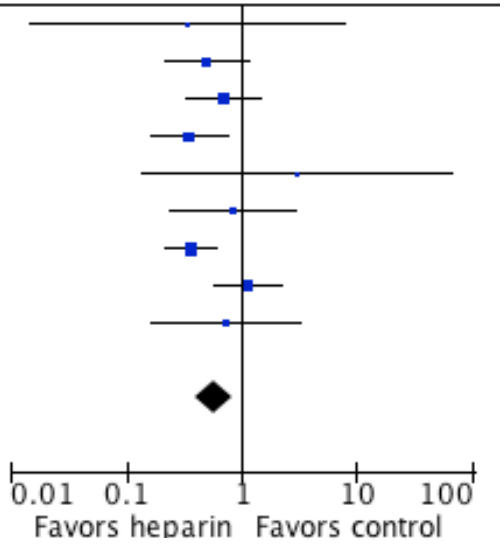
Other factors

Imprecision
Inconsistency

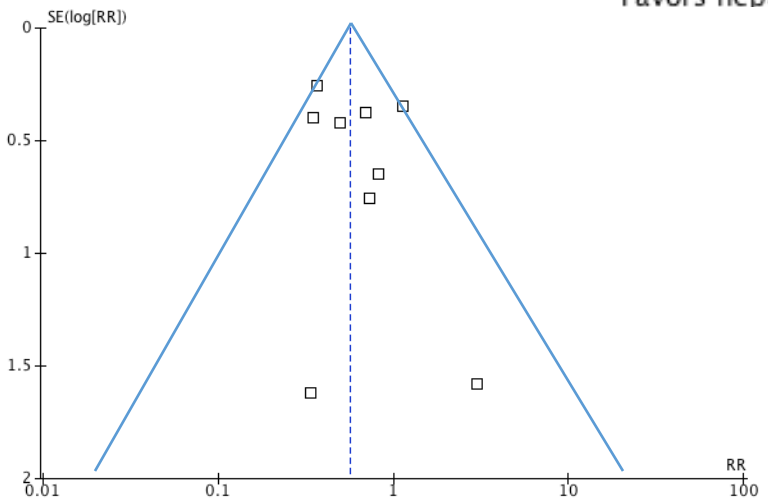
Study or Subgroup	Heparin Events	Heparin Total	Control Events	Control Total	Weight	Risk Ratio M-H, Random, 95% CI
Altinbas 2004	0	42	1	42	1.2%	0.33 [0.01, 7.96]
Agnelli 2009	11	769	11	381	13.4%	0.50 [0.22, 1.13]
Perry 2010	11	99	14	87	15.8%	0.69 [0.33, 1.44]
Pelzer 2009	8	160	22	152	14.6%	0.35 [0.16, 0.75]
Weber 2008	1	10	0	10	1.3%	3.00 [0.14, 65.90]
Sideras 2006	4	68	5	70	6.7%	0.82 [0.23, 2.94]
Agnelli 2012	20	1608	55	1604	24.6%	0.36 [0.22, 0.60]
van Doormaal 2011	16	244	15	259	17.4%	1.13 [0.57, 2.24]
Kakkar 2004	3	190	4	184	5.1%	0.73 [0.16, 3.20]
Total (95% CI)		**3190**		**2789**	**100.0%**	**0.57 [0.40, 0.81]**
Total events	74		127			

Heterogeneity: $Tau^2 = 0.07$; $Chi^2 = 10.50$, df = 8 (P = 0.23); $I^2 = 24\%$

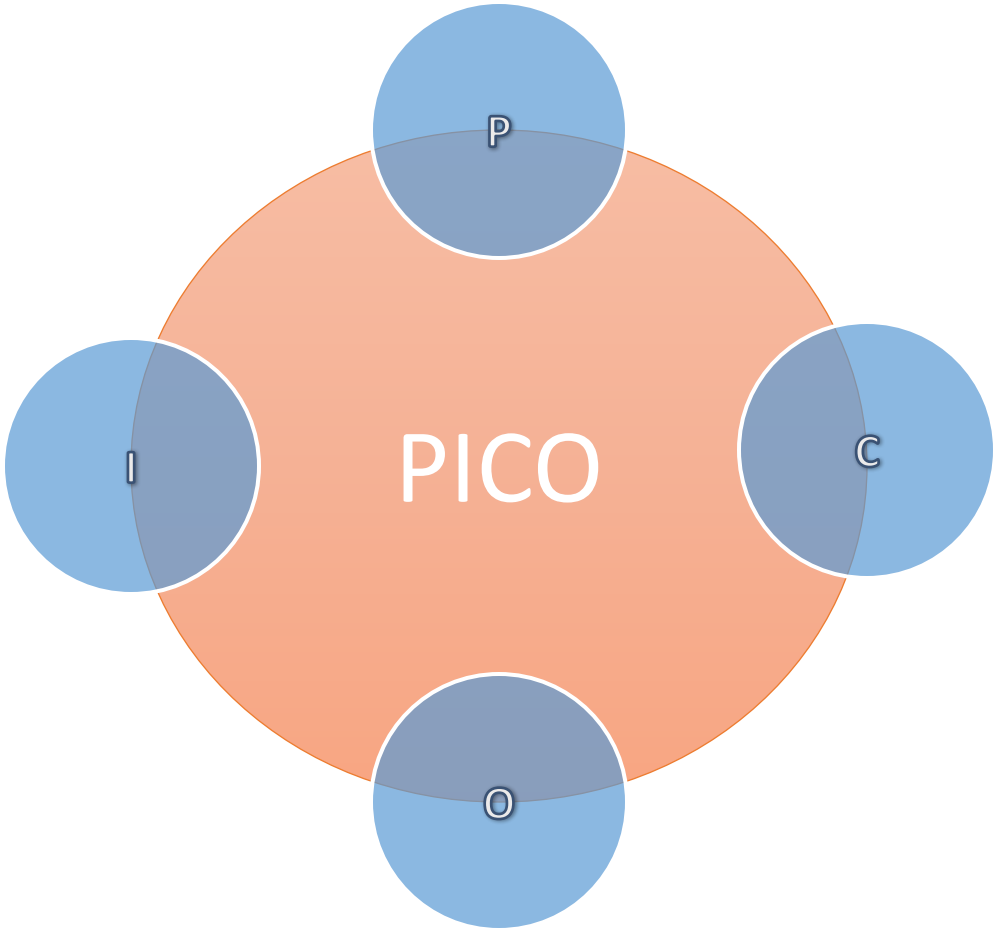
Test for overall effect: Z = 3.13 (P = 0.002)



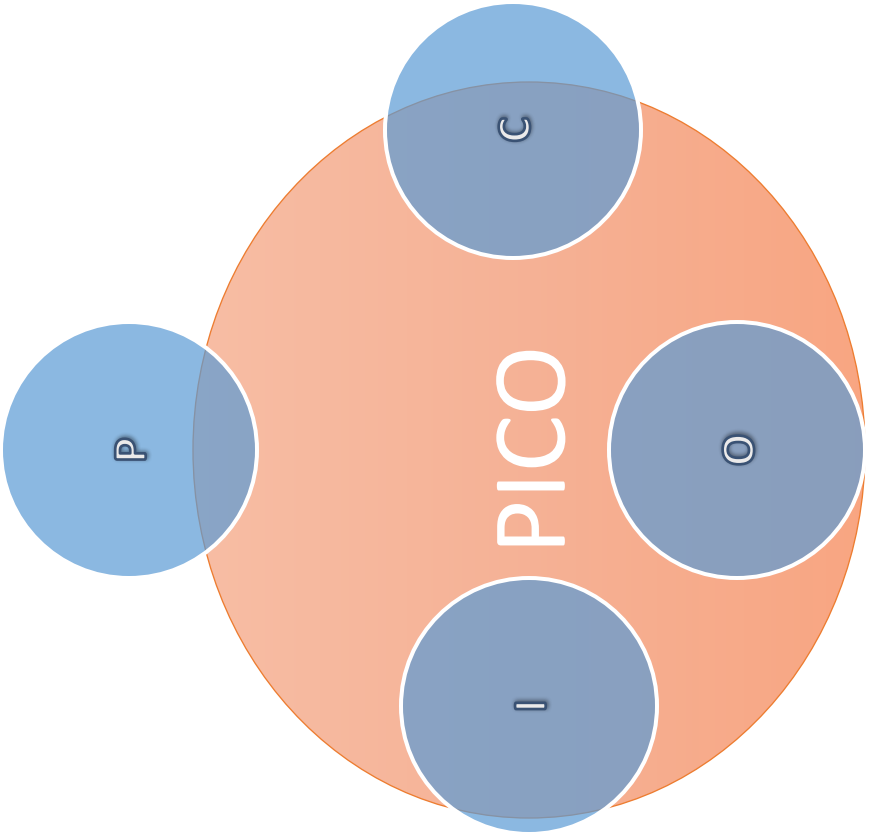
Publication bias



Relation between PICO and available evidence



ndirectness



High confidence in the effects

Table 1. Summary of Findings Table Showing the Relative Risks and Absolute Effects over 12 Months for Each Important Outcome after Treatment with a Low-Molecular-Weight Heparin in Patients Receiving Chemotherapy for Cancer.*

Outcome after 12 Months	Participants	Relative Risk (95% CI)	Anticipated Absolute Effect		Quality of Evidence (GRADE) and Comments†
			Risk without LMWH	Risk Difference with LMWH (95% CI)	
	no. (no. of studies)		*no. of events per 1000 patients*		
Death	6245 (10)	0.94 (0.88–1.00)	501	30 fewer (60 fewer to 0 more)	
Symptomatic VTE	5979 (9)	0.57 (0.40–0.81)	46	20 fewer (27 fewer to 9 fewer)	High-quality evidence; the data are combined for pulmonary embolism and symptomatic deep venous thrombosis
				fewer to 9 more)	
				5 more (3 fewer to 15 more)	

No downgrading:
No serious Risk of bias
No serious inconsistency
No serious imprecision
Undetected publication bias
No serious indirectness
Quality remains high

Akl & Schünemann, New Engl J Med, 2012

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Death	6245 (10)	0.94 (0.88–1.00)	501	30 fewer (60 fewer to 0 more)	Moderate-quality evidence owing to imprecision and concern about publication bias; a survival analysis based on data from 9 studies shows a hazard ratio of 0.83 (95% CI, 0.72–0.95)
Symptomatic VTE	5979 (9			(27 fewer o 9 fewer)	High-quality evidence; the data are combined for pulmonary embolism and symptomatic deep venous thrombosis
Major bleeding	651			ore (5 fewer o 9 more)	Moderate-quality evidence owing to imprecision; the increase may be acceptable to patients, given that VTE, which occurs more frequently, may be equally unpleasant
Minor bleeding	6020 (			more (3 fewer to 15 more)	Moderate-quality evidence owing to imprecision; however, this outcome is unlikely to be critical for decision making

Combination of judgments: Reporting bias and imprecision

Akl & Schünemann, New Engl J Med, 2012

Interpreting the certainty of the evidence

Certainty rating	Definitions
⊕⊕⊕⊕ High	The panel is very confident that the true effect lies close to that of the estimate of the effect
⊕⊕⊕◯ Moderate	The panel is moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
⊕⊕◯◯ Low	The panel's confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
⊕◯◯◯ Very low	The panel has very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

Terminology - clarifications

- GRADE approach or system – interventions?
  - Prognosis, test accuracy, values and preferences
  - Describes GRADE's conceptual underpinnings
- GRADE criteria
  - Decis
- GRADE

GRADE

- Certainty in evidence
  - Involves assessing evidence transparently
  - Confidence in an estimate of effect, association?

s

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o

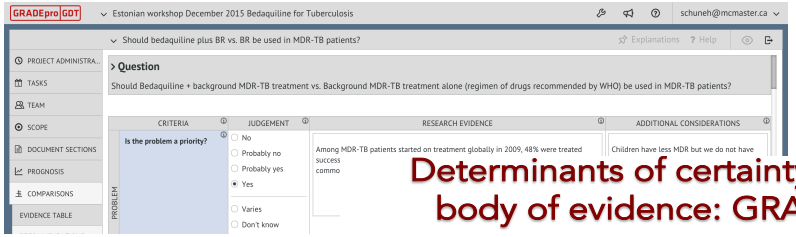
GRADE DECIDE Interactive Evidence to Decision Framework

For groups making recommendations

- Question
  - Details
  - Subgroups
  - Background
- Assessment
  - Criteria
  - Judgements
  - Research evidence
  - Additional considerations
- Conclusions
  - Type of recommendation
  - Recommendation
  - Justification
  - Implementation considerations
  - Monitoring and evaluation
  - Research considerations

Schünemann, JCE 2016

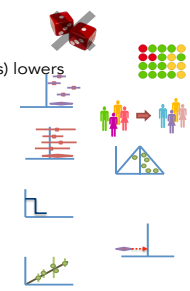
EtD frameworks



Determinants of certainty in a body of evidence: GRADE

- *Criteria* on which a
- *Judgements* that m each criterion
- *Research evidence*
- *Additional considei* explain each judgei

- A body of evidence starts as: high | ⊕⊕⊕⊕
- 5 factors that can lower quality
  1. Risk of bias criteria
     - Lack of randomization (observational studies) lowers confidence to low
  2. Inconsistency *(or heterogeneity)*
  3. Indirectness *(PICO and applicability)*
  4. Imprecision
  5. Publication bias
- 3 factors can increase quality
  1. large magnitude of effect
  2. opposing plausible residual bias or confounding
  3. dose-response gradient



GRADE-CERQual background:

Assessing our confidence in evidence from reviews of qualitative research

GRADE CERQual

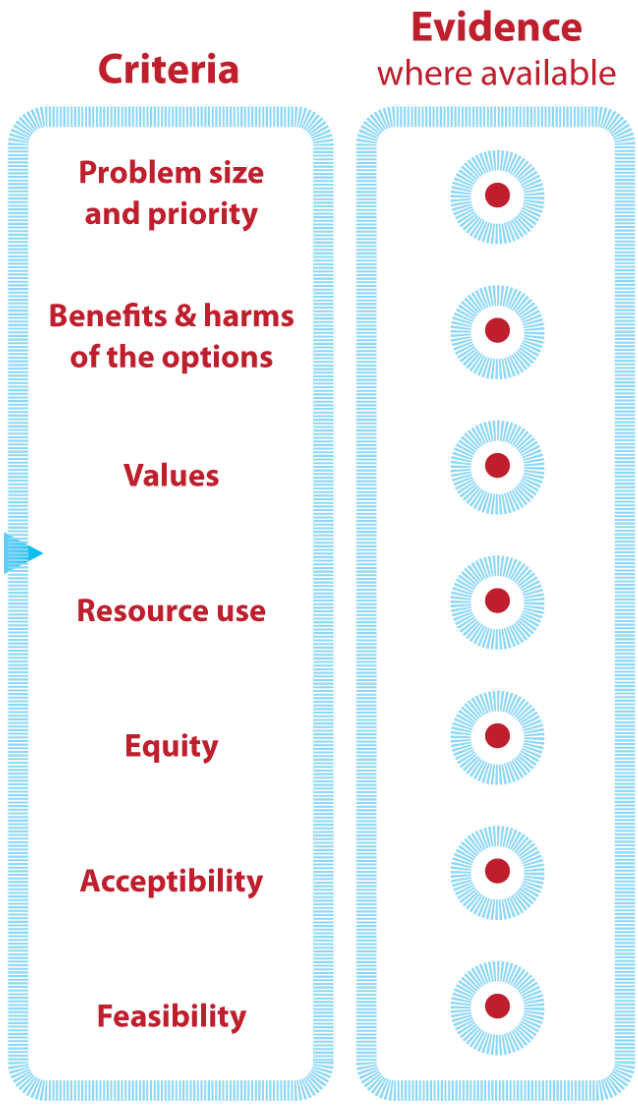
What is qualitative research?

