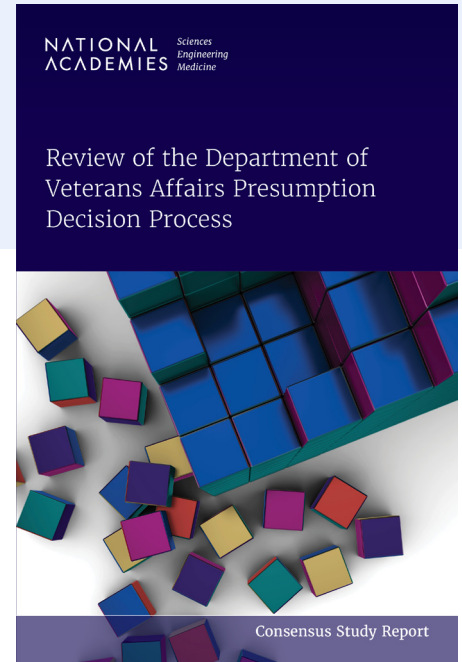


Review of the Department of Veterans Affairs Presumption Decision Process

OVERVIEW

Environmental exposures during military service may result in or exacerbate a physical or mental injury or illness (termed “disability” in statute). In some situations, the scientific information needed to connect a veteran’s service or a particular military exposure with their diagnosed condition may be impossible to obtain, not exist, or be incomplete. When this occurs, Congress or the Department of Veterans Affairs (VA) may make a “presumption” of service connection for veterans. Presumption of a diagnosed medical condition is defined by dates and locations of service or is based on a specific exposure and allows for veterans to be eligible to receive health care and benefits without having to prove that their disability or medical condition was the result of their military service. In 2022 alone, VA disbursed an estimated \$120.7 billion in benefits for service-connected disabilities to 5.9 million veterans.

The PACT Act of 2022 (PL 117-168) and VA initiatives led VA to revise its presumption decision process to ensure it was more scientifically based, fair, consistent, transparent, timely, and veteran centric. The revised process was described in VA’s eight-page pre-decisional document. The PACT Act also called for a National Academies committee to assess the VA presumption decision process pre-decisional document, which outlines (1) the revised process to identify medical conditions to evaluate for an association with an environmental exposure encountered during military service for presumption status; (2) the scientific factors that such an evaluation entails; and (3) the governance process for the review and approval of a presumption recommendation for a medical condition. The resulting National Academies’ consensus study report *Review of the Department of Veterans Affairs Presumption Decision Process* contains the committee’s findings, conclusions, and recommendations around



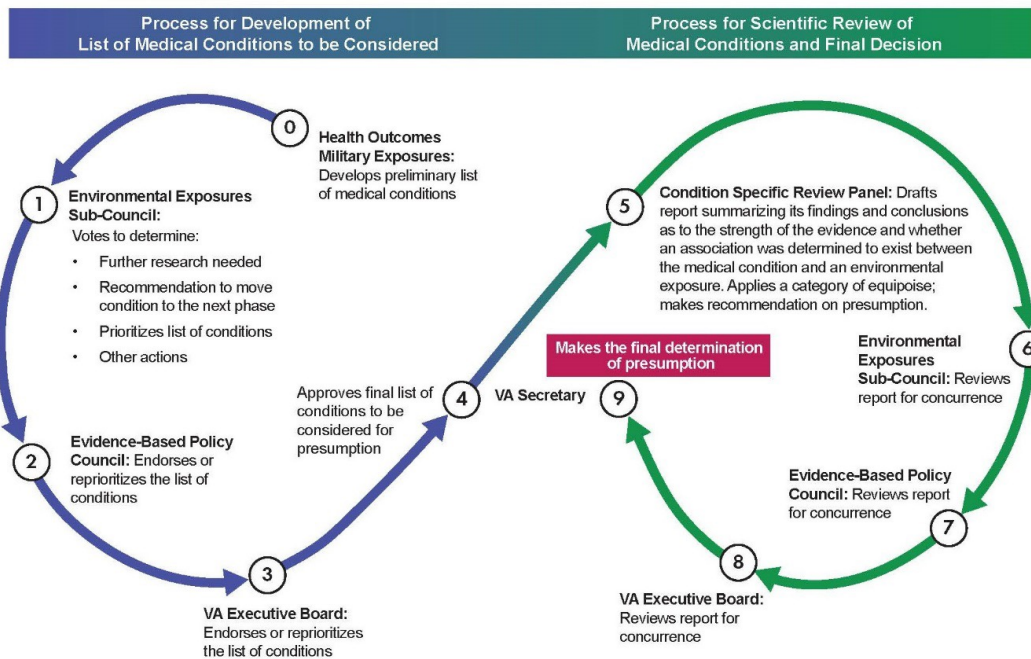


FIGURE 1 Committee’s understanding of the governance process for presumption decisions.

