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Improving decision-makers response to guidance that a new interventional procedure is 'safe and efficacious'

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Background: Definitions of 'efficacy' and 'effectiveness' are often used interchangeably and tend to vary from setting to setting; therefore it becomes unclear to meso-level decision-makers when policy-maker organisations make pronouncements about a health technology being efficacious or effective without further details of the actual types of evidence underpinning the guidance. In practice, decision-makers are more interested in whether the intervention works (does it work? - effectiveness) than whether the intervention can work (can it work? - efficacy).

Purpose: The aim of this presentation is to propose a more meaningful approach to distinguishing efficacy outcomes from effectiveness outcomes to help guide policy-makers in guidance development.

Methods: The Interventional Procedures Programme (IPP), working under the auspices of the National Institute for Health and Clinical Excellence (NICE), amongst other activities, issues guidance on the safety and efficacy of new interventional procedures. Using this programme as a case study, the nature of evidence underpinning their guidance is investigated and the ability to extrapolate effectiveness outcomes such as serious morbidity and quality of life, that are more relevant to health services and people affected is assessed using the proposed approach.

Results: A total of 198 procedures were evaluated by the IPP between July 23rd, 2003 and February 24th, 2007 of which 88 were eligible. Preliminary results suggest that evidence that goes beyond efficacy is available for some procedures. Moreover, the types and balance of evidence available varies considerably between procedures for which the same category of guidance had been issued.

Discussion: The evidence available for new procedures is broader as it can go beyond efficacy. A more meaningful approach to distinguishing efficacy outcomes from effectiveness outcomes to help guide policy-makers in guidance development should be used.