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Value of implementation and managed technology access

Precision Medicine Workshop
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EEPRU work programme

- DH commissioned work in 2013 to support the NICE Implementation Collaborative (NIC)
  - Review the effectiveness and cost-effectiveness of implementation strategies
  - Develop a framework to assess the cost-effectiveness of implementation using the results of CEAs
  - Apply the framework and review findings to two case studies
- Case studies were:
  - B-type natriuretic peptide (BNP) testing in patients with suspected heart failure
  - Novel oral anti-coagulants (NOACs) for patients with atrial fibrillation

The framework

- Fenwick framework with a few added extras (Walker et al., 2013)
  - Inclusion of patient sub-groups (NOACs)
  - Inclusion of future patient cohorts (BNP testing)
  - Inclusion of natural diffusion (NOACs and BNP testing)
- Consequences of the framework (ceteris paribus)
  - The more cost-effective the technology, the more cost-effective will any investment in implementation be
  - The higher the baseline level of diffusion and/or the faster its natural rate of diffusion, the less cost-effective will any investment be

Lessons

- Data are not always available
  - The best available ICER
  - Expected diffusion in terms of shape, gradient and maximum uptake (with the latter being especially problematic in the presence of multiple substitute technologies)
- Leakage and changing patient characteristics over cohorts could be important
- Evidence on effectiveness of implementation strategies isn't very good
- In other words, applying a simple framework can be far from simple

Implementation dynamics*

- Characterised 'static' EVPI and EVPImp by:
  - Assumption of (immediate) 100% uptake of technologies**
  - Assumption that the ICER is not influenced by the level of implementation
- Relaxing these assumptions would require an exploration of:
  - Diffusion
  - Price changes as a consequence of diffusion (experience curve effects)
  - Effect changes as a consequence of diffusion (learning curve effects)

"as a consequence of diffusion"

- Price (and effect) changes that happen irrespective of diffusion, such as price reduction in the face of generic competition are not relevant here*
- However:
  - Some price changes may only happen if the technology is implemented….economies of scale can only happen if implemented, competition will only appear if there is a 'non-zero market'**
  - Some effect changes may only happen if the technology is implemented….learning effects can only happen if patient throughput is sufficiently high

Case study

- Technology for predicting pre-term birth
- Diffusion curves generated using the Bass diffusion model parameterised through SHELF
  - Two separate curves were generated relating to different types of research being made available…diagnostic study and a clinical study
- Experience curve parameterised using a surrogate technology
- Learning curve not deemed relevant and so not incorporated into the model

Lessons

- We can parameterise theoretically grounded diffusion curves that can be incorporated into EVImp analysis
- Research can have an impact on implementation
  - Formal research
  - Observational data….ad hoc research and audits, registries and managed access data collection stipulations

NICE

- Managed access is now discussed regularly by NICE in relation to the Cancer Drugs Fund (CDF)*
- The key question is…are there any uncertainties which can be resolved by the collection of up to 2 years of data in the NHS?
- Most of the time, the answer is "no".....there are very few parameters that fit this bill....extrapolation of long-term effectiveness is usually the biggest uncertainty
  - Possible exceptions are utility data (but rarely are the results sensitive to this), discontinuations and stopping rules
  - Limitations on which data can be collected

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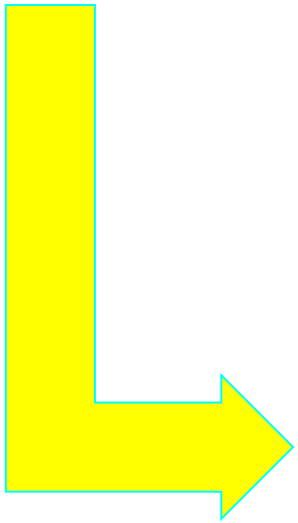
But....



Starting point: drug not recommended for routine use.

Proceed down if the answer to each question is yes.

1. Why is the drug not recommended? Is it due to clinical uncertainty?

2. Does the drug have plausible potential to be cost-effective at the current price, taking into account end of life criteria?

3. Could data collection reduce clinical uncertainty?

4. Will ongoing studies provide useful data?

and

5. Is CDF data collection feasible?

Recommended for use within the CDF

If yes to all questions then the committe recommends the drug to enter the CDF.

Source: https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/cancer-drugs-fund

Thoughts on managed access

- Access and diffusion are inextricably linked
- Access has the potential to influence price and effects
- Access has the potential to provide information on parameters that are relevant to the estimation of cost-effectiveness and this same information can influence diffusion in routine commissioning
- But, is access necessary and will the correct data be collected, then used, in the correct way?

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