

Level of Evidence for Clinical Studies

Level I: High quality randomized trial or prospective study; testing of previously developed diagnostic criteria on consecutive patients; sensible costs and alternatives; values obtained from many studies with multiway sensitivity analyses; systematic review of Level I RCTs and Level I studies.

Level II: Lesser quality RCT; prospective comparative study; retrospective study; untreated controls from an RCT; lesser quality prospective study; development of diagnostic criteria on consecutive patients; sensible costs and alternatives; values obtained from limited studies; with multiway sensitivity analyses; systematic review of Level II studies or Level I studies with inconsistent results.

Level III: Case control study (therapeutic and prognostic studies); retrospective comparative study; study of nonconsecutive patients without consistently applied reference “gold” standard; analyses based on limited alternatives and costs and poor estimates; systematic review of Level III studies.

Level IV: Case series; case control study (diagnostic studies); poor reference standard; analyses with no sensitivity analyses.

Level V: Expert opinion.