

Adaptation Process of Evidence Based Clinical Guidelines



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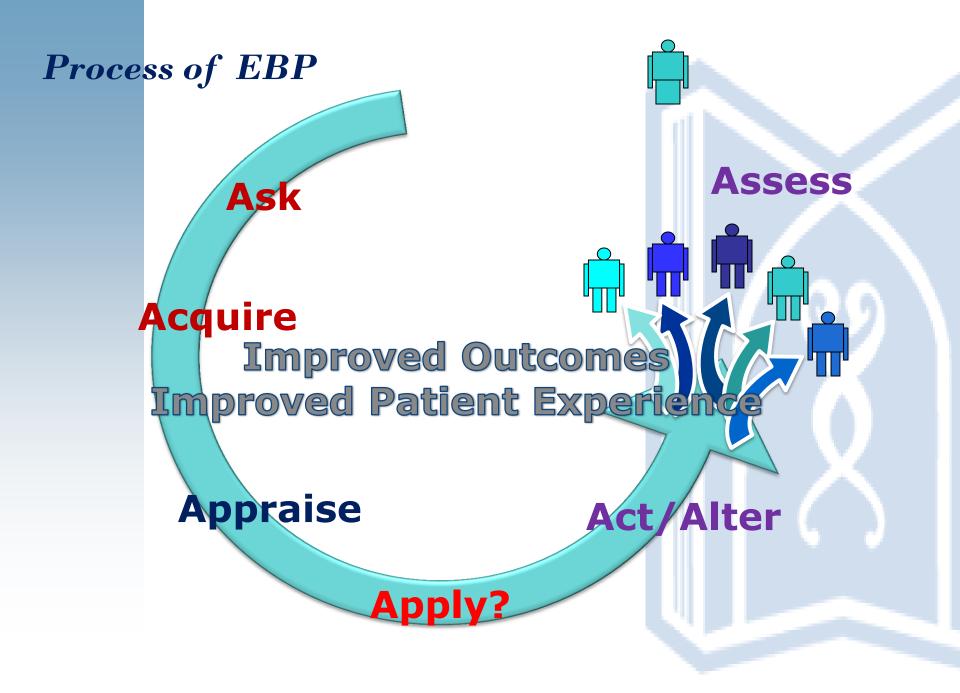
Objectives:



•Why Adaptation of the guidelines?

•What is the process of the Adaptation?





ASSURE BALANCE

Practice
By External
Evidence



Out of
Date
Practice
"Obsolete"

And Balance Between Evidence and Expertise

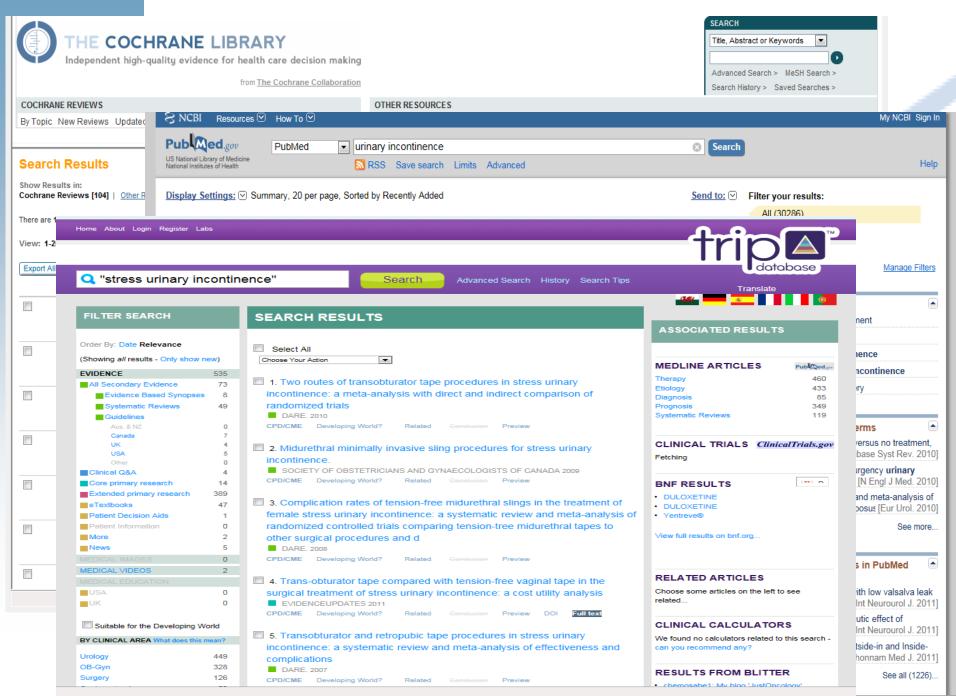
What is the E of EBM Evidence???????????





