Delivering Value through Innovation in Diabetes Care Delivery

International Diabetes Federation Europe

Contents

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Foreword

We live in extraordinary medical and scientific times. One hundred years after the discovery of insulin – probably one of the most important medical breakthroughs of the 20th century – a fully functioning artificial pancreas is now within our grasp, an absolute game changer for people living with diabetes. New medicines, therapies and technologies, coupled with novel digital tools and solutions and cutting-edge developments in healthcare delivery, have also truly revolutionised diabetes management and care, allowing many people to live their lives to the full, like never before.

Ushered partly by the COVID-19 pandemic, we are now on the cusp of a new revolution – a fifth industrial revolution led this time not just by scientists, academics, researchers and industry, but also by people living with diabetes themselves. Their quest goes beyond technological prowess. They search for technological advancement to be placed at the service of humanity's needs and preferences.

The past decade has seen a huge and growing engagement on the part of the diabetes community, led by many youths engaging with the diabetes agenda and demanding novel approaches. Advances such as the artificial pancreas would not be where they are today without the push of the OpenAPS and #WeAreNotWaiting movement.

This revolution has only just started though. For its full benefits to be reaped, collaboration between all stakeholders needs to be its linchpin, and equitable access its inalienable philosophy. Indeed, all these advances are for nothing, if they are only accessible to the few, while the many continue to suffer sub-optimal health outcomes and quality of life, as is unfortunately still the case for many people in Europe – dependent on where they live, who they are, where they come from, what they do and who they love!

We hope this publication will contribute to guide and foster the adoption of new, innovative approaches for the benefits of people living with diabetes and the diabetes eco-system at large.

Dr Niti Pall, Chair, IDF Europe

Executive Summary

Diabetes takes a heavy toll on individuals and societies, which can be mitigated through the at-scale adoption of innovation.

Diabetes imposes a heavy health and economic burden on people living with diabetes (PwD), their families, health systems and national economies, and one which continues to rise. One in 11 European adults live with diabetes (61 million), a figure projected to rise to 67 million by 2030. More than one third of them are undiagnosed and, of those that are diagnosed, up to half do not achieve adequate blood glucose management. In 2021, the total cost of diabetes across the Europe region was estimated at €167.5bn, of which 75% resulted from often-preventable complications.

Many recent innovations, defined for the purpose of this report as "novel behaviours, protocols, technologies and ways of funding and organising care delivery that are not yet delivered at European-wide scale", **have demonstrated their potential to improve the delivery of high-quality care and health outcomes for PwD**. In particular, these innovations help tackle some of the main barriers to high-quality diabetes care including low PwD empowerment, shortages of healthcare professionals, siloed and single-disease treatment approaches and lack of digitalisation, interoperability and IT integration.

Supported by the digitalisation of care, one of the two most impactful areas of innovation in recent years has been patient empowerment, which, as well as improving health outcomes, has also resulted in an enhancement of the relationship between healthcare professionals (HCPs) and PwD.

Patient empowerment has long been recognised as critical to improving engagement and self-management, promoting adherence to treatment, helping people cope with their condition, and **ultimately improving clinical outcomes**.

New approaches in this field concentrate mainly on three aspects: improving engagement and motivation through increasing support and access to knowledge and information (this includes shared decision-making); supporting self-management through digital tools and apps; and supporting self-management and providing psychological support through peer-to-peer interactions.

The digitalisation of care, including broader use of data, technologies, data analytics and artificial intelligence, has also been a game changer in other aspects of diabetes care delivery. Digitalisation supports improved diabetes prevention and management of diabetes-related complications, more personalised healthcare interventions and remote monitoring; it helps better evaluate healthcare interventions and plan resources; and it improves research and innovation. The broader use of data sets combined with big data analytics and artificial intelligence has also really started making an impact in primary diabetes prevention.

Beyond education and access to care, optimal diabetes management also requires sustained support for PwD, which is often not easily available through healthcare professionals (HCPs). In this context, peer support, both in person and digitally, has also emerged as an effective and efficient support mechanism, which ideally would be integrated by all health systems as part of the standard diabetes care.

Supporting these new approaches are a number of tools and technologies such as web portals, telemedicine, digital education services and digital therapeutics as well as

full diabetes management platforms. While increasing in prevalence, access to such tools remains very disparate though.

The most significant second area of innovation has been centred on the organisation of care itself, with a shift (still somewhat in its infancy) in understanding of what constitutes value, a move towards placing the person at its centre, and increasing use of newer, often virtual, care models.

In recent years, the re-design of healthcare delivery models has focused on innovations that are patient-centred, integrated and outcomes-focused, all absolutely key for people living with diabetes who often live with more than one condition and therefore require a more holistic approach to care to lower the disease burden. In such models, care moves from being disease-focused to person-focused. The main objective is to improve the person's experience, quality of care and cost-effectiveness of healthcare systems.

As with patient empowerment, technology and digitalisation are a key enabler of integrated care systems as are collaboration between stakeholders and aligned financial incentives.

Other major trends in new care delivery models includes the evolving role and models of primary care including broader use of digital platforms, risk stratification models, **more multi-disciplinary work as well as the increasing role of community** in prevention, diagnosis and care, **and the move towards virtual care models**.

The latter are now also evolving from the simple use of remote consultation to full-scale advanced care platforms collating a wide range of data and information, shared between PwD and their HCPs, and providing additional education and information.

Implementing innovation within national health systems requires addressing the two main constraints which have slowed down or prevented the adoption and scaling up of innovative approaches in diabetes care – the setup of foundational IT and data layers and the development of frameworks incentivising them and supporting their reimbursement.

Prerequisites to the implementation of these care models include having access to a broad range of (comparable) data, at a minimum through patient and diabetes registries as well as patient-reported outcome and experience measures to identify required actions and assess the effectiveness of interventions.

Another constraint has been the lack of integration of digital tools and platforms into public health systems and reimbursement structures, although some national health systems have started to adopt promising frameworks.

While funding is also often cited as a barrier to the adoption of innovation, it is in fact possible to make existing funding work harder, and/or catalyse funding from non-traditional sources.

Fee-for-service payment models have often shown themselves to be inefficient, incentivising the wrong activities and not achieving the best outcomes. **One novel financing approach is value-based healthcare**, which helps identify and recognise benefits or cost-savings which can be realised in a different part of the healthcare system from which it was implemented.

This is key for chronic diseases such as diabetes, where innovations which may lower the risk of diabetes and/or diabetes-related complications may, for example, focus on early prevention efforts.

A host of new financing frameworks have also emerged in recent years **to support an improvement in the quality of care**, of which the most popular have been bundled payments and managed entry agreements.

Mobilising private sector capital and other investors in the form, for example, of social impact bonds (SIBs) **also holds much promise for the financing of care delivery innovation**. Venture capital for digital health has grown by close to half between 2019 and 2020, and key to further investments lies in the ability of healthcare funders to demonstrate their willingness to invest in innovation. SIBs have also shown to be flexible and can broaden market access to Small and Medium Enterprises but require acceptance of the use of private funds into healthcare.

In order for healthcare systems to be able to implement and benefit from these innovative approaches, tools and solutions they need a frame by which to prioritise their adoption. One approach to prioritising innovation is to consider the actual health outcomes of PwD and some universal enablers.

Actual health outcomes can be combined with an assessment of the minimum components that need to be in place across three universal key enablers – people, processes and technology – to define priorities, dependent upon where a health system is currently positioned.

A system with below average outcomes for PwD would, for example, focus on establishing foundational technology layers, such as diabetes registries and electronic medical records, while a system with average outcomes would consider advanced layers of IT and data in the form of risk stratification for example. A high-performing system would look at the introduction of artificial intelligence, use of biotech, curative and novel therapies.

One hundred years after the discovery of insulin, huge progress has been made, not least driven by people living with diabetes themselves, but much remains to be done.

The diabetes community now calls on all national health systems and decision makers to invest in innovation to ensure people living with diabetes have the best possible life.

Introduction

1.1 The impact of diabetes

The global impact of diabetes has increased significantly in recent decades and is forecast to continue to rise. One in 11 European adults lives with diabetes and the prevalence is rising fast. By 2030, it is forecast that 67 million people in Europe will be living with the condition[1]. More than one third of all cases of diabetes in Europe are undiagnosed. Among those that are diagnosed, studies suggest that up to half do not achieve adequate glucose management.

This imposes a heavy health and economic burden on people living with diabetes, their families, health systems and national economies. In 2021, the total cost of diabetes care in Europe was estimated at Eur167.5bn[2], of which 75% is related to often-preventable complications. With this breadth of impact on populations and economies, it is clear that there is a large need for innovation in diabetes care delivery.

1.2 The barriers to better value, high-quality diabetes care

The fast development of ever more effective technology-led innovation as well as novel approaches in healthcare design, delivery and financing have the potential to address the key barriers to the delivery of high-quality diabetes care and improved health outcomes across Europe.

These key barriers are longstanding, complex and often a function of the wide variety of healthcare systems, economies and cultures found across Europe, but broadly speaking fall into four main categories:

Low PwD empowerment: PwD have typically not been empowered to be active actors in their care. General healthcare and self-management education is often lacking, or non-existent, as is shared decision-making. This can lead to poorer health outcomes, low satisfaction with the healthcare systems and low quality of life.

Focus on treating single diseases: healthcare has traditionally been organised around the treatment of individual diseases, rather than being prevention- and patient-centred. Disease-centred care models are appropriate for treating acute or single predominant disease. However, PwD often live with many complications or comorbidities and therefore require a more holistic approach to care. This fragmentation of care is often wasteful, does not allow for adequate prevention of complications, and adequate disease management, and places an enormous burden on PwD trying to navigate the healthcare system.

Additionally, it does not allow for optimum health outcomes, and in the case of diabetes, many people living with it still do not achieve desired health targets and outcomes.

Lack of digitalisation, interoperability and IT integration: this prevents, amongst others, aggregated data analysis. Without collecting data across a range of comparable indicators, it is hard to assess the effectiveness of given interventions (prevention programmes, treatments, medicines, etc.) and know what should be implemented. This is an even greater obstacle when it comes to innovative tools, medicines and practices.

Workforce shortage: the number of HCPs is not keeping pace with the increasing prevalence of diabetes nor is their education always keeping up with the pace of innovation. This means fewer or shorter consultations, inadequate treatment initiation or intensification/close follow-up of guidelines, and therefore less adequate support to PwD and a generally inefficient healthcare system.

Some of the main innovations supporting better care delivery explored further in this report include innovative care delivery models, which, when combined with more efficient data analysis and the use of artificial intelligence (AI), can support the deployment of more integrated and personalised care. Data and AI can also support better population health management and diabetes prevention. The use of digital therapeutics combined with blood glucose monitoring devices and remote data monitoring can also improve the quality of the interaction between HCPs and PwD, while freeing up human and financial resources for healthcare systems, thereby addressing workforce shortages.

