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Ad-o-lopment of guidelines: a way forward for Croatia

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Informed decisions.
Better health.

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Special thanks to:

Holger Schünemann

Elie Akl

Jan Brozek

Members of the KSA Team

Members of the GRADE Working Group

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Adaptation, Evaluation, and Updating of Guidelines

Article 14 in Integrating and Coordinating Efforts in COPD Guideline Development. An Official ATS/ERS Workshop Report

Jako S. Burgers, Antonio Anzueto, Peter N. Black, Alvaro A. Cruz, Béatrice Fervers, Ian D. Graham, Mark Metersky, Mark Woodhead, and Barbara P. Yawn; on behalf of the ATS/ERS Ad Hoc Committee on Integrating and Coordinating Efforts in COPD Guideline Development

TABLE 1. PHASES, MODULES, AND STEPS IN ADAPTATION ACCORDING TO ADAPTE MANUAL

Phase	Modules	Steps
I. Setup	Preparation	• Establish an organizing committee • Select a guideline topic • Check whether adaptation is feasible • Identify necessary resources and skills • Complete tasks for the set-up phase • Write adaptation plan
II. Adaptation	Scope and purpose	• Determine the health questions
	Search and screen	• Search for guidelines and other relevant documents • Screen retrieved guidelines • Reduce a large number of retrieved guidelines
	Assessment	• Assess guideline quality • Assess guideline currency • Assess guideline content • Assess guideline consistency • Assess acceptability/applicability of the recommendations
	Decision and selection	• Review assessments • Select between guidelines and recommendations to create an adapted guideline
	Customization	• Prepare draft adapted guideline
III. Finalization	External review and acknowledgment	• External review by target users • Consult with relevant endorsement bodies • Consult with developers of source guidelines • Acknowledge source documents
	Aftercare planning	• Plan scheduled review and update of adapted guideline
	Final production	• Produce final guidance document

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Decide if adaptation required

Health Research Policy and Systems 2006, 4:25 http://www.health-policy-systems.com/content/4/1/25

Table 1: Checklist for identifying guidelines requiring adaptation

Factors influencing the applicability or transferability of guidelines across different settings	Response (positive answers increase the likelihood that recommendations should be flagged as requiring adaptation)
1. Is there important variation in need (prevalence, baseline risk or health status) that might lead to different decisions?	☐ Yes ☐ Unclear ☐ No
2. Is there important variation in the availability of resources that might lead to different decisions?	☐ Yes ☐ Unclear ☐ No
3. Is there important variation in costs (e.g. of drugs or human resources) that might lead to different decisions?	☐ Yes ☐ Unclear ☐ No
4. Is there important variation in the presence of factors that could modify the expected effects (e.g. resistance patterns of microbiological pathogens), which might lead to different decisions?	☐ Yes ☐ Unclear ☐ No
5. Is there important variation in the relative values of the main benefits and downsides that might lead to different decisions?	☐ Yes ☐ Unclear ☐ No

Variation in

- Baseline risk
- Availability of resources
- Costs
- Effect modifiers
- Values & preferences

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Guideline ‘Ad-o-lopment’

- Ad-o-lopment = Adaptation + Adoption + Development
- Approach to the “adolopment” of guidelines through
  1. Identification of existing evidence syntheses (systematic reviews, HTAs, and evidence reports), which address specific clinical questions (and may have been produced to support previous guidelines)
  2. Updating the evidence syntheses
  3. Development of guideline recommendations in structured and transparent way specific to a healthcare setting (EtDs).
- Often not simply adopting recommendations given in previous guidelines.

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Selection of Guidelines

- Use transparent grading and recommendation methodology
- Use transparent criteria for moving from evidence to recommendations
- Provide evidence summaries that are transparent (to allow production of GRADE evidence tables)
- Recently published

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Credibility of the Systematic Review Process (e.g. AMSTAR)

- Did the review explicitly address a sensible clinical question?
- Was the search for relevant studies exhaustive?
- Was the risk of bias of the primary studies assessed?
- Were selection and assessments of studies reproducible?
- Did the review address possible explanations of between-study differences in results (heterogeneity)?
- Did the review present results that are ready for clinical application?
- Did the review address confidence in effect estimates (i.e, quality of evidence)?

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SAUDI ARABIAN MOH GUIDELINES – PHASE II

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Project Overview

- **Objective**: To develop health care guidelines on 12 clinical topics.
- Timeline: June 2014 through January 2015
- Focus in this project is on ***'ad-o-lopment"*** of guidelines, rather than ***de novo*** development of guidelines.
- Collaboration between Ministry of Health of Kingdom of Saudi Arabia (MoH KSA) and McMaster University, Department of Clinical Epidemiology and Biostatistics (and partners in Freiburg und Beirut)

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Ministry of Health

The Saudi Center for
Evidence Based Health Care

Saudi Arabian Handbook for Healthcare Guideline Development

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Selection of guideline topics

List of approximately 50 eligible existing guidelines or high priority topics

Definition of selection criteria and assessment of the potential topics according to the criteria.

