

PRESUMPTIVE DECISION PROCESS

1. SUMMARY OF CONTENT: This Veterans Health Administration (VHA) directive establishes the responsibilities of the VHA entities involved in the new Presumptive Decision Process (PDP). This VHA directive provides additional detail on the process VHA must use to establish new presumptive conditions and includes the following two appendices:

a. **Appendix A.** Provides a copy of the Department of Veterans Affairs (VA)'s "Improving VA's Presumptive Decision Process".

b. **Appendix B.** Demonstrates implementation of the PDP by VA as required by the Sergeant First Class Heath Robinson Promise to Address Comprehensive Toxics (PACT) Act of 2022. **NOTE:** *VA will continue to use VA Directive 0215, Management of Reports issued by the National Academies of Sciences, Engineering, and Medicine, dated October 8, 2020, for review of other National Academies of Sciences, Engineering, and Medicine (NASEM) reports not involving presumptive decisions. The PDP described in this directive must be used when any condition is being considered for a potential presumptive condition by VHA.*

2. RELATED ISSUES: VA Directive 0215, Management of Reports issued by the National Academies of Sciences, Engineering, and Medicine, dated October 8, 2020.

3. POLICY OWNER: VHA Office of Health Outcomes Military Exposures (12HOME) is responsible for this directive's content. Questions may be addressed to the Chief Consultant, HOME at VHA12POP5PDHSAction@va.gov.

4. LOCAL DOCUMENT REQUIREMENTS: There are no local document requirements in this directive.

5. RESCISSIONS: None.

6. RECERTIFICATION: This directive is scheduled for recertification on or before the last working day of December 2029 and will continue to serve as national VHA policy until it is recertified or rescinded.

7. IMPLEMENTATION SCHEDULE: This directive is effective upon publication.

December 27, 2024

VHA DIRECTIVE 1309

**BY DIRECTION OF THE OFFICE OF THE
UNDER SECRETARY FOR HEALTH:**

/s/ M. Christopher Saslo
DNS, ARNP-BC, FAANP
Assistant Under Secretary for Health
for Patient Care Services/CNO

NOTE: *All references herein to VA and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter.*

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APPENDIX B

VA IMPLEMENTATION OF THE NATIONAL ACADEMIES OF SCIENCES,
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PRESUMPTIVE DECISION PROCESS

1. POLICY

It is Veterans Health Administration (VHA) policy, pursuant to the Sergeant First Class Heath Robinson Promise to Address Comprehensive Toxics (PACT) Act of 2022, 38 U.S.C. §§1171-1173, to establish a new presumptive decision process (PDP) for reviewing potential presumptive conditions related to toxic exposure during Veterans' military service. **NOTE:** *The Department of Veterans Affairs (VA) will continue to use VA Directive 0215, Management of Reports issued by the National Academies of Sciences, Engineering, and Medicine, dated October 8, 2020, for review of other NASEM reports not involving presumptive decisions. The PDP described in this directive must be used when any condition is being considered for a potential presumptive condition by VHA.* **AUTHORITY:** 38 U.S.C. §§ 1171-1173, 7301(b).

2. RESPONSIBILITIES

a. **Under Secretary for Health.** The Under Secretary for Health is responsible for ensuring overall compliance with this directive.

b. **Assistant Under Secretary for Health for Patient Care Services/Chief Nursing Officer.** The Assistant Under Secretary for Health for Patient Care Services/Chief Nursing Officer (CNO) is responsible for:

(1) Supporting Health Outcomes Military Exposures (HOME) with the implementation and oversight of this directive.

(2) Supporting the development of mitigation or corrective actions to address noncompliance of timelines with this directive. **NOTE:** *The Secretary of Veterans Affairs has final authority for establishing presumptive conditions. The Veterans Benefits Administration (VBA) Under Secretary for Benefits maintains a corresponding VBA policy letter on PDP.*

c. **Chief Consultant, Health Outcomes Military Exposures.** The Chief Consultant, HOME, is responsible for:

(1) Ensuring that this directive is being implemented as intended and that corrective action is taken when noncompliance with timelines and scientific review are identified.

(2) Serving as the VHA Co-Chair for the Military Environmental Exposure Sub-Council (MEESC).

