AN EXPERT DECLARATION

Leveraging evidence-based practices to improve diabetes in Central Europe
SPONSORSHIP DECLARATION

This document has been written by Experts in the field of diabetes, all of whom are members of IDF Europe from the respective Central European Countries.

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FOREWORD

“Diabetes continues to challenge healthcare systems and hamper economic progress across Europe. We need to rethink our approach and start taking multipronged action to confront the cost to our societies caused by this disease”. Sehnaz Karadeniz, Chair, IDF Europe

Diabetes poses a colossal burden to people living with the condition, especially in Central Europe*. There are approximately 7.6 million adults (20-79) with diabetes in Central Europe and a pressing disparity exists between the prevalence in this region (7.3%) and across the European Union as a whole (6.4%) [1]. Diabetes related deaths in the region are a staggering ~2 times higher than in the largest five European countries (EU5) [1].

In order to address the rampant diabetes challenge in Central Europe, the Diabetes Evidence Initiative in Central Europe (DEICE) Expert Group has convened several times in 2019. The meetings were organised by the IDF European Region (IDF Europe), together with AstraZeneca. Best practices in diabetes policy-making were discussed as well as approaches by Central European countries to strengthen efforts to build effective policy and advocacy strategies to reduce diabetes prevalence throughout the region.

The Experts established three working groups, each of which was tasked with one of the key diabetes challenges faced by Central Europe, namely lack of diabetes registries, poor access to care and innovation, and limited multi-level care.

This Declaration details the outcome of this work and we hope will serve as a guideline and inspiration for positive and successful action.

We thank our Members in the respective countries and the nominated Experts for their efforts and also AstraZeneca for their support.

*Bulgaria, Croatia, Czech Republic, Hungary, Poland, Romania, Serbia, Slovakia and Slovenia.
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A CASE FOR URGENT ACTION!

“It is time for us to raise the bar and ensure that people with diabetes in Central Europe have equal opportunities for optimal care”. Nebojša M. Lalić, Serbia

Although considerable efforts have been made to deal with the diabetes epidemic it continues to increase in prevalence. The burden of disease is evidenced through premature mortality, reduction in quality of life and enormous healthcare costs. These trends highlight the need for diabetes to be a pressing public health priority – also across Central Europe. Some pertinent examples illustrate the challenges we face:

1. The diabetes prevalence rates in Romania and Serbia are 12.4% and 13.3%, respectively, topping the prevalence rates of Central Europe. Another ~720,000 people between 20-79 of age remain undiagnosed in those two countries alone. Yet, the diabetes related expenditure in both countries is amongst the lowest in Europe [1].

2. The national diabetes registry in Bulgaria is still not implemented. Yet, people with diabetes over 20 years of age account for 7.9% of the population [1]. Moreover, ~75% of the people with diabetes have poor metabolic control, potentially leading to serious complications [2].

3. Diabetes causes ~8,600 deaths in Hungary annually, equivalent to 1.2% of the diabetes population [1]. In a country with less than 10 million inhabitants this is a staggering figure.

4. In 2030, the population of Poland will reach 38 million [14] and it has been estimated that 2.2-2.5 million Poles will be affected by diabetes [3]. Diabetes is causing a growing economic burden on the healthcare system and on the Polish society in terms of healthcare and productivity losses [4].

5. In 2009 Croatia spent some 2.5 billion kuna, equivalent to 11% of the budget of the Croatian Health Insurance Fund (HZZO), towards treating diabetes and its complications. 86% of that amount went to treating chronic complications [5].

The alarming trends in the Central European region – the sharp increase in the prevalence and incidence of diabetes, as well as its complications and high costs to healthcare systems – all point to the enormity of the diabetes epidemic. There is no time to waste – we need urgent action!
THE AIM OF THE EXPERT DECLARATION

In February 2019, the Diabetes Evidence Initiative in Central Europe (DEICE) Expert Group gathered at a meeting in Belgrade to discuss evidence-based better practices in the area of cost-effective policy-making. The meeting was facilitated by IDF Europe and AstraZeneca and led by Prof. Nebojša Lalić.

At the meeting the Experts considered ways to identify and decide how best practices can be consolidated and presented in manners that can inspire effective policy advocacy in the Central Europe region.

The Experts from Bulgaria, Czech Republic, Croatia, Hungary, Poland, Romania and Serbia agreed to establish three working groups each of which was tasked with developing an assessment and providing recommendations within three key focus areas:

WORKING GROUP 1: Development of registries

The need for registries to measure, share and improve data based on (better) practices. Considerations for establishing national/regional registries, including matters related to data privacy.

