

Diabetes Fact Sheet



European Diagnostic Manufacturers Association

***In Vitro* Diagnostics**
Making a real difference
in Health & Life Quality

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Fact Sheet

1. Diabetes: Definition and types

2. Burden of illness

- » Prevalence
- » Quality of Life → Diabetic specific measurement scales
- » Complications
- » Costs (Check diversity of viewpoints)

3. Disease management

- » Devices for SMBG (episodic and continuous)
- » Critical role of HbA1C
- » Education as a prerequisite

4. Evidence-based:

- » Definition concept of Evidence
- » What is the evidence available now
- » How can the industry provide that evidence
- » What barriers exist for industry to provide evidence: ethical and finance

5. Role of Industry

- » Industry investment in design and development of devices
- » Education materials for patients and healthcare professionals, continuous training, congresses

Appendix:

- Regulatory issues (CE mark, quality)
- Evolution of glucose testing
- Quality of Life: Diabetic specific measurement scales
- Acronyms & Definitions



About Diabetes

1. About Diabetes¹

Diabetes is an illness which occurs as a result of problems with the production and supply of **insulin** in the body and at present there is no cure². The UN Resolution 61/225³ has identified it as a **major issue**.

There are two principle forms of diabetes:

- **Type 1 diabetes** (formerly known as insulin-dependent) where the pancreas fails to produce the insulin that is essential for survival. This form of diabetes develops most frequently in children and adolescents but is being increasingly noted later in life.
- **Type 2 diabetes** (formerly known as non-insulin-dependent diabetes) results from the body's inability to respond properly to the action of insulin produced by the pancreas. Type 2 diabetes is much more common than type 1 and accounts for around 90% of all diabetes cases worldwide. It occurs most frequently in adults but is being noted increasingly in adolescents as well.

Certain **genetic markers** have been shown to increase the risk of developing Type 1 diabetes. Type 2 diabetes is strongly familial but it is only recently that some genes have been consistently associated with increased risk for developing Type 2 diabetes in certain populations. Both types of diabetes are complex diseases caused by **mutations in more than one gene** as well as by **environmental factors**.

Impaired glucose tolerance (IGT) and **impaired fasting glycaemia** (IFG) refer to **blood glucose** concentrations above the normal range but below those that are diagnostic for diabetes. Subjects with IGT and/or IFG are at substantially higher risk of developing diabetes and **cardiovascular disease** than those with normal glucose tolerance results. The benefits of clinical intervention in subjects with moderate glucose intolerance are a topic of much current interest.

Diabetes during **pregnancy** may give rise to several adverse outcomes including **congenital malformations**, increased birth weight and an elevated risk of **perinatal mortality**. In that case a physician has to differentiate between pregnancy in women with Diabetes and gestational Diabetes to achieve a suitable treatment for these women.

2. Burden of Illness¹

2.1 Prevalence

Recently compiled data by the WHO¹ shows that approximately **150 million people have diabetes worldwide** and that this number may well **double by the year 2025**. Much of this increase will occur in developing countries and will be due to population growth, ageing, unhealthy diets, obesity and sedentary lifestyles. By 2025, whilst most people with diabetes in developed countries will be aged 65 years or more, in developing countries most will be in the 45-64 year age bracket and be affected during their most productive years.



Burden of Illness

In 2003, Diabetes affected an estimated 27 million people in the 27 Members States of the European Union (over 7.6% of the population) and was also a **major cause of death**. The last twenty years have seen an explosive increase in diabetes globally linked, among other factors, to the emergence of **obesity**. Recent projections, based on the assumption of a stable obesity rate, predict that about 31.5 million citizens (approximately 8.9% of the population) will be affected by diabetes in the EU by 2025⁴. This figure could be even higher as people adopt more sedentary lifestyles both at home and at work which, combined with Unbalanced diets, increases the risk of becoming overweight. In addition to the human costs of the disease discussed above the estimated Financial costs of diabetes are staggering costing the National Health Service in the UK £5,185,314,000 in 2000. Effective therapy and life-style intervention can delay the onset of disease complications yet it is estimated that a third of diabetes cases in Europe are estimated to be still undiagnosed⁵.

Prevalence estimates of diabetes mellitus (DM) - European Region Selected year: 2003

Country	Population (20-79) (000's)	DM prevalence (%)	Number of people with DM (000's) in the 20-79 age group							
			Rural	Urban	Male	Female	20-39	40-59	60-79	Total
Austria	5,991	9.60%	0.00	0.00	258.5	317.5	38.8	172.7	364.5	576
Belgium	7,531	4.20%	0.00	0.00	140.6	174.5	3.1	71.1	240.9	315.1
Bulgaria	5,894	10.00%	135.8	455.4	235.7	355.5	37.6	248.1	305.5	591.2
Cyprus	541	5.10%	0.00	0.00	12.3	15.4	0.9	9.4	17.5	27.7
Czech Rep.	7,734	9.50%	0.00	0.00	365.2	369.6	66.8	286.2	381.9	734.9
Denmark	3,863	6.90%	0.00	0.00	120.9	144	23.3	87	154.6	264.9
Estonia	991	9.70%	0.00	0.00	43.4	52.9	8.6	33.3	54.4	96.3
Finland	3,775	7.20%	0.00	0.00	130.3	143.2	10.3	56.3	207	273.5
France	42,546	6.20%	0.00	0.00	1,306.30	1,347.30	175	1,045.30	1,433.30	2,653.60
Germany	61,895	10.20%	0.00	0.00	2,879.30	3,415.00	374	1,752.70	4,167.60	6,294.30
Greece	8,069	6.10%	0.00	0.00	217	276	12.9	129	351	493
Hungary	7,350	9.70%	0.00	0.00	336.3	375.1	62.6	259.5	389.2	711.4
Ireland, Rep.	2,674	3.40%	0.00	0.00	43.7	46.2	6	34.4	49.4	89.8
Italy	43,925	6.60%	0.00	0.00	1,400.20	1,479.90	185.7	1,009.40	1,684.90	2,880.10
Latvia	1,758	9.90%	0.00	0.00	77.5	96.1	15.1	58.4	100.1	173.6
Lithuania	2,648	9.40%	0.00	0.00	114.7	134.2	24.6	84.8	139.5	248.9
Malta	280	9.20%	0.00	0.00	10.6	15.3	0.3	9	16.5	25.8
Netherlands	11,678	3.70%	0.00	0.00	203.4	228.8	5.3	118.3	308.5	432.2
Poland	27,852	9.00%	0.00	0.00	1,238.70	1,267.80	239	1,002.50	1,265.00	2,506.50
Portugal	7,471	7.80%	0.00	0.00	278.5	305.9	14.9	170.9	398.7	584.5
Romania	16,392	9.30%	0.00	0.00	760	759.2	154.7	519	845.6	1,519.20
Slovakia	3,903	8.70%	0.00	0.00	167.5	171.3	35.9	135.6	167.2	338.7
Slovenia	1,511	9.60%	0.00	0.00	72.2	73.1	13.1	53.5	78.6	145.2
Spain	30,329	9.90%	0.00	0.00	1,209.70	1,794.60	838.4	973.2	1,192.60	3,004.30
Sweden	6,290	7.30%	0.00	0.00	206.4	250.5	36.3	140.1	280.5	456.9
UK	42,423	3.90%	0.00	0.00	813.7	857.9	89.4	588.9	993.3	1,671.50
Total	355,315	7.60%	135.8	455.4	12,642.40	14,466.70	2,472.60	9,048.50	15,587.90	27,109.10

Source: IDF Diabetes Atlas, 3rd Edition, <http://eatlas.idf.org/>



Burden of Illness

Prevalence estimates of diabetes mellitus (DM) - European Region Selected year: 2025

