

Cost–benefit relation of patient empowerment in the management of type 2 diabetes

European Life Sciences Circle



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Introduction

Although the general methods of evaluation are well established^{1,2}, it is often their detailed application that raises methodological challenges. Most international guidelines for (economic) evaluation, although appearing to be generic, have been written with pharmaceuticals in mind³. For example, they typically assume that randomized controlled trials (RCTs) will be available for the assessment of relative treatment effect.

The economic evaluation of devices raises additional challenges that international guidelines frequently overlook.

¹The European Parliament and the Council of the European Union. Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007. Available from <http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uriOJ:L:2007:247:0021:0055:EN:PDF> [Accessed Feb 26, 2010]:

²Draborg E, Gyrd-Hansen D, Poulsen PB, Horder M. International comparison of the definition and the practical application of health technology assessment. *Int J Technol Assess Health Care* 2005;21:89–95.

³Tunis SR, Stryer DB, Clancy CM. Practical clinical trials: increasing the value of clinical research for decision making in clinical and health policy. *JAMA* 2003;290:1624–32.



What is Health Technology Assessment?

Health Technology assessment (HTA) is a multidisciplinary process that summarizes information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value. Despite its policy goals, HTA must always be firmly rooted in research and the scientific method.

EUnetHTA 2007¹

- Health Technology Assessment asks questions such as:
 - When is counseling better than drug treatment for depression?
 - What is the best operation for aortic aneurysms?
 - Should we screen for human papilloma virus when doing cervical smears?
 - Should aspirin be used for the primary prevention of cardiovascular disease?
- It answers these questions by investigating four main factors:
 - Whether the technology works
 - For whom
 - At what cost
 - How it compares with the alternatives

¹European Network for Health Technology assessment. Definition of HTA. <http://www.eunetha.net/Public/HTA/>



HTA and Disease Management

HTA it has come to be used primarily in assessing the value of pharmaceutical interventions, and this is reflected in the tools which have been developed

Its use in disease management with patient intervention is more complex

- **Self monitoring blood glucose (SMBG) is an integral part of Diabetes Management – it's results drive therapy change – carried out by the patient him or herself.**