MEMBERS:

Prof Gabriela Roman (Romania), co-chair, Prof Zdravko Kamenov, (Bulgaria), co-chair, Dr. Zsolt Gaál (Hungary), Prof Nebojša M. Lalić (Serbia), Prof Jan Škrha (Czech Republic).

WORKING GROUP 2: Access to care and innovation

Access to care and innovation broadly in the region, including access to innovative therapies aimed at improving outcomes and quality of life for people with diabetes.

MEMBERS:

Prof Tsvetalina Tankova (Bulgaria), co-chair, Prof Cornelia Bala, (Romania), co-chair, Ms Maya Victorova (Bulgaria), Prof Leszek Czupryniak, (Poland), Prof. Martin Prázný (Czech Republic).

WORKING GROUP 3: Multilevel care in diabetes

The hierarchy and organisation of care, from primary to secondary and tertiary care, and how this may impact on prevention, quality of care and outcomes for people with diabetes in Central Europe.

MEMBERS:

Prof Maciej Malecki (Poland), co-chair, Assoc Prof Dario Rahelic (Croatia), co-chair, Dr Miroslav Djordjevic (Serbia), Prof Predrag Djordjevic (Serbia).

In September 2019, the DEICE Experts met again to allow each working group to present and feed back on their work and agree to a set of policy recommendations for the region. This Expert Declaration forms the composite outcome of the work conducted by the DEICE Experts and working groups.

The aim of the DEICE Expert Declaration is to propose and promote policy initiatives that will significantly improve the situation for people with diabetes across Central Europe.
FOCUS AREA: DEVELOPMENT OF REGISTRIES IN CENTRAL EUROPE

“National registries are known to improve diabetes outcomes. Why, then, is so little emphasis placed on their development and implementation in our region?”

Zdravko Kamenov, Bulgaria.

Background
It is well known that diabetes affects the entire European continent, yet it is also known that there are significant regional differences both in terms of prevalence and treatment approaches. In order to address the inequalities that exist across Europe, it is critical to have region and country specific information regarding diabetes, its complications and treatment strategies – also in and within Central Europe.

Although a majority of European countries have a national diabetes register for all people diagnosed with diabetes, most consider these registers to be incomplete [6]. As for Central Europe, countries in this region are lagging further behind both when it comes to availability and current state as evidenced by the survey conducted by Working group 1 (reported below).

As is clear from the survey, most of the countries in Central Europe do not yet have accurate information about their diabetes situation. Many of them have initiated projects to establish national registries, yet in most instances these fall short of the standards required to enable real improvements.

A registry has several purposes [7]
1. Identification of individuals
2. Protection of the individual
3. Surveillance
4. Epidemiology
5. Planning, activities and evaluation of services
6. Evaluation of treatment
7. Research
8. Education
9. Other uses of disease registers

Information technology is evolving at a rapid pace and revealing new possibilities to improve the quality and safety of care. Data provided by diabetes registries may be used to improve the health of individual patients and to identify gaps in care for the broader diabetes population.

Accurate estimates of the numbers of people with diabetes support rational planning, development of services and allocation of resources at local and regional levels. A registry is a comprehensive management tool for quality improvement in diabetes care and communication among professionals.

“The national registry should be the mirror of diabetes: number of patients, type of diabetes, complications, treatment, costs, evolution. It is a mandatory instrument and a priority in the healthcare system, which ultimately reflects our activity.” Gabriela Roman, Romania.
STATUS QUO ON REGISTRIES IN CENTRAL EUROPE: THE DEICE SURVEY

The DEICE Working group 1 set out to establish the availability and state of national diabetes registries in five countries in order to improve understanding of status quo and offer up-to-date recommendations on that basis. The survey comprised 12 key questions, with a number of subquestions, pertaining to the situation with regards to diabetes registries in Bulgaria, Croatia, Czech Republic, Hungary, Poland, Romania and Serbia:

1. Is there an official and country wide registry in the country?
2. Who is the owner of the information in this registry?
3. Who is authorized to input the data in the registry?
4. How the personal data safety is secured (General Data Protection Regulation)?
5. Is the data input obligatory?
6. What is included in the registry (if existing)?
7. Is the registry directly connected/synchronized with the global health care electronic system in the country?
8. What are the measures if the authorized persons do not input data when obligatory?
9. Who controls the quality of the data in the registry?
10. Which proportion of all patients with diabetes are already included in the national registry (if existing)?
11. What are the barriers for the preparation and introduction of a national registry (if not existing)?
12. Who is paying for the software and IT support of the registry?

