Trauma Surgery
& Acute Care Open

Levels of Evidence table

	Therapeutic/Care Management	Prognostic and Epidemiological	Diagnostic Tests or Criteria	Economic & Value-based Evaluations	Systematic Reviews & Meta-analyses
Level I	RCT with no negative criteria*	Prospective† study with large effect‡ and no negative criteria*	Testing of previously developed diagnostic criteria in consecutive patients (all compared to "gold" standard) and no negative criteria	Sensible costs and alternatives; values obtained from many sources; multi-way sensitivity analyses	Systematic Review (SR) or meta-analysis (MA) of predominantly level I studies and no SR/MA negative criteria§
Level II	• RCT with significant difference and only one negative criterion*• Prospective† comparative study without negative criteria*• Prospective/retrospective† study with large effect‡ and only one negative criterion*	• Prospective† study with less than large effect‡ and no negative criteria*• Untreated controls from RCT	Development of diagnostic criteria on consecutive patients (all compared to "gold" standard) and only one negative criterion	Sensible costs and alternatives; values obtained from limited sources; multi-way sensitivity analyses	SR/MA or predominantly level II studies with no SR/MA negative criteria§
Level III	• Case-control study without negative criteria*• Prospective† comparative study with only one negative criterion*• Retrospective† comparative study without negative criteria*	• Case-control study without negative criteria*• Prospective/retrospective† study with up to two negative criteria*	Non-consecutive patients (without consistently applied "gold" standard) with up to two negative criteria	Analyses based on limited alternatives and costs; poor estimates	SR/MA with up to two negative criteria§
Level IV	Prospective/retrospective† study using historical controls or having more than one negative criterion*	Prospective/retrospective† study with up to three negative criteria*	Case-control study with no negative criteria* or other designs with up to three negative criteria	No sensitivity analyses	SR/MA with more than two negative criteria§
Level V	• Case series • Studies with quality worse than level IV	• Case series • Studies with quality worse than level IV	No or poor "gold" standard		

* Negative criteria decreasing level of evidence include: **(1)** <80% follow up; **(2)** >20% missing data or missing data not at random without proper use of missing data statistical techniques; **(3)** limited control of confounding (e.g., mortality comparisons with inadequate risk adjustment); **(4)** more than minimal bias (selection bias, publication bias, report bias, etc.); **(5)** heterogeneous populations (e.g., instructions with distinct protocols/patient volume, conditions caused by distinct pathogenic mechanisms); and **(6)** for RCT only, no blinding or improper randomization; **(7)** inadequate statistical power: this only applies to studies NOT finding statistical differences and it is defined as power <80% for declaring "failure to detect a significant difference" or power <90% for declaring "bio-equivalence or non-inferiority or comparative effectiveness" or Receiver Operating Characteristic curve <80% or both sensitivity and specificity <80%.

† Prospective versus retrospective: studies with data collected to answer predefined questions are prospective; studies with data collected for questions unrelated to the original question for which the data were gathered are retrospective.

‡ Large effect is defined as: **(1)** study with large RR (>5 or >0.2) about condition of low-to-moderate morbidity/mortality and **(2)** study with moderate-to-large RR (2-5 or 0.2-0.5) about condition of high morbidity/mortality.

§ Negative criteria for SR/MS (decreases level of evidence): **(1)** no or inadequate standard search protocol, **(2)** more than minor chance of publication bias or publication bias not assessed, **(3)** moderate heterogeneity of included studies and/or populations (e.g., elective operation and acute operation), **(4)** predominance of level III or lower studies, and **(5)** no measures or inappropriate measures of pooled risk (for meta-analysis only).

II Adequate statistical power: this only applies to studies not finding statistical differences, and it is defined as power 980% for declaring "failure to detect a significant difference" or power 990% for declaring "bioequivalence or noninferiority or comparative effectiveness."

In addition to the level, studies will receive a + to designate whether standard reporting format was followed (e.g., CONSORT for RCTs). Authors can find reporting guidelines for most studies at the international EQUATOR Network.