



A Vision For  
Digitally Enabled  
Diabetes Care  
in Europe

**Views of Leading Stakeholders**

# A Vision For Digitally Enabled Diabetes Care in Europe

## Views of Leading Stakeholders

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## Introduction

Across Europe, the demand for healthcare is exceeding the available capacity and resources. This is driven by an increasing burden of chronic diseases, associated with an ageing population, changing habits and new environmental realities. The current models of healthcare provision are likely to be unsustainable to meet these increasing demands.

There are about 60 million people with diabetes in the European Region, and the numbers are rising rapidly.<sup>1</sup> People with diabetes face a higher risk of serious health complications, including cardiovascular events, blindness, amputations, and kidney failure. Diabetes presents many challenges and requires healthcare systems to adapt and remodel to address growing threats to personal, social, and economic wellbeing.

Reducing the risk of developing diabetes is the logical first priority. However, while type 2 diabetes can be prevented or delayed in clinical trial settings, where a highly controlled environment and treatment regime is established, there has been no large-scale success of prevention at a population level. Relying on individual lifestyle changes alone has not been successful. Whole societies and governments need to drive the necessary changes. Enabling people living with diabetes or those at high risk of developing diabetes to manage their condition with integrated digital solutions will support long-term change.

A digital transformation of diabetes care has the potential to empower systems to manage costs and engage their resources efficiently; to improve the quality and continuity of care for people with diabetes, including by reducing geographical barriers to access to care; to enable better governance and policy planning in areas beyond diabetes; and finally, to foster innovation and collaboration among industry players to develop products and solutions to support diabetes care.

This paper captures the insights and ambitions of patient advocacy groups, healthcare professionals, policymakers, and industry representatives focused on a better, and achievable, future for people with diabetes.

1) <https://www.euro.who.int/en/health-topics/noncommunicable-diseases/diabetes/data-and-statistics>

# Methodology

To formulate a concrete vision for diabetes care in 2030, we interviewed a spectrum of leading professionals in the diabetes field, people with diabetes, as well as leaders of the major medical diabetes technology companies.

These interviews were conducted during April and May 2020 and coincided with the international health crisis of the Covid-19 pandemic, which continues to be the top political and public health priority across the globe.

## Interviewees and contributors:

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**Bastian Hauck**, Director, International Diabetes Federation Europe. CEO & Founder, #dedoc<sup>o</sup> Diabetes Online Community. Living with type 1 diabetes

**Lutz Heinemann**, Leading expert on diabetes technology. Co-founder and former CEO of Profil Germany. Managing editor of the Journal of Diabetes Science and Technology

**David Kerr**, Diabetologist, Director of Research and Innovation, Sansum Diabetes Research Institute, Santa Barbara, California

**Dirk Müller-Wieland**, Diabetologist, former President of the German Diabetes Association (DDG). Aachen, Germany

**Niti Pall**, Europe Regional Chair of the International Diabetes Federation. General practitioner based in the West Midlands, UK

**Louis Philipson**, Diabetologist, ex-President of the American Diabetes Association. Based at the University of Chicago, USA

**Christel Schaldemose**, Member of the European Parliament from Denmark. Chair of the European Parliament Working Group on Diabetes

**Hood Thabit**, Diabetologist, Manchester University NHS. Expert on insulin pumps, CGM and closed loop diabetes technology

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## Abbreviations:

**AI** Artificial intelligence

**T1D** Type 1 Diabetes

**T2D** Type 2 Diabetes

## The Impact of Covid-19

The Covid-19 pandemic has had a seismic impact on all aspects of life across the globe. Among these, Covid-19 has led to unprecedented strains on health systems. The crisis-driven focus on prevention of Covid-19 infection has taken the attention of health systems away from all other health concerns, particularly long-term chronic medical conditions. Waiting lists have increased and individual face-to-face consultations have had to either be cancelled or minimised and replaced by remote contacts.

It has become clear that people with diabetes and other chronic health conditions such as high blood pressure and the metabolic syndrome have much worse health outcomes with a Covid-19 infection.<sup>2,3,4</sup>

While Covid-19 has taken the attention of the public and countries' crisis responses, the diabetes pandemic has continued in the background, unabated. This heightened risk environment has led to serious consequences for people with diabetes beyond higher mortality rates, including a rise in mental health needs associated with the cognitive load of Covid-19 risks, barriers in access to care while social distancing, and delays in care. The broader impact of these consequences will become clearer in the coming months and years.

