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'What is dead may never die' – cost-minimization analysis in the context of medical devices in Europe

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Introduction

The application of health economic evaluation methods to inform reimbursement decisions for medical devices has been markedly different from pharmaceutical products. Methods such as cost-utility analysis (CUA) and cost-effectiveness analysis (CEA) have been widely applied to inform decision-making for the latter, but generally not for the former. The relative lack of application of the methods of economic evaluation for medical devices is related to several factors, including the nature of the development and usage of medical devices themselves, which often inhibits the generation of evidence for the evaluative process, and the regulatory environment, which dictates the level of evidence that is provided to inform approval and reimbursement decisions (1). This issue has been discussed in detail in several previous publications (1–3). However, recent changes to the regulatory environment will likely lead to increased requirements for economic evidence on medical devices, particularly, but not limited to high-risk or 'Class III' devices (4). The nature of the regulatory changes, along with the complexity of applying economic evaluation methods to medical devices, will have important implications for practitioners and users of these methods going forward. In this article, we consider one such implication: the potential re-emergence of cost minimisation analysis (CMA) as a method of economic evaluation for medical devices resulting from new evidentiary requirements. In 2001, Briggs and O'Brien published an article in the journal *Health Economics* entitled the 'The death of cost-minimization analysis?' (5). In their article, the authors argued that unless a study has been specifically designed to show the clinical equivalence of treatments in terms of effects, it is inappropriate to conduct CMA. Indeed, their article informed current 'best practices' in economic evaluation whereby the majority of analyses currently take the form of CEA or CUA, rather than CMA. Given the regulatory changes outlined below, it is timely to consider whether the updated guidelines might lead to the re-emergence of CMA as a method to