Multi-tasking Diabetes Management

Education



Lifestyle



Monitoring of BG



Drug Treatment



Managing Chronic Complications



Information Management & Advice



Challenges in using HTA to assess SMBG

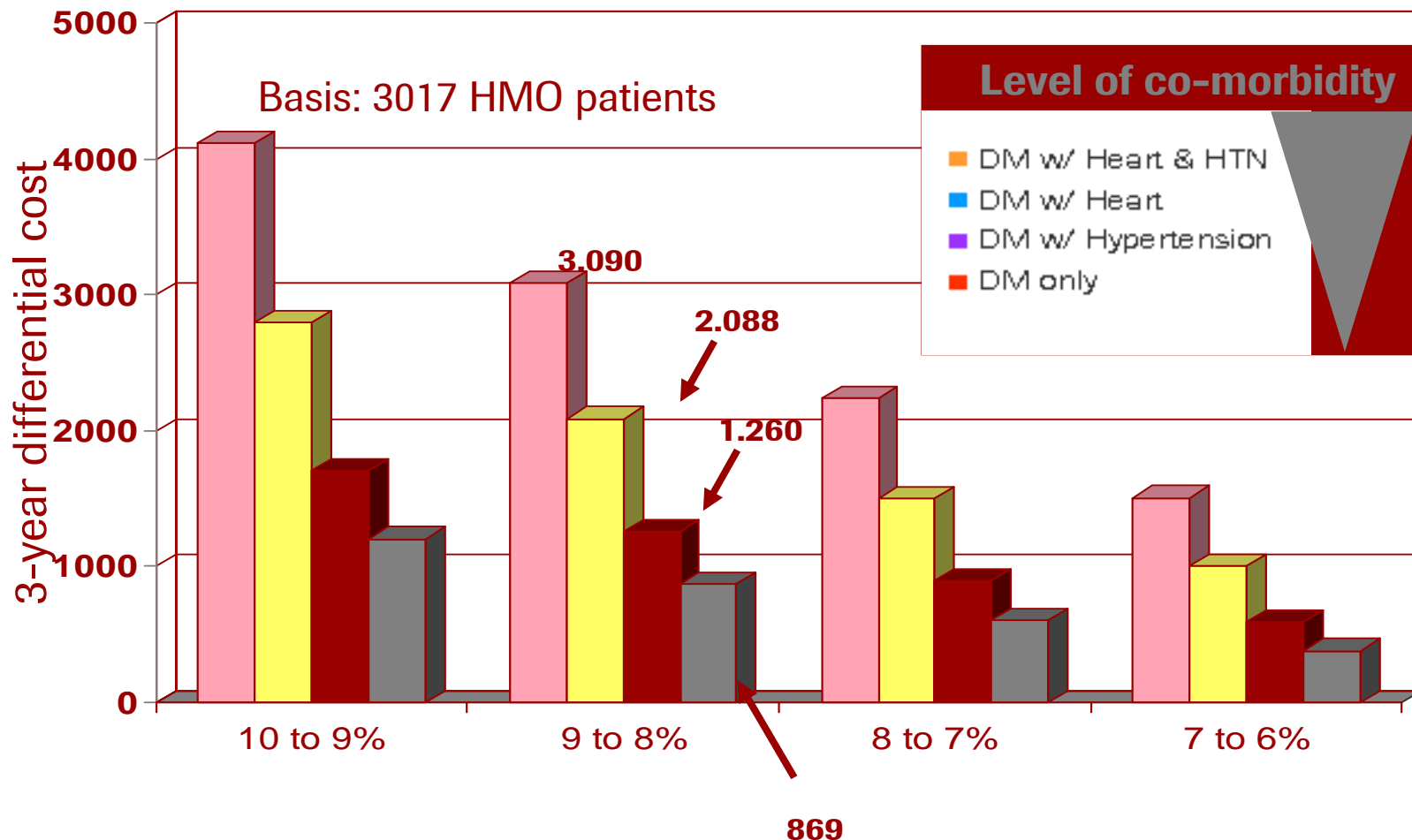
Almost all studies use HbA1c as the main endpoint

- Simple, validated short term measure which can be used as a proxy for long term outcomes
- Has been shown to relate to costs as well as outcomes



Any HbA_{1c} reduction results in reduced cost

Costs decline in US\$ related to a 1% HbA_{1c} reduction



Source: Gilmer TP et al. Diabetes Care 1997;20:1847-1853



Challenges in using HTA to assess SMBG

Almost all studies use HbA1c as the main endpoint

- Simple, validated short term measure which can be used as a proxy for long term outcomes
- Has been shown to relate to costs as well as outcomes
- HbA1c is a valid and appropriate parameter, BUT there is a mono-causal relationship only with nephropathy and retinopathy
- More frequent complications like CVD have multifactorial etiology
 - Looking at HbA1c is only part of the picture
- The ROSSO¹ study provides a valuable additional source of data
 - Large scale (3268 patients) long term (up to 8 years) retrospective epidemiological cohort study
 - Key endpoints are morbidity and mortality
- That study has been used as the basis for further country specific economic assessments

¹Martin S et al Self-monitoring of blood glucose in type 2 diabetes and long term outcome: an epidemiological cohort study Diabetologia 2006Feb; 49(2):271-8



Health Economic Assessment: *Key Messages and Outcomes*

Germany

Results:

Analysis of the cohort study data revealed that the total costs cumulated over the observation period of 8 years are lower in the SMBG than in the non-SMBG group demonstrating savings of;

- € 1'714 (OAD only)
- € 13'815 (OAD + insulin) per patient.