Across Europe, governments and health systems have reacted at an unprecedented speed to cope with the viral pandemic. The Covid-19 crisis has shown how rapidly everything in the healthcare system can change. If there is any good news from the crisis so far, it is that Covid-19 has promoted the adoption of telemedicine and various digital health solutions to address the needs of people with diabetes. Interviewees for this paper reported that the Covid-19 crisis has convinced those in the diabetes field to go virtual, and virtual solutions have been seen to work. In fact, telemedicine and new digital health solutions hold the promise of becoming an essential part of a new, high-quality standard of care, complementing, and ensuring linkage to essential services that still need physical interaction. Covid-19 has accelerated progress toward a digital diabetes clinic, and it has highlighted that this digital transformation will be led by the needs and circumstances of people with diabetes.

Diabetes care is likely to change significantly in the longer term because of the impact of the Covid-19 pandemic. While 2030 is a long time away, the viral pandemic has shown that linear thinking can be a weakness in future strategic planning for healthcare. Healthcare professionals have shown a willingness to adopt new technology if this does not add burden and helps them manage their patients. People with diabetes have also seen that continuity of care, including when provided remotely, has the potential to improve their quality of life. Systems of care have the potential to improve efficiency and spending, while providing tailored, personalised care.

However, despite some clear advantages that have been observed for people with diabetes, there is a substantial risk that payers and practitioners will revert to the pre-Covid way of working and interacting with patients. The current systems for health insurance and reimbursement of care might increase this risk of reverting to pre-Covid ways.

Covid-19 has had a profound impact on so many around the world. Supporting the adoption of teleconsultations and other digital solutions is clearly a central priority for the current and possible future pandemics and will be critical for chronic disease management.

Telemedicine opportunities have been widely adopted and shown to be helpful so far during this crisis. More expansive and holistic digital solutions are also achievable. Provided there will be the appropriate investment and leadership by policymakers, fully integrated digital diabetes care can be the norm by 2030, promising to improve outcomes and quality of life for people with diabetes.

2) <https://www.idf.org/aboutdiabetes/what-is-diabetes/covid-19-and-diabetes/1-covid-19-and-diabetes.html>

3) <https://www.thelancet.com/action/showPdf?pii=S2213-8587%2820%2930238-2>

4) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7322508/>

## Diabetes 2030: A Snapshot

Before their in-depth qualitative interviews, participants were asked a series of ranking questions about the future of diabetes care. Here is a high-level snapshot of these results..

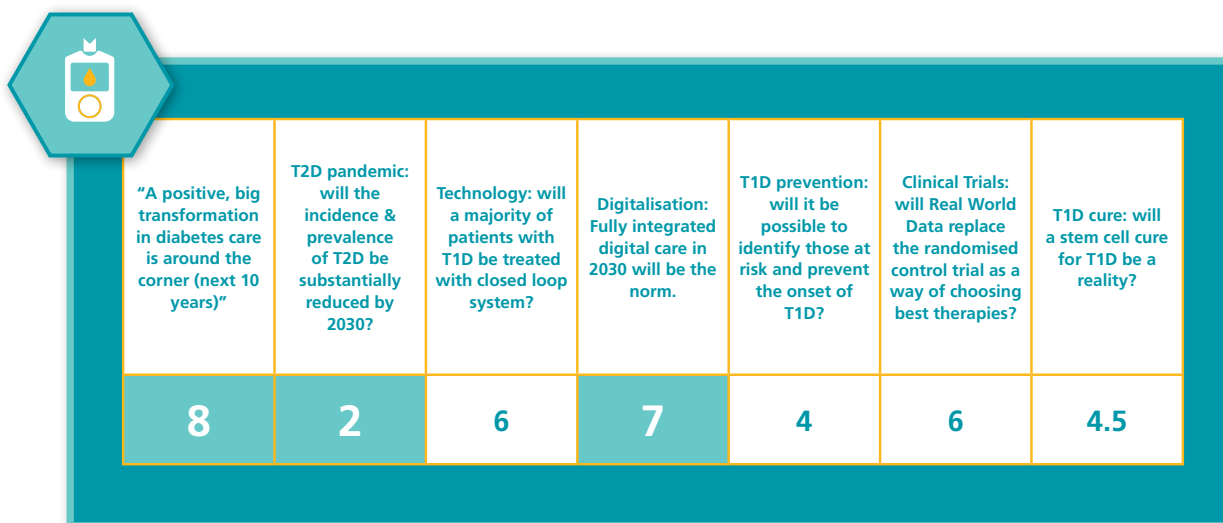


Figure 1: Average of all respondents' scored results, from 1 (complete negative) to 10 (strongest positive), on key questions about the future of diabetes care

## Chapter 1. The Digital Threshold: Common Themes on Diabetes Care in 2030

Consistent themes and conclusions emerged from our conversations with experts in the field, from healthcare professionals to policymakers, patient representatives to health system specialists and device manufacturers. We examined common threads first, followed by a focused perspective for the different stakeholder groups.