two major aspects of VA’s presumption decision process: the governance process and the evaluation of scientific evidence for a particular condition.

GOVERNANCE ASSESSMENT

The committee found that the governance process used to review and approve the list of conditions considered for presumption, and subsequently a condition-specific report with a presumption recommendation (see Figure 1), is reasonable and logical. However, the overarching governance for the entire process is not clearly described in the document, with no information on the criteria or other considerations used by the boards and councils to review and approve the list of conditions or the condition-specific reports. There is also little information on the expertise that will be included on the various panels, councils, and boards. These omissions could result in inconsistencies among panels with regard to the depth of review, adequacy of needed panel expertise, application of evidence evaluation standards, or decisions on a presumption recommendation. The committee concluded that although not all decision-making attributes can be made public, a high-level distillation of process, entities, and criteria for both positive and negative presumption decisions could be made publicly available. **Consequently, 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 (Recommendation 3-1).

The committee also 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 (Recommendation 3-2).

SCIENTIFIC ASPECTS ASSESSMENT

The committee found that VA’s presumption decision process document lacks sufficient details on the components, criteria, and methods related to the evidence evaluation process to assess how specific steps in that process (see Figure 2) would be conducted. Additionally, the committee noted that VA provides only cursory explanations for the types of data that may be reviewed

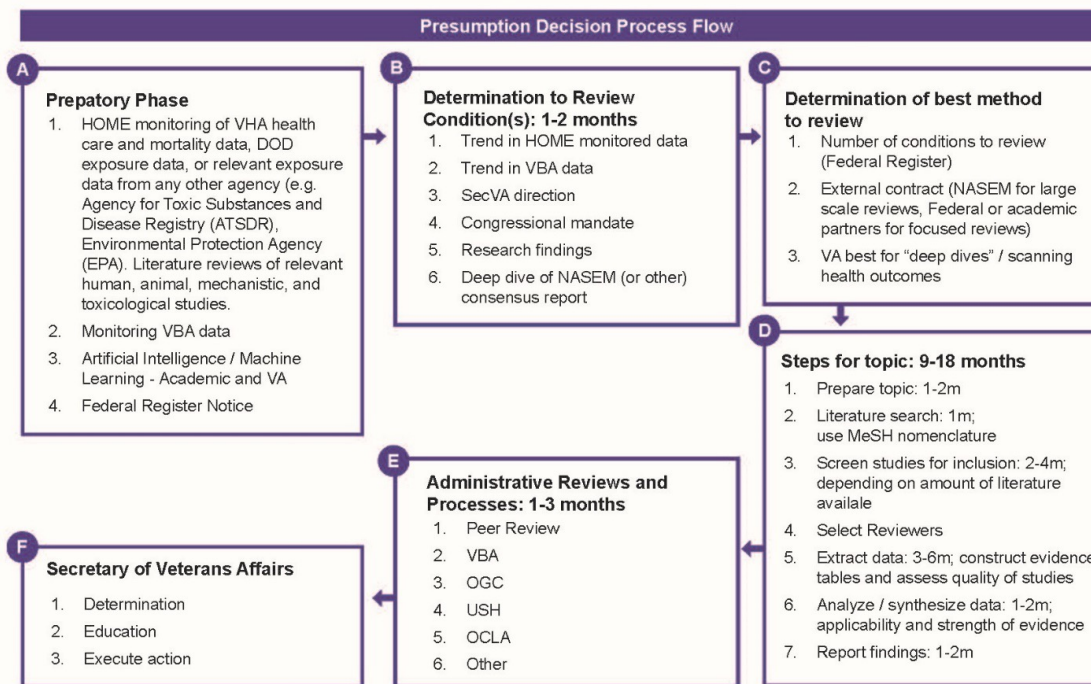


FIGURE 2 Presumption decision process flow diagram that shows the steps and time frames of the process.

