

**Department of Veteran Affairs
Veterans Health Administration
Washington, DC 20420**

**Department of Defense
U.S. Army Medical Command
Quality Management
Fort Sam Houston, TX 78234**

GUIDELINE FOR GUIDELINES

A. Guideline Development and Approval Process:

1. New Guideline Idea: When a clinician or other group wants to develop a VA/DoD guideline,

- An application is completed and submitted to VA/DoD Evidence Based Practice Work Group (EBPWG).
 - At a minimum the application will include a description of the guideline,
 - Identify end-users of the guideline and perceived gaps in care and/or
 - Identify changes in performance to be driven by the guideline. (See Attachment I: Application Form)
 - To the extent possible, data substantiating the need for the guideline will be presented.
- The applicant will also submit a brief structured review of the literature.
- The VA/DoD Evidence-Based Practice Work Group may also suggest topics/areas for guideline development using the same process described above, particularly as they relate to the frequency of occurrence and uniqueness of our military and veteran population.

2. Evidence Based Practice Work Group Prioritization Subgroup Reviews & Prioritizes Applications: Upon receipt of the application, the EBPWG Prioritization Subgroup will review the application and prioritize it for development and implementation in VA and DoD.

- Within 1 week of receipt the EBPWG Prioritization Subgroup will acknowledge receipt of each application.
- The EBPWG Prioritization Subgroup will consider the following issues:
 - High incidence or prevalence,
 - Risk and cost of the disease or condition in the general veteran/military population or sub-populations targeted by Special Emphasis Programs.
 - Potential for reduction of clinically significant variations in the prevention, diagnosis, treatment, or clinical management of a disease or condition will also be considered when establishing priorities.
- The Prioritization Subgroup will notify the applicant of the outcome of the review generally within 4 weeks of receipt.

3. Designees of the DoD and the VA Offices of Quality and Performance and VA Patient Care Services Identify Clinical Champions, Evidence Chaperone and /or EBPWG Representative: When a topic has been approved for guideline development, the DoD representatives, Offices of Quality and Performance, and Patient Care Services will:

- Identify clinical leaders who will champion the guideline development and implementation initiative at the national VA and DoD Health Care Systems levels.
- Assure there is representation from primary care and specialty services.

- Invite members of related VA QUERI (Quality Enhancement Research Initiative) groups to participate, if available.
- Assign an Evidence Chaperone from within the Working Group or from the Evidence Center to guide the integrity of the evidence process.
- Assign a representative from the EBPWG to monitor the development process.

4. Pre-Planning Conference:

The DoD and the VA Offices of Quality and Performance and Patient Care Services, in collaboration with Employee Education System, will convene a face-to-face pre-planning conference or teleconference with the identified champion(s) and other key clinical leaders in order to train champions regarding the evidence-based approach and process. At a minimum, the pre-planning conference/teleconference should accomplish the following:

- Identify the end users of the guideline.
- Define the scope of the Guideline Initiative.
- Identify seed/reference guidelines, if any.
- Specify representation from appropriate clinical specialties to be involved with the guideline development.
- Project timelines for each phase of guideline development.
- Disclose any areas of potential conflict of interest.
- Assign senior champions for each module.
- Develop a production schedule for each module.
- Specify which modules can be fast-tracked for distribution prior to publication of the comprehensive guideline.
- Identify approaches that will ensure VA and DoD collaboration and partnership with the broader community.
- Define responsibilities of champions and participants.

5. Small Group of Champion(s) and Other Key Clinical Leaders are Assembled:

- VA and DOD Champions and other key clinical leaders meet face-to-face/teleconference, as needed, with the facilitator and Evidence Chaperone to identify key questions formulated in the PICO
 - **P**opulation – Characteristics of the target patient population
 - **I**ntervention – Exposure, diagnostic, or prognosis
 - **C**omparison – Intervention, exposure, or control used for comparison
 - **O**utcome – Outcomes of interest

format to be answered by the evidence

- This is an iterative process and may require discussions on conference calls to complete the task.
- Boundaries for admissible evidence should also be set. For example, questions of the efficacy of interventions usually means that randomized controlled trials should be sought, while questions of risk usually mean that prospective cohort studies should be sought.
- Evidence-based bullets for immediate publication should also be identified.
- **Potential Conflicts of Interest: The VA/DoD has adopted a policy of transparency, disclosing potential conflicts and competing interests of all individuals who participate in the development, revision, and review of the VA/DoD clinical practice guidelines.** Champion(s) and other key clinical leaders involved with this effort will be asked to submit disclosure

statements to reveal any areas of potential conflict of interest (See Attachment II).

- Once the Scope of the Guideline is agreed on by the Co-Chairs and other key leaders, it is sent for review and approval by the VA/DoD EBPWG membership. On approval by the VA/DoD EBPWG, the guideline workgroup can begin.

6. Conference Call among Evidence Chaperone, Champions and EBPWG Representative is conducted:

- When the questions have been developed, the group will convene via conference calls to:
 - review the questions to assure that they are on track and
 - address the questions that will lead to a comprehensive, systematic review of the literature pertaining to the topic.
- When the evidence reviews are completed, the questions and the reviews will be posted on the web.
- However, prior to posting the reviews, the facilitator, Champion, and the Evidence Chaperone will convene to ensure the adequacy of the evidence reviews.

