

REPORTING GUIDE for Study Authors

For Version 1.0 of the Title IV-E Prevention Services Clearinghouse Handbook of Standards and Procedures

REPORTING GUIDE FOR STUDY AUTHORS

For Version 1.0 of the Title IV-E Prevention Services Clearinghouse Handbook of Standards and Procedures

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Title IV-E Prevention Services Clearinghouse Reporting Guide for Study Authors

This guide details the components of randomized controlled trials and quasi-experimental comparison group design studies¹ that the Prevention Services Clearinghouse uses to determine eligibility for review, assign design and execution ratings, and determine program or service ratings, as well as other recommended practices for research reporting. This guide aims to facilitate the Prevention Services Clearinghouse review process and is also intended to help study authors describe their studies completely and consistently.

Journal article page limits may constrain detailed reporting of study characteristics. As a result, the Prevention Services Clearinghouse reviews all available documents associated with a study, including published manuscripts, technical reports, supplements, and appendices. It is recommended that study authors retain data and records of analyses to facilitate response to any necessary queries.

Recommended practices for research reporting that are not strictly required as part of Prevention Services Clearinghouse reviews are noted throughout this guide, with the designation "Consider also including the following information."

For information about the Prevention Services Clearinghouse's systematic review process and standards, please consult the *Prevention Services Clearinghouse Handbook of Standards and Procedures*.

The Title IV-E Prevention Services Clearinghouse, established by the Administration for Children and Families (ACF) within the U.S. Department of Health and Human Services (HHS), systematically reviews research on programs and services intended to provide enhanced support to children and families and prevent foster care placements. These programs and services include mental health prevention and treatment services, substance abuse prevention and treatment services and in-home parent skill-based programs, as well as kinship navigator programs.

¹ A study is defined as one research investigation of a defined subject sample, and the interventions, measures, and statistical analyses applied to that sample (see section 4.1 in the Handbook).



STUDY ELIGIBILITY SCREENING

Title and Abstract

After a comprehensive literature search, the Prevention Services Clearinghouse first evaluates studies for inclusion based on a screening of their titles and abstracts. Staff assess the initial relevance of studies during title and abstract screening primarily by looking for the name of the program or service under review and assessing whether the study design is clearly ineligible (e.g., is described as a single group pretest-posttest design or qualitative case study). Staff determine final eligibility by reviewing the full text of the study. Include the following information in the title or abstract to facilitate accurate screening.

- State the name of the program or service of study in the title or abstract of the document and describe any substantive adaptations of the program or service that were made for the study.
- Clearly state the study design (such as randomized controlled trial [RCT] or quasi-experimental design [QED]).

Consider also including the following information:

- Describe the comparison condition (such as no or minimal intervention, treatment as usual, or other intervention).
- Indicate the setting of the study (e.g., outpatient clinic, psychiatric in-patient setting).
- Summarize the characteristics of the study sample (both children and adults as applicable). Include sociodemographic characteristics and presenting conditions or issues.
- Identify the outcomes measured in the study.
- Briefly describe analytic methods, results, and conclusions.
- Keywords, if allowed, should include the specific name of the intervention(s) studied.



STUDY DESCRIPTION

Intervention Condition²

- Identify the program or service by name and describe its core components. Detail all included services, therapeutic approaches, session topics, and intervention targets.
- Provide a full citation for the manual, book, or writings used to guide and implement the program or service delivery. If multiple manuals, books, or writings were used, describe.
 - ◆ Example program with a single manual: "Therapists received training in Brief Strategic Family Therapy (Szapocznik, Hervis & Schwartz, 2003)."
 - Szapocznik, J. Hervis, O., & Schwartz, S. (2003). *Brief Strategic Family Therapy for adolescent drug abuse* (NIH Pub. No. 03-4751). National Institute on Drug Abuse.
 - ◆ Example program with two manuals: Specify if the manuals are to be used in conjunction with each other or represent different options for program delivery. For example, "IY-School Age uses the Incredible Years Parents, Teachers and Children's Training Series manual (Webster-Stratton, 2011). It is implemented in conjunction with the Curriculum Set (Incredible Years, Inc., 2019) that is specific to the IY-School Age program."
 - Webster-Stratton, C. (2011). *Incredible Years parents, teachers and children's training series: Program content, methods, research, and dissemination, 1980 2011*. Incredible Years, Inc.
 - Incredible Years, Inc. (2019). School age basic curriculum set.
- Clearly describe any adjustment to or adaptations of the manual that were implemented in the study (see section 4.1.6 in the *Handbook*).

