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?
**pCODR Review Process**

1. Conduct Pre-Submission Planning activities including getting input from PAG and notifying Patient Advocacy Groups

2. Prepare & submit Request for Drug Review

3.1 Screen Submission and Initiate Review Process

3.2 Collect Patient Advocacy Group Input

4.1 Conduct Clinical Review

4.1.1/4.2.2 Clarify info with Submitter during review

4.2 Conduct Economic Review

5. Summarize & Review with pERC

6. Prepare & Publicly Post Initial Recomm, Post Reviews

7.1 Get Feedback from Submitter (and impacted manufacturer)

7.2 Get Feedback from PAG

7.3 Get Feedback from Patient Advocacy Group

7.4 Eligible for Early Conversion?

- No
  - End

- Yes
  - 8. Summarize & Review with pERC
  - 9. Prepare & Publicly Post Final Recomm & Post Input

*Includes pCODR Secretariat, Clinical Guidance Panel, Economic Guidance Panel, pCODR Expert Review Committee (pERC) and Provincial Advisory Group (PAG)

‡Next steps could include Recommendation implementation, Procedural Review or Resubmission

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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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<td>melanoma</td>
<td>economic comparator</td>
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<td>economic comparator time horizon</td>
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<td>Vemurafenib (Zelboraf)</td>
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<td>none</td>
<td>confidential price sensitivity analyses</td>
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<td>none</td>
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<td>Bendamustine (Treanda)</td>
<td>NHL</td>
<td>none</td>
<td>safety</td>
<td>sensitivity analyses</td>
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<tr>
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<td>none</td>
<td>safety</td>
<td>sensitivity analyses</td>
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<tr>
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<td>none</td>
<td>None</td>
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<tr>
<td>Ruxolitinib (Jakavi)</td>
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<td>safety</td>
<td>modeling assumption</td>
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<tr>
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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