- Attitudes and experiences
- «How» and «why» questions
- Words, not numbers

Background

- Evidence about *benefits and harms* routinely called for in guideline processes

- Decision makers are now also asking for evidence regarding other aspects of a decision



GRADE CERQual

Background

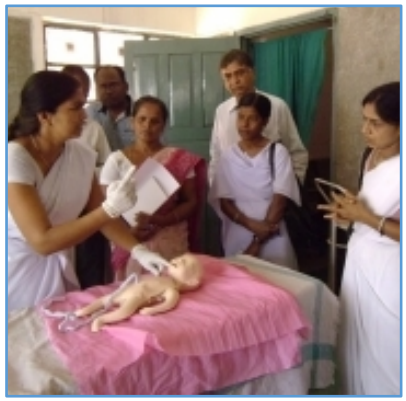
- In 2010, WHO initiated a guideline on health worker optimisation

- Which tasks for maternal and newborn care can be delivered by lower level health workers?

GRADE CERQual

Task-shifting: a complex issue

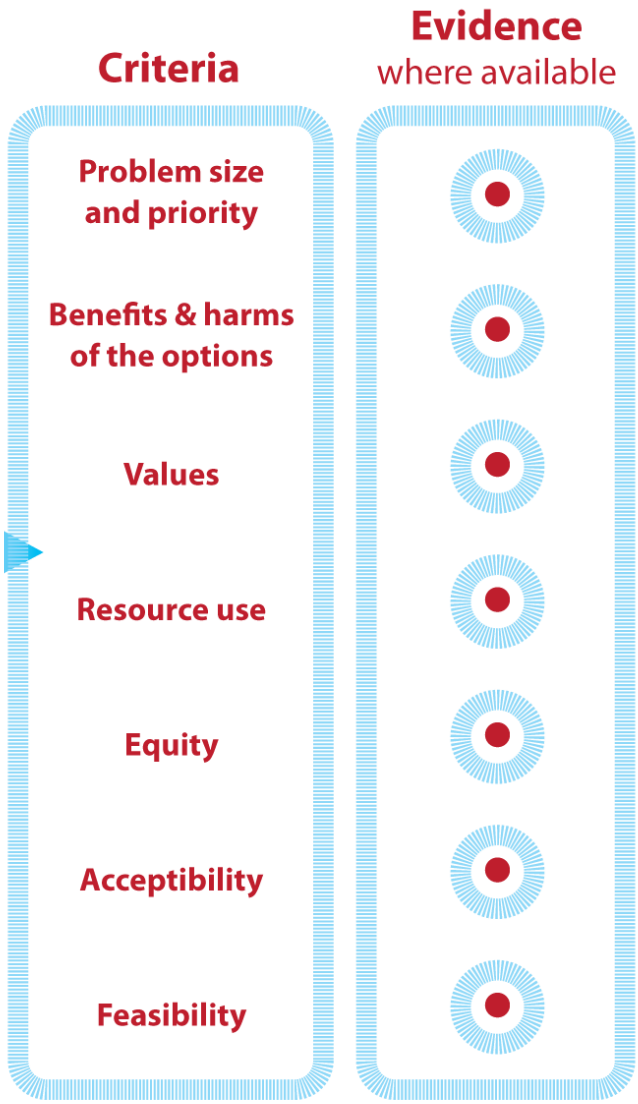
- Involves social, behavioural and organisational change
- Can involve shift in settings as well as shift in cadre
- Hailed as cheap solution
- Accused of being “second class care for the poor”
- Has met with resistance from professional organisations



GRADE CERQual

Different types of evidence called for

- WHO called for evidence about potential ***benefits and harms***
- But also wanted evidence on:
  - The ***acceptability*** of different options to patients, health workers and others
  - The ***feasibility*** of different options
  - The ***resources*** required



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Gathering evidence on acceptability and feasibility

- We wanted to bring the same level of rigour to these questions as to questions of effectiveness
- Decision to use reviews of qualitative research to answer these questions
- Methods to do this have matured and technical team members had relevant skills

GRADE CERQual

What sort of findings did the reviews give us?

Acceptability and feasibility influenced by:

- Health worker-recipient relationship
- Health worker-health worker relationship
- Role of local community
- Training and supervision
- Supplies
- Referral systems
- Transport
- Incentives

But no system for assessing the certainty of these findings

GRADE CERQual

CERQual developed

- Consultation with wide group of stakeholders, including researchers, methodologists, guideline developers
- Tested in multiple qualitative evidence syntheses

Relationship to GRADE

- CERQual is part of the GRADE Working Group – and shares the same aim as the GRADE tool used to assess the certainty of evidence of *effectiveness*

- However, CERQual is grounded in the principles of qualitative research

Assessing our certainty / confidence in the evidence

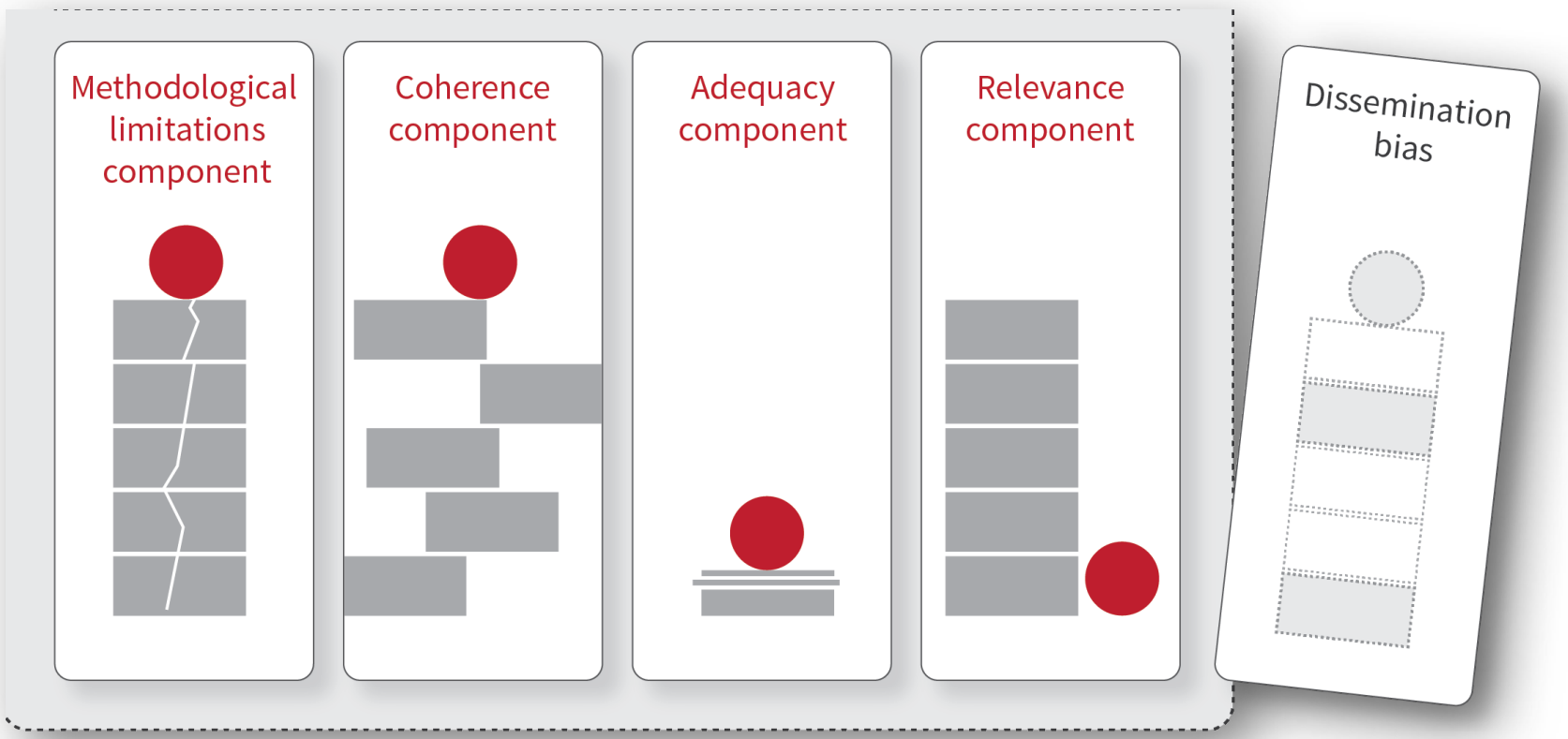
GRADE

GRADE CERQual

Assessing our certainty in the evidence

(Holger/Elena: Describe the components of GRADE. In the next slides, Claire will describe how CERQual has shared feature)

The CERQual components

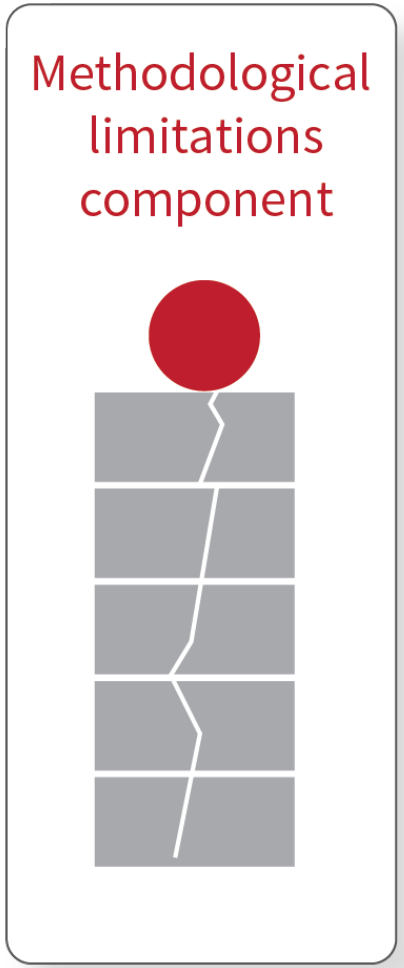


GRADE CERQual

Methodological limitations

- The extent to which there are *problems in the design or conduct* of the primary studies supporting a review finding

- (Similar to “risk of bias” in GRADE)



GRADE CERQual

Concerns about methodological limitations

We are less confident that the finding reflects the phenomenon of interest when the primary studies underlying a review finding are shown to have problems in the way they were designed or conducted

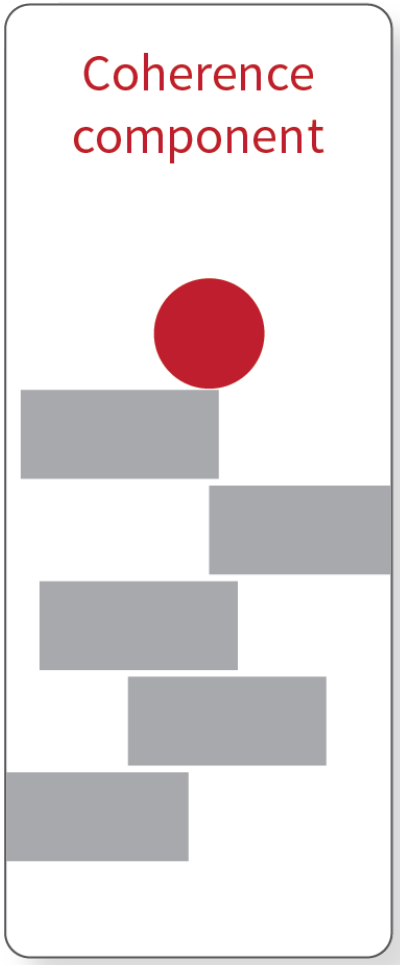
- A critical appraisal tool for qualitative studies should be used to make this assessment
- Currently no widespread agreement about the best tool – research agenda in place

GRADE CERQual

Coherence

- An assessment of how *clear and cogent the fit is* between the data from the primary studies and the review finding

- Similar to “inconsistency” in GRADE)



GRADE CERQual

Concerns about coherence

We are less confident that the finding reflects the phenomenon of interest when:

- Some of the data contradict the finding
- Some of the data are ambiguous

GRADE CERQual

Adequacy of data

- The degree of ***richness*** and ***quantity*** of data supporting a review finding

- (Similar to “imprecision” in GRADE)

GRADE CERQual

Concerns about adequacy

- We are less confident that the finding reflects the phenomenon of interest when the data underlying a review finding are ***not sufficiently rich*** or ***only come from a small number*** of studies or participants

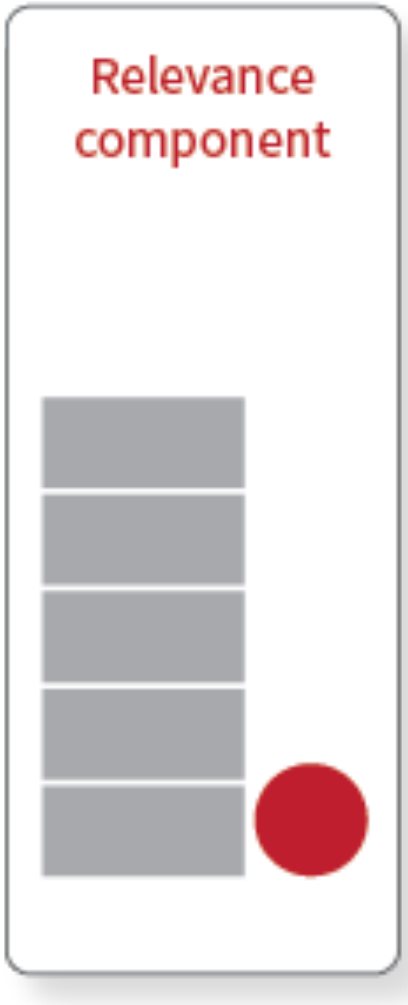
- Review authors need to make a judgement in the context of a specific review finding on what constitutes data that are not sufficiently rich or are drawn from too small a number of studies

GRADE CERQual

Relevance

- The extent to which the body of evidence from the primary studies supporting a review finding is ***applicable to the context*** specified in the review question

- (Similar to “indirectness” in GRADE)



