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The Burden of Diabetes and Options for Reform

Insights for the Greek Health System

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Disclaimer

Greek Diabetes policy reform is highly topical and is constantly evolving. Sources published after February 1st, 2025 were not used in the development of this report.

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Abbreviations

AMKA	Social Security Number
CGM	Continuous Glucose Monitoring
CKD	Chronic Kidney Disease
CRM	Cardio-renal-metabolic
CVD	Cardiovascular disease
DHTs	Digital Health Technologies
DM	Diabetes Mellitus
DPP-4i	Dipeptidyl peptidase-4 inhibitors
DR	Diabetic Retinopathy
DRD	Diabetes-Related-Distress
DRDER	Digital Repository of Diagnostic Examination Results
DTP	Diagnostic, Therapeutic and Prescribing
EHRs	Electronic Health Records
eGFR	Estimated Glomerular Filtration Rate
EMENO	National Survey of Morbidity and Risk Factors
EOPYY	National Organization for the Provision of Health Services
GDP	Gross Domestic Product
GLP-1	Glucagon-like peptide-1
GP	General Practitioner
HbA1c	Haemoglobin A1c
HDA	Hellenic Diabetes Association
HRQoL	Health-related Quality of Life
HSA	Hellenic Statistical Authority
HTA	Health Technology Assessment
ICS	Integrated Care Systems
IDF	International Diabetes Federation
IDIKA	Social Insurance Electronic Governance
IEHF	Individual Electronic Health File
LSE	London School of Economics
MDIs	Multiple Daily Injections
MoH	Ministry of Health
NAFLD	Non-alcoholic fatty liver disease
NAPPH	National Action Plan for Public Health
NCDs	Non-communicable Diseases
NDP	National Diabetes Plan
NGO	Non-governmental organisations
NHS	National Health Service
OECD	Organisation for Economic Co-operation and Development
OOP	Out-of-pocket
OTC	Over the counter
PDTA	Percorsi diagnostico-terapeutici assistenziali (Diagnostic and Therapeutic Pathways)
PLWD	People Living with Diabetes
PLWT1D	People Living with Type 1 Diabetes
PLWT2D	People Living with Type 2 Diabetes
SFEE	Hellenic Association of Pharmaceutical Companies
SGLT-2	Sodium-glucose cotransporter 2
T1D	Type 1 Diabetes
T2D	Type 2 Diabetes
THE	Total Health Expenditure
TPE	Total Pharmaceutical Expenditure
UACR	Urine Albumin-to-Creatinine Ratio
WHO	World Health Organization

Executive summary

Background
Diabetes mellitus (DM) is a chronic disease characterized by elevated blood glucose levels that poses a significant global health challenge. The World Health Organization (WHO) projects a substantial increase in diabetes prevalence, with significant implications for mortality, quality of life, and healthcare systems. Effective diabetes management requires a holistic approach that addresses the complex interplay between DM and other chronic conditions, emphasizing prevention, early intervention, and patient-centred care. This necessitates a shift from reactive to proactive care models, prioritizing patient empowerment and improving the efficiency of care delivery.

The Greek health system faces several challenges in addressing the rising burden of diabetes. This report explores the burden of DM in Greece and identifies opportunities for health system reform to improve diabetes care and management. The study aims to offer insights for Greece to improve care coordination, efficiency, and effectiveness by outlining key opportunities for reform including the establishment of a national diabetes plan, improved integrated care, increased availability of digital health technologies, more robust data infrastructure, and increased HTA capacity building.

Objectives
Given the significant burden of diabetes and its associated complications, there is an urgent need to enhance diabetes care in Greece. This project aims to a) demonstrate the burden of diabetes in Greece and the Greek system's current approach to care management, b) identify international approaches to managing the burden of diabetes and its required care delivery, and c) highlight opportunities for improvements in diabetes management in Greece by:

1. Outlining the steps that are needed to establish a national diabetes plan in Greece by drawing, among others, on best practices from a variety of settings.
2. Identifying the key levers that will enable significant changes in diabetes care and shifts from fragmented to integrated care pathways.
3. Outlining the potential that digitization offers in the Greek setting, with particular emphasis on improving data infrastructure.
4. Identifying likely changes in national pharmaceutical policy that will be conducive to improving quality of care in diabetes management

Methods
This study employed a mixed-methods approach, combining a targeted literature review with key informant interviews. The literature review encompassed peer-reviewed articles, grey literature, and government reports from international organizations and Greek sources. A comparative analysis of diabetes care in Greece with selected European countries (Denmark, Italy, Portugal, Romania, Spain, and the UK) was conducted, focusing on indicators such as primary care quality, complications management, screening programs, and national diabetes strategies. Key informant interviews were conducted with healthcare professionals, patient representatives, industry representatives, and policymakers to gather insights into the current state of diabetes care in Greece and identify opportunities for improvement. A thematic analysis was conducted to identify key themes and insights from both literature and interview data.

Results
Advanced diabetes care systems prioritize a proactive and patient-centred approach, emphasizing prevention, early intervention, and effective management throughout the care continuum. Key

features include robust screening programs, multidisciplinary care teams, and the integration of social determinants of health. These systems leverage technology to empower people living with diabetes to improve disease self-management and aid providers in delivering appropriate care. A holistic approach that considers individual needs, cultural backgrounds, and socioeconomic circumstances—coupled with a commitment to continuous quality improvement—is essential for achieving optimal health outcomes for people living with diabetes.

Greek diabetes prevalence estimates vary, but available data suggests a significant proportion of the population is affected. The burden of DM is substantial, with increasing mortality rates and a significant economic impact on the healthcare system. While the exact number of deaths attributable to diabetes is debated, it is clear that diabetes contributes significantly to mortality in Greece. Complications such as cardiovascular disease, kidney disease, and neuropathy are prevalent, significantly impacting quality of life. The presence of comorbidities, such as obesity and cardiovascular disease, further complicates diabetes management and increases the risk of adverse outcomes.

Diabetes care delivery presents several challenges, including fragmentation of care across providers, limited access to specialists in some regions, and inadequate data infrastructure. While progress has been made with expanded reimbursement for diabetes technologies, challenges remain in care coordination, data sharing, and the implementation of national diabetes care guidelines. The lack of a comprehensive National Diabetes Strategy and limited data availability hinder effective policymaking and the ability to accurately assess the burden of diabetes on the Greek healthcare system. While the economic burden of diabetes on the Greek healthcare system is substantial, precise data on the financial impact is limited. Challenges in data collection and reporting hinder a comprehensive understanding of the disease burden, including accurate prevalence estimates, incidence of complications, and the true impact on healthcare resource utilization.

Diabetes prevention primarily focuses on mitigating risk factors for Type 2 diabetes (T2D), such as obesity and poor diet. While the National Action Plan for Public Health acknowledges the importance of prevention, specific strategies for diabetes prevention are limited. Key findings include high rates of childhood obesity, limited focus on diabetes prevention in national policies, insufficient primary prevention efforts, and challenges in screening and early detection for T2D, T1D, and gestational diabetes and their related complications.

Access to essential diabetes medications and technologies is improving in Greece, with increased reimbursement coverage indicated soon for CGMs. However, challenges remain. Greece lags behind other European countries in the time it takes for new medicines to reach patients. The absence of HTA for medical devices limits the ability to assess value and negotiate fair prices. Furthermore, data limitations hinder the development of value-based healthcare models and the implementation of innovative reimbursement mechanisms.

Recommendations

Key recommendations for improving diabetes care in Greece include:

⇒ Developing and implementing a National Diabetes Strategy: This strategy should prioritize prevention, early detection, and integrated care, with a focus on addressing the needs of diverse subpopulations, including vulnerable groups.

⇒ Improving uniform care delivery: Further development of Greece's Diagnostic, Therapeutic and Prescribing protocols that include consideration of cost-effectiveness, subgroup differentiation, and individualised care plans would improve the sustainability and affordability of diabetes care.

⇒ Strengthening primary care: Enhancing the role of primary care as the first point of contact and care coordinator is crucial for improving access, ensuring continuity of care, and relieving pressure on secondary care.

⇒ Investing in health data infrastructure: Building a robust and interoperable health data infrastructure is essential for accurate epidemiological surveillance, improved care coordination, and informed policymaking.

⇒ Expanding HTA capabilities: Extending HTA to include medical devices and digital health technologies will enable more effective technology assessment and promote value-based care.

⇒ Improving access to digital health technologies: Expanding reimbursement for telehealth services and promoting the integration of digital health technologies into clinical practice can improve access to care, particularly for individuals in remote areas

1. Introduction

Diabetes mellitus (DM), a chronic condition characterised by elevated blood glucose levels, presents a significant global health challenge, impacting individuals, healthcare systems, and economies worldwide (*Diabetes*, 2024). Projections by the World Health Organization (WHO) indicate a concerning rise in prevalence, with an estimated one in ten people in the WHO European region living with diabetes by 2045 (*WHO*, 2024). The rising prevalence of diabetes is associated with increased mortality, reduced quality of life, and a significant economic burden on healthcare systems *(Zhuo et al., 2013)*. Early intervention and effective, ongoing disease management are crucial for preventing or delaying the onset of diabetes-related complications and improving overall health outcomes for people living with diabetes (PLWD). Effective disease management is further complicated by the intricate interplay between DM and other co-occurring conditions, often exacerbating the overall disease burden and requiring a multifaceted approach to care. Addressing this complexity necessitates a holistic perspective that encompasses not only medical interventions, but also considers the social, cultural, psychological, and technological aspects of care delivery. Increasingly, health systems are taking steps to shift from reactive, episodic care models to proactive, patient-centred approaches that prioritize prevention and early intervention. This approach aims to not only improve the overall quality of care for PLWD but also the overall efficiency of care, reflecting a reduced burden of disease through effective interventions. The Greek health system faces several hurdles to positioning itself proactively to tackle the rising burden of diabetes, though recent initiatives offer a promising appetite for policy change and care delivery reform. Mastering this proactive approach requires robust primary care infrastructure, advanced health information systems, equitable access to care and community resources, a skilled healthcare workforce, a strong focus on patient empowerment and self-management, and continuous quality improvement that enables prompt access to innovative medical technologies.

This report will explore the burden of DM in Greece and opportunities for health system reform. This report is structured across four main sections. Section 1 provides an introduction, outlining the research objectives and providing essential background information on diabetes. Section 2 details the research methodology, encompassing a targeted literature search, semi-structured key informant interviews, and the analytical framework employed to address the study's objectives. The core of the report resides in Section 3, which presents the Results. This section includes an analysis of the characteristics of advanced diabetes care systems. Thereafter, it examines the burden of diabetes in Greece, explores diabetes care delivery within the Greek context, investigates diabetes prevention strategies, and conducts a comparative analysis of diabetes care in Greece with selected comparator countries (Denmark, Italy, Portugal, Romania, Spain, and the UK). Finally, Section 4 provides a series of identified opportunities and recommendations for improving diabetes management in Greece. These recommendations encompass the development and implementation of a national diabetes plan, the facilitation of an integrated care system, the exploration of the potential of digital health technologies (DHTs), and the recommendation of changes to pharmaceutical policy

1.1. Background

The aetiology of diabetes is multifaceted, involving a complex interplay of genetic and environmental factors. While type 1 diabetes (T1D) is an autoimmune disease, type 2 diabetes (T2D), the most prevalent form, is strongly influenced by lifestyle factors. Sedentary behaviour, unhealthy dietary patterns, and obesity have emerged as key risk factors for the development of T2D (Reed et al., 2021).

Approximately 64 million adults and around 300,000 children and adolescents currently live with diabetes in Europe, making it one of the most common chronic conditions in the WHO European Region. In 2021, the number of deaths as a result of diabetes and its complications in Europe reached a staggering 1.1 million (IDF, 2021). In 2021, the total estimated medical cost of diabetes in Europe was $189.3 billion (IDF Atlas Report, 2021)

Following the European trend, prevalence of diabetes in Greece has also been steadily increasing over the last three decades. This rise in prevalence is attributed to the rapid socioeconomic development of recent decades, which has led to significant changes in lifestyle. These changes include increased sedentary behaviour, reduced physical activity, higher consumption of processed foods, and rising rates of obesity (V. Loupa et al., 2017). The Greek national economy and health system face a substantial economic burden due to diabetes. With the Greek healthcare system covering 90-100% of anti-diabetic medication costs, the annual prescription cost per PLWD reached €1,674.93 in 2021(IDF, 2021).

While advancements in medical science have led to effective treatments for managing hyperglycaemia in DM, the long-term consequences of the disease persist. Cardiovascular disease, kidney disease, and neuropathy remain prevalent complications that significantly reduce life expectancy and quality of life for individuals with T2D. These complications not only impose a substantial financial burden on healthcare systems but also place a significant strain on individuals and families (Reed et al., 2021). Furthermore, DM can have a bidirectional relationship with several other co-occurring conditions, worsening outcomes across therapeutic areas for people living with the disease.

Traditional approaches to diabetes treatment and care adopted a reactive approach, often focusing on glycaemic control, overlooking the broader impact of the disease and its complications (Prato et al., 2010). This underscores the need for comprehensive strategies to prevent, diagnose, and proactively manage DM effectively. A holistic, patient-centred approach is required to effectively address the multifaceted challenges posed by DM, specifically T2D. This demands the implementation of integrated care systems that involve multidisciplinary teams of healthcare professionals, including physicians, nurses, dietitians, mental health professionals, and pharmacists. By collaborating closely, these teams can provide comprehensive care, encompassing medical treatment, lifestyle modifications, and psychosocial support (Davies et al., 2022).

One promising approach to wholistic diabetes care is the cardio-renal-metabolic (CRM) perspective. By focusing on the interconnectedness of cardiovascular, renal, and metabolic disorders, the CRM approach allows for a more nuanced understanding of the disease burden associated with DM. This framework can help identify high-risk individuals, implement targeted interventions, and ultimately reduce the risk of complications and mortality (Marassi & Fadini, 2023). By adopting a CRM perspective, healthcare providers can reevaluate the true impact of DM on public health. This includes assessing the number of hospitalizations, deaths, and years of life lost due to diabetes-related complications.

The European Union (EU) Council, recognizing this interconnectedness, has consistently stressed the importance of addressing CVD and its link to diabetes. As highlighted in the Council conclusions on the improvement of cardiovascular health in the EU (2024), the EU acknowledges that CVDs can be a complication of T2D and that preventing diabetes has a direct positive benefit on other NCDs, including CVD. This aligns with previous Council conclusions on healthy lifestyles and T2D prevention (2006). Furthermore, the European Commission, through the Euro Health Union,

prioritizes NCDs, including CVD, as confirmed in their 2024 communication, and has launched initiatives like JACARDI to combat CVD and diabetes. The European Parliament also recognizes the significant overlap, noting that one-third of people living with diabetes develop CVD. Diabetes significantly increases CVD risk due to high blood sugar damaging blood vessels and nerves, a risk further amplified by impaired renal function. Similarly, chronic kidney disease (CKD) independently elevates cardiovascular risk. Recognizing the strong link between kidney complications and diabetes, early kidney screening, including assessments of eGFR and UACR, is essential for delaying cardiovascular complications and warrants consideration in population screening programs Effective management of both diabetes and CKD, including lifestyle changes and risk factor control, is therefore crucial. Early detection of related conditions like hypertension and diabetes is key to improved outcomes. The EU recognizes the cardio-renal-metabolic (CRM) syndrome, linking obesity, T2D, CKD, and CVD, further emphasizing the need for integrated care (Council of EU, 2025). The EU's commitment to addressing CVD is further demonstrated by Greece's proactive approach. The Greek Health Minister has highlighted the country's national plan, in place since 2022, to support CVD prevention at all levels. A new project launched in December 2024 offers citizens screening opportunities and data collection, reinforcing this commitment (Stavrou, 2024).

This research aims to delve deeper into the impact of diabetes and its complications on healthcare systems, particularly in the European context, with a specific focus on Greece. By exploring the nuances of diabetes care and the potential benefits of an integrated care approach, this study seeks to contribute to ongoing efforts to improve the management, prevention, and overall outcomes of diabetes and its related complications. Ultimately, this research aims to develop actionable and feasible policy recommendations to enhance diabetes care and management in Greece. These recommendations will be designed to improve patient outcomes, reduce the burden on the Greek healthcare system, and optimize the allocation of healthcare resources. By addressing the specific challenges faced by Greece in managing diabetes, this research aims to provide valuable insights for policymakers, healthcare providers, and patients.

Box 1 Overview of Diabetes Mellitus and its complications

Diabetes mellitus (DM) is a group of metabolic disorders that are characterized by elevated blood glucose levels. This happens due to the inability to produce insulin in the body, or a resistance developed to insulin or both (Papatheodorou et al., 2018). **Prediabetes** is a condition in which blood glucose levels are higher than normal but not yet high enough to be classified as diabetes. It is considered a precursor to T2D, increasing the individual's risk of developing the full-blown condition (NIDDK, 2018) .

There are three primary types of DM listed below (CDC, 2024).

1. T1D is an autoimmune disease that results in the destruction of insulin-producing beta cells in the pancreas. This leads to a complete deficiency of insulin, a hormone essential for regulating blood glucose levels. Individuals with T1D require daily insulin injections or a continuous subcutaneous insulin infusion pump to manage their condition.
2. T2D is a more common form of diabetes that develops gradually. It is characterized by insulin resistance, where the body's cells become less responsive to insulin, and impaired insulin secretion. Over time, the pancreas may become unable to produce sufficient insulin to compensate for insulin resistance, leading to hyperglycaemia.
3. Gestational DM develops during pregnancy when the body's demand for insulin increases, and the pancreas is unable to meet this demand. Gestational diabetes typically resolves after childbirth, but it increases the risk of developing T2D later in life for both the mother and the child.

T2D is the most prevalent form of diabetes, accounting for over 90% of cases. In contrast, T1D constitutes approximately 8% of cases. Gestational diabetes and other rarer forms of diabetes account for the remaining 2%. T2D is largely preventable through lifestyle modifications, including dietary changes and increased physical activity, aimed at reducing risk factors like obesity and sedentary behaviour (Magliano et al., 2021).

Complications of DM

If left untreated, diabetes can significantly impact a person's quality of life and may even lead to death. High blood sugar levels progressively damage blood vessels throughout the body, resulting in various complications affecting multiple organs, including the heart, kidneys, eyes, and nerves (Diabetic Neuropathy - NIDDK, 2024).

- *Cardiovascular disease (CVD)* is a major complication of diabetes. Hyperglycaemia, dyslipidaemia, and hypertension, commonly associated with diabetes, significantly increase the risk of atherosclerotic cardiovascular disease, myocardial infarction, stroke, and peripheral arterial disease.
- *Diabetic kidney disease* is another serious complication, often leading to progressive kidney damage and eventual kidney failure.
- *Neuropathy* is a common complication of diabetes that affects the nerves. It can cause numbness, tingling, pain, and weakness in the hands, feet, and other parts of the body.
- *Diabetic retinopathy* is a serious eye condition that can lead to vision loss and blindness. High blood sugar levels can damage the blood vessels in the retina, leading to swelling, bleeding, and the formation of scar tissue.
- *Foot ulcers* are a common complication of diabetes, particularly among individuals with neuropathy. Poor circulation and nerve damage can make it difficult to feel pain or notice injuries, leading to infections and ulcers that can be difficult to heal. In severe cases, amputation may be necessary.

1.2. Research objectives

Given the significant burden of diabetes and its associated complications, there is an urgent need to enhance diabetes care in Greece. This project aims to a) demonstrate the burden of diabetes in Greece and the Greek system's current approach to care management, b) identify international

approaches to managing the burden of diabetes and its required care delivery, and c) highlight opportunities for improvements in diabetes management in Greece by:

1. Outlining the steps that are needed to establish a national diabetes plan in Greece by drawing, among others, on best practices from a variety of settings.
2. Identifying the key levers that will enable significant changes in diabetes care and shifts from fragmented to integrated care pathways.
3. Outlining the potential that digitization offers in diabetes management and how this can be implemented and maximized in the Greek setting, with particular emphasis on improving data infrastructure.
4. Identifying likely changes in national pharmaceutical policy that will be conducive to improving quality of care in diabetes management.

2. Methods

This study, conducted between March 2024 and February 2025, utilized a mixed-methods research design involving a targeted literature search and key informant interviews.

2.1. Secondary Data Collection

To assess the current state of diabetes care and management in Greece, a targeted literature review was conducted, utilizing resources from international organizations such as the International Diabetes Federation (IDF) and the Organization for Economic Cooperation and Development (OECD), as well as local Greek institutions like the Social Insurance Electronic Governance (IDIKA). This comprehensive search included both English and Greek language sources, encompassing peer-reviewed articles, and grey literature and government reports. Additionally, diabetes care and management systems in other European countries were reviewed to identify international best practices, innovative approaches and successful interventions implemented in other countries.

A comparative analysis was conducted to identify countries with well-established integrated care systems for diabetes management, as well as countries with similar epidemiological, demographic, and sociocultural characteristics to Greece. The aim was to learn from the experiences and national plans of these countries to inform the development of effective diabetes care policies in Greece. To ensure a comprehensive assessment, the comparison criteria included indicators related to primary care management (such as the role of GPs), the effectiveness of complications management (including the prevalence of major complications such as lower foot amputations), the strength of national screening policies (encompassing the existence of screening programs, adherence to guidelines, and population coverage), and the prioritisation of diabetes within national health policies (including resource allocation, integrated care models, and the existence of national diabetes strategies). The United Kingdom and Denmark were selected as comparator countries with advanced integrated care systems for diabetes. These countries have demonstrated success in coordinating care across multiple sectors, implementing evidence-based guidelines, and improving patient outcomes. Spain, Italy, Portugal, and Romania were chosen as comparator countries with similar epidemiological, demographic, and sociocultural profiles to Greece. These countries share similar challenges related to diabetes prevalence, aging populations, and healthcare resource constraints. By understanding the strategies and outcomes of these comparator countries, Greece can identify best practices, overcome challenges, and implement effective diabetes care policies to improve the health and well-being of its population.

2.2. Primary Data Collection

Targeted literature review evidence was validated, complemented, and updated through in-depth interviews with stakeholders. This report draws upon the insights of thirteen stakeholders who were interviewed. Nineteen experts and stakeholders were initially contacted, including healthcare practitioners specializing in diabetes management, patient representatives from diabetes associations and federations, and key decision-makers such as the National Organization for the Provision of Health Services (EOPYY). Among those interviewed were four representatives from the working group of the Hellenic Association of Pharmaceutical Companies (SFEE), providing the industry perspective. Interviews, lasting approximately 1-2 hours each, were conducted from September to December 2024. Stakeholders were recruited through SFEE and London School of Economics (LSE) professional networks.

