European Reference Networks

II European Reference Network Conference
From planning to implementation
Lisbon, 8-9 October 2015

Tools and best practices for developing and appraising clinical guidelines and patient pathways

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CNMR

As a guideline user, how can you tell which health care guideline to trust?

As a guideline developer, how can you produce trustworthy guidelines?

Why have standards/tools for guideline quality assurance?

Guidelines are more likely to be of **higher quality** if they meet specific **quality criteria** such as described by standards and tools.

Standards and tools are crucial in minimizing the quality differences among guidelines and to promote the development of trustworthy guidelines.

AGREE II

Appraisal of Guidelines for Research and Evaluation II

http://www.agreetrust.org

To evaluate the process of guideline development and the quality of reporting of this process in the guideline

23 items organised into 6 domains

- Scope and purpose
- Stakeholder involvement
- Rigour of development
- Clarity of presentation
- Applicability
- Editorial independence

AGREE II

1	2	3	4	5	6	7

Strongly disagree

Strongly agree

Example - Domain: Rigour of development

7. Systematic methods were used to search for evidence.
8. The criteria for selecting the evidence are clearly described.
9. The strengths and limitations of the body of evidence are clearly described.
10. The methods for formulating the recommendations are clearly described.
11. The health benefits, side effects, and risks have been considered in formulating the recommendations.
12. There is an explicit link between the recommendations and the supporting evidence.
13. The guideline has been externally reviewed by experts prior to its publication.
14. A procedure for updating the guideline is provided.

AGREE II

Domain: Rigour of development

Item 14. A procedure for updating the guideline is provided.

User's Manual Description:

Guidelines need to reflect current research. A clear statement about the procedure for updating the guideline should be provided. For example, a timescale has been given or a standing panel is established who receives regularly updated literature searches and makes changes as required.

Where to Look:

Examine the introduction paragraph, the paragraphs describing the guideline development process and the closing paragraphs. Examples of commonly labeled sections or chapters in a guideline where this information can be found include: methods, guideline update, and date of guideline.

How to Rate:

Item content includes the following *CRITERIA:*

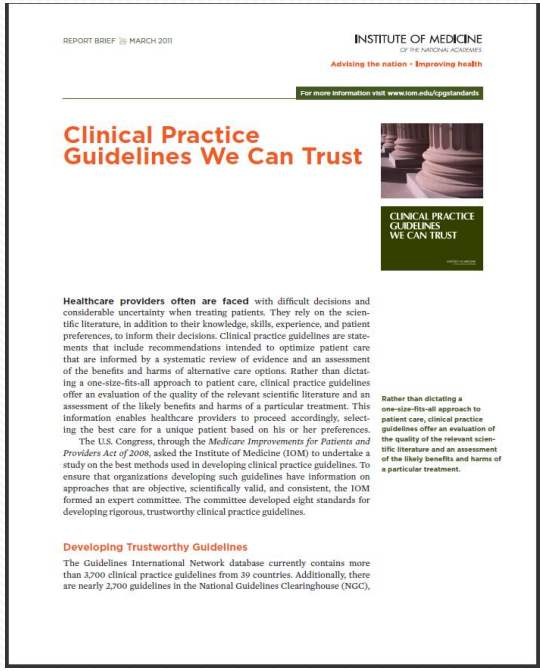
- a statement that the guideline will be updated
- explicit time interval or explicit criteria to guide decisions about when an update will occur
- methodology for the updating procedure is reported

Additional *CONSIDERATIONS*:

- Is the item well written? Are the descriptions clear and concise?
- Is the item content easy to find in the guideline?
- Is there enough information provided to know when an update will occur or what criteria would trigger an update?

Institute of Medicine (IOM)

Clinical practice guidelines we can trust



REPORT BRIEF ▪ MARCH 2011

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For more information visit www.iom.edu/cpgstandards

Clinical Practice Guidelines We Can Trust

CLINICAL PRACTICE GUIDELINES WE CAN TRUST

Healthcare providers often are faced with difficult decisions and considerable uncertainty when treating patients. They rely on the scientific literature, in addition to their knowledge, skills, experience, and patient preferences, to inform their decisions. Clinical practice guidelines are statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options. Rather than dictating a one-size-fits-all approach to patient care, clinical practice guidelines offer an evaluation of the quality of the relevant scientific literature and an assessment of the likely benefits and harms of a particular treatment. This information enables healthcare providers to proceed accordingly, selecting the best care for a unique patient based on his or her preferences.

