Delfini Critical Appraisal: Orientation

Healthcare Information & Decision Equation: **Information➔Decision ➔Action➔Outcome**
Is it true➔Is it useful ➔Is it usable?

Evaluating the Medical Literature: 5 Essential Questions

1. Are the results likely to be true?
Internal Validity
Key Questions: Can anything other than truth explain the results? Flip Side: What conditions would need to be met for the results not to be true?
We "rule out" bias and chance to be able to conclude likely to be due to cause and effect.

2. If yes, are they likely to be useful?
Internal & External Validity
Size of the outcomes + outcomes that matter to patients (the "clinical outcomes")
Morbidity + Mortality + Symptom relief + Function (emotional, mental, physical) + Quality of Life

3. If yes, to whom?
External Validity: Population similarities + circumstances for care

4. If yes, at what "price?"

5. Are they "usable"—has to do with ability to understand, access, apply and act upon, etc.

Ways to Describe Studies: Essential Contextual Elements
PICPOTS =
Patient/population (condition) + Intervention + Comparators + "Performance Outcomes*" + Outcomes + Timing + Setting
*Performance outcomes examples include study success and failure issues—
Likely success of blinding, adherence, protocol deviations, missing information, etc.

Steps in Critical Appraisal for "Are the Results Likely to be True?"
Step 1. Match Your Research Question to Study Design: Observations vs Experiments
Step 2. Identify Biases + Chance Effects
Step 3. Grade It

7 Big Routes to Bias
1. Unequal groups in any way but 1 way (although in "missingness" may be informative)
2. Unhappy comparison
3. Didn't hide things
4. Lack of or uncertainty of exposure
5. Faulty measurement
6. Missing things (with caveats)
7. Faulty analysis

Or uncertainty about bias due to lack of transparency in reporting

Stage of Trial & Area of Concern	Estimated Range of Relative Distortion of Study Results	References
Stage I: Establishing Comparable Groups (Selection Bias)		
• Inadequate Generation of Sequence	17% to 75%	4. Juni 01 PMID: 11440947 5. Kjaergard 01PMID: 11730399 6. van Tulder 09 PMID: 19770609
• Inadequate Concealment of Allocation of the Randomization Sequence	14% to 73%	1. Schulz 95 PMID: 7823387 2. Moher 98 PMID: 9746022 4. Juni 01, PMID: 11440947 5. Kjaergard 01 PMID: 11730399 7. Chalmers 83 PMID: 6633598
Stage II: Intervention and Context (Performance Bias)		
• Inadequate Double Blinding	4% to 72%	1. Schulz 95 PMID: 7823387 2. Moher 98 PMID: 9746022 4. Juni 01, PMID: 11440947 5. Kjaergard 01 PMID: 11730399
Stage III: Loss of Data (Attrition Bias)		
• Loss of Data (Up to 38%)	2% to 35%	6. van Tulder 09 PMID: 19770609 8. Tierney 04 PMID: 15561753 9. Nüesch PMID: 19736281 24. Canadian Orthopaedic Trauma Society 07 PMID: 17200303
Stage IV: Assessment (Assessment Bias)		
• Inadequate Blinding of Assessors	35% to 69%	11. Poolman 07 PMID: 17332104 25. Juni 99 PMID: 10493204
• Completer Analysis	56% with 44% early withdrawal	26. Shih 02 PMID: 11985778
• Assessment Models For Missing Data	With loss of 20% risk of type I error* is approximately 10%; With loss of 40% risk of type I is approximately 50% *Type 1 - or alpha error - A difference is reported, but there is no difference.	12. Lachin 00 PMID: 11018568

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