7. Systematic Review of the Literature Based on the Questions Identified in Step Five is Conducted & Tables of Evidence are Produced:

- A systematic review of the literature, by a disinterested party, will be performed to minimize bias, collect all appropriate evidence available, and assess its potential applicability to the clinical question under consideration.
- The Evidence Chaperone will work with staff from the Evidence Center to ensure conformity to prevailing standards for conducting high-quality systematic literature reviews.
 - The first step in gathering the evidence is to see if a suitable, recent systematic review has already been published.
 - If a current systematic review is not available, an original systematic review will be done using an established protocol, such as those of the Cochrane Collaboration or the US Preventive Services Task Force (USPSTF).
- At a minimum, systematic reviews will use explicit, reproducible methods to
 - identify relevant, eligible studies
 - assess the quality of each study and the body of evidence
 - critically appraise key studies and
 - synthesize results.
- To grade the quality of individual studies, the reviews will apply the USPSTF or GRADE criteria for quality (Harris, Helfand, & Woolf, 2001) adapting those to specific clinical areas.

8. A Group of Clinical Experts is Convened to Develop the Guideline: Once the evidence tables have been developed,

- A group of not more than 15-20 experts and other key clinical leaders will be identified and convened to evaluate the evidence and develop the guideline in accordance with it.
- In advance of the meeting, each participant will be asked to submit a disclosure statement regarding any potential conflicts of interest. These will be reviewed in advance to assure balance in the group that is forming.

- Each meeting will begin with a brief session that will permit full disclosure to the group any conflicts related to the guideline
 - Key points of the guideline will be identified.
 - A facilitator, in collaboration with the Evidence Chaperone, will ensure that the meeting stays focused and that the evidence remains the driving force behind the guidelines.
 - Most guidelines will be represented in an algorithmic format outlining step-by-step decision points in the disease management process.
 - The strength of recommendation and quality of evidence are provided at the end of each annotation in the guideline.
 - The systematic review will summarize the quality and consistency of the evidence and the magnitude of benefits and harms.
 - To make the actual recommendations, the clinical experts, led by the designated VA/DoD Champions, will
 - interpret the evidence,
 - assess its ability to be applied in the clinical setting and its applicability to the population of interest, and
 - assess the overall strength of evidence for the recommendation.
 - Recommendations based solely on clinical judgment and experience will be thoroughly scrutinized to eliminate bias and self-interest.
 - Recommendations will conform to the following guidelines:
 - Recommendation statements will be "actionable" and employ active voice rather than passive voice.
 - Recommendations will avoid vague or ambiguous recommendation statements (such as "Physicians may offer..." or "When possible...").
 - Recommendations will be explicitly distinguishable from factual statements. .
- From:
Hermann, R.C., Shekelle, P.G., Balk, E., Loeb, J.M., Lohr, K.N. Monteforte, M.J., Schneider, E.C., and Wachter, R. (December 20, 2010). Promoting Transparent and Actionable Clinical Practice Guidelines: Viewpoint from the National Guideline Clearinghouse/National Quality Measures Clearinghouse (NGC/NQMC) Editorial Board. Retrieved from <http://www.guideline.gov/expert/expert-commentary.aspx?id=24556>
- This group of clinical experts will also develop consensus-based recommendations as needed when there is inadequate evidence.

Currently, the clinical experts will grade recommendations using the USPSTF system, A transition to the GRADE system is being considered.

8a. The USPSTF system is described in Current Methods of the U.S. Preventive Service Task Force. A Review of the Process. Am J Prev Med (Harris, Helfand, & Wools, 2001). In this system, the grade for the strength of a recommendation depends on the overall quality of evidence and on the magnitude of net benefit. Clinical experts will:

1. Rate the overall quality of the evidence using the terms shown in Table 1.
2. Rate the net benefit (benefits minus harms) –substantial,” “moderate,” –small,” or –zero or negative” as described in Table 2.
3. Based on these ratings of the overall quality of the evidence and the magnitude of net benefit, the clinical experts will assign a grade to each recommendation using the definitions in Tables 3 and 4.

- Consistent results from a number of higher-level studies [LE] (see Table 1) that have been conducted across a broad range of populations support a high degree of certainty that the results of the studies are true. In such case the entire body of evidence would be considered good quality.
- The overall strength of each body of evidence that addresses a particular Key Question is then assessed. The number, quality, and size of the studies, as well as the consistency of results between studies and the directness of the evidence will be considered in assigning an overall quality[QE] of the evidence (i.e., good, fair, or poor) (see Table 2). The quality of the body of evidence is considered fair when the results could be due to true effects or to biases present across some or all of the studies. For a poor quality body of evidence, any conclusion is uncertain due to serious methodological shortcomings, sparse data, or inconsistent results. For interventions that were supported by studies of Fair or Good quality, the clinical experts evaluate the benefits and the potential harms as demonstrated by the results of the studies.
- In the final step, the Strength of Recommendation [SR] is determined based on the Quality of the Evidence [QE], and the clinical significance of the Net Benefit [NE] (see Table 3) for each intervention. Thus, the grade (i.e., A, B, C, D or I) assigned to guideline recommendations reflects both the Quality of the evidence and the potential clinical benefit that the intervention may provide to patients (see Table 4).