The U.S. Congress, through the *Medicare Improvements for Patients and Providers Act of 2008*, asked the Institute of Medicine (IOM) to undertake a study on the best methods used in developing clinical practice guidelines. To ensure that organizations developing such guidelines have information on approaches that are objective, scientifically valid, and consistent, the IOM formed an expert committee. The committee developed eight standards for developing rigorous, trustworthy clinical practice guidelines.

Rather than dictating a one-size-fits-all approach to patient care, clinical practice guidelines offer an evaluation of the quality of the relevant scientific literature and an assessment of the likely benefits and harms of a particular treatment.

Developing Trustworthy Guidelines

The Guidelines International Network database currently contains more than 3,700 clinical practice guidelines from 39 countries. Additionally, there are nearly 2,700 guidelines in the National Guidelines Clearinghouse (NGC),

http://www.iom.edu/Reports/2011/Clinical-Practice-Guidelines-We-Can-Trust/Standards.aspx

http://www.iom.edu/Reports/2011/Clinical-Practice-Guidelines-We-Can-Trust.aspx

25 standards covering 8 areas

- Establishing transparency
- Management of conflict of interest
- Guideline development group composition
- Clinical practice guideline–systematic review intersection
- Establishing evidence foundations for and rating strength of recommendations
- Articulation of recommendations
- External review
- Updating

Table. **Key Components of High-Quality and Trustworthy Guidelines**

Component	Description
Composition of guideline development group	A guideline development panel should include diverse and relevant stakeholders, such as health professionals, methodologists, experts on a topic, and patients.
Decision-making process	A guideline should describe the process used to reach consensus among the panel members and, if applicable, approval by the sponsoring organization. This process should be established before the start of guideline development.
Conflicts of interest	A guideline should include disclosure of the financial and nonfinancial conflicts of interest for members of the guideline development group. The guideline should also describe how any identified conflicts were recorded and resolved.
Scope of a guideline	A guideline should specify its objective(s) and scope.
Methods	A guideline should clearly describe the methods used for the guideline development in detail.
Evidence reviews	Guideline developers should use systematic evidence review methods to identify and evaluate evidence related to the guideline topic.
Guideline recommendations	A guideline recommendation should be clearly stated and based on scientific evidence of benefits; harms; and, if possible, costs.
Rating of evidence and recommendations	A guideline should use a rating system to communicate the quality and reliability of both the evidence and the strength of its recommendations.
Peer review and stakeholder consultations	Review by external stakeholders should be conducted before guideline publication.
Guideline expiration and updating	A guideline should include an expiration date and/or describe the process that the guideline groups will use to update recommendations.
Financial support and sponsoring organization	A guideline should disclose financial support for the development of both the evidence review as well as the guideline recommendations.

http://www.g-i-n.net/

Qaseem A et al., 2012

Guidelines 2.0

- The Guideline Development Checklist project is a partnership between the G-I-N and McMaster University

- Offer a **comprehensive toolbox of items linked to relevant resources and other tools to facilitate the development of trustworthy guidelines**

