# Levels of Evidence For Primary Research Question

As Adopted by the North American Spine Society January 2005

<table>
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<th>Types of Studies</th>
<th>Therapeutic Studies – Investigating the results of treatment</th>
<th>Prognostic Studies – Investigating the effect of a patient characteristic on the outcome of disease</th>
<th>Diagnostic Studies – Investigating a diagnostic test</th>
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| **Level I**      | • High quality randomized trial with statistically significant difference or no statistically significant difference but narrow confidence intervals  
• Systematic Review\(^2\) of Level I RCTs (and study results were homogenous\(^3\)) | • High quality prospective study\(^4\) (all patients were enrolled at the same point in their disease with \(\geq 80\%\) follow-up of enrolled patients)  
• Systematic review\(^2\) of Level I studies | • Testing of previously developed diagnostic criteria on consecutive patients (with universally applied reference “gold” standard)  
• Systematic review\(^2\) of Level I studies | • Sensible costs and alternatives; values obtained from many studies; with multiway sensitivity analyses  
• Systematic review\(^2\) of Level I studies |
| **Level II**     | • Lesser quality RCT (e.g. < 80% follow-up, no blinding, or improper randomization)  
• Prospective\(^5\) comparative study  
• Systematic review\(^2\) of Level II studies or Level 1 studies with inconsistent results | • Retrospective\(^6\) study  
• Untreated controls from an RCT  
• Lesser quality prospective study (e.g. patients enrolled at different points in their disease or <80% follow-up.)  
• Systematic review\(^2\) of Level II studies | • Development of diagnostic criteria on consecutive patients (with universally applied reference “gold” standard)  
• Systematic review\(^2\) of Level II studies | • Sensible costs and alternatives; values obtained from limited studies; with multiway sensitivity analyses  
• Systematic review\(^2\) of Level II studies |
| **Level III**    | • Case control study\(^7\)  
• Retrospective\(^6\) comparative study  
• Systematic review\(^2\) of Level III studies | • Case control study\(^3\) | • Study of non-consecutive patients; without consistently applied reference “gold” standard  
• Systematic review\(^2\) of Level III studies | • Analyses based on limited alternatives and costs; and poor estimates  
• Systematic review\(^2\) of Level III studies |
| **Level IV**     | Case Series\(^8\) | Case series | • Case-control study  
• Poor reference standard | • Analyses with no sensitivity analyses |
| **Level V**      | Expert Opinion | Expert Opinion | Expert Opinion | Expert Opinion |

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1. A complete assessment of 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. cemented hip arthroplasty) compared with a group of patients treated in another way (e.g. uncemented hip arthroplasty) at the same institution.
6. The study was started after the first patient enrolled.
7. Patients identified for the study based on their outcome, called “cases”; e.g. failed total arthroplasty, are compared to those who did not have outcome, called “controls”; e.g. successful total hip arthroplasty.
8. Patients treated one way with no comparison group of patients treated in another way.

*These documents have also been adopted by the American Academy of Orthopaedic Surgeons, Pediatric Orthopaedic Society of North America, Clinical Orthopaedics and Related Research, Journal of Bone & Joint Surgery and Spine.*

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