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IDF Europe's position on mobile applications in diabetes ☆

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ABSTRACT

Over the last decade, advances in technology and connectivity have led to the boom of Internet-based and mobile applications (Apps) which have rendered access to information easier and faster and have changed our daily lives. With 60 million people living with diabetes (PWD) in Europe and 32 million more at risk, diabetes has been a major target for software companies, with the aim to help people manage their chronic condition, and to prevent diabetes in people at risk.

IDF Europe is the voice of 70 national associations, representing PWD and health professionals in 47 European countries, and a strong supporter of innovation in healthcare. Witnessing the emergence of Apps in the field of diabetes, given the general uptake of a connected lifestyle, and recognising the potential in the ability of these Apps to make an impact on the lives of PWD, IDF Europe reflected on Mobile Applications in Diabetes, examining Diabetes and new technology through psychology, motivation and behavioral change in diabetes management; the healthcare professional perspective; potential roles of diabetes-related Apps, pointing to existing evidence and important ethical issues; and finally offering recommendations on four levels: individual, healthcare professional, political and App developers.

Contents

☆ About IDF Europe: IDF Europe is an inclusive and multicultural umbrella organisation of 70 national diabetes associations in 47 countries across the European region, representing people living with diabetes and healthcare professionals. Through our activities we aim to influence policy, increase public awareness and encourage health improvement, as well as promote the exchange of best practice and high-quality information about diabetes throughout the European region. We provide essential expertise and up-to-date evidence on diabetes, support awareness campaigns through a wide network of partners and stakeholders, and work with European and international organizations towards the development, implementation and monitoring of effective public policies for diabetes.

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1. Introduction

Over the last decade, advances in technology and connectivity have led to the boom of Internet-based and mobile applications (Apps) which have changed our daily lives. From service-related Apps to social media, access to information has been made easier and faster. This trend follows the evolution of the mobile telephone market: it is estimated that the number of smartphone subscriptions reached 550 million in 2015 in Europe, accounting for around 50% of total mobile telephone subscriptions. Furthermore, three out of four Internet users in Europe access the web via mobile broadband.[1]

This phenomenon is reaching every sector, including healthcare, in which Apps have been created to help people manage their medical chronic conditions. With 60 million people living with diabetes in Europe[2] and 32 million more at risk, diabetes has been a major target for software companies. In fact, the target audience for the majority of mHealth Apps are patients with a chronic disease such as diabetes.

Thousands of Apps are available, targeting different audiences and strategies to prevent and manage diabetes. For this policy statement, IDF Europe uses the following categories:

Tracking/Logging	These tools document relevant information including blood glucose measurement, medicine taken, and physical activity (similar to the traditional paper logbook/diary). They also can help identify patterns in the data collected. These data are what healthcare professionals typically use to modify medication doses such as insulin, and to make recommendations regarding nutrition and/or physical activity.
Nutrition	These Apps do everything from helping patients with food choice, carbohydrate and calorie counting, to calculation of medication dosage like an insulin bolus calculator. They ease the task of calculating everything a person eats, which can be very burdensome.
Fitness	These Apps keep track of physical activity, an important element of diabetes therapy, which may also be useful in losing weight or maintaining a healthy weight. Given the importance of physical activity in diabetes therapy, it can be encouraging to use Apps to measure progress and set/attain goals.

When it comes to nutrition and physical activity, by focusing on certain desired behavior, App developers have created additional tools for people with diabetes striving for better glycemic control, prevention of complications and maintenance of a satisfactory quality of life.

Device Connectivity Platforms	Connecting with existing medical devices such as blood glucose (BG) meters/pumps/sensors. A new type of Apps, sometimes called middleware platforms, has been developed in order to communicate with medical devices such as BG meters, continuous glucose monitors (CGM), and insulin pumps. Increased data points downloaded are recorded providing more in-depth data and statistics.
Coaching/Wellness	There are a diverse mix of products, largely focused on education and promotion of a healthy lifestyle, general guidance about it, as well as the motivation to achieve relevant goals and in some cases, customized coaching: * Educational Apps with useful information for people with diabetes * Texts or short videos and Apps intended to educate and break outdated stereotypes (myth busters)

[1] Ericsson, Ericsson Mobility Report: Europe, https://www.ericsson.com/res/docs/2015/mobility-report/emr-nov-2015-regional-report-europe.pdf (last accessed 8 Feb 2017).