Conclusions:

In the "OAD only" cohort, mean costs per patient of initial complications (e.g., first acute myocardial infarction) and surgical interventions (e.g., amputation) were € 1'073 , (n.s) lower in SMBG users, while in the "OAD + insulin" cohort they were € 4'527 (significant, $p < 0.05$) lower in SMBG users.

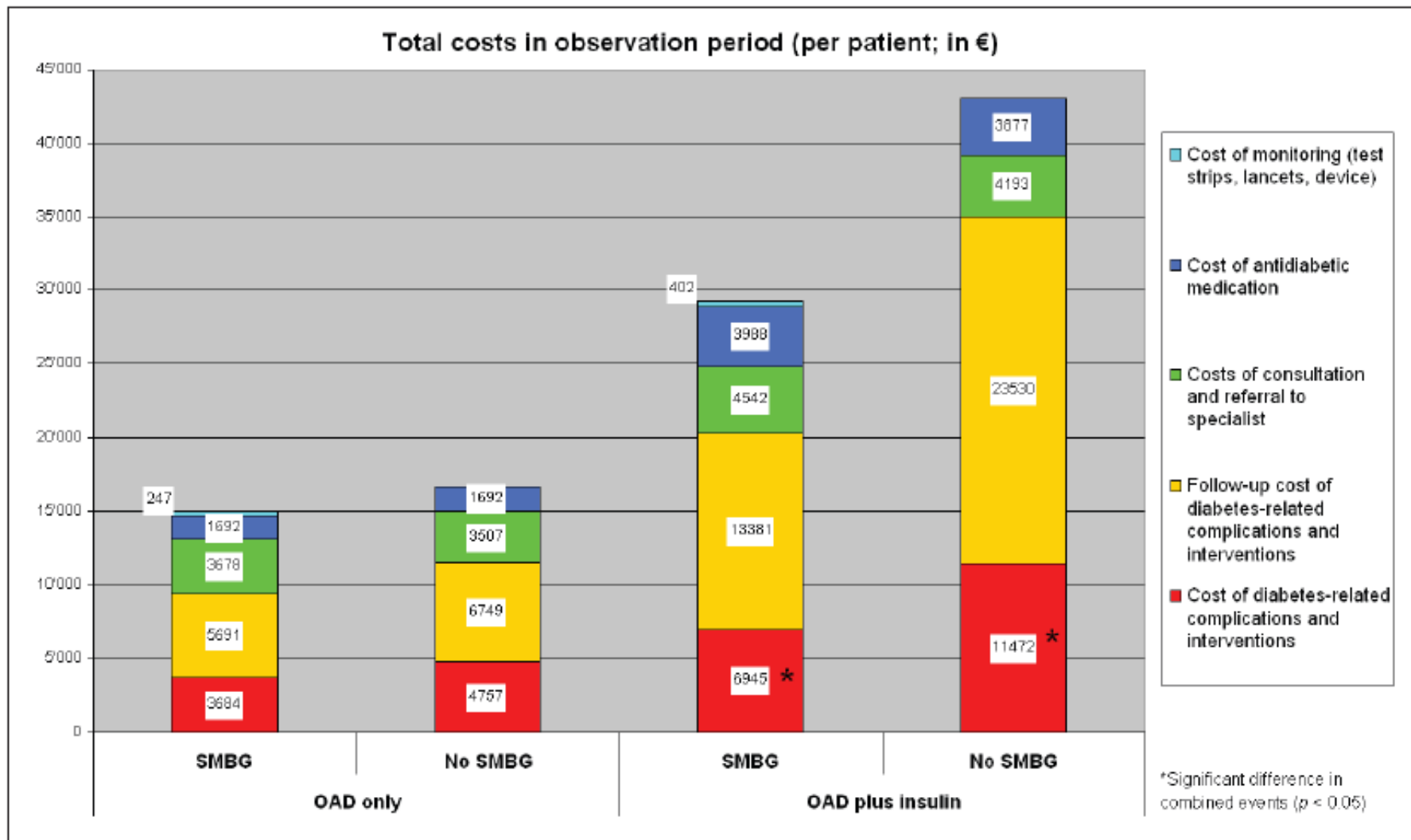
The same trends were observed in the follow-up costs of diabetic complications, with savings of € 1'058 and € 10'149 among SMBG users treated with OAD only and OAD + insulin, respectively.

