The Promise of Digital Tools in Diabetes

A roadmap for apps

European Diabetes Forum

EXECUTIVE SUMMARY

Digital technologies are driving significant changes in healthcare, offering new solutions to assist in preventing, diagnosing, and treating chronic diseases. Diabetes is ideally suited to benefit from these types of digital tools, given it is a largely a self-managed condition, and especially data-driven.

The following document and series of recommendations, compiled by a representative group of the European Diabetes Forum consisting of healthcare professionals (HCPs), researchers, industry representatives, and people with diabetes, focuses on one crucial aspect of this digital revolution: mobile health applications, or "apps". Mobile apps is a burgeoning field of innovation in healthcare with enormous potential both to help people with diabetes track the multitude of information related to their condition, while also facilitating a more informed and data-driven approach to decision-making from HCPs.

The following document examines some of general benefits of apps in diabetes, before delving into a more specific consideration of the role of medical apps. Medical apps are, appropriately, more tightly regulated and therefore require policy interventions, as they go beyond purposes of lifestyle, motivational, or educational support, and play a role in monitoring, treating, or managing diabetes.

The integration of medical apps into diabetes care poses many challenges. There are many new apps on the marketplace, but regulations and policy solutions must catch up to keep pace with the new technology. Countries are only now beginning to establish further procedures that allow for review, monitoring, and better integration of medical apps into clinical pathways.

The goal of public policy should be to nurture a **responsible and responsive environment that unlocks the positive potential of digital innovation, one that puts the needs of people with diabetes first**. To realise the potential of mobile apps, two conditions must be in place: apps must be easily **available and accessible** to people with diabetes and HCPs, and they should meet high standards of **effectiveness and quality**.

The recommendations that follow offer guidance and best practice examples on developing a user-centred app, on facilitating an access pathway for apps, and on supporting a swift and appropriate integration of medical apps into health systems.

In a continent as diverse as Europe, policy is not a one-size fits all proposition. But new solutions are needed to improve care and outcomes for people with diabetes, and apps offer enormous promise to give people with diabetes and HCPs alike the tools they need to better manage this condition.

A ROADMAP FOR APPS IN DIABETES

1. DEVELOP A USER-CENTRED APP
2. DEVELOP A BEST PRACTICE ACCESS PATHWAY FOR APPS
3. SUPPORT THE INTEGRATION AND UPTAKE OF HIGH-QUALITY APPS INTO THE HEALTH ECOSYSTEM

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THE DIGITAL REVOLUTION IN DIABETES

Digital technologies are driving significant changes in healthcare, offering new solutions to assist in preventing, diagnosing, and treating chronic diseases, while enabling the integration of care across settings and supporting the efficient allocation of staff and financial resources within constrained healthcare systems. Above all, digital technologies can empower patients to have more control and ability to manage their condition.

With 61 million people living with diabetes in Europe, and recent estimates that almost 465,900 deaths in adults aged 20–79 years are attributable to diabetes and its complications, new strategies and technologies are urgently needed to come to grips with what many have called Europe's silent pandemic[1].

Digitally enabled care is particularly relevant for diabetes, as it is a largely a self-managed disease that is also highly data driven. Digital health solutions in diabetes care encompass an ecosystem of different tools and solutions that include connected glucose monitoring systems, smart insulin delivery systems (including wearables), integrated and stand-alone algorithms, digital health applications ("apps"), as well as telemonitoring solutions, e-prescription systems and patient health records.

https://diabetesatlas.org/atlas/tenth-edition/
https://diabetesatlas.org/atlas/ninth-edition/

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OBJECTIVES

Digitalisation is proceeding rapidly in the health sector. Medical and non-medical apps have the potential to improve the self-management and decision-making for people with diabetes, leading to better personalised care and better outcomes. Medical apps can furthermore facilitate communication between people with diabetes, their HCPs and wider care teams, by sharing data and enabling coaching, support and guidance.

Fortunately, there are many countries and healthcare systems that already integrate apps into health systems and into clinical practice. The following guide provides best practices examples from different countries and systems – which features work well, what could be improved upon, how to navigate trade-offs, which outstanding questions need answering.

The paper draws conclusions by providing recommendations on how to facilitate a swift and appropriate integration of medical apps into health systems for the benefit of better diabetes management.

The goal of policy should be to nurture a responsible and responsive environment that unlocks the positive potential of digital innovation, one that puts the needs of people with diabetes first.

To realise the potential of mobile apps, two conditions must be in place:

1. **Apps must be easily available and accessible to people with diabetes and HCPs**
2. **Apps should meet high standards of effectiveness and quality**

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THE ROLE OF APPS

There are many aspects to digitalisation, but this document will focus on digital health applications, or “apps,” on mobile or other wireless devices, as apps are playing an increasingly important role as an interface of this digital ecosystem, thus helping people manage their diabetes.

