Introducing the Home Visiting Evidence of Effectiveness (HomVEE) Version 2 Handbook:

An Overview of Updated Procedures and Standards for Conducting the Annual Evidence Review

1/26/21

HomVEE

Mathematica
Progress Together

HRSA
Maternal & Child Health

OPRE

Welcome!

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Agenda and presenters

1. **Introduction** (Shirley Adelstein, OPRE, ACF)

2. **Overview of the HomVEE review process** (Emily Sama-Miller, Mathematica)

3. **Review of HomVEE procedures** (Emily Sama-Miller)

4. **Review of HomVEE standards** (Julieta Lugo-Gil, Mathematica)

5. **Rollout of Version 2 procedures and standards** (Shirley Adelstein)

6. **Questions and answers**

INTRODUCTION

HomVEE identifies evidence-based early childhood home visiting models

- Created in 2009 to identify early childhood home visiting models with evidence of effectiveness
  - Sponsored by OPRE, within ACF, in partnership with HRSA
- HomVEE helps determine which models can receive funds from the federal Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program
  - 75 percent of a state's MIECHV funding must go an evidence-based model, as determined by HomVEE
  - HRSA administers the MIECHV Program, in partnership with ACF

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HomVEE: A thorough, transparent systematic review

- Focuses on home visiting models that serve families with pregnant women and children from birth through age 5

- Uses standards like that of the What Works Clearinghouse (WWC) Version 4.1 to identify which studies are well designed

- Qualitatively summarizes findings from the reviews and identifies which models are evidence based, according to criteria from the U.S. Department of Health and Human Services (HHS)

HomVEE revised procedures and standards in 2020; rollout in 2021

- First substantial revision since the launch of HomVEE in 2009
  - Addresses critical topics in the evolution of the home visiting field
  - Reflects feedback from methods and content experts and from public comments (collected through *Federal Register* notices in August 2020)
- Version 2 of the procedures and standards:
  - Defines key terms (such as home visiting model, study, and subgroup)
  - Clarifies procedural steps: screening, prioritizing models for review, using additional information provided by authors
  - Brings HomVEE in line with standards of other federally sponsored systematic evidence reviews, including WWC Version 4.1
- Standards will not be retroactively applied in most cases; procedures and definitions will
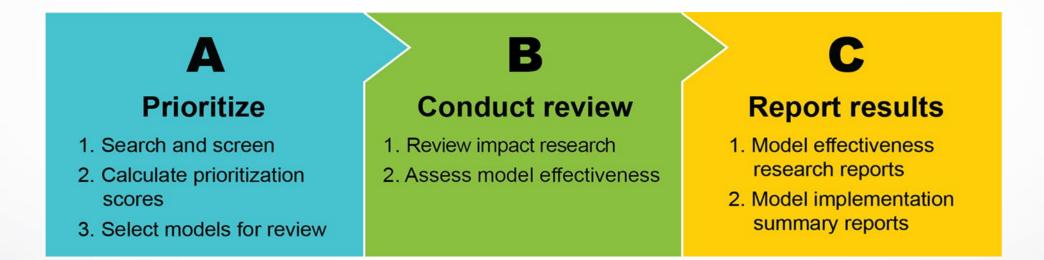
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OVERVIEW OF THE HOMVEE REVIEW PROCESS

HomVEE is a systematic review

- Independent and unbiased HomVEE staff perform each step of the evidence review

A Prioritize
1. Search and screen
2. Calculate prioritization scores
3. Select models for review

B Conduct review
1. Review impact research
2. Assess model effectiveness

C Report results
1. Model effectiveness research reports
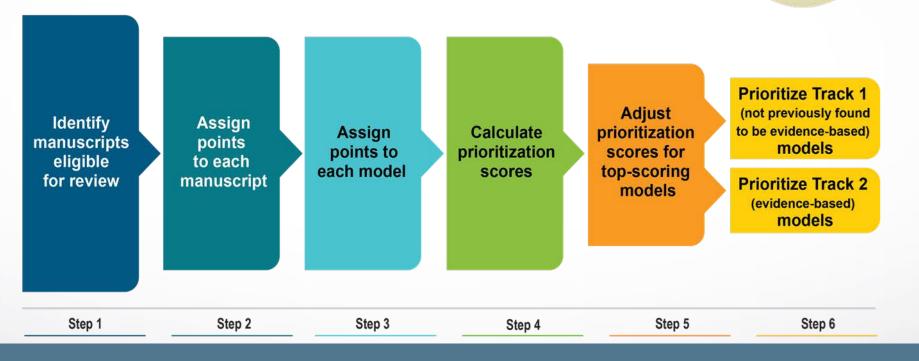2. Model implementation summary reports