Table 1: Level of Evidence (LE)	
I	At least one properly done RCT
II-1	Well-designed controlled trial without randomization
II-2	Well-designed cohort or case-control analytic study, preferably from more than one source
II-3	Multiple time series evidence with/without intervention, dramatic results of uncontrolled experiment
III	Opinion of respected authorities, descriptive studies, case reports, and expert committees

Table 2: Overall Quality [QE]	
Good	High grade evidence (I or II-1) directly linked to health outcome
Fair	High grade evidence (I or II-1) linked to intermediate outcome; <i>or</i> Moderate grade evidence (II-2 or II-3) directly linked to health outcome
Poor	Level III evidence or no linkage of evidence to health outcome

Table 3: Net Effect of the Intervention [NE]	
Substantial	More than a small relative impact on a frequent condition with a substantial burden of suffering; <i>Or</i> A large impact on an infrequent condition with a significant impact on the individual patient level.
Moderate	A small relative impact on a frequent condition with a substantial burden of suffering; <i>or</i> A moderate impact on an infrequent condition with a significant impact on the individual patient level.
Small	A negligible relative impact on a frequent condition with a substantial burden of suffering; <i>Or</i> A small impact on an infrequent condition with a significant impact on the individual patient level.
Zero or Negative	Negative impact on patients; <i>or</i> No relative impact on either a frequent condition with a substantial burden of suffering, or an infrequent condition with a significant impact on the individual patient level.

Table 4: Final Grade of Strength of Recommendation [SR]				
	<i>The net benefit of the intervention</i>			
Quality of Evidence	Substantial	Moderate	Small	Zero or Negative
Good	A	B	C	D
Fair	B	B	C	D
Poor	I	I	I	I

Strength of Recommendation [SR]	
SR	
A	<p>A strong recommendation that the clinicians provide the intervention to eligible patients.</p> <p><i>Good evidence was found that the intervention improves important health outcomes and concludes that benefits substantially outweigh harm.</i></p>
B	<p>A recommendation that clinicians provide (the service) to eligible patients.</p> <p><i>At least fair evidence was found that the intervention improves health outcomes and concludes that benefits outweigh harm.</i></p>
C	<p>No recommendation for or against the routine provision of the intervention is made.</p> <p><i>At least fair evidence was found that the intervention can improve health outcomes, but concludes that the balance of benefits and harms is too close to justify a general recommendation.</i></p>
D	<p>Recommendation is made against routinely providing the intervention to asymptomatic patients.</p> <p><i>At least fair evidence was found that the intervention is ineffective or that harms outweigh benefits.</i></p>
I	<p>The conclusion is that the evidence is insufficient to recommend for or against routinely providing the intervention.</p> <p><i>Evidence that the intervention is effective is lacking, or poor quality, or conflicting, and the balance of benefits and harms cannot be determined.</i></p>

*Harris RP, Helfand M, Woolf SH, Current methods of the U.S. Preventive Services Task Force. A review of the process. Am J Prev Med 2001.

The GRADE system is described in the series of tables below;

The GRADE system incorporates two types of ratings:

- Quality of the evidence for a single outcome for a single comparison (High, Moderate, Low, or Very Low)
- Strength of recommendation for the technology (Strong, Weak, or No recommendation)

Quality of evidence	
High quality	⊕⊕⊕⊕ or A
Moderate quality	⊕⊕⊕○ or B
Low quality	⊕⊕○○ or C
Very low quality	⊕○○○ or D
Strength of recommendation	
Strong recommendation for using an intervention	↑ ↑ or 1
Weak recommendation for using an intervention	↑ ? or 2
Weak recommendation against using an intervention	↓ ? or 2
Strong recommendation against using an intervention	↓ ↓ or 1

Fig 2 Representations of quality of evidence and strength of recommendations

Guyatt, G. H., Oxman, A. D., Vist, G. E., Kunz, R., Falck-Ytter, Y. Alonso-Coello, P. Schünemann, H. J. & the GRADE Working Group. (2008). GRADE: going from evidence to recommendations. *BMJ*, 336, 1049-1051.

Determinants of strength of recommendation

Factor	Comment
Balance between desirable and undesirable effects	The larger the difference between the desirable and undesirable effects, the higher the likelihood that a strong recommendation is warranted. The narrower the gradient, the higher the likelihood that a weak recommendation is warranted
Quality of evidence	The higher the quality of evidence, the higher the likelihood that a strong recommendation is warranted
Values and preferences	The more values and preferences vary, or the greater the uncertainty in values and preferences, the higher the likelihood that a weak recommendation is warranted
Costs (resource allocation)	The higher the costs of an intervention—that is, the greater the resources consumed—the lower the likelihood that a strong recommendation is warranted

Guyatt, G. H., Oxman, A. D., Vist, G. E., Kunz, R., Falck-Ytter, Y. Alonso-Coello, P. Schünemann, H. J. & the GRADE Working Group. (2008). GRADE: going from evidence to recommendations. *BMJ*, 336, 1049-1051.

“Box 2 | Quality of evidence and definitions”

“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— Any estimate of effect is very uncertain”

From: Guyatt, G. H., Oxman, A. D., Vist, G. E., Kunz, R., Falck-Ytter, Y. Alonso-Coello, P. Schünemann, H. J. & the GRADE Working Group. (2008). GRADE; An emerging consensus on rating quality of evidence and strength of recommendations. *BMJ*, 336, 924-926.

