Comparison Component of Evidence Table between Organizations

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Background

Evidence table of evidence-based clinical guidelines provide important information

- Brief characteristics of included studies (PICO)
- assessment of methodological quality (risk of bias)
- comparative risks (assumed risk/corresponding risk) of the study
- size of effect (relative and absolute) by primary and secondary outcomes
- and/or GRADE the quality of evidence

Background

Evidence table can be a useful tool to assist patient decisions about appropriate health care for specific clinical circumstances for the guideline users

including physicians and Other health professionals.

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Background

Common problems with evidence table

- Using different terminology for the evidence table including similar information
  - ✓ Summary of results tables
  - ✓ Assessment of methodological quality table
  - ✓ GRADE evidence profile
  - ✓ Summary of findings (SoF) table
- Illustrated with different components by health organizations and research groups
  - ✓ could not compare the same components of evidence

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Background

Common problems with evidence table

- Provide only selective information such as assessment of risk of bias and did not include important components of evidence for guideline users

Have to find out and reorganize the appropriate components of evidence

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Background

It is necessary for guideline users as well as guideline developers to define the comparable essential information and standardize the illustration components of evidence table between organizations.

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Objective

The aim of this study is to find out and compare the differences among the components of evidence table in each organization.

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Method

To compare the component of evidence table we reviewed evidence tables

- the Cochrane Collaboration; GRADEpro
- SIGN (Scottish Intercollegiate Guidelines Network)
- NICE (National Institute for Health and Clinical Excellence)
- WHO (World Health Organization)

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Method

- Analyze the evidence tables of intervention studies.
- All the components are arranged by matrix and compared by each component among organizations.
- The information comprising the evidence tables can be divided into two parts.
  - One is for quality assessment of evidence and the other is for summary of findings

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Method

Followings are categorized with the same component in quality assessment of evidence table.

- Number of studies (Ref) and volume of evidence
- Limitations and internal validity and quality (flaws)
- Consistency and inconsistency
- Other considerations and other factors

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Method

Followings are categorized with the same component in summary of findings table.

- Effect size, relative/absolute effect, and NNT/NNH/odds ratios
- Number of patients and number of participants
- Quality of evidence (GRADE), evidence level, and quality (or study quality)
- Comments, general comments, and additional comments
- Bibliographic citation, bibliographic reference, and refe

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Result

Cochrane Collaboration 1 : GRADE evidence profiles [GRADEpro]

Question:
Settings:
Bibliography:

Quality assessment							Summary of findings					Importance
							No of patients		Effect		Quality	
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations	rofecoxib	control	Relative (95% CI)	Absolute		
Acute myocardial infarction in case control studies (exposure mean 5 years[1]; assessed with: administrative databases)												

- Question/ Settings/ Bibliography
- Quality assessment
  - No. of studies/ Design/ Limitations/Inconsistency/ Indirectness/ Imprecision/ Other considerations
- Summary of Finding
  - No. of patients (Intervention, Control)/ Effect (Relative, Absolute) / Quality
- Importance

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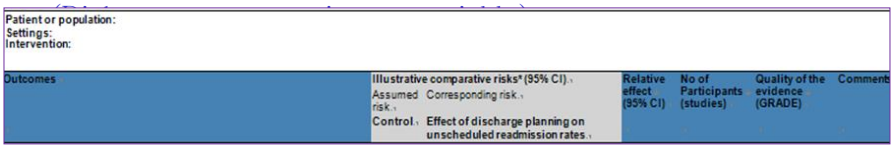
Result

Cochrane Collaboration 2 : Summary of Findings table [GRADEpro]



Patient or population: Settings: Intervention:					
Outcomes	Illustrative comparative risks* (95% CI) Assumed risk Control	Corresponding risk Effect of discharge planning on unscheduled readmission rates	Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments

- Patient or population/ Settings/ Intervention
- Outcomes
- Illustrative comparative risks (95% CI) – Assumed risk/ Corresponding risk Relative effect (95% CI)
- No. of participants (studies)
- Quality of the evidence (GRADE)
- Comments