First, apps can help people living with diabetes keep track of the multitude of information related to their condition, from glucose levels and medications to diet and exercise. Second, apps offer the potential to greatly increase the flexibility and convenience by which people with diabetes can access care; for instance, in communicating with their healthcare providers (HCPs), or electronically renewing prescriptions.

Moreover, apps can enable a more data-driven approach to diabetes. Together with the rest of this digital ecosystem, apps are driving a shift towards a new era of integrated and patient-centred care, in which people with diabetes, HCPs and researchers have access to data that can inform decision-making and lead to better diabetes management.

BENEFITS OF APPS

Track targets

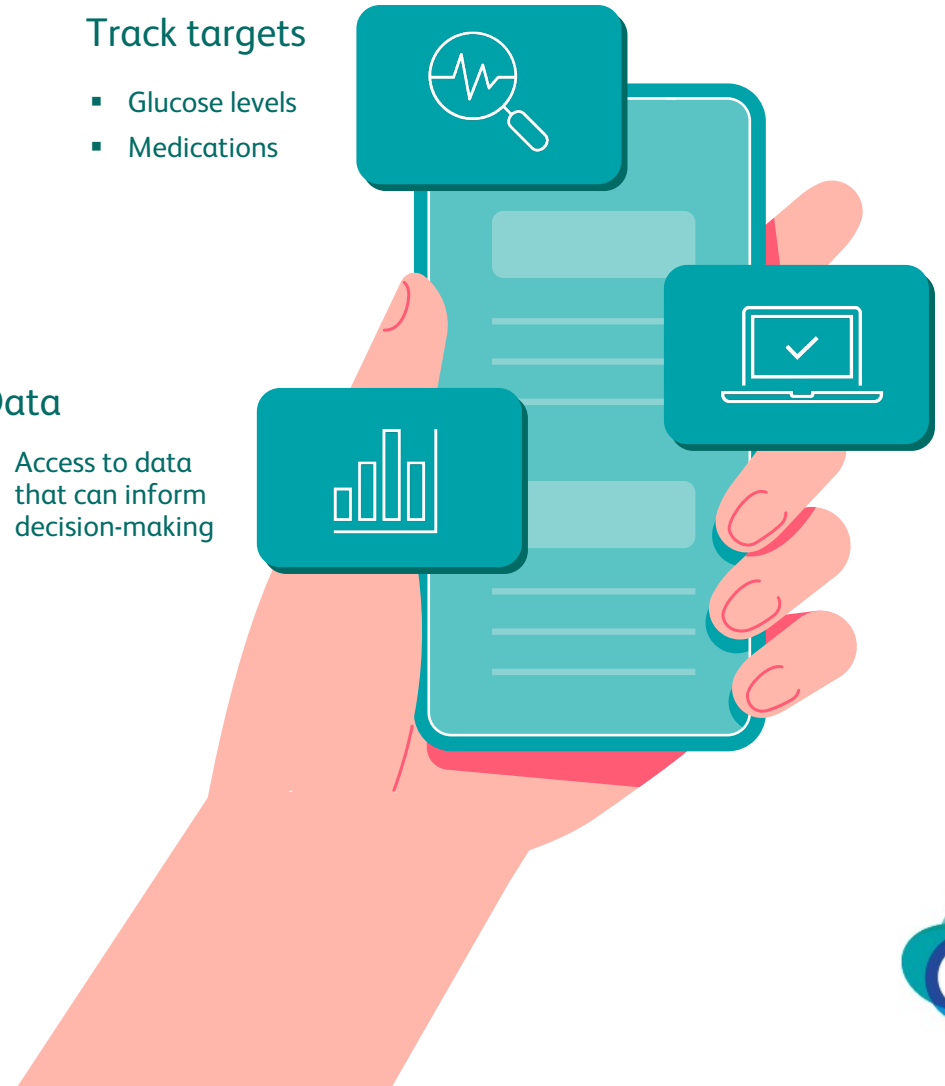
- Glucose levels
- Medications

Data

- Access to data that can inform decision-making

Access to Care

- Communication with HCPs
- Telemedecine
- E-prescriptions



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TYPES OF MOBILE APPS

The term digital health encompasses a wide scope of innovations, devices, services and solutions. They range from electronic health records, electronic medical records, telehealth, connected glucose monitoring and insulin delivery systems, including wearables, integrated and stand-alone algorithms as well as medical and non-medical mobile apps. The particular promise of medical apps is the possibility to link many of these digital health innovations onto easily accessible mobile platforms to improve diabetes management.

Diabetes apps are built in different ways and can serve different purposes. Some apps are stand-alone, while some are integrated into more complex digital systems, such as supporting trending analysis and automation of glucose analysis and management. Some apps focus on lifestyle or wellness factors, such as maintaining healthy weight and tracking diets, while others serve as vectors for information - highlighting guidelines, or providing a means to communicate with health care professionals.

