Diabetes expenditure, burden of disease and management in 5 EU countries

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List of Abbreviations

AFD	*Association Française des Diabetiques*
AFSSAPS	*Agence française de sécurité sanitaire des produits de santé*
ALD	*Affection de Longue Durée*
ALFEDIAM	Association de langue française pour l'étude du diabète et des maladies metaboliques
AMD	Italian Association of Diabetologists (*Associazione Medici Diabetologi*)
ANAES	*Agence Nationale d'Accréditation et d'Evaluation des Soins*
APHO	Association of Public Health Observatories (UK)
BAK	Bundesärztekammer
BMI	Body Mass Index (kg/m^2)
BP	Blood Pressure
CGM	Continuous Glucose Monitoring
CHD	Coronary Heart Disease
CNAM	Caisse Nationale d'Assurance Maladie (National Health Insurance Fund – France)
CP	Cumulative Prevalence
CVD	Cardiovascular Disease
DDG	Deutsche Diabetes Gesellschaft (Germany)
DMP	Disease Management Programme (Germany)
DR	Diabetic Retinopathy
DRG	Diagnosis Related Group
DSN	Diabetes Specialist Nurse
ECB	European Central Bank
ENTRED	*Echantillon National Representative des Diabétiques*
ESRD	End Stage Renal Disease
HAS	*Haute Autorité de Santé*
HbA_1C	Glycosylated Haemoglobin
HBGM	Home Blood Glucose Monitoring
HDL	High Density Lipoprotein Cholesterol
IDF	International Diabetes Federation
IGT	Impaired Glucose Tolerance
IDDM	Insulin Dependent Diabetes Mellitus
LDL	Low Density Lipoprotein Cholesterol
LOS	Length of Stay
MI	Myocardial Infarction
NHP	National Healthcare Plan (Italy)
NICE	National Institute for Health and Clinical Excellence
NIDDM	Non-Insulin Dependent Diabetes Mellitus
NPP	National Prevention Plan (Italy)
NSF-D	National Service Framework for Diabetes (UK)
OGGT	Oral Glucose Tolerance Test
OOP	Out-of-Pocket
PAD	Peripheral Arterial Disease
PAOD	Peripheral Arterial Occlusive Disease
PCT	Primary Care Trust (UK)
PMSI	Diagnosis Related Group system (France)
QOF	Quality and Outcomes Framework
SBGM	Self Blood Glucose Monitoring
SDS	Scottish Diabetes Survey
SHA	Strategic Health Authority (UK)
SHI	Social Health Insurance
SID	Italian Society for Diabetologists
SIMG	Italian Society of General Medicine
SIGN	Scottish Intercollegiate Guidelines Network
TG	Triglycerides

Abstract

Background and Aims: Diabetes mellitus (DM) is associated with a high risk of developing complications and severe co-morbidities. Over the past few years, diabetes (Type 1 and 2) and its associated costs have risen, particularly those related to treatment of complications.

Our aims are to identify and compare the diabetes burden of disease, costs (direct and indirect) and diabetes outcomes, focusing on complications across France, Germany, Italy, Spain, and the UK (EU5). We will then have an understanding of the state of diabetes management in EU5 from which to make informed policy options.

Materials and methods: A survey was designed and sent to health economists in the EU5 countries. In turn, key diabetes clinicians, decision makers and health officials were interviewed in order to answer the survey. In addition, secondary data was collected from PubMed, diabetes association publications and health government publications and websites, including national statistics.

Results: Diabetes record keeping in all EU5 countries is poor for prevalence, direct diabetes costs, cost of complications, indirect costs and diabetes outcomes. No diabetes registers exist in any of the EU5 countries. Diabetes prevalence ranges between 4.8% (Italy) to 8.9% (Germany), and has increased over time. Although none of the EU5 countries record diabetes costs directly, including complications, estimates for 2010 suggest that the total direct annual cost ranges from €5.45bn (Spain) to €43.2bn (Germany); across EU5 the total direct cost burden of people with diabetes was €90 billion; this figure includes the cost of complications or medical conditions some of which may not necessarily be caused by diabetes, but can be exacerbated by it. Incremental costs are reported in Germany only and stand at €19.7 billion in 2010. Per patient direct medical costs are more comparable across countries, with some variation (€1,708 (Spain) to €5,899 (Germany) in 2010), suggesting a key driver behind total diabetes costs is prevalence. Inpatient costs are consistently higher than outpatient costs in all countries, due to increased medical care required with diabetes-related complications. Outpatient costs on the other hand, as well as diabetes medications, can be less than half of inpatient costs due to the relatively low costs of maintaining good glycaemic control via medication and regular monitoring. Expenditure on insulin and oral anti-diabetic medicines ranges between 6.2% and 10.5% of total direct cost. A significant majority of inpatient direct costs account for treatment of diabetes related complications, affecting approximately 18.3 million diabetic patients each year across the five study countries. Indirect costs, relate to reduced productivity, absenteeism, early retirement, social benefits and carer costs; these costs are significant and, having quantified part of these costs for the first time in Europe (relating to absenteeism, early retirement and social benefits), it appears that they stand at €98.4 billion and can exceed direct costs by at least a factor of 2- or even 3- to-1 depending

on the country. Significant variations exist between countries in the availability of outcomes data and the quality of the relevant indicators. In some cases, improvements in quality of care for diabetic patients are shown over time (Italy, UK), whereas in others discrepancies exist between the quality of care in metropolitan versus rural areas (France, Spain).

Conclusions: Rising diabetes prevalence (both Type 1 & 2) and associated costs, including management of diabetes complications, are a growing concern. The absence of precise diabetes prevalence and cost data is challenging, given its prominent role in population health including its role in cardiovascular health. Furthermore, the relative lack of outcomes data (especially France, Germany, Spain) limits the ability to accurately gauge the health of the diabetes population or make any appropriate impacts on quality of care. As a result, the true impact of diabetes and its associated complications is likely to be underestimated or altogether unmeasured in all EU5 countries.

Executive summary

What this study does

This study aims to provide a comprehensive, up-to-date representation of Type 1 & 2 diabetes in 5 EU countries (Germany, UK, France, Italy, Spain) and address the associated costs, both direct and indirect, in as comprehensive a manner as possible. The study also quantifies prevalence data from the local perspective and uses a stratification of both qualitative and quantitative analysis to provide policy options – the first study of this kind since CODE2.

Background

There is increasing concern amongst government officials and public health agencies about diabetes care in Europe. Both diabetes prevalence and spending appear to be increasing. Comprehensive studies on diabetes costs are limited, particularly ones that include complications, diabetes Type 1 & 2, all ages as well as direct and indirect costs. This study attempts to rectify this by examining all aspects of diabetes management, from the macro government view to the micro patient view, and includes costs and outcomes whenever possible.

A primary search for relevant diabetes information was performed via a survey sent to a representative in each EU5 country (France, Germany, Italy, Spain, the UK[i]) encompassing national and regional programmes, patient and professional groups, incidence and prevalence, diabetes guidelines and practice, monitoring for complications, diabetes spending and costs, diabetes outcomes and complications. This was substantiated and supplemented by a secondary search for all reports coming from academic, government and other interested parties (patient groups).

Diabetes Burden and National Strategies

Diabetes prevalence has been increasing steadily over the past two decades, along with an aging European population, increasing, high obesity prevalence and changing ethnic make-up. This study estimates that Germany has the highest diabetes prevalence at 8.9%, followed by Spain (8.1%), France (6.4%), the UK (6.1%) and Italy (4.8%); based on medium-size studies and extrapolated to the national level, due to the absence of national or regional diabetes registries in the study countries, and poor prevalence data collection in all EU5 countries.

Only three countries have national diabetes programmes (NDPs) (Italy, Spain, UK), while France's has not been operational since 2005. Germany has Diabetes Disease Management Programmes (D-DMP), however, not all patients with diabetes are registered. None of these

[i] This study includes England, Wales and Scotland, but excludes Northern Ireland due to data insufficiencies on prevalence, outcomes and costs.

strategies have hard targets to achieve ideal diabetes management, instead they discuss multi-disciplinary care, patient-centred care, patient education and paediatric management among others. Only France and Germany have diabetes screening programmes for high-risk patients, although participation is variable. The UK began screening high-risk patients for vascular diseases, including diabetes, in 2009, but implementation is slow. Most patients with Type 2 are seen by their GP, while insulin-dependent Type 2 patients and Type 1 patients are seen by a diabetologist or a paediatrician respectively. Access to other services, such as chiropody, diabetes nurse specialists and dieticians, is limited or not covered (France) and partially dependent on the primary point of diabetes care (outpatient clinic versus community GP care). All countries have care guidelines, the UK's being the most prolific, but none have guidelines written for patients. Patient education appears to be highly regionalised within countries with differing content and focus; only the UK has national diabetes education training protocols (DAFNE and DESMOND) but these are not universally used. Thus, despite having national plans in place, policy and monitoring to ensure their success is either limited or applies only to some patients.

Economic Burden of Diabetes

Diabetes spending in all EU5 countries is difficult to determine precisely, as with prevalence data collection, diabetes cost collection is neglected. None of the governments collect diabetes spending accurately. In part this is due to the complexity of diabetes in conjunction with its complications, which makes cost coding more difficult and inaccurate.

The study takes into consideration the direct medical cost for treating diabetes as well as other medical cost, for instance, in terms of treating complications related to diabetes and other medical conditions, which may not be associated with or caused by diabetes, but their extent can be exacerbated by it. All five study countries include these medical cost components.

Based on the above, and being mindful of the close association between diabetes and other – often related- co-morbidities, the study estimates that in 2010, the direct cost burden of people with diabetes was highest in Germany, in part due to the greater diabetes population, at €43.2 billion, followed by the UK (€20.2 [£13.8] billion), France (€12.9 billion), Italy (€7.9 billion) and Spain (€5.4 billion). Inpatient costs are consistently higher than outpatient costs in all countries, due to increased medical care required with diabetes-related complications. Outpatient costs on the other hand, as well as diabetes medications, can be less than half of inpatient costs due to the relatively low costs of maintaining good glycaemic control via medication and regular monitoring. The presence of complications, particularly multiple complications, can multiply diabetes costs several times. Diabetes drug costs are the smallest component of drug, in- and out-patient costs combined, ranging from 6.2% (France, Italy) to 10.5% (Spain). Conversely, non-diabetes medications are 3 to 4 times the diabetes

medications in terms of total costs, with cardiovascular medicines consuming the largest portion in cost and prescribing.

Annual per patient direct costs are primarily derived from small regional studies, and in some countries the data is differentiated between diabetes types. The total per patient costs are highest in Germany (€5,899) (€2,684 if only incremental costs are taken into account), followed by France (€5,432), the UK (€4,744-€5,470 [£3,233-£3,717]), Italy (€2,756) and Spain (€1,708-€3,015 depending on the study and approach). Type 1 patients can be more expensive to treat than Type 2 annually however, they represent a minority of all diabetes patients. The inpatient costs are in some instances more than double the outpatient costs, particularly when patients experience complications involving renal failure or diabetic foot (the former requiring dialysis and transplant, and the latter amputation at last stages) (France inpatient €2,022 and outpatient €1,950, the latter including injection devices, self-blood glucose monitoring equipment, insulin pumps and other medical devices, Germany in- €1,985 out-patient €1,672; Italy in- €1,569 out-patient €373; Spain in- €829 out-patient €247; UK in- €2,681 [£1,807]-€3,786 [£2,552] out-patient €439 [£304] - €530 [£367]). Many diabetic patients experience multiple complications, compounding the complexity of treatment and thus costs.

Cardiovascular disease, including angina (16%), myocardial infarctions (1-8%), stroke (1.7-7%), ischemic heart disease and heart failure (6.3-11%) are the major complications resulting from diabetes. Treatment costs range from €2,100 (fatal MI, UK) - €9,767 (MI, Germany) for myocardial infarctions and €4,314 (UK) - €11,786 (Germany) for stroke. Renal damage is another costly complication, with up to 3% of patients annually experiencing end stage renal disease costing €41,052 (Spain) - €81,449 (France) annually for haemodialysis and €33,437 (UK) - €76,852 (Germany) for renal transplants. Diabetic foot is relatively easy and inexpensive to prevent with frequent checks and foot care.Peripheral arterial occlusive disease is the initial stage of foot disease, affecting up to 10% of diabetic patients resulting in ulcers and wounds. If blood glucose control remains poor and foot checks are not performed daily this may result in gangrene, amputation of toes or all or part of a foot (0.2-0.3% of all cases). Depending on the severity of the amputation, this can –up to 32,000 (France) per patient, not including any mobility rehabilitation or prostheses.

Very little information on the indirect costs of diabetes is available. However, the potential impact of diabetes is manifold and entails significant indirect costs, chiefly relating to the economy (i.e. external to the health care services), such as reduced productivity and sickness absence, the wider social sector, such as early retirement, drawing social benefits – particularly due to job-loss as a result of insulin use in some professions (e.g. professional driving). In addition, there is an impact on the family, through informal caring and carer costs

as well as dealing with the effects of premature mortality. This study identified costs due to absenteeism, early retirement and expenditure on social benefits, amounting to a total of €98.4 billion across the study countries in 2010 (€37.9 billion in Germany, €17.6 billion in Spain, €17.3 billion in the UK, €12.9 billion in France and €12.6 billion in Italy). In the cases of Germany, the UK and France, these indirect costs are on a par with direct costs, whereas in the cases of Italy and Spain, they are shown to exceed direct costs by a factor of 2-to-1 and 3-to-1 respectively. This is an under-estimate since the costs of reduced productivity, premature mortality or informal carer costs could not be accounted for.

Overall, the direct and indirect cost burden of people with diabetes across the 5 study countries amounts to €188 billion in 2010. The direct costs include medical costs of treating complications and other conditions not necessarily related to diabetes. The indirect costs are likely to be under-estimates, since it was only possible to account for a part of the economic impact indirectly caused by diabetes.

Current Diabetes Outcomes and Related Complications

Only France, Italy and the UK regularly collect and publish monitoring data. France do so intermittently (2001, 2007) and Italy and the UK annually. In Germany these are internal to the sickfunds.

Such data measures how many patients have one or more of the following evaluated: glycosylated haemoglobin (HbA_1C), blood pressure, BMI, cholesterol (total or LDL), urinary albumin, serum creatinine, retinal screening, foot checks and smoking status.

Examination of outcomes data finds that tight glycaemic control can be variable ($HbA_1C \leq 6.5\%$: France 24-32%; Italy 24-44%; England 25%) and slightly more with good glycaemic control ($HbA_1C \leq 7.5\%$: France 24-52%; England 28-66.5%; Scotland 22-64%). Results for blood pressure are similarly variable, in both excellent levels($\leq$130 mmHg: France 15-22%; Italy 15-36%; England 50-63%) and good levels ($\leq$140 mmHg: France 46%, England 61-69; Scotland 75-79%).

Although the measurement of these process and outcome indicators is encouraging, there are some missing or misleading elements. It is commonly recommended that many of these indicators (HbA_1C, blood pressure, urinary albumin, serum albumin, foot checks) are tested more than once annually, thus the annual period does not correspond with the monitoring guidelines. Publications focus on how many patients achieve good control, but neglect how many are in serious danger of complications. A combination of indicators, again important in identifying higher risk sub-groups, is also ignored. It appears that both process and outcome indicators are worse in Type 1 patients, suggesting these patients might be receiving poorer care than Type 2 patients, or that clinicians caring for Type 1 patients place less importance

on reporting indicator data. All but the UK appear to ignore data collection and reporting in children, a serious omission, particularly considering only 4% of all children in the UK had all monitoring variables measured (or reported) in 2008/09. Finally, the choice of outcome indicators neglects renal function, and frequently fails to differentiate between Type 1 & 2 diabetes.

Implications for National Diabetes Planning

Overall, this study suggests diabetes management in the EU5 countries is not ideal. There appears to be significant room for improvement starting with improved data collection of prevalence (and incidence, mortality), the cost burden to the health system and society (including diabetes-related complications and how diabetes exacerbates complications and other potentially unrelated co-morbidities), monitoring adherence and outcomes. Creating national diabetes registries would be an ideal platform to help steer diabetes care from patient and economic perspectives, particularly if national diabetes strategies emerged from these organisations independent from the national health services. Additionally, it would provide a better understanding of complications associated with diabetes and their impact on variables such as resource use, length of stay and, ultimately, total cost reimbursed from health insurance to providers. In many settings hospitalisations for certain conditions are not considered to be diabetes-related, even if they are caused by diabetes. It is also known that diabetes has a significant impact on hospitalisation cost because it increases the length of stay.

A greater understanding of indirect costs is also needed, not least because this is a cost borne by all segments of society, including patients, carers where applicable, employers, and the broader social protection network (pensions, social security & benefits payments), funded largely by the taxpayer.

Further, it appears that greater effort must be placed on obesity prevention to help halt diabetes incidence, in addition to targeted screening of high-risk individuals, the majority of whom are diagnosed with diabetes-related complications already in place. As with other chronic disease care, creation of hard targets to encourage monitoring in line with guideline recommendations might be needed if softer planning does not create an ideal platform for complication prevention.

Greater differentiation of care and data collection between Type 1 and 2 patients should be supported, as the life pathway is not the same, particularly with childhood diagnosis. Education programmes should be targeted to specific groups, such as time since diagnosis, age ranges, diabetes type and complications present, in order for diabetes education to be effective.

Greater effort should be placed on ideal care pathways, with guaranteed access to endocrinologists for insulin users, as well as access to other diabetes professionals (diabetes nurse specialists, dieticians, chiropodists, ophthalmologists) to prevent or halt diabetes related-complications. On the same note as multi-disciplinary care, is patient-centred care. Diabetes is a chronic illness demanding high levels of self care by patients – patients must be involved in their care plans from the beginning (including childhood if possible) to create a communicated vested interest in their diagnosis.

On the whole, greater emphasis must be placed on diabetes in the health and social care system and in the broader national context. The fact that none of these countries collects accurate prevalence data or has precise accounting for diabetes (or related complications) suggests potential neglect of a significant and populous disease, which, for the most part, is preventable. Not only must more effort be made from the bottom up in terms of patient level care, but significantly greater effort must be made from the top down to create an atmosphere and environment of prevention of diabetes and diabetes complications, in addition to ideal management.

1. Background and Objectives

1.1 Background

Diabetes[ii] presents a multi-faceted challenge to health systems in Europe and beyond. Globally, diabetes prevalence is increasing and is responsible for 5% of all deaths annually (World Health Organisation 2011). The 2010 diabetes prevalence is 285 million people and expected to increase to 438 million people by 2030 (Diabetes Help 2010). Given current projections, without urgent action, mortality due to diabetes is expected to increase by 50% in the next 10 years (World Health Organisation 2011).

Diabetes alone is a disease requiring high levels of independent self-care with regards to diet, activity and medication. The impact of diabetes and related complications on costs can be classified into two categories (International Diabetes Federation (IDF) 2009). The first is diabetes itself, with 12 people per minute globally diagnosed with diabetes and 6 per minute dying of its complications. The treatment of diabetes itself is costly; on the other hand, as much as 80% of Type 2 diabetes is avoidable through lifestyle changes and obesity prevention.

Although costly and time consuming to treat, the real impact of diabetes is through its complications, the second impact of diabetes. People with Type 2 diabetes are twice as likely to have a heart attack or stroke than non-diabetics. Cardiovascular disease is the major cause of death in diabetes with 50% of all diabetes fatalities and also a premature cause of mortality with 5-10 years of shortened life expectancy. Globally >2.5 million people are affected by diabetic retinopathy, the leading cause of vision loss in adults in developed countries. Diabetes (all types) is the most frequent cause of kidney failure and amputations. These are all extremely costly, more costly in fact than treatment and monitoring of diabetes itself.

Reducing diabetes burden requires action on prevention via lifestyle interventions, early diagnosis via targeted screening for Type 2 diabetes, high quality monitoring and treatment to delay the onset of complications, as well early identification and treatment of complications. Targeted screening of patients with a family history of diabetes or overweight can be useful in preventing more costly and complicated diabetes (Waugh et al. 2007). Furthermore, effective monitoring and treatment of diabetes patients can delay or prevent the incidence of extremely costly complications.

[ii] Type 1 diabetes is usually juvenile onset, although it may occur in mid-adulthood, and always requires daily blood glucose monitoring and injection of long- and short-acting insulin (insulin dependent diabetes IDDM). Type 2 is usually adult onset, although can be seen in obese children, and requires weight loss, oral anti-diabetic medicine (non-insulin dependent diabetes NIDDM) and may over time develop into requiring insulin injections.

1.2 Objectives

This study analyses diabetes prevention and management, including spending and policy in each area in 5 EU countries (France, Germany, Italy, Spain, the UK) (known as EU5).

The specific objectives, including comparisons between EU5, are fivefold: first, to outline longitudinal diabetes prevalence in each EU5 country; second, to outline any diabetes prevention and treatment policies (from initial diagnosis to complications as a result of diabetes) in each EU5 country. Intricacies in care will be outlined, including indices monitored and treatment pathways, as well as source of care provision. Third, to examine the cost of diabetes management in each EU5 country, providing perspectives in health systems, and including both direct and indirect costs. Fourth, to examine diabetes outcomes in each EU5 country, comparing these to monitoring and treatment guidelines outlined per country. A final objective is to provide a number of options on diabetes policies and practices at national and wider (European) levels.

The study is structured as follows: Section 2 outlines the methodology used. Section 3 considers the diabetes burden of disease and outlines national diabetes policies in the study countries. Section 4 reviews diabetes guidelines, diagnosis and treatment processes. Section 5 provides a detailed breakdown –to the extent possible- of the direct and indirect cost of diabetes and diabetes-related complications and other co-morbidities. Section 6 examines the available evidence on diabetes outcomes. Section 7 discusses the challenges in diabetes care in the study countries that have emerged from the discussion, while section 8 outlines a series of policy options for stakeholders at national and EU level, developed from the findings.

2. Methodology

In order to address the objectives outlined earlier, data from both primary and secondary sources was collected. Secondary sources included: (i) Medline peer review literature focusing on "cost of diabetes" and "outcomes of diabetes care"; (ii) grey literature (government, EU and international organisations); and (iii) reports from stakeholder groups, diabetes organisations and other NGOs (January 2000 to March 2011).

Primary data was collected through a survey, developed to collect country-level data via interviews with key diabetes stakeholders, and diabetes databases, nationally and regionally. This survey was developed in July 2010, piloted in August and September 2010 and, after having incorporated the feedback, it was subsequently administered electronically to health policy analysts in each study country to complete. The survey requested information on longitudinal prevalence, incidence, spending, as well as current screening, diagnosis, treatment, monitoring, outcomes and complications management. Additional input was acquired through direct contacts with leading clinicians, a range of decision-makers at national and/or regional level, as well as representatives from national NGOs. Issues relating to the organisation and delivery of health care related to diabetes were also included in the survey tool.

A list of experts interviewed and the country correspondents who participated is shown in Appendix 1. The section that follows outlines the data sources used in the study as well as the issues and limitations encountered in the research process with regards to prevalence, direct cost calculations, cost of complications, indirect costs and outcomes data.

2.1 Data sources and caveats

2.2.1 Precision of Prevalence

Despite reports of rising diabetes prevalence in Europe, there are a number of difficulties in determining precise diabetes prevalence. First, none of the EU5 have active national (country-wide) diabetes registries, which means there is no central data collection. Second, undiagnosed diabetes is estimated to be significant, as supported by diagnosis for another purpose (Simmons et al. 2010). Both factors are significant in determining the exact diabetes prevalence, in addition to Type 1 (insulin dependent, IDDM) versus Type 2 (IDDM or non-insulin dependent, NIDDM) differentiation.

Prevalence estimates from the International Diabetes Federation (IDF) are available. However, in view of potential underestimation and older base years (Sicree et al. 2011), alternative estimations of prevalence have been used in this study based on national or

regional data (as shown in Box 2.1 and outlined in Figure 3.2) drawn from the peer review literature.[iii]

In France, previous estimates in pharmacologically treated diabetes include 3.6% (public healthcare, 2005) (Kusnik-Joinville et al. 2008), 3.95% (with annual 5.7% increases, 2007) (Fagot-Campagna et al. 2009) and 4.4% (Type 1 & 2, 2010) (Ricci et al. 2010). The estimate of 4.57% as part of the national INSTANT study was selected as it reflects all Type 2 patients treated with lifestyle modification, oral anti-diabetics and/or insulin (2006 data) (Bringer et al. 2009). This is comparable to the national ENTRED adult data (2009 prevalence 4.4% (Fagot-Campagna et al. 2010; Ricci et al. 2010)), although the latter does not include non-pharmacologically treated patients (Fagot-Campagna et al. 2010). Unfortunately, the INSTANT study does not include either childhood or adult cases of Type 1 diabetes, thus the national ENTRED Type 1 patients (2001 data) (Lecomte et al. 2008) were added to the 2006 INSTANT Type 2 patients (all >18 years) to find a prevalence of 6.39%.

In Germany, a population-based study assessed the prevalence of treated diabetes patients using a retrospective analysis of routine health insurance data, and estimated a prevalence of 6.45% (1999) (Stock et al. 2005). This is roughly in line with another estimate of 6.5% (2000 data) (Köster et al. 2011). A more recent evaluation of 18.75% of the AOK statutory health insurance provider estimates diabetes prevalence of 8.9% as part of the CoDiM study (Köster et al. 2011). Despite the limitations of extrapolation of health insurance data nationally, this estimate was chosen as the German benchmark; this figure is also in line with other recent studies in Germany (Robert Koch Institute 2011).

In Italy, a 2006 study (Ruiz-Ramos et al. 2006) estimated prevalence for Type 1, Type 2 and gestational diabetes ranging from 0.08-0.2%, 4.8-18.7% and 4.5-16.1%, respectively. The lower end of these figures are similar to the prevalence estimate of 4.8% from ISTAT (2009) (ISTAT 2009), which was chosen as the Italian benchmark in part due to its recent collection.

In Spain, a 2004 (Oliva et al. 2004) study applied prevalence rates of 5-6% to cost estimations, determined based on a number of epidemiological studies and is considered a conservative estimate given the documented high percentage of undiagnosed cases in the country. CIBERDEM, an association of 30 Spanish diabetes research organizations, estimates national Type 2 diabetes prevalence (>18 years) as 8.1%, (2008), (Centro de

[iii] IDF calculates prevalence via comprehensive literature review of prevalence studies and registry reports (where available), hospital statistics and government estimates (1980-2006). Prevalence rates are estimated based on total number of expected cased divided by the total country population from UN data (20-79 years). A log regression controls for missing data in certain age groups. It is likely that these estimates rest on conservative predictions based on an econometric model using in all EU5 countries early 2000 data.

Investigación Biomédica en Red de Diabetes y Enfermedades Metabólicas Asociadas (CIBERDEM) 2008) which is used at the Spanish benchmark in this study.

Government sources of diabetes prevalence in the UK have been difficult to determine historically, as it was not included in health statistics or national accounting until 2006. The English prevalence estimates from the 2006 Health Survey for England (2008) (Ali et al. 2008) were 5.6% for men and 4.2% for women. Other academic sources include 3.4% (2005) (Morgan et al. 2010), 12.1% (men only 65+ years, 2005) (Thomas et al. 2009),(González et al. 2009) 4.3% (2005), and 3.3% (2004) (Millett et al. 2007). The 2010 Quality and Outcome Framework (QOF) estimate total prevalence at 4.26%, however, participation in reporting is still not ideal with only 75% of GP practices participating (although improved tremendously from its initiation in 2006) (Diabetes UK 2010b). The benchmark figure of 6.1% from the APHO Diabetes Prevalence Model was chosen over these alternatives as it was based on prevalence modeling accounting for age, sex, ethnic, deprivation and obesity, including England, Wales and Scotland, although Northern Ireland is not included (Holman et al. 2011).

Box 2.1: Diabetes prevalence benchmarks

France	INSTANT study (2009) (Bringer et al. 2009). Cross sectional representative national sample of 10,038 participants (>18 years), interviewed to determine diabetes prevalence and subsequent treatment and complications (Sept-Nov 2006). The population under 18 was accounted for regionally and integrated into the national estimate for Type 2 diabetes of 4.57%. The inclusion of Type 1 patients comes from the national ENTRED study of Type 1 & 2 patients (2009 data) to derive an estimated prevalence of 6.39% (Fagot-Campagna et al. 2010; Ricci et al. 2010).
Germany	CoDiM study (2011) (Köster et al. 2011). The estimate of 8.9% of total Type 1 & 2 diabetes was derived from an 18.8% sample of "AOK-Die Gesunheitskasse" members (German statutory health insurance) (n=357,200) (2007 data).
Italy	Italy: (ISTAT 2009). The estimate of 4.8% relates to, both, Type 1 & 2. This is based on telephone interviews conducted in 2009 with a randomly selected sample of the population (approximately 54,000 individuals in 850 cities), in which they are questioned on their chronic pathology and whether a diagnosis of diabetes had been made by their GP.
Spain	(Centro de Investigación Biomédica en Red de Diabetes y Enfermedades Metabólicas Asociadas (CIBERDEM) 2008). Prevalence estimate of 8.1% reflects Type 2 diabetes in the 18+ years population using 2008 data. An additional 3.9% have undiagnosed Type 2 diabetes (18+ years) (excluded from our benchmark prevalence).
United Kingdom	Type 1 from (NHS Information Centre 2010) (<16 years) and Type 1 and 2 from the APHO Diabetes Prevalence Model (2010) (>16 years), Prevalence over 16 years comes from the most recent data from the APHO Diabetes Prevalence Model (2010) (Holman et al. 2011), including Type 1 & 2, and estimates are in England of 7.4% (range 5.3-10.8%; 3,099,853), in Scotland of 6.7% (4.3-10.4%; 286,312) and in Wales of 9.0% (6.9-11.9%; 218,956). The addition of Type 1 paediatric patients (<16 years) were taken from the National Paediatric Diabetes Audit 2008/09, however, less than half of all paediatric practices participated in this audit in England (only 44%), and Scotland was not included. The number of registrations was 15,627, and the authors have doubled this number to roughly account for the missing practices and Scotland. The total estimated number of people living with diabetes in the UK is thus estimated at 3,636,375 (does not include Northern Ireland), which gives an estimated prevalence for the UK (excluding Northern Ireland) of 6.1% (calculated based on the diabetic populations in England, Scotland and Wales divided by the OECD 2009 population for the UK less the NI population (estimated as 1,788,896 by the Northern Ireland Statistical Research Agency) (Northern Ireland Statistical Research Agency 2010)).

Details of diabetes prevalence data used in this study [α]

	France	Germany	Italy	Spain	UK
Type 1	✓ >18y	✓	✓ >18y	✗	✓
Type 2	✓ >18y	✓	✓ >18y	✓ >18y	✓

[α] Data from the UK excludes Northern Ireland.

2.2.2 Direct costs

A small number of studies exist in different countries enabling calculations of direct costs of diabetes.[iv] In this study, we use a series of studies relying on population data in each of the study countries in order to estimate the total direct cost of diabetes, in addition to relying on primary data to provide a bottom up approach where possible. Study details, including sample size, year and what is included in costs are outlined in Box 2.2. Because the reference year for each of these studies is different, depending on the country examined, and in order to provide a uniform presentation we adjusted all pecuniary figures to 2010, by using the average GDP deflator for each year, relevant to each country.

Box 2.2: Diabetes direct cost benchmarks

France	ENTRED Study: Direct 2007 medical costs from reimbursed health expenditures of 6,710 adults with a diagnosis of diabetes (>18 years) with Type 1 (n=263) and 2 (insulin n=689, non-insulin n=2,777) covered by National Health Insurance Fund (2000-2007). Additional limited data on diabetic patients receiving dialysis (n=25) (Ricci et al. 2009). Both diabetes- and non-diabetes-related costs are included. A study of 6 million patients covered under the *Affection de Longue Durée* (ALD8) in 2004 for reimbursed treatments (not exclusively examining diabetes) (Vallier et al. 2006).
Germany	CoDiM Study: Direct costs for reimbursed diabetes health expenditures based on a sample of 18.8% AOK health insurance members, insuring one-third of Germany (random sample, matched case-control, n=357,200) (Köster et al. 2011; Köster et al. 2006). Included Type 1 and Type 2 diabetics (not differentiated in the study coding), and complications. Both diabetes- and non-diabetes-related costs are included.
Italy	Calculated for 2008 and 2010 using two studies by) (Marchesini et al. 2010) and) (Osservatorio Arno Diabete 2011); additional material from the same source has been used to check for consistency, notably, (Osservatorio Arno Diabete 2007) and (Marchesini et al. 2011). The figures are based on a cohort of pharmacologically treated Type 1 & 2 patients and include costs of complications. Per patient figures that are provided have been extrapolated to the national population by using the OECD population estimates and the ISTAT 4.8% national prevalence estimate. Both diabetes- and non-diabetes-related costs are included.

