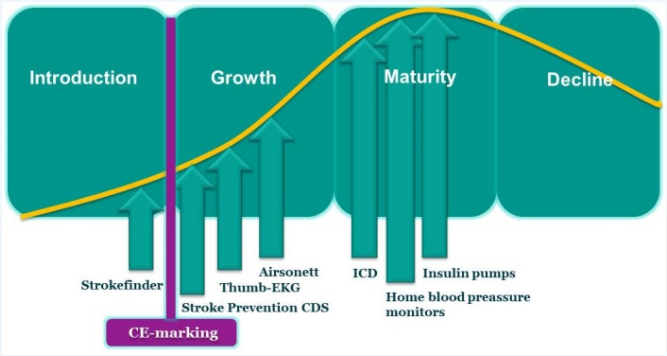
TANDVÅRDS- OCH LÄKEMEDELSFÖRMÅNSVERKET

Final report of the Government commission: Health Technology Assessments of Medical Devices

The Swedish Dental and Pharmaceutical Benefits Agency (TLV) was commissioned by the Swedish Government in April 2012 to conduct health technology assessments (HTA's) of medical devices. The project was carried out on a trial basis and initiated to aid county councils in making more informed decisions regarding medical devices. Another objective was to perform HTA's, at the national level, which would promote uniformity and equal health care.



The figure shows where in the product life cycle the medical devices were at the time of the assessment in relation to CE marking. The four phases in the product life cycle were adapted from Kotler. The yellow line shows the change in use during the four phases.

A report on TLV's first government commission to conduct HTA's was presented in November 2013. Prior to this, TLV was assigned a renewed government commission to extend and expand the project until the end of 2014. The objective with this renewed commission was to evaluate the possibility of performing HTA's in early stages of product life cycle. An interim report of this commission was presented in April 2014, and the final report was published in December 2014. In December 2014 TLV's commission to evaluate medical devices was renewed for 2015.

In the final report, TLV concludes that despite limited available scientific data on medical devices, it is possible to evaluate these products at an early stage of the product life cycle, using the same HTA methods as pharmaceuticals.

HTA of medical devices should be performed at national level

Each year, approximately SEK 20 billion is invested in medical devices in the Swedish health care system. This investment is comparable to the annual spending on pharmaceuticals in the benefits scheme. According to Swedish law, investments in health care should have a reasonable relationship between costs and effects.

This means that patients should receive the best possible health benefits from tax money spent on medical devices. However, decision-makers rarely perform HTA's of medical devices with a societal perspective (i.e. where all costs and effects, regardless by whom they are incurred, are included). TLV has concluded that there is a need for HTA's regarding medical devices at a national level.

Limited scientific data in early stages of the product life cycle

A CE-marked medical device must have sufficient evidence of the product's safety for intended use.

The scientific data for medical devices concerning effect in relation to cost which are used in HTA's are generally not comprehensive. This may result in varying degrees of uncertainty of the HTA.

HTA's always imply a certain degree of uncertainty. Therefore, it is particularly important to be transparent when describing and working with uncertainty in an economic assessment, but should not in itself be an obstacle in carrying out assessments.

When the product is CE marked and available on the market, the decision makers need to decide whether or not they should invest in the product.

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HTA regarding medical devices can be conducted in a similar manner as pharmaceuticals

HTA regarding medical devices can be conducted in a similar manner as pharmaceuticals but may present particular challenges. Besides having less comprehensive scientific data compared to pharmaceuticals, medical devices often have a shorter product life cycle and undergo minor incremental changes, making it more difficult to assess patient benefits.

Medical devices are also to a large extent affected by the circumstances under which they are used. HTA's need to include factors which influence use such as the requirements for organisational changes, follow ups and possible re-evaluations.

Not optimal to perform HTA prior to CE-marking

During 2014, TLV assessed the use of three different innovative products in the area of cardiovascular disease: thumb-ECG, Stroke prevention CDS and Strokefinder. The products were considered to have major potential for improved public health as well as offering the possibility of reduced costs for society. It is important to point out that the assessments do not evaluate the products but rather their use in clinical practice.

The project provided a deeper understanding of when in the product life cycle it is possible and most appropriate to conduct an assessment. TLV concluded that to gain most impact assessments should be conducted as soon as possible following CE-marking.

A novel and iterative approach to HTA early in the product life cycle

The purpose of TLV's HTA's is to aid decision makers in prioritising among new medical devices introduced in health care. In Sweden, there is currently no systematic process for the introduction of new products at the national level. Furthermore, county councils do not usually base decisions on HTA's with a societal perspective.

TLV's final report proposes a four-step model for HTA of medical devices. By making the various steps in the evaluation process visible it increases transparency and raises awareness among medical device companies and decision makers on how to conduct HTA's. With an increased knowledge base, the four-step approach allows us to increase the accuracy of the decision.

In the first step it is important to identify intended use of the product and currently available treatment options. The next step involves collecting data on costs and effects. The third step involves estimating the cost-effectiveness with, for example, the use of decision analytic modelling. The final step is a follow-up of results with real life data, if available. This is, therefore, an iterative process.

Every step involves identification of knowledge gaps and describes the uncertainty of parameters important for the HTA.

The future of medical devices in Sweden

In order for the assessments to make a difference, TLV has created a network of contact representatives in county councils that receives our assessments. These representatives are responsible for distributing the assessments within the county councils. The county councils are, if they chose to invest in them, responsible for implementing the assessed methods in health care.

Among the medical device companies there is a need for greater awareness of how to produce high quality economic assessments. TLV has, therefore, established an advisory function for this purpose.

There is also a need for a national authority to conduct economic evaluations of medical devices based on all available information in the early stage of the product life cycle.

It is vital to continue developing methods for evaluating medical devices to ensure cost effectiveness. This will better prepare the Swedish health care sector for when medical devices start to play an even greater role in health care than today.

More information

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