A semi-structured interview guide was developed and shared with SFEE for feedback. SFEE comments were incorporated into the guide and finalized before sharing with interviewees in advance to optimize interview time. It was tailored to the specific expertise of each stakeholder. The interview guide covered a range of topics, including the current state of diabetes care and management in Greece, the role of diabetes centres, treatment pathways for people living with diabetes (PLWD) and those with complications, the availability and accessibility of digital health technologies (DHTs) to address diabetes, and the requirements for developing a national diabetes plan and pharmaceutical policy for diabetes medicines and devices.

2.2.1. Analytical Framework

To analyse the qualitative data derived from key informant interviews, a dedicated analytical framework was constructed. This framework served as a structured approach to systematically extract and interpret relevant information from the interview transcripts. The analytical framework was developed with specific endpoints categorized as follows: Current issues; integrated care systems; the role of digital health technologies (DHTs); implementation of NDP in Greece; and pharmaceutical policy reform. A detailed description of these endpoints is outlined in Table 1. The analytical framework employed a thematic analysis to identify key themes, allowing for a systematic examination of the data.

Table 1 Analytical framework and key endpoints

Key themes of Analytical Framework	Key indicators/endpoints	Aim of framework theme and associated indicators
Current Issues	• Management • Access • Infrastructure • Underserved populations	Discusses the current issues/challenges faced by the healthcare system
Integrated care systems (ICS)	• Diagnostic pathways • Care coordination • Data Infrastructure	Examines the potential of ICS to improve patient outcomes
Digital Health Technologies (DHTs)	• Potential for DHTs • Barriers to adoption of DHTs	Explores the role of DHTs in transforming healthcare delivery
Implementing National Diabetes Plan (NDP)	• Core requirements • Stakeholder involvement • Monitoring & Evaluation • Equity	Assesses the feasibility and requirements for developing and implementing NDP
Pharmaceutical policy reform	• Health Technology Assessments (HTA) • Clawbacks • Out-of-pocket (OOP) expenditure • Shortages • Future direction	Analyses the current pharmaceutical policy landscape and explores potential reforms

2.3. Limitations

This study relied on a targeted literature review of diabetes care in Greece and comparator countries. While this approach provided valuable insights and enabled adaptability, the selection of literature was not systematic in nature.

3. Results

3.1. Characteristics of advanced diabetes care systems

A truly "state-of-the-art" diabetes care approach is holistic and patient-centric, built on a proactive health system that emphasizes prevention, early intervention, and effective management throughout the care continuum. This approach represents a paradigm shift from traditional care delivery approaches, which are historically reactive rather than proactive. To achieve this paradigm shift, health systems rely on not only prevention and early intervention strategies but also advanced technologies, comprehensive care coordination, and a personalised care approach.

Prevention and early intervention are essential components of advanced diabetes care, both in terms of the initial diabetes diagnosis and its complications. At the core of advanced diabetes care systems are robust and targeted screening programs designed to identify high-risk individuals, ideally before symptoms arise. These screening systems must be designed with interoperability across the country to ensure patients are not lost if they move to another region. Advanced health systems, such as that of the United Kingdom have begun using data-driven screening strategies to identify populations at increased risk of diabetes, especially among those with risk factors like family history, high body mass index, or metabolic syndrome (NHS Diabetes Prevention Programme (NHS DPP), 2024; NHS England, 2016). Predictive analytics can proactively flag patients based on electronic health record data, enabling outreach for early testing. While universal, comprehensive screening programs are still developing, targeted efforts in specific populations make a meaningful difference by stratifying risk, helping providers to catch the onset of diabetes earlier, before it progresses and leads to preventable complications. This population health management approach requires well-developed data infrastructure to ensure effectiveness by leveraging data from electronic health records (EHRs).

Managing diabetes effectively requires a comprehensive, multidisciplinary approach that extends beyond treating individual symptoms. Recognizing the complex and interconnected nature of the disease, advanced healthcare systems are embracing a collaborative model by assembling teams including but are not limited to, primary care physicians, endocrinologists (including diabetologists, internists specializing in diabetes), cardiologists, nephrologists, dietitians, diabetes educators, mental health professionals, and paediatricians specialized in diabetes (for younger patients). This team-based approach ensures a unified care plan that addresses all aspects of a patient's health, with clear communication facilitating timely adjustments as needed. To further streamline this model, many systems are employing diabetes care coordinators as single points of contact, guiding patients through the complexities of their care plan, managing appointments, and ensuring access to necessary resources. Primary care plays a crucial role in enabling care coordination. Complementing this, multi-specialty diabetes centres are emerging as centralized hubs where patients can access a comprehensive range of services and specialists in one location, often on the same day, facilitating real-time collaboration among providers. This integrated approach leads to demonstrably better health outcomes.

State-of-the-art diabetes care is incomplete without considering the social determinants of health—factors like access to nutritious foods, safe exercise spaces, and healthcare accessibility, which all affect how patients manage their diabetes. Integrating social care programs, addressing inequalities, and developing targeted strategies for underserved populations are essential. Equally important is providing behavioural and psychosocial support, including mental healthcare and caregiver support.

Technology is a cornerstone of state-of-the-art diabetes care, empowering patients to monitor their condition, access resources, and engage actively in their health management. Digital technology is revolutionizing diabetes care, providing patients with unprecedented tools for self-management and personalized treatment. For people living with type 1 diabetes (PLWT1D), advancements in insulin delivery systems, such as hybrid-closed-loop systems (also known as artificial pancreas systems), continuously monitor glucose levels and automatically adjust insulin delivery, mimicking the function of a healthy pancreas. Continuous glucose monitoring (CGM) systems, now widely available, offer real-time glucose readings and customizable alerts, allowing for proactive adjustments to diet and activity levels. Mobile applications seamlessly integrate with these devices, providing patients with comprehensive data visualization, trend analysis, and even remote monitoring capabilities for caregivers. For people living with type 2 diabetes (PLWT2D), the adoption of CGM is increasing, driven by growing evidence of its benefits in improving glycaemic control and reducing complications. However, access to CGM for T2D is often limited by reimbursement policies, which can vary significantly across countries and insurance plans. Advanced reimbursement policies cover CGMs for PLWT2D with multiple daily insulin injections and are increasingly moving towards more widespread coverage policies. Smart insulin pens, which track dosage and timing, and connected glucometers, enabling effortless data logging and sharing with healthcare providers, are also valuable tools for many individuals with T2D. Telemedicine platforms, particularly beneficial for rural populations, are improving access to specialized diabetes care, including virtual consultations, remote monitoring, and personalized education. Behavioural change applications, too, are emerging as promising tools for diabetes management. This integration of technology, coupled with the power of artificial intelligence and predictive algorithms, is transforming diabetes management, empowering patients, and enhancing the effectiveness of care.

Ultimately, the most advanced healthcare systems are moving beyond a one-size-fits-all approach to diabetes care, striving instead to provide a uniformly high standard of care that balances technological advancements with personalized, multidisciplinary interventions. This involves a commitment to continuous improvement, incorporating the latest research and technological advancements while recognizing the unique needs of the individual. This also involves, in part, a commitment to recognize social care as an essential component of health care. Strategies that incorporate social determinants of health are crucial to ensuring equitable access to high-quality diabetes care for all. This holistic approach recognizes that personalized care plans, tailored to individual lifestyles, cultural backgrounds, and socioeconomic circumstances, are essential for effective diabetes management. It involves fostering strong patient-provider relationships, promoting shared decision-making, and providing culturally sensitive education and support. By combining cutting-edge technology with a patient-centred ethos, systems strive to empower individuals to actively participate in their health journey and achieve optimal outcomes.

The state-of-the-art in diabetes management signifies a paradigm shift towards proactive, personalized, and technology-enabled care that extends beyond simply managing symptoms. By embracing a holistic approach that integrates prevention, early intervention, multidisciplinary collaboration, cutting-edge technology, and a deep understanding of social determinants of health, healthcare systems can help PLWD to achieve optimal health outcomes. Additionally, early diabetes management shows significant promise towards greater environmental sustainability and reducing the consumables-related carbon footprint in care delivery (Greener, 2023). While this approach necessitates upfront investments in infrastructure, technology, and workforce training, the long-term benefits far outweigh the initial costs. By preventing costly complications, reducing hospital readmissions, and improving overall health and well-being, this model of care will likely prove to be

the most cost-effective and ethically responsible approach for individuals and healthcare systems alike.

Box 2 Spotlight on diabetes care in England

England's National Health Service (NHS) demonstrates a concerted effort toward state-of-the-art diabetes care, incorporating many aspects of a proactive and patient-centric approach, though challenges persist. Utilizing a strict GP gatekeeper, the NHS offers comprehensive and largely free-at-the-point-of-use services for PLWD, encompassing screening, diagnosis, treatment, and ongoing support. A key strength lies in its structured, tiered, and integrated approach to diabetes management that is supported by digital infrastructure and financial incentives.

This ranges from primary care physicians providing initial diagnosis and routine care, to specialized diabetes clinics staffed by multidisciplinary teams, including diabetologists, nurses, dietitians, and podiatrists, for complex cases. This system aims to ensure appropriate levels of care based on individual needs without placing unnecessary burden on specialists. Automated screening programmes are available for diabetes-related complications and implemented at the community, primary, and secondary care levels where appropriate (Primary Data Collection, 2024).

"We have diabetes nurses, which is a big asset to the system. I don't know what we would do without them—they're very, very good. We have done so well with rolling out and implementing the pumps into the Trust because of the diabetes nurses. They are the ones who educate [patients] along with pharmaceutical company reps."

-Dr Vasiliki Kolovou MD, Consultant Diabetologist, UK

Still, data interoperability between levels of care delivery is imperfect and fragmented between different regions as well as between primary and secondary care (Primary Data Collection, 2024).

England actively promotes several national initiatives aimed at improving diabetes outcomes. The National Diabetes Audit collects data on key indicators of diabetes care quality, providing valuable insights for service improvement and benchmarking. Additionally, the NHS Diabetes Prevention Programme (DPP) represents a significant investment in preventing T2D, particularly in individuals at high risk. This data-driven program utilizes risk stratification and leverages electronic health record data to identify and engage those most at risk, reflecting a population health management approach (NHS Diabetes Prevention Programme (NHS DPP), 2024; NHS England, 2016). This aligns with the best-practice use of data-driven screening and predictive analytics to identify high-risk individuals early, ideally before the onset of diabetes or its complications.

Furthermore, technological advancements are increasingly integrated into diabetes management, with the growing use of telehealth, remote monitoring, and structured education programs delivered through digital platforms.

Investment into the health system's ability to deliver novel technologies is exemplified through the rollout plan for hybrid-closed loop systems for PLWT1D. This implementation is guided by NICE's HTA decision and rolled out in phases over five years to allow for staff training and capacity building (National Institute for Health and Care Excellence, 2023). This is financed through a nationally coordinated approach involving initial mobilization funding allocated to Integrated Care Boards for local implementation planning , supplemented by a commitment from NHS England to reimburse 75% of ICBs' demonstrated hybrid-closed loop system costs, with both funding streams being ring-fenced to ensure dedicated expenditure on this technological intervention (National Institute for Health and Care Excellence, 2023).In this case, financial support at the national level supports implementation of value-based care, demonstrated by HTA, and local capacity building.

3.2. Diabetes Care in Greece

As the burden of diabetes grows demonstrably across the world, it is important to review the latest available evidence regarding Greece's unique burden and current approach to delivering diabetes care. The following sections present evidence on the burden of diabetes on the Greek people and their health system, along with a comprehensive description of the current approach to diabetes care and prevention, encompassing aspects such as health system design, data infrastructure capabilities and pharmaceutical policy.

3.2.1. The Burden of Diabetes Mellitus in Greece

3.2.1.1. Prevalence & Mortality of diabetes

Prevalence of DM

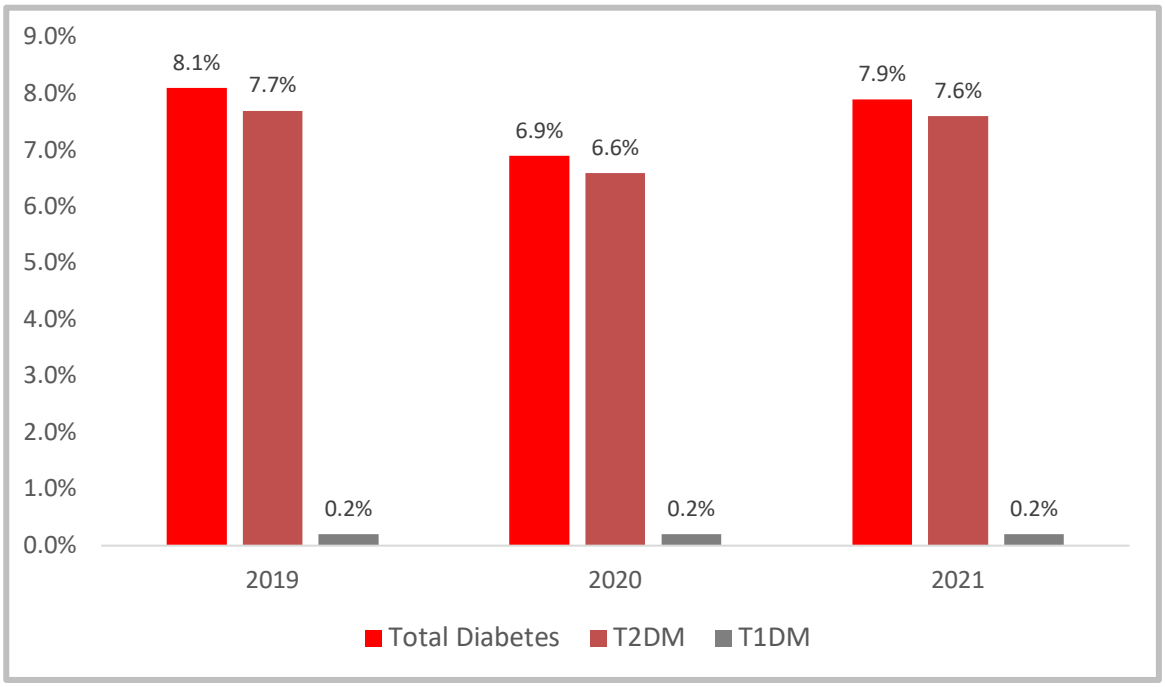
Diabetes prevalence in Greece is increasing, though the exact rate is debated. The Greek Ministry of Health cites prevalence of (diagnosed and undiagnosed diabetes) at 12%, with 95% of individuals with the condition presenting with T2DM while 5% present with T1DM (Ministry of Health, 2024a). Additional Greek sources offer prevalence estimates that range from 11.9% amongst a random sample of Greek adults in 2016 (Makrilakis et al., 2021) to 7.91% amongst medication-treated PLWD in 2021 (Siafarikas et al., 2024). The International Diabetes Federation (IDF) offers an estimate of diabetes prevalence in adults 20-79 years at 9.6% in 2021, up from 7.02% in 2011 (IDF, 2011, 2021). The same IDF atlas estimates the age-adjusted comparative prevalence of diabetes among people aged 20 to 79 in Greece at 6.4% in 2021, elevated by 1.3 percentage points from 5.1% in 2011 (IDF, 2011, 2021). The challenges in verifying diabetes prevalence estimates underscore an unclear understanding of the disease burden in Greece, exacerbated by gaps in the country's health data infrastructure and data reporting systems.

Prevalence of medication-treated diabetes is well verified based on data from the national electronic prescribing (e-prescription) database, managed by the Greek e-Government Centre for Social Security Services (Siafarikas et al., 2024). Between 2019 and 2021, prevalence of diabetes for each year was determined by the number of registered people in the database who had received at least 1 prescription for a glucose-lowering drug during the year in question. It is important to consider the

timing of this data relative to the beginning of the Covid-19 pandemic and its potential impact on access to medicines during 2020. Using the ICD-10 code of the prescribed treatment, a resolution of the prevalence between diabetes T1 and T2 was performed (see Figure 1).

The National Survey of Morbidity and Risk Factors (EMENO), a cross-sectional nation-wide health examination survey, examined diabetes in a representative national sample of adults from May 2013 to June 2016 (Makrilakis et al., 2021). This study was the first of its kind in Greece, combining interview responses with medical examinations to identify known and unknown cases of diabetes. Based on 2013-2016 data, this study found a prevalence rate of 11.9% amongst the general adult population, 1.5% of which were cases previously unknown (Makrilakis et al., 2021). This indicates that the proportion of PLWD who are unaware they have diabetes is 12.6% among total PLWD (Makrilakis et al., 2021). The IDF estimates a significantly larger proportion of people living with undiagnosed diabetes at 33.5% in 2021(International Diabetes Federation Europe, 2021) Additionally, the EMENO study identified an equally substantial prevalence of pre-diabetes at 12.4% in 2016 (Makrilakis et al., 2021). Unfortunately, as the EMENO study is nearly a decade old and other sources vary, it is difficult to determine the current prevalence of diabetes in Greece. In fact, one interview participant estimated that current diabetes prevalence in Greece is as high as 20% (Primary Data Collection, 2024).

Figure 1 Prevalence of medication - treated T1DM & T2DM in Greece

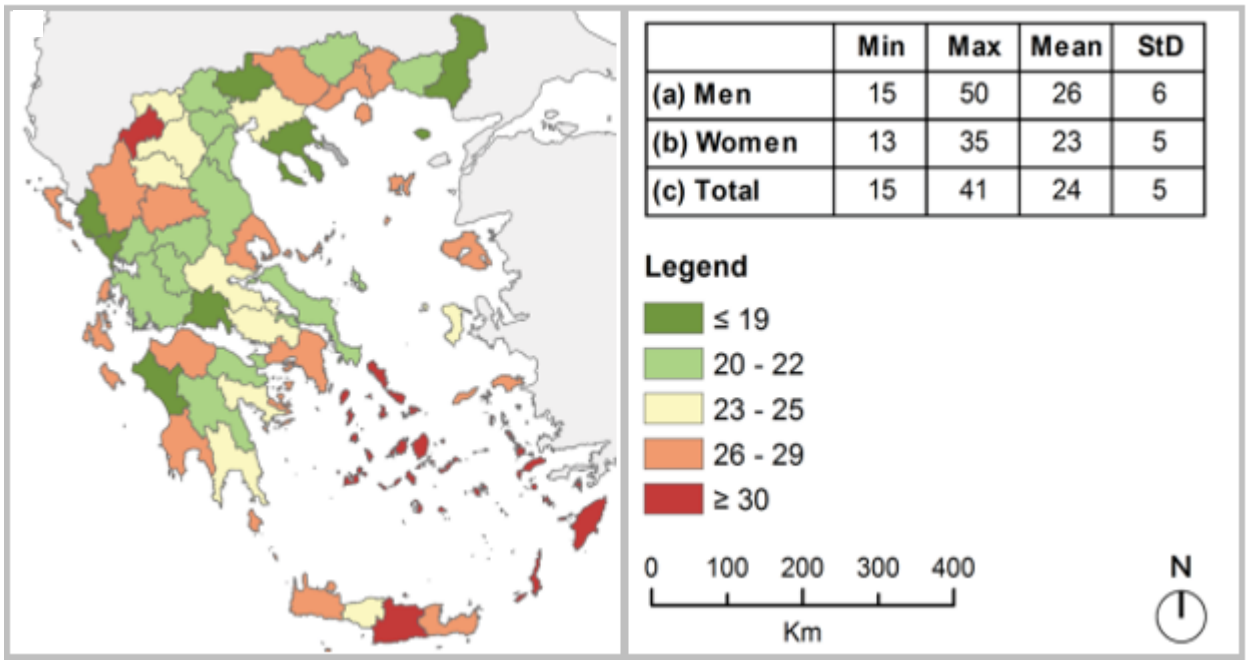


Source: Siafarikas et al., 2024

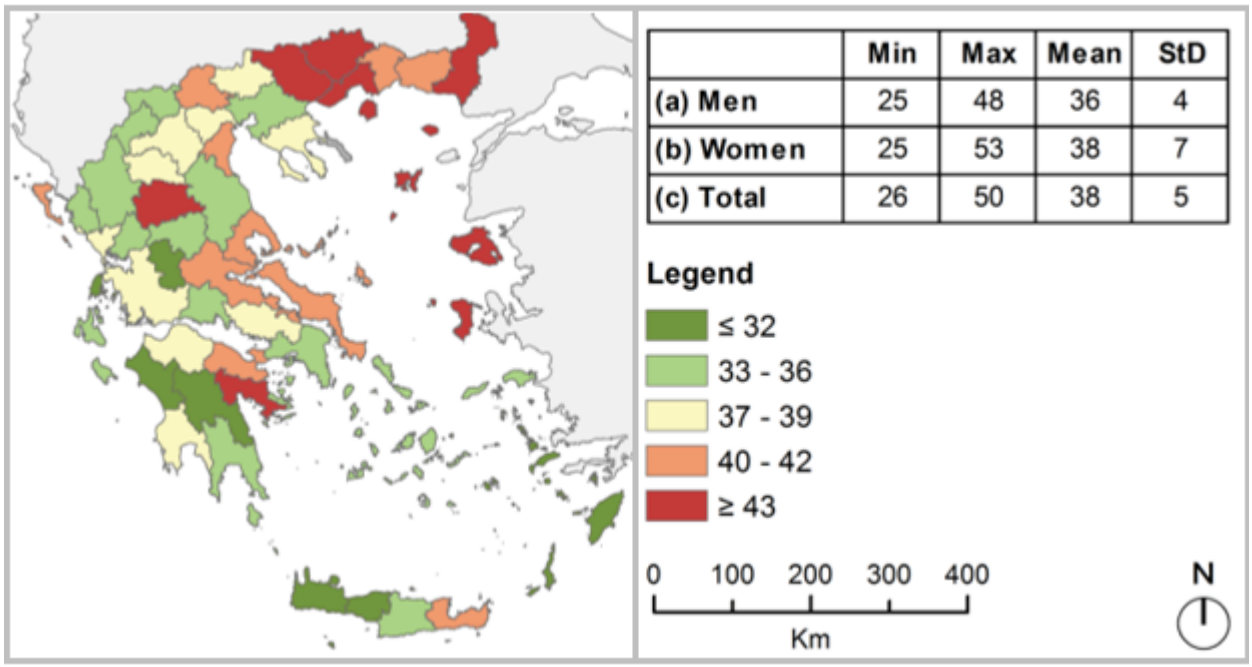
Diabetes prevalence in Greece also varies by region (Faka et al., 2023), see Figure 2. The highest rates of T1D were identified in the Greek islands while the highest rates of T2D were identified in the northern and eastern prefectures of Greece (Faka et al., 2023).

