Imprecision
Inconsistency

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Heparin</th>
<th>Control</th>
<th>Risk Ratio M-H, Random, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Events</td>
<td>Total</td>
<td>Weight</td>
</tr>
<tr>
<td>Altinbas 2004</td>
<td>0</td>
<td>42</td>
<td>1.2%</td>
</tr>
<tr>
<td>Agnelli 2009</td>
<td>11</td>
<td>769</td>
<td>13.4%</td>
</tr>
<tr>
<td>Perry 2010</td>
<td>11</td>
<td>99</td>
<td>15.8%</td>
</tr>
<tr>
<td>Pelzer 2009</td>
<td>8</td>
<td>160</td>
<td>14.6%</td>
</tr>
<tr>
<td>Weber 2008</td>
<td>1</td>
<td>10</td>
<td>1.3%</td>
</tr>
<tr>
<td>Sideras 2006</td>
<td>4</td>
<td>68</td>
<td>6.7%</td>
</tr>
<tr>
<td>Agnelli 2012</td>
<td>20</td>
<td>1608</td>
<td>24.6%</td>
</tr>
<tr>
<td>van Doormaal 2011</td>
<td>16</td>
<td>244</td>
<td>17.4%</td>
</tr>
<tr>
<td>Kakkar 2004</td>
<td>3</td>
<td>190</td>
<td>5.1%</td>
</tr>
</tbody>
</table>

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
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.*

<table>
<thead>
<tr>
<th>Outcome after 12 Months</th>
<th>Participants</th>
<th>Relative Risk (95% CI)</th>
<th>Anticipated Absolute Effect</th>
<th>Quality of Evidence (GRADE) and Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>no. (no. of studies)</td>
<td>no. of events per 1000 patients</td>
<td>Risk without LMWH (95% CI)</td>
<td>Risk Difference with LMWH (95% CI)</td>
</tr>
<tr>
<td>Death</td>
<td>6245 (10)</td>
<td>0.94 (0.88–1.00)</td>
<td>501</td>
<td>30 fewer (60 fewer to 0 more)</td>
</tr>
<tr>
<td>Symptomatic VTE</td>
<td>5979 (9)</td>
<td>0.57 (0.40–0.81)</td>
<td>46</td>
<td>20 fewer (27 fewer to 9 fewer)</td>
</tr>
</tbody>
</table>

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

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.*

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<td>501</td>
<td>30 fewer (60 fewer to 0 more)</td>
</tr>
<tr>
<td>Symptomatic VTE</td>
<td>5979 (9)</td>
<td>1.01 (0.90–1.14)</td>
<td>501</td>
<td>27 fewer to 9 fewer</td>
</tr>
<tr>
<td>Major bleeding</td>
<td>6514 (10)</td>
<td>1.08 (0.95–1.24)</td>
<td>501</td>
<td>5 fewer to 9 more</td>
</tr>
<tr>
<td>Minor bleeding</td>
<td>6020 (10)</td>
<td>1.05 (0.93–1.19)</td>
<td>501</td>
<td>3 fewer to 15 more</td>
</tr>
</tbody>
</table>

Combination of judgments: Reporting bias and imprecision
## Interpreting the certainty of the evidence

<table>
<thead>
<tr>
<th>Certainty rating</th>
<th>Definitions</th>
</tr>
</thead>
<tbody>
<tr>
<td>🟢🟢🟢🟢 High</td>
<td>The panel is very confident that the true effect lies close to that of the estimate of the effect</td>
</tr>
<tr>
<td>🟢🟢🟢🟢 Moderate</td>
<td>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</td>
</tr>
<tr>
<td>🟢🟢🟢 Low</td>
<td>The panel’s confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect</td>
</tr>
<tr>
<td>🟢🟢 Very low</td>
<td>The panel has very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect</td>
</tr>
</tbody>
</table>
Terminology - clarifications

• GRADE approach or system – interventions?
  • Prognosis, test accuracy, values and preferences
  • Describes GRADE’s conceptual underpinnings

• GRADE criteria
  • Decision criteria: Evidence to Decision Frameworks
  • GRADE Domains
    • 8 domains to assess certainty in the evidence
  • GRADE Items
    • E.g. overlapping confidence intervals, I², p-value for inconsistency

• GRADE • Certainty in evidence
  – Involves assessing evidence transparently
  – Confidence in an estimate of effect, association?
  – Starts with single studies
  – Ends with a body of evidence by outcome and a recommendation

• 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

Determinants of certainty in a body of evidence: GRADE

• Criteria on which a
• Judgements that make each criterion
• Research evidence
• Additional considerations explain each judgment

Schünemann, JCE 2016

EtD frameworks

• A body of evidence starts as: high ! ! ! !
• 5 factors that can lower quality
  1. Risk of bias criteria
  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

