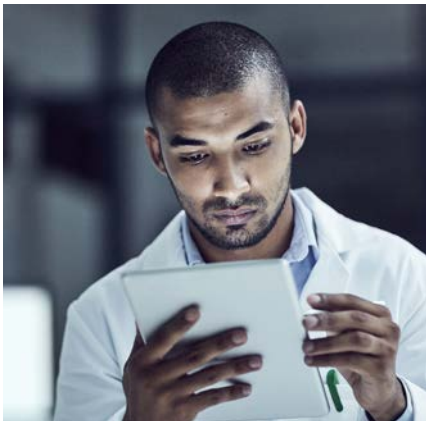
efpia

IMPROVING OUTCOMES FOR PEOPLE WITH DIABETES

The role of health data, access to innovation and rethinking care



Every
6 seconds...

someone in Europe
dies of a **diabetes**
related condition

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IMPROVING OUTCOMES FOR PEOPLE WITH DIABETES

HOW DATA, ACCESS TO INNOVATION AND RETHINKING CARE CAN UNLEASH PATIENT POWER

Sharing solutions to a growing health crisis

Europe's diabetes pandemic emerged quickly enough to challenge our health services and gradually enough to give the impression that small changes would be enough to cope with the rising burden. Like antimicrobial resistance or climate change, the scale of the problem demands a complete rethink of how we manage diabetes. We cannot expect health systems designed to care for people with acute illnesses to meet the needs of large numbers of citizens living with long-term conditions such as diabetes. It's time to reimagine how care is delivered.

In listening and collaborating widely, we identified three key elements of the diabetes challenge: we will need to unlock the full potential of data, as well as empower patients, and rethink our health systems. For each of these elements, we have set out clear and actionable recommendations for the EU.

The challenges laid out in this White Paper require a concerted response. No single company, no single stakeholder nor country has all the answers. That is why EFPIA members have come together in the EFPIA Diabetes Platform. Together, we aim to be an active partner in the fight against diabetes, improving the lives of everyone affected by the disease by optimising diabetes diagnosis, treatment and management, and focusing on delivering better outcomes.

While we do not underestimate the problem, we believe that across Europe the answers do exist – the challenge is to prioritise the right policy frameworks that allow those answers to be implemented. As you will see in the pages that follow, we have explored European and national solutions to improving diabetes care. Through research and stakeholder engagement, along with three roundtables to gather expert input, ideas and inspiration, we have taken a deep dive into diabetes. The roundtables would not have been possible without the invaluable support of LIF Sweden, Primary Care Diabetes Europe and the vfa, in Sweden, Belgium and Germany, respectively. And none of this would have come together without the collaboration of the European Diabetes Forum and the many stakeholders from across Europe that contributed their time and insights. We are sincerely grateful to all who participated in these highly interactive events.

In listening and collaborating widely, we identified three key elements of the diabetes challenge: we will need to unlock the full potential of data, as well as empower patients, and rethink our health systems. For each of these elements, we have set out clear and actionable recommendations for the EU, France, Germany and the United Kingdom.

As we start a new cycle of European policymaking, we hope this paper will offer concrete steps that can be taken at EU and Member State level to improve the lives of the growing numbers of citizens living with diabetes. It presents decision-makers with a challenge that is daunting but doable. I hope policymakers will give diabetes the attention it deserves. Anything less would be a missed opportunity.

NATHALIE MOLL
EFPIA Director General

EXECUTIVE SUMMARY

Nearly 1 out of 10 Europeans suffers from diabetes and the burden is rising fast. By 2045, more than 80 million people in Europe will be affected, with type 2 diabetes accounting for the majority of cases. People with diabetes face a higher risk of serious complications which take a personal, social and economic toll: kidney disease, cardiovascular events, blindness, amputation – all reducing quality of life and incurring heavy financial costs.

Improving diabetes care is a major public health challenge, requiring urgent action. Thirty years ago, a landmark diabetes conference produced the St Vincent Declaration which was designed to tackle a looming health crisis. It demonstrated a collective will to address an imminent threat, but fell short of delivering the required response. Today, the scale of the problem has grown substantially, despite the emergence of innovative therapeutic options and advances in digital health. There is variation across Europe in how health systems manage diabetes and prevent complications, and significant differences in outcomes for people living with the condition.

This white paper offers specific, achievable policy recommendations in three key areas:

- The use of health data to define, measure and achieve better outcomes;
- Empowering people with diabetes through digital technologies and innovative therapies; and
- Rethinking health systems to focus on primary and integrated care.

It calls on the EU to encourage Member States to embrace outcomes-driven healthcare, support registries and catalyse the development of health information infrastructure. To drive empowerment and innovation, the paper calls for training for people with diabetes and for health professionals, equitable access to innovative therapies, and incentives for clinical and digital innovation. Health systems should be reimagined to prioritise chronic conditions, with the European Semester and the cohesion policy deployed to highlight and encourage structural changes.

Along with examples from several European regions and countries, this paper puts the spotlight on three large countries: the UK, Germany and France. In the UK, there is evidence of political and system support for prioritisation of diabetes services. However, this has not yet produced improved outcomes. Greater information sharing, a long-term approach to health system organisation, and a determination to take concrete actions based on outcomes data, would accelerate progress. In Germany, political momentum to tackle chronic conditions can be translated into results by improving access to outcomes data and to innovative therapies. While France is experimenting with several digital solutions for people with diabetes, this should be matched with better integration of health data systems and improved access to innovative therapies that achieve improved long-term clinical outcomes.

Addressing the key barriers to better care can help to deliver optimal outcomes for all. In developing this paper, several examples of good practice were identified across Europe in areas such as the use of health data, diabetes registries, improving adherence, applying clinical guidelines, health system design and more. Europe has all the ingredients for a comprehensive solution to the diabetes pandemic, promising to improve the lives of citizens and make care delivery more efficient. By joining forces with a broad coalition of stakeholders and fostering the sharing of best practice, EU and national decision makers must act now to rise to one of the 21st century's greatest health challenges.

POLICY ACTION ON DIABETES

RESPONDING TO THE RISING PANDEMIC

The scale of the challenge we face demands a strong response that accelerates the shift towards reducing clinical inertia, better glucose control, and data-driven, outcomes-based healthcare

In 1989, the St Vincent Declaration aimed to tackle the emerging diabetes crisis by improving care standards and setting clear goals for participating countries.[1] In the 30 years since the landmark conference that produced the Declaration, diabetes still poses significant health and socio-economic challenges for citizens and decision makers. Around 60 million people in Europe – nearly 1 out of 10 Europeans – have diabetes, with type 2 diabetes accounting for more than 90% of all cases. The numbers are soaring: by 2045, more than 80 million will live with the disease[2].

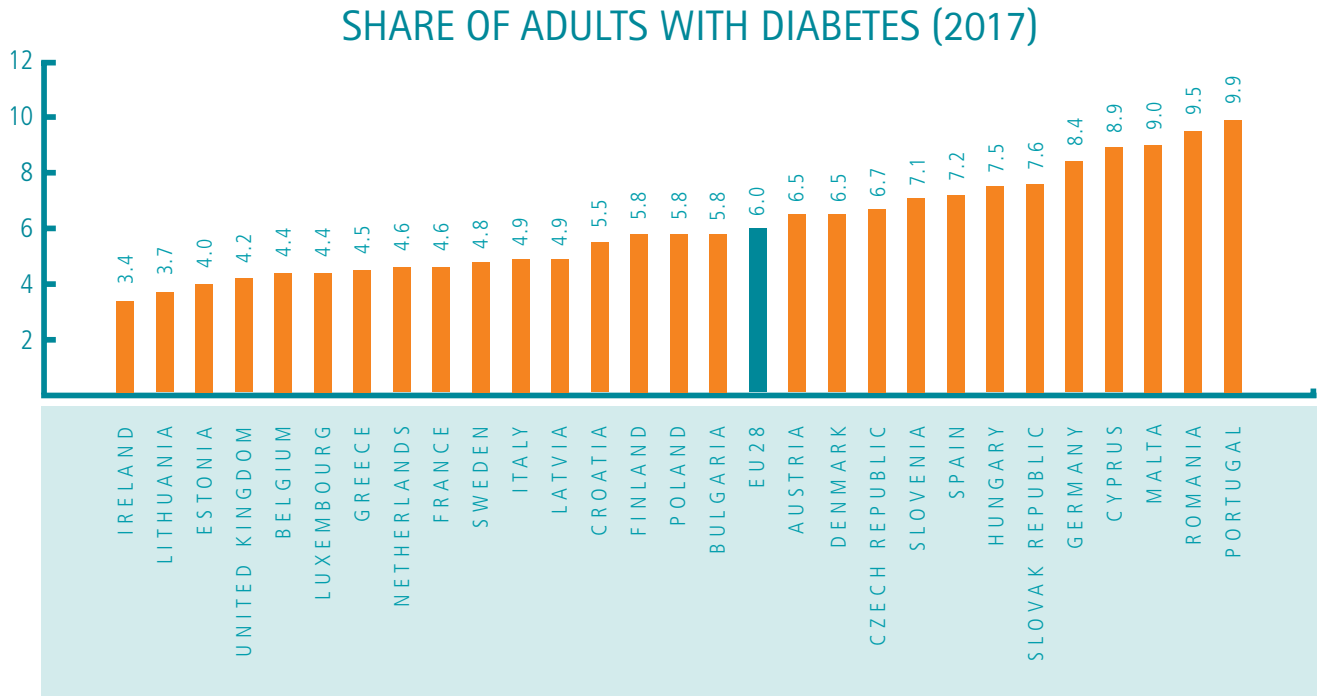
Every six seconds someone in the world dies from a diabetes-related complication.[3]

Diabetes shortens lives by up to 15 years – a rate of premature death worse than that of smokers (10 years)[4]. In addition, people living with diabetes can experience serious complications which carry significant personal, clinical, and economic costs. Type 2 diabetes increases the risk of having a heart attack or stroke, and **people with the disease have a two-to-three times greater risk of heart failure. More than half of all people with diabetes die of cardiovascular events[5,6].** Around 40% of people with diabetes develop diabetic kidney disease[7], with rates of end-stage renal disease up to 10 times higher in people with diabetes[8]. Microvascular complications, such as loss of vision or limb amputation, impose significant quality-of-life and economic burden on citizens and society.