A Scenario

• 42 y woman came to your office with chief complain of urine leakage when she cough or sneeze and any physical activity. She must use pad when she is going out and she can not go to the masque or has any other social activities.





REVIEW ARTICLE -

Minimally Invasive Synthetic Suburethral Sling Operations for Stress Urinary Incontinence in Women: A Short Version Cochrane Review

J. Ogah, 1,* D.J. Cody, 2 and L. Rogerson 3

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- Minimally invasive synthetic suburethral sling operations versus traditional suburethral slings.
- Minimally invasive synthetic suburethral sling operations versus colposuspension (abdominal surgery).
- 3. Minimally invasive synthetic suburethral sling operations versus laparoscopic procedures. One type of minimally invasive synthetic suburethral sling operations versus another, subgrouped as:
- Retropubic bottom-to-top approach versus retropubic topto-bottom approach.
- Obturator medial-to-lateral approach versus obturator lateral-to-medial approach.
- Monofilament versus multifilament.
- Retropubic versus transobturator.
- Minimally invasive synthetic suburethral sling operations versus no treatment.
- Minimally invasive synthetic suburethral sling operations versus conservative treatment.

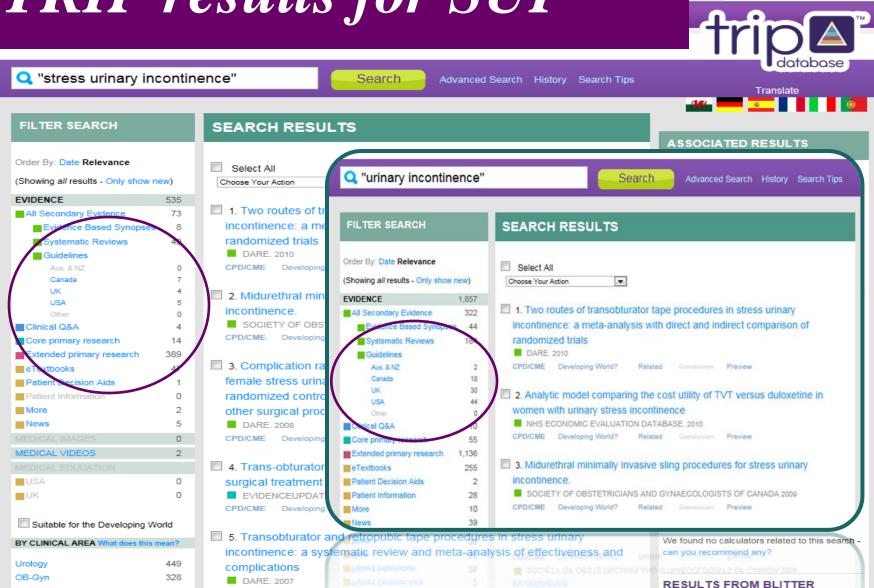
OB.

- Mostly efficacy not effectiveness
- No long-term efficacy and adverse effects determined.
- No High quality study for Patient reported outcomes or cost utility
- More trials are required to assess the clinical effectiveness of different tapes in women with urodynamic stress incontinence where hypermobility is differentiated from intrinsic urethral sphincter deficiency.