Non-medical lifestyle and wellness apps do not follow the stringent device regulations if they do not have a medical purpose.

On the other hand, there is a growing number of apps on the market that serve a medical function; these are apps that not only serve an information purpose, but actively play a role in monitoring, treating, or managing diabetes.

Such medical apps can be stand-alone or connected e.g. a glucose monitoring system, an insulin pump and/or a sensor. In addition, these apps can be connected to (non-medical) wearables (e.g. smart watches) to feed in real-time information.

A few countries in Europe have begun to actively implement strategies and policies to accelerate the uptake and use of medical apps in diabetes management by developing and implementing reimbursement and access pathways. However, many other countries are lagging behind. More work at the national level and greater harmonisation within the EU will be critical to harness the full potential of these digital solutions.

BENEFITS OF APPS IN DIABETES

People with diabetes

Flexibility

Digital apps can lead to more flexibility, allowing people to better access care when and where they need it. One of the characteristics of diabetes is the need for care is not always constant, but may fluctuate over months and years at a time.

Communication

Smartphone apps can allow for greater connectedness between clinicians and patients, enabling people with diabetes to communicate more quickly and effectively with healthcare providers, maintaining connection with clinics beyond annual check-ups.

Patient Empowerment

Apps can empower people to have more agency over the management of their health and wellbeing. People with diabetes can also have easier access to their own health records through apps.