Program or Service Implementation

- Describe the intended and actual dosage and intensity of program or service (e.g., number of sessions, length of sessions, frequency of sessions, and availability of on-call or ad hoc sessions).
- Describe the intended and actual duration of the program or service (time from start to end); if there is no
 prescribed end of treatment, indicate when the majority of a clearly defined set of services was delivered (see
 section 6.2.3 in the *Handbook*).
- Specify who delivered the program or service, including level of education, professional background (e.g., psychologist, social worker, nurse, peer mentor), and/or other available demographic information (e.g., age, gender, years experience).
- Specify how many different practitioners delivered the program or service.
- Indicate any required training the practitioners received, as indicated by the developer.
- Indicate the number of organizational or agency units (e.g., number of clinics) involved in implementation.

The intervention condition is the program or service relevant to the work of the PSC that is intended to provide enhanced support to children and families and prevent foster care placements. Studies may have more than one intervention condition.



STUDY DESCRIPTION

Program or Service Implementation

 Describe the format (e.g., group, one-on-one, self-directed) and delivery modality of the intervention (e.g., in-person, online).

Consider also including the following information:

• Indicate if fidelity to the program or service was measured and describe how the fidelity assessment was performed, including any fidelity checklists, tools, or instruments used.

Setting

- Describe where the study took place and key characteristics of the setting (e.g., hospital, community-based, outpatient, inpatient, home-based, online).
 - ◆ Confirm that the setting of the study is congruent with the recommended or required implementation settings indicated in the treatment manual, book, or available documentation.
 - ◆ Specify if the study took place in a usual care setting.³
- Specify if the study is a single site or multi-site study.
 - ◆ If multi-site, describe any differences between the sites, especially as they relate to methods used to identify participants, assignment to conditions, and baseline differences between conditions.
 - ◆ If multi-site, describe any differences in program or service delivery or personnel that were observed across sites.

Comparison Condition

Describe the comparison condition in detail by including the following information (see section 4.1.4 in the *Handbook*). If applicable, provide this level of detail about all comparison conditions in the study.

- Specify if the comparison condition is no intervention⁴, minimal intervention⁵, or treatment as usual.⁶
- Clearly describe any programs or services offered to or received by participants in the comparison condition, including frequency, intensity, and duration of the program or service. If the comparison condition receives manualized services, state the name of the intervention and cite the manual.
- Specify if participants would have access to the comparison condition services outside of the context of the study (i.e., whether the intervention is already available within the service context).

⁶ Treatment as usual comparison conditions are those in which the participants are offered or are free to seek out the usual or typical services available for the population in the study.



³ A usual care or practice setting is defined as an existing service agency or provider that delivers mental health services, substance use prevention or treatment services, in-home parent skill-based programs, and/or kinship navigator programs as part of its typical operations. See section 6.2.2 in the Handbook for additional information.

⁴ No intervention comparison conditions are those in which the participants are offered no services. Participants may be placed on a waiting list for future services or be offered no services as part of the study.

Minimal intervention conditions are those in which participants are offered minimal or limited services. These individuals may receive handouts, referrals to available services, or similar nominal interventions.

STUDY DESCRIPTION

Comparison Condition

- Specify who delivered the comparison condition, if applicable, including their level of education and professional background.
 - ◆ Specify how many different practitioners delivered the program or service.
 - ◆ Indicate if the same individual or individuals also delivered the intervention condition.