[iv] IDF also provides direct cost estimates. The 2007 IDF direct diabetes costs as alternate source accounted for national and per capita health expenditure, diabetes prevalence and a ratio of diabetic to non-diabetic medical care expenses, however, have a few methodological issues. Only 20 - 79 years diabetics are included, less weight given to national cost data and more weight to prevalence estimates and total health expenditure. They make assumptions of the calculated diabetes cost ratio (R: the ratio of medical expenditures for diabetics to age- and sex-matched non-diabetics) using limited country-specific information.

Spain	Extrapolated from 3 main studies. Oliva et al (2004) national study of Type 1 & 2 adult patients (>18y, 2002), varying the degree of prevalence (5-6%) to find national and per patient direct cost estimates (Oliva et al. 2004). Additional studies include CODE-2 data (1998/99 data) (Mata et al. 2002) and a regional Canary Islands study (0-99y) (where prevalence is higher than Spain (8.7%) (1998 data), both Type 2 only (López-Bastida et al. 2002). Both diabetes- and non-diabetes-related costs are included.
United Kingdom	The UK numbers were obtained by taking 2 studies, one focusing on outpatient data (Currie et al. 2010) and the other on inpatient data (Morgan et al. 2010) similar data times, and combining the two to create an annual per patient cost and applying to the latest APHO Prevalence Modelling data to arrive at total expenditure figures; extrapolation to 2010 was achieved by using the GDP deflator. Both diabetes- and non-diabetes-related costs are included.

Details of direct cost data used in this study

	France	**Germany**	**Italy**	**Spain**	**UK**
Type 1	✓	✓	✓	✓	✓
Type 2	✓	✓	✓	✓	✓
Age range	>18 years	Insuree population	Not detailed	>18 years Whole population	Whole population
Comments	Pharmaco-treated patients only		Pharma-treated patients		
Approach	Total medical cost burden of people with diabetes	Total medical cost burden of people with diabetes	Total medical cost burden of people with diabetes	Total medical cost burden of people with diabetes	Total medical cost burden of people with diabetes

2.2.3 Cost of complications

There are a number of difficulties in reporting the cost of complications relating to diabetes care. First, complication costs are often subsumed within diabetes in- and out-patient care, making disentangling this figure difficult. Second, the collection of diabetes cost data is far from optimal and can lead to potential inaccuracies. Third, diabetes patients treated for complications may be coded as patients under the diagnosis for which they are admitted or treated, depending on what the primary reason for their care is, rather than diabetes itself.

Procedural costs for diabetes-related complications are available in some countries, however, further extrapolation to derive complication costs is marred by lack of diabetes complication data (particularly for multiple co-morbidities) and their related treatments data.

In France, the PMSI (Diagnosis Related Group system) hospital data often does not include diabetes coding, thus identification of hospital costs associated with a specific condition is easier than identifying complications related to diabetes, nor does it identify ALD status (Kusnik-Joinville et al. 2008). Inpatient costs for diabetic patients may be considered a valid proxy for the cost of complications, as a significant proportion of these costs relate to complications. However, the data is patchy at best. The UK faces similar problems to France, in that health accounting coding does not take into account the complexity of diabetes treatment. Although some identification of diabetes patients is possible in hospital, the coding is limited in taking into account patients with diabetes in hospital for diabetes-related complications, such as cardiovascular or renal disease, or for reasons outside diabetes care. This may often result in the inclusion of costs, which are not associated with diabetes or the treatment of complications associated with diabetes. Although this is a methodological caveat, it can only be acknowledged at this point. The fact that in certain cases the use of incremental costs is promoted as a means of accounting for what is attributable to diabetes, most frequently by using a control group with the same age characteristics as the target group goes some way into addressing the problem, but does not do so completely because (a) the epidemiological profile of the control is never identical (bar diabetes) to that of the target group and (b) certain cost elements may not be captured by the target group due to reporting inconsistencies as raised above.

Because of the issues surrounding information on complications, the LSE survey to a select group of recipients encompassing academic experts, public health practitioners, clinical experts and decision-makers, was used as a means of collecting the latest available complications data on a bottom-up basis where readily available. However, there is a relative paucity of information, as is shown in Appendix 2 as well as Appendices 7A-7D.

2.2.4 Indirect costs

Indirect costs of diabetes relate, primarily, to absenteeism due to illness, early retirement due to diabetes, losses in productivity (cost of "presenteeism") and dependence on social benefits. Additional elements of indirect cost relate to premature mortality and carer costs borne by family members.

Certain aspects that can help in calculating indirect costs – particularly the probabilities for absenteeism, early retirement and social benefit reliance - have been studied in greater depth in a recent Danish registry population (Sorensen 2009). In order to approximate indirect costs in each of the study countries we used the relevant probabilities for absenteeism, early retirement and social benefit receipts from existing studies, as shown on Table 2.1.

In order to address the gap in the literature, cost data have been collected from each country's statistical services separately and relate to average annual earnings (in order to calculate the approximate cost of absenteeism), average annual pension (in order to calculate the approximate cost of early retirement due to diabetes) and average annual social benefit (in order to calculate the approximate cost of social benefit). Productivity losses due to presenteeism have not been able to be identified in any way; the same applies to caregiver costs and the costs of premature mortality. As a result, the estimates on indirect cost provided in this report are likely to be under-estimates.

Table 2.1: Absenteeism due to diabetes and its complications (days/year), early retirement and social benefits (% of diabetes patients).

Absenteeism (days per year)	41.499 days
Complications (days per year)	*7.725 days*
No complications (days per year)	*33.774 days*
Absenteeism (% of economically active diabetics)	46.5%
Early retirement (% of diabetic population)	17.36%
Social benefit (% of diabetic population)	2.38%

Sources: Based on estimates from (Sorensen 2009) and (López-Bastida et al. 2002).

2.2.5 Process and outcome indicators

Using diabetes as an example, process indicators (Mainz 2003)[v] relate to the frequency of blood glucose monitoring in Type 1 patients as well as how many patients are measured annually for cholesterol, blood pressure, eye examinations etc. These measures focus on areas where a link with particular outcomes has been established in the scientific literature, and graded by the diabetes community in terms of strength (e.g. greater strength is attached to annual retinal screening for all patients with diabetes than universal home blood glucose monitoring). In contrast, outcome indicators[vi] examine the results of these examinations as a reflection on the quality of the care delivery process (e.g. quarterly HbA_1C results across all paediatric Type 1 patients).

Evidence on outcomes is relatively limited and the methods used to monitor and evaluate these vary by country. Both process and outcomes indicators will be examined where available: information is available in Italy and the UK (England and Scotland separately) on an annual basis and in France less frequently, however, less information is readily available for Germany and Spain.

[v] Process indicators evaluate the measurement of monitoring episodes per guideline recommendations.

[vi] Outcome indicators evaluate the effect of care processes on the health and wellbeing of patients; intermediate outcome indicators capture the changes in biological status that subsequently affect health outcomes.

In France, the indicators have been collected as part of the 2001-2007 and 2007-2010 ENTRED study focusing on seven indicators, (notably HbA_1C (≤6.5%, ≤7%, >10%), blood pressure (<130/80 mmHg, <140/90 mmHg, ≥160/95 mmHg), BMI, HDL (<0.40 g/L, ≥0.40 g/L), LDL (<1g/L, <1.30 g/L, ≥1.30 g/L), triglycerides (<1.50 g/L, ≥1,50 g/L) and urinary proteins) (Ndong et al. 2010)[vii].

In Italy, outcome indicators are collated by the Italian Association of Diabetologists (AMD) annals (2004 to present) (The AMD Annals working group 2009); these examine diabetes related process and outcomes indicators to assess the performance of diabetes centres. The 2009 AMD edition undertakes longitudinal analysis of these indicators (2004-2007). Five outcome indicators examined over the period 2004-2007[viii] are: percentage of patients with HbA_1C ≤7% or ≥9%; percentage of patients with LDL cholesterol <100 mg/dl or ≥130 mg/dl; percentage of patients with blood pressure ≤130/85 mmHg or ≥140/90 mmHg; BMI; and percentage of smokers. In addition to the AMD Annals, other data regarding the quality of care for diabetes are available from the Research Institute of the Italian Society of General Medicine (SIMG). In particular, a series of indicators specifically for Type 2 diabetes have been developed based on a sample of 650 Italian GPs (The AMD Annals working group 2009)[ix].

In Germany, outcomes data have been collected since 2003 as part of the national disease management programmes (DMPs) for Type 2 patients (Schäfer et al. 2010a; Schäfer et al. 2010b) focusing primarily on patient characteristics to ascertain key enrollment criteria for DMPs, and on outcome evaluations having a keen interest in comparing DMP patients with patients in routine care in order to provide more scientific care and legitimate DMPs; in this process, DMPs are fiercely debated. Key outcome indicators in this context included systolic blood pressure, HbA_1C, complication rates, activity rates, and participation in education programmes (Schäfer et al. 2010a; Schäfer et al. 2010b).

In England, both process and outcomes indicators are collected by QOF (NHS Information Centre 2010)[x] and are reported annually in National Diabetes Audits, while in Scotland, indicators are collected as part of annual Scottish Diabetes Surveys. Of the 134 indicators that

[vii] The 2009 data is reported here, which includes data from 8,926 patients, of which for 4,277 diabetes type is known (Type 1 n=275, Type 2 n=3,894) (Fagot-Campagna et al. 2010).

[viii] A set of final outcome measures were also collected at the same time, however, they have not yet been published.

[ix] SIMG has taken more process indicators into account than the AMD Annals, such as the monitoring of other parameters such as BMI (Body Mass Index), retinal fundus, pulse, among others.

[x] QOFs were introduced in 2004 as the basis for assessing the quality of care of GP surgeries, forming the basis of financial incentives. A GP practice registers diabetic patients, as well as recording visit outcomes, which provides a database of treated diabetic patients published annually, including diabetes prevalence among registered patients. The 2009/10 QOF assessed 134 indicators in four categories: clinical care, organisation, patient experience and additional services.

were part of the QOFs in 2009/10, 17 were used specifically for diabetes management[xi]. Furthermore, both England and Scotland collate nine process and outcome measures annually into the English National Diabetes Audit and Scottish Diabetes Survey (HbA_1C, BMI, blood pressure, urinary albumin, serum creatinine, cholesterol, retinal screening, foot examination and smoking) in addition to reporting complications.

[xi] It should be noted that the majority of the QOF indicators for diabetes are process and not outcomes indicators, yet they do provide an indication of available UK information. Furthermore, this data does not establish a link between patients with diabetes and related complications, or distinguish between the different types of diabetes.

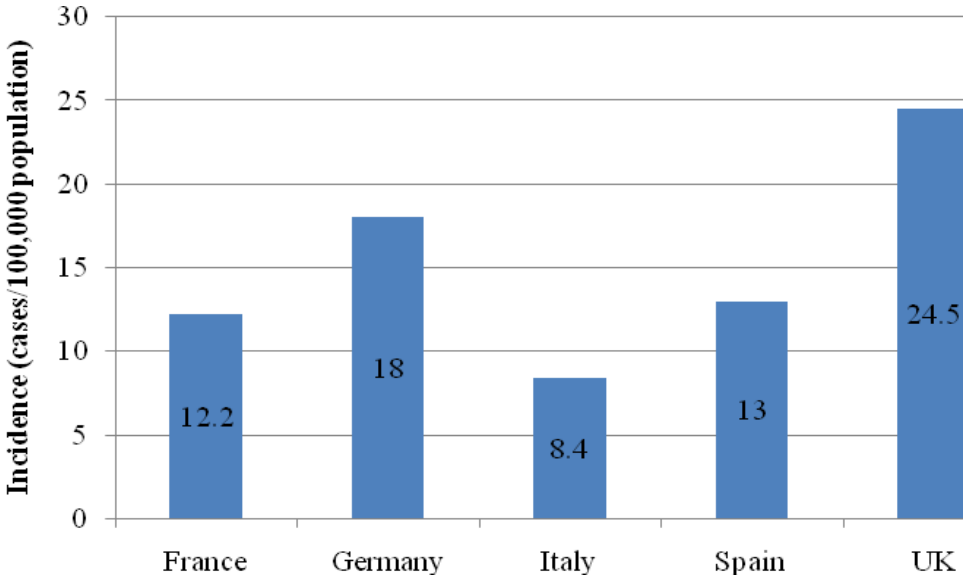
3. Diabetes Burden and Policies in Europe

3.1 Incidence

OECD estimates suggest that Type 1 diabetes incidence is highest in the UK with 24.5 cases per 100,000 population, followed by Germany (18), Spain (13), France (12.2), and Italy (8.4) (Figure 3.1). The EURODIAB study registers in 20 European countries (not including France or Italy) all report annual increases of 3.9% between 1989 and 2003, with a doubling of prevalent cases expected by 2010 (Patterson et al. 2009). These results are supported by other regional studies in Europe (Bruno et al. 2009; Imkampe et al. 2011; Thümer et al. 2010).

Type 2 diabetes incidence is increasing in both children and adults, among others due to rising obesity in the former and rising obesity in an aging population in the latter (Passa 2002). Added dimensions are the effect of socioeconomic status, with higher incidence of Type 2 diabetes in lower socioeconomic strata in Europe (Espelt et al. 2011), as well as a greater association with low birth weight and low childhood weight (Whincup et al. 2008).

Figure 3.1: Diabetes Type 1 incidence (0-14 years)



Source: (Organisation for Economic Cooperation and Development (OECD) 2009).

3.2 Diabetes prevalence

Based on IDF data, diabetes prevalence across EU5 is significant and is highest in Germany (12%) and lowest in the UK (4.9%) (International Diabetes Federation (IDF) 2009). From 2007 to 2010 all 5 countries have seen their diabetes prevalence rise (Table 3.1). Part of the increase in the UK is attributed to significant improvements in diabetes reporting during this time, which reflects documented under-reporting of diabetes pre-2007 (2006 was the first year of encouraged, but not mandatory, diabetes reporting) (Diabetes UK 2010c).

Germany has the highest number of deaths attributable to diabetes, although this figure has declined dramatically between 2007 and 2010; smaller reductions in diabetes-related mortality are indicated in Italy and Spain.

Table 3.1: Diabetes prevalence and attributable mortality (20-79 years)

	France		Germany		Italy		Spain		UK	
	2007[α]	2010	2007	2010	2007	2010	2007	2010	2007	2010
National Type 2 prevalence[β]	8.4%	9.4%	11.8%	12.0%	8.7%	8.8%	7.5%	8.7%	4.0%	4.9%
Cumulative Type 2 prevalence[δ]	5.9%	6.7%	7.9%	8.9%	5.8%	5.9%	5.7%	6.6%	2.0%	3.6%
Annual Type 2 attributable mortality	30,168	30,427	71,356	54,579	34,667	27,393	22,587	20,550	8,517[ξ]	18,707

Notes: [α] Estimates for 2007 and 2010 were calculated based on older data (e.g. 1980-2006 for the 2006 report).

[β] National prevalence estimated using UN population distribution estimates. Age- and sex-specific prevalence rates (PR) (via logistic regression) were applied to population distributions for 2007 and 2010 per country, using the formula: PR (20-79 years) = Total number of expected cases (20-79) /Total country population (20-79).

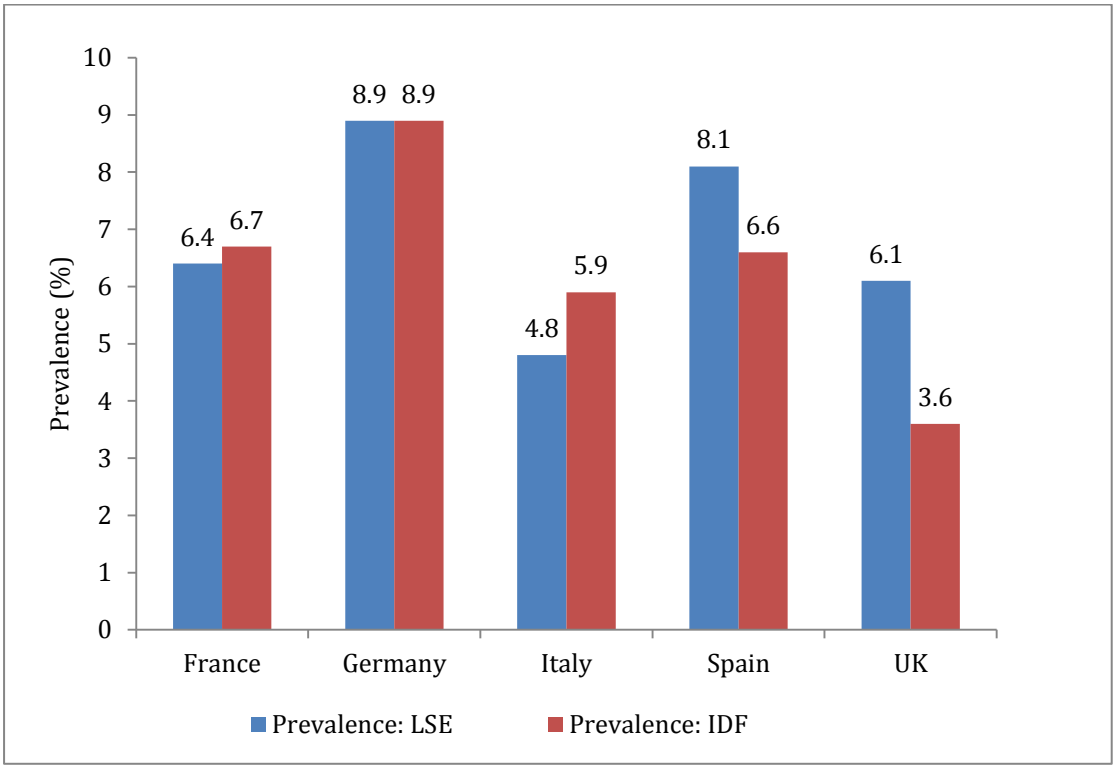
[δ] Cumulative Prevalence (CP) assumes each country has the same age profile, removing age differences between countries to create a figure appropriate for comparison. The CP should not be used for assessing the diabetes population within a country due to circularity (inaccurate to extrapolate outwards to a population, as already calculated on actual national prevalence in the population).

[ξ] Reflects annual mortality for men only as no data for women (2007).

Source: (International Diabetes Federation (IDF) 2006, 2009)

Against the evidence presented in Table 3.1, the more recent national benchmark data from our study shows significant variation, both upward and downward (Figure 3.2). Based on that, Spain and the UK report higher prevalence (8.1% and 6.1% respectively). Spain, however, only includes Type 2 adult cases, thus the 8.1% prevalence is likely to be an underestimate. France and Germany are very similar between the two.

Figure 3.2: Comparison of benchmark national diabetes prevalence versus IDF prevalence



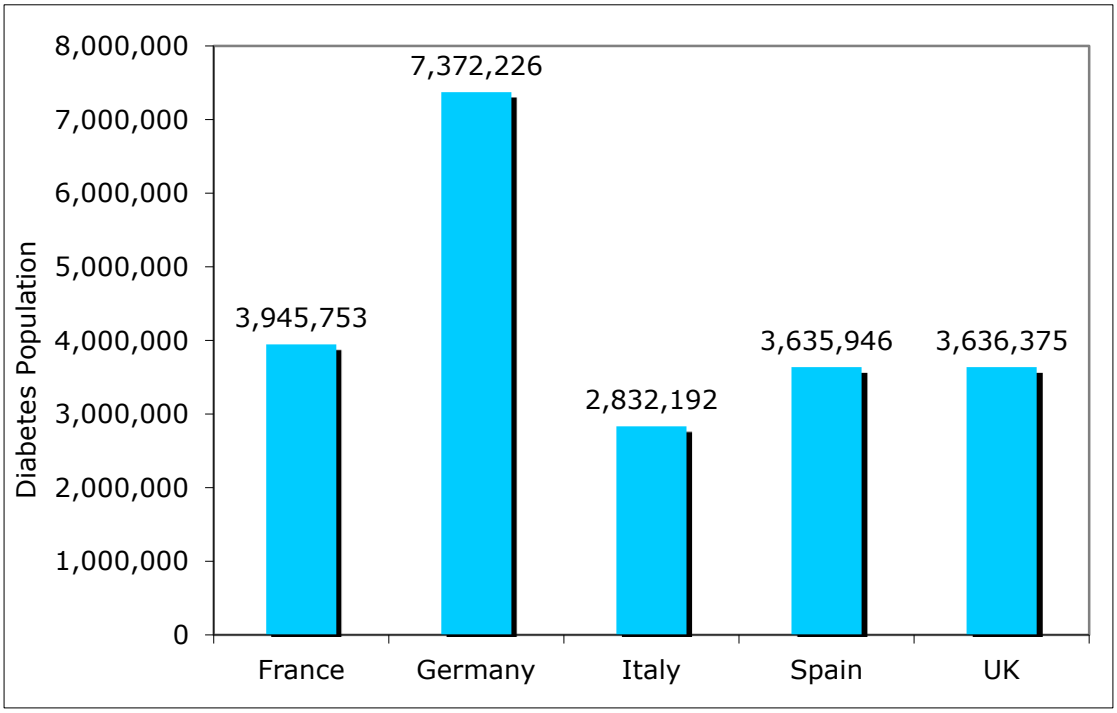
Notes: Prevalence (LSE): Germany (2007) (Köster et al. 2011), Italy (2009, >18 years) (ISTAT 2009), the UK (no N. Ireland; 2009)(Holman et al. 2011; NHS Information Centre 2010) are Type 1 and 2, 0-99 years. France (2008) (Bringer et al. 2009; Lecomte et al. 2008) is Type 1 & 2, >18 years. Spain (2008) (Centro de Investigación Biomédica en Red de Diabetes y Enfermedades Metabólicas Asociadas (CIBERDEM) 2008) is Type 2, >18 years.

Prevalence: (IDF) Cumulative prevalence for diabetes (2010 estimates, based on late 1990 and early 2000 country data) (International Diabetes Federation (IDF) 2009).

Source: Authors' compilation from a variety of sources.

Based on national prevalence and population figures, the total number of people living with diabetes in the study countries, shows Germany with the highest total diabetic population (>7 million) and Italy with the lowest (just under 3 million) (Figure 3.3). Regardless of the source, all data point to rising diabetes prevalence rates. The rationale is manifold. First, obesity and Type 2 diabetes are strongly correlated and obesity has increased over the past two decades (Figure 3.4) (OECD Statistics (2010)). This well-documented rise in obesity (concurrently with cardiovascular disease and diabetes) is largely linked to sedentary lifestyles and poor diet.

Figure 3.3: National diabetes prevalence, extrapolation from benchmark

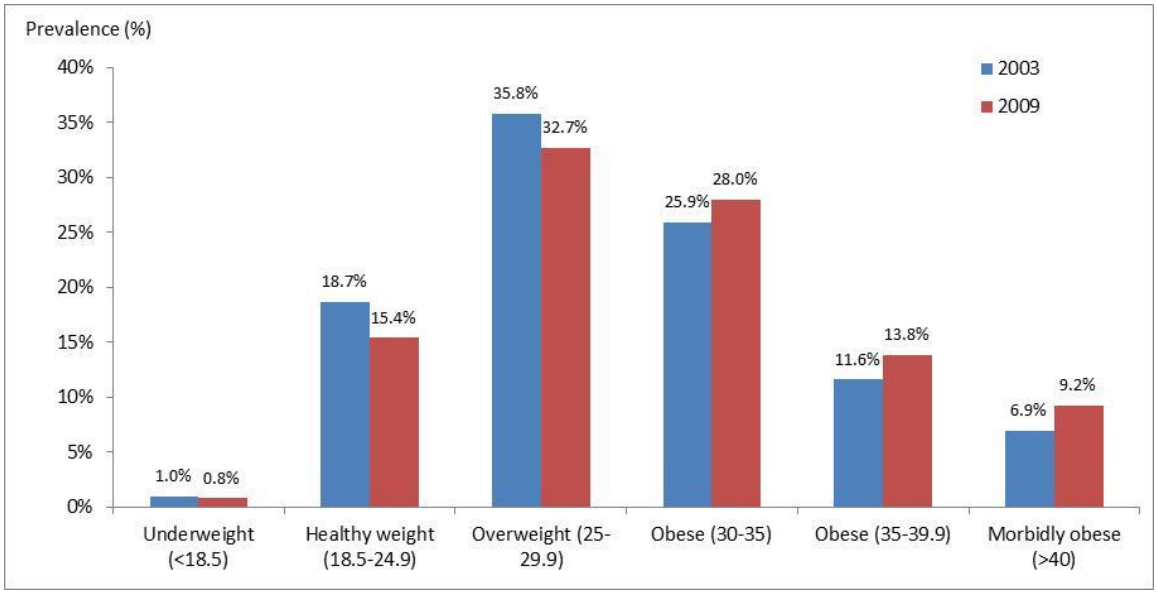


Notes: Prevalence (total): OECD population estimates (2010) (Organisation for Economic Cooperation and Development (OECD) 2010) and the benchmark prevalence estimates below, except UK (Figure 3.2, Box 2.1) [Country population * Country prevalence]

Prevalence (%): Germany (2007) (Köster et al 2011), Italy (2009, >18 years) (ISTAT 2009), the UK (no N. Ireland; 2009) (Holman et al. 2011; NHS Information Centre 2010) are Type 1 & 2, 0-99 years. France (2008) (Bringer et al. 2009; Lecomte et al. 2008) is Type 1 & 2, >18 years. Spain (2008) (Centro de Investigación Biomédica en Red de Diabetes y Enfermedades Metabólicas Asociadas (CIBERDEM) 2008) is Type 2, >18 years.

Source: Authors' compilation from various sources.

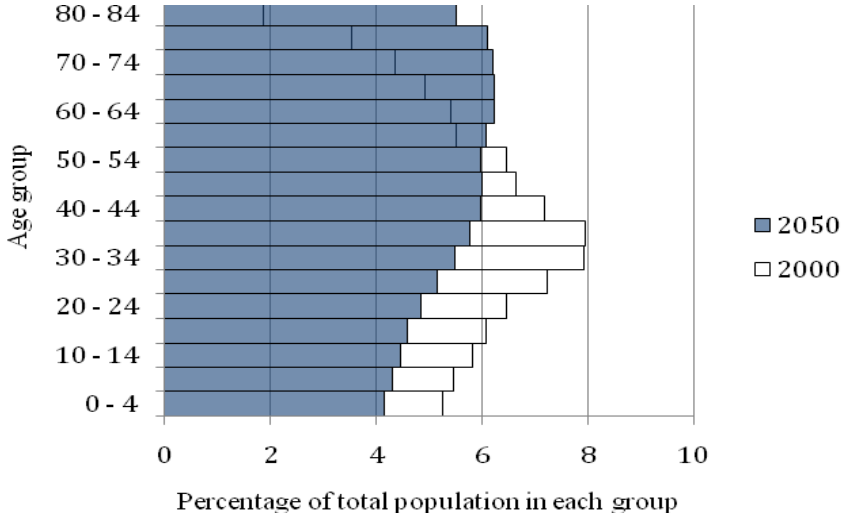
Figure 3.4: Diabetes stratification by BMI category in Scotland (2003, 2009) (Scottish Diabetes Survey Monitoring Group 2004, 2010)



Notes: Reflects 6 out of 14 NHS Boards, showing BMI distribution of 60,466 diabetes patients
Source: (Scottish Diabetes Survey Monitoring Group 2004, 2010).

Second, population aging has an additional association with diabetes. The projected inversion of the European population pyramid (Figure 3.5) is associated with a 30% increase in the lifetime risk of diabetes development (Hauner 2006).

Figure 3.5: Population estimates by age, EU5 average (2000 - 2050)



Note: Calculated as average individual country breakdowns of percent total population per age bracket.
Source: (Organisation for Economic Cooperation and Development (OECD) 2007).

Third, diabetes awareness has increased among health professionals and the public, leading to more people seeking diabetes testing alongside GPs screening their high-risk patients and being more aware of risk factors for Type 2 diabetes. Still, diabetes remains under-diagnosed as documented in all government and academic country prevalence sources.

Fourth, the ethnic make-up of all EU5 countries has changed and continues to change. Certain ethnic groups are at higher risk in developing diabetes, primarily African-Caribbean, African and Asian (Indian) (Agyemang et al. 2011; Hippisley-Cox et al. 2009) all with increasing population presence in EU5. Whether this association is due to socioeconomic status or due to genetic relationships is an interesting discussion currently occurring in the literature, but outside the scope of this study.

Finally, all countries have started to improve their diabetes data collection, some more so than others (the UK in particular). This means that part of the rise in prevalence is due to the increased reporting of diabetes patients present all along in the general population, suggesting previous prevalence estimates were too low. Appendix 3shows diabetes-related data sources in EU5 and Appendix 4 summarises data sources on diabetes health outcomes.

3.3 National Diabetes Programmes

Government health departments provide diabetes care policy frameworks. France, Spain and the UK have national diabetes planning; Italy is in the planning stages, while Germany has

Diabetes Disease Management Programmes (D-DMP) via social health insurance. While not exhaustive, this section explores the diabetes policy and programming in the EU5 (Table 3.2).

3.3.1 France

In addition to being a serious cause of morbidity, diabetes is also related to almost 30,500 deaths in France every year (equivalent to 3 citizens per hour) (International Diabetes Federation (IDF) 2009). In terms of diabetes-related complications, more than 13% of patients with Type 2 diabetes suffer from coronary heart disease and 4% from stroke (Le Floch et al. 2000); 6% suffer from nephropathy and 29% from neuropathy, while approximately 33.5% suffer from retinopathy (Delcourt et al. 1998). It is estimated that at least 20% of people with diabetes are unaware of their condition and remain untreated (International Diabetes Federation European Region et al. 2008).

The French national diabetes programme (NDP) "*Programme d'Actions de Prevention et Prise en Charge du Diabète de Type 2* (2002/05)" was implemented by the Ministry of Health, focusing on prevention, screening, quality and care organisation, epidemiology (via ENTRED) and therapeutic education (Ministère en charge de la santé 2010). However, the French NDP is no longer operational since end-2005. Despite having no active NDP anymore, diabetes is covered under the National Health Strategy, and public health law has made diabetes a priority by setting two objectives: first, to ensure that monitoring practice conforms with clinical practice guidelines 80% of the time by 2008, and, second, to reduce the frequency and severity of diabetes complications, particularly cardiovascular complications. All diabetic patients (type 1 and 2) are included under ALD (long-term disease system), i.e. receive 100% reimbursement. This is lost if patients do not follow correctly the annual planned exam i.e. eye tests, HbA1C (twice annually), electrocardiogram. Furthermore, the national health insurance fund (CNAM) has carried out the SOPHIA programme since 2008 with an extension in 2011, an adapted disease management programme where patients under ALD are followed by phone calls, newsletters and the internet. Currently, in the pilot phase, 56,775 patients are involved in the Sophia programme.

Recent evaluation of a lifestyle campaign ("*manger mieux, bouger plus*" – eat better, move more) found that a few targets were not met, specifically a reduction of obesity/overweight by 20%. The programme will be continued but modified to address weaknesses in governance (important evaluation indicators were not defined) and in the prioritization of objectives (greater focus on obesity prevention and treatment) (Jourdain Menninger et al. 2010). In a broader context, the French National Nutrition and Health Programme (PNNS) was implemented in 2001 and has since been extended to 2010 with the goal of improving the health of the French population and reducing risk factors for chronic disease through a focus on nutrition. The PNNS is a government sponsored public/private collaboration involving

government, research and education institutions, the food industry, healthcare organizations, and consumers. The PNNS programme set nine priority objectives focusing on nutrition and physical activity (French National Nutrition and Health Program (France-Public-Private) 2010).