Schünemann, JCE 2016
GRADE-CERQual background:

Assessing our confidence in evidence from reviews of qualitative research
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

---

Criteria

- Problem size and priority
- Benefits & harms of the options
- Values
- Resource use
- Equity
- Acceptability
- Feasibility

Evidence where available
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?
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
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

<table>
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<th>Criteria</th>
<th>Evidence where available</th>
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<tbody>
<tr>
<td>Problem size and priority</td>
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<td></td>
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<td>Resource use</td>
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<tr>
<td>Acceptibility</td>
<td></td>
</tr>
<tr>
<td>Feasibility</td>
<td></td>
</tr>
</tbody>
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GRADE CERQual
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
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
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
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

- Methodological limitations component
- Coherence component
- Adequacy component
- Relevance component

Dissemination bias
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)
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.
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)
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
Adequacy of data

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

• (Similar to “imprecision” in GRADE)
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.
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)
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.
Making an overall assessment
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


Presenting the results of a GRADE / GRADE-CERQual assessment
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
Comparison: usual care

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Illustrative comparative risks*</th>
<th>Relative effect (95% CI)</th>
<th>No of Participants (studies)</th>
<th>Quality of the evidence (GRADE)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality of Life</td>
<td><strong>St George's Respiratory Questionnaire</strong>.</td>
<td>The mean quality of life ranged across control groups from 38 to 60 points</td>
<td>The mean quality of life in the intervention groups was 2.58 lower (5.14 to 0.02 lower)</td>
<td>698 (7)</td>
<td>★★★☆☆ moderate²</td>
</tr>
<tr>
<td>Dyspnoea</td>
<td><strong>Borg Scale. Scale from: 0 to 10.</strong></td>
<td>The mean dyspnoea ranked across control groups from 1.2 to 4.1 points</td>
<td>The mean dyspnoea in the intervention groups was 0.53 lower (0.96 to 0.1 lower)</td>
<td>144 (2)</td>
<td>★★★☆☆ low²,³,⁴</td>
</tr>
<tr>
<td>Number and severity of exacerbations⁵</td>
<td>See comment</td>
<td>See comment</td>
<td>Not estimable⁴</td>
<td>591 (3)</td>
<td>See comment</td>
</tr>
<tr>
<td>Respiratory-related hospital admissions</td>
<td><strong>Low risk population⁶</strong></td>
<td></td>
<td>OR 0.64 (0.47 to 0.89)</td>
<td>966 (8)</td>
<td>★★★☆☆ moderate⁷</td>
</tr>
<tr>
<td></td>
<td>10 per 100</td>
<td>7 per 100</td>
<td>(5 to 9)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>High risk population⁶</strong></td>
<td></td>
<td>50 per 100</td>
<td>39 per 100</td>
<td>(32 to 47)</td>
</tr>
<tr>
<td>Emergency department visits for lung diseases</td>
<td></td>
<td>The mean emergency department visits for lung diseases ranged across control groups from 0.2 to 0.7 visits per person per year</td>
<td>The mean emergency department visits for lung diseases in the intervention groups was 0.1 higher (0.2 lower to 0.3 higher)</td>
<td>328 (4)</td>
<td>★★★☆☆ moderate⁴</td>
</tr>
<tr>
<td>Doctor and nurse visits</td>
<td></td>
<td>The mean doctor and nurse visits ranged across control groups from 1 to 5 visits per person per year</td>
<td>The mean doctor and nurse visits in the intervention groups was 0.02 higher (1 lower to 1 higher)</td>
<td>629 (8)</td>
<td>★★★☆☆ moderate⁸</td>
</tr>
</tbody>
</table>

*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;
### 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  
**Comparison:** usual care

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Illustrative comparative risks* (95% CI)</th>
<th>Corresponding risk self management</th>
<th>Relative effect (95% CI)</th>
<th>No of Participants (studies)</th>
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<tr>
<td>Quality of Life</td>
<td>St George's Respiratory Questionnaire. Scale from: 0 to 100. (follow-up: 3 to 12 months)</td>
<td>The mean quality of life ranged across control groups from 38 to 60 points</td>
<td>2.58 lower (5.14 to 0.02 lower)</td>
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<td>Lower score indicates better quality of life. A change of less than 4 points is not shown to be important to patients.</td>
</tr>
<tr>
<td>Dyspnoea</td>
<td>Borg Scale. Scale from: 0 to 10. (follow-up: 3 to 6 months)</td>
<td>The mean dyspnoea ranged across control groups from 1.2 to 4.1 points</td>
<td>0.53 lower (0.96 to 0.1 lower)</td>
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<td>See comment</td>
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<td>Effect is uncertain</td>
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<td>Emergency department visits for lung diseases (follow-up: 6 to 12 months)</td>
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</table>
Information about the systematic review and clinical question: Participants, interventions and comparisons

