

Quality Assessment Instruments and Evidence Grading Systems

*Workshop Day 2 PM
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*George A Wells
University of Ottawa*

Outline

- XV Cochrane Colloquium October 2007 Presentation
- Rating System Review
- Selected Instruments

XV Cochrane Colloquium 2007

Presentation

Systematic Review Of Quality Assessment Instruments for Randomized Controlled Trials: Selection of SIGN50 Methodological checklist

Vijay K. Shukla¹, Annie Bai¹, George Wells², Sarah Milne²

¹ CADTH

² University of Ottawa

Introduction

- Chalmers and coworkers in 1980's first formally raised the concern about study quality
- Study quality is important when producing a systematic review (Schulz et al, 1995, Khan et al, 1996)
- Many Quality Assessment Instruments (QAIs) have been developed in the past two decades
- There is no gold standard yet available

Introduction

- Systems to rate the strength of scientific evidence: Evidence report/Technology assessment No. 47, AHRQ, April 2002
- AHRQ Report 47 reviewed information from 1995 to mid 2000
- QAIs for Randomized controlled trials (RCTs) collected in the report:
 - Total number 39
 - Scales / Checklists: 32 (Jadad)
 - Guidance 7

Introduction

- Most popular scale: Jadad scale (1600 citations)
http://en.wikipedia.org/wiki/Alejandro_R._Jadad_Bechara
- Use of Jadad scale has become controversial in recent years (Berger et al., 2006)
- Number of time studies with high drop out rate scored high on Jadad scale
- AHRQ report has not recommended Jadad scale

Objective

- To review the quality assessment instruments available for RCTs
- To identify a sufficiently comprehensive and easy to use QAI

Methods

Built upon the existing review approach

- Step 1: Assembled working group
- Step 2: Searched and selected review articles (2000-2005)
- Step 3: Identified QAIs from review articles
- Step 4: Conducted initial expert consultation
- Step 5: Searched and selected individual QAIs (2000-2005)
- Step 6: Identified QAIs for evaluation
- Step 7: Evaluated QAIs identified
- Step 8: Conducted second expert consultation
- Step 9: Chose QAIs

Results

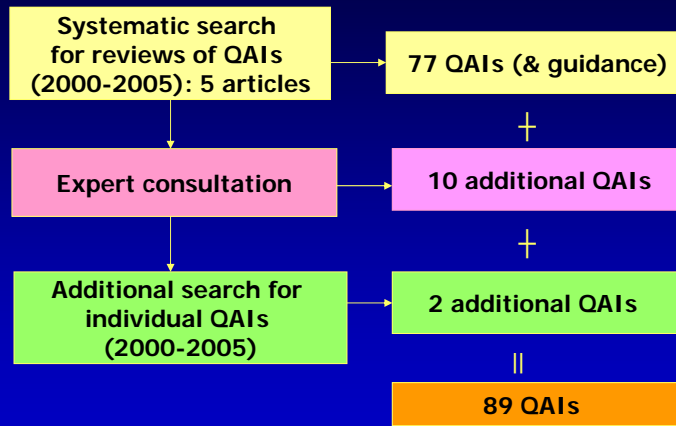
Literature selection for review articles on QAIs for RCTs

- Three thousand and six (3006) citations obtained by running a highly sensitive search strategy
- Five unique review articles were identified based on predefined inclusion criteria:
 - (1) Article comparing two or more existing QAIs
 - (2) Article containing formal evaluation of QAIs