[2] International Diabetes Federation (IDF), IDF Diabetes Atlas – 7th edition, http://www.diabetesatlas.org/.

Social Networks/blog	These are chat fora for sharing ideas and community support. While Social Media is not considered as a category in this list, these Apps are often connected to existing social media platforms. Sharing data with friends, family and other App users can be helpful when family and friends are involved in diabetes management. Simply being in contact with others and experiences sharing may help learn tips in order to improve one's diabetes management.[a]

[a] Recognizing the value of such channels, IDF Europe is awarding a Diabetes Prize in the Social Media category in 2016. IDF Europe Diabetes Prize in Social Media, http://www.idf.org/idf-europe-prizes-diabetes-1#SM. (last accessed 7 Feb 2017).

There is tremendous potential in the ability of these Apps to make an impact on the lives of people with diabetes in all corners of our Region, overcoming obstacles to access which may exist. Furthermore, citizens are quickly adopting this new way of being informed, accessing more and more virtual health care Apps and are eager to use them, including telemedicine.[3,4] According to the latest e-health report "*From innovation to implementation – e-health in the WHO European Region*" by WHO EURO, health authorities of about half of the countries in the European region promote the development and adoption of mHealth in the health sector. Around one fourth of countries (26%, or 11 countries) reported that their health authorities regulate mobile devices and software for quality, safety and reliability. Seven Member States (16%) reported that health authorities play no role in the development or adoption of mHealth. The report further shows that when governments sponsor mHealth programmes, they are also more likely to provide incentives and guidance on innovation and evaluation, as well as regulation for their use.[5] If European countries are to meet the growing demands for healthcare services, a focus should be placed on finding ways of maximizing new technology, such as telemedicine solutions.[6]

There have been "remarkably few active, completed, or published studies testing the efficacy of smart device applications using randomized controlled trials".[7] However, the International Diabetes Federation European Region (IDF Europe) believes that these new technologies deserve the same attention as other advancements in medical therapy. Further scientific studies can be useful to better understand their impact, since so many people are already using them every day.

2. Diabetes and new technology

2.1. *Psychology, motivation and behavioral change in diabetes management*

Diabetes self-management involves significant psychological and behavioral challenges, which are often ignored but perhaps represent the greatest challenge in day-to-day living with diabetes. Sometimes this is due to the impact of stress on daily diabetes management. Stigma associated with having diabetes and stereotypes prevalent in society today also represent a major contributing factor.[8]

People with diabetes often go through similar periods and transitions in their 'diabetes life.' These are sometimes called trigger points and typically include Diagnosis,[9,10] Hospitalization, First child, and first encounter with Complications. Often these are the times when they are most likely to reach out for help and search for new or better solutions. The psychological needs linked to these very demanding periods increase the need for external support, which may come from mobile Apps.

In addition to "diabetes life," other problems or stress unrelated to diabetes can influence blood glucose management at a varying degree depending on the individual.[11] This can include common occurrences such as work problems, family and friend issues, financial hardship as well as more profound experiences such as losing a loved one. In these kind of situations, Apps may aid in getting a person through this difficult period by providing structure as well as social support. Once the App is perceived as a type of support by the individual, she/he typically engages with less effort and may feel less alone in the struggle to achieve glycemic control.

[3] Irwin K. Patient Interest in Adopting Telemedicine: IndustryView 2015. Software Advice. http://www.softwareadvice.com/medical/industryview/telemedicine-report-2015/ (last accessed 8 Feb 2017).

[4] European Commission, Telemedicine, https://ec.europa.eu/digital-single-market/en/telemedicine (last accessed 7 Feb 2017).

[5] World Health Organization (WHO) Regional Office for Europe, From innovation to implementation – eHealth in the WHO European Region (2016). http://www.euro.who.int/fr/publications/abstracts/from-innovation-to-implementation-ehealth-in-the-who-european-region-2016 (last accessed 8 Feb 2017).

[6] European Commission, Telemedicine, https://ec.europa.eu/digital-single-market/en/telemedicine (last accessed 7 Feb 2017).

[7] Sutton EF, Redman LM. (2016). "Smartphone applications to aid weight loss and management: current perspectives" Diabetes Metab Synd Obes. Jul 18(9):213–2016.

[8] Wolf A, Liu N. (2014). "The numbers of shame and blame: how stigma affects patients and diabetes management" Diatribe 67.