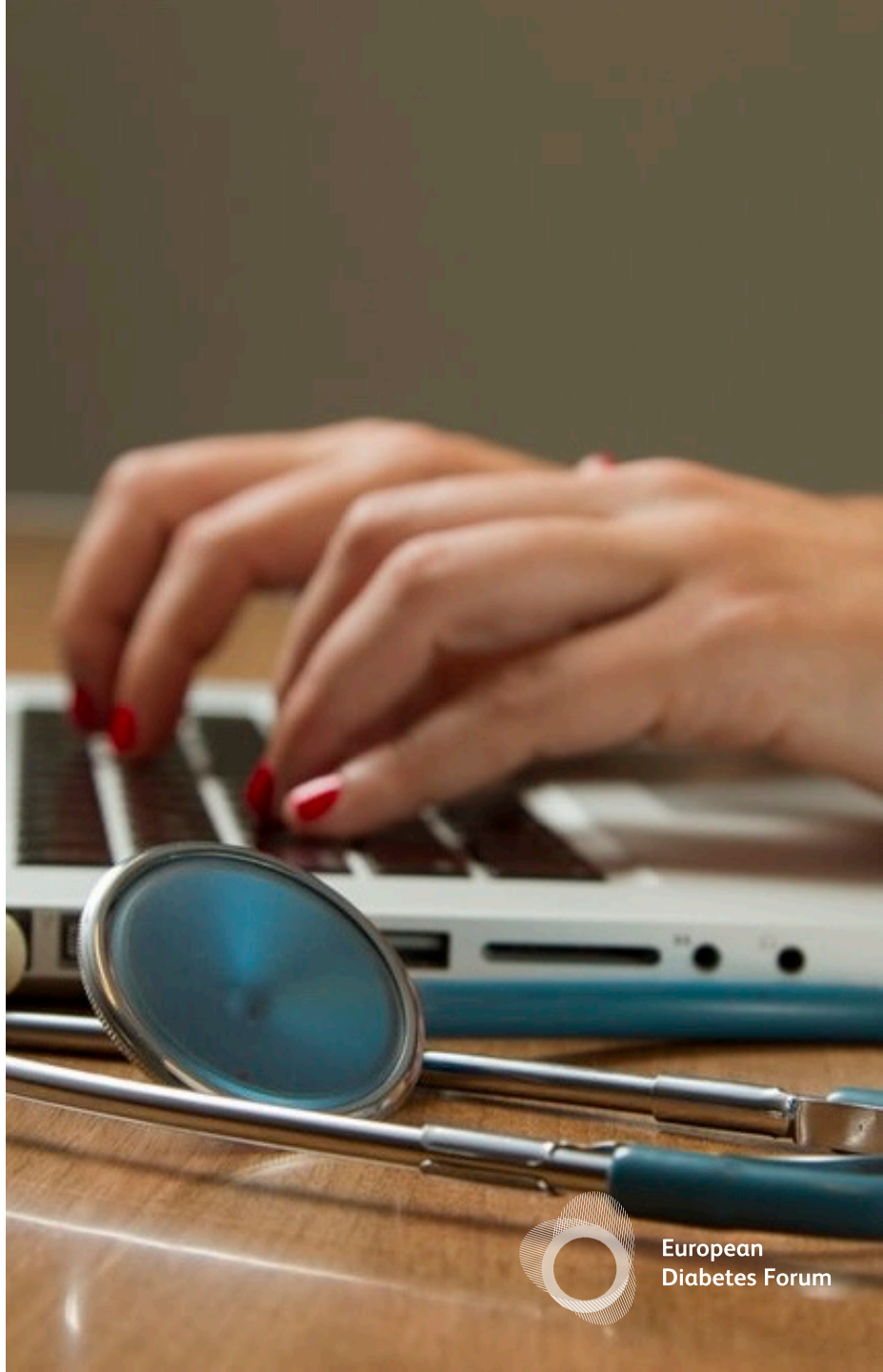
BENEFITS OF APPS IN DIABETES

Health Systems

Data: Digital apps can facilitate the flow of data and can support decision-making by generating, storing, and leveraging this information. Digital tools can give healthcare providers an extensive overview of a patient's health and health records, making it easier to make informed choices about treatments and care. Apps that display data can offer insights into trends and developments in diabetes, and provide benchmarks to comparisons against other people or with international platforms. Digital apps can also support the growth of personalised medicine by collecting data on the efficacy of different treatments or medicines.

Decision-making & treatments: Apps can lead to more informed decision-making by HCPs , who can be able to access the information from the apps used by people living with diabetes. New technologies are opening the door to remote monitoring for disease management by clinicians, and improving patient self-sufficiency.

Health efficiencies: Healthcare systems were already under enormous pressure even before the pandemic, but workforce shortages coupled with an ageing population are likely to cause further strains in managing the inflow of diabetes patients. Digital tools like apps have the potential to enable healthcare systems to save time and allocate resources more effectively. Individual data from different resources gives the opportunity to individually tailor treatment pathways, securing the best possible efficiency for the whole healthcare and social system.



POLICY CHALLENGES

As with any technological progress, apps – like digital solutions more broadly – present numerous new questions. For one, the number of diabetes health apps has increased significantly in recent years, including apps focusing on lifestyle and wellbeing (non-medical apps) and apps that have a medical purpose (medical apps). This trend leads many patients and HCPs to feel overwhelmed, and a need for meaningful signposts and orientation to navigate the growing complexity of the digital app landscape.

At the same time, the policy landscape, with the accompanying regulations and guidelines, is in constant development to embrace these technological advances appropriately. Any medical app in Europe is regulated and certified through the EU Medical Device Regulation, a harmonized EU regulatory framework that came into force in 2017 and ensures the safety, performance and clinical benefit of apps with a medical purpose that enter the EU market. The Regulation includes requirements specific for digital solutions, such as the need for mitigation and management of potential cybersecurity risks. The law also has stringent post-market market surveillance mechanism in place that apply for the full lifetime of any medical device, including medical apps, which are available on the European market.

Countries are only now beginning to establish further procedures that allow for review, monitoring, and better integration of medical apps into clinical pathways. They look at addressing questions with respect to evidence requirements, reimbursement, incentives for the use of digital apps in everyday clinical practice, data privacy and data security.

The integration of medical apps into diabetes care poses many challenges, but they are not insurmountable. The COVID-19 pandemic has dramatically accelerated the shift towards digitalisation and a change in attitudes and practices. For patients, the ability to access care online during the pandemic was a crucial lifeline, and many people with diabetes are eager to see the digital transformation of diabetes care, of which medical apps are an important element, integrated permanently into day-to-day practice.

CHALLENGES TO INTEGRATING APPS IN DIABETES CARE

For many smartphone users, apps have long become integrated into peoples' day-to-day lives, an integral part of the way people work, shop, and socialise.

However, in a vital sphere such as health, the use of digital tools including apps has lagged in comparison to other sectors.

Apps not only can offer convenience by easing aspects of daily life for people with diabetes, they also have a supportive effect on diabetes care. As such, they should become more integrated into healthcare processes and care pathways.

Apps have been slow to gain a foothold in diabetes care because the health ecosystem is a complex one, with many different actors, with varying interests, strict regulations, and often with many entrenched ways to doing business. Overcoming some of the following hurdles will be essential to realise the benefits of mobile apps in diabetes.