Consider also including the following information:

- Indicate any procedures used to identify and address potential contamination across conditions.
- Indicate the number of organizational or agency units (e.g., number of clinics) involved in implementing the comparison condition.
- If the comparison condition receives no or minimal treatment, specify whether the participants had an opportunity to participate in the program or service at a later time (waitlist) or never had the opportunity to receive the program or service.
- Describe how programs and services offered to or received by the comparison condition (if any) are tracked. If the comparison condition is a waitlist group, clearly indicate when the group was offered the intervention.

Study Participants

- Indicate how and when participants were recruited for participation in the study and, if applicable, any differences in recruitment procedures between conditions.
- Specify study participant inclusionary and exclusionary criteria.
 - ◆ Indicate whether additional treatments (e.g., psychopharmacological treatments) were permitted and, if so, describe any associated study requirements (e.g., maintaining same dosage throughout study participation; additional treatments must be for a different disorder).
 - ◆ Identify any differences in inclusion or exclusion criteria from what is prescribed in the treatment manual.
- Describe and cite any previous studies or publications that used the same or a portion of the sample of
 participants. If relevant, describe the extent to which participants are part of an overlapping sample from a
 previous report or publication.
- Clearly describe the number of participants recruited, the number enrolled, and the number included in the final analytic sample(s).

Consider also including the following information:

Illustrate the flow of participants through the study with a CONSORT diagram (<u>www.consort-statement.org</u>).



Design

- Specify the study design (e.g., block randomized controlled trial; quasi-experimental design using propensity score matching; repeated measures; no intervention control).
- Reference where the study was pre-registered, if applicable.

Consider also including the following information:

- Describe any differences between planned and actual execution of the study.
- Clearly describe the timing (i.e., month and year) of all key milestones of the study, including assignment, consent, intervention beginning and end, and data collection points. Note if these differed by condition.
- Specify the unit of assignment (individual, family, clinic, region, census block).
- Describe in detail how individuals or clusters of individuals (such as clinics or regions) were assigned to conditions (e.g., random, matched comparison).

Consider also including the following information:

- Provide a CONSORT diagram (<u>www.consort-statement.org</u>).
- ◆ If random assignment was used:
 - Specify when random assignment was performed (e.g., before or after baseline measures completed, before or after consent, etc.).
 - Describe any anomalies or ways that random assignment was compromised and solutions used.
 - If randomization was performed within blocks, sites, or strata, describe the process of randomization for each, including differences in assignment across blocks and how this was handled in the impact analyses.
 - If cluster randomization was used, include information about whether any participants joined a cluster after random assignment. If applicable, describe how and when they joined. Also, discuss whether the individual joining the cluster or the person making the assignment to the cluster knew the condition of the cluster at the time of joining.
- ◆ If a matched comparison group was used:
 - Describe the procedure used to construct the groups, including the method and software used.
 - Specify the characteristics that were used to construct the matched groups; if an equation or model was used in matching, specify the variables used in the model.
 - Describe how matching was handled in baseline and impact analyses, including how weights were applied (if applicable).



Design

- ◆ If non-random, non-matched groups were used:
 - Describe the procedure used to construct or identify the groups.
 - Specify the characteristics that were used to determine who was in each condition.
- If there are multiple conditions of the program or service tested in the study (e.g., multi-arm study with two
 different intervention conditions and a comparison condition), provide a clear description of each condition and, if
 applicable, how conditions differ or were modified from the manual, books or writings describing the program or
 service.

Sample Sizes and Attrition

- For RCTs:
 - ◆ Report the number of participants (and clusters, if applicable) randomized to each condition, including any who were dropped from the study after randomization. If cluster randomization was used, indicate the total number of participants in each condition at the time of randomization. If the study analyzes a subset of participants, report the full randomized sample size and describe how the subset was selected.
 - ◆ Include the number of participants by intervention and comparison condition who were randomized but were excluded or dropped for the study for reasons other than non-response/attrition (e.g., randomized in error, did not meet enrollment criteria). Provide numbers dropped by reason for dropping.
 - ◆ Report participant and cluster sample sizes by condition for each outcome separately at each measurement point (pre-test, post-test, and follow-up).
- For QEDs:
 - ◆ Provide analytic sample sizes by condition for each outcome at each measurement point (pre-test, post-test, and follow-up).