### The Effect of The Covid-19 Pandemic

All respondents stated in one way or another that diabetes care will change permanently because of the impact of the Covid-19 pandemic. The crisis has accelerated the evolution of health systems to deploy digital health solutions and virtual care. Many saw this as constituting a permanent change.

“ The Covid-19 crisis has convinced people to go virtual – and it works! ”

Some commented that governments would pay more attention to diabetes, having seen the extent to which it was a significant additional risk factor for those with Covid-19.

The crisis has also strengthened the case for greater investments in staff, technology, and treatment to drive improvements in diabetes care, particularly after many years of underfunding. Clearly, however, the Covid-19 crisis will also bring significant budget pressure, at least in the short term.

“ Covid-19 has accelerated progress towards a fully digital clinic. ”

### More Personalised Care

Another recurring theme is that diabetes care will become more personalised and precise as a result of our growing understanding of the genetic and underlying physiological bases of different forms of diabetes. We know that type 2 diabetes is not just one disease, but rather a complex array of many sub-types.



## TYPE 1 VS TYPE 2 DIABETES. WHAT IS THE DIFFERENCE?

Type 1 diabetes: people with T1D have a complete lack of insulin. The only treatment is insulin. An increasing number of people with T1D are using technologies such as continuous glucose monitoring devices, insulin pumps and closed-loop systems. Around 10% of people with diabetes have T1D.

Type 2 diabetes: people with T2D typically have a metabolic syndrome combining insulin resistance (many still have endogenous insulin) and a cluster of other cardiovascular risk factors such as increased BMI, high blood pressure and abnormal lipid profile. Currently, only a minority of people with T2D use technologies such as continuous glucose monitoring. Most of the remaining 90% of people with diabetes have some form of T2D.

This has important implications for medical undergraduate and postgraduate education, due to the need to foster a better appreciation of complexity. This will be matched by better diagnostics and personalised treatment strategies including through coaching.

### A New Clinic Setup

Experts agree that by 2030, routine clinical practice will have been transformed, with a move towards telemedicine, at the time of the patients' choosing and often in their home. The current system, where less than 0.1% of time is spent with a specialist (and the rest of the time the patient is left to fend for themselves), is far from optimal. Health systems need to rethink the diabetes care paradigm in the face of rapidly increased diabetes prevalence, increased obesity, and serious long-term negative outcomes.

*“ This is the end of the routine clinic appointment. ”*

Most routine care (80% of episodes) could be handled fully via telemedicine. Much of this could be via artificial intelligence (AI) and smart algorithms, or even with an Avatar as clinician. This is virtual diabetes care. In contrast to today, there will be much better support between telemedicine visits and more individual care in response to acute episodes (i.e. the other 20% of consultations, including situations such as a new diagnosis, change in therapy, emergency episodes, and intercurrent illness).

Functioning electronic health records are crucial to a virtual clinic and digitally enabled care in general. They pool available data in one place and allow it to be translated into valuable information that can drive better decision making and thus improve individual and societal outcomes. Policymakers have been preoccupied by privacy concerns, but these concerns are now outweighed by the inflating costs of diabetes care and the potential benefits for people with diabetes. Experts believe that people with diabetes would be willing to share their data with diabetes teams given a sense of mutual respect and trust. People with diabetes will be much better informed and empowered following the provision of better education.

### The Risks of Social Inequality and Lack of Access

While interviewees were generally optimistic, concern was expressed by some that socio-economic factors, including poverty as well as lack of digital and health literacy is a serious barrier for virtual diabetes care. Many people do not and will not have the resources or capabilities to interact digitally. A joined-up healthcare system with an electronic health record is a crucial prerequisite to realise the vision of a virtual diabetes care model.

### 'Smart' Technologies that will Change Practice

There has been a giant leap in digitisation because of the Covid-19 crisis, accelerating the use of telemedicine and strengthening the foundations for more integrated AI in diabetes. The experts' view is that this digital transformation will be driven mostly by the needs and experience of the people with diabetes. A simple analogy here is the smartphone, which was designed with the user journey in mind and is now widely available, easy to use and fully interoperable.