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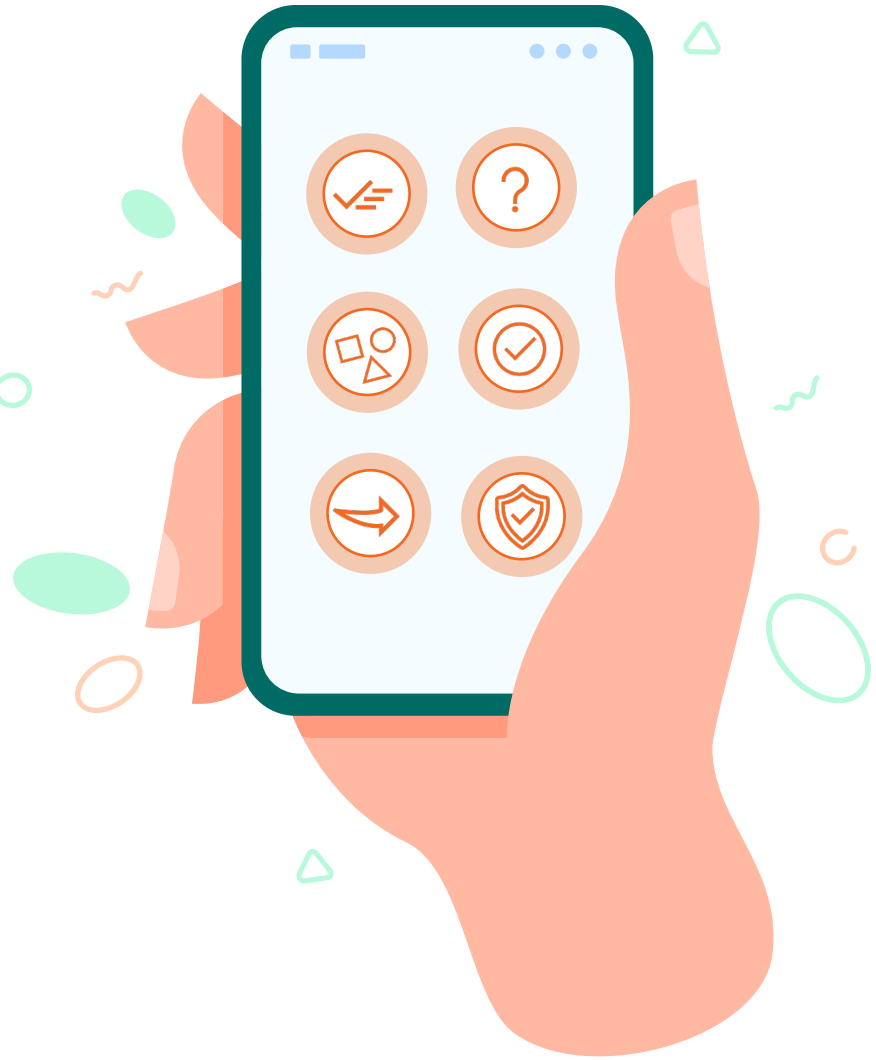
CHALLENGES



Quantity and Quality:

The sheer number of health apps in the marketplace makes it difficult for people with diabetes and healthcare professionals to sort through the vast and overwhelming jungle of digital solutions.

Similarly, while there are many good apps on the marketplace, there are many poor ones as well. People with diabetes typically have to peruse through blogs, forums, or literature to learn more about apps. Finding a way to identify and then guide people living with diabetes and HCPs towards trustworthy and useful apps is a prerequisite to playing a more prominent role in diabetes care.

Digital Hesitancy:

The awareness of digital solutions both among people with diabetes and their healthcare providers remains rather low. Moreover, knowledge about how to use and take advantage of apps can be lacking. There is a risk that a widening digital divide could lead to schisms in diabetes care and outcomes. Though in Type I diabetes, which often affects people at a younger age, the issue of digital literacy is not as strong.

In addition, for a variety of reasons, physicians and payers sometimes feel indifferent towards digitalisation. Overcoming this hesitancy will be critical to achieve a more widespread use of apps.

Attrition:

The uptake of many digital apps can be small, and many people with diabetes abandon apps after only a short period of use. A framework or perceived added value of an app is needed – with backing from HCPs – to increase usage over the long-term.

Evidence:

Evidence supporting the effectiveness of apps can be difficult to obtain. There is no agreement on even how to measure the effectiveness of an app. There are multiple factors influencing the effectiveness of an app and it is highly dependent on how it is used. Must clinical evidence and real-world performance link apps to improvements in quality of care and the management of health conditions? Or is to some extent the satisfaction of those with diabetes – in terms of ease of use or quality of life – itself a validation of efficacy?

Furthermore, to accumulate evidence takes time and requires resources. This often discourages the development of new apps because of the uncertainty of financial viability. There is typically a trade-off between evidence and availability. In regulatory systems that impose comprehensive efficacy requirements, there may be fewer apps that make it to the marketplace. While clear guidance and transparency on evidence are certainly needed, the regulatory environment should be sufficiently flexible to account for different evidence levels, depending on the function and the relative medical risk levels of the app.

Integration:

For meaningful uptake by people with diabetes and HCPs, apps need to be more integrated into healthcare processes and pathways. This requires more reimbursement/funding, investing in the appropriate technical infrastructure, and putting incentives in place to encourage healthcare providers to prescribe apps. The key requirement for the integration of apps is the need to demonstrate benefits for all actors in the diabetes landscape – people with diabetes, HCPs, payers, and app developers. Otherwise, success is not guaranteed.

