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Review of the Department of Veterans Affairs Presumption Decision Process

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Committee to Review the Department of Veterans Affairs Presumption Decision Process

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Origin of Study

- Sergeant First Class Heath Robinson Honoring Our Promise to Address Comprehensive Toxics Act of 2022 (PACT Act; Public Law 117-168) Section 202 §1176
 - Directed the National Academies to review VA's presumption decision process (PDP)
 - Review and assessment to include the governance process and scientific factors
 - The PDP is used by VA to identify medical conditions to evaluate for an association with an environmental exposure encountered during military service
- §1171, §1172, §1173, §1174 of the PACT Act specify components of or processes related to the presumption decision process

Statement of Task

An ad hoc committee under the auspices of the National Academies of Sciences, Engineering, and Medicine will conduct an assessment of the revised administrative process to be used by the Department of Veterans Affairs to evaluate medical conditions and possible relationships to military environmental exposures. The review of the revised Presumption Decision Process will examine

1. whether the process is in accordance with current scientific standards for assessing the link between exposure to environmental hazards and the development of health outcomes, and
2. assess whether the elements of the process are fair and consistent.

The committee shall produce a final report detailing its process and offer any findings, conclusions, and recommendations it deems appropriate to improve the process.

The Committee Did Not

- Design, redesign, or develop a new framework for the PDP
- Apply the proposed process to an example condition as a case study or vignette
- Use or apply the process to readjudicate any existing presumption decisions
- Perform a comprehensive assessment of the scientific evidence regarding any associations between exposures that may have been encountered during military service and medical conditions, nor would it draw conclusions regarding the strength of evidence for any associations
- Assess the extent to which the recommendations in the 2008 NASEM report were accepted or implemented by VA

The use of the PDP to make a presumption of exposure (not specifying a medical condition) is outside the committee's charge.

Defining Presumption

- For some medical conditions, the scientific information needed to connect a veteran's service or a particular military exposure with them may be impossible to obtain, not exist, or be incomplete; when this occurs, Congress or VA may make a “presumption” of service connection
- Two types of presumptive disability connections: service and exposure.
 - Presumption of service connection, where a certain condition is considered to have been incurred during or aggravated by service if it manifests within the time frame specified for that condition under regulation or statute, even with no evidence of such condition during service.
 - Presumption of exposure, when a veteran is presumed to have been exposed based on service at a particular location and during a specific period, as stipulated in regulation or statute.
- If a veteran is a member of a specific group, defined by dates and locations of service and has a diagnosed disability that has been determined to be service connected, then the veteran may be entitled to compensation and associated medical care without having to prove that the disability was the result of their military service; that is, the veteran no longer has the burden of proof.

Desired Characteristics

Fairness: A process that is free from prejudice to the greatest extent possible, designed to be fair to veterans across all eras and cohorts, and considers the same types of information and applies the same threshold for granting a presumption for all eligible veterans.

Consistency: The elements of the process are applied consistently and reproducibly for veterans of all eras and cohorts.

Transparency: Allows veterans and the general population to have visibility into it and trust that the process is conducted without bias and in a manner supporting other goals, such as fairness and consistency.

Timeliness: Does not unnecessarily lengthen or delay any step in the process or the time between evidence evaluation and a presumption recommendation decision.

Veteran Centric: Guiding principle of reaching presumption decisions that favor veterans when the available information regarding an association between an exposure and the medical condition of interest is equivocal.