However, the deployment of innovative tools and approaches and/or their diffusion beyond their original settings is often constrained by many obstacles. For example, innovations in care delivery may raise significant structural, technical or regulatory issues and the need for additional investment. The latter, which is often needed at the early stages of introducing innovation, increases the already high costs of diabetes care, but would most probably reduce the diabetes economic burden in the long term. Overcoming those barriers and making innovations sustainable is not an isolated issue, but represents a challenge to all health systems across Europe.

1.3 What constitutes innovative diabetes care delivery?

In this report, we consider a holistic approach to innovative diabetes care delivery – exploring how innovation helps place PwD at the centre of their care and supports HCPs to provide high-quality care – and examine the key enablers of innovation in this space, such as technology, funding and the re-organisation of the healthcare system.

This report focuses heavily on innovation in care delivery related to the experience of PwD post diagnosis but it is important to recognise that there is also great innovation in the fields of prevention, diagnosis and behaviour change more broadly.

Defining what is innovative is notoriously difficult, so we have used a simple frame that focuses on novel behaviours, protocols, technologies and ways of funding and

organising care delivery that are not yet delivered at European-wide scale. Some may be well known and backed by strong evidence (but not delivered at scale) and others are at earlier stages of R&D. What they all have in common is their potential to improve health outcomes, optimise the use of resources and enhance patient experience and quality of life.

1.4 A new chapter in diabetes care delivery

The story of diabetes is one of innovation and advancement, with innovation in diabetes care stemming from the extent of the day-to-day needs of PwD and their care providers. Managing diabetes is highly complex, requiring the tracking of blood glucose data (currently captured invasively), interpreting this data, making careful nutrition and exercise decisions and, in some cases, self-administering insulin treatment.

The arrival of the COVID-19 pandemic has both highlighted the need for further innovation in care delivery and helped to spur on new advancements. We are hopeful that the current rapid pace of innovation will continue for many years.

As such, the stories and learnings presented in this report should be considered a snapshot of the great innovation happening today and not an exhaustive list.

It is our hope that studying the progress, learnings and gaps in care innovation for diabetes can guide and improve the next waves of innovation, help innovation to be more widely accepted and integrated into healthcare systems and be instructive to innovation in other areas of healthcare.

Empowering & engaging PwD

2.1 Why do we need empowerment?

According to the World Health Organization (WHO) patient empowerment is "a process through which people gain control over decisions and actions affecting health"[3]. Patients are empowered when they have the knowledge, skills, critical thinking, autonomy to make decisions and ability to influence their own treatment goals. **Empowered patients are generally more actively engaged** in their own care, follow and manage their treatment more closely, show increased satisfaction with care and have positive interactions with other patients, helping them to cope with the disease[4].

Engaging patients in their care, and patient empowerment at large, is a critical issue in the treatment and management of diabetes and plays a key role in improving the clinical outcomes of diabetes. Diabetes is a long-term condition with treatment complexity that requires PwD to become experts in their condition in order to make daily self-care decisions regarding food, physical activity, monitoring and medication. It is common for PwD, especially those living with Type 1 Diabetes (T1D) and those on insulin treatment, to have their daily life and work affected by high or low blood glucose levels and to be ever-alert to the possibility of needing emergency support.

Patient empowerment, participation and engagement are starting to be used across healthcare systems from designing new research projects through to assessing the value of new medicines and interventions. And it is beginning to radically change the nature of interactions between PwD and their HCPs.

Many of the recent innovations to support empowering PwD have fallen into three categories

Improving engagement and motivation through increasing support and access to knowledge and information (including shared decision-making)

Supporting self-management through digital tools and apps

Supporting self-management and providing psychological support through peer-to-peer interactions

"While empowerment and engagement of PwD can be uncomfortable for some, as it challenges the traditional roles of HCP and patient, it is not a question of if but when. The nature of diabetes itself as a demanding condition means that we already have a group of individuals who have no choice but to be engaged; PwD are experts on their own condition and should be acknowledged as such. With the way that the diabetes community has developed and strengthened this past decade, meaningful engagement is the only way forward that will be accepted. Outcomes are better in every aspect when PwD are empowered in their care - so what are we waiting for?"

- **Cajsa Lindberg, Living with Diabetes, Sweden**

2.2 Education and engagement

There are many topics that PwD can learn about to make it easier for them to engage in, and influence, their care delivery. But these are not necessarily easy concepts to learn and expert knowledge is not always accessible.

Topics that can help PwD include understanding the condition and its associated complications, the key principles of diabetes management and how the healthcare system works in their country (and how to effectively engage with it). It is this last area that can prove especially tricky.

Education fosters empowerment, the ability and motivation to self-manage and also facilitates shared decision-making between PwD and HCPs about personal health, goals and priorities, and opportunities to personalise their individual care programme[5].

Nevertheless, while this empowerment can be very powerful, it can also, at times, lead to some confusion and become an obstacle to full engagement, especially when differing levels of education, confidence and knowledge exist among distinct healthcare teams and PwD themselves.

New tools to empower and educate PwD, and tackle obstacles, include **web portals, telemedicine, digital education services and digital therapeutics that are grounded in the individual patient experience.** On the more novel side of the spectrum, there are tools that make it easier to learn and gain emotional and social support from peers (other PwD), connect more easily with HCPs and integrate with more advanced care management tools.

‘My Diabetes My Way’ (Scotland) - http://www.mydiabetesmyway.scot.nhs.uk/

Background

My Diabetes My Way (MDMW) (University of Dundee, 2021) is the NHS Scotland interactive website for PwD and carers. It contains validated multimedia resources including traditional information leaflets, interactive educational tools, videos describing diabetes-related complications and testimonials from PwD talking about their experiences with health services. It also includes nine online structured eLearning courses. All these features aim to help people improve diabetes self-management.

Main Objectives/Components

A key feature of MDMW is that it also offers PwD online access to their clinical data, using information captured via Scotland’s national diabetes electronic patient management system and diabetes registry, SCI-Diabetes (NHS Scotland, 2021). The MDMW electronic personal health record (ePHR) offers access to data from primary and secondary care, specialist systems and laboratories, including diagnostic information, demographics, process outcomes, screening results, medication and clinical correspondence. PwD can contribute their own home recorded results (weight, blood pressure, etc), device data (blood glucose, activity) and patient-reported outcomes. These data provide a more complete overview of diabetes than would be available from any single data source.

The system contains several areas of functionality to explain information and to support PwD in their understanding. Descriptive text is available alongside each data item, explaining assessments or results, detailing why data are recorded and what normal range values are. Further educational materials are presented alongside clinical results and are tailored to those using the service. e.g., foot care advice is based on the patient’s recorded foot risk assessment category. History graphs and tables allow individuals to track changes over time for the full duration of their clinical record, from multiple electronic data sources. MDMW aims to provide highly tailored information for users allowing them to make best use of consultation time. e.g., it highlights tests that are overdue or outside normal ranges.

The system supports secure messaging, allowing PwD to ask non-urgent questions for their clinical team to respond to, without relying on traditional methods, such as telephone or face-to-face appointments. This new way of working has cost-saving benefits for PwD and health services while reducing delays in accessing necessary advice. MDMW has traditionally been accessed via the web. In June 2018, a mobile app was launched, allowing online and offline access natively through Apple and Android devices. Anecdotal feedback from PwD has indicated that most will now use this as their main way of accessing and inputting their diabetes data. The features outlined allow people to take control of their diabetes, communicate better with their care providers and become more empowered to enhance their understanding, self-management and ability to live independently.

Impact

PwD report that MDMW improves their knowledge of diabetes (90.3%) and their motivation to manage it better (89.3%). It allows them to make better use of consultation time (89.6%) and means that they do not need to keep paper records (84.4%) or phone their doctor for results (85.2%). Users found graphs helpful to monitor changes (95.9%) and 83.5% said the system helped them meet their diabetes goals[6].

The results of a ten-year analysis indicate that MDMW is both cost-saving to the health service and improves the quality of life of PwD[7]. Wider use could result in significant cost savings through delay or reduction of long-term complications, alongside increased life expectancy. MDMW may be among the most cost-effective interventions currently available to support diabetes, with analysis showing a return on investment of 5:1. In February 2021, MDMW reached the milestone of 30,000 people logging in to access their diabetes data. The service is now being extended and implemented beyond Scotland to around 30% of the diabetes population in NHS England, with further expansion expected over the coming months.

"Access to diabetes records through My Diabetes My Way has meant a step change in the care and understanding of my condition. I am much more in control of my condition but importantly I now understand the goals that I should be achieving and am able to have a constructive discussion with my consultant. I have a note of my "numbers" that are so important to the care of diabetes such as HbA1C, blood pressure, cholesterol, weight and how this affects my Body Mass Index (BMI) and of course the situation with my eyes and feet. Instead of the consultant having this information and not passing it on to me - usual response was "everything is fine" (which meant nothing!) - I am now able to discuss each of my goals and importantly reach an agreement with the consultant as to what actions I need to take to achieve those goals. The different windows I can access to give me more information about different aspects of diabetes is so good it has indeed been a great education tool to help me. This patient access through My Diabetes My Way is an outstanding achievement in the care, education and involvement of people with diabetes."

- Person Living with Diabetes (Scotland)

2.3 Supporting self-management and PwD-HCP interactions: digital therapeutics

While knowledge and information are required for self-management, on their own they are not sufficient for optimal diabetes care.

The next stage is a personalised and digital care wrapper that includes closer analysis and monitoring of blood glucose levels and other health indicators, and/or nutritional and medicinal intake as well as physical activity levels.

9am.health (USA) - https://www.9am.health/

Background

9am.health is a virtual diabetes care clinic that was launched in 2021 in the USA. It combines a personalised treatment plan with regular delivery of medicines and tests and easy access to specialists. The experience is designed to be easy to use with regular opportunities to review and personalise the treatment plan. It was founded by entrepreneurs that live with diabetes and have scaled other diabetes innovations.

Main Objectives/Components

At its heart, the 9am model is about shifting diabetes care from pull to push. Pull models are characterised by requiring PwD to constantly be proactive to get the best from their care providers. This means booking appointments, querying decision making and demanding time when treatment is not working. Push models instead aim to automate care delivery wherever possible. In the 9am context, this means constant virtual access to specialists and automated delivery of medicines and tests to a predetermined schedule.

Impact

As with any new model, time is required fully to measure the impact of such new systems. But as noted earlier, models that seek to empower, educate and support patients are likely to lead to benefits, which could include better outcomes being achieved with less proactive effort, lower mental burden for PwD and a reduction of the time required from HCPs.