Figure 2 Geographical variation in Prevalence of T1DM &T2DM (2019)

(a) T1D total patients per 10,000 population, 2019



(b) T2D total patients per 10,000 population, 2019



Source: Reproduced from Faka et al., 2023

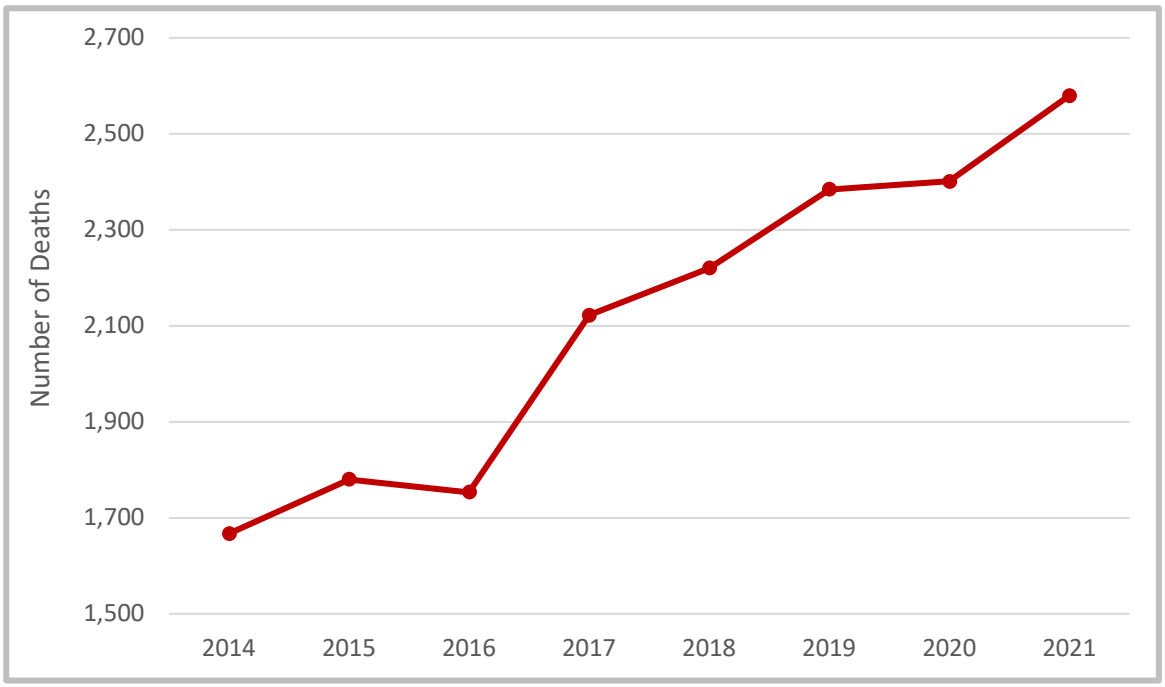
Deaths attributable to diabetes

Evidence on the number of deaths attributable to diabetes in Greece is available from two sources, the "Causes of Death" reports published by the Hellenic Statistical Authority (HSA) (Hellenic Statistical Authority, 2021), and the IDF's 2021 Diabetes Atlas estimates on diabetes-related

mortality in adults (IDF, 2021). However, the respective methods of calculation are markedly different and subject to limitations (see Appendix I), yielding divergent results for the suggested mortality burden associated with diabetes in the country. However, despite these data limitations, the number of deaths attributable to diabetes is clearly rising.

The IDF estimates the total number of deaths attributable to diabetes among people aged 20-79 at 22,350 in 2021 (IDF, 2021). This a figure representing more than a 4.5x increase in deaths per year over the 10-year period since last reporting— 4,858 deaths in 2011 (IDF, 2011, 2021). This estimation combines a variety of sources (see Appendix I). With strict reference to cause of death listed on deaths certificates, the number of deaths attributable to diabetes is much lower. According to the HSA, the total number of deaths attributed to diabetes in a given year steadily increased in Greece between 2014 and 2021, rising from 1,667 deaths in 2014 to 2,580 deaths in 2021 (see Figure 3) (Hellenic Statistical Authority, 2021; Hellenic Statistical Authority, 2024). During the same time period, the mortality burden of diabetes, the estimated number of deaths per 100,000 PLWD, increased from 22.2 in 2019 to 24.5 in 2021 (Hellenic Statistical Authority, 2022, 2024a).

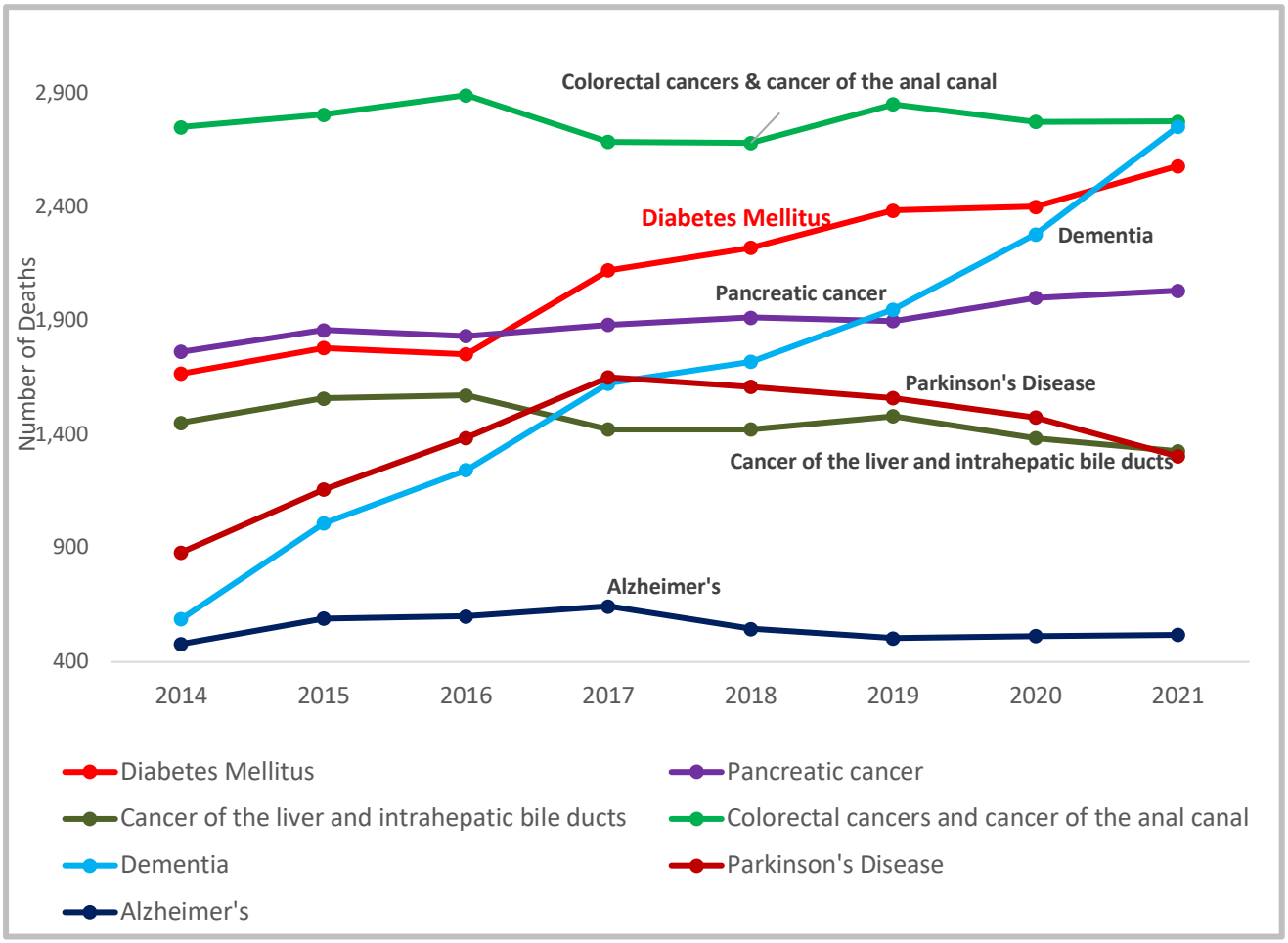
Figure 3 Deaths attributable to DM as cause of death in Greece, 2014 – 2021



Source: Hellenic Statistical Authority, 2021, 2024

Evaluated against other selected causes of death, the findings of HSA reports indicated that, between 2014 and 2021 diabetes had been responsible on a yearly basis for mortality burden comparable to that of various cancers, neurological disorders and dementia in Greece. In fact, during this time, HSA data reports that the annual death toll of diabetes remained consistently higher than that of liver cancer, Parkinson's disease and Alzheimer's, while it surpassed the respective figure for pancreatic cancer and even approached the number of deaths attributed collectively to colorectal cancers and cancer of the anal canal, in 2021 (Hellenic Statistical Authority, 2021, 2024a). (see Figure 4).

Figure 4 Deaths per cause of death category, for selected categories in Greece, 2014 – 2021



Source: Hellenic Statistical Authority, 2021, 2024

3.2.1.2. *Complications and related conditions*

There is no systematic monitoring or reporting of diabetes complications by the Greek national health system or any public health or government authority. As a result, very limited real-world evidence is available on the incidence and epidemiology of complications in the country, their management in clinical practice and the care outcomes achieved in PLWD T1 and T2. A small number of published studies have derived estimates on the prevalence of common diabetes complications in Greece based on data collected in specialized diabetes centres or outpatient clinics of selected public hospitals, located mostly in urban centres across the country. However, the estimates are typically reliant on evidence that is outdated and/or extracted from small samples, which may be geographically concentrated or even generated from a single centre. As a result, their external validity is often limited, meaning findings cannot be reliably extrapolated to describe the burden of the studied diabetes complications at the national level. Reporting on these results can be found in Appendix II. Furthermore, inconsistencies in the definition of certain complications, such as diabetic neuropathy, hinder accurate diagnosis and reporting (Primary Data Collection, 2024).

DM is frequently associated with a range of other health conditions, commonly referred to as comorbidities or co-occurring conditions. These conditions are distinct from complications, which are direct consequences of the disease itself. However, the classification of a condition as a complication or a comorbidity in diabetes can be subjective, influenced by the physician's diagnostic approach

and their interpretation of the condition's relationship to the underlying diabetes *(Yen et al., 2023)*. Some of the most commonly reported co-occurring conditions include cardiovascular diseases (CVD), chronic kidney disease, obesity, osteoarthritis, back pain, fatty liver diseases, and depression *(Pearson-Stuttard et al., 2022)*. According to the 2022 WHO European Regional Obesity Report, Greece exhibits a high prevalence of obesity, with 24.9% of the adult population classified as obese. This trend extends to adolescents, with an obesity rate of 10.6% among 10-19-year-olds. This alarming prevalence underscores obesity's critical role as both a significant risk factor for developing T2D and a major comorbidity in PLWD (Kluge & Weltgesundheitsorganisation, 2022). Additionally, the prevalence of diabetic chronic kidney disease among PLWT2D was reported at 45% in 2015 in a sample produced across 41 Greek hospital-based diabetes clinics (Migdalis et al., 2020).

The presence of comorbidities significantly increases the risk of severe complications, accelerates disease progression, and negatively impacts overall health outcomes for individuals with diabetes. Managing DM effectively requires recognizing the bidirectional relationship between diabetes and these co-occurring conditions. Multiple co-occurring conditions can complicate treatment regimens, increase the risk of adverse drug reactions due to medication interactions, and hinder adherence to treatment plans *(Naha et al., 2000)*. Moreover, PLWD often face the significant and often-overlooked challenge of managing the mental and psychological implications of their condition. PLWD, their families, and/or caregivers may experience emotional burdens, including feelings of overwhelm, anxiety about complications, and stress related to inadequate support. This collection of negative emotions is known as Diabetes-Related-Distress (DRD).

"A soft spot for PLWD, particularly T1, is their psychology. In Greece, it is an underestimated issue. We instruct patients to visit their ophthalmologist, their nephrologist, the dietician...but almost never to have a talk with a psychologist."

-Dr Christos Zisidis, Consultant Diabetologist

DRD can significantly impact PLWD, manifesting as subclinical emotional distress or even evolving into conditions like depression. Studies conducted in urban care settings in Greece have shown higher levels of DRD to be associated with higher HbA1c levels, indicating that DRD is a barrier to achieving optimal metabolic outcomes in PLWD with T2D. Notably, individuals with T2D experiencing higher levels of DRD face an increased risk of cardiovascular disease and exhibit a diminished quality of life (Kintzoglanakis et al., 2020). This intricate interplay underscores that not only can diabetes exacerbate existing conditions, but conversely, these conditions can significantly worsen diabetes control.

Hospitalizations

In Greece, hospitalizations are recorded in every patient's Individual Electronic Health File (IEHF), which is stored and managed by the e-Government Centre for Social Security Services (IDIKA) (Government of the Hellenic Republic, 2024a). However, it is unclear how or whether their tracking is being leveraged since there is no public reporting on any aggregated evidence of hospital admissions, stays or services delivered in inpatient care.

3.2.1.3. Self-Reported Outcomes

Recent evidence on health-related quality of life (HRQoL) of PLWD in Greece has been derived from small-scale studies, often with geographically concentrated or single-clinic samples, and almost exclusively referring to T2DM. The preferred HRQoL instruments have been the EQ-5D-5L

questionnaire and the 15D questionnaire. Neither of these instruments are diabetes-specific, but the translated 15D questionnaire has been validated in the Greek population (Anagnostopoulos et al., 2013) and evidenced to support higher sensitivity to complications such as retinopathy and coronary artery disease in PLWD in comparison with alternative QoL questionnaires (Kontodimopoulos et al., 2012). On the other hand, due to unavailability of estimates of value trade-offs from the Greek population, the application of the EQ-5D questionnaire employs health utilities calculated based on valuations recorded in the UK general population(Yfantopoulos & Chantzaras, 2020). These caveats notwithstanding, studies have indicated that the self-reported total HRQoL score of PLWDT2 in Greece on the 15D-questionnaire is significantly lower than that of people with normal glucose tolerance – controlling for the effects of age, BMI, co-occurring conditions and complications in the sampled cohorts – with decrements reported in the "mobility", "breathing", "usual activities" and "sexual activity" dimensions of wellbeing (Makrilakis et al., 2018). Albeit contingent on the model specification and estimation methods used in respective studies, results have generally pointed to diabetic retinopathy and neuropathy being the complications associated with the largest reduction in HRQoL in magnitude, whereas the same has been shown for depression, stroke, arterial hypertension and coronary artery disease among co-occurring conditions (Kintzoglanakis et al., 2024; Yfantopoulos & Chantzaras, 2020).

3.2.1.4. Underserved Populations

Underserved DM populations are individuals who experience significant barriers in accessing and effectively utilizing diabetes prevention, care, management, and educational resources. These barriers arise from a complex interplay of socioeconomic, geographic, and cultural factors. Underserved populations encompass a broader spectrum, including not only those already diagnosed with DM but also those at risk of developing the condition and those at risk of being overlooked by the healthcare system. Individuals at risk include those with prediabetes, a family history of diabetes, and those with risk factors like obesity and sedentary lifestyles. These individuals often lack access to effective prevention programs. Individuals at risk of being overlooked by the healthcare system may not receive timely diagnoses or adequate support due to factors such as lack of health insurance, limited access to healthcare providers, cultural barriers, or discrimination, among others.

Underserved DM populations in Greece face significant barriers to accessing and effectively utilizing diabetes prevention, care, management, and educational resources. Based on interviews with stakeholders and experts, several populations were identified as underserved in Greece, with regards to diabetes care and management. Socioeconomically disadvantaged individuals face significant financial barriers to accessing and affording diabetes care. Individuals residing in rural areas and remote islands may have limited access to healthcare providers and specialized care. Ethnic and minority groups, such as the Roma population, may face additional challenges due to limited health literacy, language barriers, and cultural differences. Refugees and immigrants may also encounter significant barriers due to language barriers, cultural differences, and limited access to social support systems. These challenges can hinder their ability to navigate the healthcare system, understand treatment instructions, and effectively manage their diabetes (Primary Data Collection, 2024) According to one of our interviewees, there is a particular issue with uninsured individuals accessing several critical antidiabetic medications through outpatient pharmacies, leading to inequities in access to care. With regards to this, one of the interviewees reported that "many of the uninsured patients struggle because they are unable to obtain essential diabetes medications from outpatient pharmacies. They often have to rely on emergency hospital services or

find alternative, less ideal solutions. This lack of access is a critical gap in our healthcare delivery and leaves a portion of the Greek population underserved. (Primary Data Collection, 2024).

3.2.1.5. Financial burden of diabetes

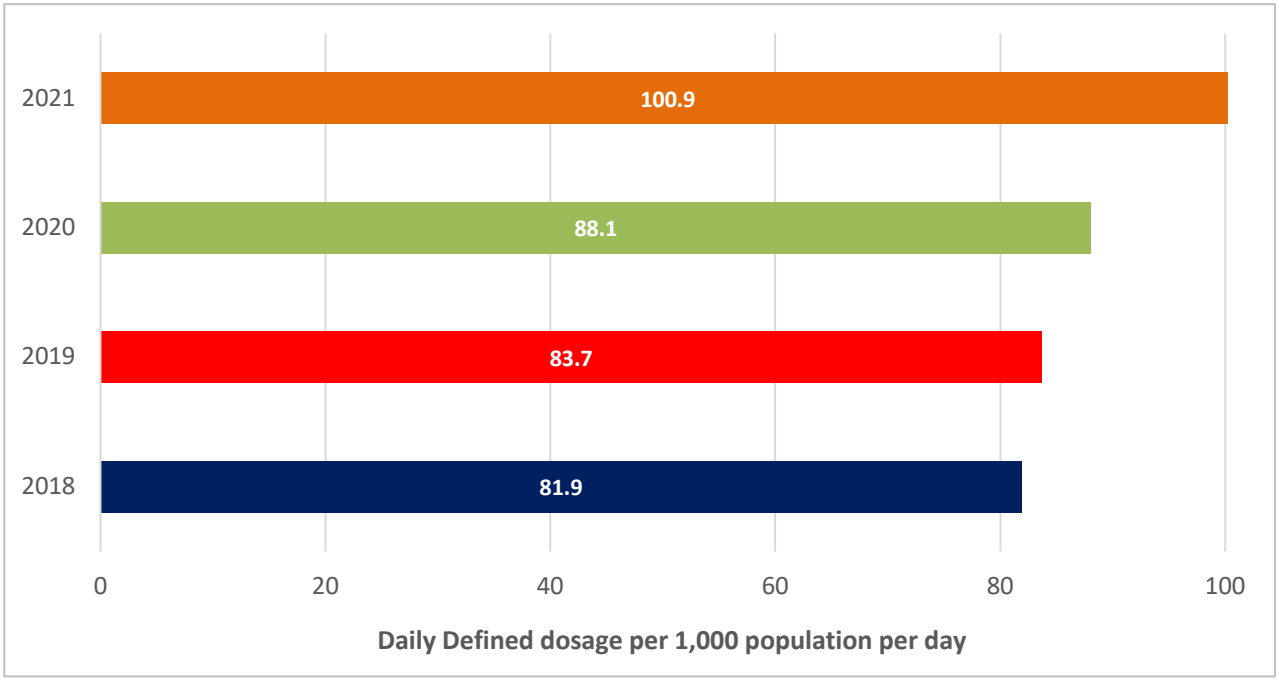
An essential component of understanding the burden of diabetes in Greece is the financial burden on its health system and its people. The direct financial burden of diabetes is represented by the total expenditure by public and private sources on care services provided across primary, secondary and tertiary levels, inpatient and outpatient, as well as on pharmaceutical therapies, digital health technologies, lifestyle interventions and treatment of complications. In addition, indirect costs accrue to both PLWD and society at large owing to reduced productivity associated with absenteeism and premature mortality in PLWD, as well as informal care burden (Hex et al., 2024). Ideally, to understand the full financial impact of diabetes an analysis must consider the costs related to co-occurring conditions inextricably linked with diabetes and its renal, metabolic and cardiovascular implications in both PLWD T1 and T2. As discussed previously (see section 3.2.1.2), the relationship between diabetes and other conditions can be mutually exacerbating, conducive to worse clinical outcomes and higher care spending across conditions. Unfortunately, due to limited data collection and reporting, these burdens remain obscure.

Total health expenditure (THE) as a share of GDP in Greece has increased in recent years rising from 7.85% in 2014 to 8.4% in 2023 (Hellenic Statistical Authority, 2020, 2024b; OECD Data Explorer, 2024). The relative breakdown of the financing mix between public and private sources has remained consistent. Namely, total expenditure has on average been supported by 29% from the Greek government's central budget, 31% from social insurance organizations and by almost 40% of the total from private and other contributions, including households' OOP spending on health, private insurance and a small share of funding from NGOs and the Church of Greece (Hellenic Statistical Authority, 2020, 2024b). These figures represent expenditure across all therapeutic areas and no diabetes-specific data is available.

Total pharmaceutical expenditure (TPE) has also been increasing steadily in absolute terms, although the share of total health expenditure it represents has regressed from 29% in 2012 to 27% in 2022 (OECD Data Explorer, 2022). Since reaching a trough of €3.8 billion in 2014, total pharmaceutical spending has unwaveringly increased every year ultimately arriving at a peak of approximately €7.1 billion in 2023 (SFEE & IOBE, 2023). The true total burden of medicine expenditure for Greece is in fact even greater than the findings reported suggest, since the specific measurement does not incorporate OOP payments. These may entail purchases of medicines by uninsured individuals, which have to be partially or fully covered OOP, spending on drugs that are not part of the positive list reimbursed by social insurance, and on over the counter (OTC) products (SFEE & IOBE, 2023).

Again, diabetes-related pharmaceutical expenditure cannot be identified from this aggregate data. Nonetheless, evidence on consumption of medicines indicates that the volume of antidiabetic drug usage in Greece has been growing. Namely, the defined daily dosage of antidiabetic medication per 1,000 people per day, including both insulin and non-insulin glucose-lowering agents, has increased by 21% between 2018 and 2021 (see Figure 5) (OECD Data Explorer, 2023).