The use of AI will increase, as will precision care, not so much from genetics but from much better physiological and behavioural phenotyping. This will lead to the identification of sub-groups, greater use of individual parameters and better customised coaching. Clinical care will be mainly telemedicine, often by an avatar as clinician who could handle most routine care with face-to-face consultations available on demand.

People with diabetes could own, access, or even commercialise their data more seamlessly across systems and geographies. Patient-led projects regarding data (such as dedoc.org and diabetes.co.uk) will have much greater power and influence on future drug and technological developments. Data should be integrated from different sources (e.g. continuous glucose monitoring, EKGs, wearable devices) and will be further enabled by AI to tailor care to the individual, allowing for specialist review in cases of higher diabetes distress. People with diabetes will have greater responsibility for self-care, but they will also be greatly empowered by new technology.

Continuous Glucose Monitoring will be used in T2D management and for those at risk of developing T2D, allowing for much earlier interventions. Hypertension management systems will have a renaissance, especially in light of the Covid-19 experience. There will be much better home blood pressure monitoring technology. Non-traditional outcomes such as sleep (a surrogate of wellness) will receive much more attention. Food monitoring and control (which is still very weak) will improve, with more accurate recording of both food composition with a focus on carbohydrates and caloric content, as well as the food that is actually consumed.

Sensor technology will be universally used. Closed loop systems currently represent a remarkably diverse array of systems with multiple software platforms. These are likely to become interoperable in the future. An AI advisor system could become a commonly used option to support whatever treatment is being used, helping to interpret data and confirm dose titration.

“ Some people still struggle with technology, even with a phone call, or downloading home glucose data. Lack of education is a serious barrier for virtual care. ”

### Data Platforms and Supply Chains

New platforms will be developed to support the assimilation and integration of data (continuous glucose monitoring, other devices, etc). Remote testing, including drive-by services, will be available as needed, with electronic health records key to progress.

Automated interventions will be needed to cover staffing shortages, particularly in primary care, which will struggle to cope. There will be a need for regional digital centres to monitor whether a treatment or therapy fits the individual person’s needs. Diabetes education and support will be available online and across time zones. Supply chains will also adapt, for example with new drone delivery systems for medicines and medical devices, meaning patients could have rapid access to their treatment supplies.