A recent advance supporting the empowerment of PwD and making it easier to self-manage their treatment, behaviours and day-to-day decisions is digital therapeutics.

Digital therapeutics are digital products, usually delivered through a smartphone app, that make it easier for PwD to self-manage their condition, interact with HCPs and improve their knowledge. Well-designed digital therapeutics, automated where possible, are personalised to the patient's needs and context, reduce the mental strain of condition management and incentivise PwD to follow treatment plans and recommendations related to nutrition and exercise.

Digital therapeutics is a fast-evolving space and every month new product features are tested and released that have the potential to help PwD manage their conditions better. Early versions of these products focused on education as a key tool to supporting self-management.

Most recent iterations are exploring a variety of more complex techniques.

New iterations allow for comprehensive patient engagement and empowerment

Personalising the information and advice for the user (e.g., algorithms that tailor information based on an individual's lifestyle)

Tracking and analysing personal health data, including different types of activity

Using incentives from the real world to reward behaviour (e.g., movie tickets)

Facilitating peer-to-peer encouragement and support

Integrating into established health-care systems and payment modalities

There are a number of great examples of digital therapeutics for diabetes and other chronic conditions such as Oviva, Changing Health, 9am.health and Second Nature. Alongside the success of these more disease-specific products is the inclusion of similar features in more general primary care services delivered by large health technology companies such as Ada, Babylon and Healthily.

With a smartphone (and internet access), PwD can access a limited set of features for free. But for the full benefits to be realised, health systems need to better accept these services, integrate with them (e.g., referrals, prescriptions) and figure out how to pay for them.

Integrating these services into public health systems and reimbursement structures is only just beginning. Germany is a leader in this space, and now allows some digital therapeutics that are in the directory of digital health applications (DIGA) at the Federal Office for Drugs and Medical Devices (BfArM) to become reimbursable. Approved apps can be prescribed by healthcare professionals and are reimbursed by the health system. As of May 2022, more than 30 digital health services were available in the DIGA database with information about how they can be reimbursed.

> *"I tried 9am because of the price. Affordable and life saving for me. But I stay with 9am because they make me feel like I'm important. Like I matter. Always there when I need them. I like that and it makes you all stand out from the crowd."*
>
> **- Person living with Diabetes (USA)**

Oviva (France. Germany, Switzerland, UK)

Background

Oviva was founded in 2014 by an interdisciplinary team consisting of both medical and technology professionals who recognised the challenges PwD were experiencing accessing tailored and effective treatment as mandated by national guidelines. It is a fully remote, digitally enabled structured education and behaviour change programme for people living with, and those at risk of developing, Type 2 Diabetes (T2D). In September 2021, Oviva closed US$80m of Series C funding from Venture Capital funds in Europe.

Main Objectives/Components

The focus of Oviva is to help users to better manage their nutrition. This is achieved by making it easy for users to track their behaviour (through their app), providing a personalised nutrition plan and easy (and regular) access to a personal coach.

In some countries, the Oviva model is integrated into the health system where it can be prescribed by a General Practitioner (GP), reimbursed by the health system and coaching recommendations coordinated with the user's GP.

Impact

There are over 23 peer-reviewed publications that support the Oviva approach. Its results include 53% of people living with T2D achieving remission through its specialist programme in the UK.

From digital therapeutics to full diabetes management systems

Full digital diabetes management systems are available in some countries that make it easier for people living with T1D and some people with T2D on insulin therapy to better self-manage their condition. These models are a big breakthrough and a window to a world where people living with other long-term conditions are supported in care management 24/7 by advanced tech-enabled care systems.

Features included in these systems include:

- Integration with continuous glucose monitors (and other methods of measuring blood glucose levels)
- Recommendations regarding the correct insulin dosage throughout the day (particularly advanced systems automatically deliver insulin dosages based on the calculations of the algorithm)
- Analysis of time in range
- Alerts to PwD when their blood glucose levels are entering either hypoglycaemia or hyperglycaemia levels (some include the option to alert a close contact too)

These systems are not yet widely used by PwD due to cost, lack of healthcare system integration and lack of funding integration. But their potential to improve the lives of PwD is large. Systems with these advanced features are able to provide 24/7 support that is not possible for clinical professionals in any healthcare system. They can also provide specific additional benefits to certain population groups who may find it difficult to manage their condition well, such as older adults, people with lower educational attainments, etc.

As well as improving self-management, digital therapeutics also act as a complement to physical consulting and enable more productive interactions between the physician and the PwD, around a common analysis and understanding of how best to adapt PwD's diabetes management plan.

HeLP Diabetes (UK)[8]

Background

In January 2019, the English National Health System (NHS England) released 'Healthy Living for People with Type 2 Diabetes' (HeLP Diabetes). This is an online self-management support programme with an accompanying education pathway for adults with T2D.

Major Objectives/Components

HeLP provides personalised information about T2D and its treatment, helps with adopting and maintaining healthy behaviours (e.g., diet, exercise) and offers emotional support, by providing cognitive behavioural therapy and well-being advice.

Users can also record their weight, blood sugar, daily steps and mood changes. The digital portal can be accessed more frequently and easily than face-to-face diabetes information sessions and is designed to keep people motivated between twice-yearly appointments.

Impact

A randomised controlled trial in English primary care practices showed that PwD who had access to HeLP Diabetes programme improved glycaemic control over 12 months and saw a reduction in their diabetes-related distress. There were also cost savings of £111 per person (about €130) for reduced healthcare use compared to regular care (includes primary care, outpatients, prescriptions and community appointments).

2.4 Peer support - expanding and integrating the diabetes care ecosystem

Diabetes management is complex. Beyond information and access to care, optimal diabetes management requires sustained support for PwD. It is often impossible or too costly for professional health workers to provide this support on a regular one-to-one basis. There is a growing body of evidence that peer support can be an effective and cost-efficient method of providing support, while also further empowering PwD.

Peer support has been defined as support from a person who has experiential knowledge of a specific behaviour and similar characteristics as the target population[9]. Within the diabetes community, peers are people who either live with diabetes or are affected by diabetes (i.e., family members).

Peer-to-peer models are based on the assumption that PwD have a great deal to offer one another in terms of knowledge and emotional support.

The role of peers is distinct from that of professional health workers involved in diabetes care. Trained peers provide PwD with emotional and social support, education and skills training. Peer channels support the existing willingness and capacity of humans to help each other into specific benefits. Peers do not have the professional status, social or financial recognition that formal caregivers or HCPs have. Their role and contributions to diabetes care are acknowledged by their communities, but today they are viewed as volunteers, not employees.

In the past, peer-to-peer support programmes have largely developed organically, driven by some dedicated PwD. The success of these models has led to the model being increasingly embedded in progressive healthcare systems and new healthcare products.

Examples of digital health models that place peer support at its heart include 7cups, Careology and Noora Health. Notable examples within diabetes include the #WeAreNotWaiting movement and national variations of the Diabetes Online Community (DOC).

OpenAPS is an online, open-source project that was set up and led by people living with T1D. It discovered how to build an artificial pancreas system (APS) and provided online information and guidance to enable PwD to set it up themselves. This is a hugely powerful development and demonstrates how far peer support and community collaboration can go. Some of the most important innovation in care delivery can come from the people most affected.

> *"I was diagnosed with T2D 10 years ago. Several of my family members also live with diabetes. I am now 48 years old. We live in a small town in Hatay. Three of them lost their sight because of diabetes and one had his feet amputated. Although we tried to adhere to the recommendations of the GP at our family care unit, several of us could not bring down our blood glucose. The peer education programme has made a big change in our family. It was wonderful to communicate with another person who had real life experience of diabetes; his wife has diabetes and they have been married for at least 40 years, so more than 30 years' experience. They have experienced several diabetes-related difficulties like us but have overcome them together. We have learnt so many things and now we are doing much better; our communication with our GP has improved. Our quality of life with diabetes has also improved a lot."*
>
> **- Damla Gurses, Living with Diabetes, Turkey**

Peer-to-Peer Diabetes Education Project, P2P (Turkey)

Background

Turkey has one of Europe's highest diabetes prevalence. The condition and other diabetes-related diseases account for a quarter of the country's health budget. Three-quarters of the cost of diabetes is directly related to the treatment of complications. The P2P Project was a three-year project started in 2012 by the Turkish Diabetes Foundation and was akin to a 'train the trainer' model, whereby HCPs trained PwD who, in turn, trained other PwD.

It was grounded in the realisation that diabetes education is required not only at the time of diagnosis but also throughout a person's life; that peer programmes create relationships which are often impossible to replicate between an HCP and a PwD; and that they help support healthcare systems with limited resources available for such activities.

Main Objectives/Components

Through the project PwD were trained to become peer educators able to bring knowledge across all of Turkey, in particular to rural areas with limited outreach services, and help PwD perform adequate self-management. Peer candidates went through an intensive two-day "train-the-trainer" programme delivered by HCPs, with both pre- and post-training tests. The training covered the condition itself, self-management, nutrition, exercise and diabetes complications. In a second phase, peers were also trained in education and presentation skills as well as in how to evaluate the results of education and on additional diabetes-related topics such as psychological problems and diabetes in pregnancy.

The peer diabetes education programme itself was delivered through a weekly (over ten weeks) 45-60 minute session. After the initial training, there were monthly meet ups so that participants could stay connected. The educational sessions were interactive, encouraging participants' experience sharing and mutual emotional support between PwD, allowing people to be more active members of the healthcare team. The project also contributed to the increase in social relations between PwD by strengthening the existing and new patient organisations and helping new ones to take root.

Impact

The project started in all of Turkey and reached 27,000 PwD recruited through diabetes outpatient clinics, HCPs and the local branches of the Turkish Diabetes Foundation and Living with Diabetes Association.

In a post-training assessment of its quality, more than 98% of participants recorded that the training met their expectations. Two-thirds of PwD were able to define the condition after the training programme, up from just 46% at the beginning; and three-quarters of them could define the difference between T1D and T2D, up from 42% pre-training. After the training, more than three-quarters of all participants were also able to understand/perform self-care; had a good understanding of diabetes-related complications, what a balanced diet looks like and the role of insulin therapy.

One year after the training, a one-on-one survey was conducted with 1,601 participants. Overall, mean HbA1C had dropped from 7.6% to 6.9%. Monotherapy had increased from 19% to 28% of participants. The proportions were also up for people using dual and triple therapy while the proportion of PwD on four or more medications per day had fallen from 53% to 27%.

Redesigning healthcare delivery models

How we organise care and better support HCPs is fundamental to improving care delivery. In this section, we consider how recent innovations can help make care more patient-centred, integrated and focused on outcomes.