(3) Ensuring that the MEESC fulfills the functions and duties as included in the MEESC Charter (available at:

[dvagov.sharepoint.com/sites/vawriisc/HOME/Forms/AllItems.aspx?id=%2Fsites%2Fvawriisc%2FHOME%2FPolicy%2FMilitary Environmental Exposure Sub-Council%28MEESC%29 Signed Charter%2Epdf&parent=%2Fsites%2Fvawriisc%2FHOME%2FPolicy](https://dvagov.sharepoint.com/sites/vawriisc/HOME/Forms/AllItems.aspx?id=%2Fsites%2Fvawriisc%2FHOME%2FPolicy%2FMilitary%20Environmental%20Exposure%20Sub-Council%28MEESC%29%20Signed%20Charter%2Epdf&parent=%2Fsites%2Fvawriisc%2FHOME%2FPolicy). **NOTE:** *This is an*

*internal VA website that is not available to the public.) and reporting any issues with this VHA directive (e.g., noncompliance with stated responsibilities, decisions made as part of the PDP in Appendix A and B) to the MEESC. **NOTE:** The other Co-Chair for the MEESC is the VBA Co-Chair (the Executive Director, VBA Compensation Service, or designee).*

(4) Developing, coordinating, and working with offices within VA, VBA, and VHA to develop the new presumptions.

(5) Briefing other VA, VBA, and VHA offices or programs on this directive and the any changes to the PDP.

(6) Revising or updating the PDP as needed in conjunction with VA's governance process (see Appendix A, paragraph 8 for details on the VA governance process for final presumptive decisions).

(7) Coordinating and collaborating with VBA Compensation Service to develop necessary changes to the VBA policy letter on PDP and this VHA directive.

(8) Tracking the length of time for each phase of the PDP to ensure the timely review of the conditions.

3. OVERSIGHT AND ACCOUNTABILITY

a. **Internal Controls.** The internal controls in this directive are:

(1) The Chief Consultant, HOME: Providing oversight for each phase of the PDP. (See Appendix A, paragraph 7 for the PDP flow map and time frames.)

(2) The Chief Consultant, HOME: Reporting any issues with this directive (e.g., noncompliance with stated responsibilities, decisions made as part of the PDP in Appendix A and B) to the MEESC, which is part of VA's governance process.

b. **Metrics.** The metrics in this directive are:

(1) The Chief Consultant, HOME: Tracking the length of time for each phase of the PDP to ensure the timely review of the presumptive conditions being considered (see Appendix A, paragraph 7 for the PDP flow map and time frames).

(2) Compliance with the operating procedures and timelines as included in the MEESC Charter.

4. TRAINING

There are no formal training requirements associated with this directive.

5. RECORDS MANAGEMENT

All records regardless of format (for example, paper, electronic, electronic systems) created by this directive must be managed as required by the National Archives and Records Administration (NARA) approved records schedules found in VHA Records Control Schedule 10-1. Questions regarding any aspect of records management can be addressed to the appropriate Records Officer.

6. BACKGROUND

a. The PACT Act of 2022 required NASEM to review the decision process for reviewing potential presumptive conditions related to Veterans' military service. That report, titled "Review of the Department of Veterans Affairs Presumptive Decision Process", was completed with an overall favorable review and published by NASEM in 2023 (available at: <https://nap.nationalacademies.org/read/27166/chapter/1>). In their 2023 report, NASEM made five recommendations for improving the PDP, including a reevaluation in a few years and four content-related recommendations (see Appendix B, paragraph 1).

b. A document co-authored by VBA and VHA, titled "Improving VA's Presumptive Decision Process (PDP)" (see Appendix A), was published as an annex to NASEM's 2023 report, "Review of the Department of Veterans Affairs Presumptive Decision Process". VA and the Office of Management and Budget approved this content, and it was reviewed and approved by NASEM as the primary document that provides details on the PDP.

c. VA will continue to use VA Directive 0215 for other NASEM reports not involving presumptive decisions. The PDP described in this directive will be used when any condition is being considered for a potential presumptive condition. VA began implementation of this new PDP prior to the PACT Act of 2022 and continues to use it in evaluating new potential presumptive conditions. Steps in that process involve input on conditions from Federal Register notices, listening sessions with the public and Veteran Service Officers (VSOs), and other input for the MEESC to decide whether to recommend potential conditions be evaluated formally for presumptive conditions to the Secretary of Veterans Affairs.

7. DEFINITIONS

Presumptive Condition. For purposes of this directive, a presumptive condition is a specific medical condition that VA presumes was caused by an environmental exposure during a Veteran's military service. If a Veteran is diagnosed with a presumptive condition, they can be awarded disability compensation without requiring proof that the condition was incurred in, or aggravated by, military service.

8. REFERENCES

a. 38 U.S.C. §§ 1171-1173, 7301(b).

b. PACT Act of 2022, Section 202.

c. U.S. Department of Veterans Affairs. (2023). Military Environmental Exposures Sub-Council Charter.