Country	Population (20-79) (000's)	DM prevalence (%)	Number of people with DM (000's) in the 20-79 age group							
			Rural	Urban	Male	Female	20-39	40-59	60-79	Total
Austria	5.887	11.9%	0	0	338.3	364.5	28.2	187.0	487.5	702.8
Belgium	7.658	5.2%	0	0	180.4	214.2	2.6	74.9	317.1	394.6
Bulgaria	4.871	11.6%	93.7	471.2	223.1	341.7	28.8	233.3	302.8	564.9
Cyprus	637	6.3%	0	0	39159.00	21.8	1.0	10.5	28.6	40.1
Czech Rep.	7.599	11.7%	0	0	441.9	445.5	51.9	292.2	543.3	887.4
Denmark	3.988	8.3%	0	0	148.2	182.2	20.3	83.3	226.8	330.4
Estonia	814	11.0%	0	0	41.7	47.7	6.4	30.2	52.8	89.4
Finland	3.822	10.0%	0	0	186.0	198.0	9.3	47.1	327.6	383.9
France	45.141	7.3%	0	0	1,609.5	1,675.8	156.3	1,058.2	2,070.8	3,285.3
Germany	60.03	11.9%	0	0	3,459.1	3,684.5	293.8	1,852.9	4,997.0	7,143.7
Greece	7.767	7.3%	0	0	254.3	312.1	9.2	153.4	403.8	566.4
Hungary	6.807	11.2%	0	0	364.7	397.0	49.4	261.7	450.6	761.7
Ireland, Rep.	3.29	4.1%	0	0	66.0	68.5	6.0	45.3	83.2	134.5
Italy	40.482	7.9%	0	0	1,583.5	1,614.8	116.4	1,093.1	1,988.8	3,198.3
Latvia	1.61	11.1%	0	0	84.4	93.7	12.7	60.0	105.5	178.2
Lithuania	2.626	10.8%	0	0	136.0	148.1	21.2	96.8	166.1	284.1
Luxembourg	415	4.4%	0	0	39180.00	9.8	0.2	3.7	14.3	18.1
Malta	303	11.6%	0	0	39187.00	49.4	0.3	7.9	26.9	35.1
Netherlands	12.538	5.1%	0	0	290.9	344.4	4.4	127.8	503.2	635.3
Poland	28.567	11.0%	0	0	1,545.9	1,606.7	217.8	1,017.5	1,917.3	3,152.6
Portugal	7.456	9.5%	0	0	344.4	361.8	11.0	210.7	484.5	706.2
Romania	15.86	10.6%	0	0	834.3	842.7	123.0	645.1	908.8	1,676.9
Slovakia	4.127	10.7%	0	0	219.2	224.1	31.7	153.6	258.1	443.3
Slovenia	1.451	12.0%	0	0	86.8	86.7	9.5	54.7	109.2	173.5
Spain	29.155	10.1%	0	0	1,478.9	1,466.0	40.0	874.0	2,030.9	2,944.9
Sweden	6.373	8.6%	0	0	245.6	302.6	32.9	131.5	383.8	548.2
UK	45.322	4.7%	0	0	1,079.8	1,061.5	79.4	628.2	1,433.7	2,141.4
Total	354.597	8.9%	93.7	471.2	15,285.0	16,136.3	1,363.7	9,434.6	20,623.0	31,421.4

Source: IDF Diabetes Atlas, 3rd Edition, <http://eatlas.idf.org/>

Diabetes Type 1

Frequency:

- In the USA about 5-15% of all cases of diabetes are type 1 diabetes. It is the most common metabolic disease of childhood with a yearly incidence of 15 cases per 100,000 people younger than 18 years. Approximately 1 million Americans have type 1 diabetes and physicians diagnose 10,000 new cases annually.
- Scandinavia has the highest prevalence rates for type 1 diabetes with approximately 20% of the total number of people with the disease whilst China and Japan have the lowest prevalence rates with less than 1% of all people with diabetes. Some of these differences may relate to definitional issues and the completeness of reporting.



Burden of Illness

Mortality/Morbidity:

Type 1 diabetes is associated with **high morbidity and premature mortality** due to the complications associated with the disease. The annual financial cost from diabetes overall in the USA exceeds \$100 billion accounting for almost \$1 of every \$7 of US health expenditures in 1994 in terms of medical care and loss of productivity. Advances in treatment that permit tight glycaemic control and control of co-morbidities (e.g. hyperlipidaemia) can greatly reduce the incidence of micro- and macro vascular complications.

As a result of these complications people with diabetes have an increased risk of developing ischaemic heart disease, cerebral vascular disease, peripheral vascular disease with gangrene of lower limbs, chronic renal disease, reduced visual acuity and blindness and autonomic and peripheral neuropathy.

Sex: Type 1 diabetes is more common in men than in women.

Age: Type 1 diabetes usually starts in children aged 4 years or older with the **peak incidence of onset at 11 - 13 years** of age coinciding with early adolescence and puberty. Also a relatively high incidence of Diabetes occurs in people in their late 30s and early 40s when it tends to present in a less aggressive manner (early hyperglycaemia without ketoacidosis and gradual onset of ketosis)⁶.

Diabetes Type 2

Frequency:

In the USA in 2002 the estimated prevalence of diabetes was 6.3% (18.2 million people) with approximately one quarter of cases being undiagnosed. **More than 90% of cases of diabetes are type 2** diabetes. With increasing obesity in the population, an older population and an increase in the population of higher-risk minority groups (see Race); the **prevalence of type 2 diabetes is increasing**.

Type 2 diabetes is **less common in non-western countries** where the diet contains fewer calories and calorific expenditure on a daily basis is higher; however, as people in these countries adopt western lifestyles, weight gain and type 2 diabetes are becoming virtually epidemic.

Mortality/Morbidity:

Diabetes is one of the leading causes of morbidity and mortality in the United States because of its role in The development of **optic, renal, neuropathic and cardiovascular disease**. These complications, and Particularly cardiovascular disease (which accounts for between 50-75% of medical expenditures), are the major sources of expenses for patients with diabetes. Approximately two thirds of people with diabetes die from heart disease or stroke. Men with diabetes face a 2-fold increased risk for coronary heart disease and women have a 3- to 4-fold increase in risk. The 2002 estimate for direct medical costs due to diabetes in the United States was \$92 billion with another \$40 billion in indirect costs. Approximately 20% of Medicare funds are spent on these patients.



Burden of Illness

In the United States of America Type 2 diabetes is:

- **The leading cause of blindness** in working-age adults accounting for 12,000-24,000 newly blind persons every year. The National Eye Institute estimates that 90% of cases of lost vision are preventable.
- **The leading cause of end-stage renal disease (ESRD)** accounting for 44% of new cases according to the Centres for Disease Control and Prevention (CDC). In 2001 42,813 people began renal replacement therapy and 142,963 people with diabetes were on dialysis or had received a kidney transplant.
- **The leading cause of non-traumatic lower limb amputations** with a 15- to 40-fold increase in risk compared to that of the non-diabetic population. In 2000-2001, about 82,000 non-traumatic lower limb amputations were performed related to neuropathy and vasculopathy.

Sex: Type 2 diabetes mellitus is slightly more common in older women than men.

Age: While type 2 diabetes traditionally has been thought to affect individuals older than 40 years it is being recognized increasingly in younger persons, particularly in highly susceptible racial and ethnic groups. In some areas more type 2 than type 1 diabetes is being diagnosed in prepubertal children, teenagers and young adults. Type 2 diabetes is observed even in some obese children. **Prevalence of diabetes increases with age.** Virtually all cases of the disease in older individuals are type 2 diabetes.⁷

Pregnancy in Women with Diabetes ^{8, 9, 10, 11}

Pregnancy poses a major challenge to the health and management of people with diabetes. To achieve a healthy pregnancy for a woman with diabetes her **blood glucose should be maintained in the normal range** both before she becomes pregnant and during the pregnancy. This requires a **diabetes management plan** that keeps meals, exercise and insulin in balance with the plan evolving during the pregnancy to reflect the **changing needs** of the mother. A major part of this care is the **frequent measurement of the woman's blood glucose concentrations**. With blood glucose in the target range and good medical care the probability of women with diabetes having a trouble-free pregnancy and a healthy baby is almost the same as for women without the disease.

Despite modern medical advances babies born to women with diabetes, and especially to women who have poor control of their diabetes, are still at greater risk of suffering **birth defects**. As most women do not know they are pregnant until the foetus is between two and four weeks old good **blood glucose control before getting pregnant is very important**. During the first six weeks of pregnancy the foetus's organs are forming. Blood glucose levels during these early weeks affect these developing organs. High blood glucose levels cause glucose and ketones to pass through the placenta to the foetus. Women with poorly controlled diabetes in the early weeks of pregnancy are two to four times more likely than women without diabetes to have a baby with a serious disorder such as a heart or a neural tube defect; however, good blood glucose control around the time of conception greatly reduces these risks.



Burden of Illness

High blood glucose levels also results in the foetus being "fed" extra glucose during gestation. This excess **glucose can make the foetus too big and fat** with the delivery of the resultant big baby being harder for both mother and baby. Also, because the foetus is getting extra glucose, its pancreas makes extra insulin. After birth the baby must be monitored and treated if blood glucose level drops too low as a result of the production of extra insulin.

