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MedTech Europe from diagnosis to cure

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# Executive summary

An increasing number of people in the EU are affected by diabetes. According to figures of the International Diabetes Federation, currently 55 million people in the European region have diabetes. As a serious chronic condition, if not managed effectively, diabetes can lead to severe and costly complications, including cardiovascular disease, renal failure and blindness.

Self-management plays a key role in diabetes: the person with diabetes, family members and / or carers are mostly responsible for the management of the condition. However, managing the condition on a daily basis and throughout different stages of life can be very challenging.

With the Internet playing a key role in enabling access to data and services to a large part of the global population and given the reach of mobile networks and connected services that are becoming ever more intelligent, mobile health solutions (mHealth) can play an important role in improving primary prevention of diabetes through supporting lifestyle changes, supporting healthcare professionals in screening, diagnosing, treating and managing the condition and addressing the important challenges of self-management. In addition, mHealth can support sustainable healthcare systems by offering innovative cost-effective and patient-centred solutions and also by means of data collection, continuous monitoring and analysis in relation to, for example, disease trends.

This paper aims to raise awareness of the diabetes epidemic in Europe and to highlight key challenges and opportunities in addressing the burden of diabetes. In this respect, policy recommendations are put forward highlighting the need to:

- Develop policies that support integrated patient-centred chronic disease care
- Ensure processes that facilitate meaningful end-user involvement
- Centralise information on existing mobile solutions and their status
- Improve mHealth literacy
- Develop mHealth and chronic disease awareness campaigns, using diabetes as a model
- Bridge 'regulatory gaps'
- Encourage and facilitate mHealth stakeholder engagement





#### The diabetes epidemic in Europe

Diabetes is one of the most common non-communicable diseases, affecting 55 million people (or 8.4% of the adult population) in the European region. At least 38.6-50% of all people with diabetes are undiagnosed at the moment and remain, as such, untreated.

These alarming figures are largely due to the growing prevalence of type 2 diabetes, accounting for 90% of all diabetes in the EU, and an ageing population. However, the increasing number of people with type 1 diabetes is also a contributing factor: Europe has the highest number and incidence rates of children with diabetes in the world.<sup>1,2</sup>

Diabetes is a chronic condition that requires lifelong and intensive management in order to achieve good metabolic control. If not managed in a timely manner and effectively, diabetes can lead to blindness, kidney failure, lower limb amputation and stroke. Moreover, one in 10 deaths in adults can be attributed to diabetes, i.e. 622,114 deaths in 2012. Many other deaths are due to diabetes-related complications, such as cardiovascular diseases. These numbers are not included in the current data which, as such, do not provide a complete picture of the ravages caused by diabetes and ineffective diabetes care. In general, diabetes is estimated to be the fourth leading cause of death in Europe.<sup>34</sup>

#### The cost of diabetes

Although there seems to be an important lack of precise data in this area, it is clear that the cost burden of diabetes across the European region is growing in response to the increasing prevalence. Health expenditure in EU Member States in 2011 to prevent and treat diabetes was estimated by the International Diabetes Federation (IDF) at USD 110 billion<sup>3</sup> and about 10% of the total annual healthcare expenses in the EU are spent on diabetes.<sup>1</sup>

Two large diabetes cost-related studies, clustering several EU countries, calculated that 50-75% of diabetes spend is attributed to treating complications of the disease; only about 6-10% of all diabetes direct costs are attributable to the prescription of diabetes medicines, while 50% or more is related to hospitalisation.<sup>5,6</sup> Indirect costs due to diabetes, relating to reduced productivity, absenteeism, early retirement, social benefits and carer costs, would exceed the direct diabetes costs by at least a factor of 2- or even 3-to-1 depending on the country.<sup>3</sup>

Diabetes and related costs place a considerable burden on EU Member States. Innovative mHealth and other medical technologies that aim to improve prevention, diagnosis and management of diabetes can contribute to the sustainability of healthcare systems.

- 1 IDF Europe, FEND, PCDE, EURADIA, Diabetes The Policy Puzzle: Is Europe Making Progress? Third edition, November 2011
- 2 WHO, European Observatory on Health Systems and Policies Observatory Studies Series, Volume 19 "Health in the European Union, Trends and Analysis"
- 3 IDF Atlas 2012 update
- 4 IDF Diabetes Atlas, 3rd edn.(2006) and IDF Diabetes Atlas, 4th edn (2009) Brussels, Belgium, International Diabetes Federation
- 5 Kanavos P, van den Aardweg S, Schurer W, Diabetes expenditure burden of disease and management in 5 EU countries, LSE Health, January 2012
- 6 Jönsson B (2002) Revealing the cost of Type II diabetes in Europe, Diabetologia 45(7):S5-12



#### The importance of self-management

Self-management plays a key role in diabetes: the person living with diabetes, family members and / or carers are mostly responsible for daily management of the condition, rather than the health care team.

