



<b>Title</b>	<b>A Review of Policies and Processes for the Introduction of New Interventional Procedures</b>
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## Aim

To identify and review Australian and international policies and processes for introducing new interventional procedures into clinical practice, specifically:

1. how decisions on adopting new interventional procedures are made
2. the extent to which evidence-based information, particularly health technology assessment (HTA), is used in the decision-making process.

## Conclusions and results

Searches of the published literature revealed only 1 paper outlining relevant policy information. Targeted website searches were more fruitful, and uncovered many relevant policy documents, most of which were from NHS Trusts in the UK. Six policies (2 Australian, 2 Canadian, and 1 each from Denmark and the UK) were selected for this review. Each of these policies contained a clearly defined purpose and an explicit description of the approval process, including the role of relevant clinical governance structures.

Five of the 6 included policies use an application form as part of the approval process, while 1 (Canada) bases its policy decisions largely on recommendations from its Technology Assessment Unit. These HTAs evaluate safety, efficacy, cost effectiveness, and ethical and legal implications. The 5 policies that use application forms in the approval process all required information on clinical outcomes, need, disease burden, the safety, efficacy, and effectiveness of the procedure, and organizational outcomes (eg, cost, training requirements). Both Australian policies required patient information sheets and informed consent forms in the approval process. Similarly, the UK policy also required that patient information and informed consent be addressed, but these issues were not addressed by the Canadian or Danish policies.

Three studies that evaluated the outcomes of specific policies in Australia, Canada, and the UK were found

by searching the published literature, while targeted website searches revealed 1 document describing the outcomes of a second Australian policy. These studies have focused largely on the number and type of procedures approved since the implementation of specific policies, and 2 studies provided information on organizational impact.

Searches of the published literature uncovered 3 studies, 2 in Israel and 1 in Denmark, that examined decision-making at the hospital level, while targeted website searches revealed 1 document describing a decision-making processes in New Zealand. The results from these studies have shown that while the safety, efficacy, and clinical and cost effectiveness are important considerations in the decision-making process, other factors also play a role, and decisions are never based solely on the findings of HTAs. A lack of access to relevant and timely HTAs was identified as a barrier to an optimal decision-making process.

## Methods

*Search strategy:* MEDLINE, EMBASE, CINAHL, Current Contents, and PubMed were searched from inception to February 2007. Several relevant journals were hand-searched from 2000 to February 2007. Relevant online sources were also searched.

*Study selection:* Documents outlining specific policies and processes were included if they evaluated the clinical need, safety, efficacy, effectiveness and/or financial implications of a new intervention. Where outcomes were reported for specific policies, these policies were given preference for inclusion. Studies addressing the use of HTAs in decision-making were also included.

*Data collection and analysis:* One researcher extracted the data and a second checked it using standardized data extraction tables developed *a priori*. Data for the main outcomes were reported narratively.