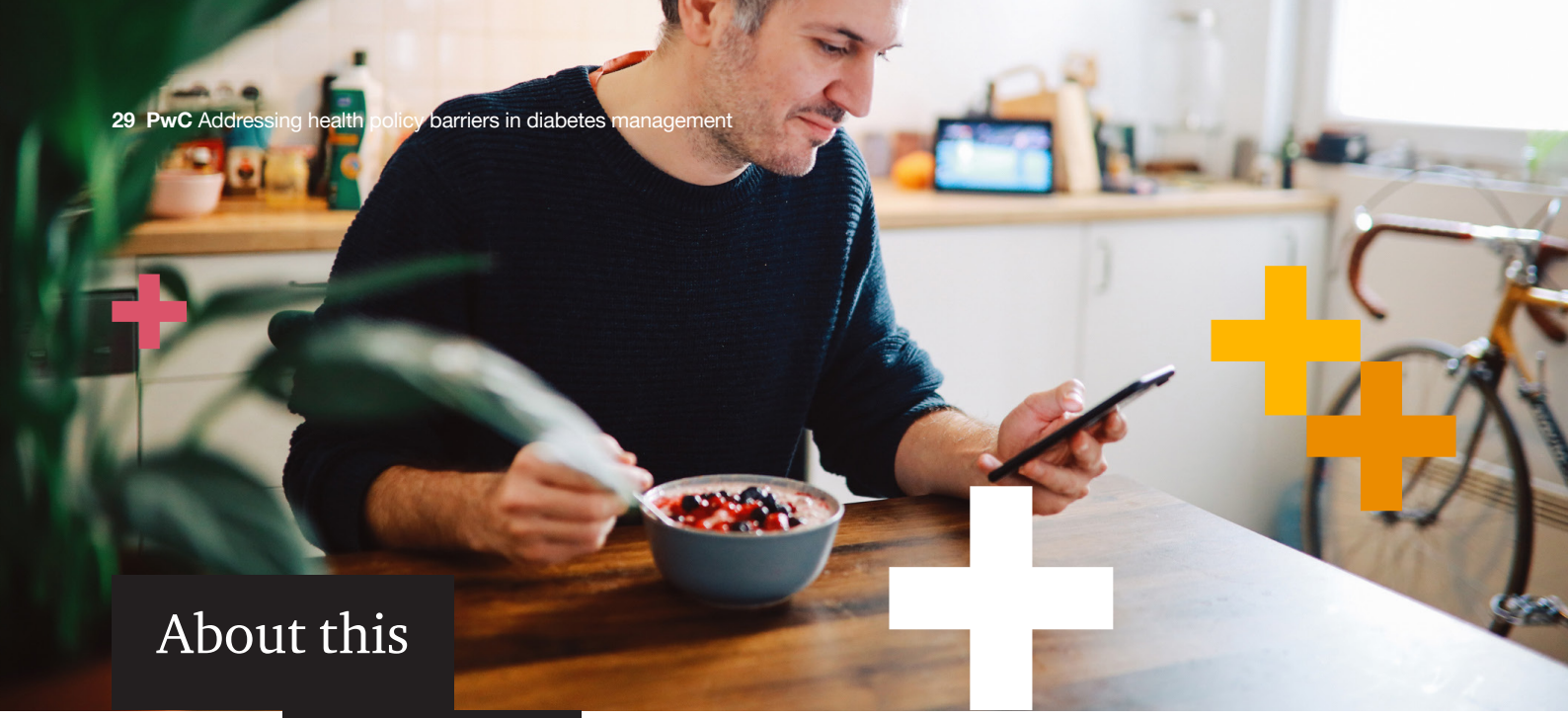
- improve the ability of HCPs and PwD to monitor and manage diabetes as a long-term condition
- focus on long-term outcomes, especially in the context of value-based agreements, which can potentially address concerns about the financial impact of innovative therapies
- address inequities, especially affecting the most vulnerable subpopulations (e.g. seniors, low socioeconomic status, multimorbid/frail individuals).

Integrated care

Overcoming existing siloes across care settings, budgets, clinical management approaches and infrastructure would make it possible to:

- take care of PwD holistically, addressing not only their medical problems, but their social and mental struggles, too
- relieve hospitals and specialised institutions of the burden of managing chronic patients, who instead need continuous community support
- foster knowledge exchange and dialogue across stakeholders working in different settings.

Overall, data, technology and integration of care have the potential to enable population health management approaches in diabetes (and beyond), and therefore to translate investments into valuable health in return.



About this research

This report is the result of an independent assessment conducted by PwC between October and December 2022, sponsored by the EFPIA Diabetes Platform. The assessment was based on individual expert interviews (see Acknowledgements) addressing the barriers to clinical guideline adherence in Europe, with a focus on those driven by policy. Research was focused on, but not limited to, six sample countries (France, Germany, Italy, Poland, Spain, UK).

All key findings were verified through desktop research, privileging the use of institutional sources and peer-reviewed scientific literature. Statements that could not be verified were excluded from the assessment or indicated in the report as 'expert opinion'. Emerging findings and themes were regularly discussed with the EFPIA Diabetes Platform; the study also drew on input from EUDF board members. Local industry representatives and trade associations reviewed draft findings for each of the countries in scope.

Taxonomy (Figure 3). The PwC team ideated the GAP (Guidelines, Access, Processes) framework to frame the findings from the research. Categorisation was discussed and validated with the EFPIA Diabetes Platform and representation from EUDF.

Barriers heatmap (Figure 5). PwC team colour-coded the intensity of each barrier type by category and country based on extensive expert discussions, desktop research and policy analysis (see table below). The EFPIA Diabetes Platform, local experts and representatives from national trade associations, together with the PwC team, thoroughly reviewed and refined, the resulting map, which included ensuring cross-country consistency. See table on page 30).