Funding diabetes care poses a significant challenge to health systems across Europe. An estimated 9% of total health expenditure in the EU is allocated to diabetes and this is forecast to rise by 12% over the next 25 years[9]. An estimated 75% of diabetes costs is associated with treating preventable complications[10].

There is considerable variation across Europe in spending on diabetes care and prevention, as well as differences in access to innovative treatments, technologies, and digital health tools. This variation is compounded by the lack of implementation of guidelines across the spectrum of care from diagnosis to disease management.

Poor adherence to treatment has been shown to be a key determinant of diabetes outcomes, leading to higher rates of preventable complications. By improving healthcare, supporting adherence, and empowering people with diabetes to actively manage their condition, it is possible to reduce costly complications, improve health outcomes and productivity.



Note: Age-standardised prevelance of population aged 18-99 with Type 1 or Type 2 diagnosed Diabetes.
Source: IDF Atlas, 8th Edition, 2017.

BARRIERS TO SUCCESS

Despite the potential of data-driven healthcare, there are significant gaps in the evidence base along with variations in the application of guidelines by healthcare professionals and in health systems' capacity to gather data. These challenges combine to limit access to innovative therapies shown to improve outcomes.

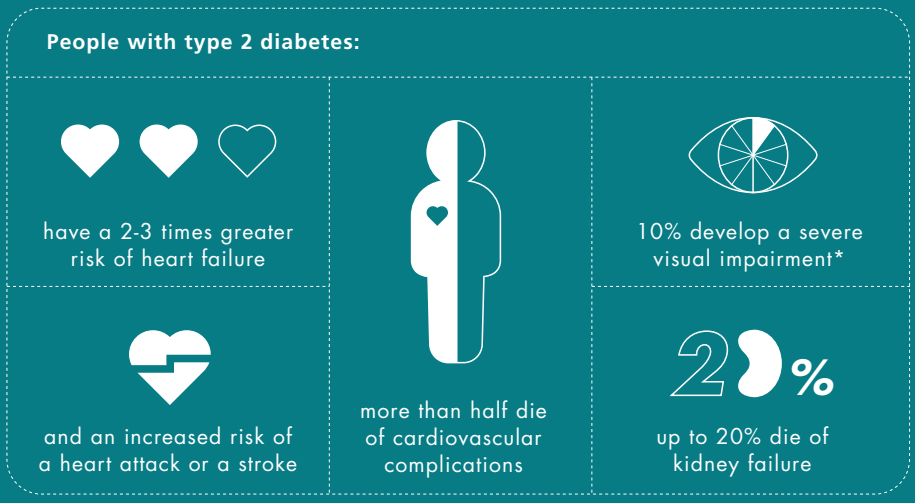
There is an urgent need to improve diabetes care to suit the nature of the disease. Health systems that were historically designed to respond to acute episodes of illnesses are ill-equipped for the challenges posed by the large and growing numbers of people with chronic conditions.

Taking a short-term view of long-term illnesses is a recipe for poor outcomes and waste. Designing and implementing new models of care for diabetes, and supporting access to innovative technologies for people with diabetes, could help deliver the outcomes-based health systems required to sustainably address the diabetes epidemic.

Only 15 European countries (39%) have national diabetes registries[11]. Even where these have been developed, there is considerable fragmentation and variation. Other long-standing challenges also persist: training for healthcare professionals, coaching for people with diabetes and their families, as well as access and adherence to prescribed therapies remain significant barriers to diabetes control and secondary prevention.

Digital technologies have the potential to address several of the technical, infrastructural, and behavioural change challenges. However, here too, there are gaps in the evidence base which lead to a reluctance to fund innovation. Addressing these would support the development of funding streams and new pathways for proven technologies and therapies.

The solutions to many of the challenges outlined here can be found at a European level. The development of new evidence, application of existing knowledge, adoption of standard outcomes, reduced fragmentation in registry data, the integration of new technologies, access to innovative therapies, and a reimagining of how care is delivered can be driven by EU policy action and close collaboration of Member States. Across health systems, stakeholders view the shift to outcomes-based healthcare as essential to delivering what matters to people with diabetes and to ensuring that money is well spent and health systems become more efficient and sustainable. Interventions that do not offer value must be sidelined while those that deliver for people with diabetes and health systems are rewarded[12].



*people with type 1 and type 2 diabetes

EU POLICY RECOMMENDATIONS

DEFINE, TRACK, MEASURE, IMPROVE: REGISTRIES, HEALTH DATA AND DIABETES

Measuring and comparing diabetes outcomes – and identifying the causes of variation – helps to highlight areas where better outcomes and efficiency gains can be achieved. Standardised outcome definitions and common methods of data collection are essential to outcome comparison and subsequent improvements.

However, barriers lie ahead. Addressing silos in funding, and making health data a priority in healthcare management, are vital to unlocking the potential of registries and data. **It is also essential that data is captured to ensure complete datasets are available for analysis and use.** Making data input as simple as possible, and developing guidelines to support the collection of essential data elements, would help to reduce the burden of data collection. The broader challenge of securing trust in how data is collected and used can shape public perception and political priorities. Communicating the value of health data to the public, and engaging people with diabetes in developing outcome measures would foster buy-in from key stakeholders. Ultimately, people with diabetes will value data collection when they see it translated into better outcomes.

The International Consortium on Health Outcome Measurement (ICHOM) is leading the way by systematically engaging with clinical experts and patients to find consensus on outcomes that matter to patients[13]. In 2019 ICHOM published the first standard set of outcomes for adults with type 1 and type 2 diabetes[14]. The OECD PaRIS initiative is working to define, collect and compare diabetes outcomes for people with chronic diseases, including diabetes, using patient-reported outcome measures (PROMS) and patient-reported experience measures (PREMs). Diabetes should be considered as a case study for chronic conditions[15].

Establishing the infrastructure to collect and analyse health data scattered across the health system, as well as securing the political will to apply learnings from outcomes data, is crucial.

Registries have proven potential to collect large datasets that can inform decision-making. They can highlight and reward excellence, flag failing services, and identify therapies and treatment models that deliver for people with diabetes and payers. Buy-in from policymakers, patients and physicians is essential to ensure rigorous data collection and sharing with registries. Registries also require leadership, financial and human resources, and strong links with the wider health system. Some EU Member States have well-developed registries; some have lower-quality registries; others have none.

RECOMMENDATIONS FOR THE EU

The European Commission should develop a policy framework promoting outcomes-based healthcare and actively encourage Member States to embrace outcomes-based diabetes care. Alignment on what data to collect is essential to the analysis of health system performance and to inform decision making at EU and national level. This data should be used as part of the European Commission's State of Health in the EU and the European Semester processes to support a policy framework promoting an outcomes-based approach to the management of diabetes.

The European Commission should support a scaling-up of digital services infrastructure across Member States through the development and deployment of a European Health Data Space. An ambitious approach to digital health data should put electronic health records at the heart of modern healthcare. This should be supported by standardised data collection methods, interoperability principles, as well as robust data governance frameworks to enable privacy while ensuring data can be securely used for healthcare improvement. These principles should underpin a network of national data nodes supported at EU level by a secretariat.

The European Commission should champion success stories in the implementation of registries and ensure EU funding support for pilot diabetes registries across Europe. This will further advance work to capture data in comparable formats. Such data would drive diabetes outcomes targets at EU and Member State level and support a transition to outcomes-based diabetes care. Via EU projects and through the EU Health Policy Platform, the European Commission should also share good practices and experiences of Member States or regions where registries have informed public health policy and clinical practice leading to improved outcomes for people with diabetes.

DIABETES DATA: SHARING EXPERIENCES GATHERED FROM THE EFPIA AND LIF SWEDEN DIABETES ROUNDTABLE, SWEDEN, JUNE 2019

NATIONAL DIABETES REGISTER, SWEDEN

The Swedish National Diabetes Register (NDR) was established in 1996 and has been available online since 2002. It collects data on HbA1c, blood pressure, blood lipids, statin treatment, use of glucose sensors and insulin pumps. The system is based on personalised identifying numbers, making data input and retrieval easier. By enabling comparisons between regions, it drives improved outcomes in areas such as heart attack mortality and tackles regional variation. A Europe-wide initiative based on this model could have a profound impact on the lives of European citizens.