What was happen between 2008-2012

- 22 more trial
- TVT vs TOT 11 trial, 2772 pts (almost low to moderate quality)
- TVT or TOT vs mini sling 5 trial ,810 pts
- Minimally sling vs traditional methods 4 trial ,354 pts
- One cost analysis
- One patient reported outcome for minimally invasives

TRIP results for SUI



abase.com/about

Surgery

126

C'uneugos braunià resentru l'er

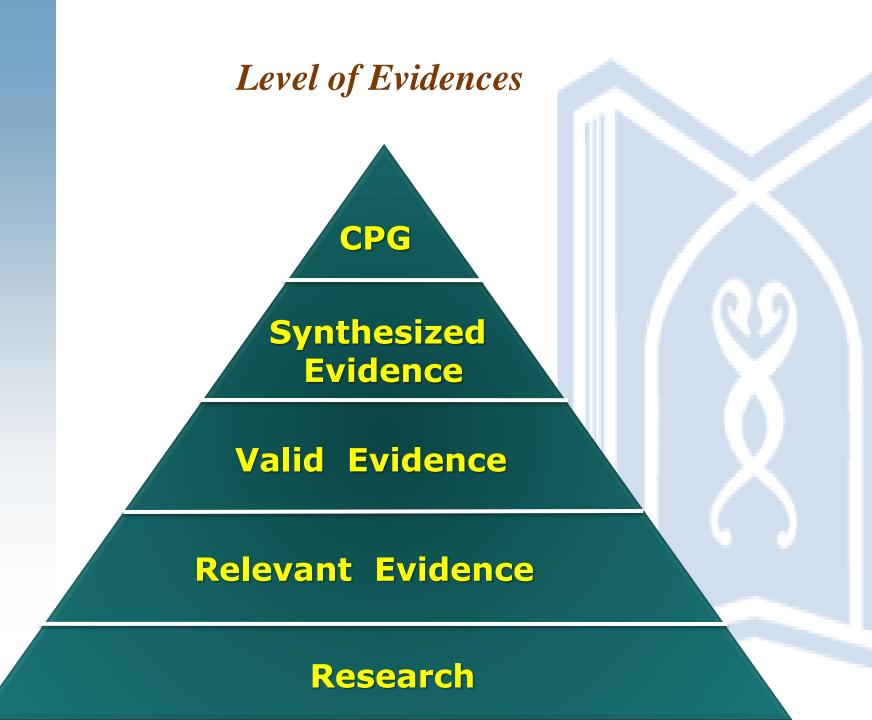
chemosabe1: My blog 'JustOncology'

CPD/CME Developing World? Related Genelusiem

Clinical Effectiveness:

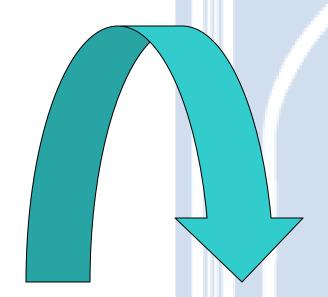
- Clinical effectiveness is thinking critically about what you do,
- questioning whether it is having the desired result,
- making a change to practice.
- It is based on evidence
- what is effective in order to improve patient care and experience.





PIPOH in Guidelines

- Patients
- Intervention
- Practitioner
- Outcome
- Health System



All those is as same as my setting?

Patient Centeredness

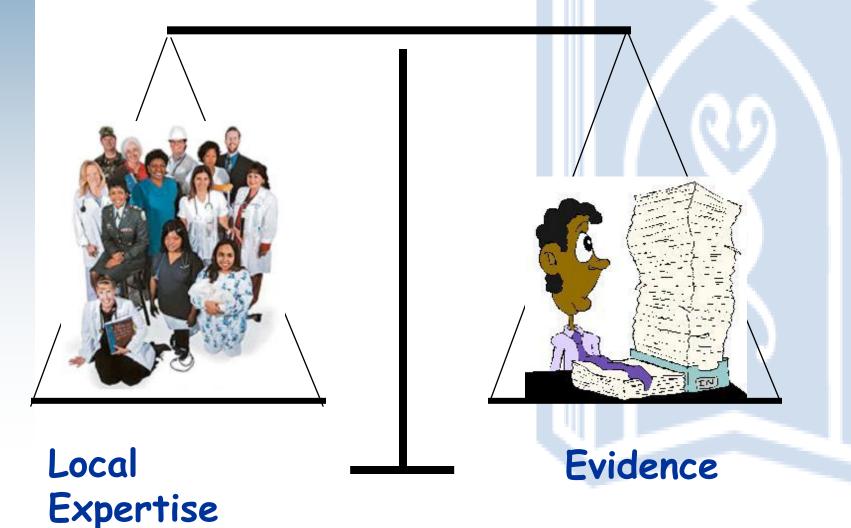
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Is their patients are as same as my patients