Measures

- For each outcome measure:
 - ◆ Identify the instrument and subscale (if relevant).
 - Specify the construct the instrument or subscale intends to measure.
 - ◆ Provide descriptive information about the measure, including number of items, subscales, response format, and sample questions.
 - ◆ If an instrument or scale is modified from its standard or prior use, please indicate how the original measure was modified.
 - ◆ Describe how the measure is administered (e.g., questionnaire, interview, or observation), scored (e.g., summative, weighted, etc.), and interpreted (e.g., higher scores are better, clinical range, etc.).



Measures

◆ Provide references about measure development and psychometrics, including reliability and validity, and state whether the measure has been normed.

Consider also including the following information:

- Provide applicable psychometrics regarding measure reliability computed on the study sample.
- Clearly specify when (i.e., month and year) data were collected from study participants and from administrative
 records, if applicable. Specify the relationship between each data collection or measurement point and the timing
 of the intervention, including relative to when the intervention and comparison conditions ended (e.g., baseline,
 mid-treatment, post-treatment, etc.).
- Describe whether data collection procedures or timing differed by condition or measurement point.

Baseline Equivalence

- Provide descriptive statistics for baseline measures of outcomes (pre-tests) by condition for each analytic sample⁷ in the study (see Table Shells 1 and 3).
- If pre-tests are not feasible, provide descriptive statistics by condition for each analytic sample for other baseline constructs (i.e., pre-test alternatives) in the same or similar domain to the outcome. Pre-test alternatives should be correlated with the outcome and/or may be a common precursor to the outcome (see section 5.7.2 in the *Handbook*).
- Provide the following baseline characteristics *by condition* for each analytic sample (see section 5.7.1 in the *Handbook*).
 - ◆ Demographic characteristics required for assessing baseline equivalence (age, racial and ethnic background, information pertaining to socioeconomic status).
 - Include information for both parents and children, if applicable.

Consider also including the following information:

• Provide other background characteristics not required for assessing baseline equivalence. In particular, gender, presenting problem(s), risk level, and prior history are recommended.

⁷ The *analytic sample* is the sample of participants included in an analysis of the impact of the program or service on an outcome. Studies may have multiple analytic samples because the number of participants available for analysis may differ for different outcomes and different time points within a study.



Data Analysis and Findings

- Describe the method used to estimate program impacts (e.g., linear regression, analysis of variance, etc.).
- Describe all control variables or weights used in the analysis, including methods for statistical controls for pre-test measures (see section 5.8 in the *Handbook*).
- Clearly indicate the unit of analysis (individual or cluster) and, if applicable, explain how clustering was addressed.
- Describe whether any participants or units of analysis were excluded from the analysis and, if so, why.
- Report descriptive statistics (e.g., means, standard deviations, and proportions) and sample sizes by condition for each outcome measure at each time point (see Table Shells 2 and 4).
- Report model coefficients, their standard errors, and exact p-values from impact analyses (see Table Shells 2 and 4).

Consider also including the following information:

- Display complete impact analysis models.
- For impacts estimated from variations of growth modeling analysis (e.g., growth curve analyses, latent growth models, etc.).
 - ◆ Provide unadjusted and adjusted means, unadjusted standard deviations, and sample sizes at each measurement time point (see Section 6.2.3 in the *Handbook*).
- For impacts estimated from variations of survival analysis (e.g., hazard ratio, relative risk).
 - ◆ Report model estimates (e.g., hazard ratios), model predicted survival probabilities, and standard errors.
 - ◆ Provide the cumulative number of participants experiencing the event and sample size that remains under observation by condition at the end of the observation period; clearly state when the observation period ended relative to the end of the intervention.