Consultation costs in the "OAD only" cohort were € 171 higher in SMBG users than in nonusers. In "OAD + insulin" cohort the consultation costs are € 349 higher in SMBG users.

Annual antidiabetic medication costs in the OAD only cohort were equal in SMBG users and non-users. In the "OAD + insulin" cohort, medication costs were € 111 higher among SMBG users.



Cost savings from SMBG in Germany



Weber C, Neeser K, Schneider B, and V. Lodwig. Self-Measurement of Blood Glucose in Patients with Type 2 Diabetes: A Health Economic Assessment. *J Diab Sci Tech* 1 (5):676-684, 2007.



Health Economic Assessment: *Key Messages and Outcomes*

Czech Republic

Results:

In patients treated with oral antidiabetic drugs only, total annual costs in Czech koruna (CZK) were 16,476 in SMBG users and CZK 19,440 in non-users.

In patients treated with oral antidiabetic drugs plus insulin, total annual costs were CZK 32,590 and CZK 48,600, respectively.

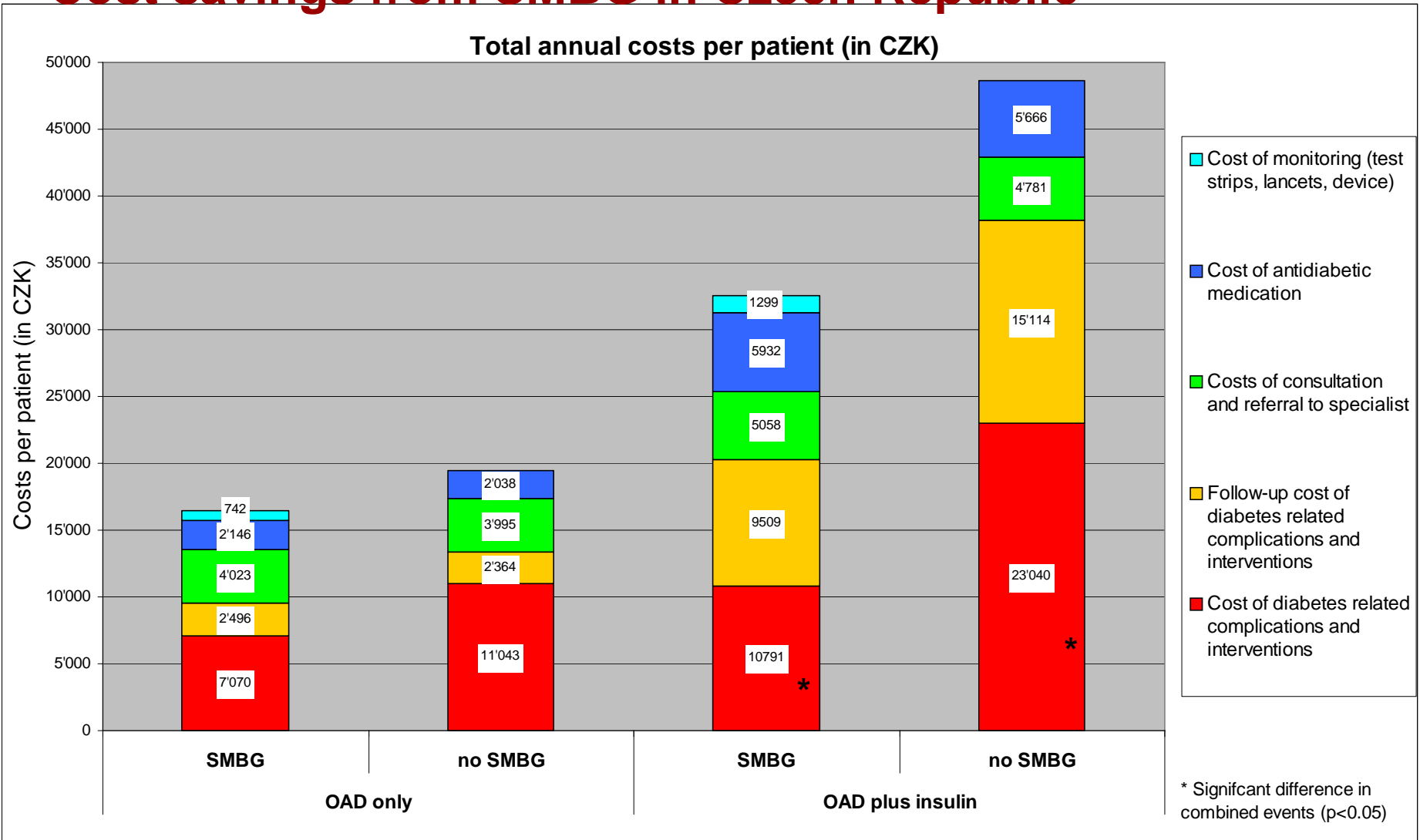
Conclusion:

Assuming that 5 % of the non-users will switch to SMBG annually, the total cost after 5 years will be CZK 6.15 billion in the patients treated with OAD and CZK 2,44 billion in the patients treated with OAD plus insulin.

Computing these calculated cost savings until 2013 for patients who are presently not performing SMBG, the increased use of SMBG would save the statutory health insurance system of the Czech Republic approximately **CZK 488 million annually**.



Cost savings from SMBG in Czech Republic



Weber, Bartaskova, Kocher, Neeser: Impact of self-measurement of blood glucose (SMBG) on complications of type 2 diabetes: an economic analysis from a Czech perspective. *In press CRMO, 2009*



Health Economic Assessment: *Key Messages and Outcomes*

Spain

Results:

In patients treated with oral antidiabetes drugs (OADs) only, total annual costs were € 1,934 in SMBG users and €1,982 in nonusers

In patients treated with OADs plus insulin, total annual costs were e3,451 and € 4,167, respectively

By increasing the number of patients using SMBG, the Spanish statutory health insurance system might save several million Euros annually

Conclusions:

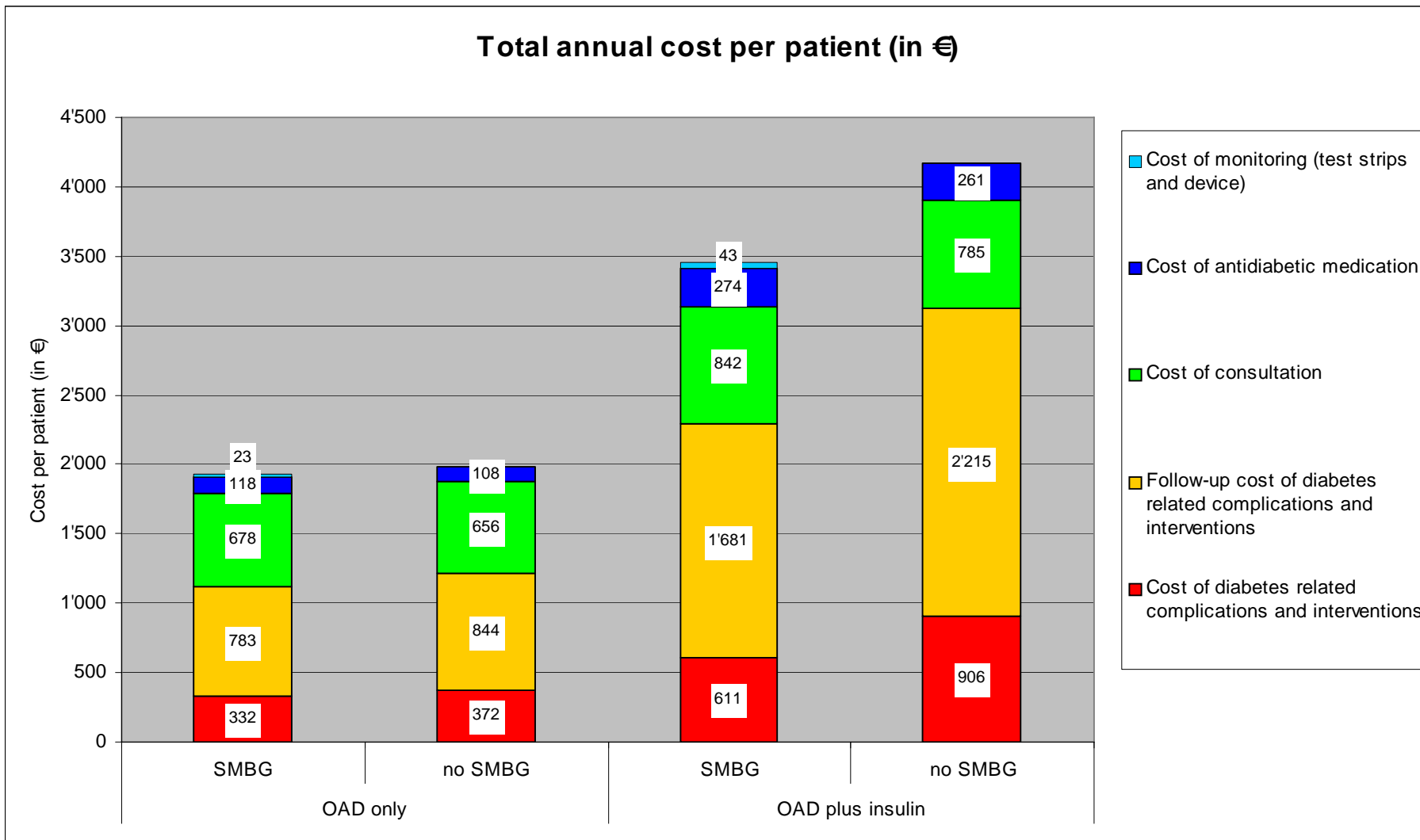
Total costs. In SMBG users versus nonusers, the total annual costs per patient-year were €1,934 versus € 1,982 in those treated with OAD only and € 3,451 versus € 4,167 in those treated with OAD plus insulin

Assuming that 5% of the nonusers annually switch to SMBG, the total cost after 5 years will be € 3.393 billion in the patients treated with OAD and € 647 million in the patients treated with OAD plus insulin

If we estimate these calculated cost savings until 2013 patients who are not presently performing SMBG, the increased use of SMBG would save the Spanish statutory health insurance system approximately **€53 million annually**



Cost savings from SMBG in Spain



K. Neeser and C. Weber. Cost impact of self-measurement of blood glucose on complications of type 2 diabetes: the Spanish perspective. *Diabetes Technol Ther* 11 (8):509-516, 2009.