3.3.2 Germany

Evidence suggests that approximately 55,000 German citizens die from diabetes each year (equal to 6 people per hour) (International Diabetes Federation (IDF) 2009). In terms of diabetes-related complications, more than 10% of patients with Type 2 diabetes suffer from coronary heart disease and 6.7% from stroke (Liebl et al. 2002); 16% suffer from retinopathy (Hesse et al. 2001), 8% suffer from nephropathy and 15% suffer from micro-albuminuria, which may lead to nephropathy (Bennett et al. 2001).

In Germany, because of decentralized/regional governments' responsibilities in policies there is no legitimacy for "national plans" on specific diseases, be it cancer, cardiovascular disease or diabetes. De facto, no national diabetes prevention programme exists, but there is a more generalised primary prevention approach as exemplified by the national action plan "In-Form" since 2008, which focuses on healthy lifestyle in general as primary prevention and is supported by the MoH (Bundesministerium für Gesundheit), or the the "Gesundheitsziele" programme from federal and regional ministries, focussing on healthy lifestyle in childhood, reducing tobacco consumption and detecting T2 diabetes early (Gesellschaft für Versicherungswissenschaft und -gestaltrun e.V). In addition, a number of D-DMP facilitating diabetes care have been in operation since 2002/04 by all health insurance funds, of which 40-50% of Type 1 & 2 patients are members (and voluntary check-up for individuals aged upwards of 40 years). Both programmes (DMP and check-ups) were defined by law and implemented via guidelines issued by the Federal Joint Committee. The evaluation of D-DMP versus non-DMP patients found D-DMP patients felt they had better care, despite the lack of difference in clinical outcomes between groups. Conclusions about D-DMP programme are difficult, as there is significant selection bias and voluntary self-monitoring of care (Birnbaum et al. 2010).

3.3.3 Italy

It is estimated that every year, approximately 27,000 Italian citizens (approximately 3 people per hour) die from diabetes (International Diabetes Federation (IDF) 2009). Type 2 diabetes accounts for 90% of diabetes in Italy (Mladovsky et al. 2009). In terms of diabetes-related complications, 10% of patients with Type 2 diabetes suffer from coronary heart disease (DAI Study Group 2004); 32% suffer from neuropathy (Fedele et al. 1997) and about 34% of diabetics suffer from retinopathy (Giuffre et al. 2004).

In Italy, people with diabetes are subject to Law 115/1987 on provisions for the treatment of diabetes mellitus, and a Memorandum of Understanding between State and Regions on diabetes dated 1991, which partly implements the law. They set the legislative framework for the care management of people living with diabetes, as well as state their rights, including discrimination at work and school. Italy was the first country in the world to adopt such a law, which identifies the standards of care and rights of people with diabetes, and contributed to raising awareness on the care of patients with long-term diseases. The Regions are in charge of implementing these provisions.

The National Healthcare Plans (NHP) – 2003-2005, 2006-2008, 2009-2010, and 2011-2013 - and National Prevention Plans (NPP) - including the latest one, 2010-2012 - mention, *inter alia*, diabetes, and call for horizontal models to better respond to the need of chronic patients and patients with diabetes. In particular, the 2011-2013 NHP is to be considered a National Diabetes Programme, because it includes diabetes among the diseases of public health interest, acknowledges the need to take action to tackle this disease, and allocates financial resources to its prevention and care. The latest NHP also insists on the need to implement 'clinical governance' for the treatment of diabetes with a multidisciplinary and integrated patient-centred approach, which fosters cooperation among the parties involved in care management and information sharing. It also calls to identify areas of improvement, create a platform to enhance dialogue between various healthcare-related players, initiate cooperation activities, and actively involve patients with diabetes in volunteer organisations.

Diabetes is also specifically addressed in the National Prevention Plan (NPP) 2010-2012. The diabetes-related goals include improving early diagnosis in the population at risk, defining protocols for integrated management of diabetes, defining appropriate health paths, assessing the care network with reference to acute event and chronic illness, and encouraging the implementation of IT systems and databases to facilitate the management and assessment of the programmes.

3.3.4 Spain

It is estimated that every year, diabetes is the underlying cause of approximately 20,550 deaths in Spain (equal to more than 2 people per hour) (International Diabetes Federation (IDF) 2009). Regional variations in diabetes prevalence are evident in Spain, where diabetic patients in the south of Spain are three times more likely to die from the disease than those in the north of the country (International Diabetes Federation European Region et al. 2008). In Spain, Type 2 diabetes accounts for 80-90% of diabetes (Mladovsky et al. 2009). In terms of diabetes-related complications, 12% of patients with Type 2 diabetes suffer from coronary heart disease, 10% suffer from stroke (Arteagoitia et al. 2003), 24% from neuropathy

(Cabezas-Cerrato 1998), 29% from retinopathy (Esmatjes et al. 1996), 23% from nephropathy (Arteagoitia et al. 2003) and 1.4% undergo a lower limb amputation. It is estimated that poorly controlled diabetes is related to 8-15% of all deaths in the Spanish population (International Diabetes Federation (IDF) 2006).

In Spain, the national "*Estrategia Nacional de Diabetes del Sistema Nacional de Salud*" (Strategy on Diabetes Mellitus of the National Health System) programme has been used to coordinate regional health plans and develops guidelines for prevention, care and treatment of complications, since 2007. As part of the *Plan de Calidad del Sistema Nacional de Salud* (Plan for Quality of the National Healthcare System) from March 2006, the NDP aims to set consistent operational standards and objectives to be achieved by the healthcare systems in place at regional level in order to ensure consistent, quality prevention, diagnosis and care of diabetes across the country.

3.3.5 United Kingdom

Type 1 diabetes prevalence in children in the UK ranks in the top 10 globally. Diabetes is associated with around 19,500 deaths in the UK each year (equal to 52 people per day) (International Diabetes Federation (IDF) 2009). In terms of diabetes-related complications, 25.2% of patients with Type 2 diabetes suffer from coronary heart disease and 9.6% suffer from stroke (Morgan et al. 2000); 28.5% suffer from peripheral neuropathy (Young et al. 1993). In the UK, 73 lower limb amputation are undertaken each week on diabetic patients, while, annually, 1,280 people become blind due to diabetes-related complications (Diabetes UK; UK Parliament 2010). Diabetes is related to 11.6% of all deaths in the UK population (Department of Health 2010). It is estimated that as many as 1million UK citizens who have diabetes are unaware of their condition (UK Parliament 2010).

England implemented the National Service Framework for Diabetes (NSF-D) in 2003, with seven main objectives including prevention and early diagnosis, decision-making via patient empowerment, quality of care during adulthood and childhood, treating diabetic emergencies and inpatient care, pregnancy care, and complications management. The NSF-D is supported by QOF, encouraging, among other things, diabetes data collection, alongside the annual National Diabetes Audit, which reports key indicators. The Diabetes UK patient group also conducts regular surveys on quality of care and monitors access and availability of treatments. Part of diabetes goals and policies fall under the NSF-D while others sit outside the Framework, such as the Expert Patient Programme and self-management courses. Wales has introduced a NSF since 2003 (All Wales Consensus Group; NHS Wales 2003), while Scotland adopted its NSF in 2010 (The Scottish Government), and has also produced guidelines by the Scottish Intercollegiate Guidelines Network (Scottish Intercollegiate Guidelines Network 2010).

Other NHS points of reference for diabetes care are NHS Diabetes, which aims to improve diabetes services and encourage evidence based practice, and the Yorkshire and Humber Public Health Observatory which has developed a number of modeling tools as well as a national prevalence model (part of the basis for our UK prevalence benchmark).

3.3.6 Overall

Despite the recognition in the early 1990s of the impact of increasing obesity rates on national health projections for cardiovascular disease and diabetes (Type 2), all EU5 countries have only recently implemented national diabetes policies (absent in Germany and Italy). It appears the policies implemented, in the case of France and the UK, are clearly projected in terms of objectives, although there are a number of caveats. First, monitoring and evaluation appears to be soft, as objectives in place do not have hard targets (for example theoretically creating a target stating 90% of diabetics will have HbA_1C measured at least bi-annually). Second, there does not appear to be a strong data collection service underpinning any objectives, further confounded by poor national capacity to identify people suffering from diabetes, particularly those with undiagnosed diabetes.

Table 3.2: Compilation of all national diabetes policies, and their goals and evaluations.

	France	Germany	Italy	Spain	United Kingdom
National Diabetes Policy	▪ SOPHIA ▪ ALD	▪ Prevention: Regionally ▪ Treatment: Disease Management Programmes	▪ Prevention: National Diabetes Prevention Plan (2010/12) + other lifestyle programmes (Guadagnare Salute) ▪ Treatment: None, but NDP under development ▪ National and Regional programmes (IGEA, chronic disease management (Maggini 2009))	▪ Estrategia Nacional de Diabetes del Sistema Nacional de Salud	▪ National Service Framework for Diabetes, QOF, NICE, Diabetes UK and National Diabetes Audit
Goals	▪ Prevention, screening, quality and organisation of care, epidemiology, therapeutic education	N/A	▪ Primary and secondary prevention. Integrated management of care (IGEA project)	▪ Coordinate regional health plans and investigation on diabetes in Spain	▪ Prevention, diagnosis, quality, adolescent transitions, education, screening
Monitored	▪ Evaluation only - indicated that programme has met its objectives and should be continued	Not formally	▪ No national or regional monitoring, however, the AMD undertakes annual comprehensive monitoring.	No	▪ Annual reporting via National Diabetes Audit and Scottish Diabetes Survey, National Diabetes Inpatient Audit, YPHO diabetes profiles, QOF reports
National Obesity Policy	▪ Programme national nutrition et santé (2010)	No	No	▪ Estrategia para la Nutrición, Actividad Física y Prevención de la Obesidad	▪ Change4Life, National Obesity Observatory, “Healthy Lives, Healthy People”

3.4 Conclusions

It appears that data on diabetes patients in the study countries is highly variable and diffuse. Compared to cancer, which has a similar burden of disease in all EU countries and either a national or regional cancer registries, estimation of burden of diabetes is currently neither accurate nor precise. This has a number of implications.

First, the lack of accurate prevalence data is disappointing for stakeholders in academia and health policy and health care financing & resource allocation, resulting in difficulties for governments in terms of managing diabetes care and accurately undertaking future planning, both from a policy and financial perspective.

Second, although some countries collect detailed data on small samples of patients (i.e. France ENTRED), other countries do not collect any data nationally (Germany) or do so only periodically (France, Spain). There appears to be a lack of representation of outlying patients (i.e. brittle diabetes, paediatrics, elderly and minorities), vital yet little understood subsets of the diabetes population in all EU5 countries.

Third, potentially neglecting Type 1 patients or including them within the Type 2 adult dataset makes it difficult to target services for patients who suffer for proportionally longer periods, often with higher risks of complications than Type 2 patients.

Fourth, the data collected may not be relevant to all patients – particularly the adult versus paediatric populations – with more important information in younger age groups being neglected.[xii]

Fifth, a number of important variables appear to be ignored or overlooked in surveys, including involvement by auxiliary health professionals (diabetes specialty nurses, dietitians, chiropody), use of psychiatric services, participation in diabetes education programmes, use of other specialist services (nephrology, cardiology, urology, surgery), documentation of complications, and identification of patients with pre-diabetes (impaired glucose tolerance) or brittle diabetes[xiii].

Finally, the diffusion of responsibility between diabetologists, endocrinologists and primary care professionals means that the creation and maintenance of such a registry would prove challenging, however, without improvements in the validity and availability of diabetes data, improvements in care will be difficult at best.

On the other hand, our survey suggests that patient and physician advocacy and support groups appear to be well developed and supported in all countries. As this may be one of the first and most

[xii] For instance the UK National Diabetes Audits have far greater data completion rates for adults than children, suggesting an underpinning rationale for paediatric clinics not to participate.

[xiii] Brittle diabetes occurs in a minority of Type 1 and 2 patients with uncontrolled hyper- and hypo-glycaemia, and associated with greater rates of complications and earlier mortality.

consistent points of contact for patients, their ongoing activity and involvement is encouraging and valued.

Box 3.1: Burden of disease - Key takeaways

- Diabetes prevalence, using national figures described, is variable across the EU5: France 6.39% (Type 1/2 >18y), Germany 8.9% (Type 1/2, 0-99y), Italy 4.8% (Type 1/2, 0-99y), Spain 8.1% (Type 2, >18y), and the UK 6.1% (Type 1/2, 0-99y).
- The total number of patients with diabetes in the EU5 is over 20 million, and this is likely to be an underestimation due to poor data collection as none of the study countries have national diabetes registries limiting data collection and availability.
- Rising diabetes prevalence is driven by increasing obesity, aging populations, earlier identification of patients with diabetes, change in ethnic distribution, and improvements in data collection (UK).
- Italy, Spain and the UK have national diabetes programmes (NDPs), although some are not monitored and none appear to have hard targets. Neither Germany, nor France have NDPs.
- Monitoring nationally of diabetes outcomes occurs periodically in France and Spain, annually in Italy and the UK and occurs through DMPs in Germany.

4. Diabetes Guidelines, Diagnosis and Treatment

This section explores aspects of diabetes treatment, including the existence and content of guidelines, screening and diagnosis as well as routine monitoring for diabetes control. Diabetes specific complications will be highlighted.

4.1 Diabetes Guidelines

All countries have diabetes treatment guidelines, key aspects of which are outlined in Table 4.1. In France, the *Haute Authorité de Santé* (HAS) and the *Agence Française de Sécurité Sanitaire des Produits de Santé* (AFSSAPS) develop guidelines covering Type 1 & 2 diabetes treatment and monitoring under ALD8[xiv], pediatric Type 1 diabetes treatment, and pharmaceutical treatment of Type 2 diabetes (jointly issued in 2006). In Germany, the Deutsche Diabetes Gesellschaft (DDG) and physicians' chamber (Bundesärztekammer - BAK) have developed evidence-based guidelines for the diagnosis and treatment of diabetes (Types 1, 2 and gestational). In Italy, national treatment guidelines are produced by the Associazione Medici Diabetologici (AMD), in conjunction with the Societa Italiana di Diabetologia (SID) (Associazione Medici Diabetologi (AMD) - Società Italiana di Diabetologia 2010). These cover screening, prevention and treatment of Type 1, 2 and gestational diabetes. In Spain, the Ministry of Health and National Health Service have published national diabetes guidelines (via Guiasalud), focused on the treatment of Type 2 patients – prevention, treatment, education and screening for complications (Consumo 2008), while regional authorities (e.g. Valencia) have also launched clinical guidelines for management of diabetes. Finally, in England, the National Institute for Health and Clinical Excellence (NICE) produces a multitude of guidelines for diabetes, including screening, diagnosis, specific treatment (Type 1, 2, gestational), medical technology (insulin pumps), medications (e.g. liraglutide), and management of complications. As of March 2011, 48 guidelines and recommendations have been made for diabetes management, although no separate division exists within NICE for diabetes as for cancer management.

[xiv] The *affections de longue durée* system grants 100% SHI coverage for 30 chronic illnesses requiring prolonged treatment including Type 1 and 2 diabetes (ALD8). The universal coverage applies only to diabetes treatment, while non-diabetes costs are covered under the general SHI reimbursement. Certain payments are excluded: excess consultant charges, patient surcharges and transport costs (in certain cases).

Table 4.1: Aspects of treatment addressed by national diabetes guidelines

		France	Germany	Italy	Spain	UK
Guideline	Type 1	✓	✓	✓	✗	✓
	Type 2	✓	✓	✓	✓	✓
	Gestational	✗	✓	✓	✗	✓
	Pre-diabetes	✗	✗	✗	✓	✓
Treatment pathway	Type 1	✗	✗	✓	✗	✓
	Type 2	✗	✗	✓	✓	✓
	Gestational	✗	✗	✓	✗	✗
	Pre-diabetes	✗	✗	✗	✓	✗
Lifestyle	Type 2: DES 1st, then medication	✓	✗	✓	✓	✓
	Discussion of co-morbidities	✓	✓	✓	✓	✓
	Discussion of DES with patients	✓	✗	✓	✓	✓
Monitoring guidelines	General	✓	✓	✓	✓	✓
	Type 1	✓	✗	✗	✗	✓
	Type 2	✓	✗	✗	✓	✓
	Gestational	✗	✗	✗	✗	✓
	Pre-diabetes	✗	✗	✗	✗	✓
Prevent	Prevention to reduce incidence	✓	✓	✓	✓	✓
	Community Awareness	✗	✓	✓	✗	✓
	Max waiting times for treatment	✗	✗	✗	✗	✗
Routine monitoring:	Haemoglobin A_1C	q3m	✓	q3m	q6m	q3-6m
	Fasting blood glucose	✗	✗	✗		✓GC
	Urinary Proteins	✓	✓	✓	q1yr	q1y
	Body Mass Index	✗	✓	✓	q6m	q11y
	HDL cholesterol	✓	✓	✓	q1yr	q1yr
	LDL cholesterol	✓	✓	✓	q1yr	q1yr
	Triglycerides	✓	✓	✓	q1yr	q1yr
	Waist to Hip Ratio	✗	✗	✗	q6m	✗
	Blood pressure	✗	✗	✓	q1y	q1y
	Foot examination	✗	✗	✓	q1y	q1yr
	Serum creatinine	✗	✗	✓	q1y	q1y
	Retinal examination	✗	✗	✓	q1yr	q1y
	ECG	✗	✗	✗	q1yCVD	q1yCVD
Referrals	Dietician	✓	✗	✓		✓
	Exercise specialist	✗	✗	✗		✓
	Renal Physician	✓	✗	✓	✓	✓
	Opthalmologist	✓	✗	✓	✓	✓
	Cardiologist	✓	✗	✓	✓	✓
Patient care and management	Diabetes emergency care	✓	Poor	✓	✓	✓
	In-patient care	✓	Poor	✓	✗	✓
	Diabetes and pregnancy	✗	✓S	✓	✗	✓
	Long-term complications	✗	✓	✓	✓	✓

	Psychological issues	✗	✓	✓	✓ DES	✓
	Choice of diabetic clinics	✗	✓	✓	✗	✓
	Improving quality of care	✗	✓	✓	✗	✓
	Improving access to diabetes care	✗	✓	✓	✗	✓
	Promote multi-disciplinary teams	✗	✓	✓	✓	✓
	Promoting patient-centred care	✗	✓	✓	✗	✓
	Training for diabetes personnel	✗	✓	✓	✗	✓

Notes: q = every (e.g. q3m means every 3 months; q1y means every year); *CVD* only in CVD; *DES* diet, exercise, smoking; *GC* dependent on glucose control and medication (home blood glucose monitoring more likely in patients with either poor control or patients taking insulin); *S*: only in specialised centres.

4.2 Diagnosis

4.2.1 Patient testing and screening

There are some variations in the target patient groups and basis risk factors for routine diabetes testing (Table 4.2). Only France and Germany appear to have concerted efforts to routinely screen high-risk patients for diabetes, although these constitute recommendations to physicians and it is not known whether they are followed on a routine basis. In Germany a general health check-up is voluntarily available to all statutorily insured people every 2nd year for all insures aged 35 and over and this is also endorsed by law. Blood and urine glucose as well as other parameters are measured at no extra cost to the insuree, but uptake remains low. This screening is also targeted to detect T2D early (Bundesministerium für Gesundheit). Screening for gestational diabetes is also offered free of charge to all pregnant women by the German sickness funds. Testing for Type 2 diabetes in Italy, Spain and the UK is at GP discretion, although screening for gestation diabetes in high-risk (overweight, obese) mothers is routinely performed.

All countries recommend testing for diabetes in patients who present the classical symptoms of polydipsia, polyuria and weight loss, or have a family history of the disease. Additional testing criteria for high-risk patients in France are personal or family history of CVD, birth to a baby weighing more than 9 pounds, or previous gestational diabetes diagnosis. Testing criteria in Germany are similar to France, with the addition of patients tested previously for Impaired Glucose Tolerance (IGT) and those with acanthosis nigricans (a skin condition highly associated with diabetes). Italian criteria are identical to Germany, with the addition of testing obese patients.

Spain undertakes diabetes testing in patients with the following risk factors (although up to GP discretion to do so) obesity, high blood pressure, high cholesterol levels, CVD history, acanthosis nigricans, polycystic ovary syndrome, birth to a baby more than 9 pounds or gestational diabetes diagnosis.

In the UK, testing of patients for diabetes beyond the routine presentation is dependent on GP discretion. Some GPs may test all their overweight or obese patients, however, no firm guidance

exists on this matter (although it may in upcoming May 2012 Pre-Diabetes guidelines(National Institute for Health and Clinical Excellence (NICE) In progress, expected May 2012)). The same GP dependency exists for patients with CVD, hypertension and hyper-cholersterolaemia for additional diabetes testing associated with these conditions. In 2009, the NHS implemented the Health Check programme, which invites adults aged between 40-74 years without heart disease, stroke, diabetes or kidney disease to be screened for the forenamed diseases by their GP, pharmacist or nurse. This programme is still in the early stages, and as yet no information is available on uptake or outcomes.

Table 4.2: Patient groups tested and screened for diabetes by family physician

	France	Germany	Italy	Spain	UK
Patients routinely tested for diabetes					
Classic: polyuria, polydispia, weight loss	✓	✓	✓	✓	✓
Obese patients	✗	✗	✓	✓	✓ GP, NICE
Family history: parent, sibling	✓	✓	✓	✓	✓ GP
High blood pressure	✗	✓	✗	✓	✓ GP
History of CVD	✓	✓	✗	✓	✓ GP
High cholesterol levels	✗	✓	✗	✓	✓ GP
Previous test for IGGT	✗	✓	✓	✓	✓
Acanthosis nigricans	✗	✓	✓	✓	✓
Birth of a baby ≥9 lbs or gestational diabetes	✓	✓	✓	✓	✓
Polycystic ovary syndrome	✗	✗	✗	✓	✓
Retest of patients testing normal	✓ q3y (depending on age, sex, RF)	✗	HR tested with OGTT	✓ q1-5y	GLD
Pre-diabetes: next test	✓ 1 year	✗	✓ 6m	✓ 6-24 m	GLD
Diabetes screening initiatives					
Type 2 screening program	✓	✓	✗	✗	✗
Patient groups screened	HR	HR and all age >35	GP	GP	GP
Conditions for screening	>45y + >1RF; OR >45y + unstable	Age >35	-	-	-
Screening frequency		q2yr	-	-	-
Screening rate	71.2%	0-20%	-	-	-

Notes: *GLD*: guidelines under development, expected May 2012; *GP*: Dependent on GP decision; *NICE*: NICE includes diabetes in its 2010 obesity guidelines however makes no recommendations on routine diabetes testing: HR: High risk patients; RF: risk factor

Source: The authors.

4.2.2 Physician involvement

There is some variation in physician responsibilities in terms of diagnosis and treatment across EU5. In general, GPs are responsible for diagnosis of Type 1, Type 2 and pre-diabetic patients, particularly in the UK, Italy and Spain, although diabetologists/endocrinologists may be involved, paticularly if the patient is first diagnosed with diabetes in emergency care. Treatment is usually differentiated between physicians, with endocrinologists/diabetologist focused on Type 1 or insulin-dependant Type 2 treatment, while GPs concentrate on the treatment of non-insulin dependent Type 2 diabetics and patients with pre-diabetes. There is little consistency in the physicans consulting on

Type 2 insulin dependent cases, with some seen by diabetologists/endocrinologists and others seen by their GP who may have additional diabetes training.

Individual care plans are developed for patients in Germany, Italy and the UK. In Germany, this tends to occur primarily for patients seen by a multi-disciplinary care team, academic teaching hospitals and occasionally by GP-led care. In Italy, individual care plans are defined for (and by) patients seen by a multi-disciplinary care team and those treated in academic teaching hospitals. The UK encourages all patients with diabetes to receive a patient centred care plan in its National Diabetes Framework, however, actual delivery is difficult to measure or monitor. A Diabetes UK survey of its members found 60% discussed their diabetes goals with their physician, but only 30% received their diabetes test results prior to the appointment in order to plan their discussion (Diabetes UK 2010c). Individual care plans are not defined in France and Spain. Each physician that a patient sees decides on a course of action, within the boundaries of the national diabetes treatment guidelines.

4.2.3 Treatment processes, timelines and patient education

In all EU5 countries only unstable patients are admitted to hospital upon diagnosis, regardless of diabetes type (1 or 2). Outpatient multi-disciplinary diabetes teams exist in all EU5, while in the UK there are specialist GP diabetes clinics with GPs who have additional diabetes certification and offer multi-disciplinary care (dietetics, chiropody). In France, patients are treated by a multi-disciplinary team only if they are hospitalised or consult outpatient physicians, otherwise Type 1 patients are generally seen by endocrinologists or diabetologists and Type 2 patients by their GPs. In Italy and the UK, only Type 1 & 2 insulin-dependent Type 2 patients are seen by multi-disciplinary teams in hospital outpatient clinics, while non-insulin dependent Type 2 patients are seen by community GPs. In Spain, only Type 1 patients are monitored by multi-disciplinary diabetes teams and Type 2 patients are seen by community GPs.

Formal patient education programmes for new patients have been instituted nationally in Germany, Italy, Spain and the UK (content and intended audience varies regionally). In France, *Sophia* is currently in the pilot phase (Box 4.1), and 70% of general education is provided by diabetologists (Jaffiol 2009). In Germany, education is provided to all Type 1 & 2 patients in private practice and hospitals, as well as by some GPs, with 50-70% receiving patient education. In Italy, education programmes are offered only for diabetic patients being treated by a multi-disciplinary team, delivered in diabetic centres focusing on dietary advice and physical activity.

In Spain, education programmes are provided only in academic teaching hospitals. The composition of programmes varies by centre, although all usually include the following: general diabetes information, diet and exercise, glucose monitoring, hypoglycaemia identification and treatment, insulin delivery (when applicable), complications and their prevention. Education programmes are

given to the majority (95%) of Type 1 diabetics at diagnosis. Education for Type 2 diabetics is offered to a considerable number of patients by GPs and family nurses and, less often, by multidisciplinary teams.

In the UK, all hospital outpatient clinics and specialist GP clinics offer diabetes education as recommended by the National Diabetes Framework. The difficulty, however, lies in its content and its provision, funding and take-up. In some regions programmes are only available for Type 1 patients, while others offer education only to Type 2 patients. There are national guidelines and programmes for content, namely DAFNE for Type 1 and DESMOND for Type 2 diabetes however, regional education programmes do not need to adhere to their content. A recent survey of diabetes patients did reveal a need for continuous diabetes education, including refresher courses (Diabetes UK 2010c). It appears that there is no concerted focus, or guaranteed provision of programmes to all patients with different diabetes types in any of the EU5.

4.2.4 Patient monitoring

Routine visits

Type 1 patients are seen by an endocrinologist or diabetologist on a quarterly basis (in all countries but less frequently in Spain), while Type 2 patients irrespective of medication requirements are seen either a GP or endocrinologist with similar frequency. Patients with gestational diabetes seem to be treated by a specialist (diabetologist, endocrinologist or gynaecologist depending on the country) most regularly in Germany (once to twice per week) and least frequently in Spain (1-2 times per trimester). Patients with impaired glucose tolerance are monitored more variably across countries. In Spain, these patients are seen up to four times a year by a GP, whereas in France they are seen once or twice a year.

Box 4.1: Patient education & monitoring pilot programme in France (Sophia)

Sophia is a voluntary pilot programme offered gratis to Type 1 & 2 patients over 18 years covered by the Affections de Longue Durée (ALD8) programme (80% of diabetics are part of this universal coverage regime for chronic diseases) to encourage regular contact with patients (ideally every 6 weeks). Services include information and educational tools, telephone advice provided by medical staff (primarily nurses), and Internet services. The tools include a quarterly magazine, patient reminders provided through post-it notes, calendars and posters and a magnet with the Sophia contact details. The pilot programme, covering 10 departments (administrative divisions), is available to approximately 136,000 patients (nearly 6% of the total diabetic population).

Sophia stems from 2007 social security financing law providing the development of programmes to accompany patients with chronic conditions. The goal is to improve the quality of life of diabetic patients and to reduce costs of complications. A medical and economic evaluation of the programme is currently underway.

Home blood glucose monitoring, continuous glucose monitoring & insulin pumps

Home blood glucose monitoring (HBGM) via glucometers is not routine practice in all EU5 and/or for all diabetes types. In France, all Type 1 patients and one third of Type 2 patients, treated with insulin or oral anti-diabetic medication, undertake HBGM. In Spain and Italy, all Type 1 patients and those Type 2 patients treated with oral anti-diabetic drugs are advised to undertake HBGM, however, uptake is unclear. In Germany, only patients on insulin therapy and/or unstable diabetes may have HBMG covered by statutory health insurance. In the UK, only patients treated with insulin (Type 1 or 2) are advised to HBGM. Patients with gestational diabetes are advised to self-monitor in Germany, Italy and Spain. Patients with pre-diabetes are not advised to undertake self-monitoring in any of the countries studied.

Continuous glucose monitoring (CGM) is available to unstable patients in Germany, Italy, Spain and the UK (by individual application), however, "very few" patients in Germany, 5-10% of patients in Italy and fewer than 1% of patients in Spain and the UK receive CGM. In France CGM is available, however it is not currently covered by SHI.

Insulin pumps are available and wholly reimbursed for unstable and Type 1 patients in France, Italy (7-8% uptake) and the UK. In Germany, approximately 50% of unstable patients and 20-30% of Type 1 patients use insulin pumps. Spain provides insulin pumps to all unstable patients, however, only a fraction (about 1-2%) use it. Differences also exist in UK uptake, ranging from less than 1% to almost 8% of paediatric patients. Significant differences in costs of insulin pumps also exist across countries.[xv]

[xv] The average cost of an insulin pump is highest in France (€19,633) and lowest in Italy (€2,000-3,000). Costs in the other EU5 are: €6,000-6,500 in Spain (at an estimated annual per patient cost of €3,000), €3,680 in Germany, and in the UK £4,580 (pump and placement cost) for the first year and £1,145 annually thereafter.

Table 4.3: Diabetes treatment practices across EU5 (2010)

	France	Germany	Italy	Spain	UK
Diagnosis to treatment					
Type 1: Time diagnosis to treatment	0-3 days	Quick	Immediate	< 15 days	-
Type 2: Time diagnosis to treatment	Depends on GP	Unknown	Immediate	< 15 days	-
Target time diagnosis to treatment	Type 2: 3m diet pre-drugs, unless unstable	⅄	N/A	⅄	⅄
Education programme for new patients	Sophia pilot programme expanded	All diabetic patients	Only patients treated by multi-disciplinary diabetes team	Only in academic teaching hospitals	✓ Reg
Frequency of stable patients visits to health professionals					
Type 1	q3-4m E/D	q3m D	q2-4m	q3-6m E/D q3-4m GP	q3m D/E
Type 2 (insulin)	q3-4m E/D	q3m GP/D	q2-4m	q0-4m E/D q2-4m GP	q3m D/E/GPs
Type 2 (oral anti-diabetic)	q3-4m GP	q3m GP	q4-6m	q2-6m GP	q3-4 m GP
Gestational diabetes	0.5-1m E	q1-2w D		q1-2/trimester Gyn/E	q2-4wks D/E/O
Pre-diabetes	q6-12m GP	Not regular	Not regular	✓	q6-12m

Notes: Reg: depends on region *GP*: primary care family physician; *E*: endocrinologist; *D*: diabetologist; *O*: obstetrics; *Gyn*: Gynaecologist

Source: LSE survey in diabetes and diabetes costs in 5 EU countries.

4.3 Diabetes care delivery

All study countries report a variety of issues in delivering diabetes care (Table 4.4). In France, the primary problems relate to regional differences in access to care, insufficient human resources, insufficient funding for lifestyle change initiatives and inadequate physician diabetes training. Although experts in France consider the level of care to meet international standards, a recent evaluation of ENTRED data concluded a number of improvements could be made in the prevention and treatment of complications (e.g. when to intensify treatment to include insulin), as well as monitoring for micro- and macro-vascular complications. Additional recommendations included reinforced access to paramedical care and greater coordination of treatment (Robert et al. 2009).

