Decision Making Under Uncertainty: Coverage with Evidence Development in the Context of Medical Devices

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Background

- Making coverage decisions on promising technologies is an enduring challenge for payers.
- Often the available evidence for new technologies is suboptimal or inconclusive at the time of coverage determination.
- CED provides provisional coverage for a promising intervention, on the condition that additional data are generated to inform a final coverage/payment decision.
- To date, CED for devices has been conducted on a limited basis.
Study Aims

• Explore CED policies in different countries and their application to medical devices.
• Understand the key challenges for CED policies in general and for medical devices in particular.
• Identify strategies to improve current use of CED.
Study Overview

- **Approach:**
  - Literature review on CED policies in general and in select countries: Canada, France, Germany, the Netherlands, UK, and US. *Switzerland to be added.*
  - Semi-structured interviews with payers/HTA bodies, industry representatives, and academics/policy analysts.

- **Key issues to explore include:**
  - Use of CED policies in various jurisdictions.
  - Cases where CED has been applied to devices and the details of such arrangements.
  - Key issues/challenges in applying CED to medical devices.
  - Opportunities for improvement.
Results Overview

- 50 articles were retrieved and reviewed.
- 25 experts were invited to participate in the interviews; 20 agreed (80% response rate).
  - 7 policy makers
  - 5 industry representatives
  - 8 academics/policy analysts
Divergent National Approaches to CED

- Established (US, UK) versus new/under development (Germany, Netherlands).
- Generally similar aims, but those with cultural traditions supporting innovation/industry (France, Germany) consider CED as a way to speed patient access and support industry.
- Main differences:
  - Eligibility criteria
  - Governance and funding of CED studies
  - Stakeholder groups involved
  - Evidence/methods preferences
## National Approaches to CED: Examples of Canada, US, UK

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<th>Country</th>
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<th>Aims</th>
<th>Year Established</th>
<th>Technologies Included</th>
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| Canada  | Conditionally-funded Field Evaluations | Assess real world performance; address outstanding uncertainty about benefits/costs; improve coverage decision making. | 2003 | Non-drug technologies (devices and procedures) | OHTAC, PATH, THETA, ICES, Ontario Health Ministry | OHTAC funds the evaluations; Ministry funds device (or procedure) if not yet insured. | Over 40 studies to date. Examples include:  
  - PET  
  - DES  
  - CT angiography  
  - Sleep apnea device |
| US      | CED             | Allow greater flexibility in coverage determinations; link coverage to efforts to generate evidence needed to gain greater certainty on the benefits and harms of particular technologies. | 2006 | Procedures, devices, and drugs. | CMS | No standard or requirements for funding. Public agencies, such as NIH or AHRQ may fund studies, as well as manufacturers, medical associations, or academic research groups. | Over 15 studies to date. Examples include:  
  - PET  
  - ICDs  
  - Lung Volume Reduction Surgery  
  - Angioplasty and stenting  
  - Transcutaneous Electrical Nerve Stimulation |
| UK      | Only in Research (with limited use of Approval with Research) | Provide coverage to promising interventions not yet supported by sufficiently robust evidence, while additional data is collected. | 1999 | Procedures, devices, and drugs. | NICE, NIHR | No standard or requirements for funding. NIHR or manufacturer may fund study. | Over 25 studies to date. Examples include:  
  - PET  
  - ICDs  
  - Metal-on-metal hip implants  
  - Drainage, irrigation and fibrinolytic therapy (DIFT)  
  - Laparoscopic surgery |
CED Device Case Studies

- Drug-eluting stents (Canada)
- Intracranial stenting (US)
- ICDs (US)
- TAVI (US)
- Laparoscopic surgery (UK)

- CMS issued CED policy for ICDs in 2005.
- Observational registry, operated by the American College of Cardiology (ACC).
- Aims of registry:
  - Ensure patients met clinical criteria for appropriate use of ICD.
  - Develop longitudinal outcome data to inform future clinical and coverage decisions.
- Range of stakeholders collaborated to fund registry.
- In the end, original registry did not address CMS’s questions – use of ICD for life-threatening heart rhythms and LT survival.
- CMS, ACC, and other stakeholder later designed research effort to collect longitudinal firing and survival data over 5 yr period.
- AHRQ provided $3.5 million in funding.
- Three and half year study will follow 3,500 patients.
Perceived Benefits of CED

- Potential to enhance coverage decisions and strengthen existing evidence bases on the benefits and costs of new technologies.
- Enable payers to participate in the research process.
- Allow hospitals and clinicians to monitor more closely procedures being performed and manage costs until benefit is substantiated.
- Encourage industry to generate the data needed to support the value claims of their innovations.
- Allow earlier access for patients to potentially valuable treatments than they might otherwise be granted.
Key Challenge: Establishing Clear Frameworks CED

- Many informants considered current process “unpredictable”, “case-by-case”, and “reactive”.
- Considered particularly important given growing number of devices on the market.
  - CED not the sole tool for addressing issues of uncertainty.
- Informants generally considered high-risk devices most appropriate for CED.
Key Challenge: Establishing Clear Frameworks for CED

- Insufficient clarity and transparency of process.
- Must consider feasibility of collecting necessary data and whether it can be considered in decision making in a timely way.
- Industry, in particular, highlighted the need of greater predictability.
- A lack of clear roles/incentives for different stakeholder also seen as problematic.
Key Challenge: Identifying & Applying Appropriate Study Methods

- Almost all informants thought devices introduce unique challenges to this process.
- Accounting for the diversity of devices in designing studies – introduces challenges for pre-determining standard or requirements for studies.
- However, some differences in opinion regarding the challenges in conducting RCTs for devices.
Key Challenge: Funding CED Studies

- Considered to be one of the most important challenges.
- Most account for the range of costs involved – direct and indirect costs.
- Study costs may pose problems for device companies, many of which are SMEs.
- Many payers/decision makers do not have designated research budgets for CED studies.
- Funding issues may hinder the quantity and quality of CED studies.
Key Challenge: Incentivizing Research

- Problems getting commitment from physicians and manufacturers to collect necessary data.
- Lack of incentives for CED evidence generation relates to:
  - Issues associated with the CED approach and process itself.
  - Inherent characteristics of a given health care system.
  - Particular characteristics of the device industry.
Key Challenge: Applying New Evidence to Coverage Policy

- Time frame of CED studies considered a hindrance.
- Policy impact of CED has been somewhat limited, as study timelines are often extended or studies do not start in the first instance.
- Data collected may not be relevant or conclusive in the end...or, it may be negative, supporting modified coverage, which can introduce political issues.
Suggested Areas for Improvement

- Develop clear and predictable processes for CED policies.
- Greater collaboration (amongst HTA bodies/payers) with different stakeholder groups:
- Link CED with other evidence collection initiatives.
- Strengthen obligations amongst clinicians to collect required data.
- Establish requirements that collected evidence be used to inform/update coverage decision.
- Greater collaboration on evidence development in Europe.
Thank you. Please contact c.sorenson@lse.ac.uk for any questions.