[9] Bedfordshire Diabetes, Diabetes – Psychological Effects & Emotional Support. http://bedfordshirediabetes.org.uk/guidelines/psychological-issues.html (last accessed 8 Feb 2017).

[10] Nash J. (2014). "Understanding the psychological impact of diabetes and the role of clinical psychology"Journal of Diabetes Nursing, 18:137–142.

[11] Lloyd C, Smith J, Weinger K. (2005). "Stress and diabetes: A review of the links" Diabetes Spectrum, 18(2): 121–127.

Unfortunately, experiencing psychological distress may also cause a person to ignore their diabetes or run away from it, since other problems may demand their full attention. Apps are being explored as a new avenue to engage with patients and prevent 'drop-out' during these difficult times. These challenges are often ignored by people with diabetes, therefore the role of healthcare professionals,[12] family and friends is crucial[13] as people with diabetes typically have an easier time with diabetes management when there are other people who are interested in their medical condition.

Certain Apps offer external help via extended communities and fora[14]. They can help a person with diabetes feel more motivated and less "judged" about the ups and the downs of diabetes control.[15] Being actively involved in diabetes management can help people accept and adapt the behavior required to achieve better control. Using a mobile App with step-by-step methods can help fulfill this objective and may ultimately improve the quality of life for people living with diabetes.

3. The healthcare professional perspective

The challenge for healthcare professionals (HCP) to keep up with new diabetes therapies is never ending. Certain clinical care teams adopt methods and tools more quickly than others and often the reasons for doing so - or not - are beyond their control (e.g. economic, equipment, regulatory, etc). Resistance to change, nevertheless, is natural, especially when it involves the clinical care of a patient. Some healthcare professionals may adopt a more conservative approach regarding the introduction of new technologies which are providing more information, more tools and more "power" to patients. They may focus on shortcomings rather than concentrating on the potential advantages linked to these new technologies. In fact, diabetes is a chronic disease which needs certain continuity in the relationship between the patient and the HCP and studies have demonstrated that a good relationship between the persons living with diabetes and their HCPs could improve the quality of life and also the outcomes of diabetes management.[16] For years, it was considered that the HCPs were the authority in managing the medical condition of their patients and the patients would follow the prescriptions without any question. Nowadays, things have changed as there is an intention to actively involve the person with diabetes in their own management. However and unfortunately, the idea that the HCP is the only authority is still very present on both sides. A change in attitude is beginning to be observed but further active efforts are needed in order to achieve a good collaboration. Once the barrier of hierarchy is broken, the collaboration between the HCP and the patient will improve significantly. Those HCPs who are orientated to find new solutions for improving their relationship with their patients, but also those who are trying to be more present in the diabetes management of their patients without very much effort, will probably embrace the idea of using different mobile Apps for diabetes.[17]

The fact is, however, that mobile Apps are already in the hands of millions of people and the trend is increasing at a staggering pace. Some Apps are considered medical products by regulatory authorities. Clinicians cannot be expected to know over 1200 diabetes-related Apps,[18] but understanding the nature of how these Apps work and how their patients are using them would allow clinicians to provide guidance on the topic when appropriate. In fact, a growing number of health care professionals have embraced this new technology because they have understood its potential.

Certain Apps were developed using SMS/text messaging or push notifications. This can be as simple as sending a reminder to check blood glucose and/or inject insulin. Simple single-use Apps have proven very useful, especially for those who forget critical therapy tasks[19,20]. Studies indicate that this happens more often than we might imagine.[21] With regard to insulin injections, these are important reminders as they may help prevent hyperglycemia and the long-term complications associated with prolonged hyperglycemia. The SMS/ push messaging tool can also remind people with diabetes when to take other medications. More sophisticated versions of pill reminders exist in the form of Apps with well-designed visuals illustrating how each pill looks like and crossing it off of a daily or weekly checklist.

A well-designed App can help physicians by giving them the opportunity to gather more information about their patients' diabetes management, especially if they have all the information they need in one place. Some Apps allow patients to give access to data to other people including physicians who can, in turn, see how their patients are handling their diabetes in real-time.

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[12] Wagner E. (2000). "The role of patient care teams in chronic disease management" BMJ, 320(7234):569–572.

[13] Miller TA, DiMatteo MR. (2013). "Importance of family/social support and impact on adherence to diabetes therapy" Diabetes Metab Syndr Obes, 6:421–426.

