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Factors influencing coverage decisions on medical devices: A retrospective analysis of 78 medical device appraisals for the Austrian hospital benefit catalogue 2008–2015

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ABSTRACT

Background: Health technology assessments of medical devices (MD) present a well-recognized challenge to evaluators: the evidence on safety and clinical effectiveness is often of lower quality than for pharmaceuticals making a reliable assessment of the risk-benefit ratio difficult. Thus other factors might gain importance in decision making.
Objective: To analyse which factors impact MD reimbursement decisions within the Austrian appraisal programme on "extra medical services" (procedures reimbursed in addition to case flat rates) for inpatient care over the past eight years.
Methods: We collected variables on evidence base and device characteristics from all MD appraisals and assessed their impact on the reimbursement decision by means of odds ratios. Separate analyses were carried out for subgroups based on the risk class of the medical device subject of the assessment or the number of randomised controlled trials (RCTs) available for the assessment.
Results: Of 59 devices, 23 (39%) were accepted for reimbursement (18 with restrictions) and 36 (61%) were rejected. Variables addressing the quality of the evidence base were positive predictors for risk class II devices only, whereas no significant association could be determined in devices of risk class III. Inversely, high risk device characteristics were positive predictors in the subgroup not supported by RCTs only.
Conclusion: Our data indicate that the combination of high risk characteristics and a low evidence base are factors favouring a positive reimbursement decision of MD, albeit with restrictions. Further research should analyse if these restrictions are appropriate to generate evidence development and to contain risks associated with early access to these MD.

1. Introduction

Facing cost-driving developments in medical technology while health care resources are increasingly limited, many European countries have implemented processes to incorporate evidence assessments in policy decisions on medical technologies [1]. These health technology assessments (HTA) are carried out by dedicated institutions that evaluate the technologies with regards to the risk and the benefits they provide in comparison to the current standard of care [2]. In addition to summarising the effect estimates from the clinical studies, these assessments also determine the validity of these estimates – the so called "strength of evidence". As a general principle of evidence-based medicine, randomized controlled, double blinded

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Box 1

Category	Description
Recommendation, acceptance	There is strong evidence for a net benefit of the intervention in comparison to standard therapy.
Recommendation with limitations	There is indication of a net benefit, but the evidence is of moderate quality and further evidence might have influence on the re-evaluation of the intervention at a later date.
Preliminary rejection	There is no or only low-quality evidence to assess the net benefit of the intervention at this time.
Rejection	There is strong evidence of no net benefit of the intervention.

clinical trials (RCTs) are regarded as the gold standard providing effect estimates with the highest confidence level and minimal risk of bias.

HTA of medical devices (MD) present a well-recognized challenge to evaluate: in particular due to a less stringent regulatory environment in Europe in comparison to pharmaceuticals, the evidence on safety and clinical effectiveness is often of lower quality than for pharmaceuticals [3–5]. In the absence of sound evidence from RCTs, a reliable assessment of the risk-benefit ratio is often difficult and other factors might gain importance in decision making (e.g., device risk class, evidence from uncontrolled studies, unmet medical need). Several studies have analysed the factors influencing reimbursement decisions of pharmaceuticals in specific countries (UK [6–11], The Netherlands [12], Australia [13,14]. A similar study for reimbursement of MD in France has been published recently [15]. To shed light on factors influencing MD reimbursement decisions in Austria, we analysed the appraisals and subsequent reimbursement decisions on MD produced within the Austrian appraisal programme on "individual medical services" (in German: "Medizinische Einzelleistungen", MEL) for inpatient care over the past eight years.

The Austrian Ministry of Health maintains a benefit catalogue of procedures provided in the inpatient sector, where case flat rates are attributed based on a Procedure and Diagnosis-related Groups (DRG) System, which is the basis for reimbursement for all Austrian hospitals [16]. The catalogue also contains a list of extra medical services (MEL): a positive list of cost-intensive procedures, mostly MD, for which costs are reimbursed in addition to the DRG's case flat rates. Since 2008 the annual maintenance of this MEL list includes an evidence-based decision making process: an evidence synthesis in form of single technology assessments is produced within 3–5 months by an independent advisory body (the Ludwig Boltzmann Institute for Health Technology Assessment, LBI-HTA), and is submitted as a decision support with a recommendation (see Box 1 for details on the description of the categories) to the Federal Health Commission [17].

To arrive at a recommendation, the LBI-HTA conducts systematic literature searches of the scientific evidence on clinical efficacy and safety to determine the net benefit of the intervention in comparison to standard therapy. The studies are subject to a critical appraisal based on the GRADE framework to judge the overall strength of the evidence supporting the conclusions. This judgement takes into account the study design, with head-to-head RCTs considered to provide the most reliable and objective evidence over non-randomised or uncontrolled study designs [1,18,19], but also other sources of uncertainty, e.g. risk of bias, inconsistency or imprecision of the results. Besides methodological quality, the external validity is evaluated, e.g. whether characteristics of the study population and the conduct of the intervention correspond to the planned clinical application of the MD and if relevant clinical endpoints and comparators were used to demonstrate benefit. The recommendations fall into one of four possible categories (Box 1). In case of a recommendation with limitations, the recommendation includes a statement on recommended restrictions (e.g. use in specialised centres). In case of a preliminary rejection, the recommendation is accompanied by a description of the gaps in clinical evidence (e.g. longer follow-up times, controlled studies, clinical endpoints etc.).

Based on the compiled reports by the LBI-HTA, decisions are made by the Federal Health Commission which could fall into three categories: (1) Yes - the coverage is accepted and the technology is included in the MEL list; (2) Yes with restrictions - the technology is included in the catalogue via a special coding "XN code", meaning that the technology is only reimbursed up to the existing DRG flat rate, the corresponding procedure may only be provided in specialised centres and the procedure has to be reassessed within a defined time frame; (3) No – the technology is not included in the MEL list.

2. Methods

2.1. Data collection

We performed a retrospective analysis of all MD appraisals performed by the LBI-HTA since inception of the MEL programme, covering the time period from 2008 until 2015. In total 78 appraisals of interventions involving the application of MD were carried out in the frame of this programme [20]. Each of these appraisals included several MD products (e.g. former versions of a same product or similar products from different manufacturers) grouped in generic device classes that were jointly assessed. Some reports included different device subgroups. If these MD were applied in a similar medical procedure, but had substantial differences with regards to their mechanism of action (e.g. slings versus balloons for the treatment of stress urinary incontinence), evidence was assessed separately and recommendations were issued for each subgroup. In these cases, each of these device subgroups was counted separately for our analysis. In the following, "MD" will always refer to a class of generic MD, not to individual MD products. 19 of the reports were updates of earlier assessments. To avoid duplicate counting, we considered those reports only once.

Each appraisal was reviewed to extract individual components of evidence (see Tables 1a–1c), the