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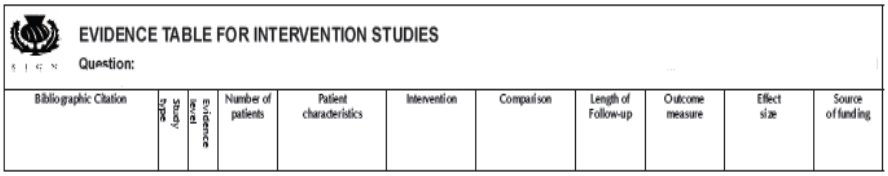
Result

SIGN 1 : Evidence table for intervention studies (Annexes)



EVIDENCE TABLE FOR INTERVENTION STUDIES

Question:

Bibliographic Citation	Study type	Evidence level	Number of patients	Patient characteristics	Intervention	Comparison	Length of Follow-up	Outcome measure	Effect size	Source of funding

- Bibliographic citation
- Study type/ Evidence level/ Number of patients
- PICO – Patient characteristics/ Intervention / Comparison/ Length of follow-up/ Outcome measure
- Effect size
- Source of funding
- General comments

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Result

SIGN 2-1 : Methodology Checklist (Annex D)

(Components analyzed as a proxy of quality assess

METHODOLOGY CHECKLIST 2: RANDOMISED CONTROLLED TRIALS			
Study identification (Include author, title, year of publication, journal title, pages)			
Guideline topic:	Key Question No:		
Checklist completed by:			
SECTION 1: INTERNAL VALIDITY			
In a well conducted RCT study...		*In this study this criterion is:*	
1.1	The study addresses an appropriate and clearly focused question.	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
1.2	The assignment of subjects to treatment groups is randomised	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable

- Key question
- Limitations of design (9 items)
  - Lack of randomization/ allocation concealment/ blinding
  - Incomplete accounting of patients and outcome events
  - Other limitations

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Result

SECTION 2: OVERALL ASSESSMENT OF THE STUDY		
2.1	How well was the study done to minimise bias?	+
2.2	If coded as +, or - what is the likely direction in which bias might affect the study results?	Overestimate of effect.

- Bias/ Overall effect/ Applicability (4 items)

SECTION 3: DESCRIPTION OF THE STUDY *(The following information is required to complete evidence tables facilitating cross-study comparisons. Please complete all sections for which information is available).* **PLEASE PRINT CLEARLY**		
3.1	How many patients are included in this study? *Please indicate number in each arm of the study, at the time the study began.*	24;12 immediate treatment and 12 deferred.

- No. of patients
- PICO – Patient characteristics/ Intervention / Comparison/ Length of foll ow-up/

  Outcome measure
- Size of effect
- Sources of funding
- Relationship to the key question (9 items)

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Result

SIGN 2-2 : Considered judgement form (Annexes)

(Components analyzed as a proxy of quality assess

CONSIDERED JUDGEMENT FORM	
Key question: What is the evidence that cardiovascular risk in patients with Type 2 diabetes and nephropathy can be reduced by specific interventions?	Evidence table ref: 3
1. **Volume of evidence** Comment here on any issues concerning the quantity of evidence available on this topic and its methodological quality.	

- Key question/ Volume of evidence/ Consistency
- Applicability/ Generalisability/ Clinical Impact/ Other factors
- Evidence statement (level)/ Recommendation (Grade)

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Result

NICE 1 : Evidence tables (Appendix k)

Bibliographic reference [1]	Study type [2]	Study quality [3]	Number of patients [4]	Patient characteristics [5]	Intervention [6]	Comparison [7]	Length of follow-up [8]	Outcome measures and effect size [9]	Source of funding [10]	Additional comments [11]