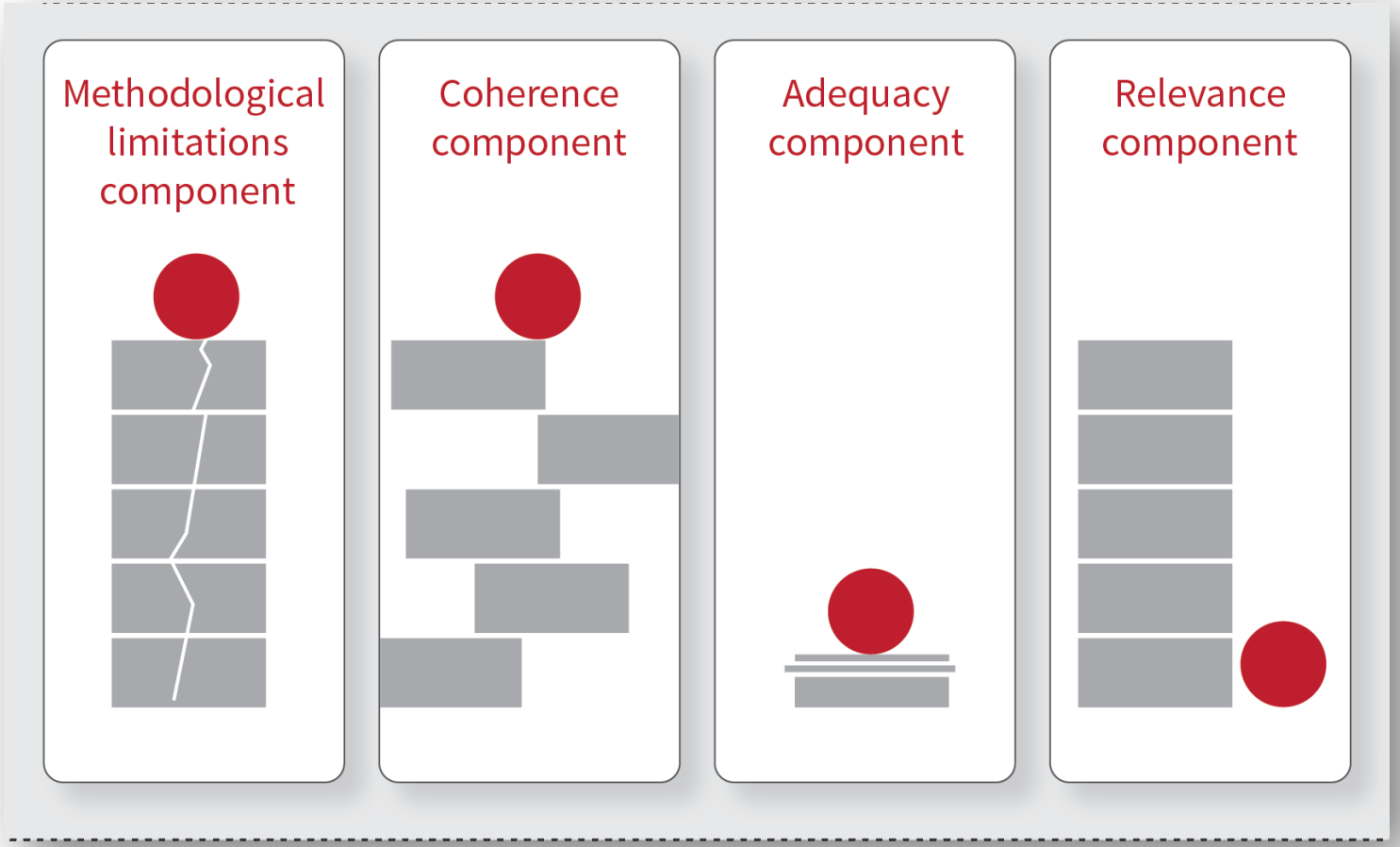
GRADE CERQual

Concerns about relevance

- We are less confident that the finding reflects the phenomenon of interest when the contexts of the primary studies underlying a review finding are substantively different from the context of the review question

GRADE CERQual

Making an overall assessment



GRADE CERQual

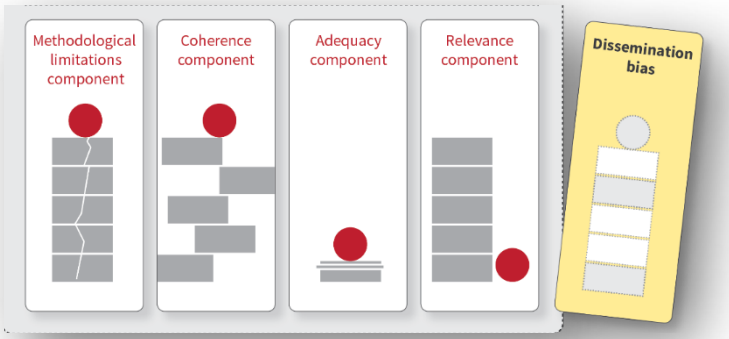
Confidence can be assessed as high, moderate, low or very low

- **High confidence**: It is highly likely that the review finding is a reasonable representation of the phenomenon of interest
- **Moderate confidence**: It is likely that the review finding is a reasonable representation of the phenomenon of interest
- **Low confidence**: It is possible that the review finding is a reasonable representation of the phenomenon of interest
- **Very low confidence**: It is not clear whether the review finding is a reasonable representation of the phenomenon of interest

GRADE CERQual

Dissemination bias in qualitative research

Toews I, Glenton C, Lewin S, Berg RC, Noyes J, Booth A, Marusic A, Malicki M, Munthe-Kaas HM, Meerpohl JJ. **Extent, Awareness and Perception of Dissemination Bias in Qualitative Research: An Explorative Survey**. *PLoS One*, 2016 Aug 3;11(8)



Toews I, Booth A, Berg RC, Lewin S, Glenton C, Munthe-Kaas HM, Noyes J, Schroter S, and Meerpohl JJ. **Dissemination Bias in Qualitative Research: conceptual considerations.** *Journal of Clinical Epidemiology* (in press)

GRADE CERQual

Presenting the results of a GRADE / GRADE-CERQual assessment

GRADE

GRADE CERQual

Cochrane reviews….

…interpret results and draw conclusions?

GRADE criteria *(MECIR standards: mandatory)*

….present results to reader/users?

Summary of Findings Tables *(MECIR standards: highly desirable)*

Self management for patients with chronic obstructive pulmonary disease

Patient or population: patients with chronic obstructive pulmonary disease
Settings: primary care, community, outpatient
Intervention: self management[1]
Comparison: usual care

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk **usual care**	Corresponding risk **self management**				
Quality of Life St George's Respiratory Questionnaire. Scale from: 0 to 100. (follow-up: 3 to 12 months)	The mean quality of life ranged across control groups from **38 to 60 points**	The mean quality of Life in the intervention groups was **2.58 lower** (5.14 to 0.02 lower)		698 (7)	⊕⊕⊕O **moderate**[2]	Lower score indicates better quality of life. A change of less than 4 points is not shown to be important to patients.
Dyspnoea Borg Scale. Scale from: 0 to 10. (follow-up: 3 to 6 months)	The mean dyspnoea ranged across control groups from **1.2 to 4.1 points**	The mean dyspnoea in the intervention groups was **0.53 lower** (0.96 to 0.1 lower)		144 (2)	⊕⊕OO **low**[3,4]	Lower score indicates improvement
Number and severity of exacerbations[5]	See comment	See comment	Not estimable[5]	591 (3)	See comment	Effect is uncertain
Respiratory-related hospital admissions (follow-up: 3 to 12 months)	**Low risk population**[6]		OR 0.64 (0.47 to 0.89)	966 (8)	⊕⊕⊕O **moderate**[7]	
	10 per 100	**7 per 100** (5 to 9)				
	High risk population[6]					
	50 per 100	**39 per 100** (32 to 47)				
Emergency department visits for lung diseases (follow-up: 6 to 12 months)	The mean emergency department visits for lung diseases ranged across control groups from **0.2 to 0.7 visits per person per year**	The mean emergency department visits for lung diseases in the intervention groups was **0.1 higher** (0.2 lower to 0.3 higher)		328 (4)	⊕⊕⊕O **moderate**[4]	
Doctor and nurse visits (follow-up: 6 to 12 months)	The mean doctor and nurse visits ranged across control groups from **1 to 5 vists per person per year**	The mean doctor and nurse visits in the intervention groups was **0.02 higher** (1 lower to 1 higher)		629 (8)	⊕⊕⊕O **moderate**[8]	

*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; OR: Odds ratio;

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Information about the systematic review and clinical question: Participants, interventions and comparisons

Self management for patients with chronic obstructive pulmonary disease

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Settings: primary care, community, outpatient
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Outcomes – most important for decision making

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	10 per 100	**7 per 100** (5 to 9)				
	High risk population[b]					

Results – Number of Participants/studies

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Results – Relative effects

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Comparison: usual care

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk **usual care**	Corresponding risk **self management**				
Quality of Life St George's Respiratory Questionnaire. Scale from: 0 to 100. (follow-up: 3 to 12 months)	The mean quality of life ranged across control groups from **38 to 60 points**	The mean quality of Life in the intervention groups was **2.58 lower** (5.14 to 0.02 lower)		698 (7)	⊕⊕⊕O **moderate**[2]	Lower score indicates better quality of life. A change of less than 4 points is not shown to be important to patients.
Dyspnoea Borg Scale. Scale from: 0 to 10. (follow-up: 3 to 6 months)	The mean dyspnoea ranged across control groups from **1.2 to 4.1 points**	The mean dyspnoea in the intervention groups was **0.53 lower** (0.96 to 0.1 lower)		144 (2)	⊕⊕OO **low**[3,4]	Lower score indicates improvement
Number and severity of exacerbations[5]	See comment	See comment	Not estimable[6]	591 (3)	See comment	Effect is uncertain
Respiratory-related hospital admissions (follow-up: 3 to 12 months)	**Low risk population**[b]		**OR 0.64** (0.47 to 0.89)	966 (8)	⊕⊕⊕O **moderate**[7]	
	10 per 100	**7 per 100** (5 to 9)				
	High risk population[b]					
	50 per 100	**39 per 100** (32 to 47)				
Emergency department visits for lung diseases (follow-up: 6 to 12 months)	The mean emergency department visits for lung diseases ranged across	The mean emergency department visits for lung diseases in the intervention groups		328 (4)	⊕⊕⊕O **moderate**[4]	

Results – Absolute effects

Self management for patients with chronic obstructive pulmonary disease

Patient or population: patients with chronic obstructive pulmonary disease
Settings: primary care, community, outpatient
Intervention: self management[1]
Comparison: usual care

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk **usual care**	Corresponding risk **self management**				
Quality of Life St George's Respiratory Questionnaire. Scale from: 0 to 100. (follow-up: 3 to 12 months)	The mean quality of life ranged across control groups from **38 to 60 points**	The mean quality of Life in the intervention groups was **2.58 lower** (5.14 to 0.02 lower)		698 (7)	⊕⊕⊕O **moderate**[2]	Lower score indicates better quality of life. A change of less than 4 points is not shown to be important to patients.
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Number and severity of exacerbations[5]	See comment	See comment	Not estimable[5]	591 (3)	See comment	Effect is uncertain
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	10 per 100	**7 per 100** (5 to 9)				
	High risk population[b]					
	50 per 100	**39 per 100** (32 to 47)				
Emergency department visits for lung diseases (follow-up: 6 to 12 months)	The mean emergency department visits for lung diseases ranged across	The mean emergency department visits for lung diseases in the intervention groups		328 (4)	⊕⊕⊕O **moderate**[4]	

what happens to people with and without interventio n

Certainty of the Evidence

Self management for patients with chronic obstructive pulmonary disease

Patient or population: patients with chronic obstructive pulmonary disease
Settings: primary care, community, outpatient
Intervention: self management[1]
Comparison: usual care

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk **usual care**	Corresponding risk **self management**				
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	10 per 100	**7 per 100** (5 to 9)				
	High risk population[b]					
	50 per 100	**39 per 100** (32 to 47)				
Emergency department visits for lung diseases (follow-up: 6 to 12 months)	The mean emergency department visits for lung diseases ranged across	The mean emergency department visits for lung diseases in the intervention groups		328 (4)	⊕⊕⊕O **moderate**[4]	

Explanations

[1] Self-management is a term applied to any formalized patient education programme aimed at teaching skills needed to carry out medical regimens specific to the disease, guide health behaviour change, and provide emotional support for patients to control their disease and live functional lives. Of the 14 studies, there were four in which the education delivery mode consisted of group education; nine which were individual education and one study which was written education material only. In six studies the use of an action plan for self-treatment of exacerbations was assessed.

[2] Seven other studies were not pooled and some showed non-significant effects.

[3] No allocation concealment in 1 study. Incomplete follow-up.

[4] Sparse data.

[5] Different definitions of exacerbations used and studies could not be pooled.

[6] The low and high risk values are the two extreme numbers of admissions in the control groups from two studies (8% was rounded to 10% and 51% to 50%).

[7] Two studies with very severe COPD patients weighted heavily in meta-analysis. Therefore, there is some uncertainty with the applicability of effect to all risk groups.

[8] Unexplained heterogeneity.

- Clarification
- Judgements
- Transparency

Preparatory work

- revealed that users would appreciate a summary of the findings upfront to facilitate interpretation
- evaluated the type and amount of information users want
- e.g. number of outcomes ≤ 7
- presenting information on all important outcomes
- ordering of outcomes

Pilot study of Cochrane review groups

- 17 Cochrane Review groups participated
- 20 review authors participated (20 new or updated reviews)
- spent an additional 4 hours (2 to 40 hours)

Preliminary summary of findings table for Cochrane systematic reviews:

Outline and pilot test

Gunn E Vist, Andrew D Oxman, Paul Glasziou and Holger J. Schünemann

Contact information:

Gunn Elisabeth Vist
Norwegian Health Services Research Centre
PO Box 7004
St Olavs Plass
0130 Oslo
NORWAY

E-mail: gunn.vist@kunnskapssenteret.no

Results of first pilot

- layout clear
- generally found to be helpful
- 11/17 increased accessibility
- 5/17 improved quality
- 1/17 rephrased conclusions
- software difficulties
- Additional user testing!!!

What do SoF tables add?