[dvagov.sharepoint.com/sites/vawriisc/HOME/Forms/AllItems.aspx?id=%2Fsites%2Fvawriisc%2FHOME%2FPolicy%2FMilitary Environmental Exposure Sub-Council %28MEESC%29 Signed Charter%2Epdf&parent=%2Fsites%2Fvawriisc%2FHOME%2FPolicy](https://dvagov.sharepoint.com/sites/vawriisc/HOME/Forms/AllItems.aspx?id=%2Fsites%2Fvawriisc%2FHOME%2FPolicy%2FMilitary%20Environmental%20Exposure%20Sub-Council%28MEESC%29%20Signed%20Charter%2Epdf&parent=%2Fsites%2Fvawriisc%2FHOME%2FPolicy). **NOTE:** *This is an internal VA website that is not available to the public.*

d. National Academies of Sciences, Engineering, and Medicine. (2023). "Review of the Department of Veterans Affairs Presumptive Decision Process". National Academies Press. <https://nap.nationalacademies.org/read/27166/chapter/1>.

IMPROVING VA'S PRESUMPTIVE DECISION PROCESS

NOTE: This document is the final document approved by the Office of Management and Budget on the current Presumptive Decision Process (PDP).

1. PURPOSE

This document describes the new process the Department of Veterans Affairs (VA) will use to evaluate whether a specific medical condition is or is not associated with an environmental exposure. If an association is found, this document further describes how the condition could reach presumptive status.

2. BACKGROUND

VA is responsible for the administration of health care and benefits programs for eligible Veterans, caregivers and their survivors. In evaluating the association between an environmental exposure and a specific medical condition, multiple challenges exist. First, while the gold standard in medical research is the Randomized Clinical Trial (RCT), there are no such studies when it comes to military environmental exposures. Moreover, it would be unethical to conduct this type of study. The use of RCT methodology, therefore, cannot be applied to the evaluation of environmental exposures. Other methods are needed. In addition, it can take years postexposure for many of these medical conditions to present themselves (in the case of certain cancers, for example), making the determination of an association with an exposure even more difficult. The National Academies of Sciences, Engineering, and Medicine (NASEM) in their 2008 report noted:

For some medical conditions that develop after military service, the scientific information needed to connect the health conditions to the circumstances of service may be incomplete. When information is incomplete, Congress or [VA] may need to make a "presumption" of service connection so that a group of Veterans can be appropriately compensated. The missing information may be about the specific exposures of the Veterans, or there may be incomplete scientific evidence as to whether an exposure during service causes the health condition of concern.

The presumptive process VA historically used was often a decades-long process. It required waiting for Veterans to develop medical conditions, having providers or scientists observe and report potential patterns, and publishing these findings in peer-reviewed journals. VA would also conduct its own public health surveillance studies and conduct scientific literature reviews to evaluate whether certain conditions occurred more frequently among specific cohorts of Veterans who may have been exposed to the same environmental agent. This, too, often took years. A valuable instrument in this regard were the NASEM reports, some of which were mandated by Congress (such as through the Agent Orange Act of 1991, Public Law 102-4, 105 Stat. 11 (codified in part

at 38 U.S.C. § 1116), and the Omnibus Consolidated and Emergency Supplemental Appropriations Act of 1999, Public Law 105-277, 112 Stat. 2681, Title XVI—Service Connection for Persian Gulf War Illnesses (codified in part at 38 U.S.C. § 1118). NASEM consensus reports, however, require an average of two years to complete, and during this time, the conditions of concern may change and increases in incidence/prevalence or new information may become available, such that in some cases, by the time the NASEM reports are published, they are already out of date. This process is frustrating for Veterans, their families and caregivers, as well as their clinical teams, and has led to delays in Veterans receiving the health care and benefits they have earned and deserve.

When the most recent NASEM report found evidence of an association between particulate matter and three respiratory symptoms, the Veterans Health Administration (VHA) examined recent surveillance data from VHA health care records and then partnered with the Veterans Benefits Administration (VBA) to obtain claims data. VA conducted additional scientific reviews of recently published studies not available to NASEM, (including relevant articles in non-Veteran populations). This led to three newly added presumptive conditions in fiscal year (FY) 2021: asthma, rhinitis and sinusitis. This experience led VA to recognize that it could improve its presumptive decision-making process to be more proactive and transparent. The Secretary of Veterans Affairs directed VA to update the Presumptive Decision Process (PDP) to assess the available scientific data in as timely a fashion as possible, consider the addition of other relevant information, including VBA claims data, and enhance the transparency of the process.

