COMED
PUSHING THE BOUNDARIES
OF COST AND OUTCOME ANALYSIS
OF MEDICAL TECHNOLOGIES

Coverage with Evidence Development schemes for medical devices

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Agenda

- Introduction – Coverage with evidence development schemes
- Challenges of CED schemes. Results from a systematic literature review
- Next steps

There exist a number of uncertainties at the times of the approval, launch and reimbursement of health technologies

- Safety & Performance
- Effectiveness in the target population
- Link surrogate/final endpoints
- Relative effectiveness
- Cost-effectiveness
- Budget impact etc….

Traditionally regulators and payers have borne the risk of taking such uncertain decisions (both rejecting valuable technologies or approving others which do not confirm claimed value)

POPULAR MECHANICS ADVERTISING SECTION 63

New Kind of Hat
Worn 10 Minutes a Day
Grows Hair in 30 Days
—or No Cost

No matter how thin your hair may be, this remarkable new scientific invention is absolutely guaranteed to give you a brand new growth of hair in 30 days—or it costs you nothing. Don't send a cent. Just mail coupon below.

By ALOIS MERKE
Founder of Famous Merke Institute, Fifth Ave., N. Y.

I HAVE perfected a new invention that I absolutely guarantee will give you a new head of hair in only 30 days—or the trial costs you nothing.

This new invention—the result of an experience gained in treating thousands of cases of baldness—is in the form of a new kind of hat. It is worn on the head just 10 minutes a day. No unnecessary fuss of

No Risk of Any Kind

At the Merke Institute, Fifth Avenue, N. Y., which I founded, stage and social

Ideally…

CED main characteristics

1. These arrangements provide a different distribution of risk between payers and manufacturers than the traditional adopt/reject paradigm
2. There is a programme of data collection agreed between the manufacturer and the payer
3. The data collected are intended to address existing uncertainties previously identified
4. This data collection is tipically initiated in the time between the regulatory approval and price/reimbursement decision
5. The price, reimbursement, and/or revenue for the product are linked to the outcome of the data collection; either explicitly by a pre-agreed rule or implicitly through an option to rinegotiate price, reimbursement or revenue at a later date

Source: ISPOR, PBRSA task force

Challenges of CED schmes – a systematic review

Objectives:

1) To review and classify critical features that affect implementation and success of CED schemes.
2) To review specific CED schemes for MDs, and to explore how the relevant features identified were addressed

Results of the literature review: critical features of CED

General lack of an a priori strategy and lack of guidance to support decisions on CED schemes.

Issues identified with eligibility/appropriateness, design, implementation and evaluation of CED schemes

Results of the literature review: critical features of CED

Initiation of schemes

Critical features:

- Decide whether a CED is required.
- Lengthy and complex negotiations .

Results of the literature review: critical features of CED

Initiation of schemes

Design

Critical features:

- Identifying appropriate study design and outcomes.
- Who does what? (governance issues and COI)
- Type of CED (e.g., approval with research – AWR, only in research - OIR) and data collection.
- Duration of the scheme and stopping rules.
- Defining who will pay for the research.

Results of the literature review: critical features of CED

Initiation of schemes

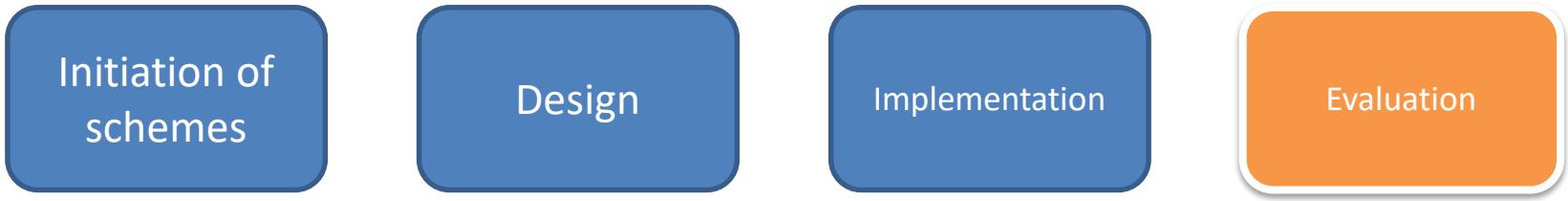
Design

Implementation

Critical features:

- May be costly and complex to administer
- Lack of incentives to collect the data or lack of experience with CED
- Use of registries:
  - ✓ Need accuracy, reliability and completeness of the information
  - ✓ Need to respect confidentiality

Results of the literature review: critical features of CED



Critical features:

- Difficulty to turn results into policy
- Account for confounders and lack of controls with RWD
- For manufacturers, risk associated with being responsible for outcomes when they cannot control the way a technology is prescribed or used
- Difficult to withdraw technologies, especially on cost-effectiveness grounds

Ethical challenges

- Coercion of patients to participate in trial as condition of coverage
- Geographical inequalities due to practical arrangements under *only in research* schemes
- Withdrawing technologies as a consequence of not conducting the study

Specific aspects for MDs?