STENO DIABETES CENTER, COPENHAGEN, DENMARK

The Steno Diabetes Center in Copenhagen is using health data to deliver significant improvements. Between 2000 and 2011, incidence of all lower-extremity amputations has decreased by 87.5% among men and 47.4% among women with type 1 diabetes, and by 83.3% among men and 79.1% among women with type 2 diabetes. This has helped to preserve quality of life and avoided health and social care costs.

NATIONAL DIABETES REGISTER, BULGARIA

The Bulgarian National Diabetes Register is a pseudonymised register of diabetes patients generated in 2015 using outpatient records collected by the Bulgarian National Health Insurance Fund. It captures epidemiological and complications data from across Bulgaria, supporting the study of diabetes and cardiovascular complications as well as life expectancy. It is also used by the Ministry of Health to reward general practitioners for managing people with diabetes.

EMPOWERING PEOPLE WITH DIABETES: SUPPORTING SELF-MANAGEMENT THROUGH DIGITAL TECHNOLOGIES AND INNOVATIVE THERAPIES

Digital tools and innovative therapies are game-changers in diabetes prevention, management and research[16]. For example, **the latest consensus view of experts in Europe and the Unites States is that some newer treatments for type 2 diabetes deliver reductions in mortality, heart failure and progression of renal disease in people with established cardiovascular disease[17],** and that glucose lowering therapies can contribute to a lower risk of hypoglycaemia. Data has driven a shift in experts' view, prompting them to favour innovative medicines that offer additional secondary benefits to people with diabetes, allowing healthcare professionals to tailor treatment to the individual needs of people with diabetes (such as those with higher cardiovascular disease risk, for example).

New technologies are enabling a shift from traditional diabetes care based on a limited number of recent clinical measurements to a new era where people with diabetes, healthcare professionals and researchers have access to and share data at thousands of timepoints. Not only can this inform decisions by healthcare professionals in clinics, it has opened the door to remote disease management by healthcare professionals and to greater disease self-management by people with diabetes. This in turn paves the way for significant increases in secondary prevention – reducing the risk of serious complications which can be devastating for people with diabetes and impose heavy burdens on health systems.

With the advent of big data and artificial intelligence tools, the potential for major research insights using real-world data is significant. The digital revolution in diabetes (and elsewhere) will complement clinical trial data by integrating information from electronic health records, disease registries, PROMs, mobile health apps and more. **Researchers will have the power to determine what works based on large real-world, real-time datasets.** Health systems must be ready to incorporate this evidence as it emerges. Armed with this data, access to the most effective treatments across Europe should improve.

People with diabetes are more willing to play an active role in self-monitoring than people with other chronic conditions[18]. Many people with diabetes treated with insulin already monitor glucose levels closely. This offers unprecedented opportunities for secondary prevention and behavioural changes, supporting better adherence. This approach can deliver better outcomes for people with diabetes, helping them avoid hypoglycaemia and macrovascular and microvascular events that result from poor glucose control, and can reduce spending on managing complications.

These profound changes to diabetes care, and to the patient-healthcare professional relationship, bring new challenges.

> *To optimise the use of innovative tools, and guard against health inequalities, training and support for people with diabetes is required. Health professionals will also have access to more precise patient data. To handle this improved quality and quantity of information, they will also require upskilling and support in navigating a rapidly-changing dynamic between care providers and people with diabetes.*

Additional challenges are posed by the varied frameworks and regulatory systems for managing health data within European countries. This is exemplified by the implementation of the General Data Protection Regulation (GDPR). Implementation of this regulation varies across, and within, Member States creating barriers to the development and application of innovative technologies. Other policy and practical barriers to the development and uptake of innovative technologies also exist. Policymakers struggle to strike a balance between ensuring the safety and efficacy of innovative technologies in a field that is evolving quickly.

The 2018 Commission Communication on the "digital transformation of health and care in the Digital Single Market" outlines several priority action areas including the need for interoperability, digital infrastructures, and training. The strong focus on digital health is also evident in the mandate of the new European Commission, as highlighted in the mission letters to several Commissioners. The EU and its Member States can improve outcomes, shift towards person-centred healthcare and reduce inequality by encouraging swift uptake of innovative therapies shown to deliver value.

RECOMMENDATIONS FOR THE EU

The European Commission and the European Parliament, in collaboration with Member States, should foster alignment on clinical evidence requirements. The EU should foster greater alignment on clinical evidence generation requirements, and encourage a common approach to clinical assessment of evidence centred on person relevant outcomes. This must be done in a timely manner to avoid delays in access to innovative therapies. This approach would deliver consistency in how Member States assess evidence and bring the benefits of innovation to people with diabetes more quickly, while helping to reduce outcome variation.

The European Commission, in collaboration with Member States, should promote clear and sustainable funding pathways for innovative treatments and digital health. The uptake of proven interventions, including medicines, e-health and m-health solutions, that improve outcomes and implement the highest clinical standards should be encouraged. Experiences should be shared between Member States where innovative therapies and tools have been successfully integrated into health systems. Best practices on funding and reimbursement models for new technologies should be highlighted and shared.

The European Commission should support implementation of the Clinical Trials Regulation to help make Europe a world leader in clinical research by embracing new trial designs supported by real-world data. The implementation of the Clinical Trials Regulation should be accelerated, removing wasteful duplication of processes between Member States.

The European Commission should support the development of digital skills for healthcare professionals and digital health literacy for people with diabetes. This must include preparing healthcare professionals for the digitally-powered changes that are on the horizon, including sharing best practice in the use of digital tools to support diabetes management via EU projects and through the EU Health Policy Platform.

APPLICATION OF DIGITAL TOOLS: SHARING EXPERIENCES GATHERED FROM THE EFPIA AND vfa DIABETES ROUNDTABLE, GERMANY, SEPTEMBER 2019

DIACARE PROJECT, CATALONIA, SPAIN

Diacare is a project seeking to support people with type 2 diabetes as well as their personal and healthcare environment via digital support and devices. The project is supported by the regional political bodies, pharmaceutical industry and scientific expert groups.

Diacare is a system for real-time care that supports the self-management of people with diabetes via personalised features. Via the Diacare platform, profiles of the respective users are created to record their individual needs in dealing with their diabetes. People using Diacare get digital personal assistance helping with daily decisions, such as what to buy in the supermarket and setting incentives for physical activity. People with diabetes also report their physical and psychological well-being, so that all actions can be put in correlation with how overall well-being evolves. Therapeutic measures can be adapted as soon as possible. Diacare is not managed by an anonymous algorithm; people using Diacare can always contact a case manager for assistance.

VALUE-BASED PROCUREMENT SYSTEM FOR DIGITAL INNOVATIONS

In order to promote digital healthcare, some countries in Europe, such as Denmark, use value-based tenders. Medical technology companies receive financial subsidies for the development of innovative medical devices as soon as they can prove the benefit of the innovation and demonstrate improvement of patient outcomes. In case the developed digital tools do not bring the expected benefit, the companies do not receive any financial subsidies and can be obliged to repay already granted subsidies.

Due to the excellent cost-efficiency ratio, this type of tender-system could be more widely encouraged across Europe. It can provide incentives for digital innovation while ensuring that public spending on research and development of innovative tools does not spiral out of control.

RETHINKING HEALTH SYSTEMS: INTEGRATED CARE AND EMPOWERMENT OF PRIMARY CARE

Integrated care seeks to improve care outcomes by overcoming fragmentation. Through linkage or coordination of services and providers along the continuum of care, it has the potential to improve continuity, drive patient empowerment and foster health system sustainability[19]. This approach can close the gaps between primary care and hospital services, between health and social services, and between e-health infrastructures including registries and electronic patient records.

Integrated care is central to improving the quality of diabetes care and addressing fragmentation in the provision of healthcare services[20]. However, making the transition from the current model to an integrated system poses challenges. EU Member States are at a variety of stages of evolution in their journey towards an integrated model.

There are several common barriers to more integrated and coordinated care across EU Member States: lack of effective information structures, organisational differences, and resistance from health professionals[21].Political support and commitment, strong governance mechanisms, stakeholder engagement, organisational change and leadership have been identified as prerequisites for advancing integrated care. Appropriate financing and incentives, along with integrated ICT solutions and evaluation mechanisms, are also key enablers.

Primary care is a crucial component of an integrated health system, particularly in the management of chronic diseases such as diabetes. Primary care services are often the main point of contact for people with diabetes and play a vital role in primary and secondary prevention. **Patient satisfaction with primary care across EU Member States is high.** In an integrated health system where primary care plays a central role, patients can become active members of the care team. This requires patient awareness and education, but also new skills – and an appropriate mindset – from health professionals. In a survey of EU Member States, 15 of 19 countries said they had education programmes for patients; just two out of three provided relevant education modules for health professionals.[22]

The empowerment of people with diabetes to take the lead in managing their own condition must be at the heart of a successful approach to organising integrated and primary care.

This requires building care around their needs. Shifting from a model focused on clinical outcomes to a more holistic approach which takes into account the real needs of people with diabetes should be a priority. Using PROMS and PREMs data to support communication between patient and physician can support this transition, but also support leadership and accountability amongst care providers and policymakers.