ELSEVIER

Journal of Clinical Epidemiology 63 (2010) 620–626

Journal of Clinical Epidemiology

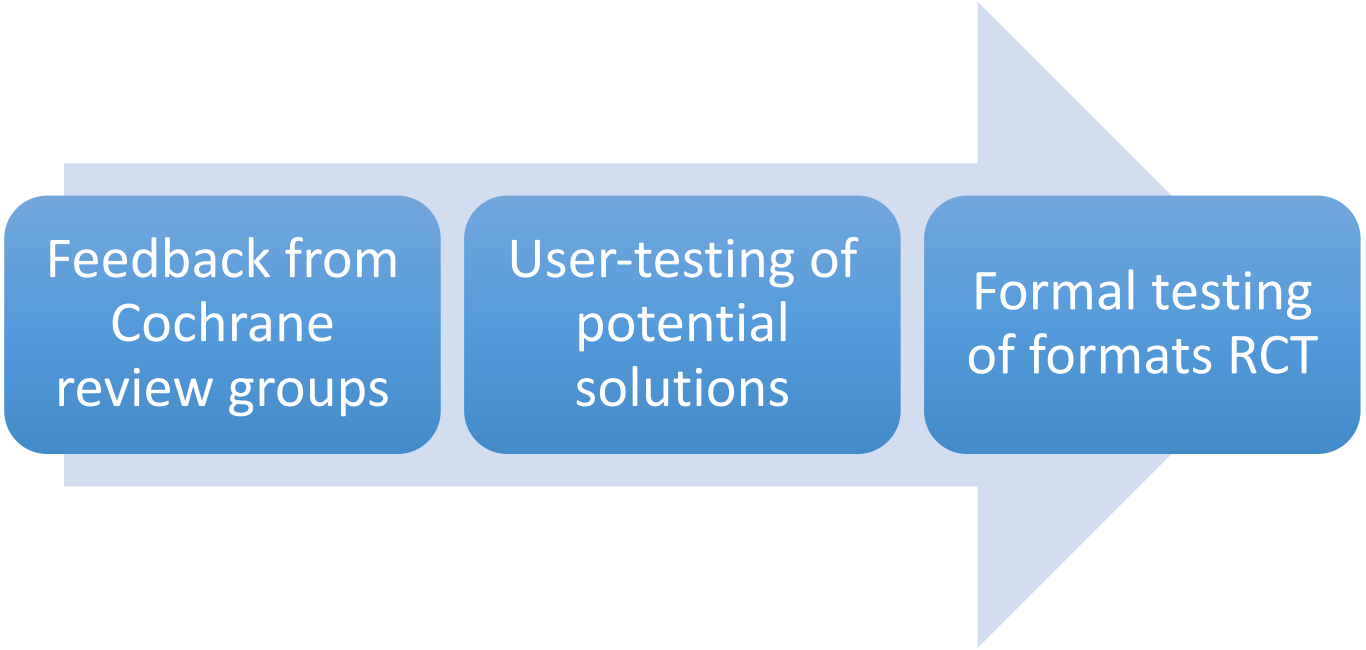
Summary-of-findings tables in Cochrane reviews improved understanding and rapid retrieval of key information

Sarah E. Rosenbaum[a,*], Claire Glenton[b], Andrew D. Oxman[a]

- RCTs
  - 1 EBCP workshop (N 72); 2 Cochrane entities meeting (N 33)
- RCT 1: easy to find results, SoF versus no: 68 vs. 40% ($p = 0.02$)
- RCT 2: SoF more correct answers to two questions re results
  - 93% vs 44% ($p = 0.003$) and 87% vs. 11% ($p < 0.001$)
- SoF participants spent average of 90 seconds to find key information vs 4 minutes without SoF table

Cochrane method innovation fund project

- Enhancing the acceptance and implementation of SoF tables in Cochrane reviews
- Initiated in 2012



Enhancing the acceptance and implementation of SoF tables in Cochrane reviews

User testing

- More than 40 participants
- Cochrane review users (clinicians, guideline developers, researchers)
- Participants prefer simple, less crowded SoF tables
- Dichotomous: NNTs and Risk Difference over natural frequencies
- Continuous: Minimal important difference units over MD and SMD
- “what happens” column:
  - statement of presence/direction of effect and qualitative statement of confidence

Table 1. *Comparison between items included in the current and alternative SoF tables formats*

	Current formats (Table B)	**Alternative formats (Table A)**
1	Inclusion of the Nº of participants and studies column	Exclusion of the Nº of participants and studies column. Information presented in the outcomes column
2	Quality of evidence presented with symbols and labeled as High, moderate, low, or very low. Reasons for downgrading presented in the footnotes	Quality of evidence presented with main reasons for downgrading in the same column (e.g. MODERATE due to imprecision)
3	"Footnotes" label	"Explanations" label
4	Baseline risk and corresponding risk expressed as natural frequencies	Baseline risk and corresponding risk expressed as percentages
5	No column presenting absolute risk reduction (risk difference) or mean difference	Inclusion of a column presenting absolute risk reduction (risk difference) or mean difference
6	Comments column included	Comments column deleted
7	No "what happens" column*	"What happens" column included*
8	Description of the GRADE Working Group grades of evidence definitions below the table	No description of the GRADE Working Group grades of evidence definitions

Probiotics as an adjunct to antibiotics for the prevention of pediatric antibiotic-associated diarrhea in children

Patient or population: children given antibiotics
Settings: inpatients and outpatient
Intervention: probiotics
Comparison: no probiotics

Outcomes	Illustrative comparative risks* (95% CI) Assumed risk No probiotics	Corresponding risk Probiotics	Relative effect (95% CI)	No of participants (studies)	Quality of the evidence (GRADE)	Comments
Incidence of Diarrhea: Probiotic dose (equal to/greater than) 5 billion CFU/day Follow-up: 10 days to 3 months	**Children < 5 years**		**RR 0.4**[1] (0.29 to 0.55)	1474 (7 studies)	⊕⊕⊕⊖ **moderate**[2]	
	223 per 1000[1]	**89 per 1000** (65 to 122)				
	Children > 5 years		**RR 0.8**[1] (0.53 to 1.21)	624 (4 studies)	⊕⊕⊖⊖ **low**[2, 3]	
	112 per 1000[1]	**90 per 1000** (59 to 136)				
Adverse events Follow-up: 10 to 44 days	**18 per 1000**[1]	**23 per 1000** (8 to 38)	Not estimable[4]	1575 (11 studies)	⊕⊕⊖⊖ **low**[5, 6]	Side effects: rash, nausea, gas, flatulence, vomiting, increased phlegm, chest pain, constipation, taste disturbance, and low appetite
Duration of diarrhea Follow-up: 10 days to 3 months	The mean duration of diarrhea in control groups was **4 days**	**0.6 fewer days** (1.18 to 0.02 fewer days)		897 (5 studies)	⊕⊕⊖⊖ **low**[7, 8]	

Probiotics as an adjunct to antibiotics for the prevention of pediatric antibiotic-associated diarrhea in children

Patient or population: children given antibiotics
Settings: inpatients and outpatient
Intervention: probiotics
Comparison: no probiotics

Outcomes No of Participants (studies)	Relative effects (95% CI)	Anticipated absolute effects* (95% CI) Without probiotics	 With probiotics	 Difference	Quality of the evidence (GRADE)	What happens
Incidence of Diarrhea: Probiotic dose 5 billion CFU/day Follow-up: 10 days to 3 months		**Children < 5 years**				
Children <5 years 1474 (7 studies)	**RR 0.4**[1] (0.29 to 0.55)	**22.3%**[1]	**8.9%** (6.5 to 12.2)	**13.4% fewer children**[1] (10.1 to 15.8 fewer)	⊕⊕⊕⊖ **moderate**[2] Due to risk of bias	Probably decreases the incidence of diarrhea
		Children > 5 years			⊕⊕⊖⊖ **low**[2, 3] Due to risk of bias and imprecision	May decrease the incidence of diarrhea
Children >5 years 624 (4 studies)	**RR 0.8**[1] (0.53 to 1.21)	**11.2%**[1]	**9%** (5.9 to 13.6)	**2.2% fewer children**[1] (5.3 fewer to 2.4 more)		
Adverse events[4] Follow-up: 10 to 44 days	-	**1.8%**[1]	**2.3%** (0.8 to 3.8)	**0.5% more adverse events**[5] (1 fewer to 2 more)	⊕⊕⊖⊖ **low**[6, 7] Due to risk of bias and inconsistency	There may be little or no difference in adverse events
1575 (11 studies)						

Enhancing the acceptance and implementation of SoF tables in Cochrane reviews

RCT design

- Clinicians, guideline developers, researchers (300)
- Alternative vs current formats
- Understanding, accessibility, satisfaction, preference

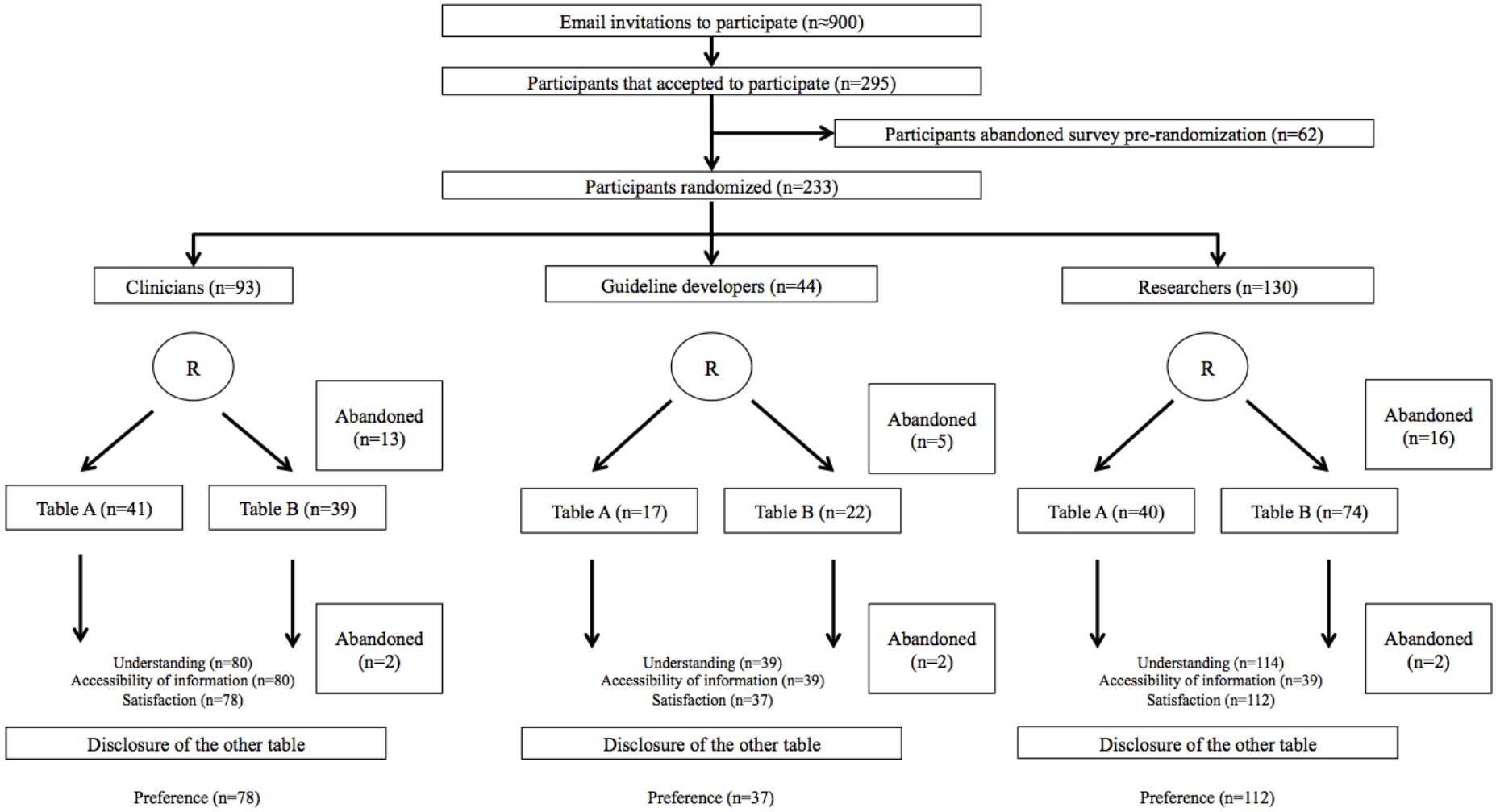

Email invitations to participate (n≈900)
Participants that accepted to participate (n=295)
Participants abandoned survey pre-randomization (n=62)
Participants randomized (n=233)
Clinicians (n=93)
Guideline developers (n=44)
Researchers (n=130)
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Table A (n=41)
Table B (n=39)
Table A (n=17)
Table B (n=22)
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Abandoned (n=2)
Understanding (n=80)
Accessibility of information (n=80)
Satisfaction (n=78)
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Preference (n=112)

	Alternative formats	Current formats
1	Quality of evidence presented with main reasons for downgrading in the same column (e.g. MODERATE due to imprecision)	Quality of evidence presented with symbols and labeled as High, moderate, low, or very low. Reasons for downgrading presented in the footnotes
2	Baseline risk and corresponding risk expressed as percentages	Baseline risk and corresponding risk expressed as natural frequencies
3	Inclusion of a column presenting absolute risk reduction (risk difference) expressed as percentage for benefit and harm or mean difference	No specific column presenting absolute risk reduction (risk difference) or mean difference
4	No description of the GRADE Working Group grades of evidence definitions	Description of the GRADE Working Group grades of evidence definitions below the table

Enhancing the acceptance and implementation of SoF tables in Cochrane reviews

Percentage of participants that answered correctly understanding questions					
Concept	**Question asked**	**Alternative formats (N=122)**	**Current formats (N=168)**	**Difference**	**P value**
Ability to determine risk difference	How many fewer children < 5 years will have diarrhea if they have probiotics than if they do not?	98%	35%	63%	<0.001
Understanding of quality of evidence and treatment effect	Which of the following statements best represents the results informing the outcome adverse events?	88%	26%	62%	<0.001

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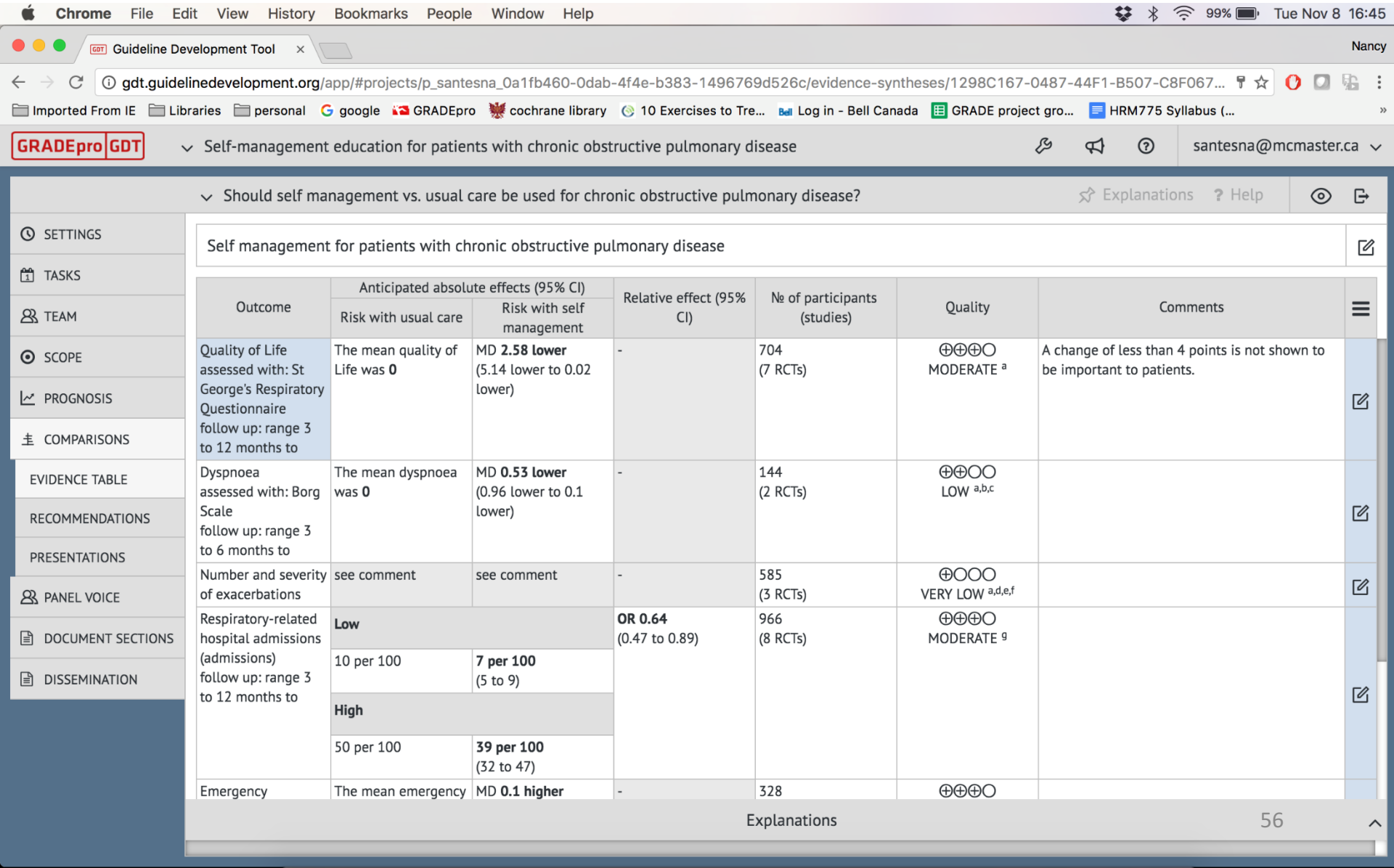