During pregnancy a mother's body changes as the foetus grows and, if the mother is suffering from diabetes, these changes will affect blood glucose levels. Pregnancy can also make **symptoms of low blood glucose hard to detect** and is another reason why good glucose control is important during a pregnancy. Thus a **key part of the care for both the mother and the developing foetus is the self monitoring of blood glucose before conception and during and after pregnancy.**

Gestational Diabetes

Gestational diabetes usually develops **midway through a pregnancy** (20 to 24 weeks) and is caused by the **changes in the body's hormones** during the pregnancy. In addition to supplying the foetus with nutrients and water the placenta produces a number of hormones vital to the pregnancy, some of which inhibit insulin. As the placenta grows larger during the course of the pregnancy the more **placental hormones** it produces resulting in **increased insulin resistance**. In most women the pancreas is able to make additional insulin to overcome this insulin resistance; however, if the pancreas is unable to make sufficient insulin, gestational diabetes results. About three to five percent of all pregnant women develop gestational diabetes during pregnancy. Gestational diabetes **ends at the birth of the baby** because the removal of the placenta means that the source of the hormones that inhibit insulin is removed.

The most important means of treating gestational diabetes is to control blood glucose levels by diet, regular exercise and the self-monitoring of the blood glucose by the patient. **A frequent self-monitoring of blood glucose helps to achieve an uncomplicated pregnancy and a healthy baby.** Despite making the above lifestyle changes a few women's blood sugar levels remain too high and they may need daily **injections of insulin**. The extra insulin will not cross the placenta and will not affect the foetus.

2.2 Quality of Life

Quality of life is the appropriate way **to understand the burden of disease** and consequently the improvement of care. It is appropriate because it is determined by the **value of health** from the viewpoint of the people with diabetes and their carers.

Quality of life has different aspects (physical, psychological and social) that can be measured with the following tools that emphasise the different aspects:



Burden of Illness

Diabetic specific measurement scales¹²

Diabetes Care Profile (DCP)
Diabetic Foot Ulcer Scale (DFS)
Diabetes Impact Measurement Scales (DIMS)
Diabetes Knowledge Test (DKT)
Diabetes Mellitus History (DMH)
Diabetes Quality of Life Clinical Trial Questionnaire (DQLCTQ)
Diabetes Quality of Life measure (DQOL)
Diabetes Quality of Life for Youth scale (DQOLY)
Diabetes Self-Management Profile (DSMP / DSMP-F)
Diabetes specific quality of life scale (DSQOLS)
Audit of Diabetes Dependent QoL (ADDQoL)
Appraisal of Diabetes Scale (ADS)
Hypoglycaemia Fear Survey (HFS)
Impact of Child Illness scale (ICI)
Multidimensional Diabetes Questionnaire (MDQ)
Well-Being Questionnaire (WBQ)
Diabetes Fear of Injecting and Self-testing Questionnaire (D-FISQ)
Diabetes Health Profile (DHP-1 and DHP-18)
Diabetes Symptom Questionnaire (McColl, Steen et al., 1995)

[See Annex 3: Diabetes Specific Measurement Scales]

Patient outcomes studies show that **people who maintain their glucose levels under control have better quality of life**. Quality of Life (QOL) plays an important role in depicting the burden of illness from a patient's view. In a multi centre study the researchers found that with the onset of either micro-vascular or macrovascular complications quality of life (0.69 and 0.69, respectively) is adversely affected, and the presence of both types of complications further reduced the quality of life score to 0.59.

Treat-ment with insulin was also associated with a reduced quality of life (0.62). Multivariate analysis showed that the following factors independently predict a poorer quality of life: gender, compli-cations, treatment type, age, obesity and hyperglycaemia. The findings lead to the conclusion hat **health-related quality of life is an important issue in type 2 diabetes and these decreases with disease¹³**.

In the French QUODIEM study, the researchers also found that the QOL of type 2 diabetics is negatively influenced by age (>75 years), female gender, loneliness, and the absence of professional or physical activity. But they also stress that **self-management of glycaemia was associated with improved QOL¹⁴**

An important psychological aspect of quality of life for people with diabetes is the high prevalence of **depression**. People suffering depression are less likely to make lifestyle changes that meet treatment goals. Patient education necessarily has to take this fact into account to ensure the proper management of the disease.

Evidence from prospective and cross-sectional studies demonstrates that the **presence of diabetes doubles the risk of co-morbid depression**. This commonly overlooked co-morbidity affects more than one quarter of the diabetic population, making its recognition and treatment in diabetic patients clinically relevant. Concurrent depression is associated with a decrease in metabolic control, poor adherence to medication and diet regimens, a reduction in quality of life, and an increase in health care expenditures. In turn, poor metabolic control may exacerbate depression and diminish response to antidepressant regimens. Psychotherapy and pharmacotherapy are effective in the presence of diabetes; both cognitive behaviour therapy and selective serotonin re-uptake inhibitors are weight neutral and have been associated with glycaemia improvement in some studies¹⁵



Burden of Illness

2.3 Complications ^{16, 17, 18, 19, 20}

Complications associated with diabetes

Diabetes lowers the average life expectancy by up to 18 years, increases cardiovascular disease risk two to four fold and is the leading cause of kidney failure, lower limb amputations and adult-onset blindness. Amongst the complications of diabetes are:

- **Diabetic retinopathy** - this is a leading cause of **blindness and visual disability**. Diabetes is associated with damage to the small blood vessels in the retina resulting in loss of vision. Findings, consistent from study to study, make it possible to suggest that, after 15 years of diabetes, approximately 2% of people become blind whilst about 10% develop severe visual handicap. Loss of vision due to certain types of glaucoma and cataract may also be more common in people with diabetes. Good metabolic control can delay the onset and progression of diabetic retinopathy. Loss of vision and blindness in persons with diabetes can be prevented by early detection and treatment of vision-threatening retinopathy by regular eye examinations and timely intervention with laser treatment and, in cases of advanced retinopathy, surgical intervention. There is evidence that, even in developed countries, a large proportion of those patients with diabetes that are in need of treatment for their retinopathy are not receiving such care due to lack of public and professional awareness compounded by an absence of treatment facilities. In developing countries, in many of which diabetes is now common, such care is inaccessible to the majority of the population.
- Diabetes is among the leading causes of **kidney failure** but its impact varies between populations and is also related to the severity and duration of the disease. Several measures to slow down the progress of renal damage have been identified including control of high blood glucose, control of high blood pressure, intervention with medication in the early stage of kidney damage and restriction of dietary protein. **Screening and early detection of diabetic kidney disease are an important means of prevention.**
- **Heart disease** accounts for approximately 50% of all deaths among people with diabetes in industrialized countries. Risk factors for heart disease in these populations include smoking, high blood pressure, high serum cholesterol and obesity. Diabetes negates the protection from heart disease which pre-menopausal women without diabetes experience. Recognition and management of these conditions may delay or prevent heart disease in people with diabetes.
- **Diabetic neuropathy** is probably the most common complication of diabetes. Studies suggest that up to 50% of people with diabetes are affected to some degree. A major risk factor that contributes to this condition is the **level and duration of elevated blood glucose**. Neuropathy can lead to **sensory loss and damage to the limbs** and is also a major cause of **impotence** in diabetic men.
- **Diabetic foot disease**, due to changes in blood vessels and nerves, often leads to **ulceration** and subsequent **limb amputation**. It is one of the most costly complications of diabetes especially in communities with inadequate footwear. It results from both vascular and neurological disease processes. Diabetes is the most common cause of non-traumatic amputation of the lower limb. Regular inspection and good care of the foot may prevent the development of such conditions.



Burden of Illness

Risks of Hypoglycaemia

Hypoglycaemia is the clinical syndrome that results from **low blood sugar**, the symptoms and severity of which can vary from person to person. Classically, hypoglycaemia is diagnosed by a low blood sugar with symptoms that resolve when the sugar level returns to the normal range. True hypoglycaemia usually occurs in patients being treated for [diabetes](#) (type 1 and type 2). Hypoglycaemia is dangerous. As a complication of diabetes it is perhaps the most **easily treated**, but can also be the most **immediately fatal**. Awareness of the signs, symptoms and risks of hypoglycaemia and diligent monitoring of blood sugars allows hypoglycaemia to be controlled and even avoided.