Flexibility is also key. The delivery of diabetes care is often organised around rigid protocols that fail to assist those who need the most support to manage their condition. **Diabetes care should be organised in a flexible way that enables clinicians to differentiate care and tailor it to the needs of individual patients,** thus allowing health systems to concentrate time and resources on the most problematic cases. Flexibility should also encompass having the capacity and capability for healthcare systems, and healthcare providers, to be able to adjust to new, disruptive practices.

Evidence indicates that targeting an integrated care approach to those people who would most benefit improves outcomes. This approach should be complemented by having the right incentives in place. Guideline updates are not always implemented as thoroughly and swiftly as expected, but financial incentives can drive change more effectively.

RECOMMENDATIONS FOR THE EU

The European Commission should use the European Semester to guide Member States in transitioning their healthcare systems. The European Semester should be used to drive changes in structural provision of healthcare and allocation of workforce to ensure appropriate support for primary and integrated care. Consideration should be given to ensuring Member States have the appropriate resources, capabilities and capacity to manage this change. This should include training for healthcare professionals and avoiding siloed budgeting. The recommendations of the European Semester should be linked with the allocation of structural funds to support Member States in transitioning to a model focused on primary and integrated care.

The European Commission and the European Parliament should prioritise diabetes within the scope of the EU's work on non-communicable diseases. The scope of the Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases should be broadened to make diabetes a focus area. This would facilitate the promotion of evidence-based best practices across the EU.

The European Commission should support Member States to implement an integrated and person-centred care model of diabetes management. Through voluntary exchanges under the State of Health in the EU process, the EU should help Member States to map and define effective models of diabetes care and management. Areas of high value that deliver improved outcomes for people with diabetes should be rewarded, and identified alongside low-value practices and incentives that do not achieve improved outcomes. Member States should also ensure that measures to improve diabetes care promote self-management, are person centric, evidence based and supported by healthcare professionals who have time for their patients. Using health data such as PROMs and PREMs, and taking account of the needs of people with diabetes in processes such as health technology assessment, are essential components of this transition.

The European Commission should collaborate with Member States to build a network of centres of excellence. The EU should explore leveraging the European Reference Network model to connect leading diabetes centres across Europe, equipping them with the resources and digital tools to become world leaders in diabetes management and research.

RETHINKING HEALTH SYSTEMS: SHARING EXPERIENCES GATHERED FROM THE EFPIA AND PRIMARY CARE DIABETES EUROPE (PCDE) DIABETES ROUNDTABLE, BELGIUM, SEPTEMBER 2019

CENTRE FOR DIABETES, COPENHAGEN, DENMARK

The centre is a central element in the Copenhagen municipality's diabetes action plan. The centre aims to bring together various components of diabetes management into one place to make it easier for people with type 2 diabetes to navigate the healthcare system. An essential element is the focus on a continuous collaboration between patients, hospitals, primary care practitioners and civil society. This is based on strong communication, leadership and data-driven decision making to target care effectively. A collaboration amongst healthcare professionals, municipalities and hospitals – the so-called healthcare triangle – is essential to improve cross-sector communication and understanding of the needs and hurdles faced by the different stakeholders involved in the continuum of care.

DIABETES PROJECT AALST, BELGIUM

This project provides chronic disease management in a primary care setting. It focuses on establishing an integrated care team, including diabetes educators, that helps patients self-manage their condition. Coaching is also provided by secondary care specialists. Care is organised around a Regional Diabetes Coordination Cell which coordinates interdisciplinary working. 69% of primary care physicians within the Aalst region signed up to participate. The project has led to a significant improvement in patient outcomes within a short period. The rapid success of the project led to adoption and promotion of this approach by the national authorities across Belgium.

ASSOCIATION FOR PEOPLE LIVING WITH DIABETES (APDP), LISBON, PORTUGAL

APDP has evolved into a nationwide institution which provides healthcare and a wide range of other services to people with diabetes. Stemming from the fact that education is a vital part of the care provided, APDP organises training courses for healthcare professionals, for people with diabetes, their families and caregivers in order to promote better disease management and thus increased quality of life for people with diabetes. APDP has developed a number of projects focused on the community, providing screenings and educational programmes to encourage behavioural lifestyle changes in those at risk of developing type 2 diabetes.

THE UK: NATIONAL CONTEXT SETTING AND RECOMMENDATIONS

THE SCALE OF THE DIABETES CHALLENGE IN THE UK

A person is diagnosed with diabetes in the UK every two minutes and the total number of people diagnosed has more than doubled in the last twenty years to reach about 3.7 million. In reality, the number may be closer to 4.7 as some suggest there are currently around one million people living with the condition unknowingly. If nothing changes, more than 5 million people will have diabetes in the UK by 2025.

Across the UK, the prevalence of diabetes has continued to grow consistently. The number of people diagnosed with diabetes in England now exceeds 3.2 million, in Scotland it is more than 295,000, Northern Ireland currently exceeds 96,000 whilst Wales has an estimated 61,000 people living with diabetes - the highest prevalence in the UK.[23]

Diabetes remains a complex and progressive disease with severe and costly but avoidable complications. In England, over 1 million people with diabetes were admitted to hospital in 2017 but only 8% were a direct result of diabetes. Every week, diabetes leads to over 160 amputations, 680 strokes, 530 heart attacks, almost 2,000 cases of heart failure and more than 500 premature deaths[24]. In Scotland, between 15 and 20% of patients in hospital have diabetes[25] while in Wales, around 2,000 people with diabetes have foot ulcers and about 330 amputations are carried out each year. About 24,000 hospital admissions occur annually in the UK due to complications of the diabetic foot alone.[26]

Currently the NHS spends at least £10 billion every year on diabetes in the UK, which is equivalent to almost 10% of the entire NHS budget[27]. In Scotland, diabetes costs the NHS about £1 billion a year – or around 12% of the total NHS Scotland expenditure – of which approximately 80% is spent treating potentially avoidable complications[28]. In England, around 11% (about £2.4 billion) of total NHS expenditure on inpatient care is spent on people with diabetes every year, of which an estimated 30% (£686 million) is "excess expenditure", which means expenditure over and above the sum spent on a population of the same age and gender without diabetes.

AN INCREASING POLICY PRIORITY THOUGH IMPROVEMENTS ARE SLOW TO COME

Despite the fact that priorities across the nations often differ due to political differences, diabetes has increasingly been seen as a policy priority across the UK, achieved largely through a wider policy shift towards embracing primary and secondary prevention, integrated health services and digital innovation.

In England, broad strategies like the NHS Five Year Forward View and the New Care Models programme accelerated a radical upgrade in prevention and public health, including new integrated care teams, individual care plans and specialist support for people with diabetes. More recently, the NHS Long Term Plan prioritises diabetes as one of five major health conditions and includes commitments to doubling the funding of the NHS Diabetes Prevention Programme over five years[29]. The government's mandate to NHS England includes reducing the risk of diabetes along with associated illness and hospital admissions[30].

In Scotland, a web-based database of all people with diabetes was rolled out in 2004 (SCI Diabetes). This tool can be used by healthcare professionals of both primary and secondary care and provides accurate real-time information to improve the care of people with diabetes[31]. More recently, the Diabetes Improvement Plan identifies diabetes as a priority for all NHS Boards and sets out priority issues including prevention and early diagnosis, person-centred care and equality of access. Meanwhile the Diabetes Delivery Plan for Wales 2016-2020 introduced national leadership and delivery structures in addition to refocusing health board planning on diabetes[32].

Support for the prioritisation of diabetes services has been reflected in political priorities and system changes. NHS England announced an additional package of measures to curb diabetes including £40 million for Sustainable Transformation Partnerships (STPs) to invest in diabetes treatment and care,[33] alongside a major evaluation of how digital technology could provide better support. At the same time the NHS England Diabetes Prevention Programme is being expanded.[34]

While some progress has been made across the UK, there is still significant variation in diabetes services and people of working age are still less likely to receive good care.[35] In 2018, the National Audit Office concluded that "diabetes healthcare in England does not represent value for money and that poorly performing areas are not being held to account"[36] while the latest National Diabetes Audit of England and Wales acknowledged "all measurements showed marked geographical and inter-service variation."[37]

THE ONGOING SHIFT TOWARDS GREATER INTEGRATION AND PERSON-CENTRED CARE

Over the past few years, health services across the UK have actively promoted integration between primary and secondary care and services designed around patient needs through national strategies, notably in diabetes services. **New programmes have been introduced to redesign whole health and care systems around the patient,** creating new integrated care teams, individual care plans and specialist support for people with diabetes.[38]

In England, Integrated Care Systems (ICSs) were introduced to bring together health and care organisations and local authorities to provide integrated services for a defined population and improve its health and care outcomes.[39] Similarly, the National Institute for Health and Care Excellence (NICE) Connect Initiative introduced a new approach to curating and presenting guidance across all NICE products in a single, pathway format. This also includes a Diabetes Pathway Committee to help define what good diabetes care should look like for healthcare professionals, practitioners, people with diabetes, providers and commissioners. Diabetes guidelines on topics including the prevention of diabetes in people at high-risk and the management of diabetes in adults are updated to set out the ideal patient pathway. The NHS RightCare pathway aspires to drive down variations in care by working with local systems and organisations to identify barriers to improving care.