Missing Data⁸

- Describe extent of missing data by outcome and condition for the baseline and all follow-up data collection time points.
- Describe how missing data were addressed, including the method used to address missingness and the software used.
 - ◆ Specify whether the method was used for missing baseline data, missing outcome data, or both.
 - ◆ If relevant, specify the method used to adjust the standard errors of the impact estimates accounting for missing data.
- See the Appendix for additional information required for studies with imputed or missing baseline data or imputed outcome data.

⁸ For more information on the Prevention Services Clearinghouse missing data standards, refer to the *Handbook* (Section 5.9.4). The Prevention Services Clearinghouse missing data standards are based on the What Works Clearinghouse missing data standards (What Works Clearinghouse Handbook of Procedures, v. 4.0), which can be found online at <u>whatworks.ed.gov</u>.



STUDY DATA TABLE SHELLS • TABLE SHELLS FOR STUDIES WITH ONE POST-TEST OR FOLLOW-UP TIME POINT

The following Data Table Shells are examples of tables that contain information required to complete a *Prevention Services Clearinghouse* review.

Sample size of the intervention group analytic sample for this measure at post-test or follow-up.

 The unadjusted baseline mean and standard deviation of the intervention group analytic sample at post-test or follow-up. 3. Sample size of the comparison group analytic sample for this measure at post-test or follow-up.

4. The unadjusted baseline **mean** and **standard deviation** of the comparison group analytic sample at post-test or follow-up.

Table Shell 1. Information to Include for Establishing Baseline Equivalence

5. If different outcomes have different sample sizes (as shown in Table Shell 2), provide baseline information separately for each analytic sample.

6. If a direct pre-test is either impossible or not feasible and a suitable pre-test alternative is not available, baseline equivalence must be established on both race/ethnicity and SES.

| . Information to morage for Establishing Baser | | | | | | |
|--|-------------|--------------|-------------|-------------|--------------|-------------|
| | Interventio | n Group-Anal | ytic Sample | Compariso | n Group–Anal | ytic Sample |
| Measure | Sample size | Mean | (SD) | Sample size | Mean | (SD) |
| Analytic Sample for Outcome 1 | | | | · | | |
| Pre-test | 350 | 84.42 | (17.5) | 420 | 80.80 | (16.4) |
| Other baseline measure or pre-test alternative | 350 | 990 | (58) | 420 | 1000 | (62) |
| Low income (%) | 350 | 0.77 | n/a | 420 | 0.72 | n/a |
| Race/ethnicity (% minority) | 350 | 0.45 | n/a | 420 | 0.46 | n/a |
| Analytic Sample for Outcome 2 | | | | | | |
| Pre-test | 327 | 84.42 | (17.5) | 415 | 80.80 | (16.4) |
| Other baseline measure or pre-test alternative | 327 | 990 | (58) | 415 | 1000 | (62) |
| Low income (%) | 327 | 0.77 | n/a | 415 | 0.72 | n/a |
| Race/ethnicity (% minority) | 327 | 0.43 | n/a | 415 | 0.47 | n/a |
| Analytic Sample for Outcome 3 | | | | | | |
| Pre-test | 310 | 84.42 | (17.5) | 409 | 80.80 | (16.4) |
| Other baseline measure or pre-test alternative | 310 | 990 | (58) | 409 | 1000 | (62) |
| Low income (%) | 310 | 0.77 | n/a | 409 | 0.72 | n/a |
| Race/ethnicity (% minority) | 310 | 0.40 | n/a | 409 | 0.47 | n/a |

Table Note. n/a - Not applicable. The Prevention Services Clearinghouse uses the means of binary variables to calculate effect sizes, so it is not necessary to provide the standard deviation of binary variables.



STUDY DATA TABLE SHELLS · TABLE SHELLS FOR STUDIES WITH ONE POST-TEST OR FOLLOW-UP TIME POINT

The following Data Table Shells are examples of tables that contain information required to complete a *Prevention Services Clearinghouse* review.