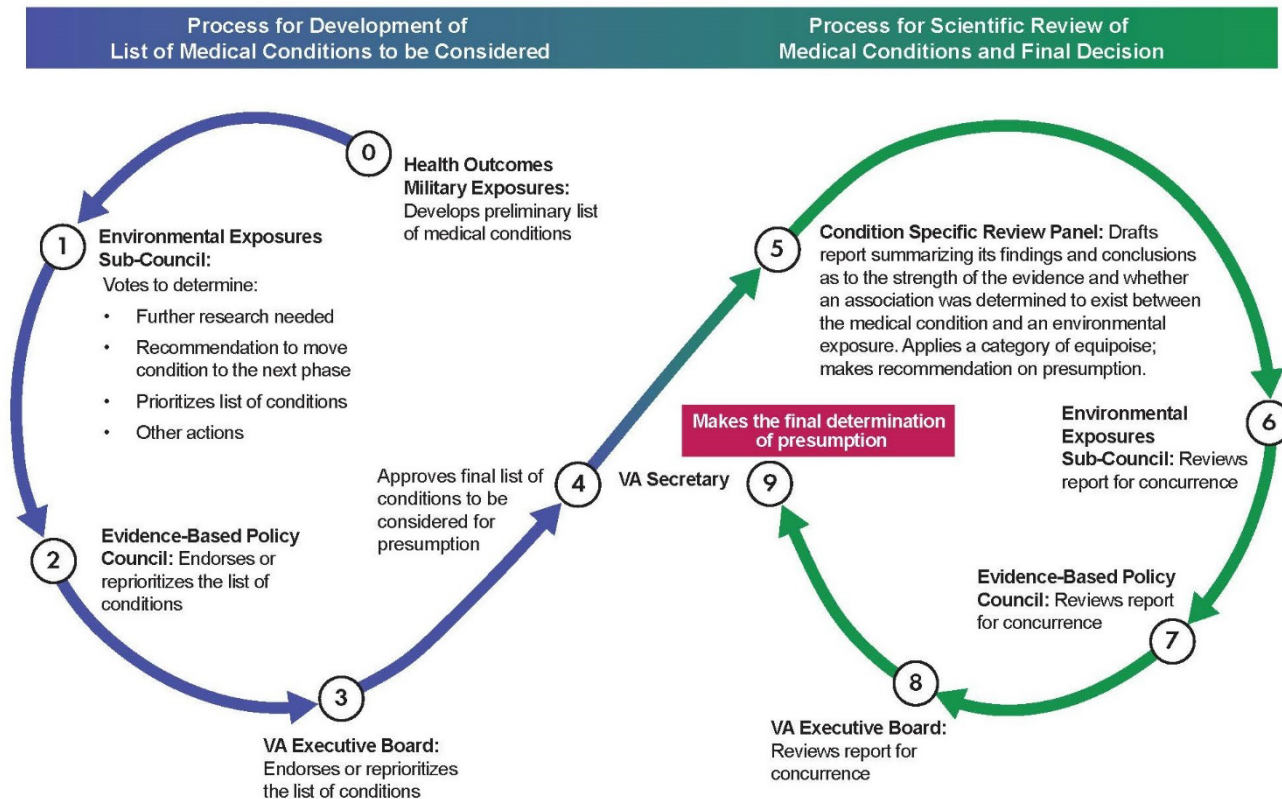
Positive Association

- The term “positive association” is used in the PACT Act Section 202 §1173, which describes elements of the process.
- The committee chose to adopt the term “positive association” (rather than “equipoise”), which it uses to mean that the medical condition is caused by the exposure in at least some members of the population.
- The condition may also occur in unexposed individuals so that a positive association may not definitively demonstrate that the condition was caused by the exposure in any particular individual.
- Not based solely on assessment of causation.
- The PDP seeks to determine whether a positive association exists between an exposure and a medical condition of interest.

Governance

- Described in sections 3, 4, and 8 of the PDP document (see Annex to Chapter 1)
- VA Office of Enterprise and Integration provides the overarching governance for the entire PDP
- Two groups of panels and councils have a role in PDP governance:
 - those that directly perform or are involved in the scientific-based reviews leading to a decision to consider and then recommend a condition for presumption or not (Environmental Exposures Sub-Council, a condition-specific review panel, and the Evidence-Based Policy Council).
 - entities that are focused on the nonscience (policy, political, and finance) aspects (Evidence-Based Policy Council, VA Executive Board, and VA Secretary).
- VA stated that the presumption decision process is specifically the process that prepares recommendations for the VA Secretary on presumptions, and it starts when analysis of the evidence for a medical condition is complete and a presumption recommendation is submitted to the governance process for review.