3. SELECTION OF CONDITIONS

VA will use several factors to develop a list of medical conditions to be considered for presumptive status. These factors include, but are not limited to, the number of Veterans potentially affected, severity of the condition, amount of literature available, and VHA and/or VBA trends. VA will solicit input for conditions to be reviewed from external stakeholders, including Veterans and their families and caregivers, Veterans Service Organizations, Congress, and the public at large. This is in keeping with recommendations in the NASEM report on improving the presumptive decision-making process.

a. **Federal Register Notification:** At least once each year, VA will publish in the Federal Register a list of conditions the Department plans to evaluate, explain why the conditions were chosen for evaluation, and solicit input from the public. This approach allows for public participation and enables transparency. VA will use the feedback to finalize the list of conditions for evaluation.

b. **Data Gathering:** VHA and VBA data for the conditions of interest, including those that come from the Federal Register feedback, will be compiled and submitted to the Environmental Exposures Sub-Council (EESC). **NOTE:** *The name of this council was changed to the Military Environmental Exposures Sub-Council (MEESC) in December 2023. It is referred to as the MEESC in the main body of this directive and Appendix B.*

The EESC will review and propose a prioritization scheme for the order in which the conditions are recommended to be reviewed and prepare the rationale for the Evidence-Based Policy Council (EBPC).

c. **Evidence Base Policy Council:** The EBPC will endorse or reprioritize the EESC list and forward to the VA Operations Board and/or the VA Executive Board for Secretary of Veterans Affairs approval to determine the final list and prioritization.

4. COMPOSITION OF REVIEW PANEL

Once the list is approved by the VA Secretary, the EESC co-chairs will convene a review panel. There will be one panel convened per medical condition or set of related medical conditions, and the composition and size of the panel will be based on the amount of scientific evidence and data available for review.

At a minimum, each panel will include:

- a. Four members from VHA (Health Outcomes Military Exposures (HOME) and/or the Office of Research and Development).
- b. Two members from VBA.
- c. One member from a Federal Agency with subject-matter-experts with a substantive understanding of the exposure(s).
- d. One member from the U.S. Department of Defense (DoD) Deployment Health Working Group.
- e. VA or other Federal agency medical specialty members as needed for the specific condition(s) for review.

5. EQUIPOISE

When the evidence of an association between an environmental exposure and a medical condition is uncertain, and a case for an association can be made just as easily as a case against an association, a state of equipoise exists. Use of the concept of equipoise was suggested by the 2008 NASEM report as one of the ways to improve VA's presumptive decision-making process and has been adapted by the PDP. Drawing from the suggestions in that report, a presumptive status recommendation would be based on the strength of the evidence for or against an association (NASEM used causation, but VA's standard is association). Those standards are defined as:

- a. **Sufficient:** The evidence is sufficient to conclude that an association exists.
- b. **Equipoise and Above:** The evidence is sufficient to conclude that an association is at least as likely as not, but not sufficient to conclude that an association exists.

c. **Below Equipoise:** The evidence is not sufficient to conclude that an association is at least as likely or not or is not sufficient to make a scientifically informed judgment.

d. **Against:** The evidence suggests the lack of an association.

In the event that the strength of the evidence is at equipoise (that is, when the weight of the evidence is equally balanced as to whether an association exists), VA will make the determination after review of VBA claims data and other factors.

6. COMPONENTS AND METHODS THAT ARE PART OF THE REVIEW PROCESS

a. **Health Care Data:** The PDP will review VHA data in the form of epidemiological research studies and ongoing health care and population surveillance.

b. **Scientific Literature:** Relevant medical and scientific literature will be pulled using recognized Medical Subject Headings (MeSH) keywords. This data pull will include military and civilian human, animal, toxicologic and mechanistic studies. Research will be evaluated for the strength of the science based on study design, size, sources, reproducibility, or number of papers with similar findings, existence of conflicting studies, whether the study was peer-reviewed, whether there are limitations or flaws noted in the study, and whether there are any criticisms of a study and for what issues. In the future, and when possible, the use of machine learning algorithms and text-mining tools for continuous review of scientific literature will be used.

c. **VBA Claims Data:** The PDP will include a review of VBA claims data for trends, such as claim rate, grant rate, and service connection prevalence, analysis of differences in deployed and non-deployed or other cohort characteristics and may be used to assist in development of presumption when the science is at equipoise. VBA claims data may also be used to inform which reviews of conditions are indicated.

d. **Other Factors:** Additional factors will be reviewed, and include, but are not limited to, deployments to combat zones, morbidity, mortality and prognosis associated with the medical condition, rarity of the condition, quantity/quality of available science and data, and feasibility of producing future, methodologically sound scientific studies.