Health care should honor the individual patient, respecting the patient's choices, culture, social context, and specific needs

The new guideline should integrate local expertise and local context of practice with the best available evidence



Evidence Based Practice: Perspectives of Iranian Urologists

(A questionnaire based survey April 2009)

- They as well appreciate the impact of use of guidelines on clinical decision making and quality of health services (>45%) and the outcome of surgery (76.2%)
- More than half believed that utilization of research is costly and time consuming (62.8% and 64.3% respectively)
- 54.5 % disagreed with the point that they can't use information sources
- 53.4% agreed that there are not enough facilities to practice evidence based

Outcomes









Outcomes

What is the meaning of the cure?

Subjective?

Objective?

Primary outcome?

Secondary outcomes?

Patient reported

Physician seeking

 What is the quality of life(Persian Validation of ICIQ-UISF)

Review

Is Evidence-Based Medicine Relevant to the Developing World?

Systematic reviews have yet to achieve their potential as a resource for practitioners in developing countries

Paul Chinnock*, Nandi Siegfried and Mike Clarke

Paul Chinnock is Senior Editor, PLoS, Medicine. Nandi Siegfried is a South African Nuffield Medical Fellow at the University of Oxford (Oxford, United Kingdom). Mike Clarke is Director of the United Kingdom Cochrane Centre (Oxford, United Kingdom). The authors are involved in the work of the Cochrane Collaboration, but the views expressed in this article are their own and are not necessarily those of the Cochrane Collaboration

Box 1. Comparison of the Health Care Experiences of Patients in the Less Developed and Developed Worlds

Features of the typical health care experience of a patient living in the less developed world include

- · late presentation
- · self-medication of "prescription" drugs or traditional treatments
- · poor facilities may delay diagnosis
- referral (if needed) not easily arranged
- · if a child, may be malnourished
- · if a woman, may be anaemic
- will experience problems because of shortages of trained staff
- · ... and because of poor infection control
- ... and because of a lack of follow-up care
- patient may be unable (e.g., because of lack of funds) to fully adhere to treatment.

Features of the typical health care experience of a patient in a clinical trial in a developed country include

· none of the above

Equity



The system should seek to close racial and ethnic gaps in health status



How to Get These Improvements?



Need for an evolution for developing CPGs hand-in-hand

The way forward ...

- Prioritize health care issues
- Search for intervention that fulfills five us
- Make evidence accessible and affordable
- Generate evidence locally
- Assess external evidence for internal applicability
- Make evidence assessable

To do....

the right thing
at the right time
in the right place
with the right result



Guideline Adaptation DEFINITIONS

Clinical Practice Guidelines are <u>systematically</u> developed statements to assist provider and patient

decisions about appropriate healthcare for specific clinical circumstances. (Field & Lohr, 1990)

Their purpose is to make explicit recommendations with a definite intent to influence what clinicians do.

(Hayward et al, 1995)

► Explicit links between the recommendations & scientific evidence

Being clear about what is a Guideline

Guidelines about clinical oncology practice or about

cancer program planning or policy are defined by the

Partnership's Guidelines Action Group as "cancer control guidelines". *Traditional* cancer control guidelines consist of 3 elements:

- 1. synthesis of the body of scientific/research evidence
- 2. an interpretive summary of the evidence
- 3. specific evidence-based recommendations linked to a level of evidence

Guideline ADAPTATION

A **systematic process** that guides local groups to identify, evaluate, adapt and use already available guidelines for their own purposes.



