How should HTA methods be adapted to meet the rising expectations of decision makers for medical devices and diagnostics reimbursement?

Issue Panel – ISPOR 12th Annual European Congress
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10-11 am
Moderator

• Annie CHICOYE, expert to IMS Pricing and Market Access EU

Panelists

• Geoffroy WILSON, Reimbursement Leader, GE Healthcare, EMEA
• Adrian GRIFFIN, VP Strategic Affairs, LifeScan EMEA
• Pr Olivier GOEAU-BRISSONNIERE – Chairman of the Fédération des Spécialités Médicales, ex member of the medical devices HTA commission at the HAS
Medical devices and diagnostics: a wide range of health care products...

**Medical devices**
(directive 2007/47/EC)

« any instrument, apparatus, appliance, software, material or other article, *whether used alone or in combination*, including the software intended by its manufacturer to be used specifically for diagnostics and/or therapeutics purposes and necessary for its proper application, intended by the manufacturer to be used for human beings *for the purpose of diagnosis, prevention, monitoring, treatment or alleviating the disease* »

**In Vitro diagnostics**
(directive 98/79/EC)

“Any medical device which is a *reagent, reagent product*, calibrator, control material, kit, instrument, apparatus, equipment, or system, *whether used alone or in combination*, intended by the manufacturer to be used *in vitro* for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally *for the purpose of providing information*: concerning a physiological or pathological state, or — concerning a congenital abnormality, or — to determine the safety and compatibility with potential recipients, or — to monitor therapeutic measures”
ISPOR Initiatives for HTA / Medical Devices / Diagnostics

- Two issue panels were held in Dublin in 2007:
  - Are medical devices more challenging to evaluate than drugs?
  - Adherence to clinical guidelines: a key concept in clinical and economic models for diagnostics devices
  ➔ Two papers published in Value in Health
    « HTA community should reflect on whether the current assessment methods adequately take into account of the specific features of medical devices »

- A dedicated working group within the SIG HTA has been set up in 2009 with two objectives:
  - To deliver roadmaps information for devices and diagnostics
  - To identify the topics on which good research practices could be developed and discussed with decisions makers

- Over 70 ISPOR members joined from more than 20 countries with 35 active members
Issues for discussion

- Medical devices and diagnostics have various positions in the medical pathways
- They are generally not submitted to extensive clinical requirements for getting market approval
- Their characteristics differ significantly from drugs (life-cycle, intellectual property, etc.)
- The business model, the procurement processes and the pricing dynamics are specific

• How far should clinical evidence be generated for access to reimbursement?
• Should appropriate outcomes and methods be developed for assessing their value?
• Should be specific international guidelines for C/E analysis, Budget impact analysis be elaborated?

• How can a dialogue be developed with HTA bodies and decision makers?
• Are the business model and the pricing dynamics of the sector adapted to meet the growing decision-makers expectations?
“How should HTA methods be adapted to meet the rising expectations of decision makers for medical devices and diagnostics reimbursement”

October 27, 10:00 –

Geoff Wilson
Reimbursement Leader
GE Healthcare, EMEA
If a picture is worth a thousand words, how valuable is an image that saves your life?
## Background:

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
</tr>
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<tbody>
<tr>
<td>Nov. 2007</td>
<td>reviewed assessment methods for diagnostic technologies – decided new appraisal methods required</td>
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<tr>
<td>June 2008</td>
<td>Lord Dharzi report on the future of the NHS (to the PM) improvements recommended to the evaluation &amp; adoption processes for clinically and cost-effective innovative new medical technologies (&amp; medicines) …and promises that “for new medical technologies, the pathway by which they pass from development by the manufacturer into wider use within the NHS will be simplified”</td>
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<tr>
<td>Sept. 2009</td>
<td>NICE requested to coordinate the evaluation of innovative new medical devices &amp; diagnostic technologies</td>
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<tr>
<td>Nov. 2009</td>
<td>NICE plans to establish Medical Technologies Advisory Committee (MTAC) to evaluate medical devices with a “thin” evidence base + introduce a new assessment process for diagnostic products</td>
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“Effectiveness of a diagnostic technology is the extent to which it improves health outcomes”