**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  
**Comparison:** usual care

<table>
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<tr>
<th>Outcomes</th>
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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) | | | 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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| | | 144 (2) | | | Lower score indicates improvement |
Outcomes – most important for decision making

<table>
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<tr>
<th>Outcomes</th>
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| **Number and severity of exacerbations$^5$**                              | See comment                                                                             |                           |                             |                               |                                                                          |
| **Respiratory-related hospital admissions**  
(follow-up: 3 to 12 months)                                                 | Low risk population$^b$  
10 per 100  
7 per 100 (5 to 9)                                                                            | OR 0.64 (0.47 to 0.89)                  | 966 (8)                      | ☄️☉☉ moderate$^7$                                                   | Effect is uncertain                                                                 |

Notes:
$^a$ Estimate not possible.
$^b$ Estimate not possible.
$^c$ Estimate not possible.
$^d$ Estimate not possible.

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
## Results – Number of Participants/studies

**Self management for patients with chronic obstructive pulmonary disease**

**Patient or population:** patients with chronic obstructive pulmonary disease  
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</tr>
<tr>
<td><em>High risk population</em></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Emergency department visits for lung diseases</strong></td>
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<td></td>
</tr>
<tr>
<td><em>High risk population</em></td>
<td>The mean emergency department visits for lung diseases ranged across</td>
<td>The mean emergency department visits for lung diseases in the intervention groups</td>
<td>328 (4)</td>
<td>☒ ☒ O moderate⁴</td>
<td></td>
</tr>
</tbody>
</table>

*Illustrative comparative risks are estimates and may not reflect actual outcomes.*  
⁵See comment  
⁶See comment  
⁷See comment  

Effect is uncertain
## Results – Relative 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  
**Comparison:** usual care

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Illustrative comparative risks* (95% CI)</th>
<th>Corresponding risk self management</th>
<th>Relative effect (95% CI)</th>
<th>No of Participants (studies)</th>
<th>Quality of the evidence (GRADE)</th>
<th>Comments</th>
</tr>
</thead>
</table>
| 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) | ★★★★ 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) | ★★★★ low 3,4 | Lower score indicates improvement |
| Number and severity of exacerbations 5 | See comment | See comment | Not estimable | 591 (3) | See comment | Effect is uncertain |
| Respiratory-related hospital admissions  
(follow-up: 3 to 12 months) | Low risk population  
10 per 100  
7 per 100 (5 to 9) | OR 0.64 (0.47 to 0.89) | 906 (8) | ★★★★ moderate 5 |  |
| | High risk population  
50 per 100  
39 per 100 (32 to 47) | | 328 (4) | ★★★★ 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  
**Comparison:** usual care

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

---

<sup>*</sup> Assumed risk usual care

<sup>b</sup> Low risk population

<sup>c</sup> High risk population

<sup>d</sup> Respiratory-related hospital admissions

<sup>e</sup> Number and severity of exacerbations

<sup>f</sup> Emergency department visits for lung diseases

---

what happens to people with and without intervention
### 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  
**Comparison:** usual care

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Illustrative comparative risks* (95% CI)</th>
<th>Relative effect (95% CI)</th>
<th>No of Participants (studies)</th>
<th>Quality of the evidence (GRADE)</th>
<th>Comments</th>
</tr>
</thead>
</table>
| 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) | 3 | Moderate  
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**  
See comment | 144 (2) | 3  
Low  
Lower score indicates improvement |
| Number and severity of exacerbations*  
(follow-up: 3 to 12 months) | See comment | Not estimable* (3) | 3 | See comment  
Effect is uncertain |
| Respiratory-related hospital admissions  
(follow-up: 3 to 12 months) | Low risk populationb  
10 per 100  
7 per 100  
(5 to 9) | OR 0.64  
(0.47 to 0.89) | 966 (6) | Moderate  
Moderate  
Moderate |
|  
High risk populationb  
60 per 100  
39 per 100  
(32 to 47) | 328 (4) | 3  
Moderate  
Moderate  
Moderate |
| Emergency department visits for lung diseases  
(follow-up: 6 to 12 months) | The mean emergency department visits for lung diseases ranged across |
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 \( \leq 7 \)
• 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?

