INTERNATIONAL CONSENSUS CONFERENCE
ICC·PBM
FRANKFURT
2018

INTRODUCTION TO THE FORMAT AND CONDUCT OF THE INTERNATIONAL CONSENSUS CONFERENCE ON PATIENT BLOOD MANAGEMENT

INDEX

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CONSENSUS DEVELOPMENT CONFERENCE

SCIENTIFIC COMMITTEE

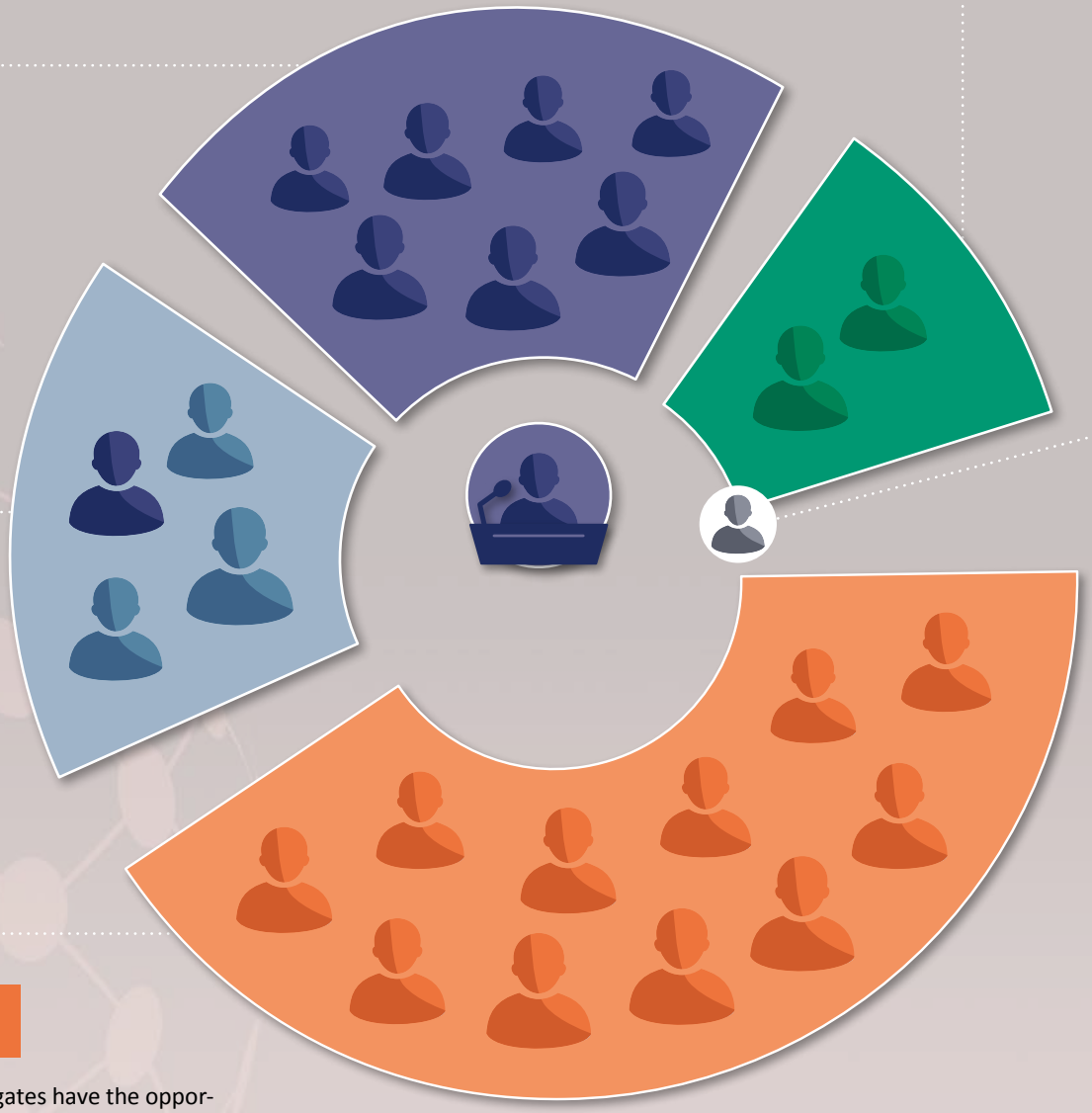
Over 20 International experts to review and summarise available data and other relevant information regarding the 17 PICO questions and present the evidence to the conference audience.