Improved blood glucose control through intensive self-management has been shown to result in near-normal blood glucose levels and, as such, in the reduction of mortality and incidence rates of severe and costly complications.<sup>7</sup> However, despite the availability of an extensive range of effective treatments and lifestyle interventions, 34-76% of people with diabetes are not in good control and have unsatisfactory blood glucose levels (HbA1C≥7,5%).<sup>8</sup>

An important factor contributing to poor control in people at risk of or with type 2 diabetes is poor adherence to medication requirements and the lack of implementing received lifestyle modification information, such as regular physical activity and a balanced diet, in their daily life.<sup>9,10</sup> In the UK, for example, about 47% of type 2 diabetes can be attributed to obesity.<sup>11</sup> A recent study indicated however that 35% of people with type 2 diabetes are still overweight<sup>3</sup>, while lifestyle interventions have been shown to achieve sustained weight loss, delayed onset of type 2 diabetes by 4 years and reduced diabetes incidence rate by 34%.<sup>12</sup>

In turn, poor control leads to serious complications and subsequent hospital admission. According to the OECD, there are too many hospital admissions in Europe for uncontrolled diabetes.<sup>13</sup> Of all people with diabetes in Europe, up to 40% suffer from coronary heart disease, 12% suffer from stroke, 23% suffer from nephropathy (kidney disease), 68% suffer from neuropathy and 52% suffer from retinopathy which may lead to blindness. Every week, 830 to 3,500 limb amputations occur due to diabetes complications.<sup>14</sup> The World Health Organisation furthermore indicates that 70-80% of people with diabetes in the EU die of heart disease or stroke.<sup>2</sup>

# What is mHealth?

The World Health Organisation considers mHealth as a component of eHealth. Whereas eHealth comprises "the use of information and communication technologies for health", mHealth is defined as "medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices".<sup>15</sup>

mHealth solutions can be described in different ways. In general, they can be categorised into two broad areas: solutions across the patient pathway and healthcare systems strengthening. Solutions across the patient pathway include wellness, prevention, diagnosis, treatment and monitoring and entail direct touch points with patients. Healthcare systems strengthening solutions include emergency response, healthcare professional support, healthcare surveillance and healthcare administration and do not involve direct interactions with patients, but are primarily aimed at improving the efficiency of healthcare professionals in delivering patient care.

- 8 When a more strictly definition of tight blood glucose control is applied (HbA1C ≤ 6,5), 66–76% are not in good control.
- 9 Bailey CJ and Kodack M, Patient adherence to medication requirements for therapy of type 2 diabetes. International Journal of Clinical Practice 2011; 653: 314-322.
- 10 Diabetes in Europe: results of the diabetes awareness survey (2011), TNS Gallup on behalf of Novo Nordisk
- 11 National Audit Office (February 2001). Tackling Obesity in England.
- 12 Betzlbacher AF, et al. Behaviour change among people with impaired glucose tolerance: Comparison of telephone-based and face-to-face advice. Journal of Health Services Research and Policy; April 2013 18: 2-6,
- 13 OECD Health at a glance: Europe 2012
- 14 IDF Diabetes Atlas, 3rd edn. (2006) and IDF Diabetes Atlas, 4th edn (2009) Brussels, Belgium, International Diabetes Federation. Figures are based on research in a specific pool of EU countries.

15 WHO, Global Observatory for eHealth series - Volume 3 "mHealth: New horizons for health through mobile technologies: second global survey on eHealth"

<sup>7</sup> Pimazoni-Netto A, et al. Rapid Improvement of Glycemic Control in Type 2 Diabetes Using Weekly Intensive Multifactorial Interventions: Structured Glucose Monitoring, Patient Education, and Adjustment of Therapy—A Randomized Controlled Trial, Diabetes Technology & Therapeutics. 2011 October; 13(10): 997–1004.