“Box 2: Criteria for assigning grade of evidence: Type of evidence “

–Randomised trial = high
Observational study = low
Any other evidence = very low

Decrease grade if:

- Serious (– 1) or very serious (– 2) limitation to study quality
- Important inconsistency (– 1)
- Some (– 1) or major (– 2) uncertainty about directness
- Imprecise or sparse data (– 1)
- High probability of reporting bias (– 1)

Increase grade if:

- Strong evidence of association—significant relative risk of > 2 (< 0.5) based on consistent evidence from two or more observational studies, with no plausible confounders (+1)⁴⁶
- Very strong evidence of association—significant relative risk of > 5 (< 0.2) based on direct evidence with no major threats to validity (+2)
- Evidence of a dose response gradient (+1)
- All plausible confounders would have reduced the effect (+1)”

Grade Working Group. (2004). Grading the quality of evidence and strength of recommendations. *BMJ*, 328.

“Box 3: Imprecise or sparse data”

–There is not an empirical basis for defining imprecise or sparse data. Two possible definitions are:

- Data are sparse if the results include just a few events or observations and they are uninformative
- Data are imprecise if the confidence intervals are sufficiently wide that an estimate is consistent with either important harms or important benefits

These different definitions can result in different judgments. Although it may not be possible to reconcile these differences, we offer the following guidance when considering whether to downgrade the quality of evidence due to imprecise or sparse data:

- The threshold for considering data imprecise or sparse should be lower when there is only one study. A single study with a small sample size (or few events) yielding wide confidence intervals spanning both the potential for harm and benefit should be considered as imprecise or sparse data
- Confidence intervals that are sufficiently wide that, irrespective of other outcomes, the estimate is consistent with conflicting recommendations should be considered as imprecise or sparse data”

Grade Working Group. (2004). Grading the quality of evidence and strength of recommendations. *BMJ*, 328.

A computer program exists to assist in developing GRADE recommendations:
Brozek, J., Oxman, A., Schünemann, H. (2008). GRADEpro. [Computer program].
Version 3.2 for Windows. <http://www.ims.cochrane.org/revman/other-resources/gradepro> .

9. Follow Up Conference Calls will be Conducted to Discuss Unresolved Issues and Compile the Annotations of the Guideline.

- The resulting product is the first draft of the guideline that will be distributed.
- Prior to this review, the Champions and the Facilitator will confer with the Evidence Chaperone to confirm the timeline and assure that the recommendations are consistent with the evidence.

10. The First Draft of the Guideline will be posted on a Development Website for Field Review and Comment:

- DoD Evidence-based Practice Division, Patient Care Services and the VA Network Clinical Managers will solicit feedback from a broader group of end users.
- VA Network designated staff and DoD end users will be asked to review the guideline and provide feedback to the Guideline Champions and/or directly to the guideline development experts via the web page which is available for online comment. This portion of the field test is more specifically **directed towards an evaluation of the content and the logic and flow of the guideline.**
- Comments and recommendations regarding proposed changes to the content of the guideline must be supported by evidence.
- The VA/DoD Guideline Champions will reply to the respondents and will integrate comments and suggestions into the evidence review as appropriate.

11. An executive panel of the guideline work group re-convenes to finalize the guideline and identify the content of the provider education tools:

- The executive panel will be reconvened to integrate the comments of the reviewers, as appropriate, and to complete the guideline.
- At this same face-to-face meeting, the group will also begin to identify the components of the guideline summary, pocket card, health tips and performance measures that could be used to assess guideline implementation and outcomes.
- Emphasis will be placed to assure that level of evidence for the recommendations captured in the pocket card, and/or health tips, etc. is identified on the printed materials.
- All guideline modules must contain the date of the last systematic evidence review.

Step 12: There are 2 Steps in the Review of the Final Guideline Draft:

12 A: The Final Draft of the Guideline is posted on the web for review and comment:

- This portion of the review is directed towards an **evaluation of the content** of the recommendation, **the logic of the algorithm**, and the **format and usability** of the guideline.
- Comments and recommendations regarding proposed changes to the content of the guideline must be supported by evidence.
- A summary of the comments and suggestions collected through the web page will be sent to the champion/executive panel of the working group

12 B: The Final Draft is then submitted for Independent Review:

- The final draft of the guideline is assigned to at least three VA /DoD staff or outside national experts who have been trained in the review of scientific literature and have agreed to perform an independent review of each guideline.
- This independent review is directed towards an **evaluation of the content** of the guideline, as well as the **format and usability** of the guideline.
- The rating tool containing the reviewer's comments and recommendations will be forwarded to the Office of Quality and Performance. Major issues are forwarded to the EBPWG as needed. (See Attachment III)
- The reviewer's comments and recommendations regarding the content of the guideline will be provided to the champions / the executive panel of the working group.

13. Final Editing Incorporates Feedback as Appropriate:

- The Champion(s), in consultation with key experts from the editorial panel of the guideline, and the facilitator and the Evidence Chaperone will integrate the comments and suggestions into the final document as appropriate. **This includes the guideline summary and provider education tools.**
- Discussion of serious controversies regarding interpretation of the evidence will be included in the introduction to the guideline and may be the subject of discussion at the time of review with the EBPWG.

14. The Final Guideline, Tools, and Comments from Independent Review are Submitted to VA/DoD Evidence Based Practice Workgroup Subgroup for Review:

- The VA/DoD EBPWG again reviews comments from independent reviewers and verifies that all appropriate suggestions have been incorporated into the final document.
- An electronic copy of the guideline along with a summary of the comments from the reviewers will be provided to the entire VA/DoD EBPWG at least two weeks in advance of the meeting.