- Published recently (i.e. 3-4 year max) in English language
- Risk of bias assessment for the evidence
- Existing, or accessible or reproducible, evidence tables or summaries,
- Transparent grading methodology of the quality of the evidence (ideally)
- Published (or otherwise accessible) search strategies with inclusion and exclusion criteria, for updating

Reasonably good scoring on credibility assessment tools (well done evidence review)

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Topics

1. Prevention of venous thromboembolism (VTE) in nonsurgical patients
2. Prevention of VTE in surgical patients
3. Management of pre-eclampsia
4. Management of eclampsia
5. Screening for hypertension
6. Management of ST-elevation myocardial infarction
7. Screening for colon cancer
8. Management of obesity/overweight in adults
9. Management of breast lump
10. Migraine diagnosis and treatment
11. Management of thalassemia – treatment of iron overload and supplementation
12. Management of sickle cell anemia – acute and chronic

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Groups and Roles

McMaster Guideline Working Group:

- Methodological support and training
- Evidence synthesis and updating
- Preparing evidence summaries for panels
- SRs on values and economic data
- Preparing guideline reports

Saudi Centre for EBHC

Saudi Expert Guideline Panels

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Groups and Roles

McMaster Guideline Working Group

Saudi Centre for EBHC:

- Project coordination
- Recruiting panel members
- Facilitating communication with panels
- Dissemination of guidelines

Saudi Expert Guideline Panels

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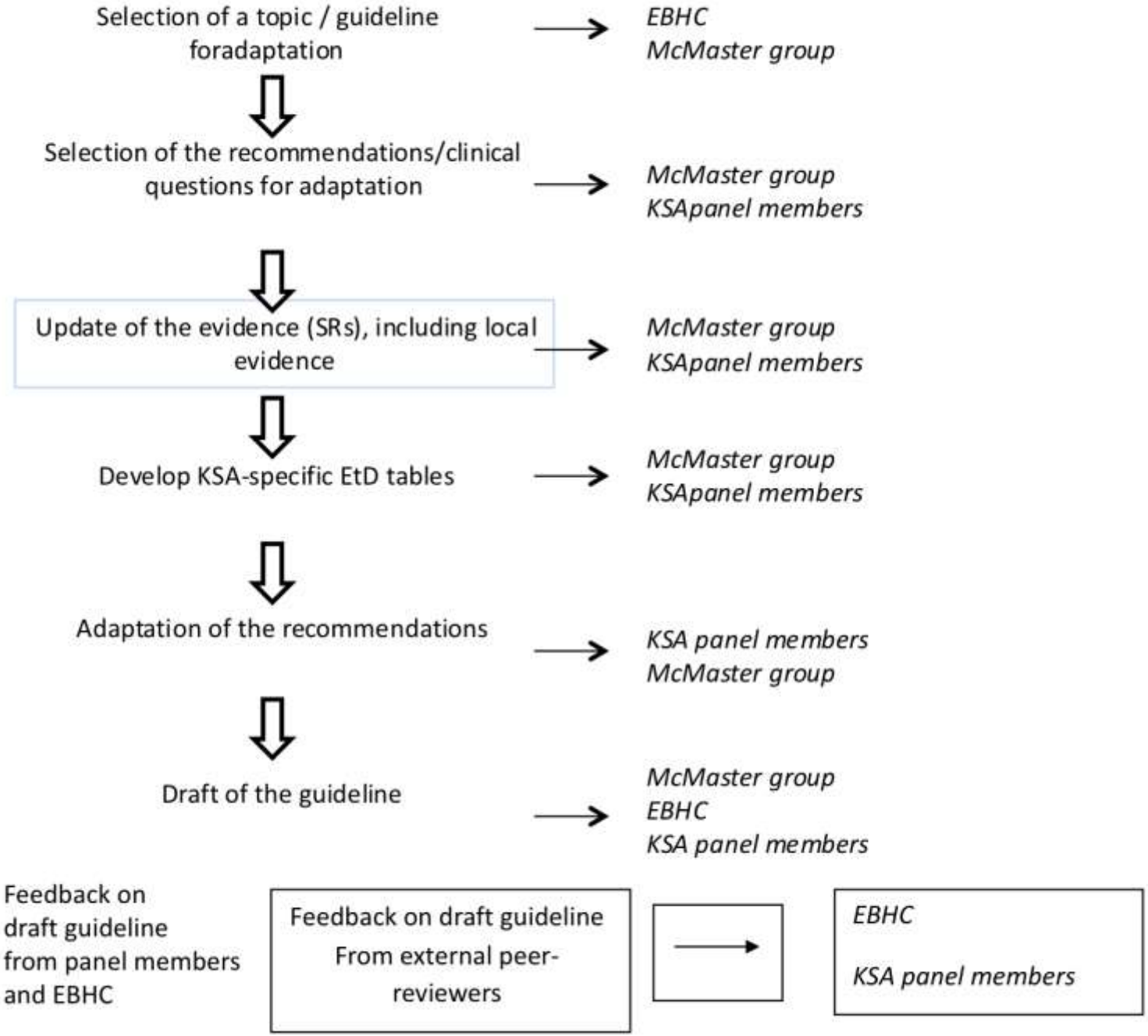
Groups and Roles

McMaster Guideline Working Group

Saudi Centre for EBHC

Saudi Expert Guideline Panels:

- Prioritization of questions for guidelines
- Suggesting local evidence and input on local data and contextual factors
- Reviewing evidence summaries
- Making judgements and formulating recommendations in final panel meeting
- Dissemination of guidelines


Selection of a topic / guideline foradaptation
EBHC
McMaster group
Selection of the recommendations/clinical questions for adaptation
McMaster group
KSApanel members
Update of the evidence (SRs), including local evidence
McMaster group
KSApanel members
Develop KSA-specific EtD tables
McMaster group
KSApanel members
Adaptation of the recommendations
KSA panel members
McMaster group
Draft of the guideline
McMaster group
EBHC
KSA panel members
Feedback on draft guideline from panel members and EBHC
Feedback on draft guideline From external peer-reviewers
EBHC
KSA panel members

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The Question

Key questions

1. Should home treatment vs. hospital treatment be used for patients with acute DVT of the leg?
2. Should early discharge vs. standard discharge be used for patients with acute PE?
3. Should heparin vs no heparin be used in outpatients with cancer who have no other therapeutic or prophylactic indication for anticoagulation?
4. Should oral anticoagulation vs no oral anticoagulation be used in outpatients with cancer who have no other therapeutic or prophylactic indication for anticoagulation?
5. Should parenteral anticoagulation vs no anticoagulation be used in patients with cancer and central venous catheters?
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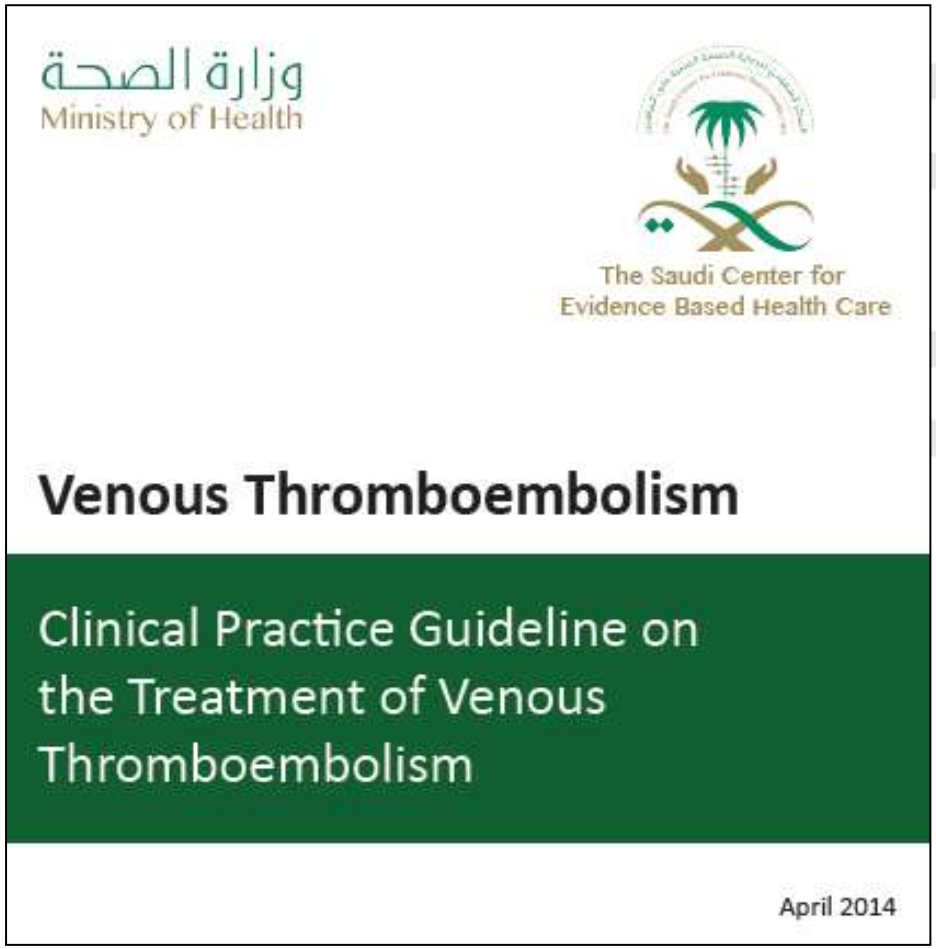

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The GRADE SoF table

Home treatment compared to hospital treatment for patients with DVT

Patient or population: patients with patients with DVT[1,2]
Settings:
Intervention: home treatment[3,4]
Comparison: hospital treatment
Bibliography: Othieno R, Aby A, Okpo E. Home versus inpatient treatment for DVT. Cochrane database of Systematic Reviews 2007 Issue 3. Algahtani 2013

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk Hospital treatment	Corresponding risk Home treatment				
Mortality	46 per 1000	33 per 1000 (21 to 53)	RR 0.72 (0.45 to 1.15)	1708 (6 studies)	⊕⊕⊖⊖ low[3,4,5,6]	
Recurrent VTE	76 per 1000	49 per 1000 (33 to 71)	RR 0.65 (0.44 to 0.94)	1769 (7 studies)	⊕⊕⊕⊖ moderate[3,4,5]	
Major bleeding	21 per 1000	14 per 1000 (7 to 29)	RR 0.67 (0.33 to 1.36)	1708 (6 studies)	⊕⊕⊖⊖ low[3,4,5,6]	
Quality of life	-	-	-	0 (3 studies[7])	⊕⊕⊖⊖ low[6,8,9,10]	
Post thrombotic syndrome - not reported	-	-	-	-	-	

