Market Access: The Benefits and Challenges of ‘Coverage with Evidence Development’
16 October 12.00-13.15
Introduction to the Workshop

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Background

• Often the available evidence for new technologies is suboptimal or inconclusive at the time of coverage determination.

• Coverage with Evidence Development (CED) provides provisional coverage (ie reimbursement) for a promising intervention, on the condition that additional data are generated to inform a final coverage/payment decision.

• To date, CED for medical devices has been conducted on a limited basis.

• CED may be worthwhile pursuing if it can enable patient access to new therapies whilst reassuring payers of their clinical value.
Aims of the Workshop

• To discuss developments in CED in Europe
• To understand the main challenges of conducting and implementing CED schemes
• To identify ways forward
Speakers

• Michael Drummond
  Professor of Health Economics, University of York, UK
• Fülöp Scheibler
  Deputy Head of Non-Drug interventions, Institute for Quality and Efficiency in Healthcare (IQWiG), Germany
• Hedi Schelleman
  Advisor, National Institute of Health Care (ZiN), The Netherlands
Study Overview

• **Research team:**
  - Corinna Sorenson and Michael Drummond of the London School of Economics

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

• **Key issues explored included:**
  – 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
Perceived Benefits of CED

• Potential to enhance coverage decisions and strengthen the existing evidence base 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 for CED (1)

• 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 (2)

- 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 of the outcomes from using CED.
- A lack of clear roles/incentives for different stakeholders 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 small and medium-sized enterprises.
• 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 (e.g., lack of data exclusivity).
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.
Suggested Areas for Improvement

- Develop clear and predictable processes for CED policies.
- Encourage greater collaboration (amongst HTA bodies/payers) with different stakeholder groups:
  - Link CED with other evidence collection initiatives.
  - Strengthen obligations amongst clinicians to collect the required data.
- Establish requirements that collected evidence be used to inform/update coverage decisions.
- Encourage greater collaboration on evidence development in Europe.
Questions to be Addressed in the Workshop

• How do we decide which technologies should undergo/are good candidates for CED?
• How do we make sure that CED schemes are adequately financed (both access to the technology and funding for the research)?
• How do we plan from the outset for the use of CED study results in funding or coverage decisions?