DECISION MAKING PANELS

One Decision Making Panel for each of the three parallel sessions. 7-15 individuals of diverse backgrounds to form each of the panels and write the final consensus conference statement.

AUDIENCE

200-300 invited delegates have the opportunity to give input during the conference.



CHAIRS

Chair and co-chair are responsible for guiding and controlling the proceedings of both the open part of the conference and the executive discussions of the panel to help to reach consensus. Each of the three sessions has a chair and co-chair.

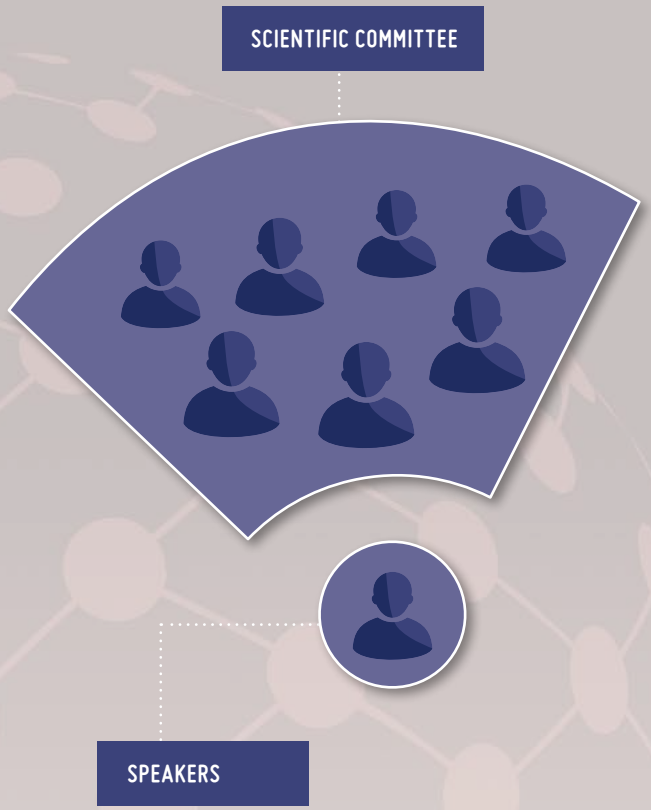
RAPPORTEURS

Record discussion and outcomes according to the GRADE's Evidence-to-Decision framework

MAJOR STEPS IN THE CONSENSUS DEVELOPMENT CONFERENCE FORMAT

1. The Evidence will be presented by the scientific committee to the conference in three public (open) parallel sessions followed by a discussion. The audience can register to the session of their preference.
2. Private (executive) session by the decision making panel to further deliberate on the evidence and discussion to reach consensus on the three topics. The result will be a draft consensus statement.
3. Presentation of draft consensus statement in a plenary session + review/comment by conference attendees.
4. Final executive session with final consensus statement by decision-making panel.

TASKS OF THE SCIENTIFIC COMMITTEE



BEFORE THE CONSENSUS MEETING

- Chair nominates Scientific Secretariat to support conference arrangements
- Selection and definition of PICO questions and corresponding selection criteria
- The Centre for Evidence-Based Practice (Belgian Red Cross) carries out the systematic review
- Review the evidence summaries of the assigned PICO question
- Select speakers to present the evidence at the conference
- Select members to join the Decision-Making Panels
- Learn how to use and apply the GRADE approach (via videoconference)
- Declaring any potential financial, professional and/or personal Conflict of Interest

DURING THE CONSENSUS MEETING

- Selected members present the evidence in the 3 parallel sessions (Day 1)
- Selected members participate in the Decision-Making Panels (Day 1 and 2)

AFTER THE CONSENSUS MEETING

- Involvement and (co-)authorship in peer-reviewed publications

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TASKS OF THE DECISION-MAKING PANEL

Decision-Making Panels consist of Scientific Committee members and other multidisciplinary experts

BEFORE THE CONSENSUS MEETING

- Review the evidence summaries of the session
- Learn how to use the GRADE approach and its Evidence-to-Decision framework (via videoconference)
- Declaring any potential financial, professional and/or personal Conflict of Interest

DURING THE CONSENSUS MEETING

- Executive/private session after the parallel session (day 1) to further deliberate on the evidence and discussion to reach consensus -> draft recommendations (cfr. evidence to recommendation frame-work (GRADE template))
- Final executive/private session after plenary session (day 2) to finalise consensus statement

