Specificity of the Evaluation of Medical devices versus Drugs

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1. Introduction

- **What is Health Technology Assessment (HTA)?**
  - It is the systematic evaluation of properties, effects, and/or impacts of health care technology
  - Addresses both the direct, intended consequences of a technology as well as the indirect unintended consequences

- **What is the purpose of an HTA?**
  - Improves the allocative efficiency by enabling policy makers make informed decisions
  - Promoting the introduction and adoption of inventive and cost-effective medical technologies
  - And prevent the uptake of technology with little beneficial value

- **Types of HTA evaluations**
  - Full-scale HTAs,
  - Rapid reviews,
  - Horizon scanning reports,
  - Hospital based HTA

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2. Key considerations to be made when applying HTA

- Thorough understanding of the Policy question
- Evidence is Global, but decision making needs to be Local
- It has to be contextualized
- Both HTA and HTM need to be equally effective

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2. Health technology assessment of medical devices. WHO Medical device technical series, June 2011
3. Key considerations to be made when applying HTA

• The gold standard for the evaluation of any technology is a Randomized Controlled trial\textsuperscript{5}

• And Economic Evaluations though not always, but are an important element of a Health Technology Assessment\textsuperscript{2}

• There do exist a number of international guidelines laying down the frameworks and norms for conducting ‘Economic Evaluations’, but most of these are developed keeping pharmaceuticals in mind\textsuperscript{5}

\textsuperscript{2}Health technology assessment of medical devices. WHO Medical device technical series, June 2011
\textsuperscript{5}Tarn TY, Smith MD. Pharmacoeconomic guidelines around the world. ISPOR Connections 2004;10:5–12.
4. Specificity of Economic Evaluations for Medical devices

Generalizing outcomes - Class effects
Medical devices belonging to a specific class, unlike drugs may have differing properties, such as the make, materials, which may have an effect on the outcomes.

Learning curve
The "clinical effectiveness" of a medical device is dependent not just on the efficacy of the device itself, but also on the adeptness and expertise of the surgeon using it.

Blinding is a challenge
It is not always possible to blind patients when conducting a study involving Medical devices.

Incremental Innovation
Medical devices undergo periodic and incremental improvements over time, since inception, thereby making it challenging to achieve a "steady state".

5. Specificity of Economic Evaluations for Medical devices

IP in medical devices
Unlike drugs, IP in medical devices being not as stringent, me-too products are easily available in the market. These products are available at much lower prices than the original and do not necessarily face stringent evidence requirements.

Isolated vs Systemic economic impact
Economic impact of medical devices need to be viewed not just from an immediate cost benefit standpoint, but more holistically - from a systemic, societal perspective.

Distorted Input costs
With the introduction of newer Medical devices older technologies may become redundant and experience price-cuts. Costs of such obsolete technologies are frequently used as comparators when conducting economic evaluations.

6. Economic evaluation of a DES vs BMS

- This was rescinded not on the basis of safety and efficacy considerations for a DES vs BMS, but on the basis of ‘Cost-effectiveness’ alone.

- An ICER for DES vs BMS,

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\frac{(\text{Costs of DES} - \text{Costs of BMS})}{(\text{Outcomes with DES} - \text{Outcomes with BMS})}
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- In an ICER/ QALY based approach, only outcome looked at is the ‘days without angina’

- What is the effect of reduced mortality or reduced MI rates on the ICER?
  - Mortality rates associated with a DES are lower in comparison to a BMS, and one year of life saved is almost equivalent to 7-10 times the QALY benefit of one revascularization avoided, and can significantly impact the ICER if included.

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Fig. 1: TIMELINE & PRICE EVOLUTION OF UK DES MARKET

8. Griffin A et al, Do HTA requirements and procurement incentives in medical devices need re-aligning? iSPOR, June 2012
7. Economic evaluation of a DES vs BMS

$\text{(Costs of DES - Costs of BMS)}$

$\text{(Outcomes with DES - Outcomes with BMS)}$

• Not just the costs of the actual devices, but downstream Cost implications need to be considered (no. of re-interventions avoided)

• Following the final recommendation, if even 20% of patients were offered a CABG in place of a PCI, would result in cost escalations for the NHS amounting to 54.7 million GBP per annum, which could be easily offset the incremental cost associated with a DES - Additional cost to the NHS
8. Conclusions

• What people desire is ‘Health’; ‘Health technology’ is only a means to achieving that.

• HTA is an able tool which if used in the right way can promote innovation, and foster progressive healthcare delivery, but
  – The evaluation needs to be performed within a specific context- HC system, industry specific, keeping the policy question in mind
  – And only when HTA evaluations are performed pervasively-
    • The benefits offered by a technology are viewed holistically, and
    • Cost implications assessed by considering the ‘net budgetary impact’ on overall HC delivery.

• Will it be an enabler for policy makers to make ‘well- informed decisions’

10. Shavit O. Utilization of health technologies – do not look where there is a light; shine your light where there is a need to look!
THANK YOU