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

CI: Confidence interval; **RR:** Risk ratio;

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

[1] RCTs included recruited patients "whose home circumstances were adequate"
[2] RCTs included patients with leg DVT. They excluded those with PE and pregnant women
[3] 4 RCTs had partial hospital treatment for some participants in the home group: Levine 1996 (mean hospital stay 2.1 vs. 6.5 days in home and hospital arms respectively), Koopman 1996 (2.7 vs. 8.1 days), Boccalon 2000 (1 vs. 9.6 days), and Ramacciotti 2004 (3 vs. 7 days). Chong 2005 and Daskalopoulos 2005 did not report mean duration of hospital stay.
[4] One RCT (Baccalon 2000) used LMWH in both treatment groups. Remaining studies used LMWH in the outpatient group and UFH in the inpatient group.
[5] Of 7 RCTs, allocation was clearly concealed in 3 (unclear in 4), outcome adjudicators were clearly blinded in the 2 largest RCTs (unclear in remaining 5), missing data was significant in one small RCT, and analysis was ITT in 4 (unclear in remaining 3). These limitations did not warrant downgrading of quality of evidence, particularly because it had already been downgraded by at least one level for other reasons.
[6] CI includes values suggesting benefit and values suggesting harm
[7] Backman 2004, using EQ 5D, found no differences in mean QoL scores or in proportion of participants showing improvement in self-rated health state. Koopman 1996, using the Medical Outcome Study Short Form–20 and an adapted version of the Rotterdam Symptom Checklist, found that changes over time were similar in both arms (exception: had better scores for physical activity (P=0.002) and social functioning (P=0.001) in those receiving LMWH at the end of the initial treatment. O'Brien 1999, using SF-36 in 300 participants from Levine 1996, found no significant differ-

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The GRADE/DECIEE EtD

Key questions

1. Should home treatment vs. hospital treatment be used for patients with acute DVT of the leg?
2. Should early discharge vs. standard discharge be used for patients with acute PE?
3. Should heparin vs no heparin be used in outpatients with cancer who have no other therapeutic or prophylactic indication for anticoagulation?
4. Should oral anticoagulation vs no oral anticoagulation be used in outpatients with cancer who have no other therapeutic or prophylactic indication for anticoagulation?
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6. Should oral anticoagulation vs no anticoagulation be used in patients with cancer and central venous catheters?

→ Evidence-to-Decision Framework

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Welcome | DECIDE

www.decide-collaboration.eu

DECIDE GRADE

DECIDE

Developing and Evaluating Communication Strategies to Support Informed Decisions and Practice Based on Evidence

European Commission

SEVENTH FRAMEWORK PROGRAMME

- Home
- Queries & Staying Informed
- Project Partners & Coordinating Person
- Work Packages & Strategies
- Keypoints
- Publications
- Contact & Disclaimer
- Monthly Round Up
- Member login

Welcome

DECIDE GRADE
Developing and Evaluating Communication strategies to support Informed Decisions and practice based on Evidence

is a 5-year project (running from January 2011 to 2015) co-funded by the European Commission under the Seventh Framework Programme.

Project Objective

"To improve the dissemination of evidence-based recommendations by building on the work of the GRADE Working Group to develop and evaluate methods that address the targeted dissemination of guidelines."

Background

Healthcare decision makers face challenges in understanding guidelines, including the quality of the evidence upon which recommendations are made, which often is not clear. Guidelines are also typically developed as a one-size-fits-all package. By developing and evaluating targeted dissemination strategies, DECIDE aims to increase the use of evidence-based interventions in a sustainable way and to reduce the use of interventions where benefits are uncertain.

Methods

GRADE is a systematic approach towards assessing and communicating the quality of evidence and the strength of recommendations. It has been developed to address the weaknesses of other grading systems and is now widely used internationally. The DECIDE consortium, which is composed of members of the GRADE Working Group, will further develop this approach to ensure effective dissemination of evidence-based recommendations targeted at the key stakeholders (healthcare professionals; policymakers and managers; patients and the general public) who determine what happens in clinical practice. We will collect stakeholder input from advisory groups, consultations and user testing. This will be done across a wide range of health systems in Europe. The targeted dissemination strategies that are developed will be evaluated in randomized trials, refined and used and evaluated with real guidelines developed by the DECIDE partners and other guideline developers that we support.

Expected results

Dissemination strategies for recommendations that have been rigorously evaluated in diverse settings, support the transfer of research into practice, and are adapted to real-world healthcare systems.