AFTER THE CONSENSUS MEETING

- Involvement and (co-)authorship in peer-reviewed publications

PANEL 1 → PARALLEL SESSION 1 DAY 1 (PREOPERATIVE ANEMIA)

PANEL 2 → PARALLEL SESSION 2 DAY 1 (RBC TRANSFUSION TRIGGERS)

PANEL 3 → PARALLEL SESSION 3 DAY 1 (PBM IMPLEMENTATION)

TASKS OF THE CHAIRS

BEFORE THE CONSENSUS MEETING

- Review the evidence summaries of the session
- Learn how to use the GRADE approach and its Evidence-to-Decision framework (via video conference)
- Declaring any potential financial, professional and/or personal Conflict of Interest

DURING THE CONSENSUS MEETING

- Moderators responsible for guiding and controlling the proceedings of their public session and corresponding private session with the Decision-Making Panel
- Help to reach consensus according to evidence to desicion framework (GRADE)
- Presenting draft recommendations in plenary session

AFTER THE CONSENSUS MEETING

- Involvement and (co-)authorship in peer-reviewed publications

CHAIRS 1 → PARALLEL SESSION 1 DAY 1 (PREOPERATIVE ANEMIA)

CHAIRS 2 → PARALLEL SESSION 2 DAY 1 (RBC TRANSFUSION TRIGGERS)

CHAIRS 3 → PARALLEL SESSION 3 DAY 1 (PBM IMPLEMENTATION)

CHAIRS 4 → PLENARY SESSION DAY 2

TASKS OF THE RAPPORTEURS

RAPPORTEUR 1 → PARALLEL SESSION 1 DAY 1 (PREOPERATIVE ANEMIA)

RAPPORTEUR 2 → PARALLEL SESSION 2 DAY 1 (RBC TRANSFUSION TRIGGERS)

RAPPORTEUR 3 → PARALLEL SESSION 3 DAY 1 (PBM IMPLEMENTATION)

RAPPORTEUR 4 → PLENARY SESSION DAY 2

BEFORE THE CONSENSUS MEETING

- Review the evidence summaries of the session
- Learn how to use the GRADE approach and its Evidence-to-Decision framework (via videoconference)
- Declaring any potential financial, professional and/or personal Conflict of Interest

DURING THE CONSENSUS MEETING

- Keep notes of all questions, answers and debates and provide a summary of the most significant information of your session
- Record outcomes of the Executive (closed) sessions of respective Decision-Making Panel according to the Evidence-to-Decision framework (GRADE)