Care that is better organised achieves better outcomes with the same resources and makes things easier for HCPs and PwD. Healthcare systems are large and complex and often managed by separate organisations, driven by different priorities, outcome measures and budgets, and supported by siloed financing and technology systems. Updating this structure to incorporate new models and ways of doing things is an important part of its evolution.

It may seem unreasonable that innovations need to fit the needs of PwD and HCPs, integrate into care pathways and complex procurement models while also delivering a clinical (and/or financial) improvement to be successful. This complexity is exactly why innovation in care delivery is difficult to achieve. It is not uncommon for innovations with a positive clinical and economic impact to fail because they do not fit into care pathways, procurement flows or the trained behaviours of HCPs.

Recent improvements in the organisation of care have centred around the integration of care, often accompanied by a strengthening of the primary care system, and, more recently, around the greater use of data (including real-world data and patient-reported outcomes) and digital tools to support better health management and prevention, at the individual and population level.

3.1 Placing PwD at the centre of an integrated care model

The most recent and powerful structural innovation in healthcare delivery has been the move towards more integrated and patient-centred care[10,11,12].

In large and complex healthcare systems, care delivery has traditionally been disease-focused, rather than patient-centred, and can become disjointed and out of sync. This is further exacerbated for PwD when you consider that many have diabetes-related complications or live with other conditions too. For PwD, who interact with the healthcare system multiple times a year, not only can this be a huge burden and a source of frustration but it also prevents the realisation of optimal health outcomes.

Integrated care tends to bridge gaps in care delivery, or poor care coordination, especially for people living with long-term chronic illnesses with medically complex needs. The goal is to improve patient experience (e.g., satisfaction, confidence, trust), quality of care and cost-effectiveness of care systems.

A starting point for making a system more patient-centred is understanding who they are. This means that healthcare systems need to be able to identify patients early, understand their needs, clearly articulate and organise their care pathways and empower them to take steps towards better outcomes.

A fully integrated, patient-centred healthcare system requires a large and complex set of practices, pathways, processes etc. to come together, with the ultimate goals of meeting patients' needs, desires and preferences and achieving the best possible health outcomes, within limited budgets.

Key components of a patient-centred care system include:

- A partnership approach across all decision-making stakeholders (including PwD). This applies to both the front line of care provision and also in management and procurement.
- Shared data and technology systems that make it easy for all HCPs involved in a patient's care (particularly between primary, secondary and tertiary care) to be aware of the patient's entire care journey and context. A fundamental building block for this that still needs to be implemented at scale is an electronic medical record system that all HCPs can access and interact with.
- Shared data systems are also important for healthcare systems when making investment and procurement decisions regarding people, processes and treatments.
- Aligned financial incentives across the different tiers of care provision (including community care and preventive measures) to realise opportunities that save costs or achieve better health outcomes.
- Care pathways that are patient-centred rather than only disease-focused and coordinate care across different tiers of care and different specialities.
- Use of risk stratification systems to identify and manage patients, regions and facilities that are high risk (health outcomes, financial).
- Further patient engagement and empowerment - providing the skills and knowledge for participation in their care management (e.g., shared decision making). Many patients could highlight breakdowns or inconsistencies in their care continuum if given the opportunity.

As a person with diabetes, my needs in different healthcare areas have grown as I get older and live with the condition longer. Knowing what is available to me and how to get it can be a challenge. Care pathways need to be signposted to us and our entry point known and clear of obstacles. If it's difficult to find the pathway or there are obstacles in our way then treatment may be delayed, or we may even give up. Delay in treatment can lead to poorer outcomes with physical and subsequently mental health. Living with diabetes is hard enough without having to navigate complex healthcare systems to get the treatment and care we need.

- Chris Aldred, Living with Diabetes, UK

Recent innovations in the field of integrated care rely on the increasing use of data, the digitalisation of health services and the use of artificial intelligence at all levels of prevention, care planning and delivery. Some of these innovations are covered in Chapter Four - Enabling Innovation through data and technology.

Air Liquide Healthcare

Background

Leveraging its unique proximity with patients at their home, Air Liquide Home Healthcare's philosophy relies on the conviction that the management of complex chronic diseases such as diabetes requires a solid understanding of the patient's personal and clinical objectives and social environment to provide personalised support according to the patient's profile.

To this end, Air Liquide brings all relevant diabetes care and expertise into PwD's homes. This includes the supply of medical devices (insulin pumps and glucose monitoring systems using readers/sensors), as well as a full range of services, including motivational, educational and technical support with the use of the devices, personalised care plans and e-health solutions. *Making Diabetes Easier*, an online platform, aims at empowering PwD in the management of the disease. Air Liquide Healthcare has developed a clinical evidence generation programme to support the value of its diabetes offerings. Initially launched in France, Air Liquide now offers home healthcare activities for PwD in 17 countries across the globe, and especially in diabetes in France, Spain, Germany, the Nordics, the Benelux, the UK, Switzerland, Saudi Arabia, Hong Kong and South Africa.

Key objectives/components

In France, Air Liquide Healthcare acts as a service provider upon prescription from healthcare providers. Air Liquide supplies devices, and its home diabetes nurses provide initial and ongoing diabetes support, personalised advice and assistance with the use of their medical devices, advice about nutrition and healthy living, as well as motivational support. As an example, GlucoZor is an educational application developed (by Dinno Santé) with AJD (French Association of Young People with Diabetes) to help children (8 to 12 years old) understand T1D. The Glucozor app has been deployed by other Air Liquide Healthcare affiliates in different European countries. Advice and technical assistance on devices are supported by ongoing research and assessment, conducted in Air Liquide Healthcare's technical lab Centre Explor! which evaluates the efficacy, performance and comfort of medical devices to guide HCPs and patients.

PwD with an insulin pump get at least two annual home visits, a 24/7 call-in system and a hotline staffed with nurse advisors. The treating physician is kept regularly updated and the tech platform remotely monitors PwD with an alert system if medical interventions are required. The online platform further provides educational programmes with video tutorials on the use of pumps, the basics of nutrition and physical exercises tailored to the PwD's profile.

Impact

Diabetes nurses accompany PwD throughout their chronic care pathway and strengthen integrated, personalised diabetes care delivery. This patient-oriented healthcare is essential for PwD's autonomy in decision-making, improves PwD's adherence to treatment, lowers the risk of costly complications and/or hospitalisation and helps PwD to live better with the disease. As well as improving the quality of life and health outcomes of PwD, this also represents an integrated pathway, with much potential for time-saving for the HCPs and cost-savings for the healthcare system.

Diabetes Primary Care Units, DPCUs (Serbia)

Background

The healthcare system in Serbia is centralised and mostly state-owned. It is organised around three levels and structured in a way that ensures that care always starts at the primary level. To improve the coordination of services and integration of care for PwD, the remodelling of diabetes care at a primary level was undertaken through the introduction of Diabetes Primary Care Units (DPCUs). These bring comprehensive prevention, training and care management services into communities.

Key objectives/components

The DPCU team consists of HCPs specialised in diabetes, diabetes specialist nurses and nutritionists. DPCUs aim to provide comprehensive and integrated care that is organised around the needs of PwD:

1. **Prevention and early detection of T2D**

2. **Management of diabetes and its complications (diabetes management)**
   - patient self-monitoring of blood glucose and other risk factors
   - additional controls in terms of therapy adjustment
   - adding/intensifying insulin treatment

3. **Prevention of diabetes-related complications**
   - regular yearly check-ups for complications
   - detection of high-risk patients

4. **Education of patients, self-care training and patient empowerment**

5. **Education of physicians and other healthcare professionals and**

6. **Comprehensive implementation and integration of information technologies**
   - focus on shared e-health records and registries of patients and individuals at high risk of developing T2D
   - integration of IT services in primary care. This allows an evaluation of the quality of care and facilitates shared decision-making

Impact

By establishing partnerships between multidisciplinary HCPs in Primary Health Centres, the DPCU coordinates the activities of the care team and facilitates shared decision-making. This solution could be a good example for collaborative diabetes care delivery in primary care.

"Until recently, introducing or prescribing a new therapy or solving other problems related to diabetes required visiting different specialists in several hospitals. The result was waiting too long for too many physical exams. Now, the situation has changed significantly. We have these Diabetes Primary Care Units, where I can get all the necessary information about the disease, dietary advice, instructions for the optimal use of diabetes aids and my therapy can be changed, all in a very short time and in one place. Besides, through an E-record system in primary care, my physician is informed about my yearly check-ups in DPCU, changes in therapy, as well as screening exams for diabetes-related complications. This has made my life with diabetes much easier and contributed to better disease control. As a result, I feel safer and motivated to better manage my illness. I think that the practice of DPCU is very good for PwD, because we are better prepared for all the challenges that life with this disease brings. Also, in the DPCU, I can fulfil almost all my needs and better regulate my diabetes".

- Aleksandar Opacic, President of Diabetes Association of Serbia

3.2 The foundations for integrated care

Several of the building blocks for an integrated care system are not new innovations, but still need to be implemented at scale. This is most notably the case for national patient registries and electronic health records (EHRs). National registries make it possible to better evaluate the impact of new programmes and models while EHRs make it possible for care providers to coordinate care provision from different parts of the healthcare system.

Both of these systems also help give PwD a greater voice within the system and a chance to be more involved in their own care.

Another building block is Patient-Reported Outcome Measures (PROMs) and Patient-Reported Experience Measures (PREMs). There is growing evidence showing the link between a patient's view of the clinical outcome and their actual clinical outcomes.

PROMs are standardised, validated self-reporting instruments (e.g., surveys or questionnaires) which measure the quality of care, from the patient's perspective. The data obtained from PROMs provide insights into the effectiveness of various therapeutics and the impact of interventions on patients' well-being and quality of life. PROMs can also complement traditional sources of data derived from clinical trials to inform policies, programmes and value-based healthcare delivery.

PREMs are standardised questionnaire-based instruments which measure a patient's perception of their personal experience while receiving care. Data collected from PREMs help identify the areas where improvements in patient experience are needed and assess the possibilities of enhancing the patient journey or operational workflows. PREMs are distinct from PROMs as the former asks patients about their experience of care and the latter about their view on the outcome of the treatment.

Recent pragmatic studies support the integration of PROMs in routine diabetes care as they have the potential to improve multiple aspects of care such as screening, monitoring, decision support, personalisation of self-management support and goal-setting. PROMs and PREMs can also be used to monitor depression and diabetes-related distress (which are connected to impaired self-management, greater hospitalisation and worse long-term outcomes).