Figure 5 Antidiabetic Pharmaceutical Consumption in Greece, 2018 to 2021

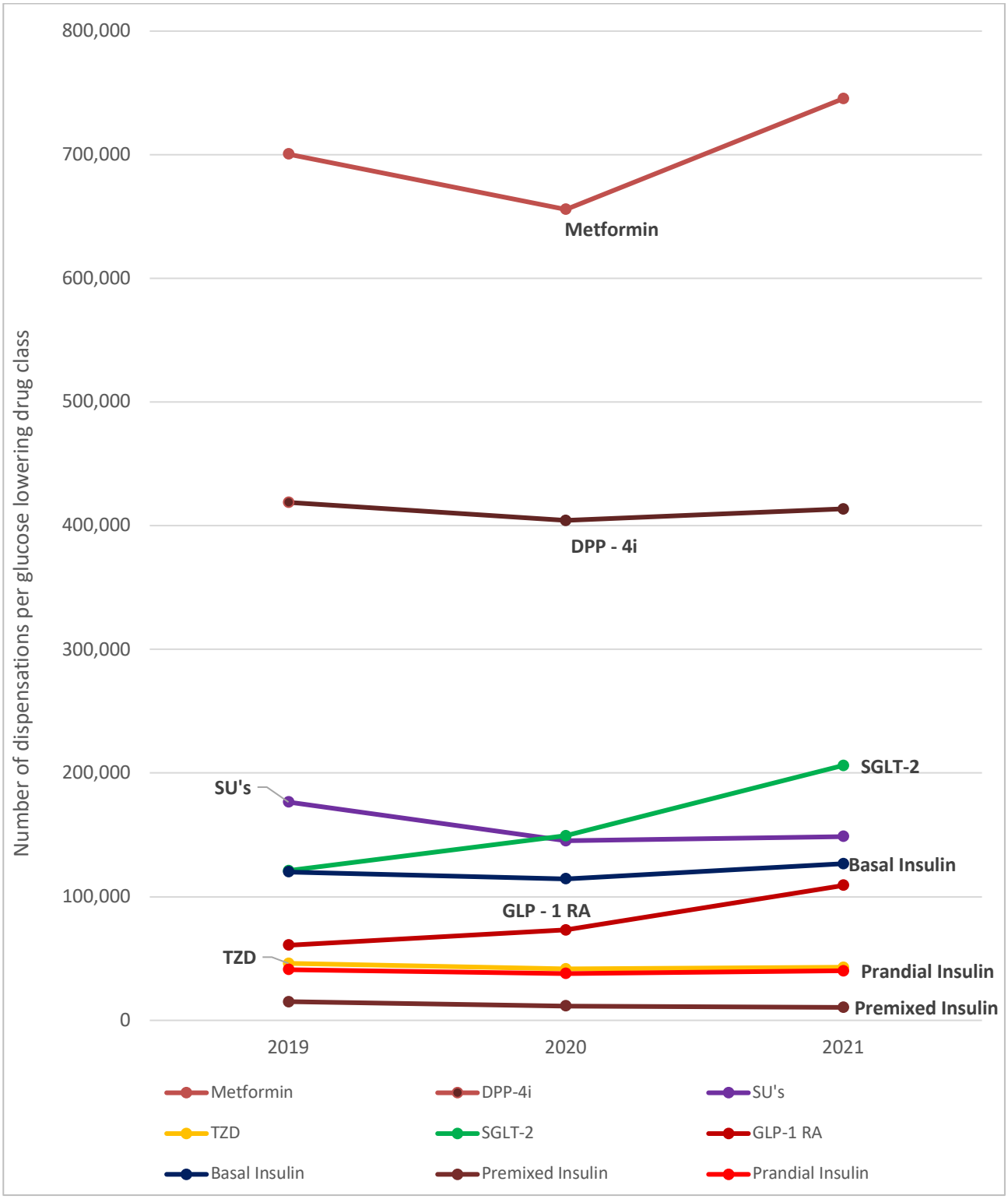


Source: OECD, 2023

During the same period, patterns in dispensations of glucose-lowering drugs for PLWT2D, as documented in the national e-prescription database, reveal that the consumption of SGLT-2 and GLP-1 receptor agonists has been on the rise (Siafarikas et al., 2024). Namely, the total number of dispensations involving GLP-1 receptor agonists experienced an 80% increase between 2019 and 2021, escalating from almost 61,000 to approximately 109,000 (Siafarikas et al., 2024). Similarly, for SGLT-2 drugs the observed rise was equal to 70%, with the 2019 total of 121,000 dispensations developing to more than 206,000 in 2021. Crucially, at the same time, all other therapeutic classes of non-insulin antidiabetic agents, except for Metformin, instead exhibited stagnation or decline in their frequency of administration to PLWT2D (see

Figure **6**). In detail, the dispensations of sulfonylureas were 16% fewer in 2021 than 2019, those of thiazolidinediones were reduced by 7% while the ones citing DPP-4i's were effectively unchanged (reduced by approximately 1%). Metformin remained the most dispensed therapy by a significant margin across the period recorded, experiencing a modest 6% increase in its dispensation.

Figure 6 Total Dispensations of non-insulin glucose-lowering drugs for medication treated PLWT2D in Greece



DDP-4i = Dipeptidyl peptidase-4 inhibitors, **SU's** = Sulphonylureas, **SGLT-2** = Sodium-glucose co-transporter-2 inhibitors, **GLP-1 RA** = Glucagon-like peptide-1 receptor antagonists, **TZD** = thiazolidinediones

Source: Siafarikas et al.,2024

Consequently, this data implies a prescribing shift taking place between 2019 and 2021, in favour of SGLT-2's and GLP-1's for blood sugar control of PLWT2D and away from alternative options commonly administered previously, such as sulfonylureas. Not only do the SGLT-2 and GLP-1 drug classes appear to be capturing larger shares of total antidiabetic consumption against other non-insulin treatments, but their dispensation is simultaneously increasing in absolute terms, alongside the increasing prevalence of PLWT2D in Greece discussed earlier. Given the high cost of novel products which have been authorized in the last decade in these classes, it can be inferred that this trend has resulted in increased spending by the Greek health system to be able to accommodate the proliferated dispensation of these agents. Nonetheless, it must be noted that all novel therapies have been subject to HTA and deemed to be cost-effective for reimbursement by the national payer. In conclusion, despite the lack of corroborating primary data, it is reasonable to assume that the total pharmaceutical expenditure on diabetes in Greece has been growing and can be expected to continue to do so.

3.2.2. Diabetes care delivery

The Greek healthcare system is making progress in diabetes care delivery on several fronts, including access to therapies for PLWD, primary prevention and uptake of latest innovative treatments. Positive developments are taking place promoting the expansion of reimbursement coverage of DHTs for the management of diabetes, including CGMs, insulin pumps and hybrid closed-loop systems, to all populations of PLWD in Greece who can benefit from their use (Panhellenic Federation of People with Diabetes (POSSASDIA), 2024c). In the antidiabetic medicine portfolio, new innovative drugs for the management of T2 diabetes, belonging to the therapeutic classes of GLP-1 agonists and SGLT2 inhibitors, have been approved for reimbursement by public insurance, incorporated in clinical practice and made available to PLWD in Greece (Ministry of Health, 2024b). Finally, health policy initiatives aimed at prevention and primary care offer potential help contain the growing burden of the disease (Ministry of Health, 2021b) but the need for more substantial national action is indicated.

There is significant fragmentation in the coordination of care under the current design of the Greek national health system. PLWD in Greece experience mixed treatment pathways involving primary healthcare providers, outpatient clinics, diabetes centres in public hospitals, which offer specialized care by multidisciplinary teams but are concentrated only in large urban centres across the country, and private practitioners (Primary Data Collection, 2024). As a result, PLWD may be faced with discontinuities in their treatment journey and increased burden of the responsibility of managing the coordination of their care. Immature data collection practices and digital infrastructure inhibit the Greek national health system from monitoring diabetes care holistically and effectively leveraging real-world data to improve outcomes in PLWD, prevent complications and inform evidence-driven reimbursement negotiations and decisions.

All these elements of diabetes care organization, delivery and access are strongly interlinked and coexist against a backdrop of increasing burden of disease for diabetes and its CRM implications for the Greek population, as well as growing budget pressure applied by the rapid ongoing pharmaceutical innovation in the therapeutic area.

3.2.2.1. National Action on Diabetes

A key obstacle to improving diabetes care in the Greek health system is the lack of a clearly defined and officially ratified National Action Plan for Diabetes by the government or any other competent public health authority.

Although Greece does not have a National Action Plan for Diabetes, in March 2021 the MoH introduced the National Action Plan for Public Health (NAPPH) 2021-2025 (Ministry of Health, 2021b). The stated aim of the NAPPH was to facilitate a targeted and strategically designed public health policy for Greece over the next 5 years, developing specialized and cost-planned interventions for all critical risk factors affecting population health (Ministry of Health, 2021a) including National Action Plans against Smoking and against Antimicrobial Resistance, as well as National Action Plans for AIDS and Cancer. No provision was made in the NAPPH 2021-2025 for a National Action Plan for the management of diabetes in Greece, while the condition itself was only referenced explicitly twice in the full published text of the NAPPH (Ministry of Health, 2021b). This omission suggests that diabetes was not perceived as a priority disease, even though diabetes-related mortality steadily increased between 2016 and 2021 in the country, eventually surpassing the mortality rates of certain malignancies such as pancreatic and large intestine cancer (Hellenic Statistical Authority, 2024a).

3.2.2.2. Therapeutic Protocols and Prescribing

National clinical guidelines validated and enforced by the government have been an important missing element of diabetes care in Greece. The Hellenic Diabetes Association (HDA) develops clinical guidelines for the management of diabetes since 2011, with the most updated edition published in 2024 (Hellenic Diabetes Association (HDA), 2024). These guidelines outline recommendations for the prevention and successful management of diabetes as well as cardiovascular and renal comorbidities and complications (Hellenic Diabetes Association (HDA), 2024). They are informed by the latest clinical evidence in the international diabetes literature and addressed to physicians of all specialties involved in the delivery of care to PLWD in Greece. However, HDA guidelines are not formally adopted by the Greek government and their compliance in clinical practice is not mandated. Research has estimated adherence to the treatment algorithm outlined in HDA guidelines for T2DM at 53.5% among practicing Greek physicians (Bimpas et al., 2021), and to the recommended patient follow-up protocol for T2DM at 43.6% on average (Papanas et al., 2020).

Nonetheless, the introduction of a Diagnostic, Therapeutic and Prescribing Protocol (DTP) for diabetes, first published by the Greek MoH in 2023 and subsequently updated in 2024 (Ministry of Health, 2024a), can arguably be considered as a step towards the formal adoption of guidance on diabetes management on a set of important aspects, albeit narrower in scope than a guideline. This protocol provides guidance to HCPs on diagnostic criteria, targets for successful disease management, treatment algorithms for T1 and T2 diabetes and prescribing recommendations, including recommended drug regimens for the management of diabetic neuropathy (Ministry of Health, 2024a). The goal of the application of DTP protocols is to ensure best-practice effective delivery of care and contribute to the rationalization of public pharmaceutical expenditure through appropriate regulation of prescribing (Ministry of Health, 2018).

The implementation of the diabetes DTP protocol in prescribing through the national e-prescription system remains a work-in-progress (Primary Data Collection, 2024). A key challenge has been the

establishment of an adequate monitoring mechanism to track adherence to the prescribing rules outlined in the protocol and identify violations (Primary Data Collection, 2024). To this end, in February 2024, the MoH decided to reinforce surveillance by introducing monitoring indicators on compliance with the existing DTP diabetes protocol that would enable the detection of incidents of prescribing inconsistent with protocol recommendations (Government of the Hellenic Republic, 2024b). The design of the indicators was tailored to identify cases of physicians engaging in overprescribing based on statistical criteria of deviation of the total number of prescriptions they issued from the average number expected, estimated based on the relevant protocol guidance (Ministry of Health, 2024c). In such instances, a warning message addressed to the prescribing physician would be activated on the e-prescription system and, upon inspection from the MoH and EOPYY, restrictions could be levied on their prescribing rights in the platform (Ministry of Health, 2024c).

However, the choice of this configuration and trigger for the indicators creates limitations in their effectiveness. Notably, flagging a monitored prescriber as suspect of violating the DTP protocol only based on their total number of prescriptions exceeding the average benchmark results in the indicator having limited sensitivity to other types of departures from the protocol recommendations. For example, under the current architecture of the e-prescription platform, diagnostic exam findings for each person are manually input rather than uploaded automatically through digital copies of verified lab results from the healthcare providers administering them (Primary Data Collection, 2024).This leaves the system vulnerable to potential gaming by way of submitting inaccurate diagnostic test results to make the prescription of specific agents which would not otherwise be permitted eligible to the prescriber (Primary Data Collection, 2024). This type of breach of protocol would go undetected by the implemented monitoring indicators. At the same time, even in cases of high, above-average volume of prescriptions by a given physician, Greece's particular geographic characteristics could make such patterns justifiable, for instance, by a doctor servicing a specific subpopulation or an entire island prefecture (Ministry of Health, 2024c). Consequently, there is room to improve upon the enforcement of the protocol on prescribing.

The limited national implementation of protocols hampers the implementation of a uniform approach to diabetes care, leaving PLWD liable to wide variations in the healthcare services they receive and relying on a mixed treatment pathway. This was corroborated by interviewees who noted that the quality of care can vary significantly across regions and healthcare providers, with some areas offering more advanced and comprehensive services than others. This lack of standardization can lead to inconsistencies in diagnosis, treatment decisions, and access to essential services, ultimately impacting the health outcomes of PLWD (Primary Data Collection, 2024).

3.2.2.3. *Health system design*

The Greek healthcare system is a mixed public-private system funded by taxes and social insurance contributions. It aims to provide universal access to healthcare services, with primary care delivered through a network of public and private health centres. Legislative efforts since 2017 have focused on reorganizing primary healthcare services, establishing a two-tiered system of PHCUs and aiming to improve coordination and planning at both national and local levels (Mavridoglou & Polyzos, 2022). However, challenges persist, including fragmented care coordination, limited nurse roles, and potential educational gaps between specialists, all of which complicate care delivery. While specialist centres play a crucial role in diabetes care, access to these centres can be challenging for individuals residing in remote areas, such as islands and rural regions of Greece. The geographic disparities exacerbate these challenges, creating inequities in access and quality of diabetes care across the country.

Primary care

The Greek healthcare system faces challenges in establishing a clear first point of entry and a robust gatekeeping function at the primary care level. This creates considerable challenges for PLWD, who are left to navigate the system independently, often without clear guidance on appropriate points of contact or the services to which they are entitled. Although the role of a personal physician is legally established, its implementation remains incomplete in practice (see Box 3). This can lead to situations where PLWD may directly access specialists, potentially bypassing the primary care level. This undermines the system's ability to track patient pathways, monitor healthcare utilization, and ensure that services are used appropriately and in a timely manner. This lack of a defined referral pathways may contribute to issues such as appointment backlogs, extended waiting times, and limited interaction between patients and healthcare providers. Insights from interviews indicate that, in some regions of Greece, PLWD may experience wait times of 4 to 5 months for a specialist appointment due to these systemic inefficiencies (Primary Data Collection, 2024).

"[Regarding the multi-specialty care coordination burden] Sometimes we need to pick up the phone and start making a lot of calls in order to find, let's say, an ophthalmologist … in our city. That might cost me 20 or 30 minutes."

-Dr Christos Zisidis, Consultant Diabetologist

Furthermore, challenges exist in coordinating care among healthcare providers, including primary care, specialist centres, hospitals, and private practitioners. In peripheral areas, accessing care from multiple sources becomes particularly challenging. The lack of a formal communication protocol necessitates ad-hoc coordination efforts, often reliant on individual physician relationships. (Primary Data Collection, 2024).

Box 3 Policy Progress on Improving Greek Primary Care

Efforts to establish the personal physician as an institution of primary care in Greece date as far back as 1983 to the founding legislation of the Greek National Health System, where the role was first outlined and originally referred to as the 'family doctor' (Government of the Hellenic Republic, 1983). However, from its inception, the implementation of the policy has proven a perennial challenge and objective of subsequent targeted interventions by several governments and MoH leaders (Ministry of Health, 2024d).

A key juncture in this endeavour was the 2022 Law on the Restructuring of Primary Care which (re)introduced the personal physician as the designated first point-of-contact with the Greek healthcare system for the population and the agent responsible for coordination and continuity of patients' care, for the first time (Government of the Hellenic Republic, 2022a). Namely, in their capacity as primary care professionals, personal physicians were made responsible for: the management of chronic diseases and major risk factors in the community; the execution of prevention programs and presymptomatic screening; the coordination and interconnection with specialists and hospitals in their local care network; the support, orientation and guidance of patients in their use of the Greek NHS; the referral of patients to specialists and other levels of care services (secondary, tertiary care); and the creation and updating of the Individual Electronic Health File (IEHF) for all patients (Government of the Hellenic Republic, 2022a).

Registration with a personal physician of their choice was mandated for all people in Greece, while recruitment for the role was opened up to general practitioners, internists and certain specialists, to address the adult population, and to paediatricians for patients under 18 years old (Government of the Hellenic Republic, 2022a). The candidates could originate from both the public health system and private practice, while each personal physician would be assigned to service a population of 2,000 registered patients (Government of the Hellenic Republic, 2022a).

The uptake of the institution has been a work-in-progress, supplemented by incentives to boost enrolment of qualified physicians and penalties for people not engaging with registration (Kourlibini, 2023). As of December 2024, almost 5.1 million people have registered, representing 57% of the total eligible population (prosopikos.gov.gr, 2024). At the same time, a total of approximately 3,500 doctors have assumed the role of personal physician (prosopikos.gov.gr, 2024). This means that almost 1.6 million additional places for patients to sign up can be supported with the current capacity and remain available (prosopikos.gov.gr, 2024).

Access to Specialized Care and Geographic Disparities

Greece has 22 diabetes centres based in general and university hospitals (Hellenic Diabetes Association, 2024). These centres typically consist of a multidisciplinary team comprising endocrinologists, internists, potentially ophthalmologists, as well as nurses and dietitians. While these centres provide valuable care, their concentration in larger cities can limit access for individuals residing in smaller urban areas, rural regions, and on islands (Primary Data Collection, 2024). In regions lacking a diabetes centre, access to specialized care may be primarily through private healthcare providers, which can pose a financial burden for some PLWD (Primary Data Collection, 2024). Furthermore, even within these centres, the provision of comprehensive care may be limited as they may not always have on-site specialists like nephrologists or cardiologists for complication check-ups (Primary Data Collection, 2024).

The majority of PLWD receive care within the primary care setting. Interviews with experts reveal that approximately 80% of PLWD are managed by primary care providers, while only 20% are referred to specialists, such as endocrinologists (Primary Data Collection, 2024). While GPs play a

vital role in diabetes management, challenges arise when their authority to adjust prescriptions without specialist consultation impact coordinated care and potentially compromise optimal treatment outcomes. This observation further underscores the importance of a robust primary care network within the Greek healthcare system.

These disparities contribute to inequities in healthcare access across Greece. While telemedicine offers potential solutions, its utilization remains limited. Interviews revealed that telemedicine services are not proactively utilized, partly due to the lack of reimbursement for telemedicine consultations, which creates a disincentive for healthcare providers. Furthermore, the absence of a clear legal framework governing telemedicine and remote consultations contributes to uncertainty and reluctance among providers to adopt these services (Primary Data Collection, 2024).

As part of ongoing efforts to improve the quality of diabetes care, smaller diabetes clinics are currently being evaluated. A key requirement for these clinics is to demonstrate a scientific connection to an established diabetes centre. This requirement specifically focuses on care coordination, particularly concerning knowledge and referral pathways for patients requiring insulin pump therapy, as prescriptions for insulin pumps in T1D can only be issued by certified diabetes centres (Primary Data Collection, 2024).

Medical Staff

Beyond the geographical limitations, the Greek healthcare system faces significant challenges in terms of human resources within the diabetes care sector.

In smaller clinics and rural primary care units, access to specialists is limited or even absent, with primary care being the sole point of contact. This lack of access is further exacerbated by the shortage of specialists within the public health system, particularly endocrinologists. Within diabetes centres, the retirement of long-serving specialists and endocrinologists is creating challenges. Recruiting replacements proves challenging due to a shortage of these specialists within the public health system. This shortage can be attributed to several factors, including the longer duration of endocrinology training compared to internal medicine (six years versus five years) (Primary Data Collection, 2024), and the potential preference of young endocrinologists for private practice (Primary Data Collection, 2024). To address this shortage, a training program was introduced in 2018 to enable paediatricians and pathologists to gain formal qualifications and licenses to support the care of PLWD. However, the uptake of this program has been limited due to legislative gaps and implementation challenges. These include delays in program start dates, unclear eligibility criteria, and insufficient support for trainees' work commitments during study, such as lack of compensation via NHS salary, educational leave, or the option to practice privately while studying part-time (Primary Data Collection, 2024). This underutilized training program highlights the need for reinforcement and incentivization to effectively address the shortage of diabetes specialists.

Finally, the role of nurses in diabetes care is currently limited. While Greece historically has had a strong emphasis on physician training, resulting in a relatively high number of doctors, the system has traditionally faced a shortage of nurses. This imbalance in the healthcare workforce contributes to challenges in care delivery (Kanavos et al., 2020). While some graduate courses in diabetes nursing are available at the National and Kapodistrian University of Athens (NKUA), these programs are not state-funded and require tuition fees. Training initiatives are also undertaken by associations of PLWD, scientific societies (HDA), and diabetes centres, but these efforts remain limited in scope. Moreover, the overall role of nurses in the Greek healthcare system is constrained, hindering their ability to contribute more significantly to diabetes care. This lack of specialized training contributes

to the inefficient allocation of healthcare resources, which is further reflected in the inadequate training of school nurses to manage students living with T1D (Primary Data Collection, 2024).

These findings underscore significant challenges within the Greek healthcare system that hinder optimal diabetes care. System design flaws, including limited access to specialists, fragmented care pathways, and inadequate resource allocation, contribute to delays in accessing appropriate care. This delayed access often necessitates managing complications at the initial physician visit, leading to increased healthcare costs and potentially compromising patient outcomes.

Representation – Advocacy

Two large federations of PLWD are active at the national level in Greece, the Panhellenic Federation of Associations of People with Diabetes Mellitus ("POSSASDIA") and the Hellenic Diabetes Federation ("ELODI"). Both federations were founded in 1997 and are recognized as member-organizations of the IDF (International Diabetes Federation, 2024b, 2024a). POSSASDIA and ELODI encompass 26 and 14 smaller member-associations of PLwD based across Greece under their respective umbrellas, many of which have regional focus but collectively contribute to nationwide reach for both federations. The Panhellenic Association for the Fight Against Juvenile Diabetes ("PEAND") also maintains a national presence, its work focusing on supporting children and adolescents with T1DM in Greece.