NICE Proposed to follow Australian Medical Services Advisory Committee (MSAC)

- Clinical Presentation
- Preliminary Diagnosis
- Diagnostic Test
- Diagnosis
- Treatment
- Outcomes

Relative Accuracy

Treatment Decisions

Impact on treatment/patient management

Treatment Effectiveness

Impact on patient outcomes

Whole system costs & benefits

Care pathway

• altered treatment based on diagnostic result
• Staging of disease

Drug

Effectiveness of a diagnostic technology is the extent to which it improves health outcomes
Cost Effectiveness achieved by linking evidence

1. Target Population
   - Randomize
   - New Diagnostic Test
     - Result
     - Comparative Accuracy
   - Existing Diagnostic Test
     - Result
     - Comparative Effectiveness

2. Target Population
   - Randomized
   - New Treatment
     - Outcome
     - Comparative Effectiveness
   - Alternative Treatment
     - Outcome
     - Comparative Effectiveness
Example: Use of Positron Emission Tomography (PET) to diagnose liver metastases in patients with CRC

150-patient randomized study by Ruers et al., JOURNAL OF NUCLEAR MEDICINE • 50 (7) • July 2009
Reference: “Improved Selection of Patients for Hepatic Surgery of Colorectal Liver Metastases with 18F-FDG PET”

Primary outcome: futile surgery (i.e benign, inoperable, or disease-free >6mo)
Study duration: 5 years

Issue: cost effectiveness of PET+CT (versus CT alone) for selecting patients with operable liver metastases is affected by whether surgeons take notice of results
PET/CT to detect liver metastases

Courtesy of Hermes Medical Solutions, Skeppsbron, Stockholm
PET/CT Liver Metz study I – Comparative Effectiveness

**Outcome = futile surgery**

- 34 (45%)
- 21* (28%)
- 11 (15%)

*Surgery to resect liver metastases

- 38% reduction
- 67% reduction

- *PET results ignored in 10 patients*

Benign or unresectable metastases in 5 patients
PET Liver Metz study II - Economic Analysis (Alison Sweet et al, GE Healthcare)

75 patients → CT

75 patients → +PET

PET results ignored in 10 patients

34 futile surgeries + chemotherapy for unresectable liver mets

21 futile surgeries + chemotherapy for unresectable liver mets

Saving £22,000 - £80,000 (depending on duration of chemotherapy)

11 futile surgeries saving £27,000 - £110,000 (depending on duration of chemotherapy)

Cost/effectiveness of PET/CT affected by physician’s decision to follow results of diagnostic test information.
Issues for HTA of Devices & Diagnostic Procedures

- Necessary to evaluate the relative cost-effectiveness (v-f-m) of medical technologies
- Data driven and based on best available evidence
- Patient safety and improved patient outcomes paramount
- HTAs should assist the process of accelerating access to medical technologies to provide improved patient outcomes

**Intellectual Property**
- NCE is ‘unique’ & patent protected
- Diagnostics (& some devices?) are generally not, e.g. X-ray, CT, MRI

**Evidence Requirements**
- Comparative clinical data not required for registration (CE Mark)
- If multi-centre/multi country RCTs are not feasible in some cases – how do we agree on alternative levels of acceptable evidence?

**Timing**
- Development times for diagnostic & devices can be short e.g. 24 months
- ‘Learning curve effect’ for devices & diagnostics
- Most appropriate time to assess the comparative effectiveness of devices & diagnostics?

**Access to Reimbursement**
- Some reimbursement requires a “full HTA”
- Reimbursement for procedures can take 2-4 years excluding HTA
- Need for alternative arrangements, e.g. provisional reimbursement (based on initial HTA)? ‘Reimbursement with evidence development’, etc
Thank you!
“How should HTA methods be adapted to meet the rising expectations of decision makers for medical devices and diagnostics reimbursement”

Adrian Griffin
VP Strategic Affairs, LifeScan EMEA

Johnson & Johnson

Issue Panel: IP9 – 27th October 2009
Disclaimer

- Employed by Johnson & Johnson
- Member of NICE Technology Appraisal committee

The views / observations expressed here are my own, and not necessarily those of JnJ or NICE
Diagnostic not therapeutic