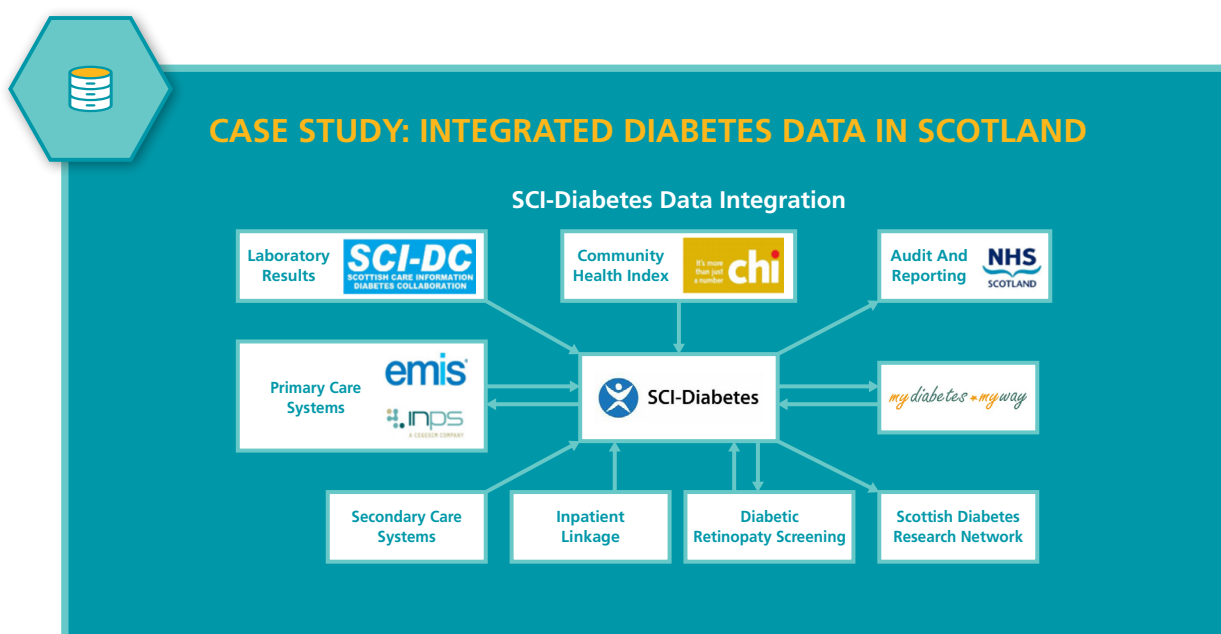


Figure 2: Data integration as seen in Scotland could become a standard across Europe, and promote better decision-making and advance diabetes care outcomes across Europe.

Source: Dr Brian Kennon, National Clinical Lead for Diabetes, Queen Elizabeth Hospital, Glasgow



## The Challenges Arising from Digitising Diabetes Care

Despite these exciting technological trends, numerous challenges have been highlighted that might obstruct or limit the uptake of digital innovation into daily practice.

### Data Privacy, Security and Trust

Legal protection of data security and data privacy are concerns shared by most interviewees. The misuse of healthcare data is seen as a real risk. Healthcare data needs to be handled under the strictest compliance with the EU General Data Protection Regulation, and consistently integrate existing and upcoming EU ethical principles related to AI when further developing digital diabetes care. This will help to maintain and improve societal trust in digitisation of diabetes care. Digital health literacy and transparent communication will also be critical to foster trust in the security of data and systems of care.

### Costs

Costs remain a major challenge for diabetes care. Investing now to save on preventable complications in the longer term remains an issue, as governments usually work on 3 to 4-year timelines and with highly siloed budgets. An increased use of technology ultimately comes with an investment, and this might not reduce direct healthcare expenditure for diabetes care and digitalisation in the short-term. However, if solutions are simple, effective, and achievable for most diabetes population segments (an analogy is smartphone applications), they can be a key element to manage the condition and prevent progression or postpone a deterioration of the disease status. This will ultimately help to avoid or reduce long-term healthcare and societal costs.

### Inequality

The 'digital divide' could become an example of social and educational inequality. Many people will continue to lack access, health literacy, and education to engage with the digital transformation of care. Current clinical practitioners may also lack the skills to identify whether people have actually gained the necessary knowledge to self-care. More positively, regional and wider geographical distribution of care will become more equal as experts will be able to access isolated and marginalised social groups more easily.

### Changes in Medical Practice

Medical practice itself is confronted with the many changes entailed in the digital transformation. The role of the specialist will change greatly, from that of an in-person clinician to more of a manager of larger clinical cohorts from a distance. The increase in telemedicine will necessarily impact the doctor-patient relationship, with reduced eye contact and the possibility of touch. One example cited is that of a paediatrician, whose care benefits greatly from seeing a child in person to assess his or her overall wellbeing and progress (e.g. clothing, care, developmental status, interaction with parents and others).

## Chapter 2. Stakeholder Perspectives on the Future of Diabetes Care

In addition to the common themes and challenges outlined above, respondents reflected upon specific, desirable changes for individual stakeholder groups for diabetes treatment and care to enter into a new, better era.

### The Person with Diabetes

Respondents set out a positive picture overall for people with diabetes, with improvements in care driven by better technology and medicines, as well as a more holistic approach.

#### Decreased Burden

Experts see a significant lessening in the daily burden of living with diabetes, with a resulting improvement in quality of life. Quality of life and wellness include important desired non-traditional and not directly medical outcomes, such as improved sleep and time in range (the proportion of time when the blood glucose level is within safe and pre-defined limits, i.e. not too high or too low). Several interviewees (people with diabetes as well as clinicians) stressed the importance of these quality of life parameters in living with diabetes. Greater autonomy for the people with diabetes and having access as needed to specialist input would help. While these benefits are likely to apply to many with T1D, this might not be the case for older people, especially with T2D. Interaction with complex IT systems and loss of one-to-one contact with clinicians could be a problem for these individuals. Giving more responsibility to people for self-care might in fact increase their burden while still reducing their dependency on the physician.

#### Empowered Patient as *Customer*

Several interviewees described a future diabetes care service that is much more customer-focused and egalitarian. The service will be based on need and ability to respond to need. People with diabetes will have much more say in when and how to be seen. They will have more power and will play a much greater role in informing policy and guidelines. These policies and guidelines will be much more on the terms of people with diabetes. Coaching and support in clinical care will be provided by 'people like me' as opposed to the traditional clinical setting.