• 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>
<thead>
<tr>
<th>Current formats (Table B)</th>
<th>Alternative formats (Table A)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1</strong> Inclusion of the N° of participants and studies column</td>
<td>Exclusion of the N° of participants and studies column. Information presented in the outcomes column</td>
</tr>
<tr>
<td><strong>2</strong> Quality of evidence presented with symbols and labeled as High, moderate, low, or very low. Reasons for downgrading presented in the footnotes</td>
<td>Quality of evidence presented with main reasons for downgrading in the same column (e.g. MODERATE due to imprecision)</td>
</tr>
<tr>
<td><strong>3</strong> “Footnotes” label</td>
<td>“Explanations” label</td>
</tr>
<tr>
<td><strong>4</strong> Baseline risk and corresponding risk expressed as natural frequencies</td>
<td>Baseline risk and corresponding risk expressed as percentages</td>
</tr>
<tr>
<td><strong>5</strong> No column presenting absolute risk reduction (risk difference) or mean difference</td>
<td>Inclusion of a column presenting absolute risk reduction (risk difference) or mean difference</td>
</tr>
<tr>
<td><strong>6</strong> Comments column included</td>
<td>Comments column deleted</td>
</tr>
<tr>
<td><strong>7</strong> No “what happens” column*</td>
<td>“What happens” column included*</td>
</tr>
<tr>
<td><strong>8</strong> Description of the GRADE Working Group grades of evidence definitions below the table</td>
<td>No description of the GRADE Working Group grades of evidence definitions</td>
</tr>
</tbody>
</table>
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*  
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><em>(95% CI)</em></td>
<td><em>Relative effect (95% CI)</em></td>
<td><em>No of participants (studies)</em></td>
<td><em>Quality of the evidence (GRADE)</em></td>
<td><em>Comments</em></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Assumed risk</td>
<td>Corresponding risk Probiotics</td>
<td>RR 0.4¹</td>
<td>1474</td>
<td>✪ ✪ ✪</td>
<td>☻</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>No probiotics</td>
<td></td>
<td>(0.29 to 0.55)</td>
<td>(7 studies)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Incidence of Diarrhea: Probiotic dose (equal to/greater than) 5 billion CFU/day</td>
<td><strong>Children &lt; 5 years</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Follow-up: 10 days to 3 months</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>223 per 1000¹</td>
<td>89 per 1000 (65 to 122)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Children &gt; 5 years</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>112 per 1000¹</td>
<td>90 per 1000 (59 to 136)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adverse events</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Follow-up: 10 to 44 days</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>18 per 1000¹</td>
<td>23 per 1000 (8 to 38)</td>
<td></td>
<td>Not estimable⁴</td>
<td>1575</td>
<td>✪ ✪ ✪ ✪</td>
<td>☻</td>
<td>low⁵,⁶</td>
</tr>
<tr>
<td>Duration of diarrhea</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Follow-up: 10 days to 3 months</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>The mean duration of diarrhea in control groups was 4 days</td>
<td>0.6 fewer days (1.18 to 0.02 fewer days)</td>
<td></td>
<td>897</td>
<td>✪ ✪ ✪</td>
<td>☻</td>
<td>low⁷,⁸</td>
<td></td>
</tr>
</tbody>
</table>

*Note: ¹RR denotes relative risk. ²Moderate quality of evidence. ³Low quality of evidence. ⁴Not estimable. ⁵Low quality of evidence. ⁶Side effects: rash, nausea, gas, flatulence, vomiting, increased phlegm, chest pain, constipation, taste disturbance, and low appetite. ⁷0.02 fewer days. ⁸Low quality of evidence.
# 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

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Relative effects (95% CI)</th>
<th>Anticipated absolute effects* (95% CI)</th>
<th>Quality of the evidence (GRADE)</th>
<th>What happens</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Incidence of Diarrhea</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Probiotic dose 5 billion CFU/day</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Follow-up: 10 days to 3 months</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Children &lt;5 years</td>
<td>RR 0.4¹</td>
<td>13.4% fewer children¹ (10.1 to 15.8 fewer)</td>
<td>☩☉☉☉ moderate²</td>
<td>Probably decreases the incidence of diarrhea</td>
</tr>
<tr>
<td>1474 (7 studies)</td>
<td>(0.29 to 0.55)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Children &gt;5 years</td>
<td>RR 0.8¹</td>
<td>2.2% fewer children¹ (5.3 fewer to 2.4 more)</td>
<td>☩☉☉☉ low²,³</td>
<td>May decrease the incidence of diarrhea</td>
</tr>
<tr>
<td>624 (4 studies)</td>
<td>(0.53 to 1.21)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Adverse events</strong></td>
<td></td>
<td></td>
<td>☩☉☉☉ low⁶,⁷</td>
<td>There may be little or no difference in adverse events</td>
</tr>
<tr>
<td>Follow-up: 10 to 44 days</td>
<td></td>
<td>0.5% more adverse events⁵ (1 fewer to 2 more)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1575 (11 studies)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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
<table>
<thead>
<tr>
<th>Alternative formats</th>
<th>Current formats</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1</strong> Quality of evidence presented with main reasons for downgrading in the same column (e.g. MODERATE due to imprecision)</td>
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</tr>
<tr>
<td><strong>2</strong> Baseline risk and corresponding risk expressed as percentages</td>
<td>Baseline risk and corresponding risk expressed as natural frequencies</td>
</tr>
<tr>
<td><strong>3</strong> Inclusion of a column presenting absolute risk reduction (risk difference) expressed as percentage for benefit and harm or mean difference</td>
<td>No specific column presenting absolute risk reduction (risk difference) or mean difference</td>
</tr>
<tr>
<td><strong>4</strong> No description of the GRADE Working Group grades of evidence definitions</td>
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</tbody>
</table>
Enhancing the acceptance and implementation of SoF tables in Cochrane reviews