Much like the rest of the UK, NHS Scotland has increasingly embraced a person-centric approach to diabetes care, focused on providing the right medicine at the right time. NHS Scotland's State of the Nation report in 2015 highlighted variations in essential diabetes care across Scotland and called for the implementation of integrated pathways across all local health systems.[40] The Diabetes Improvement Plan reiterated the importance of integrated care while the House of Care framework was designed to achieve the delivery of coordinated person-centred care. Like NICE, the Scottish Intercollegiate Guidelines Network (SIGN) provides additional support by maintaining guidelines on how to streamline the patient pathway for diabetes and ensure people with diabetes get what they need when they need it.

As nurses are often charged with providing diabetes care and support, and medicines like insulin are often initiated in hospitals, secondary care continues to play a crucial role in diabetes services. This is particularly true in Scotland where a lot of diabetes care is delivered in a secondary rather than primary care setting. However, **the evolving approach to diabetes in the UK is increasingly primary care based.** This is partly a result of the overarching trend across the health system of integrating health services and uniting healthcare providers around individuals' needs. For example, Scotland has introduced Managed Clinical Networks for people with diabetes, where multi-functional teams operate at a health board level to ensure adherence to national standards and guidelines.

This process is not without challenges. In England for example, while the NHS and general practitioners (GPs) recognise the importance of primary care as the first port of call, there has been a tendency amongst GPs to feel as though diabetes should be dealt with through the prism of public health. This is in part a consequence of their limited time to support people with diabetes, in addition to resource constraints, poor training and a low level of awareness.

MEASURING AND IMPROVING OUTCOMES VIA HEALTH DATA AND REGISTRIES

The National Diabetes Audit (NDA) is one of the largest annual clinical audits in the world, integrating data from both primary and secondary care sources. It measures the effectiveness of diabetes healthcare in England and Wales against NICE Clinical Guidelines and NICE Quality Standards, checking whether people with diabetes get the care and treatment recommended, in order to drive changes and improvements in the quality of services and patient outcomes. **The NDA enables commissioners and providers to be held to account and/or supported to improve outcomes through specific initiatives like NHS RightCare.** While all GPs and specialist diabetes services are legally required to supply data and are expected to follow these guidelines, there are no significant consequences for poor performance.

In Scotland, SCI Diabetes provides a national online database of people with diabetes to streamline a patient's journey between primary and secondary care. It is considered one of the most comprehensive databases in the world and since its inception, it has provided 99.5% coverage of the Scottish population with diabetes.[41] Another long-standing programme, My Diabetes, My Way is a website launched by NHS Scotland and the University of Dundee providing information on diabetes, medication and wider effects. It also provides access to medical records to help facilitate more personalised care.

Collecting this data has helped highlight key issues, such as differences in outcomes between different specialty services; younger and older people with diabetes; and people with different types of diabetes. It has also revealed the effectiveness of certain policies, such as the rising number of people being checked for HbA1C, as well as areas in need of improvement, for example less than 10% of people with diabetes attended a structured education course in 2016/17.

However, the ability of the NHS to capitalise on the value of data registries is constrained by a number of long-standing barriers, including: absence of integrated digital systems to offer all providers in a pathway access to a person's data; lack of appropriate data-sharing and governance structures; and poor interoperability of different digital systems.

RECOMMENDATIONS:

Knowledge and awareness of diabetes amongst the public and healthcare professionals should be expanded. Improved diabetes services and outcomes depend in large part on ensuring the public and healthcare professionals have a solid understanding of the causes, characteristics and necessary checks for diabetes. This may require a renewed national awareness campaign.

Better uptake of health checks should be encouraged. Health checks are crucial to prevention, early diagnosis and timely treatment. Better and earlier diagnosis could help identify and support the approximately 1 million people in the UK currently living with undiagnosed diabetes.

Reduce variation in service quality and access to treatments. This should include improving adherence to local guidelines which are updated and reviewed more regularly than national guidelines. This would help ensure people with diabetes are moved onto the most beneficial medication as soon as possible.

Facilitate greater data sharing across the NHS. For example, a programme of data and experience sharing in Ipswich allowed participants to map treatments to the most appropriate professionals and settings, and ultimately improve outcomes.[42]

Providers should act upon health outcomes data to inform health services for diabetes and related long-term conditions. An online national database of patient data like SCI Diabetes can be used to streamline decision making and facilitate collaborative working between primary and secondary care. More specifically, the use of health outcomes data has demonstrated a reduction in diabetes amputation and in retinopathy requiring laser treatment over the period of informatics implementation and data usage.[43]

Stakeholders should make better use of real-world data to demonstrate the long-term benefits of early investment in the best available medicines and technologies. Manufacturers, local clinical champions, Managed Clinical Networks and Clinical Commissioning Groups should collaborate to develop long-term commissioning plans using real-world data on the potential impact of new medicines and technologies on patient outcomes and health budgets.

SUPPORTING SELF-MANAGEMENT FOR PEOPLE WITH DIABETES: THE ROLE OF DIGITALISATION, TECHNOLOGY AND INNOVATIVE THERAPIES

The UK has seen the growing digitalisation of diabetes management and care, also as a consequence of the increasing prioritisation of diabetes within the NHS. Governments have invested billions in the research and development of new technologies including artificial intelligence (AI) and mobile applications, which have filtered into diabetes services. While variation in services persists, people with diabetes are increasingly benefitting from technologies like non-invasive blood-glucose monitoring, wearable technologies, mobile apps and online support.[44]

The NHS Diabetes Programme in England includes a national digital workstream to support improvements in diabetes outcomes by implementing and evaluating the effectiveness of digital behavioural change interventions; improving the provision of information to support self-management and care; and scaling digital flexible learning resources. In addition to NHS Scotland's online information portal for people with diabetes to access records, test results and treatment plans,[45] the Scottish Government has invested heavily in continuous glucose monitoring devices.

In addition to novel technologies, the NHS has attempted to embrace innovative therapies. The UK has been a pioneer in novel therapies for diabetes involving artificial pancreases, gene replacement and immunotherapy.[46]

In Scotland, the government has made significant progress in increasing the uptake in Insulin Pump Therapy from 2.5% to 9.5% of the type 1 diabetes population within a six-year period.[47]

While many people are benefiting from access to diabetes treatments and technologies, a 2017 survey found that 28% of respondents reported problems getting the medication or equipment they need to manage their diabetes.[48] Regional variations and access remain a key challenge. For example, while flash glucose monitoring was made available via the NHS across the UK in November 2017, local decision makers still needed to agree on prescribing policies in their area. It was only in April 2019 that flash glucose monitoring was made available across the UK on prescription for all who meet the criteria.[49]

The adoption and diffusion of novel technologies and innovative therapies is constrained by a number of long-standing barriers: the costs of new technologies compared with the standard equipment; inconsistent digital patient data systems; variation in commissioning and patient access; a lack of understanding and training amongst healthcare professionals.

RECOMMENDATIONS:

Support access to the best treatments and devices via national and local policies and procurement. This includes streamlining the evaluation process and overcoming systemic barriers to ensure people with diabetes can access proven digital innovations and novel therapies as soon as possible.

Shape care pathways to enable early intervention of innovative medicines. This may include revising funding mandates to prioritise access to new technology and therapies, thereby reducing barriers to implementation and improving outcomes. These innovations are vital to overcoming treatment inertia and supporting optimal care for people with diabetes, thereby benefiting health systems and the wider society.

Facilitate empowerment of people with diabetes through education and other means. People with diabetes must be informed about and empowered to choose continuously evolving innovative treatments and technologies for diabetes management.

Train healthcare professionals. Training is crucial given the vital role that NHS staff plays in informing and supporting people with diabetes in the adoption of diabetes technologies. For this, healthcare professionals must allocate the right amount of timing.

INTEGRATED CARE AND EMPOWERMENT OF PRIMARY CARE

As part of the overarching shift towards joining up health services to centre around people with diabetes rather than the needs of the system, there is a growing emphasis on primary care management of diabetes across the UK. Key policy documents like the NHS RightCare Pathway for Diabetes in England and Diabetes Action Plan in Scotland stress the importance of multidisciplinary teams designed around the needs of the people with diabetes, where GPs and diabetes nurses are acknowledged as the key initial contact points. This will be increasingly true as greater focus is put on primary prevention and early diagnosis, for which primary care health professionals are responsible, along with referrals for further assessments and education. For example, the evolution of **Integrated Care Systems in England has included a growing emphasis on easier access to better care,** including local teams focused on providing support closer to the people with diabetes.

While the NHS England RightCare Pathway for Diabetes and the Diabetes Improvement Plan in Scotland fully embrace and encourage integrated care, in practice, the level of integration of diabetes services varies across the UK and while there are case studies of good practice, there remain examples of poor integration and service delivery. Barriers to implementing integrated diabetes care include outdated or incompatible digital systems across NHS Trusts; a lack of staff with diabetes training, especially diabetes nurses; conflicting clinical and financial priorities between clinical specialties; and the poor sharing of best practice between NHS Trusts.

