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Department of Veteran Affairs
Veterans Health Administration
Washington, DC 20420

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 Working 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 Sub Group Reviews & Prioritizes Applications: Upon receipt of the application, the EBPWG Prioritization Sub Group will review the application and prioritize it for development and implementation in VHA and DoD.

- Within 1 week of receipt, the Chairperson, EBPWG Prioritization Sub Group, will acknowledge receipt of each application.
- The EBPWG Prioritization Sub Group 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 Co-Chairs of the Prioritization Subgroup will notify the applicant of the outcome of the review generally within 4 weeks of receipt.

3. Designees of the DoD, 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 Service 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 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 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 means 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 CoChairs 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.
- At a minimum, systematic reviews will use explicit, reproducible methods to
 - identify relevant, eligible studies
 - assess the quality of each study and of the body of evidence
 - critically appraise key studies and
 - synthesize results.
- To grade the quality of individual studies, the reviews will apply the USPSTF criteria for quality [*Harris RP, Helfand M*, etc], 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.
- This group of clinical experts will also develop consensus-based recommendations as needed when there is inadequate evidence.

The clinical experts will grade recommendations using the system described in Current Methods of the U.S. Preventive Service Task Force. A Review of the Process. Am J Prev Med 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.

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.

Table 1: Overall Quality

I	High grade evidence (I or II-1) directly linked to health outcome
II	High grade evidence (I or II-1) linked to intermediate outcome or Moderate grade evidence (II-2 or II-3) directly linked to health outcome
III	Level III evidence or no linkage of evidence to health outcome
IV	Insufficient Evidence

Table 2: Net Effect of the Intervention

Substantial	More than a small relative impact on a frequent condition with a substantial burden of suffering - or - 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 - or - 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 - or - A small impact on an infrequent condition with a significant impact on the individual patient level.
Zero or Negative	Negative impact on patients - or - 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 3. Grade the net benefit.

<i>Quality of Evidence</i>	<i>The net benefit of the intervention</i>			
	Substantial	Moderate	Small	Zero or -
I	A	B	C	D
II	B	B	C	D
III	C	C	C	D
IV	I	I	I	D

Table 4: Grade the Recommendation

A	A strong recommendation that the intervention is always indicated and acceptable
B	A recommendation that the intervention may be useful/effective
C	A recommendation that the intervention may be considered
D	A recommendation that a procedure may be considered not useful / effective, or may be harmful.
I	Insufficient evidence to recommend for or against – the clinician will use their clinical judgment

*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.

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 test the guideline in the direct care setting 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 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, key points 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 and provider tools are 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 and the Co Chairs of the EBPWG/subcommittee. (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.
- All EBPWG members are expected to review the guideline and submit comments to the Co Chair/designee at least 5 days before the work group meeting to minimize discussion at the meeting.

14. The Final Guideline, Tools, and Comments from Independent Reviewers 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 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 VHA.
- The Senior 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, the VA Employee Education System will put the provider tools in the final format.

16. EBPWG Forwards Recommendations to OQP , PCS and appropriate offices for Concurrence/Approval:

- Within 3 weeks following the meeting of the EBPWG, the recommendations of the EBPWG and a summary of the guideline and the provider tools will be forwarded to the Under Secretary for Health for signature and distribution.
- If there is disagreement with the EBPWG's recommendations, the guideline will be returned to the VA/DoD Co Chairpersons for action.

17. The Guideline and Other Related Tools are Posted on the Office of Quality and Performance (<http://www.healthquality.gov>). All guidelines placed on the Web will conform to the requirements described in Section 508.29 U.S.C. &798 of the Rehabilitation Act. (See <http://www.va.gov/accessible/disvetres.html>).

B. Guideline Update and Approval Process:

1. 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 two years. The process that will be followed mirrors that of guideline development.