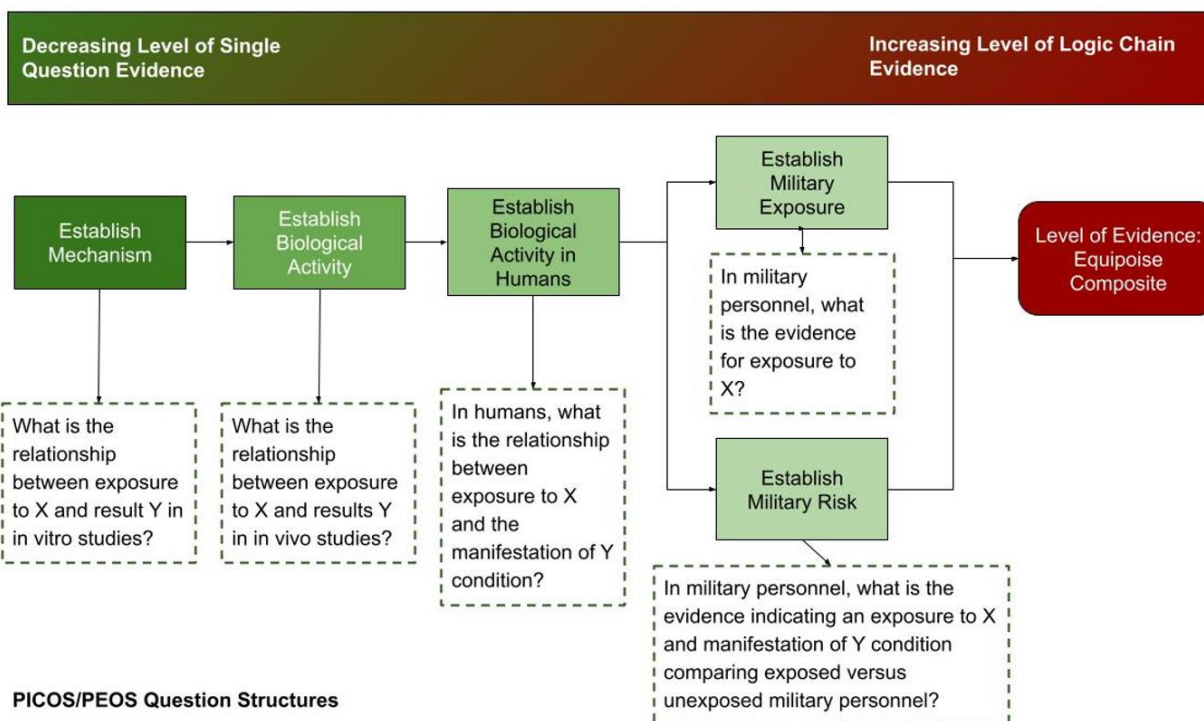
e. **Rare Conditions:** In some cases, the incidence of a disease, particularly certain types of cancer, is considered to be rare. VA defines rare cancers as those with an annual U.S. incidence rate of fewer than 6 cases per 100,000 individuals in the general U.S. population. This standard was adopted by the American Cancer Society and is used by the National Institutes of Health. The same standard has also been adopted internationally. The consortium from the European Union, Surveillance of Rare Cancer in Europe (RARECARE), defines rare cancers as those with fewer than 6 cases per 100,000 people per year. When scientific evidence is available, it will be used in the evaluation of these conditions. In some cases, it is unlikely that there will ever be sufficiently well-designed epidemiologic studies of different cohorts for VA to evaluate and make a determination using the general standards of the presumptive model alone. In these cases, there need to be additional standards or an alternate process to evaluate the available evidence regarding such rare conditions. Beyond rarity of the

condition, VA developed guiding principles that will be incorporated as part of the evaluation process and include, but not be limited to, the catastrophic nature of the disease and biological plausibility. VA also adapted and will utilize the nine principles of the Bradford Hill Criteria to further evaluate these rare conditions. The Bradford Hill Criteria have been used widely in public health research to evaluate the strength of an association between a presumed exposure and an observed effect. VA will also examine VHA health outcomes clinical data and VBA claims data for trends that may signal an association between the target condition and environmental exposure of interest. Cancer, in particular, may have its onset long after military service, is often a challenging illness, and prognosis may depend on quick identification and treatment at early stages to achieve the best outcomes. These guiding principles ensure that benefits are not denied simply due to the rarity of a condition.

