Transparency in Health Technology Assessment

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CADTH Symposium
Why have transparency in HTA?

- Values based assessment
  - whose values
  - how applied
  - what was considered

- Legitimacy and trust
  - public and patients have right to know quality and nature of information
  - may not agree with outcome but need to ensure process was fair

- Quality
  - transparency forces attention to be paid to quality, leading to better decision making
**pCODR’s Approach to Transparency**

- pCODR has committed itself to transparency and the need to be accountable to patients and the public, and responsive to industry.

- pCODR considers it essential that the evidence upon which pERC recommendations are based be publicly available.

- Accountability for Reasonableness (A4R)
  - ethical framework used by pCODR to enact one of Guiding Principles
  - publicity as a component of a fair process involves internal and external transparency

**Question:** how much transparency is enough?
Public posting of review information

- Initial pERC recommendation: key messages, summary of pERC deliberations, relevant background information

- Full clinical guidance report

- Summary of economic guidance report:
  - List price
  - Manufacturer and EGP estimates of cost-effectiveness

- Final pERC recommendation: key messages, summary of pERC deliberations, relevant background information

- All feedback by stakeholder submitted on an initial recommendation

- Conflicts of Interest of any review participant (no dollar amounts)
  - pCODR staff, PAG members, clinical and economic guidance panelists, patient advocacy groups, pERC members
pCODR Disclosure of Information Guidelines - Principles

- Submitters should keep to a minimum the types and volume of information they consider to be non-disclosable.
- Submitters are accountable for self-identifying that information which they consider to be non-disclosable.
- pCODR recognizes and respects that information owners retain right to make final decision in relation to release of information into public domain.
- pCODR reserves right to determine how non-disclosable information is used in pERC deliberations, if at all.
# Experiences to Date: Summary of Redactions (as of Mar 31, 2013)

<table>
<thead>
<tr>
<th>Generic Name / Brand Name</th>
<th>Indication</th>
<th>Recommendation</th>
<th>Clinical Report</th>
<th>Economic Report</th>
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<tbody>
<tr>
<td>Pazopanib (Votrient)</td>
<td>mRCC</td>
<td>confidential price</td>
<td>none</td>
<td>confidential price HR for OS/PFS</td>
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<tr>
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<td>melanoma</td>
<td>economic comparator</td>
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<td>economic comparator time horizon</td>
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<td>Sunitinib (Sutent)</td>
<td>pNETS</td>
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<td>none</td>
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<tr>
<td>Vemurafenib (Zelboraf)</td>
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<td>time limited</td>
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<td>safety</td>
<td>sensitivity analyses</td>
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<td>safety</td>
<td>sensitivity analyses</td>
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<td>indirect comparison</td>
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</table>
pCODR’s Approach to Transparency - Process Issues

- formal process step, submitter and pCODR dialogue in-person
- 10-day dispute resolution period to have clear, up-front understanding of use of non-disclosable information
- if submitter still decides information cannot be disclosed, it will not be included in information going to deliberative committee
  - Important safety information is exempt
- under exceptional circumstances, information that owner has decided not be allowed into public domain could be accepted for inclusion under agreement of confidentiality through time-limited redaction e.g., journal has publication embargo
Data sources beyond published literature

- FDA review
- EMA’s EPAR
- Manufacturer on-file data
- Peer reviewed meeting abstracts and oral presentations
- Company trial registry information
- Lead investigator

Notably missing:
- Health Canada review
- Investigators from Cooperative Groups/Research Consortia
Practical Issues with Transparency

- Requires commitment, time and resource, but not “hard”
- Submitters need to be thoughtful in putting submission together (not a data dump)
- Reviewers need to be thoughtful in questions they ask (not a data dredge)
- Timing of data availability can manage many issues of disclosure
Transparency in HTA – what’s next?

• Easier retrieval of clinical data
  • trial registries detailing results
  • open data
  • regulatory submissions especially for new indications

• More consistent economic information for disclosure

• Better COI information
  ▪ non-pharma research funding sources
  ▪ non-commercial interests

• Open deliberative meetings
  • consider timeliness of reviews, resource requirements