15. Presentation of Guideline to full VA/DoD EBPWG for Approval:

- When the EBPWG is convened, the Champion(s) and the Evidence Chaperone will present the guideline to the EBPWG and recommend endorsement for implementation throughout VA and DoD.
- The Champion(s) will hear the deliberations of the EBPWG and will be provided feedback that will be entered into the minutes of the EBPWG.
- The Guideline will then be either endorsed or further modifications will be made.
- When endorsed, Employee Education System will put the tools into final format.

16. The final Guideline and Guideline Summary will explicitly identify any conflict of interest by participants and will explicitly identify and describe all funding sources for the development of the CPG.

17. The Guideline and Other Related Tools are Posted on the Office of Quality and Performance internet and intranet and the DoD internet sites

DoD Internet: <https://www.qmo.amedd.army.mil/pguide.htm>

VA Internet: <http://www.healthquality.va.gov/>

VA Intranet: <http://vaww.ogp.med.va.gov/programs/cp/clinicalPractic.aspx>) .
All guidelines placed on the Web will conform to the requirements described in Section 508 of the Rehabilitation Act of 1973, as amended. 29 U.S.C. §798 (see <http://www.access-board.gov/sec508/guide/act.htm>)

B. Guideline Update and Approval Process:

Evidence Based Practice Work Group Approves Schedule for Update of Clinical Practice Guidelines: The immediate update of guidelines will be triggered if any recommendation contained in a guideline is identified as harmful to patients (i.e., pharmaceutical or device recall, etc.) Routine guideline updates will ideally occur approximately every five years. The process that will be followed mirrors that of guideline development.

Revised February 1, 2011

Attachment I - Guideline Project Submission Form

VA/DoD Evidence-Based Clinical Practice Guidelines

Guideline Project Submission Form

Project Name			
Project Description			
Project Champion			
Last Name		First Name	
Service/Organization/Command		Title	
Address			
City		State	Zip Code
Phone		Fax	E-mail

MAKING A CASE FOR CHANGE – Provide narrative to support guideline development.

Perceived gap in health status:

[Is there new information from the medical literature? What about current outcomes (e.g., prevalent conditions, diagnosis)? Are there clinical areas for improvement suggested by clinicians? Are there benchmarks available that suggest a need to change practice? Are there existing evidence-based guidelines on this subject? What is the impact of this guideline on patient outcomes?]

Perceived gap in patient satisfaction:

[Is there survey information available addressing patient satisfaction that indicates an opportunity for improvement? Are there benchmarks available that suggest a need to change practice?]

Perceived gap in provider satisfaction:

[Are there surveys or suggestions addressing provider satisfaction that indicate an opportunity for improvement? Are there benchmarks available that suggest a need to change practice?]

Perceived gap in cost/utilization:

[Are there areas of care with high utilization? Is there significant variation or an opportunity for improvement in utilization patterns (e.g. drug utilization, lab utilization, referral rates, or local variation)? Are there benchmarks available that suggest a need to change practice? Rational and supporting evidence of relevance/importance of topic to the VA and/or DoD population?]

Perceived organizational issues:

[Are there political or organizational reasons why a change in practice might be warranted? Are there benchmarks available that suggest a need to change practice? Is the implementation of this project feasible? Is there evidence available to support evidence-based guideline development?]

Revised February 1, 2011

Attachment II –VA/DoD Evidence-Based Clinical Practice Guideline Workgroup

DISCLOSURE STATEMENT

VA/DoD Evidence-Based Clinical Practice Guideline Workgroup

DISCLOSURE STATEMENT

The VA/DoD Evidence-Based Clinical Practice Guideline (EBCPG) Workgroup members (voting and non-voting), as well as developers, reviewers, and others involved in the clinical practice guideline (CPG) process, are asked to sign a disclosure statement annually to detail involvement, of any kind, with manufacturers that may benefit from the inclusion or recommendation of their products within a VA/DoD CPG. This includes, but is not limited to, pharmaceuticals, diagnostic products/equipment, and monitoring supplies.

Please list the various projects you are involved with in regards to the following areas:

- | | | | |
|---|---|-----|----|
| 1 | Do you participate in research funded by pharmaceutical manufacturers?
If YES, please list the company(ies), product(s), or disease state(s): | YES | NO |
| 2 | Do you serve on a Speakers Bureau?
If YES, please list the company(ies), product(s), or disease state(s): | YES | NO |
| 3 | Do you receive remuneration for activities (such as board member or member of an advisory council) for any company or product that is coming to market?
If YES, please list the company(ies), product(s), or disease state(s): | YES | NO |
| 4 | Do you have financial holdings (to include, but not limited to, company stock, bonds, or other shares, etc.) of said companies and/or products?
If YES, please list the company(ies), product(s), or fund(s): | YES | NO |

I affirm, to the best of my knowledge, the above statement is inclusive of my functions with said product(s), company(ies), and disease state(s). I acknowledge that if my involvement changes, I am to contact the respective VA or DoD EBCPG Workgroup co-chair and update this disclosure form immediately. I will recuse myself from voting on guideline selection, development, adaptation, or tool kit development matters concerning issues where a conflict of interest (or appearance of a conflict of interest) may exist.