It should be noted that the mapping in Figure 5 refers to 2018 ADA/EASD guidelines. The team and experts notice that, while progressing towards the implementation of the 2022 update, there is a risk that some barrier types will become stronger (especially 'discrepancies vs latest guidelines', 'narrow reimbursement' and before oragnisational hurdles').

'Access' barriers are assessed across all drug classes. 'Delayed access' refers to the current access state, independently of the time it took for each product to reach the market.

Detailed color legend for the barriers heatmap (see Figure 5)

Barrier		Assessment question	No PwD or HCPs affected/Minor impact	Some PwD or HCPs affected/Moderate impact	Most PwD or HCPs affected/Major impact	All PwD or HCPs affected/GL not implementable
Guidelines-related	Discrepancies vs latest guidelines	Are national guidelines aligned with recent international guidelines, e.g. 2018 ADA/EASD?	There is general alignment	There are minor differences/gaps, but treatment principles are kept	There are notable differences in treatment algorithms	Updated national guidelines are not available
	Fragmentation of guidance	Are local guidelines diverse or inconsistent across different locations/settings?	There is no fragmentation of guidance	Some PwD are treated inconsistently vs national guidelines	Most PwD are treated inconsistently vs national guidelines	There are no national guidelines and local ones are inconsistent
Access-related	Delayed access	Does delayed access impact on the availability of antidiabetics?	Antidiabetics are widely available	1 to 3 antidiabetics are not available	Several (3+) antidiabetics are not available	The majority of antidiabetics are not available
	Narrow reimbursement vs drug label	Are reimbursement restrictions narrowing the patient population that can be prescribed an antidiabetics vs an approved label?	Reimbursement is according to the label	There are restrictions that limit prescription for some PwD	There are restrictions that limit prescription for most PwD	There are restrictions, and add-on approaches are strongly limited
	Limitations to authorisation to prescribe	Are there limitations affecting HCP ability to prescribe according to guidelines?	There are no limitations	There are limitations affecting some PwD	There are limitations affecting most PwD	There are limitations that do not allow prescription for some PwD
	Financial barriers	Are there copays/ OOP costs related to antidiabetic? If so, what is the impact on PwD?	There are no financial barriers	Financial barriers exist and have a limited impact on PwD	Financial barriers exist and put some PwD at risk of catastrophic spend	Financial barriers exist and put most PwD at risk of catastrophic spend
Process-related	Indications on expected prescription behaviour	Do prescriptions need to fit given prescription patterns/ quotas?	Prescriptions do not need to match any predefined pattern	Prescription is monitored but there are no formal recommendations/ quotas	Prescriptions need to match formal quotas	There is no flexibility in prescription patterns
	Organisational hurdles	Are there organIsational barriers limiting the adherence to guidelines?	There are no organisational barriers affecting adherence	There are some barriers to adherence that can be generally overcome	There are considerable barriers that widely affect guideline adherence	There are insurmountable barriers that prevent guideline adherence
	Lack of knowledge/ time to prescribe	Do physicians have enough time, knowledge and access to resources to manage PwD?	Physicians have enough time, knowledge and resources	Physicians may have some gaps in and/ or limited time and resources	Physicians have considerable gaps in and/or limited time and resources	Physicians lack time, knowledge and resources

The way forward and recommendations. PwC independently derived the guiding principles for action based on learnings from the research. Recommendations to local policymakers and suggested strategic areas of action were identified by reviewing expert opinions, the existing EUDF strategy and vision, and EFPIA initiatives around diabetes management. Actions were included as long as they were in line with the suggested guiding principles. Strategic areas are directional and not exhaustive.

The report has been written by the PwC team. The entire narrative, including findings, guiding principles and strategic areas, was reviewed in February-April 2023 by the EFPIA Diabetes Platform and all experts involved in individual discussions. The PwC team finalised the narrative based on the suggestions received, as long as were in accordance with the prevalent expert opinion and were backed up by scientific evidence.

About PwC

At PwC, our purpose is to build trust in society and solve important problems. We're a network of firms in 156 countries with over 295,000 people who are committed to delivering quality in assurance, advisory and tax services. PwC Switzerland has over 3,380 employees and partners in 14 locations in Switzerland and one in the Principality of Liechtenstein. Find out more and tell us what matters to you by visiting us at www.pwc.ch.

About EFPIA

The European Federation of Pharmaceutical Industries and Associations (EFPIA) represents the biopharmaceutical industry operating in Europe. Through its direct membership of 37 national associations, 39 leading pharmaceutical companies and a growing number of small and medium-sized enterprises (SMEs), EFPIA's mission is to create a collaborative environment that enables our members to innovate, discover, develop and deliver new therapies and vaccines for people across Europe, as well as contribute to the European economy.

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Abbreviations

ADA	American Diabetes Association
BMI	Body Mass Index
EASD	European Association for the Study of Diabetes
EFPIA	European Federation of Pharmaceutical Industries and Associations
EMA	European Medicines Agency
EUDF	European Diabetes Forum
GLP-1	Glucagon-like Peptide-1
GP	General Practitioner
HbA1c	Haemoglobin A1C (or Glycated Haemoglobin)
HCP	Healthcare Professional
IDF	International Diabetes Federation
NICE	National Institute for Health and Care Excellence
PwD	Person/people with Diabetes
T2D	Type 2 Diabetes
YLD	Year of healthy Life lost to Disability
ESC	European Society of Cardiology
WHO	World Health Organization
OOP	Out of pocket

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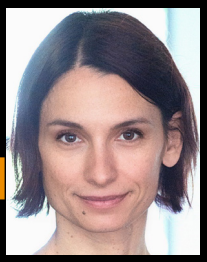

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