While diabetes has been increasingly prioritised within the health system, the NHS needs to do more to promote and support the primary care management of diabetes. Diabetes is a clinical priority in the Clinical Commissioning Group Improvement Assessment Framework and there are NICE-recommended treatment targets for various factors including cholesterol and blood pressure. In England, many perceive the latest guidelines on managing type 2 diabetes as unambitious and generic, which is in contrast to the more bold and ambitious SIGN guidelines in Scotland.

There are, however, also opportunities to improve primary care management of diabetes: the NHS's overarching commitment to integration, embodied in a series of policy documents including the Five-Year Forward View and the NHS Long Term Plan; new technologies and commitment to digitalisation; creating a standardised approach to coding and data-collection; sharing care plans; access to specialist advice for healthcare professionals working in primary care; ensuring all members of the practice team have a stake in diabetes care, including by standardising training.

RECOMMENDATIONS:

Integrate and personalise diabetes care and services in local communities. Commissioners and providers should engage with their whole community to increase awareness and understanding of diabetes and encourage uptake of health checks

Primary care professionals should be equipped with the training and capacity to provide diabetes care. This means encouraging workforce development, embracing professional education, to enable appropriate awareness and understanding of diabetes care across a wider range of health professionals, including pharmacists. It also includes training to support the adoption of diabetes technologies.

Ensure healthcare professionals has the necessary time and resources. High-quality diabetes care depends on specialist nurses and other healthcare professionals having the necessary time and support to consult with people with diabetes and provide the necessary advice.

Implement compatible digital systems across the NHS. For example, the implementation of a whole information system in Wolverhampton meant GPs and specialists could see the same patient records and ultimately identify and target people at risk of developing diabetes.[50]

Embrace collaborative care planning. Care programmes are more effective when healthcare professionals and people with diabetes collaborate to agree goals, identify support needs and develop and implement action plans[51].

Health system organisations should adopt a more long-term view. Rather than an overwhelming and short-sighted focus on cutting costs, organisations like Health Boards should be encouraged to embrace a new long-term mindset of "invest now to save later".

GERMANY: NATIONAL CONTEXT SETTING AND RECOMMENDATIONS

THE SCALE OF THE DIABETES CHALLENGE IN GERMANY

An estimated 9% of the German population (7.6 million people) suffers from diabetes. Every day about 1,000 new cases are diagnosed. Additionally, diabetes experts suspect a high number of unreported cases. Around 11% of the overall public health expenditure is on type 2 diabetes, which means that associated healthcare costs are on average twice as high as those for people without diabetes.[52]

A significant part of the cost is related to the treatment of diabetes-related complications, including macro- and microvascular diseases. Higher investments in prevention, disease management and treatment could not only significantly improve the quality of life of people with diabetes, but also drastically reduce indirect healthcare costs in Germany.

A NEED TO CAPITALISE ON POLITICAL MOMENTUM

Political attention on the issue of chronic diseases has increased following the recent federal elections. While progress has stalled due to political differences on the coalition agreement signed between the Christian and Social Democrats (CDU/CSU and SPD) in 2018, which announced a national plan to combat diabetes, new political momentum means a diabetes strategy could soon be adopted. It could address the following five fields of action: primary prevention; early detection; research funding; a diabetes registry as a basis for healthcare research; and patient information and training.[53]

This political attention is welcomed, as unfortunately, previous efforts to address diabetes have only achieved minimal success. For example, since 2016 the German Federal Centre for Health Education (BZgA) has had sufficient funds available for a broad awareness campaign on diabetes prevention, but implementation is still pending.

Sources: Diabetologen Hessen eG: Behandlungsleitfaden Diabetes Mellitus (2018)
Deutsches Zentrum für Diabetesforschung Regionale Unterschiede bei der Behandlung von Typ-1-Diabetes und Zusammenhang mit Deprivation (2018), accessible online at https://www.dzd-ev.de/aktuelles/news/news/article/regionale-unterschiede-bei-der-behandlung-vontyp-1-diabetes-und-zusammenhang-mit-deprivation/index.html

AN EFFECTIVE CARE SYSTEM COULD BE STRENGTHENED BY BETTER DATA ON OUTCOMES AND INNOVATIVE THERAPIES

The German healthcare system is characterised by high quality in the diagnosis and treatment of type 2 diabetes thanks in part to strong professional expertise.[54] However, inequalities in access to diabetes care and treatments still persist. Access to insulin pumps and some innovative treatments such as long-acting insulin analogues are limited in some more socially deprived regions. As a result, people living in these regions develop higher blood sugar levels and have a higher risk of obesity and its associated complications.[55]

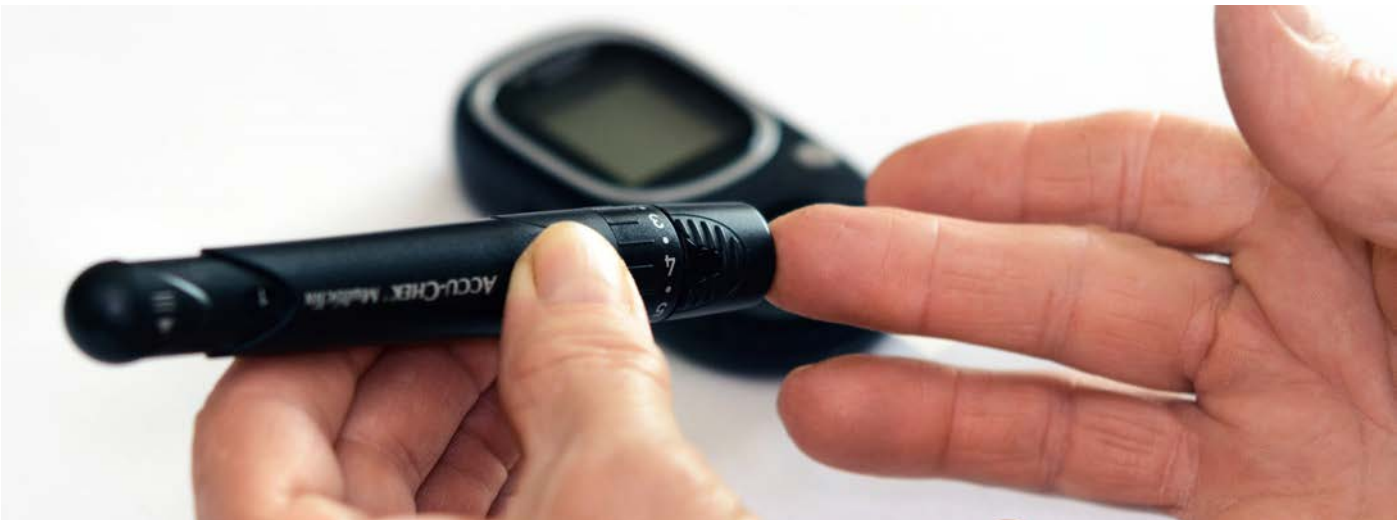
Evidence-based guidelines are constantly reviewed and revised[56] to provide orientation for healthcare professionals regarding the treatment of different forms of diabetes and different people's statuses, for example pregnancy or adolescence.[57] **In addition, several position papers provide advice to healthcare professionals working in hospitals,[58] and seek to ensure that health outcomes are constantly tracked and recorded to support better treatment.**

Coordination between primary and secondary care is ensured by Disease Management Programmes (DMPs), which were adopted by the Federal Joint Committee and introduced by health insurance funds. These offer people with diabetes tailored treatments and close monitoring by specialists.[59] DMPs aim to actively involve people with diabetes in their treatment in order to support them in better managing their own condition.[60] **A large majority of people with diabetes participate in DMPs, and attending healthcare professionals assess the quality of the programmes and their output positively.[61]** This is supported by the decreasing number of hospital stays due to diabetes complications. However, more concrete impacts on health outcomes of people with diabetes are impaired due to a lack of data.

The weaknesses of the German healthcare system lie in the coordination of efficient prevention measures and the collection of care data. Further problems arise from large regional differences in treating type 1 and type 2 diabetes, due in part to regional drug control, difficulties in reimbursement and different levels of expertise amongst treating healthcare professionals. Restrictive ruling on data protection, as well as strong regulation on market access for innovative therapies, are also a cause for concern in addressing the diabetes challenge.

Germany is lacking a national diabetes registry as there is no legal requirement to record and evaluate disease progression and treatment. However, the establishment of a "diabetes surveillance" at the Robert Koch Institute is an important positive development. **The objective of the surveillance system is to collate all available data sources at the federal, state and self-governing levels in order to create a reliable database** to inform evidence-based health policies.

People with diabetes in Germany are advocating for more information concerning their health outcomes, and the use of tools that enable the tracking of their health in order to maximise the efficiency of their treatment[62]. People with diabetes have highlighted the usefulness of digital solutions to improve their ability to self-manage their condition.[63]



MEASURING AND IMPROVING OUTCOMES VIA HEALTH DATA AND REGISTRIES

Type 2 diabetes is becoming an increasing burden on the healthcare system, and registries are a reliable instrument for monitoring and evaluating treatment and management. Previous regional diabetes registries in Germany have concentrated primarily on clinical parameters and often neglected both the quality of life and well-being of people with diabetes.

Organisations representing people with diabetes and professional associations have been calling for the establishment of a central diabetes registry for many years.