SIGNATURE _____ DATE _____

Printed Name: _____

Revised February 1, 2011

Attachment III-External Reviewer Form

VA/DoD CLINICAL PRACTICE GUIDELINES

(Guideline Rating Tool 4-1-2010)

Reviewer _____ Date _____

Title of the
Guideline _____

Do you have any conflict of interest or potential conflict of interest in reviewing this guideline?

No Yes (Specify if yes.) _____

A. SCOPE AND PURPOSE	Strongly Agree	Agree	Disagree	Strongly Disagree
1. Targeted patient population is specified.				
2. Intended users of guideline are specified.				
3. Guideline addresses a documented gap in performance, safety, or quality.				
COMMENTS				
B1. PRESENTATION	Strongly Agree	Agree	Disagree	Strongly Disagree
4. The guideline is clearly written.				
5. Guideline defines unfamiliar terms and those that are critical to applying the recommendations.				
6. The recommendations are specific and unambiguous.				
B2. PRESENTATION	Strongly Agree	Agree	Disagree	Strongly
7. The algorithm is logically complete and internally consistent.				
COMMENTS				

C1. SYSTEMATIC REVIEW METHODS	Strongly Agree	Agree	Disagree	Strongly Disagree
8. Systematic methods were used to search for evidence.				
9. The criteria for selecting the evidence are clearly described.				
10. The quality of the studies was explicitly assessed.				
C2. SYSTEMATIC REVIEW METHODS	YES	NO	NOT SURE	
11. Eligible studies were summarized in evidence tables.				
COMMENTS				
D. INTERGRATING EVIDENCE INTO RECOMMENDATIONS	Strongly Agree	Agree	Disagree	Strongly Disagree
12. The methods used to formulate the recommendations are clearly described?				
13. There is an explicit link between the recommendations and the supporting evidence.				
14. Was sufficient information provided to understand the rationale behind key or controversial recommendations?				
COMMENTS (on D. Integrating the Evidence)				
E. BENEFITS, HARMS AND OUTCOMES	Strongly Agree	Agree	Disagree	Strongly Disagree
15. All important benefits and harms of recommended treatments or procedures are specified.				
16. Benefits and harms of recommended treatments and procedures are quantified.				
17. The effect of the recommended interventions on health care costs is quantified.				
COMMENTS				

F. AUTHORSHIP	Strongly Agree	Agree	Disagree	Strongly Disagree
18. The guideline clearly notes author(s).				
19. The guideline clearly notes the authors' conflicts of interest.				
20. All relevant disciplines are represented including primary care?				
COMMENTS				
G. TESTING AND REVIEW	Strongly Agree	Agree	Disagree	Strongly Disagree
21. The guideline has been evaluated by field testing.				
22. An expiration date or procedure for updating the guideline is specified.				
COMMENTS				
H. FLEXIBILITY	Strongly Agree	Agree	Disagree	Strongly Disagree
23. The guideline clearly indicates the intended flexibility of the recommendation(s).				
24. The role of patient preferences is discussed.				
25. The guideline addresses special patient populations when appropriate.				
COMMENTS				

I. FEASIBILITY OF IMPLEMENTING THE GUIDELINE	Strongly Agree	Agree	Disagree	Strongly Disagree
26. The guideline recommendations are feasible to implement in all intended care settings (consider organizational characteristics, implementation costs, opportunity costs.)				
COMMENTS				

OVERALL ASSESSMENT

27. Describe the predominant method(s) used to develop this guideline:

- Evidence-based (key recommendations are supported by fair or good evidence with explicit estimation of benefits and harms)
- Evidence-based (all recommendations are supported by fair or good evidence)
- Structured consensus with systematic literature reviews
- Global subjective judgment or consensus panel
- Other (describe) _____

28. Would you recommend these guidelines for use in practice?

- STRONGLY RECOMMEND**
- RECOMMEND**
- WOULD NOT RECOMMEND**
- UNSURE**

COMMENT: (What are this guideline’s specific strengths? What are this guideline’s specific weaknesses? Use additional space as necessary.)

Revised February 1, 2011

Additional Review Comments: How can/might this guideline be improved?

Name of Reviewer _____

Address _____

Phone _____

E-Mail _____

Attachment IV
Development of National Clinical Reminders
Version 12
February 3, 2005

Development of Clinical Reminders Related to Clinical Practice Guidelines

1. General Background on National Clinical Reminders

Clinical Reminders are decision support tools that assist healthcare providers and healthcare systems to implement recommended actions and practices. Such practices are encapsulated in, for example, evidence-based clinical guidelines and performance measures. The VA's electronic medical record system, known as Computerized Patient Record System (CPRS) offers the ability to develop electronic clinical reminders that can assist clinical decision-making and educate providers about appropriate care that corresponds to approved VA and VA-DoD evidence-based clinical practice guidelines.

Electronic clinical reminders may also be used to improve documentation and follow-up, by allowing providers to easily view when certain tests or evaluations were performed as well as to track and document when care has been delivered. They can direct providers to perform certain tests or other evaluations that will enhance the quality of care. While clinical reminders may be useful to educate providers, as part of the goal of enhancing care for specific conditions or doing specific tasks, they are not well designed for general dissemination of information.

To date, most clinical reminders in use in VA have been developed locally. There are a number of benefits to creating national clinical reminders. National reminders can help to standardize care across VHA. National reminders may also help facilitate a national assessment of performance and quality of care.