Hypoglycaemic episodes are often the limiting factor in achieving optimal blood sugar control. In large scale studies looking at tight control in both type 1 and type 2 diabetes, low blood sugars occurred more often in the patients who were managed most intensively. This is important for patients and physicians to recognize, especially as the goal for treating patients with diabetes becomes **tighter blood sugar control**.

In order to function properly the brain depends on glucose and, as the brain is unable to make its own glucose, it is 100% dependent on the rest of the body for its supply. Thus if blood glucose levels fall the function of the brain can be adversely affected.

Hypoglycaemia is dangerous because it **impacts the brain or nerve centre**, which derives almost all of its energy from glucose. The first set of symptoms of hypoglycaemia is the result of the nervous system's response to low glucose levels. Patients may experience any of the following:

- nervousness,
- sweating,
- intense hunger,
- trembling,
- weakness,
- palpitations, and
- often have trouble speaking.

If the person's blood glucose levels continue to fall then the brain does not get enough glucose and symptoms progress to **confusion, drowsiness, changes in behaviour, coma** and **seizure** and, ultimately, even **death**. Clearly there is significant risk to an individual should they experience severe Hypoglycaemia especially if they are driving, operating machinery in the workplace or by themselves (and especially if they are in a remote location). Additionally such severe symptoms are distressing to family and carers and, under certain circumstances (if the person is driving), may also pose a **risk to the general public**.

The **self-monitoring of blood glucose** by people with diabetes is a key technique in enabling them to identify when their blood glucose levels are beginning to decrease significantly thereby enabling them to take **preventive action** (i.e. ingest some glucose). Additionally it is important for people with diabetes to measure their blood glucose levels before they drive a car, operate heavy machinery and do anything physically taxing.



Burden of Illness

Risks of Hyperglycaemia

Diabetes is ranked among the leading causes of **blindness**, **renal failure** and **lower limb amputation** and is also one of the **leading causes of death** through its effects on **cardiovascular disease** (70-80% of people with diabetes die of cardiovascular disease). From a public health perspective the complications of diabetes are important and they represent a major cause of **human suffering and disability** with the huge **socio-economic costs** through premature morbidity and mortality. These costs are manifested directly as health care costs but, importantly, indirectly by their impact on economic development and the pain and distress suffered by friends and families of sufferers.

Chronic elevation of blood glucose eventually leads to **tissue damage** with consequent, and often serious, disease. Whilst evidence of tissue damage can be found in many organ systems, it is the kidneys, eyes, peripheral nerves and vascular tree that show the most significant diabetic complications. Keeping blood glucose levels as close to normal as possible reduces the risks of long-term complications as poorly managed diabetes can lead to a host of long-term complications, i.e. cardiovascular disease, retinopathy, renal failure, effects on peripheral nerves and arteries and neuropathy, as discussed above.

However, keeping blood glucose as close to normal as possible reduces the risk of developing some of these complications by 50% or more and the **self-monitoring of blood glucose** is key to achieving this; but, as diabetes affects the whole body including blood vessels and nerves, controlling cholesterol and blood pressure also plays a major role in decreasing long term complications of diabetes. As well as routinely measuring blood pressure and undergoing eye and foot examinations people with diabetes should have their **HbA1c**, **cholesterol** and **microalbumin** measured regularly.

Therefore **diagnostics play a major role in the care and management of people with diabetes**.

2.4 Costs of Diabetes

As the diabetes epidemic progresses and the healthcare sectors of countries remain under pressure, economic aspects of diabetes and diabetes care continue to raise awareness. When discussing the topic, it is significant to differentiate between its impact on national productivities, health services, individuals and families. Therefore diabetes cost estimates can be distinguished into²¹:

Costs of diabetes healthcare

- attributable to diabetes itself and/or the complications
- includes the cost of hospital, of hospital admission and other healthcare episodes for diabetic ketoacidosis, hypoglycaemia and other direct results of diabetes or its therapy

Total cost of care

- includes all episodes of care for people with diabetes (diabetes related healthcare and those of care in which the main reason for the encounter is unrelated to diabetes). Here it is considered that the course of diseases is more severe and costly in patients with diabetes.

Indirect and intangible costs

- including cost of lost production and aspects of quality of care

Stagnation of national economies due to diabetes²².

- A new aspect that has not been quantified yet



Burden of Illness

There have been many publications on the cost of diabetes over the years but the information is inconsistent and outcomes are mostly based on cross-sectional data or model calculations. *“Direct comparisons between the studies are usually not a good thing to do, because the methods used to estimate costs differ significantly between the studies.”*²³. Cost estimates differ also in timing, which makes it hard to draw conclusions. Nevertheless the following data gives a reliable impression on the cost consequences and the impact on the budgets.

Cost of Diabetes worldwide

- The annual direct healthcare expenditures of diabetes worldwide, for people in the age of 20-79 are estimated to be in the range between \$153 billion and \$286 billion. These data are based on an epidemiological model and assume that care for a patient with diabetes (PwD) is 2 to 3 times more expensive than for a comparable person without diabetes (relative costs).
- In 2025 total direct healthcare expenditures on diabetes worldwide is expected to be between \$213 billion and \$396 billion.
- This means that between 7% and 13% of the world's health care budget will have to be spent on diabetes care²¹.

Costs in the UK:

NHS expenditure²⁴ on diabetes, projected on the basis of 9% of NHS costs in 2000, is about £5,185,314,000.

Cost of Type 2 Diabetes in Germany:

In a cross-sectional study (CODE-2) the annual cost per patient to the health insurance were estimated to be between 2,832 € at 1998 prices²⁵ or 3,499 € at 2005 prices. The societal costs were about 4'611 € per patient and year. Based on a longitudinal study (ROSSO²⁶), the costs that are covered by the German health insurance were calculated to be between 3,489 € and 3,493 € at 2005 prices per patient and year. Both study types provided comparable data. Based on prevalence rates between 5% and 10% the direct costs of type 2 diabetes in Germany is expected to be between 10,7 billion € and 23 billion €²⁷.

Cost of Diabetes in the United States:

Total (direct and indirect): \$132 billion in 2002.

Direct medical costs: \$92 billion

Indirect costs: \$40 billion in disability, work loss, premature mortality.

These data are from a study conducted by the Lewin Group, Inc., for the American Diabetes Association and are 2002 estimates of both the direct costs (cost of medical care and services) and indirect costs (costs of short-term and permanent disability and of premature death) attributable to diabetes. This study uses a specific cost-of-disease methodology to estimate the health care costs that are due to diabetes²⁸.

According to CODE-2 between 48% and 85% of the expenditures are spent on hospital stays. The variation between the countries reflects also differences in the health care systems, care practice and financing (reimbursement).



Burden of Illness

Europe²⁹

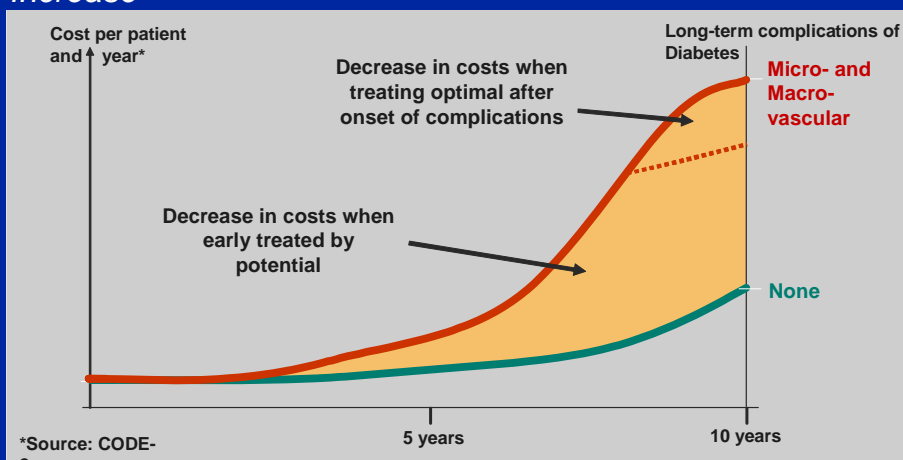
Country	Costs for outpatient care(€)	Hospital costs per patient (€)	Sum (€)
Belgium	603	1 800	2 403
France	683	1 500	2 183
Germany	388	2 200	2 588
Italy	525	2 200	2 725
Netherlands	462	600	1 062
Spain	334	400	734
Sweden	813	1 100	1 913
UK	866	800	1 666

Country	Costs for outpatient care (%)	Hospital costs per patient (%)
Belgium	25.09	74.91
France	31.13	68.87
Germany	15.00	85.00
Italy	19.27	80.73
Netherlands	43.50	56.50
Spain	45.50	54.50
Sweden	42.50	57.50
UK	51.98	48.02

More important than the sheer size of expenditures is the **impact of complications on costs** and its **development over time**. The following figure shows the increase in cost by time and potential savings according to appropriate care.