- Bibliographic reference
- Study type/ Study quality/ Number of patients/ Length of fol low-up
- PICO – Patient characteristics/ Intervention / Comparison/ O utcome

  measures and effect size
- Source of funding

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Result

NICE 2 : Modified GRADE profile (Appendix L)-Evidence pr

Quality assessment							Summary of findings				
Clinical evidence											
No. of studies	*Design*	*Limitations*	*Inconsistency*	*Directness*	*Imprecision*	*Other considerations*	*Intervention*	*Control*	*Relative effect*	*Absolute effect*	*Quality*
Outcome											
Outcome											
Outcome											
Economic evidence											
Study	*Limitations*	*Applicability*	*Other comments*				*Incremental cost (£)*	*Incremental effects*	*ICER*	*Uncertainty*	

- Quality assessment (Clinical evidence)
  - No. of studies/ Design/ Limitations/ Inconsistency/ Directness/ Imprecision/
    Other consideration
- Summary of Finding
  - Intervention/ Control/ Relative effect/ Absolute effect/ Quality
- Economic evidence
  - Study/ Limitations/ Applicability/ Other comments
  - International cost/ International effects/ ICER/ Uncertainty

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Result

WHO 1 : Evidence summary (Example)

Question: Should depressed patients be treated with SSRIs or tricyclics?

Setting: Primary care

Baseline risk: Moderately depressed adult patients

Reference: The choice of antidepressants for depression in primary care. North of England evidence-based guideline development project, 1997

SSRIs vs tricyclics

Outcome: **Depression severity** (measured with Hamilton Depression Rating Scale after 4 to 12 weeks)							
Studies	Design	Quality	Consistency	Directness	SD*	SA*	PB*
8 trials Citalopram 38 trials Fluoxetine 25 trials Fluvoxamine	RCTs	No serious flaws	No important inconsistency	Some uncertainty about directness (outcome measure)	No	No	No

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Result

WHO 2 : Balance sheet (Example)

Question: Should depressed patients be treated with SSRIs or tricyclics?

Setting: Primary care

Baseline risk: Moderately depressed adult patients

Reference: The choice of antidepressants for depression in primary care, North of England evidence-based guideline development project, 1997

Outcome	SSRI	Tricyclics	Effect		Quality	Relative importance
			Relative (95% CI)	NNT		
Depression severity	5044 patients	4510 patients	WMD 0.034 (-0.007 to 0.075)	No difference		
Transient side effects	1948/7032 (28%)	2072/6334 (33%)	RRR 0.13 (0.05 to 0.20)	20		
Poisoning fatalities*	1/100,000 per year of treatment	58/100,000 per year of treatment	RRR 98% (97% to 99%)	1754		

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Result

Compare evidence tables
(Quality assessment or risk of bias table)

The information comprising the evidence tables of 4 organizations can be divided into two separate compo nents.

- quality assessment of evidence
- summary of findings (or results)

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Result

Compare evidence tables (quality assessment of evidence)

① Cochrane	② SIGN		③ NICE	④ WHO
No of studies	Volume of evidence		No. of studies	No of studies(Ref)
Design		Methodology check list by design	Design	Design
Limitations		Internal validity (limitation)	Limitations	Quality (flaws)
Inconsistency	Consistency		Inconsistency	Consistency
Indirectness			Directness	Directness
Imprecision			Imprecision	
Other considerations (publication bias)	Other factors*	Overall assessment (bias, applicability)	Other considerations *	Publication bias
	Applicability			

-GRADE Evidence profiles
-Quality assessment

-Considered judgement Form

-Methodology checklist (Annex D)

-Modified GRADE profile
-Evidence profile

-Evidence summary (Example)

* Other factors : Generalisability, Clinical impact, Evidence statement, Recommendation

* Economic evidence: Study/ Limitations/ Applicability/ Other comments/ International cost/ International effects/ ICER/ Uncertainty

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Result

Compare evidence tables (PICO & Summary of findings or results)