Guideline ADAPTATION

- An alternative to *de novo* development which requires extensive search and synthesis of primary research data
- Reduces duplication of effort while maintaining the validity of recommendations
- Encourages participative approach involving key stakeholders to foster local ownership of recommendations and promote utilization

Guideline ADAPTATION

- Ensures consideration of (regional and local) contextual factors to ensure relevance for practice and improve uptake by targeted users
- Increases knowledge and commitment to evidence-based principles by using reliable methods to ensure quality and validity
- Promotes explicitness and transparency in documenting recommendations

STEP 1: Call-to-Action

Guide pp. 20-23

- 1.1 Clarify the motivation, purpose and scope of the proposed initiative. Consider:
- What is the agency/ institutional mandate and infrastructure supporting evidence-informed practice?
- Is this a response to a specific practice challenge?
- Is a guideline the most appropriate solution to the challenge?
- Who (person/group) will lead, implement and maintain these recommendations?
- What is the intended practice jurisdiction (local, regional, national?

STEP 1: Call-to-Action

Guide pp. 20-23

- A critical, strategic element requiring strong facilitation and leadership skills; establishes legitimate guideline development mandate and infrastructure; especially important for new groups
- Plan an orientation session for participants
- Discuss: What is a "guideline"?



STEP 2: Plan

Guide pp. 24-36

- 2.1 Establish scope of guideline and articulate Health Question(s).
- 2.2 Determine feasibility of adaptation.
- 2.3 Form steering committee and working panel(s) and determine key stakeholders and necessary resources
- 2.4 Determine consensus process.
- 2.5 Write the Work Plan.

STEP 2: Plan

- Use the PIPOH instrument to develop health questions
- Determine required expertise and resources;
 (using the Skills Assessment Checklist)
- Understand Facilitation and the role of the Coordinator
- Draft Work Pan an essential document outlining:
 - Scope of topic and health questions
 - Terms of reference (steering committee and working panel(s)
 - Funding and resource commitments
 - Consensus process
 - Conflicts of interest
 - Projected timeline
 - Meeting arrangements

Tool 2.1a PIPOH Checklist

- Patient population: average risk women
- <u>I</u>ntervention: screening
- Professionals: family physicians/ GPs/nurses
- Outcomes: screening interval/modality
- ▶ **H**ealthcare setting: family practice

Example Question:

What is appropriate cervical cancer screening (CCS)

for average risk women seen in family practice?



Tool 2.3a Skills Assessment checklist

- 1 = Low (we will need to plan for added support/training)
- 5 = High (we have access to the necessary resources and expertise)

Recommended Expertise	Our strength in this area			
1. Clinical knowledge in the selected topic area, for e.g.	1 2 3 4 5			
expertise managing issues related to the application of the guideline in local practice				
knowledge of the latest research in the topic area				
Comments:				
Personal experience with the topic area to ensure patient or consumer needs are discussed and that salient outcomes such as quality of life are considered, for e.g.	1 2 3 4 5			
living with the disease				
having undergone the intervention				
· caring for someone with the disease				
3. Methodological expertise to support members on issues related to the systematic	1 2 3 4 5			
and rigorous nature of the review process, including:	1 2 3 4 3			
· previous experience in guideline development: de novo or adaptation				
· evidence-based principles				
knowledge of research design: RCTs, Qualitative Studies				
ability to interpret levels of evidence				
· critical appraisal and guideline appraisal skills				
Comments:				
4. Information retrieval/health information literacy	1 2 3 4 5			
knowledge of databases and sources of evidence: (systematic reviews, journal reviews)				

