A review of policies and processes for the introduction of new interventional procedures.

Report No. 58

Australian Safety and Efficacy Register of New Interventional Procedures - Surgical

Record Status
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Citation

Authors' objectives
To identify and review both Australian and international policies and processes for the introduction of new interventional procedures into clinical practice, with the aim of determining:

(1) how decisions about the adoption of new interventional procedures are made

(2) the extent to which evidence-based information, particularly health technology assessments (HTAs), is used in the decision-making process.

Authors' conclusions
Searches of the published literature revealed only one paper outlining relevant policy information. Targeted website searches were more fruitful, and uncovered a large number of relevant policy documents, the vast majority of which were from NHS Trusts in the UK. A total of six policies, two Australian, two Canadian, and one each from Denmark and the UK, were selected for inclusion in this review. Each of the included 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 six included policies employ an application form as part of the approval process; while the McGill University Health Centre in Canada bases its policy decisions largely on the recommendations of Technology Assessments produced by its own Technology Assessment Unit. These Technology Assessments evaluate the safety, efficacy and cost-effectiveness of the new technology, as well any ethical and legal implications its introduction may have for the organisation. Information on clinical outcomes, including the clinical need and burden of disease, as well as the safety, efficacy and effectiveness of the procedure were required by all five policies that incorporated application forms as part of their approval process, as was information on organisational outcomes including the cost considerations and training requirements of the procedure. Both Australian policies required patient information sheets and informed consent forms as part of their approval process. Similarly, the policy of the Luton and Dunstable NHS Trust in the UK also required that the issues of patient information and informed consent be addressed, however these issues were not addressed by the Canadian or Danish policies.

Three studies that have evaluated the outcomes of specific policies in Australia, Canada and the UK were uncovered through searches of the published literature, while targeted website searches revealed one document describing the outcomes of a second Australian policy. These studies have focused largely on the number and type of procedures that have been approved since the implementation of specific policies; however two studies have provided additional information on their organisational impact.

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

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