

Adapting HTA Methods and Processes to Meet the Special Characteristics of Medical Devices

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Some Background

- Medical devices (MDs) have a number of special characteristics that differentiate them from other health technologies, especially pharmaceuticals
- The EU MedtechHTA project explored how methods and processes could be adapted to meet these characteristics. Tarricone *et al* *Health Economics* 2017; 26(suppl1): 1-152 (**Available open access**)
- These efforts are now continuing, with the EU COMED project (www.comedh2020.eu)

Existing Practice in HTA

- The MedtechTA project reviewed existing practice in the HTA of medical devices
- Several jurisdictions had a separate programme or process for medical devices
- Only one jurisdiction had specific methods guidelines (Ciani *et al*, *Int J Tech Asses Health Care* 2015; 31:154-165)
- Based on a methods review undertaken for the MedtechHTA project, some guidelines for the assessment of comparative effectiveness were developed (Schnell-Inderst *et al* 2015 *Guideline: Therapeutic Medical Devices*. EUnethTA JA2. www.eunetha.eu)

Tackling the Challenges

- Uncertainties in the clinical data
- Estimating the learning curve
- Incremental innovation
- Organizational impact
- Dynamic price changes

Uncertainties in the Clinical Data

- Early dialogue should take place between regulators, HTA agencies and manufacturers in order to determine the appropriate clinical studies
- High quality registries should be developed, either on a disease basis, or containing multiple devices
- Data collected in registries should facilitate the estimation of the relative clinical and cost-effectiveness of devices
- Methods should be used to minimize the potential selection bias in observational studies (eg propensity scoring, multivariate analyses using instrumental variables)

Uncertainties in the Clinical Data(Continued)

- More studies should be undertaken of methods to 'correct' for the biases in observational studies by using expert opinion (Schnell-Inderst *et al Health Economics* 2017;26(suppl 1):46-69)
- Value of information analysis should be used to determine (i) additional data needs and (ii) the reimbursement status for devices , as more evidence on effectiveness and cost-effectiveness accumulates (Rothery *et al Health Economics* 2017;26(suppl 1):109-123)

Estimating the Learning Curve

- Varabyova *et al* used an administrative dataset on over 40,000 patients treated in 553 hospitals over a 7 year period to estimate the learning curves for endovascular aneurism repair (EVAR) and fEVAR (fenestrated EVAR)
- They found impacts of the learning curve in EVAR on improved in-hospital mortality and reductions in hospital stay
- There were no corresponding effects for fEVAR, since the procedure was familiar to clinicians who could perform EVAR

Varabyova *et al* *Health Economics* 2017;26(suppl 1): 92-107

Estimating the Learning Curve (Continued)

- Ideally, those performing HTAs would like to estimate the likely learning curve for a new device in advance
- Once the learning curve effects have been studied for more devices, it might be possible to categorize new devices into those likely to have large or small learning effects. (This is being investigated in the COMED Project, Work Package 1, by eliciting expert (physician) opinion.)
- These estimates could inform a process of 'coverage with evidence development', where reimbursement conditions are changed as more evidence is accumulated

Incremental Innovation

- Incremental innovation may involve minor changes in device specification that may only have small impacts on device performance
- Often these may not effect clinical or cost-effectiveness of the device, but may increase ease of use or convenience for the patient
- HTA bodies in many jurisdictions may not consider these changes to be important enough to justify changes in reimbursement
- The changes may not be identified by standard economic benefit measures such as the quality-adjusted life-year (QALY)
- If there is interest in estimating them, other approaches, such as discrete choice experiments, or willingness-to-pay studies, may be required
- See **Wilkinson, G. and Drummond, M.F.** (2015). Alternative approaches for assessing the socioeconomic benefits of medical devices: a systematic review. *Expert Review of Medical Devices*, 12(5), 629-648

Organizational Impact

- An inventory should be made of the likely organizational impacts of a new device (eg training requirements, investment in new facilities, etc; potential shift to outpatient care).
- This inventory can then be used to estimate the likely additional costs or potential savings from adopting the new device in different settings
- These data may then help determine the policy for the most efficient diffusion of the device (eg tertiary clinical centres only, or local hospitals)
- The review by Tarricone *et al Health Economics* 2017;26(suppl 1): 70-92 indicated that this is rarely done in HTAs or published economic evaluations

Dynamic Price Changes

- HTAs of devices should be revisited every 2-3 years in order to assess whether dynamic price changes have affected relative cost-effectiveness
- It may also be possible to specify thresholds of price differences that could impact on the choice of device
- For example, in its second HTA on drug-eluting stents (DES), the National Institute for Health and Care Excellence (NICE) determined that DES would only be preferred for some categories of patient if the price differential to bare metal stents was less than £300 (NICE, TA 152, 2008).

Conclusions

- The special characteristics of medical devices do lead to additional challenges for HTA
- The EU MedtecHTA project showed that a number of these challenges could be tackled
- In many areas further research is required and this is being pursued in the EU Horizon 2020 COMED project. (Details below)

Key Work Packages in the COMED Project

WP1 Real World Evidence for Economic
Evaluation of Medical Devices

WP2 Use of Surrogate Outcomes for
Medical Devices

WP3 Assessment of Patient-Reported
Outcomes in mHealth

WP4 Scientific Model for Assessing Medical
Practice Variations in Medical Devices

Key Work Packages in the COMED Project (Continued)

WP5 Medical Practice Variations for Medical
Devices Within and Between European
Countries

WP6 Early Dialogue and Early Assessment
of Medical Devices

WP7 Coverage with Evidence Development
for Medical Devices

WP8 Transferability of Medical Device HTAs
and Economic Evaluations Across EU
Member States