#### What is the adequate treatment of the entire end-to-end system? Are they part of a single medical device or can the components be managed separately? Should all components Intended use Ouality of Will the classification of the medical service for both device also mean that the mhealth of the device within an mhealth device obey health regulations? asynchronous platform will have to be regulated and real-time too? Under which classification? Mobile network ted by Hosted by Not he mHealth device nobile service mobile service provider provider Privacy and security -Regulation consent to share of health Healthcare service professionals regulation providers Privacy and security issues Technical standards Device manager potential issues: A multi-user device may require for health information Electronic Health Record raises privacy and exchange registration of different patient security questions Where is the system hosted? accesses and personal data storage What is the secondary use of data? Controls for engineering and support

#### mHealth solutions: ensuring quality, safety and trust

#### How mobile solutions can help people with diabetes and their healthcare professionals

Technological developments have introduced important new dimensions in healthcare, with the Internet playing a key role in enabling access to information, data and services to a large part of the global population. Given the reach of mobile networks<sup>16</sup> and connected services that are becoming ever more intelligent, mobile solutions can play an important role in addressing the important challenges of prevention, early diagnosis and effective self-management of diabetes. The recent Mobile Diabetes Intervention Study has shown that the combination of behavioural mobile coaching with blood glucose data, lifestyle behaviours and patient self-management data shared with healthcare professionals had a positive impact on diabetes management outcomes over one year.<sup>17</sup> This is supported by two additional studies that highlighted how mobile phone interventions can improve glycaemic control in people with diabetes.<sup>18,19</sup> Similarly, diabetes education administered through telemedicine<sup>20</sup> instead of through the typical face-to-face consultation has proven its merits already.<sup>21</sup> More generally, mobile solutions have the potential to support more effective and qualitative diabetes care, which could be translated via patient-centred disease management, personalised healthcare and cross-border mobility.

#### 'Renewing Health' in the EU

In order to support and reinforce the positive role of mobile and telemedicine solutions, the 'Renewing Health' project aims to evaluate whether these solutions produce benefits for people with type 2 diabetes, in terms of clinical outcomes such as HbA1c, health-related quality of life (HRQoL), self-management and empowerment. In addition, the economic and organisational impact of the new services will be assessed, together with their acceptability by patients and health professionals. Renewing Health is a project co-funded by the European Commission, involving a consortium of European regional authorities or healthcare providers.

- 16 According to the GSMA European Mobile Industry Observatory 2011, mobile services are ubiquitously available with a population coverage rate of nearly 100% and a mobile penetration rate of 128% in Europe. This represents 656 million individual subscriptions held by an estimated 456 million Europeans (89% of the population). Mobile services are being used across all age groups and socio-economic segments of the population.
- 17 Quinn C., et al. Cluster-Randomised Trial of a Mobile Phone Personalized Behavioural Intervention for Blood Glucose Control, Diabetes Care, volume 34, September 2011, 1934-1942
- 18 Liang X., et al. Effect of mobile phone intervention for diabetes on glycaemic control: a meta-analysis. Diabet Med. 2011 Apr;28(4):455-63

19 Bujnowska-Fedak MM, Puchala E, Steciwko A (2011) The Impact of Telehome Care on Health Status and Quality of Life Among Patients with Diabetes in a Primary Care Setting in Poland. Telemedicine and e-Health. 17(3): 153-163. doi:10.1089/tmj.2010.0113.

- 20 Telemedicine is described by the World Health Organisation as "the use of telecommunications to diagnose and treat disease and ill-health". http://www.who.int/trade/glossary/ story021/en/
- 21 Izquierdo RE, et al. A comparison of diabetes education administered through telemedicine versus in person. Diabetes Care. 2003 Apr; 26(4):1002-7



Lifestyle changes play a key role in diabetes prevention and management. Interactive and selfdirected mHealth can support and motivate people with diabetes and people at risk of developing diabetes to make improved and informed lifestyle choices, for example, with respect to healthy eating, stopping smoking and regular exercise.<sup>22,23</sup> Important parameters for diabetes management and prevention, such as physical exercise and food intake, can be registered, monitored and shared with the diabetes care team by means of mobile solutions. A recent study produced by PwC and GSMA estimates that around 14 million of the 18.1 million people in the EU at risk of developing type 2 diabetes could better manage their weight or hypertension by using mHealth solutions regularly. Of these 14 million, about 5 million could successfully reduce the risk of developing type 2 diabetes and some 161,000 cases of diabetes could be prevented. In addition to a reduction in direct healthcare costs (e.g. fewer visits to healthcare professionals and hospital admissions), these positive impacts could lead to around EUR 13 billion in earnings by avoiding absenteeism and EUR 5.3 billion by avoiding early retirement.<sup>24</sup>

Apart from the benefits for patients (mHealth effectiveness), healthcare professionals also benefit from mobile solutions such as disease- or patient-related information platforms (mHealth efficiency). These services connect different healthcare infrastructures with each other to improve coordination, collaboration and information flow among all the traditional players in the healthcare profession. Finally, remote monitoring between healthcare professionals and patients can result in reduced healthcare costs by, for example, decreasing the frequency of clinic visits, hospitalisations and emergency department visits. A common platform for healthcare professionals can furthermore result in a reduction in medical test duplications.