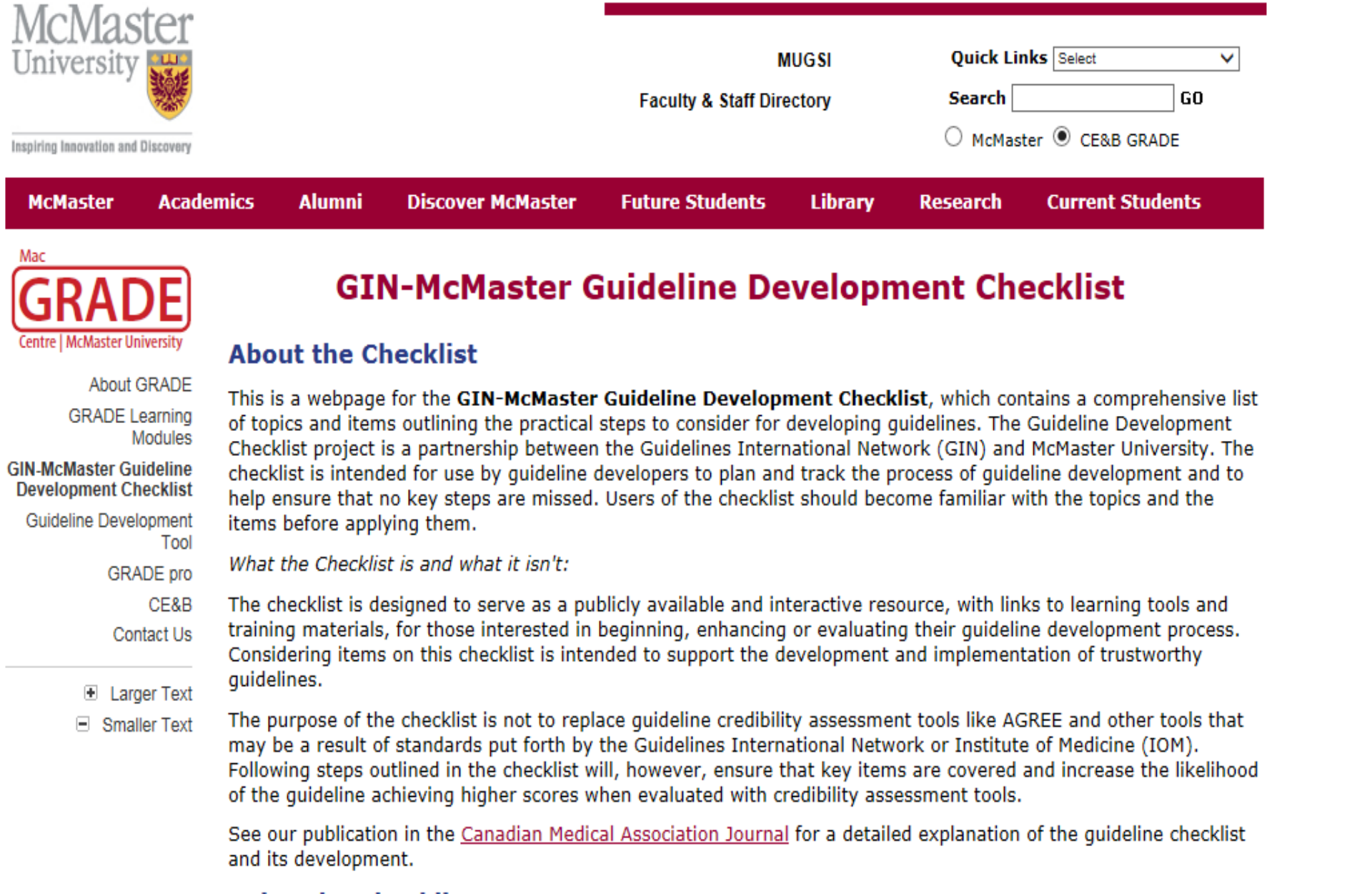
- Not to create a guideline credibility or quality checklist, but a tool to plan and track all stages of the guideline enterprise and to help the developers ensure that not key steps are missed.

- 18 overarching topics and 146 items

Schuenemann HJ *et al.*, 2014

Guideline Development Steps	Source(s)	Learning Tools, Guides, & Links	Resources & Tools for Implementing Step	Feedback (Click to Open)
18. Updating				Feedback
1. Set a policy, procedure and timeline for routinely monitoring and reviewing whether the guideline needs to be updated (e.g. update systematic review every 3 years to determine if there is any new evidence available).	3-9,11,12,14-16, 19-25,27,35, 39,42,44,66,69	AWMF Rules for Guidelines: Updating (in German; see AWMF Manual pg. 57 for English)		Feedback
2. Decide who will be responsible for routinely monitoring the literature and assessing whether new significant evidence is available (e.g. consider involvement of experts not previously involved in the guideline development group to periodically review the guideline).	3,5-9,14-16, 20,24,39,44,66			Feedback
3. Set the conditions that will determine when a partial or a full update of the guideline is required (e.g. if only certain recommendation statements need to be updated, or whether many recommendations are out of date making the entire guideline invalid, or when recommendations are necessary for newly available treatments).	3-7,9,11,15, 16,20,22-24, 42,66,69			Feedback
4. Make arrangements for guideline group membership and participation after completion of the guideline (e.g. rotating membership every 1-2 years, selection of a new group at time of updating, continuing participation by guideline panel chair).	5,9,13,20,25, 39,66			Feedback
5. Plan the funding and logistics for updating the guideline in the future (e.g. securing ongoing funding, standing oversight committee to oversee the updating process).	15,16,66			Feedback
6. Document the plan and proposed methods for updating the guideline to ensure they are followed.	3,15,16,27, 35,69	Cancer Care Ontario Program in Evidence-Based Care: Document Assessment and Review		Feedback