Tool 2.5a Sample Work Plan

*			<u> </u>					
STEP	Meeting Type	Tasks/Activities	Tools	Assigned To	Projected Timeline	Done ☑	Completion Date	Notes
1: CALL TO ACTION		1.1 Clarify the motivation, purpose and scope of the proposed initiative.	1.1a-1.1g					
2: The PLAN		2.1 Establish scope of guideline and articulate Health Question(s)	2.1a-2.1b					
		2.2 Determine feasibility of adaptation	2.2a					
		2.3 Form steering (organizing) committee and working panel(s) and determine key stakeholders and necessary resources	2.3a-2.3f					
		2.4 Determine consensus process	2.4a					
		2.5 Write the work plan	2.5a-2.5b					
3: SEARCH and SCREEN		3.1 Search existing guidelines, systematic reviews, and new or emerging areas of evidence; confirm if guideline is <i>de novo</i> , adaptation or mixed initiative	3.1a-3.1f					
		3.2 Screen search results to develop short list for full appraisal.	3.2a-3.2e					

STEP 3: Search and Screen

Guide pp. 37-41

- 3.1 Search existing guidelines, systematic reviews, and new or emerging areas of evidence; confirm if guideline is de novo, adaptation or mixed initiative.
- 3.2 Screen search results to develop short list for full appraisal; document selection.

STEP 3: Search and Screen

- Designing and executing the search engaging services of a health science librarian or information specialist
- Managing citations: Developing a screening protocol and documenting selection decisions
 - Library Science Supplement and Toolkit resources



Designing the search: Choosing inclusion/exclusion criteria

Selecting only evidence-based guidelines (guideline) must include a report on systematic literature searches and explicit links between individual recommendations and their supporting evidence Selecting only national and/or international guidelines; selecting guidelines written in a particular language (Fr/Eng?) Specifying a range of dates for publication; selecting only those published since an important review was published Selecting peer reviewed publications only; excluding guidelines written by a single author not on behalf of an organization – ideally has multidisciplinary input Excluding guidelines published without references -

panel must have access to the evidence

STEP 4: Assess and Select

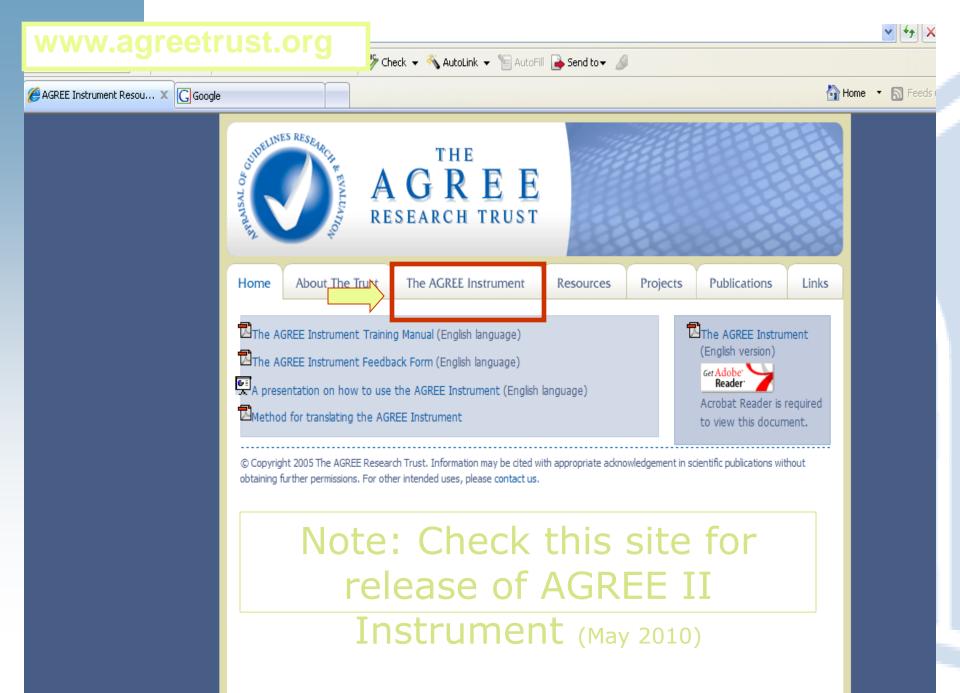
Guide pp. 42-54

- 4.1 Assess shortlisted guidelines (recommendations and supporting evidence) in detail for: quality (e.g. AGREE), currency, content, coherence between evidence and recommendations, and applicability and acceptability to local context.
- 4.2 Decision and Selection: review all assessments and achieve consensus with respect to Selecting, Rejecting or Modifying specific recommendations