[14] See the example of HelpAround App. http://helparound.co/ (last accessed 8 Feb 2017).

[15] Wolf A, Liu N. (2014). "The numbers of shame and blame: how stigma affects patients and diabetes management" Diatribe 67.

[16] Ha JF, Longnecker N. (2010). "Doctor-Patient communication: a review" Ochsner J, 10(1):38–43.

[17] Yip WWL, Quiroga LM. (2009). "A holistic approach to enhance the Doctor-Patient Relationship for diabetes using social networking, personalized alerts, reminders and recommendations" CEUR Workshop Proceedings. http://ceur-ws.org/Vol-532/paper11.pdf (last accessed 8 Feb 2017).

[18] QuintilesIMS, http://www.imshealth.com/ (last accessed 8 Feb 2017).

[19] Cole-Lewis H, Kershaw T. (2010). "Text messaging as a tool for behavior change in disease prevention andManagement" Epidemiol Rev.,32(1):56–69.

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[21] Chase P et al. (2014). "Mutlicenter closed-loop/hybrid meal bolus insulin delivery with type 1 diabetes"Diabetes Technol Ther., 16(10): 623–632.

The importance of a collaborative relation between patients and healthcare professionals has been demonstrated at the patient level[22] and at the healthcare level. Therefore Apps can represent an opportunity to allow for a stronger connection with their patients' real lives at home, at work or during active times. Helping patients understand and find good Apps may feel like additional work for some healthcare professionals but will be an important task in the future as we are becoming more mobile/digital as a society: it may even become part of the job description of physicians!

3.1. The potential role of diabetes-related apps

The number of new technology and Apps dedicated to healthcare has boomed in the last few years, however, the quality and usefulness of the Apps is not consistent: a recent study evaluating 65 freely available Apps for self-management of diabetes showed that only nine could be useful for successful self-management of diabetes.[23]

On top of playing a role in the management of diabetes as explained above, mobile Apps can help prevent 'drop-out' during difficult times. For example, documenting diabetes therapy and behavior is a tedious task but it can help identify patterns and may reveal actions/habits with unintended negative consequences on diabetes self-management. The exercise of documenting on its own can prove educational, creating a whole new level of awareness for the individual. This kind of tool is helpful right after diagnosis since it helps provide structure to a seemingly overwhelming amount of information regarding the medical condition. However, many claim it is as helpful, if not more, even after many years of living with diabetes because they can interpret it more easily. This is particularly true since many people with diabetes develop poor habits over the years which gradually seem hard to break. Using an App can help regain control by increasing one's awareness and understanding of food and medication intake and blood glucose trends after eating specific foods or experiencing stressful situations.

An important feature of Apps must be their interoperability - not only with the whole e-ecosystem (mobile phones, devices, computers, tablets...) but also with larger networks and systems. For people with diabetes, interoperability of Apps and devices means that blood glucose meters, insulin pumps and continuous glucose monitoring devices can easily communicate with each other as well as with other devices and programmes (especially if they are from different companies). Interoperable diabetes devices have the potential to, improve the quality of the interaction between patients and HCP, among HCP themselves, reduce patient and HCP frustration, save time and hassle, expand patient choice, enable new products and Apps that leverage different sources of data, and even help patients achieve better glucose levels. Interoperability can also help patients get more out of existing technology and provide HCPs more tools to help people with diabetes manage their care.

Similar to any consumer product, a major success factor in mobile applications has to do with knowing and understanding the needs of the App's audience. Within the diabetes population, there are important differences. Here are a few major groups:

- Type 1 diabetes
- Type 2 diabetes
- Children vs. Young Adults vs. Seniors
- Gestational diabetes
- Insulin users vs. Others

Knowing the targeted audience is crucial for the uptake of an App. As an example, elderly people may not be familiar with newer and more complicated smartphone features and a simpler interface with visuals could be more aligned with their needs. Apps should therefore be adapted to the use of their targeted audience.

4. Current limitations

4.1. *Studies and clinical evidence*

Literature has demonstrated that it is difficult for patients to stay motivated to sustain behavior for self-management and that most patients need on-going support.[24] This type of support, however, doesn't appear to be provided in a standard manner via Apps. The sheer number of products available on the market makes it hard to control the contents of each one. Quantity does not often rhyme with quality. Furthermore, so far there is limited scientific research to back why certain Apps are more successful than others. Two recent literature and clinical trial searches found remarkably few active, completed or published studies testing the efficacy of smart device applications using randomized control trials[25] and limited research examining the feasibility, acceptability and effectiveness of mobile-based technology to promote active lifestyles and subsequently good diabetes management in people with type 2 diabetes.[26] Perhaps it is time that we begin exploring new ways to provide such literature/evidence beyond traditional clinical study design and metrics such as Hemoglobin A1c, given the nature of App products.