Related Resources

Grade Working Group

Cochrane Applicability and Recommendations Methods Group

Search

Search this site: Search

Our news

DECIDE article is "Highly Accessed" (18/06/2013)

New DECIDE publication (04/06/2013)

DECIDE International Conference - initial planning phase

Accepted abstracts for G-I-N 2013

DECIDE Consortium and GRADE meetings, January 2014

New venue for Consortium meeting

DECIDE protocol is published

Angela Morelli has been selected as a Young Global Leader by the World Economic Forum

NICE have paper published about GRADE at Science Direct

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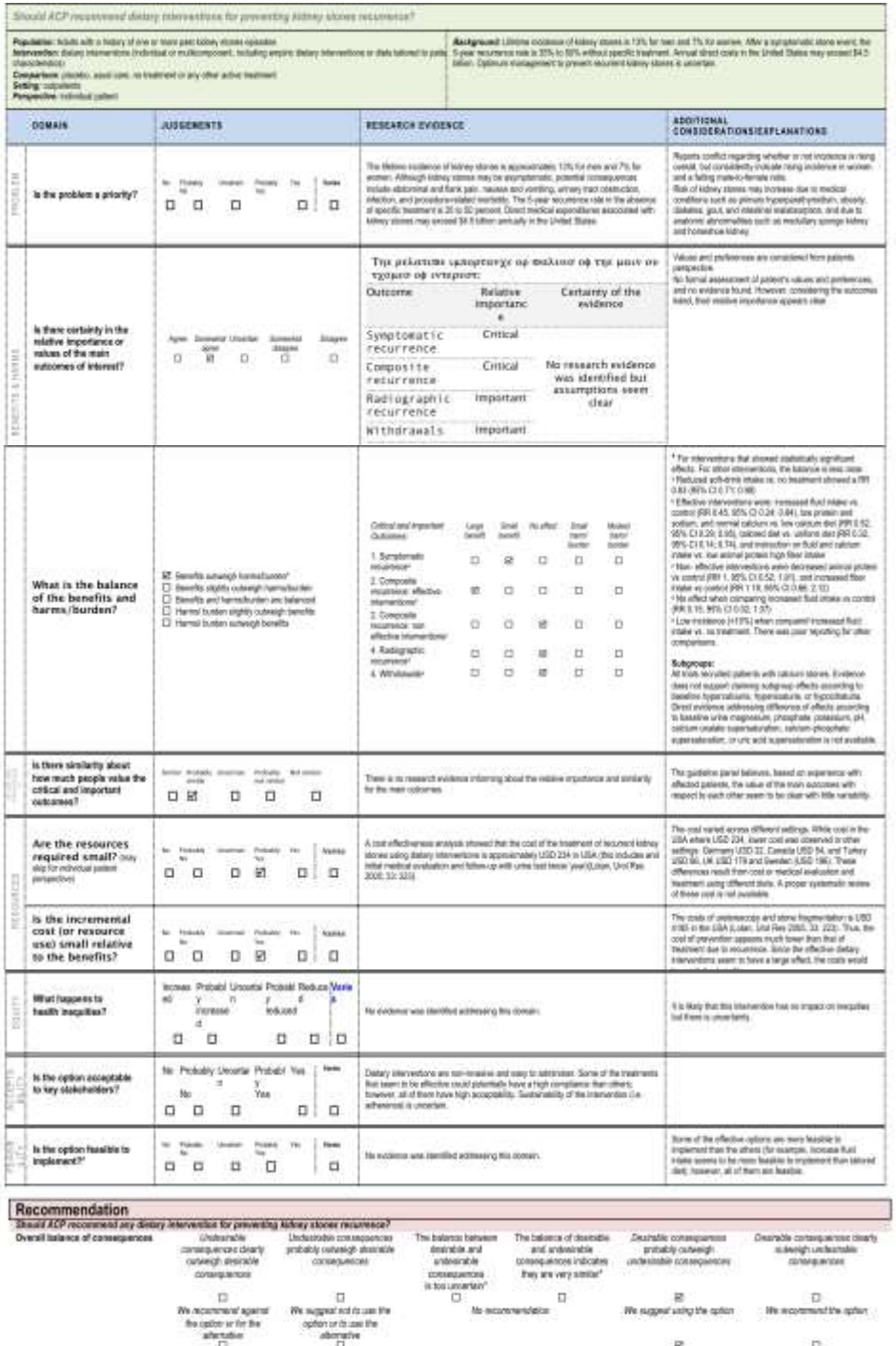
- Question/Problem
- Benefits and harms
- Quality of evidence
- Values
- Resources
- Equity
- Acceptability
- Feasibility
- Recommendation