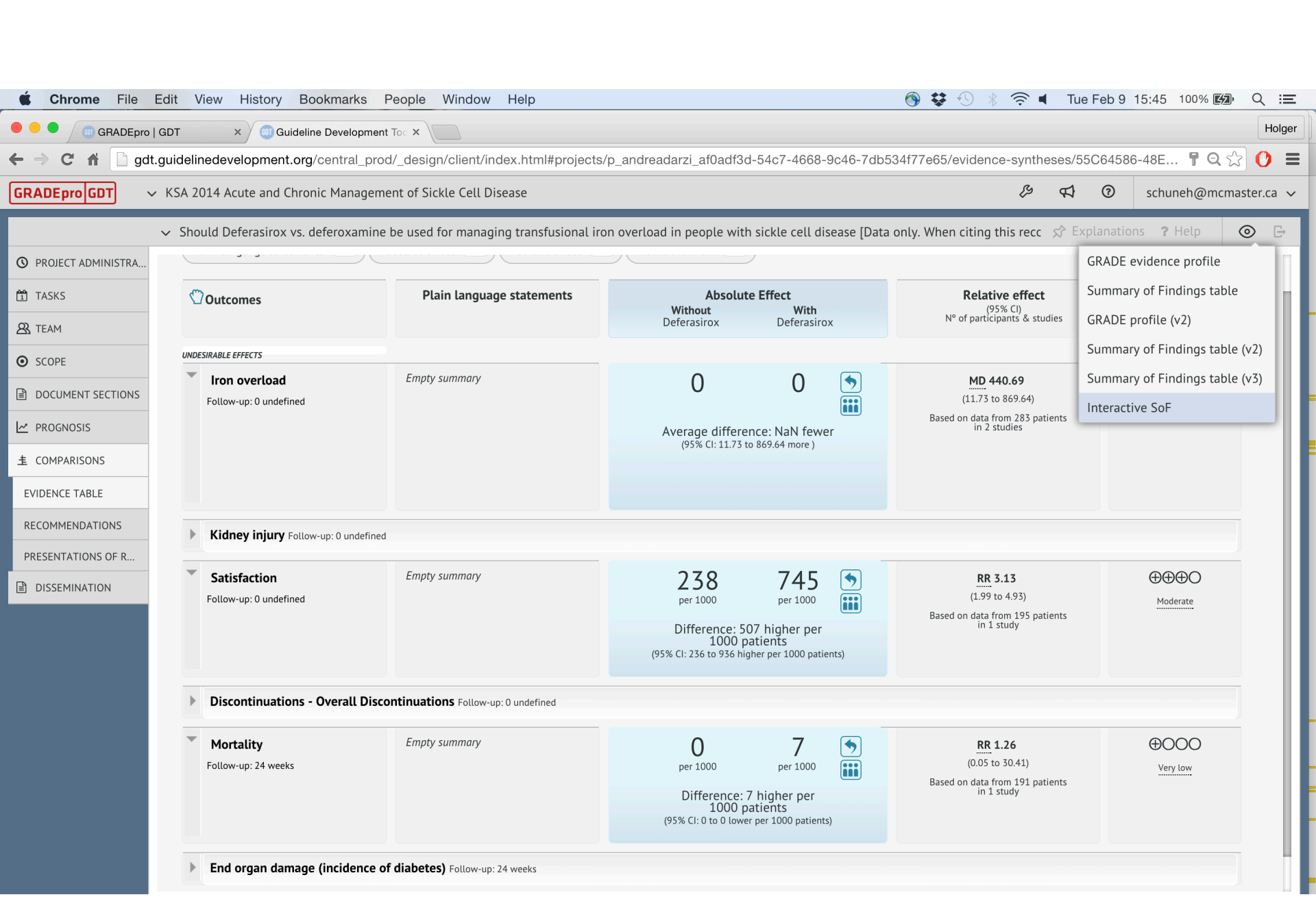
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GRADEpro GDT
KSA 2014 Acute and Chronic Management of Sickle Cell Disease
schuneh@mcmaster.ca
Should Deferasirox vs. deferoxamine be used for managing transfusional iron overload in people with sickle cell disease [Data only. When citing this recc
Explanations
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PROJECT ADMINISTRA...
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SCOPE
DOCUMENT SECTIONS
PROGNOSIS
COMPARISONS
EVIDENCE TABLE
RECOMMENDATIONS
PRESENTATIONS OF R...
DISSEMINATION
GRADE evidence profile
Summary of Findings table
GRADE profile (v2)
Summary of Findings table (v2)
Summary of Findings table (v3)
Interactive SoF
Outcomes
Plain language statements
Absolute Effect
Without Deferasirox
With Deferasirox
Relative effect
(95% CI)
N° of participants & studies
UNDESIRABLE EFFECTS
Iron overload
Follow-up: 0 undefined
Empty summary
0
0
Average difference: NaN fewer
(95% CI: 11.73 to 869.64 more)
MD 440.69
(11.73 to 869.64)
Based on data from 283 patients in 2 studies
Kidney injury Follow-up: 0 undefined
Satisfaction
Follow-up: 0 undefined
Empty summary
238
per 1000
745
per 1000
Difference: 507 higher per 1000 patients
(95% CI: 236 to 936 higher per 1000 patients)
RR 3.13
(1.99 to 4.93)
Based on data from 195 patients in 1 study
⨁⨁⨁◯
Moderate
Discontinuations - Overall Discontinuations Follow-up: 0 undefined
Mortality
Follow-up: 24 weeks
Empty summary
0
per 1000
7
per 1000
Difference: 7 higher per 1000 patients
(95% CI: 0 to 0 lower per 1000 patients)
RR 1.26
(0.05 to 30.41)
Based on data from 191 patients in 1 study
⨁◯◯◯
Very low
End organ damage (incidence of diabetes) Follow-up: 24 weeks

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gdt.guidelinedevelopment.org/central_prod/_design/client/index.html#projects/p_andreadarzi_af0adf3d-54c7-4668-9c46-7db534f77e65/evidence-syntheses/55C64586-48E...

GRADEpro GDT | KSA 2014 Acute and Chronic Management of Sickle Cell Disease | schuneh@mcmaster.ca

PROJECT ADMINISTRA... | TASKS | TEAM | SCOPE | DOCUMENT SECTIONS | PROGNOSIS | COMPARISONS | EVIDENCE TABLE | RECOMMENDATIONS | PRESENTATIONS OF R... | DISSEMINATION

Should Defera... | Explanations | Help

Plain langua...

Outcome

Certainty of the evidence
GRADE

UNDESIRABLE EFFECT

Iron ove...
Follow-up: ...
⨁⨁⨁◯ Moderate

Kidney i...

Satisfac...
Follow-up: 0 undefined
per 1000 per 1000
Difference: 507 higher per 1000 patients
(95% CI: 236 to 936 higher per 1000 patients)
(1.99 to 4.93)
Based on data from 195 patients in 1 study
⨁⨁⨁◯ Moderate

Discontinuations - Overall Discontinuations Follow-up: 0 undefined

Mortality
Follow-up: 24 weeks
Empty summary
0 per 1000
7 per 1000
Difference: 7 higher per 1000 patients
(95% CI: 0 to 0 lower per 1000 patients)
RR 1.26
(0.05 to 30.41)
Based on data from 191 patients in 1 study
⨁◯◯◯ Very low

Chance of: **Satisfaction** Follow up: 0 undefined

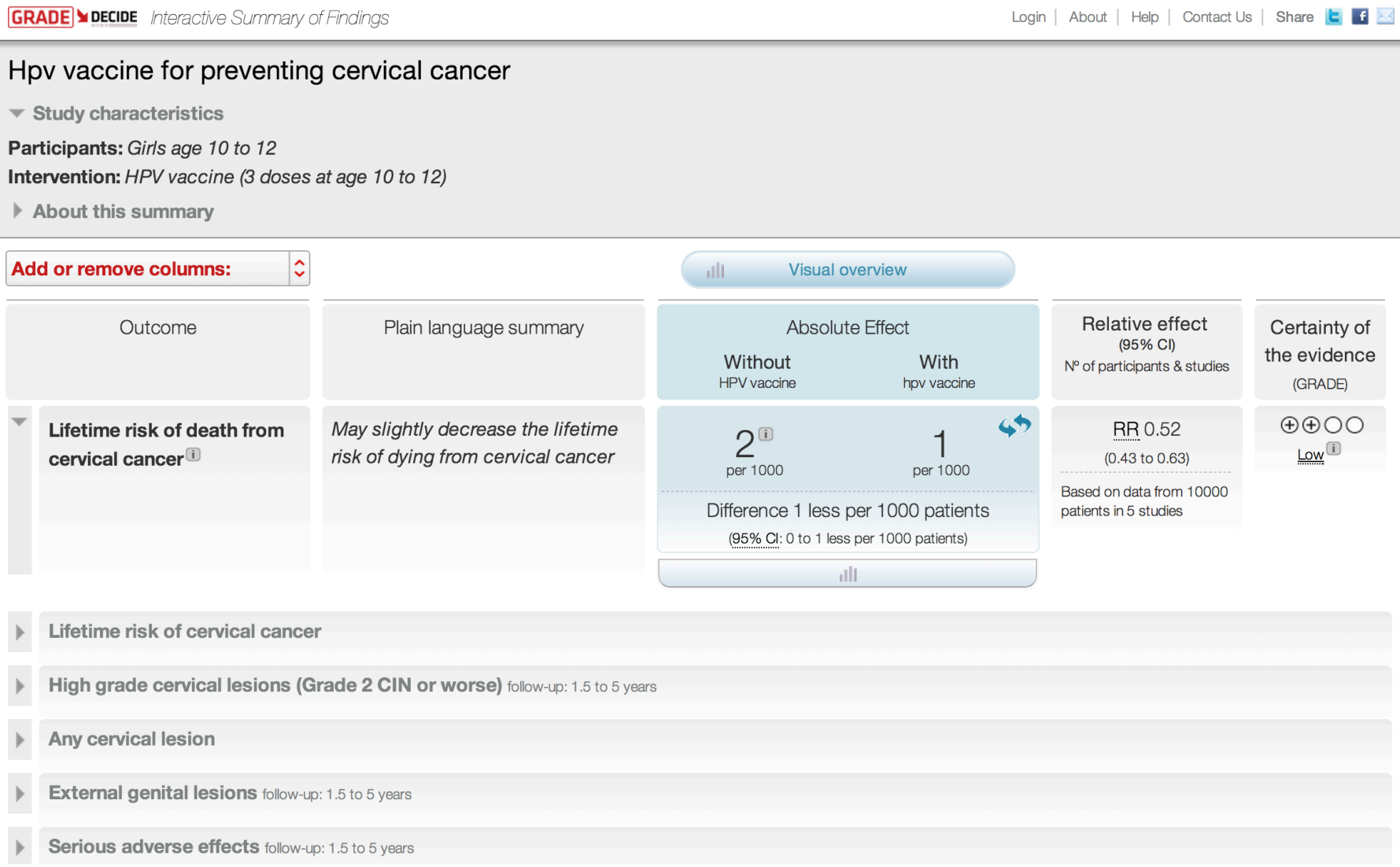
1 2 3 4 5 6

Let's zoom in. **507 higher** patients with Deferasirox will develop an outcome compared to without. This is our best estimate of the difference.

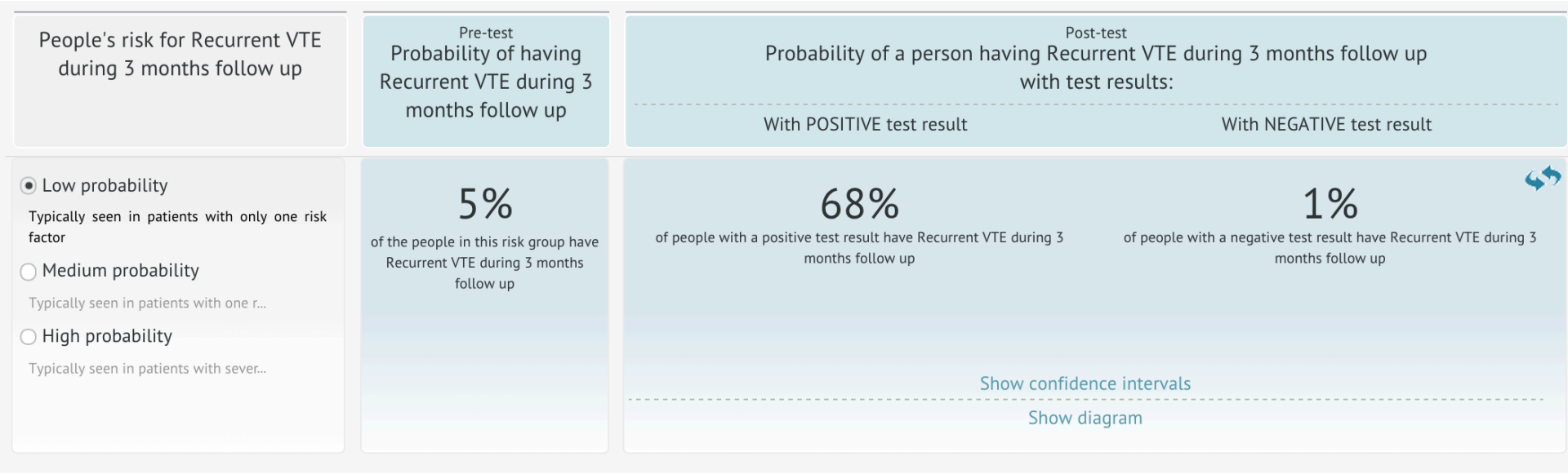
WITHOUT Deferasirox: **238 out of 1000** patients will develop an outcome