4.2. *Ethics: data ownership and safety*

The rapid expansion of the number of mobile Apps using personal data presents interesting ethical questions about data

[22] Delmater AM. (2006). "Improving patient adherence" Clinical Diabetes, 24(2):71–77.
[23] Brzan PP, Rotman E, Pajnikihar, Klanjsek P. (2016). "Mobile applications for control and self management of diabetes: A systematic review" J Med Syst, 40(9):210.
[24] Shigaki C, Kruse R, Mehr D et al. (2010)."Motivation and diabetes self-management. Chronic Illness" Chronic Illn.6(3):202–214.
[25] Sutton EF, Redman LM. (2016). "Smartphone applications to aid weight loss and management: current perspectives" Diabetes Metab Synd Obes. Jul 18(9):213–2016.
[26] McMillan KA, Kirk A, Hewitt A, MacRury S. (2016). "A systematic and integrated review of mobile-based technology to promote active lifestyles in people with type 2 diabetes" J Diabetes Sci Technol, In press. DOI: 10.1177/1932296816656018.

ownership and data privacy. Laws in the European Union are some of the strictest worldwide and each App developer is required to validate their product accordingly. This has been reinforced by Regulation 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data which should apply from 25 March 2018.

In addition to data privacy, regulations oversee certain Apps classified as medical products. The USFDA (U.S. Food and Drug Administration) provides guidance on this subject, which is worth checking before using Apps.[27]

The "brave new world" of Apps can be intimidating because there are so many. Accreditation and content quality are not always enforced, which means that it is important to know about who develops the product just as with drug manufacturers. It is important to know which Apps have carried out proper validation and verification procedures. Mistakes in medical products can be serious, such as errors in calculating insulin doses.[28] If there are errors in the algorithms or content created by people who don't understand diabetes, an App could in fact be harmful, as noted for some of the web-based tools or Apps which serve as carb counters and bolus calculators. Certain bolus calculators may have errors in how they calculate dosages of insulin (more or less than needed). This kind of error is dangerous as it could lead to a severe hypo or hyperglycemia.

5. Recommendations from IDF Europe

Technology is changing the world today. A well-suited App could transform a mobile phone into a medical device helping ease the burden of diabetes, preventing complications and improving a patient's quality of life, so it's probably worth a try! However, an overwhelming number of products and services are available to patients with diabetes. Patients and providers must recognize the characteristics of these products and services to capitalize on the advantages while avoiding harmful deficiencies. Furthermore, the majority of Apps have not been tested or evaluated for improvements in health outcomes and therefore should be used and promoted carefully. Those that have, however, should be recognized.

Successful investment in eHealth requires far more than just the acquisition of technology. A holistic view of the impact and changes required to organizational processes, structures, roles, standards and legislation is needed, as well as consideration of the specifics of human resources, education, reimbursement and the culture of those who will be utilizing the eHealth services. There is a clear need for stronger political commitment for eHealth, backed by sustainable funding, and for effective implementation of policy that is protected from frequent changes in the national political landscape.[29]

5.1. *At the individual level*

- Look at reviews from both patients and health care professionals including clinical outcomes literature, if it exists, before using an App. Remember that many Apps are developed by programmers who may not be in the healthcare field, so they can sometimes contain outdated or inaccurate information.
- Look for information on the company that developed the App and who was involved in the development (e.g.: do they have a medical committee, where the information provided comes from, do they understand daily life with diabetes?. . ..).
- Determine the primary purpose of the App and how it fits into your daily diabetes routine. Diabetes is very individual and therefore the App should be customizable.
- Try and test the App on a short-term basis in coordination with your healthcare provider. For example, if you are using a carbohydrate calculator, first double-check the calculation to see if it is accurate. If you are using an App suggesting the amount of insulin you should take according to different criteria (e.g.: food intake, physical activity. . .) be sure that these suggestions work for you and check in with your healthcare provider.
- Smartphone Apps may be used as helpful tools but are intended to optimize or complement, rather than be a substitute for regular appointments or follow-up with healthcare professionals.