GRADE DECIDE

EVidence to decision

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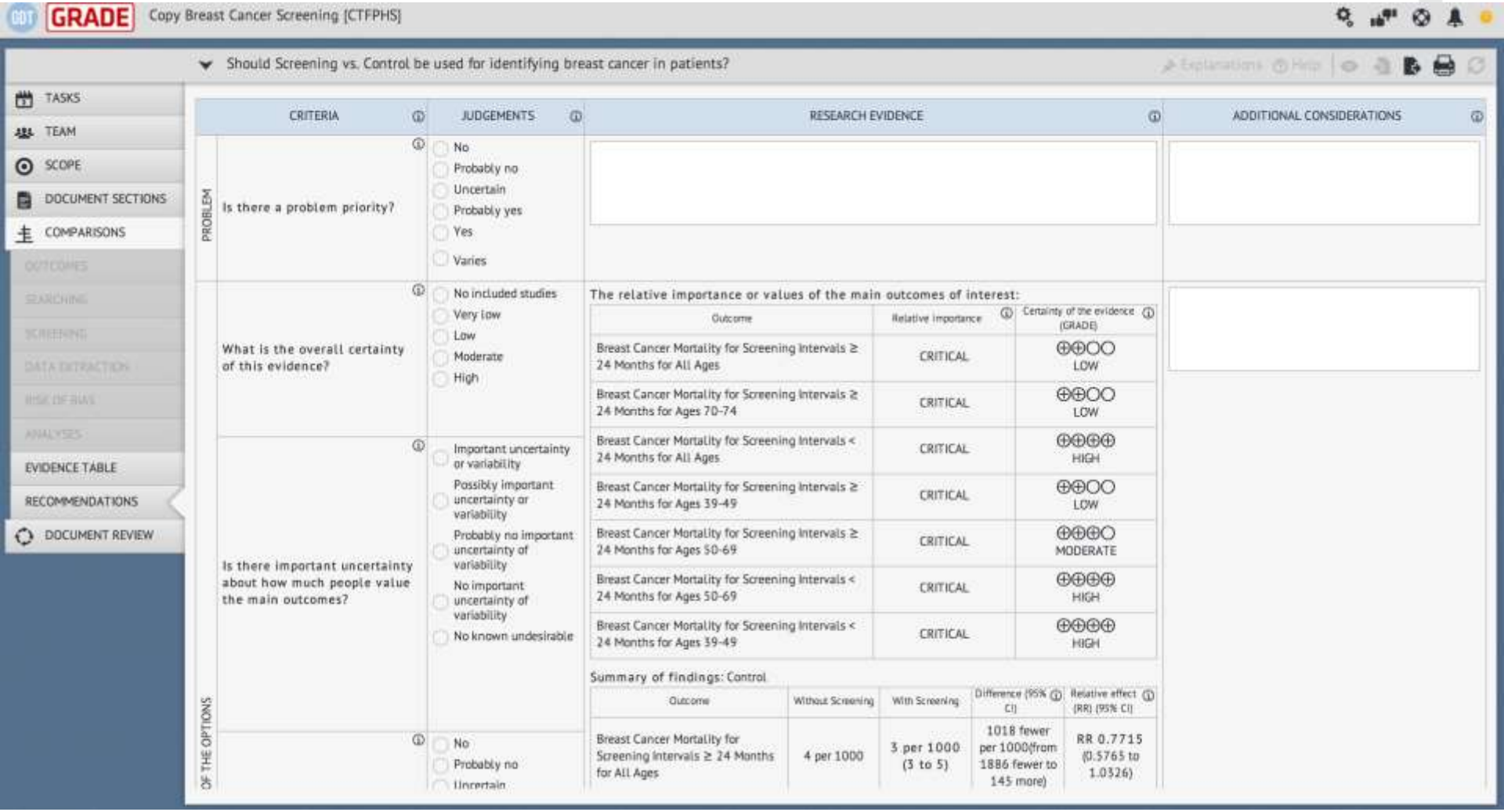
GRADE Evidence to Decision Frameworks



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The Final Product

Key questions

1. Should home treatment vs. hospital treatment be used for patients with acute DVT of the leg?
2. Should early discharge vs. standard discharge be used for patients with acute PE?
3. Should heparin vs no heparin be used in outpatients with cancer who have no other therapeutic or prophylactic indication for anticoagulation?
4. Should oral anticoagulation vs no oral anticoagulation be used in outpatients with cancer who have no other therapeutic or prophylactic indication for anticoagulation?
5. Should parenteral anticoagulation vs no anticoagulation be used in patients with cancer and central venous catheters?
6. Should oral anticoagulation vs no anticoagulation be used in patients with cancer and central venous catheters?

Recommendation 1:

For patients with simple acute DVT of the leg, the Saudi Expert Panel suggests home treatment over hospital treatment (conditional recommendation; moderate quality evidence)

Remarks:

- Ensure that patients have support from family, access to a phone, access to a physician, and the ability to get to a hospital in a reasonable time if needed
- Consider patient level of education, knowledge about the disease, and likelihood of compliance
- Consider hospital treatment for patients with severe acute DVT of the leg and patients who are apprehensive
- This recommendation applies to anticoagulation treatment with LMWH but not NOACs

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Breast cancer screening

CMAJ GUIDELINES

Recommendations on screening for breast cancer in average-risk women aged 40–74 years

The Canadian Task Force on Preventive Health Care

See related commentary by Gøtzsche on page 1957 and at www.cmaj.ca/lookup/doi/10.1503/cmaj.111721

Women aged 40–49 years

For women 40–49 years of age, we recommend not routinely screening for breast cancer with mammography. (Weak recommendation; moderate-quality evidence.)

