Challenges in Assessing the Economic Value of Devices

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Outline of Presentation
• Some background
• Economic evaluation of health technologies
• Additional challenges posed by devices
• Ways forward

Some Background
• The economic value of devices can be established using ‘macro’ and ‘micro’ analyses
• At the micro level, the established approach is to conduct an economic evaluation of alternative treatments or strategies
• In principle, the same methods of economic evaluation should apply to all health technologies
• Many of the national guidelines for conducting studies have (implicitly) applied more to drugs than devices

Are Devices Different?
• Point/counterpoint articles in Value in Health (in press)
  Drummond, Griffin and Tarricone – Economic evaluation for devices and drugs: same or different?
  Taylor and Iglesias – Assessing the clinical and cost-effectiveness of medical devices: are they that different?

Additional Challenges Posed by Devices
• Some devices are diagnostic
• Product modifications can occur
• Learning curve in the use of devices
• Economic value can depend on organisational response
• Relative lack of comparative clinical studies
• Prices can change over time

Product Modifications Can Occur
• Unlike drugs, devices are frequently modified once on the market
• One of the consequences of product modifications is that it can be difficult to accumulate clinical evidence on the performance of a given device
**Example**

**Stapled Haemorrhoidectomy**

In a comparison of stapled haemorrhoidectomy with standard surgery, Burch *et al* (2008) found that:
- some of the staple guns used were adaptations of those used for other procedures
- the first circular gun had been modified in 2004
- there were very few clinical studies of the modified gun

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**Learning Curve in the Use of Devices**

- The value of a device is sometimes dependent on the skill of the user (eg surgeon)
- Several studies have shown that performance of users improves over time
- It would therefore be important to assess the outcomes once an average performance level has been reached

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**Example**

**Laparoscopic-assisted Surgery in Patients with Colorectal Cancer**

In the MRC – CLASICC trial comparing conventional with laparoscopic-assisted surgery the rate of 'conversions' to standard surgery varied by year:
- 38% in Year 1
- 16% in Year 6

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**Economic Value Can Depend on Organisational Response**

- In order to obtain the full value from devices, training may be required
- Sometimes the value of a device can depend on the particular organisational context

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**Example**

**Stapled Haemorrhoidectomy**

In their evaluation for NICE, Burch *et al* concluded that the cost-effectiveness of the staple gun would depend on the local potential to switch more patients to day-case surgery

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**Relative Lack of Comparative Clinical Studies**

- Unlike drugs, it is not necessary to undertake studies to demonstrate the efficacy of every ‘follow-on’ product
- This leads to an increased tendency to consider alternative products to be equivalent, whereas in fact there may be important differences between them
Example

Suburethral Slings and Related Technologies for Stress Urinary Incontinence
In a Technology Appraisal (56), NICE examined the cost-effectiveness of one particular product. However, in subsequent NICE Clinical Guidelines (40,44), several products and technologies were not differentiated in terms of efficacy and other characteristics.

Prices Can Change Over Time

• In the case of drugs, prices do not often change until the product loses patent protection
• Because of the way devices are purchased, prices are much less stable through time, or from location to location

Example

Drug–Eluting Stents
When NICE first considered drug-eluting stents, (TA71) it concluded that they were cost-effective as compared with bare metal stents. However, when this issue was revisited 4 years later, the change in the price differential was one reason why NICE concluded (in its Appraisal Consultation Document) that drug-eluting stents were no longer cost-effective.

Ways Forward

• Solutions to some of these challenges will require careful thought
• However, we might consider:
  - developing new methods to evaluate diagnostic technologies;
  - discuss the most appropriate time (in device development) to undertake evaluations;
  - develop appropriate incentives for companies to undertake more clinical studies;
  - discuss the organisational context when reporting economic evaluations of devices;
  - report a range of pricing scenarios, or build interactive models, where different prices can be entered.

Differences among reimbursement schemes for medical devices in Europe

ISPOR 11th Annual European Congress, Athens
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Effects of reimbursement

• Reimbursement might influence the providers’ use of medical devices
  ⇒ Influence on the demand
• Reimbursement tariffs set a framework for the prices that can be paid by the providers of health services
  ⇒ Influence on the prices
  ⇒ Influence on future revenues of manufacturers
  ⇒ Influence on the incentives to develop new devices
Reimbursement landscape in Europe

<table>
<thead>
<tr>
<th>Category of medical devices</th>
<th>Common reimbursement schemes</th>
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<tbody>
<tr>
<td>Cat I - Medical aids:</td>
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<tr>
<td>e.g. Incontinence pads</td>
<td>For outpatient care:</td>
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<tr>
<td>For inpatient care:</td>
<td>Reimbursement limits</td>
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<tr>
<td>Cat II – Implants and artificial bodyparts:</td>
<td>Included in case fees</td>
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<tr>
<td>e.g. Coronary Stents</td>
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<tr>
<td>Cat III - Technical equipment for professionals</td>
<td>Included in reimbursement of services (e.g. case fees)</td>
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<td></td>
<td>Investment for long-life equipment financed from other public sources</td>
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Reimbursement limits (I)
The example: Incontinence pads