The full survey questionnaire, including responses, can be found in Appendix A.
KEY FINDINGS:
THE STATE OF AFFAIRS OF DIABETES REGISTRIES IN CENTRAL EUROPE

Countries in DEICE survey with functional registries:
ZERO

None of the countries in the survey have a fully functional national diabetes registry.

MoH is the key stakeholder

As the owner and sponsor of the national registries across four of the seven countries, The Ministry of Health is a key stakeholder.

Registries in progress:

All seven countries have initiated efforts to develop/implement a registry, albeit not necessarily encompassing all patients.

Who can input data into national registries?

Specialists: All countries

100%

GPs: 3/7 countries

43%

It is mainly specialists (endocrinologists/diabetologists) who are authorised to input data into national registries. Only in three countries can GPs do so (Bulgaria, Croatia and Serbia).

2 in 7 Countries

Inputting data into the registries is only obligatory in two of the seven countries so far (Czech Republic and Serbia). There are no measures/consequences of not inputting data into the registries.

Low priority for MoH

No/limited Resources

Key barriers to development/implementation of diabetes registries: Low priority for MoH, no resources.
Registry data linked/synchronised to e-healthcare systems (not necessarily universal):

**4 of 7 Countries**

In 4 of 7 countries (Bulgaria, Croatia, Czech Republic and Serbia) the registry is directly connected/synchronised with the global electronic healthcare system. In Poland it is linked/synchronised to e-healthcare systems, although no single universal nationwide system exists.

Proportion of patients included in national registries:

Only two countries report the proportion of all patients with diabetes as included in the national registry: Czech Republic estimates that 80-90% of patients are registered, in Croatia it is approximately 20%.
POLICY RECOMMENDATIONS: DEVELOPMENT OF REGISTRIES IN CENTRAL EUROPE

On the basis of experience from countries with solid national registries, as well as the outcome of the DEICE survey in the Central European region, it is clear that by having firm and strong data about the quality of diabetic care, health authorities will be motivated to enhance diabetes care in our countries.

Hence, Working group 1 (Development of registries in Central Europe) puts forward the following policy recommendations for immediate attention by policymakers:
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<th>No.</th>
<th>Proposed policies / actions</th>
<th>Proposed timeline</th>
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<tbody>
<tr>
<td>1</td>
<td>Build national registries, with all the actions that are required by the MoH, Health insurances, etc. Leverage existing efforts to get national diabetes registries implemented, as soon as possible.</td>
<td>Now ’20 ’21 ’22 ’23</td>
<td>Low Medium High</td>
</tr>
<tr>
<td>2</td>
<td>Analyse already existing national registry efforts and form a common minimum data set as a first step towards a Central European diabetes registry. Further develop and unify the content of the CE registry.</td>
<td>Now ’20 ’21 ’22 ’23</td>
<td>Low Medium High</td>
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<tr>
<td>3</td>
<td>Gather all relevant stakeholders, country by country, with the aim of establishing national advisory groups to the MoH that can focus solely on supporting ongoing efforts to get a national diabetes registry fully implemented. Experts in the fields of diabetes, medical, legal, IT, GDPR and epidemiology should be included.</td>
<td>Now 1H,’20 ’21 ’22 ’23</td>
<td>Low Medium High</td>
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<tr>
<td>4</td>
<td>National registries should be integrated with the existing official database/e-health record systems in the countries (if such exists) to avoid duplication of data.</td>
<td>Now ’20 ’21 ’22 ’23</td>
<td>Low Medium High</td>
</tr>
<tr>
<td>5</td>
<td>Undertake to commission a study of relevant countries that have experience with national diabetes registries. Extract learnings relevant for the CE region countries and build on those in the continued efforts to implement national registries.</td>
<td>Now ’20 ’21 ’22 ’23</td>
<td>Low Medium High</td>
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<td>6</td>
<td>Build an economic case for investing in national registries. With improved data comes improved management, and as a consequence direct and indirect treatment costs may be reduced potentially paving the way for a self-financed solution (long-term).</td>
<td>Now ’20 ’21 ’22 ’23</td>
<td>Low Medium High</td>
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<tr>
<td>7</td>
<td>If not possible to build a national diabetes registry then, as a first step, extract data from existing official databases to facilitate improved availability of national data and insights.</td>
<td>Now ’20 ’21 ’22 ’23</td>
<td>Low Medium High</td>
</tr>
<tr>
<td>8</td>
<td>Strive for standardisation, completeness and precision of the data in all national registries.</td>
<td>Ongoing ’20 ’21 ’22 ’23</td>
<td>Low Medium High</td>
</tr>
<tr>
<td>9</td>
<td>Ensure compliance with current &amp; future GDPR requirements.</td>
<td>Ongoing ’20 ’21 ’22 ’23</td>
<td>Low Medium High</td>
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FOCUS AREA: ACCESS TO CARE AND INNOVATION