Data security & interoperability:

Health data is by its nature sensitive which creates challenges in navigating the balance between privacy and security, and the ability to access, integrate, and share data.

BEST PRACTICE EXAMPLES

GERMANY

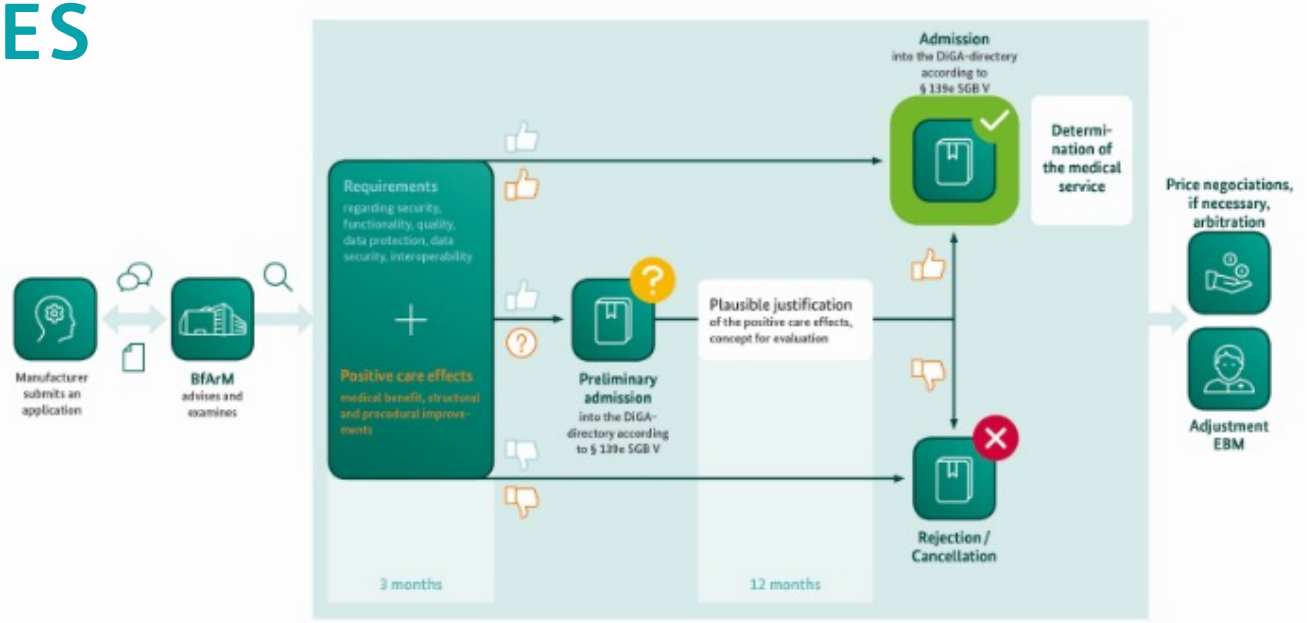
DIGA

The Digital Healthcare Act in 2019 introduced the “app on prescription” as part of healthcare provided to patients. 73 million insured patients are entitled to healthcare through digital health applications.

All medical apps in scope of DIGA – mobile apps that are CE-marked as a medical device – must have the EU regulatory approval as a prerequisite, ensuring the safety, performance and demonstration of clinical benefit, as well as deploying a robust market surveillance system. The DIGA system then has a set of requirements and criteria that a medical app has to meet in order to be prescribed by HCPs and to be reimbursed by health insurers.

A key innovation of DIGA is the so-called fast-track process for the access and reimbursement of the apps for the first year, giving the provider time to compile evidence of its efficacy. If the evidence is convincing and confirms the initial claims, the price negotiation with health insurances begins (based on the evidence only) with a current average price 430 Euro per quarter. If convincing data and evidence is not provided within 12 months, then the application is denied and closed permanently.

The benefit of this system is that it facilitates access to end users to generate real world evidence which would otherwise be difficult to obtain. With reimbursement in the first year of use, manufacturers can use the time to gather data and make the case for effectiveness.



DIGA's fast track procedure"

https://www.bfarm.de/EN/Medical-devices/Tasks/Digital-Health-Applications/_node.html

Still, this can still be a difficult and risky process, especially for start-ups. As DIGA evolves, it will have to address some of the challenges the programme has encountered so far, including: (1) the listing process is very lengthy and complex, (2) more than 90 % of the DiGAs being listed in the end are randomised control trials and (3) more than 80 % of the withdrawn apps (withdrawn in the filing process) are due to insufficient preliminary data or study design.