STEP 4: Assess and Select

- Assessing Quality of guidelines
 - Using the AGREE instrument
 - Summarizing and displaying AGREE scores
 - Assessing Quality of Systematic Reviews
- ☐ Assessing guideline Currency
- □ Assessing guideline Content
 - Preparing the `Recommendations Matrix'
 - The evidence: type and level; classification systems
 - Critical appraisal (interpretation and Consistency of evidence)
- □ Assessing Acceptability and Applicability
- Making Decision to Accept, Reject or Modify
 - Achieving and documenting consensus



Tool 4.1b: AGREE Instrument

SIX Domains

23 items

4 (7) point Likert Scale

Overall Assessment

User Guide & Manual

1. Scope & purpose					
2. Stakeholder involvement	(4)				
3. Rigour of development	(7)				
4. Clarity & presentation	(4)				
5. Applicability	(3)				
6. Editorial independence	(2)				

CURRENCY Assessment

- Is there any new evidence relevant to guideline?
- Does new evidence invalidate any of the recommendations?
- Are there any plans to update the guideline in the near future?
- When was the guideline last updated?



CONSISTENCY Assessment

- Quality of source guideline search strategy and study selection (ADAPTE Tool 13)
 - Was the search for evidence comprehensive?
 - Is there any bias in the selection of articles?
- □ Consistency between evidence and interpretations; between interpretations and recommendations (ADAPTE Tool 14)
 - Is the evidence valid, overall?
 - Are the recommendations based on data and interpretations?

APPLICABILITY Assessment

- Review of each of the recommendations with respect to 2 main questions (ADAPTE TOOL 15)
 - Can the recommendation be put into practice?
 - Consider patient similarity, interventions, outcomes, patient preferences, availability of equipment, availability of expertise, any constraints?
 - Is the benefit from this recommendation worth implementing?

Tool 4.10 Recommendations Matrix

(template	line 1	Guide	line 2	Guidel	ine 3	Guidel	ine 4	Guideline 5			
Title of Guideline											
Publication Year											
AGREE Rigour Scores											
Overall Quality	\top										
Assessment:	# of ra	ters	# of raters		# of raters		# of raters		# of raters		
 Strongly Recommend 											
Recommend with											
Alterations											
Would not											
recommend											
 Unsure 											
Strengths/Limitations	Streng	Strengths:		Strengths:		Strengths:		Strengths:		Strengths:	
Note: Sources include											
AGREE comments,	Limita	tions:	Limita	ations:	Limita	tions:	Limita	tions:	Limitat	ions:	
content expert review, and guideline content.											
Algorithms/Tools	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	
provided?											
Description:											
Health Questions:	_										
Health Question #1:											
Is question addressed?	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	
Cassifia											
Specific recommendation:											
Level of evidence:											
Source of	1										
recommendation											
(reference/evidence)											
Health Question #2:	1		1		1		1		1		

Task 4.2 Decision and Selection Options

1. ACCEPT a whole guideline and all of its recommendations

After reviewing all of the assessments, the panel accepts the guideline as is.

2. REJECT a whole guideline and all of its recommendations

After reviewing all of the assessments, the panel decides to reject the complete guideline. The decision will be based on how the panel weighs the assessments (e.g., poor AGREE scores, guideline is out-of-date, the recommendations do not apply to the panel's context).

3. ACCEPT the evidence summary of the guideline

After reviewing all of the assessments, the panel decides to accept the description of the evidence (or parts) but to reject the interpretation and the recommendations.

4. ACCEPT single recommendations

After reviewing the recommendations from the guideline or guidelines, the panel decides which to accept and which to reject which may be from one or more guidelines.