> *The introduction of PROMs and PREMs represents the evolution of the concept of "patient centred" healthcare: the patient (or better, the person with a need for healthcare) is not just at the centre, but is an integral, active part of the healthcare system, equally contributing to the identification of needs and to the evaluation of outcomes through indicators previously considered "soft" in respect to the "hard" ones derived by the various activities of the healthcare providers. Just as an example of the change this is producing in the daily clinical activity: any healthcare professional should start their consultation by asking "How do you feel?" and close by asking "How do you consider the quality of the care to which you have been exposed?" not as a mere act of courtesy, but to collect solid information equally ranking in respect (in the case of diabetes) to the level of glycated haemoglobin or any other clinical evidence.*
>
> **- Massimo Massi Benedetti, IDF** Europe President, 1997-2003

The DiaProfile project found that PROMs help patients reflect on their diabetes needs and priorities and how they can self-manage their condition better. A study by the Swedish National Diabetes Register identified that PROMs and PREMs are important determinants of health-related quality of life and patient preferences. PREMs can measure how well the HCP and the patient share information, and in which areas the communication can be improved[13].

3.3 Evolving primary care towards a patient-centred medical home

The role of primary care within an integrated system is key. It is often the gateway to specialist care and, in the case of T2D, the place where the majority of care is provided.

Today, we ask more of primary care than ever before: HCPs manage more patients, more complex conditions, and have access to additional data and insights related to diseases and care pathways for each individual patient. And as we learn more about the nature of conditions like diabetes, HCPs are being required to do more than only diagnose and treat. They must also offer counsel and try to engage/support patients on topics such as medication adherence, nutrition, exercise and other behaviours.

In response to these challenges, primary care is starting to evolve. New models of primary care are emerging that have much potential.

Digital platforms	Data and risk stratification	Multi-disciplinary teams
• The use of digital platforms for consultations, self-management and remote monitoring. These types of platforms aim to enable primary care providers to support more patients with the same number of staff. • Digital platforms that specialise in diabetes are also starting to include continuous glucose monitoring and home testing (including home collection for lab processing) for HbA1C and urine albumine home testing, and have the potential to expand to include footcare and eye screening.	• Use of data and risk stratification models to identify patients early and initiate proactive care delivery for higher risk patients. Examples include Ribera Salud, Mendelian and Sollis.	• Broadening the disciplines in primary care to become more multi-disciplinary (GPs, nurses, dietitians, podiatrists, clinical pharmacists, paediatricians, ophthalmologists etc.).

This also includes:

The introduction of diabetes as a specialism within primary care for GPs and for nurses (diabetes specialist nurses).

Task shifting and sharing care responsibilities between members of primary healthcare teams (e.g., the assessment, education and monitoring of PwD by diabetes specialist nurses (DSNs), identification of barriers to medication management by clinical pharmacists).

Homecare services to support the education and management of PwD in their own homes.

The success of these new developments depends on the staff that work in primary care. Achieving the benefits that these new features offer requires the support and collaboration of the broader primary care team - doctors, nurses, pharmacists, dieticians, care coordinators and administrators. It also means further training and upskilling HCPs in using new tools, e.g., virtual clinics, motivating and supporting self-management etc.

Diabetes Specialist Nurses (DSNs)

Background

Several healthcare systems across Europe have embraced the concept of Diabetes Specialist Nurses, who can act as advanced care providers and trainers/educators. Exact roles and responsibilities vary by country though. For example, in Sweden and the Netherlands, more than half the DSNs are part of the integrated care team and have prescribing rights. By contrast, in Ireland the majority are hospital-based and not all are allowed to prescribe, although this is now evolving.

Most DSNs focus on directly caring for or educating PwD. They play a crucial role in direct complex patient care and medicines management, and they manage treatment recommendations and provide telephone consultations for outpatients that require follow-ups. DSNs can also provide specific diabetes education to other HCPs, helping to decrease medication and prescription errors.

Impact

The involvement of DSNs in clinical care, education and psychological care of patients and HCPs leads to better health outcomes for patients and improves the expertise and work settings of HCPs. The continuous integration of DSNs also has positive effects on healthcare systems' resources as their service leads to a reduction of in-patient harm, a reduction of length of hospital stays as well as prevention of hospital admissions and increased patient satisfaction[14].

One study found that early reviews of PwD by DSNs in the UK help prevent hospital admissions. The estimated savings over 3.5 years amounted to £35,000 (€41,000) due to reduced bed occupancy.

3.4 The role of the community in prevention, diagnosis and care

Community-level interventions (where we live, work, socialise, eat, exercise and sleep) can have a big impact on better diabetes prevention, diagnosis and care. Better coordinated and integrated healthcare systems are able to harness the benefits this has on patient outcomes and cost savings.

These dynamics include the role of the community (and its norms) in influencing an individual's behaviour, what services and activities are available within the community, population-level interventions that can change behaviours at a large scale and reaching people earlier in the care journey (e.g., preventing readmission).

Families across **E**urope following a h**E**althy **L**ifestyle **4 Diabetes** prevention **(Feel4Diabetes)**

Background

Feel4Diabetes was a five-year EU-funded study under Horizon2020. The project consisted of the development of an evidence-based and potentially cost-effective school- and community-based intervention, aiming to promote healthy lifestyles and tackle obesity and obesity-related metabolic risk factors for the prevention of T2D in vulnerable populations in high-income countries in Europe.

Main components/objectives

The intervention aimed firstly at identifying high-risk families, using schools as an entry point in the community. Once identified, high-risk parents were invited for a brief medical check-up, in a community centre or equivalent setting. The check-up included measurements of BMI, blood pressure and blood indices and lifestyle questionnaires. Following the initial screening, interventions were designed to take place both in schools and the community for all (e.g., promoting and encouraging physical activity and healthy habits in the everyday life of children and their parents), with additional interventions being implemented for high-risk families (e.g., counselling sessions).

Impact

Through the screening of 11,396 families, 4,484 families were identified as being high risk; 3,153 parents attended the baseline medical check-up, of whom close to a quarter lived with pre-diabetes and 3% lived with diabetes. After the two-year intervention, favourable changes were observed both for parents and children at 1st and 2nd follow-up. A follow-up project, DigiCare4You (www.digicare4you.eu), has now been financed, which will build on the work undertaken in Feel4Diabetes.

A particularly novel aspect that is still being researched is the impact of how a community is designed on chronic conditions such as T2D. This considers topics such as whether active travel (e.g., walking and cycling) is encouraged through the physical layout and design of a neighbourhood, how easily accessible is nature, air quality and whether there are spaces that foster new connections, friendships and collaborations.

We now know that our day-to-day choices have a big impact on our health. This is true for all of us - not only people with diabetes. Our friends, family and community have a big influence on our lifestyle choices - how much alcohol we choose to drink, how we spend our leisure time and which risks we pay attention to. Similarly, it can be hard to do more exercise if you live in an inner-city neighbourhood where the roads are filled with traffic and air pollution.

Today, getting diagnosed with diabetes requires a patient to visit a primary care service. Yet we know (as covered earlier in this report) that more than one third of PwD are not yet diagnosed. These patients exist at the community level and models that bring HCPs into the community or use data platforms to give HCPs a window into what is happening at community level could help to diagnose the undiagnosed.

Another promising model that connects community-level services with the healthcare system is **social prescribing**. Through social prescribing, primary care can refer patients to relevant local services that provide practical and emotional support. This can include walking groups, gardening activities, social housing initiatives and many more.

At its heart, social prescribing is about providing HCPs with a database of relevant community-level services and organisations that they can connect to patients who need that support. It is also about empowering people to identify their needs and find solutions in the community. It may sound simple, but most healthcare systems do not have social prescribing models in place yet, although this is changing. In Europe, countries such as the Netherlands, Denmark, Norway and the UK have launched social prescribing programmes, many of them focused on supporting people with mental health issues.

Enabling innovation
- the role of data, technology and artificial intelligence

Some of the major improvements to existing healthcare delivery and diabetes management include the digitalisation of healthcare systems, increased access to, and use of, much broader data sets including those based on real-world evidence (gathered, for example, through the digital therapeutics mentioned earlier and other digital devices), coupled with the emergence of big data analytics and artificial intelligence.

These hold the potential to ensure better prevention of diabetes, personalise healthcare interventions more effectively, enhance shared decision-making, improve remote monitoring and self-management, evaluate healthcare interventions and plan healthcare resources better (potentially lowering costs and freeing up resources), and finally improve research and innovation, all of which would lead to improved health outcomes for PwD and more resilient healthcare systems.

In this chapter we look at recent and potential future innovations based on the broader use of data, digitalisation and AI. Innovation in digital therapeutics is presented in more detail in Chapter Two.

4.1 Diagnosis, earlier intervention and value for money

Knowing which patients are in most need and whom to intervene with sooner is important to achieve better outcomes at a population-level and the greatest impact with the resources available.

Population-level data that takes into account both healthcare and non-healthcare data (e.g., socio-economic) can be used by healthcare systems to identify patients with the greatest need and ensure they receive care in a timely manner. With just over one third of all PwD across Europe not yet diagnosed, and 75% of the total diabetes cost stemming from diabetes complications, it is clear that we need to do more to find and reach undiagnosed PwD.

In this area, big data platforms are emerging that can not only help diagnose people who have not yet been diagnosed, but can also more clearly identify specific individual characteristics, with a view to better tailoring treatments. Mendelian is an example of a platform that analyses healthcare data to find patients at the community-level who have not yet been correctly diagnosed. Their model is proven to find patients with hard to diagnose diseases up to five years earlier than existing models of diagnosis.

Transforming Diabetes Management and Prevention in Primary Care, Kingston Health Centre (UK)

Background

The Kingston Health Centre manages care for 18,000 patients in South West London. It is part of a Primary Care Network of three practices and of the South West London Clinical Commissioning Group (CCG). Driven by the higher risk for PwD of developing severe forms of COVID-19, the move towards more virtual care and increasing numbers of people requiring care during the pandemic, it introduced new care models for PwD. Through the CCG, it commissioned a health analytics company to build an analytical model to create risk profiles for PwD in the practice and identify previously undiagnosed PwD.

Main components/objectives

The analysis model was built using the practice's historical data from both primary and secondary care, such as those based on the diabetes registry, and also including some additional population data, sourced directly by the health analytics company. As well as helping identify a number of people who had not been diagnosed, this led to the creation of a risk score for each PwD in the practice, which not only detailed their risk level, but also the reasons behind this risk (e.g., blood pressure level, cardiovascular disease, etc.). Alongside this data model, the practice also set up new systems to better manage patients, such as a diary function to keep track of appointments, reminders etc.

Impact

This has enabled a shift from reactive to more proactive and personalised diabetes care. This segmentation is now used in determining the frequency and type of consultations required, referrals to health coaches and other care pathways. PwD with a high-risk score may be invited to a physical consultation with a GP and/or referred to a specialist, while PwD with a medium-risk score may receive routine telephone consultations. Every week, GPs are provided with a list of PwD having had an HbA1c test, which allows for close monitoring and management. The new model of care has freed GPs to concentrate on, and personalise, the care of those who need it the most.