“Without proper access to care and innovation in our region, our diabetic populations will continue to suffer from suboptimal treatment. Is now not the time to do something about it?” Cornelia Bala, Romania.

Background
In European countries access to diabetes care, medicines, medical devices and innovation is uneven. Citizens do not have the same range of choices for diabetes treatment [8]. The options available to individual people with diabetes and healthcare providers depends on cost, availability and supplies and is affected by the assessments made by health institutions of each product’s clinical role, and by controls over health spending both resulting in prescription guidelines and criteria.

The goals of improving the quality of diabetes care are to close gaps between current and best medical practice, improve access to care, and eliminate disparities.

Ensuring access to medicines, devices and innovation is certainly a costly, complex and resource-consuming challenge and it is only one element in high-quality, comprehensive diabetes care.

Access to quality medicines and medical devices for diabetes care
Access to medicines and medical devices can be achieved by ensuring the following:

Availability
Availability is defined as the presence in a country of products that meet the population’s health needs. It refers to the range of products marketed in a country; which of them are selected by the health system; and how and according to which indications and guidelines they should be prescribed and delivered.

Accessibility
Accessibility refers to physical access to the products, or where the products can be delivered to people. It involves the overall organisation of the health system and especially, its procurement, supply and dispensing systems.

Affordability
Affordability refers to a product’s cost vs. the ability and willingness of people (as well as health systems and third-party payers) to pay for it. It is pertinent to bridge the gaps between technology providers, pharmaceutical companies, science, regulators and academia to better understand the missed opportunities and challenges in managing diabetes. Central Europe should embrace innovation more effectively, support new initiatives and take the lead in stakeholder consultation.
Status quo on Access to care and innovation in Central Europe

As part of the work conducted in Working group 2, Bulgaria and Romania have provided a detailed overview of the status on availability, accessibility and affordability in their countries. The overviews can be found in Appendix B. Albeit not representative for all countries across the Central European region, the overviews are good indicators of the diabetes status quo in the region as well as a pertinent reminder of the changes required to achieve optimal care.

Policy recommendations: Access to care and innovation

IDF Europe member organisations for both healthcare professionals and people with diabetes have indicated that access to medicines or medical devices is uneven in EU countries and the co-payment system (which is often not proportionate to the economic situation of the country) also contributes to increased non-adherence to recommended treatments. Cost, availability and lack of supplies are the most frequently cited problems amongst low-income countries.

The recommended policy goals of Working group 2 with regards to improving the quality of diabetes care are to close gaps between current and best medical practice, improve access to care, and eliminate disparities as follows:

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<th>Proposed timeline</th>
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<tr>
<td>1</td>
<td>Review current policies regarding the structure of funds spent on diabetes care, eg. assessing the levels of system resources spent on test strips vs oral agents vs insulins vs new glucose monitoring systems (large variations between the countries expected). Based on this analysis identify “best in class” countries to improve accuracy in allocation of funding.</td>
<td>Now ’20 ’21 ’22 ’23</td>
<td>Low Medium High</td>
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<tr>
<td>2</td>
<td>Conduct studies in local populations which would allow more exact and direct assessment of care costs and outcomes.</td>
<td>Now ’20 ’21 ’22 ’23</td>
<td>Low Medium High</td>
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<tr>
<td>3</td>
<td>Set up a Central European registry as a subset of national registries. The purpose of this would be the ability to gather data and analyse the use of new therapies in local populations and link these to costs and outcomes for the entire region.</td>
<td>Now ’20 ’21 ’22 ’23</td>
<td>Low Medium High</td>
</tr>
<tr>
<td>4</td>
<td>Ensure that new treatments and technologies are used by trained and certified specialists to maximise the effect and resources spent.</td>
<td>Now ’20 ’21 ’22 ’23</td>
<td>Low Medium High</td>
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<tr>
<td>5</td>
<td>Prescription of new treatments and technologies based on assessment of the effect of therapy by referring the patients for adequate tests and procedures (regular follow-up of patients).</td>
<td>Now ’20 ’21 ’22 ’23</td>
<td>Low Medium High</td>
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<td>6</td>
<td>Develop ‘package deals’ between payers and pharmaceutical companies (eg. where a new drug is reimbursed only if a company decides to lower the price of their older products thus helping bring the reference price level down for entire drug groups).</td>
<td>Now ’20 ’21 ’22 ’23</td>
<td>Low Medium High</td>
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<td>7</td>
<td>Encourage payers and pharmaceutical companies to agree on limits for total reimbursement levels (i.e. if reimbursement costs go above the limit, the company rather than the payer, will cover the surplus).</td>
<td>Now ’20 ’21 ’22 ’23</td>
<td>Low Medium High</td>
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<td>8</td>
<td>New financing models to maximise clinical profit against the net cost should be explored and agreed between all stakeholders, including patients with diabetes.</td>
<td>Now ’20 ’21 ’22 ’23</td>
<td>Low Medium High</td>
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FOCUS AREA:
MULTILEVEL CARE IN DIABETES

“With multilevel care comes improved solutions. With improved solutions come enhanced management. With enhanced management comes superior outcomes”.
Dario Rahelic, Croatia.

Background
Diabetes is a serious global public health issue which has been described as the most challenging health problem in the 21st century. This single disease places a significant burden of care on the individual, healthcare professionals and the healthcare system. GPs are often reluctant to take on diabetes care in the community because of lack of resources in primary care, lack of time and lack of access to members of the diabetes multidisciplinary team within the community. Furthermore, a significant proportion of diabetes patients still remain undiagnosed. It is anticipated that the Integrated Care Model will increase the numbers of people being diagnosed with Type 2 diabetes and ensure that people with diabetes receive the highest standard of medical care possible.

Status quo on multilevel care in diabetes
The term ‘multilevel care’ in diabetes is widely used and has come to be understood in different ways. In the context of Central Europe, the focus of multilevel should be:

- Diabetes prevention
- Improved management of diabetes in primary care
- Better self-management support
- Enhanced management of diabetes in secondary and tertiary care

Diabetes prevention
One of the key aspects of diabetes prevention is management of people with high risk of diabetes, e.g. women with gestational diabetes, children born from mothers with gestational diabetes, children with low and high birthweight, people with Type 2 diabetes in their family history. To that end, having solid country-wide diabetes registries that allow for diabetes risk assessment is key. As alluded to in this Expert Declaration, Central Europe is notoriously behind when it comes to diabetes registries and as such, countries in our region are compromised in their abilities to carry out strategies and implementation of diabetes prevention.

Another element of diabetes prevention is allowing treatment to be initiated earlier in the pathway via e.g. a pro-active approach to treatment of people with pre-diabetes, considering non-pharmacological treatment options, conducting studies on prediabetes and new treatments and frequently revising and updating guidelines. Working with the Ministry of Health or National Insurance Companies to create registries for diabetes will, again, enable improved outcomes and lead to better prevention.

Lastly, our countries should allow earlier initiation of medicines with confirmed effect on mortality and CV and renal event reductions. As a point in case, it takes 2-3 times longer for novel diabetes treatments to reach countries in Central Europe compared to EUS.
Improved management of diabetes in primary care

Primary care plays an increasingly significant role in the management of diabetes in Central Europe. Therefore, annual risk assessments in connection with regular visits would go a long way to improve diabetes. A number of tools could be applied to aid GPs in our region, such as the FINRISK score calculator [9] and chronic complication screening in connection with diagnosis. Moreover, guidelines/updated guidelines specifically aimed at primary care would improve management of diabetes in general. Moreover, continuous training and education of GPs in diabetes treatment and management, including changing undergraduate curriculae at universities, is critical in order to raise the quality levels of care provided by GPs in our region.

Better self-management support

Self-management of diabetes encompasses all levels of care – from primary to tertiary. At the primary level, initial and basic education of people with prediabetes and diabetes needs to improve. Patients should receive nutritional and physical activity counselling as well as help with glucose monitoring, including the use of various techniques such as continuous glucose monitoring systems.

Our region also has a long way to go in terms of structured patient education that is based on national consensus and developed in collaboration with people with diabetes as well as professional diabetes associations.