The core missions of ELODI and POSSASDIA consist in raising awareness on diabetes and its risk factors in the Greek population, supporting PLWD and their families and/or carers in the management of the disease by providing education on effective self-management and use of available healthcare services (including explaining to all PLWD in Greece their entitlements to care) and advocating for the rights of PLWD to best-quality care and social inclusion, including equitable opportunities for employment and access to education (Hellenic Diabetes Federation (ELODI), 2024; Panhellenic Federation of People with Diabetes (POSSASDIA), 2024a). To this end, both federations proactively engage with government and public health institutions as official representatives of PLWD, making use of all means available to communicate their needs and demands. This includes requesting meetings with decision-makers in the MoH to inform them of ongoing challenges for PLWD and discuss solutions, contacting the national payer (EOPYY) to address disruptions in medicine access and supply, and submitting feedback and recommendations on the design and implementation of diabetes policies to competent authorities.

Nonetheless, in the current legal framework governing health policymaking and the administration of the public healthcare system in Greece, the capacity of associations representing people living with chronic diseases to influence decision-making and effectively induce change varies. Certain empowering provisions do exist, alongside persisting limitations.

"[The main problem is that] we do not have a formal procedure or specific rules for interaction with patients in Greece."

-Anonymous, Payer & HTA Organization

On policy formulation, a promising step was taken in May 2022, when by MoH decision the possibility for patient associations to be formally recognized as official partners of the Greek State in matters concerning the provision of health services was enacted in law (Government of the Hellenic Republic, 2022a). This enabled representatives of PLWD to participate in state bodies with decision-

making power on health policy design and evaluation of practices implemented in the Greek NHS (Government of the Hellenic Republic, 2022a). Nonetheless, the legislation did not specify the process or terms by which their participation would be regulated, limiting our understanding of the extent to which this change effectively empowered representatives of PLWD to impact policy outputs.

On the other hand, the involvement of representatives of PLWD in the HTA process for diabetes medicines in Greece remains conditional and their input limited. Namely, the HTA Committee is entitled by law to invite representatives of PLWD to attend committee meetings to provide input entirely at its discretion (Government of the Hellenic Republic, 2018b). If invited, PLWD representatives can express their views but there is no formal legal provision specifying how their contributions to meeting deliberations are recorded or requiring that they be factored into the assessment of the HTA Committee in any way (Primary Data Collection, 2024). As a result, the influence that advocates of PLWD can exert on reimbursement decisions is at best uncertain, strictly speaking minimal.

"We need more time to communicate and give them [government stakeholders] an understanding of the problems."

-Dr Christos Daramilas, President, POSSASDIA

Ultimately, in practice, the effectiveness of the federations' calls to action in eliciting response from competent authorities primarily relies on the latter's willingness to listen and oblige, and the application of pressure through public advocacy. Going forward, representatives of the federations have emphasized the need for more time at the table with government and public health stakeholders to offer them a better understanding of the problems PLWD are confronted with on the ground, as well as of the burden of complications and the missed opportunity by the state to generate savings and improve health outcomes by pre-emptively managing their risks (Primary Data Collection, 2024). At the same time, they have expressed their desire for more partnerships between all agents in the diabetes space; government, MoH, the public health system, scientific societies, the national payer and associations of PLWD, to join forces and leverage synergies in tackling the problems of diabetes care in Greece collectively (Primary Data Collection, 2024).

"For implementation, we need communication, and we need partnerships."

-Dr Christos Daramilas, President, POSSASDIA

3.2.2.4. Data Collection and Infrastructure

The data infrastructure underpinning diabetes care in Greece is underdeveloped and fragmented, featuring significant gaps and limited integration between the existing data resources, which have not been designed for interoperability. At the same time, implementation of data interventions often remains a work in progress, suffering from delays and coordination shortcomings. There is no centralized registry of PLWD in place at the national level.

The scope of diabetes data that is available is limited, as mechanisms for collecting and recording data on key aspects of disease management and outcomes of care are currently lacking in Greece. Namely, complications of diabetes are not systematically monitored or documented, resulting in the absence of data at any jurisdiction level on their incidence, treatment and clinical outcomes in PLWD in Greece (Primary Data Collection, 2024).

Hospitalizations are recorded in every patient's Individual Electronic Health File (IEHF), which is stored and managed by IDIKA (Government of the Hellenic Republic, 2024a) . However, it is unclear

whether their tracking is being leveraged since there is no public reporting on any aggregated evidence of hospital admissions, stays or services delivered in inpatient care.

In fact, the IEHF appears to be an underutilized resource overall, owing to incomplete implementation. It was first legislated in 2014 as a digital record of the personal medical history of each healthcare service user in Greece in possession of a social security number (AMKA) (Government of the Hellenic Republic, 2014). The file was mandated to include all data relevant to the health status and clinical progression of the individual as well as details on their full care journey and the services delivered to them (Government of the Hellenic Republic, 2014). For each person, the IEHF was to be set up by their personal physician and edited by all healthcare professionals providing them care, who were obligated to document all necessary information for their diagnosis, treatment, monitoring, hospitalization and rehabilitation (Government of the Hellenic Republic, 2014).

The IEHF was destined to be both a patient-facing resource and accessible to all physicians to support care delivery. However, a decade later the IEHF remains an ongoing project, with its completion cited as part of the Greek government's Digital Transformation agenda for 2025 (Government of the Hellenic Republic, 2023). Currently, the information available on the file for each registered individual is limited to electronically issued prescriptions, hospitalizations and visits to physicians (Government of the Hellenic Republic, 2024a).

The results of all diagnostic tests that the person is subjected to by both public and private healthcare providers are destined to be the next addition to this dataset. The effort to digitize this data and integrate them into the IEHF began in 2022, with the creation of the Digital Repository of Diagnostic Examination Results (DRDER) hosted by IDIKA (Government of the Hellenic Republic, 2022b). This database is linked to the IEHF and enables every patient to access a digital copy of their diagnostic test results by logging into the government services website or the "MyHealth" mobile government app using their unique tax and social security credentials (Government of the Hellenic Republic, 2022c).

Since the introduction of the DRDER, follow-up legislation has mandated public and private healthcare units to upload all test results thereon, providing a target deadline for them to ensure the interoperability of their internal information systems with the repository (Government of the Hellenic Republic, 2022c). However, in 2024, this has elapsed without full compliance amidst pushback from the Coordinating Body of Primary Healthcare Providers protesting the lack of funding support or financial incentive from state authorities to assist with the necessary adjustments to their digital infrastructure that connectivity with the DRDER requires (OloYgeia.gr, 2024).

As a result, the policy remains only partially implemented with gaps in the recording of diagnostic findings persisting. At the same time, in practice there is inadequate provision for the results to be directly and uniformly accessible by physicians across all levels in the Greek health system (Primary Data Collection, 2024). As pointed out in our interviews, endocrinologists are still having to rely on PLWD sharing the results of their screening exams or blood glucose tests with them, unable to access them through internal hospital data systems unless they have been conducted on-site (Primary Data Collection, 2024). Retrieving and communicating the results can be challenging for PLWD who are in older age brackets, migrant populations in Greece or less comfortable with technology, often leading ultimately to reordering of already undertaken examinations which would otherwise be redundant, wasting time and resources (Primary Data Collection, 2024). This also hinders the systematic monitoring of treatment and management outcomes for PLWD at the national

level which may be assessed based on the results of tests measuring biomarkers such as HbA1c for glycaemic control and Time-In-Range (TIR).

Another key resource administered by IDIKA is the national electronic prescribing (e-prescription) database. The e-prescription database registers all Greek citizens and legal residents of the country who possess a unique social security number (AMKA) and facilitates the issuance by physicians and fulfilment by patients of all medicine prescriptions. The data on all drugs prescribed and dispensed to each registered individual includes specification of the ATC therapeutic class, allowing for diabetes-related pharmaceutical consumption to be tracked but also information on co-occurring conditions to be extracted from the e-prescription database.

Finally, since 2019, the National Organization for Health Care Services (EOPYY) maintains a registry on which accredited physicians are required to register PLWD to prescribe them diabetes supplies and medical device consumables such as test strips, glucose monitor sensors, and infusion sets for insulin (Government of the Hellenic Republic, 2022d). Consequently, the registry likely fails to capture PLWD who do not need to be prescribed any consumables, such as PLWD T2 treated by way of lifestyle interventions or only with antidiabetic drug therapy. In addition, this EOPYY registry is used solely for the prescription of consumables and is not connected to the IDIKA e-prescription database.

"I am not fond of registries because registries are highly expensive."

-Anonymous, Payer & HTA Organization

In general, the establishment of full interconnectivity and interoperability of data gathered, stored and owned by EOPYY and IDIKA respectively has been a long-standing challenge. According to a public interview of the Managing Director of IDIKA in December 2022 (HealthWebTV, 2022), data on monitored variables such as drug prescriptions issued or filled, was previously shared between the two bodies by exchanging data files. This method could lead to delays as data extracts had to be generated from the respective local databases of EOPYY and IDIKA to be sent to their counterpart, which were then potentially required to undergo transformation to ensure compatibility with the recipient organization's data structure to be loaded and accessed (HealthWebTV, 2022). By 2022, the transition had been made for data exchange between EOPYY and IDIKA to be facilitated via web services, enabling improved access, better quality of shared data shared and real-time communication, with updates to records of the e-prescription system shared daily (HealthWebTV, 2022). However, the full integration of all data that is managed by the two institutions is an ongoing process.

3.2.3. Diabetes Prevention

Diabetes prevention encompasses a range of strategies aimed at reducing the risk of developing T2D (primary), early disease detection (secondary), and delaying the progression of established disease (tertiary). Primary prevention strategies are relevant to T2D, as it is not possible to prevent T1D, but secondary and tertiary prevention strategies are relevant to all types of diabetes.

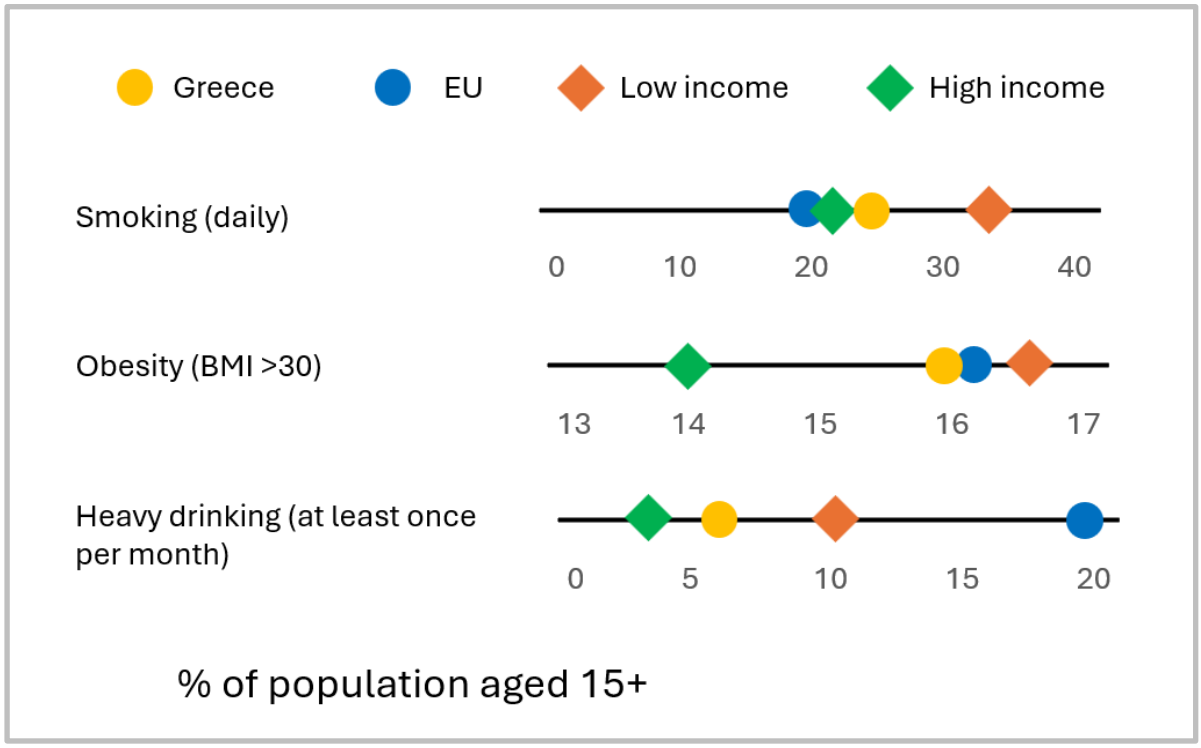
3.2.3.1. Primary prevention of T2D and prediabetes

Primary prevention refers to action taken before the manifestation of a disease to safeguard against its onset (World Health Organization, 2025). In diabetes, primary prevention comprises interventions aimed at mitigating controllable behavioural risk factors associated with the development of T2D, such as obesity, poor diet and lack of physical activity (Hellenic Diabetes Association (HDA), 2024). Primary prevention was acknowledged in the National Action Plan for Public Health (NAPPH) 2021-

2025 as a fundamental strategic objective for the long-term improvement of the health and quality of life of the Greek population (Ministry of Health, 2021b).

In Greece, in 2019, the obesity rate in the population aged 15 years old or older was equivalent to the EU average, at approximately 16% (see Figure 7) (OECD/European Observatory on Health Systems and Policies, 2023). At the same time, smoking was evidenced to be prevalent amongst Greek people, with 1 in 4 adults engaging in the habit on a daily basis (OECD/European Observatory on Health Systems and Policies, 2023).

Figure 7 Prevalence of Smoking, Obesity and Heavy Drinking



Source: OECD/European Observatory on Health Systems and Policies, 2023

Crucially, however, the obesity rate in Greece is considerably higher when focusing exclusively on the adolescent population. Namely, in 2022, 28% of 15-year-olds in the country were overweight or obese, a share increased from its 2018 mark of 22% (OECD/European Observatory on Health Systems and Policies, 2023). The main driver of this trend appears to be poorly balanced diet; from 2014 to 2022, the reported daily consumption of both fruits and vegetables by Greek teenagers declined (OECD/European Observatory on Health Systems and Policies, 2023).

To address the obesity and sedentary lifestyle risk factors, especially in Greek children and adolescents, the National Program of Promotion of Physical Exercise and Healthy Diet (PEHD) constituted the largest component of the NPP (Ministry of Health, 2021b). This policy scheme outlined interventions targeting all school students and teachers in Greece to raise awareness for the benefits of healthy eating, measures to reinforce compliance to health and safety mandates in school canteens and development plans to upgrade sport amenities and promote exercise across the country. Over the intended 5-year horizon, these actions could contribute to the primary prevention of T2D among young people in Greece by mitigating the incidence of child obesity and improving nutrition. However, their design and implementation has not been explicitly linked with this objective in the National Prevention Program. It is crucial to note that Greek schools continue to rely on meals provided by companies that often fall short of nutritional standards. The lack of clear

nutritional information on meal packaging, including carbohydrate, protein, and fat content, poses a significant risk to the health of children, not only those with diabetes but also those at risk of obesity and other health issues (Primary Data Collection, 2024).

In fact, the prevention of diabetes is completely unmentioned in the NPP, despite the recognition of the rising trend of diabetes-related mortality in Greece in the overarching NAPPH (Ministry of Health, 2021b). Furthermore, interviews with experts reveals that DM awareness and screening efforts in the local community appear to be primarily driven by a short, annual awareness campaign around World Diabetes Day (November 14th). These efforts typically involve limited public outreach, such as informational booths and occasional media appearances. A significant portion of DM detection relies on individual initiative, with individuals seeking medical advice based on family history, personal risk factors, or the presence of symptoms. Notably, while acknowledging the higher risk for certain subgroups, the community lacks targeted outreach strategies specifically designed for these population (Primary Data Collection, 2024).

3.2.3.2. Secondary Prevention (Screening)

Secondary prevention consists of early screening for timely diagnosis of diabetes in people living with or at increased risk of developing the disease (Ministry of Health, 2021b).
In Greece, according to the 2024 DTP protocol for DM, presymptomatic screening for T2D via measurement of fasting blood glucose is recommended in the general population from the age of 35 years (Ministry of Health, 2024a). If glucose levels are detected to be within the normal range, rescreening is advised on a 3-year basis. Prior to the age of 35, presymptomatic screening is only recommended for people who present with designated risk factors for the development of diabetes (Ministry of Health, 2024a). These include, but are not limited to, BMI ≥ 30 kg/m2, family history of first-degree relatives living with DM, history of cardiovascular disease, hypertension or dyslipidaemia, as well as polycystic ovary syndrome and history of childbirth with a high birth weight (>4kg) for women (Ministry of Health, 2024a). If these risks are incident, or fasting blood sugar is measured to be close to the upper boundaries of the normal range, more frequent repetition of the screening is indicated.

In response to the rising prevalence of T2DM in obese adolescents in Greece, presymptomatic screening in this population is recommended starting from the age of 10, when obesity is coincident with at least 2 factors among family history of DM, signs of increased resistance to insulin and minority ethnic group (Ministry of Health, 2024a). The examination is also recommended for adolescents with sedentary lifestyle or history of maternal gestational diabetes (ref).

In the 2024 HDA guidelines, presymptomatic screening with autoantibodies for T1DM is suggested for the purposes of research in first-degree relatives of PLWT1D or people who are interested in investigating their risk of developing T1DM based on family history, only if the screened subjects can manage a potential diagnosis without experiencing great psychological distress (Hellenic Diabetes Association (HDA), 2024). However, this recommendation is not integrated in the DM protocol (Ministry of Health, 2024a).

The guideline-suggested screening strategy for gestational diabetes involves measurement of fasting blood glucose at first visit for all pregnant people (Hellenic Diabetes Association (HDA), 2024). Unless they are diagnosed with pre-existing T1 or T2 DM, then the management of the person is dictated by the level of the recorded glucose concentration. If that is found to be between 92 mg/dL and 126 mg/dL, the person is managed as exhibiting gestational diabetes, while if it is lower than 92mg/dl, it is recommended that they be scheduled for a glucose loading test between the 24th and

48th weeks of pregnancy (Hellenic Diabetes Association (HDA), 2024). Similarly to T1 screening, however, this is not adopted in the DM protocol (Ministry of Health, 2024a).

3.2.3.3. Tertiary Prevention

Tertiary prevention relates to efforts to forestall the progression of established disease, mitigate the impact of clinical consequences and avoid complications and relapses (Ministry of Health, 2021b). In diabetes, prevention and timely diagnosis of complication risks through appropriate screening are crucial objectives for successful management (Hellenic Diabetes Association (HDA), 2024).

In Greece, the 2024 DTP protocol by the MoH on diabetes indicates screening tests for common complications, such as CKD and diabetic retinopathy in all PLWD (Ministry of Health, 2024a). The first screening test is to be performed upon diagnosis for PLWT2D and at 5 years post-diagnosis for PLWT1D with yearly re-examination indicated thereafter, if no clinical findings are observed (Ministry of Health, 2024a). This screening strategy for CKD and retinopathy is aligned with the recommendations of the 2024 HDA clinical guidelines (Hellenic Diabetes Association (HDA), 2024). However, gaps still exist in other complications, including diabetic neuropathy and diabetic foot, where the screening recommendations of the HDA clinical guidance have not been incorporated into the diagnostic protocol (Hellenic Diabetes Association (HDA), 2024).

During the semi-structured interviews, it was explained that another pitfall undermining the prevention of diabetic complications is the restricted allocation of prescribing rights for different screening tests exclusively to physicians of specific specialties deemed relevant to the respective diagnostic (Primary Data Collection, 2024). As a result of this, primary care physicians or even endocrinologists serving as coordinators of care for PLWD in Greece, may be unauthorized to prescribe screening tests which are indicated for people with T1 and T2 diabetes, but considered beyond their remit of prescription. Consequently, PLWD are then forced to seek access to specialists such as ophthalmologists, for example, in order to be prescribed dilated fundus examination to detect signs of diabetic retinopathy (Primary Data Collection, 2024). This increases the risk of necessary screening being foregone and the start to the management of complications being delayed, which significantly exacerbates severe prognoses. In addition, this bottleneck is likely to disproportionately affect residents in Greek islands and rural mainland regions far from large cities, where access to specialist care is limited and challenging.

3.2.4. Pharmaceutical Policy

3.2.4.1. *Access to Medical Technologies*

Essential diabetes medicines and consumables are widely available and reimbursed through the health system, though copayments are applied for T2D at 10% and for complications at 25% (Ministry of Health, 2024a). No copayments are applied in T1D. Novel medications including GLP-1 antagonists are also available for T2D, though shortages have been observed (Primary Data Collection, 2024). DHTs including CGMs, insulin-pumps, and hybrid-closed loop systems are available for PLWT1D and policymakers have indicated a willingness to expand coverage for people living with severe T2D (Primary Data Collection, 2024).

The EFPIA WAIT indicator shows that new diabetes medications take longer to reach PLWD in Greece (761 days) compared to the European average (647 days) (IQVIA, 2024). Furthermore, Greece lags behind many other European countries in the total number of new medicines approved annually across all therapeutic areas. In the period 2019-2022, the total availability by approval of new medicines in Greece stood at 79 approved products. Over the same timeframe, in considered comparator countries, 147 were approved in Italy, 109 in Denmark, 103 in Spain, 93 in England, 83

in Portugal and 29 in Romania. These figures translate to the rate of availability, measured by the ratio of medicines approved in a country compared to those available in at least one other European country. This rate is as follows: 77% in Italy, 65% in Denmark, 56% in England, 50% in Portugal, 47% in Greece – which is slightly above the EU average of 43% - and 17% in Romania (IQVIA, 2024). Given the chronic and long-term nature of diabetes, access to innovative medicines could greatly improve health outcomes in the long term. Specific provisions could be put in place by the recently established Greek HTA body to enhance access to innovative medicines: currently, Greece does not provide early access schemes for innovative medicines that have not yet received MA (Kanavos et al., 2019). Furthermore, it is unclear whether specific types of agreement, such as financial or outcome-based agreements, will be set by the Greek HTA and negotiation committee. These types of negotiation agreement could streamline pricing and reimbursement negotiations, ultimately improving access to diabetes care (Kanavos et al., 2019).

3.2.4.2. Reimbursement

The reimbursement process in Greece is funded by EOPYY, the nation's main health insurer, and largely administered within the Greek National Health Service (OECD/European Observatory on Health Systems and Policies, 2023). Before a drug can be considered for HTA in Greece, it must first receive reimbursement in five out of eleven EU member states: Austria, Belgium, France, Spain, Netherlands, Portugal, Sweden, Finland, Germany, Denmark and Italy (Beletsi et al., 2023). This precondition, known colloquially as the “5 out of 11”, has been cited by manufacturers as a stumbling block in the reimbursement process contributing to delays in assessment and consequently access to new on-patent medicines for Greek PLWD (Primary Data Collection, 2024).

The actual rate of drug reimbursement in Greece, that is, the inclusion of medicines on the reimbursement list across all therapeutic areas, represents an issue regarding access. The rate of full availability in the period 2019-2022 saw Greece report 52% of authorised products having full public availability, while the remaining 48% had limited availability. This differs significantly from some of the other comparator countries – for example, Italy and Romania report 80% and 69% of full public availability respectively, while Denmark, England and Portugal report 45%, 51% and 41% respectively (IQVIA, 2024).