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BEST PRACTICE EXAMPLES

GERMANY

Diadigital

One of the challenges in the digital space is the difficulty of knowing which apps are high quality and worth using. DiaDigital initiative German Working Group for Diabetes Technology of the German Diabetes Society (DDG) aims to provide patients, relatives and healthcare professionals with more orientation in this field by evaluating apps.

How does this process work, and what criteria are used? The app development companies initiate the process by filling out a self-report questionnaire. After performing a technical check, registered testers (anyone interested can register) use the app for four weeks and check off a set of criteria using a questionnaire. Criteria include usability, functionality, adherence to data protection, and more .

DiaDigital aims for a cooperative process, engaging app developers to make recommendations for improvements if it does not pass its evaluation process on the first try.

BEST PRACTICE EXAMPLES

FRANCE

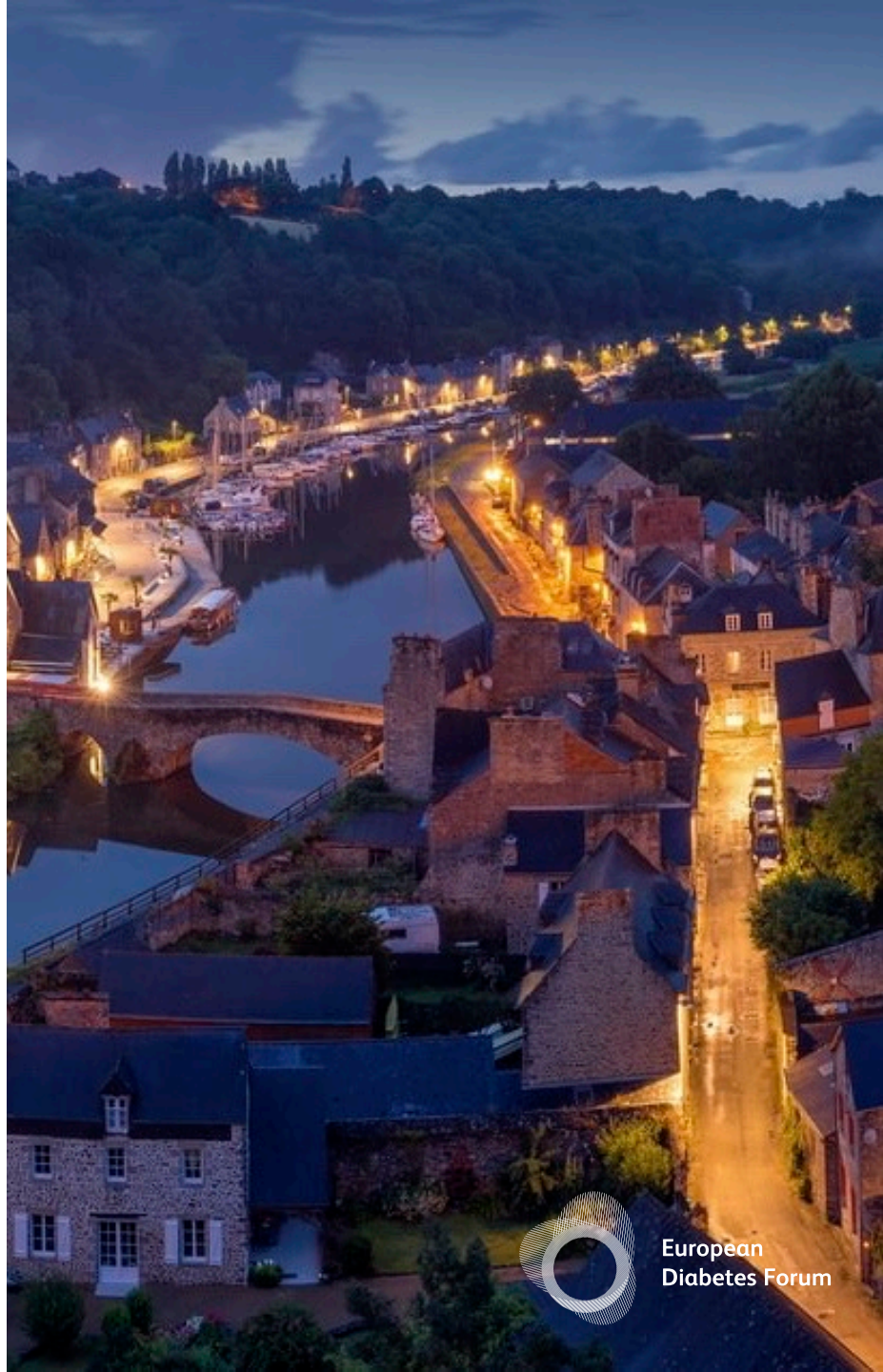
ETAPES

ETAPES is a public health initiative from the French authorities to test the use of remote monitoring solutions. The pilot program covers four chronic diseases, including diabetes. ETAPES offers a fixed rate reimbursement for HCP telemonitoring, nurse providing therapeutic support, and technical solution provider, and reimbursement rates for all three elements. There is real world data that the program has been effective, and patients have been happy to be engaged.

