

## Instructions for Authors (continued)

### Levels of Evidence for Primary Research<sup>1</sup>

Types of Studies				
	Therapeutic Studies— Investigating the Results of Treatment	Prognostic Studies— Investigating the Effect of a Patient Characteristic on the Outcome of Disease	Diagnostic Studies— Investigating a Diagnostic Test	Economic and Decision Analyses—Developing an Economic or Decision Model
Level I	<ul style="list-style-type: none"> <li>• High-quality randomized controlled trial with statistically significant difference or no statistically significant difference but narrow confidence intervals</li> <li>• Systematic review<sup>2</sup> of Level-I randomized controlled trials (studies were homogeneous<sup>3</sup>)</li> </ul>	<ul style="list-style-type: none"> <li>• High-quality prospective study<sup>4</sup> (all patients were enrolled at the same point in their disease with ≥80% follow-up of enrolled patients)</li> <li>• Systematic review<sup>2</sup> of Level-I studies</li> </ul>	<ul style="list-style-type: none"> <li>• Testing of previously developed diagnostic criteria in series of consecutive patients (with universally applied reference “gold” standard)</li> <li>• Systematic review<sup>2</sup> of Level-I studies</li> </ul>	<ul style="list-style-type: none"> <li>• Sensible costs and alternatives; values obtained from many studies; multi-way sensitivity analyses</li> <li>• Systematic review<sup>2</sup> of Level-I studies</li> </ul>
Level II	<ul style="list-style-type: none"> <li>• Lesser-quality randomized controlled trial (e.g., &lt;80% follow-up, no blinding, or improper randomization)</li> <li>• Prospective<sup>4</sup> comparative study<sup>5</sup></li> <li>• Systematic review<sup>2</sup> of Level-II studies or Level-I studies with inconsistent results</li> </ul>	<ul style="list-style-type: none"> <li>• Retrospective<sup>6</sup> study</li> <li>• Untreated controls from a randomized controlled trial</li> <li>• Lesser-quality prospective study (e.g., patients enrolled at different points in their disease or &lt;80% follow-up)</li> <li>• Systematic review<sup>2</sup> of Level-II studies</li> </ul>	<ul style="list-style-type: none"> <li>• Development of diagnostic criteria on basis of consecutive patients (with universally applied reference “gold” standard)</li> <li>• Systematic review<sup>2</sup> of Level-II studies</li> </ul>	<ul style="list-style-type: none"> <li>• Sensible costs and alternatives; values obtained from limited studies; multi-way sensitivity analyses</li> <li>• Systematic review<sup>2</sup> of Level-II studies</li> </ul>
Level III	<ul style="list-style-type: none"> <li>• Case-control study<sup>7</sup></li> <li>• Retrospective<sup>6</sup> comparative study<sup>5</sup></li> <li>• Systematic review<sup>2</sup> of Level-III studies</li> </ul>	<ul style="list-style-type: none"> <li>• Case-control study<sup>7</sup></li> </ul>	<ul style="list-style-type: none"> <li>• Study of nonconsecutive patients (without consistently applied reference “gold” standard)</li> <li>• Systematic review<sup>2</sup> of Level-III studies</li> </ul>	<ul style="list-style-type: none"> <li>• Analyses based on limited alternatives and costs; poor estimates</li> <li>• Systematic review<sup>2</sup> of Level-III studies</li> </ul>
Level IV	Case series <sup>8</sup>	Case series	<ul style="list-style-type: none"> <li>• Case-control study</li> <li>• Poor reference standard</li> </ul>	<ul style="list-style-type: none"> <li>• No sensitivity analyses</li> </ul>
Level V	Expert opinion	Expert opinion	Expert opinion	Expert opinion

1. A complete assessment of the quality of individual studies requires critical appraisal of all aspects of the study design.
2. A combination of results from two or more prior studies.
3. Studies provided consistent results.
4. Study was started before the first patient enrolled.
5. Patients treated one way (e.g., with cemented hip arthroplasty) compared with patients treated another way (e.g., with cementless hip arthroplasty) at the same institution.
6. Study was started after the first patient enrolled.
7. Patients identified for the study on the basis of their outcome (e.g., failed total hip arthroplasty), called “cases,” are compared with those who did not have the outcome (e.g., had a successful total hip arthroplasty), called “controls.”
8. Patients treated one way with no comparison group of patients treated another way.

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