

benefit. (iv) The discounted cash flow model for orphan medicines with information about health benefit. (v) The value-based rate of return pricing for innovative orphan medicines with information about health benefit. (vi) The P-quad model for drugs with a high budget impact for which there is no generic competition after intellectual property an regulatory exclusivity end.

**Conclusions.** We argue that it would be more logical for different categories of medicines to base prices on average costs, possibly combined with a bonus for innovation: the cost-based pricing method. The next step is to discuss the possible application of cost-plus methods with stakeholders including patients, industry, payers, and healthcare professionals.

## PP153 The Economic And Fiscal Impact Of Public Health Programs For Diabetic Patients In Italy

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**Introduction.** Technological innovations in the health sector have economic implications that go beyond their effects on health expenditure, expanding into other areas of the state budget (e.g., the social security system). Furthermore, innovation can affect the production of wealth by workers and companies, which in turn affects tax revenues. In addition, the presence of chronic diseases tends to reduce the propensity to consume and changes the allocation of consumption between the different sectors. Allocative decisions in the health system are rarely supported by an analysis that combines the health effects of innovations and their consequences in the economic system.

**Methods.** The objective of this study was to estimate the value of management programs for patients suffering from type 2 diabetes mellitus that involved different levels of use of innovative technologies and drugs. A tax impact assessment methodology was adopted in the context of chronic conditions to analyze the effect of adopting alternative management models for patients with diabetes on the broader economic system.

**Results.** Assuming a policy that reduces annual complications by 0.42 percent, there was an increase in tax revenue (cumulative value) of approximately EUR 28,175 and a reduction in productivity losses (cumulative value) of EUR 4,049,890. Projecting the impact on the age trend of the population up to 65 years of age with these estimates, it is possible to have an increase in tax revenue (cumulative value) equal to approximately EUR 7,050,598 and a reduction in productivity losses (cumulative value) equal to EUR 140,235,923.

**Conclusions.** In light of this work, providing remote patient support (telemedicine) and expanding the provision of innovative oral anti-diabetic drugs to family physicians could improve care for patients with type 2 diabetes mellitus. This study provides decision makers with an immediately usable model to broaden the information base for planning and regulatory choices. In addition, it supports the use of economic evaluations that calculate the entire value of a technological innovation or health program.

## Poster Debate

### PD01 Using ELISA Tests For Monitoring Response To Anti-TNFs In Rheumatoid Arthritis: Findings From A NICE Health Technology Assessment

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**Introduction.** Patients with severe rheumatoid arthritis (RA) disease may be treated with tumor necrosis factor (TNF)- $\alpha$  inhibitors. However, their efficacy is reduced by the presence of anti-drug antibodies. The objective of this HTA was to conduct a systematic review to investigate the effectiveness of using enzyme-linked immunosorbent assay (ELISA) tests (Promonitor, IDKmonitor, LISA-TRACKER, RIDASCREEN, MabTrack, and Sanquin Diagnostic Services) to measure levels of the drug and anti-drug antibodies for monitoring response to TNF- $\alpha$  inhibitors in patients with RA.

**Methods.** A range of bibliographic databases including MEDLINE, EMBASE and CENTRAL were searched from inception to November 2018. Studies were eligible for inclusion if they investigated ELISA tests in RA patients receiving treatment with a TNF- $\alpha$  inhibitor who had achieved the treatment target (remission or low disease activity [LDA]) or experienced a primary or a secondary non-response. The tests must compare with standard care where treatment decisions are based on clinical judgements and monitoring using a composite score such as the disease activity score 28 joints (DAS28). Risk of bias was assessed using the Cochrane (ROBINS-1) tool for non-randomized studies.

**Results.** Two studies were included. One non-randomized controlled trial (non-RCT) compared standard care with therapeutic drug monitoring using Promonitor test kits in RA patients in remission/LDA receiving adalimumab, and a historically controlled study investigated Sanquin ELISA kits. The non-RCT study showed that there was a non-significant reduction in the risk of flare in the intervention group compared with the control group. Patients' health-related quality of life outcomes were higher in the intervention group at all visits compared with the control group. However, this study had serious limitations because analyses were not performed using an intention-to-treat approach. The historically controlled study did not provide valid evidence on whether ELISA-based monitoring is clinically effective.

**Conclusions.** There is only limited, poor evidence available. There are considerable uncertainties on the effectiveness of using ELISA tests for monitoring response to TNF- $\alpha$  inhibitors in RA. Further controlled trials are required.