平成 25 年 12 月 15 日 東京北社会保険病院 総合診療科 南郷 栄秀 http://spell.umin.jp

目標: GRADE system を理解し, 個々の論文から Summary of Findings table と GRADE evidence profile を作成することができる.

 課題:あなたは診療ガイドライン作成委員である.以下の4つのクリニカルク エスチョンのうち1つを選び,家のグループのメンバーと協力して, GRADE system に従い,GRADE profiler を用いて,Summary of Findings table と GRADE evidence profile を作りなさい.実践大会当日は、その作 成手順について発表を行う.
 注)GRADE profiler とは、GRADE working group が無償で提供している

注) OKADE profiler とね, OKADE working group パー無償 C促展している 診療ガイドライン作成ソフトである. GRADE working group のサイト (<u>http://ims.cochrane.org/revman/other-resources/gradepro/download</u>) からダ ウンロード・インストールした上で作業する.

クリニカルクエスチョン:

- 1. COPD 患者は抗菌薬の予防投与を行うべきか(1COPD\_ProphylacticABx).
- 2. 小児の下痢にプロバイオティクスを使用するべきか(2ChildrenDierrhea\_Proviotics)
- 3. 糖尿病性足感染は通常治療に G-CSF を加えた方がいいか. (3DiabeticFootInfection\_G-CSF)
- 4. 急性心筋梗塞を起こした患者は酸素を吸入した方がいいか. (4AMI\_Oxgen)

進め方:

①家ごとに、他の家と重なることのないように、4つのテーマのうち1つを選ぶ.

②Google site 上に、クリニカルクエスチョンごとのフォルダが作成されている。各フォルダには、クリニカルクエスチョン (PICO で示したもの、RevMan を用いて作成した Forest plot と Funnel plot 付き)、PICO に従って検索した結果集められた原著論文、原著論文をもとに作成されたデータ入力済み RevMan ファイルが入っている。

注) RevMan (Review Manager) とは, Cochrane Collaboration が無償で提供しているシ ステマティックレビューの作成ソフト (<u>http://ims.cochrane.org/revman</u>) である.

- ③3 ページ以降の手順に従い、インストールした GRADE profiler を用いて、家ごとに選んだ クリニカルクエスチョンの RevMan ファイルを import する. 家のメンバーで相談しアウト カムごとにバイアスの評価 (Downgrade/Upgrade) を行い、その結果を入力した上で、 Summary of Findings table と GRADE evidence profile を作成する.
- ④完成した Summary of Findings table (ファイル名: "SoF\_家の名前") と GRADE evidence profile (ファイル名: "GRADE\_EP\_家の名前") を南郷にメールで提出する.
- ⑤12月10日(火)に一度,進捗状況を南郷に報告すること.

GRADE system についての詳細な解説は、以下のスライドを参考にするとよい. http://homepage3.nifty.com/aihara/how\_to\_use\_grade\_aihara\_20120426.ppt 特に、Downgrade/Upgrade については、スライド 33~69 で解説されている. 作業に必要な Grade profiler の使用法は、以下の url に説明がある. http://homepage3.nifty.com/aihara/GRADEproHelp.html

Risk of bias の bias 項目にはいくつかのバージョンがあるが、本課題では以下の項目で評価する.

- 1. Random sequence generation (selection bias)
- 2. Allocation concealment (selection bias)
- 3. Blinding of patients?
- 4. Blinding of providers?
- 5. Blinding of data collectors?

- 6. Blinding of outcome adjudicators?
- 7. Blinding of data analysts?
- 8. Incomplete outcome data addressed?
- 9. Free of selective reporting?
- 10. Free of other bias?
- 11. Intention to treat analysis?

Risk of bias の評価について, 詳しくはコクランハンドブックの「Table 8.5.c: Criteria for judging risk of bias in the 'Risk of bias' assessment tool」を参照のこと. 以下に説明がある. <u>http://hiv.cochrane.org/sites/hiv.cochrane.org/files/uploads/Ch08\_Bias.pdf</u>

EBM 実践大会は, pES club で1年間 EBM を学んだ集大成となるものである.これまでに 学んだこと全てを活用して取り組むこと.課題を進める上で不明な点,困ったことなどが生 じた場合には,早めにメーリングリスト上か,南郷に直接質問すること.

## 【GRADE system 全体図】



# 課題作成手順

①以下の url から GRADE profiler をダウンロードし、インストールする. http://ims.cochrane.org/revman/other-resources/gradepro/download



# ②GRADE profiler を開いたら、"New profile"をクリックする.



③タイトルを付けて保存する.