7. STANDARDIZED EVALUATION OF THE SCIENCE

a. **PECOTS Framework:** The scientific review panels will employ a consensus-based evaluation process that incorporates and adapts the PICOTS (Patient, Intervention, Comparator, Outcomes, Timing, Setting) Framework to define the strength of the evidence base. Though originally designed for clinical trials, the PICOTS framework is commonly modified in exposure science literature to PECOTS whereby 'E' refers to exposure of interest (See PECOTS Schematic.) Though full consensus regarding presumptive status is the objective, an 80% majority with notation of disagreement is the benchmark for presumptive status recommendations that will be sent to the Secretary for final decision-making. Dissenting views will be included in the recommendations.

PECOTS SCHEMATIC

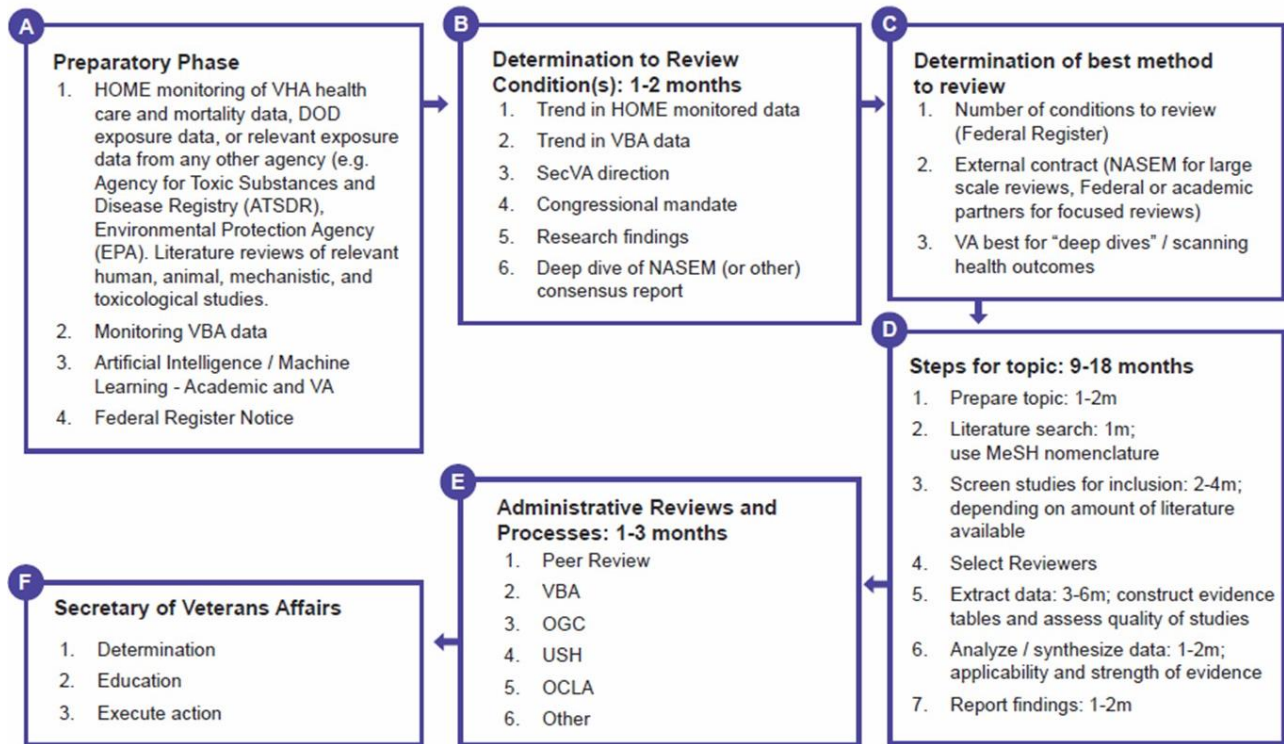


b. Extraction of key data elements from evidence sources to facilitate evaluation:

Relevant information from each source of evidence (e.g., published literature, claims data) will be abstracted using a standardized review process which will facilitate expediting the evaluation. This can be performed in parallel with the PECOTS framework to streamline review. For example, a template can be provided for data extractors to identify key data elements (e.g., number of patients, type of exposure, exposure duration, etc.) to facilitate evaluation by subject matter experts (SME). Future efforts may consider artificial intelligence strategies to further expedite this process and perform quality assurance activities.

c. **Determination of Levels of Evidence:** A semi-quantitative approach to evaluate the quality of evidence be employed based on the “Grading of Recommendations Assessment, Development and Evaluation (GRADE)” structure. The GRADE structure allows SMEs to assign certainty ratings to the strength of evidence. Importantly, it considers factors that diminish (e.g., bias, imprecision) and enhance (e.g., large effect, dose-response) the overall quality of evidence.