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Ministry of Health

Center for
ed Health Care

Recommendations

Recommendation 1:

The Saudi Expert Panel suggests screening with mammography in women aged 40–49 years every 1 to 2 years. (Conditional recommendation; low-quality evidence)

Clinical Practice Guideline on the Use of Screening Strategies for the Detection of Breast Cancer

Remarks:

Based on local cancer registry data, the incidence of breast cancer in the KSA seems to be higher than in the other countries in which studies were conducted. This fact may indicate that higher benefit on breast cancer mortality justifies a recommendation in favor of implementing breast cancer screening using mammography in this age group. Since the guideline panel determined that there is a close balance between desirable and undesirable consequences, they also suggest implementing shared-decision making strategies as a way to incorporate actively patients' perspective into the decision.

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Reason

Different baseline risk in Saudi Arabia

Multi vessel vs single vessel intervention for myocardial infarction (not recommended)

National Clinical Guideline Centre

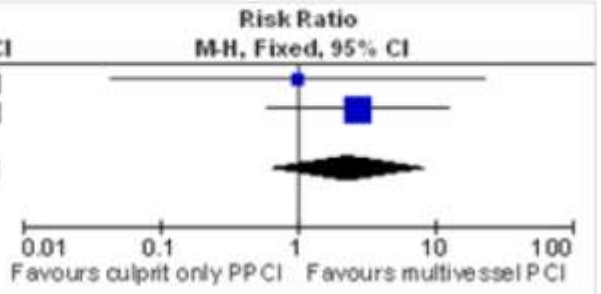
I.5 Culprit versus complete revascularisation

I.5.1 Culprit-only PPCI versus immediate multivessel PCI

Figure 180: RCTs: all-cause mortality (≤ 30 days)

Study or Subgroup	Culprit only PPCI Events	Total	Multivessel PCI Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
HELP-AMI 2004	0	17	1	52	25.2%	0.98 [0.04, 23.03]
Politi 2010	7	84	2	65	74.8%	2.71 [0.58, 12.60]
Total (95% CI)		**101**		**117**	**100.0%**	**2.27 [0.58, 8.85]**
Total events	7		3			

Heterogeneity: $Chi^2 = 0.32$, $df = 1$ ($P = 0.57$); $I^2 = 0\%$
Test for overall effect: $Z = 1.18$ ($P = 0.24$)



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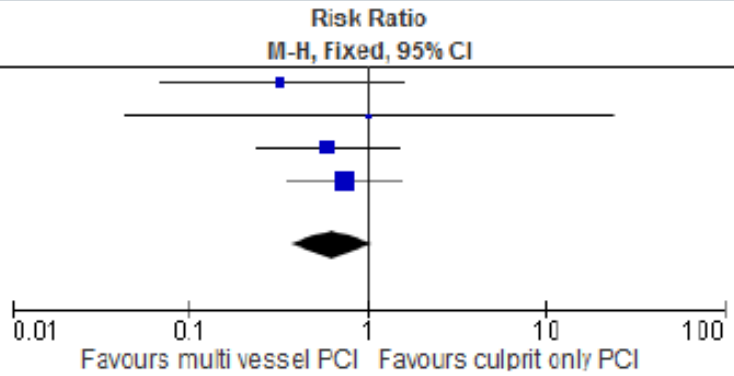
Study or Subgroup	Multi vessel PCI Events	Total	Culprit only PCI Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
CvLPRIT 2015	2	150	6	146	17.7%	0.32 [0.07, 1.58]
Di Mario 2004	1	52	0	17	2.2%	1.02 [0.04, 23.91]
Politi 2010	6	65	13	84	33.1%	0.60 [0.24, 1.48]
Wald 2013	12	234	16	231	47.0%	0.74 [0.36, 1.53]
Total (95% CI)		**501**		**478**	**100.0%**	**0.63 [0.37, 1.05]**
Total events	21		35			

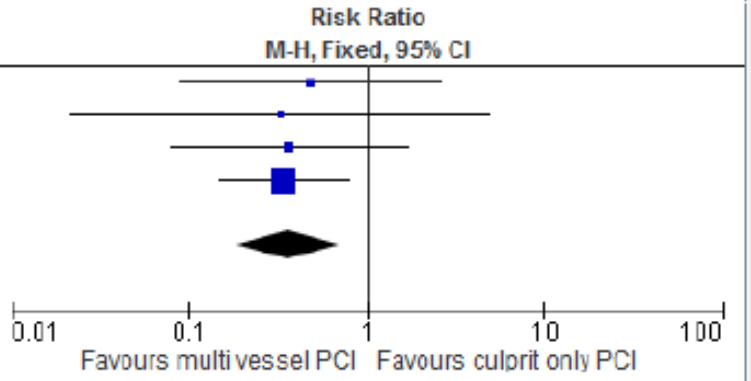
Heterogeneity: Chi² = 0.97, df = 3 (P = 0.81); I² = 0%
Test for overall effect: Z = 1.76 (P = 0.08)



Mortality-long term

Study or Subgroup	Multi vessel PCI Events	Total	Culprit only PCI Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
CvLPRIT 2015	2	150	4	146	12.7%	0.49 [0.09, 2.62]
Di Mario 2004	1	52	1	17	4.7%	0.33 [0.02, 4.95]
Politi 2010	2	65	7	84	19.2%	0.37 [0.08, 1.72]
Wald 2013	7	234	20	231	63.3%	0.35 [0.15, 0.80]
Total (95% CI)		**501**		**478**	**100.0%**	**0.37 [0.19, 0.71]**
Total events	12		32			