WITH Deferasirox: **745 out of 1000** patients will develop an outcome

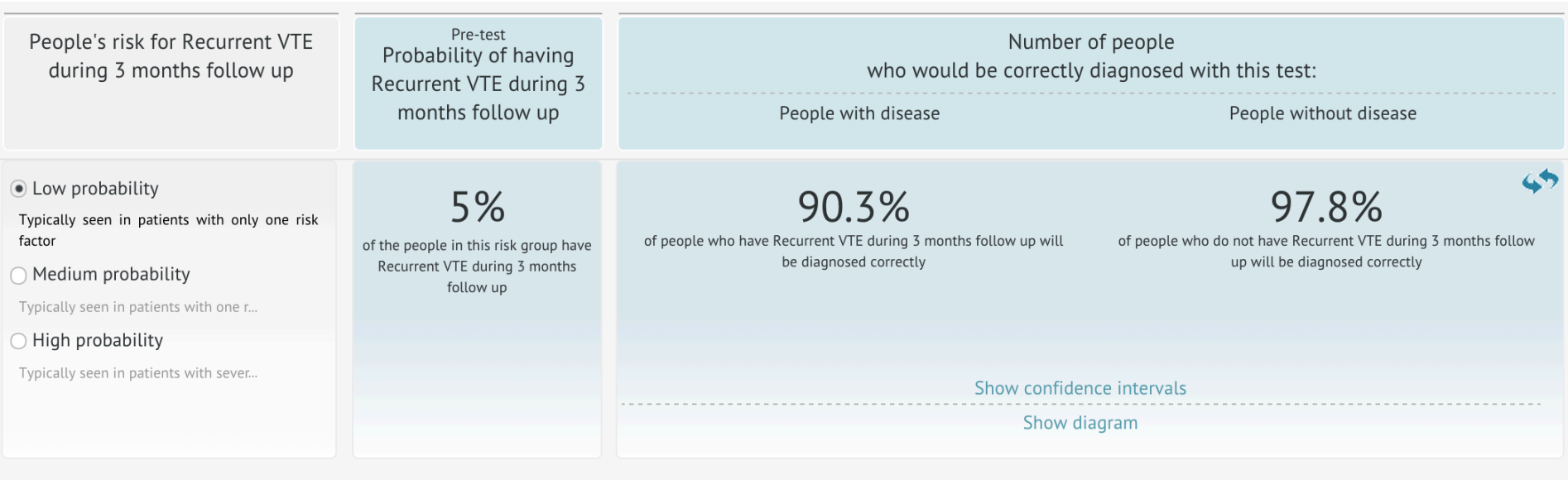
Interactive Summary of Findings tables



Ultrasound for patients suspected of having a deep venous thrombosis



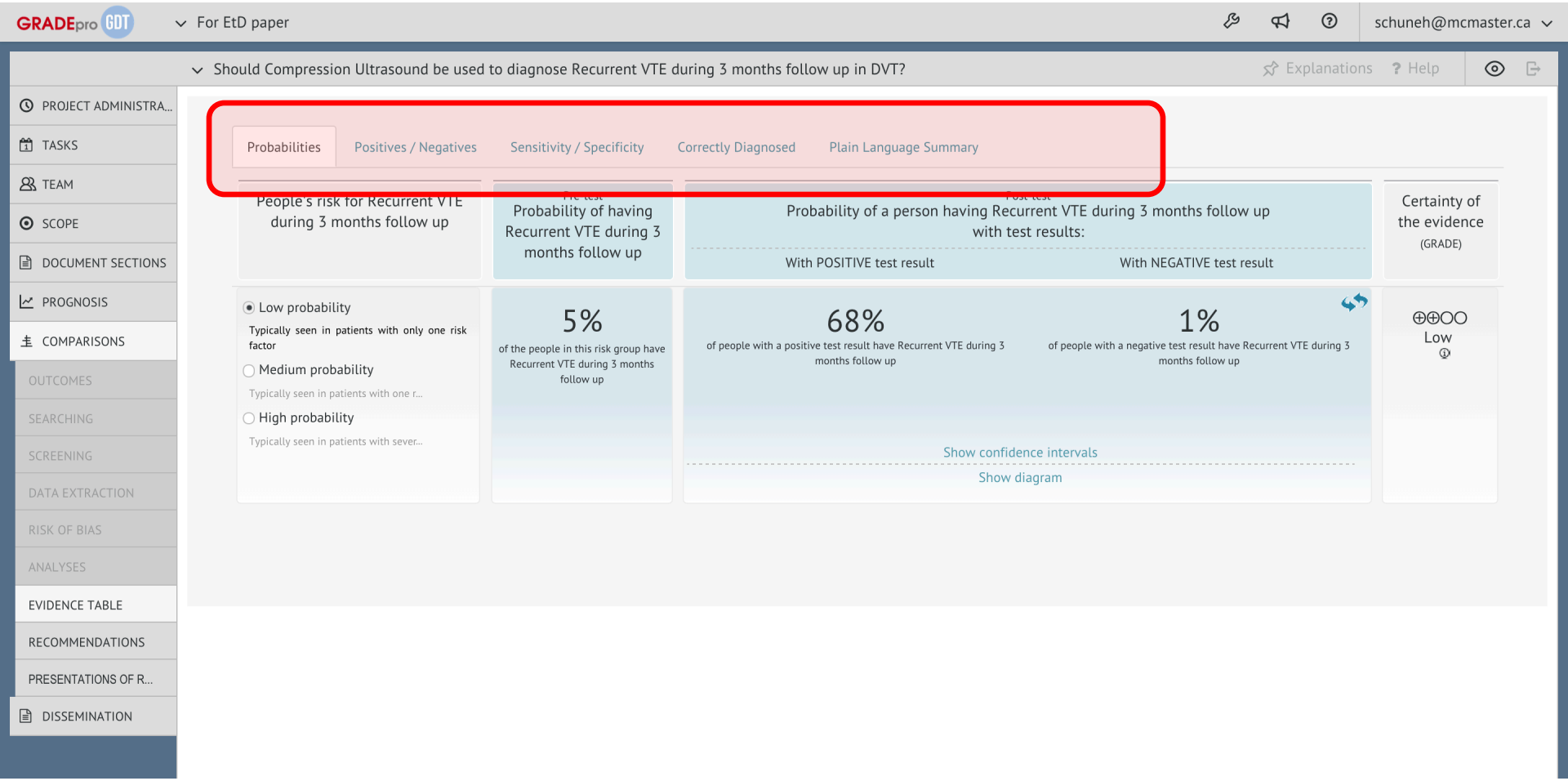
Probabilities

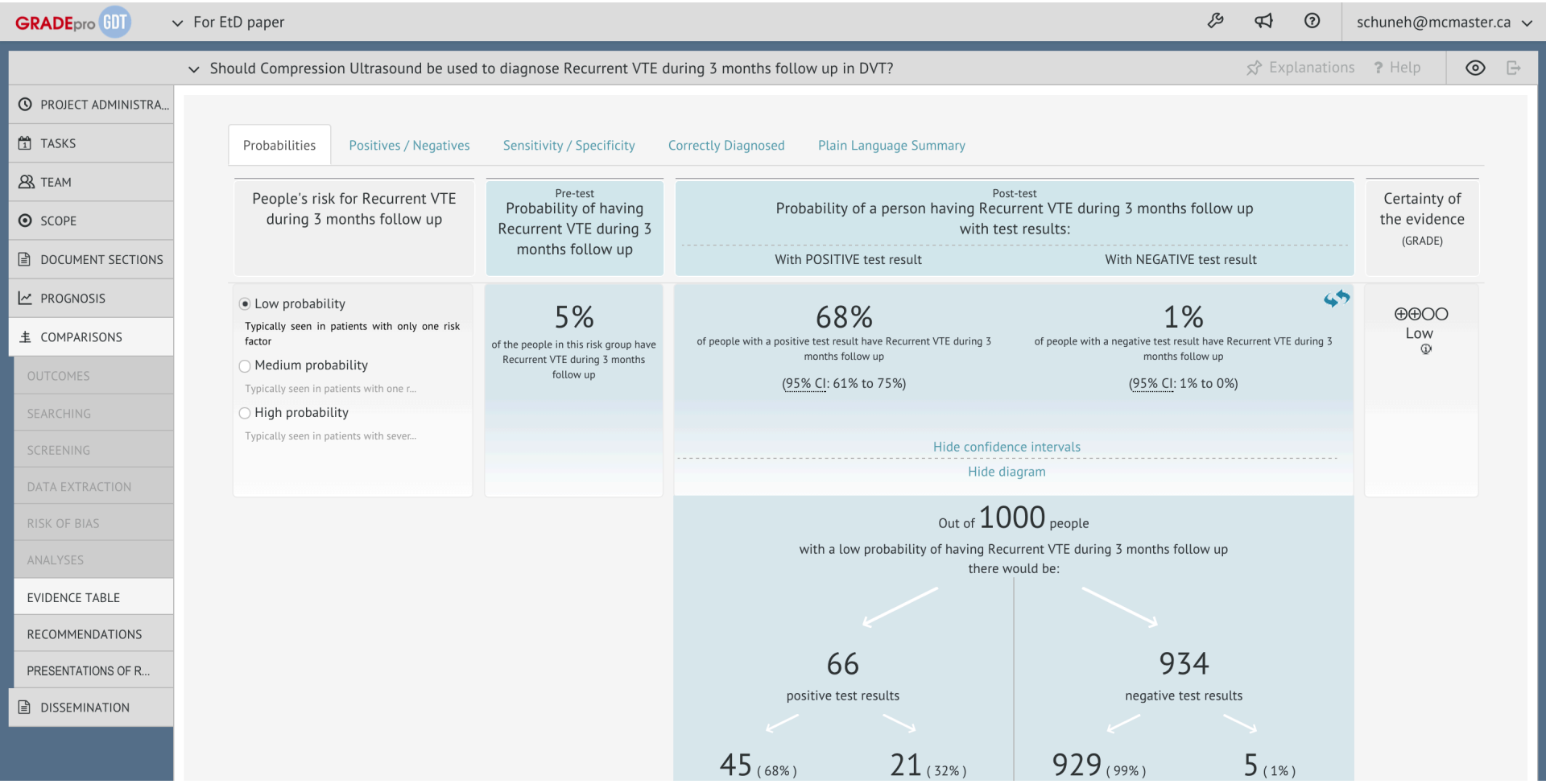


Correct diagnosis

Prevalence	People with POSITIVE test result		People with NEGATIVE test result		Pooled Sensitivity/Specificity
	True positives	False positives	True negatives	False negatives	
50 per 1000 Typically seen in patients with only one risk factor	45 per 1000 (95% CI: 44 to 46 per 1000)	21 per 1000 (95% CI: 28 to 15 per 1000)	929 per 1000 (95% CI: 922 to 935 per 1000)	5 per 1000 (95% CI: 6 to 4 per 1000)	**Sensitivity** 0.903 (95% CI: 0.884 to 0.92) **Specificity** 0.978 (95% CI: 0.97 to 0.984)
100 per 1000 Typically seen in patients with one r...					
150 per 1000 Typically seen in patients with sever...					

Positive and negative test results


GRADEpro GDT
For EtD paper
schuneh@mcmaster.ca
Should Compression Ultrasound be used to diagnose Recurrent VTE during 3 months follow up in DVT?
Explanations
Help
PROJECT ADMINISTRA...
TASKS
TEAM
SCOPE
DOCUMENT SECTIONS
PROGNOSIS
COMPARISONS
OUTCOMES
SEARCHING
SCREENING
DATA EXTRACTION
RISK OF BIAS
ANALYSES
EVIDENCE TABLE
RECOMMENDATIONS
PRESENTATIONS OF R...
DISSEMINATION
Probabilities
Positives / Negatives
Sensitivity / Specificity
Correctly Diagnosed
Plain Language Summary
People's risk for Recurrent VTE during 3 months follow up
Probability of having Recurrent VTE during 3 months follow up
Probability of a person having Recurrent VTE during 3 months follow up with test results:
With POSITIVE test result
With NEGATIVE test result
Certainty of the evidence
(GRADE)
Low probability
Typically seen in patients with only one risk factor
Medium probability
Typically seen in patients with one r...
High probability
Typically seen in patients with sever...
5%
of the people in this risk group have Recurrent VTE during 3 months follow up
68%
of people with a positive test result have Recurrent VTE during 3 months follow up
1%
of people with a negative test result have Recurrent VTE during 3 months follow up
⊕⊕◯◯
Low
Show confidence intervals
Show diagram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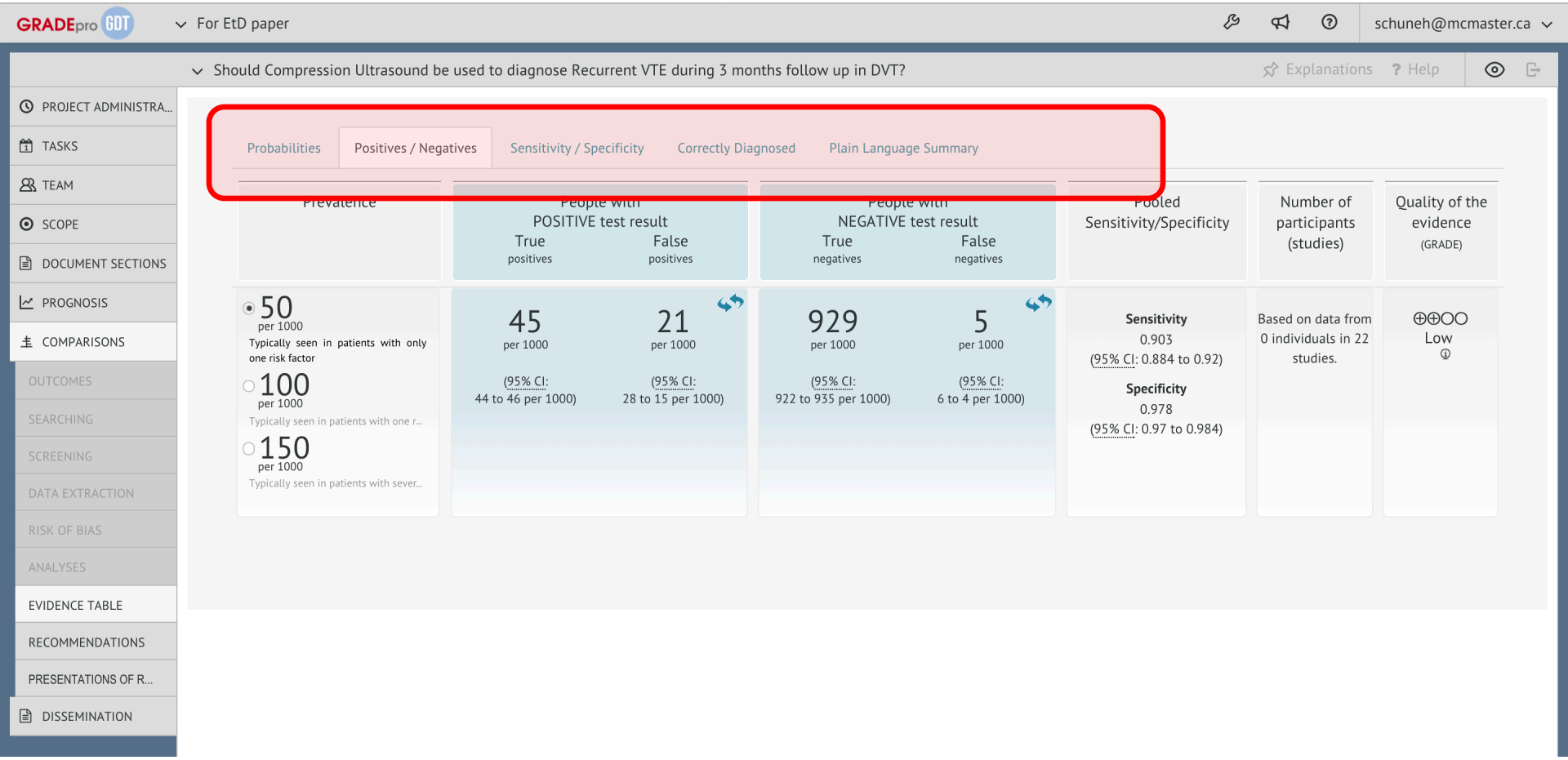
Should Compression Ultrasound be used to diagnose Recurrent VTE during 3 months follow up in DVT?
Explanations
Help
PROJECT ADMINISTRA...
TASKS
TEAM
SCOPE
DOCUMENT SECTIONS
PROGNOSIS
COMPARISONS
OUTCOMES
SEARCHING
SCREENING
DATA EXTRACTION
RISK OF BIAS
ANALYSES
EVIDENCE TABLE
RECOMMENDATIONS
PRESENTATIONS OF R...
DISSEMINATION
Probabilities
Positives / Negatives
Sensitivity / Specificity
Correctly Diagnosed
Plain Language Summary
People's risk for Recurrent VTE during 3 months follow up
Pre-test
Probability of having Recurrent VTE during 3 months follow up
Post-test
Probability of a person having Recurrent VTE during 3 months follow up with test results:
With POSITIVE test result
With NEGATIVE test result
Certainty of the evidence
(GRADE)
Low probability
Typically seen in patients with only one risk factor
Medium probability
Typically seen in patients with one r...
High probability
Typically seen in patients with sever...
5%
of the people in this risk group have Recurrent VTE during 3 months follow up
68%
of people with a positive test result have Recurrent VTE during 3 months follow up
(95% CI: 61% to 75%)
1%
of people with a negative test result have Recurrent VTE during 3 months follow up
(95% CI: 1% to 0%)
⊕⊕◯◯
Low
Hide confidence intervals
Hide diagram
Out of 1000 people
with a low probability of having Recurrent VTE during 3 months follow up there would be:
66
positive test results
934
negative test results
45 (68%)
21 (32%)
929 (99%)
5 (1%)


