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Title **A Framework for the Assessment of Emerging Medical Devices**

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Reference 2006. KCE reports 44A (D/2006/10.273/32).
http://kce.fgov.be/index_nl.aspx?ID=0&SGREF=5264&CREF=7935

Aim

To establish a transparent, scientifically valid procedure in Belgium for early evaluation of medical devices.

Conclusions and results

The KCE in collaboration with the Belgian Health Insurance (RIZIV/INAMI) elaborated a procedure for early evaluation of medical devices. The procedure combines a process of managed uptake, limiting the budgetary risks with the production of solid and impartial evidence on clinical and cost effectiveness.

Implementation of the new procedure will help policy makers reach informed and well-balanced decisions. For the manufacturers that produce innovative devices with 'added value', the procedure allows the gradual and controllable introduction of an emerging device on the market, preventing inappropriate use and operator problems. Moreover, such a procedure guarantees a (partially or fully) government-supported clinical trial and a health technology assessment that presents conclusions on effectiveness, costs and possibly cost-effectiveness, and organizational and patient issues. The framework also assures patients that the emerging interventional technologies are introduced in a state-of-the-art research setting and reviewed to protect their safety.

Recommendations

A transparent registration and vigilance system should be developed. This can lead to more readily accessible information about existing products, procedures, and potentially major safety issues.

Methods

The first part of the report gives a general description of key concepts and provides an overview of the regulatory context for medical devices in developed countries at the European and international levels. The available literature was identified through a search in MEDLINE and the CRD HTA database.

Furthermore, existing procedures to identify, assess, and monitor emerging medical devices were described. Information was collected from national and/or local governmental agencies, and from private agencies when relevant. To validate or add to this information, contact was made with one or more experts in the specific country.

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