- German reference prices for certain categories of medical aids
  - Products are grouped in homogeneous classes, for each group, reference prices are set
  - Any difference between the reference price and the actual price has to be paid by the patients
  - Only patients willing and being able to pay the difference between the reference price and the actual price may decide for products with a price higher than the reference price
  - Manufacturers have to convince the patients that their product is worth a certain additional payment

Reimbursement limits (II)
The example: Incontinence pads

- Further measures for medical aids:
  - Additional limits for volume – France, Italy, Poland
    - Limits the market size, might induce undersupply
  - Contracts for procurement – UK, Italy, Germany
    - Price competition, less choice for patients
    - Less incentives for innovation

Design of case-fees (I)
The example: Incontinence pads

- The design of case-fees
  - Different DRG systems in certain countries
    - Big variety of regulations, different supply of the patients within the countries
  - Different intervals of updating tariffs and catalogues
    - Differences in uptaking innovations in reimbursement schemes
  - Different sources for the calculation of tariffs
    - Suitability of DRG tariffs to reimburse adequately
  - Different degrees of detail
    - Influences the suitability of reimbursement for certain groups of patients

Case-fees and medical devices
The example: Coronary Stents

Different incorporation of medical devices
- The payment for the medical device is arranged apart from the case-fee
  - France:
    - DRG only covers the treatment itself
    - Coronary stents are reimbursed separately
    - For the coronary stent, maximum reimbursement from public sources exists
    - If the actual price for the device is cheaper, the hospital and the Social Health Insurance share the surplus
  - Incentives for the hospitals to achieve low prices from the manufacturers

Other regulations:
- General DRGs not relating to a particular type of device
  - No economical incentives to use more expensive stents
- For certain medical devices there is an additional payment
  - Additional payment for drug-eluting-stents (Germany, Italy)
  - Higher incentives to use these types of stents
Case-fees and the uptake of innovations

• Even regularly revised systems create a time lag for the uptake of new treatment measures
  – D: The DRG version of 2009 is the result from data of 2007
  – UK: The HRG4 system is the result of data from 2006/2007
• This implies that innovative medical devices that create higher (short term) costs are not reimbursed adequately
  ⇒ This creates an economical disincentive to use these medical devices
  ⇒ There exist different measures to encourage the diffusion of these technologies

Encouraging the uptake of innovations

• The German „NUB“ surcharges
  – Hospitals may apply for the approval as a „NUB“ for innovative technologies
  – The German InEK is judging on the approval as a „NUB“
  – For the next DRG version, accepted NUBs are considered automatically to be integrated in the „regular catalogue“
  – If a technology is accepted, the hospital may negotiate additional payments with the sickness funds to cover the additional costs
  – An approval as an NUB does not guarantee these additional payments
• Similar reimbursement schemes exist in the UK and in some regions of Italy as well

Conclusion

• Various reimbursement schemes exist within Europe
• Even the same schemes (such as DRGs) vary largely between – and within - the different countries.
• Resulting economical incentives differ substantially
• Most reimbursement schemes seem to constrict the use of innovative technologies
• Programs for the uptake of innovations exist
• So far there are comparative no results for the effectiveness of these programs

Perspectives

Next steps in the analysis of the influence of reimbursement on the uptake and diffusion of medical devices:
- Correlation between reimbursement and the uptake of innovation (Bocconi)
- Judging on the practical relevance of surcharges for innovative medical devices (TU Berlin)

Agenda

• Background:
  – the relevance of procurement
  – main results of EHTI research on procurement
  – Health care purchasing consortia: the case of UK and Italy
• Purchasing consortia for medical devices: further analysis
  – Expected advantages
  – Are these advantages really gained?
• Conclusions: which generalisations can be drawn from the analysis?
• Future perspectives
Background: The relevance of procurement

Procurement plays a relevant role as:

- It shapes the relationship between manufacturers and providers
- It determines the kind of products being used/implanted and, therefore, the patient access to high quality technologies
- If properly regulated, it enables the diffusion of high costly innovative devices.

Background: EHTI research on procurement

**Dimensions of Analysis**

- What are the main characteristics of price regulation/setting/negotiations?
- At which level are prices set, regulated or negotiated?
- Is it possible for a manufacturer to get different prices/payments from different service providers and/or goods distributors?
- Which actors are involved in the establishment of prices?
- Is there central procurement?