In parallel, the development of new types of tests that can identify the risk of developing T1D earlier[15] is equipping families with more knowledge, potentially preventing acute complications such as diabetic ketoacidosis (DKA) at the time of diagnosis and allowing for closer monitoring pre-diagnosis once the risk has been established. Additionally, precision medicine holds the potential of enabling researchers to better understand the risks, reasons and mechanisms behind T1D onset. For example, research is underway to determine how using information derived from genetic profiles can be used to undertake some prevention interventions (e.g., based on diet interventions or immunotherapy).

Alongside better resource allocation through earlier and/or more targeted action on the prevention of diabetes and diabetes-related complications, AI also allows for an in-depth analysis of health outcomes taking into account the specific interventions/medications used (as well as a number of individual characteristics and factors, e.g. socio-economic, environmental), and paves the way for the move towards a value-based healthcare system, which truly reflects the value of these interventions/medications, both to healthcare systems and individuals.

Using AI in that manner can, for example, highlight which medication works best for a given group of people that share a number of characteristics; or outline the need to start therapy earlier/later for certain groups. Better capturing the ultimate societal and health value of the intervention would also result in a better assessment of what constitutes a fair remuneration of these interventions/medications for pharmaceutical and medtech companies and other key stakeholders. This is especially important in the context of an ever-greater number of actors participating in innovative diabetes care, including therapeutic education providers, app developers, medical devices and digital platforms, remote monitoring and support (technical - e.g., device use; medical - e.g., consultations with GPs and/or specialists, nurses, other health/para-health professionals, etc.).

4.2 Personalising care - Precision medicine

Precision medicine is a new wave of innovation in healthcare that aims to personalise prevention, diagnosis and treatment to an individual rather than caring for each person with a model that is the same as another patient.

Precision medicine relies on the use of artificial intelligence, such as machine learning, deep learning and artificial neural networks, to analyse large data sets from a variety of sources.

Taking into account a raft of complex factors such as genetics, epigenetics, lifestyle, environment and behaviour, precision medicine covers a range of possibilities such as, for example, more refined characterisation of the diabetes diagnosis (precision diagnosis), tailored treatment plans (precision therapeutics/precision treatment); responses to specific interventions, risk factors, etc. (precision prevention) and precision prognostics, covering predictions of health outcomes[16].

Such applications already exist including establishing more targeted therapies for people living with MODY. The field is new though and many research and scientific gaps as well as obstacles to implementation still exist but there is much to be excited about, both in terms of managing the condition and preventing/delaying the onset of diabetes and its complications.

4.3 AI-powered decision-support tools

Another field of application for AI is in the development of decision-support tools that help HCPs and PwD better understand and adapt treatments through the identification and prediction of patterns.

Previously mentioned digital therapeutics and other supporting tools (presented in more detail in Chapter Two) combined with data analysis using AI can help PwD make decisions regarding nutrition and medication such as calculating insulin dosage and managing blood glucose.

In addition to these "conventional" uses, AI is now also starting to be applied to a broader range of factors influencing diabetes and its management. One example includes the use of AI for food recognition or recommendations based on the microbiome.

DayTwo is a system which, using a person's microbiome, as well as a series of other indicators, health data and a nutrition diary, seeks to predict glycaemic responses to various foods, thereby allowing for more precise action than that offered by the simple counting of carbohydrates.

Recent studies also underline the potential of AI in blood glucose management; one study, for example, has been looking at predicting HbA1c responses after moving people living with T2D onto insulin therapy, based on baseline clinical variables[17]. Another looked at predicting the risk of hospitalisation linked to adherence to oral hypoglycaemic medications and complexity of medication[18].

More routinely, support tools for clinicians (and self-management tools for PwD) can help facilitate the analysis of the vast array of data now available through traditional health indicators as well as wearables and other digital tools and devices, and suggest courses of action in adapting treatments, for example, thereby improving the likelihood of good health outcomes.

Zoe is a startup that is researching the body's response to nutrition. Their hypothesis is that each individual has a unique response to food and drink that is based on their genetics, biology, family history, health status and other factors that we have not yet discovered. Today thousands of people are testing their products to learn about nutritional response as part of a large research effort to learn more about this space. In the future, it may be possible to tailor a person's treatment plan based on their unique response to nutrition.

4.4 Virtual care models

Telehealth's usage recently skyrocketed due to COVID-19 and during the worst of the lockdowns it was critical in enabling some continuity of care, through the substitution of physical consultations with virtual interactions. In Norway, for example, the proportion of digital primary care consultations rose from 5% pre COVID-19 to close to 60% during COVID. In France, the number of weekly remote consultations was around 1 million in April 2020, compared to just 10,000 prior to March 2020[19].

As was its use in the past, telehealth continues, for a large part, to consist of routine consultations and sometimes monitoring, performed on the phone, via online platforms or other similar methods.

We are now starting to see the emergence of more advanced models that include complex care platforms where information from different devices (blood glucose meters, continuous blood glucose monitoring devices (CGMs), insulin pumps, and even fitness trackers) and other tools (nutrition and exercise diaries) can be combined, displayed and analysed by HCPs and/or PwD, dependent on the platform type. These platforms may also include other functionalities such as education material and support.

They offer many advantages over traditional care models:

- By allowing HCPs and PwD to access and analyse data ahead of consultations, they create more space to address subjects that matter most to PwD and discuss factors affecting fluctuations in data.
- Additionally, they allow HCPs/PwD more flexibility in the schedule and format of consultations. HCPs may conduct some consultations remotely, with the option of shorter and/or more frequent or longer physical and virtual consultations, based on the information collected and analysed.
- They can alert PwD and HCPs when low/high blood glucose events are detected, which can be acted upon remotely by the healthcare team.
- They help all PwD reduce the burden of managing such data and through better education help them use the data in their self-management plans.

Those platforms are evolving every day, not least through the increasing availability and improved features of devices such as CGMs and insulin pumps as well as a variety of wearables and digital therapeutics (discussed further in Chapter Two), and more functionalities are expected over the short to medium term. They are also starting to be integrated within healthcare systems.

> *"Tech innovation in the way diabetes healthcare is managed and supported has transformed the relationship I have with my diabetes. The ability to have real time data at the tips of my fingers and to analyse for trends, means that within one year I have managed to lower my A1c significantly. More importantly, I feel empowered and confident with my diabetes care, with a new quality of life"*
>
> **- Cameron Keighron, living with Diabetes, Ireland**

Remote monitoring of PwD in France

Background

In 2010, France adopted a framework for the implementation of telemedicine in the country, which includes five aspects - teleconsultation (remote consultation between an HCP and a patient); tele-expertise (conversations between two or more HCPs about the medical file of a patient); telemonitoring (monitoring of a patient at home according to pre-specified clinical and/or biological factors, collected by a medical device or directly by the patient and transmitted to HCPs); medical teleassistance (by which an HCP assists remotely a non-medical professional); medical response (provision of various services such as remote advice and urgent medical help).

Main components/objectives

Since 2011, the first national strategy regarding the deployment of telemedicine identified five strategic areas for improvement, including the telemonitoring of PwD and other chronic diseases, with a view to preventing Accident & Emergency (A&E) visits and hospitalisations

In 2017, the strategy was strengthened with the development of Etapes (Experimentation in Telemedicine for the Improvement of Healthcare Pathways), a four-year programme (starting 2018) which seeks to encourage and financially support the deployment of telemonitoring projects for people living with one of five chronic diseases (including diabetes) across the country.

Each provider is reimbursed according to a predetermined, fixed fee schedule, alongside a pay-per-performance model (e.g., for diabetes, performance payments are based on a 15% reduction in hospitalisation and a 16% reduction in healthcare costs). The services covered by the telemonitoring programme must include telemonitoring, provision of a medical device and therapeutic support.

One of the objectives is to evaluate the benefits for people living with chronic conditions as well as for healthcare systems of this remote monitoring approach in terms of better targeting people at risk of recurring hospitalisations or complications over the medium to long term; stabilise or improve the disease via access to rapid advice from a HCP; improve the efficiency and quality of care and improve the quality of life of people living with chronic diseases.

Impact

The full impact is not yet known. An evaluation report is expected in 2022.

4.5 Managing diabetes-related complications

Technological advances in artificial intelligence are now also making it easier than ever to diagnose diabetes, and diabetes-related complications, in an automated way.

Diabetic retinopathy (DR) is one of the most common complications of diabetes, affecting one in three adults and as a result making diabetes the leading cause of adult-onset blindness. DR can be diagnosed early by identifying changes to blood vessels at the back of the eye. This normally requires a trained ophthalmologist to analyse images of the back of the eye.

New machine learning algorithms are now being used autonomously to analyse images of dilated pupils to detect DR with very high sensitivity and specificity. Some devices have been approved in the US since 2018 for diagnosing greater than mild retinopathy. The analysis of the images can be done remotely by transmitting the retina images to a trained algorithm in a cloud system that scans and spots anomalies. Such devices are beginning to be used in some European countries.

Such tools allow for increased access/frequency of screening since they do not require access to a specialised clinician at the time of the screening.

New platforms are also being developed to standardise photos of diabetes feet, engage PwD in self-management of their feet etc., while telehealth also supports more frequent assessment of foot-related complications such as ulcers. Newer tools are now being developed for self-management at home, for example, to measure foot temperature. Across the world, various estimates put the proportion of PwD with a lifetime incidence of foot ulcers to be between 15% and 34%, again underlining the potential of new technologies.

Whether fully automated, or supported by digitalisation, new ways of screening can be conducted in the absence of specialists. This opens the door for more systematic, and broader, screening at primary care (or community) level, thereby enhancing access to screening and increasing the number of people being diagnosed, while reducing the pressure on specialists such as ophthalmologists. It also helps treat the complication in a timely manner, and overall reduces or keeps screening costs at existing levels, while screening more people.

Enabling innovation - how to fund healthcare?

Better use of funding is key to developing and scaling new innovations in care. In some cases, this requires new funding but there are also ways to make existing funding work harder and to catalyse funding from other sources - such as investment from the private sector. Countries without the ability to invest in Research & Development (R&D) directly can still benefit by building pathways that make it easier for new models (developed elsewhere) to scale into their region.

5.1 Doing more with less - value-based care

It is widely recognised that 'fee for service' payment models are inefficient, incentivise the wrong activities and do not achieve the best health outcomes. They also do not necessarily facilitate the implementation of universal healthcare coverage, a goal which many governments have subscribed to across the world, as part of their commitment to achieve the 2030 Sustainable Development Goals.

The starting point is to achieve more with the financial and human resources already available. It is this ethos that underpins the shift towards value-based care. There are many novel initiatives across Europe in health financing, enabling and fostering innovations in care delivery, where value is a key funding instrument - value being defined as improving health outcomes while reducing costs, or getting better outcomes for the same cost.

