Do Evidence Review Groups Bias NICE Decisions?

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NICE Single Technology Appraisal (STA) Process

Manufacturer submits evidence  
ERG reviews evidence and produces a report for NICE

ERG may ask for additional data

Consultees (clinical and patient experts) make submissions to NICE

NICE meets to consider all evidence and develop a final appraisal document

Their evidence includes company’s submission, ERG report, and submissions from consultees
**Background**

ERGs are independent, academic organizations. They systematically review the clinical efficacy and cost-effectiveness of products based on manufacturer-submitted dossiers.

**Evidence Review Groups (ERGs)**

- Aberdeen Health Technology Assessment (HTA) Group
- BMJ-Technology Assessment Group (BMJ-TAG)
- Kleijnen Systematic Reviews
- Liverpool Reviews and Implementation Group (LRiG)
- Peninsula Technology Assessment Group (PenTAG)
- School of Health and Related Research (ScHARR)
- Southampton Health Technology Assessments Centre (SHTAC)
- University of York
- Warwick Evidence
- West Midlands HTA Collaboration
Objective

This presentation explores how the different ERGs behave:

1. Trends in how ERGs are commissioned by NICE
2. How ERGs are related to NICE’s reimbursement decisions
3. How ERGs affect NICE’s cost-effectiveness assessments

This evaluation is important from policy and industry perspectives, as it sheds some light on the factors that might influence NICE’s technology appraisal process.
How Do ERGs Behave?

Description of data sample
Methods

178 reimbursement events were included in the data set.

HTAs
STAs from Context Matters, comprising 72% of the total STAs published by NICE, published from 2005 to March 2015

Exclusions
Terminated appraisals, MTAs, Draft guidances

ERGs
Frequency
Therapeutic areas
Year of publication
Number of Assessments by ERG

There was an unequal distribution in ERG frequency.

- LRiG: 28
- SHTAC: 26
- Univ. of York: 24
- Aberdeen HTA group: 22
- ScHARR: 20
- PenTAG: 16
- West Midlands HTA: 16
- BMJ-TAG: 11
- Warwick Evidence: 9
- Kleijnen Systematic Reviews: 6
Number of Assessments by Therapeutic Area

Oncology drugs were the most frequently assessed.
There was a difference in the therapeutic areas each ERG evaluated.
Cumulative ERG Assessments by Year

There was a difference in the years that ERGs were commissioned.

* The West Midlands HTA is no longer listed as an ERG on NICE’s website.
Decisions and ERGs

The relationship between ERGs and NICE’s reimbursement decisions
## Methods

<table>
<thead>
<tr>
<th>NICE decision</th>
<th>Definition</th>
<th>Decision classification</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Recommend</strong></td>
<td>Drug is recommended in line with the marketing authorisation from the European Medicines Agency</td>
<td>Positive</td>
</tr>
<tr>
<td><strong>Optimised</strong></td>
<td>Drug is recommended for a smaller subset of patients than stated by the marketing authorisation</td>
<td>Positive</td>
</tr>
<tr>
<td><strong>Only in Research</strong></td>
<td>Drug is recommended for use only in the context of a research study (clinical trial)</td>
<td>Positive</td>
</tr>
<tr>
<td><strong>Not recommended</strong></td>
<td>Drug is not recommended</td>
<td>Negative</td>
</tr>
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</table>
The majority of reimbursement decisions were positive.
There was a correlation between ERG and decision (p=0.024).
Decisions by ERG: Controlling for Therapeutic Area

In logistic regression, when controlled for therapeutic area:

SHTAC: 8x odds of positive reimbursement decisions

West Midlands HTA: 10x odds of positive reimbursement decisions

No difference was found for the 8 other ERGs.
ICER Analysis

Manufacturer base-case ICER compared to the NICE most-plausible ICER
Methods

Determination of ICER difference:

NICE most-plausible ICER – Manufacturer base-case ICER

Assumptions:

The difference between NICE’s most-plausible ICER and the manufacturer’s base-case ICER can be attributed to the ERG report.

A large ICER difference indicates a stricter ERG assessment of the economic model.

A small ICER difference indicates ERG agreement with the manufacturer’s economic analysis.

<table>
<thead>
<tr>
<th>Comparator</th>
<th>Manufacturer base-case ICER</th>
<th>NICE’s most-plausible ICER</th>
<th>ICER difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Docetaxel</td>
<td>£41,544</td>
<td>£100,001</td>
<td>£58,457</td>
</tr>
<tr>
<td>BSC</td>
<td>£35,455</td>
<td>£50,201</td>
<td>£14,746</td>
</tr>
</tbody>
</table>

Ex: Lung Cancer, Xalkori (Sept 2013)
ICER Difference

On average, NICE’s most-plausible ICER was £6,200/QALY more than the manufacturer’s base-case ICER.
Conclusions

Implications for the objectivity of the NICE approval process.

NICE commissioned ERGs differently.

They were commissioned for different therapeutic areas.
They were commissioned during different years.

NICE’s decisions were different across ERGs.

When controlled for therapeutic area, SHTAC and West Midlands HTA were more likely to be associated with positive decisions.

On average, manufacturers underestimated their drugs’ ICERs by £6,200/QALY.

There was wide range in ICER differences across ERGs.

Maximum: PenTAG (£14,000); Minimum: Kleijnen Systematic Reviews (-£8,424)

What do these differences mean for manufacturers?
Thank You.

Your Blueprint for Market Access™

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