Care delivery issues in Germany relate primarily to insufficient training and care resources, both human and facility, limitations in access due to geographical inequities, particularly for the latest treatment options, inadequate funding for lifestyle change initiatives and lack of screening

programmes. These may be the result of insufficient political support for diabetes care. While a good framework for diabetes care delivery exists, substantial improvements could be made both in terms of diabetic practice and standards.[xvi] Furthermore, practical problems resulting from limited financial resources, excessive regulation, poorly trained health professionals and a lack of integrated care (between GPs, specialists and hospitals) need to be addressed.

In Italy, substantial regional variations exist in demand and access to care. In the south and central regions, the number of diabetes centres is proportional to the number of patients. In the north, the diabetic population is larger, resulting in an imbalance in demand versus existing resources. As a result, a system of coordinated care and integrated diabetes management is developing in the north with diabetic care teams operating within hospitals as well as shared care between GPs and diabetologists – however, this is still a minority situation and an ongoing experiment. By contrast in the south, while an integrated management plan is a national goal, diabetes care still tends to be ambulatory and undertaken by a diabetologists only rather than. care teams. Additional problems include insufficient human resources (particularly diabetologists) and facility resources (north - diabetic centres, south - equipment), plus long waiting times (particularly in the north due to greater total prevalence). Specific areas of improvement relate to the integrated management of diabetes, coordination of duties among professionals, increased training for professionals and greater use of outcomes to monitor progress (a recent AMD undertaking).

Spanish diabetes care is also organized regionally with geographical variations in resources and management, resulting in limited screening, long waiting times for diagnosis and treatment, problems in accessing care and inadequate patient surveillance following diagnosis (particularly rural regions). In some regions, there are shortages in endocrinologists, specialised nurses and trained GPs. As public health care does not provide funding for dietetic care and other lifestyle change initiatives, greater demand for these services is shouldered by GPs and general nurses. In some instances, physicians do not receive adequate training, particularly for preventative care. While experts interviewed for this study agreed that overall diabetes care meets international standards, improvements in the following are sought: increased resources for prevention and lifestyle initiatives, and improved co-ordination between primary and specialised care.

There are a number of issues in the UK in delivering optimal diabetes care. Despite a stable number of diabetologists and increased GPs with additional diabetes care training, Diabetes Specialist Nurses (DSN) and dietitians specializing in diabetes care (Diabetes UK 2010a; Diabetes UK et al. 2009), there appears to be large variations in care between regions and individual practices (Department of Health 2010; Diabetes UK 2010c; NHS Information Centre 2011). Under the QOF, all GP practices and PCTs must submit data including biomarkers, retinal and foot screening, and

[xvi] For example, diabetes guidelines based on diabetes type and treatment would be welcome in improving the standards and quality of diabetes care.

complication notation. The 2010 National Diabetes Audit found only 44% of paediatric practices participated, only 75% of GP practices contributed, while all PCTs for adult care participated. Not only was the submission rate highly variable (i.e. paediatrics highest in Wales, lowest in England; adult lowest in Wales and highest in England), but content of their outcomes was also highly inconsistent (discussed in Section 6). Access to diagnosis and treatment for complications relating to diabetes is also regionally dependent, as is access to new treatments such as insulin pump therapies. There is also concern from a workforce perspective, that there is decreasing protection and job security of DSN (Diabetes UK et al. 2009) while the number of new vacancies for diabetologists in the UK has shown a steady decline since 2004 (Diabetes UK 2010a). This is unfortunate on both counts, as DSNs play a major role in patient care and decision making, and diabeteologists provide specialist care in a disease that is increasing steadily, including insulin dependent cases.

Overall, there is little consistency in who delivers diabetes care across EU5, plus all countries indicate regional inequalities in access to diabetes care. General trends include insufficient human resources, lack of screening programmes, insufficient funding for lifestyle initiatives and waiting times for some patient groups.

4.4 Conclusion

All EU5 countries have diabetes treatment guidelines, developed either by national agencies or diabetes associations, although Spain does not for Type 1, and France and Spain do not for gestational diabetes. The UK appears to be the most prolific in its diabetes guidance development, with over 40 recommendations produced to date.

Table 4.4: Problems in delivering diabetes care [α]

	France	Germany	Italy	Spain	UK
Main delivery of care problems					
Regional differences in access to care	✓	✗	✓	✓	✓
Insufficient human resources	✓	✓	✓	✓	✓ AH, E
Insufficient facility resources	✗	✓	✗	✗	✗
Poor distribution of resources	✗	✗	✗	✓	✓
Inadequate diagnostic facilities	✗	✗	✓ South	✗	✗
Inadequate treatment facilities	✗	✗	✗	✗	✗
Absence of screening programs	✗	✗	✓ Gestational	✓	✗ R
Poor funding complications treatment	✗	✗	✗	✗	✗
Poor funding lifestyle changes initiatives	✓	✓	✗	✓	✗/✓ Reg
Long waiting times for diagnosis	✗	✗	✗	✓	✗/✓ C
Long waiting times for treatment	✗	✗	✓ North	✓	✓ C
Poor access due to geographical inequities	✗	✓	✓	✗	✗
Poor quality treatment	✗	✗	✗	✗	✗/✓ Reg
Poor or no practice guidelines	✗	✗	✗	✗	✗
Poor physician diabetes resources	✗	✗	✗	✗	✗
Inadequate physician diabetes training	✓	✓	✗	✓	✗
Poor political interest in diabetic care	✗	✓	✗	✗	✗/✓ Reg
Poor press coverage of diabetic care	✗	✗	✗	✗	✓
Inadequate patients monitoring	✗	✗	✗	✓	✗/✓ Reg
Inadequate services for complications	✗	✗	✗	✗	✗/✓ Reg
High out-of-pocket cost to patient[1]	✗	✗	✗	✗	✗
Delays and/or poor access to the latest treatments/medicines	✗	✓	✗	✗	✗/✓ Reg
Poor participation in diabetes research	✗	✗	✗	✗	✗
International comparison					
Leading diabetic practice	✗	✗	✓	✗	✗
Meeting international standards	✓	✗	✗	✗	✓
Room for improvement	✗	✓	✗	✗	✓
International practice does not apply	✗	✗	✗	✗	✗

Notes: *AH*: after hours care; *C*: complications (depending on specialty); *E*: patient education; *R*: annual retinal screening (+ minimal annual monitoring for micro- and macro-vascular damage); *Reg*: depends on the region;

[α] The information in this table reflects the opinions of survey respondents from the individual study countries.

[1] There may be out-of-pocket costs associated with having the condition, rather than – strictly speaking – treating the condition. The latter are included, whereas the former are not.

Source: The authors from the LSE survey.

Routine diabetes screening programmes for high-risk patients exist in France and Germany, both countries with social health insurance, but participation is variable. In the remaining countries diabetes testing is at the discretion of the GP and usually based on high-risk situations such as,

diabetes family history, obesity, and abnormal lipid profiles. Diagnosis still occurs via testing for another medical purpose; however, emergency care diagnosis is becoming more rare.

In all study countries, care of diabetic patients is largely shared between GPs, DSNs, endocrinologists and diabetologists. The majority of cases are diagnosed or identified by GPs and then referred onto more specialist care depends on diabetes type with insulin dependent cases are usually seen by endocrinologists or diabetologists. Individual care plans are developed for patients in Germany, Italy and the UK, where patient focused care is becoming encouraged. In France care pathways are the responsibility of the treating physician.

Formal patient education programmes for new and existing patients have been instituted nationally in Germany, Italy, Spain and the UK. France is piloting a new education programme. All countries, however, profess a need to further their tailored education for diabetes patients, realising that 'one size fits all' is not the case, with diversity in cultures, age, diabetes type and time since diagnosis.

Box 4.2: Diabetes guidelines, diagnosis and treatment - Key takeaways

- Despite all EU5 producing diabetes guidelines, there is little uniformity in the types of organisations producing the guidelines across the EU5. This may have implications for the quality of the guidelines, effectiveness of their implementation as well as their potential impact on individual and population diabetes outcomes.
- Only France and Germany appear to have concerted efforts to routinely screen patients at risk for diabetes, the remaining countries appear to rely on GP discretion on testing high-risk patients. However, uptake appears to be poor.
- It appears that only insulin dependent Type 1 or 2 patients receive specialised endocrinology or diabetologist care in (perhaps) multi-disciplinary hospital outpatient care, the remaining patients cared for in the community by their GP. This may affect the ability to access auxiliary services (diabetes nurse specialists, dieticians, chiropody), as well as exposure to patient education programmes.
- The process and quality of care delivery differs between countries – the primary problems being regional inequalities in access to diabetes care, insufficient human resources, lack of screening programmes, and insufficient funding for lifestyle change initiatives.

5. Cost burden of diabetes and its complications

As diabetes prevalence is increasing across the EU5, so is total health expenditure, including diabetes spending. Available estimates (e.g. IDF) suggest that the cost attributable to diabetes can be substantial, as shown in Appendix 5. Based on the methods outlined in section 2, this section summarises and discusses the total costs of people with diabetes for the study countries, including direct (inpatient, outpatient, pharmaceutical), indirect, as well as the limited sources of costs of complications resulting from diabetes.

5.1 Total health expenditure in EU5

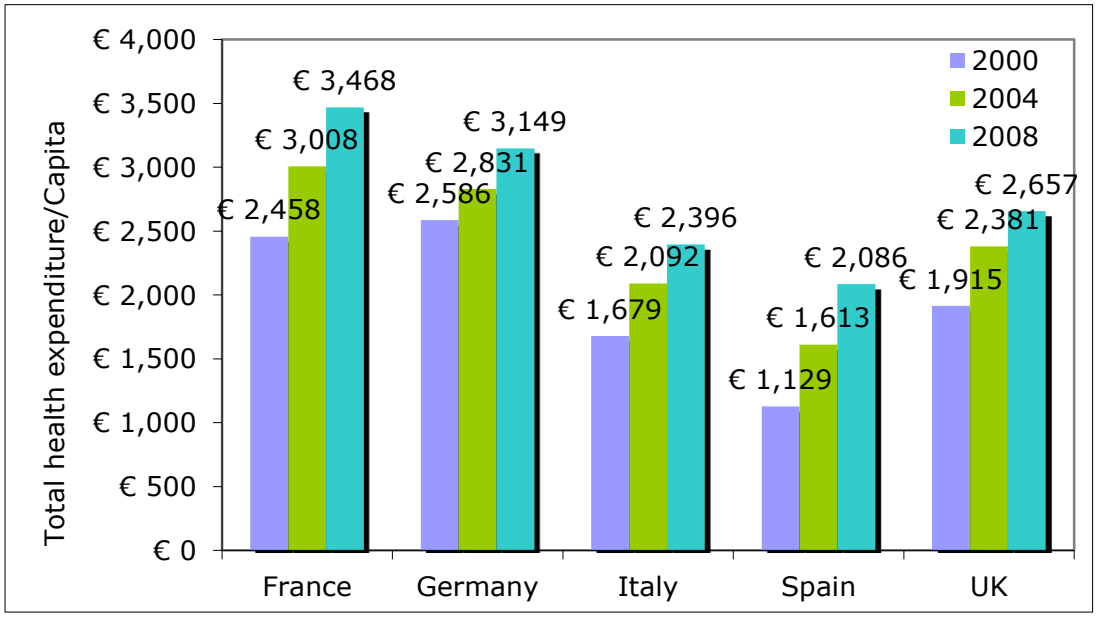
Health care expenditures are increasing rapidly: from 2000 to 2008, total health expenditure increased by 49% in France, 22% in Germany, 48% in Italy, 111% in Spain and 45% in the UK (Table 5.1). The greatest health spending growth per capita was in Spain (85%), followed by Italy (43%), France (41%), UK (39%) and Germany (22%) (2000-2008) (Figure 5.1).

Table 5.1: Total health expenditure in EU5, 2000-2008 (€, million)

	France	Germany	Italy	Spain	UK
2000	€ 145,182	€ 212,435	€ 96,040	€ 45,446	€112,793
2004	€ 182,707	€ 233,543	€ 120,421	€ 68,868	€142,491
2006	€ 199,228	€ 244,917	€ 133,585	€ 82,064	€163,883
2008	€ 216,063	€ 258,620	€ 142,167	€ 95,130	€163,593

Source: (World Health Organisation 2009). Current population estimates are used to arrive at total figures per country. Average exchange rates are used to convert to Euros.

Figure 5.1: Total health expenditure per capita in EU5, 2000-2008 (in €)[α]



Notes: [α] Country National Health Accounts data (WHO) (World Health Organisation 2009) divided by total population (OECD) estimates (Organisation for Economic Cooperation and Development (OECD) 2010). Average exchange rates are used to convert to Euros.

5.2 Direct cost burden of diabetes

5.2.1 Costs in In- and Out-patient Care Settings

Both in- and out-patient costs are major components of direct diabetes costs. Difficulties arise in their computations: differentiation between Type 1 & 2, whether diabetes medications are included or reported separately, and whether the cost of complications is included. National-level data is unavailable for most or all EU5 countries, thus the majority of data is obtained from regional studies, as shown on Table 5.2 reporting total direct costs and Table 5.3, reporting per patient costs.

France

In France, total direct costs reached €12.9 billion in 2010. The components of direct costs were: hospital costs 37.2% (€4.9bn), outpatient costs (excluding drugs), 36% (€4.6bn) and drugs 26.8% (€3.5bn).[xvii]

Germany

In Germany, the total direct cost burden arising from the treatment of people with diabetes has been estimated to be €43.2 billion in 2010. Inpatient and outpatient direct costs for Type 1 & 2 are very close in proportion (33.7% versus 28.2%), while 19.5% (€8.2bn) is expended on pharmaceuticals (both diabetes- and non-diabetes-related pharmaceuticals). The incremental cost of diabetes on health care costs increased from €12.9 billion in 2000 to €19.1 billion in 2007 (Köster et al. 2011) and €19.7 billion in 2010. A comparison of diabetes DMP members versus non-members found non-significant, higher annual hospital costs in non-members (€1,277 versus €1,158/patient; 2006 costs) (Linder et al. 2011).

Italy

Total direct costs in Italy amounted to €7.94 billion in 2010. The largest component of total direct costs in Italy is the cost of hospitalisation at 56.9% (€4.5bn), followed by 29.5% for drugs (€2.34bn) (Osservatorio Arno Diabete 2011).

Spain

In Spain, the total direct cost of diabetes reached €5.45 billion in 2010 and the largest component thereof was the cost of pharmaceuticals at 46% (€2.55bn), followed by inpatient care at 36% (€1.95bn) and by outpatient care (excluding pharmaceuticals) at 18% (€0.95bn) (Oliva et al. 2004). The most recent study of Spanish national diabetes direct costs calculate per patient costs at €1,708 annually (Type 1 & 2); 2002 costs extrapolated to 2010), whereas the average cost of a person without diabetes annually are €995 (Oliva et al. 2004) (in both cases 2002 costs extrapolated to 2010). An older regional study of the Canary Island estimate lower total diabetes costs per patient at €758 annually (1998 costs) (López-Bastida et al. 2002).

[xvii] 2010 extrapolations based on the 2009 ENTRED study reporting 2007 data.

United Kingdom

From national government sources, the UK only has total diabetes expenditure estimates. The Department of Health in England report direct diabetes costs as 5% of total health spending (2002-2006) based on estimates from a Type 2 cost study (Wanless 2002; Williams et al. 2002; Yorkshire and Humber Public Health Observatory et al. 2006), and thereafter increased this estimation to 10% (c. £9 billion), however, no costs were directly measured (Department of Health (2006) 2006; Diabetes UK March 2010). A few studies have attempted to quantify the cost of diabetes in the past (Bagust et al. 2002; Currie et al. 2004; Currie et al. 2005). Of these, (Bagust et al. 2002) found total annual costs £11.49bn for Type 2 diabetes patients (2000 costs inflated to 2010).

In the context of this study, two recent sources (one focusing on outpatient data over the 1997-2007 period (Currie et al. 2010) and the other on inpatient data in 2004 (Morgan et al. 2010)) are used to calculate the total direct cost of diabetes in the UK on a per patient basis and extrapolate to 2010, based on a national prevalence of 6.1%. Based on these, the total direct cost in the UK has been calculated to be £13.8 billion (€20.2 billion using the base year rate of exchange).

5.2.2 Costs by Diabetes Type

There is little national information regarding diabetes costs by type (Table 5.3).

France

French ENTRED 2007 data estimates for total costs were €6,927 for Type 1 patients and €4,890 for Type 2 patients. Expenditure for Type 2 patients treated with insulin (€10,413) was nearly 3 times higher than that of patients treated with oral anti-diabetic agents (€3,625). Annual outpatient costs per patient at €4,329 for Type 1 patients, €3,180 for all Type 2 - €6,546 for Type 2 with insulin and €2,409 with Type 2 without insulin. Annual inpatient costs per patient are €2,597 for Type 1, €1,710 per Type 2 - €3,866 for Type 2 with insulin, and €1,216 for Type 2 without insulin (Ricci et al 2009).

Germany

The German CoDiM study did not differentiate between Type 1 & 2 patients, however, patients treated with insulin mono-therapy (predominately Type 1 patients) had 3.4 times higher costs and patients with insulin plus oral hypo-glycaemic drugs had 3.1 times higher costs than matched non-diabetic controls (Köster et al. 2006).

Italy

Italian data also suggests Type 1 patients are twice as costly as Type 2 patients (Marchesini et al. 2010).

Spain

The Spanish data did not differentiate between Type 1 and 2 patients.

United Kingdom

As already discussed, no formal national government data exists on diabetes expenditure by diabetes type in the UK, partly due to the poor reporting of Type 1 versus 2 cases and also due to a lack of data systems to do so. In 2007, The Economist estimated per patient costs to be $4,794, as part of an international study (The Economist Intellegence Unit 2007). The academic literature points at the influence of diabetes type on costs. A simple combination of the in- (Morgan et al. 2010) and out-patient (Currie et al. 2010) costs by type (inflated to 2010 costs), estimates Type 1 annual costs per patient as €4,744 (£3,233) and Type 2 €5,470 (£3,717); the cost of pharmaceuticals is included in these calculations. It is estimated the percentage of patients with Type 1 diabetes is 8% for adults (15% for children) in the UK, and its application to national prevalence suggests spending €2.64bn (£1.8bn) for Type 1 and €17.28bn (£11.94bn) for Type 2, annually.

Table 5.2: Total direct diabetes cost burden: Medicines, In- and Outpatient care (estimates in € million)[1]

	France		Germany (total cost burden)[2]		Germany (incremental cost burden)		Italy[3]		Spain		UK
	Base year (2007)	2010	Base year (2007)	2010	Base year (2007)	2010	2008 [β]	2010 [β]	Base year (2002)	2010	2010
Total drug	€3,350[ξ]	€3,466	€8,190[α]	€8,438	€4,053	€4,175	€3,078	€2,344	€1,389	€2,549	€904 (£626)[T1] €3,644 (£2,522)[T2ψ]
Diabetes Drugs	*€770*[ξ]	*€797*	-	-	*€2,060*	*€2,122*	*€592*	*€492*	*€311*	*€570*	*€497 (£344)*[T1] *€1,029(£712)*[T2ψ]
Non-diabetes Drugs	*€2,580*[ξ]	*€2,669*	-	-	*€1,993*	*€2,053*	*€2,486*	*€1,852*	*€1,078*	*€1,978*	*€406(£281)*[T1] *€2,615(£1,810)*[T2ψ]
Inpatient	€4,700[ξ]	€4,862	€14,154[α]	€14,582	€6,003	€6,184	€3,636	€4,519	€1,060	€1,949	€1,494*(£1,007)*[T1] €11,926*(£8,038)*[T2ψ]
Outpatient (w/out drugs)	€3,450[ξ]	€4,604	€11,860[α]	€12,219	€4,735	€4,878	€921	€1,074	€515	€949	€245*(£170)*[T1] €1,674*(£1158)*[T2 ψ]
Other	€1,000[ξ]	-	€7,770[α]	€8,005	€4,310	€4,440	-	-	-	-	€336*(£230)*[ϫ]
Total[ζ]	**€12,500**[ξ]	**€12,932**	**€41,974**	**€43,244**	**€19,100**	**€19,677**	**€7,635**	**€7,937**	**€2,674**[δ]	**€5,447**	**€20,223**[ψ] (£13,812)

Notes: [1] With the exception of Germany, where costs are presented both as total direct burden as well as incremental costs, in the other study countries it is not possible to disentangle the non-diabetes-related costs. While a significant proportion of the latter can be attributed to diabetes (e.g. complications), others do not. Totals may be different from the addition of individual components due to rounding.

France: [ξ] Based on ENTRED 2007 data (Type 1 & 2), published in 2009 (Ricci et al. 2010). Inpatient includes private and state hospitals. "Outpatient" include GP, specialist, physiotherapy, nursing, pharmacy, dentistry and laboratory. Other costs include injection devices, self-blood glucose monitoring equipment, insulin pumps (€7m), oxygen-therapy and other medical devices. The total figure can be even higher than the one reported on this table if the prevalence of 6.39% is applied.

Germany: [α] CoDiM 2007 data (Type 2), published in 2011. Outpatient costs include physician and nursing care, transportation, other remedies, other outpatient services, care at home and long-term care (nursing insurance). Breakdown between diabetes and non-diabetes drugs was not available. Data was inflated to 2010 (Köster et al. 2011).

[2] Individual cost items arising from extrapolation of per patient costs to population level based on prevalence information used in the study.

Italy: [3] Italian cost data relies on 2 studies published in 2010 (Marchesini et al. 2010) and 2011 (Osservatorio Arno Diabete 2011) and referring to 2008 and 2010 respectively.

[β] Extrapolation of proportional direct cost composition applied to estimate of total direct cost for 2008 and 2011 from per capita figures as reflected in Table 5.3.

Spain: [δ] Spanish national data (2002) including Type 1 & 2 patients (Oliva et al. 2004). The 2010 figures are extrapolations based on the 2002 data.

UK: [ψ] Bottom up approach based on in-patient 2005 cost data from (Morgan et al. 2010), and out-patient 2007 cost data from (Currie et al. 2010); .The UK figure is susceptible to exchange rate fluctuations; the direct cost figure of £13.8 billion has based on 2005 and 2007 data, which have been converted to Euros using the prevailing exchange rates (2005: £0.674/€; 2007: £0.692/€), and extrapolated to 2010, then multiplied by UK prevalence (3.6 million) with a 15:85 Type 1:2 ratio (includes children, excludes N. Ireland) in order to arrive at the €20.2 billion figure.
[ϫ] Annual social services cost (2007, £230m), converted to 2007 Euros (£0.692/€) and added to the other direct cost extrapolations.

Other: [ζ] Cumulative sum of column. Estimate reflects extrapolated figures across years and studies. Differs from total direct cost estimate in Table 5.3.

[μ] Costs extrapolated to 2010 using annual GDP deflator for each country (International Montary Fund (IMF); Trading economics Main website; World Bank).

Table 5.3: Per patient direct diabetes cost burden: Medicines, In- and Outpatient care (estimates in €) [1]

	France		Germany (total cost burden)		Germany (incremental cost)		Italy[2]		Spain		UK	
	Base year (2007)	2010	Base year (2007)	2010	Base year (2007)	2010	2008	2010	Base year (2002)	2010	Base year (2005, 2007)	2010
Total Drugs	€1,409[ξ]	€1,458	€1,115[α]	€1,149	€553	€569	€1,076	€814	€649	€632	€1,532 (£1,060)[T1] €1,089 (£754)[T2]	€1,622 (£1,122)[T1] €1,153 (£798)[T2]
Inpatient Costs	€1,955[ξ]	€2,022	€1,927[α]	€1,985	€819	€843	€1,271	€1,569	€557	€829	€2,419 (£1,630)[T1] €3,417 (£2,303)[T2]	€2,681 (£1,807)[T1] €3,786 (£2,552)[T2]
Outpatient Costs (w/o drugs)	€1,483[ξ]	€1,533	€1,623[α]	€1,672	€646	€665	€322	€373	€128-193	€247	€415 (£287)[T1] €500 (£346)[T2]	€439 (£304)[T1] €530 (£367)[T2]
Physician	*€409[δ,ξ]*	*€423*	*€752[α]*	*€775*	*€339*	*€349*	-	-	*€128-193*	-		-
Nursing	*€440[ξ]*	*€455*	*€871[α]*	*€897*	*€307*	*€316*	-	-	-	-		-
Other	€403[ξ]	€417	€1,061[α]	€1,093	€588	€605	-	-	-			-
Total	**€5,251[ξ]**	**€5,432**	**€5,726**	**€5,899**	**€2,605**	**€2,684**	**€2,669**	**€2,756**	**€1,334-€1,476[3]**	**€1,708 (€3,015)[n]**	**€4,367 (£2,977)[T1] €5,007 (£3,403)[T2]**	**€4,744 (£3,233)[T1] €5,470 (£3,717)[T2]**

Notes: [1] With the exception of Germany, where costs are presented both as total direct burden as well as incremental costs, in the other study countries it is not possible to disentangle the non-diabetes-related costs. While a significant proportion of the latter can be attributed to diabetes (e.g. complications), others do not. Totals may be different from the addition of individual components due to rounding.

France: ENTRED 2007 cost data (Type 1 & 2) (Ricci et al. 2009). Inpatient includes private and state hospitals. Outpatient costs include GP, specialist, physiotherapy, nursing, pharmacy, dentistry and laboratory. Other costs include injection devices, self-blood glucose monitoring equipment, insulin pumps (€7m) and other medical devices.

Germany: [α] CoDiM 2007 data. "Other services" encompass medical devices, remedies, professional home nursing, transportation (Köster et al. 2011).

Italy: [2] Italian cost data relies on 2 studies published in 2010 (Marchesini et al. 2011) and 2011 (Osservatorio Arno Diabete 2011) and referring to 2008 and 2010 respectively.

Spain: Total drugs include diabetes and non-diabetes (complications) drugs. Outpatient costs include primary and endocrinology outpatient visits. All include Type 1 & 2 nationally, assuming 5% prevalence (1.675m patients) (Oliva et al. 2004)

[n] The figure in brackets relates to an extrapolation of the CODE-2 figure (1998) (Mata et al. 2002) and is inserted here for expositional purposes, although the two figures are not directly comparable.

[3] Range figures relate to different prevalence scenarios in (Oliva et al. 2004).

UK: [ς] Inpatient 2005 costs from (Morgan et al. 2010) and outpatient 2007 costs from (Currie et al. 2010). Inflated to 2010 costs and converted to Euros.

Other: [μ] Costs extrapolated to 2010 using annual GDP deflator for each country (International Montary Fund (IMF); Trading economics Main website; World Bank).

5.2.3 Direct Costs: Diabetes Medications

Diabetes medications are primarily consumed in outpatient settings, although emergency care medications will be administered in inpatient settings. Medication expenditures reported here are for all purposes including, but not specific to, complications.

France

In France of the €12.9 total direct diabetes cost burden in 2010, spending on medicines for patients with diabetes reached €3.47 billion (Ricci et al. 2009)[xviii]; of this, diabetes medication (oral €445m, insulin €352m) constitutes only 6.2% of the total diabetes direct costs. The largest component of non-diabetes medication was cardiovascular medication (€1.29bn), including cholesterol lowering (€320m) and anti-platelet (€207m), followed by psychotropic drugs (€165m), antacids (€155m), antibiotics (€62m), immune-suppressants (€54m), anti-anaemic drugs (€54m) and other drugs (Ricci et al. 2009).

Germany

In Germany, the CODiM study found that total drug costs do not exceed 20% of total diabetes expenditure (€8.4 billion of the total 43.2 billion spending in 2010) and that total per capita drug spend stands at €1,149 (Köster et al. 2011). A comparison of diabetes DMP members versus non-members found significantly higher annual prescription costs in non-members (€1,164 versus €1,309/patient; 2006 costs) (Linder et al. 2011).

Italy

In Italy, total expenditure on medicines in 2010 amounted to €2.34 billion (31.8% of total direct cost), of which €492 million are for glucose lowering drugs (6.2% of total direct cost) and the remainder for drugs treating co-morbidities and complications of diabetes.

Spain

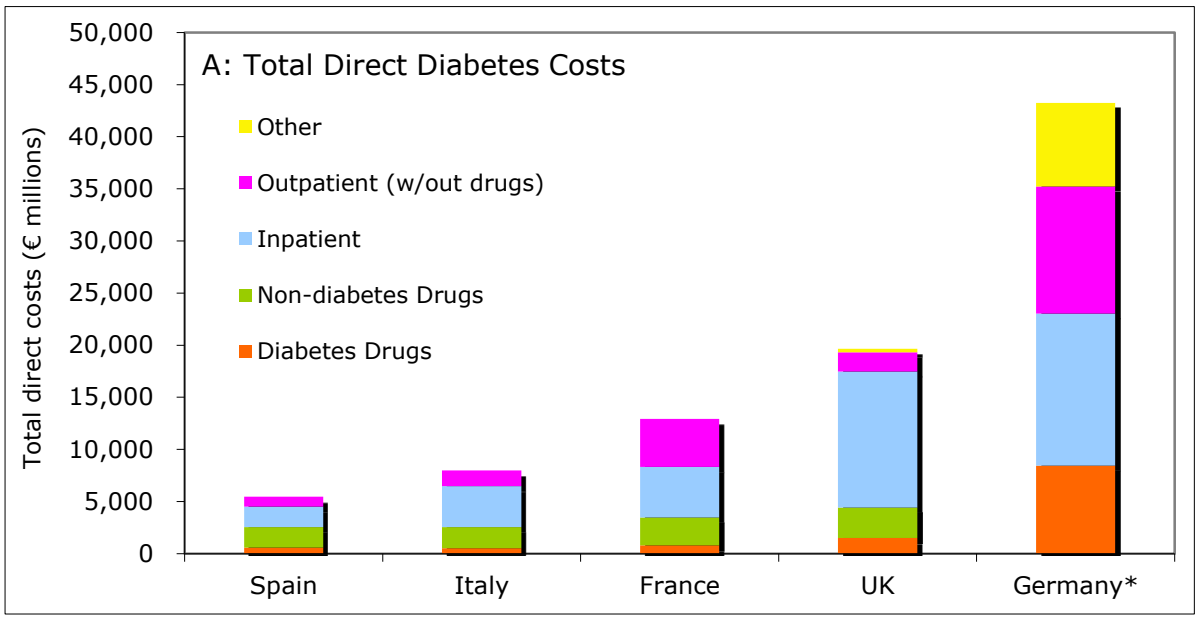
In Spain, 2002 projections suggest that total expenditure on pharmaceuticals stood at €2.55 billion in 2010, of which only 22% (€570 million) related to diabetes medicines (10.5% of the total direct cost of diabetes), whereas the remaining 78% related to non-diabetes drug costs. This split between diabetes and non-diabetes drugs is also confirmed by other studies in the Spanish context (López-Bastida et al. 2002; Oliva et al. 2004).

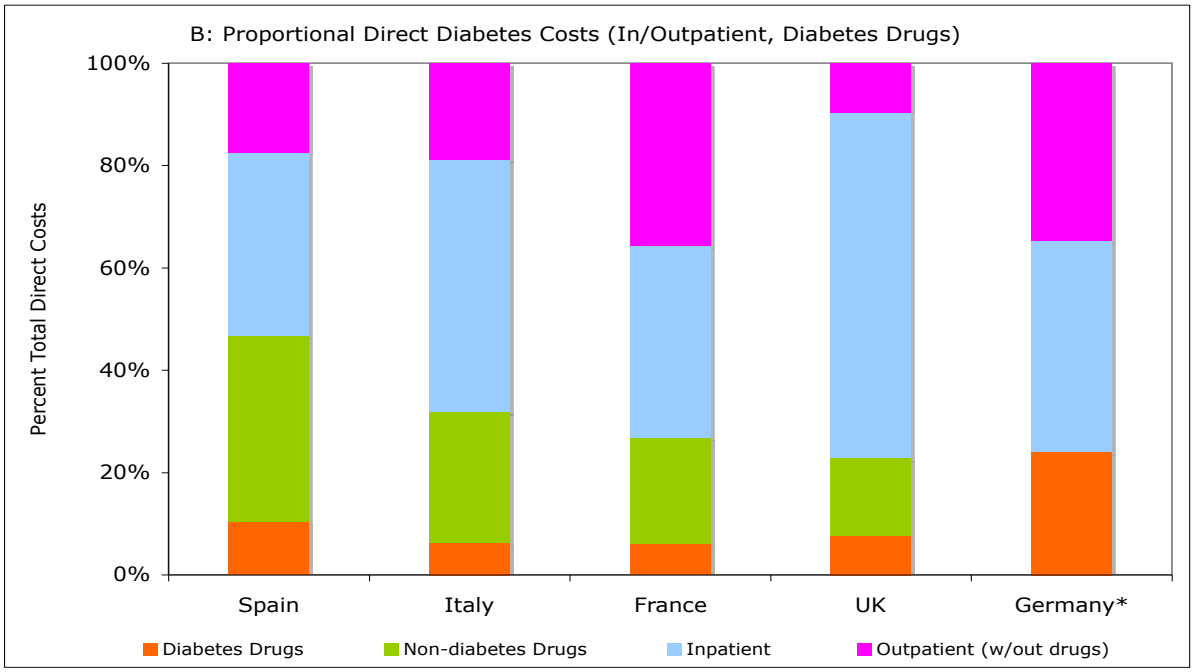
United Kingdom

In the UK, total drug spend related to diabetes reached €4.54 billion (£3.148 billion), of which €1.52 billion (£1.056 billion) (7.5% of total direct cost) was related to diabetes per se. Overall, diabetes medications are a fraction of total diabetes direct costs (Table 5.2): 6.2% in France, 6.2% in Italy, 7.5% in the UK, and 10.5% in Spain; in Germany it was not possible to calculate this figure.

