HTA for Medical Devices: National Prioritisation Processes

WHO Medical Devices Forum,
Bangkok, September 2010

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Director, NICE International
A medical device is:

any instrument, apparatus, appliance, software, material or other article, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes, intended by the manufacturer to be used for human beings. Devices are to be used for:

- Diagnosis, prevention, monitoring, treatment, alleviation of disease.
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap.
- Investigation, replacement or modification of the anatomy or of a physiological process.
- Control of conception and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

The regulatory pathway

• EU – National Competent Authorities
  – Essential requirements ➔ EU Directives ➔ National law
  – Member states’ responsibility: National Competent Authorities (e.g. MHRA in UK) and Notified Bodies (audit and certification)
  – CE mark: Conformité Européenne; European passport

• USA – Food and Drug Administration
  – Pre Market Approval application (usually non-randomised trials; ~1% of total applications)
  – Pre Market Notification application: 510(k): requirement: "substantially equivalent" to a device that's already on the market – under review
# Drugs vs. devices: the arguments

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<tr>
<th>Different…</th>
<th>…or not that different…</th>
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<td><strong>learning curve effect</strong>&lt;br&gt;Device impact depends on user training and experience, care delivery setting…that can vary and are hard to evaluate.</td>
<td>Drug impact also depends on exogenous factors such as comorbidities, drug-to-drug interactions, adherence, genetics…rarely assessed in regulatory RCTs</td>
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<td><strong>incremental innovation</strong>&lt;br&gt;Devices can have multiple indications and rely on incremental product modifications/improvements.</td>
<td>So can drugs. Indication creep complicates things – e.g. cancer and paediatric drugs regularly used off-license.</td>
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<td><strong>comparative effectiveness research</strong>&lt;br&gt;Devices cannot be evaluated with RCTs – hard to blind and randomise. Early evaluation not possible</td>
<td>Several good examples of RCTs for devices/procedures exist. Non-RCT data often used for drugs.&lt;br&gt;“It is always too early until it is too late!”</td>
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Conclusions
Arthroscopic surgery for osteoarthritis of the knee provides no additional benefit to optimized physical and medical therapy.


Conclusions
Laparoscopic-assisted surgery for cancer of the colon is as effective as open surgery in the short term and is likely to produce similar long-term outcomes.

NICE recommendation for reimbursement in NHS and is likely to produce similar long-term outcomes.
US Congressmen urged the FDA “to avoid unnecessary regulatory barriers that will needlessly lengthen the review and approval process,’ especially for small companies trying to bring new technologies to market.”
Challenges!

• Current licensing process focus on demonstrating conformity and assumption of class effect:
  – incentivises fast followers (minimal R&D costs)
  – stifles incremental innovation
  – may compromise safety
  – may lead to inappropriate diffusion and waste of resources
  – minimises the need for comparative evidence
  – makes it harder for clinicians, payers and patients to make informed decisions!
Should we give up?

• “Based on still limited evidence, interim funding of a new product...would ensure that the legitimate need of patients to have access to the most promising innovative technology is satisfied. Simultaneously, effectiveness data for a subsequent assessment could be collected.”

EUCOMED industry position statement on HTA for devices, 2002
Making research work…

• Licensing trials for carefully selected technologies and
• To account for learning curve, incremental innovation and CER challenges:
  a) Pragmatic research in real world settings – use intrinsic health system variation for cluster randomisation
  b) Adaptive designs, modelling and statistical techniques (time series, latent curve…) and more methods research
  c) Meaningful post-marketing research and surveillance and appropriate use of observational data, registers, IT systems
As the use of stents has grown, the drug-coated stent has quickly come to dominate the field. ~90%

U.S. stent sales

1.6 million
1.4
1.2
1.0
0.8
0.6
0.4
0.2
0.0

'BARE METAL'

'DRUG COATED'

'Dr Les Levine, reproduced with permission'

Doctors Rethink Widespread Use of Heart Stents
Effectiveness and Safety of Drug-Eluting Stents in Ontario

Impact of DES Findings

- Controlled diffusion of technology ($15 to $38 million)
- Potential 2007/08 savings (decreased expenditures) from using HTA findings in making policy decision ~ $20 million
Ontario HTA programme for non-drug technologies: a success story!