GRADEpro GDT
For EtD paper
schuneh@mcmaster.ca
Should Compression Ultrasound be used to diagnose Recurrent VTE during 3 months follow up in DVT?
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Sensitivity / Specificity
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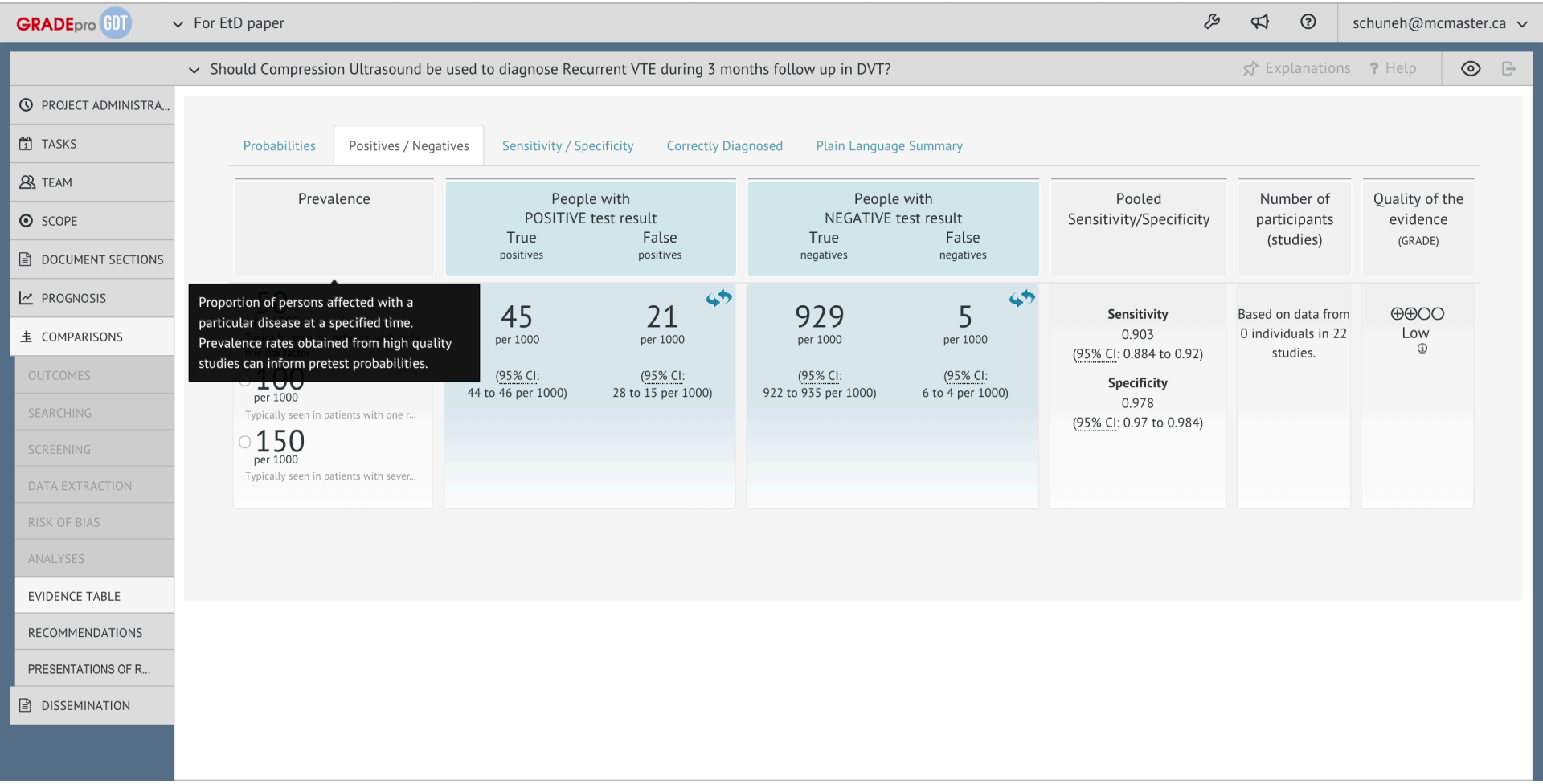
Prevalence
People with POSITIVE test result
True positives
False positives
People with NEGATIVE test result
True negatives
False negatives
Pooled Sensitivity/Specificity
Number of participants (studies)
Quality of the evidence (GRADE)
50 per 1000
Typically seen in patients with only one risk factor
100 per 1000
Typically seen in patients with one r...
150 per 1000
Typically seen in patients with sever...
45 per 1000
(95% CI: 44 to 46 per 1000)
21 per 1000
(95% CI: 28 to 15 per 1000)
929 per 1000
(95% CI: 922 to 935 per 1000)
5 per 1000
(95% CI: 6 to 4 per 1000)
Sensitivity
0.903
(95% CI: 0.884 to 0.92)
Specificity
0.978
(95% CI: 0.97 to 0.984)
Based on data from 0 individuals in 22 studies.
⊕⊕◯◯
Low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Number of participants (studies)
Quality of the evidence (GRADE)
Proportion of persons affected with a particular disease at a specified time. Prevalence rates obtained from high quality studies can inform pretest probabilities.
per 1000
Typically seen in patients with one r...
150
per 1000
Typically seen in patients with sever...
45
per 1000
(95% CI: 44 to 46 per 1000)
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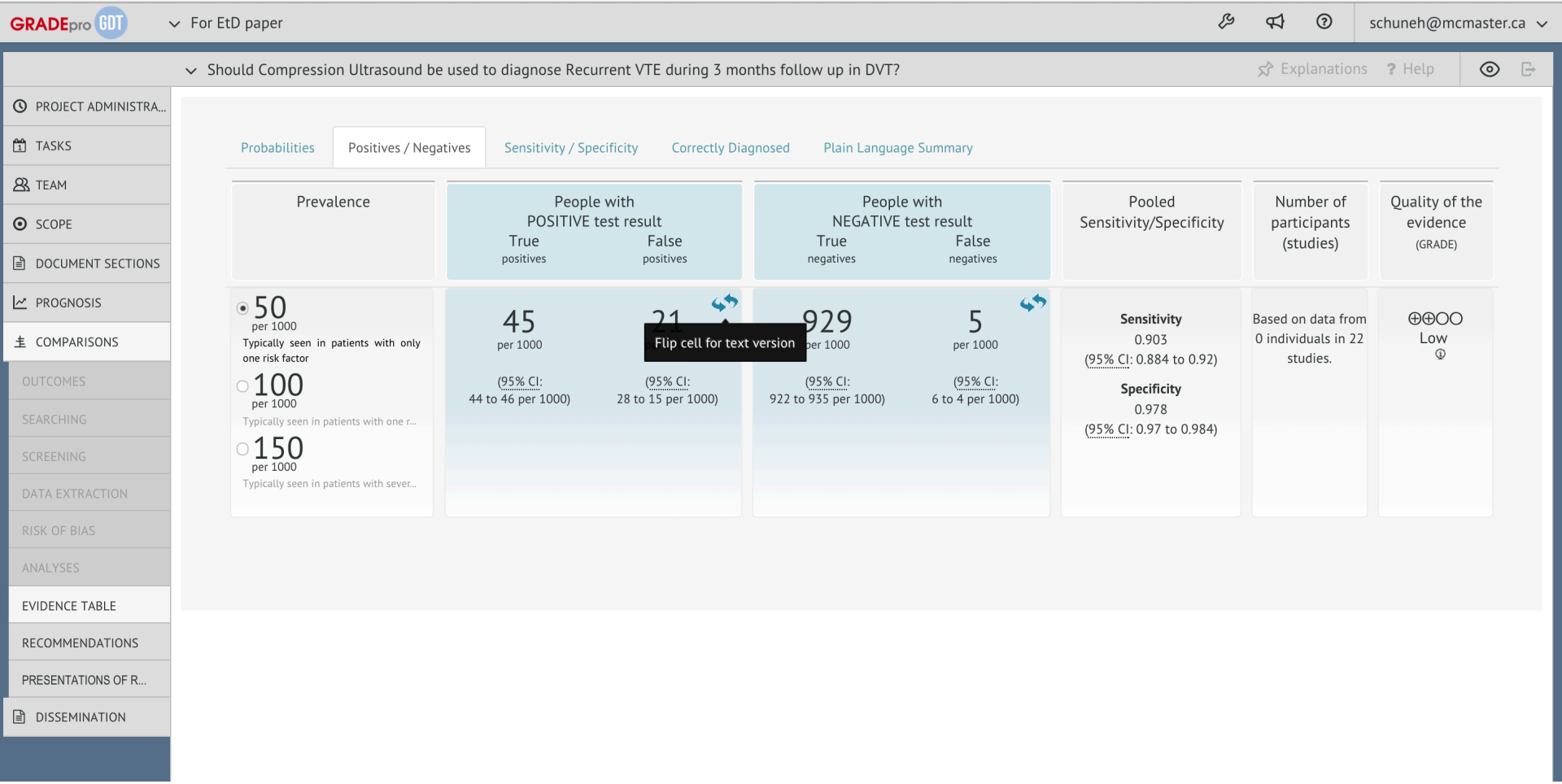
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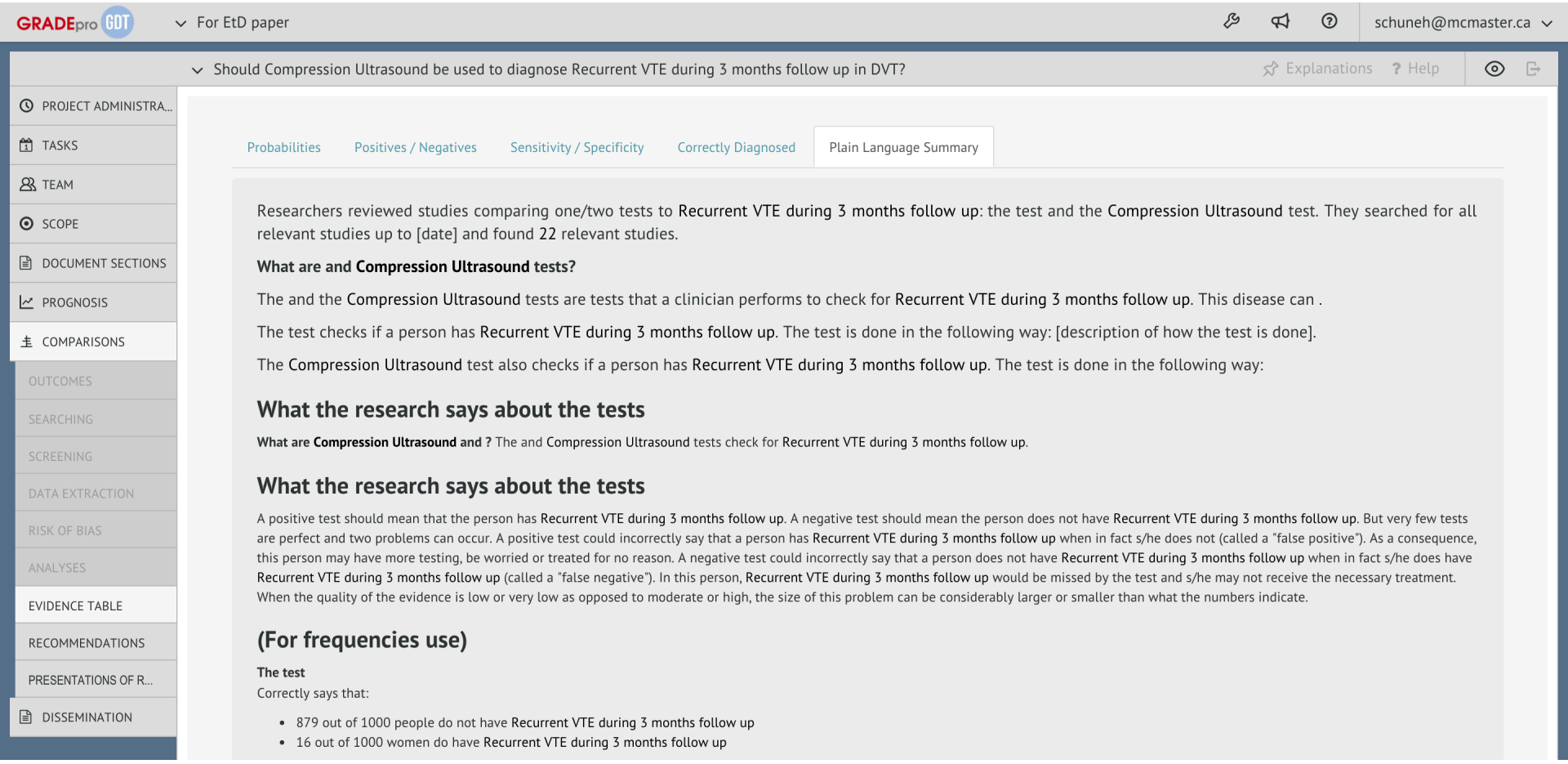
DISSEMINATION

Probabilities | Positives / Negatives | Sensitivity / Specificity | Correctly Diagnosed | Plain Language Summary

Prevalence	People with POSITIVE test result: True positives	People with POSITIVE test result: False positives	People with NEGATIVE test result: True negatives	People with NEGATIVE test result: False negatives	Pooled Sensitivity/Specificity	Number of participants (studies)	Quality of the evidence (GRADE)
50 per 1000 Typically seen in patients with only one risk factor 100 per 1000 Typically seen in patients with one r... 150 per 1000 Typically seen in patients with sever...	When the test shows a positive result, some of those results are correct and some are not. For the Compression Ultrasound test: • 66 out of 1000 people tested will have a "positive" test result. • 45 of these will have Recurrent VTE during 3 months follow up (true positive) However, 21 of these people will not have Recurrent VTE during 3 months follow up, even though their test result was positive (false positive).		929 per 1000 (95% CI: 922 to 935 per 1000)	5 per 1000 (95% CI: 6 to 4 per 1000)	**Sensitivity** 0.903 (95% CI: 0.884 to 0.92) **Specificity** 0.978 (95% CI: 0.97 to 0.984)	Based on data from 0 individuals in 22 studies.	⨁⨁◯◯ Low



Plain language summary

Inadvertent user test(imonial)

I have twice been asked by the BBC to discuss a review I haven't read before at 20 minutes notice. If there is a summary of findings table it is possible. If not, I am in trouble!

