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 Levels of Evidence for Primary Research Question^{1,2}

Study Type	Question	Level I	Level II	Level III	Level IV	Level V
Diagnostic — Investigating a diagnostic test	Is this (early detection) test worthwhile?	· Randomized controlled trial	· Prospective ³ cohort ⁴ study	· Retrospective ⁵ cohort ⁴ study · Case-control ⁶ study	· Case series	· Mechanism-based reasoning
	Is this diagnostic or monitoring test accurate?	· Testing of previously developed diagnostic criteria (consecutive patients with consistently applied reference standard and blinding)	· Development of diagnostic criteria (consecutive patients with consistently applied reference standard and blinding)	· Nonconsecutive patients · No consistently applied reference standard	· Poor or nonindependent reference standard	· Mechanism-based reasoning
Prognostic — Investigating the effect of a patient characteristic on the outcome of a disease	What is the natural history of the condition?	· Inception ³ cohort study (all patients enrolled at an early, uniform point in the course of their disease)	· Prospective ³ cohort ⁴ study (patients enrolled at different points in their disease) · Control arm of randomized trial	· Retrospective ⁵ cohort ⁴ study · Case-control ⁶ study	· Case series	· Mechanism-based reasoning
Therapeutic — Investigating the results of a treatment	Does this treatment help? What are the harms?	· Randomized controlled trial	· Prospective ³ cohort ⁴ study · Observational study with dramatic effect	· Retrospective ⁵ cohort ⁴ study · Case-control ⁶ study	· Case series · Historically controlled study	· Mechanism-based reasoning
Economic	Does the intervention offer good value for dollars spent?	Computer simulation model (Monte Carlo simulation, Markov model) with inputs derived from Level-I studies, lifetime time duration, outcomes expressed in dollars per quality-adjusted life years (QALYs) and uncertainty examined using probabilistic sensitivity analyses	Computer simulation model (Monte Carlo simulation, Markov model) with inputs derived from Level-II studies, lifetime time duration, outcomes expressed in dollars per QALYs and uncertainty examined using probabilistic sensitivity analyses	Computer simulation model (Markov model) with inputs derived from Level-II studies, relevant time horizon, less than lifetime, outcomes expressed in dollars per QALYs and stochastic multilevel sensitivity analyses	Decision tree over the short time horizon with input data from original Level-II and III studies and uncertainty is examined by univariate sensitivity analyses	Decision tree over the short time horizon with input data informed by prior economic evaluation and uncertainty is examined by univariate sensitivity analyses