At a more general level, shared data facilitated by mHealth solutions could stimulate and enhance research and innovation, leading to improved diabetes care services.

#### mHealth examples:16

A variety of mobile applications are currently available to help users monitor the calories eaten and the calories burnt when physical activity is undertaken. Daily personal health records can be kept and shared with social communities to encourage and motivate one another. Some applications also rate nutritional details of food items to help people eat more healthy food in order to **prevent** lifestyle diseases such as obesity, type 2 diabetes and hypertension.

Other mobile solutions are typically developed to help with the **management** of a chronic condition, such as diabetes. These solutions help to track various relevant parameters, including blood glucose, blood pressure, exercise levels, food intake, medication, pulse and weight, in order for patients to better manage their disease, delaying diabetes-related complications. The solutions can also produce a variety of graphs and reports and can create a log book which can be shared with healthcare professionals for analysis.

Finally, a group of smartphone applications enable healthcare professionals to review important health parameters, such as electrocardiograms, on their mobile devices. These allow them access to updated patient records anytime and anywhere, along with enhanced analytics, helping them to apply faster, more informed decisions, treatment and care. When treating cardiac patients for example, these extra minutes can help patients recover quickly by expediting medical intervention and prevent heart damage.

Nundy S, Dick JJ, Solomon MC, Peek ME (2013) Developing a behavioral model for mobile phone-based diabetes interventions Patient Education and Counseling 90(1): 125-132
Arora S, Peters AL, Agy C, Menchine M (2012) A Mobile Health Intervention for Inner City Patients with Poorly Controlled Diabetes: Proof-of-Concept of the TExT-MED Program. Diabetes Technology & Therapeutics 14(6): 492-6. doi:10.1089/dia.2011.0252.

<sup>24</sup> PWC and GSMA, Socio-economic impact of mHealth - an assessment report for the European Union, June 2013



Joining forces for diabetes: the mHealth Grand Tour Presented by the GSMA and IDF Europe, under the patronage of European Commissioner for the Digital Agenda Neelie Kroes, the mHealth Grand Tour cycle ride from Brussels to Barcelona brings together diabetes



patient communities and the mobile and healthcare industries to raise awareness of diabetes, to promote healthy and active living and showcase how mobile technology can help address the challenge of managing the condition and reduce the cost of care. The ride involves more than 100 participants, including riders with type 1 diabetes. Focusing on the effect of multi-day exercise on glycaemic and hypoglycaemic levels in elite and sub-elite athletes with type 1 diabetes, as well as with riders without diabetes, the Grand Tour will feature a unique live observational study of up to 36 volunteer riders. The study will use data captured and transmitted wirelessly and securely through a collaborative technical solution provided by mobile and medical technology partners. The solution's component mobile broadband technologies all comply with Continua Health Alliance guidelines for interoperability.

The mHealth Grand Tour will start in Brussels on 5 September and will finish in Barcelona on 18 September 2013. For more information: http://www.mhealthtour.com/

#### Realising the potential of mHealth for diabetes: a call to action

Chronic diseases, including diabetes, are increasingly recognised as a priority on global, EU and national health agendas. This is reflected in recent important policy and stakeholder initiatives, such as the UN political declaration on prevention and control of non-communicable diseases<sup>25</sup>, EU Council Conclusions on innovative approaches to chronic diseases in public health and healthcare systems<sup>26</sup> and the resulting reflection process<sup>27</sup>, the European Parliament Resolution on diabetes<sup>28</sup> and the Copenhagen Roadmap which resulted from the European Diabetes Leadership Forum<sup>29</sup>. In addition to recognising the burden of chronic diseases, these initiatives also highlight the role of new and innovative technologies, including eHealth<sup>30</sup> solutions, in addressing the challenges raised by the growing prevalence of chronic diseases, including diabetes. In this respect, the European Commission's eHealth Action Plan (2012-2020)<sup>31</sup> is an important framework for the deployment of mobile health services across Europe.

Moreover, a Joint Action on chronic diseases, with a specific work package dedicated exclusively to diabetes, will be launched. Involving the European Commission, Member States and other key stakeholders, this Joint Action will form a unique opportunity to integrate the role of new technologies, including mHealth, in diabetes prevention, diagnosis and management.