Committee's Understanding of the PDP Process



Selected Findings on the PDP Governance Process

- In general, the governance process used to approve the list of conditions and a condition-specific report and presumption recommendation is reasonable and logical.
- Leveraging a variety of data and evidence sources to inform the selection of conditions is appropriate. Specifying how each data source is used and weighted and the criteria for selection of conditions as well as making this information publicly available will enhance transparency.
- Using the Federal Register to seek input from veterans and other stakeholders is appropriate. However, the PDP document does not specify how VA might use any public comment to inform the final list of conditions for evaluation.
- Without standard criteria, there may be potential inconsistencies among condition-specific review panels regarding depth of review, adequacy of needed panel expertise, use of evidence evaluation standards, or the basis of reasoning for recommendations regarding presumption status.

Conclusions on the PDP Governance Process

- Making public the process and criteria used for selecting conditions to evaluate for presumption status will further the goals of transparency, fairness, consistency, and make the process more veteran centric.
- The composition of each condition-specific review panel needs to ensure that there is sufficient subject matter expertise including core methodologic expertise in the systematic review of environmental health, and that there is a mechanism to obtain the perspective of the affected community.
- The PDP document provides insufficient detail on the governance process for both the review and approval of the list of conditions to be considered for presumption and the review of a condition-specific presumption report.
- There is a lack of detail, specificity, and criteria for how conditions are identified, selected, and prioritized for addition to the list of medical conditions for consideration for presumptive status and for how condition-specific evidence is to be identified, extracted, analyzed, synthesized, and integrated to determine the strength of evidence.
- Although not all decision-making attributes can be made public, a high-level distillation of the process and the entities and criteria for presumptions decisions could be made publicly available, regardless of whether the decision is for or against a presumption.

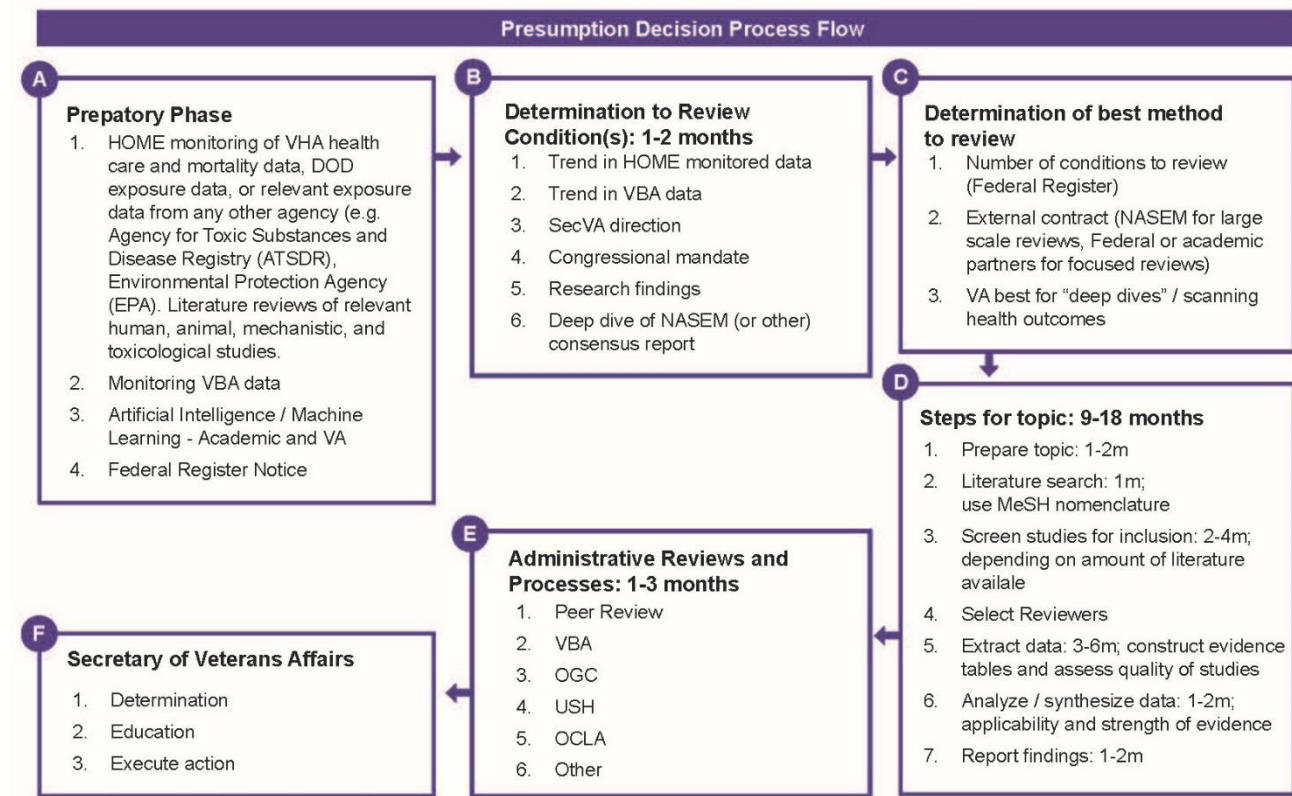
Recommendations for the PDP Governance Process