5.2. *At the healthcare professional level*

Whatever the opinion on mHealth tools is, healthcare professionals will need to deal with them as they have been adopted by patients. Healthcare professionals need to be familiar with the most popular mHealth Apps to optimize care for people with diabetes. When searching for an App, they should keep the following steps in mind[30]:

- Review the scientific literature.
- Search App clearinghouse websites.
- Search App stores.
- Review App descriptions, user ratings, and reviews.
- Conduct a social media query within professional and, if available, patient networks.
- Pilot the App.
- Elicit feedback from patients.

[27] Center for Devices and Radiological Health. (2015). "Mobile Medical Applications – Guidance for Industry and Food and Drug Administration Staff" http://www.fda.gov/downloads/MedicalDevices/. . ./UCM263366.pdf (last accessed 8 Feb 2017).

[28] Klonoff D. (2012). "The current status of bolus calculator decision-support software" J Diabetes Sci Technol, 6(5): 990–994.

[29] World Health Organization (WHO) Regional Office for Europe, From innovation to implementation – eHealth in the WHO European Region (2016). http://www.euro.who.int/fr/publications/abstracts/from-innovation-to-implementation-ehealth-in-the-who-european-region-2016 (last accessed 8 Feb 2017).

[30] Boudreaux ED, Waring ME, Hayes RB, Sadasivam RS, Mullen S and Pagoto S. (2014). "Evaluating and selecting mobile health apps: strategies for healthcare providers and healthcare organizations" Transl Behav Med.,4(4):363–371.

- Check the Apps that are made for patients and not only the medical-looking Apps.

Furthermore, scientific research should be implemented to measure the efficacy and efficiency of mobile Apps

5.3. D-3: At the political level

Some of the latest data published by WHO Europe are alarming

- Only 6 WHO EURO Member States have a national policy to govern the use of social media in health professions.
- Only 6 WHO EURO Member States have a national policy or strategy to regulate the use of big data in the health sector. Four countries have a national policy or strategy regulating the use of big data by private companies.
- 24 WHO EURO Member States do not have legislations that allow individuals' electronic access to their own health data in their electronic health records. However, 36 Member States have legislations protecting the privacy of an individual's health-related data in electronic health records.
- 33 Member States do not have an entity that is responsible for the regulatory oversight of the quality, safety and reliability of mHealth applications.
- Therefore, IDF Europe supports the key recommendations of WHO EURO[31]:
- Explicit political commitment by governments in the European Region to adopting eHealth is required. This commitment needs to be backed by sustainable funding for the implementation of eHealth programmes and actions for capacity-building and evaluation that are aligned with a national strategy for eHealth.
- An inclusive and intersectoral approach to the development of national eHealth strategies is recommended – to ensure their relevance to all stakeholders and to promote shared action in achieving health objectives. Member States are further recommended to use the methodology described in the WHO and International Telecommunication Union National eHealth strategy toolkit as a basis for developing their national vision, action plan and monitoring and evaluation frameworks for eHealth. Having a national eHealth strategy that embodies the elements of achieving Health 2020 policy is a key enabler for strengthening people-centered health systems and public health capacity.
- Detailed legislation surrounding the use of national electronic health records should be further developed and harmonized by countries. Such legislation should ensure that patient rights in relation to access and management of data are appropriately addressed.
- A systematic approach to the adoption of eHealth standards for data exchange and interoperability needs to be taken, with a national body in each country clearly identified to govern this process. Countries are recommended to adopt the European Union's Refined eHealth European Interoperability Framework and to introduce a quality management system for interoperability testing, a set of appropriate testing tools and quality label and certification processes.
- Countries are recommended to establish an entity responsible for the regulatory oversight of mHealth applications and to carry out evaluations on the impact and benefits of mHealth applications operating in their national settings.
- National policies and strategies on regulating the use of big data in the health sector need to be addressed by national health and information and communication technology entities, and should include a clear position on the use of big data by private companies. Similarly, countries are recommended to develop national policies governing the use of social media in health professions.
- Standards, certifications and accreditations at the national and European levels are needed especially regarding interoperable medical devices such as the ones developed in 2016 by the Food and Drug Administration.[32]

