

Response to Comments from the Public on Revised HomVEE Procedures and Standards and Updated HomVEE Definitions, Rules, and Procedures Related to Model Versions

For the first time since its inception, the Home Visiting Evidence of Effectiveness Review (HomVEE) has substantially revised several of the review's procedures and standards. These revisions were released in the <u>Version 2 Handbook of Procedures and Evidence Standards</u>, which was published in December 2020. HomVEE *procedures* describe how HomVEE conducts its review process. That is, procedures are the definitions, rules, and steps that HomVEE follows to ensure its evidence review process is systematic, consistent, and minimizes bias. This includes how HomVEE identifies eligible research, prioritizes models for review, applies criteria to determine a model's evidence rating, and reports its results. HomVEE *standards* describe the rubric that HomVEE applies to a manuscript to determine its level of confidence that the home visiting model caused any reported impacts. These standards are used to assess the rigor of the research design and rate the quality of research findings.

The final set of revisions was informed by consultation with experts, staff of other federal evidence reviews, and staff at the Health Resources and Services Administration (HRSA) and the Administration for Children and Families. In addition, the HomVEE team carefully considered public comments in response to two simultaneous *Federal Register* notices (FRNs), published on August 5, 2020. The first notice proposed changes and clarifications to HomVEE's procedures and standards for rating the quality of impact studies and determining which home visiting models meet U.S. Department of Health and Human Services (HHS) criteria for evidence of effectiveness. The other notice proposed updated definitions, rules, and procedures related to handling home visiting model versions in the HomVEE review (model versions are commonly referred to in the home visiting literature as adaptations and enhancements).

Based on the public and expert consultant comments in response to the two FRNs, HomVEE has issued the Version 2 Handbook to formalize some of the changes. HomVEE will continue to consult with stakeholders to refine its approach to some other changes (including defining model versions). The changes implemented in the published handbook bring HomVEE generally into alignment with procedures and standards for other federally sponsored systematic evidence reviews (specifically, the <u>What Works Clearinghouse</u> and <u>Title IV-E</u> <u>Prevention Services Clearinghouse</u>) and address critical topics in the evolution of the home visiting field. An HHS work group that included HomVEE staff collaboratively developed the new definitions and rules. Not all comments were addressed in this handbook revision, but they will all be used to inform future development of HomVEE's procedures and standards.

This document summarizes key comments from the public and expert consultants in response to the two FRNs and HomVEE's approach to addressing them in the final Version 2 Handbook. While this brief is intended to provide a rationale for changes, the Version 2 Handbook is the definitive statement of definitions, rules, procedures, and standards. Unless otherwise indicated, HomVEE will implement the revised procedures and standards summarized here and described further in the Version 2 Handbook beginning with the 2021 annual

review. A summary of the updates to HomVEE procedures and standards can be found in Exhibit I.2 of the HomVEE Version 2 Handbook of Procedures and Evidence Standards.

RESPONSE TO COMMENTS ON REVISED HOMVEE PROCEDURES AND STANDARDS

Many of the public and expert consultants' comments on the revised HomVEE procedures and standards reflected concerns related to screening, scope of review, and approach to prioritizing manuscripts to review. Several comments also requested clarification about the timeline for implementing the annual review. In response to the feedback from the public and expert consultants, HomVEE incorporated the following adjustments and additions to its procedures and standards into the final HomVEE Version 2 Handbook.

TOPIC 1: EXPANDING THE LITERATURE SEARCH, AND ADOPTING OPEN SCIENCE PRACTICES

Multiple commenters and expert consultants had suggestions for expanding the literature search. For example, one set of commenters suggested adopting open science practices such as searching preprint servers and clarifying authors' conflicts of interest, and other commenters suggested searching grey literature.

HomVEE response to comments. To ensure that the search strategy is thorough, replicable, and meets the research objectives, HomVEE will use a modified Peer Review of Electronic Search Strategies method to refine the search terms (McGowan et al. 2016).¹ With this method, trained librarians use a structured tool to map the search terms to the population, intervention, comparators, outcomes, timing, and setting criteria that research must meet to be eligible for inclusion in HomVEE's review. This enhances the quality and comprehensiveness of the search by checking for things such as correct use of Boolean search operators, and alternate words and spellings for search terms.