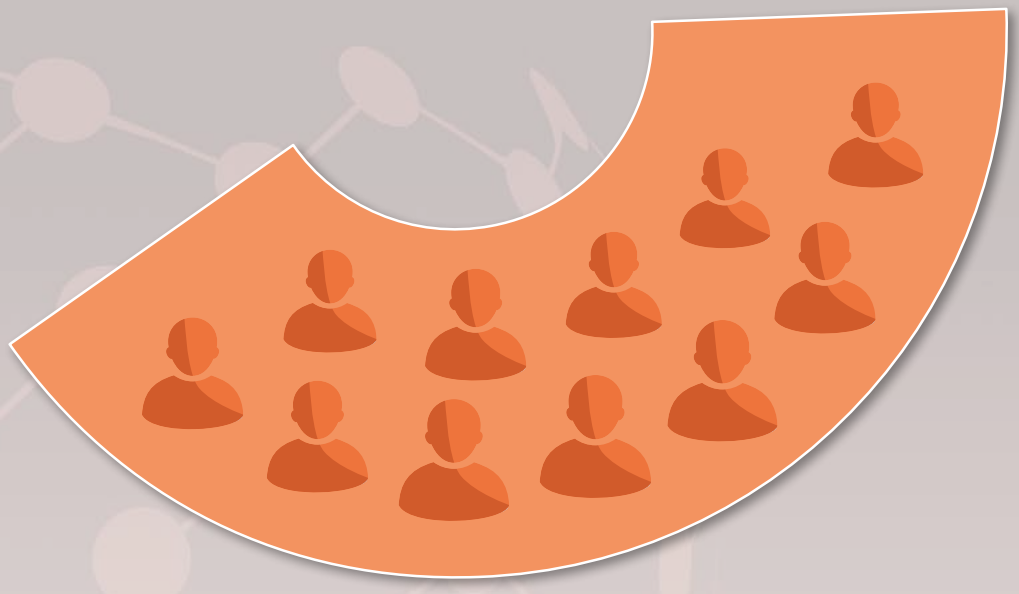
AFTER THE CONSENSUS MEETING

- Involvement and (co-)authorship in peer-reviewed publications

TASKS OF THE AUDIENCE

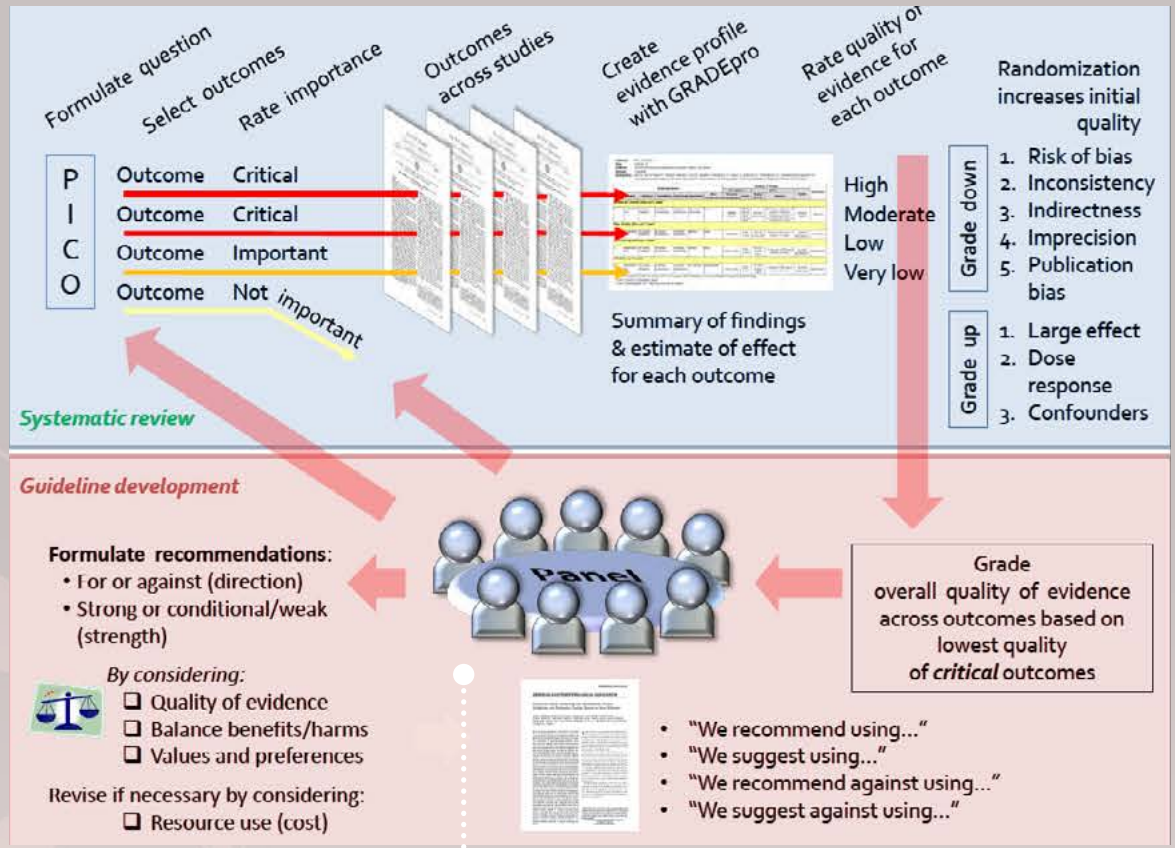
DURING THE CONSENSUS CONFERENCE

- Review of the evidence summaries and presentations at the consensus conference
- Opportunity to ask questions, give an indicative vote and make remarks during open sessions on Day 1 and during the plenary session on Day 2



GRADE APPROACH

A schematic view of the GRADE approach for synthesizing evidence and developing recommendations. The upper half describe steps in the process common to systematic reviews and making health care recommendations and the lower half describe steps that are specific to making recommendations (based on GRADE meeting, Edingburgh 2009). The involvement/roles of the different groups in this approach is showed.



WHAT IS THE GRADE APPROACH?