Assessment is only needed for devices which generate medical data. Reimbursement rates are negotiated.

Patient satisfaction is high in this program. HCPs can choose among several apps and they have the same reimbursement rates.

This program ended in December 2021 and should be replaced by a new telemonitoring program integrated into the health common French law.

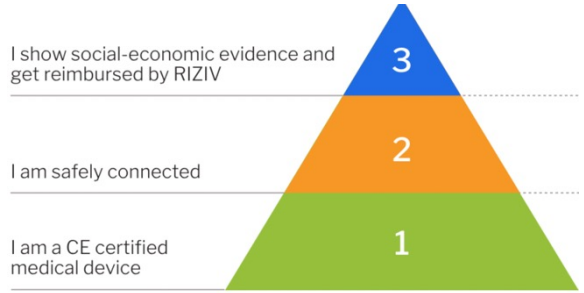


BEST PRACTICE EXAMPLES

BELGIUM

mHealthBELGIUM

Belgium has developed the platform mobile health Belgium, or mHealthBelgium, for mobile apps that are CE-marked as a medical device. mHealth Belgium centralises all relevant and required information, including CE marking, data protection, interoperability, and financing on mobile apps for patients, healthcare professionals and healthcare institutions.



mHealthBELGIUM Validation Pyramid.
https://mhealthbelgium.be/validation-pyramid

The platform utilises a validation pyramid to categorise apps based on various criteria. An app always enters the lower level, M1, and can then climb in hierarchy via M2 to the top level, M3. An app enters the M1 level when a CE declaration as a medical device is submitted. M2 is established when a risk assessment is performed and the app is then interoperable and connected to the basic services of the Belgian eHealth platform. Finally, an app reaches the top of the pyramid, and is eligible for reimbursement, when it is able to show evidence of social-economic added value.

Multiple stakeholders are involved in the mHealth Belgium initiative. This platform is managed by beMedTech (sector federation for industry of medical technologies) and Agoria (sector federation of technological industry), in close cooperation with three national authorities.

RECOMMENDATIONS

1. Develop a User-Centred App
2. Develop a best practice access pathway for apps
3. Support the integration and uptake of high-quality apps into the health ecosystem

1 Develop a User-Centred App

Design and technical specifications:

- People with diabetes and healthcare professionals should be included in all stages in the development and validation of apps
- The app should be user-friendly and easy to navigate
- High standards of data security are essential, and consideration must be given to ownership of data
- Data must be interoperable

Objectives/features of the app:

- Apps should focus on empowering people with diabetes by offering support for self-management
- Apps should support a personalised, data-driven approach to diabetes care, one that improves decision-making in a meaningful way
- Data collected should be relevant and actionable

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2

Develop a best practice access pathway for apps

Identify requirements for access:

- Each member state should create a process to enable/accelerate access to digital health apps and agree on requirements/criteria… The process should be harmonised at the EU level
- People with the diabetes should be consulted throughout the process
- Patient-reported outcomes (PROMS criteria) should be part of the evaluation of apps

Reimbursement:

- Apps that can prove real value – by supporting patient self-management and reducing the efforts of HCPs – should be reimbursed/funded.
- Real life evaluations of apps should be published to provide data to payers to assess apps

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3 Support the integration and uptake of high-quality apps into the health ecosystem

Develop training opportunities to become more familiar with apps

- Develop “digital diabetes training programs” for healthcare professionals and people with diabetes that includes education on the use of selected apps. HCPs should be able to advise people living with diabetes about which app to use. And people with diabetes should have a better sense of what is currently on the market.
- Digital health training should be incorporated into all healthcare professional and specialist training
- Highlight the benefits of apps to payers to ensure they are allocated proper funding

Encourage uptake and integration of apps into healthcare pathways:

- Apps should be prescribed, as a drug or a medical device, to increase credibility and encourage full patient involvement.
- Data should be automated as much as possible to encourage the long-term use of these apps.
- Incentives should be in place for HCPs to recommend apps
- Payment models should focus more on outcomes versus visits . Likewise, the clinical model should be person-centred instead of service-based.
- Engage with medical societies to elicit the support HCPs for apps and digital solutions

Integrate apps in diabetes treatments and care:

- Apps can play an important role in telemedicine and personalised care, although they should complement, not restrict, access to in-person care
- Apps should share information with HCPs , and data should be integrated into monitoring and treatment schemes.
- Apps that are validated, licensed, and have proven efficacy should be considered for inclusion in chronic disease including diabetes management programs and guidelines

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Recommended Literature

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