The Nordic countries Denmark, Sweden, Finland, and Norway are all tax-based healthcare systems comprised of regional authorities for national and local government purposes around funding of medical devices are made by hospital management, which is to make informed decisions with limited time and resources at hand. The funding process for medical devices in the Nordics has traditionally been based on non-systematic assessments which has led to different methodological approaches being used every time a technology has been assessed.14

Health technology assessment (HTA) is a multidisciplinary process that summarizes information about the medical, social, economic and ethical issues related to the use of a medical technology. This is done in a systematic, transparent, unbiased, robust manner, with the drawback of being resource intensive and time consuming.15 In situations where time and resources are insufficient for executing a comprehensive HTA, the need for a scaled-down version of a full HTA becomes evident. A mini-HTA is defined in the form of a standard checklist directed to quickly advise evidence-based decision-making around funding technology and includes questions regarding prerequisites for and consequences of using the technology.

The purpose of this study is to describe the existing structures and trends for the use of mini-HTAs in the decision-making process for the approval of funding medical devices in the Nordic countries.

A structured web-based search and interviews with stakeholders were conducted to compile information from national, regional, and local authorities and agencies. The mini-HTA processes were assessed by comparing the different structures across the Nordic countries.

All the Nordic countries are either currently developing a system for or are already holding a system for structured mini-HTA processes for decisions on the use of medical devices at the national or regional level. However, due to the widespread regional autonomy in the Nordics, the execution of a mini-HTA is compulsory only in certain settings.1,14,15 The framework of a standard mini-HTA process is largely similar across the Nordic countries, with minor variations (Table 1). The process starts with a request for a mini-HTA being sent to the institution or agency that will review the mini-HTA or conduct the assessment criteria, assign a project group and initiate the evaluation. The project group is generally multidisciplinary, including health economists, librarians and clinical experts.1,14,15

The mini-HTA process in Denmark has been developed and redefined since the early 1990s and is focused on assessing four perspectives of the application (Figure 1). Non-compliance with these four perspectives may lead to rejection of funding for the medical device.1,19

The Danish mini-HTA is standardized at the national level and compulsory in some settings.14 At the national level, all Regional Boards of Health use mini-HTA as a window for permission to introduce new treatments. Mini-HTAs are also compulsory to conduct for Danish Regions’ annual collection of early warnings on rejection of medical devices. At the local level, some hospitals have made mini-HTAs compulsory when clinical need is shown for new treatments. All national as well as the majority of the regional mini-HTAs have been published on the National Board of Health’s website which includes hundreds of assessments.14,15

A review of the literature shows that the Nordic countries, and especially the Nordics, have made HTA approaches in the Nordic countries.14,15

Finland

Mini-HTAs are not compulsory in Finland. However, a format similar to that used in Denmark was used for a few years by the Finnish Managed Uptake of Medical Methods group for the assessment of medical devices at the national level (Figure 1). A Finnish national mini-HTA format is under development and will be finalized in 2012. The Finnish format will be broader and more extensive than the Danish version. In Finland, the hospital districts have the autonomy to individually decide whether they want to use the mini-HTA. So far, only one hospital district has adopted the mini-HTA process.14,15

Sweden

Four regional HTA units, located in the most densely populated areas of Sweden, are already using mini-HTAs. Other county councils are also developing standardized processes resembling a mini-HTA (Figure 1). Sweden, which has also limited resources are using the results of mini-HTAs conducted in the same county councils, Vastra Gotaland and Oderbro, have made mini-HTAs compulsory for costly new medical devices, specified in Vastra Gotaland, with an annual cost exceeding SEK 1 000 000.14,15

Conclusions

Mini-HTAs can be used in many situations, such as when purchasing new medical devices or equipment, for approval of new treatments and for general budget planning. The assessment has been recognized to be large support in the decision-making process. The challenges of mini-HTAs concern insufficient quality control of the data on which a mini-HTA is based. Another issue is the question of who should have the organizational responsibility and cover the costs of the assessments (Figure 2).14,15

However, the systematic, rapid, and flexible features that the mini-HTAs provide have clearly shown to be beneficial and are therefore attractive to Nordic authorities. An upcoming trend is increasing cross-country collaboration of utilizing other countries’ mini-HTA results.14,15

References