Specifically with regards to diabetes care delivery, a significant issue is the largely absent reimbursement of telehealth services in Greece. Three of our interviewees reported that the reimbursement of telehealth services, in the context of diabetes care, would be a "game changer" in Greece, particularly for patients who struggle to attend clinics. This is especially relevant given the country's particular geographical composition, comprising many islands and remote areas, which in several cases are difficult to service and treat, particularly for chronic conditions. In this context, telehealth would be particularly useful for delivering remote glucose monitoring and consultations. One of our interviewees also pointed out that, if the uptake of these technologies is low compared to other countries, it is likely due in part to this lack of reimbursement (Primary Data Collection, 2024).

3.2.4.3. Controlling Pharmaceutical Expenditure

The total pharmaceutical expenditure in Greece has been on a rising trend in nominal terms over the last decade, though the proportion of total health expenditure attributed to pharmaceuticals has decreased while total health expenditure has increased. This reflects that, within a growing budget, the Greek health system is allocating increased funds to other priority areas. Further, the public proportion of pharmaceutical spending has decreased while OOP burden has been steady, reflecting an increased burden on industry to make up the difference. Shown in Figure 8 is the total expenditure combining both outpatient and inpatient distribution channels at the national level in nominal terms for the years 2012 to 2023, as an aggregate of public pharmaceutical spending, including both the

central government medicine budget and social insurance funding, industry paybacks and contributions of the insured population in reimbursement through statutory copayment (SFEE & IOBE, 2023). Since reaching a trough of €3.8 billion in 2014, total pharmaceutical spending in Greece has unwaveringly increased every year, arriving at the latest peak of approximately €7.1 billion in 2023 (SFEE & IOBE, 2023). This evolution signifies a total 86% increase between the two timepoints. Notably, the true burden of medicine spending in Greece over this period is even greater than the displayed findings indicate, since the specific calculation does not factor in spending on patients' OOP payments (SFEE & IOBE, 2023). In fact, as of 2021, it has been estimated that 33% of total healthcare spending in Greece is borne OOP by households, as already mentioned, with the largest share (25%) of this absorbed by direct payments for pharmaceuticals (OECD/European Observatory on Health Systems and Policies, 2023).

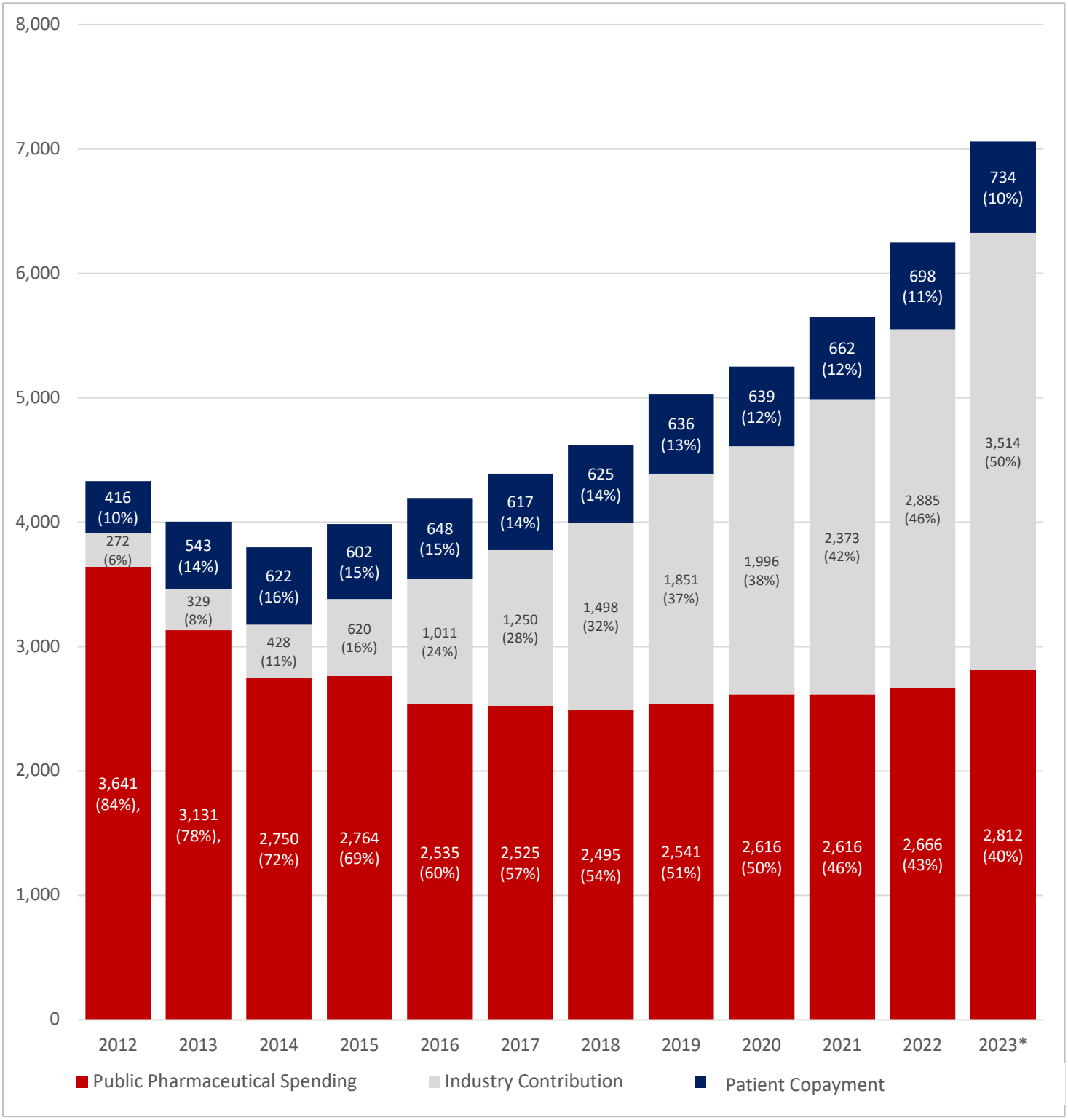
At the same time, the breakdown of total pharmaceutical spending into the relative shares covered by different financing sources reveals a crucial imbalance. Namely, between 2014 and 2023, a massive redistribution of the financial burden of pharmaceutical reimbursement is evidenced to have taken place, increasing reliance on pharmaceutical industry paybacks (clawbacks and rebates) while funding from public sources was scaled back. Indicatively, in 2014, public medicine spending as a sum of both government budget and expenditure by EOPYY financed through social insurance, amounted to 72% of the total pharmaceutical bill. Only 11% was covered by industry. Conversely, in 2023, drug manufacturers are shouldering 50% of the total spending via multiple forms of paybacks to the Greek state, a share five times larger than that they contributed less than a decade ago. On the other hand, public institutions have significantly cut down their spending to almost half of its 2014 level, in relative proportions, to only 40% of total pharmaceutical cost. As highlighted in the interviews, the outcome of this progressive shift in the financing mix year after year has been a status quo where "the industry contribution is actually larger than what the government pays" for medicines in Greece (Primary Data Collection, 2024). During interviews, it was emphasized by industry stakeholders that the magnitude of mandatory clawbacks, which may amount to 60% – 70% of expenditure on medicines concerned, is assessed as a critical deterrent by pharmaceutical manufacturers contemplating entry to the Greek market across both diabetes and all other disease areas (Primary Data Collection, 2024). The clawback regulation is regarded as a key component of a policy environment perceived to be "unfriendly to innovation" and requiring companies to "concede" rather than market their new treatment technologies (Primary Data Collection, 2024).

Perhaps more importantly, interviewees raised the alarm that this circumstance carries the risk of jeopardizing access to the latest clinical developments in medicines and digital health technologies for Greece in the long run, including anticipated innovations in the diabetes space (Primary Data Collection, 2024). If manufacturers' caution develops to unwillingness to launch products in the country entirely, this could mean that the update of therapeutic options for PLWD in Greece is disrupted (Primary Data Collection, 2024).

In the medical device segment of the diabetes market, the retention of products already on the positive list may also be at immediate risk due to the unsustainable burden of paybacks levied on marketing authorization holders (Primary Data Collection, 2024). In April 2024, the Association of Medical & Biotechnological Product Enterprises ("SEIV") in Greece stressed that clawback obligations arising from overrun of the EOPYY's budget for diabetes medical devices and consumables represent more than 30% of expenditure in the insulin pumps item and 26% in glucose sensors (Insider Newsroom, 2024). The Association protested this as a result of overreliance of funding on the industry, accusing the national payer of failing to make any effective increases to their corresponding budget in the last seven years, despite the incorporation of innovations in non-

invasive monitoring and infusion pumps into the reimbursement portfolio during this time (Insider Newsroom, 2024).

Figure 8 Evolution of Total Pharmaceutical Expenditure in Greece 2012- 2023



Source: Adapted from SFEE & IOBE, 2023

In conclusion, SEIV contended that suppliers of diabetes devices and DHTs are faced with the prospect of withdrawal from the Greek market, citing that this has already been actioned by certain multinational manufacturers, and cannot support the introduction of new products under these conditions which compromise their financial viability (Insider Newsroom, 2024). Notably, in October 2024, serious concern about the possibility of withdrawals and the ramifications these would have on the health outcomes and quality of life of PLWD in Greece was echoed by the Panhellenic Federation of People with Diabetes in a formal letter to the MoH and EOPYY leadership calling for an urgent preventive action against this development (Panhellenic Federation of People with Diabetes (POSSASDIA), 2024b).

Finally, beyond access to treatments, aspects of the payback policy framework were spotlighted in interviews as impediments to the implementation of innovative financing mechanisms and the promotion of clinical research for diabetes therapies in Greece (Primary Data Collection, 2024). Namely, the extent of clawbacks and rebates imposed in reimbursement negotiation was cited as a spanner in the works for the development of risk-sharing contracts and value-based reimbursement agreements for medicines and health technologies between the national payer and manufacturers active in diabetes in Greece. Characteristically, one industry representative suggested:

"We have the shadow of clawback and rebate. If there is something more indicative, more scientific, more HTA-oriented, that should be done if the shadow is to be lifted, so that we have more effective ways of negotiating based on science, based on data, based on experience. Otherwise, we just add a hurdle."

- Working Group on Diabetes, *SFEE*

At the same time, the clawback mechanism was indicated as a stumbling block to the conduct of clinical trials based in Greece for the development of new therapies (Primary Data Collection, 2024). According to interviewees, this is not only due to diminishing the ultimate profitability prospects for manufacturers in the domestic market, but also on account of failure to safeguard incentives for international clinical trials to be extended to Greece in the legislation governing clawbacks (Primary Data Collection, 2024). Namely, a clause is in place for pharmaceutical companies undertaking R&D initiatives domestically in Greece, such as clinical trials to support local evidence generation for the development of a new drug or health technology, to benefit from reconciliation of their expenditure on these endeavours with their clawback payment obligations to the EOPYY for their reimbursed products (Primary Data Collection, 2024). However, the eligibility criteria for this clause to apply reject clinical trials which involve at least 1 site located outside Greece as ineligible for reconciliation (Primary Data Collection, 2024). As a result, multinational drug manufacturers who typically organize and carry out international trials including sites across different countries do not qualify for recompensation against the clawback if they integrate a centre in Greece to their trial design (Primary Data Collection, 2024). Given that the feasibility of executing an RCT exclusively based in Greece is open to question, this criteria structure consequently undermines the effectiveness of the clause intended to encourage the uptake of innovative clinical research in Greece, deeming it instead more of a barrier than an incentive. The effects of this are not only incident on diabetes, but across all therapeutic areas.

3.2.4.4. Health Technology Assessment

Health technology assessment (HTA) was established in Greece in 2018 (Chantzaras & Yfantopoulos, 2022), and therefore represents a recent new institutional feature compared to other European countries. The Health Technology Assessment and Reimbursement Committee is

responsible for the pricing and reimbursement of medicinal products. Over the years, the body has seen an increasing number of applications, signifying a gradual full implementation of its mechanism within the Greek pricing and reimbursement regulatory framework for medicinal products (Chantzaras & Yfantopoulos, 2022). The Negotiation Committee is also responsible for performing economic evaluations and negotiating prices and discount rates for all reimbursed medicinal products (Chantzaras & Yfantopoulos, 2022). Most reimbursement negotiations between manufacturers and the Drug Negotiation Committee result in framework agreements based on discounts (Primary Data Collection, 2024). In the diabetes medicine portfolio, closed budget agreements have been applied in recent years to the GLP-1 and SGLT-2 therapeutic classes. However, shortages in the supply of these drugs in conjunction with insufficient monitoring of prescribers' compliance with the diabetes therapeutic protocol have caused problems. Namely, the leeway to sidestep restrictions on the e-prescription system by manipulating the submitted results of lab exams to falsely portray potentially obese individuals as PLWD to enable the prescription of GLP1 and SLGLT-2 agents has compromised the estimate of expected volume demand for the medicines by the Greek national payer, EOPYY. Shortages have also occurred of insulin analogues and oral antidiabetic medications, which often force patients to switch therapies and can compromise treatment efficacy (Primary Data Collection, 2024). These shortages are not only disrupting care but are also increasing the Greek healthcare system's costs due to reactive measures, such as emergency procurement or reliance on less cost-effective alternatives.

No provision currently exists in Greece for application of HTA to medical devices. As a result, medical device products for which reimbursement is sought in Greece do not undergo HTA but are instead referred directly to negotiation for agreements to be reached between EOPYY and suppliers. The negotiation is facilitated by a dedicated committee, the Negotiation Committee for Reimbursement Prices for Health Services, Medical Technology Products and Materials ("Negotiation Committee for Devices and Consumables") (Government of the Hellenic Republic, 2018a). This committee belongs to the EOPYY and is distinct and independent from the Drug Negotiation Committee (Government of the Hellenic Republic, 2018a). The absence of medical device assessment has been identified as a significant limitation in access to diabetes technologies by multiple interviewees (Primary Data Collection, 2024). The main point raised in various interviews is that the absence of this type of assessment limits not only effective access to technologies, but also the implementation of a value-based care pricing and reimbursement regulatory framework. Its absence is seen as a critical factor that can cause low-value care and further exacerbate treatment shortages, as it hinders systematic evaluation and planning for procurement and distribution.

"[Regarding overpayment for medical devices] We receive many complaints about CGM sensors that don't last as long as they should and need to be replaced earlier than expected, or they keep giving low glucose readings below 70 or stop in the warm-up and never start. These are problems caused by the lack of HTA for medical devices."

--Dr Christos Daramilas, President, POSSASDIA

A number of different CGM systems are fully reimbursed for people living with T1 disease, while coverage is expected to be extended to PLwT2 as well in 2025 (Panhellenic Federation of People with Diabetes (POSSASDIA), 2024c). However, the price of all these products is set the same, in the absence of comparative evidence-driven assessment of the value of them as alternative treatment solutions (Primary Data Collection, 2024). Sometimes a CGM sensor doesn't last as long

as the manufacturer advertises and the PLWD must pay OOP for another CGM. What emerges, then, is an overpayment: by the health system who does not receive the value for which they paid and by the PLWD who incurs additional expense for their consumables (Primary Data Collection, 2024).

An additional limiting factor in Greece's capacity to deliver value-based care linked with HTA decisions is its ability to demonstrate impact in target populations through evidence. As outlined in section 3.2.2.4, population-level data related to diabetes, complications, and co-occurring conditions is limited. To be helpful for negotiations, this information should be further divided into subgroups to identify estimates of Greek PLWD for whom the intervention would be most beneficial (Primary Data Collection, 2024). Additionally, manufacturers feel disincentivized to conduct clinical trials in the country due to clawback policies (Primary Data Collection, 2024). Further investment into Greece's national health data infrastructure is warranted to improve Greece's ability to provide value-based care by identifying gaps in delivery and performing evidence-based assessments on the impacts of potential solutions. According to our interviewees, a more established and expanded implementation of HTA in Greece would introduce opportunity for implementation of innovative pricing and reimbursement mechanisms directly applicable to diabetes drugs and technologies, such as risk-sharing agreements, or subscription-based models (Primary Data Collection, 2024).

3.3. State of care in comparator countries: Portugal, Demark, Spain, UK, Italy, and Romania

The selected comparator countries—Denmark, England, Italy, Portugal, Romania, and Spain—provide, on the one hand, a benchmark of best practices on how to set up diabetes care-related policies; on the other hand, these countries share, to varying degrees, epidemiological, demographic, and social similarities with Greece. Therefore, an analysis of comparator countries might serve to discuss the current best practices and challenges in diabetes management and to reflect on diabetes reform options for Greece.

3.3.1. The Diabetes Epidemiological Context of Comparator Countries

Age-standardised diabetes prevalence among adults in comparator countries ranges from 5.3% in Denmark, the lowest rate, to similar rates in the UK (6.3%), Italy (6.4%), Romania (6.5%), and higher rates in Portugal (9.1%) and Spain (10.3%)(Organisation for Economic Cooperation and Development, 2023). Among this group of countries, Spain has the highest number of adults (20-79 years old) that have undiagnosed diabetes (1.557 million people, i.e., 32.85 per 1,000 people), while Denmark reports the lowest number of undiagnosed people with diabetes (103.6 thousand people, 17.74 per 1,000 people)(IDF, 2021).

Regarding T1D prevalence among children and adolescents between 0 and 19 years old, the UK reports the highest rate (31.6 cases per 1000 people), followed by Spain (17.2) and Italy (13.7), and lower rates from Romania (3.9), Denmark (3.1), Greece(2.9), and Portugal (2.4) (IDF, 2021).

With regard to secondary care treatments, Romania reports the highest number of diabetes hospital admissions among adults (148 per 100,000 people), followed by Denmark (102), the UK (80), Spain (57), Portugal (53), and Italy (31). Furthermore, Romania has also the highest number of major lower extremity amputations (18.6 per 100000 people). For the same indicator, Portugal recorded the highest value (11.1 per 100,000 people), while all the other countries with the exception of Italy (2.5) reported between 6.4 and 7.5 cases(Organisation for Economic Cooperation and Development,

2023). Daily antidiabetic doses per 1,000 people range from 65 in Italy to 101 in Greece, with an average of 81 across the countries of interest (Organisation for Economic Cooperation and Development, 2023).

Across the considered countries, age-standardised prevalence of obesity among adults ranged, in 2016, between 19.7% in Denmark and 27.8% in the UK, with an average of 22.7%. However, in adolescents between 10 and 19 years, the difference between the considered countries is narrower, ranging from 6.2% in Denmark to 10.6% in Greece(World Health Organization, 2022). More recent estimates report that, in 2019, obese adults were, as share of total population, 16% in Greece, 17% in Portugal, 15% in Spain, and 11% in Italy(OECD/European Observatory on Health Systems and Policies, 2023).

Overall, based on the various health and epidemiological indicators, Denmark emerges as the country, among the considered ones with better baseline health conditions, reporting the lowest diabetes and obesity prevalence in adults, the lowest number of undiagnosed patients, the lowest mortality attributable to diabetes, and at the same time the lowest recourse to daily medications, and the second lowest number of major lower extremity amputations. At the same time, Spain reported, among adults, the highest levels of diabetes' prevalence and missed diagnosis. Romania instead reported concerning levels of lower extremity amputations and diabetes-related hospital admissions. In the table below are grouped several epidemiological and policy indicators related to the comparator countries of interest.

3.3.2. Denmark

The Danish health system employs a decentralised approach to diabetes care, delegating responsibilities and tasks to regions and municipalities and by giving a central role to primary care in diabetes care management. The Danish diabetes plan ("*Nationale Diabeteshandlingsplan*") provides a national framework that sets out the broader vision of developing and improving diabetes care. However, Danish decentralised approach devolves large autonomy to municipalities, which have the responsibility for health promotion and preventive measures, and can set out their own local diabetes plan, such as in the case of the City of Copenhagen (City of Copenhagen, 2022). Integration across national and local institutions and across different healthcare providers is ensured through coordinated care pathways, i.e., "*Forløbsprogrammer*", which clearly set out the roles, responsibilities, and terms of collaborations across different providers and institutions. The overall aim of this decentralised approach is to provide the most tailored local interventions and to develop programmes that are fit for the needs of local communities, while at the same time the national framework ensures that high standards are met everywhere in the countries.

The most relevant and innovative insights that emerge from the Danish diabetes plan are related to the development of personalised treatment pathways. This modality aims at providing tailored treatment plans that consider the unique circumstances, preferences, and health profiles of each individual rather than uniquely rely on more generic treatment guidelines. Additional to the personalised treatment approach, the plan promotes the "Same day under the same roof" approach, which proposes an integrated care model through which patients receive multiple services in one visit. For example, a patient can access diagnostic tests, consultations, and follow-up care on the same day and at the same location. Specialised diabetes care centres are typically set in hospitals or big clinics; the centres include general multidisciplinary services with the support of multiple specialists, such as endocrinologists, diabetes nurses, dietitians, podiatrists and ophthalmologists. Given the highly integrated care system, diabetes centres are closely coordinated with GPs, which

act as gatekeepers to specialised services, and are generally responsible for the initial diagnosis of T2D.

Access to innovative tools and equipment is also part of the Danish plan, focused on providing tools that are used to monitor and control blood glucose levels, such insulin pumps and CGMs. Denmark has a decentralised HTA appraisal process, devolved to regional level, and coordinated nationally by the Danish Centre for Health Technology Assessment (DACEHTA), which is part of the Danish Health Authority ("*Sundhedsstyrelsen"*). HTA appraisal in Denmark is performed for both medicinal products and medical devices, thus providing efficient access to the above-mentioned diabetes devices *(Okkels Birk et al., 2024).*

Another distinctive initiative of the Danish plan relates to specific support for families with children diagnosed with diabetes, young people, and vulnerable patients. The plan provides targeted support and counselling services for families, as well as for young people, to help them integrate diabetes care in their daily lives. Elderly patients, those with multiple chronic conditions, or people from low socioeconomic backgrounds are framed as vulnerable diabetes patients and are identified as groups in need to receive more comprehensive care and therefore in need to receive more inputs from the health system. Finally, screening programmes for earlier detection of T2D and specifically for high-risk groups are in place to prevent the onset of the disease or severe complications. Furthermore, children with T1D are screened at 12, 15, and 18 years of age for retinopathy using fundus photography to prevent visual impairment (Herskin et al., 2020). Overall, the Danish diabetes plan provides in many aspects some best practices for its focus on comprehensive, patient-centred management of the disease, with the help of specialised structures, technologies, community resources and screening programs for diabetic patients *(The National Diabetes Action Plan 2017-2020, 2017).*

3.3.3. Italy

The Italian National Health Service (NHS) is decentralised, devolving care management and many financial and legislative functions to its regions. Therefore, the national plan on diabetes ("*Piano sulla malattia diabetica*") sets the broader goals that each regional health service needs to perform. The plan's focus on coordination and governance across regions, patient education, social inequality, and access to innovation.