[xviii] Based on 2007 data that has been inflated to 2010.

Figure 5.2: Total direct diabetes cost burden (A), and proportional comparison of in- and outpatient costs, and diabetes medicines (B) (2010 estimates, € million).[α]





Notes: [α] All data and sources as per cost outline in Table 5.2.
No non-diabetes medicine costs are available for Germany. No 'Other' costs available for France, Italy, Spain.
* Germany diabetes drugs include also non-diabetes drugs (ie drugs for managing diabetes complications and other non-diabetes-related conditions) as both diabetes and non-diabetes drugs were included in the same accounting.
^ UK 'Other' includes social care costs, and overall total derived from a bottom-up approach.
Source: The authors from Table 5.2.

5.3 Complications related to diabetes and associated costs

There are several complications arising from diabetes, due to the damaging nature of glucose molecules on the micro- and macrovascular system, particularly when combined with obesity (especially in Type 2 patients). The main complications are cardiovascular disease, coronary heart

disease, blindness, nephropathy, peripheral neural disease, amputations, depression and erectile dysfunction. Scant data on the costs of screening, monitoring and treatment exists; few studies have addressed this in a comprehensive way (Ray et al. 2005). As discussed in the methods section, there are significant difficulties with examining cost of complications resulting from diabetes (poor coding of complications, inclusion of complications cost data in general diabetes costing and poor identification of diabetic patients with complications). None of the study countries collect *national* data on costs of complications resulting from diabetes, thus all cost data come from regional studies.

Complications can lead to hospitalisation of patients. The hospitalisation rate is highest among patients under age 20 (54%) and patients over age 80 (42%). In the UK, the 2010 National Diabetes Inpatient Audit (with 93% PCT participation rate with 12,191 visits) found the median length of stay was 8 nights versus 5 for non-diabetic patients. Other significant findings were that older patients (75 years versus 67) experienced higher rates of emergency admissions (86% vs 58%) and almost half were treated with insulin (NHS Diabetes 2010). The Audit also found that 9% of in-patient diabetes admissions were due to complications such as ketoacidosis, hyperosmolar hyperglycaemic state, active diabetic foot disease, hypoglycaemia or hyperglycaemia with established diabetes (NHS National Information Centre 2010). Of this 9%, 44.4% had been admitted for active diabetic foot disease and 20.4% for hypoglycaemia (NHS National Information Centre 2010).

Köster et al. (2011) estimate that the average incremental direct in-patient costs attributed to diabetic patients in Germany (in comparison to non-diabetic patients) were €819 per patient in 2007 (Köster et al. 2011)[xix]. Complications relating to diabetes substantially inflate per patient treatment costs. Findings from the French ENTRED 2007 study indicate that the cost for diabetic patients with complications is 1.7 times higher for macrovascular complications, 1.1 times higher for microvascular complications, 6.7 times for nephrology complications, 2.51 times for major comorbidities (cancer, dementia, Parkinsons, stroke, heart disease) and 1.55 times higher for morbid obesity (BMI>40) (Ricci et al. 2009). The German CoDiM study found 41% of Type 2 patients on oral antidiabetic agents had macrovascular complications compared to 52% of Type 1 and Type 2 with insulin (Köster et al. 2006). Total Spanish annual direct costs per patient with no complications are €883; this figure increases significantly with the addition of complications: microvascular €1,403, macrovascular €2,021 and multiple complications €2,132 (1998 costs) (Mata et al. 2002). Eighty-six percent of total chronic complication costs relate to macrovascular complications, the remaining 14% relates to microvascular complications (Oliva et al. 2004).

Many patients present with more than one complication; the cost of two complications is greater than one, while the addition of a third complication further raises this cost substantially. An exploration of a UK patient dataset finds that coronary heart disease plus cardiovascular disease costs €3,339

[xix] Cost figures were standardised to match the age and gender distribution in the overall population in Germany.

(£2,250) (per patient, while the addition of a diabetic foot raises it to €4,175 (£2,814) (Currie et al. 2005)[xx].

Finally, the perspective used in cost analysis impacts the estimated cost calculations; for example, the total cost of diabetic retinopathy in Germany, from a societal perspective, using 2002 data, was 46 – 60% higher than the same cost when applying a payer perspective (Happich et al. 2008).

5.4 Selected complications related to diabetes and associated costs

This section outlines the relevant costs of individual complications based on available evidence from the literature and the survey tool that was administered in each of the 5 study countries. For the latter, data has been collected from regional and/or small scale national studies, as well as from cost effectiveness analyses of diabetes treatments. Individual costs are also given from hospital tariff data if comprehensive costs could not be found.

The part of data obtained from the survey tool is summarised in Appendix 7 for diabetic retinopathy (Appendix 7A), diabetic foot (Appendix 7B), cardiovascular disease (Appendix 7C) and renal disease (Appendix 7D).

5.4.1 Diabetic retinopathy and blindness

The literature suggests that diabetic retinopathy affects 10-28.7% of patients (Delcourt et al. 2009; Jaffiol 2009), while blindness develops in 0.5- 3.7% of diabetic patients (Fagot-Campagna et al. 2009; Linder et al. 2011). The general cost of eye disease is estimated at €3,124 per patient (Agenzia sanitaria e sociale regionale 2009), with specific costs for cataract operations estimated at €1,041-€1,878 (Spain, Italy), laser treatment €60-€3,477 (Italy, Germany) and blindness €382-€10,547 (France, Germany) (Ray et al. 2005). The LSE survey found that the cost of cataract surgery ranged between €397 (France) and €2,830 (UK). Examination of the UKPDS data for diabetic patients found the cost of blindness in one eye was €1,589 (£1,100) (1998, inflated to 2010) (Clarke et al. 2003). Some issues in the delivery of care exist, particularly with respect to inequitable access to eye services as a result of an insufficiency of optometrists and appropriately qualified ophthalmologists in France (Delcourt et al. 2009) and long waiting times for diagnosis in Spain.

5.4.2 Foot disease

Peripheral arterial occlusive disease (PAOD) is the initial stage of foot disease, affecting 1.5-9.9% of diabetic patients (annual incidence 0.5-3% (Fosse et al. 2006)), resulting in ulcers and wounds (Fagot-Campagna et al. 2009; Linder et al. 2011). If blood glucose control remains poor and foot checks are not performed daily this may result in gangrene, amputation of toes or all or part of a foot (0.2-0.3% of all cases) (Linder et al. 2011).

[xx] 1999 data inflated to 2010.

Microvascular complications, including diabetic foot, have been shown to increase diabetes costs in the French ENTRED study (Ricci et al. 2010). A French study found that total healthcare costs without inpatient care were €840/patient monthly and €2,546-€2,772 with inpatient care (2000 costs inflated to 2010)[xxi] and that costs are highest in patients with inpatient care or amputations, particularly in the first month and decreasing thereafter (Girod et al. 2003). The 2009/10 hospital tariffs in the UK for foot disease are classified via cardiac status and electivity and range from £7,432-£13,490 (€8,427-€15,305) for amputation, £863-£5,109 (€979-€5,796) for diabetes foot procedures. Amputation in the UKPDS study cost €16,763 (£11,298) (Clarke et al. 2003), and diabetic foot annual per patient costs were €1,523 (£1,026) (Currie et al. 2005), while per admission costs were €5,780 (£3,890)(Morgan et al. 2010) (2001 and 2006 costs respectively both inflated to 2010). Other broader per patient estimates include neuropathy €63-€3,855 (France, Germany), lower limb amputations €9,515-€32,000 (Italy, France), prosthesis €1,138-€3,241 (France, Germany), gangrene treatment €1,783-€5,611 (Germany, Spain) and ulcer treatment €1,783-€1,999 (Germany, France) (Ray et al. 2005).

5.4.3 Cardiovascular disease

Cardiovascular disease, including angina (16%), myocardial infarctions (1-8%), stroke (1.7-7%), ischemic heart disease and heart failure (6.3-11%) are the major complications resulting from diabetes (Fagot-Campagna et al. 2009; Linder et al. 2011; Williams et al. 2002), in particular when combined with being overweight or obese, which is very common in Type 2 diabetes. The triad of excess body adipose, poor blood glucose control and other cardiovascular risk factors (high blood pressure and lipid abnormalities)is often accompanied by additional complications such as diabetic foot, increasing costs substantially (Currie et al. 2005).

A significant proportion of diabetes patients are treated with prescription medicines, including ACE inhibitors, with angiotensin 2 receptor blockers, statins, calcium-channel blockers, beta-blockers, aspirin, and clopidogrel. Therapeutic options are comparable across the study countries and in some cases there is a quantification of the relevant cost (e.g. in France (Robert et al. 2009)). The cost of treating MI and stroke among diabetic patients is also important as the cost is substantial due to the intensity of treatment and length of stay (LOS), as shown in UK (Clarke et al. 2003; Currie et al. 2005; Morgan et al. 2010) and French settings. Compared to all inpatients for non-diabetes reasons, diabetes results in 6-23% greater costs in this particular therapeutic area (Colin et al. 2007). Indicatively, treatment costs range from €2,100 (fatal MI, UK) - €9,767 (MI, Germany) for myocardial infarctions and €4,314 (UK) - €11,786 (Germany) for stroke (Appendix 7C).

[xxi] This study also provides costs per Grade 1-4.

5.4.5 Renal disease

Poor blood glucose control results in permanent macro-and microvascular damage of the nephron tubules in the kidneys. Renal insufficiency starts with microabuminuria (20-25%), progressing onto renal disease, end stage renal disease (ESRD) (0.4-3.0%) requiring haemo- or peritoneal dialysis, and finally kidney transplant (Type 1 incidence 7.7-9.2%; Type 2 0.3-2.6%) (Linder et al. 2011; Soedamah-Muthu et al. 2008a; Soedamah-Muthu et al. 2008b; Williams et al. 2002). The incidence of ESRD associated with diabetics is 46.7 per million inhabitants and 129 per 100,000 diabetics (Couchoud et al. 2008). The majority of annual nephrology treatment costs are attributed to Type 2 patients, although Type 1 patients reflect 25% of all ESRD patients and 85% of all diabetes kidney transplants (Gordois et al. 2004).

French ENTRED patients with dialysis or transplant (n=25) had inpatient costs at €42,625/patient while outpatient costs were €22,758/patient (2007 costs), leading to a total cost of €65,383 (Ricci et al. 2010). A Monte Carlo stimulation suggested a total cost of €70,364/patient/year for ESRD treatment with dialysis[xxii] (2002 costs inflated to 2010) (Palmer et al. 2006). Primary evidence collected for the purposes of this study showed that in 2010 haemodialysis carried an annual cost of €81,449 and peritoneal dialysis €49,953 (see Appendix 7D).

In Spain, it is estimated that diabetic patients are 25 times more likely to suffer from renal insufficiency. Survey data suggest that the cost of haemodialysis is Spain €41,052 and peritoneal dialysis at €24,515 per annum (Appendix 7D). Similarly, ESRD disease carries an annual cost estimated at €53,764 (£36,237) reflecting the higher costs of dialysis, while the cost of renal transplants in the UK is estimated to be €33,437 (£22,537) per patient (Appendix 7D). Early stages of microalbuminuria are estimated at €166 annually for monitoring, while overt nephropathy already raises costs substantially to €11,993 (£8,083) per patient annually (2001 costs inflated to 2010) (Gordois et al. 2004). A more recent 2006 costing exercise found that renal disease cost €1,742 per admission (inflated to 2010) (Morgan et al. 2010).

5.4.6 Erectile dysfunction

Approximately 32% of Type 1 male patients and 46% of Type 2 male patients suffer from erectile dysfunction (Phé et al. 2009)[xxiii]. Treatment options include inter-cavernosal injections, penile implants and PDE-5 inhibitors are available to treat erectile dysfunction. The cost of penile implants is not high and has been reported to be between €225.9 (rigid or semi-rigid) and €261.3 (hydraulic penile implants) plus anaesthesia costs in France. In the UK, erectile dysfunction treatment in hospital treatment costs £232 (National Tariff). Typical problems in this context are (a) the long waiting times

[xxii] No information on peritoneal versus haemodialysis.

[xxiii] Data based on France. These figures correlate with an overall prevalence estimate for erectile dysfunction in male patients of 30% in Spain.

for both diagnosis and treatment as well as the regional variations in this regard (France, Spain, UK), (b) the relative lack of urology and andrology specialists (reported in France) and (c) the reduced reimbursement potential of treatments in this diagnosis.

5.4.7 Neurological complaints

In Spain, 25% of diabetic patients have some form of neurological complaint. Patients can be treated pharmaceutically at considerable cost. Treatment options include duloxetine, amitriptyline, tramadol, pregabaline and gabapentine. In Spain and the UK, the primary problem is long waiting times for both diagnosis and treatment, which vary between regions and can range between 3-4 months.

5.5 Indirect cost burden of diabetes

5.5.1 Historical evidence

Very little information on indirect costs related to diabetes is available. However, the potential impact of diabetes is manifold: the inability to work to full capacity or at all, resulting in reduced productivity or early retirement; routine contact with medical services resulting in absenteeism; inability to work during hypoglycaemic episodes; parents involved in the care of their Type 1 children and other (family) carers looking after elderly patients. The long-term impact includes, early retirement due to complications from diabetes, premature mortality and potential mobility issues with amputations and blindness. Indirect costs from all five countries are explored here (in as much detail as possible), using multiple sources.

A French study has suggested that indirect costs could represent at least one-third of the total costs of diabetes (Ricci et al. 2009). Examination of diabetes patients under the aforementioned ALD8 scheme finds that 3.6% of diabetes patients receive disability pensions of €7,060 annually, as well as a monthly allowance averaging €228/patient (8.5% of diabetics receive this monthly allowances averaging €2,661 annually) (2004 data) (Vallier et al. 2006). Utilising the costs calculated in the ENTRED study (2009) indirect cost have been estimated at approximately €5bn (Santé log 2010).

In Germany, annual indirect costs were estimated to be averaging €5,019/patient (range: €0-€35,808 based on 2001 data), including productivity losses due to the inability to work (€764 per patient) and early retirement (€4,255 per patient). When this figure is multiplied by the German prevalence an estimated indirect cost of €36.5bn is produced.

Older indirect costs estimates are available for Italy, including productivity losses, early retirement in Type 2 patients, and produce an estimate of 4.5% of total diabetes costs (1998) (Lucioni et al. 2000). When this estimate is applied to 2009 total diabetes costs (Table 5.2), indirect costs are estimated at approximately €356.5m – much lower than the other countries and potentially a significant underestimation given the date of the data.

As a proxy for indirect costs in Spain, a study that calculated indirect costs for Canary Islands was used (López-Bastida et al. 2002). Costs were calculated using the costs of prevalence in 1998 based

on a Type 2 patient cohort. The costs of premature mortality and time off work were estimated as €6.4 billion and €8.4 billion respectively, a total of €14.8 billion. In contrast, a subsequent national examination estimated total indirect national costs as €2.8 billion (Oliva et al. 2004).

There are no government or academic sources of direct versus indirect costs for the UK. The publication, The Economist, published a special edition on the costs of diabetes, which estimated that the 2007 productivity loss costs of diabetes were €1,078 (£746)/patient and the average lifetime earning loss to be €54,920 (£38,005)/patient. Total productivity loss in the UK was estimated to be €2.41 billion (£1.7 billion) (The Economist Intellegence Unit 2007).

5.5.2 Estimates of indirect cost in 2010

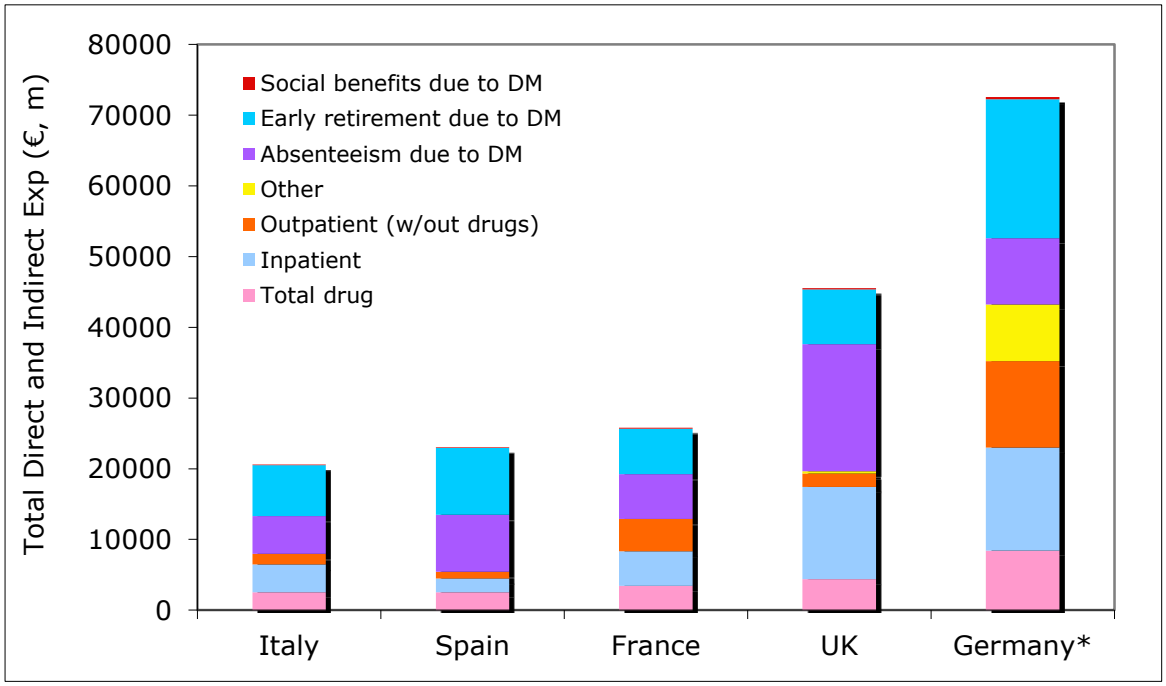
For the purposes of this study we have attempted to calculate the indirect cost of diabetes, focusing on three components, namely, the cost of absenteeism due to illness, the cost of early retirement, and the cost of social benefits. These were variables for which data was available, both in terms of the relevant probabilities and costs.

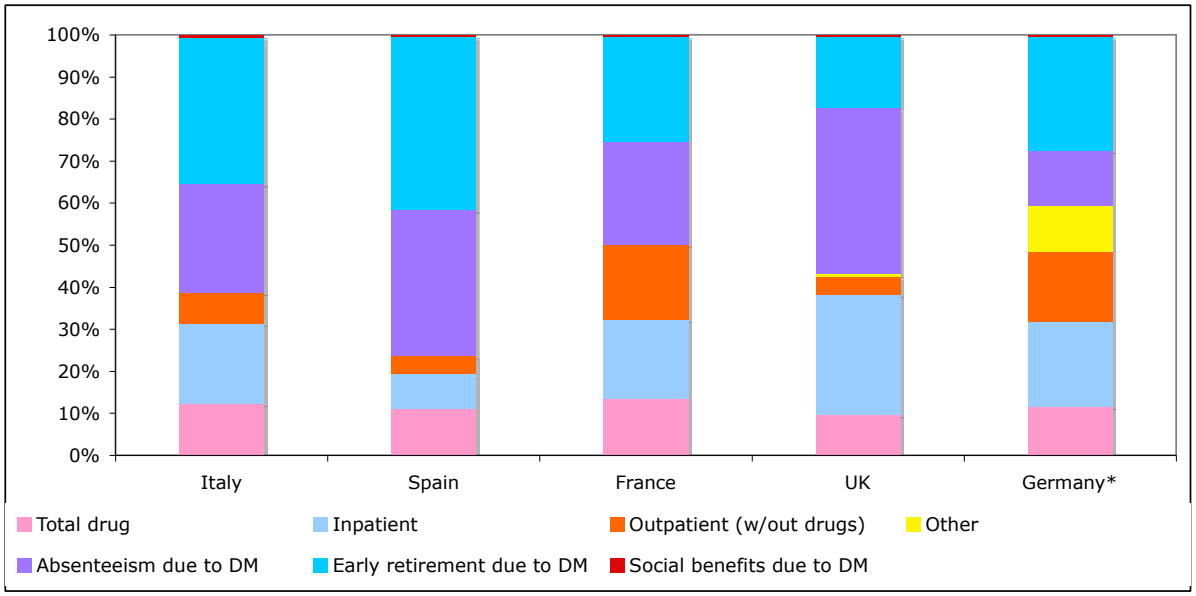
Cost estimates for each of these parameters come from national sources, while the respective probabilities have been pooled from national sources as discussed in the methods section and, in particular, as shown in Table 2.1. Based on these estimates, the indirect and measurable cost of diabetes in EU5 stands at €98.4 billion and exceeds that of the total direct cost (Table 5.4). The indirect cost calculations are €17.3 billion (£15.4 billion) in the UK, €37.9 billion in Germany, €12.9 billion in France, €12.6 billion in Italy and €17.6 billion in Spain. Indirect costs are shown to be comparable in size to direct costs in Germany, France and the UK, exceed direct costs by a factor of 2-to-1 in Italy and by a factor of 3.5-to-1 in Spain.

It has not been possible to include estimates on productivity losses (presenteeism), the cost of premature mortality and any carer costs associated with caring for a diabetic relative. Consequently, the figures on Table 5.4 potentially under-estimate the true indirect cost of diabetes.

Based on the calculations in this section regarding direct and indirect cost and taking into consideration the limitations in the available evidence and the issues concerning exclusion of the costs of conditions not necessarily related to diabetes, the direct and indirect cost burden of people with diabetes across the 5 study countries amounts to €188 billion in 2010. A comparison of direct and indirect costs is shown on Figure 5.3.

Figure 5.3: Direct and indirect cost burden of diabetes in EU5 (2010 estimates, € million)





Notes: No 'Other' costs available for France, Italy, Spain. The UK figures are susceptible to exchange rate fluctuations; the UK direct cost figure stands at £13.8 billion and is based on data from 2005 and 2007, which have been converted to Euros using the prevailing exchange rates (2005: £0.674/€; 2007: £0.692/€), and extrapolated to 2010 in order to arrive at the €20.2 billion total direct cost figure. For the 2010 indirect cost data (£15.4 billion or €17.3 billion) the prevailing (2010) exchange rate has been used (£0.893/€).
* Germany diabetes drugs include also non-diabetes-related drugs as this figure could not be disaggregated.
Source: The authors based on Table 5.2 Table 5.4.

Table 5.4: Estimated total cost of absenteeism, early retirement, and social benefit among diabetes patients in EU countries, 2010.

	Diabetic population in active employment (estimate)	Average daily earnings (2010)	Average annual cost: absentee-ism (per person, €)	**Total annual national cost: absentee-ism (in € million)**	Diabetic population: early retirement	Average annual pension (per person, €)	**Total annual national cost: early retirement (€ million)**	Diabetic population receiving social benefits	**Total annual cost: social benefits (in € million)**	**Total cost: absenteeism early retirement & social benefit (€ million)**
UK	1,728,290	**€**130.8 (£117) [A]	**€**5,428 (£4,847)	**€9,382.7** (£8,379)	645,214	**€**11,988.6 (£10,705)	**€7,736.6** (£6,909)	89,202	**€169.5** (£152)	**€17,288.8** (£15,440)
Germany	3,389,597	€127.8 [C]	€5,303.7	**€17,977.4**	1,265,449	€15,518	**€19,637.2**	174,947	**€324.8**	**€37,939.4**
France	1,330,940	€114.2 [C]	€4,739.3	**€6,307.7**	496,884	€13,015	**€6,466.9**	68,694	**€113.9**	**€12,888.5**
Italy	1,333,671	€96.9 [C]	€4,021.4	**€5,363.2**	497,904	€14,439	**€7,189.2**	68,835	**€97.1**	**€12,649.5**
Spain	1,729,934	€78 [C]	€3,237	**€8,044.2**	645,842	€14,686	**€9,484.8**	89,287	**€101.2**	**€17,630.2**
Total		NA	NA			NA			**€806.5**	**€98,396.4**

Notes: NA: not applicable; for the UK sterling data have been converted to Euros using the Sterling/Euro rate of 0.893, which was the prevailing exchange rate at the time of data availability (2010).
Sources: A: UK ASHE (2010) (Office for National Statistics 2010); B: UK PPI (2010) (Policy and Pensions Institute (PPI)); C: Eurostat (2009) (Eurostat 2009); OECD (2011) (Organisation for Economic Cooperation and Development (OECD) 2011).

5.6 Summary and discussion

None of the 5 countries have accurate or detailed government cost data, either nationally or per patient. However, a number of academic studies have delivered figures, which when extrapolated to a common point in time – 2010 - provide an indication of what the direct and indirect cost of diabetes is likely to be at national level, or per patient, per diabetes type or per complication(s).

Overall, the direct cost burden of a person with diabetes varies considerably across countries (France €5,432; Germany €5,899 (€2,684 if only the incremental costs are considered), Italy €2,756, Spain €1,708, UK €4,744 (£3,233) (T1) - €5,470 (£3,717) (T2)). France, Germany and the UK have considerably higher per patient diabetes costs than Italy and Spain.

The total direct national diabetes cost burden varies substantially across countries in 2010 (France €12.9 billion, Germany €43.2 billion (or €19.7 billion if only the incremental cost is considered), Italy €7.94 billion, Spain €5.45 billion and the UK £13.8 billion or €20.2 billion), and if they are put together they amount to €90 billion in 2010.

Diabetes drug costs (insulin and oral hypoglycaemic agents) are the smallest component of drug, in- and out-patient costs combined, ranging from 6.2% (France and Italy) to 10.5% (Spain). All countries have reported increases in diabetes medication spending, although the majority of diabetes medicines are generic and lower cost. Conversely, non-diabetes medications are 3 to 4 times the cost of diabetes medications, with cardiovascular medicines consuming the largest portion in terms of both cost and prescribing.

Inpatient costs are consistently higher than outpatient costs in all countries, due to increased medical care required with diabetes-related complications. Outpatient costs on the other hand, as well as diabetes medications, can be less than half of inpatient costs due to the relatively low costs of maintaining good glycaemic control via medication and regular monitoring.

Measurement of direct costs is poor in all countries and accounting for indirect costs is either absent (UK) or poor which prevents total diabetes costs from being accurately quantified.

The presence of complications, particularly multiple complications, can multiply diabetes costs several times, particularly in conditions such as renal failure.

Very little information on indirect costs arising due to diabetes is available. However, the potential impact of diabetes is manifold and entails significant indirect costs, chiefly relating to the economy (but outside the remit of health care services), such as reduced productivity and sickness absence, the wider social sector, such as early retirement and drawing social benefits, as well as the impact on family, through informal caring and carer costs as well as dealing with the effects of premature mortality. Having identified costs due to absenteeism, early retirement and expenditure on social benefits, these amounted to a total of €98.4 billion across the study countries in 2010 (€37.9 billion in Germany, €17.6 billion in Spain, €17.3 billion (£15.4 billion) in the UK, €12.9 billion in France and €12.6 billion in Italy). In the cases of Germany, the UK and France, these indirect costs are on a par

with direct costs, whereas in Italy and Spain, they are shown to exceed direct costs by a factor of 2-to-1 and more than 3-to-1 respectively. This is an under-estimate since the costs of reduced productivity, premature mortality or informal carer costs could not be accounted.

Country variations in the direct cost estimates provided in this study are due to two reasons: the first is prevalence, which altogether affects total cost at country level and, as outlined in the methodology, prevalence estimates can vary significantly in the absence of a single monitoring tool that provides robust estimates both within and across countries. The second reason for cost estimate variations is attributed to the type of costs included in them. All data accounts for portions of diabetes costs differently and there appears to be little consistency within and across countries. This is a point that merits further discussion, however, due to the complexity of diabetes as a disease. Treating diabetes per se represents a fraction of the total cost because of complications arising from diabetes. It is known that hospital expenditures for diabetic patients are likely to be even higher because hospitalisations for conditions such as a cataract or dialysis sometimes will not be considered diabetes-related hospitalisations. In addition, hospitalisation costs can be impacted further because diabetes increases the length of stay. For example, the average length of stay for diabetes patients following cardiovascular events is longer (stroke: +2.5 days; MI: +1.5 days; unstable angina: +1.3 days; revascularisation: +2.8 days) and, therefore, costlier (non-fatal stroke: +23.9%; non-fatal MI: +10.4%; unstable angina: +6.1%; revascularisation: +9.1%) than for non-diabetic patients (Chevreul et al. 2011).

In this context, disentangling costs that - *sensu stricto* – are attributed to diabetes and those that are not (for example due to a pre-existing co-morbidity) is challenging for two reasons: first, because diabetes may exacerbate a pre-existing co-morbidity and the cost, as a result, can be higher than would otherwise be the case and, second, health accounting is not always particularly helpful in attributing costs in a precise manner, for example, those which are diabetes-related and those that are not. Consequently, the majority of direct cost figures represent an approximation rather than a true reflection of reality.

Box 5.1: Cost burden of diabetes - Key takeaways

- Direct per patient diabetes costs vary considerably across countries (France €5,432; Germany €5,899 (€2,684 considering only the incremental cost), Italy €2,756, Spain €1,708, UK €4,744 (£3,233) (T1) - €5,470 (£3,717) (T2)). France, Germany and the UK have considerably higher per patient diabetes costs than Italy and Spain.
- The direct national diabetes cost burden varies substantially across countries (France €12.9 billion, Germany €43.2 billion [or €19.7 billion if incremental costs are taken into account], Italy €7.94 billion, Spain €5.45 billion and the UK £13.8 billion or €20.2 billion), predominantly driven by prevalence, but also due to higher per patient costs in France, Germany and the UK. As a result, total direct cost burden of people with diabetes in the study countries in 2010 has been estimated to amount to €90 billion.
- Data availability as well as the chosen cost calculation approach may vary through countries, and this can contribute to cost differences. With the data currently available for most countries it can be difficult to capture the actual costs of diabetes, in particular because it is hard to disentangle diabetes-related costs from the costs of co-morbidities which are not directly related to diabetes. In some settings hospitalisations for conditions such as cataracts or dialysis are not considered diabetes-related, even if they are the result of diabetes. Furthermore, in an unrelated condition, diabetes is known to often have a significant impact on hospitalisation costs because it will increase the length of stay.
- Diabetes drug costs are the smallest component of drug, in- and out-patient costs combined, ranging from 6.2% (France and Italy) to 10.5% (Spain). Conversely, non-diabetes medications are 3 to 4 times the diabetes medications in terms of total costs, with cardiovascular medicines consuming the largest portion in cost and prescribing.
- Inpatient costs are consistently higher than outpatient costs in all countries, due to increased medical care required with diabetes-related complications. Outpatient costs on the other hand, as well as diabetes medications, can be less than half of inpatient costs due to the relatively low costs of maintaining good glycaemic control via medication and regular monitoring. The presence of complications, particularly multiple complications, can multiply diabetes costs several times.
- The indirect cost of diabetes exceeds €98.4 billion in the 5 study countries, although this is more than likely to be an under-estimate, as it does not take into consideration the cost of premature mortality, productivity losses and carer costs.
- The total (direct and indirect) cost burden of diabetes has been estimated to amount to €188 billion in the 5 study countries.