Only comprehensive recording of health outcomes can reveal possible regional differences in diabetes care. In addition, a broader database will create the basis for validated and detailed findings on the long-term outcomes of diabetes therapies. Additionally, the effect of non-medicine interventions such as education, self-monitoring and lifestyle changes could be captured. Hence, a national diabetes registry, which should include data from all people with diabetes in Germany, urgently needs to record patient reported outcomes as well.

There are currently two diabetes registries in Germany: the Diabetes Patient Progression Documentation (DPV) and the Diabetes Care Evaluation (DVE). Together, these registries contain data from more than 500,000 patients. However, since more than 7.6 million people in Germany have diabetes, there is clearly a need to increase the number of people monitored via registries. In order to improve the quality of health reporting in the medium term, further regional registries must be brought together and evaluated.[64]

RECOMMENDATIONS:

Introduce central and interoperable electronic patient files. The electronic patient file is a key element of integrated healthcare and the basis for digital management of people with diabetes. For this reason, it is of crucial importance to introduce these electronic patient files as soon as possible in Germany. Instead of conducting pilot projects based on different standards, an interoperable digital patient file must be introduced nationwide.

Create the conditions for the establishment of a national diabetes registry as part of a national diabetes plan in Germany. Healthcare professionals treating people with diabetes should be required to collect data. The responsibility for the use of data could then - analogously to the existing Centre for Cancer Registry Data - be borne by a new Centre for Diabetes Registry Data (to be established). This should be included within a national diabetes plan for Germany. In this context, it will be important to incentivise healthcare professionals to use this system to ensure that data is collected nationwide. The data should also be made available to stakeholders involved in health systems evaluation, research and development, including the medical devices and pharmaceutical sectors.

Foster discussions between people with diabetes and healthcare professionals to ensure the mapping of all health outcomes. Diabetes-related professional societies and organisations representing people with diabetes should discuss and define which data should be recorded to ensure that both clinical parameters and patient-reported outcomes are mapped. Only in this way can a comprehensive picture of the efficacy and effectiveness of diabetes care be drawn. Regional differences in data collection must be avoided.

A framework for the use of health data for research purposes should be clearly defined. While the protection of patient data must always remain the priority, making data available for research purposes can add value and support the development of innovations that can lead to better outcomes for people with diabetes.

SUPPORTING SELF-MANAGEMENT FOR PEOPLE WITH DIABETES: THE ROLE OF DIGITALISATION, TECHNOLOGY AND INNOVATIVE THERAPIES

The pharmaceutical market in Germany is strongly regulated. Consequently, access to innovative medication is restricted and only 14% of therapies pass the early benefit assessment in the Joint Federal Committee.[65] The same applies to the promotion of digital solutions to treat diabetes.

The Federal Joint Committee recognises that Real-Time Continuous Glucose Monitoring (rtCGM) can be an important tool to support self-monitoring of blood sugar[66] and has in principle included rtCGM amongst the standard care offering.[67] However, this has not yet been integrated in the standard care system on a nationwide basis. Although some health insurance funds cover the costs of real-time measuring devices on the basis of selective contracts, access to such devices is still not regulated in a uniform manner. The current status quo is neither satisfying for people with diabetes, nor for healthcare professionals and researchers. Digital tools could make significant real-world evidence available and, thus, contribute to both a quantum leap in the development of modern diabetes therapies and a more accurate benefit assessment of digital tools.

There is already proof of the positive impact on well-being of digital devices for diabetes self-management: the mortality rate is lower for people with diabetes who have a high index of self-management, who are supported by digital devices, and who constantly measure their health outcomes.[68] Pharmaceutical and medical technology companies have developed digital devices that empower people with diabetes to measure, track, and control their health outcomes for several years.[69] However, policymakers and health insurers are reluctant to promote digital solutions and technologies that gather information and help people with diabetes to manage their condition on a daily basis. Their main concern relates to data protection and proven efficacy of the tools.

The promotion of innovative technologies to treat diabetes is not only necessary to support a person's self-management. Digital innovations can also assist healthcare professionals' work, by reducing the need for consultations while improving a person's quality of life.[70] Digital innovations help to make healthcare more integrated. They enable a personalised approach to care so that they can directly receive the appropriate treatment and do not have to schedule various and sometimes unnecessary appointments with healthcare professionals.

RECOMMENDATIONS:

Promote digital solutions for measuring health outcomes and data protection guidelines review. A first step would be to set up promoting programmes in the digital treatment of diabetes and to ease the conditions for data collection for research

The added value of digitalisation for integrated care must be highlighted. As digital innovations and innovative therapies have the capacity to make treatment more effective and efficient, digital devices and technology should be introduced into standardised treatment pathways. A first step could be to initiate pilot projects that promote the application of digital innovations in the treatment of people with diabetes across Germany.

Revise the medical technology system. In order to make innovations available for people with diabetes during the process of assessment in the Federal Joint Committee, an interim remuneration system could be introduced. New technologies could then be tested by people with diabetes during the assessment process, which will be simultaneously fed by the data of these people.

A new multi-stakeholder platform should be established. Industry, relevant German expert associations and organisations representing people with diabetes should develop a common call for more political and financial support for digital diabetes care.

INTEGRATED CARE AND EMPOWERMENT OF PRIMARY CARE

Integrated care seeks to improve outcomes by overcoming fragmentation. Through linkage or coordination of services and providers along the continuum of care it has the potential to improve continuity, drive empowerment of people with diabetes and foster health system sustainability.[71] This approach can close the gaps between primary care and hospital services, between health and social services, and between e-health infrastructures including registries and electronic patient files.

Integrated care has been established in Germany via the DMPs for type 1 and 2 diabetes. People with diabetes have been able to access special treatment beyond standard care since the early 2000s. **DMPs make sure that people with diabetes are treated in an organised and structured way.** The programmes aim at improving diabetes care according to national medical guidelines. Patients receive personalised treatment, their health outcomes are closely monitored, and they get involved in their medical treatment.[72]

DMPs for people with type 1 and type 2 diabetes are welcomed by medical experts, but additional data are needed to evaluate their results and, if necessary, to adapt over time, experience, and changing framework conditions. Using digital devices and technologies in integrated care could thus foster the efficiency of the DMPs.

Digital applications can be the constant link between healthcare professionals and people with diabetes; they could avoid time-consuming appointments with healthcare professionals and make the evaluation of a person's data even more traceable.

RECOMMENDATIONS:

Regularly review and adjust DMPs implementation and contents. Data collection on treatment, management and outcomes should be captured in a central registry. Such a registry is necessary to gather evidence about the effectiveness of structured diabetes care. Additionally, improvements in integrated care for diabetes can only be ensured by constant evaluation of the existing programmes and systems. Registries with health outcomes data should be regularly evaluated in order to support the development of innovative models of integrated diabetes care.

Establish digital devices in DMPs. Digital devices have the potential to strengthen the link between healthcare professionals and people with diabetes and can reduce unnecessary appointments with healthcare professionals. Moreover, they can increase the feeling of safety by providing personal control over data.

FRANCE: NATIONAL CONTEXT SETTING AND RECOMMENDATIONS

THE SCALE OF THE DIABETES CHALLENGE IN FRANCE

An estimated 5.4% of the French population (3.7 million people[73]) live with diabetes and the prevalence is increasing. Diabetes costs €6.8 billion, which amounts to 5% of the total expenditure reimbursed by the French National Health Insurance system[74] – around €8.12 billion, when all public and other insurance schemes are included. This translates into an average expenditure of €2,177[75] per person with diabetes each year. France has introduced several programmes to support people with diabetes in the management of their condition. Improved data collection offers more accurate insights into a person's behaviour, while providing people with diabetes with access to innovative therapies improves outcomes.

IMPROVED POLITICAL AWARENESS HAS LED TO INVESTMENT IN PREVENTION, BUT HURDLES REMAIN

France has launched a range of initiatives designed to address the risks associated with diabetes. Some have focused on diabetes and chronic disease management while others target primary prevention.[76] These initiatives share the following objectives:

- **Integrating and developing a person with diabetes' therapeutic education within the healthcare system;**
- **Adapting the healthcare system to chronic diseases by improving coordination between healthcare professionals working in primary and secondary care;**
- **Developing an incentive financing model based on fixed price and performance price;**
- **Enhancing data collection and data generation to better evaluate and adapt health policies;**
- **Improving outreach to high-risk populations.[77]**

While there is consensus on these objectives among stakeholders (such as policymakers, healthcare professionals and organisations representing people with diabetes), the various initiatives have only partially achieved them. This can be explained both by the choice of financing tools and by the difficulty of transforming the care system from one dedicated to the treatment of acute pathologies to a system for the treatment of chronic conditions.

Primary care, and in particular GPs, form the basis of the management of people with diabetes in France. A number of challenges exist with the management of diabetes in the French primary care system: the healthcare system is not adapted to the management of chronic diseases; the financing of preventative action is not efficient; and there is a lack of coordination between GPs and other healthcare professionals and social support structures.

