

The Swedish Dental and Pharmaceutical Benefits Agency (TLV) has performed an economic evaluation of the method primary preventive screening of atrial fibrillation (AF) with thumb ECG. Thumb ECG is a mobile device for ECG recordings and TLV concludes that the use of the method is reasonably cost-effective according to available data.



Image: Zenicor Medical Systems AB

### TLV's commission on medical devices

TLV has been commissioned by the Government to conduct health technology assessments of medical devices in an early stage of the product life cycle. The commission was initiated to aid the county councils in making more informed decisions. The county councils have also expressed a need for the assessments to contain aspects such as ethical considerations, legal aspects, organisational consequences and environmental issues. Another goal was to perform economic evaluations at the national level, previously not done in Sweden, which enables uniformity and equal health care. The present evaluation constitutes a part of the commission and has been conducted on a trial basis during the last three years.

Despite limited available scientific data, TLV considers that it is possible to evaluate medical devices at an early stage of the product life cycle, based on the same methods as for pharmaceuticals. A final report has been submitted at the end of December 2014. The Government has commissioned TLV to continue evaluating medical devices at an early stage of the product life cycle throughout the year 2015.

### Introduction

Every year approximately 25,000 cases of acute stroke are registered. Approximately 20 per cent of all ischaemic strokes are caused by AF. Stroke is the most common cause of chronic functional impairments among adults and results in considerable health care needs. If AF is detected medical treatment with anticoagulants can be initiated, with the aim to prevent future strokes.

Thumb ECG is a CE marked medical device still in an early stage in the product life cycle. Thumb ECG is a mobile device for ECG recordings used for population screening for AF outside health care services. This method allows the individual to register his/ her ECG data at home by pressing a button and placing their thumbs on the device for approximately 30 seconds. It can be used over an extended period (e.g. twice daily over a period of two or four weeks). The results are electronically transmitted to the health care provider.

### The STROKESTOP study

Primary prevention screening of AF has not previously been studied in a clinical study. The STROKESTOP study is an ongoing clinical study in two county councils in Sweden. The aim of the

study was to find individuals with AF and to be able to treat these preventatively with anticoagulants to avoid stroke.

All persons born in 1936 and 1937 in the studied county councils were identified and by means of randomisation invited to participate in the screening programme or in the control arm. Approximately 13,000 persons were approached for inclusion in the screening programme and approximately 7,000 persons participated.

TLV has used the preliminary results from the STROKESTOP study in the cost-effectiveness analysis in this assessment.

## Aim of the assessment

The purpose of this assessment was to study whether the method of primary preventive screening of AF with thumb ECG is cost-effective for 75 year old individuals.

## Uncertainty regarding the number of detected atrial fibrillation

The AF detection rate used in this economic evaluation is based on the ongoing clinical STROKESTOP study. The clinical study shows that primary preventive screening results in both earlier and higher detection rate of AF compared to routine health care.

An economic evaluation is always associated with a certain degree of uncertainty. The scientific evidence base for medical devices is usually less comprehensive than for pharmaceuticals. The uncertainty in this case is largely related to the number of AF cases detected during screening. There is considerably less uncertainty regarding whether the stroke prevention treatment is cost-effective for those diagnosed with AF.

## Primary preventive screening is cost-effective

The assessment shows that the cost of primary preventive screening with thumb ECG is approximately SEK 39,000 per quality-adjusted life-year (QALY) gained.

TLV has also analysed how the budgets of county councils and municipalities will be affected if screening with thumb ECG is introduced for

In Sweden, the county councils are responsible for specialised care, in this case acute stroke care. The municipalities, on the other hand, are responsible for rehabilitation of stroke patients. For county councils it will result in higher costs due to the introduction of the screening programme. However, the costs will be offset as the numbers of strokes will decline as a result of the screening programme. The costs for municipalities will decrease as the number of stroke patients are expected to decline. Avoiding stroke will not only result in health benefits for the patients, but also decreased health care costs related to stroke for the society.

TLV concludes that the benefits of primary preventive screening with thumb ECG seem large enough to justify the costs of screening for the studied population. This evaluation is based on the best available knowledge and might change in the future.

## Follow-up and evaluation

There is currently no information regarding when to initiate a national screening programme i.e. at which cut-off age the method becomes cost-effective. TLV have the intention to evaluate this in a separate report in the future.

## More information

For more information on the TLV's commission on medical devices please visit [www.tlv.se/medicinteknik](http://www.tlv.se/medicinteknik).