Value-based healthcare (VBHC) is an approach that delivers better outcomes for PwD, healthcare staff, providers and society in a cost-effective way. For promising innovations, it is their ability to evidence better value that paves the way for adoption. Countries without VBHC structures or principles will struggle to account for the benefits created by these new models and are unlikely to implement them.

An important principle of VBHC is that it is able to identify and recognise when the benefit (or cost saving) of a new innovation is realised in a different part of the healthcare system from where it was implemented. This is a common occurrence in healthcare and a structural barrier to implementing new models. For example, in VBHC it is financially beneficial to implement proactive primary care models that reduce the number of patients that need hospitalisation. Most innovations, especially those that are aimed to reduce/delay the onset of diabetes and its complications, explored in this report, make more financial sense from a value perspective than in a fee-for-service payment structure.

One of the key barriers to the widespread adoption of VBHC, however, includes the difficulty for health systems across Europe to develop a comprehensive system integrating all components supporting the development and delivery of a VBHC framework - e.g., how to implement payment schemes across providers and organisations; how to ensure the full collection of PROMs and PREMs as well as all other required indicators.

Integrated Personalized Diabetes Management Goes Europe, iPDM-Go[20,21]

Launched in 2019, iPDM-Go is an EIT Health-funded project that focuses on improving diabetes care by implementing integrated Personalized Diabetes Management (iPDM). The project seeks to enhance the iPDM approach with innovative tools and promote innovative financial models based on performance and outcomes.

The iPDM approach consists of six steps[22] based on a structured recurring approach for personalised diabetes (self)-management and joint decision making between care provider and patient, supported by digital solutions to enable process efficiencies and remote access. It includes: 1) structured assessment and training; 2) therapy-adapted self-management of blood glucose levels; 3) structured documentation of clinical information; 4) systematic analysis of patient-generated data using digital tools; 5) joint decision-making about treatment strategies; and 6) regular assessments of the effectiveness of treatment.

The project builds on the findings of the PDM-ProValue study[23], a 12-month prospective, controlled, cluster-randomized, multi-centre program that enrolled 907 eligible PwD and demonstrated that the implementation of iPDM supported by digital tools in daily outpatient practice improved glycaemic control, more timely treatment adjustments and increased patient adherence and treatment satisfaction among patients and physicians.[24]

With the ultimate goal of implementing the iPDM model at a regional level in Denmark, iPDM-Go encourages the adoption of digitally enabled individualised treatment of diabetes, as well as payment systems that reward better healthcare. Its rationale is based on the understanding that the use of digital tools and telemedicine can contribute to improve diabetes management, patient experience and health outcomes (e.g., reducing the number of hypoglycaemic events; improving HBA1c, etc.).

A core deliverable of the iPDM-Go project is a patient-assessment tool, designed to monitor, tailor and prioritise PwD's management plans. The development of patients' profiles based on the tool and integration of supplementary information such as real-world data helps develop fully personalised and adapted diabetes care plans.

While the iPDM-Go project has not been fully implemented for diabetes care in Denmark, its approach has been adapted to other chronic conditions in the country (COPD and heart failure), in a clinic built as part of a PreCare[25] project. The project is developed by Region Zealand and Odsherred municipality and offers support and treatment to citizens in their own homes and led to significant cost-decrease by reducing the hospital activity per chronic patient[26]. The method has shown potential for both transferability and scalability.

5.2 Reimbursing new tools and technologies

Digital health as a sub sector within healthcare has existed for nearly two decades yet today its journey to being properly reimbursed by public health systems and other payers (e.g., insurers) is only just beginning.

Germany's DIGA system is currently the best example of a model where proven digital health models can be prescribed by HCPs and their costs covered by the healthcare system.

Other European countries are further behind and it is common for innovators to travel door-to-door visiting different commissioners and providers across the system looking for open-minded collaborators willing to test or procure their models. In a system such as the UK NHS, primary care is delivered according to a clear national framework that outlines the services and quality that is expected. If new models of care are not strongly embedded within this framework, then there is little incentive for the (largely) locally procured system to accept new models of care delivery.

Most innovations covered in this report have used loss capital from private investors to make progress. If they continue to be reliant on consumers and employers as their main routes to being procured then innovation will scale slowly and always be out of reach of poorer countries and patients.

If we want to take innovation seriously, and realise the benefits for patients, HCPs and healthcare systems outlined in this report then a change is needed.

5.3 Developing new frameworks – bundled payments

Many initiatives to enhance the effectiveness and quality of diabetes management focus on multidisciplinary cooperation. Some major stumbling blocks in the creation of collaborative arrangements in healthcare are the fragmented pricing of the various components of diabetes care and the inadequate funding of supporting services that do not belong to the direct provision of healthcare.

The latter components include the coordination of healthcare services, the information technologies and the collecting and reporting of reflective feedback data. They are essential for delivering cohesive care but are sometimes funded on a project-by-project basis with no guarantee of continuity.

The aim of bundled payments is to improve the effectiveness and quality of care and to ensure affordable costs. This new pricing model enables all the necessary services for a disease management programme to be contracted as a single package or product.

Bundled payments represent one form of alternative payment models (APMs) that are designed to move toward value-based care by incentivising providers to advance coordination and efficiency of care while also improving quality and outcomes at lower costs.

Experimenting with a bundled payment system for diabetes care in the Netherlands[27]

Background

Faced with the challenges of managing a rising number of people living with chronic conditions, the Dutch Ministry of Health launched a series of disease management programmes, revolving around the concept of multidisciplinary cooperation, with a view to improve the quality of care and reduce costs.

Main objectives/components

As part of this, a new pricing model for chronic diseases including diabetes was introduced in 2007 on an experimental basis, which became permanent in 2010. It consisted in contracting, as a single package, all the necessary services for a chronic disease management programme. By 2010, 100 care groups (affiliated healthcare providers working together in a programme) operated diabetes management programmes.

Impact

An evaluation by the Ministry of Health three years after the introduction of the bundled payments showed mild to moderate improvement in healthcare delivery, notably concerning health checks (HbA1C, BMI etc.), testing (cholesterol) and screening components (foot, DR etc.). Several outcome indicators showed similar improvements. The proportion of people meeting systolic blood pressure and cholesterol targets rose, while the average Hba1C level increased marginally (by 0.5mmol/mol). More than 90% of PwD rated cooperation and coordination between the various healthcare providers as good or excellent. The new system also led to practice nurses taking a more important role as part of diabetes management programmes, while there was a shift away from DR screening being conducted by ophthalmologists and an increasing proportion of people on insulin therapy without complications being managed by GPs. After just three years, it was difficult to assess the impact of the payment systems on polypharmacy and the management of complications but this had not been flagged as an issue. Among the challenges still to be addressed at the time were: raising the voice of PwD as part of their care and ensuring full transparency regarding care quality.

5.4 Developing new frameworks - managed-entry agreements

Managed-entry agreements (MEAs) - also sometimes referred to as risk-sharing agreements or patient access schemes - are contracts between medicines/health technology companies and payers, allowing for faster patient access to novel medicines/health technologies under a series of conditions, often reflecting the uncertainty surrounding their performance vs cost. For the payers, MEAs ensure that costs will not go beyond a certain predetermined level.

Performance-based/outcomes-based managed entry agreements are an extension of the MEAs that condition the payments to those medicines/health technologies reaching certain performances. Both types can be set up at the individual or population level, and are mainly used for totally new products, products meeting unmet needs or whose clinical value remains unclear.

While the use of MEAs is relatively common and has increased mainly due to the high cost of many medicines and constrained health budgets, fewer performance-based MEAs have been set up, notably reflecting their complexity, and the need for close monitoring of a medicine/technology's performance, which the healthcare system may not be set up to provide. According to an OECD Health Working Paper[28], by 2019, MEAs had been used in 28 of the 41 OECD countries and/or EU, with many having both finance-based and outcomes-based MEAs. Across nine countries with 76 known instances of performance-based MEAs, six related to endocrine, nutritional and metabolic diseases.

5.5 Supporting early-stage innovators

Scientists, clinical innovators, entrepreneurs and engineers are big drivers of innovation in diabetes care. They create the models of the future that improve health outcomes and reduce costs. Actively supporting and enabling this type of innovation is an important route to sustainably funding care.

Innovation ecosystems around the world are maturing in recent years and great models exist that foster and fund innovation. In addition to the leading innovation hubs that exist (e.g., NHS incubators in the UK, Spanish and German start-up ecosystems, variety of European universities, etc.), it is important for every country to actively support new innovation so that new models can be adapted to their local context and needs. Countries that do not actively support innovation will be some of the last in the queue to benefit from new developments.

In recent years, the UK NHS has implemented a variety of models such as the Clinical Entrepreneurs programme, NHS Innovation Accelerator and the network of Academic Health Science Networks that focus on translating new science into scalable models.

Medical devices: transitory reimbursements for medical devices

Background

In February 2021, a decree was enacted by the French National Health Authority (HAS) which allows for transitory reimbursement of some CE-marked medical devices, and related services for 12 months (renewable once) ahead of submitting an application to be included on the list of Reimbursed Products and Services (LPPR). The objective is to speed up access to innovative devices through speedier access to reimbursement.

Main objectives/components

The decree aims to reimburse products which are believed to be innovative, while waiting to be approved for reimbursement and be added to the LPPR. Products that are covered by this decree include products that can help manage serious or rare diseases or help mitigate a disability; that cater for an unmet or poorly-met medical need; that have the potential to bring a significant improvement to the person living with the condition/handicap; that is innovative beyond simply representing a technical advance on an existing product; and can bring a clinical effectiveness with potential side effects that remain acceptable.

There are great learnings from these models that can be adapted to different contexts:

- Frontline clinicians of all types have great ideas to improve care and efficiency. They will pursue and drive forward these models if provided with some basic support. In many cases, they will often self-fund development of these ideas if they can see potential for the system to adopt it.
- The private sector is very willing to invest 'loss capital' in R&D for new models if they see a pathway for new models to scale up and be procured by the system.
- Having access to the healthcare system to complete research and test new models is of high value to innovators and does not need to be costly.

5.6 Mobilising private sector capital

The growth in private sector funding for healthcare innovation is a powerful development. In 2020, the amount of Venture Capital (VC) funding for digital health in Europe grew to €41.6bn from €28.3bn in 2019[29]. By enabling and incentivising private sector capital for innovation, health systems do not need to be responsible for being the sole funder.

This is important because the pace of innovation is accelerating. It is driven by success in other sectors, more powerful technology, new infrastructure and greater patient demand. The willingness to convert to digital during COVID-19 has only further hastened the appetite of investors, entrepreneurs and patients for further improvements.

