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Pentagon

Response to STAC Recommendations on the P&P for Adding Non-Cancer Health Conditions to the List of WTC-Related Health Conditions

**World Trade Center (WTC) Health Program
Meeting of the Scientific/Technical Advisory Committee (STAC)
June 22, 2023**

Summary of revisions to the *Policy and Procedures for Adding Non-Cancer Health Conditions to the List of WTC-Related Health Conditions*

- Administrator's response to the four STAC recommendations received February 17, 2023
- Clarify application of Bradford Hill criteria in Section IV.A.1.

STAC Recommendation 1:

In the Policy & Procedure for adding non-cancer conditions, with respect to the consideration of health conditions for which a high or limited likelihood of causal association is being assessed, the Science Team [should] consider studies that go beyond peer-reviewed and published epidemiologic studies of 9/11-exposed populations and US Government authoritative scientific publications, to the extent feasible. This is to include peer-reviewed clinical, mechanistic, toxicologic, biomedical, and mental health literature that are relevant to the 9/11 exposures.

Response:

The discretionary secondary evaluation procedures outlined in Section V.B.1.a of *High Likelihood* were revised to allow the Science Team to supplement its review of U.S. government sources with additional highly-relevant, peer-reviewed, published scientific information.

The expanded literature review was not extended to *Limited Likelihood*.

STAC Recommendation 2:

In IV.B.1.a. [the STAC recommends] revis[ing] the highlighted phrase in the first sentence from “Substantial likelihood of causal association means that “the scientific evidence demonstrates that a causal association exists” to “the association is strongly supported by peer-reviewed evidence in 9/11-exposed populations” [sic] and there is high confidence that the association cannot be explained by chance, bias, confounding, or any other alternative explanation.”

Response:

The sentence was revised as recommended.

STAC Recommendation 3:

The Committee recommends that the Program develop and add to the Policy and Procedures a table [flowchart] that clearly delineates the categories that will be used at various stages of the review process.

Response:

The Administrator is developing a flowchart as a job aid and communications tool separate from the *Policy and Procedures* document.

A table or flowchart was not formally added to the *Policy and Procedures* because neither instrument could fully capture all requirements documented in the text, which could lead to misinterpreting requirements.

STAC Recommendation 4:

The Committee endorses the use of five weight-of-evidence categories and recommends that these five mutually exclusive categories be maintained in all sections of the Policy and Procedures, as appropriate.

Response:

The P&P was revised to clarify and maintain the five mutually exclusive categories. These categories are: (1) substantial likelihood of causal association, (2) high likelihood of causal association, (3) limited likelihood of causal association, (4) no likelihood of causal association, and (5) inadequate evidence to determine the likelihood of causal association (see Section IV A.).

Additional Clarification: The use of Bradford Hill (BH) “Criteria” in Section IV.A.1

- Removes reference to “select” BH criteria
- Expands list of BH criteria, clarifies consideration of criteria, and adopts footnotes describing the applicability of BH criteria
 - **Strength** of the association between a 9/11 exposure and the health condition and precision of the risk estimate;
 - **Consistency** of the association across multiple studies;
 - **Specificity** observed in the cause and effect;
 - **Temporality** of the cause and effect (the exposure must precede the health condition);
 - **Biological gradient**, or exposure-response, relationships between 9/11 exposures and the health condition;
 - **Biological plausibility** of the studies with known facts about the biology of the health condition;
 - **Coherence** between a causal association and known disease etiology; and
 - **Analogy** with an established causal relationship (an analogy can inform of biological plausibility).