Background: main results of EHTI research on procurement

- Policy regulations enforced by European countries:
  - Introduction of maximum tender prices: Italy for specific devices;
  - Volume caps: Italy for incontinence pads, France for stents
  - Reference prices: Spain and Germany for incontinence pads;
- Medical devices (and medical aids in particular) are usually treated as commodities;
- Characteristics of public procedures:
  - Focus on price;
  - Quality criteria do not really screen the offers;
  - Obsolescence of the catalogues of reimbursable devices affects the kind of products purchased by providers;

Background: main results of EHTI research on procurement

- Medical device purchasing is usually managed at local level
- However, evidence from the analysis shows:
  - Increasing trend towards the establishment of purchasing consortia at:
    - Regional/interprovincial level: ex. Italy and UK
    - Interregional level: ex. Germany

Health care purchasing consortia: the case of UK

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<td>- Pre-care South Central</td>
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<td>- Re: Source East Midlands</td>
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<tr>
<td>- NHS Yorkshire and the Health Commercial Procurement Collaborative</td>
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<td>- South West CPH</td>
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<td>- North West Collaborative Procurement Hub</td>
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<tr>
<td>- London CPH (London procurement programme)</td>
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<tr>
<td>- NHS Healthcare Purchasing Consortium - West Midlands and North Central London</td>
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<tr>
<td>- East of England NHS Collaborative Procurement Hub</td>
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Health care purchasing consortia: the case of Italy

- Puglia, Basilicata, Calabria
- Lombardia, Liguria, Umbria, Lazio, Marche, Campania, Sicilia, Sardegna

* Start up
• Established

Products: New, Start up Consortium, Established Consortium
Purchasing consortia for medical devices: further analysis

Given the evidence collected in the cross country comparative research on the relevance of purchasing consortia for medical devices, we investigated the phenomenon more in depth:

1. Which benefits do local service providers aim to pursue when promoting purchasing consortia for medical devices?
2. Are these advantages really gained?
3. Which generalisations can be drawn from the analysis?

Expected advantages

• First research question: Synthesis of the main advantages retrieved from the literature:

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Are these advantages really gained?

• Second research question: development of a multidimensional model and of a case study analysis

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Are these advantages really gained? (cont)

Case study approach:

2 Italian purchasing consortia of medical devices:
A: Top down binding consortium at regional level;
B: Bottom up voluntary consortium at interprovincial level.

Are these advantages really gained? Results: Economic Dimension

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Are these advantages really gained? Results: Economic Dimension (a)

A. Adjudication price

The analysis highlighted savings related to decreases in adjudication prices in both experiences.

**CASE A**: 225 tenders reported savings, with an average 4% reduction on the previous adjudication price*

- 2005 savings: 4,369,247.37
- 2006 savings: 1,430,216.05
- Total savings: 5,799,463.42

* Figures relate to the whole portfolio of purchases medical and non-medical appliances and phonosciences
Are these advantages really gained?

Results: Economic Dimension (b)

A. Adjudication price (cont)

Nevertheless:

- Savings are correlated to the degree of product standardizability:
  - **Case B**: 15% syringes, 8% sterilisations, 17% disinfectants
- Savings decrease over time

B. Administrative costs and general expenses

Savings achieved thanks to the decrease in the total number of tenders issued for the same product:

- **Case B**: 15% syringes, 8% sterilisations, 17% disinfectants
- Savings decrease over time

Are these advantages really gained?

Results: Organisational Dimension

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Are these advantages really gained?

Results: Organisational Dimension (a)

A. Staff reduction

- In binding consortia centralised procurement implied:
  - I. Creation of an independent body
  - II. Reduction in the number of employees in the single members’ purchasing departments

B. Staff specialisation

- In both cases economies of specialisation have been achieved in regards to:
  - I. Product criteria in the call for bidding
  - II. Post-tender management

Are these advantages really gained?

Results: Strategic Dimension

A. Product standardisation

- It represents one of the essential conditions for the success of the experiences
- It might be critical for MD in large binding consortia:
  - Difficulty to counterbalance homogeneity of purchases and single provider’s requirements:
  - Call for bidding: pure sum of lots or real value added?
- Resistances in purchasing medical devices that require a high degree of personalisation (e.g. mammary prosthesis)

B. Relationship with manufacturers

- Service providers’ contracting power generally increased
- Changes occurred in the supply market:
  - Bigger lots put pressure on local manufacturers

Are these advantages really gained?

Results: Strategic Dimension

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Conclusions: Which generalisations can be drawn from the analysis?

Lesson 1: ECONOMIC DIMENSION
- Savings are mainly achieved in the short run
- Decrease in purchasing price does not represent a sustainable competitive advantage

Lesson 2 and 3: ORGANISATIONAL DIMENSION
- Strategies for members’ staff reduction should be carefully considered and not be the exclusive aim of consortia
- Strengthen Technical Committees working on criteria for tenders (and including members’ representatives) in order to achieve:
  - Higher commitment and social acceptance
  - Higher specialisation and focus on quality criteria for devices (rather than price)

Lesson 4: STRATEGIC DIMENSION
- Products: not all MD are suitable to standardised purchases: need to carefully plan in advance the type of devices object of centralised strategies
- Supply market: need to enforce strategies to avoid negative repercussions on local SME;
- Need to ensure a certain degree of independence of the consortium from political cycles:

Consortia can achieve positive results only if their long term sustainability is guaranteed.

Future perspectives
The current analysis has investigated the implications of purchasing consortia for the public sector
- Which implications for the industry?
- Which impacts for the patients?

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