Efficiency Goals in Diabetes Management

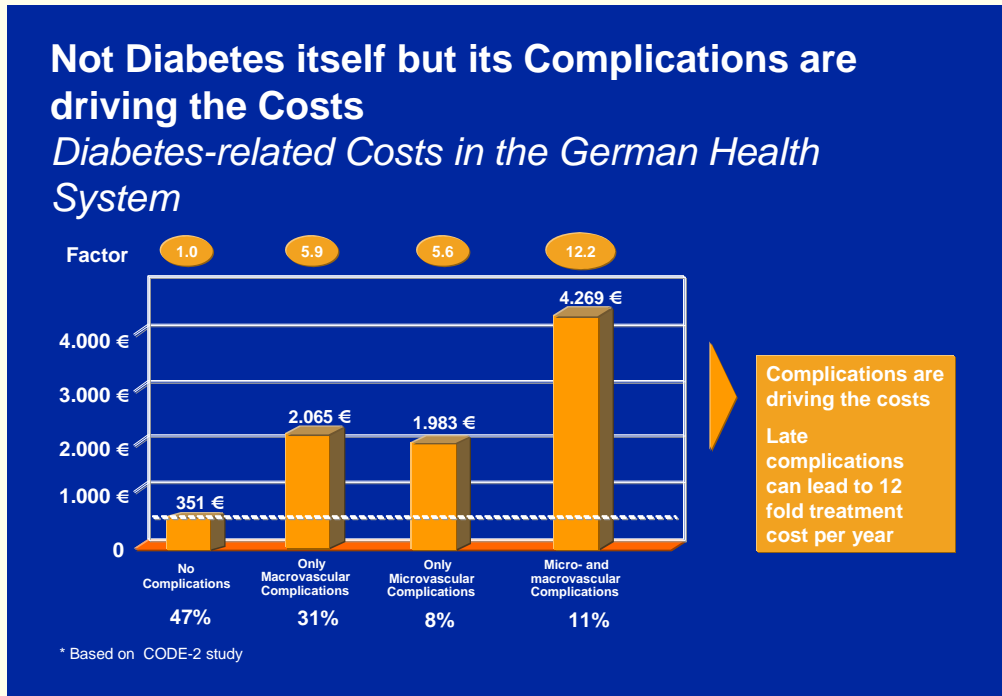
Impact of Complications on Long Term Cost Increase



Only the prevention of complication can really reduce long term cost of diabetes.

Burden of Illness

According to CODE-2 the annual cost can rise up to 12 times the cost of patients with no complications (see figure).



Costs of Diabetes complications in six industrialized countries: ³⁰

In a model based calculation the cost of diabetes and its complications were depicted for six industrialised countries. The costs were subdivided into:

Indirect costs:

- Management costs (cost of standard medication and screening programmes for complications)

Direct costs:

- Cost of cardiovascular disease (CVD) complications
- Cost of renal complications
- Cost of acute events
- Cost of eye disease
- Cost of neuropathy and foot ulcer complications

Burden of Illness

An overview is given in the following tables²⁸:

Table 1. Management costs (2003 Euros)

	Australia	Canada	France	Germany	Italy	Spain
Annual cost of statins	304 ⁷	535 ²⁹	578 ⁸⁰	530 ⁸¹	683 ⁸⁰	358 ⁸²
Annual cost of aspirin	25 ⁷	55 ³⁰	n/a	n/a	38 ⁸³	22 ⁶¹
Annual cost of ACE inhibitors	206 ^{7,8}	209 ²⁹	387 ⁸⁴	180 ⁸⁵	223 ⁸⁶	110 ⁸⁷
Annual cost of screening for MA	13.16 ¹⁷	7.88 ²¹	1.38 ⁸⁸	1.58 ⁴⁴	4.85 ⁵⁹	10.95 ⁸⁹
Annual cost of screening for GPR	23.00 ¹⁷	7.88 ²¹	1.38 ⁸⁸	6.42 ⁹⁰	4.85 ⁵⁹	10.95 ⁸⁹
Cost of stopping ACEs due to SEs	81 ¹⁷	n/a	n/a	42.32 ⁹¹	n/a	n/a
Annual cost of eye screening	81 ¹⁷	29 ²²	98 ⁴¹	58 ⁵⁵	773 ⁷¹	61 ⁶⁴
Monthly cost of foot screening	n/a	29 ²²	18 ⁸⁸	33 ⁹²	17 ⁹³	11 ⁸⁹
Monthly cost of non-standard ulcer treatment	71 ⁸	341 ²⁹	233 ⁸⁴	516 ⁹⁴	n/a	n/a

ACE = angiotensin converting enzyme inhibitors; MA = microalbuminuria; GPR = gross proteinuria; SEs = side effects; n/a = not available

Table 2. Direct cost of CVD complications (2003 Euros)

	Australia	Canada	France	Germany	Italy	Spain
Cost of MI, year 1	12 292 ⁸	12 985 ²²	15 592 ³²	15 011 ^{44,45}	13 816 ⁶⁰	19 277 ⁶⁰
Cost of MI, year 2+	203 ^{7,8}	831 ²²	1226 ³²	1168 ^{44,45}	2400 ⁶⁰	776 ⁶⁰
Cost of angina, year 1	1716 ^{7,8}	2218 ²²	2613 ³³	3342 ^{46,47}	2297 ⁵⁸	2207 ⁶⁹
Cost of angina, year 2+	25 ^{6,7}	1035 ²²	n/a	n/a	n/a	n/a
Cost of CHF, year 1	3158 ^{7,9}	1423 ²⁵	3950 ³⁵	6034 ^{48,95}	3694 ⁹⁶	4968 ³⁴
Cost of CHF, year 2+	386 ⁸	1423 ²⁵	1934 ³²	800 ⁴⁹	3694 ⁹⁶	4968 ³⁴
Cost of stroke, year 1	13 443 ^{9,10}	23 173 ²²	11 754 ³²	19 399 ⁵⁰	6583 ⁹⁶	4638 ⁶¹
Cost of stroke, year 2+	25 ⁷	6110 ²²	2478 ³²	6060 ⁵⁰	7991 ⁶⁰	1722 ⁶¹
Cost of stroke, death within 30 days	n/a	12 251 ⁹⁷	5288 ³⁴	9006 ⁵⁰	6583 ⁶⁰	3201 ⁶¹

MI = myocardial infarction; CHF = coronary heart failure; n/a = not available

Table 3. Direct costs of renal complications (2003 Euros)

	Australia	Canada	France	Germany	Italy	Spain
HD costs, year 1	17 188 ^{9,11,12}	58 159 ²¹	56 487 ³⁸	58 116 ⁵¹	43 075 ^{98,99}	31 233 ⁶²
HD costs, year 2+	n/a	93 840 ²¹	n/a	n/a	n/a	n/a
PD costs, year 1	27 552 ^{9,11,12}	33 811 ²¹	n/a	46 296 ⁵¹	n/a	32 706 ⁶²
PD costs, year 2+	n/a	47 447 ²¹	n/a	n/a	n/a	n/a
RT costs, year 1	16 246 ⁹	60 903 ²¹	24 608 ³⁸	68 175 ⁵²	56 717 ^{98,99}	28 370 ⁶³
RT costs, year 2+	791 ⁹	19 986 ²¹	6866 ³⁸	10 904 ⁵²	11 582 ^{98,99}	8336 ⁶³

HD = haemodialysis; PD = peritoneal dialysis; RT = renal transplantation; n/a = not available



Burden of Illness

Table 3. Direct costs of renal complications (2003 Euros)

	Australia	Canada	France	Germany	Italy	Spain
HD costs, year 1	17 188 ^{9,11,12}	58 159 ²¹	56 487 ³⁸	58 116 ⁵¹	43 075 ^{98,99}	31 233 ⁶²
HD costs, year 2+	n/a	93 840 ²¹	n/a	n/a	n/a	n/a
PD costs, year 1	27 552 ^{9,11,12}	33 811 ²¹	n/a	46 296 ⁵¹	n/a	32 706 ⁶²
PD costs, year 2+	n/a	47 447 ²¹	n/a	n/a	n/a	n/a
RT costs, year 1	16 246 ⁹	60 903 ²¹	24 608 ³⁸	68 175 ⁵²	56 717 ^{98,99}	28 370 ⁶³
RT costs, year 2+	791 ⁹	19 986 ²¹	6866 ³⁸	10 904 ⁵²	11 582 ^{98,99}	8336 ⁶³