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# ④ "File-Import Form...-Review Manager file"をクリックする.

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⑤家で選んだクリニカルクエスチョンのフォルダにある Review Manager 5 file を選択して開く.



# ⑥以下のように表示されるので, "OK"をクリックする.

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⑦左カラムに表示された profile をクリックすると,右にその内容が表示される.

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a in riepanir ta	pieces in anicougu	Question	Should Heparin vs placebo be us	ed for anticoagulation?	Bibliography (syste	imatic reviews):	-	
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	Heparin vs planeo for anticoagulation	SoF title	Heparin compared to placebo for	anticoagulation	Dickinson HO, Br	yant A, Schünemann H.		
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			64.5%			45 fewer per 1000 (fro more)	m 97 fewer to 13	
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# ⑧Risk of Bias をクリックするとこのような表示になる.

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⑨上から3段目の "Study design"のところの "--choose--"をプルダウンして, "randomized trials"を選ぶ

Profiles tree «	C_Edit						
Parenteral anticoaguidation in patients     Heppainv a placebo for anticoagui     Mortality at 12 months     Mortality at 12 months - Non-s     Mortality at 12 months - Small     Mortality at 24 months - Small     Mortality at 24 months     Symptomatic VTE     Major bleeding     Minor bleeding		Name of outcome: Mont. Assessed/measured with No of studies: 8 Length of follow up: The edition until your of contributing	ality at 12 months	Short name ose wiced trials oppear empty of studies Ouality of evides	Inportance ··· ···	3	
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⑩すると、1番目の outcome についての、"Downgrade quality of evidence"と "Upgrade quality of evidence"の項目が現れる.

Parenteral anticoaguiation in patienti Heparin v placebo for anticoagui Mortality at 12 months Mortality at 12 months - Small Mortality at 24 months Mortality at 24 months Mortality at 24 months Mortality at 24 months Mortality at 22 mon	Name of Assessed/mee No Length of Sowingray	outcome Mortality at 12 months sured with f studies: 8 () () () te quality of evidence Visk of bias () opisitency	Short name 로 고 고 고 고 고 고 고 고 고 고 고 고 고 고 고 고 고 고	Importance: ・ ・ 東		
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Pro	ofile: Heparin vs placebo for anticoa	ulation				
Mortal	ity at 12 months   8 studies					
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	Patients (Heparin)	Control (placebo)	Relative effect	Abr	solute effect	Quality
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Mortal	ity at 12 months - Non-small cell lung	cancer   6				
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⑪Downgrade する 5 項目を1 つずつプルダウンして選んでいく.

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"serious(-1)"や"very serious(-2)"を選ぶと, footnote にコメントを入力するの が義務であるとのアラートが表示されるが,本課題では無視して"Save"ボタ ンを押して先に進んで良い.

12全部選択し終わるとこのようになる. Profile の表に 5 項目の Downgrade の評価が入り,最終的な Quality が表示される.

Profiles tree «	Q_ Edit						
Parenteral anticoagulation in patient		Name of outcome: Mr	ortality at 12 months	Short name	Importance:	国	
Heparin vs placebo for anticoagu     Mortality at 12 months		A	ontainty of 12 months	CHOIC Hanne-	importance.		
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		No of studies: 8	章 투 Study design: random	ised trials * 早			
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以上で1つ目の outcome についての評価の入力が完了する.

<sup>(13)</sup>2 つ目の outcome をクリックして, 同様に Downgrade/Upgrade を入力してい

Parenteral entire pulation in patients								
Heparin vs placebo for anticos					100000	8		
Heparin vs placebo for anticou		Name of outcome: Morta	ality at 12 months - Non-small o	ell lung canci Short name:	Importance:	····		
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Mortality at 24 months		Length of follow up:	- 0		亭			
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	Profile: Heparin vs placebo for	r anticoagulation					
	Mortality at 12 months   8 studies						
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	randomised trials	serious	no serious inconsistency	no serious indirectness	no serious imprecision	none *	
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	Mortality at 12 months - Non-small	cell lung cancer   6 stur	dies	1			
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<sup>15</sup> "Export as"の "Summary of Findings table"を "Save as Image"で保存する. ファイル名は、 "SoF 家の名前(英語で)"とすること.

