The checklist and summary tables should be updated as

Efficiencies can be gained by conducting SLRs designed to

CADTH, NICE, and HAS require both an SLR and a critical

Five agencies require both a clinical SLR and a critical

•

Catherine Rycroft, PhD

CONTACT INFORMATION

Please see handout for complete reference list.

NICE and G-BA requirements are the most prescriptive,

RESULTS

The requirements for systematic literature reviews (SLRs)

•

The requirements for systematic literature reviews (SLRs)

Table 1. Checklist for Submission to Nine HTA Bodies

Table 2. Comparing Clinical SLR Requirements of HTA Bodies

Table 3. Comparing Economic SLR Requirements of HTA Bodies

CONCLUSIONS

•

Although SLR requirements vary between HTA agencies, a clinical SLR is a key requirement for eight of the nine agencies investigated.

•

Efficiencies can be gained by conducting SLRs designed to

satisfy requirements of several HTA bodies.

•

Clinical SLRs funded by one agency for another market

should be conducted in line with the most prescriptive
guidance (i.e., NICE and NICE). However, quality assurance
during the conduct of the SLR is not required.

•

SLRs of economic models, utility data, and cost and

resource use intended for use across several markets

should be conducted to satisfy the prescriptive CADTH

and NICE criteria. In addition, requirements for critical appraisal

of economic models vary between HTA bodies requiring

two (NICE, CADTH, and HAS).

•

The checklist and summary tables should be updated as

newer HTA guidance is issued.

REFERENCES

Please see handout for complete reference list.

CONTACT INFORMATION

Catherine Rycroft, PhD

RTI Health Solutions

Phone: +44.161.441.9222

E-mail: ctrycroft@rti.org

Presented at: ISPOR 16th Annual European Congress

November 2-4, 2013

Dublin, Ireland

Table 1. Checklist for Submission to Nine HTA Bodies

<table>
<thead>
<tr>
<th>Submission Requirement</th>
<th>Australia</th>
<th>Canada</th>
<th>England</th>
<th>France</th>
<th>Germany</th>
<th>Ireland</th>
<th>Scotland</th>
<th>Sweden</th>
</tr>
</thead>
<tbody>
<tr>
<td>PAE</td>
<td>NICE</td>
<td>STA</td>
<td>HAS</td>
<td>G-BA</td>
<td>NICE</td>
<td>SMC</td>
<td>HAEW</td>
<td>AVMSG</td>
</tr>
</tbody>
</table>

Table 2. Comparing Clinical SLR Requirements of HTA Bodies

<table>
<thead>
<tr>
<th>Type of Methodology</th>
<th>PAE</th>
<th>NICE</th>
<th>STA</th>
<th>HAS</th>
<th>G-BA</th>
<th>SMC</th>
<th>HAEW</th>
<th>AVMSG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Search strategy and literature search</td>
<td>Include search strategy, date of search, data source and database selected</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Databases</td>
<td>Medicine, Embase, and Cochrane, at least</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Critical appraisal of RCTs and non-RCTs</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Critical appraisal of economic models</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Directness of evidence</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Summary and reference list</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
</tbody>
</table>

Table 3. Comparing Economic SLR Requirements of HTA Bodies

<table>
<thead>
<tr>
<th>Type of Methodology</th>
<th>PAE</th>
<th>NICE</th>
<th>STA</th>
<th>HAS</th>
<th>G-BA</th>
<th>SMC</th>
<th>HAEW</th>
<th>AVMSG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Search strategy and literature search</td>
<td>Include search strategy, date of search, data source and database selected</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Databases</td>
<td>Medicine, Embase, and Cochrane, at least</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Critical appraisal of RCTs and non-RCTs</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Critical appraisal of economic models</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Directness of evidence</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Summary and reference list</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
</tbody>
</table>

BACKGROUND AND OBJECTIVES

• The requirements for systematic literature reviews (SLRs)

within a health technology assessment (HTA) submission vary

across the world.

• The objective of this study was to compare clinical

and economic SLR requirements issued by nine HTA agencies

in Australia, Canada, and Europe (England, France, Germany,

Ireland, Scotland, Sweden and Wales).

METHODS

• Requirements for SLRs as issued within guidance for HTA

submissions in Australia (Pharmaceutical Benefits Advisory

Committee (PBAC)), Canada (Canadian Agency for Drugs

and Technologies in Health (CADTH)), England and Wales

(National Institute for Health and Care Excellence (NICE)

Single Technology Appraisal (STA) guidance), France (Haute

Autorité de santé (HAS)), Germany (Gemeinsamer Bundesausschuss

(G-BA); Federal Assessment Agency of the Federal Ministry

for Economic Affairs and Energy for Pharmacoeconomics (NICE),

Scotland (Scottish Medicines Consortium (SMC)), Sweden (The

Dental and Pharmaceutical Benefits Agency (TUV)), and Wales

(All Wales Medicines Strategy Group (AWMSG)) were examined

for the relevant, recent websites available in September 2013.

• Requirements were compared, and a summary checklist of

requirements and a more detailed summary of guidance were

compiled.

RESULTS

Table 1 presents a summary checklist comparing the submission requirements for each of the nine HTA bodies investigated.

Table 2 and 3 provide more detail on the requirements for clinical systematic reviews for each HTA body. Table 4 provides detail on the requirements for economic reviews (including clinical models, methodologies, and cost and resource use) for those HTA bodies that provide guidance on these topics (CADTH, NICE, HAS, NICE, and SMC).

• NICE and G-BA requirements are the most prescriptive, whereas AWMSG and TUV have few stated SLR requirements.

• All agencies require a clinical SLR. AWMSG does not specify this requirement but a clinical SLR is required to determine economic model input.

• Five agencies require both a clinical and a critical appraisal of the included studies (PBAC, NICE, HAS, G-BA, and NICE). Although the required appraisal tools vary, both NICE and NICE require both a clinical and a critical appraisal of economic evaluations for the intervention of interest. PAE requires an SLR of only economic evaluations and no critical appraisal.

• NICE, NICE, SMC, and AWMSG require an SLR of utility data, but only NICE and SMC specify the need for an SLR of cost and resource use data.

CONCLUSIONS

• Although SLR requirements vary between HTA agencies, a clinical SLR is a key requirement for eight of the nine agencies investigated.

• Efficiencies can be gained by conducting SLRs designed to satisfy requirements of several HTA bodies.

• Clinical SLRs funded by one agency for another market

should be conducted in line with the most prescriptive
guidance (i.e., G-BA and NICE). However, quality assurance
during the conduct of the SLR is not required.

• SLRs of economic models, utility data, and cost and resource use intended for use across several markets

should be conducted to satisfy the prescriptive CADTH

and NICE criteria. In addition, requirements for critical appraisal

of economic models vary between HTA bodies requiring
two (NICE, CADTH, and HAS).

• The checklist and summary tables should be updated as

newer HTA guidance is issued.