25 Political Declaration of the High-level Meeting of the General Assembly on the Prevention and Control of

Non-communicable Diseases, 19 September 2011, http://www.who.int/nmh/events/un\_ncd\_summit2011/political\_declaration\_en.pdf

<sup>26</sup> Council Conclusions 'Innovative approaches for chronic diseases in public health and healthcare systems', 7 December 2010, http://www.consilium.europa.eu/uedocs/cms\_Data/ docs/pressdata/en/lsa/118282.pdf

<sup>27</sup> http://ec.europa.eu/health/major\_chronic\_diseases/key\_documents/index\_en.htm#anchor0

<sup>28</sup> European Parliament Joint Motion for a Resolution on addressing the EU diabetes epidemic, 12 March 2012, http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP// TEXT+TA+P7-TA-2012-0082+0+DOC+XML+V0//en

<sup>29</sup> http://www.idf.org/sites/default/files/CopenhagenRoadmap.pdf

<sup>30</sup> The WHO considers mHealth a component of eHealth: WHO, Global Observatory for eHealth series – Volume 3 "mHealth: New horizons for health through mobile technologies second global survey on eHealth"

<sup>31</sup> http://ec.europa.eu/digital-agenda/en/news/ehealth-action-plan-2012-2020-innovative-healthcare-21st-century

In support of these key policy initiatives and in order to ensure appropriate implementation of effective, trusted and accessible mobile health solutions for people living with diabetes, we invite the European Commission and EU Member States, in cooperation with key stakeholders, including people with diabetes and their carers, healthcare professionals, the mobile and health technology industry ecosystems, to:

#### Develop policies that support integrated patient-centred chronic disease care

With mobile technologies becoming pervasive across the continent, diabetes patients are given a tremendous opportunity to measure and manage their blood glucose levels and diabetes care in a more precise and continuous mode than ever before.

In order to succeed, however, in this process of self-management, patients need to be empowered to take control of their condition and be reassured that feedback and necessary adjustments from a healthcare professional are available when necessary. New policies, supporting such integrated patient-centred diabetes care, need to be developed and can serve as a model for the remote treatment and management of other chronic diseases.

#### Ensure processes that facilitate meaningful end-user involvement

mHealth solutions have the potential to significantly empower people with diabetes and support their healthcare professionals. It is therefore essential that patients be involved at all stages of mHealth development from inception to delivery, monitoring and evaluation. Initiatives in this area should be encouraged and good practice examples promoted at EU and national levels.

#### Centralise information on existing mobile solutions and their status

An overview of mHealth services, their regulatory status and accessibility should be available to all EU citizens. Providing up-to-date, relevant information about mHealth solutions is essential to empower patients and to inform them if a product or service that could assist in their treatment is available in their country and is reimbursed.

#### Improve mHealth literacy

A perceived lack of knowledge and skills needed to be able to use mobile health services is one of the most common barriers to user acceptance of mHealth. In line with the European Commission's eHealth Action Plan 2012-2020, initiatives aimed at developing mHealth training and education programmes for patients and healthcare professionals should be developed, e.g. through relevant EU programmes and/or policy initiatives.

### Develop mHealth and chronic disease awareness campaigns, using diabetes as a model

Despite overall recognition of the potential benefit of eHealth, including mHealth, general awareness seems to be low.<sup>32</sup> Campaigns should be supported at EU and national levels to increase awareness of the potential of mHealth in the prevention, diagnosis and management of major chronic diseases, using diabetes as a model.

32 European Patients' Forum, Chain of Trust project report, January 2013; GSMA US and Brazil end-user research: http://www.gsma.com/connectedliving/resources?project=mHealth

### Bridge 'regulatory gaps'

A solid regulatory framework should be in place that adequately addresses the key concerns of various stakeholders around safety and trust. In order to work towards the deployment of safe, effective and trusted mHealth, progress in the following areas should be made:

- Increase clarity on the application of EU medical device regulation with respect to mHealth, based on a proportionate risk-based approach that ensures quality and safety while stimulating innovation and patient access.
- Clarify data protection regulation as it applies to mHealth, ensuring end-user trust and ease of use, while recognising the power of data in disease management, diagnosis and prevention.

# Encourage and facilitate mHealth stakeholder engagement

Given the potential of mHealth in offering innovative and sustainable solutions to the prevention, treatment, care and management of chronic diseases, an mHealth stakeholder working group should be created where opportunities and challenges could be discussed and the exchange of information and good practice could be stimulated. This platform or working group could be linked to or be a subgroup of the EU eHealth Stakeholder Group<sup>33</sup>.

33 http://ec.europa.eu/digital-agenda/en/news/ehealth-stakeholder-group-members



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