To ensure a uniformity of treatment across the country, the plan developed national guidelines, and specifically established standardised care pathways, called PDTA (*Percorsi diagnostico-terapeutici assistenziali)*. These pathways aim at harmonising regional networks among diabetes care centres and ensuring coordination between these centres and primary care providers, such as general practitioners (GPs) and paediatricians. In addition to PDTAs, a specific goal of the plan is to enhance coordination between national and regional authorities, together with healthcare professionals, and patient associations, through the establishment of working groups which reflect on the needs of the various regional communities (Piano Sulla Malattia Diabetica, 2013).

Regarding care management, the plan is particularly focused on prioritising the regular screening, early intervention, and appropriate clinical management of complications such as retinopathy, nephropathy, neuropathy, as well as vascular complications. In 2023 Italy introduced a nationwide screening for T1D in children aged 1-17 years, with the goal of identifying presymptomatic PLwT1D, and to delay disease progression (Bosi & Catassi, 2024). While there isn't a national systematic screening program for detecting T2D, the Italian Association of Diabetologists recommends an *ad hoc* screening from GPs, which act as gatekeepers in the Italian NHS, in the at-risk population(Nolte

& Knai, 2015). Specialised health centers, knows as "*centri diabetici*", are set out at national level and generally treat complex diabetic patients after GP referral. However, the availability of such facilities can significantly vary across regional health system due to the NHS decentralised structure, leading to inconsistencies in care management and resource availability. Similarly to other comparator countries, a focus on the uptake of continuous glucose monitors (CGM) and insulin pumps is encouraged. The Italian NHS offers reimbursement for insulin pumps and CGMs for people who meet clinical guidelines, such as inadequate glycemic control or hypoglycaemia unawareness (Musacchio et al., 2020). Given the regional structure of the health system, the process for obtaining reimbursement varies from region to region, but in the entire country is performed by the diabetes centres case-by-case. Generally, reimbursement of these technologies is provided to PLwT1D with inadequate glycaemic control, frequent episodes of hypoglycaemia, and/or pregnant women. The reimbursement availability varies across regions, for instance some regions are reimbursing CGM in full – i.e., Piedmont and Basilicata – while others still reimburse CGM on a case-by-case basis (Seidel et al., 2019).

Education and training goals for both patients and healthcare providers are also set out in the plan: for patients, on top of public health campaigns to increase awareness, such programme focus on insulin management, glucose monitoring, and lifestyle modifications, while for providers. A specific mention in the Italian plan is devoted to the treatment of special and vulnerable subgroups, such as people in fragile social conditions, such as low-income groups or immigrants, young people, and pregnant women with diabetes, for which pre-pregnancy counselling and enhanced monitoring are encouraged. Finally, a missing feature of the Italian diabetes plan is the lack of a national diabetes register; however, Italy provides some useful examples of integrated care planning practices, such as the PDTA, and a reasoned approach to targeting high-risk populations through prevention and primary care activities (Piano Sulla Malattia Diabetica, 2013).

3.3.4. Portugal

Portugal has a National Health Service (SNS) system and established the Diabetes Functional Coordinating Units (UCFD) to synchronise diabetes primary and secondary care. Given that the Portugal has established an NHS system, GPs have a pivotal role as gatekeepers of the system and are central figures in diagnosing diabetes and providing ongoing management. GPs management is integrated with diabetes care centres, which offer services from endocrinologists, diabetes nurses and dietitians. The Portuguese health system also aims at integrating care through coordinated services, from primary care's family health units to chronic disease programs and e-health initiatives, such as enhancing the implementation of electronic health records and information sharing support integration.

In 2023, Portugal implemented a comprehensive national diabetes plan (i.e. the *Programa Nacional para a diabetes*) based on 9 goals, mainly focusing on education, prevention, and early diagnosis. The plan enhanced the existing screening process for diabetic retinopathy, with the goal of improving the rates of early detections. To do so, the specific intervention aims at standardising screening protocols and covering a larger share of the population, particularly in the remote and underserved areas (Portuguese National Diabetes Program, 2023).

Furthermore, three programmes were implemented to improve access to care, i.e., first, the advanced hybrid closed-loop system for insulin delivery, which automates insulin delivery based on continuous glucose monitoring (CGM) data; second, the articulation of the PSCI (Program with Continuous Subcutaneous Insulin Infusion) programme to improve coordinated care across different

treatment centres; and third, the working group for the development of the CSII (Continuous Subcutaneous Insulin Infusion**)** strategy, which mainly aimed at improving access to this treatment.

The National Authority of Medicines and Health Products (Infarmed) is responsible for the HTA appraisal process and evaluates medical devices as well as medicinal products. Therefore, reimbursement for medical devices is provided for individuals who meet specific criteria, such as children and adolescents or adults who have poor glycaemic control.(World Health Organization, 2021). Specifically, PLWT1D, pregnant women and/or adults with frequent hypoglycaemic episodes have access to insulin pumps; PLWT1D needing intensive glycaemic monitoring also are reimbursed for CGMs (Portuguese National Diabetes Program, 2023).

A standardised care management framework for T1D has been developed to set uniform guidelines for healthcare providers, provide a comprehensive strategy from diagnosis to long-term management, and start implementing the latest medical and technological innovation in routine care.

Regarding prevention, a particular focus has been dedicated to education and awareness programmes and to specific strategies directed at tackling social stigma on the disease. The Portuguese plan included two educational programs, i.e. “Mais Saúde, Menos Diabetes” (“More Health, Less Diabetes”), and Diabetes e as Escolas 2022” (“Diabetes and Schools 2022”), which are aiming at increasing awareness on the behavioural causes of the disease, its risk factors, and how to manage it. Furthermore, the “Diabetes em Movimento” (“Diabetes on the Move”) programme was developed to promote physical activity among diabetic people. Finally, the “Falar Abertamente da Diabetes” (“Talk Openly About Diabetes”) programme was specifically designed with the public television channel to destigmatise the condition and increase its public understanding for the broader audience(Portuguese National Diabetes Program, 2023; Regulation No. 016/2018 - Diabetic Retinopathy Screening, 2018)

Overall, Portugal’s national diabetes plan provides some relevant examples on how to promote awareness and increase prevention, harmonise care management across different care structures, and improve the uptake and appropriate use of innovative techniques.

3.3.5. Romania

The Romanian health system is based on a centralised social health insurance (SHI) system. The Ministry of Health oversees the implementation of diabetes management policies; however, the reach and quality of these services varies across the country. The Romanian health system faces several challenges in improving health outcomes; these include challenges arising from infrastructure limitations and funding constraints, limited access to advanced technologies, as well as those related to tackling unhealthy behaviours.

In 2022, the National diabetes plan (*Programul Național de Diabet*) was implemented. Its broader goals are related to 1. Increasingly prevent diabetes-related complications; 2. Improve the efficiency of healthcare spending; 3. Enhancing the health outcomes of people with diabetes.

Monitoring and increased access are the main interventions that are considered in the plan. Different screening monitoring goals are set out: Ensure regular monitoring of blood glucose levels in patients with diabetes by measuring glycated hemoglobin (HbA1c), empower patients to take control of their diabetes management through regular self-monitoring of blood glucose, and facilitate access to insulin pumps and related consumables, particularly those for whom multiple daily insulin injections are not sufficient(National Diabetes Program, 2022). For people at risk of, or unaware of having, T2D, screening efforts primarily target high-risk individuals; however, the extent of this action varies

significantly across geographical areas (Rais et al., 2020). Currently, availability of hybrid closed-loop systems is reimbursed with no co-payment for children with T1D reporting specific CGM levels (Janez et al., 2021). Finally, HTA appraisal of medical devices is not performed for reimbursement decisions.

Adherence to care plans is also a major goal, together with improving patient education and self-management. Two distinct screening subprogrammes are set out, respectively for T1D, and for those with T2D gestational, and other specific forms of diabetes. There is additional focus on vulnerable populations, which are identified as children, pregnant women, and individuals with complex health needs; these population subgroups are recognised as in need to receive further monitoring and of specialised care (National Diabetes Program, 2022).

3.3.6. Spain

Spain's health system is based on a National Health System (SNS) that establishes a framework at the national level and coordinates 17 autonomous regional authorities, which can independently implement diabetes prevention and management programmes based on their regional demographics and local health demands. Despite the existence of a national health system, due to the high level of regional autonomy health care coordination is fragmented throughout Spain. This implies that the availability of the services, the implementation of new technologies, and the delivery of preventive strategies may significantly differ from one region to another. Primary care services have a central role in monitoring and managing patients with diabetes, and general practitioners act as gatekeepers, managing referrals to specialists. Multi-specialty diabetes centres are established at the national level; however, their availability and use, especially when it comes to providing more advanced technologies like insulin pumps, can widely vary by region.

The Spanish National Diabetes Plan is based on six key strategic lines related to patients' education, screening, providers' training, and management of specific population subgroups. Two strategic lines focus on patients' awareness. The first is based on the development of integrated care between different levels of the health system (primary, specialised, and hospital care), with the goal of ensuring continuity of care across different stages of the disease and of improving therapeutic education and patient self-management. A specific strategic line focuses on developing public health campaigns to promote healthy lifestyles, e.g., reduce sedentary behaviour, improve daily consumption of fruit and vegetables, and encourage physical activity.

A particular focus in this plan is devoted to health professionals' continuing education to keep up with the latest developments in diabetes care, such as new technologies and treatment protocols. Furthermore, the plan encourages the development of diabetes projects that include gender and social equity considerations that are often neglected in research. Finally, health professionals are encouraged to learn the use of digital tools to improve access to specialist care.

Similarly to other national diabetes plans, improving screening is considered a pivotal intervention to enhancing diabetes care. The Spanish plan focuses on improving early diagnosis by promoting systematic screening for T2D in at-risk populations, particularly those over 45 years of age. Screenings are also promoted across already diagnosed patients, with the main goal of reducing serious complications. Specific regular screenings have been implemented, such as eye exams to catch diabetic retinopathy, and recommendations to improve care for hospitalised diabetic patients even when they are admitted for reasons unrelated to diabetes(Diabetes Strategy of the National Health Service, 2012; Public Health Strategy 2022, 2022). The use of medical devices is supported by HTA appraisals performed both by the national and regional HTA agencies; some regions fully

reimburse hybrid closed-loop systems for children and adolescents (Toscas et al., 2024). Finally, the plan dedicates one strategic line to gestational diabetes and prediabetes, promoting the screening for diabetes during pregnancy, managing blood glucose levels, and providing appropriate care during and after delivery. Furthermore, the plan promotes breastfeeding and other good maternal health practices to reduce the risks associated with gestational diabetes (Diabetes Strategy of the National Health Service, 2012; Public Health Strategy 2022, 2022).

3.3.7. United Kingdom

The UK has a National Health Service (NHS) system, subdivided in the four countries comprising it, a diabetes prevention plan has been developed involving different institutions, such as NHS England, Public Health England, and Diabetes UK. The country suffers relatively high levels of obesity and other unhealthy behaviours, and diabetes represents a significant economic burden for the health system, accounting for about 10% of the annual NHS budget (NHS Diabetes Prevention Programme (NHS DPP), 2024; NHS England, 2016). For these reasons, the main drive of the UK strategy is to focus on prevention and early identification of subjects at risk of developing the disease or of complicating their condition. The establishment of the integrated care systems in 2022 had an impact on diabetes care management, enhancing coordination across local care facilities and health providers. Through the HTA appraisal of medical devices performed by NICE, the NHS has embraced the use of hybrid-closed loop systems in T1D which is supported by a 5-year implementation plan (National Institute for Health and Care Excellence, 2023).

The British NHS Diabetes Prevention Programme and the NHS Long Term Plan, have, as main long-term goals, the reduction of the T2D incidence, lowering the number of complications associated with diabetes, such as heart disease, stroke, and diabetic foot ulcers, and tackling health inequalities, given that there is an uneven distribution of diabetes prevalence across different population groups. Local sites, including Clinical Commissioning Groups (CCGs) and Local Authorities (LAs), work with the selected providers to implement the programme. The programme is implemented at the regional level through Sustainability and Transformation Plans (STPs), which are responsible for integrating the NHS DPP into local care pathways.

Incidence reduction is planned to be achieved by identifying at-risk individuals through health checks and screenings, particularly focusing on individuals with "non-diabetic hyperglycaemia" (NDH). A pivotal role is given to general practitioners, which are equipped of GP registers where some key patients' metrics are registered, such as elevated levels of HbA1c or fasting plasma glucose. Together with this effort, a behavioural intervention is designed to follow patients and helping them achieving healthier lifestyles, i.e., achieving a healthy weight, meeting dietary recommendations, and meeting physical activity guidelines. This programme includes 13 sessions over nine months, with a minimum of 16 hours of face-to-face contact time(NHS Diabetes Prevention Programme (NHS DPP), 2024; NHS England, 2016). The NHS DPP is a great example of population health management strategy which has been implemented to in tackle a major health issue like diabetes in the UK. By September 2020, almost 300,000 people had been referred to the programme, and approximately 5000 self-referrals were made each week (NHS England, 2020). A 2024 modelling study suggested the UK prevention programme generated greater quality adjusted life years, and it is cost-effective in the long term by reducing the burden of T2D on the NHS (McManus, 2024).

3.3.8. Summary of findings from countries' National Diabetes Plans

Table 2 Summary of comparator countries

Indicator /Country	**Greece**	**Denmark**	**UK**	**Italy**	**Portugal**	**Romania**	**Spain**
Health expenditure as % of GDP	8.5	9.5	10.9[1]	9	10.5	5.8	9.7
Public expenditure as % of total health expenditure	54	85	83.7	76.1	64.4	80.1	73.3
National diabetes plan	N/A	Nationale diabetes-handlingsplan (2017)	NHS Diabetes Prevention Programme (2016)	Piano sulla malattia diabetica (2012)	Programa Nacional para a diabetes (2023)	Programul Național de Diabet Zaharat (2022)	Estrategia en Diabetes del Sistema Nacional de Salud (2012)
Presence of National Therapeutic Protocols	Yes[2]	Yes	Yes	Yes	Yes	Yes	Yes
Presence of prescribing guidance based on clinical and economic criteria	No[3]	Yes	Yes	Yes	No	No	No
National diabetes registry	Partial[4]	Yes	Yes	No	Yes	No	No
Pediatric Diabetes Registries	No	Yes	Yes	No	Yes	No	No
Strong role of GP as care coordinator	No	Yes	Yes	Yes	Yes	No	Yes
Integrated Care system	No	Yes	Yes	Yes	Yes	No	Yes
Diabetic retinopathy screening programs	National DR program	National DR program	National DR program	Local DR program	Local DR program	No program	No program
Age at when T1D screening starts	N/A	12	N/A	1 (to 17)	N/A	1 (to 18)	N/A
T2 risk-factor based screening program	Yes, with general population screening from age 35	Yes, for high-risk population	Yes, with general population screening from age 40	Yes, for high-risk population	Yes, with general population screening from age 45	Yes, with general population screening from age 45	Yes, with general population screening from age 45

Reimbursed access to Digital Health Technologies (DHTs)							
Access to technologies for people with T1D	CGMs, insulin pumps, hybrid-closed loop systems	CGMs, insulin pumps, hybrid-closed loop systems	CGMs, insulin pumps, hybrid-closed loop systems	CGMs, insulin pumps, hybrid-closed loop system	CGMs, insulin pumps, hybrid-closed loop system	CGMs, insulin pumps, hybrid-closed loop systems	CGMs, insulin pumps, hybrid-closed loop systems
Access to technologies for people with T2D[5]	No	CGMs, insulin pumps (severe patients)	CGMs, insulin pumps (severe patients)	CGMs, insulin pumps (severe patients)	CGMs (severe patients)	No	CGMs (severe patients)

1 For the British value, the UK Office of National Statistics source was used, while for all other countries the Eurostat source was used

2 The national therapeutic protocol is implemented in Greece but is not as detailed as other countries' protocols. Clinicians have greater flexibility in determining the first-line and stepwise approach for treatments, and there is generally weak personalization of treatments.

3 The Greek national therapeutic protocol does not include any health economic considerations (i.e., there is an absence of any cost-effectiveness or budget impact-based recommendations).

4 The Greek diabetes registry only includes PLWD who are treated with medication and does not track complications.

5 Where available, reimbursed technologies for T2D patients are only granted on a case-by-case basis; in regional health systems there could be discrepancies in reimbursement.

Source: Denmark (The National Diabetes Action Plan 2017-2020, 2017) ; City of Copenhagen (Cty of Copenhagen, 2022) ; Italy (Piano Sulla Malattia Diabetica, 2013); Italy (Diabete.com, 2023) ; Portugal (Portuguese National Diabetes Program, 2023); Portugal (Portuguese General Direction of Health, 2011) ; Romania (National Diabetes Program, 2022); Spain (Diabetes Strategy of the National Health Service, 2012); Aragon (Aragon's Government, 2021) ; United Kingdom (NHS England, 2016); NHS Long Term Plan (NHS England, 2019); ONS UK data (Office for National Statistics, 2023); Eurostat EU data (Eurostat, 2024); World Bank (World Bank, 2021)

4. Opportunities for Greek Diabetes Care Reform

Greece is shouldering a substantial and growing burden of diabetes while the Greek health system faces several challenges to effectively delivering consistent, high quality diabetes care to meet their population's needs. This section presents opportunities for diabetes care reform in Greece, drawing insights from the literature, expert stakeholders, and comparator countries. Identified areas for diabetes care improvement include opportunities to improve care coordination, leverage technology and data insights, and deliver more value-based care.

4.1. Learnings for Greece from Comparator Countries

Diabetes care delivery in Greece is reactive and variable across modes and locations of provision. Health system fragmentation—resultant from a combination of factors including but not limited to Greece's innate geographical challenges, cultural approach to care self-coordination, and limited data infrastructure—presents significant barriers to leveraging an integrated approach to care delivery. Health systems with decentralised care delivery such as Denmark, Spain, and Italy often face similar fragmentation challenges. While decentralization can lead to variations in care quality, comparator countries demonstrate that integrated care can be achieved even within decentralized systems. Learnings from comparator countries shed insight into opportunities to overcome these significant barriers through coordination pathways, particularly in health policy and digital infrastructure.

Policy solutions to improve this are seen through coordination mechanisms, which typically offer a national framework with opportunities for local adaptation in implementation. For example, through its national plan, Denmark managed to define a framework of principles, roles and responsibilities in which each of the health providers is included and encouraged to align care delivery (The National Diabetes Action Plan 2017-2020, 2017). The city of Copenhagen has an additional plan that emphasizes local priorities (City of Copenhagen, 2022). Through standardised care pathways (PDTAs), Italy ensures that diabetes care standards, are uniform across regions, and sets clear pathways in which different providers collaborate (Piano Sulla Malattia Diabetica, 2013). Finally, the regional structure of Spain's health system has led to the development of a national plan which is complemented by region-specific strategies, such as the Andalusian plan, that are developed within the broader national goals (Diabetes Strategy of the National Health Service, 2012).

In their respective national plans, comparator countries provided a focus on specific sub-populations, which include not only high-risk patients, but also those affected by socio-economic issues, or vulnerable segments of the population, such as young, elders and pregnant women. Denmark, for example, focused on elderly patients, individuals with multiple chronic conditions, and families with children diagnosed with diabetes; for them, enhanced counselling local interventions sets by city or regional plans are encouraged (The National Diabetes Action Plan 2017-2020, 2017).Similarly, Spain's efforts can be traced in their strategy related to Gestational diabetes and gestational prediabetes, promoting the screening for diabetes during pregnancy, managing blood glucose levels, and providing appropriate care during and after delivery (Diabetes Strategy of the National Health Service, 2012). The Italian diabetes plan also focuses on women with gestational diabetes, including also immigrants and low-income individuals as vulnerable groups (Italian NDP). The establishment of Italian diabetes centres is thought as a hub for complex cases referred by GPs, which act as gatekeepers (Piano Sulla Malattia Diabetica, 2013). Finally, Portugal's goals focus on providing access to screening programmes, such as diabetic retinopathy, in remote and underserved areas through standardised screening protocols (Portuguese NDP).

A key component of health system coordination demonstrated by comparator countries is the capacity of a strong primary care system to support the delivery of integrated care. This capacity is easy to demonstrate in a system like the UK in which the GP acts as strict gatekeeper to specialists for diabetes, complications, and co-occurring conditions. Decentralised systems also benefit from and can enforce a strong role of primary care providers who act in care coordination roles and invest in information sharing between primary care, specialist centres, and hospitals. Italy, for example, stands out for its primary care capabilities to coordinate diabetes care and refer complex cases where required. When primary care is the default health system entry point, specialists' time is reserved for the patients who need them most which improves the efficiency of care delivery.

Continuing education plays a pivotal role in various comparator countries' national diabetes plans, particularly Spain, the UK, Italy and Denmark. Providing up-to-date information to healthcare providers about national care protocols and novel technologies are essential to improving care efficacy. In this regard, staff training is also seen as essential to improving DHT integration. The Portuguese diabetes plan, for example, names staff training as a key component of digital integration (Portuguese National Diabetes Program, 2023). An educated healthcare workforce that is able to efficiently contribute to a digital health infrastructure, deliver virtual care, and onboard PLWD to the latest medical devices is considered an important lever to enabling change.

Naturally, advanced data infrastructure can improve the efficiency of primary care and ease of care coordination. For example, the UK Diabetes Prevention Program outlines the detection of key patient metrics, such as HbA1c levels or fasting plasma glucose, through registers that allow GPs in the UK to monitor PLWD's risk of complications, including sub-group level monitoring (NHS Diabetes Prevention Programme (NHS DPP), 2024; NHS England, 2016). The NHS also has automated outreach and scheduling of screenings for common complications (Primary Data Collection, 2024). Additionally, within hospitals and specialist centres, risk-stratification support is increasingly offered by medical device providers to improve monitoring and interventions for those using eligible devices (Primary Data Collection, 2024). Additionally, telehealth services can improve access to care, particularly in remote areas. In Portugal, for example, Diabetes Functional Coordinating Units are responsible for promoting the uptake of telehealth, particularly across vulnerable populations (Portuguese National Diabetes Program, 2023).

