

Instructions for Authors (continued)

Levels of Evidence for Primary Research

Types of Studies				
	Therapeutic Studies— Investigating the Results of Treatment	Prognostic Studies— Investigating the Outcome of Disease	Diagnostic Studies— Investigating a Diagnostic Test	Economic and Decision Analyses— Developing an Economic or Decision Model
Level I	1. Randomized controlled trial a. Significant difference b. No significant difference but narrow confidence intervals 2. Systematic review ² of Level-I randomized controlled trials (studies were homogeneous)	1. Prospective study ¹ 2. Systematic review ² of Level-I studies	1. Testing of previously developed diagnostic criteria in series of consecutive patients (with universally applied reference “gold” standard) 2. Systematic review ² of Level-I studies	1. Clinically sensible costs and alternatives; values obtained from many studies; multiway sensitivity analyses 2. Systematic review ² of Level-I studies
Level II	1. Prospective cohort study ³ 2. Poor-quality randomized controlled trial (e.g., <80% follow-up) 3. Systematic review ² a. Level-II studies b. Nonhomogeneous Level-I studies	1. Retrospective study ⁴ 2. Study of untreated controls from a previous randomized controlled trial 3. Systematic review ² of Level-II studies	1. Development of diagnostic criteria on basis of consecutive patients (with universally applied reference “gold” standard) 2. Systematic review ⁴ of Level-I-II studies	1. Clinically sensible costs and alternatives; values obtained from limited studies; multiway sensitivity analyses 2. Systematic review ² of Level-II studies
Level III	1. Case-control study ⁵ 2. Restrospective cohort study ⁴ 3. Systematic review ² of Level-III studies		1. Study of nonconsecutive patients (no consistently applied reference “gold” standard) 2. Systematic review ² of Level-III studies	1. Limited alternatives and costs; poor estimates 2. Systematic review ² of Level-III studies
Level IV	Case series (no, or historical, control group)	Case series	1. Case-control study 2. Poor reference standard	No sensitivity analyses
Level V	Expert opinion	Expert opinion	Expert opinion	Expert opinion
<ol style="list-style-type: none"> 1. All patients were enrolled at the same point in their disease course (inception cohort) with ≥80% follow-up of enrolled patients. 2. A study of results from two or more previous studies. 3. Patients were compared with a control group of patients treated at the same time and institution. 4. The study was initiated after treatment was performed. 5. Patients with a particular outcome (“cases” with, for example, a failed total arthroplasty) were compared with those who did not have the outcome (“controls” with, for example, a total hip arthroplasty that did not fail). 				
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