Value of implementation and managed technology access

Precision Medicine Workshop
University of Leeds
Professor Simon Dixon, HEDS, Sheffield
Contents

- EEPRU projects
- Implementation dynamics
- NICE
- Lessons?
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
But....

| Starting point: drug not recommended for routine use.  
   Proceed down if the answer to each question is yes. |
<table>
<thead>
<tr>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Why is the drug not recommended? Is it due to clinical uncertainty?</td>
</tr>
<tr>
<td>-------------------------------------------------------</td>
</tr>
<tr>
<td>2. Does the drug have plausible potential to be cost-effective at the current price, taking into account end of life criteria?</td>
</tr>
<tr>
<td>-------------------------------------------------------</td>
</tr>
<tr>
<td>3. Could data collection reduce clinical uncertainty?</td>
</tr>
<tr>
<td>-------------------------------------------------------</td>
</tr>
<tr>
<td>4. Will ongoing studies provide useful data? and 5. Is CDF data collection feasible?</td>
</tr>
<tr>
<td>-------------------------------------------------------</td>
</tr>
</tbody>
</table>

Recommended for use within the CDF  
If yes to all questions then the committee recommends the drug to enter the CDF.

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?