HomVEE selects models to review in two tracks each year

HomVEE's process for prioritizing models to review each year

HomVEE uses a systematic process to select models that will be reviewed each year by calculating prioritization scores based on manuscript- and model-level criteria.

Identify manuscripts eligible for review	Assign points to each manuscript	Assign points to each model	Calculate prioritization scores	Adjust prioritization scores for top-scoring models	Prioritize Track 1 (not previously found to be evidence-based) models
					Prioritize Track 2 (evidence-based) models
Step 1	Step 2	Step 3	Step 4	Step 5	Step 6

HomVEE's evidence ratings are low, moderate, and high

Rating	What rating indicates about findings in the manuscript	What rating indicates about the manuscript overall
High	Strong evidence that at least one finding is attributable to the intervention.	At least one finding in the manuscript rates high. Well-designed research can point to evidence-based models.
Moderate	Some evidence that at least one finding is attributable, at least partly, to the intervention. However, other factors not accounted for in the study might also have contributed to the finding.	At least one finding in the manuscript is rated moderate (but no findings in the manuscript rate high). Well-designed research can point to evidence-based models.
Low	Little evidence that the reported finding is attributable, partly or wholly, to the intervention.	All findings that were eligible for review in the manuscript rate low.

Well-designed research can point to evidence-based models.

Models are designated "evidence based" if they meet HHS criteria

- Models must meet at least one of the following criteria:
  - At least one high- or moderate-rated study shows favorable (statistically significant) impacts in two or more of the eight outcome domains
  - At least two high- or moderate-rated studies (using non-overlapping analytic study samples) show one or more favorable (statistically significant) impacts in the same domain
- In both cases, the impacts must either:
  - Be found in the full sample for the study or
  - If found for subgroups but not for the full sample for the study, be replicated in the same domain in two or more studies using non-overlapping analytic study samples
- Additional criteria apply to models with research solely from a randomized controlled trial (RCT)

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HomVEE reports effectiveness results and implementation details

- Effectiveness reports: Model impacts and whether model is evidence based

- Implementation profiles: Details on how model is designed to be implemented

REVIEW OF HOMVEE PROCEDURES

Key content

- New definitions of key terms
- Revisions to search and screening procedures
- Detailed discussion of how models are prioritized for review
- Other procedural changes: supplemental information and subgroup findings

V.2 **V.2 badge highlights procedural changes in Version 2**

Version 2 defines key terms

A *study* evaluates a distinct implementation of an intervention

Each study may produce one or many *manuscripts*—published or unpublished research that describe study results

Each manuscript includes *findings,* which describe the effect of a model on a specific outcome measure (at a specific time point, from a specific analysis)

Version 2 revised how HomVEE finds relevant research

V.2

- Searches for research within the last 20 years
  - Keeps review focused on more current research
- Uses a formal method to refine search terms
  - Peer Review of Electronic Search Strategies (PRESS) method: a pair of trained librarians use a structured tool to map search terms to the review's scope
  - Enhances quality and comprehensiveness of the search
- Expands search to include new grey literature databases
  - Four additional databases to identify manuscripts that are not published in journals
  - Ensures search is open and comprehensive
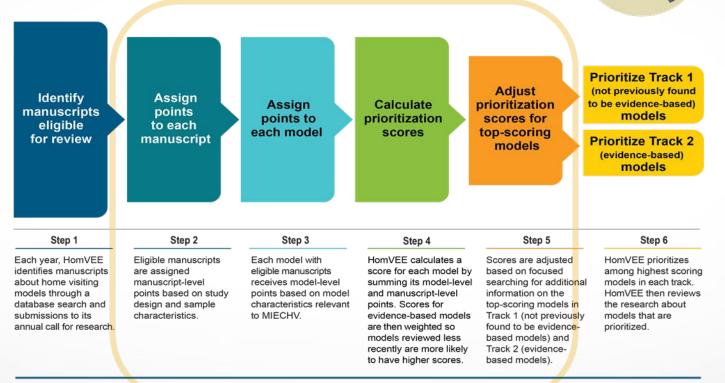
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HomVEE uses prioritization points to select models