Timing of evidence generation

Incremental development

Learning curve / user ability

Service implications

Eagerness to ‘genericise’ recommendations

Faster evolution of market prices
## Reality of Thin Evidence Base

### Laparoscopic Surgery for Colorectal Cancer
  - ‘Open should be preferred surgery…’
  - LAP only in RCT
- **TA105 (2006)**
  - ‘Recommended as alternative to open…’

### Laparoscopic Hernia Repair
- **TA18 (2001)**
  - ‘Open should be preferred surgery…’
- **TA83 (2004)**
  - ‘Recommended as treatment option for…’

### Continuous Subcutaneous Insulin Infusion (Insulin Pumps)
- **TA57 (2003)**
  - ‘Yes where MDI ‘failed’
- **TA151 (2008)**
  - ‘Recommended as treatment option for…’
  - Paeds; uncontrolled adults
“For new clinical technologies, we will simplify the way in which they pass from development into wider use by creating a single evaluation pathway, and will develop ways to benchmark and monitor their successful uptake”

Lord Darzi, NHS Next Stage review Jun08
New Policy Focus with NICE
- Devices are different?

“NICE has also been asked to increase its evaluation of non-pharmaceutical technologies. Such technologies present particular challenges: due to **differences in the regulatory requirements** such technologies are **rarely supported by RCT-based evidence** of clinical utility; there is **rapid development** to products; and a case has been made to NICE that there is a **smaller exclusivity period** and **faster erosion of prices**.

NICE must be **careful to ensure that there are not unjustifiable inequities** between different industry sectors in the approach it takes.”
THERMACHOICE
4 countries – 4 decisions

- **1997: Switzerland**
  - ELK: clinically and economically effective
  - Reimbursement for in- and out-patients

- **2000: Germany**
  - Joint Federal Committee: neither clinically necessary nor cost effective
  - Still no reimbursement for out-patients

- **2002: France**
  - AFSSAPS/CEPP und ANAES: clinical and cost effectiveness accepted
  - Reimbursement agreed 2008

- **2003: UK**
  - NICE: clinical and cost effectiveness accepted
  - Recommendation for inclusion into NHS
Decline in NHS Hysterectomy Rates & Inc. in IUD, Endometrial Resec. and 2nd Gen Ablation Techs.

The decline in hysterectomy rates seen in the UK is not mirrored across Europe.

Hysterectomy (all indications) (Q07 & Q08)
Endoscopic resection of lesion of uterus (Q17.1)
Introduction of intrauterine contraceptive device (Q12.1)
Endoscopic destruction of lesion of uterus (Q17.4)
Other vaginal operations on uterus (Includes TBA) (Q16.8)

NHS England Hospital Episode Statistics data

The decline in hysterectomy rates seen in the UK is not mirrored across Europe.
Devices with a Service Impact through Policy

- Intra-Operative BLN test Kit
  - A rapid test to identify the genes indicative of metastatic cancer in the sentinel lymph nodes of breast cancer patients
- Can avoid ~90% of follow up procedures
  - Requires agreement between commissioner-provider to fund test
What Evidence is Required?

Initial Mastectomy Surgery plus:

- Traditional Histology
  - Primary Surgery
    - Path. Lab (H&E)
      - Follow-up Surgery
        - Block dissection 29%
      - GeneSearch™
        - IOP
          - Block dissection 29%
    - +ve
    - -ve
  - -ve
  - +ve

- GeneSearch™
  - +ve
  - -ve
Evolution of Market Prices
Procurement is Effective

Application of the Experience Curve to price trends in medical devices

Figure 4: Two-phase Experience Curve for one of the DES purchased by the central supplies agency regional supplies service between 2003 and 2007, showing an initial slope of 99 per cent followed by a slope of 80 per cent. The break points in this curve coincide with specific procurement activity
Considerations for HTA of Medical Devices

- Fit for the intended purpose
- Importance of System Wide benefits
- Flexibility of approach
- Dealing with the class effect

- Guide rationale decision making – graded recommendations?
- Impact on hospitals, access, waiting times
- Guided by strength of evidence base; recommendation to fit
- Care to ensure correct incentives for evidence generation by both 1st in class and “fast followers”