- **GRADING OF RECOMMENDATIONS ASSESSMENT, DEVELOPMENT AND EVALUATION**
- **COMMON, SENSIBLE AND TRANSPARENT APPROACH TO GRADING:**
  1. Quality (or certainty) of evidence
  2. Strength of recommendations
- **INVOLVEMENT MANY INTERNATIONAL ORGANIZATIONS — STANDARD IN GUIDELINE DEVELOPMENT**
  More than 100 organizations from 19 countries worldwide have endorsed or are using GRADE.

GRADE
WWW.GRADEWORKINGGROUP.ORG

5 FACTORS THAT CAN LOWER THE QUALITY OF EVIDENCE

- METHODOLOGICAL LIMITATIONS
- INCONSISTENCY OF RESULTS
- INDIRECTNESS OF EVIDENCE
- IMPRECISION OF RESULTS
- PUBLICATION BIAS

3 FACTORS THAT CAN RAISE THE QUALITY OF EVIDENCE

- LARGE MAGNITUDE OF EFFECT
- DOSE-RESPONSE GRADIENT
- PLAUSIBLE CONFOUNDING

HOW WILL WE USE THE GRADE APPROACH?

1. ASSESSING THE QUALITY OF EVIDENCE

- On a scale from high (A) to very low quality (D)
- Initial quality for experimental studies (RCTs): high
- Initial quality for observational studies: low

  → 5 FACTORS THAT CAN LOWER THE QUALITY OF EVIDENCE

  → 3 FACTORS THAT CAN RAISE THE QUALITY OF EVIDENCE

- Will be performed by methodologist (CEBaP)
- Available in a table in the evidence summary and in an evidence table via the GRADE software (https://gradepro.org)

	INITIAL GRADING E.G. LOW [C]	DOWNGRADING DUE TO
Limitations of study design	[-2 / -1 / 0]	See table 'Quality of evidence'
Imprecision	[-2 / -1 / 0]	[Limited sample sizes/low number of events/lack of data/ large variability of the results]
Inconsistency	[-2 / -1 / 0]	
Indirectness	[-2 / -1 / 0]	
Publication bias	[-2 / -1 / 0]	[Conflict of interest]
		UPGRADING DUE TO
Large magnitude of effect	[0 / +1 / +2]	
Dose-response gradient	[0 / +1 / +2]	
Plausible confounding	[0 / +1 / +2]	
QUALITY (GRADE)	Final grading e.g. Very low [D]	

HOW WILL WE USE THE GRADE APPROACH?

2. MOVING FROM EVIDENCE TO RECOMMENDATIONS

- Strength of recommendations should be assessed using 2 categories: weak versus strong recommendations (for or against an option)

- Consistent/unambiguous terminology is required:
  → Terminology STRONG recommendations:
  we recommend…
  clinicians should…
  clinicians should not…
  Do…, Don't…

  → Terminology WEAK (conditional, discretionary or qualified) recommendations:
  we suggest…
  clinicians might…
  we conditionally recommend…
  we make a qualified recommendation that…

HOW WILL WE USE THE GRADE APPROACH?

2. MOVING FROM EVIDENCE TO RECOMMENDATIONS

- 10 domains contribute to the strength of recommendation

	FACTORS THAT SHOULD BE CONSIDERED WHEN FORMULATING RECOMMENDATIONS	COMMENT
1 DESIRABLE EFFECTS	How substantial are the desirable anticipated effects?	How large are the desirable effects of the intervention taking into account the importance of the outcomes, and the size of the effect?
2 UNDESIRABLE EFFECTS	How substantial are the undesirable anticipated effects?	How large are the undesirable effects of the intervention taking into account the importance of the outcomes, and the size of the effect?
3 CERTAINTY OF EVIDENCE	What is the overall certainty of the evidence of effects?	How good an indication does the research provide of the likely effects across all of the critical outcomes; see GRADE evidence tables
4 VALUES	Is there important uncertainty about or variability in how much people value the main outcomes?	How much do individuals value each of the main outcomes? Is uncertainty about how much they value each of the outcomes or variability in how much different individuals value the outcomes large enough that it could lead to different decisions?
5 BALANCE OF EFFECTS	Does the balance between desirable and undesirable effects favor the intervention or the comparison?	What is the balance between the desirable and undesirable effects, taking into account how much individuals value the main outcomes, how substantial the desirable and undesirable effects are, the certainty of those estimates, discount rates, risk aversion and risk seeking?
6 RESOURCES REQUIRED	How large are the resource requirements (costs)?	How large is the cost of the difference in resource use between the intervention and comparison?
7 COST-EFFECTIVENESS	Does the cost-effectiveness of the intervention favor the intervention or the comparison?	Is the intervention cost-effective, taking into account uncertainty about or variability in the costs, uncertainty about or variability in the net benefit, sensitivity analyses, and the reliability and applicability of the economic evaluation?
8 EQUITY	What would be the impact on health equity?	Are there plausible reasons for anticipating differences in the relative effectiveness of the intervention for disadvantaged subgroups or different baseline conditions across disadvantaged subgroups that affect the absolute effectiveness of the intervention or the importance of the problem?
9 ACCEPTABILITY	Is the intervention acceptable to key stakeholders?	Are key stakeholders likely not to accept the distribution of the benefits, harms and costs; or the costs or undesirable effects (benefits) in the future? Are they likely to disagree with the values attached to the desirable or undesirable effect, or not to accept the diagnostic intervention because of ethical concerns?
10 FEASIBILITY	Is the intervention feasible to implement?	Is it feasible to sustain use of the diagnostic intervention and to address potential barriers to using it?