David Tovey, Editor-in-Chief, Cochrane Collaboration

Evidence profile

Summary of review finding	Studies contributing to the review finding	Methodological limitations	Coherence	Adequacy	Relevance**	CERQual assessment of confidence in the evidence	Explanation of CERQual assessment
1. Use of force: Women across the world reported experiencing physical force by health providers during childbirth. In some cases, women reported specific acts of violence committed against them during childbirth, but women often referred to these experiences in a general sense and alluded to beatings, aggression, physical abuse, a rough touch and use of extreme force. Pinching, hitting and slapping, either with an open hand or an instrument were the most commonly reported specific acts of physical violence.	6, 9, 10, 13, 21, 61, 67, 68, 73, 75, 77, 80, 84, 86, 87, 91, 96, 97	Moderate methodological limitations (6 studies with minor, 6 studies with moderate (unclear recruitment and sampling), and 3 studies with serious methodological limitations (unclear reflexivity, insufficiently rigorous data analysis))	No or very minor concerns about coherence (Good fit between data from primary studies and the review finding)	No or very minor concerns about adequacy (15 studies total from 10 countries. Rich data.)	Minor concerns about relevance (5 studies with direct relevance, 8 studies with partial relevance, and 1 study with unclear relevance. 15 studies total from 10 countries, including 1 high income, 2 middle income and 7 low income countries. Geographical spread: 2 studies in Asia, 1 study in Europe, 1 study in LAC, 1 study in MENA, 1 study in South America, and 8 studies from sub-Saharan Africa.)	High confidence	15 studies with moderate methodological limitations. Thick data from 10 countries across all geographical regions, but predominantly sub-Saharan Africa. No or very minor concerns about coherence.

GRADE CERQual

Summary of Qualitative Findings

Objective: To synthesize qualitative and quantitative evidence on the mistreatment of women during childbirth in health facilities.

Perspective: Experiences and attitudes of stakeholders in any country about the mistreatment of women during childbirth

Summary of review finding	Studies contributing to the review finding	CERQual assessment of confidence in the evidence	Explanation of CERQual assessment
1. Use of force: Women across the world reported experiencing physical force by health providers during childbirth. In some cases, women reported specific acts of violence committed against them during childbirth, but women often referred to these experiences in a general sense and alluded to beatings, aggression, physical abuse, a rough touch and use of extreme force. Pinching, hitting and slapping, either with an open hand or an instrument were the most commonly reported specific acts of physical violence.	6, 9, 10, 13, 21, 61, 67, 68, 73, 75, 77, 80, 84, 86, 87, 91, 96, 97	High confidence	15 studies with moderate methodological limitations. Thick data from 10 countries across all geographical regions, but predominantly sub-Saharan Africa. No or very minor concerns about coherence.
2. Physical restraint: Women reported physical restraint during childbirth through the use of bed restraints and mouth gags.	86, 97	Very low confidence	Two studies (Tanzania and Brazil) with moderate methodological limitations. Limited, thin data from 2 countries. Minor concerns about coherence but limited data available.

Using the results of a GRADE / GRADE-CERQual assessment

GRADE

GRADE CERQual

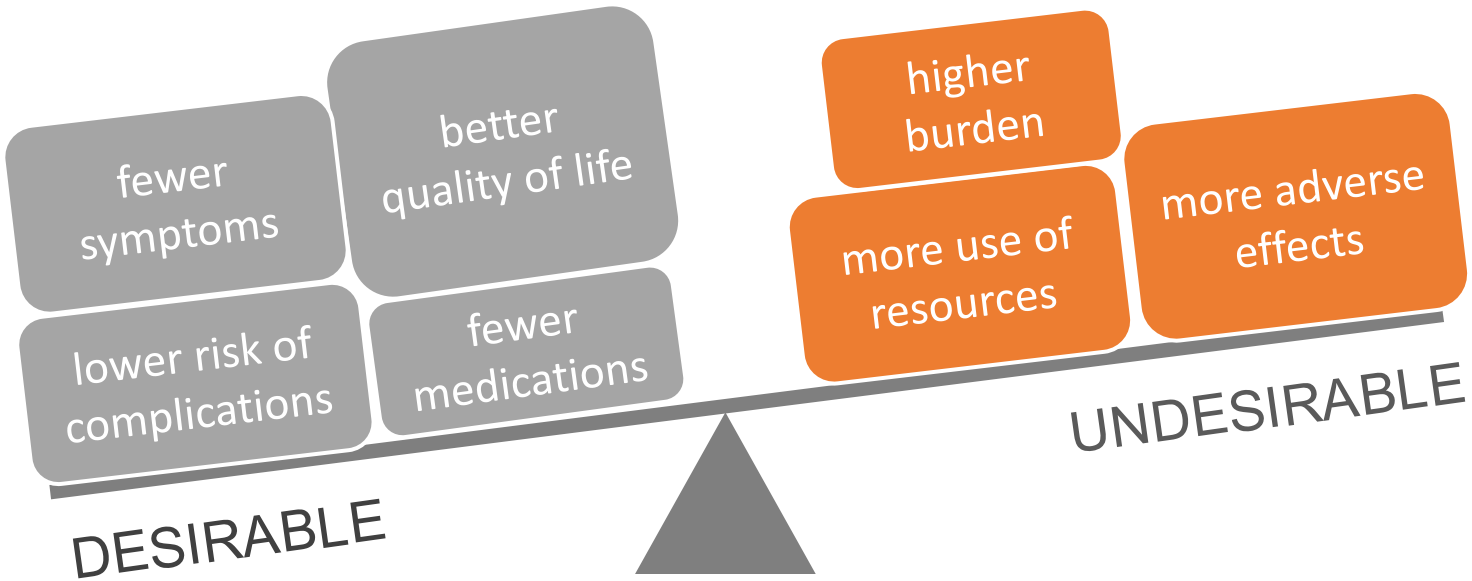
Now that we have transparent evidence summaries

Table 1. Summary of Findings Table Showing the Relative Risks and Absolute Effects over 12 Months for Each Important Outcome after Treatment with a Low-Molecular-Weight Heparin in Patients Receiving Chemotherapy for Cancer.*

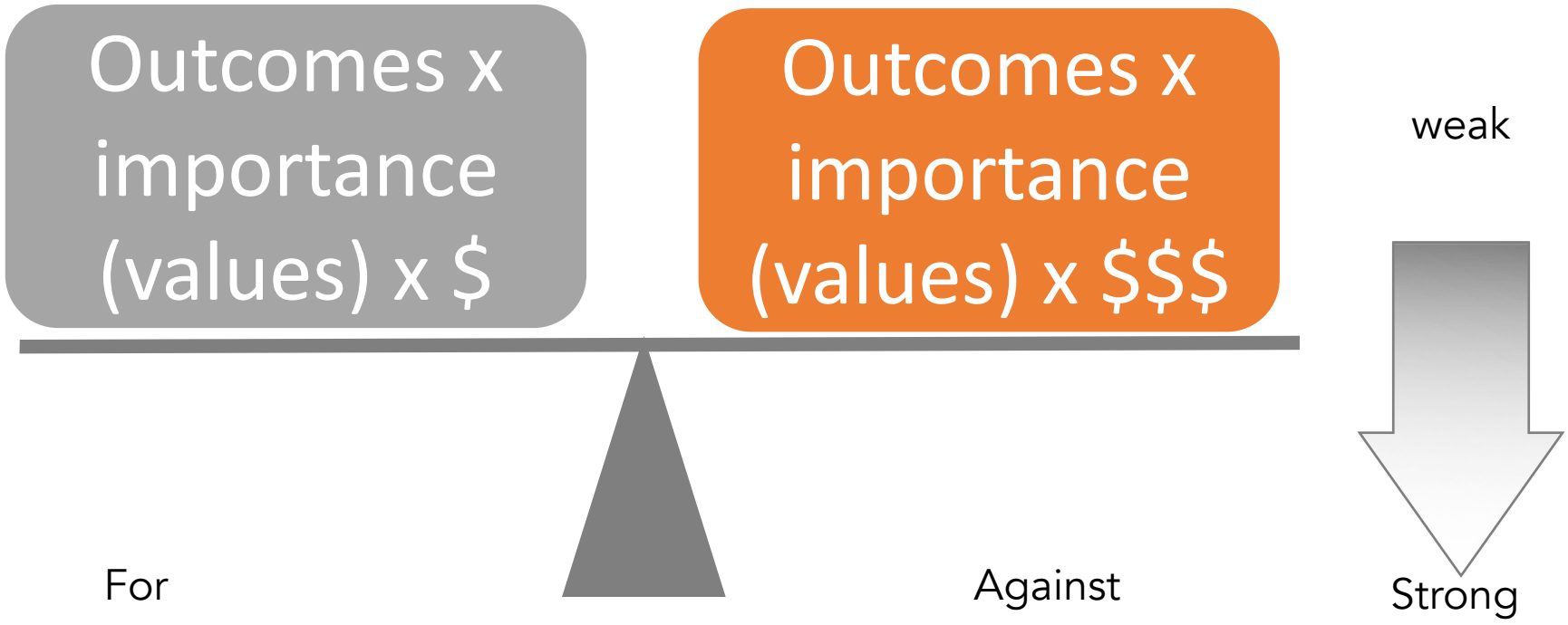
Outcome after 12 Months	Participants	Relative Risk (95% CI)	Anticipated Absolute Effect		Quality of Evidence (GRADE) and Comments†
			Risk without LMWH	Risk Difference with LMWH (95% CI)	
	no. (no. of studies)		*no. of events per 1000 patients*		
					venous thrombosis
Major bleeding	6518 (11)	1.06 (0.71–1.57)	16	1 more (5 fewer to 9 more)	Moderate-quality evidence owing to imprecision; the increase may be acceptable to patients, given that VTE, which occurs more frequently, may be equally unpleasant
Minor bleeding	6020 (9)	1.18 (0.89–1.55)	27	5 more (3 fewer to 15 more)	Moderate-quality evidence owing to imprecision; however, this outcome is unlikely to be critical for decision making

Should every cancer patient receive heparin?

Akl & Schünemann, New Engl J Med, 2012

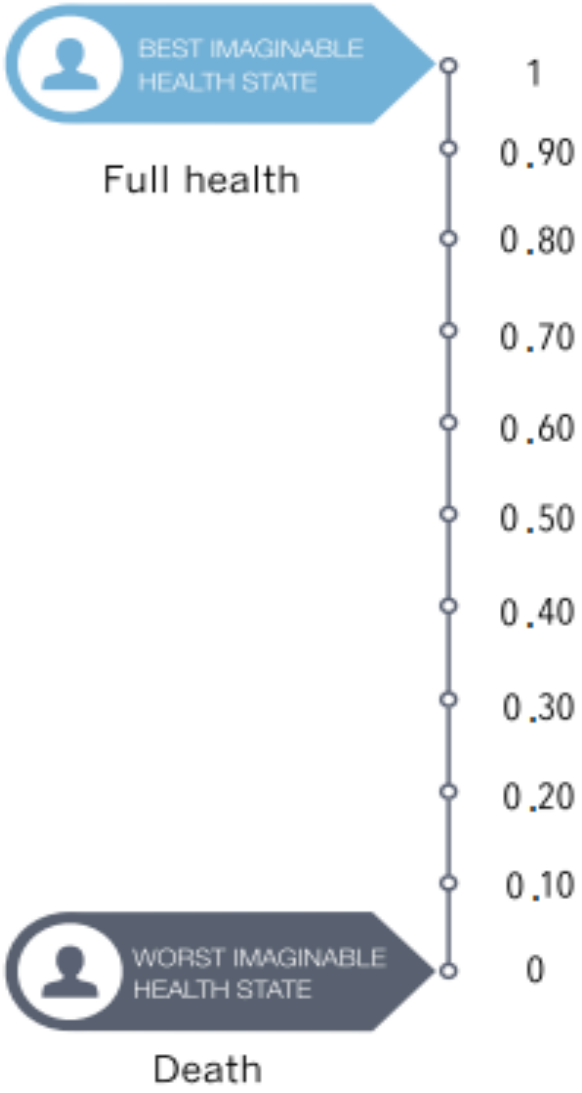

fewer symptoms
better quality of life
lower risk of complications
fewer medications
higher burden
more use of resources
more adverse effects
DESIRABLE
UNDESIRABLE

Balancing desirable and undesirable consequences



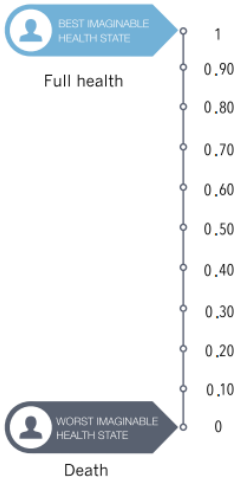
Many different ways to get at importance of outcomes

- Qualitative studies
- Standard gamble
- Time trade off
- Visual analogue scales
- Willingness to pay
- Utility indices


BEST IMAGINABLE HEALTH STATE
Full health
1
0.90
0.80
0.70
0.60
0.50
0.40
0.30
0.20
0.10
0
WORST IMAGINABLE HEALTH STATE
Death

Summary of finding table

Question: What are the views about the relative value/importance of outcomes of interest in decision making for patients with chronic obstructive pulmonary disease?



*Utilities represent the strength of an individual's preferences for different outcomes. They are measured on an interval scale, with zero reflecting states of health equivalent to death/worst imaginable health and one (or 100 in some cases) reflecting perfect health/ best imaginable health.

Health state/Outcome (Categories of values and preferences)	**Estimates of outcome importance** (range across studies / pooled mean, 95% CI)	**No. of participants /studies**	**Certainty in evidence**	**Interpretation of findings**
Exacerbation (Utility* measured with visual analogue scale [1])	range across studies: 0.259-0.466/ pooled mean: 0.377 (95% CI: 0.294, 0.461) [2]	1076 participants/ 4 studies [2]	⊕⊕⊕ Moderate certainty due to inconsistency [2]	Most people find exacerbation of COPD probably has a large impact on lives. There is likely no important variability for this assessment.
Exacerbation (EQ-5D Utility [3])	range across studies 0.43-0.683/ pooled mean: 0.525 (95% CI: 0.434, 0.615) [4]	927 participants/ 3 studies [4]	⊕⊕ Low certainty due to inconsistency and indirectness [4,5]	Most people find exacerbation of COPD probably has a large impact on lives. There is likely no important variability for this assessment.
Exacerbation (disutility) [6]	Visual analogue scale: One non-serious exacerbation: -0.037 (0.005); Two non-serious exacerbations: -0.068 (0.005); One serious exacerbation: -0.090 (0.007); One non-serious and one serious exacerbation: -0.130 (0.007) Time trade off: One non-serious exacerbation: -0.010 (0.007); Two non-serious exacerbations: -0.021 (0.007); One serious exacerbation: -0.042 (0.009); One non-serious and one serious exacerbation: -0.088 (0.009)	239 participants/ 1 study	⊕⊕⊕⊕ High certainty	Most people find exacerbation of COPD has an impact on lives, which grows larger as the severity of exacerbation progresses. There is likely no important variability for this assessment.

But more than estimates of intervention effects influence the recommendation

- Priority of the problem
- Disease/condition frequency and burden
- Balance of the benefits - harms
- For example, VTE – unnecessary bleeds
- Patients' values and preferences related to VTE outcomes
- Equity
  - Can all patients be given the same attention and care
- Acceptability of intervention by different stakeholders
- Feasibility of administering the intervention