IDEAL AND HTA
(AND REIMBURSEMENT)

IDEAL 2017 CONFERENCE

Sean Tunis, MD, MSc
5 May 2017
SESSION OBJECTIVE

• To explore how the IDEAL framework could inform HTA methods for assessing clinical studies of implanted medical devices
SESSION OUTLINE

Presentations:
• Art Sedrakyan – IDEAL-D
• Tammy Clifford – CADTH / MedTechHTA
• Bruce Gingles – Cook / ISPOR
• Bruce Campbell – MHRA / NICE

Reflections:
• Louis Jacques – ADVI / CMS
• Suzanne Belinson – BCBSA
• Perry Bridger – Edwards Life Sciences
• Danica Marinac-Dabic – FDA/CDRH
“ADEQUATE EVIDENCE” – IN PRACTICE

- How much evidence does a typical payer need in order to be persuaded to cover a clinical intervention?

  Just a little bit more than you currently have.
Ladder of Evidential Strength

<table>
<thead>
<tr>
<th>Higher</th>
<th>Meta-analysis of individual patient data</th>
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<tbody>
<tr>
<td></td>
<td>Large, multi-center RCTs</td>
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<tr>
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<td>Meta-analysis of grouped data</td>
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<td>Smaller, single site RCTs</td>
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<td></td>
<td>Prospective cohort studies</td>
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<td></td>
<td>retrospective cohort</td>
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<td></td>
<td>Poorly controlled)</td>
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<tr>
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<td>studies (hx control)</td>
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<tr>
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<td>Uncontrolled studies</td>
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<td>(case-series or reports)</td>
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(Steve Goodman)
ADEQUATE EVIDENCE

- Binary Coverage
- Non-Binary Coverage (CED)

Certainty of Benefit

Time (years) / Investment