“ Sleep quality is a surrogate of wellness for people living with diabetes. ”

“ People with diabetes will become decision-makers, enabled by remote technologies and greater freedom of choice. ”

#### The Clinical Visit

Different views emerged on how the clinical visit will evolve. Respondents generally agreed that the traditional routine diabetes clinic (often 3-monthly) visit will disappear. In the future, it is likely that visit formats will vary according to the personal preference of the person with diabetes. Some will prefer to have problem-oriented visits on an as-needed basis. Some will want open-ended access to discuss anything, including non-diabetes issues. Nevertheless, there will be a move towards shared decision-making and shared ownership, which will require training, and which can be digitised and leveraged.

## The Health System

Experts see the need for health systems to evolve in order to deal with the rising prevalence of diabetes. They also addressed key themes, including 1) clinic function and manpower, 2) information systems, 3) the need for long-term policy and planning, and 4) funding at every level.

### Clinic Function and Manpower

The lack of diabetes specialists is forecast to be a rapidly escalating problem over the coming years across Europe as the number of people with diabetes is expected to continue to increase and potentially overwhelm services. Experts feel that tasks will need to be allocated in a different and better way between allied health professionals, primary care practitioners and specialists, allowing the latter group to focus on prioritised complex cases. Clinical care will also shift away from individual clinical care towards population health.

“ *The coming decade will be about the healthcare workforce, where there will not be enough practitioners and clinical specialists to cope.* ”

### Lack of Electronic Health Records as an Obstacle

An effective population approach requires an adequate electronic health record, which is currently lacking in many regions in Europe. One expert stated the need for a single European electronic health record. Another stated that integration is the common denominator and crucial point for future IT systems. There should be a single platform for the download of any and all devices. The same system should be shared by all healthcare stakeholders – above all, by people with diabetes.

“ *Annual budgeting and 4-year governmental cycles simply are not suited for diabetes management.* ”

### Policy Planning and Timescale

Political cycles are too short to allow strategic planning for diabetes. Providing the right policy framework to create the virtual diabetes clinic needs a strategic long-term view over decades. This, in turn, should focus on outcomes and not clinical processes. This is the main political task.

### Costs

The current costs of diabetes are unsustainable. A future approach to proper funding of care needs to be viewed more as investment, with emphasis on value-based care. More work is required to assess the costs and benefits of telemedicine, as well as to assess and predict reimbursement of care delivered by telemedicine. A critical component of the cost debate in the next decade will be efforts to address the reduction of risk of developing T2D in those at risk.

“ *Systems are spending a lot of money on the consequences of diabetes because intervention takes place too late. We need to shift resources to prevention and into the early stages of disease progress.* ”

## Industry: Changing Business Paradigms

Interviewees focused on the role being played by both the medical technology and the pharmaceutical sectors in the digital transformation of diabetes care. Roles are changing and the sectors are moving closer together with some shared goals. Both sectors aim at offering value and not just new products. Several experts stated that there has been a false dichotomy between the two sectors and that they will increasingly merge in the field of diabetes.

### Providing Leadership

Interviewees across the spectrum agreed that it is industry and not the clinical world that is currently leading the digital transformation of diabetes care. Furthermore, it is expected that healthcare systems will increasingly adopt a value-based approach, where digital care will become a significant factor and where industry supports an increased patient focus.

### Safety, Quality, Access

Almost unilaterally, respondents highlighted a speed gap between industry developments on one side and adoption rates on the other. Expert views underscored that EU regulatory frameworks must be able to ensure the availability of safe technology at high quality to people with diabetes without sacrificing innovation and technological breakthroughs. The newly adopted medical devices and in vitro diagnostic medical devices regulations that are currently being implemented across Europe are an important pillar of this necessity.

Another challenge is around financing and ensuring access to services and technologies. Diabetes has unfortunately been relegated to the category of a common disease, with payers and purchasers taking a penny-pinching approach to financing (in contrast to cancer, for example). The development of a more personalised approach to diabetes care based on the sub-classification of the disease, risk and treatment options will help. The use of big data will enable a truly value-based approach, as it will identify who responds to treatment and monitor adherence. With this approach, there should be a parallel differential approach to reimbursement and other business models, such as procurement for innovation based on value in the longer term, whilst real-world evidence is still being generated.