Heterogeneity: Chi² = 0.13, df = 3 (P = 0.99); I² = 0%
Test for overall effect: Z = 2.99 (P = 0.003)



Reinfarction

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Recommendation:
Two small trials vs four trials
~200 vs 1000 patients

Evidence Profile: Multi-vessel PPCI compared to culprit only PPCI in patients with STEMI and multi-vessel coronary artery disease undergoing PPCI

Author(s): Veena Manja & Wojtek Wiercioch
Date: 2014-12-15

Quality assessment							№ of patients		Effect		Quality	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	multi-vessel PPCI	culprit only PPCI	Relative (95% CI)	Absolute (95% CI)		
Mortality - long term												
4	randomised trials	serious [1]	not serious	not serious	serious [2]	none	21/501 (4.2%)	35/478 (7.3%)	**RR 0.63** (0.37 to 1.05)	27 fewer per 1000 (from 4 more to 46 fewer)	⊕⊕◯◯ LOW	CRITICAL
Reinfarction												
4	randomised trials	serious [1]	not serious	not serious	not serious	none	12/501 (2.4%)	32/478 (6.7%)	**RR 0.37** (0.19 to 0.71)	42 fewer per 1000 (from 19 fewer to 54 fewer)	⊕⊕⊕◯ MODERATE	CRITICAL
Revascularization												
4	randomised trials	serious [1]	not serious	not serious	not serious	none	38/501 (7.6%)	92/478 (19.2%)	**RR 0.37** (0.26 to 0.53)	121 fewer per 1000 (from 90 fewer to 142 fewer)	⊕⊕⊕◯ MODERATE	CRITICAL

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Reason

Saudi Arabian panel more certain in decision/recommendation

- NEW EVIDENCE IDENTIFIED during our effort

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Summary: Adolopment

Advantages

- Methodological team required
- Faster
- Less resources required
- Transparent consideration of factors beyond QoE (EtDs) with focus on local/regional setting
- Greater buy-in / better implementation
- Builds capacity
- Good fun

Challenges

- Methodological team required
- Solid guideline/SRs required as starting point
- Challenging if no comprehensive guideline available
- Challenging if existing SR restricted inclusion to RCTs or highly selected outcomes
- Panels need to commit to follow rigorous methodological approach and stick to timelines

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Thank you:

Questions?

Discussion?

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EtD Purpose

To help guideline panels (and decision makers) move from evidence to a recommendation or decision by:

- Inform judgements about the pros and cons of each option (intervention) that is considered
- Ensure that important factors that determine a decision (criteria) are considered
- Provide a concise summary of the best available research evidence to inform judgements about each criterion
- Help structure discussion and identify reasons for disagreements
- Make the basis for decisions transparent to target audiences

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CRITERIA	JUDGEMENTS	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS

Criteria on which a recommendation is based

Judgements that must be made in relation to each criterion

Research evidence to inform each judgement

Additional considerations that inform or explain each judgement

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Support tools for GRADE guidelines?

CMAJ RESEARCH

Guidelines 2.0: systematic development of a comprehensive checklist for a successful guideline enterprise

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ABSTRACT

Background: Although several tools to evaluate the credibility of health care guidelines exist, guidance on practical steps for developing guidelines is lacking. We systematically compiled a comprehensive checklist of items linked to relevant resources and tools that guideline developers could consider, without the expectation that every guideline would address each item.

Methods: We searched data sources, including manuals of international guideline developers, literature on guidelines for guidelines (with a focus on methodology reports from international and national agencies, and professional societies) and recent articles providing systematic guidance. We reviewed these sources in duplicate, extracted items for the checklist using a sensitive approach and developed overarching

omissions and involved experts in guideline development for revisions and suggestions for items to be added.

Results: We developed a checklist with 18 topics and 146 items and a webpage to facilitate its use by guideline developers. The topics and included items cover all stages of the guideline enterprise, from the planning and formulation of guidelines, to their implementation and evaluation. The final checklist includes links to training materials as well as resources with suggested methodology for applying the items.

Interpretation: The checklist will serve as a resource for guideline developers. Consideration of items on the checklist will support the development, implementation and evaluation

Competing interests: None declared. Authors of this manuscript have been involved in the development of various guideline manuals which are referenced in this article.

This article has been peer reviewed.

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CMAJ 2014. DOI:10.1503/cmaj.131237

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Main limitation

Time

- May through December 2014

Focus this project on ***updating*** existing, highly credible systematic reviews and provide other information, rather than completely ***de novo*** development of guidelines

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A new version of GRADEpro proudly engineered by: Evidence Prime
The tools for health care decisions

The official tool of GRADE and DECIDE

A new quality in guideline development

Brought to you by the creators of GRADEpro

Guideline Development Tool is an easy to use all-in-one web solution for summarizing and presenting information for healthcare decision making. It supports creating concise summary tables for systematic reviews and health technology assessments as well as facilitates development

Best for both worlds

Guideline developers and authors of systematic reviews

Anyone preparing a systematic review will benefit from a simple online solution that assists creating summaries of evidence. Anyone developing clinical guidelines or other recommendations in healthcare will also benefit from a tool that smoothens the way of following a systematic and