Enhanced management of diabetes in secondary and tertiary care

Secondary and tertiary health staff are a critical component of diabetes care. Continuous education of healthcare professionals in diabetes treatment, including courses focusing on outcome measures, continuous medical education courses, etc. is key to improving outcomes in Central Europe. Other initiatives that will encourage enhanced management are changing the residency and fellowship curriculae for specialists in internal medicine and endocrinology as well as for specialists who generally participate in the care of people with diabetes.

Finally, a multidisciplinary approach involving all key stakeholders with their own expertise is critical to achieving optimal diabetes results in Central Europe. Not only will people with diabetes benefit, but benefits such as reduced costs, decreased length of hospital stays, fewer readmissions, improved compliance and reduced mortality are likely to follow as well.

In conclusion, multilevel care in Central Europe can provide:

- earlier diagnosis
- reduction in the incidence of diabetes-related complications
- improvement of diabetes-related mortality and morbidity
- improvement of healthcare access
- reduction of direct and indirect costs of diabetes care
In order to achieve these goals, Working group 3 proposes the following policy recommendations:

### POLICY RECOMMENDATIONS: MULTILEVEL CARE IN DIABETES

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<th>Proposed timeline</th>
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<tr>
<td>1</td>
<td>Establish country-wide diabetes registries in all Central European countries. Registries to include data on pre-diabetes to enable prevention.</td>
<td>Now '20 '21 '22 '23 '24 '25</td>
<td>Low Medium High</td>
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<tr>
<td>2</td>
<td>Promote studies in pre-diabetes with new pharmacological treatment options to create documentation on preventative effect.</td>
<td>Now '20 '21 '22 '23 '24 '25</td>
<td>Low Medium High</td>
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<tr>
<td>3</td>
<td>Change legislation/remove barriers to introduce novel and innovative medicines faster across Central Europe.</td>
<td>Now '20 '21 '22 '23 '24 '25</td>
<td>Low Medium High</td>
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<td>4</td>
<td>Change legislation/adjust guidelines to allow treatment to be initiated earlier in the disease pathway.</td>
<td>Now '20 '21 '22 '23 '24 '25</td>
<td>Low Medium High</td>
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<td>5</td>
<td>Review current professional diabetes educational initiatives across Central Europe with the aim of recommending improved focus on diabetes in the curriculae.</td>
<td>Now '20 '21 '22 '23 '24 '25</td>
<td>Low Medium High</td>
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<td>6</td>
<td>Establish a national patient education initiative involving all key stakeholders.</td>
<td>Now '20 '21 '22 '23 '24 '25</td>
<td>Low Medium High</td>
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<td>7</td>
<td>Invest in and promote national diabetes plans that focus on multidisciplinary management of diabetes. Boost focus on patient self-management support and education programmes and support diabetes self-management education at all stages of diabetes care.</td>
<td>Now '20 '21 '22 '23 '24 '25</td>
<td>Low Medium High</td>
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CALL TO ACTION

Major structural challenges across the Central European region continue to stifle the ability to provide proper care for people with diabetes.

We call for urgent political prioritisation and action in Central Europe.

There are 7.6 million people living with diabetes in Central European countries and a pressing disparity exists between the diabetes prevalence in this region and Europe as a whole.

It is time to close the gap!

The majority of people with diabetes across our region are suboptimally treated due to a) lack of diabetes registries, b) poor access to care and innovation, and c) limited multi-level care.

We urge all responsible policymakers in our region to pay attention to these challenges, and act accordingly.
KEY RECOMMENDATIONS

