

efpia*

vfa Die forschenden
Pharma-Unternehmen

ENABLING SELF-EFFICACY THROUGH DIGITAL TECHNOLOGIES AND INNOVATIVE THERAPIES



Patients have the tools to measure and record data and, increasingly, have access to innovative technologies and therapies that give them an active role in their care. This offers unprecedented opportunities for secondary prevention and behavioural changes and can spare people with diabetes from suffering complications that result from poor glucose control. But which digital health interventions could be most beneficial for people with diabetes? How can data sharing improve outcomes, reduce health system costs and support up-take of innovative approaches to diabetes management and care? What are the barriers that need to be overcome in order to benefit from innovative technologies and therapies?

In order to explore these questions and build consensus on possible policy solutions, EFPIA and vfa convened a multi-stakeholder roundtable in Berlin on 13 September 2019. The purpose was to share different stakeholder perspectives on the barriers and opportunities of digital tools and innovative therapies and to explore the value of innovation in improving diabetes care and outcomes. These insights provided the backdrop to a roundtable discussion that engaged all participants to address three core questions:

1. What should be the role of digitalisation, technology and innovative therapies in improving health outcomes for people with diabetes?
2. What are the barriers and opportunities that need to be addressed in order to benefit from these approaches?
3. How can these tools best support self-management for people with diabetes?

1. WHAT SHOULD BE THE ROLE OF DIGITALISATION, TECHNOLOGY AND INNOVATIVE THERAPIES IN IMPROVING HEALTH OUTCOMES FOR PEOPLE WITH DIABETES?

1.1 Precondition for value-based healthcare

The data-driven generation of individual healthcare parameters, in addition to their interpretation, is an essential prerequisite for value-based healthcare. The success of a treatment should not only be measured by the effect of isolated procedures or general outcomes (such as mortality rates), but also by its value for the individual patient. To achieve this, a continuous measurement of clinical and patient-reported outcomes is needed, which in turn can only be achieved by a common data infrastructure, easily accessible standards for treatments and central point for the collection of patient outcomes data.

The comprehensive and continuous collection of data, complimented by digital tools, can also support the personalisation of care for people with diabetes. At the same time, health data can enable researchers to identify significant impacts on patient outcomes as well as to develop tailor-made treatments.

1.2 Empowering people with diabetes

Modern diabetes measurement systems collect numerous data points which can support people with diabetes in their self-management. The analysis and interpretation of one's own data strengthens the understanding of a person's own body. Digital tools can be more than mere data collectors – they are learning tools that have been proven to increase therapy adherence and empower people with diabetes to manage their condition in a more effective way.

Digital applications can provide people with diabetes with important information that allow them to have an informed dialogue with their doctor. Together, they can discuss, evaluate and interpret an individual's data and create an optimised therapy plan to achieve a person's therapy goals. The sheer number of data as well as the growing knowledge about the disease and how to deal with it, enable all actors involved to adapt the therapy to the individual progression of the disease. Without the collection of corresponding data, it would be challenging to individualise care in a way that considers the complex nature of each individual's condition.

1.3 Healthcare transformation

The digital transformation leads to a healthcare paradigm shift. Today, the ability to digitally record, pool and evaluate data offers a unique opportunity to significantly improve clinical and patient-reported outcomes in diabetes care and management as well as patients' self-management.

Identifying and exploiting these potentials demand an adequate database at both the individual and collective level. However, the necessary data sets are not widely available due in part to regulatory barriers (see section 2.1). In the age

of an arguably unstoppable digitalisation, this means that alternative solutions must be considered. One option might be to store data according to the methodology of "negative consent", meaning that patients would not have to agree to the collection of their individual health data, but to explicitly reject it, as is common in the United States. In this case, data sovereignty remains with patients, while the amount of data that physicians and scientists could use to develop innovative and even more specific treatments would increase dramatically.

2. WHAT ARE THE BARRIERS THAT NEED TO BE ADDRESSED IN ORDER TO BENEFIT FROM THESE APPROACHES?

2.1 Regulatory barriers

The use of digital technology in diabetes healthcare is still an exception in most countries in Europe. Among other reasons, this can be explained by regulatory barriers to both market access and the prescription of technologies by the treating physician.

The different interpretations of the General Data Protection Regulation (GDPR), which came into force in May 2018, also present a challenge. While some regions and Member States such as Estonia interpret the new data protection directive rather liberally, this approach does not apply to all countries. In Germany, the existence of no less than 18 different national Data Protection Authorities (DPA) with a wide range of differing approaches is aggravating. Given that Germany considers itself a champion of personal data protection, it is hardly surprising that the relevant authorities view the nationwide introduction and use of digital technologies in the health sector very sceptically. As a result, established and market-ready technologies are not reimbursed by health insurance companies and thus are not readily available for people with diabetes.