HomVEE's process for prioritizing models to review each year

HomVEE uses a systematic process to select models that will be reviewed each year by calculating prioritization scores based on manuscript- and model-level criteria.

Identify manuscripts eligible for review	Assign points to each manuscript	Assign points to each model	Calculate prioritization scores	Adjust prioritization scores for top-scoring models	Prioritize Track 1 (not previously found to be evidence-based) models
					Prioritize Track 2 (evidence-based) models

Step 1	Step 2	Step 3	Step 4	Step 5	Step 6
Each year, HomVEE identifies manuscripts about home visiting models through a database search and submissions to its annual call for research.	Eligible manuscripts are assigned manuscript-level points based on study design and sample characteristics.	Each model with eligible manuscripts receives model-level points based on model characteristics relevant to MIECHV.	HomVEE calculates a score for each model by summing its model-level and manuscript-level points. Scores for evidence-based models are then weighted so models reviewed less recently are more likely to have higher scores.	Scores are adjusted based on focused searching for additional information on the top-scoring models in Track 1 (not previously found to be evidence-based models) and Track 2 (evidence-based models).	HomVEE prioritizes among highest scoring models in each track. HomVEE then reviews the research about models that are prioritized.

Evidence-based models meet HHS criteria for an "evidence-based early childhood home visiting service delivery model."

1. HomVEE assigns points to each eligible manuscript

- Points are based on information in the manuscript's title and abstract
  - It is not feasible to examine the full text of all manuscripts identified each year
- Manuscript-level criteria reflect HomVEE's emphasis on:
  - Well-designed impact studies
  - Outcomes of interest
  - Alignment with criteria in MIECHV's authorizing statute

Each manuscript can earn up to 6.5 points

Criterion	Points	Notes
Study design	2 or 3 per manuscript	3 points for an RCT, single-case design, or regression discontinuity design 2 points for a non-experimental comparison group design
Sample size	1 per manuscript	Total sample size contains 250 or more pregnant women and/or families
Outcomes of interest	1 per manuscript	Examines outcomes in one or more of the following domains for which HomVEE has seen comparatively less research over time: (1) family economic self-sufficiency; (2) linkages and referrals; (3) reductions in child maltreatment; and (4) reductions in juvenile delinquency, family violence, or crime
Sample location	0.5 per manuscript	Entire sample lives in the United States
Indigenous population	0.5 per manuscript	Entire sample is an indigenous population living inside or outside the United States
Priority population	0.5 per manuscript	Entire sample belongs to one or more priority populations named in the MIECHV authorizing statute

2. HomVEE assigns points to each model

- Criteria include factors related to the eligibility requirements for the MIECHV Program
  - This increases the likelihood that models potentially eligible for MIECHV funding will be prioritized
- Points are based on:
  - Information from model websites
  - Information a model developer has supplied (HomVEE may contact authors or model developers to confirm publicly available information)
  - Previous HomVEE reviews

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Each model can earn up to 4 points

Criterion	Points	Notes
Associated with national organization or institution of higher education?	1 point per model	Organizations can be inside or outside the United States
Currently serving or available to serve families?	1 point per model	Based on (1) information from developers, (2) information from web searches, and (3) review of communications that developers and authors have submitted
Implemented for at least three years?	1 point per model	Models can receive this point even if the model is not currently active Based on (1) information from developers, (2) information from web searches, and (3) review of communications that developers and authors have submitted
Implementation support available in the United States?	1 point per model	HomVEE assumes international models support U.S. replication if the models have already been implemented in the U.S. or if developers notify HomVEE that they would support U.S. implementation