HomVEE has expanded its annual search to include four additional databases. These will be sources for HomVEE to identify manuscripts that are not published in journals; this category of manuscripts is known as grey literature. These databases are Google Scholar, the Harvard Think Tank Search, and a pair of preprint servers (the Open Science Framework database and MedRxiv).² This change helps ensure that the HomVEE approach to the literature search is open and comprehensive. In addition, when reporting review results for well-designed research, HomVEE will disclose any obvious conflicts of interest that authors of the research have with the model being evaluated, and whether the research was peer reviewed. Authors can access <u>reporting guidelines</u> on the HomVEE website.

TOPIC 2: ADDITIONS TO THE SEARCH TERMS

Some commenters from the field recommended several specific additions to the search terms.

HomVEE response to comments. In the draft handbook, HomVEE did not recommend any substantive new search terms. However, in response to public comments, HomVEE indicated in the final handbook that the search will use these additional terms:

- positive parenting
- family engagement
- family involvement

• parent-child interaction

TOPIC 3: APPROACH TO PRIORITIZING MANUSCRIPTS

Several commenters expressed concern that the handbook rules, and the prioritization points structure in particular, could adversely affect models that serve smaller and comparatively disadvantaged communities.

HomVEE response to comments. HomVEE's Version 2 procedures are not intended to make it more difficult for models that are less widely used and researched, including those specifically focused on underserved populations, to become evidence-based models. HomVEE's existing efforts to ensure these models are not adversely affected in the prioritization approach is twofold. First, models with effectiveness research that focuses on priority populations, as specified in the authorizing statute for the Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program, earn priority points for being reviewed.³ The second way HomVEE supports these models is by prioritizing and reviewing the models included in the annual review on two separate tracks. Track 1 focuses solely on models that are not yet evidence based. All Track 1 models are weighted equally. Track 2 focuses on evidence-based models HomVEE has already reviewed. Track 2 models are prioritized for re-review so that models HomVEE has reviewed less recently have a higher likelihood of being prioritized for review than models that have been reviewed more recently.

In light of commenters' emphasis on the importance of carefully considering which specific populations should get points at the prioritization stage, HomVEE has adjusted relative point values to assign equal weight to manuscripts focused on key populations. Specifically, a manuscript will receive equivalent points for describing a home visiting model delivered to a population named as a priority in the MIECHV statute as it would for characteristics related to sample location and composition.

TOPIC 4: PROVIDING TRANSPARENCY ABOUT WHEN A GIVEN MODEL IS REVIEWED

Commenters suggested that HomVEE alert developers when a model has been prioritized for review in a given year.

HomVEE response to comments. Beginning with the 2021 review, HomVEE will notify developers in the spring of each year if their model has been initially prioritized for review. Initial prioritization indicates that a model is among the top-scoring models in a given year and may receive a full review depending on available resources, literature, and updated information obtained during the review process.

TOPIC 5: SCOPE OF REVIEW, INCLUDING PRECISION HOME VISITING

Some commenters provided feedback in favor of HomVEE continuing to exclude mediating analyses, moderating analyses, and comparisons isolating the effect of a model feature. Other commenters expressed concern about the exclusion of these types of research because they address precision home visiting research questions, such as information about for whom and under what conditions home visiting models work. Other comments included: (1) a suggestion to include this type of research as part of the HomVEE model reports, if not in the review, and (2) a suggestion that HomVEE broaden its scope of eligible effectiveness research to include interventions that are enhancements that could be applied within or across home visiting models.

HomVEE response to comments. HomVEE recognizes that both research on specific features and research that examines the differential effects of home visiting models for various populations is potentially useful for many purposes. For now, however, HomVEE will generally continue to exclude research that isolates the

impact of models' features and differential effects because that research does not answer the review's core charge of determining whether an early childhood home visiting model is effective.

TOPIC 6: RETROACTIVE APPLICATION

Several commenters had questions when models and specific manuscripts would be reviewed under Version 2 procedures and standards and whether there will be implications for model evidence ratings.