An additional concern is the implementation of the Medical Devices Regulation (MDR). First there is a legal uncertainty, as downstream legal acts for its implementation are still missing. Secondly, there is a shortage of Notified Bodies, which are responsible for the conformity assessment procedures for medical devices. The result will be a slowdown in market access for many medical devices – to the disadvantage of people with diabetes.

Finally, the lack of interoperability of modern digital solutions remains a major challenge. If pilot projects and isolated solutions are to be rolled out across Europe, it will be necessary to guarantee complete interoperability in the future. Therefore, the definition of clear technical standards and requirements that all innovative digital products must meet is necessary. Only technology-open, updatable, intersectoral and interoperable system solutions fully benefit people with diabetes.

2.2 Policy barriers

At the political level, decision-makers clearly struggle to strike a balance between ensuring product safety, necessary levels of data protection and the fastest possible market introduction of digital innovations. Differing views of the responsible bodies (including Ministries, Parliaments and Data Protection Authorities) result in compromised solutions which limit the benefits for people with diabetes.

The new Digital Care Act in Germany, which is currently under parliamentary review, is an example of this issue. While other European Member States have already made considerable progress in promoting digital health innovations, the German government is only now introducing a "fast track implementation" for digital medical devices. However, the new regulation only applies to medical devices up to risk class 2a, which excludes the rapid market introduction of quality-of-life-enhancing diabetes tools such as the close loop system.

In the future, decision-makers need to act collectively in order to maximise the potential of digitalisation and digital tools for diabetes care. The widespread "silo budgeting" makes it difficult to roll out successful pilot projects and make modern forms of medical care accessible to all people. When it comes to political solutions, a holistic strategic approach rather than the lowest common denominator between the involved stakeholders is essential – at both the national and European level.

2.3 Practical barriers

Even if innovative diabetes tools are successfully developed, approved and reimbursed, there are further barriers that need to be overcome. The median age of people with diabetes is more than 60 years, and the physicians treating them are usually not much younger. The individuals involved in the treatment process are generally people who have grown up without any

digital tools, which suggests that their affinity for digital healthcare is significantly lower than younger people. Conversely, there is a need to educate people with diabetes and assist them to use digital tools. Only then can they benefit from the potential of digital innovations in everyday life.

The same applies to the health professionals involved in diabetes care and management. They do not only need to be familiar with digital healthcare solutions, but also with their use in order to provide people with diabetes with the necessary assistance. Accordingly, digital healthcare should be an integral part of their training. In addition, in order to increase digital affinity and improve usability of digital tools and technological devices, it is advisable to involve end-users in the development process from the start.

3. WHAT ARE THE OPPORTUNITIES THAT NEED TO BE ADDRESSED IN ORDER TO BENEFIT FROM THESE APPROACHES?

3.1 Education

The removal of the existing barriers will be key to advancing the digital transformation of the healthcare system. However, such measures alone are not likely to be sufficient. There is still a wide-spread degree of scepticism regarding the use of collected health data. Education is needed and might be able to highlight the numerous advantages and potentials of greater utilisation of data.

3.2 Incentive systems

Financial incentives can be considered an adequate instrument for influencing collective behaviour in a sustainable and long-term manner. To advance the digitalisation of diabetes care, the European Union and its Member States need to ensure that neither people with diabetes nor medical personnel are penalised for using or prescribing digital tools. On the contrary: a value-based procurement system should be set up to financially support service providers in researching and developing innovative digital tools.

Regarding the medical prescription of digital applications, it is important to ensure that physicians do not suffer any financial disadvantages as a result of people with diabetes abstaining from visiting the doctor. The additional costs incurred, such as the cost of training patients in using innovative digital tools, need to be reimbursed accordingly.

While financial support in various ways alone is not sufficient, it nonetheless represents a necessary precondition to improve diabetes care in Europe. Such support should be provided across the whole European territory and must not be limited to individual players, countries or regions.

3.3 A role for Europe

The promotion of digital health should be made a priority during the mandate of the new European Commission. The European Union should press for the removal of existing barriers, enhance collaboration between all Member States in the field of digital health, establish exchange platforms for sharing best-practices and proactively promote digitalisation.

4. HOW CAN THESE TOOLS BEST SUPPORT SELF-MANAGEMENT FOR PEOPLE WITH DIABETES?

4.1 Personalisation of devices

Digital solutions have to address the daily medical needs of people with diabetes. People concerned will only accept and use applications and solutions that have a real and practical impact in their everyday lives. This means that the digital devices must be structured in such a way that they simplify the lives of those affected and are easy to use.

4.2 Enabling self-management for people with diabetes

Digital solutions have the potential to encourage people with diabetes to actively engage in order to improve their health-outcomes and live as carefree as possible. Currently, the highest usage of digital tools is seen within people with type 1 diabetes. However, to ensure that the large population of 90% of people with diabetes is also using them, it is critical to make digital solutions available to support people with type 2 diabetes.

4.3 Complementation of medical treatment

Digital devices can fundamentally support the therapy of people with diabetes. Despite all progress and opportunities arising from digitalisation, the human factor in treatment cannot be neglected. The role of physicians should be enhanced rather than being replaced, as digital tools should be implemented when they offer potential efficiency savings, for example by improving adherence to therapy.