and no information on how to assess the quality, validity, or reliability of the various data sources or on how they will be obtained and screened for inclusion or exclusion. VA also does not define the decision-making criteria for evidence synthesis to determine the strength of association between an exposure and a medical condition, or the evidence-to-decision process. Some scientific concepts, including the patient, exposure, comparator, outcomes, timing, and setting (PECOTS) framework; grading of recommendations, assessment, development, and evaluation (GRADE); and equipoise, are applied to the presumption decision process in ways that are inconsistent with best practices by other organizations that use these concepts for environmental health assessments.

Thus, 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 evidence review, to the application of a standard on the likelihood of a positive association (Recommendation 4-1).

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 (Recommendation 4-2).

Finally, the committee recommends that VA use existing frameworks, tools, and approaches designed for environmental health assessments (e.g., National Toxicology Program Office of Health Assessment and Translation Approach for Systematic Review and Evidence Integration; World Health Organization 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 (Recommendation 4-3).

OVERARCHING THEMES OF BOTH GOVERNANCE AND SCIENTIFIC ASPECTS

The committee identified several areas with substantial problems while evaluating both the governance and the scientific aspects of the presumption decision process:

- The use of scientific best practices—Many of the elements necessary for the presumption decision process to be scientifically based, fair, consistent, transparent, timely, and veteran centric are identified in the document. However, the descriptions of these elements are inadequate. Specific components and methods need to be logically organized and described in a manner that is consistent with best practices.
- Logical flow—Internal consistency is lacking. A natural progression from developing the research question to determining a positive association is not presented. Moreover, sections that cover aspects of governance and scientific evidence review are not grouped together. Additional content related to governance functions or decision making is embedded in the scientific sections. This lack of logical flow has implications for nonconformance with scientific best practices and may lead to misperceptions and misunderstandings.

- Details, criteria, and standards—A lack of detail in the entire presumption decision process document and supplemental documentation VA provided to the committee makes it difficult to judge scientific appropriateness and determine whether elements of the process are fair, consistent, and veteran centric.

MOVING FORWARD

To ensure that the presumption decision process serves its intended purpose, decisions made using it must be scientifically sound, with clear acknowledgment of the many challenges, assumptions, and uncertainties that are inherent in the scientific evidence base and the scientific review and governance processes that go into the decision regarding a condition-specific recommendation for or against presumption. To promote understanding by veterans and other stakeholders, it is vital to make the rationales and justifications for decisions and the criteria and methods used to make them publicly available. Additionally, the presumption decision process should be periodically evaluated and updated to ensure it uses current scientific best practices.

The recommendations within *Review of the Department of Veterans Affairs Presumption Decision Process* will bolster VA's efforts to make decisions that put the needs of the nation's veterans first.

COMMITTEE TO REVIEW THE DEPARTMENT OF VETERANS AFFAIRS PRESUMPTION DECISION PROCESS **Bruce N. Calonge** (Chair), University of Colorado School of Medicine; **Lawrence Deyton**, The George Washington University School of Medicine and Health Sciences; **Javier I. Escobar**, Rutgers University; **James Giordano**, Georgetown University Medical Center; **Francine Laden**, Harvard T.H. Chan School of Public Health; **Juleen Lam**, California State University East Bay; **Roger Lewis**, Los Angeles County Department of Health Services, David Geffen School of Medicine at UCLA, Berry Consultants LLC; **Jennifer S. Lin**, Kaiser Permanente Evidence Based Practice Center, Kaiser Permanente Northwest Center for Health Research; **Lorenz Rhomberg**, Gradient; **Daniele Wikoff**, ToxStrategies, Inc.

STUDY STAFF **Anne N. Styka**, Study Director; **Roberta Wedge**, Senior Program Officer; **Alexandra McKay**, Research Associate; **Nerissa Hart**, Senior Program Assistant (through May 2023); **Rose Marie Martinez**, Senior Director, Board on Population Health and Public Health Practice

FOR MORE INFORMATION

This Consensus Study Report Highlights was prepared by National Academies' staff based on the Consensus Study Report *Review of the Department of Veterans Affairs Presumption Decision Process* (2023).

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Health and Medicine Division

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