<table>
<thead>
<tr>
<th>Concept</th>
<th>Question asked</th>
<th>Alternative formats (N=122)</th>
<th>Current formats (N=168)</th>
<th>Difference</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ability to determine risk difference</td>
<td>How many fewer children &lt; 5 years will have diarrhea if they have probiotics than if they do not?</td>
<td>98%</td>
<td>35%</td>
<td>63%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Understanding of quality of evidence and treatment effect</td>
<td>Which of the following statements best represents the results informing the outcome adverse events?</td>
<td>88%</td>
<td>26%</td>
<td>62%</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>
### Should self management vs. usual care be used for chronic obstructive pulmonary disease?

#### Self management for patients with chronic obstructive pulmonary disease

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Anticipated absolute effects (95% CI)</th>
<th>Relative effect (95% CI)</th>
<th>No of participants (studies)</th>
<th>Quality</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality of Life assessed with: St George's Respiratory Questionnaire follow up: range 3 to 12 months to</td>
<td>The mean quality of Life was 0</td>
<td><strong>MD 2.58 lower</strong> (5.14 lower to 0.02 lower)</td>
<td>704 (7 RCTs)</td>
<td><strong>MODERATE</strong></td>
<td>A change of less than 4 points is not shown to be important to patients.</td>
</tr>
<tr>
<td>Dyspnoea assessed with: Borg Scale follow up: range 3 to 6 months to</td>
<td>The mean dyspnoea was 0</td>
<td><strong>MD 0.53 lower</strong> (0.96 lower to 0.1 lower)</td>
<td>144 (2 RCTs)</td>
<td><strong>LOW</strong></td>
<td></td>
</tr>
<tr>
<td>Number and severity of exacerbations</td>
<td>see comment</td>
<td>see comment</td>
<td>585 (3 RCTs)</td>
<td><strong>VERY LOW</strong></td>
<td></td>
</tr>
<tr>
<td>Respiratory-related hospital admissions (admissions) follow up: range 3 to 12 months to</td>
<td>Low</td>
<td>10 per 100</td>
<td><strong>7 per 100</strong> (5 to 9)</td>
<td><strong>OR 0.64</strong> (0.47 to 0.89)</td>
<td>966 (8 RCTs)</td>
</tr>
<tr>
<td></td>
<td>High</td>
<td>50 per 100</td>
<td><strong>39 per 100</strong> (32 to 47)</td>
<td>-</td>
<td>328</td>
</tr>
<tr>
<td></td>
<td>Emergency</td>
<td>The mean emergency</td>
<td>MD <strong>0.1 higher</strong></td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>
Should Deferasirox vs. deferoxamine be used for managing transfusional iron overload in people with sickle cell disease [Data only. When citing this recommendation, please include the GRADE evidence profile.]

### Outcomes

**Undesirable effects**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Plain language statements</th>
<th>Absolute Effect Without Deferasirox</th>
<th>Absolute Effect With Deferasirox</th>
<th>Relative effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iron overload</td>
<td>Empty summary</td>
<td>0</td>
<td>0</td>
<td>MD 440.69</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(11.73 to 869.64 more)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Average difference: NaN fewer</td>
<td>238 per 1000</td>
<td>RR 3.13</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(95% CI: 11.73 to 869.64 more)</td>
<td></td>
<td>(1.99 to 4.93)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Moderate</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kidney injury</td>
<td>Empty summary</td>
<td>745 per 1000</td>
<td>238 per 1000</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Discontinuations - Overall Discontinuations</td>
<td>Empty summary</td>
<td>0 per 1000</td>
<td>7 per 1000</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mortality</td>
<td>Empty summary</td>
<td>0 per 1000</td>
<td>7 per 1000</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>End organ damage (incidence of diabetes)</td>
<td>Empty summary</td>
<td>0 per 1000</td>
<td>7 per 1000</td>
<td></td>
</tr>
</tbody>
</table>
Chance of: Satisfaction Follow up: 0 undefined

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
## Hpv vaccine for preventing cervical cancer