4.4 Support in doctor's communication

Telemedicine tools such as video consultations can make it easier for physicians and patients to interact. Additionally, they make it possible for people with diabetes to consult a doctor only when necessary. This eliminates the need for additional, time-consuming routine examinations.

5. SHARING INSIGHTS AND EXPERIENCES

5.1 Data-driven patient pathway management, Hungary

Throughout Hungary patients' pathways and mobility can be tracked with the help of the diagnosis-related group (DRG) system and a specific national system for organising health data. Digital mapping of these cumulative data makes it possible to identify unnecessarily long patient pathways and a possible shortage of medical services in different regions. Political decision-makers can then draw conclusions from the information for the improvement of integrated medical care, such as establishing specialised centres in regions with particularly high prevalence. This example demonstrates the importance of health data collection and aggregation in order to derive appropriate policy solutions that support healthcare system efficiency and improved outcomes for people living with diabetes.

5.2 Diacare project, Catalunya, Spain

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

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

5.3 Value-based procurement systems for digital innovations

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

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

Annex 1: Programme

9.00 – 9.10	Welcome and introduction	Dr. Nick Fahy, Senior Researcher, University of Oxford (moderator) Milena Richter, Co-Chair, EFPIA Diabetes Platform Udo Schauder, Representative, vfa Diabetes Alliance
9.10 – 9.20	Setting the scene and European context	Prof. John Nolan, Executive Director, European Diabetes Forum; Special Advisor to the President, EASD; Adjunct Professor, Endocrinology and Metabolism, Trinity College Dublin
9.20 – 9.35	National German experience with using digital tools <i>How people with diabetes are using digital tools to support them in managing their condition?</i>	Bastian Hauck, CEO & Founder, #dedoc° Diabetes Online Community
9.35 – 9.45	Non-German experience with using digital tools	Dr. Miklós Szócska, Director, Institute of Digital Health Services of Semmelweis University, Budapest, Hungary
9.45 – 10.45	Roundtable discussion on the barriers and opportunities of digital tools and innovative therapies	
10.45 – 11.10	Break	
11.10 – 11.55	Workshop session <i>The following thematic areas will be addressed in a workshop setting:</i> <ol style="list-style-type: none">1. <i>What should be the role of digitalisation, technology and innovative therapies in improving health outcomes for people with diabetes?</i>2. <i>What are the barriers and opportunities that need to be addressed in order to benefit from these approaches?</i>3. <i>How can these tools best support self-efficacy for people with diabetes?</i>	
11.55 – 12.15	Plenary <i>Highlight key conclusions, themes and recommendations</i>	
12.15 – 12.20	Concluding remarks	Ulf Birke, Manager Health Policy, vfa Milena Richter, Co-chair, EFPIA Diabetes Platform

Annex 2: Participant list

Name	Job Title	Organisation
Dr. Alexander Schellinger	Team Leader Development Supply Management	Techniker Krankenkasse
Bastian Hauck	CEO & Founder	#dedoc° Diabetes Online Community
Dr. Carsten Michels	Manager National Healthcare Affairs	Boehringer Ingelheim
Clemens Kuhne	Director Policy & Patient Engagement, Head of the MSD Hub Berlin	MSD
Daniela Rimpf	Patient Relations Manager Market Access & Public Affairs	NovoNordisk
Gesa Schöttke	Consultant	FIPRA
Joan Escudero	Business Development and Innovation Director	PULSO
Lukas Löffler	Consultant	FIPRA
Maurizio Guidi	Diabetes External Engagement Leader EUCA	Lilly
Dr. Miklos Szócska	Director	Institute of Digital Health Services, Semmelweis University
Milena Richter	Co-Chair	EFPIA Diabetes Platform
Nick Fahy	Senior Researcher	University of Oxford
Prof. John Nolan	Executive Director, Special Advisor to the President, Adjunct Professor, Endocrinology and Metabolism	European Diabetes Forum EASD Trinity College Dublin
Roberta Savli	Senior Manager Healthcare Systems	EFPIA
Sorina Chivu	Senior Account Executive	FIPRA
Dr. Stefanie Gerlach	Head of Health Policy	DiabetesDE
Dr. Thomas Kostera	Senior Expert	Bertelsmann Stiftung
Thomas Renner	Head of Sub-Department Digitalisation and Innovation	German Federal Ministry of Health
Sabrina Vité	Head of Health Policy and Communication	German Diabetes Society (DDG)



The **EFPIA Diabetes Platform** brings together six companies whose aim is improving the lives of everyone affected by diabetes. Together with various stakeholders across the research and health community, we look at how to improve diabetes management and to reduce complications.

vfa is the German Association of Research-Based Pharmaceutical Companies.

**We remain ambitious about the future for people living with diabetes. Through research, better management and collaboration,
#WeWontRest until diabetes is defeated.**