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Heparin compared to placebo for anticoagula attent or population: patients with anticoagulator settings: comparison: placebo huitcomes Antality at 12 months	tion Illustrative comparative risks* (95% CI) Assumed risk Corresponding risk Placebo Heparin Study population S57 per 1000	Relative effect (95% CI) RR 0.93 (0.85 to 1.02) RR 0.96	No of Participants (studies) 2530 (8 studies) 2169	Quality of the evidence Comment (GRADE) #888 moderate <sup>1</sup>	×	JW of Findings morecision 39 fewer per 10 45 fewer per 100	Other considerationa none Abaokrie effect 000 (from 84 fewer to 11 mote) 00 (from 97 fewer to 13 mo	Quality Quality MODERATE
Heparin compared to placebo for anticoagula attent or population: patients with anticoagulator settings: Comparison: placebo Duttoomes Aortality at 12 months Aortality at 12 months - Non-small cell lung ancer	tion  Illustrative comparative risks* (85% CI) Assumed risk Corresponding risk Placebo Heparin Study population S57 per 1000 618 per 1000 (474 to 568)  Moderate  454 per 1000 600 per 1000 (548 to 658)  Study population 513 per 1000 492 per 1000	Relative effect (95% CI) (0.6% to 1.02) RR 0.93 (0.6% to 1.02) (0.6% to 1.07)	No of Participants (studies) 2530 (8 studies) 2169 (6 studies)	Quality of the evidence Comments (GRADE) eeee moderate <sup>1</sup>		JW of Findings sission imprecision 39 fewer per 10 45 fewer per 100 scision	Other considerations none Absolute effect 000 (from 94 fewer to 11 more) 00 (from 97 fewer to 13 more) Other considerations	Importance     Quality     Importance     Importance
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leparin compared to placebo for anticoagula attent or population; patients with anticoagulator ettings: intervention; Hoparin omparison; placebo uucomes fortality at 12 months fortality at 12 months - Non-small cell lung ancer	tion Illustrative comparative risks* (35% CI) Assumed risk Corresponding risk Placebo Keparin Study population S57 per 1000 (474 to 568) Moderate 454 per 1000 (568 per 1000) (546 to 565) Study population 513 per 1000 492 per 1000 resplanation was provided	Relative effect (95% CI) (0.85 to 1.02) (0.85 to 1.02) RR 0.96 (0.85 to 1.07)	No of Participants (studies) 2530 (8 studies) 2169 (8 studies)	Quality of the evidence Comment (GRADE) eeee moderate <sup>1</sup>		W of Findings imprecision 39 fewer per 10 45 fewer per 100 coston	Other considerations none Absolute effect 200 (from 94 ferwer to 11 more) 20 (from 97 ferwer to 13 mo Other considerations	Importance Quality Couliny MODERATI Importance

<sup>10</sup>続いて, "GRADE evidence profile"も同様に"Save as Image"で保存する. ファイル名は, "GRADE\_EP\_家の名前(英語で)"とすること.

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Summary of Findings table (ファイル名: "SoF\_家の名前")と GRADE evidence profile (ファイル名: "GRADE\_EP\_家の名前")を南郷に提出する.

#### Summary of Findings table とは、以下のような表である.

Heparin compared to placebo for anticoagulation	1					
Patient or population: patients with anticoagulation Settings: Intervention: Heparin Comparison: placebo						
Outcomes	Illustrative comparative risks* (95% CI) Assumed risk Corresponding risk Placebo Heparin		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
Mortality at 12 months	Study populatio	n	RR 0.93	2530		
	557 per 1000 518 per 1000 (474 to 568)		(0.85 to 1.02)	(8 studies)	moderate <sup>1</sup>	
	Moderate		_			
	645 per 1000	600 per 1000 (548 to 658)				
Mortality at 12 months - Non-small cell lung cancer	Study populatio	n	RR 0.96 (0.86 to 1.07)	2169 (6 studies)	⊕⊕⊕⊕ high	
	513 per 1000	492 per 1000 (441 to 549)				
	Moderate					
	593 per 1000	569 per 1000 (510 to 635)				
Mortality at 12 months - Small cell lung cancer	Study populatio	n	RR 0.86	361	***	
	773 per 1000 665 per 1000 (580 to 758) Moderate		(0.75 to 0.98)	(2 studies)	low <sup>1</sup>	
	753 per 1000	648 per 1000 (565 to 738)				
Mortality at 24 months	Study populatio	n	RR 0.92 (0.88 to 0.97)	1174 (5 studies)	eeee high	
	859 per 1000	790 per 1000 (756 to 833)				
	Moderate					
	831 per 1000	765 per 1000 (731 to 806)				
Symptomatic VTE	Study population	n	RR 0.55	2264 (7 studies)	0000 (	
	62 per 1000	34 per 1000 (23 to 50)	(0.37 10 0.82)		moderate <sup>1</sup>	
	Moderate					
	29 per 1000	16 per 1000 (11 to 24)				
Major bleeding	Study populatio	n	RR 1.3	2843	@@@@	
	19 per 1000 25 per 1000 (11 to 54)		(0.59 to 2.88)	(9 studies)	very low <sup>1</sup>	
	Moderate					
	7 per 1000	9 per 1000 (4 to 20)				
Minor bleeding	Study population		RR 1.05	2345 (7 abudias)	000	
	51 per 1000	54 per 1000 (38 to 74)	(0.75 to 1.46)	(/ studies)	low <sup>1</sup>	
	Moderate					
	27 per 1000	28 per 1000 (20 to 39)				