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3. HomVEE calculates prioritization scores for each model

- For each model, sums (1) the points from all manuscripts about the model and (2) the model-level points
  - This prioritizes models with larger volumes of unreviewed research
  - Manuscripts about all versions of a model are grouped together for one combined score
- Adjusts each model's point total to give priority to models reviewed less recently
- Calculates a model's final prioritization score as follows:

  Prioritization score = Model point total * Adjustment

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Adjustment depends on the status and timing of the previous review

Track and timing of previous HomVEE review	Weight	Effect of weighting	Rationale and notes
Reviewed the previous year, in either track	0	Lower score to 0	Ensures no model is reviewed in two consecutive years
Not reviewed the previous year, Track 1	1	No adjustment	Point total is equal to the final model prioritization score
Not reviewed the previous year, Track 2	Weight = $[1 + 0.1 * (\text{current year} - \text{release date of prior report})]^2$	Multiply score by a factor that is larger when the model was reviewed less recently	Multiplication factor based on the number of years since HomVEE last reviewed and reported on the model; models reviewed less recently receive higher weights

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4. HomVEE gathers more information on top-scoring models and updates scores

- Sort models from the highest to lowest prioritization score, separately within each track

- For the top-scoring models in each track:

  - Conduct a second, focused database search on model names to identify additional manuscripts

  - Examine the full text of all eligible manuscripts about top-scoring models

  - Update the model's prioritization score, based on the full-text review of all manuscripts

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HomVEE uses prioritization points to select models to review

- Use the adjusted prioritization scores to re-sort models separately in each track

- Select models from each track, starting with the highest prioritization scores and moving down the list in order of score
  - The MIECHV Program may coordinate with HomVEE to prioritize the review of promising approaches implemented and evaluated under a MIECHV grant

- The number of models HomVEE selects depends on available project resources in the given year

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HomVEE accepts supplemental information only under specific circumstances

- HomVEE incorporates new information about a study's methods or procedures only if:
  - It is provided in direct response to an author query, and
  - It is submitted in time
- If new information is not submitted in time, authors can request a reconsideration of evidence, after HomVEE releases the results of its annual review
- HomVEE treats all new research as a submission to the following year's call for research
  - Exception: New research can be incorporated into a review if it consists of new analyses conducted at HomVEE's explicit request (for example, see repeated measures standards)

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Subgroup findings are only reported if they are replicated

- Subgroup: An analytic choice (subset of the overall sample examined in a study)
- *Replicated* subgroups are those with an identical definition in two non-overlapping research samples
  - Exclusions: Subgroups defined by cohort, time, or location are not replicable
- A model can earn an evidence-based rating through findings from *replicated* subgroups
- HomVEE only reviews and reports review results for *replicated* subgroups
  - Beginning with 2021 reviews, however, HomVEE will list nonreplicated subgroups that are examined in a manuscript

REVIEW OF HOMVEE STANDARDS

Key content

- Eligible designs, comparisons, and analyses
  - New validity and reliability standards
- Revisions to baseline equivalence requirement
- Summary of other key changes
  - Acceptable adjustment methods
  - Approaches with imputed missing data
  - Repeated measures approaches
  - Structural equation models