5.4. At the App developer's level

- App developers should consult with patients and patient organizations during the development and the improvement of their Apps.
- The effectiveness, use and impact of the App should be evaluated before its launch. Mobile Apps and their effectiveness must be properly tested before being launched.
- App developers should develop Apps which can be used both by healthcare professionals AND people with diabetes. The content of too many Apps is either too complex for people with diabetes or not sufficient for healthcare professionnals. There is a real need for Apps which can be used by both parties as well as an efficient communication tool between them.
- App developers should consider the interoperability of their products not only with the whole e-ecosystem (mobile phone, devices, computers, tablets. . ..), but also with larger networks and systems for the benefit of people with diabetes. For example if out of range values are

[31] World Health Organization (WHO) Regional Office for Europe, From innovation to implementation – eHealth in the WHO European Region (2016). http://www.euro.who.int/fr/publications/abstracts/from-innovation-to-implementation-ehealth-in-the-who-european-region-2016 (last accessed 8 Feb 2017).

[32] Center for Devices and Radiological Health. (2016). "Design Considerations and Pre-market Submission – Recommendations for Interoperable Medical Devices – Draft Guidance for Industry and Food and Drug Administration Staff" http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm482649.pdf (last accessed 8 Feb 2017).

continuously spotted by the Apps, information could be sent to a healthcare professional selected by the patient; contrariwise, a consistently well managed diabetes could lead to a reduction in the number of visits to the doctor.

- App developers should refer to existing and impartial scientific research including information related to diabetes and diabetes management strategies in their Apps. References to these researches should be clearly identifiable on the Apps. App developers should create and refer to a scientific committee to support the development of their products whenever possible.

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[2] diatribe: http://diatribe.org/.

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[5] Huckvale K, Adomaviciute S, Prieto JT, Leow MKS, Car J. Smarthpone apps for calculating insulin dose: a systematic assessment. BMC Med 2015;13:106.

[6] iBGStar Diabetes Manager: https://itunes.apple.com/us/app/ibgstar-diabetes- manager/id506018173?mt=8.

[7] iMedicalApps: http://www.imedicalApps.com.

[8] Klonoff DC. The current status of mHealth for diabetes: will it be the next big things? J Diabetes Sci Technol 2013;7(3):749–58.

[9] Loick Menvielle et al. (Eds): The Digitization of Healthcare, 978-1-349-95172-7, 396016_1_En, (9).

[10] Neumman B, Stefanik M, Gonzalvo J, Weber Z. Diabetes mHealth applications: where are we now? AADE Practice 2016;4(5):28–32.

[11] Ristau RA, Yang J, White JR. Evaluation and evolution of diabetes mobile applications: key factors for heath care professionals seeking to guide patients. Diabetes Spectrum 2013;26(4):211–5.

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GLOSSARY

App: App refers to Mobile Applications, which are software applications designed for running on mobile devices such as smartphones and tablet computers. Users of any mobile device can search for an appropriate App on platforms like Google Play store or Apple App Store. These Apps can be downloaded sometimes for free, or at a cost. Data entered by user might allow further synchronisation with multiple devices, such as between a smartphone and a tablet computer, allowing users' instant access to one's data, e.g. physical activity or food intake records.

Big data: Big data can be understood as a new way of data collection where a large amount of information, such as demographics, preferences, habits and other information of a large population is routinely collected. Subsequently these data are used for analysis to find out patterns or characteristics of the population.

Continuous Glucose Monitoring (CGM): CGM refers to the practice of assessing an individual's glucose level on a continuous basis (every few minutes). This is done through a glucose sensor, which can be inserted under the skin to measure glucose in the fluid in and around your body's cells. This technique allows glucose level to be measured without finger pricking.

Ehealth: eHealth is the use of information and communication technologies (ICT) for health.

Interoperability: The ability of computer systems or software to exchange and make use of information.

mHealth: Mobile Health or "mHealth" is defined as "mobile, computing, medical sensor and communication technologies" used for health improvements, including chronic disease management and wellness. mHealth includes medical applications that run on a cell phone, sensors that track important symptoms and health activities, and cloud-based computing systems for collecting health data.

Push notification: A message that pops up on a mobile device. App publishers can send them at any time; users don't have to be in the App or using their devices to receive them.

Smartphone: a cell phone that includes additional software functions such as e-mail or an Internet browser.

Social media: Forms of electronic communication (such as websites for social networking and microblogging) through which users create online communities to share information, ideas, personal messages, and other content (such as videos).

Telemedicine: Telemedicine refers to the provision of medical care remotely with the use of telecommunications or information technology.