### Partnerships and Convergence of Sectors

There are many reasons why the convergence of solutions from different industry sectors makes sense. The Covid-19 pandemic could accelerate this process towards higher collaboration and integration based on value-based care and accountable care. Partnerships that integrate medical technology, pharma and information, communications and technology solutions, with a clear focus for patient journeys and developing holistic care, will be the most successful.

### Clinical Research

The virtual environment for most clinical care will create the need for significant adaptation in how clinical research is organised. The data quality standards required for clinical research and clinical trials are significantly more stringent than in routine clinical practice. Questions arise on how to assess laboratory results and real-life evidence, how to monitor adverse events and how to adjudicate them when most contact is virtual. Recruiting patients for clinical research will be a new challenge. It was stated that this challenge will create the need to develop new best practices for research and to maintain study integrity.

### New Industry Players

Innovation is continuing at a rapid pace. Tech monitoring and digital devices may play a much bigger role in the future of diabetes care. Furthermore, private companies outside the traditional health technology sectors will enter the diabetes field and demonstrate success (e.g. Livongo, Babylon Health, Orbimed, Janacare). In the future, sectors in the areas of food or gaming are likely to become value-adding partners in digital diabetes care.

## The Healthcare Professional

The major highlights for change by 2030 with regards to the healthcare professional include:

- Care will move from the single clinician to a team-based approach (with allied health professionals)
- Care focus of the clinician will shift from the individual to the population
- Care will shift in 80% of consultations from in-person visits to telemedicine (the virtual clinic)

Technology will have a profound impact on the relationship between healthcare professionals and people with diabetes. As virtual care becomes more prominent, diabetes could be managed by algorithms, with consultations moving to virtual environments empowered by data. This will lead to a change in the doctor-patient interaction, ideally with equally informed patients and doctors. Both will have access to the same data and data interpretation.

### Better Use of Specialist Time and Expertise

Specialists will be able to focus on problem-solving in more complex cases, including the 20% in-person and non-telemedicine consultations. The specialist role will continue to change, with a greater emphasis on consultation, supporting networks of primary care, managing clinical quality, and seeing more complex cases that require personal intervention. The specialist, rather than managing patients one by one, will provide a sort of concierge service e.g. able to support networks of clinicians in different disciplines. The specialty of diabetes itself is evolving to better address the complications and closely related clinical patterns that are diabetes 'adjacent' like obesity and non-alcoholic fatty liver disease. Cardio-metabolism is a new and developing medical specialty, recognising the significance of vascular complications in diabetes treatment and the need to prevent them.

### A Digital Front Door to Better Outcomes

The current divisions between primary, secondary and specialist care will disappear if the new system is integrated based on a common electronic health record. One respondent described this system as a 'digital front door' between primary and secondary care. Such a system offers real-time feedback after each clinic consultation and in each setting. This allows benchmarking for all clinical parameters, including HbA1c, blood pressure, cholesterol, etc., as well as for patient satisfaction. This allows real-time adjustment and correction for weaknesses. Such a system will rely on common agreements between all participants on clinical and non-clinical outcomes. Steno Diabetes Center Copenhagen and Diabeter in the Netherlands are European examples of this approach already in action, where clinical care is guided by common agreement on targets and outcomes.

### Attracting Talent

There is a fear that talented clinicians will not see diabetes as an attractive specialty choice. Precision medicine and new technological options could make it a more attractive speciality, however. To support these developments, there will be a need for much more specialised training for nurses, doctors, and allied health professionals who work in diabetes care.

## Regulatory Processes

Regulatory frameworks for processing data will need to evolve and speed up to realise the digital transformation of diabetes care by 2030. The EU data strategy and the initiative for a European Health Data Space are pointing in the right direction. These frameworks need to provide rules applicable and relevant for healthcare. They need to ensure legal clarity for all actors, and avoid overlap with existing legislation, such as the new regulatory frameworks for medical devices and in vitro diagnostics or the EU General Data Protection Regulation (GDPR) rules, which already include key elements of regulating 'digital elements'. The Covid-19 crisis could be a catalyst to accelerate the response to these open questions regarding data and digital transformation.

There is a need for increased expertise on digital solutions among regulators both in the pre-market phase before a product or solution is available on the market (for CE marking) and the post-market phase, when the product or solution is already available on the market (for decisions on access). It is also crucial to consider the correct attitude to risk mitigation and ultimately what degree of uncertainty is acceptable for a given technology application. Regulators of other global regions such as the US have paved the way to embrace digital health, and regulators in Europe EMA need to do the same.