V.2 **V.2 badge highlights standards changes in Version 2**

Eligible designs include RCTs and QEDs

- Randomized controlled trials (RCTs)
  - Assignment is random; groups are expected to be equivalent across measured and unmeasured characteristics
  - Sample members can be assigned as individuals or groups (cluster RCT)
- Quasi-experimental designs (QEDs)
  - Assignment is nonrandom; groups could differ across measured and unmeasured characteristics
  - Single-case designs: Assignment within a family changes over time
  - Regression discontinuity designs: Assignment based on cutoff point
  - Non-experimental comparison group designs (NEDs): Assignment based on convenience or statistical techniques that match sample members in each group
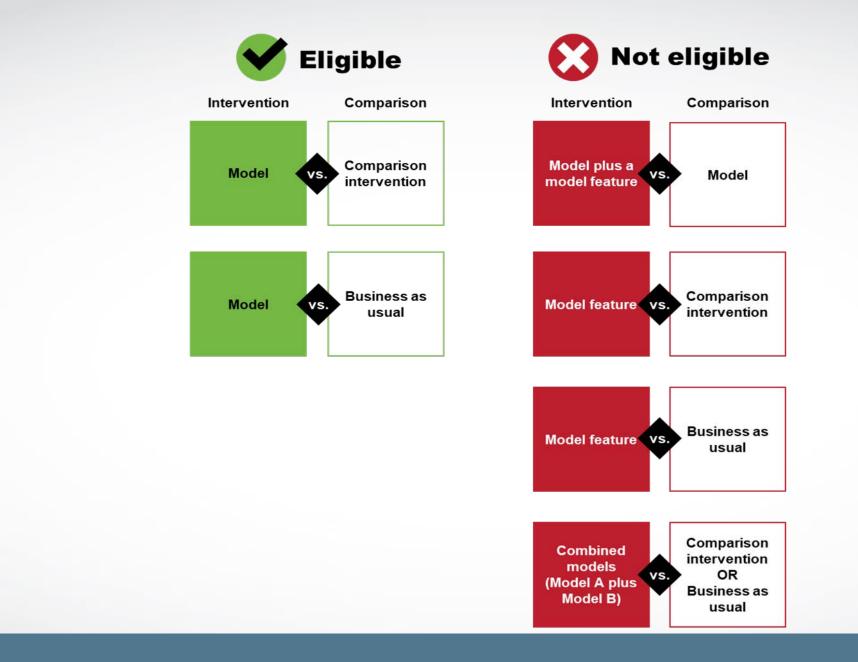- Ineligible: Simple pre-post comparison of outcomes for one group

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Eligible comparisons

- HomVEE's core question is whether an early childhood home visiting model is effective
- Knowing that a certain model feature is effective does not establish that a model, or a version of a model, with more than one feature is effective overall

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Outcomes must now demonstrate face validity and reliability

- Face validity
  - Clear description of the source of the measure or how it was created and what it was designed to measure
  - Belongs in one of the eight outcome domains of interest to HomVEE
  - Clear connection to the construct that it claims to measure
- Reliability
  - Measures from administrative records, demographic characteristics, and medical or physical tests are assumed to be reliable
  - Other measures must demonstrate that they meet thresholds on internal consistency, test-retest reliability, or inter-rater reliability
- Findings based on measures that do not meet the face validity and reliability requirement will rate low
  - HomVEE may follow up with authors to query them for for this information and request citations

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Some analytic approaches are ineligible

- *Ineligible*: most mediating and moderating analyses
- *Ineligible*: all analyses that control for endogenous characteristics
- *Eligible*: treatment-on-the-treated (TOT) findings in RCTs
  - However, HomVEE will focus on the intent-to-treat (ITT) finding, if available
  - TOT findings are subject to additional criteria not required for ITT findings (following WWC's standards for Complier Average Causal Effects)

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Revised baseline equivalence requirements for RCTs and NEDs

- Low-attrition RCTs no longer need to establish baseline equivalence or control for baseline variables to achieve a high rating

- All high-attrition RCTs and NEDs still need to establish baseline equivalence to achieve a moderate rating

- Baseline equivalence for the analytic sample is still required on baseline measures of the outcome, race/ethnicity, and socioeconomic status (SES)

  - Maternal education was promoted to be a preferred measure of SES

HomVEE now uses effect size to verify baseline equivalence

- Effect size (ES) is computed as the absolute value of the difference between intervention and comparison groups in standard deviation units

- HomVEE looks at ES to assess whether baseline equivalence has been met

  - ES > 0.25: does not meet the baseline equivalence requirement (and the finding rates low)

  - 0.05 < ES ≤ 0.25: requires an acceptable statistical adjustment to meet the baseline equivalence requirement (and the finding can rate moderate)

  - ES < 0.05: meets the baseline equivalence requirement and requires no statistical adjustment (and the finding can rate moderate)