- 3-1: The committee recommends that VA make explicit the operational criteria or guiding principles for each of the governance steps and provide 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.
- 3-2: The committee recommends that, once the presumption decision process has been used by several condition-specific review panels, 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.

Scientific Aspects of the PDP

- The scientific approach for the selection and review of a condition is presented in sections 3, 5, 6, and 7 of the PDP document.
- The PDP document flow diagram shows six discrete steps, including data collection, evaluation, and synthesis.
- The overall scientific approach begins with a planning and preparatory phase that includes section of conditions and determination of review type, followed by the conduct of a standardized evaluation.
- The PDP document indicates that a PECOTS framework and GRADE methodology will be used to conduct the standardized evaluation resulting in a determination of the likelihood of a positive association (equipoise).

PDP Flow Diagram



Best Practice Steps for an Environmental Health Assessment

- Problem formulation
- Protocol development
 - Determine search strategy
 - Identify most appropriate type of review (systematic, rapid, scoping)
- Evidence identification and selection
 - Literature review
 - Identify other evidence sources (e.g., health care data, VBA claims data, other factors [deployment, rarity of conditions], rare conditions)
- Individual study assessment
- Synthesis evidence and rate confidence in body of evidence
- Translate confidence or strength of the evidence to level of evidence of health effects
- Integrate evidence to develop conclusion about link between exposure and health effects

PECOTS (population, exposure, comparison, outcome, timing, and setting)

- PECOTS defines the scope of the research question and guides the development of the protocol for all steps in the review process, including the methodology for conducting the evidence review and selection of evidence types (human, animal, mechanistic).
- VA's use of PECOTS, and the corresponding figures and content of the PDP document, are not consistent with the standard use of this term and PECOTS is not generally recognized as a consensus-based evaluation process as stated by VA.
- However, VA used the PECOTS framework and description appropriately in its rule for "Presumptive Service Connection for Respiratory Conditions Due to Exposure to Particulate Matter".
- The VA PECOTS schematic broadly demonstrates how various sources of evidence may be used to determine a level of evidence, but it does not show how a PECOTS research question is applied to support a determination of "equipoise."

GRADE (grading of recommendations, assessment, development, and evaluation)

- The VA PDP document indicates that VA uses a “semi-quantitative approach” to evaluate the quality of evidence and come to a determination of the levels of evidence based on the GRADE structure. GRADE is a tool used to grade the quality or certainty of evidence.
- Applying GRADE to environmental and occupational health questions is a relatively new concept and practice and it may need to be modified to address various types of evidence.
- Several organizations have developed approaches to incorporate the findings of a body of evidence and confidence in it as part of developing conclusions, for example, NTP uses a modified GRADE approach.
- The committee notes that the use of a structured process to assess confidence in the body of evidence need not be limited to the GRADE method, as GRADE may not fully address aspects important to VA for environmental health assessments, e.g., use of claims data.
- PECOTS, GRADE, and other such tools are not algorithmic and their use does not result in a determination of equipoise.

