Diabetes
Key Messages

In Vitro Diagnostics
Making a real difference in health & life quality

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Diabetes

Diabetes is an illness which occurs as a result of problems with the production and supply of insulin in the body for which currently there is no cure. Diabetes has been identified as a major issue by UN Resolution 61/225.

Diabetes affected in 2003 an estimated 27 million people in the 27 Member States of the European Union (over 7.6 % of the population), being also a major cause of death. Recent projections predict that by 2025 8.9 % of the population (31.5 million people) will suffer from diabetes in the EU.

**Diabetes:**
- lowers average life expectancy of the patient: an average person with type 2 diabetes with moderate or high risk for cardiovascular disease lives 18 years less than the average individual who does not have diabetes.
- increases cardiovascular disease risk two to four fold, and
- is the leading cause of kidney failure, lower limb amputations and adult-onset blindness
- *puts a significant economic burden on society and healthcare programmes*
- leads to considerable stagnation of national economies
- the costs of caring for patients that are suffering the consequence of complications, that can affect the eyes, kidney, heart and body extremities are four times higher than those without complications

**Investment in diabetes care prevents complications of the disease**

Blood glucose monitoring gives short-term (2 years) and long-term (5 to 10 years) economic benefits. In the case of SMBG, a model analysis of a health services research study showed an economically determined testing frequency. In the following figure the medical outcome “life expectancy” is plotted against testing frequency, resulting in an s-shaped “production-curve”. The two vertical dashed lines enclose the area of optimal testing frequency: 1 to 2 strips per day on an average.

**Testing Frequency and LE**

**Area of favourable Resource-Outcome Ratios**

<table>
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<tr>
<th>Diabetes Model</th>
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<tr>
<td>• ROSSO population</td>
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<tr>
<td>• Average age 61</td>
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<td>• 51% male</td>
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<td>• OAD: SU (60%) + Metformin (40%)</td>
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<td>• Efficacy estimates based on Karter (2005, 2006) and Schütt (2006)</td>
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Derives optimal operating area between:
- 1 to 2 strips per day on average
Diabetes

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.

Diagnostics play an important role

- **in early diagnosis** by measuring blood glucose levels in populations at risk thereby allowing for early detection and treatment,
- **in self-management of the disease** by regular measurements of blood glucose levels and adapting insulin dosage or adjustment of life-style by the patients themselves thus reducing the risks associated with very high and/or very low blood glucose levels,
- **in monitoring** of the quality of self-management by measuring the level of HbA1c, a hemoglobin variant which is indicative of longer term glucose levels,
- **in early detection of kidney complications** by detecting significant amounts of albumin in urine (microalbuminuria)
- **to establish disease management strategies** by Continuous Glucose Monitoring (CGMS)

Appropriate monitoring and treatment/change of lifestyle contributes significantly to improved health outcome

- For each 1% reduction in HbA1c the risk of eye disorders, renal impairment and lower-extremity amputation is reduced by 40%7
- Glycaemic control to near normal levels yields an extra 5 years of life, 8 years of near normal sight and 6 years of unimpaired kidney function8

Patient outcomes studies show that people who maintain their glucose levels under control have better quality of life (QOL) which 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 macro-vascular 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.

Treatment 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 that health-related quality of life is an important issue in type 2 diabetes and these decreases with disease9. 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 QOL10

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An important psychological aspect of quality of life for people with diabetes is the high prevalence of depression: evidence from prospective and cross-sectional studies demonstrates that the presence of diabetes doubles the risk of co-morbid depression which today affects more than one quarter of the diabetic population. People suffering depression are less likely to make lifestyle changes that meet treatment goals. 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. Patient education necessarily has to take this fact into account to ensure the proper management of the disease.

An appropriate and rational use of In Vitro Diagnostics for the detection, monitoring and management of diabetes leads to significant cost savings for healthcare systems and society by helping reduce long-term complications of diabetes and improves the quality of life of the patient and their carers.

The Diagnostics industry has invested, and continues to invest, in developing easy to use, fast and reliable devices for detection and monitoring of the most important blood parameters, as well as educational materials, to allow appropriate management of diabetes by the patient, their carers and healthcare professionals.

The Diagnostics industry agrees with the current evidence demonstrating that investing in making these tools available, society, as well as the individual person with diabetes will gain.

This paper has been prepared by the EDMA Value of IVDs Task Force.

EDMA, the European Diagnostic Manufacturers Association is the voice of the In Vitro diagnostic industry active in Europe. EDMA membership brings together National Associations and the major companies, representing in total more than 500 companies (or over 700 legal entities) engaged in the research, development, manufacture or distribution of IVD products. EDMA cooperates with other European and international trade associations as well as with scientific societies and patients organisations, to make a real difference in health and life quality.
References

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