This also applies to the work of Health Technology Assessment (HTA) authorities, as some interviewees were critical of their level of independence and objectivity.

Many respondents see the future of regulatory processes relying on at least the following elements:

- Real-world data used in combination with – not replacing—randomised control trials
- Interoperability of systems through standardisation and/or a robust electronic health record
- Ensuring security and privacy
- Misuse of data being punishable by law

There are some promising models of political action that embrace digital care. One of these is the reform of the German health system in 2020.



### CASE STUDY: GERMAN DIGITAL HEALTH REFORM

In November 2019, Germany passed the Digital Care Act (“Digitale-Versorgung-Gesetz”) as part of its efforts to promote healthcare digitisation. Among other things, the new Digital Care Act encourages doctors to offer video consultations and informs patients of this option. This also allows patients to find practitioners that offer remote consultations more easily. Additionally, as of 2020, doctors can prescribe digital applications, and German health insurers must reimburse approved applications, including for diabetes management. The new Digital Care Act will also allow patients to use an ‘electronic patient file’ “nationwide and as soon as possible”, and the new Act obliges pharmacies and hospitals to comply by September 2020 and January 2021, respectively.<sup>5,6</sup>

5) <https://www.bundestag.de/dokumente/textarchiv/2019/kw45-de-digitale-versorgung-gesetz-664900>

6) <https://www.bundesgesundheitsministerium.de/digital-healthcare-act.html>

## Looking Ahead & Recommendations

The Covid-19 crisis has accelerated progress towards digital, interconnected diabetes care and has highlighted the need for a future diabetes service to better match the individual needs and circumstances of people with diabetes. The viral pandemic should be a turning point in healthcare delivery, marking the end of the routine clinic appointment for chronic medical conditions like diabetes. The current system, where only a tiny fraction of time is spent with a diabetes specialist, seems outdated and inadequate to meet the expectations and needs of people with diabetes today. A digital transformation allowing for connected and integrated care with the person with diabetes, rather than the clinic setting itself, is achievable. To succeed in the longer term, however, the digital transformation will need to be supported by electronic health records and common, shared data platforms, as well as by appropriate financing models that embrace digital, patient-centric, integrated care solutions and approaches. The inputs from a wide spectrum of stakeholders and leaders in the field has been striking in the level of agreement on these key points.

The main caveat for this vision of future care is that inequalities due to poverty, socio-economic factors and lack of education could limit the impact of virtual diabetes care. Many people do not and may not in the future have the financial and non-financial resources to interact digitally – resulting in a digital divide in the population.

### What are the main recommendations for the future?

#### 1. Validate the experience of telemedicine during the Covid-19 pandemic

The shift to remote consultations and telehealth during 2020 has been rapid and widespread. Despite the background stress and worries about Covid-19 infection, many positives have been reported both by people with diabetes and healthcare practitioners. The different impacts of these changes need to be documented and studied. Data will become available on many positive aspects of this experience, from resource use, clinical parameters, short-term outcomes, economic costs through to customer satisfaction. It will be crucial for future policymaking to document and validate this experience in Europe.

#### 2. Engage people with diabetes at the forefront of policymaking and service development

It has become increasingly clear that people with diabetes can have a major input to policymaking and to the design of a future clinical service. By sheer numbers (one in ten people in Europe have diabetes) people with diabetes have a powerful public voice and potential influence on political decisions. A future diabetes service that is more egalitarian and customer-focused is now within reach, where the care provided is based on need and can respond to individual changes in real time. People with diabetes should be empowered further to stimulate digital transformation by having their demands and expectations heard.

#### 3. Clearly articulate the case with policymakers for future diabetes care, based on data, outcomes (rather than process) and value

The diabetes community needs to articulate its case very clearly for digitally enabled transformation of care. The costs of complications such as myocardial infarction, stroke, amputations and kidney failure are all largely preventable, and the diabetes world must be much more assertive on this to shift the agenda from other areas of healthcare that currently attract political attention and funding. The type of data and IT infrastructure needed to provide excellent diabetes care are relatively simple and pragmatic, and they should be clearly explained in policy development.

The future vision for excellent diabetes care rests upon the needs of people with diabetes, the availability of necessary data to people with diabetes and clinicians in a fully integrated system, and on supporting technologies that allow for autonomy, precision, and personalised care. Instruments like value-based healthcare, as well as appropriate up-to-date financing models, are furthermore indispensable for making people-centric, integrated and digitally enabled care a reality in what is hopefully the near future.



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