2007
- Anal Dysplasia Screening
- Coronary Artery Screening
- Interim report on Integrated
  HTPA: Heart Failure
- Interim report on Integrated
  HTPA: Diabetes
- Clopidogrel (Flavix®)
- Myozyme
- Screening Mammography for
  Women Aged 40 to 48 Years
  at Average Risk for Breast
  Cancer
- Elective Endovascular
  Repair Compared To Open
  Surgical Repair Of Abdominal
  Aortic Aneurysms

2006
- Functional Brain Imaging
- Optimum Methadone
  Compliance Testing
- Utilization of DKA Bone
  Mineral Densitometry in
  Ontario
- Nanotechnology
- In Vitro Fertilization and
  Multiple Pregnancies
- Energy Delivery Systems for
  Treatment of Benign Prostatic
  Hyperplasia
- Gastric Electrical Stimulation
- Routine Eye Exams
- Negative Pressure Wound
  Therapy - Updated
- Computed Tomography
  Radiation Safety Issues in
  Ontario
- Polysomnography in
  Patients with Obstructive
  Sleep Apnea
- Intravascular Ultrasound to
  Guide Percutaneous Coronary
  Interventions
- Portable Bladder Ultrasound
  Artificial Disc Replacement for
  Lumbar and Cervical
- Degenerative Disc Disease -
  Updated
- Magnetic Resonance
  Imaging (MRI) Environment
  Safety in Ontario Hydrophilic
  Catheters
- Advanced Electrophysiologic
  Mapping Systems
- Ablation for Atrial Fibrillation
- Extracorporeal
  Photopheresis (ECP)
- Enhanced External
  Counterpulsation (EECP) -
  Updated
- Metal-on-Metal Total Hip
  Resurfacing
- Arthroplasty Midurethral
  Slings for Women with Stress
  Urinary Incontinence -
  Updated
- Ultrasound Screening for
  Abdominal Aortic Aneurysm
- Coll Embolization for
  Intracranial Aneurysms -
  Updated

2005
- Automated External
  Defibrillators
- Interim Report on Drug
  Eluting Stents
- Endovascular Repair of
  Descending Thoracic Aortic
  Aneurysm
- Air Cleaning Technologies
  Positron Emission
  Tomography for the
  Assessment of Myocardial
  Viability
- Technologies for
  Ostearthrits of the Knee
- Implantable Cardioverter
  Defibrillators (ICD)
- Bi-ventricular Pacing (Cardiac
  Resynchronization Therapy)
  (Updated)
- Arthroscopic Lavage and
  Debridement
- Hyperbaric Oxygen Therapy
  for Non-Healing Ulcers in
  Diabetes Mellitus
- Interim Report on
  Endovascular Repair of
  Abdominal Aortic Aneurysms
- Intra-Articular
  Viscosupplementation With
  Hylan G-F 20 To Treat
  Osteoarthrits of the Knee
- Total Knee Replacement
  Physiotherapy Rehabilitation
  After Total Knee or Hip
  Replacement Intrathecal
  Baclofen Pump for Spasticity
- Osteogenic Protein-1 for
  Long Bone Nonunion
- Multi-Detector Computed
  Tomography Angiography for
  Coronary Artery Disease
- Spinal Cord Stimulation for
  Neuropathic Pain
- Sacral Nerve Stimulation For
  Urinary Urge Incontinence,
  Urgency-Frequency, Urinary
  Retention, and Fecal
  Incontinence
- Deep Brain Stimulation in
  Parkinson’s Disease and
  Other Movement Disorders
- Bariatric Surgery