Implementing digital transformation requires investment in staff training and health system infrastructure. Financial support at the national level is essential for successful transformation initiatives. This is exemplified through the adoption of hybrid-closed loop systems for T1D in the UK, which observes a 5-year implementation plan (National Institute for Health and Care Excellence, 2023). An example of financial incentives implementation at regional level can be found in Italy, where the national framework gives responsibilities to regional health systems in administering the reimbursement of CGM technologies. With regards to this, regions like Basilicata and Piedmont prioritised CGM for all eligible patients providing full reimbursement, while other Italian region provide reimbursement only on a case-by-case basis (Seidel et al., 2019).

Cost-effectiveness considerations implementation in therapeutic guidance is another area that could improve efficiency in prescribing behaviour, insurers' budget allocation, and consistency of treatment quality. Of the six comparator groups, three – Denmark, the UK and Italy - explicitly integrate cost-effectiveness into therapeutic prescribing protocols, providing cost-related information that physicians take into account when prescribing. In the UK, NICE guidelines provide cost-effectiveness information that is integrated into guidance, reporting the lowest cost options within each therapeutic class (Curtis et al., 2018; NICE, 2022); similarly, the Danish Medicines Agency provides physicians

with a Medicine Profile database, where prices of equivalent prescribed medicines can be compared (Generic and Biosimilar Initiative, 2011). In Italy, AIFA's Note 100 informs physicians of cost-effectiveness therapeutic options (Guacci, 2023). While these measures are set at the national level, in all three countries significant geographic disparities in physicians' prescribing behaviour have been observed (Curtis et al., 2018; Guacci, 2023; Sundhedspolitisk Tidsskrift, 2017), representing a still unresolved challenge for policymakers.

4.2. Towards a National Diabetes Strategy

Diabetes represents a significant and escalating public health challenge in Greece, which demands a comprehensive and coordinated response. Aligning political priorities is an essential first step towards implementing necessary improvements to diabetes care delivery. This response can be well supported through the implementation of a comprehensive National Diabetes Strategy. As demonstrated by comparator countries, national plans and strategies for diabetes are a prevalent and effective approach to national coordination within diabetes priority setting and implementing interventions. Additionally, interview participants agree that a national strategy could help improve education, prevention, care coordination, and data collection in Greek diabetes care (Primary Data Collection, 2024). Further, nationwide alignment on key policies for diabetes management could drive care delivery improvements that go beyond the therapeutic area of diabetes, including investments in digital infrastructure, primary care capabilities, and population health literacy.

"To be effective, we have to know what targets we have for the next 5 years."

-Anonymous, Payer & HTA Organization

A National Diabetes Strategy should focus on programs for early diagnosis, screening, prevention and management of diabetes and its complications. Implementation of these programs and guidelines will support the delivery of uniform care nationwide and introduce clear health system access points for PLWD. To meet the current gaps in policy and care delivery it is essential that the national strategy integrates with existing national and local strategic policy initiatives, for example the NAPPH. Various other policy initiatives including movements to strengthen the role of primary care are complementary to the goals of improved diabetes care coordination. Further, there is a clear opportunity for improved procedures around formal and regular channels of engagement with PLWD and patient advocacy organisations (Primary Data Collection, 2024).

A challenge in policymaking that aims to drive change at the national level is the ability to meet the specific needs of subpopulations. This issue is highlighted by the different clinical approaches required for T1DM, T2DM, and gestational diabetes as well as the different socio-cultural interventions required in response to differing causes of the disease and its age of onset. Risk stratification approaches are needed to divide the population into subgroups with unique strategic approaches to patient identification and care delivery (Primary Data Collection, 2024). Particularly considering challenges facing underserved populations, it is crucial that targeted strategies are implemented for high-risk populations. This need is well exemplified by the need for personalised DSME and preventative education, which is not a one-size-fits-all approach. Expert interviews emphasized the need for a focus on youth and nutrition amongst these educational initiatives (Primary Data Collection, 2024).

An often-raised issue in the literature and amongst interview participants is the limitations posed by inadequate data infrastructure in Greece, particularly regarding a diabetes registry and the ability for the health system to track complications. While baseline registry infrastructure exists through

EOPYY and IDIKA prescription tracking, PLWD without a prescribed intervention remain unaccounted for and there is no systematic tracking of complications (Primary Data Collection, 2024). This issue is highlighted by the wide range of estimates of diabetes prevalence in Greece. This data gap obfuscates both the scale of the disease's impact, in terms of PLWD and the severity of their disease, and the health system's ability to provide adequate care to those who need it. A comprehensive diabetes registry is often cited as too costly (Primary Data Collection, 2024) but remains an important factor in understanding Greece's true burden of diabetes. The inability to clearly demonstrate the burden of diabetes on the Greek healthcare system remains a major obstacle to securing political support for important policy changes.

To demonstrate impact, a national strategy should consider mechanisms for self-evaluation. Indicators to measure policy performance should be pre-agreed with input from key stakeholders and aid in demonstrating the burden of diabetes upon Greek individuals and its health system as well as the effectiveness of interventions.

4.3. Improving comprehensive, cost-effective, and uniform care delivery

The DTP for diabetes, implemented by the MoH in 2023 and mandatory, represents a major step forward in delivering uniform care throughout the nation. Yet, several opportunities are available to improve the efficiency and comprehensiveness of these protocols. Most importantly, the DTP does not consider the cost-effectiveness of a drug (whether the additional benefits justify the additional costs) or its performance within different subgroups of the population (and whether all subgroups need to be equally prioritized) in its decision-making about prescribing protocols (Ministry of Health, 2024a). Currently, the Greek DTP approach only considers clinical effectiveness—how well a treatment works—across an entire population. Treatment recommendations are uniform and do not consider differentiations in drug performance across population subgroups. This means that, while the latest diabetes drugs may be included in protocols, there is no structured approach to prioritizing treatments for specific high-risk populations or considering affordability on a national scale. This approach is not aligned with the approaches of health systems with more advanced diabetes care capabilities, as noted in Table 2.

Other European countries, including some comparators, consider clinical and cost-effectiveness as a decision-making criterion for their prescribing protocols and offer individualised pathways based on patient subgroups in the second line of treatment. For example, the UK recommends adding an SGLT2 to an existing metformin regimen for PLWD with established CVD or at high risk of CVD (NICE, 2022),while Greece allows physician discretion between SGLT2s and GLP-1s. Greece gives prescribers wide autonomy to pursue various treatments from the first line, without consideration of the economic implications of these choices or the support to achieve individualised success through custom clinical outcomes targets.

Interestingly, the Greek approach enables individualized physician choice in prescribing but does not facilitate individualized treatment goals. For example, Greek guidelines refer mainly to drug profiles and their use/combination to achieve a target HbA1c of equal or less than 7% (in T2D). Meanwhile, UK guidelines refer to the importance of individualised treatment goal (target HbA1c) and treatment plan depending on person, age, and co-morbidities.

4.4. Enabling integrated care

A precursor to enabling integrated care is a health data infrastructure system capable of collecting patient-level data and enabling relevant access to that data for various providers where necessary. Data interoperability is required to prevent fragmented care. At present, the Greek health system is fragmented and places a burden on the PLWD to coordinate their own care, as there is no clear care coordinator or standardised system access point (Primary Data Collection, 2024). Greece currently does not have the capacity to track patients across health system access points but is taking meaningful steps to improve data sharing, though primarily with patients rather than between providers (Primary Data Collection, 2024). In most instances, the patient remains the party responsible for coordinating data sharing between providers. This approach often places a significant burden on patients, particularly those who are vulnerable or without adequate resources. This can exacerbate inequalities in healthcare access and outcomes as DSME, the ability for PLWD to self-manage their disease, and access to care will vary between persons. Delivering an integrated care approach to diabetes means a shift in this culture, enabling baseline access to health records for all providers involved in the person's care as well as a channel for those providers to communicate with each other (Primary Data Collection, 2024). For Greece to achieve this, investments in health data infrastructure are essential.

The first step in enabling integrated care is to remove barriers to delivering it. For example, an often-identified bottleneck in diabetes management is screening for complications (Primary Data Collection, 2024). Though international clinical guidelines provide a framework for the early detection and management of diabetes-related complications, the approach is not standardised within Greece. As noted in section 3.2.3.3, endocrinologists in the private healthcare, are unable to prescribe diagnostic tests for common complications (Primary Data Collection, 2024). Removing this barrier by improving access to standard diagnostics for common complications, particularly screening for end-organ damage, would streamline referrals and improve early detection. For example, allowing primary care physicians (PCPs) in private practice to order tests such as carotid ultrasound for IMT thickness and asymptomatic atherosclerotic disease, fundoscopy, and mandatory renal function screening (including e-GFR and UACR) for at-risk patients would facilitate earlier identification of complications. Furthermore, automatically including e-GFR calculation in all lab tests, both in the public and private sectors, would enhance renal function screening An additional barrier noted in expert interviews regards the lack of reimbursement for telehealth consultations, which were reimbursed at the beginning of the Covid-19 pandemic but have since been excluded from reimbursement (Primary Data Collection, 2024). While telehealth is not necessarily appropriate in all cases, restricting access entirely places undue burden on remote populations and presents disincentives to physicians who lose money when consulting remotely. To remove these issues and prevent further obstacles to delivering integrated care, policymakers should consult with key stakeholders to understand current barriers.

Strengthening primary care capabilities is a key next step to enabling integrated care, which aims to enable proactive care delivery. The design of the Greek health system creates obstacles to delivering efficient and effective care. A weak primary care system fails to deliver sufficient prevention and education efforts, creates undue burden on specialists, and leaves PLWD without clear system access and care coordination procedures. The fragmented nature of the system, allowing PLWD to move freely between primary and secondary care without a clearly defined entry point, creates significant challenges. Culturally, there is an expectation for the individual to navigate the system on their own rather than relying on a personal physician/GP for specialist referrals and treatment guidance. This is further reflected by the obscurity of diabetes protocols. This lack of care

coordination can lead to disjointed management, potentially delaying diagnosis, hindering consistent monitoring, and compromising adherence to treatment plans. Further, a primary care system with improved capabilities will serve to relieve pressure on secondary care as experts often cited unnecessary appointments as an issue facing endocrinologists (Primary Data Collection, 2024). For a disease like diabetes, which necessitates substantial self-management, this fragmented system exacerbates the individual burden as well as the financial burden to the system. Strengthening health system capabilities around prevention, early detection, care continuity, and patient education are cost-effective and high impact in the long term. While a dedicated care coordinator isn't strictly required for integrated care, it's often a highly beneficial component. However, strengthening the role primary care physician as a type of care coordinator for PLWD would require a significant cultural and systemic shift in attitudes towards care delivery in the Greek system. Improved primary care capabilities are already on the political agenda and should continue to be prioritised.

Ultimately, an integrated care approach aims to deliver holistic and patient-centric care delivery. To achieve this, coverage is necessary for a wide range of interventions including nutritional support, mental health care, digital health technologies and telehealth, and behavioural interventions, for example. Additionally, an integrated care approach should consider diabetes complications and co-occurring conditions. Examining diabetes through a CRM lens cluster highlights the cumulative morbidity, the diminished quality of life, and the substantial economic burden on both individuals and the healthcare system. This integrated perspective is crucial for developing and implementing comprehensive care strategies that address not just diabetes in isolation but the constellation of related conditions that affect overall health. Therefore, Greece should consider expanding the scope of diabetes treatment. Advancements in line with this are already observed, as some diabetes specialist centres expand to include treatment for obesity (Primary Data Collection, 2024). Improved digital infrastructure will aid in efforts to deliver holistic and patient-centric care delivery as data can help shed light onto care delivery gaps. As health data infrastructure improves, Greece may begin to leverage population health management approaches that utilise sub-group risk stratification to deliver early interventions. Finally, improving capabilities around patient empowerment and self-management education will support Greek PLWD in navigating their health system to access comprehensive care.

4.5. The potential of digital technology

Integration of digital technologies into diabetes management offers potential to enhance care in Greece through innovative solutions that can improve both clinical outcomes and service delivery. Greece continues to make policy progress in expanded coverage for DHTs. For example, CGMs, insulin pumps, and hybrid-closed loop systems from a variety of manufacturers are available and reimbursed for PLwT1D while in T2D policymakers have indicated expanded coverage for CGMs (Primary Data Collection, 2024). This trend is positive but requires further national policy support for uniform adoption and integration into clinical practice as the standard of care.

Given Greece’s geographical landscape, which includes numerous islands and remote areas, telehealth can significantly improve access to specialist care for individuals who face challenges traveling to urban centres. This reduces disparities in care and ensures timely interventions. However, experts indicated that telehealth must be thoughtfully integrated, as it is not always an appropriate approach—for example, when someone is first diagnosed or onboarding to a DHT (Primary Data Collection, 2024). Still, Greece faces challenges related to healthcare workforce distribution, with shortages of specialists in certain regions. Telehealth consultations can help bridge these gaps by enabling remote patient consultations and support from specialists to primary care

physicians in underserved areas, yet they are not eligible for reimbursement. Urgent policy attention is needed to determine the conditions for telehealth reimbursement in diabetes care, and across therapeutic areas, to remove this care delivery bottleneck.

Though regulatory bottlenecks hinder advancements in telehealth consultations, remote monitoring offerings continue to advance and often offer real time data (Primary Data Collection, 2024). PLwT1D using a hybrid-closed loop system must provide their data to their provider manually but those using CGMs can often allow their provider to access reading in real time (Primary Data Collection, 2024). Overall, there remains a significant burden on PLWD to facilitate knowledge transfer between care providers, as HCPs are unable to access health data outside of their organisation. For example, an endocrinologist does not have oversight of recently completed diagnostics at the primary care level which can lead to repeat orders of costly tests and wasted time (Primary Data Collection, 2024). Interoperable health records are required to improve the efficiency of care delivery.

Greece's limited data collection capabilities and fragmented data infrastructure present significant obstacles across many areas. As more data and health insights become available through DHTs, it is essential that Greece leverages this knowledge into a better understanding of the burden of diabetes on its people and health system. While policy interventions offer promising insights into the political appetite for reform, financial support for the realities of technological transformation is required. Greek diabetes care, as well as the health system at large, requires significant investment into its data infrastructure to enable integrated care delivery and advanced prevention capabilities for early detection and intervention. Data gaps hinder accurate epidemiological surveillance, making it difficult to determine the true prevalence of diabetes and its associated complications. Without reliable data, policymakers lack the necessary evidence to understand the magnitude of the problem and allocate resources effectively. This data deficit pervades the entire care continuum, impacting access, diagnosis, management, and ultimately, patient outcomes. The lack of accessible and transparent data, even for Greek-speaking researchers, highlights a significant departure from FAIR (Findable, Accessible, Interoperable, and Reusable) data principles. Adopting FAIR data practices would not only facilitate research and informed policymaking but also promote transparency and accountability within the healthcare system, ultimately contributing to improved diabetes care and outcomes. The current opacity surrounding data access presents a significant barrier to progress and underscores the urgent need for reform.

4.6. Expansion of HTA capabilities for the introduction of novel technologies

Expanding Greece's HTA capabilities is critical to advancing diabetes care delivery. Greece's nascent HTA system, formalised in 2018, is understandably limited in its ability to promote value-based care without the ability to assess medical devices and other DHTs. Effective HTA can support Greece in transitioning toward value-based care, improving technology assessment, and promoting access to novel therapeutics for diabetes management. At present Greece provides access to a number of DHTs for diabetes management that do not undergo HTA and, as a result, may be overpaying for certain technologies. One example identified in interviews is CGM sensors that need to be replaced more often than the manufacturer claims (Primary Data Collection, 2024). As the HTA committee continues to increase its capabilities, further capacity building focused on assessment of medical devices and other DHTs would improve value-based diabetes care delivery.

"We need that data. Only then can we sit at the table and exchange ideas but based on the same data – not on perception or interpretation."

-Working Group on Diabetes, SFEE

HTA is a tool to help decision-makers introduce policies to promote the uptake of and access to novel technologies through sustainable health system incentives. The assessment process involves evidence review which could be supported by real world evidence if Greece manages to improve its health data infrastructure system. Improved data collection and analysis capabilities could facilitate more advanced payment agreements which ultimately improve the efficiency of resource allocation and quicker access to novel medical technologies.

Enhancing formal processes for stakeholder engagement, particularly patient advocacy groups, represents another opportunity for improvement. This participatory approach would ensure that assessments consider the diverse needs and values of all stakeholders, promoting greater transparency and acceptance of HTA recommendations.

A major effort is currently under way to improve Greece's alignment with the European HTA Regulation and to upgrade its capabilities in technology assessment overall (for drugs as well as a range of other technologies, particularly medical devices and digital health technologies). This will enable two things: first, a more nuanced approach to technology assessment, probably on cost-effectiveness grounds, alongside having increased capabilities to make judgements on evidence at patient sub-group level, among other things; and second, the ability to produce prescribing guidelines based on clinical, cost-effectiveness and budgetary considerations, which are necessary for care prioritisation by the health care system.

Conclusion

Greece faces a significant and growing burden of diabetes which presents a complex challenge to its healthcare system, those the precise burden is difficult to demonstrate due to limited data availability. While the current system struggles with fragmentation, reactive care delivery, and limited data infrastructure, this report has outlined key opportunities for reform, drawing valuable insights from comparator countries and stakeholder perspectives. Implementing a comprehensive National Diabetes Strategy that prioritizes early diagnosis, screening, prevention, and management of diabetes and its complications, establishing clear, holistic, and integrated health system access points and ensuring nationwide uniformity in care delivery and presence of multidisciplinary teams of healthcare professionals. This strategy must integrate with existing national policy initiatives and establish formal channels for engagement with people living with diabetes (PLWD) and patient advocacy organizations. Addressing the diverse needs of subpopulations, including abet education (DSME) and preventative education focused on youth and nutrition.

A critical component of reform lies in strengthening primary care capabilities to improve care coordination efforts, relieving pressure on specialists and promoting proactive care delivery. This necessitates a cultural and systemic shift, prioritizing prevention, early detection, and patient education. Furthermore, significant investment in health data infrastructure is crucial. Improving the current partial diabetes registry to include all PLWD as well as complications are essential for accurate epidemiological surveillance, effective resource allocation, and facilitating integrated care delivery. This includes addressing the current data opacity and by promoting interoperability, transparency and accountability. Digital technologies, including telehealth and remote monitoring, offer immense potential to improve access to care, particularly in remote areas, but require policy support for reimbursement and seamless integration into clinical practice. Finally, expanding Greece's HTA capabilities to include medical devices and digital health technologies is vital for promoting value-based care, ensuring appropriate access to novel therapeutics, and optimizing resource allocation. By addressing these key areas, Greece can move towards a more effective, integrated, and patient-centric approach to diabetes care, ultimately mitigating the burden of this chronic condition on individuals and the healthcare system.

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Appendix I. Deaths attributable to diabetes

International Diabetes Federation Data

The estimation of the total number of deaths that diabetes is responsible for in the age range 20 to 79 by the IDF is determined by synthesizing evidence from several different sources. The yearly death tolls from all-causes for the given country, stratified by age and sex, are derived from the WHO Global Health summary tables (Saeedi et al., 2020). This data is used in conjunction with contemporaneous country-level estimates of diabetes prevalence by age and sex by the IDF, as well as age- and sex-specific relative mortality risk calculations for PLWD compared to people without diabetes, which are based on cohort studies (Saeedi et al., 2020). Depending on evidence availability, the cohort studies drawn upon may be specific to the country which the estimation refers to or conducted in a different national or international setting, their results applied to the country in question as a proxy.

This derivation process is liable to propagate uncertainties associated with the estimation of each of the variables involved, including prevalence of diabetes and relative mortality risks for PLWD, stratified by age and sex. In the case of Greece, as already discussed, the measurement of diabetes prevalence is ambiguous, with large variation among the available estimates based on different evidence channels. As a result, the choice of the precise figure used in the IDF's calculation of the total number of deaths would stand to significantly impact the resulting mortality estimate, potentially undermining the accuracy and consistency of the finding. At the same time, it is worth noting that the reported total of 22,350 deaths refers to the year 2021, during which the rise in all-cause mortality in Greece associated with the COVID-19 pandemic (Naftemporiki.gr, 2022) could have contributed to an outlier overestimation of the number of deaths owing to diabetes for the specific year. The possibility of bias is further reinforced by consideration of the increased risk of death for people living with diabetes who contracted COVID-19 compared to people without the disease (Apicella et al., 2020) as well as the difficulty in disentangling the effects of underlying co-occurring conditions in the determination of cause of death in people with COVID-19 (Russell et al., 2023).

Hellenic Statistical Authority Data

It is important to emphasize that HSA data on the causes of deaths documented in a given year in Greece is derived from the corresponding death certificates which may constitute a limitation (Hellenic Statistical Authority, 2021). As a result, the reported figures of total number of deaths associated with each cause may be influenced by reporting policies dictating how cause of death is designated by clinicians on an individual's death certificate. In addition, given that PLWD are likely to be experiencing co-occurring conditions *(Yen et al., 2023)*, it is not unfair to assume that the distinction of diabetes as the single determinant cause of death cited may be challenging to standardize and at times uncertain or dependent upon the caring physician's judgement (IDF Diabetes Atlas Group, 2013).

Appendix II. Evidence on diabetes-related complications and co-occurring conditions

The last available estimates of the prevalence of diabetic neuropathy, at 33.5 %, and diabetic foot ulcers, at 4.75 %, originate from a 2002 study on a population of PLWD in Northern Greece (Manes et al., 2002). Prevalence of diabetic retinopathy has been investigated in two more recent studies carried out in a University Hospital ("Attikon") and a General Hospital ("Ippokrateion") in Athens, respectively. The former study included a sample of 1,739 PLWD who underwent eye screening in the specialized outpatient diabetes clinic within the Department of Ophthalmology of "Attikon" hospital between 2015 and 2019, of whom 80% lived with T2 and 20% with T1 disease (Bourouki et al., 2022). Results showed that approximately 42% of subjects presented with diabetic retinopathy of differing degrees of severity. Namely, 77% among them were diagnosed with non-proliferative retinopathy (mild, moderate or severe) while the remaining 22% suffered with proliferative disease (Bourouki et al., 2022). In addition, diabetic macular oedema (DMO) was observed in 263 PLWD, representing 15% of the total study group. It is important to note that while the mean age of participants was reported at 69 years old, no information was provided on the mean duration of diabetes in the examined sample, which is known to be a key risk factor for the development of diabetic retinopathy (National Eye Institute, 2024). On the other hand, the study conducted in the Ophthalmology Department of "Ippokrateion" General Hospital was based on a sample of 300 people at mean age 70 years old who had been living with diabetes for an average of 15 years (Syriga et al., 2022). Diabetic retinopathy was present in 39% of total participants, while 6% had DMO. Similarly to the other study, amongst PLWD who were diagnosed with retinopathy, the majority exhibited non-proliferative disease.