### Study characteristics

**Participants:** Girls age 10 to 12  
**Intervention:** HPV vaccine (3 doses at age 10 to 12)

### Outcome

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Plain language summary</th>
<th>Absolute Effect</th>
<th>Relative effect (95% CI)</th>
<th>Certainty of the evidence (GRADE)</th>
</tr>
</thead>
</table>
| Lifetime risk of death from cervical cancer | May slightly decrease the lifetime risk of dying from cervical cancer | Without HPV vaccine: 2 per 1000  
With hpv vaccine: 1 per 1000 | RR 0.52 (0.43 to 0.63) | 🏷️ 🏷️ 🏷️ 🏷️ |

### Additional Outcomes

- Lifetime risk of cervical cancer
- High grade cervical lesions (Grade 2 CIN or worse) follow-up: 1.5 to 5 years
- Any cervical lesion
- External genital lesions follow-up: 1.5 to 5 years
- Serious adverse effects follow-up: 1.5 to 5 years
Ultrasound for patients suspected of having a deep venous thrombosis

People’s risk for Recurrent VTE during 3 months follow up

- **Low probability**
  Typically seen in patients with only one risk factor

- **Medium probability**
  Typically seen in patients with one risk factor

- **High probability**
  Typically seen in patients with severe risk factors

Pre-test
Probability of having Recurrent VTE during 3 months follow up

- 5% of the people in this risk group have 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:
  - 68% of people with a positive test result have Recurrent VTE during 3 months follow up

- With **NEGATIVE** test result:
  - 1% of people with a negative test result have Recurrent VTE during 3 months follow up

Probabilities
Correct diagnosis
<table>
<thead>
<tr>
<th>Positive and negative test results</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Prevalence</th>
<th>People with POSITIVE test result</th>
<th>People with NEGATIVE test result</th>
<th>Pooled Sensitivity/Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>True positives</strong></td>
<td><strong>False positives</strong></td>
<td><strong>True negatives</strong></td>
</tr>
<tr>
<td></td>
<td>50 per 1000</td>
<td>45 per 1000 (95% CI: 44 to 46 per 1000)</td>
<td>21 per 1000 (95% CI: 28 to 15 per 1000)</td>
</tr>
<tr>
<td></td>
<td>100 per 1000</td>
<td>100 per 1000</td>
<td>100 per 1000</td>
</tr>
<tr>
<td></td>
<td>150 per 1000</td>
<td>150 per 1000</td>
<td>150 per 1000</td>
</tr>
</tbody>
</table>

*Typically seen in patients with only one risk factor*

*Typically seen in patients with one risk factor*

*Typically seen in patients with several risk factors*
### Should Compression Ultrasound be used to diagnose Recurrent VTE during 3 months follow up in DVT?

<table>
<thead>
<tr>
<th>Probabilities</th>
<th>Positives / Negatives</th>
<th>Sensitivity / Specificity</th>
<th>Correctly Diagnosed</th>
<th>Plain Language Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>People's risk for Recurrent VTE during 3 months follow up</td>
<td>Probability of having Recurrent VTE during 3 months follow up</td>
<td>Probability of a person having Recurrent VTE during 3 months follow up with test results:</td>
<td></td>
<td>Certainty of the evidence (GRADE)</td>
</tr>
<tr>
<td>Low probability</td>
<td>Typically seen in patients with only one risk factor</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medium probability</td>
<td>Typically seen in patients with one r…</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High probability</td>
<td>Typically seen in patients with severe…</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5%</td>
<td>68%</td>
<td>1%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>of the people in this risk group have Recurrent VTE during 3 months follow up</td>
<td>of people with a positive test result have Recurrent VTE during 3 months follow up</td>
<td>of people with a negative test result have Recurrent VTE during 3 months follow up</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Show confidence intervals
Show diagram
Should Compression Ultrasound be used to diagnose Recurrent VTE during 3 months follow up in DVT?

People's risk for Recurrent VTE during 3 months follow up

- **Low probability**
  Typically seen in patients with only one risk factor
  - ![Small icon]
- **Medium probability**
  Typically seen in patients with two risk factors
  - ![Small icon]
- **High probability**
  Typically seen in patients with severe symptoms
  - ![Small icon]

Pre-test

- Probability of having Recurrent VTE during 3 months follow up
  - 5%

Post-test

- Probability of a person having Recurrent VTE during 3 months follow up with test results:
  - **With POSITIVE test result**
    - 68% of people with a positive test result have Recurrent VTE during 3 months follow up
    - (95% CI: 61% to 75%)
  - **With NEGATIVE test result**
    - 1% of people with a negative test result have Recurrent VTE during 3 months follow up
    - (95% CI: 1% to 0%)

Certainty of the evidence (GRADE)

Out of 1000 people with a low probability of having Recurrent VTE during 3 months follow up there would be:

- 66 positive test results
  - 45 (68%)
- 934 negative test results
  - 929 (99%)
  - 5 (1%)
<table>
<thead>
<tr>
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<tr>
<td><strong>Prevalence</strong></td>
<td><strong>People with</strong></td>
<td><strong>Sensitivity</strong></td>
<td><strong>Specificity</strong></td>
<td><strong>Quality of the evidence (GRADE)</strong></td>
</tr>
<tr>
<td></td>
<td><strong>POSITIVE test result</strong></td>
<td><strong>True positives</strong></td>
<td><strong>False positives</strong></td>
<td><strong>Sensitivity/Specificity</strong></td>
</tr>
<tr>
<td>50 per 1000</td>
<td>Typically seen in patients with only one risk factor</td>
<td>45 per 1000</td>
<td>21 per 1000</td>
<td>(95% CI: 44 to 46 per 1000)</td>
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<tr>
<td>100 per 1000</td>
<td>Typically seen in patients with one risk factor</td>
<td>929 per 1000</td>
<td>5 per 1000</td>
<td>(95% CI: 922 to 935 per 1000)</td>
</tr>
<tr>
<td>150 per 1000</td>
<td>Typically seen in patients with severe risk factors</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Should Compression Ultrasound be used to diagnose Recurrent VTE during 3 months follow up in DVT?

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<td>Prevalence</td>
<td>People with POSITIVE test result</td>
<td>People with NEGATIVE test result</td>
<td>Pooled Sensitivity/Specificity</td>
<td>Number of participants (studies)</td>
</tr>
<tr>
<td></td>
<td>True positives</td>
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<td>True</td>
<td>False</td>
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<td></td>
<td>(95% CI: 44 to 46 per 1000)</td>
<td>(95% CI: 28 to 15 per 1000)</td>
<td>(95% CI: 922 to 935 per 1000)</td>
<td>(95% CI: 6 to 4 per 1000)</td>
</tr>
</tbody>
</table>

**Proportion of persons affected with a particular disease at a specified time.** Prevalence rates obtained from high quality studies can inform pretest probabilities.

- **100 per 1000** Typically seen in patients with one risk factor.
- **150 per 1000** Typically seen in patients with severe...
### Prevalence

<table>
<thead>
<tr>
<th>Prevalence</th>
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<th>People with NEGATIVE test result</th>
<th>Pooled Sensitivity/Specificity</th>
<th>Number of participants (studies)</th>
<th>Quality of the evidence (GRADE)</th>
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</thead>
<tbody>
<tr>
<td>50 per 1000</td>
<td>45 per 1000 (95% CI: 44 to 46 per 1000)</td>
<td>21 per 1000 (95% CI: 28 to 15 per 1000)</td>
<td>Sensitivity 0.903 (95% CI: 0.884 to 0.92)</td>
<td>Based on data from 0 individuals in 22 studies.</td>
<td>Low</td>
</tr>
<tr>
<td>100 per 1000</td>
<td>929 per 1000 (95% CI: 922 to 935 per 1000)</td>
<td>5 per 1000 (95% CI: 6 to 4 per 1000)</td>
<td>Specificity 0.978 (95% CI: 0.97 to 0.984)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>150 per 1000</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Typically seen in patients with only one risk factor.

Typically seen in patients with severe...
### Should Compression Ultrasound be used to diagnose Recurrent VTE during 3 months follow up in DVT?

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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>50 per 1000</td>
<td>Positives</td>
<td>False positives</td>
<td></td>
<td></td>
</tr>
<tr>
<td>100 per 1000</td>
<td>True positives</td>
<td>False positives</td>
<td></td>
<td></td>
</tr>
<tr>
<td>150 per 1000</td>
<td>False positives</td>
<td>True positives</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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).

### People with POSITIVE test result

- True positives: 929 per 1000
- False positives: 5 per 1000

### People with NEGATIVE test result

- True negatives: 912 to 935 per 1000
- False negatives: 6 to 4 per 1000

### Quality of the evidence (GRADE)

- Low

- Based on data from 0 individuals in 22 studies.
Researchers reviewed studies comparing one/two tests to Recurrent VTE during 3 months follow up: the test and the Compression Ultrasound test. They searched for all relevant studies up to [date] and found 22 relevant studies.

**What are and Compression Ultrasound tests?**

The and the Compression Ultrasound tests are tests that a clinician performs to check for Recurrent VTE during 3 months follow up. This disease can . The test checks if a person has Recurrent VTE during 3 months follow up. The test is done in the following way: [description of how the test is done]. The Compression Ultrasound test also checks if a person has Recurrent VTE during 3 months follow up. The test is done in the following way:

**What the research says about the tests**

What are Compression Ultrasound and ? The and Compression Ultrasound tests check for Recurrent VTE during 3 months follow up.

