

## Assessment Regarding Primary Preventive Screening of Atrial Fibrillation with Thumb ECG

The Swedish Dental and Pharmaceutical Benefits Agency (TLV) has performed an updated and expanded economic evaluation of screening with Thumb ECG. This method is used to discover atrial fibrillation, abnormal heartbeat, which can amongst other things lead to stroke.



Image: Zenicor Medical Systems AB

### Introduction

Every year approximately 25,000 cases of acute stroke, including both first-ever stroke and recurrent stroke, are registered. Approximately 20 per cent of all ischaemic strokes are caused by atrial fibrillation. Stroke is the most common cause of chronic functional impairments among adults and results in considerable health care needs. Presently, not all individuals in need of stroke prevention treatments have been identified. The greatest risk factors for stroke for individuals with atrial fibrillation are old age and previous stroke.

### TLV's assessment of Thumb ECG

In November 2014 TLV published an assessment of primary preventative screening of atrial fibrillation with Thumb ECG. The aim of the assessment was to investigate if primary preventative screening of atrial fibrillation with Thumb ECG is cost-effective for individuals that are 75 years old. This was done by performing an economic evaluation of the screening method. The assessment also sought to provide the county councils with a basis for making decisions that enable national unity and equitable healthcare.

### Increased detection of atrial fibrillation

Detection rates of atrial fibrillation come from the STROKESTOP study. The study demonstrates that primary preventative screening could detect more atrial fibrillations than routine healthcare. TLV's initial assessment of Thumb ECG in 2014 was based on the unpublished research results of the STROKESTOP study that had been submitted to a journal for publication. TLV determined that assessment of Thumb ECG could still be published but planned to update the assessment when the results were published in full.

### An updated assessment of Thumb ECG

In the spring of 2015 TLV decided to update and expand the assessment and economic evaluation of Thumb ECG. In this version of the assessment certain parts have therefore been updated and an entirely new chapter that contains further analysis has been added.

The majority of individuals diagnosed with atrial fibrillation in Sweden are between 55 and 85 years old. Furthermore, women with atrial fibrillation have a higher risk of stroke than men. Upon these grounds TLV finds it relevant to investigate the cost-effectiveness for the age group 55 to 85 years old as well as for differences between men and women. TLV has also

investigated the cost-effectiveness of screening the same individual on two separate occasions.

Due to a lack of studies about screening programs other than for individuals that are 75 years old and the effects of multiple screening occasions, calculations were done to simulate the effects with amongst other things the prevalence of atrial fibrillation in different ages. This has led to a greater degree of uncertainty in the results of economic evaluation.

### Screening is cost-effective

The results of the economic evaluation indicate that it is cost-effective to screen 75 year olds with Thumb ECG at a cost of approximately 39 000 Swedish Kronor (SEK) per quality adjusted life year (QALY) gained. Screening with Thumb ECG is not expected to be cost saving but the total costs are low in relation to the health benefits gained. Every person who is screened contributes to increased costs that are to some degree offset by a reduction of costs connected to a decrease in individuals that sustain a stroke. The costs are expected to decrease for the municipalities as stroke patients decreases.

When TLV included individuals between the ages of 55 to 85 years old in the analysis, the age that was most cost-effective for screening of atrial fibrillation was 75 years old for both men and women. Nevertheless, the cost per gained QALY is lower for women due to a higher risk for stroke if diagnosed with atrial fibrillation. The cost per gained QALY for women is 7 000 SEK, while the corresponding cost for men is 91 000 SEK per gained QALY.

TLV's assessment also indicates that the cost per gained QALY increases with the number of screening occasions. The value of multiple screening occasions is lower since the majority of atrial fibrillation cases are discovered during the first screening occasion. The assessment nonetheless concludes that it could be a relevant to screen women on two occasions since the cost per gained QALY is lower for woman than it is for men.

With fewer individuals suffering from stroke, health benefits and lower societal costs for healthcare and social care can be achieved. TLV considers the benefits are great enough to motivate the screening costs based on the knowledge currently available.

### Uncertainty in the amount of detected atrial fibrillation

An economic evaluation is always associated with a certain degree of uncertainty. The results of the expanded economic evaluation contain a high degree of uncertainty. The uncertainty in this assessment comes from a lack of studies on: screening at different ages, screening that include the differences between women and men, and screening on multiple occasions.

There is considerably less uncertainty regarding whether the stroke prevention treatment is cost-effective for those diagnosed with atrial fibrillation.

TLV, in this assessment, has made an assumption that the county councils have the same willingness-to-pay for medical devices as that which has been deemed acceptable for pharmaceuticals in the Swedish benefits and reimbursement system. Whether or not this is in agreement with the county councils' actual willingness-to-pay cannot be stated by TLV.

### About Thumb ECG

Thumb ECG is a device for mobile screening of atrial fibrillation. The user can take readings of their ECG at home by placing their thumbs on the device. Each reading takes approximately 30 seconds. Thumb ECG is a CE marked medical device.

### TLV's commission

TLV has been commissioned by the Government to conduct health technology assessments of medical devices in an early stage of the product life cycle. 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.