5. MODIFY single recommendations

After reviewing all of the recommendations from the guideline(s), the panel decides which are acceptable but need to be modified.

STEP 5: Draft, Revise, and Endorse Recommendations Guide pp. 55-61

- 5.1 Draft Customized Guideline
- 5.2 Conduct internal review and make revisions
- 5.3 Conduct external review and obtain endorsement
- 5.4 Prepare final documents, including any practitioner and patient information, records or application tools, and appropriate source acknowledgments
- 5.5 Establish a Renewal Plan

STEP 5: Draft, Revise, and Endorse Recommendations Guide pp. 55-61

- Customizing recommendations:
 - Using a template for structure and content
 - Authors, acknowledgements, permissions and copyright issues from source developers
 - Using brief, unambiguous, actionable language
 - Including application tools, algorithms, patient information
 - Including a short preface summarizing recommendations, and methodology; appendices and possible web links to documents

Transparency of all decision making (e.g., consensus process is described, how decisions were arrived at and resolved; if recommendations were modified, how and why they were modified);

External Review

- External review with those affected by uptake, e.g., experts (practitioners, patients) and users (policy makers, managers)
- Consultation with endorsement bodies
 - Inclusion of representative on panel throughout process?
- Consultation with source guideline developers
- Acknowledgement of source documentS



Sustainability/Planning for renewal

Guideline maintenance

 specifying in the guideline when, how and by whom the recommendations will be updated



STEP 6: Plan Implementation

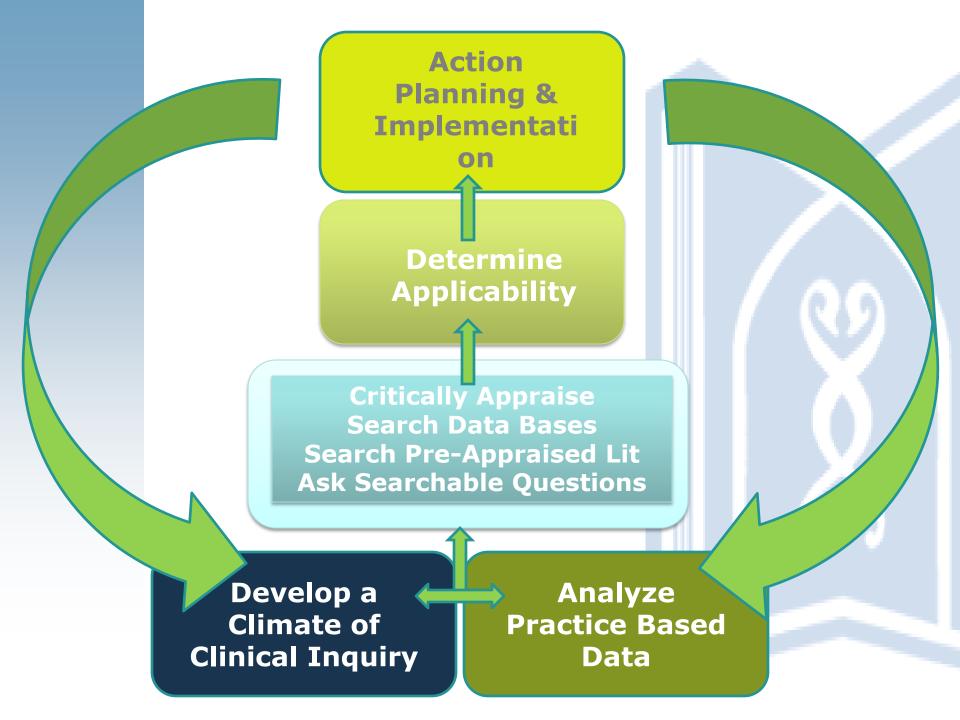
Guide pp. 62-64

- 6.1 Dissemination and launch of guideline
- 6.2 Address implementation requirements

Note: Planning Implementation continues under study and will be fully developed

for version 2.0 of the CAN-IMPLEMENT© Resource.







Thanks