HD = haemodialysis; PD = peritoneal dialysis; RT = renal transplantation; n/a = not available

Table 4. Direct costs of acute events (2003 Euros)

	Australia	Canada	France	Germany	Italy	Spain
Hypoglycaemic event requiring medical assistance	282 ^{9,13-15}	78 ²²	227 ³⁶	359 ^{46,51}	108 ^{13,58}	338 ⁶⁵
Hypoglycaemic event resulting in coma/seizure	282 ^{9,13-15}	78 ²²	227 ³⁶	359 ^{46,51}	108 ^{13,58}	338 ⁶⁵
Ketoacidosis/lactic acid event	1345 ⁹	948 ²⁶	n/a	6144 ^{46,51}	2724 ⁵⁸	997 ^{26,66}

n/a = not available

Table 5. Direct costs of eye disease (2003 Euros)

	Australia	Canada	France	Germany	Italy	Spain
Laser treatment	1390 ¹⁶	478 ²¹	406 ⁴¹	3477 ⁵⁵	60 ⁵⁹	177 ⁶⁴
Cataract operation	1509 ⁹	892 ¹⁰⁰	1771 ⁴⁰	1322 ⁵⁴	1978 ⁵⁸	1041 ¹⁰¹
Annual cost following cataract operation	9 ¹⁷	n/a	112 ⁴³	n/a	37 ⁸⁶	915 ¹⁰²
Annual cost of blindness	20 904 ^{15,18-20}	1471 ²²	382 ⁴¹	10 457 ⁵³	5515 ⁷³	n/a

n/a = not available

Table 6. Direct costs of neuropathy and foot ulcers (2003 Euros)

	Australia	Canada	France	Germany	Italy	Spain
Neuropathy, year 1	1138 ⁹	103 ²²	63 ³⁶	3855 ⁴⁶	n/a	2531 ¹⁰¹
Lower extremity amputation	18 547 ⁹	17 130 ²²	31 998 ³⁸	22 096 ⁵⁶	10 177 ⁵⁸	14 787 ⁶⁷
Prosthesis	1687 ¹⁴	711 ²²	1138 ⁴²	3241 ⁵⁶	n/a	2480 ^{68,69}
Gangrene treatment	11 568 ⁹	5436 ²²	2266 ⁴²	3186 ⁵⁷	n/a	5611 ¹⁰¹
Infected ulcer	2433 ⁹	1521 ²²	1999 ⁴²	1783 ⁵⁷	n/a	n/a
Standard uninfected ulcer	204 ¹⁴	727 ²²	1142 ⁴²	877 ⁵⁷	n/a	n/a

n/a = not available

In the ROSSO study, the direct costs of complications make up about 60% and monitoring costs are about 4% of the expenditures in Germany³¹.



Disease Management

3. Disease Management

3.1 Devices for Self Monitoring of Blood Glucose (SMBG)

(episodic and continuous)

An important tool on the management of diabetes is the ability to measure blood glucose. There have been major advances in the development of such diagnostic testing equipment to permit **simple, rapid and easy home testing** by people with diabetes. The first tests that were available for home use were **dipsticks** that estimated the concentration of glucose present in the patient's **urine**. Unfortunately dipsticks provide only a very crude estimate of blood glucose concentrations and are totally **inadequate for achieving good glycaemic control** for a number of reasons:

- Glucose does not appear in the urine until it is in excess of about 180 mg/dl in the blood stream therefore urine testing **does not give the user early indication** of the risk of hypoglycaemia
- The concentration of **glucose in urine varies** upon factors such as the level of hydration of the patient and the amount of urine that they produce
- The tests themselves are **semi-quantitative** therefore of restricted value when trying to achieve tight glycaemic control.

The testing of blood glucose in the home started to become widespread in the 1970s and early 1980s with the development of **optical biosensor technologies** that exploited the reaction of an **enzyme** that has unique specificity for glucose (glucose oxidase) and the development of reliable optoelectronics. This combination of technologies enabled the production of relatively simple, **portable instrumentation**. The great benefit of such systems compared with the urine dipsticks was that they offered, for the first time, **accurate, quantitative blood glucose measurement in the home**.

During the late 1980s technological advances in the field of electrochemistry allowed further improvements to be made to blood glucose sensors. Importantly **electrochemistry** allowed for test times to be significantly reduced (from typically between 45 seconds and 1 minute to the current norm of 5 seconds or less to run the test) and, just as importantly, for the sample of capillary blood needed to perform the test to decrease (from in excess of 10 microlitres to the current norm of 1 microlitre or less). These advances were of great importance to the patient as they made **home testing easier to perform, more discreet and, significantly, less painful** to obtain the blood sample required for the test. Less obvious to the person with diabetes, but just as important clinically, was that electrochemical blood glucose test systems gave **more accurate results** and, with the development of **mass production technologies** for both the meters and disposable test strips, enables blood glucose test systems to be manufactured cost effectively on a large scale.

Currently effort is being focuses on the development of simple **data management tools** to give the user more insight into their disease allowing them to manage their health more effectively. Additionally much resource is being expended on the development of continuous blood glucose monitoring to obviate the need for the user to obtain a sample of capillary blood. Currently there is a wide range of technologies under investigation to realize continuous glucose monitors with there are devices commercially available that measure **glucose in interstitial fluid** (by sampling a very small distance underneath the skin – so called minimally invasive devices).



Disease Management

There have been major **advances in blood glucose monitoring systems** over the last 30 years with current devices offering discrete, easy to use systems that help people with diabetes understand, and Therefore control, their blood glucose levels thereby reducing the risks of long term complications of the disease. (See Annex II)

3.2 Critical role of HbA1C

Diagnostic Parameters and Their Use

Blood Glucose³²

All humans have glucose present in their blood stream. For healthy individuals the concentration of blood glucose is under tight control. As has been discussed above, in people suffering from diabetes, their bodies are unable to regulate the amount of glucose present in the blood stream. Measurement of the concentration of glucose present in the blood stream is indicative of the presence of diabetes. For diagnostic purposes **blood glucose values detailed below are diagnostic for diabetes:**

Fasting Blood Glucose	
From 70 to 99 mg/dL (3.9 to 5.5 mmol/L)	Normal fasting glucose
From 100 to 125 mg/dL (5.6 to 6.9 mmol/L)	Impaired fasting glucose (pre-diabetes)
126 mg/dL (7.0 mmol/L) and above on more than one testing occasion	Diabetes

Oral Glucose Tolerance Test (OGTT) [except pregnancy] (2 hours after a 75-gram glucose drink)	
Less than 140 mg/dL (7.8 mmol/L)	Normal glucose tolerance
From 140 to 199 mg/dL (7.8 to 11.1 mmol/L)	Impaired glucose tolerance (pre-diabetes)
200 mg/dL (11.1 mmol/L) or more on more than one testing occasion	Diabetes

Based on the above physiological data, the glucose ranges for managing people with diabetes are as follows:³³

Global guidelines for Type 2 Diabetes, IDF, 2005 ²⁷	
Capillary plasma glucose	Recommended
Before meals	< 110 mg/dl (< 6.0 mmol/l)
1-2 hrs after meals	< 145 mg/dl (< 8.0 mmol/l)
HbA1c (%)	<6.5



Disease Management

Glycated Haemoglobin (HbA1c)

The **long-term measure of blood sugar control** is known as HbA1C or glycated haemoglobin. The HbA1C test measures how many A1C haemoglobin cells (a specific part of red blood cells) have sugar attached to them. Because these cells live for about four months, this gives a picture of how well blood sugar has been controlled for the past few months. The American Diabetes Association recommends HbA1C result of 7% or less to help reduce the risk of long-term complications of diabetes³⁴.

Glycation of haemoglobin has been implicated in **nephropathy** and **retinopathy** in diabetes. In the normal 120-day life span of the red blood cell, glucose molecules join haemoglobin, forming glycated haemoglobin. In individuals with poorly controlled diabetes, increases in the quantities of these glycated haemoglobins are noted.

Once a haemoglobin molecule is glycated, it remains that way. A build-up of glycated haemoglobin within the red cell reflects the average level of glucose to which the cell has been exposed during its life cycle. Measuring glycated haemoglobin **assesses the effectiveness of therapy of long-term serum glucose regulation**. The HbA1c level is proportional to average blood glucose concentration over the previous four weeks to three months (some research states that the major proportion of its value is related to a rather short term period of two to four weeks).