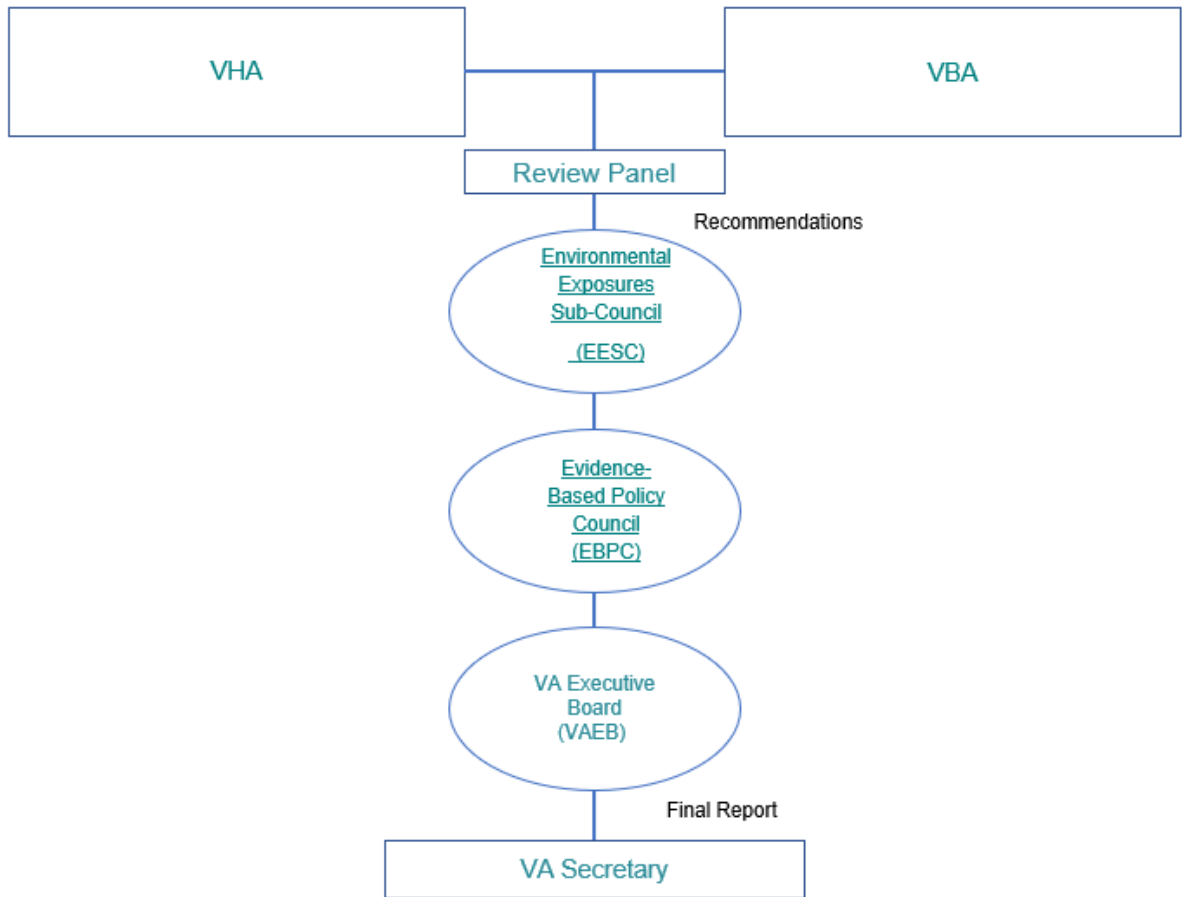
Presumptive Decision Process Flow



8. GOVERNANCE PROCESS FOR FINAL PRESUMPTIVE DECISIONS

Once the review panel completes its work, it will draft a report summarizing its findings and conclusions as to the strength of the evidence and whether an association exists between a medical condition and an environmental exposure. If the panel concludes an association exists or does not exist, the panel will submit its recommendations, for or against, in the form of a written report to the Environmental Exposures Sub-Council Charter (EESC). Once concerns and questions are addressed and the EESC concurs, the report will be presented to the Evidence-Based Policy Council for additional concurrence, and then to VA Executive Board for approval of the recommendation. The report is then submitted to the Secretary for final approval (Governance Schematic).