6. Outcomes

6.1 Recommendations for monitoring patients with diabetes

A number of tests are recommended for monitoring diabetic patients (Table 6.1). In practice, the percentage and frequency of patients tested does not always reflect the guidelines. Routine measurement of glycosylated haemoglobin (HbA_1C[xxiv]) every 3 to 12 months is recommended, depending on country and diabetes type (more frequent in Type 1 and Type 2 with insulin). While quarterly HbA_1C monitoring is recommended in France, 2007 survey data found only 44% of Type 2 diabetics had their HbA_1C tested three times, although 90% had at least one test (Robert et al. 2009). The 2008/09 UK National Diabetes Audit found over 86% of adult and paediatric patients had their HbA_1C measured during the past year, with 25% of adult patients and 16% of paediatric patients meeting the recommended target of $HbA_1C<6.5\%$. Spanish data indicates that, in 2007, 82% of Type 2 patients had their HbA_1C tested. However, these figures are misleading, as they do not allow a measurement of the degree of quarterly or biennial testing, which is actually recommended (NHS National Information Centre 2011). No data is publicly available on the frequency of HbA_1C testing in Germany, as this information is specific to the sickness funds, or Italy (although in Italy, the AMD collects information on process measures relating to HbA_1C).

Total cholesterol (TChol), high density lipoprotein (HDL), low density lipoprotein (LDL) and triglyceride (TG)) monitoring is recommended as markers for cardiovascular disease, particularly when combined with HbA_1C, body mass index (BMI) and blood pressure. Monitoring frequency varies between countries, but all recommend minimum annual testing (Table 6.1). In France, ENTRED evidence indicates that only 72% were monitored for LDL-cholesterol and 76% for Triglycerides (TG). In Spain, 85% had their cholesterol levels tested and 77.5% had their total cholesterol measured in 2007. In the UK, at least 75% 90% of adults and 30% of children received cholesterol monitoring, with over 73% of both groups achieving recommended total cholesterol levels of <5.0mmol/L (NHS National Information Centre 2010). No data is available for Germany.

Both creatinine and albumin should be tested regularly to monitor for renal damage. In France, annual urinary albumin testing is recommended, however, in 2007 only 26% of patients were monitored. In Germany only 20% of diabetics are tested annually, while in Italy, urinary protein measurements are rarely undertaken, based on available information. Survey feedback from Italy indicates that creatinine and albumin levels are checked as part of routine exams, however the frequency is not clear. In Spain the recommendation is 1-2 times per year, with 71% tested in 2007. In the UK, evidence from 2008/09 found that 65% of adults were monitored for albumin and 91% for creatinine, however, these figures dropped significantly to 30% for both proteins in paediatric patients (NHS National Information Centre 2010).

[xxiv] HbA_1C is a measure of the average blood glucose levels over the past 3 months, which is a robust indicator as it cannot be manipulated just prior to a monitoring visit. This indicator reflects the average glycaemic management and provides evidence on which physicians can make necessary adjustments in diet or medication.

Regular measurement of blood pressure is recommended to test for hypertension. This occurs as part of regular physician visits in France. In the ENTRED study, Type 2 patients were seen nine times (on average) during the year by their doctor, at which time blood pressure is routinely measured (Robert et al. 2009). In Spain, Type 1 patients have their blood pressure measured 3-4 times per year, while Type 2 patients undergo this testing with more variation, between 1-6 times per year. In the UK, over 90% of adult patients had their blood pressure monitored during the 2008/09 period, with 50% achieving the targeted blood pressure (NHS National Information Centre 2010).

Other physical tests are also recommended, including foot exams to look for microvascular and neural damage, eye exams for retinopathy, and anthropometry (BMI, hip to weight circumference). In France, the Association de langue française pour l'étude du diabète et des maladies metaboliques (ALFEDIAM)[xxv], recommends a foot examination at each visit, even if asymptomatic. But an ENTRED study in 2002 found that only 20% of patients questioned said that they had received a screening with monofilament. In Spain, fewer than 50% had their feet examined in 2007. The UK 2008/09 National Diabetes Audit found that in adult patients BMI was measured in 89%, retinal screening in 77%, and foot examinations in 83% of patients during the period. In children, the uptake of these examinations was worse at 66%, 27% and 23% respectively (NHS National Information Centre 2010).

Clinically, all the monitoring processes mentioned above should occur at least annually in all patients with diabetes, however, there is evidence that this is not occurring. In the UK (2009/10), monitoring all nine care processes occurred in 52.9% of adult Type 2 patients, but only 31.9% of adult Type 1 patients and 4.1% in paediatric patients (decrease from 5% in 2008/09). This suggests either poor monitoring of children or that the measures chosen for adults and indiscriminately applied to children are largely inappropriate for the paediatric population. Lack of monitoring procedures results in diagnosing complications and co-morbidities later and, potentially, proving costly to both patients and the health system.

[xxv] ALFEDIAM is now known as the Société Francophone du Diabète (SFD), however the website remains the same – www.alfediam.org.

Table 6.1: Recommended frequency and cost of diabetes biomarker monitoring

		France	Germany	Italy	Spain	UK
HbA_1C	Type 1	q3m	na	q1-3m	q3-4m	q3m
	Type 2 (insulin)	q3m	na	q6m	q0-4m	q3m
	Type 2 (oral hypoglycaemic)	q3m	na	-	q0-4m	q6m
	Average cost	€50.00		€10.50	€59.00	€18
HDL	Type 1	q12m	q12m	q6-12m	q6-12m	q12m
	Type 2 (insulin)	q12m	q12m	q6-12m	q4-12m	q12m
	Type 2 (oral hypoglycaemic)	q12m	q12m	q6-12m	q4-12m	q12m
	Average cost	€36[HDL, LDL, TG]	-	-	€3.00	€18
LDL	Type 1	q12m	q12m	q6-12m	q6-12m	q12m
	Type 2 (insulin)	q12m	q12m	q6-12m	q4-12m	q12m
	Type 2 (oral hypoglycaemic)	q12m	q12m	q6-12m	q4-12m	q12m
	Average cost	€36[HDL, LDL, TG]	-	-	€2.00	
Triglyceride	Type 1	q12m	q12m	q12m	q6-12m	q12m
	Type 2 (insulin)	q12m	q12m	q12m	q4-12m	q12m
	Type 2 (oral hypoglycaemic)	q12m	q12m	q12m	q4-12m	q12m
	Average cost	€36[HDL, LDL, TG]	-	-	€ 2.20	
Urinary albumin	Type 1	q12m	Rarely: 20% patients/y	Rarely	q6-12m	q6-12m
	Type 2 (insulin)	q12m	Rarely: 20% patients/y	Rarely	q6-12m	q12m
	Type 2 (oral hypoglycaemic)	q12m	Rarely 20% patients/y	Rarely	q6-12m	q12m
	Average cost	€28.00			€3.00	€2
Blood pressure	Type 1	per Dr visit			q3-4m	q3-4m
	Type 2 (insulin)	per Dr visit			q2-12m	q3-4m
	Type 2 (oral hypoglycaemic)	per Dr visit			q2-12m	q3-4m
Serum creatinine	Type 1	q12m			q6-12m	q12m
	Type 2 (insulin)	q12m			q4-12m	q12m
	Type 2 (oral hypoglycaemic)	q12m			q4-12m	q12m
	Average cost	€8.00			€2.10	€3

Note: na: not available.
Source: The authors based on data from the LSE country survey.

6.2 Available evidence on diabetes outcomes

There is relatively good information on outcomes compared to costs, particularly in France, Italy and the UK (England, Wales and Scotland) (Table 6.2). The latter is due to recent improvements in data collection by the QOF and annually reported Diabetes Audits (England/Wales, Scotland, Paediatrics). France is also collecting data periodically (2001, 2007) via their ENTRED study and Italy, via the AMD data collection. All three have longitudinal capacities, which will hopefully improve over time with greater participation and precision. The current capacities are: longitudinal (France ENTRED

2001-2010; Italy 2004-2009, UK 2006-2010), regional (France: ENTRED Metropolitan v La Reunion, ITALY: nationwide, UK: PCTs), Type 1 versus 2 (France, Italy, UK) and treatment groups (Germany: diabetes DMP v non-DMP).

6.2.1 France

The 2007 ENTRED study shows that the percentage of patients with $HbA_1C \leq 6.5\%$, indicating tight control, in Metropolitan areas was 32% compared to 24% in La Reunion Island), while HbA1c ≤7% (still meeting recommended levels) was 52.1% and 24% respectively. This means 84% of Metropolitan and 48% of La Reunion residents with diabetes are showing poor glycaemic control.

Only 15% of diabetic patients in Metropolitan areas and 22% in La Reunion had blood pressures <130/80 mmHg, while 16.5% and 22.9% respectively had worryingly high pressures of ≥160/95 mmHg (Ndong et al. 2010).

6.2.2 Germany

The implementation of evidence-based guidelines into routine outpatient and inpatient treatment is difficult. In order to improve the outcomes of diabetic patients and to delay the development of complications the implementation of Disease Management Programmes (DMP) started in Germany in 2002 (for Type 2) and 2004 (for Type 1). As of December 2010, 136,574 patients were enrolled in Type 1 DMPs and 3,413,643 patients in Type 2 DMPs according to the Federal Insurance Bureau (Bundesversicherungsamt). These enrolled patients amount to approximately half of all estimated diabetic patients in Germany.

The DMP for diabetes includes different medical services, for example, regular laboratory, foot and eye examinations, rules for referrals to specialists and participation in diabetes education courses and offer a structured approach of diabetes management in GP surgeries, diabetes specialists in health care centres ("Schwerpunktpraxen") and hospitals.

The scientific evaluation of DMP is a matter of controversial discussion. Certain recent studies appear to prove the effectiveness of DMPs in improving health outcomes (2008), but significant concerns remain about their validity (Linder et al. 2011). Some studies also raise the concern that DMPs cannot yet be positively assessed because of the inherent selection bias and unclear data quality. For instance, it has been found that future DMP patients had a lower risk for diabetes complications, were treated more intensively and were more active and motivated in managing their disease than usual-care patients (Schäfer et al. 2010a; Schäfer et al. 2010b).

However, these results underline the problem that DMPs do not yet reach the higher-risk patients and, this impairs the assessment of outcome quality between enrolled and non-enrolled patients. Other studies have found that outcomes generally improve, but this is the case in both groups of patients, DMP- and non-DMP-enrolled (see also Table 6.3) (Linder et al. 2011; Schäfer et al. 2010a; Schäfer et al. 2010b). However, DMP-enrolled patients *felt better taken care of* and were, therefore, more motivated to attend education programmes or foot and eye examinations. The same studies reported

that, in contrast, no differences could be found between enrolled and non-enrolled patients concerning outcome quality indicators, e.g. self-rated health, haemoglobin (HbA1c) levels and blood pressure.

The finding that DMP-enrolled patients felt they were better looked after and reported better quality of care is confirmed by other studies. For instance, it has been found that DMP-enrolled patients felt better informed about diabetes, complied more closely with medical advice and participated more often in diabetes education programmes (Schunk et al. 2009). The mean HbA1c decreased and they reported increased physical activity. However, the authors found that the DMP-enrolled group had an increasing Body Mass Index (BMI). Being overweight or obese are relevant risk factors, among others, that could lead to the deterioration of the metabolic systems and the development of complications. These findings stress the ambivalent effect of DMP enrolment: while feeling better informed, patients stick to an unhealthy life style and diet.

The participation and enrolment in a DMP is optional for physicians and patients. Although the programme is open for everyone, it is expected that patients that benefit most from it take part in the programme. In reality these are mainly active, educated, motivated and compliant patients. This so called 'short-term benefit approach' including the less severely ill, compliant and active patients ("good patients") could lead to a misperception of the success of DMP by assessing the outcome of enrolled patients in contrast to non-enrolled patients. Concerns are raised that DMPs exclude patients who are in significant need of assistance and education. However, due to the multi-morbidity of patients, especially older patients, individuals may fit into several DMPs e.g. diabetes *and* coronary heart disease. Therefore, it is difficult to assess the appropriate coverage of DMPs. From the physicians' perspective it could be adverse to run DMPs and include more severely ill patients as physicians could fear negative consequences from health insurance, e.g. offering exclusive contracts to surgeries which produce 'better' results.

Overall, it is very difficult to evaluate the success of DMPs for diabetes in Germany (Birnbaum et al. 2010). However, the enrolment in DMP is a substantial step in the direction of implementing evidence-based guidelines into the daily routine treatment of diabetes patients and a positive development. Greater efforts should be made for the integration of 'difficult', high-risk patients – those who need to be taken care of the most, e.g. by providing case management programmes for selected patient groups.

6.2.3 Italy

The AMD annals have been collecting data from 2004 to 2009, excluding 2008 (The AMD Annals working group 2009). Measurement of average quarterly glucose control via HgA1C, has been high in both Type 1 & 2 patients (>90%). Blood pressure measurement is also stable, but at much lower adherence (or data entry) at roughly 75%, however, measurement of lipids has increased (Type 1 59.5%-73%, Type 2 63.9-73%, 2004-2009). Renal sufficiency testing is decreasing (Type 1 56.7%-51%, Type 2 49.2-41%) along with foot checks (Type 1 23.8-15%, Type 2 15.4-15%) despite the addition of 100 new diabetes centres in 2009 to the dataset (Figure 6.1).

Monitoring outcomes in Italy shows that 24-44%% of patients are achieving good glycemic control, 37-42% good lipid management and up to 57% have good blood pressure levels (Figure 6.1). There are a number of patients who have warning signs, almost 20% with poor glycemic control (46% in 2009) and poor lipid management, and 30% with high blood pressure. These patients will have greater likelihood of developing complications.

Table 6.2: Diabetes monitoring: Proportion of patients testing annually and their results (yellow shaded figures show recommended biological ranges) where available

	France	Germany[α]	Italy		Spain	England		Scotland	
			Type 1	Type 2		Type 1	Type 2	Type 1	Type 2
HbA_1C									
% tested	90%				81.6%	85.8% (90)	91%	87.7%	91.9%
<6.5%	24-32%		24%	44%		25% (16)			
≤7%	24-52%				59%				
≤7.5%						28.2%(16)	66.5%	21.8%	64%
>9%			46%	29%	4.6%	(30)		38.3%	13.7%
>10%	8%					17%	6.7%		
Blood pressure									
% tested					-	68.6% (59)	95.4%	93.9%	
<140/80mmHg						69.3%	60.7%	79%	74.5%
Targeted BP^{CVD} ≤130/80mmHg	15-22%		36%	15%		63.3%	49.5%	45.4%	31.5%
≤140mmHg	46%								
≤140/90mmHg			31%	57%	65%				
Albumin									
% tested	26%				71%	54.4% (36)	73.7%	48.6%	53.6%
Creatinine									
% tested	79.7%				-	54.4% (33)	73.7%	82%	92%
Cholesterol									
% tested	72%				85%	74.8% (30)	92.4%	89.6%	
Total ≤5.0mmol/L					77.5%	72.5% (75)	78.3%	71.5%	81.4%
Total ≤4.0mmol/L						30.2%	40.9%		
LDL <100mg/dl	34%		37%	42%		μ			
LDL ≥130 mg/dL	18%		25%	26%		μ			
Triglycerides TG - % tested	76%								
BMI									
% tested					-	83.2% (70)	90.5%	82%	82%
Overweight: BMI 25-29.9	30-40%					35.3%	34.5%	36.6%	31.9%
Obese: BMI ≥ 30	14-40%				48.5%	17.3%	28%	25.4%	55.1%
Eye exam									
% tested					57%	68.1% (25)	78.9	80%	86%
Foot exam									
% tested	20%				48%	67.8% (24)	85.2	59.5%	78.1%
Foot lesion								7%	4%
Smoking									
% tested					-	86.8% (na)		99%	
All care processes tested (%)					-	31.9%(4.1)	52.9%		

Notes: The numbers in brackets are paediatric patients; α Results based on patients in disease management programmes (DMP) at time of follow-up (2003); for HBA_1C, a figure of 81.1% has been reported, however, this is specific to a particular study; see also Table 6.3; β 2008, combined result for Type 1 and Type 2 patients tested;

μ May be measured but is not part of the QOF reporting.

Sources: France ENTRED 2007 (Ricci et al. 2009), Germany 2003 (Schäfer et al. 2010a; Schäfer et al. 2010b), Italy (Cimino et al. 2010), Spain (Franch Nadal et al. 2010), England (NHS National Information Centre 2010, 2011), Scotland (Scottish Diabetes Survey Monitoring Group 2010).

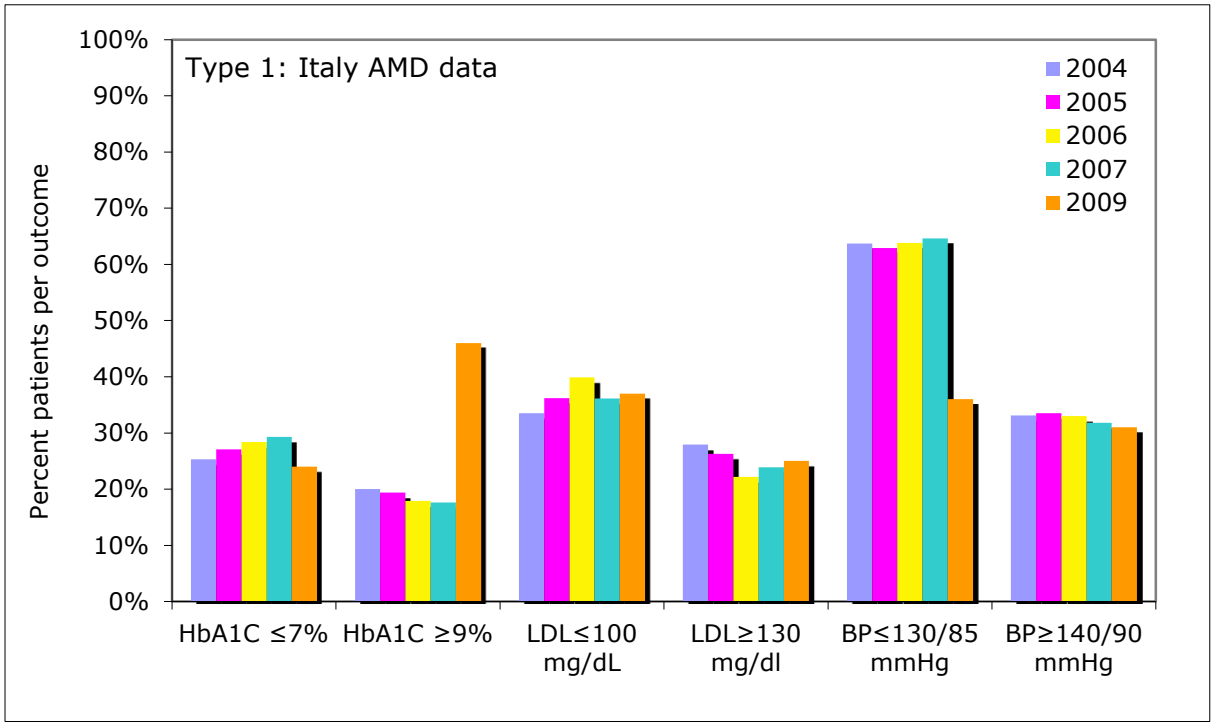
Table 6.3: Key outcome indicators results from a German DMP (2003)

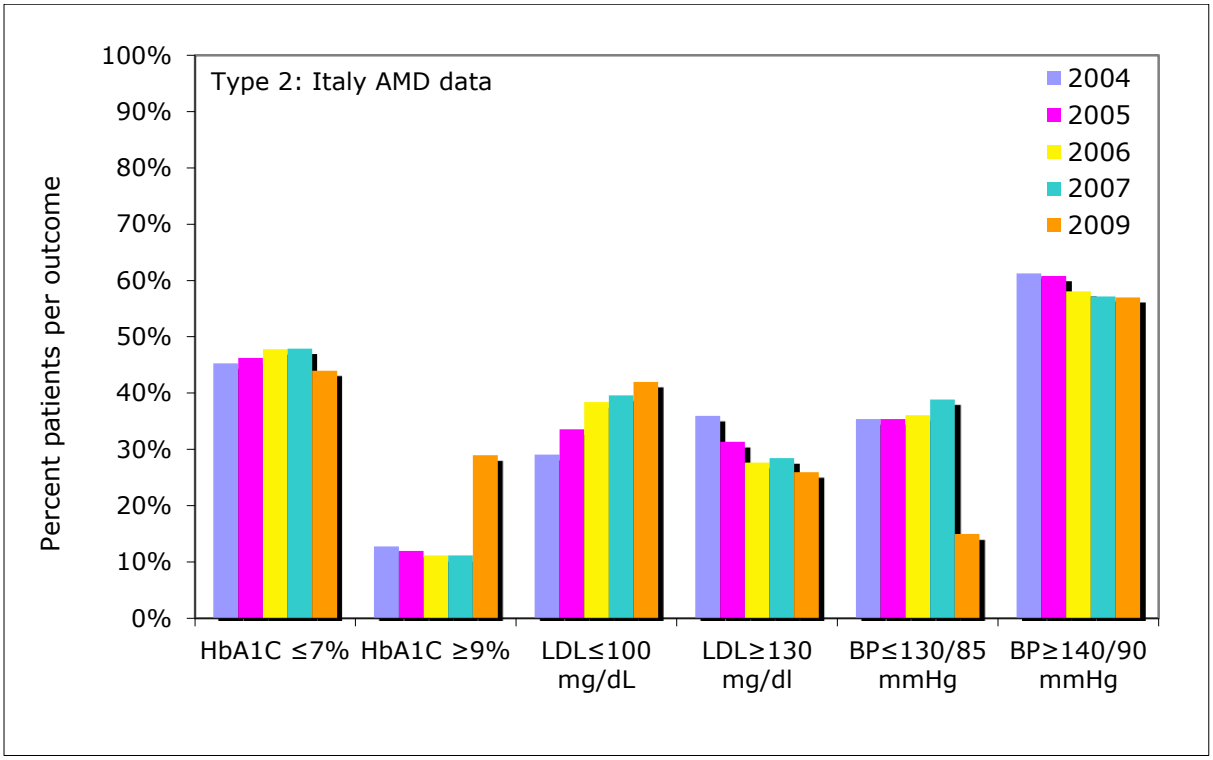
	DMP Baseline (%)	Patients not enrolled Baseline (%)	DMP (Follow-up)*	Patients not enrolled (Follow-up)*
Mean HbA_1C (%)	6.9	6.9	6.9	6.8
High HbA_1C (>7.5) ((>8,5 for over 75+	72 (21.8%)	52 (18.1%)	46 (18.8%)	35 (17.5%)
Mean BP	132/79	135/80	133/80	133.9/81
High BP (>140/90)	137 (38.1%)	186 (46.7%)	129 (44%)	116 (42%)
Mean BMI	29,7	29,4	29,5	28,3
Obese (BMI>30)	188 (42.7%)	191 (39.6%)	149 (42.5%)	137 (40.1%)
Diabetic foot lesions	45 (10%)	49 (10%)	29 (8.3%)	29 (8.5%)

Note: * Follow-up occurred approximately 10.4 months after baseline interviews.

Source: Based on (Schäfer et al. 2010a; Schäfer et al. 2010b).

Figure 6.1: Diabetes outcomes: Italy AMD data 2004 – 2009[1,α, β]





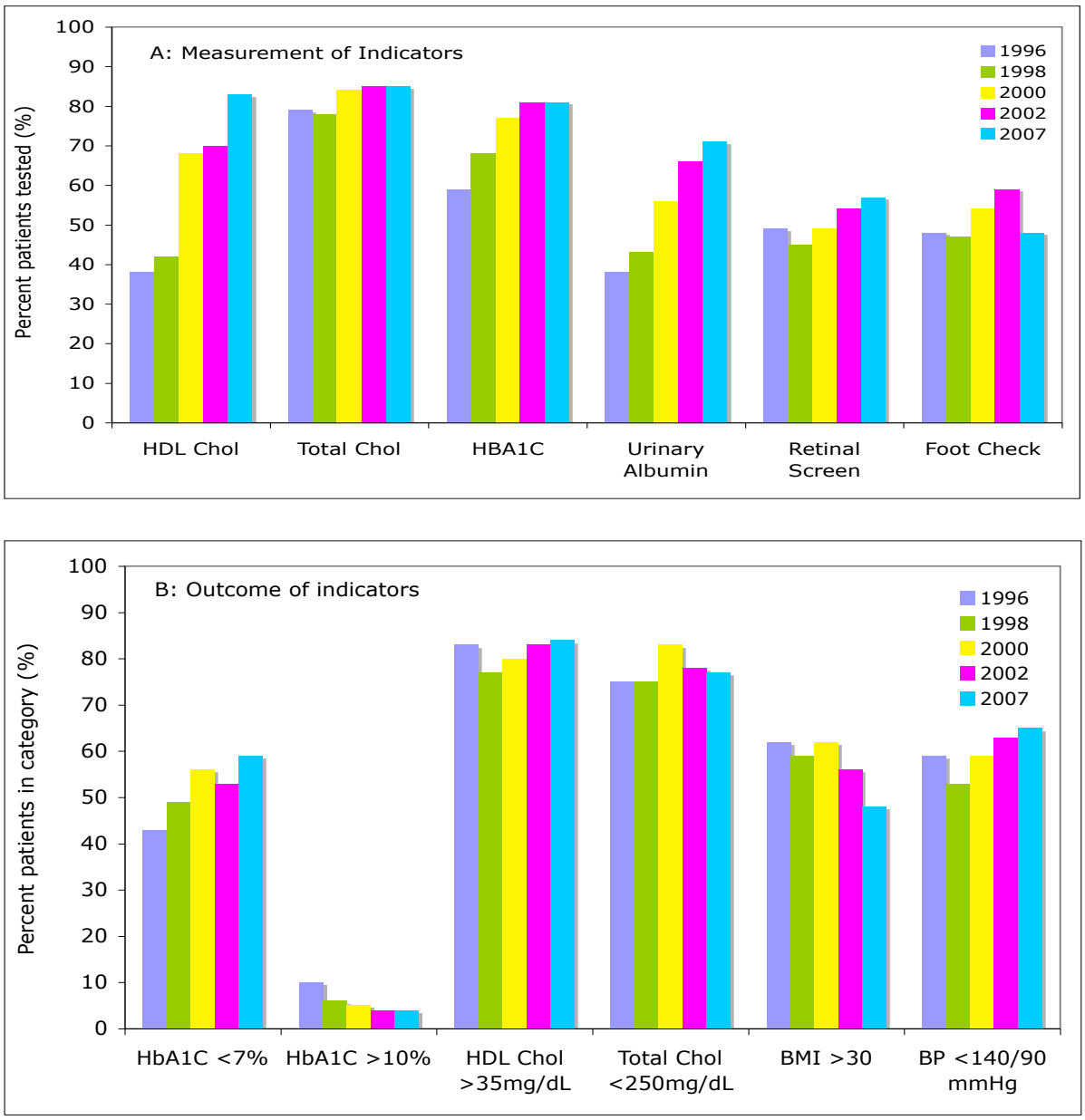
Notes: HbA1C ≥9%, LDL≥130mg/dL, BP (blood pressure) ≥140/90 mmHg are associated with poor outcomes. No data for 2008 available. In 2009 100+ new diabetes centres were added to the database, which may explain some of the variations. In 2009, new interpretations were added of a lower BP limit (BP≤130/80 mmHg v ≤135/80 mmHg) and higher HbA1C (HbA_1C ≥9% v HbA_1C ≥8%).

Source: The authors based on (The AMD Annals working group 2009).

6.2.4 Spain

The GEDAPS Network study of Diabetes in Primary Care publishes diabetes process and outcomes every 2 to 5 years, with the latest results published for 2007 (Franch Nadal et al. 2010). Results show a gradual improvement in both types of indicators since 1996, particularly in a reduction of dangerous HbA_1C levels, as well as obese diabetes patients (Figure 6.2). Measurement of lab work is good, yet physical measurements for retinal screening and foot checks are less impressive.

Figure 6.2: Adherence to patient monitoring (A) and results of monitoring outcomes (B) in Spain (1996-2007).



Source: (Franch Nadal et al. 2010)

6.2.5 United Kingdom

Some of the key finding from the UK National Diabetes Audits (NDA) are the differences between paediatric (UK) and adult patients (England, Wales), both in the adherence to measuring indicators and their outcomes. The number of children being tested for relevant indicators was significantly less than for adult patients, even for albumin (32% versus 64%) and creatinine (31% in children versus 91% in adults), which are important indicators to screen for early kidney damage especially in Type 1 patients. Only 4.1% of children were tested for all monitoring indicators compared to 52.9% of Type 2 adult patients and 31.9% of Type 1 adult patients (NHS Information Centre 2010; NHS National Information Centre 2010).

Examining the outcomes of the monitoring indicators finds only 25% of adults and 16% of children meet tight blood glucose control ($HbA_1C \leq 6.5\%$) (2008/09). More than 60% of Type 2 adults had $HbA_1C \leq 7.5$ (28.2% of adult Type 1), however, over 30% of children had HbA_1C levels $\geq 9.5\%$ and some with $HbA_1C > 15.5\%$ associated with significant permanent damage. Examination of Scottish Diabetes Survey (SDS) data found only 22% of Type 1 patients achieved good control ($HbA_1C \leq 7.5$) (Scottish Diabetes Survey Monitoring Group 2004). Over 61% of English/Welsh adult patients met adequate blood pressure control (<140/80 mmHg) and 74% of Scottish patients (≤140 mmHg). Approximately 30% of Type 1 English/Welsh adult patient met tight lipid management criteria (total cholesterol ≤4.0 mmol/dL), and 41% of Type 2 English/Welsh adult patients, while over 70% of all UK adult patient met adequate lipid management (≤5.0 mmol/dL). Higher cholesterol measures were more common in both adult and paediatric patients with certain ethnic origins (Asian, black).

The 2009 SDS found the degree of overweight (BMI 25-29.9) in Type 1 patients was 37% and in Type 2 32%, while the degree of obesity (BMI >30) in Type 1 patients was 25% and Type 2 55% (Scottish Diabetes Survey Monitoring Group 2010). The NDA was similar for overweight, but far less for obese, particularly Type 1 obese (26%, Type 2 50%).

There are other measures relating to complications, which are reported in the NDA for both children and adults: ketoacidosis (adults 0.48%, children 7.4% with 10% in 12-24 age group, and 10% having ≥2 episodes), angina, myocardial infarction, cardiac failure, stroke, renal failure, diabetic retinopathy treatments, as well as minor and major amputations.

Both the NDA (2003/04-2009/10) and the SDS (2003-2009) have longitudinal information (Figure 6.3, Figure 6.4). Although the degree of overweight appears to be decreasing in Scotland, obesity is increasing in both Type 1 & 2 patients in Scotland, England and Wales. This partially represents 'graduation' of overweight patients to obese, although it appears that fewer 'new' patients are joining overweight patients. More patients are meeting outcome targets for glucose, lipid and blood pressure management, and the degree of dangerous glucose control has slightly decreased. Measurement of all key diabetes processes has increased from 7% to 47% (2004/05-2009/10), but only 4.1% of paediatric patients have all key processes measured annually (NHS Information Centre 2010; NHS National Information Centre 2010).

Figure 6.3: Diabetes outcomes National Diabetes Audit (2003/04-2009/10).