Interactive website
cebgrade.mcmaster.ca/guidecheck.html



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Rare Best Practices

RARE-Bestpractices

A platform for sharing best practices for the management of rare diseases

Coordinated by the Istituto Superiore di Sanità
National Centre for Rare Diseases

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- RAREGUIDELINE
- RAREGAP
- Glossary
- Training activities

RARE-Bestpractices promotes communication on the clinical management of rare diseases by disseminating trustworthy best practice guidelines globally

Rare Diseases and Orphan Drugs

An International Journal of Public Health

JOURNAL WEBSITE
CALL FOR PAPER SUBMISSIONS

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To know project achievements and events

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NEWSLETTER ARCHIVE

Leaflet

Concise information about project objectives and participants

DOWNLOAD PDF
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NEWS AND EVENTS

MORE NEWS

Rare-Bestpractices Glossary is on line!

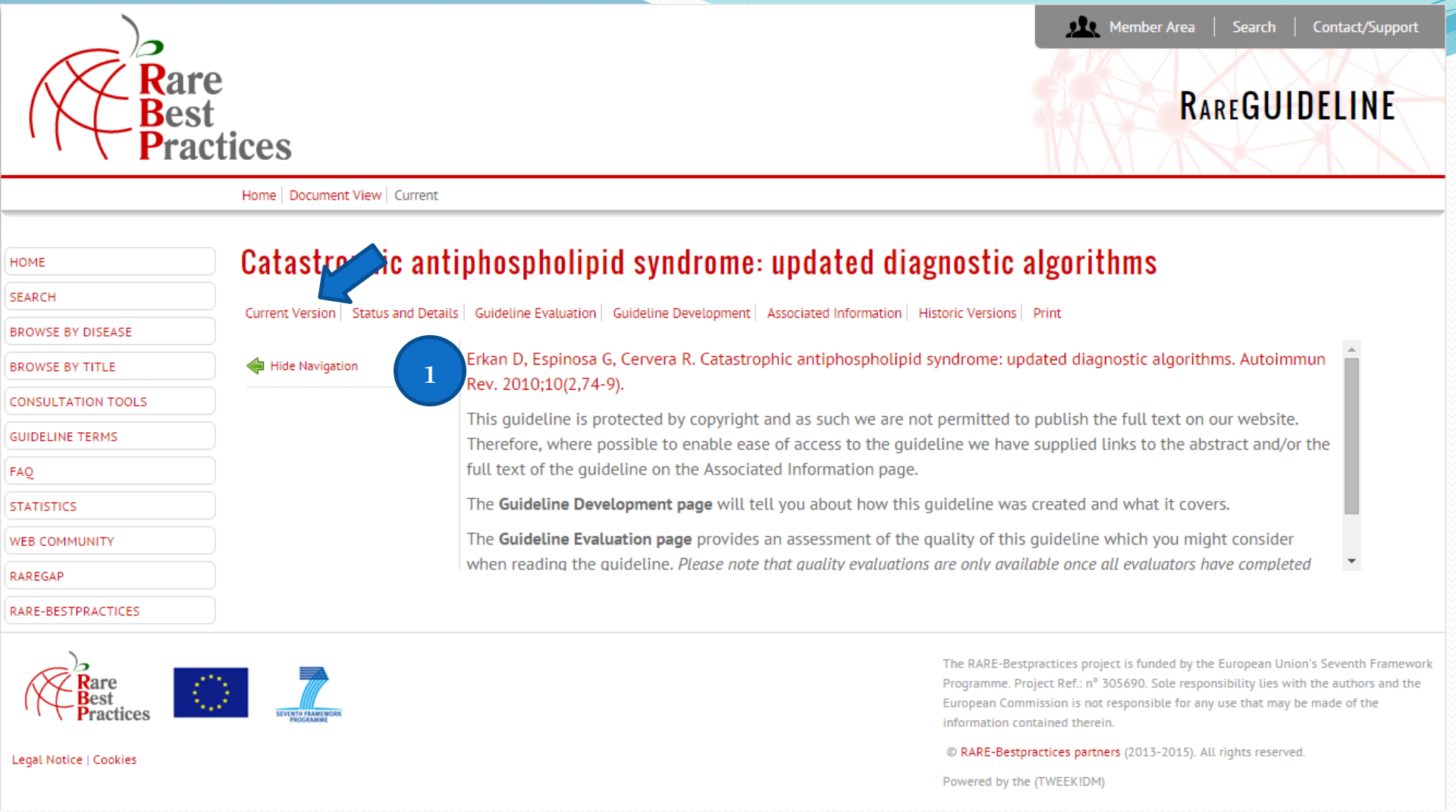
2nd EU Conference on European Reference Networks
Lisboa, Oct 8-9, 2015
See the draft programme