DEVELOP
Develop and implement diabetes registries across Central Europe

IMPROVE
Improve access to care and innovation

PROVIDE
Provide multilevel care in diabetes

HOW RECOMMENDATIONS CAN BE ACHIEVED

Increase investments in development of registries

Study best practices

Strive for inclusiveness

Improve accuracy in allocation of funding

Encourage improved collaboration between payers and pharmaceutical companies

Enhance the use of registries

Enable faster access of novel medicines

Improve educational initiatives

Boost multidisciplinary management of diabetes

SUMMARY
# APPENDICES

## Appendix A: The DEICE Survey (2019)

### Current state of the registries in Central Europe countries

<table>
<thead>
<tr>
<th>Questions</th>
<th>BULGARIA</th>
<th>CROATIA</th>
<th>CZECH REPUBLIC</th>
<th>HUNGARY</th>
<th>POLAND</th>
<th>ROMANIA</th>
<th>SERBIA</th>
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</thead>
<tbody>
<tr>
<td>1. Is there an official and country wide registry in the country?</td>
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<td>1.1. No attempts to do it</td>
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<td>1.2.Existing willingness for having a registry at governmental (ministry of health) level</td>
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<td>1.3. In preparation</td>
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<td>1.4. Prepared, but not introduced into the practice</td>
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<td>1.5. Introduced, but no compliance from the physicians</td>
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<td>1.6. Fully functional</td>
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<td>2. Who is the owner of the information in this registry?</td>
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<td>2.2. Professional/medical associations</td>
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<td>3. Who is authorized to input the data in the registry?</td>
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<td>3.3. Endocrinologists/diabetologists and GPs</td>
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<td>3.4. All physicians</td>
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<td>4. How the personal data safety is secured (GDPR)?</td>
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<td>5. Is the data input obligatory?</td>
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<td>6. What is included in the registry (if existing)?</td>
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<td>6.3. Anthropometric data</td>
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<td>6.4. Duration of diabetes</td>
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<td>6.6. Biochemical results</td>
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<td>6.8. All other</td>
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<td>7. Is the registry directly connected/synchronized with the global health care electronic system in the country?</td>
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<td>7.3. Planning - please explain</td>
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<td>8. Control of the quality of the data in the registry?</td>
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<td>8.3. Dept. of Health Statistics</td>
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<td>9. Who is paying for the software and IT support of the registry?</td>
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<td>10. Which proportion of all patients with diabetes are already included in the national registry of existing? (still open question)</td>
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<td>11. Barriers for the preparation and introduction of a national registry (if not existing) (still open question)</td>
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<td>12. DEICE DECLARATION</td>
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</table>
In health system management, fair and equal access/availability of:

a. Medicines
   - innovative medications (insulin analogues, DPP-4 inhibitors, GLP-1 RA, SGLT2 inhibitors) are evaluated through a national Health Technologies Assessment (HTA) system and thereafter included in a positive list for reimbursement; they are 100% reimbursed and prescribed by specialist endocrinologists according to special criteria of the National Health Insurance Fund at initiation of therapy and during follow-up at 6-month intervals.
   - innovative medications are preferentially prescribed for patients according to the indications in the SmPC.
   - SUs, metformin, TZDs, human insulin may be prescribed by GPs.

b. Health services
   - the diabetes patients are taken care of by GPs, specialist endocrinologists, and other specialists for the assessment of complications.
   - all patients on innovative therapies are seen by a specialist endocrinologist at 6-month intervals for assessment of the effect of therapy and for prescribing the medications.
   - patients on only SUs, metformin, TZDs and human insulin are followed-up by GPs; they are referred to specialists/endocrinologists for adjustment of therapy in case of worsening of the glycaemic control.

c. Education to people living with diabetes or peer support
   - education of patients with diabetes is offered as part of the in-patient and out-patient consultation.
   - structured education of patients is available in just a few university centres.
   - education of patients with diabetes is not reimbursed.

d. Prevention
   - there is no program for diabetes prevention at a national level.
   - there are some activities and programs implemented in just a few university centres.

e. Self-management
   - self-monitoring of blood glucose (SMBG) is reimbursed only for patients on insulin therapy – a glucose meter and 450 test-strips per year for those on intensive insulin therapy and 300 test-strips per year for those on conventional insulin therapy; 1100 test-strips per year are reimbursed for patients under the age of 18 years and for pregnant women.
   - SMBG is not reimbursed for insulin-naïve patients.

f. Medical devices
   - Glucose meters and test strips are reimbursed only for patients on insulin therapy – a glucose meter and 450 test-strips per year for those on intensive insulin therapy and 150 test-strips per year for those on conventional insulin therapy; 1100 test-strips per year are reimbursed for patients under the age of 18 years and for pregnant women.
g. New technologies, medical devices, modern treatments and testing
- insulin pumps are reimbursed since 2017, but only older models; the new models need to be paid by the patients.
- sensors are not registered in the country and are not reimbursed and therefore need to be paid by the patients.
- measurement of HbA1c is reimbursed twice per year for patients with diabetes.
- modern treatments (insulin analogues, DPP-4 inhibitors, GLP-1 RA, SGLT2 inhibitors) are 100% reimbursed for patients meeting special criteria of the National Health Insurance Fund and when prescribed by specialist endocrinologists.

h. Personnel, dieticians
- the diabetes team currently includes physicians and nurses.
- there are over 500 specialists endocrinologists in Bulgaria but they are not evenly available throughout the country.
- there are only a few dietitians, and such service is not available for the majority of patients.
- there are no registered podiatrists.
- psychological care is not available for patients with diabetes.