**What the research says about the tests**

A positive test should mean that the person has Recurrent VTE during 3 months follow up. A negative test should mean the person does not have Recurrent VTE during 3 months follow up. But very few tests are perfect and two problems can occur. A positive test could incorrectly say that a person has Recurrent VTE during 3 months follow up when in fact s/he does not (called a “false positive”). As a consequence, this person may have more testing, be worried or treated for no reason. A negative test could incorrectly say that a person does not have Recurrent VTE during 3 months follow up when in fact s/he does have Recurrent VTE during 3 months follow up (called a “false negative”). In this person, Recurrent VTE during 3 months follow up would be missed by the test and s/he may not receive the necessary treatment. When the quality of the evidence is low or very low as opposed to moderate or high, the size of this problem can be considerably larger or smaller than what the numbers indicate.

**(For frequencies use)**

**The test**

Correctly says that:

- 879 out of 1000 people do not have Recurrent VTE during 3 months follow up
- 16 out of 1000 women do have Recurrent VTE during 3 months follow up
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

<table>
<thead>
<tr>
<th>Summary of review finding</th>
<th>Studies contributing to the review finding</th>
<th>Methodological limitations</th>
<th>Coherence</th>
<th>Adequacy</th>
<th>Relevance**</th>
<th>CERQual assessment of confidence in the evidence</th>
<th>Explanation of CERQual assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td>6, 9, 10, 13, 21, 61, 67, 68, 73, 75, 77, 80, 84, 86, 87, 91, 96, 97</td>
<td>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))</td>
<td>No or very minor concerns about coherence (Good fit between data from primary studies and the review finding)</td>
<td>No or very minor concerns about adequacy (15 studies total from 10 countries. Rich data.)</td>
<td>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.)</td>
<td>High confidence</td>
<td>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.</td>
</tr>
</tbody>
</table>
### 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.

<table>
<thead>
<tr>
<th>Summary of review finding</th>
<th>Studies contributing to the review finding</th>
<th>CERQual assessment of confidence in the evidence</th>
<th>Explanation of CERQual assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td>6, 9, 10, 13, 21, 61, 67, 68, 73, 75, 77, 80, 84, 86, 87, 91, 96, 97</td>
<td>High confidence</td>
<td>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.</td>
</tr>
<tr>
<td>2. Physical restraint: Women reported physical restraint during childbirth through the use of bed restraints and mouth gags.</td>
<td>86, 97</td>
<td>Very low confidence</td>
<td>Two studies (Tanzania and Brazil) with moderate methodological limitations. Limited, thin data from 2 countries. Minor concerns about coherence but limited data available.</td>
</tr>
</tbody>
</table>
Using the results of a GRADE / GRADE-CERQual assessment
Now that we have transparent evidence summaries should every cancer patient receive heparin?

<table>
<thead>
<tr>
<th>Outcome after 12 Months</th>
<th>Participants</th>
<th>Relative Risk (95% CI)</th>
<th>Anticipated Absolute Effect</th>
<th>Quality of Evidence (GRADE) and Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major bleeding</td>
<td>6518 (11)</td>
<td>1.06 (0.71–1.57)</td>
<td>16</td>
<td>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</td>
</tr>
<tr>
<td>Minor bleeding</td>
<td>6020 (9)</td>
<td>1.18 (0.89–1.55)</td>
<td>27</td>
<td>5 more (3 fewer to 15 more) Moderate-quality evidence owing to imprecision; however, this outcome is unlikely to be critical for decision making</td>
</tr>
</tbody>
</table>

fewer symptoms
lower risk of complications
better quality of life
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
### 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?

<table>
<thead>
<tr>
<th>Health state/Outcome (Categories of values and preferences)</th>
<th>Estimates of outcome importance (range across studies / pooled mean, 95% CI)</th>
<th>No. of participants/studies</th>
<th>Certainty in evidence</th>
<th>Interpretation of findings</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Exacerbation</strong> (Utility measured with visual analogue scale)</td>
<td>range across studies: 0.289-0.466/ pooled mean: 0.377 (95% CI: 0.294, 0.461)</td>
<td>1076 participants/4 studies</td>
<td>🌟🌟🌟 Moderate certainty due to inconsistency</td>
<td>Most people find exacerbation of COPD probably has a large impact on lives. There is likely no important variability for this assessment.</td>
</tr>
<tr>
<td><strong>Exacerbation</strong> (EQ-5D Utility)</td>
<td>range across studies 0.43-0.683/ pooled mean: 0.525 (95% CI: 0.434, 0.615)</td>
<td>927 participants/3 studies</td>
<td>🌟🌟 Low certainty due to inconsistency and indirectness</td>
<td>Most people find exacerbation of COPD probably has a large impact on lives. There is likely no important variability for this assessment.</td>
</tr>
<tr>
<td><strong>Exacerbation</strong> (disutility)</td>
<td>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)</td>
<td>239 participants/1 study</td>
<td>🌟🌟🌟 High certainty</td>
<td>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.</td>
</tr>
</tbody>
</table>

*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.*
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