Governance Schematic



VA IMPLEMENTATION OF THE NATIONAL ACADEMIES OF SCIENCES, ENGINEERING, AND MEDICINE'S RECOMMENDATIONS

This appendix provides a checklist that analysts, managers, and leaders may use to verify that all elements of the directive are being addressed by the scientific review being undertaken. The checklist aims to implement the four recommendations made by the National Academies of Sciences, Engineering, and Medicine (NASEM) in the 2023 evaluation of the Department of Veterans Affairs (VA)'s Presumptive Decision Process (PDP). VA has accepted and addressed all of NASEM's recommendations, as identified below.

1. 2023 NATIONAL ACADEMIES OF SCIENCES, ENGINEERING, AND MEDICINE RECOMMENDATIONS

a. **Recommendation 3-1:** "The committee recommends that VA make explicit the operational criteria or guiding principles for each of the governance steps and include a description of the expertise and the entities represented at each step. To the extent possible, these criteria or principles and descriptions should be made publicly available either in the presumption decision process document or by reference to other documentation."

b. **Recommendation 3-2:** "The committee recommends that once several condition-specific review panels use the PDP, it be reviewed periodically (by an entity internal or external to VA with the appropriate expertise) to assess whether scientifically based, fair, consistent, transparent, timely, and veteran-centric decisions have been made and whether any modifications to improve the process are necessary."

c. **Recommendation 4-1:** "The committee recommends that VA's PDP contain sufficient detail to define how it will operationalize each step of the scientific process, either in the presumption decision process document or by reference to other documentation, beginning with condition identification and selection, through application of a standard on the likelihood of a positive association."

d. **Recommendation 4-2:** "The committee recommends that VA model its scientific evaluation of the environmental health evidence using existing standardized and structured approaches. Such a standardized evaluation process should include the following:

- (1) A formal problem assessment and study planning phase.
- (2) Development of a protocol that addresses the structured research question (e.g., Patient, Exposure of Interest, Comparator, Outcomes, Timing, Setting (PECOTS)) and includes a detailed literature search strategy and inclusion/exclusion criteria.
- (3) A report that presents the systematic identification and selection of evidence, critical appraisal of the validity and reliability of studies, synthesis, and integration of a

body of evidence, and a structured approach to determining conclusions (levels of evidence) about the scientific evidence.”

2. CHECKLIST FOR VA IMPLEMENTATION OF THE NATIONAL ACADEMIES OF SCIENCES, ENGINEERING, AND MEDICINE’S RECOMMENDATIONS

a. A brief rationale for the conditions to be studied that includes at least one source of suggestive data. This can include a formal problem assessment or any other relevant information (e.g., VA data, Federal Register Notice).

b. An Executive Decision Memorandum (EDM) that includes a recommendation to conduct a scientific review sent through VA’s governance process is recommended.

c. A full composition of the scientific review panel that includes at least one representative of an agency besides VA (refer to Appendix A, paragraph 4) and a paragraph on how and why the team members were selected (including a rationale for the co-chairs).

d. A Detailed Plan of Action and Milestones (POAM) that provides an overview and justification; review of goals and objectives; and identifies an executive sponsor, project manager, milestones, deliverables, timeline, risks, and mitigations.

e. An approach to conducting the review and rationale for which components will or will not be used (e.g., health care data, literature review, Veterans Benefits Administration (VBA) claims data). (Refer to Appendix A, paragraph 6).

f. A list of search terms, keywords, approaches, and sources for searching for scientific articles based on the Patient, Exposure of Interest, Comparator, Outcomes, Timing, Setting (PECOTS) parameters.

g. Identify which standardized frameworks, tools, and approaches must be used in the review (e.g., PECOTS, Grading of Recommendations Assessment, Development and Evaluation (GRADE), National Toxicology Program, Office of Health Assessment and Translation (NTP-OHAT)). Describe how they must be used and in which component of the review.

h. If needed, an approach and tool to screen literature for analysis to determine whether an association exists between an environmental exposure and a disease or illness.

i. Identify the method used to determine a positive association if one exists.

j. An approach and tool to calculate whether the strength of the evidence is at or above equipoise by implementing GRADE (i.e., assessing certainty and quality, and downgrade and upgrade factors).

k. Final report and the EDM draft will be submitted to the Military Environmental Exposure Sub-Council (MEESC) for discussion, feedback, and approval, to then submit to the Evidence-Based Policy Council (EBPC).

l. Submission of the final report and recommendation must follow VA's governance process:

(1) The MEESC voting members must decide whether the report and recommendation should be submitted to the EBPC.

(2) The EBPC must decide on submission to the VA Operations Board (VAOB).

(3) VAOB must submit the final report to the Secretary of Veterans Affairs through the VA Executive Board.

m. The final report and EDM with recommendations must be submitted to the Secretary of Veterans Affairs for signature through VA's governance process.