For the medical professionals, access/availability of

a. Resources/funding for treatment/care
- funding for diabetes care is provided by the National Health Insurance Fund – define payment for outpatient consultation and for hospitalisation.
- specific activities related to diabetes (screening, education, training) are not paid for.

b. Prevention/early diagnosis/screening
- laboratory methods/equipment/facilities for screening and early diagnosis of diabetes are available at specialist endocrinology centres.

c. Equipment and facilities
- equipment/facilities for screening and diagnosis of micro- and macrovascular complications of diabetes are available at other specialist (neurology, cardiology, nephrology, ophthalmology) centres, but referral is limited to once in two years.

d. Continuous training of diabetes specialists and general practitioners
- continuous training of specialists and GPs is provided by the scientific societies in the field and by the CME at the medical universities.

Barriers and opportunities for managing diabetes in resource-limited settings:

a. Policy barriers: institutional, regulatory financial
- limited and quite insufficient number of test-strips for SMBG reimbursed per year.
- sensors not registered and not available.
- prescription of innovative medications according to restrictive criteria of the National Health Insurance Fund.

b. Lack of training of staff
- diabetes specialists nurses not available.
- dietitians, podiatrists, psychologists not available.

c. Lack of diagnostic tools in health centers

d. Lack of information for patients

e. Lack of performance measures indicators of quality of diabetes care
- no audit system for the quality of care indicators is currently in place.
APPENDICES
Appendix B: Status on availability, accessibility and affordability in Bulgaria and Romania

Romania [11,12,13]

Health system management
- Consultations (at diabetes specialists, GPs, other specialists), specific medications and devices for diabetes management are 100% reimbursed for people with diabetes enrolled in the National Health Insurance system; those who are not eligible for a health insurance coverage (e.g. unemployed, or lack of any financial income) are granted health insurance coverage following diagnosis of diabetes (all types).
- All patients with diabetes are included as beneficiaries of the National Diabetes Program which grants 100% reimbursement for HbA1c testing, diabetes medication, self-monitoring of blood glucose, CGMS, insulin pumps based on eligibility criteria.
- Innovative medications are evaluated through a national Health Technologies Assessment (HTA) system and are prescribed according to national protocols approved by the Ministry of Health and the National Insurance Company.
- Education for people with diabetes is offered as part of the diabetes consultation; no diabetes self management education (DSME) services are reimbursed in the framework of the health insurance system.
- Prevention of diabetes is done on an individual basis, with no structured system in place.
- Consultations with a dietician are not reimbursed.
- Psychological care is offered free-of-charge for patients with diabetes.

Medical professionals
- Availability of innovative medication has improved since 2016 when the approvals for prescription granted by a commission established at county level was withdrawn.
- Some treatment combinations are excluded from reimbursement based on HTA scoring and prescription protocols.
- All methods/equipment/facilities of screening and early diagnosis of diabetes and of micro- and macrovascular complications are available, but waiting lists may apply for more complex methods (e.g. imaging techniques for vascular assessment) or for diabetes consultations (the latter applies in some regions/counties where the number of diabetes specialist is low). Continuous specialist training for GPs is provided by the scientific societies in the field.

Barriers and opportunities
- HbA1c testing is covered for a limited number of patients with diabetes (around 60,000 tests/year for over 900,000 patients enrolled in the National Diabetes Program).
- Number of strips is considered insufficient for patients with insulin-treated diabetes (100 strips at 3 months) but it was recently increased to 200 strips at 3 months for patients with Type 1 diabetes over the age of 18 years and maintained at 300 strips at 3 months for patients with Type 1 diabetes< 18 years of age.
- The lack of structured DSME programs offered free of charge as a part of the National Diabetes Program represents a limitation to better use of diabetes medication and devices and to better adherence to diabetes management.
- No audit system for the quality of care indicators is currently in place.
**REFERENCES**

2. Tsanova, D.K et al, Diabetes in Bulgaria and the need for mental health technology assessment, 2017. Management in Health XXI/4/2017;11-15
6. Diabetes in Europe, Policy Puzzle, The state we are in; European Coalition for Diabetes; 2014

Additional/general references:
https://www.openaccessgovernment.org/diabetes-a-global-health-challenge/46992/