2004
- Vacuum Assisted Closure for
  Wounds (Updated: please see
  July 2006 Listing)
- Balloon Kyphoplasty
- Thermal Balloon Endometrial
  Ablation for Dysfunctional
  Uterine Bleeding (TBEA)
- Primary Angioplasty for the
  Treatment of Acute ST-
  Segment Elevated Myocardial
  Infarction
- Bispectral Index Monitor
- Radio Frequency Ablation
  for Primary Liver Cancer
- Repetitive Transcranial
  Magnetic Stimulation for the
  Treatment of Major
  Depressive Disorder
- Coil Embolization for
  Intracranial Aneurysms
  (Updated: please see
  January 2006 Listing)
- Pyrocyanic Finger Joint
  Implant
- Video Laryngoscopy for
  Tracheal Intubation
- Bone Morphogenetic
  Proteins and Spinal Surgery
  for Degenerative Disc Disease
- Artificial Discs: Applications
  to Cervical and Lumbar Spinal
  Surgery for Degenerative Disc
  Disease (Updated: please see
  April 2006 Listing)
- Left Ventricular Assist
  Devices Bi-ventricular
  Pacemakers
  (Updated: please see
  September 2006 Listing)
CT Angiography in the US: when things go wrong…

• Medicare provides coverage of CCTA regionally (2005)
• AHRQ-commissioned report from Duke University (2006)
  – Limited evidence of clinical utility in any population
  – Suggest RCTs, natural experiments or models
• Medicare Coverage Advisory Committee mtg (2006)
  – “Uncertain confidence about existing evidence”
• Medicare proposes Coverage with Evidence Development, nationally (2007)
• Draft protocol developed through multi-stakeholder process by CMTP, non-profit institute
Industry, patients and clinicians lobbied…

“…proponents of cardiac CT argued, among other things, that the CMS had never before insisted on evidence of benefit, and it would be unfair to discriminate against this particular technology by imposing such a requirement.”

Dhruva et al., NEJM, 360:2699-2701, June 2009
And Medicare gave way…

• Medicare final decision (2008)
• “There are a lot of technologies…that have not been unequivocally shown to improve health outcomes in a definitive manner,” Medicare’s chief medical officer, explained when announcing that the agency would keep covering the tests.
• In other words, the lack of evidence that the CT scans provide measurable medical benefit would not stop Medicare from paying for them.

Can Americans continue ignoring costs?

**A Big Force in Washington**
Companies that collect millions of dollars from Medicare also spend millions lobbying Congress.

<table>
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<tr>
<th>Company</th>
<th>Charges allowed by Medicare in 2006, in millions</th>
<th>Federal lobbying expenditures since 2004, in millions</th>
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<tr>
<td>Lincare</td>
<td>$789</td>
<td>$1.5</td>
</tr>
<tr>
<td>Apria Healthcare</td>
<td>455</td>
<td>1.5</td>
</tr>
<tr>
<td>Kinetic Concepts</td>
<td>159</td>
<td>0.96</td>
</tr>
<tr>
<td>American HomePatient</td>
<td>107</td>
<td>1.0</td>
</tr>
<tr>
<td>Pacific Pulmonary Services</td>
<td>101</td>
<td>0.84</td>
</tr>
<tr>
<td>Hoveround</td>
<td>85</td>
<td>0.94</td>
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Sources: HME News; OpenSecrets.org; Securities and Exchange Commission filings; federal filings
NICE’s approach: multiple and inter-related programmes

• Safety and Efficacy of Interventional Procedures
• Best Practice Clinical Guidelines incorporating the use of devices and diagnostics
• Comparative Clinical and Cost-Effectiveness of individual or class of devices and diagnostics based on price set by manufacturers
• New Medical Technologies Evaluation Pathway
NICE Interventional Procedures

- Lack of licensing process for new interventional procedures
- Assessment of efficacy and safety
- Over 200 interventions including devices and surgical and diagnostic instruments evaluated
- National guidance adopted by private insurers in the UK
- We can recommend:
  - Use in clinical studies only
  - Special measures for gaining patient consent
  - Safe for general use
Laser surgery for refractive errors

Current evidence suggests that photorefractive (laser) surgery for the correction of refractive errors is safe and efficacious for use in appropriately selected patients.