2nd International Course "Health care guidelines on rare diseases. Quality assessment" - SAVE THE DATE!
December 3-4, 2015

RELATED LINKS

- International Rare Diseases Research Consortium
- Rare Diseases-European Commission
- Guidelines International Network
- RARE-Bestpractices on Twitter

www.rarebestpractices.eu



1. The citation also contains a link to the abstract or full text for ease of access.

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Catastrophic antiphospholipid syndrome: updated diagnostic algorithms

Current Version | Status and Details | Guideline Evaluation | Guideline Development | Associated Information | Historic Versions | Print

This guideline has been subjected to an evaluation conducted applying the AGREE II methodology. The details of the evaluation are shown below, including the number of evaluators and their individual responses to each review question.

Note that the response range is: Strongly Disagree (1) (2) (3) (4) (5) (6) (7) Strongly Agree.

Question	Evaluators: 2	
Scope and Purpose	**Response**	**Comments**
1. The overall objective(s) of the guideline is (are) specifically described.	7	The purpose of this paper is to summarize the diagnostic challenges and propose updated diagnostic algorithms for catastrophic APS.
	6	Aim to summarize diagnostic challenges and propose diagnostic algorithms for CAPS.
2. The health question(s) covered by the guideline is (are) specifically described.	4	Not specifically described but section 2 groups particular issues of differential diagnosis which essentially form the guideline questions.
	6	Specific to appropriate diagnosis of patients with suspected CAPS (either no previous APS or with previous APS) in acute care.
3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.	6	The updated algorithms were created to provide a "step-by-step" approach to clinicians (and researchers) while assessing patients with multiorgan thrombosis.
	6	Classification criteria for definite or probably CAPS patients based on previous consensus statement from International Congress on aPL.
Stakeholder Involvement	**Response**	**Comments**
4. The guideline development group includes individuals from all relevant professional groups.	1	Three authors, not clear how many constituted Catastrophic APS Task Force or involvement of the wider International Congress on aPL in Galveston, Texas, USA, in 2010

17. Key recommendations are easily identifiable.	6	Algorithms are clearly presented.
	7	Recommendations clearly presented as algorithms A, B and C.

Applicability	Response	Comments
18. The guideline describes facilitators and barriers to its application.	1	No specific information identified.
	1	No information on facilitators or barriers to application.
19. The guideline provides advice and/or tools on how the recommendations can be put into practice.	1	No information identified.
	2	No advice or tools for implementation but the algorithms are themselves diagnostic tools.
20. The potential resource implications of applying the recommendations have been considered.	1	None
	1	No discussion of potential resource implications.
21. The guideline presents monitoring and/or auditing criteria.	1	None
	1	No monitoring or auditing criteria.

Editorial Independence	Response	Comments
22. The views of the funding body have not influenced the content of the guideline.	1	None
	1	No details of funding so unclear if any influence on content.
23. Competing interests of guideline development group members have been recorded and addressed.	1	None
	1	No details on development group so no competing interests can be identified.

Overall Guideline Assessment	Response	Comments
1. Rate the overall quality of this guideline.	2	None
	2	None
2. I would recommend this guideline for use.	Not Specified	
	Not Specified	

Notes
Clear scope and purpose but lacking in details on method of development. Useful algorithms to aid clinicians and researchers on diagnosing this rare condition.

Rare Best Practices

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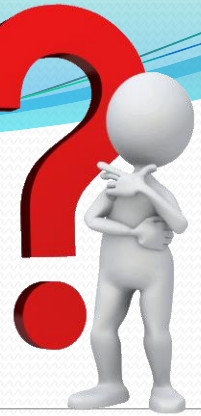
Training tools

- **Aim**: To promote and support the development and use of trustworthy health care guidelines for rare diseases.

1) a glossary (61 definitions), available at http://www.rarebestpractices.eu/pagine-23-glossary
2) a video tutorial on how to consult RareGUIDELINE and RareGAP
3) a tutorial on the application of AGREE II on guidelines for rare diseases by using a practical example
4) a tutorial to assess the quality of evidence utilizing the GRADE methodology

- Timeline: all to be released by the end of December 2016.



Thank you!!

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