HOW WILL WE USE THE GRADE APPROACH?

2. MOVING FROM EVIDENCE TO RECOMMENDATIONS

- Strong recommendation (unconditional):
  → Desirable effects of an intervention clearly outweigh the undesirable effects (or clearly do not)
  → High-quality research with large, precise effect
  → Low variability or uncertainty in patient values and preferences
  → Low resource allocation

- Weak recommendation (conditional, discretionary, qualified):
  → Desirable effects not clearly greater or smaller than undesirable effects
  → Low quality evidence with imprecise estimate
  → Patient values and preferences very important
  → High resource allocation

- Template *Evidence-to-decision framework* will be used to enhance transparency when moving from evidence to recommendation.

EVIDENCE TO DECISION FRAMEWORK (GRADE)

	JUDGMENT			RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
PROBLEM Is the problem a priority?	☐ No ☐ Probably no	☐ Probably yes ☐ Yes	☐ Varies ☐ Don't know		
DESIRABLE EFFECTS How substantial are the desirable anticipated effects?	☐ Trivial ☐ Small	☐ Moderate ☐ Large	☐ Varies ☐ Don't know		
UNDESIRABLE EFFECTS How substantial are the undesirable anticipated effects?	☐ Large ☐ Moderate	☐ Small ☐ Trivial	☐ Varies ☐ Don't know		
CERTAINTY OF EVIDENCE What is the overall certainty of the evidence of effects?	☐ Very low ☐ Low	☐ Moderate ☐ High	☐ No included studies		
VALUES Is there important uncertainty about or variability in how much people value the main outcomes?	☐ Important uncertainty or variability ☐ Possibly important uncertainty or variability ☐ Probably no important uncertainty or variability ☐ No important uncertainty or variability				
BALANCE OF EFFECTS Does the balance between desirable and undesirable effects favor the intervention or the comparison?	☐ Favors the comparison ☐ Probably favors the comparison ☐ Does not favor either the intervention or the comparison	☐ Probably favors the intervention ☐ Favors the intervention	☐ Varies ☐ Don't know		
RESOURCES REQUIRED How large are the resource requirements (costs)?	☐ Large costs ☐ Moderate costs ☐ Negligible costs and savings	☐ Moderate savings ☐ Large savings	☐ Varies ☐ Don't know		
COST-EFFECTIVENESS Does the cost-effectiveness of the intervention favor the intervention or the comparison?	☐ Favors the comparison ☐ Probably favors the comparison ☐ Does not favor either the intervention or the comparison	☐ Probably favors the intervention ☐ Favors the intervention	☐ Varies ☐ No included studies		
EQUITY What would be the impact on health equity?	☐ Reduced ☐ Probably reduced ☐ Probably no impact	☐ Probably increased ☐ Increased	☐ Varies ☐ Don't know		
ACCEPTABILITY Is the intervention acceptable to key stakeholders?	☐ No ☐ Probably no	☐ Probably yes ☐ Yes	☐ Varies ☐ Don't know		
FEASIBILITY Is the intervention feasible to implement?	☐ No ☐ Probably no	☐ Probably yes ☐ Yes	☐ Varies ☐ Don't know		

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European Blood Alliance
Plesmanlaan 125
1066 CX Amsterdam
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24 & 25 APRIL 2018

International consensus conference
on patient blood management

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