- If baseline data were imputed, HomVEE applies different standards

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Only some statistical adjustments for baseline characteristics are acceptable

- Acceptable analytic methods to adjust for baseline differences
  - Regression adjustments
  - Analysis of covariance or multivariate analysis of covariance
  - Estimating impacts only for groups defined at baseline (for example, ever had a baby versus never had a baby)
  - Repeated measures analysis of variance or multivariate analysis of variance
  - Growth curve modeling
- Acceptable methods only if baseline and follow-up measure of an outcome are the same and have a strong correlation (0.60 or higher)
  - Gain or change scores (pre-post differences)
  - Difference-in-differences adjustments
  - Fixed effects for individuals

Analyses with missing data are subject to new standards

- Acceptable methods for handling missing data (otherwise the findings rate low)
  - Complete case analysis
  - Regression imputation (must be conducted separately by treatment status)
  - Maximum likelihood
  - Nonresponse weights (should account for treatment status; acceptable only for missing outcome data, not for missing baseline data)
  - Replacing missing data with a constant and including a missing-data indicator (acceptable only for missing baseline data, not for missing outcome data)
- For attrition calculations, sample members with imputed outcome data are counted as missing
- Version 2 also adopted the WWC standards (Version 4.1) for reviewing analytic approaches based on missing data

Standards for reviewing analyses with imputed data

- Besides using an acceptable approach to imputation, high-attrition RCTs and NEDs using imputation must:

  - Limit potential bias from imputed outcome data, and/or

  - Establish baseline equivalence using the largest baseline difference, accounting for missing or imputed baseline data

- A What Works Clearinghouse webinar covers these standards in detail:

  - https://www.youtube.com/watch?v=TVBeBUUcbzQ

Repeated measures analyses require individual time-point estimates

- Findings from these analyses are eligible only when the findings are available for individual time points
  - HomVEE assesses and assigns a separate rating to each time point
- HomVEE will query authors for individual time-point findings if they are not reported
- If only a combined impact estimate is available (after querying the author), that estimate is ineligible for review

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Only some structural equation model (SEM) analyses are eligible

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- SEM is a statistical technique that involves examining the relationships between a dependent variable and two or more independent variables

- To be eligible for review:
  - Path diagram must be present
  - Path diagram must include outcomes with a direct pathway from the intervention to the outcome AND no pathways leading to that outcome from another outcome
  - The model must be identified

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ROLLOUT OF VERSION 2 PROCEDURES AND STANDARDS

HomVEE will apply Version 2 procedures and standards beginning with the 2021 review

- HomVEE will not retroactively apply the new standards to previously reviewed research on *evidence-based* models
  - Two exceptions:
    - Single-case design research on a model that HomVEE selects for review
    - When replicated subgroups straddle the timing of an update to HomVEE standards
- However, HomVEE will retroactively apply its procedures (including clarified terminology) to all research. For example:
  - Clarified definitions of study, manuscript, and subgroup
  - Eligibility and domain categorization of findings, including eligible contrasts

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Refer to the handbook for complete details on the revised procedures and standards

- The HomVEE Handbook of Procedures and Evidence Standards: Version 2 is available on the HomVEE website
  - https://homvee.acf.hhs.gov/publications/methods-standards

Home Visiting Evidence of Effectiveness (HomVEE) Systematic Review

Handbook of Procedures and Evidence Standards: Version 2

December 2020
Emily Sama-Miller, Julieta Lugo-Gil, Jessica Harding, Lauren Akers, and Rebecca Coughlin

OPRE Report 2020-151

Next steps

- **Model versions:** HomVEE has decided to continue refining plans for defining and reviewing model versions
    - HomVEE proposed definitions and procedures related to model versions in an August 2020 *Federal Register* notice
    - Based on public comments, HomVEE has decided to continue refining its approach in consultation with stakeholders before adopting a new approach

- **Single-case designs:** HomVEE plans to propose procedures for applying the HHS criteria to single-case designs in the coming months to account for the new standards

QUESTIONS, COMMENTS?

Please send any further questions and comments to HomVEE@acf.hhs.gov

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