2. Definitions

A clinical reminder is software decision support tool that defines evaluation and resolution logic for a given clinical activity. The evaluation logic defines conditions in the database including the presence or absence of specified criteria such as diagnoses, procedures, health factors, medications, or demographic variables (e.g. age, gender). A reminder may or may not require provider resolution, depending on its purpose and design, through a user interface, also known as a reminder dialog. Also, as per the underlying logic, reminders may be used to collect specified patient information related, or not related, to the dialog. For the purposes of this document, a clinical reminder refers to the logic and associated dialog that is designed to support selected clinical activities. This document focuses on reminders that require resolution through use of a reminder dialog and that, to some degree, collect data on the designated clinical action.

Note that this document does not include administrative reminders or clinical reminders that are to be used for purposes of national data collection. This document also does not include reminders that are developed by individual facilities or VISNs or by national groups and that are to be shared, on a voluntary basis, through Clinical Reminder Exchange Utility (CREU) unless that reminder is being used for a nationally approved clinical practice guideline as per VA or VA-DOD programs.

3. Principles of National Electronic Clinical Reminders

- a. National Clinical reminders will be considered to be an integral component of an established an/or approved clinical practice guideline, as determined by the Evidence Based Practice Work Group (EBPWG). As such,
 - i. The content and intent of any national level clinical reminder must be consistent with its parent national clinical practice guideline.
 - ii. National clinical reminders are the responsibility of the jurisdiction of the EBPWG and its delegated advisory subcommittee.
 - iii. National Clinical reminders will not usually be reviewed and/or approved as a separate entity from a parent guideline. Exceptions may be for specified mandates or statutes.

- b. National Clinical reminders will be developed in a cooperative partnership between the EBPWG and the Office of Information (OI). As such,
 - i. The EBPWG and/or its delegated advisory subcommittee, the Clinical Reminder Committee, will be responsible for assessing all requests for development of national clinical reminders, as consistent with the principles stated above. Requests to the OI will be re-directed to the EBPWG.
 - ii. The EBPWG will be responsible for approving the initial development of and final version of a national clinical reminder.
 - iii. The EBPWG will develop a prioritization scheme and tracking method and updating schedule for national clinical reminders.
 - iv. The EBPWG will assist in providing appropriate clinical experts when needed for reminder development.
 - v. The OI will assist in creating a resource pool of informatics experts to assist groups with building national clinical reminders, as needed. Direct assistance will not routinely be provided by OI.
 - vi. The OI will assist in developing the requisite national patch(es) for dissemination of approved reminders. This will usually occur within 2-3 months after EBPWG approval.
 - vii. The OI will assist in developing new functionalities as needed to implement the national patches
 - viii. The OI will maintain the VA's clinical reminder website.
<http://vista.med.va.gov/reminders/>

- c. National reporting reminders, for gathering data, will be considered as a separate entity from national clinical reminders.

4. Considerations when Designing National Clinical Reminders

There is increasingly widespread use of electronic clinical reminders across VA and there is reasonable concern that continued implementation of new reminders will cause undue burden to end-users who must complete these reminders during the course of patient encounters. The following general principles should be considered when designing and implementing national clinical reminders:

- a. Clinical reminders will generally be prioritized for performance measures tracked by the Office of Quality and Performance that, in turn, are predicated on the highest level of evidence from the scientific literature. This usually means that the action would merit an Evidence Level (LE) I and Strength of Recommendation (SR) "A"

(see Guidelines on Guidelines, above). Exceptions may include mandated programs (e.g. military sexual trauma or hepatitis screening) or other areas of special importance to VA.

- b. Clinical reminders will generally be reserved for issues related to quality of care, where it has been previously shown that quality does not meet expectations or where significant variation in care across sites has been demonstrated.
- c. Clinical reminders will not be used solely for educational purposes but should prompt providers to complete a specific clinical task during a patient care encounter.
- d. Clinical reminders should be simple to use and resolve, creating the least possible amount of provider burden. Cumulative burden on providers, meaning the effort necessary to resolve all implemented reminders by end-users, should be considered when adding new reminders.
- e. Clinical reminders should be developed by, or in consultation with, anticipated end-users of the specific reminder (see below).
- f. National clinical reminders will supplant local initiatives to every extent possible, once approved. However, reminder dialogs may undergo minor, local modifications as long as these changes do not interfere with the intent of the reminder.
- g. Clinical reminders should target a specific patient population unless they are being used for general screening. The logic must be explicit so that the reminder will include all patients for whom the intervention is relevant and exclude those for whom the intervention is not.
- h. Facilities will be responsible for determining which providers will see and/or act on the reminder.

5. Prioritizing National Reminder Development:

The goal of the EBPWG is to systematically standardize all clinical reminders associated with national clinical guidelines and mandated preventive care. Therefore, priority for developing and implementing national reminders will correspond to new quality of care priorities as well as ones already incorporated into the External Peer Review Program (EPRP) process. For example, existing preventive care guidelines will receive a high priority as these interventions generally involve screening large populations of veterans. Also receiving a high priority will be existing national clinical practice guidelines, particularly when updating occurs.

More specifically, new national clinical guidelines will be designated as Priority 1, unless the reminder development is already incorporated within the development of that guideline. Existing measures will receive priority 2, unless the guideline is being updated, in which case they are considered “new” (Priority 1). Other reminders will generally be listed as Priority 3, as below. Decisions regarding the approach to developing new clinical reminders, as part of ongoing clinical guideline development will be made by EBPWG.

