

The Swedish Dental and Pharmaceutical Benefits Agency (TLV) performed an economic evaluation of a computerised clinical decision support (Stroke Prevention CDS) for stroke risk assessment. Stroke Prevention CDS is a tool when estimating the risk of ischaemic stroke in patients with atrial fibrillation (AF) and also offers the administering physician in the choice of preventive stroke treatments according to national guidelines. The results of the assessment indicate that Stroke Prevention CDS may be cost effective.

TLV's commission on medical devices

TLV was commissioned by the Swedish Government to conduct health technology assessments of medical devices in the early stage of the product life cycle. The commission was initiated to aid county councils in making informed decisions. The county councils have also requested that the assessments contain aspects such as ethical considerations, legal aspects, organisational consequences and environmental issues. Another objective of the commission was to perform economic evaluations at the national level to enable uniformity and equal health care. The evaluation presented herein constitutes a part of the commission and has been conducted on a trial basis over the last three years.

Using the same methods as for pharmaceuticals, TLV deems it possible to evaluate medical devices at an early stage of the product life cycle, even though available scientific data is limited. A final report was submitted to the Swedish government at the end of December 2014. Based on the findings of said report, the Government commissioned TLV to continue evaluating medical devices at an early stage of the product life cycle throughout 2015.

Introduction

In Sweden, approximately 25,000 cases of acute stroke are reported every year. Stroke is, thereby, considered to be the third most common cause of death. Half of the patients die or suffer severe functional impairment resulting in long-term care.

Patients with AF run a greater risk of suffering a stroke. According to current guidelines, these patients are recommended treatment with anticoagulants to reduce the risk of stroke. AF is, nevertheless, rarely diagnosed and rarely treated.

The computerised clinical decision support (Stroke Prevention CDS) is as medical device using medical record data to calculate risk of stroke for AF patients. Stroke Prevention CDS also offers the administering physician a choice of preventive stroke treatments according to national guidelines.

Aim of the assessment

The purpose of this assessment was to evaluate whether Stroke Prevention CDS is cost-effective compared with the current process in clinical practice of detecting AF patients. In addition, TLV evaluated whether more patients requiring stroke prevention were found and, as a result, treated with anticoagulants.

Uncertainty regarding the effectiveness associated with Stroke Prevention CDS

Stroke Prevention CDS is not currently used in clinical practice and no clinical study of its effects has been completed. Thus, limited information is available of the number of "at-risk" patients to be detected or diagnosed using Stroke Prevention CDS.

As basis for the economic analysis, hypothetical scenarios were used for different outcomes regarding the effect. The result should be considered an estimate of the potential a decision support has, such as Stroke Prevention CDS, compared to how these patients are detected in clinical practice today.

Economic evaluations are always associated with a certain degree of uncertainty. TLV have also conducted sensitivity analyses of the number of patients requiring stroke prevention that can be found using Stroke Prevention CDS.

Clinical decision support is potentially cost-effective

The results indicate that Stroke Prevention CDS is potentially cost effective. In order to cover the cost of Stroke Prevention CDS, approximately 10 previously un-diagnosed AF patients per 100 000 inhabitants need to be detected and begin treatment with anticoagulants during the first year. If more than 10 patients receive anticoagulants, it will lead to cost savings for society.

TLV analysis also included how budgets of county councils and municipalities will be affected by the introduction of Stroke Prevention CDS. The first year will incur a cost of approximately SEK 370 000 per 100,000 inhabitants covering staff education, cost for software etc. Thereafter, the cost is expected decrease to approximately SEK 270 000 per year as only maintenance costs remain.

Follow-up and evaluation

A clinical trial regarding the effect of Stroke Prevention CDS is ongoing and will be completed during 2015. Upon completion, more data will be available and the uncertainty surrounding this assessment may be reduced.

More information

For more information on TLV's government commission on medical devices please visit www.tlv.se/medicinteknik