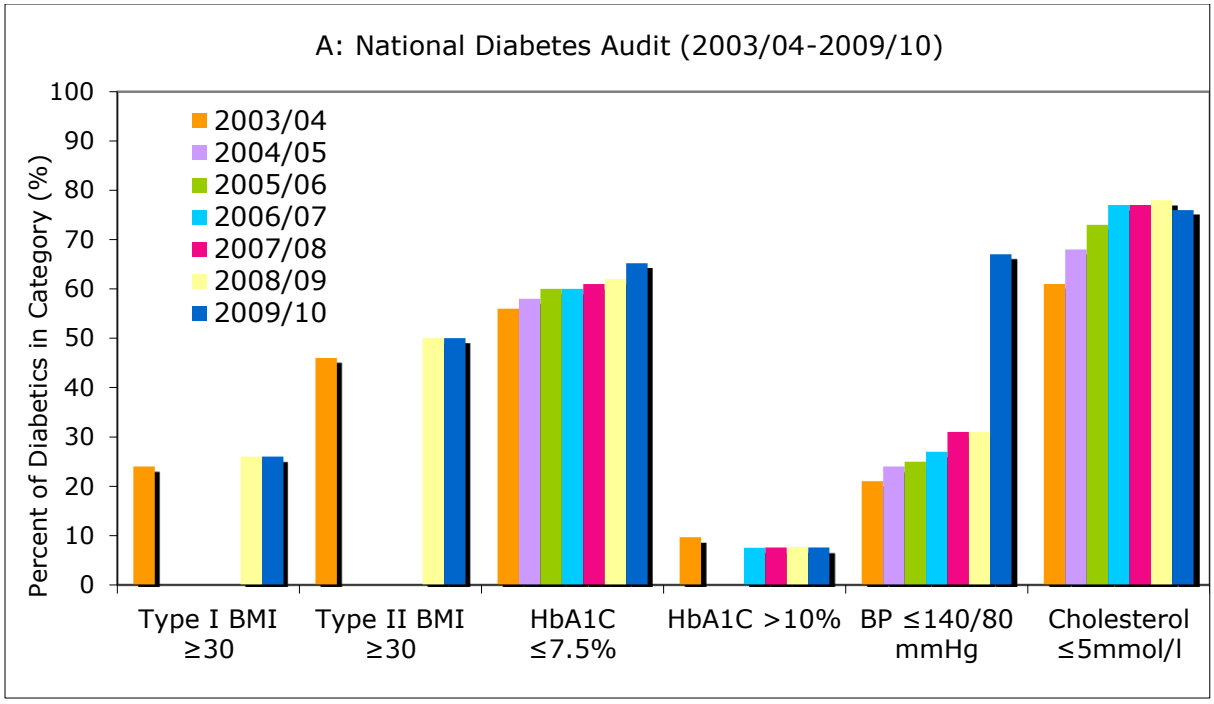
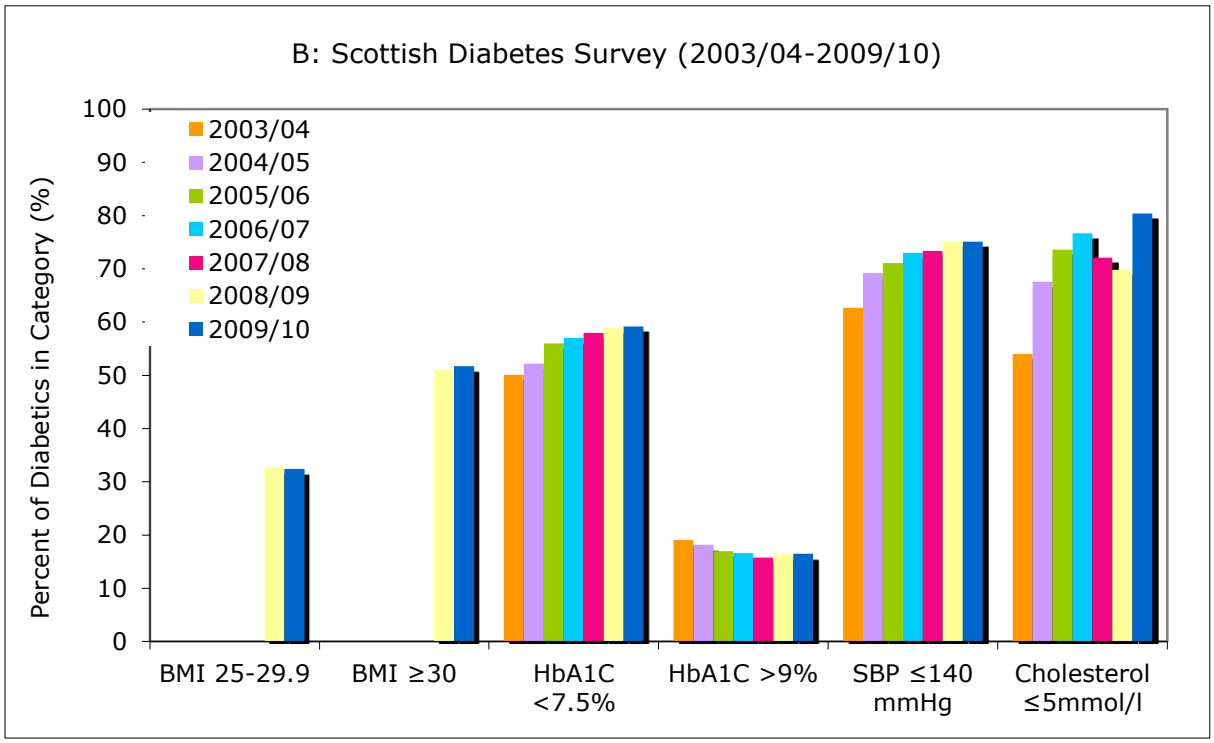


Figure 6.4: Diabetes outcomes Scottish Diabetes Survey (2003-2010).



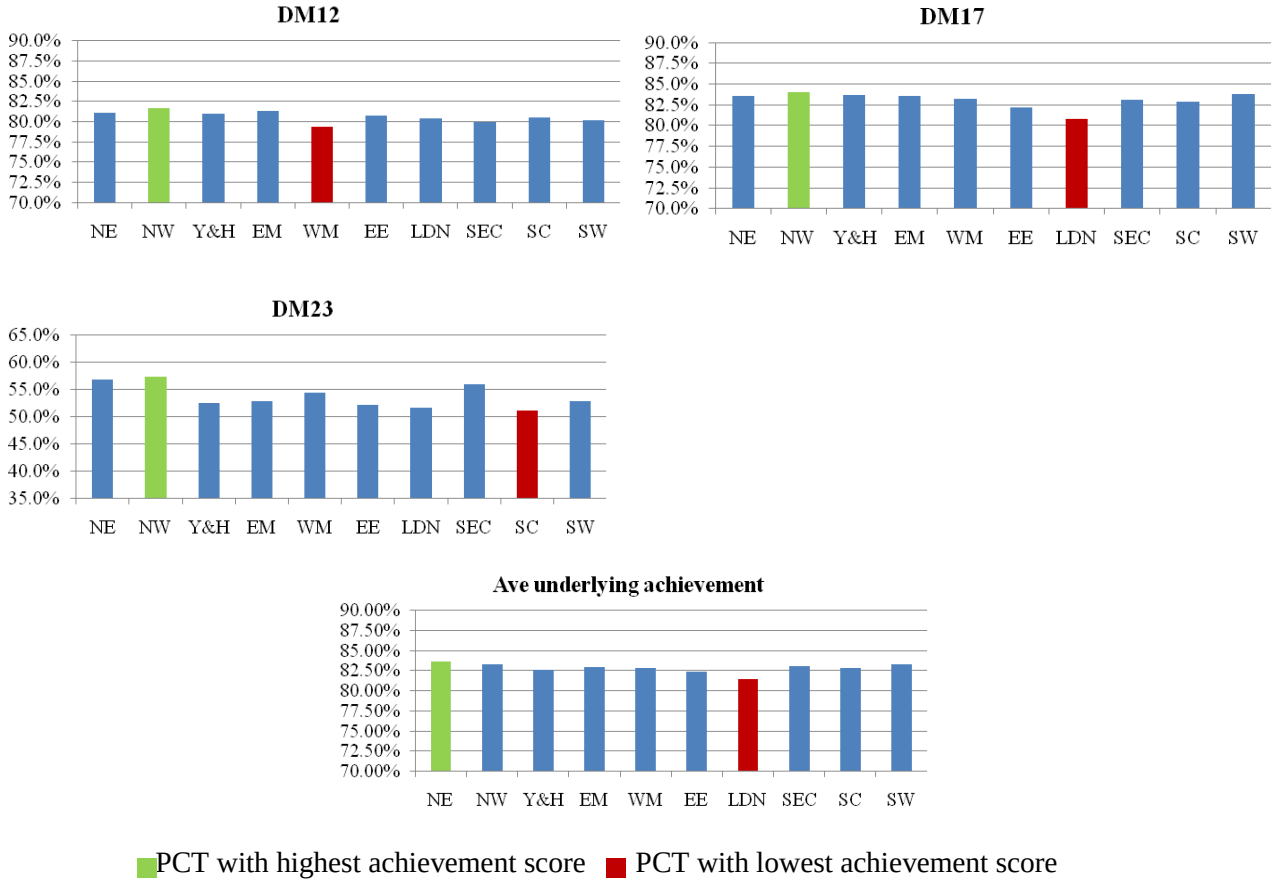
Source: (Scottish Diabetes Survey Monitoring Group 2010).

The Quality and Outcomes Framework (QOF)

The UK QOF voluntarily collects data from GP practices, including 17 diabetes specific indicators (Appendix 8). Aggregated results are available by PCT and Strategic Health Authority (SHA). Practice level QOF data is available, but only to the medical community. This data is due to be made publicly available later this year. Of note, only a minority of QOF diabetes indicators are outcomes

indicators (blood pressure (1), cholesterol (1), and low but not high HbA_1C levels (3)), but they do provide an indication of information available in the UK. This data does not establish a link between patients with diabetes and related complications, or distinguish between the different types of diabetes. When aggregated SHA figures are compared, outcome disparities across different regions are less marked (Figure 6.5) outlining 3 of the 17 quality targets), and conversely when data for individual practices within a PCT is compared, the variation can be considerable. Examination of DM12 (blood pressure), DM17 (cholesterol), DM23 (HbA_1C) outcomes indicators across all SHAs in England finds small variations, and the poorest performing variable was only half of patients achieving glycaemic control (Figure 6.5).

Figure 6.5: QOF indicators (DM12 (blood pressure), DM17 (cholesterol), DM23 (HbA_1C)) in individual SHAs (2009/10)*



Notes: * '*Underlying achievement*' equals number of QOF points per indicator (numerator) over total QOF points available per indicator (denominator)
DM12: Percentage diabetic patients with the last blood pressure is ≤145/85 mmHg;
DM17: Percentage of diabetic patients with last total cholesterol in previous 15 months is ≤5mmol/l;
DM23: Percentage of diabetic patients with last HbA1c is ≤7 (or equivalent test/reference range depending on local laboratory) in the previous 15 months.
Source: The authors.

6.3 Conclusions

Evidence on outcomes is highly variable between countries, with Italy and the UK having fairly good annual data collection procedures in place, while countries have intermittent (France, Spain), or limited and private (Germany, insurance). Some of the indicators point to how frequently a monitoring test is performed (process indicator) while others report results of the monitoring test. Both are important, as adherence to monitoring guidelines is important to catch early signs of complications quickly, and change treatment accordingly (such as change from oral hypoglycaemic to insulin). The difficulty lies with the disagreement in timing between these process indicators and the actual guideline. For example, the guidelines for HbA_1C measurement are quarterly to biannually, but the collection and reporting are annual (or every 15 months in Scotland). This makes it much easier for the health system to appear to be adhering to monitoring guidelines, when in fact it may not be.

Monitoring results of the outcome indicators are usually banded into categories created to find 'safe' and 'danger' zones. For example, HbA_1C tight control is ≤6.5% and good control is ≤7.5% in most countries. These are both reported across countries, however, Germany neglect to report the dangerous levels of HbA_1C ≥9-10% which may be more telling. It is also impossible to see if patients end up in more than one 'safe' or 'danger' zone to identify patients at high risk for developing or experiencing complications.

Finally, the identification of which monitoring indicators to track or report is not always ideal. Most of the emphasis appears to be placed on cardiovascular risk factors, by reporting outcomes for BMI, lipids and blood pressure, however, no results are given for urinary albumin, serum creatinine or foot checks. The latter three are significant and prevalent complications, and are very costly (in fact, more costly than cardiovascular complications).

Box 6.1: Outcomes - Key takeaways

- Outcomes datasets are available in France (intermittent), Italy (annual), Spain (intermittent) and the UK (annual), but not in Germany.
- More process than outcome indicators are measured, and the number varies between countries: France 7, Italy 5, Spain 14 and the UK 17.
- Due to a scarcity of complete, longitudinal diabetes outcomes datasets, little comparison of outcomes is possible across countries or over time, however, this is to some extent possible in Italy and the UK particularly in recent years, with greater participation.
- There are some variations in outcomes targets between countries. France, Italy and England data report proportion of patients with HbA_1C ≤6.5% ('tight' control), while Spain and Scotland report proportion of patients with HbA_1C ≤7.5% ('good' control).
- Monitoring uptake and reporting is variable across and within countries, none reflecting the more frequent testing frequency actually recommended by the guidelines.
- The cost of testing outcomes varies substantially – for example, the cost of HbA_1C test is lowest in Italy (€10.50) and highest in Spain (€59.00).
- In the UK, the uptake of monitoring is worse in children than adults, although whether this is due to poor selection of paediatric variables (application of adult variables to paediatric population), poor recording or actual poor monitoring is unknown.

7. The Challenges of Diabetes – Outlook for the future

This chapter discusses the various limitations and challenges facing the EU5 countries with regards to diabetes prevalence trends, data insufficiency and information problems, inadequate prevention strategies and resources (human and financial), variations in access to and quality of care, incomplete outcomes data and insufficient national diabetes treatment plans and guidelines. In doing so, it builds on the discussion in the previous sections as well as material from the survey that was conducted for this study and opinions of experts that contributed to it.

All 5 study countries face several challenges in terms of the rapidly increasing numbers of patients with diabetes, pre-diabetes and obesity in their population; rising morbidity and mortality related to diabetes and its associated risk factors and the escalating costs (both direct and indirect) relating to diabetes and its complications. For instance, a particular challenge for Germany is in addressing the Type 2 diabetes prevalence rate (14.9%) of the Turkish origin population in the country, which is well above the national average (Parmakerli-Czemmel et al. 2007); in Italy, poor levels of diabetes education and health awareness are also a problem, particularly as these tend to result in low rates of medical compliance and unhealthy lifestyle choices among patients and in the broader population; for the UK, a further key concern is the population of African/Afro-Caribbean and south Asian origin, who are three to six times more likely to develop Type 2 diabetes.

7.1 Current and future trends in prevalence and the impact of aging

Despite acknowledging diabetes as a leading cause of morbidity associated with serious disability, health complications and premature mortality, few countries collect diabetes prevalence data. This means accurate prevalence figures are not available for any of the EU5, however, available data does show steady increases during the past two decades, particularly for Type 2 diabetes.

Primary reasons for increasing diabetes prevalence are (a) an aging population including those who were children during the second world war, often experiencing food shortages associated with higher diabetes development, (b) increasing rates of obesity and overweight, (c) improvements in data collection methods (e.g. the UK) and wider implementation of diabetes screening programs (France, Germany) and (d) changes in the ethnic make-up of the EU5 population, with increasing African, Afro-Caribbean and Asian populations with higher (genetic) prevalence of diabetes.

7.2 The challenge of poor data: prevalence, costs and complications

7.2.1 Scarce prevalence statistics

None of the study countries have national diabetes registries; in contrast cancer registries exist in most of these countries, with the exception of Scotland in the UK. This omission becomes apparent when searching for comprehensive diabetes data. Accurate national prevalence is not available, as no population-size databases exist on which true prevalence estimates can be based.

7.2.2 Incomplete direct cost data

There are few robust datasets relating to diabetes costs and related complications, those that exist are mostly academic studies. These studies often focus on only one aspect of diabetes, thus the resulting estimates here are piecemeal and cross-sectional. Diabetes costs gathered from these studies are likely to be underestimates, usually neglect indirect costs and potentially under-estimate the cost of complications. For example, ENTRED (2007) is based on reimbursement data, excluding non-pharmacologically treated patients (i.e. patients treated through diet and exercise).

Hence, our calculations were based on a small selection of academic studies and government sources, none of which were comprehensive. French cost estimates are principally derived from ENTRED, using 2007 as a base year. German cost estimates are derived from the CoDiM study. Italian cost estimates are derived from two key sources, notably (Marchesini et al. 2011) and (Osservatorio Arno Diabete 2011), while further material has been obtained from three earlier studies by the same authors (Marchesini et al. 2010 ; Osservatorio Arno Diabete 2007), and (Marchesini et al. 2011). Spanish cost estimates are derived from two studies, one national and one regional (Mata et al. 2002; Oliva et al. 2004) and supplemented with another regional study (López-Bastida et al. 2002). The UK cost estimates are primarily sourced from two regional studies (2005, 2007 data) (Currie et al. 2010; Morgan et al. 2010), and supplemented by various smaller studies.

As each data source has differing methodologies (cost dates, sample size, region, which costs are included) and the underpinning assumptions (diabetes prevalence, ratio Type 1:2, per patient cost), opportunity for accurate comparison across countries is limited.

7.2.3 Direct diabetes cost burden

Despite the paucity of data, the direct cost of diabetes was estimated to be €90bn in the study countries in 2010. As diabetes prevalence and its related complications increase, direct costs, particularly for inpatient care, will continue to rise. All EU5 countries show increases in diabetes spending estimates (regardless of the poor data precision), but highlighted by Germany where total diabetes costs increased by 49% (2000-2007) due to the concurrent increase in prevalence of 37%.[xxvi]

7.2.4 Cost of diabetes-related complications

The true costs of diabetes-related complications are unclear, with complication cost estimates difficult to disentangle and considerable variation across countries. These costs are likely underestimated either as a result of the way the DRGs are coded (primarily by diagnosis at the time of discharge), the lack of detail in coding, the omission of diabetes in the coding, and coding via admission versus per

[xxvi] Further evidence these cost increases are not a result of increased in direct per patients costs (approximately 8.5% over 2000-2007, lower than the rate of inflation). Patients with the highest incremental costs are those treated with insulin and insulin & OAD, but those treated with diet only had the highest rise in incremental costs (+42%).

patient. Patients with diabetes related complications are very complex to treat and to follow from a cost perspective as they use a variety of in- and outpatient services from different sources.

The available evidence suggests complications represent a considerable economic problem. Diabetic patients without complications represent a small proportion of the national health expenditure, since both insulin and oral glucose lowering drugs are relatively inexpensive nowadays. When complications occur, the direct costs of diabetes increase dramatically, primarily due to amplified instances of hospitalisation and the cost per patient almost proportionally increases according to the number of complications. If patients have multiple co-morbidities (common in Type 2 patients), estimating the cost per complication is a difficult, if not impossible, task using current cost data collection methods in the EU5 countries.

7.2.5 Insufficient outcomes data

Comprehensive outcomes data is vital in order to understand where deviations from optimal diabetes practice and patient care may occur, including regional variations. Unfortunately for diabetes care, outcomes data is limited in most countries, except Italy and the UK. Although regular monitoring and evaluation is recommended in all EU5 countries, it is unclear how often monitoring occurs and what outcomes are achieved. Italy and the UK have measured both process and outcome indicators since approximately 2004, showing improvements in both measurement and laboratory outcomes, as well as increases in complication rates. Academic sources for outcomes are available in Germany, but are not comprehensive. Both France and Spain intermittently produce both outcomes and process indicators.

National Prevention Plans (France, Spain, UK) appear to have done little to reduce the rate of complications. These plans are usually idealistic yet none encompass targets or pathways to success and the lack of monitoring leaves a platform without a path. This is unfortunate, as it leaves useful documents and plans, but powerless to act or implement change.

7.2.6 Indirect diabetes cost burden

None of the EU5 countries have comprehensive information on the indirect costs of diabetes or its complications. What is available is limited data on the components of indirect costs (early retirement, disability benefits, absenteeism, productivity losses, premature mortality). Diabetic patients often represent a ‘duplicate’ cost to public systems, in need of health care and placing a burden on the social security system, by requiring social benefits and making frequent labour market exits and re-entries. The time family members spend caring for an ill relative is also largely unaccounted for. These costs are an important component of total diabetes cost, as they work to shape our understanding of the costs of diabetes from the perspectives of employers, society, and the family. It is increasingly important these are measured accurately and incorporated into cost estimates.

Due to the paucity of indirect cost information, calculations in this study are even more of an approximation than - and, most certainly an under-estimate of - direct costs. Based on these, the total indirect cost of diabetes across the five study countries was found to be €98.4 billion.

7.3 Lack of effective prevention strategies

Prevention is the most powerful approach to stop the rise in diabetes prevalence, as excess body adipose and diabetes are highly correlated. It appears there is still much work to be done in preventative health. Most country campaigns appear to be broad, rather than targeting at-risk populations, and there is insufficient encouragement of lifelong exercise participation and activities in daily living. In many instances there is poor access to professionals who may help with non-pharmacological aspects of glycemic control. A Diabetes UK survey (Diabetes UK 2010c) found many patients had poor access to dieticians and psychologists who may help with maintaining good glycemic control.

7.4 Inadequate human and financial resources

Rising diabetes prevalence creates challenges in meeting the increasing demand for diabetes care. In certain countries (France, Germany, Italy) the lack of some types of specialists has been indicated as a problem. In Italy, this occurs particularly in highly populated regions where the number of treatment centres is inadequate to address patient needs. The excess burden on services often results in a breakdown in care coordination, creating inefficiencies where uncomplicated patients without complications are referred for specialist treatment rather than being cared for by GPs. Due to financial constraints and education policy reforms, the number of trained endocrinologists in Italy is limited; as a result there will not be sufficient clinicians to replace those retiring, let alone to meet the growing demand for care.

7.5 Variations in access and quality of care

There are a number of causes of disparities in patient access and quality of care across EU5 countries:

- Service provision based on geography has resulted in variations in patient access to comprehensive care, specialist care and education services (Italy, Germany, Spain, UK). In Italy, differences between the North-Centre regions and the South, payment structures and care delivery result in variations in comprehensive care. In Spain, insufficient endocrinologists, specialised nurses and trained family physicians limit access to appropriate care in some regions. In the UK, educational services are regionally variable, some regions only offering education to Type 1 patients and others only to Type 2, however, all regions indicated a need for periodic diabetes 'refresher' courses for their patients.
- Inconsistencies in the quality of care within all countries are evident. For example, in the UK the QOF results vary between GP practices from 51 to 100 points (maximum 100 points for 17 QOF

diabetes indicators) (NHS Information Centre 2010). The specific variation in care is unknown in all other countries, as none publish regional outcomes.

- Access to care may be erratic as a result of variations in payment structures within the health system. In France, different tariffs are allocated to different professionals. The majority of endocrinologists (64.74%) practice in "sector 2", meaning that they may charge fees in excess of the officially set tariffs, not covered by the ALD8 programme. In contrast, 92% of GPs practice in "sector 1" and accept the statutory tariffs. Dietician consultations are not covered and podiatrist visits have only recently become covered, but only for grade 2+ lesions. Patients incur these additional treatment costs as out-of-pocket expenses, unless they have complementary insurance, acting as a barrier to care access and possibly greater rates of complications due to poorly managed care.
- There may be variability in access to the services dictated by guidelines. In the UK, access to endocrinologists and multi-disciplinary care appears to be limited to patients treated with insulin (both Type 1 or 2), or patients with poor control. This is also true of all other countries surveyed - specialist care appears to be reserved for patients treated with insulin or with poor control.
- There may be variability in the quality of treatment guidelines. Guidelines for diabetes management have been produced in all EU5 countries, either by a national health body (HAS and AFSSAPS in France, Guiasalud in Spain and NICE in UK) or by professional diabetes associations (DDG and Bundesärztekammer in Germany and AMD and SID in Italy), however, the focus of the recommendations varies by country. Although some countries (Germany, Italy, UK) have begun to include patient-centred care in their treatment guidelines, most countries have little focus on individuality of diabetes type, complications (except the UK), and care plans. None have patient-specific pathways (i.e. for care tailored to each patient), significant in a disease with high patient involvement and diversity in daily treatment and monitoring.

7.6 Incomplete outcomes data

Although robust datasets pertaining to diabetes outcomes are not available in Germany (where such information may be the privilege of the sickfunds), good progress has occurred in developing outcome measures and improving annual data collection in the UK and Italy. France and Spain have periodic collections, which are less useful, but still important. Only the UK includes separate reporting for children and young people. General outcome indicators are: HbA_1C, blood pressure, urinary albumin, serum creatinine (rarely), cholesterol and BMI, although target thresholds vary (France, Italy, England use $HbA_1C \leq 6.5\%$; Scotland and Spain use $HbA_1C \leq 7.5\%$).

Compliance with monitoring and evaluation recommendations for diabetes process and outcome indicators is unclear as measurements are rarely recorded and reported in a central national database. The UK appears to be the exception, with annual reporting via their National Diabetes Audit and Scottish Diabetes Survey, as well as a separate pediatric report, and Italy with their annual AMD

reports. Limited longitudinal data hinders assessment of whether countries are delivering improvements in patient care, or the risks that the current population or sub-populations are at for complications.

Patient involvement in daily self-care is very high with medications, HBGM, periphery checks, injection site rotations, dietary limitations, carbohydrate counting and frequent physician visits. If patients do not receive sufficient medical and family support in their care, ideal control of the disease becomes difficult. This problem is more relevant where multi-disciplinary case management is less developed, for example in the Southern regions in Italy (compared to the North and Centre).

Due to these data limitations, it is currently not possible to accurately establish causality between costs and the prevalence of diabetes complications on patient outcomes. As a result, it is difficult to assess the efficacy of diabetes guidelines and diabetes related spending on patient outcomes.

8. Policy options

Based on the analysis so far, it appears that across the study countries, the main policy priorities need to be a focus on diabetes prevention, the implementation of lifestyle strategies to improve population health, investing in early detection or screening initiatives for people with diabetes and pre-diabetes and enhancing cooperation between healthcare professionals and patients to avert severe complications. In France, additional priorities are the establishment of diabetes as a public health issue, rather than a socio-economic problem and the training medical staff to educate patients better about the disease. In Germany, further precedence needs to be given to targeting women and immigrants as vulnerable groups (i.e. not just children) in the existing diabetes guidelines as well as the new diabetes plan. In Italy, improving awareness and education about diabetes is also key. For the UK, precedence could also be given to increasing the number of specialist diabetes foot teams, in order to reduce amputations. Additionally, enhancing access to (and ensuring receipt of) the recommended annual healthy checks for diabetics is important, so as to reduce the risk of complications.

Overall, five main areas emerge where policy development can be targeted to best address diabetes and related complications: first, data systems for the trio of prevalence, costs (direct and indirect) and outcomes; second, prevention of diabetes development (primary prevention) plus complication development (secondary and tertiary prevention); third, creation and use of evidence-based guidelines, including patient perspective; fourth, emphasis on patient-centred multi-disciplinary care; and, fifth, monitoring, evaluation and learning from each other. This section discusses various options for each of the above policy development areas (see also Box 8 for a summary).

8.1 Understand the effects of diabetes through data

Three areas of diabetes data collection need improvement: prevalence (and incidence), costs (direct and indirect) and outcomes. Creation of national diabetes registers, like cancer registers, linked to primary care systems would be a good start to enable precise monitoring of existing and new diabetes diagnoses, differentiating between Type 1 and 2, the latter including details of control via oral medication, insulin injections, or lifestyle intervention. Furthermore, patients with impaired glucose tolerance should also be registered along with their intervention. The primary diabetes treatment provider (GP, endocrinologist, diabetologist, paediatrician) should also be included. In order to deal with the paucity of indirect costs data, this register could also collect age of retirement, employment status, procurement of social benefits as well as primary caregiver details. This would provide a starting point for indirect cost calculations.

The direct diabetes costs should have the following improvements in accounting data collection services. A diabetes diagnosis (Type 1 injections, Type 1 pump, Type 2 lifestyle, Type 2 oral, Type 2 insulin) should be attached to a patient accounting record once diagnosed and updated when treatment classification changes. This ‘tag’ should follow the patient in all treatment access points, community

and hospital, regardless of whether the treatment access is not at all related to diabetes or complications. The majority of treatment received is directly related to the diabetes diagnosis; where necessary, DRG payments ought to risk-adjust for diabetes. Furthermore, the 'tag' should follow the patient longitudinally, to understand how the diabetes diagnosis unfolds and impacts on treatment choices over time.

Indicators of care (process and outcome) should be reported and collated annually. Participation should be mandatory, and linked to primary and specialist funding to facilitate participation.[xxvii] Indicators should include minimum annual testing and reporting of HbA1C, blood pressure, total cholesterol/LDL/HDL, urinary albumin, serum creatinine, BMI, foot checks, retinal screening and smoking status. Additional paediatric indicators should include weight and height percentiles, insulin pump use, ability to carbohydrate count, and number of hyper- and hypo-glycaemic episodes over the past year. Annual complications data should include ketoacidosis, diabetic comas, foot ulceration, minor and major amputations, microalbuminuria, ESRD (haemo- or peritoneal dialysis), kidney transplantation, MI, angina, pacemaker, cardiac arrest, congestive heart failure, stroke, hypoglycaemia, retinopathy, blindness, presence of lung disease, and any type of cancer. Additional data collection considerations are attendance of education services, specialist services (i.e. cardiologists, nephrologists), retinal screening attendance and outcome, and allied health professional visits (DSN, dietician, chiropodist). All this data is useful in halting the onset of complications and best direction of preventative care, but also aids in examination of the direction of best use of limited health care resources.

8.2 Enhance and expand prevention strategies for diabetes

Of the two key drivers of Type 2 diabetes - ageing and obesity, only obesity can be actively targeted by policy and treatment. In most instances, Type 2 diabetes can be considered a potentially preventable, non-communicable disease, thus diabetes prevention could aid in prevalence reduction and associated lifetime costs. To do so, a number of macro and micro steps need to be considered.

Obesity has been found to be socially 'contagious' via social networking, meaning that a person has a higher chance of getting obese if obesity is present in their network. Norms and social acceptability of obesity need to be modified, particularly during childhood. A broad macro approach of socially responsible health messages targeted at specific age and social groups could be a start. Further, promoting of activities of daily living and lifelong exercise to all age groups is key to obesity prevention and weight management. In Italy in 2007 the "*Guadagnare Salute*" project coordinated a series of prevention activities addressing poor diet, physical inactivity, smoking and alcohol consumption. In the Emilia Romagna Region cities have tailored town planning to facilitate movement of pedestrians and cyclists to promote elevated activities of daily living. These macro

[xxvii] The UK shows that pediatric reporting is minimal, and pediatric treatment is diverse from endocrinologists to pediatricians, the latter perhaps not having a vested interest in diabetes outcome reporting.

multi-sectoral approaches involving different agencies to promote exercise and good health are integral to obesity prevention.

From a micro standpoint, a series of programmes and projects targeted to high risk or high obesity prevalence groups are needed. For example, cooking classes for new immigrants at risk for diabetes can help to modify cooking habits as well as deliver targeted messages. Schools can disseminate messages about optimal nutrition to bring home, as well as ensure that all children exercise daily.

The second area for prevention activities is for diabetes patients of all ages to prevent the development of complications. Education programmes targeted to specific age groups, social groups and diabetes types are useful in this regard, particularly when supported by a good multi-disciplinary care team that monitors patients regularly (minimum bi-annually). Use of accredited web-based materials to reach diabetes patients, as well as telephone support lines, can also be effective in aiding patients in their daily self-care. *Sophia*, a (pilot) patient support programme in France, provides free information, monitoring and educational support to diabetes patients covered by ALD8 and is currently being expanded due to its success.

The third area for prevention activities is the population at high-risk, individuals with undiagnosed diabetes, or impaired glucose tolerance. Targeted message campaigns to find these patients early on, when inexpensive lifestyle modification can be used, is one method, in addition to the implementation of GP screening (France, Germany, implementation UK). Recent German studies have proven that the cost-effectiveness of preventive screening (Schaufler et al. 2010), and early identification may provide individuals with motivation to lose weight, particularly if there are programmes in place to support such action.

8.3 Evidence-based guidelines

Diabetes guidelines across countries are not ideal, as many are not tailored to diabetes type or complication, and are produced by different organisations. The best scenario is when guidelines are produced by either the diabetes register or by the central medical guideline agency. All countries could develop and consolidate further evidence-based guidelines via consensus, with input from clinical experts; these should be specific to diabetes type. Further guidelines of management under complication conditions must also be created, as well as paediatric care and pregnancy care. All guidelines should be based on the most recent clinical evidence, including care pathways, screening and monitoring protocols, and separate guidance should be produced for patients themselves (in a multitude of languages, to assist and inform the broadest possible spectrum of the relevant patient population). These guidelines must be created with full support and input from clinicians in order to aid implementation and ownership; current adherence to monitoring measurements suggests there is room for improvement. An education campaign directed at clinicians should accompany their implementation.