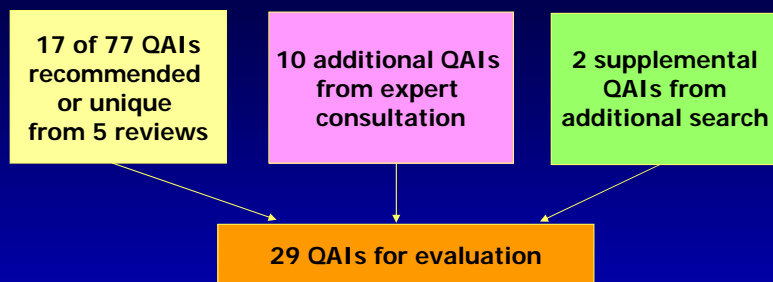
Results: Relevant reviews

No.	First author & Year	Title	Journal (Lit search year)
1	Brouwers 2005	Evaluating the role of quality assessment of primary studies in systematic reviews of cancer practice guidelines	BMC (1995-2000)
2	Colle 2002	Impact of Quality Scales on Levels of Evidence Inferred From a Systematic Review of Exercise Therapy and Low Back Pain.	Arch Phys Med Rehabil (NA)
3	Deeks 2003	Evaluating non-randomised intervention studies.	Health Technol Assess (Earliest to 1999)
4	Katrak 2004	A systematic review of the content of critical appraisal tools	BMC (Not clear)
5	West 2002	Systems to Rate the Strength of Scientific Evidence. Evidence Report/Technology Assessment No. 47	AHRQ Publication (1995 to 2000)

Results: Identification of QAIs for RCTs



Results: Identification of QAIs for RCTs



Domains	1	2	3	4	5	6	7
RCT	Study Population	Randomization	Blinding	Interventions	Outcomes	Statistical analysis	Funding
		●	●	○			

Results: Evaluation of 8 QAIs from AHRQ Report 47

Instrument	Study population	Randomization	Blinding	Interventions	Outcomes	Statistical analysis	Funding
Chalmers 1981	●	●	●	●	●	●	●
Liberati 1986	●	●	●	●	●	●	○
Reisch 1989	●	●	●	●	●	●	●
van der Heijden 1996	●	●	●	●	●	●	○
de Vet 1997	●	●	●	●	●	●	○
Sindhu 1997	●	●	●	●	●	●	○
Downs and Black 1998	●	●	●	●	●	●	○
Harbour and Miller 2001	●	●	●	●	●	●	○

Results: Evaluation of 9 QAIs from other four reviews

Instrument	Study population	Randomization	Blinding	Interventions	Outcomes	Statistical analysis	Funding
Gyorkos 1994	◐	●	●	◐	●	●	○
Crombie 1996	◐	●	◐	●	●	●	○
Joanna Briggs 1999	◐	●	●	○	◐	◐	○
NMHRC 2000	○	●	●	○	○	◐	○
FOCUS 2001	◐	●	●	○	◐	◐	○
Oremus 2001	●	●	●	○	◐	●	○
CASP (PHRU) 2002	◐	●	●	○	◐	●	○
Moseley 2002	●	●	●	○	◐	●	○
van Tulder 2002	○	●	●	◐	○	●	○

Results: Evaluation of 10 additional QAIs from experts

Instrument	Study population	Rando- mization	Blinding	Inter- ventions	Outcomes	Statistical analysis	Funding
Modified Downs and Black 2000	●	●	●	●	●	●	○
Eccles 2001	◐	●	●	○	◐	○	○
NZGG 2001	●	●	●	●	●	●	○
DERP 2002	●	●	●	○	○	●	●
EPOC 2002	◐	●	◐	○	●	◐	○
Bandolier (OPVS) 2003	○	○	●	○	●	●	○
van Tulder 2003	◐	●	●	○	○	◐	○
SIGN50 2004	●	●	●	●	●	●	●
EPHPP 2005	○	●	◐	○	◐	◐	○
van Tulder 2005	○	●	●	○	○	◐	○

Results: Evaluation of 2 additional QAIs from search

Instrument	Study population	Rando- mization	Blinding	Inter- ventions	Outcomes	Statistical analysis	Funding
Chalmers 1985	○	●	◐	○	○	◐	○
Kleijnen 1994	◐	○	●	●	●	●	○

Results: Top 3 QAIs and Jadad scale

Instrument	Study population	Rando- mization	Blinding	Inter- ventions	Outcomes	Statistical analysis	Funding
Chalmers 1981	●	●	●	●	●	●	●
Reisch 1989	●	●	●	●	●	●	●
SIGN50 2004	●	●	●	●	●	●	●
Jadad 1996	○	●	●	○	○	●	○