Equipoise

PACT Act (and PDP document) has four standards for the strength of the evidence:

1. **Sufficient:** the evidence is sufficient to conclude that an association exists.
 2. **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.
 3. **Below Equipoise:** the evidence is not sufficient to conclude that an association is at least as likely as not or is not sufficient to make a scientifically informed judgment.
 4. **Against:** the evidence suggests the lack of an association.
- VA presumption decision process uses “equipoise” to denote a threshold for a presumption in which the probability of a positive association is judged to be as equally likely as not, equivalent to a probability of exactly 50%.
 - The standards for “equipoise” only refer to the probability of an association; the assignment of an equipoise standard or category is much more nuanced and semi-subjective.
 - There is a lack of information on how the “standard” for an association (that is, as likely as not) is to be operationalized and applied to produce a presumption recommendation for a condition.
 - The term “equipoise” denotes a lack of consensus across the medical community and the term, as required by law to be used in the presumption decision process, is inconsistent with current scientific use.

Selected Findings on Scientific Aspects

- The committee is unable to judge whether the pre-decisional VA PDP document and the activities in individual steps in the process align with scientific best practices. Moreover, it is not able to comment on the fairness or consistency of the process primarily due to the lack of detail on how the process will be operationalized, and the lack of specifics for each step in the process, such as the lack of criteria on how the evidence will be extracted and reviewed and individual studies will be appraised for validity and reliability.
- The standardized assessment process that VA has described in its PDP document does not identify or describe general methods, processes, or tools for identifying and selecting the evidence for a condition.
- In general, the flow diagram in the VA PDP document is logical, beginning with a planning and preparatory phase, determination of conditions to review, and determination of methods for the review, followed by a scientific review by VA or an external entity. However, there is an inconsistent correspondence between the four sections (sections 3, 5, 6, and 7) in the VA PDP document that pertain to scientific aspects of the process and in the steps in the flow diagram.

Selected Findings, continued

- Given the variety of conditions to be evaluated and the differences in the amount, type, and quality of the evidence to be reviewed for any condition, the scientific evaluation process will need to be flexible to address the research question that is formulated using PECOTS.
- The PDP document has insufficient information to determine what VHA and VBA data will be used and how they will be obtained and evaluated. The committee also finds no description of how this information will be incorporated into the presumption decision process for condition list generation or condition-specific reviews.
- The document has a brief mention of future use of “machine learning algorithms and text-mining tools for continuous review of scientific literature.” As the use of such tools is speculative, the committee finds that including this information is not helpful and distracts from the assessment of what is currently being done to identify and retrieve relevant scientific literature.

Conclusions on Scientific Aspects

- There are insufficient details in the PDP document regarding condition identification, prioritization, and selection, for either the list of medical conditions to be considered for presumption or for condition-specific evaluation, to assess how these steps would be conducted.
- The PECOTS terminology, the PECOTS schematic (including its content, order, and organization), and the accompanying text in the PDP document are not consistent with scientific best practices.
- Leveraging existing reviews (e.g., systematic reviews, NASEM reports) could obviate the need to start from scratch in identifying the available scientific literature for a condition, although the reviews may need to be updated.
- The overall usefulness of the PDP document could be improved by enhancing the existing description of the evaluation process, including details on how each step will be operationalized, providing a logical one-to-one correspondence between the text and the flow diagram, and incorporating scientific best practices, by either including additional details in the document itself or by referencing other documentation.

Recommendations for Scientific Aspects

- 4-1: The committee recommends that VA's presumption decision process 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.
- 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 a formal problem assessment and study planning phase; development of a protocol that addresses the structured research question (e.g., PECOTS) and includes a detailed literature search strategy and inclusion/exclusion criteria; and 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.
- 4-3: The committee recommends that VA use existing frameworks, tools, and approaches designed for environmental health assessments (e.g., NTP-OHAT; WHO Framework on the use of systematic review in chemical risk assessment) and apply or adapt them in a manner that aligns with scientific best practices.