In brief, the priority assessment for clinical reminders is as follows:

1. Priority 1:

- a. New national preventive care measures, as determined by the EBPWG.
- b. New national guidelines, as determined by the EBPWG

2. Priority 2

- a. Existing national preventive care measures, as determined by the EBPWG
- b. Existing national guidelines, as determined by the EBPWG

- c. Other mandated assessments including but not limited to hepatitis C, military sexual trauma
3. *Priority 3*
- a. Programs or protocols, including medication usage reminders, not specified under Priority 1 or 2, above.

6. Requests for National Clinical Reminders

Developing new national clinical reminders requires the same sort of triage process and prioritization that has been described for the creation of new clinical practice guidelines. To improve communication among stakeholders, and to assure appropriate oversight, the EBPWG will generally consider requests only when the appropriate administrative channels have been followed to include a Headquarters-based Chief Officer, Chief Consultant, or Program Director in the routing mechanism. Alternatively, the EBPWG or its advisory subcommittee may itself request a national clinical reminder as part of an existing clinical practice guideline or as part of a new or updated guideline.

a. Interested parties will inform the EBPWG and/or subcommittee of the following:

- i. Description of the reminder
- ii. Intended patient population and magnitude of the problem for that population.
- iii. Evidence that care for the disease or condition in question is not optimal or that significant variation exists.
- iv. Identification of the clinical guideline or scientific evidence that forms the foundation for the reminder.
- v. Suggested representatives from appropriate clinical specialties who can help in the development of the reminder.
- vi. Project timeline for development
- vii. Disclosure of any conflicts of interest
- viii. Identification of approaches to assure partnership within VA, or outside VA if applicable.

b. Designating Participants:

The initiating group will inform the EBPWG and/or subcommittee of intended designers and collaborators, including:

- i. Principal clinical liaison who will be responsible for the reminder
- ii. Clinical leaders and experts, at least two of which must be end users.
- iii. Informatics experts, including the individual who will be responsible for the actual building of the reminder. If one is needed, the EBPWG will work with the OI to assist in finding such experts who are willing to work with the development group.

c. Approval or Denial of Requests:

As with clinical guideline development, upon receipt of the application the EBPWG and/or its advisory subcommittee will review the application. The Chairperson or his/her delegate Committee Chairperson, will notify the applicant of the outcome of the review as follows:

- i. Approved, development may proceed.
- ii. Approval pending a modification or clarification, as specified.
- iii. Not approved, with reasons stated
- iv. Deferred, sent for further review.

7. Development Process:

- a. Once approval to proceed is given, an expert group will design the designated reminder as part of a field-based process.
- b. This process may include local testing and/or iteration to complete a working version of the reminder.
- c. Once the draft version has been completed, the EBPWG and/or its advisory subcommittee will review the reminder for content and intent, and assure that it is consistent with relevant national clinical practice guideline(s). Recommendations on changes may be made at that time.
- a. d. The reminder will be piloted in the final draft version over a 1 to 2 month time period, at a minimum of three sites that represent different clinical settings and environments (e.g. large urban tertiary center, rural primary care center, multi-specialty VAMC).
- e. Reminder assessments should be qualitative and quantitative. Useful information may include:
 - i. Ease of using the reminder
 - ii. Understandability of the reminder
 - iii. How reminders were resolved
- f. If the template requires minor modifications after pilot testing, these should be completed before the final template is presented to the EBPWG. If major changes are required, a further pilot test will be needed.
- g. Once pilot testing is complete, the EBPWG will assess the final product and results of the testing and make a recommendation as to implementation. The development group will supply the data requested and also provide a PowerPoint, or similar, presentation of the reminder as well as details on the underlying logic.
- h. The OI will then be informed if a national patch is required for dissemination. They will then develop the necessary infrastructure and instruction packet for implementation.
- i. If during the process of development there exists a divergence of opinion that cannot be resolved among the expert group, the final determination of how to proceed will be the responsibility of the EBPWG and/or its delegated advisory subcommittee.

8. Implementing National Reminders

- a. The EBPWG will recommend approval and/or implementation across VA for national reminders along the same basic scheme as the Priority designation.
- b. All national reminders will be delivered to the sites as a software patch that by nature mandates installation into each site clinical information system.
- c. Sites will be responsible for mapping appropriate local findings and quick orders to national guideline terms and dialogs so as to assure that the reminder and associated dialog functions appropriately at the facility.

- d. Reminders are intended to be decision support tools that facilitate compliance with and implementation of critical guidelines. Sites are expected to optimally utilize the reminder and dialog to facilitate guideline compliance.
- e. At a minimum, sites should evaluate compliance with the guideline using reminder reporting functions and establish additional implementation efforts when appropriate. Where local reminders exist that overlap with the national reminder, the national reminder will be used in its place.
- f. To maximize flexibility while preserving the intent of the national reminder, customization, such as adding orderable items or linking a dialog box to laboratory or consult requests, may be completed at local or VISN facilities, depending on local resources and needs. Additional changes may be undertaken, as long as this does not interfere with the intent of the national reminder.

9. Updating reminders

The EBPWG will assess all national reminders periodically, usually as part of guideline updating, and decide whether changes or improvements are warranted. It may review any comments from the field that have been collected and collated over the course of the year. Modifications, if necessary, will be recommended to the EBPWG and deferred back to the developers.