The closer a patient with diabetes (PwD) can keep their A1c to 6%, the better their diabetes is in control. **As the A1c increases, so does the risk of complications**³².

Microalbumin

A microalbumin urine test detects the presence of the **protein albumin in urine**. In a properly functioning body **albumin is not normally present** in urine because it is filtered from the bloodstream by the kidneys. **Microalbuminuria** is a condition determined by the presence of very small amounts of protein in urine. This is a very early sign of kidney damage³².

Moderately increased microalbumin levels in urine indicate that a person is in one of the very early phases of developing **kidney disease**. Very high levels are an indication that kidney disease is present in a more severe form. Normal levels are an indication that kidney function is normal³².

3.3 Education as a prerequisite

Patient education has played a major role in the care of people with diabetes for many years. In 1918, for example, the Joslin Institute commenced an education programme for its patients and, since that time, the importance of education of both the patient and the health care professional has become ever more important in helping people with diabetes to lead a long, complication-free life. Indeed the **European Association for the Study of Diabetes** (EASD) declared that *"The aim of the diabetes education sub group shall be to improve the quality of life of the diabetic patient through the development and evaluation of educational programmes designed to foster independence for the patient, improve the quality of metabolic control, emphasize the importance of prevention and early recognition of the disease and encourage relevant research"*.



Disease Management

Currently education takes many forms:

- The moving of the management of diabetes from a secondary care specialty into primary care by the **training of the primary care team** (doctors, nurses, dieticians, podiatrists etc)
- The emergence of diabetes educators and **diabetes specialist nurses** who train and counsel patients at all stages on their diabetes journey
- The development of a wide range of **educational materials** for both people with diabetes and their family/carers to help them in the understanding and management of the disease and its complications
- Provision of **information from manufacturers** who are in the field of diabetes. Such information is disseminated in a wide variety of ways ranging from web sites to printed materials supplied with products such as blood glucose meters.
- **Patient support groups** (e.g. Diabetes UK), **professional associations** (e.g. the American Diabetes Association) and **diabetes charities** (e.g. the Juvenile Diabetes Research Foundation) all have prepared a wide range of educational materials directed at all involved with diabetes (the health care professional, the patient, patients' carers etc). Again these materials are designed to facilitate the effective management diabetes and reduce the long-term complications of the disease.

The **diagnostics industry** understands that the provision of educational materials is fundamental to improving the quality of life of the users of their blood glucose measurement technologies. Consequently these companies devote significant resources to develop appropriate materials for people with diabetes of all ages, cultures and educational attainment with the aim of helping them lead as normal a life as possible.

Additional support is also offered by **customer care help lines** that, as well as recording and resolving customer complaints, also help people with diabetes understand how to use the blood glucose measurement systems correctly.

4. Evidence-base:

Evidence refers to anything that is used to **determine or demonstrate the truth of an assertion**. Philosophically, evidence can include propositions that are presumed to be true when used in support of other propositions that are presumed to be falsifiable.

The term has specialized meanings for specific fields, such as scientific research, criminal investigations, and legal discourse. The most immediate form of evidence available to an individual is the set of **observations** made by that person. In science, evidence is accumulated through observations of phenomena that occur in the natural world or via **experiments**. Scientific evidence is accumulated for the purpose of accepting or rejecting a **hypothesis**.



Evidence-Base

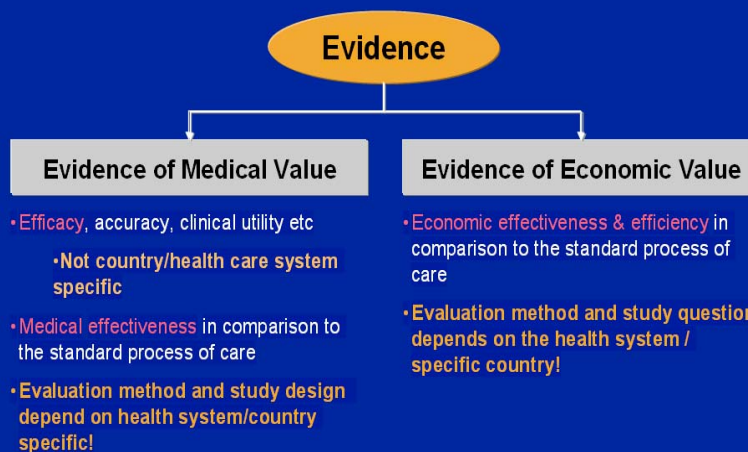
Evidence-Based Medicine (EBM) seeks to apply the **scientific method to medical practice**. According to the Centre for Evidence-Based Medicine, "*Evidence-based medicine is the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients.*"³⁵ This definition refers to the classical **health care professional's tasks and views**. But it does not reflect the societal view or those of other decision-makers that affect the adoption and use of health care technology. Whilst EBM is a tool that was developed to help medical practitioners ensure that their patients receive the best possible care,³⁶ it may not present the best decision-support tool for others. Perhaps other evidence-based tools can support decisions that are in the best interests of patients.

The **public health³⁷ perspective** best describes the health care tasks from a **societal or governmental perspective**. Taking into account that resources are a pre-requisite for creating actionable information, a definition from the public health viewpoint might read as follows: "*Evidence-based decision making is the conscientious, explicit and judicious use of current best evidence about the outcomes of care of populations and subgroups. Health care decisions are made at the level of the process, structure, program or system. The practice of evidence-based public health means integrating medical expertise on a population basis with the best available evidence on resources needed and their efficient use.*"³⁸

Although decision-making at these different levels calls for different types of information, all should be supported by unbiased, scientific principles of proof. In social sciences, the measurement proposal of a quality or attribute begins with clarifying the dimensions of the attribute that is broken down into measurable indicators. The definition and measurement of intelligence provides an example in which an abstract notion is broken down into different dimensions of intelligence with corresponding measurement scales. In the case of evidence pertaining to health care technology, we could subdivide evidence into medical and economic dimensions. **Medical evidence**, in turn, could have two main types: evidence of medical efficacy and evidence of medical effectiveness. **Economic evidence** is based on efficacy and effectiveness, the latter being more important for practicing physicians, payers and national health authorities.

Value Can Be Defined In A Medical And Economic Sense

Definition Of Medical And Economic Value



Role of Industry

The estimation is based on data from a sample of the German type 2 population - the ROSSO study²⁰ – and the correlation between testing frequency and HbA1c published by Karter and Schütt. The effects were simulated then with a validated Diabetes-model (Mellibase).

One of the biggest hurdles in discussing the benefits of SMBG and diabetes disease management is the **timing of cost and savings**. Investment occurs today and the savings mostly are seen after ten years. In The above mentioned health services research study it could be shown that cost reduction occurs very early, i.e. from the first year on.

5. Role of Industry:

Industry Investment in Design and Development of Devices

In order to improve patient care manufacturers of blood glucose monitoring equipment typically invest up to 10% of their annual turnover into the design and development of improved glucose monitoring devices. This R&D effort is driven by unmet **customer needs** (e.g. the desire for pain free testing, simplicity and ease of use of blood glucose meters etc) in the hope that increased use by people with diabetes will improve compliance to diabetes therapies thereby reducing the long term complications of the disease, **improving the quality of life** of the users and **decreasing the costs** of diabetes to the healthcare system.

The costs associated with the launch of new products have increased recently as there is an **increasing requirement to produce clinical evidence** that new products in the area do give an improved clinical outcome and patient benefit. Such trials are often lengthy and costly to design and execute but are key in convincing health care payers that new devices offer an improvement in patient outcome.

Industry Involvement in Education

As previously stated in section 3, *In Vitro* Diagnostic manufacturers are committed to **providing Information** to diabetic patients through a wide variety of ways ranging from web sites to printed materials supplied with products such as blood glucose meters.

Based on the understanding that educational materials are fundamental to improving the quality of life of glucose tests' users, the diagnostics manufacturers devote significant resources to develop appropriate materials for diabetic patients of all ages, cultures and educational attainment with the aim of helping them lead as normal a life as possible.

Moreover, the industry also commits to the continued **education of health professionals**, through the participation in scientific congresses, long-life training courses, etc.



Appendix

Annex 1: CE – Mark: What does it imply?

The CE mark, when affixed on a product, informs the user of the product that the product is following the laws set out in the European Union for the marketing of a product.