Overarching Themes

- The PDP is not specific to any one era or cohort of veterans and must be able to accommodate of a broad range of environmental exposures and medical conditions, including mental health conditions.
- The process must be feasible, flexible, and have the appropriate elements to fulfill its purpose and the document must balance a need for brevity with sufficient information to explain and implement it.
- The committee identified several overarching concerns with the document: the lack of description so that the committee was unable to judge if scientific best practices are used; weak logical flow; and lack of details, criteria, or standards.

Use of Scientific Best Practices

- On the whole, many of the elements necessary for the PDP to be scientifically based, fair, consistent, transparent, timely, and veteran centric are identified in the document. However, the elements are not presented in the order in which they would be conducted, and there are insufficient details on how they would be operationalized for the committee to determine whether they are in accordance with scientific best practices.
- Given the variation in the amount, types, and quality of the available information, guidance that addresses data selection, quality, bias, validity, and reliability and how they might be analyzed and synthesized to reach a presumption recommendation may be more practical and would permit the process to be more flexible, adaptable, and scientifically justified.
- Scientific best practices do not require rigid rules or absolute criteria for assessing the evidence of a condition.

Logical Flow

- The presumption decision process document lacks internal consistency.
- The governance and scientific aspects of the process are labeled as distinct sections but are intertwined throughout the document and presented inconsistently and with an unclear flow, which may lead to misperceptions and misunderstandings. Sentences related to governance functions or decision making are embedded in the scientific sections.
- The mixing of governance and scientific processes also has implications for nonconformance with scientific standards or best practices. For example, the process as presented in the PDP document does not follow a logical progression from developing the research question (PECOTS) to determining the likelihood of a positive association (equipoise).
- There is not a one-to-one correspondence between the document sections that pertain to the governance or scientific aspects of the process and the flow diagram. The section order and content narrative in the PDP document do not provide sufficient detail to understand the activities in each box of the flow diagram or the items within a box—specifically, how the items are defined or operationalized.

Details, Criteria, and Standards

- The lack of detail is a pervasive problem in the entire PDP document, from the planning and preparatory phase (identifying, prioritizing, and selecting conditions for evaluation) to the approval process for a recommendation of a condition for presumption, and is of concern for both the scientific and governance processes.
- The lack of information on how the governance steps are implemented and the decision-making criteria or standards at each step does not ensure a process that is high quality, scientifically sound, fair, and consistent and does not promote stakeholder understanding, particularly by those veterans and their families who may be affected by a presumption decision.
- VA published a 24-page explanation of its most recent presumption decision in the Federal Register (2021) that included the sources of evidence used and what each contributed. The description also included the PECOTS parameters used, types of studies considered (human and nonhuman), and use of GRADE framework with accompanying scoring matrix. Providing such detailed rationale for each presumption decision, whether that decision is positive or negative, is important and should be continued.
- The committee finds that the presumption decision process is not inherently flawed; rather, the incomplete and opaque documentation of it makes it difficult to ascertain whether the process is fair, consistent, timely, and veteran centric.

Final Observations

- Those responsible for drafting the PDP document assembled many well-recognized and commonly used tools that support evidence synthesis and evidence-based decision making throughout the environmental health field.
- The committee concludes that a final PDP document that separates scientific and governance aspects to the extent possible, presents each step in sequential order, and provides a sufficient level of detail (for example, membership and criteria or standards used for decision making by each governance council or board, or how data sources will be used and weighted for scientific evaluation) would help to clarify decision factors and decision points along the process, leading to a more understandable, consistent, and cohesive process.
- The committee believes that by reviewing and implementing its recommendations, VA will meet its objective of creating a presumption decision process that supports scientifically based, fair, consistent, transparent, timely, and veteran-centric decisions and puts the needs of our nation's veterans first.

For more information

Online information on the study may be found at <https://www.nationalacademies.org/our-work/review-of-the-department-of-veterans-affairs-presumption-decision-process>

The report may be read online and downloaded in digital form (at no cost) at nap.edu/catalog/27166