\*The basis for the assumed risk (e.g. the median control group risk across studies) is provided in footnotes. The corresponding risk (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

CI: Confidence interval; RR: Risk ratio;

GRADE Working Group grades of evidence

High quality: Further research is very unlikely to change our confidence in the estimate of effect. Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate. Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate. Very low quality: We are very uncertain about the estimate.

<sup>1</sup> No explanation was provided

### GRADE evidence profile とは、以下のような表である.

Author(s): Elie A Akl, Sameer Gunukula, Maddalena Barba, Victor E D Yosuico, Frederiek F van Doormaal, Saskia Kuipers, Saskia Middeldorp, Heather O Dickinson, Andrew Bryant, Holger Date: 2013-12-06 Question: Heparin vs placebo for anticoagulation Settings: Bibliography: Akl EA, Gunukula S, Barba M, Yosuico VE D, van Doormaal FF, Kuipers S, Middeldorp S, Dickinson HO, Bryant A, Schünemann H. Parenteral anticoagulation in patients with cancer who have no therapeutic or prophylactic indication for anticoagulation. Cochrane Database of Systematic Reviews [Year], Issue [Issue].

			Quality assessment				No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Heparin	Placebo	Relative (95% CI)	Absolute	Quality	Importance
Mortality	at 12 months	5			2. A	2		5); 10				
8 ra tr	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	735/1464 (50.2%)	594/1066 (55.7%)	RR 0.93 (0.85 to 1.02)	39 fewer per 1000 (from 84 fewer to 11 more)	CODERATE	
								64.5%		45 fewer per 1000 (from 97 fewer to 13 more)		
Mortality	at 12 months	s - Non-smal	I cell lung cancer									
6 ri tr	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	617/1284 (48.1%)	454/885 (51.3%)	RR 0.96 (0.86 to 1.07)	21 fewer per 1000 (from 72 fewer to 36 more)	eeee High	
								59.3%		24 fewer per 1000 (from 83 fewer to 42 more)		
Mortality	at 12 months	s - Small cell	lung cancer									
2	randomised trials	serious <sup>1</sup>	serious <sup>1</sup>	no serious indirectness	no serious imprecision	none <sup>1</sup>	118/180 (65.6%)	140/181 (77.3%)	RR 0.86 (0.75 to 0.98)	108 fewer per 1000 (from 15 fewer to 193 fewer)	eeoo Low	
								75.3%		105 fewer per 1000 (from 15 fewer to 188 fewer)		
Mortality	at 24 months	5										
5	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	461/586 (78.7%)	505/588 (85.9%)	RR 0.92 (0.88 to 0.97)	69 fewer per 1000 (from 26 fewer to 103 fewer)	BBBB HIGH	
								83.1%		66 fewer per 1000 (from 25 fewer to 100 fewer)	]	
Symptom	atic VTE											
7	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	38/1338 (2.8%)	57/926 (6.2%)	RR 0.55 (0.37 to 0.82)	28 fewer per 1000 (from 11 fewer to 39 fewer)	eeeo Moderate	
								2.9%		13 fewer per 1000 (from 5 fewer to 18 fewer)		
Major ble	eding			i.	<u>.</u>							
9	randomised trials	serious <sup>1</sup>	serious <sup>1</sup>	no serious indirectness	no serious imprecision	reporting bias <sup>1</sup>	30/1624 (1.8%)	23/1219 (1.9%)	RR 1.3 (0.59 to 2.88)	6 more per 1000 (from 8 fewer to 35 more)	COOO VERY LOW	
								0.7%		2 more per 1000 (from 3 fewer to 13 more)		
Minor ble	eding		1	1		-						
7	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	reporting bias <sup>1</sup>	85/1365 (6.2%)	50/980 (5.1%)	RR 1.05 (0.75 to	3 more per 1000 (from 13 fewer to 23 more)	eeoo Low	
								2.7%	1.40)	1 more per 1000 (from 7 fewer to 12 more)		

<sup>1</sup> No explanation was provided