In the case of IVDs, and glucose monitors in particular, the requirements which have to be met by the device are laid out in directive 98/79/EC, commonly known as the IVD Directive.

For glucose meters these requirements guarantee the following:

- » State-of-the-art – The device will be designed and manufactured using state of the art technology and specifications, this is guaranteed through the compliance to technical standards, which unlike legal texts are frequently revised.
- » Safe to use – All known and potential risks which can arise when using the device have been taken into consideration and insofar as possible, eliminated from the device.
- » Quality System – the manufacturer who makes the device has to be operating under a quality system to ensure that each and every device meets the specifications.
- » Market vigilance system – In Vitro Diagnostic medical devices, such as blood glucose monitors operate under one of the strictest market surveillance system of any CE marked product. This means that if ever there is a problem with a device, the manufacturers and the authorities will be made aware of the fact, and rapid corrective action will be taken
- » Third party certification – For blood glucose monitors, all of the above points are controlled by external parties with detailed technical expertise (known as notified bodies) which guarantee that all of the claims above are true.

The CE Mark on a blood glucose monitor is thus a mark of safety, quality and it demonstrates that the device is state-of-the-art.



Appendix

Annex 2: Evolution of Glucose Testing

Key Technology Trends in Blood Glucose Testing ...
are dedicated to make testing more accurate, less invasive and more convenient for patients



Appendix

Annex 3: Diabetic Specific measurement scales

Diabetic specific measurement scales	Purpose	Characteristics
Diabetes Care Profile (DCP)	Disease: Diabetes mellitus Objective: To assess the social and psychological factors related to diabetes and its treatment Population: Adult	Type of instrument: Quality of life Mode of administration: Self-administered Number of Items: 234
Diabetic Foot Ulcer Scale (DFS)	Disease: Diabetes mellitus Leg ulcer Objective: To measure the impact of diabetic foot ulcers and their treatment on Quality of Life from the patient's perspective Population: Adult	Type of instrument: Quality of life Mode of administration: Self-administered [for patients, for caregivers] Number of Items: 58
Diabetes Impact Measurement Scales (DIMS)	Disease: Diabetes mellitus [Insulin-dependent (type I) and non-insulin-dependent (type II) diabetes] Objective: To measure health status in adult type I and type II diabetic patients Population: Adult	Type of instrument: Quality of life Mode of administration: Self-administered Number of Items: 44
Diabetes Knowledge Test (DKT)	Disease: Diabetes mellitus Objective: To obtain a general assessment of a patient's knowledge about diabetes and its care Population: Adult	Type of instrument: Quality of life Mode of administration: Self-administered Number of Items: 23
Diabetes Mellitus History (DMH)	Disease: Diabetes mellitus Objective: To collect basic clinical diabetes information from community-based patients Population: Adult	Type of instrument: Quality of life Mode of administration: Self-administered Number of Items: 34 core items and 13 optional items
Diabetes Quality of Life Clinical Trial Questionnaire (DQLCTQ)	Disease: Diabetes mellitus [Type 1 – IDDM, Type 2] Objective: To measure the quality of life of diabetic patients in clinical trials Population: Adult	Type of instrument: Quality of life Mode of administration: Self-administered Number of Items: DQLCTQ:142; DQLCTQ-R: 57

Appendix

Diabetes Quality of Life measure (DQOL)	<p>Disease: Diabetes mellitus [Type 1- IDDM]</p> <p>Objective: To assess the relative burden of an intensive diabetes treatment regimen</p> <p>Population: Adult</p>	<p>Type of instrument: Quality of life</p> <p>Mode of administration: Interviewer-administered, Self-administered</p> <p>Number of Items: 46</p>
Diabetes Quality of Life for Youth scale (DQOLY)	<p>Disease: Diabetes mellitus [Type 1- IDDM]</p> <p>Objective: To assess the psychosocial impact of treatment regimens for diabetes in youth population</p> <p>Population: Adolescent, Paediatrics</p>	<p>Type of instrument: Quality of life</p> <p>Mode of administration: Self-administered</p> <p>Number of Items: 52</p>
Diabetes Self-Management Profile (DSMP / DSMP-F)	<p>Disease: Diabetes mellitus [Type 1- IDDM]</p> <p>Objective: To measure self-management of type 1 diabetes in children</p> <p>Population: Adolescent, Paediatrics</p>	<p>Type of instrument: Quality of life</p> <p>Mode of administration: Interviewer-administered</p> <p>Number of Items: 24</p>
Diabetes specific quality of life scale (DSQOLS)	<p>Disease: Diabetes mellitus</p> <p>Objective: To assess individual treatment goals among patients with type 1 diabetes</p> <p>Population: Adult</p>	<p>Type of instrument: Quality of life</p> <p>Mode of administration: Self-administered</p> <p>Number of Items: 64, of which 10 focus on treatment goals, 10 on treatment satisfaction, and 44 on the perceived burden of diabetes</p>
Audit of Diabetes Dependent QoL (ADDQoL)	<p>Disease: Diabetes mellitus [Type 1 - IDDM, Type2 - NIDDM]</p> <p>Objective: To measure individuals' perceptions of the impact of diabetes on their quality of life</p> <p>Population : Adult</p>	<p>Type of instrument: Quality of life</p> <p>Mode of administration: Self-administered</p> <p>Number of Items: 20 (18 + 2 overview items) 21 (19 + 2 overviews items)</p>
Appraisal of Diabetes Scale (ADS)	<p>Disease: Diabetes mellitus</p> <p>Objective: To asses a diabetic person's appraisal of disease</p> <p>Population: all</p>	<p>Type of instrument: Quality of life</p> <p>Mode of administration: Self-administered</p> <p>Number of Items: 7</p>
Hypoglycaemia Fear Survey (HFS)	<p>Disease: Diabetes mellitus</p> <p>Objective: For monitoring continuing diabetes care</p> <p>Population: Adult</p>	<p>Type of instrument: Quality of life</p> <p>Mode of administration: Self-administered</p> <p>Number of Items: 23</p>

Appendix

Impact of Child Illness scale (ICI)	<p>Disease: Diabetes mellitus Epilepsy</p> <p>Objective: To assess parental perception of the Quality of Life among children with Epilepsy or Diabetes</p> <p>Population: Paediatrics</p>	<p>Type of instrument: Quality of life</p> <p>Mode of administration: Proxy-administered</p> <p>Number of Items: Diabetes version: 31; Epilepsy version: 30</p>
Multidimensional Diabetes Questionnaire (MDQ)	<p>Disease: Diabetes mellitus</p> <p>Objective: To provide a comprehensive assessment of diabetes-related cognitive and social factors</p> <p>Population: Adult</p>	<p>Type of instrument: Quality of life</p> <p>Mode of administration: Self-administered</p> <p>Number of Items: 41</p>
Well-Being Questionnaire (WBQ)	<p>Disease: Diabetes mellitus</p> <p>Objective: To provide a measure of depressed mood, anxiety, and various aspects of positive well-being</p> <p>Population: Adult</p>	<p>Type of instrument: Quality of life</p> <p>Mode of administration: Self-administered</p> <p>Number of Items: WBQ-22: 22 items; WBQ-12: 12 items (short version); WBQ-28: 28 items</p>
Diabetes Fear of Injecting and Self-testing Questionnaire (D-FISQ)	<p>Disease: Diabetes mellitus</p> <p>Objective: To quantify the degree of fear of self-injecting insulin and self-testing of blood glucose in adult insulin-treated diabetic patients</p> <p>Population: Adult</p>	<p>Type of instrument: Quality of life</p> <p>Mode of administration: Self-administered</p> <p>Number of Items: 15</p>

Appendix

Annex 3: Acronyms and Definitions

COC	Centres for Disease Control and Prevention
Cholesterol	A blood test that measures the amount of fat (lipid) circulating in the blood stream
CVD	Cardiovascular Diseases
EASD	European Association for the Study of Diabetes
EBM	Evidence-Based Medicine
ESRD	End-Stage Renal Disease
HbA1C	Glycated haemoglobin, a blood test that measures average blood glucose over the past 2-3 months and is the best way to measure overall glucose control. It should be measured 2-4 times a year with a goal of less than 7%.
IFT	Impaired Fasting Glycaemia
IGT	Impaired Glucose Tolerance
Microalbumin	A urine test that measures kidney function
NHS	National Health Services (UK)
PwD	Patient with Diabetes
RCT	Randomised Control Trial
SMBG	Self Monitoring of Blood Glucose
QOL	Quality of Life



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