- Very little on how MDs characteristics affect design/implementation of schemes
- Some features of MDs may be relevant:

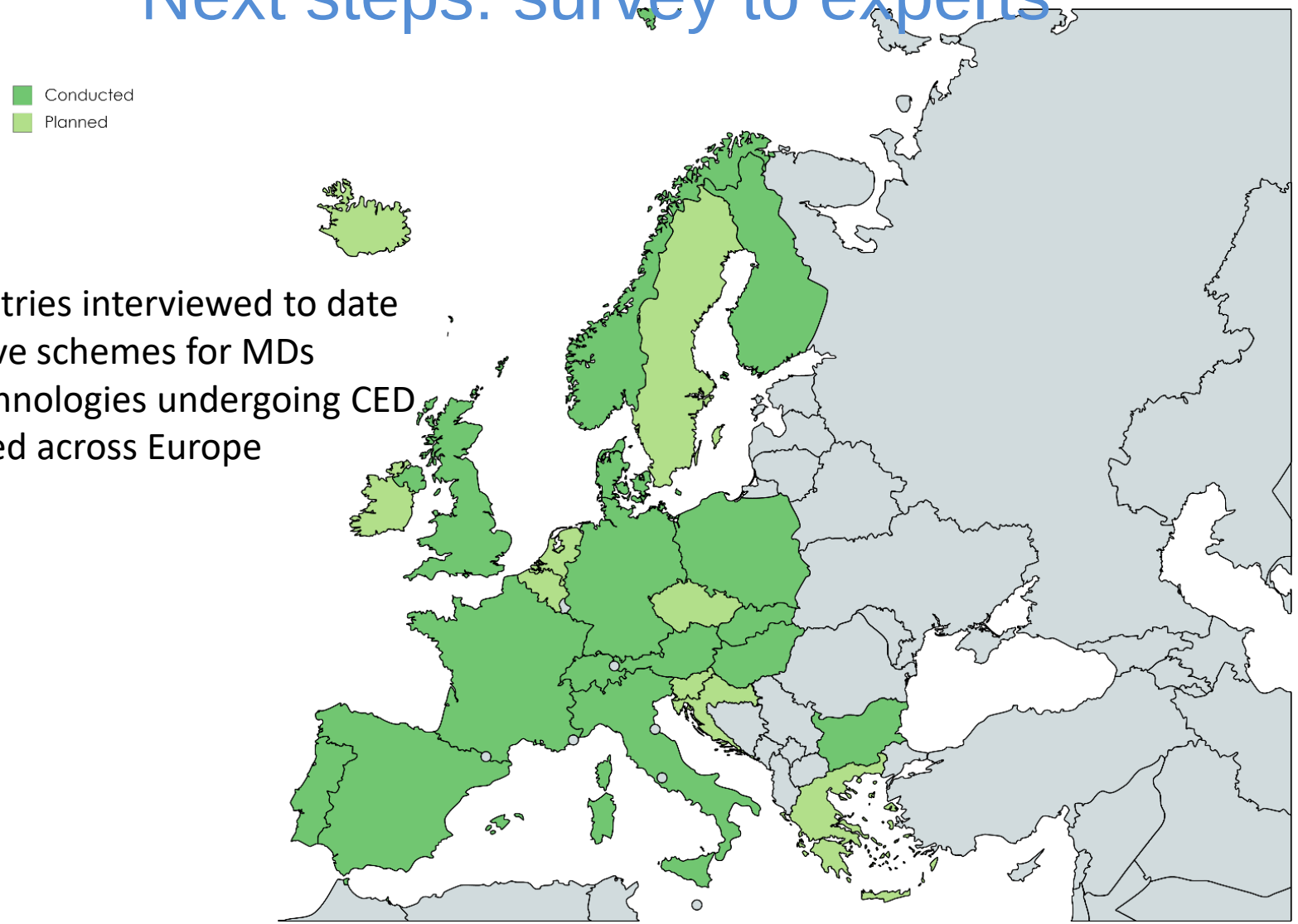
Greater uncertainty at market access	Appropriateness of schemes; higher need for RCTs and patient relevant outcomes?
Device/user interaction (Learning curve)	Attribution of effects; require careful data collection planning and statistical analysis; conflicts in the interpretation of results
Unrecoverable investment costs	Higher opportunity costs of reverting the decision (unrecovreable costs); less likely to be worthwile
Product modifications and shorter life-cycle	Enhanced planning of statistical analysis; include other products entering the market?; time horizon of the analysis
Dynamic pricing	*Freezing* costs at the onset; impact uncertainty on cost-effectiveness and BIA

Next steps

- Survey to experts in each country, (possibly) with direct experience on negotiating, designing and/or conducting CED schemes for Medical Devices

- Provide guidelines and policy raccomandations on how to implement and design CED schemes for MDs

Next steps: survey to experts



17 countries interviewed to date
47% have schemes for MDs
~30 technologies undergoing CED identified across Europe

NHS Commissioning Through Evaluation – MITRACLIP

- Residual uncertainties on procedure costs and effectiveness
- Set up of a registry link with administrative datasets.
- 199 patients enrolled in three patients (single arm study)
- FU up to 2 years
- CtE evaluation concluded that MitraClip is associated with reduced mortality and associated symptoms of HF in at least the short term
- Also associated with fewer resource consumption (hospital admissions and LOS, but unlikely to offset the initial procedure costs)

Questions from NHS England
1. Can UK clinical teams undertaking MitraClip
7. What are the short-term and long-term complications of MitraClip therapy? Is there a risk of longer-term mitral stenosis? Is the frequency of complications sufficiently low to provide a positive risk-benefit ratio?
8. What are the characteristics of patients who are successfully treated compared to those in whom treatment is unsuccessful? Are there subsets of patients who get a particularly advantageous result? Conversely, are there subsets of patients for whom this treatment is not effective? Do patients of different gender or from different ethnic origins respond equivalently?
9. What is the true procedural cost of MitraClip therapy in the NHS?
10. What costs savings might occur in the NHS as a result of MitraClip therapy?
11. What is the cost-effectiveness of MitraClip therapy based on UK procedural and follow-up costs?
become routinely funded, what is the likely clinical need in England?)

Thank you

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