Conclusion

The literature on the cost-effectiveness of SMBG demonstrates varied results

- A recent UK study of 453 patients over 1 year was inconclusive¹
- “While the data do not exclude the possibility of clinically important benefit ... SMBG by non-insulin-treated patients did not lead to a significant improvement in glycaemic control”

The scale, duration and use of clinical endpoints of the ROSSO study provides a sound basis for the assessment of the benefits of SMBG

- The results can be extended from Germany to other markets

Other studies based on long term cohort data have shown broadly similar results²

- “With cost assumptions reflecting current reimbursement levels in France, Germany, Italy and Spain SMBG was found to be cost-effective across a 40 year time horizon”

**In addition to empowering patients, SMBG
can save costs for the healthcare system**

¹Farmer et al Health technology Assessment 2009:13:15

² S.L.Tunis, W.D.Willis, and V.Foos. "Self-monitoring of blood glucose (SMBG) in patients with type 2 diabetes on oral anti-diabetes drugs: cost-effectiveness in France, Germany, Italy, and Spain." Curr.Med Res Opin. 26, no. 1(January 2010):163-75

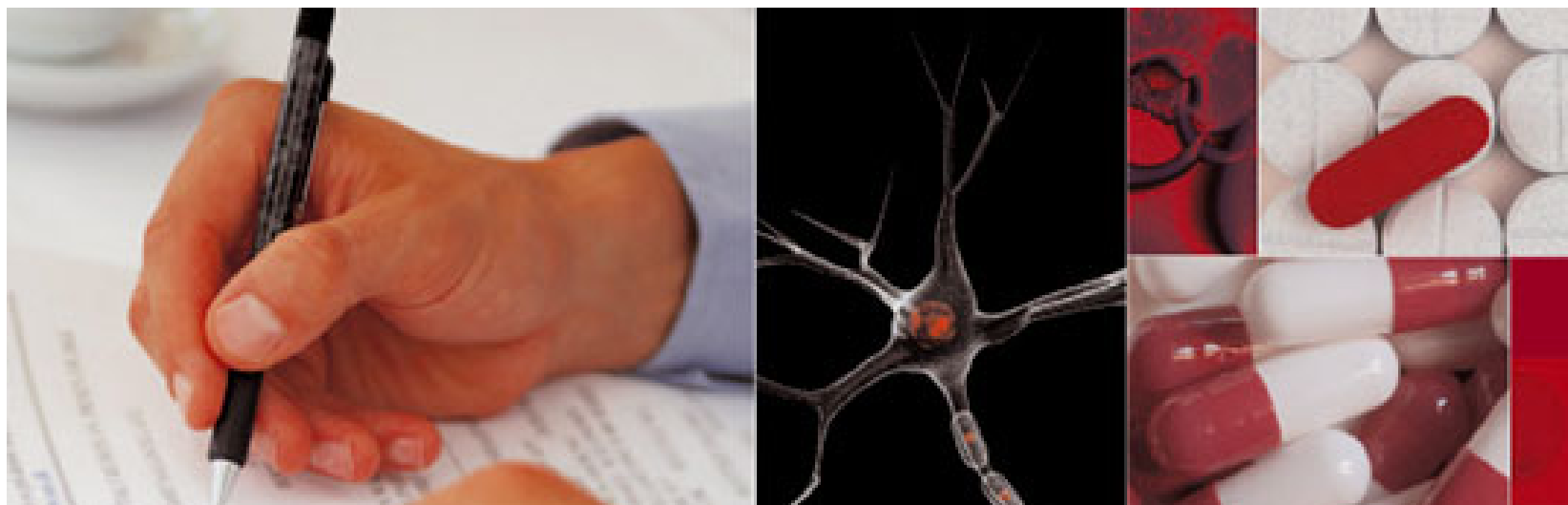


Recommendation for EU Policy Makers

Ensure that core models and recommendations for Health Technology Assessments currently developed at EU level follow predictable, common criteria and methodologies which take into account the actual patient-self-management activity in the investigated treatment procedure.

¹Farmer et al Health technology Assessment 2009:13:15

² S.L.Tunis, W.D.Willis, and V.Foos. "Self-monitoring of blood glucose (SMBG) in patients with type 2 diabetes on oral anti-diabetes drugs: cost-effectiveness in France, Germany, Italy, and Spain." Curr.Med Res Opin. 26, no. 1(January 2010):163-75



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