8.4 Multi-disciplinary diabetes care

Despite diabetes being largely patient-centred, requiring high self-care involvement, only recently have patients become part of the care strategy. As discussed above, ideal guideline content for clinical professionals should incorporate as much patient-centred care as they are comfortable with and able to facilitate; in addition, literature and guidelines for patients and caregivers should also be developed and disseminated.

In the same regard, patient care should also include multi-disciplinary care, due to its multi-faceted nature. This is for two main reasons: first, each speciality will have its own merits and perspectives, and second, dividing particular care responsibilities among providers, provided it is appropriate to the professional, can be less costly (e.g. DSN and dietician fees are lower than those for endocrinologists and GPs). Additional advantages include variations in disclosure to DSN versus physicians, and increased access to care. Care plans that are developed need to include patients and main treatment providers, as well as caregivers (when needed). Education should also be included in these plans, ideally as outlined previously. Complex patient cases require the participation of several parties - patients, caregivers, and multiple treatment providers (GP, endocrinologist, DSN, dietician and other specialists) to plan for complication restriction and possible scenarios.

Multi-disciplinary care requires improved communication between caregivers. Electronic charting should support the communication between primary treatment providers and specialist providers, as well as other allied health professionals. Division of patients between GPs and endocrinologists should be supported as long as GP care provides good patient monitoring and prompt response to required treatment changes.

Psychology services need to have a greater role in diabetes treatment. Primary diabetes care physicians must recognise that depression is a common scenario for many patients with diabetes, adversely affecting their ability to self-care. Monitoring of social networks and observing patients' emotions with respect to their diabetes diagnosis during regular diabetes monitoring visits must be included in order to respond promptly to compromised mental health.

Finally, clearly delineating treatment pathways and the roles of each professional along the way, including the mechanisms for referral and interaction, is a key area. This could include early detection of diabetes, access to a spectrum of healthcare professionals (not just GPs and diabetes specialists), and early intervention with appropriate treatments to prevent complications. This should of course be based on an individual patient's needs and best practice.

8.5 Monitoring, evaluating and learning from each other

Each country has made progress into diabetes care in one way or another. What is important is for countries to look at each other and investigate whether successes in one country can be applied elsewhere. Here are some examples of country improvements in diabetes care.

Three countries in particular (France, Italy and the UK) have made some progress in data collection of outcomes. The UK in particular has made some aspects of diabetes reporting mandatory through the QOF, which culminates in the production of annual National Diabetes Audit, Scottish Diabetes Survey and the Paediatric Diabetes Audit. Further improvements would include investigation of poor Type 1 monitoring in adults and in children, broadening monitoring methods (i.e. report dangerous levels, measure LDL/HDL, measure paediatric specific variables) as well as aligning ideal outcome measures between Scotland and England/Wales. France has recently widened their ENTRED data collection to include Type 1 patients, further improvements would include national data collection with annual reporting. Italy reports almost annually and the recent expansion of participating centres is encouraging. Germany needs to begin reporting outcomes data collected by various SHI providers, while Spain's GEDAPS needs to increase their data collection and report more regularly. Ideally, all countries participating in outcome data collection should specify which indicators are notable, what levels to report as 'normal' and 'abnormal', which diabetes details should be reported (Type 1, Type 2 (oral), Type 2 (insulin), multiple complications, among others), inclusion of paediatrics, as well as how to collect data for longitudinal examination.

All countries have poor prevalence estimates due to the lack of national registries. All countries have poor cost data services – at best only regional piecemeal situations. Germany could provide better cost estimates via their SHI systems, however the SHI institutions need to co-operate. Improvements to cost accounting services are costly in themselves, however, without implementation health systems are powerless to drive forward needed changes.

Many countries have micro and macro prevention activities targeted to general population, specific age groups and social groups. These programmes need to be shared at conferences, or via a European Diabetes Observatory, to give their ingredients of success to others along with their failures. Identification of undiagnosed patients is beginning to occur in France, Germany and the UK via screening of high-risk patients; however, it appears that uptake is low. Factors for poor uptake need examination, as early identification of diabetes or identification at pre-diabetes stages can avoid costly treatments and complications.

Data on the cost implications of diabetes and improved formal monitoring of the disease should be used to shape holistic national policies (such as National Diabetes Programmes) for managing diabetes. National Diabetes Programmes should encompass national diabetes registries, screening programmes, effective prevention strategies, evidence-based guidelines and ensure a multi-

disciplinary, patient-centred approach to providing diabetes care. In order for these policies to be effective, they must be based on clear objectives measured against hard targets, underpinned by strong data collection. This will require a significantly greater top down effort if the current policy framework for managing diabetes is to be improved.

All countries appear to have guidelines in one shape or another – only the UK appears to have made a concerted effort and instigated a substantial uptake of these recommendations, with over 40 guidelines or discussion papers produced by NICE. As a minimum, the remaining countries need to have guidelines for Type 1 and Type 2, plus, ideally, additional guidelines for paediatrics, pregnancy, and complications. Barriers to uptake by physicians need to be examined in all countries, and the creation of guideline documents written for patients should be initiated by examining the patient guidelines and pathways produced by the American Diabetes Association. Linked to these guidelines then is the emphasis on multi-disciplinary care, in which all countries could improve their participation.

The purpose of these internal and external examinations is to prevent new diabetes diagnosis (where possible), improve overall health of our populations, improve overall health of our diabetes populations and ensure that diabetes-related complications are kept to a minimum. This effort requires participation by many players in society, including political influences, health care structures, community organisations, schools, transportation and medical personnel. This will benefit actual and potential diabetes patients, averting costly care from personal, social and health system perspectives.

The European Union has the potential to play a crucial role in supporting Member States to share their best practices in the fields of data collection, screening, prevention strategies, management programmes and the establishment of diabetes registries. The Lisbon Treaty gives the European Commission the mandate to implement initiatives to promote coordination between Member States in the field of health. Such initiatives can lead to the establishment of guidelines and indicators, the organisation of exchange of best practice and ensure periodic monitoring and evaluation. There is a need to follow-up on the European Council's Conclusion of 2006 on *promotion of healthy lifestyles and prevention of Type 2 diabetes*, which clearly sets out a number of initiatives to support cooperation between Member States in this area. The establishment of a European Diabetes Observatory could provide the vehicle for greater coordination between EU Member States, partly by establishing criteria for standardised data that is internationally comparable, and by encouraging the establishment of national diabetes registries. This approach has already been successful in the field of cancer (European Cancer Observatory). A European Diabetes Observatory could also monitor and report on the level of implementation of national policies for managing diabetes in order to identify potential gaps and assist in the sharing of best practice across Europe.

Box 8: Policy options - Key takeaways

National level policy options

1. Establish **national diabetes registries** to drive improvements in data collection methods, including improving methods for direct and indirect cost measurements of diabetes and its complications. As diabetes can exacerbate the amplitude and extent of potentially unrelated co-morbidities, it may be necessary to risk-adjust payment formulae, particularly in in-patient care (e.g. through DRGs), where this is not done. National registries should also be used to improve formal monitoring of diabetes care, including collection of prevalence, outcomes and complications data.
2. Data on the cost implications of diabetes and improved formal monitoring of the disease should be used to shape holistic national policies (such as **National Diabetes Programmes**) for managing diabetes.
3. Enhance and expand **prevention strategies** by investing in coordinated lifestyle awareness initiatives and promotion of healthy diet and lifelong physical activity with specific focus on childhood obesity; targeting high risk groups; applying a multi-sector approach involving sectors outside of the health arena; patient education programmes that enable patients to manage diabetes through diet and exercise.
4. Support and encourage tailored high risk **screening programmes** for diabetes to identify patients at an earlier stage.
5. **Ensure guidelines are evidence-based** with input from clinical experts, including screening protocols, best treatment pathways and management of complications.
6. **Improve primary healthcare** to enhance disease management and increase adherence whilst also improving tertiary prevention targeted to reach at risk groups to reduce complications.
7. **Expand co-ordinated and integrated multidisciplinary care** that clearly delineates treatment pathways and the roles of each professional along the way to create care pathways in conjunction with individual patient's needs.
8. Develop **diabetes care and quality targets** that are specific, measurable and realistic.

European Union policy options

9. Under the mandate of article 168 of the Lisbon Treaty, the European Union should facilitate the sharing of best practice between countries; monitor and report on data related to cost, prevalence, outcomes, and complications; establish criteria for standardised data that is comparable between Member States; monitor and report on national policies to manage diabetes in order to facilitate and support best practice sharing amongst Member States. The above could be achieved via the establishment of a European Diabetes Observatory.

Appendix 1 LSE survey of diabetes and diabetes costs in 5 EU countries: Experts interviewed, by country

United Kingdom	
Ann Dolben	Cardiff and Vale UHB
Iona Lidington	NHS Kingston: Public Health
Olivia Winchester	NHS Diabetes, Leicester
Dr Craig Currie	Cardiff University
Naomi Holman	Diabetes Health Intelligence
Gavin Terry	Diabetes UK
Spain	
Dr Julio Lopez Bastida	Spanish Health Care Service, Santa Cruz de Tenerife and University of Castilla la Mancha
Dr Mauro Boronat	Section of Endocrinology and Nutrition, Hospital Universitario Insular, Las Palmas de Gran Canaria
Dr Pedro Serrano Aguilar	Spanish Health Care Service, Santa Cruz de Tenerife
Dr Juan Oliva Moreno	University of Castilla La Mancha
Germany	
Professor Dr Andrea Icks	University of Duesseldorf and German Diabetes Centre
Professor Dr Hans Hauner	Technical University of Munich
Professor Dr Ferdinand Gerlach	German College of General Practitioners and Family Physicians (DEGAM) and University Hospital Frankfurt am Main
Dr Christina Scheidt Nave	Robert Koch Institute, Berlin
Dr Lutz Altenhofen and Dr Bernd Hagen	Central Research Institute of Ambulatory Health Care, Berlin/Cologne
France	
Dr Karine Chevreul, Karen Berg Brigham and colleagues	URC Eco (AP-HP) (Paris Health Economics and Health Services Research Unit), Paris, France
Clara Bouche	Endocrinology Department, Saint-Louis Hospital, Paris
Italy	
Dr Roberto D'Elia	General Department of Prevention, Ministry of Health, Rome.
Dr Emanuela Faloia	Endocrinologist at the Endocrinology Unit of the Regional Hospital of Ancona "Ospedali Riuniti"
Dr Paolo Foglini	Director of the diabetic centre of Fermo (Regione Marche) and Member of the directive panel of AMD (Italian Association of Diabetologists)
Dr Franco Gregorio	Director of the diabetic centre of Fabriano (Regione Marche)
Prof. Giulio Marchesini	Director of the metabolism diseases Unit of the S.Orsola-Malpighi University Hospital of Bologna, Regione Emilia Romagna
Dr Paola Pisanti	General Department of Health Planning, Ministry of Health, Rome and President of the Italian Commission of diabetes
Dr Vincenzo Pomo	Health Regional Agency, Regione Puglia
Dr Franco Stazio	Health Department of Marche Region, Diseases with Social Relevance Unit (PO Area delle patologie a rilevanza sociale e del sistema residenziale)
Dr Giacomo Vespasiani	Director of the diabetic centre of San Benedetto, Madonna del Soccorso Asl 12, San Benedetto del Tronto (Ap) (Regione Marche) and Former President of AMD (Italian Association of Diabetologists)

Appendix 2 Availability of cost and prevalence of diabetes-related complications data

		France		Germany		Italy		Spain		UK	
	Treatment	Cost	Prev	Cost	Prev	Cost	Prev	Cost	Prev	Cost	Prev
General	Microvascular			✓				✓			
	Macrovascular			✓			✓	✓			
	Emergency visits							✓		✓	
	In-patient visits							✓		✓	
Diabetic Retinopathy	Eye disease - total					✓	✓				
	Retinopathy			✓		✓			✓		✓
	Eye disease - general		✓			✓	✓				
	Eye screening	✓		✓				✓			
	Cataract surgery	✓		✓		✓		✓		✓	✓
	Post cataract surgery	✓				✓		✓			
	Laser treatment	✓	✓	✓		✓		✓			
	Blindness (general)	✓		✓				✓			
	Blindness - one eye		✓							✓	
Foot disease	Neutropathy	✓									
	Amputation - foot									✓	✓
	Amputation - lower extremity	✓	✓			✓		✓			
	Amputation -minor										✓
	Amputation - major										✓
	Diabetic foot									✓	
	Prosthesis	✓						✓			
	Gangrene treatment	✓						✓			
	Ulcer treatment	✓	✓								
Cardio-vascular disease	CVD general									✓	
	CHD general									✓	
	Statin therapy	✓		✓				✓			
	Coronary revascularisation		✓								
	Coronary bypass									✓	
	Heart failure		✓							✓	✓
	Myocardial infarction	✓	✓	✓		✓	✓	✓			✓
	MI - non-fatal									✓	
	MI – fatal									✓	
	Angina		✓	✓		✓		✓		✓	✓
	Congestive heart failure	✓		✓		✓		✓			
	Stroke	✓	✓	✓		✓		✓			✓
	Stroke - non-fatal									✓	
	Stroke - fatal									✓	
	IHD									✓	
Renal disease	Renal disease - general					✓	✓	✓	✓	✓	
	Microalbuminuria screen	✓		✓		✓		✓			
	Proteinuria screen	✓		✓		✓		✓			
	Microalbuminuria									✓	
	Glomerular filtration					✓					
	Dialysis	✓	✓			✓	✓				
	Peritoneal dialysis			✓				✓			
	Haemodialysis			✓				✓			
	Transplant	✓	✓	✓		✓	✓	✓		✓	

	2nd renal transplant									✓	
	Nephropathy			✓					✓	✓	
	ESRD									✓	✓
Erectile issues							✓				
Neuro-logical disease	Neurological complaints										
	Neuropathy			✓					✓		
Acute events	Ketoacidosis	✓		✓		✓		✓			✓
	Hypoglycaemic events	✓		✓		✓		✓			
Multiple	CHD+CVD									✓	
	CHD+Diabetic Foot									✓	
	CHD+Diabetic Foot + CVD									✓	
	CVD+CHD									✓	
	CVD+Diabetic Foot									✓	
	CVD+Diabetic Foot + CHD									✓	
	Diabetic Foot+CVD									✓	
	Diabetic Foot+CHD									✓	
	Diabetic Foot+CVD + CHD									✓	

Notes: Prev: prevalence; ✓: data available

Source: LSE survey in diabetes and diabetes costs in 5 EU countries.

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Appendix 3: Diabetes databases and information sources in EU5 countries

France	Germany	Italy	Spain	United Kingdom
▪ No regional or national diabetes registries ▪ 4 regional registries of Type 1 (1988-1997). Discontinued for financial reasons. ▪ ENTRED (Echantillon National Témoin Représentatif des personnes Diabétiques): Periodic survey (2001, 2007, 2010). Random sample of 9,781 Type 2 patients. In 2007 added paediatric Type 1 patients (n=924). Longitudinal periodic sampling includes specific Type 1 and Type 2 questions, quality of life, adherence, hospitalisations, socioeconomic position, sleep apnea, sexual problems, paediatrics, treatments, outcomes and complications: eye disease, renal disease, foot ulcers, amputations, hypertension, stroke, angina and myocardial infarctions (Fagot-Campagna et al. 2009).	▪ No regional or national diabetes registries ▪ Care data collected by social health insurance, but limited access. ▪ CoDiM: Sampling of 18.8% of the AOK social health insurance regarding costs and outcomes of diabetes care. ▪ DiaRegis: Prospective, observational study on Diabetes Treatment Patterns and Goal Achievement in Primary Diabetes Care, based on a multi-centre registry of 313 primary care covering 3,810 patients (2009-10). Data collected included anthropometrics, HbA_1C, plasma glucose levels, co-morbidities and medications. ▪ Praxisstudien: GP surgery surveys of 40,000 patients, and includes diabetes care and complications prevalence. ▪ Zentralinstitut Kassenärztliche Vereininung: Diabetes disease management programme data collected by the central institute for state health insurances.	▪ No regional or national diabetes registries ▪ DAI: Incidence of macrovascular complications in the Type 2 diabetes population, based HbA_1C levels, HDL cholesterol, smoking and microvascular complications (2007).	▪ Regional registries for Type 1 diabetes, including the "Diabetes Catalonia Registry" – (Abellana et al. 2009). ▪ A number of studies have been conducted to collect patient-level data (primarily focused on costs) that relate to diabetes - (Mata et al. 2002; Oliva et al. 2004) and updated by (López-Bastida 2010) .	▪ No national diabetes registries ▪ UKPDS (UK Prospective Diabetes Study Group): Followed 5,102 Type 2 patients for over a decade, examining complications, glycemic control, anthropometrics and biochemical data. Costs data were retrospectively added when it became apparent this information would be useful (Adler et al. 2000; Stratton et al. 2000) . ▪ GPRD (General Practice Research Database): GP practice database recording Type 1 and 2 patients for complications, prescribing and resource use (Soedamah-Muthu et al. 2008a; Soedamah-Muthu et al. 2008b). ▪ National Diabetes Audit (England and Wales): Annual compilation of key diabetes data from Primary Care Trusts (PCTs) and participating GP practices via the Quality and Outcomes Framework (suffers from problems in participation and reporting particularly in paediatric patients).All collect limited data on complications (primarily prevalence), often not addressing treatment or intermediate. ▪ Scottish Diabetes Survey: Annual survey of Scottish NHS Boards for Type 1 and 2, very similar to the English National Diabetes Audit (similar variables collected), (Scottish Diabetes Survey Monitoring Group 2010) ▪ SCI-DC Scotland diabetes information technology system

Source: Authors' compilations from our survey and PubMed searches.

Appendix 4: Diabetes databases and information on health outcomes

France	Germany	Italy	Spain	United Kingdom
▪ ENTRED: HbA_1C, blood pressure, BMI, HDL cholesterol, LDL cholesterol, triglycerides and urinary proteins; also includes information on key complications and their prevalence within the diabetic population (Ricci et al. 2009).	▪ DMP: HbA_1C >7.5%, blood pressure (systolic) ≤140mmHg, BMI (Birnbaum et al. 2010; Schäfer et al. 2010a; Schäfer et al. 2010b). ▪ Information on complications only through sickness fund databases.	▪ AMD Annals: Annual examination of diabetes centres. Include proportion of HbA_1C <7% and >8%, LDL <100mg/dl and >130 mg/dl, blood pressure <130/80 mmHg and >140/90 mmHg, BMI classes and percentage of smoker patients; information on complications also included (AMD Annals 2009). ▪ A study of the Emilia Romagna Region in Italy examined specific costs associated with eye and renal complications and myocardial infarction (Agenzia sanitaria e sociale regionale 2009).	▪ No national outcomes data is collected. Complication data scarce. ▪ Longitudinal quality of care study (RedGEDAPS) (1996-2007 data) examining HbA1C, total cholesterol, HDL, BMI, blood pressure (Franch Nadal et al. 2010).	▪ National Diabetes Audit and Scottish Diabetes Survey: complications, HbA_1C, albumin, creatinine, systolic blood pressure, total cholesterol, smoking, foot checks and retinal screening (Scottish Diabetes Survey Monitoring Group 2004). ▪ UKPDS and GPRS: anthropometrics, additional biochemistry, costs and mortality.

Note: Additional information pertaining to outcomes data, databases and monitoring can be found in Section 7 of the report.

Source: LSE survey in diabetes and diabetes costs in 5 EU countries.

Appendix 5 Direct diabetes costs based on International Diabetes Federation estimates (2007, €)

		France	Germany	Italy	Spain	UK
Diabetes health expenditure (millions) [α, β]	2007 IDF (Lower)	€6,941	€14,607	€5,090	€2,326	€3,033
	2007 IDF (Upper)	€13,032	€26,596	€9,641	€4,410	€6,029
Diabetes % total expenditure	2007	3.3 - 6.3%	5.8 - 10.5%	3.8 - 7.2%	2.6 - 4.9%	1.7 - 3.5%
Per patient diabetes expenditure[δ]	2007	€1,921	€1,982	€1,324	€932	€1,776
	2010	€3,125	€2,831	€2,118	€1,718	€2,697

Notes: [α] Lower and upper IDF diabetes expenditure derived from lower (R=2) and upper (R=3) estimates (R = all medical care expenditures for diabetes patients / non-diabetes patients age- and sex-matched) (IDF Diabetes Atlas, 2006 for 2007 estimates).

[β] Converted EUR (2007: USD/EUR=0.7296724; 2010: USD/EUR=0.75)

[δ] Per patient diabetes expenditure derived from (International Diabetes Federation (IDF) 2006).

Source: (International Diabetes Federation (IDF) 2006).

Appendix 6: Total direct diabetes costs: estimates from regional studies extrapolated nationally (France, Germany, Italy, Spain) or from government data (UK) (2001-2010)

		France[d]	Germany[c]	Italy [β]	Spain [α]	UK
Diabetes direct costs (millions)	2001	€5,700	€30,616[Koster06]	-	-	-
	2002	-	€33,300	-	€2,964	€2,067[ɤ]
	2003	-	€35,500	-	€3,003	-
	2004	€8,966	€35,400	-	€3,135	-
	2005	-	€38,200	-	€3,875	
	2006	-	€40,000	€6,640	€4,033	-
	2007	€12,500	€41,974	-	€4,246	€13,488[ε]
	2008	-	-	€7,635	€5,023	-
	2009	-	-	€7,921	€5,120	-
	2010[μ]	€12,932	€43,244	€7,937	€5,447	€20,322[n]

Notes: [d] (Ricci et al. 2009; Vallier et al. 2006).

[c] (Köster et al. 2011; Köster et al. 2006).

[α] Based on (López-Bastida 2010; Mata et al. 2002; Oliva et al. 2004)

[β] Based on annual cost estimates of €2,762/patient (Marchesini et al. 2010 ; Marchesini et al. 2011; Osservatorio Arno Diabete 2011), extrapolated nationally using 4.8% total diabetes ISTAT prevalence and 2009 OECD population estimates. Accounting for inflation of 3.5% (2008) and 0.8% (2009) (Eurostat).

[ε] Based on 10% total health expenditure (c.£9bn) (DOH, 2007). Additional annual social services costs of £230m added to 2007, but not 2002 or 2005. Converted to Euros (2007 GBP/EUR=1.46127).

[ɤ] (Wanless 2004).

[n] Based on (Currie et al. 2010; Morgan et al. 2010).

[μ] Costs extrapolated to 2010 using annual GDP deflator for each country (International Montary Fund (IMF); Trading economics Main website; World Bank).

Source: The authors based on the scientific literature.

Appendix 7: Diabetes complications and their cost: data collected through the LSE survey

Appendix 7A: Diabetic retinopathy - Screening, diagnostic and treatment costs

		France	Germany	Italy	Spain	UK
Patients routinely receiving eye checks:						
Type 1	Frequency	q12m	-	q12m	80%	>90%
	Treated	OPTH	-	OPTH	OPTH	OPTH
Type 2 (insulin dependent)	Frequency	q12m	-	✓	70%	>90%
	Treated	OPTH	-	n/a	OPTH	OPTH
Type 2 (oral hypoglycaemic)	Frequency	q12m	-	✓	50%	>90%
	Treated	OPTH	-	-	OPTH	OPTH
Treatment Costs (per patient annually)						
Laser treatment	(%)	16.6%	-	-	18%	-
	Cost	€113.36	-	-	€177	-
Panretinal photocoagulation	Cost	€125.40	€2,058	-	€50.29	€1,096
Cataract surgery	Cost	€271.70 + €125.40 for anaesthesia	-	-	€1,564	€2,830

Notes: OPTH: ophthalmologist.
Germany: Markov modelling in Type 2 patients with macrovascular disease, 2005 costs (inflated to 2010) collected from variety of government sources and other German CEA studies.
UK: UKPDS dataset 1998 costs inflated to 2010 costs and converted to Euros (€1,549/£). Monitoring frequency from the 2009/10 National Diabetes Audit (England and Wales).
Source: LSE survey in diabetes and diabetes costs in 5 EU countries.

Appendix 7B: Diabetic foot: Costs of monitoring and treatment

		France	Germany	Italy	Spain	UK
Patients routinely receiving foot checks						
Type 1	Frequency	q12m	-	q12m	50%	82% (23%*)
	Treated by	Endo/Diab	-	-	Endo/Diab	Endo/GP
Type 2 (insulin dependant)	Frequency	q12m	-	q12m	50%	82%
	Treated by	Endo/Diab	-	-	Endo/GP	Endo/GP
Type 2 (oral hypoglycaemic)	Frequency	q12m	-	✓	50%	82%
	Treated by	Endo/Diab	U-	-	GP	GP
Treatments costs (per patient annually)						
Debridement, wound care	€/patient		-	-	€1,598-2,510	€979-5,796
Diabetic foot ulcer	€/patient	€2,546-2,772/month	€988-2,010	-		€979-5,796
Amputation: toe	€/patient	€ 32,000	-	€ 9,515	€3,897-3,980	-
Amputation foot	€/patient	€ 32,000	-	€ 9,515	€4,606-5,489	€8,427-15,305
Amputation lower limb	€/patient	€ 32,000	Event €15,405 Follow up €3,652	€ 9,515	€4,606-5,489	€8,427-15,305

Notes: Endo/Diab: Endocrinologist or Diabetologist.

*refers to paediatric patients.

France: Retrospective detailed study of 239 patients with diabetic foot (n=192) and amputations (n=40). 2000 costs inflated to 2010.

Germany: Markov modelling in Type 2 patients with macrovascular disease, 2005 costs (inflated to 2010) collected from variety of government sources and other German CEA studies.

UK: NHS 2009/10 Hospital tariffs, converted to Euros (€1.1346/£). Range due to presence of cardiovascular disease (increasing costs) and emergency procedure (increasing costs). Monitoring frequency from the 2009/10 National Diabetes Audit (England and Wales).

Source: LSE survey in diabetes and diabetes costs in 5 EU countries.

Appendix 7C: Cardiovascular disease resulting from diabetes - Costs of testing and treatment

		France	Germany	Italy	Spain	UK
Patients routinely receiving cardiovascular disease checks						
Type 1	Frequency	q12m	-	q12m	90%	>90% (30-50%*)
	Treated by	-	-	-	Endo/Diab	Endo/Cardio
Type 2 (insulin dependent)	Frequency	q12m	-	q12m	90%	>90%
	Treated by	-	-	-	Endo/GP	Endo/ Cardio/GP
Type 2 (oral hypo-glycaemic)	Frequency	q12m	-	q12m	90%	>90%
	Treated by	-	-	-	GP	Endo/ Cardio/GP
Treatments used for cardiovascular disease						
ACE inhibitors	Generic: €/patient	-	-	-	€42.36	
ACE inhibitors	Branded: €/patient	-	-	-	€110 (Captopril 25mg/day)	
Myocardial infarction inpatient	€/patient	€5,272/patient (non-fatal) €4,737/patient (fatal)	MI: €9,767 Follow up: €4,032	-	€6,960	Non-fatal: €7,418 Fatal: €2,100
Congestive heart failure inpatient	€/patient	-	-	-	€3,428	-
Stroke inpatient	€/patient	€6,368/patient (non-fatal) €7,537/patient (fatal)	Stroke: €11,786 Follow up: €6,831	-	€6,375	Non-fatal: €4,314 Fatal: €6,166

Notes:

France: Tuppin P et al. Characteristics and management of diabetic patients hospitalized for myocardial infarction in France. *Diabetes Metab* (2010)36:129-36.

Endo: Endocrinologist; Cardio: Cardiologist; *: paediatrics

France: DRG/PMSI dataset 2003 costs (inflated to 2010) of inpatient visits for diabetic patients with CVD (Colin et al, 2007).

Germany: Markov modelling in Type 2 patients with macrovascular disease, 2005 costs (inflated to 2010) collected from variety of government sources and other German CEA studies.

UK: UKPDS dataset 1998 costs inflated to 2010 costs and converted to Euros (€1,549/£). Monitoring frequency from the 2009/10 National Diabetes Audit (England and Wales).

Source: LSE survey in diabetes and diabetes costs in 5 EU countries.

Appendix 7D: Renal disease resulting from diabetes - Costs of testing and treatment

		France	Germany	Italy	Spain	UK
Patients routinely receiving renal checks						
Type 1	Frequency	q12m	✓	✓	q6-12m	60-90% (30%)
	Treated by	Urinary albumin, serum creatinine	-	-	Endo/Diab	Endo/Nephr
Type 2 (insulin)	Frequency	q12m	✓	✓	q6-12m	60-90%
	Treated by	Urinary albumin, serum creatinine	-	-	GP / Endo	Endo/Nephr
Type 2 (oral hypo-glycemic)	Frequency	q12m	✓	q12m	q6-12m	60-90%
	Treated by	Urinary albumin, serum creatinine	-	-	GP / Endo	Endo/Nephr/ GP
Treatments costs in renal disease (per patient annually)						
Dialysis	% patients	20.9% haemodialysis patient are diabetic	-	-	23% haemodialysis patient are diabetic	-
	€/patient	€81,449	€65,511	-	€41,052	€53,764
Peritoneal Dialysis	€/patient	€49,953	€52,187	-	€24,515	-
Kidney transplants	€/patient	-	Transplant €76,852 Follow up €12,291	-	€35,171	€33,437

Notes:

Germany: Markov modelling in Type 2 patients with macrovascular disease, 2005 costs (inflated to 2010) collected from variety of government sources and other German CEA studies.

Spain: Oliva et al (2002); Amenabar et al, 2000; costs inflated to 2010.

UK: Haemodialysis cost comes from ESRD costs from study comparison of US (n=2.5m) and UK (n=0.33m) nephrology patients, 2001 costs inflated to 2010 and converted to € (€1.549/£). No annual UK peritoneal costs found, kidney transplant costs come from same source. Monitoring frequency from the 2009/10 National Diabetes Audit (England and Wales).

Sources: LSE survey in diabetes and diabetes costs in 5 EU countries and evidence from the literature.

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Appendix 8: Quality and Outcomes Framework (QOF)

Diabetes QOF indicators (17) (2009/10). Outcome indicators are highlighted yellow.	
DM19	The practice can produce a register of all patients aged 17 years and over with diabetes mellitus, which specifies whether the patient has type 1 or type 2 diabetes.
DM02	The percentage of patients with diabetes whose notes record BMI in the previous 15 months
DM05	The percentage of patients with diabetes who have a record of HbA1c or equivalent in previous 15 months
DM09	The percentage of patients with diabetes with a record of the presence or absence of peripheral pulses in the previous 15 months
DM10	The percentage of patients with diabetes with a record of neuropathy testing in the previous 15 months
DM11	The percentage of patients with diabetes who have a record of the blood pressure in previous 15 months
DM12	The percentage of patients with diabetes in whom the last blood pressure is 145/85 or less
DM13	The percentage of patients with diabetes who have a record of micro-albuminuria testing in the previous 15 months (exception reporting for patients with proteinuria)
DM15	The percentage of patients with diabetes with proteinuria or micro-albuminuria who are treated with ACE inhibitors (or A2 antagonists)
DM16	The percentage of patients with diabetes who have a record of total cholesterol in previous 15 months
DM17	The percentage of patients with diabetes whose last measured total cholesterol within the previous 15 months is 5mmol/l or less
DM18	The percentage of patients with diabetes who have had influenza immunisation in preceding 1 September to 31 March
DM21	The percentage of patients with diabetes who have a record of retinal screening in previous 15 months
DM22	The percentage of patients with diabetes who have a record of estimated glomerular filtration rate (eGFR) or serum creatinine testing in the previous 15 months
DM23	The percentage of patients with diabetes in whom the last HbA1c is 7 or less (or equivalent test/reference range depending on local laboratory) in the previous 15 months.
DM24	The percentage of patients with diabetes in whom the last HbA1c is 8 or less (or equivalent test/reference range depending on local laboratory) in the previous 15 months.
DM25	The percentage of patients with diabetes in whom the last HbA1c is 9 or less (or equivalent test/reference range depending on local laboratory) in the previous 15 months.

Source: UK NHS.

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