Results: SIGN 50 methodological checklist

SECTION 1: INTERNAL VALIDITY	
In a well conducted RCT study.....	
1.1	The study addresses an appropriate and clearly focused question.
1.2	The assignment of subjects to treatment groups is randomised
1.3	An adequate concealment method is used
1.4	Subjects and investigators are kept 'blind' about treatment allocation
1.5	The treatment and control groups are similar at the start of the trial
1.6	The only difference between groups is the treatment under investigation
1.7	All relevant outcomes are measured in a standard, valid and reliable way
1.8	What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?
1.9	All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis)
1.10	Where the study is carried out at more than one site, results are comparable for all sites
SECTION 2: OVERALL ASSESSMENT OF THE STUDY	
2.1	How well was the study done to minimise bias? Code ++, +, or –
SECTION 3: OTHERS	
3.1	How was this study funded? List all sources of funding quoted in the article, whether Government, voluntary sector, or industry.
Well covered; Adequately addressed	
Poorly addressed; Not reported	
Not applicable; Not addressed	

Conclusion

We selected SIGN 50 as the best fit to meet our needs:

- It covers most of the important domains to check the quality of the RCT
- It allows reviewers to use judgment to understand the limitation of RCTs
- It is neither too long nor too short

Outline

- **XV Cochrane Colloquium October 2007 Presentation**
- Rating System Review
- Selected Instruments

Rating System

- Quality assessment instruments (QAIs)
 - systematic reviews
 - randomized controlled trials
 - cohort studies
 - case-control studies
- Evidence grading system (EGSs)

AHRQ 47 - Existing QAIs

Study design	Total number	Scales checklists	Guidance
Systematic Reviews	20	11 Oxman	9
Randomized controlled trials	39	32 Jadad	7
Observational studies	17	12	5
Diagnostic tests	15	6	9

**Oxman and Guyett 1991* and
Oxman et al., 1991**
evaluated in AHRQ 47*****

- Study question ●
- Search strategy ●
- Inclusion /exclusion ◐
- Intervention ○
- Outcomes ◐
- Data extraction ◐
- Study quality /validity ●
- Data synthesis & analysis ●
- Results ●
- Discussion ○
- Funding /support ○

* Oxman AD, Guyatt GH. Validation of an index of the quality of review articles. J Clin Epidemiol. 1991;44:1271-8

** Oxman AD, Guyatt GH, Singer J, et al. Agreement among reviewers of review articles. J Clin Epidemiol. 1991;44:91-8

*** AHRQ 47. April 2002. Page 113

**Jadad et al. 1996*
evaluated in AHRQ 47****

- Study Question ○
- Study population ○
- Randomization ●
- Blinding ●
- Interventions ○
- Outcomes ○
- Statistical analysis ◐
- Results ○
- Discussion ○
- Funding /Support ○

* Jadad AR, Moore RA, Carroll D, et al. Assessing the quality of reports of randomized clinical trials: is blinding necessary? Control Clin Trials. 1996;17:1-12

** AHRQ 47. April 2002. Page 117

Problems with existing QAIs

- Wide variation of instruments*
- Quality varies based on different instruments**
- Based on expert opinion***
- Few scales and checklists with rigorous development techniques***
- No consensus for a 'gold standard' instrument****

* Lohr, et al. Joint Commission J Qual Improvement. 1999.

** Juni et al. JAMA. 1999.

*** AHRQ 47.

**** Katrak, et al. BMC 2004

AHRQ 47 - Existing EGSs

Type of grading systems	Total	Related to development of CPGs	Not related to development of CPGs
Number of Grading systems	34	23	11

Problems with existing grading systems

- Various systems exist*
- Less uniform than quality assessment instruments**
- No system is completely satisfactory***
- Increasing complexity**

* GRADE Working Group. BMJ 2004.
** AHRQ 47.
*** Liberati, et al. West J Med. 2001

Approach

- Step 1: Assembled working group
- Step 2: Searched and selected review articles (2000-2005)
- Step 3: Identified QAIs and EGSs from review articles
- Step 4: Conducted initial expert consultation
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- Step 6: Identified QAIs and EGSs for evaluation
- Step 7: Evaluated QAIs and EGSs identified
- Step 8: Conducted second expert consultation
- Step 9: Chose QAIs and EGSs for COMPUS
- Step 10: Conducted stakeholder consultation

Choice QAIs and EGSs

QAIs

- SYSTEMATIC REVIEW
 - AMSTAR 2005
- RCT
 - Methodology Checklist 2: RCT (SIGN 50, 2004)
- OBSERVATIONAL
 - Methodology Checklist 3: Cohort studies (SIGN 50, 2004)
 - Methodology Checklist 4: Case-control studies (SIGN 50, 2004)

EGSs

- GRADE working group, 2004

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