Photodynamic endometrial ablation

Current evidence does not appear adequate to support the use of this procedure outside formal research. It is suitable for use only within good quality research studies approved by a research ethics committee and with explicit patient consent.
NICE Evaluation Pathway Programme:

• Focuses specifically on the evaluation of innovative medical technologies including devices and diagnostics with CE mark.

• Designed to help the NHS adopt clinically effective and resource-releasing medical devices and diagnostics more rapidly and consistently.

• Independent advisory committee (MTAC) comprising clinicians, policy makers, lay people, industry, economists…

‘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, Quality Care for All, 2008
Aims of the programme

• Identify promising potentially beneficial and/or resource releasing technologies
• Help generate data/evidence on their effectiveness
• Assess their overall value, including downstream impact on care pathway (e.g. reduced LOS)
• Encourage timely adoption by the NHS
• Engage with manufacturers productively
• Support disinvestment from wasteful technologies
• Inform procurement
Costs modelled included the cost of the PCI, of clopidogrel, the differential costs of £300 of the SeQuent vs. the DES and the cost of managing downstream complications such as revascularisation.

The cost models used indicated that the SeQuent Please balloon catheter was associated with a cost saving of £630 per patient compared with standard therapy.

NICE recommends (provisionally) the use of SeQuent Please for patients with in-stent restenosis following BMS (July 2010)
Applying the same core principles

- **Independence**: independent advisory committee and assessment by academic group
- **Scientific basis**: scientific evidence and evaluation
- **Transparency**: evidence and process published online; open committee meetings
- **Inclusiveness**: Broad stakeholder consultation incl. patients, industry and professionals
Questions…

• How can we incentivise evidence generation
  – Licensing requirements: is conformity enough all of the time?
  – Flexible Pricing and Risk Sharing
  – Coverage with Evidence Development and Only In Research; functioning links with public funders of research
  – Early engagement with industry through scientific advice
  – Clear, consultative and independent HTA processes

• Cross national (e.g. EU) standardisation/harmonisation: is it feasible, is it desirable?

• How can we design holistic clinical pathway programmes to include devices as part of broader disease management plans and clinical guidelines
Africa’s growing market

• “The bulk of sub-Saharan Africa's hospital medical equipment is third world in standard.

• The hospital medical equipment market in sub-Saharan Africa will be spurred largely by the demand for patient monitoring and diagnostic equipment [due to the HIV/AIDS epidemic], but…

• Hospitals lack the necessary expertise to operate and maintain equipment and therefore limit such purchases…The lack of technical support from suppliers leads to chronic equipment failures.”

Frost & Sullivan, 2008, First World or Third World? End-user Perceptions of Hospital Medical Equipment in Key sub-Saharan African Countries
Devices in emerging markets

CT Scan Makers Gun for China

By VANESSA FUHRMANS And PAUL GLADER

The world’s largest CT-scanner makers, including General Electric Co., Philips Electronics, are zooming in on China.
A changing world makes HTA more important.

Doctors barred from using new cancer treatment equipment
NHS bosses argue that Mount Vernon hospital's £3m Cyberknife technology may not work

Denis Campbell, Health Correspondent
The Observer, Sunday 2 May 2010
Article history

In Strategy Shift, G.E. Products

By STEVE LOHR
Published: May 7, 2009

General Electric is shifting the strategy of reaching health care technology and technology reach with more lower-cost products.

A Cyberknife which is being used in an American hospital. Photograph: AP
“Technology is anything that doesn’t work yet”

Danny Hillis, American Inventor and Entrepreneur
Selected papers

- Drummond et al., Economic evaluation for devices and drugs – same or different? Value in Health 12(4):402-4, 2009
- Taylor et al., Assessing the clinical and cost-effectiveness of medical devices and drugs: are they that different? Value in Health 12(4): 404-6, 2009
- Siebert et al. (on behalf of Eucomed), HTA for medical devices in Europe: What must be considered, Intl J Tech Assess Health Care 18(3):733-740, 2002
- Eucomed HTA position paper, 2008
- Eucomed, Competitiveness and innovativeness of the European medical technology industry, A survey of members, 2007
- www.nice.org.uk
Thank you!

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