① Cochrane	② SIGN	③ NICE	④ WHO
No of studies			No of studies
Outcomes	Outcome measure	Outcome measures and effect size -Relative effect -Absolute effect (NNT, NNH, Odds ratios)	Outcome
Assumed risk			
Corresponding risk			
Relative effect	Effect size		Relative effect(95%CI) (NNT)
Absolute effect (if needed)			
No of participants (or studies)	Number of patients	Number of patients	Number of studies or participants
Quality of evidence (GRADE)	Evidence level	Quality (study quality)	Quality
Comments	General comments	Additional comments	
	Bibliographic citation	Bibliographic reference	Reference
	Study type	Study type	
	Patient characteristics	Patient characteristics	
	Intervention	Intervention	
	Comparison	Comparison	
	Length of Follow-up	Length of Follow-up	
	Source of funding	Source of funding	
Importance	*-Evidence table for intervention studies(Annexes)*	*-Evidence tables (Appendix K)*	Relative Importance

-GRADE Evidence profil

-Balance sheet(Examp

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Conclusion

Standardization of the components of evidence table

- ✓ can be improve the quality of guidelines
- ✓ can be compare the evidence summary between organizations and research groups
- ✓ can be assist the important patient decisions

To help proper decision making for guideline users
it is necessary to provide appropriate important information using standardized evidence table.

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Conclusion

In conclusion
evidence table needs to improve standardiz ation
of the illustration components
having core essential information
not only brief study characteristics and assessment of risk of bias
but also summary of findings or results
for achieving the best clinical goals.

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Implications for guideline developers/users

The evidence table is very useful tool for summarizing the evidence, increasing the quality of guideline, and providing useful information for both guideline developer and users.

Therefore international standardization regarding the components of evidence table is needed in the near future.

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Reference

- WHO. Guidelines for WHO guidelines. 2003. 1
- SIGN. SIGN 50. A guideline developer's handbook (Revised edition). January 2008
- NICE. The guidelines manual. January 2009
- GRADEpro. [Computer program]. Version 3.2 for w indows.

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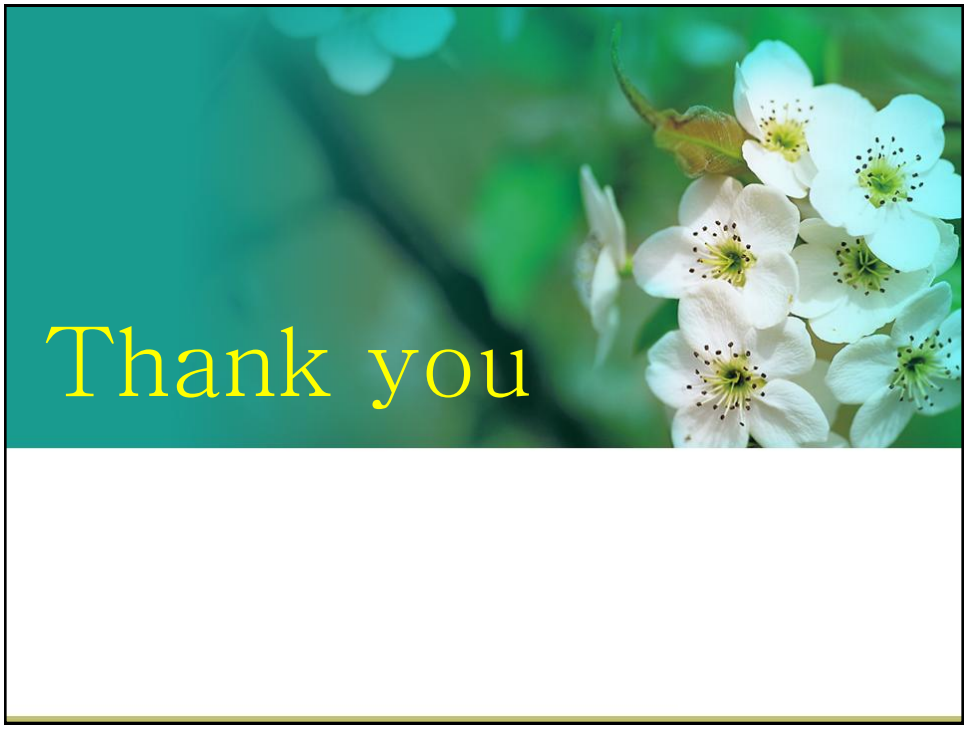
Thank you