HomVEE response to comments. HomVEE will apply the Version 2 procedures and standards beginning with the 2021 annual review. In addition, HomVEE will retroactively apply its clarified *terminology* along with certain procedures. Specifically, to promote consistency in reporting across the review, clarifications about the outcomes eligible for review in each domain and the clarified definitions of study, manuscript, and subgroup will retroactively apply to all research on models, regardless of (1) the model's evidence-based status according to HHS criteria, (2) whether the model is prioritized and selected for review, and (3) whether HomVEE has reviewed the manuscript before. Additionally, procedural clarifications (especially those regarding which outcomes are eligible for review in which domains) will be applied retroactively.

HomVEE generally will not retroactively apply the new *standards* to previously reviewed research about evidence-based models unless it is single-case design (SCD) research about a model HomVEE selects for review. (As noted in the Version 2 Handbook, revised procedures for applying HHS criteria for how SCD research can contribute to a model's evidence rating and opportunities for public comment are forthcoming.) For example, manuscripts that have findings excluded or moved from the domain where HomVEE initially reported the finding to another domain reviewed by HomVEE will not be reviewed again with HomVEE Version 2 standards. If a model is not yet evidence based but has been reviewed by HomVEE, the new standards will be retroactively applied to previously reviewed research if the model is reviewed again, beginning with the 2021 annual review.

RESPONSE TO COMMENTS ON UPDATED HOMVEE DEFINITIONS, RULES, AND PROCEDURES RELATED TO MODEL VERSIONS

Public comments on the updated HomVEE definitions, rules, and procedures related to model versions reflected significant concerns about fundamental aspects of HomVEE's proposed approach to model versions, especially:

- Whether HomVEE's proposed list of core features are truly "core" to a given model, or if a model's theorized or empirically tested interventions, techniques, or "active ingredients" are more appropriate core features
- Whether developers should have input when HomVEE identifies a model's core features and versions or iterations
- Whether the basis for the decision rules to determine whether a change to a model is substantial should be revisited with stakeholder input, given the lack of empirical evidence
- Whether virtual and telehealth interventions are considered home visiting, and whether the addition or substitution of virtual and telehealth interactions in a home visiting model should be considered a model adaptation

 Whether HomVEE should review precision home visiting research to identify a model's core features or active ingredients

In light of the importance of a systematic and transparent approach to handling model versions, HomVEE has

decided to continue refining its approach in consultation with stakeholders before adopting a new approach to defining and reviewing model versions. In the meantime, HomVEE will continue to rely on model developers to identify model versions, consulting experts as needed.

Specifically, although HomVEE is adopting the definition of an early childhood home visiting model presented in the *Federal Register* notice (with minor edits), the proposed definitions of a base model, model version, and iteration and the proposed list of "core features" that were offered in the *Federal Register* notice are not being implemented in the Version 2 handbook. HomVEE also will not adopt strict rules and thresholds around substantial changes to core features at this time. This delay in using a new approach to handle model versions will allow HomVEE to (1) respond to concerns about lack of consensus on core features and substantial change thresholds; (2) provide more flexibility and opportunity for developer input (while leaving final determinations with HomVEE); and (3) use information gained through new processes implemented in 2021 to inform longer-term decisions.

ENDNOTES

- ¹ McGowan, Jessie, Margaret Sampson, Douglas M. Salzwedel, Elise Cogo, Vicki Foerster, and Carol Lefebvre. "PRESS Peer Review of Electronic Search Strategies: 2015 Guideline Statement." Journal of Clinical Epidemiology, vol. 75, 2016, pp. 40– 46.
- ² HomVEE also searches a fifth database for grey literature, which was also searched before this handbook update: Child Care & Early Education Research Connections.
- ³ According to the Social Security Act, Section 511 [42 U.S.C. 711], priority populations are as follows: Low-income families; Families with pregnant women who have not reached age 21; Families that have a history of child abuse or neglect or have had interactions

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with child welfare services; Families that have a history of substance abuse or need substance abuse treatment; Families that have users of tobacco products in the home; Families that are or have children with low student achievement; Families with children with developmental delays or disabilities; Families that include individuals who are serving or formerly served in the Armed Forces, including such families that have members of the Armed Forces who have had multiple deployments outside of the United States