There is also low compliance with recommendations on monitoring and treatment by healthcare professionals, alongside passive management of people with diabetes and low support for self-management. According to a study[78] conducted in the Paris region, more than 40% of people with diabetes do not follow their treatment because of the side effects associated with type 2 diabetes therapies. Poor adherence to therapy can lead to serious complications, such as the development of cardiovascular disease, kidney failure, lower limb amputation and blindness. The burden of cardiovascular and kidney complications is massive, costly and expanding.[79] This is one of the priorities which emerged at the 2018 Etats Généraux of the French diabetes patient group (FFD), and in its subsequent 2019 awareness campaign.

It is essential to set clear objectives and indicators to monitor and reduce the complications of diabetes. To increase adherence to diabetes treatment, it is recommended that GPs are better informed of the risks of non-compliance, that pharmacists are more responsive and supportive to people with diabetes, and that they are integrated into therapeutic education programmes.

French authorities tried to tackle demands from people with diabetes for a more personalised approach with the SOPHIA project launched in 2012. The initiative is managed by the Caisse Nationale d'Assurance Maladie (CNAMTS) and features information brochures and tailored telephone support from nurses. It aims to take account of the personal situation of each person with diabetes to support behavioural change, better comply with health professional prescriptions and quality of life improvements that respect a person's choice. The programme is well perceived by both people with diabetes and health professionals, and significantly helps participants to understand diabetes and its implications. From an outcome perspective, the programme has had a positive impact on the performance of ophthalmology consultations and renal and lipid check-ups. It also appears to have positively impacted the death rate and the rate of use of emergency services.

Sources: Assurance Maladie, Améliorer la qualité du système de santé et maîtriser les dépenses Propositions de l'Assurance Maladie pour 2018, p. 24 figure 20 : 3.7 Million people are taking an antidiabetic treatment : Assurance Maladie, Améliorer la qualité du système de santé et maîtriserles dépenses Propositions de l'Assurance Maladie pour 2018, p. 34 figure 12.

MEASURING AND IMPROVING OUTCOMES VIA HEALTH DATA AND REGISTRIES

France has approximately 260 public health databases.[80] The most extensive one, **the French administrative healthcare database, covers around 99% of the population** but its main limitation is the absence of clinical information.

In recent years, France has undertaken structural reforms to adapt its health system to future digital applications, such as the creation of a shared medical record for each patient (Dossier Medical Partagé, DMP) and of the Health Data Hub,[81] the objective of which is to aggregate various data sources on a national scale to optimise the use of French medical data.

With its centralised system, the French healthcare system has a large amount of data on diabetes, providing an accurate picture of the disease epidemiology. This data is currently used mainly to target the at-risk population with prevention and education campaigns on diabetes. Nonetheless, with this kind of data, the French healthcare system could go further and propose personalised health assistance.

The French healthcare system can capitalise on its experience and large health dataset to better evaluate patient care strategies, integrate digital technology into healthcare practices and thus improve the organisation of care pathways. The M4P Consortium,[82] supported by the Ministry of Economy and Finance, has launched a clinical database on diabetes called Diatabase, which should improve care, knowledge about the disease, information sharing and research on diabetes. The database will be populated by information from several sources including hospitals, community medicine and research centres, and cross-referenced with the data from the National Health Data System and economic databases. The success of the initiative depends on the ability to make the data collected interoperable.

The availability of real-world evidence could significantly improve the measure of quality, pertinence and efficiency, as well as better assess the impact of medicines in real world conditions. The paradox is that while supporting data generation to measure efficiency, health authorities do not recognise the value of real-world evidence in product assessment, even when the methodology used has been acknowledged by international standards and authorities.

RECOMMENDATIONS:

Facilitate the structuring and industrialisation of health data by third parties. The Health Data Hub should be developed into a technological platform for making health data available. Technical support should be organised for producers to collect and improve data quality. Clear procedures to give access to health data should be defined. Political will is needed to expand the collection of data, develop a clear policy for registries and involve more stakeholders – including industry and patient groups – in establishing the Health Data Hub and health data policies.

The deployment of the shared medical record (Dossier Médical Partagé) should be accelerated. General practitioners should be encouraged to assist people with diabetes in creating their own record in order to reach the objective of 40 million people with a DMP by 2023.[83] The possibility for people with diabetes to store data from connected devices on their DMP should be also facilitated.

Support the definition and implementation of common terminology, formats and standards. Stakeholders should be mobilised to participate in discussions on norms and standards, preferably international, in collaboration with national agencies and actors such as trade unions. Promising initiatives should be identified, shared and scaled up. New assessment standards and methodology frames of reference are needed to fully integrate and recognise the value of real-world evidence in the evaluation of medicines.

SUPPORTING SELF-MANAGEMENT FOR PEOPLE WITH DIABETES: THE ROLE OF DIGITALISATION, TECHNOLOGY AND INNOVATIVE THERAPIES

There are benefits associated with the use of connected tools or mobile applications in the prevention and day-to-day management of diabetes. These tools can, for example, promote the adoption of healthy behaviours to prevent disease onset or ensure accurate, daily monitoring.

Telemedicine can be a valuable tool for the health system and improving the quality of life of people with diabetes. Thanks to digital tools, health professionals will be able to provide more targeted follow-up while being less of a burden on people with diabetes. For example, the ETAPES initiative aims at improving pathways for people with diabetes and encourages (and supports financially) the deployment of telemonitoring projects throughout France. Launched in 2018, this four-year programme addressing diabetes as well as heart failure and renal failure embraces the potential of remote monitoring technologies to detect critical changes in the health status of people with diabetes and issue an alert that triggers medical intervention. **The overall objective is to use remote surveillance to avoid recurrent hospitalisation, increase the quality and efficiency of care, and improve people's quality of life.**

While France is experimenting with several digital solutions for people with diabetes, it should also ensure that they have access to treatments that achieve improved long-term clinical outcomes leading to equity of access across Europe.

RECOMMENDATIONS:

Support the self-management of people with diabetes by promoting remote consultations and monitoring. The deployment of tele-consultation and tele-surveillance should be accelerated to offer real-time, personalised monitoring and improve compliance with treatment.

Strengthen the capacity of people with diabetes to take ownership of their health data. People with diabetes should be empowered with the knowledge and skills necessary to access, understand, evaluate and use information by making them actors in the management of their condition.

Develop support communities for people with diabetes. Social networks should be improved to develop peer support and improve emotional experiences, attitudes towards diabetes and engagement in diabetes management.

The adoption of innovative therapies should be accelerated. The overall benefit for people with diabetes and society should be integrated in medication evaluation by taking into account not only immediate costs but also long-term improvements in health outcomes.

INTEGRATED CARE AND EMPOWERMENT OF PRIMARY CARE

In France, healthcare professionals working in primary care are not sufficiently involved in primary prevention because the healthcare system is not adapted to the management of chronic diseases; **the financing of preventative interventions is not efficient; and there is a lack of coordination between primary care and other healthcare professionals and social support structures, as well as uneven or defective compliance with recommendations on monitoring and treatment.** The Haute Autorité de Santé (HAS) updated its strategy regarding the secondary prevention of diabetes in 2014 which has a stronger focus on targeting high-risk populations.

Some diabetes screening is carried out not only by GPs, but also in health examination centres, municipal health centres and sometimes by pharmacists as part of local campaigns. Actions can be carried out outside these areas, as close as possible to the most affected populations. This local multiplication of screening has the merit of showing a real interest in this condition and these actions make it possible to raise public awareness of diabetes.

However, these initiatives are carried out without a real coherence of approach framed by a national and regional public health strategy and without a public health or health economic evaluation. Undertaken outside the attending healthcare professional's office, the actions raise the question of follow-up and treatment, by the attending healthcare professional or hospital.

The 2022 governmental health plan and the "Say no to diabetes" programme aim at responding to these issues by putting in place fixed-price financing of healthcare for chronic diseases; mobilising and coordinating the various social and healthcare professionals; and better targeting high-risk populations.

Considering the current programmes on diabetes prevention and other governmental initiatives, such as the Health Data Hub or the Diatabase, it is clear that data management paves the way for better care and improved outcomes. In addition, the time window seems particularly favourable as there is a consensus among the different stakeholders regarding the margins for progress in the French health system: coordination of the healthcare and social professionals; fixed price financing to better accompany people with diabetes and avoid complications and hospitalisation costs; and better targeted prevention actions to vulnerable populations.

If the fight against diabetes and chronic diseases benefits from strong political support in France with clear and consistent objectives, the main barriers will be the effective implementation of the action plans and policies.

RECOMMENDATIONS:

Promote a quality approach based on medical outcome. Appropriate health technologies that improve the quality of life of people with diabetes should be provided, as well as access to a transparent, high-quality care offer. Outcomes should be improved through integrated care pathways as timely intervention is a key component of providing safe and high-quality healthcare.

Communities of healthcare professionals and social workers should be created to serve the needs of people with diabetes. Structures where healthcare and social professionals can work together to address all aspects of diabetes should be created. Care adapted to the needs of people with diabetes, involving the coordination of the professionals involved, should be offered.

The financing of prevention and primary care should be restructured. Fixed-price financing of healthcare for chronic diseases should be developed to improve the care of people with diabetes, for instance through a flat-rate financing method. Healthcare institutions should be encouraged to do more prevention and coordination with solo practitioners.

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We need to re-imagine how diabetes care is delivered and work together to make its diagnosis, treatment and management better.

#WeWontRest
until diabetes is defeated.

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