More work is required to understand how health systems can support new innovation to thrive. As analysed earlier in this report, there are barriers unique to healthcare (e.g., regulatory) that naturally slow adoption and scale of new innovation.

Based on what is working in other sectors, it is clear that private sector capital will invest in innovation if they see the potential for their investments to be accepted and procured by the healthcare system, healthcare consumers, healthcare funders (e.g., insurers) and employers.

To achieve this, there are tactics for healthcare systems to explore:

- Fair and transparent procurement processes
- Strong regulatory systems that ensure a fair playing field
- A variety of 'sandbox' and pilot testing sites where new models can be safely tested for efficacy
- Tax breaks and incentives for angel investors
- Awards and certificates that recognise and publicise new innovations
- Advice and mentorship for early-stage innovators

5.7 Mobilising Investors - social impact bonds

Of the various procurement models that have been tested, social impact bonds (SIB) are one type that holds much promise for the financing of care delivery innovation.

According to a definition by the OECD, SIBs are "an innovative financing mechanism by which governments or commissioners enter into agreements with social service providers, such as social enterprises or non-profit organisations, and investors to pay for the delivery of pre-defined social outcomes".

Through a SIB, investors provide funds to a service provider, which then executes a particular task or contract, with a predefined outcome. If the outcome is realised, the government/public authority supports the cost or future cost of the intervention.

SIBs come in a variety of formats, provisions and deal options. A major advantage of SIBs is that they allow for innovative programmes/initiatives to be put in place, at no risk to the health system unless the intended benefits are realised. The intended benefits for a programme could include cost savings, so a public health system only has to pay their contribution if the intended savings are achieved.

This allows for increased focus on models related to better condition management (less readmissions or complications) or prevention. The provision of up-front funding may also broaden market access to SMEs, which may otherwise struggle to raise finance. Engaging in SIBs nevertheless requires a high level of transparency and acceptance of the use of private funds into healthcare.

Across Europe, a broad range of countries have used SIBs, although the UK remains one of its main proponents.

Social Impact Bond - Prevention of Type 2 Diabetes in Israel[30]

Background

Intervention programmes for people with impaired glucose tolerance or impaired fasting glucose (sometimes referred to as "pre-diabetes") have been proven to help reduce the risk or delay the onset of T2D. In 2016, the Israeli Health Maintenance Organisations (HMO) Clalit and Leumit, and the National Insurance Institute engaged in a €5.1 million SIB. Investment was provided by multiple investors and the intervention delivered by Movement Group. The SIB was structured as a pay-for-success initiative, with the aim of reducing healthcare allowances and insurance costs.

Major components/objectives

This five-year intervention is an intensive lifestyle modification programme (based on a programme previously carried out in Finland), implemented across three groups of 2,250 people living with pre-diabetes. Over the first two years of the programme, participants receive guidance regarding nutrition and exercise as well as personalised guidance.

The intervention also includes the provision of wearables and apps that provide real-time analysis of the intervention and communication. At the end of the two-year intervention, participants are followed for a further three years, with blood glucose testing. The programme's final objective will be assessed on the programme's success in preventing the development of T2D in people at risk.

Impact & financial terms

The assessment impact is not yet available, but aims to prevent the onset of diabetes as well as generate best practices in diabetes prevention. If the project proves to be successful, significant savings are expected, and the Israeli HMO/Social security system will repay the investors a pre-agreed amount for each success case.

Implementing care delivery innovation

Implementing innovation in care delivery requires collaboration across a range of components, processes, departments, organisational levels, etc. A prerequisite to these elements is the implementation of a series of universal key enablers that support care delivery innovation on which all healthcare systems and countries should focus.

The structure and maturity of individual health systems in relation to the sophistication of their current care delivery for diabetes care will also determine specific elements that additionally need to be in place to foster the adoption and scaling of innovation.

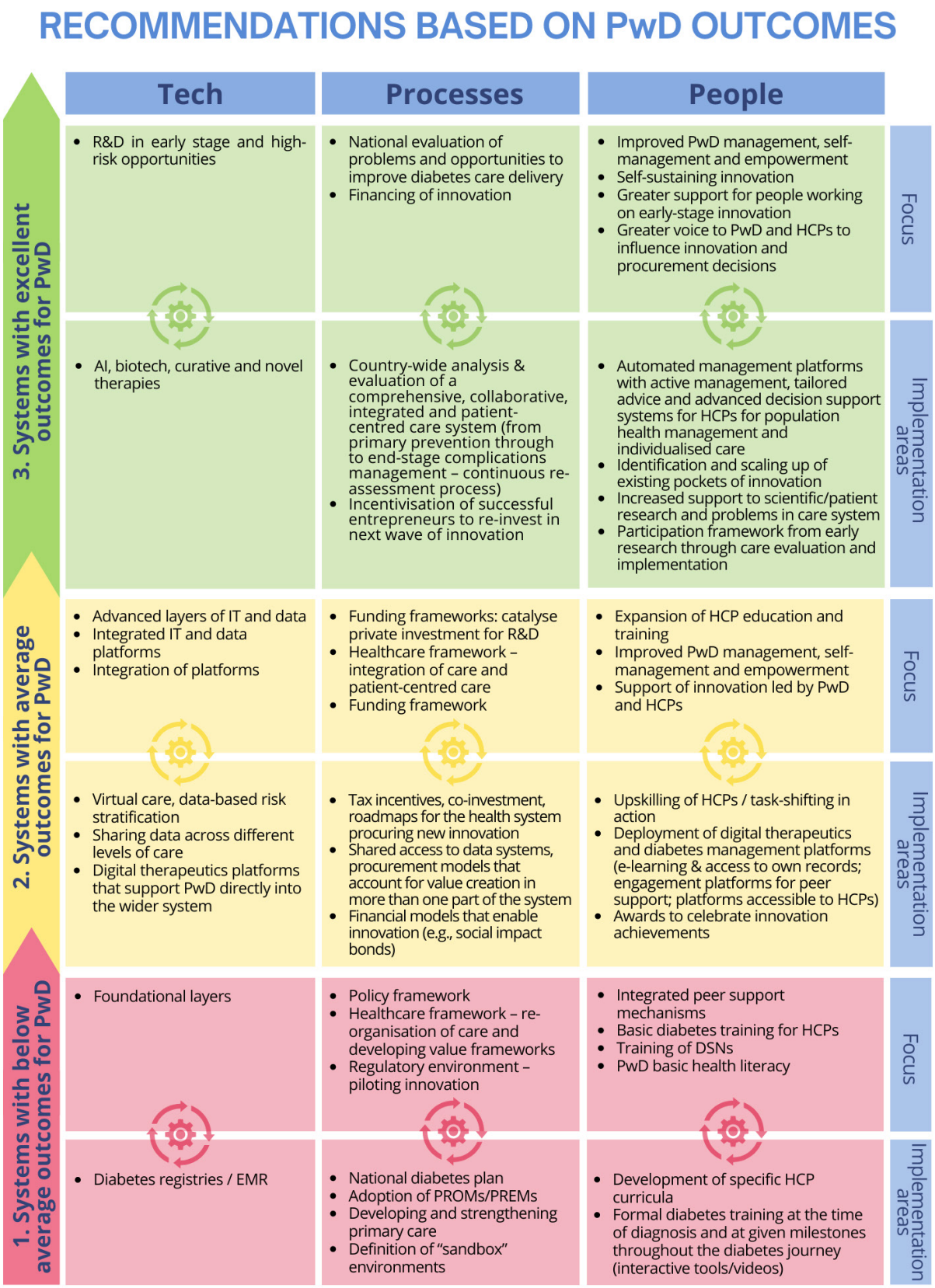
6.1 Universal key enablers

No matter how sophisticated a healthcare system is, a supportive framework for the adoption and scaling of innovation needs to include the following components.

People	Processes	Technology
• Creating optimal & continuous communication channels/ opportunities and feedback loops between HCPs and PwD • Ensuring ongoing education and upskilling of HCPs as well as education and empowerment of PwD • Rewarding innovators and celebrating innovation successes (e.g., creating a framework for awards, media promotion, etc. of innovation and success)	• Developing clear objectives and a supportive policy environment • Putting in place a supporting regulatory environment: - Framework to foster, safely pilot and evaluate innovation early on - Models of reimbursement for new care models • Healthcare framework for integration of care • Funding frameworks for innovation development and testing (e.g., catalysing private investment) • Financial incentives to encourage coordination and integrated care	• Foundational layers of IT and data

6.2 Recommendations based on PwD Outcomes

Based on national diabetes care outcomes, it is recommended that innovation components be included at a minimum in order to improve care delivery for PwD.



Conclusion

This year is great timing to reflect on the wins and misses regarding diabetes care innovation. One hundred years since the discovery of insulin, it is clear from our review that there is much innovation to celebrate from all aspects of care delivery – be it in how PwD are involved in their care through to how care is organised and ways of funding care.

We deliberately aimed to look at care innovation from a broad perspective. Innovation that solves a problem for PwD, an HCP problem; that integrates into clinical flows; delivers a financial benefit (or at least not a penalty) and harnesses the power of the latest technology and data models. Thus, we have sought to review diabetes care innovation from these connected perspectives.

If you are working on a care innovation yourself, we applaud you and hope this report sheds light on your journey. PwD are hungry for better models of care and HCPs desperately need better support to provide the quality of care they and PwD expect.

The challenge and opportunity of our time is not creating new models that make a difference, but instead how to scale up innovation to reach more people and healthcare systems than they currently do. Every innovation we have highlighted in this report has not yet reached satisfactory scale across Europe despite some of them being well known and regarded (e.g., strengthening of primary care systems).

It is not possible for one individual to be an expert in all these connected areas that enable innovation to scale. To achieve scale, more collaboration is required – both within healthcare systems (between the frontline and management) and between healthcare systems and key innovation stakeholders (e.g., PwD, governance, innovators, researchers, investors and the wider innovation ecosystem).

For someone who has been managing diabetes for years as for somebody newly diagnosed, this process can feel onerous and exhausting. For the diabetes community as a whole, impatience for things to get better is now the resounding feeling. The good news is that there are many great improvements in the pipeline. The question is how we bring these new models to more people who need them.

> *"100 years after the discovery of insulin, people living with diabetes came together to drive the development and adoption of the artificial pancreas. This truly is the most far-reaching breakthrough in diabetes care of the last 100 years – all driven by PwD themselves, who endeavoured to support its adoption by all those who wanted it.*
>
> *Much more can still be achieved. We can't do it alone though – we need the support and investment of decision makers in agile healthcare systems that will work with all stakeholders to make life with diabetes as good as possible."*
>
> **- Bastian Hauck, IDF Europe Board Member, Living with Diabetes, Germany**

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