Table Shell 2. Information to Include when Reporting the Findings of Impact Analyses

| | Intervention Group | | | | | Comparis | on Group | | Estimated Effect | | | |
|---|---|--|--|--------------------|---|--------------------|--|--|------------------|---|---|--|
| Outcome Measure | Sample size | Unadjusted Mean | Adjusted Mean | Unadjusted (SD) | Sample size | Unadjusted Mean | Adjusted Mean | Unadjusted (SD) | Impact | p-value | Effect Size | |
| Outcome 1 | 350 | 4.10 | 4.21 | (1.09) | 420 | 3.97 | 3.98 | (1.14) | 0.22 | .0843 | 0.15 | |
| Outcome 2 | 327 | 19.2 | 18.6 | (48.1) | 415 | 46.9 | 47.5 | (74.1) | -28.9 | .0002 | -0.33 | |
| Outcome 3 (%) | 310 | .039 | 0.042 | n/a | 409 | .063 | 0.069 | n/a | -0.027 | .2328 | -0.07 | |
| able Note. n/a - Not a | pplicable. The | Prev <mark>ention Services</mark> | Clearinghouse u | ses the means | of binary variables | to calculate effec | ct sizes, so it is not | necessary to pro | vide the standa | ard deviation of t | oinary variables. | |
| 1. Sample the interver group analy sample for outcome m | ntion on starting or starting | Unadjusted outcon utcome mean, and andard deviation o oup analytic sample | unadjusted outcomers of the intervention | ome of the grou | e comparison o analytic ole for this ome measure. | adjusted outco | outcome mean, ome mean, and itcome standard e comparison groue. | 5. Estimatimpact of assignme intervention group on | test | value of of statistical ficance of act. | 7. Effect size of estimated impact in standard deviation units. | |
| | | | | | | | | outcome measure. | | | | |



STUDY DATA TABLE SHELLS • TABLE SHELLS FOR STUDIES WITH MORE THAN ONE POST-TEST OR FOLLOW-UP TIME POINT

The following Data Table Shells are examples of tables that contain information required to complete a *Prevention Services Clearinghouse* review.

Table Shell 3. Information to Include for Baseline Equivalence from Studies with More than One Follow-up Time Point

| | Analytic | In | tervention Grou | ір | Comparison Group | | | | |
|------------------------------------|----------------------|--|-----------------|--------|------------------|------|--------|--|--|
| Measure | Sample Time Point | Sample size | Mean | (SD) | Sample size | Mean | (SD) | | |
| Pre-test for Outcome 1 | 6 mos | 350 | 3.98 | (1.04) | 420 | 3.99 | (1.01) | | |
| Pre-lest for Outcome 1 | 12 mos | 315 | 3.96 | (1.03) | 382 | 3.96 | (0.98) | | |
| Dra toot alternative for Outcome | 6 mos | 345 | 990 | (58) | 419 | 1000 | (62) | | |
| Pre-test alternative for Outcome 2 | 12 mos | 310 | 991 | (52) | 410 | 997 | (63) | | |
| Lawingana (0/) | 6 mos | 348 | 0.77 | n/a | 416 | 0.72 | n/a | | |
| Low income (%) | 12 mos | 327 | 0.74 | n/a | 409 | 0.73 | n/a | | |
| Daga (athoriaity (0/ pain avity) | 6 mos | 348 | 0.60 | n/a | 416 | 0.61 | n/a | | |
| Race/ethnicity (% minority) | 12 mos | 327 | 0.59 | n/a | 409 | 0.61 | n/a | | |
| | 1. Specify the | Table Note. n/a - Not applicable. The Prevention Services Clearinghouse uses the means of binary variables to calculate effect size it is not necessary to provide the standard deviation of binary variables. | | | | | | | |

1. Specify the analytic sample time point for the baseline equivalence assessment

2. If a direct pre-test is either impossible or not feasible and a suitable pre-test alternative is not available, baseline equivalence must be established on both race/ethnicity and SES.



STUDY DATA TABLE SHELLS • TABLE SHELLS FOR STUDIES WITH ONE POST-TEST OR FOLLOW-UP TIME POINT

The following Data Table Shells are examples of tables that contain information required to complete a *Prevention Services Clearinghouse* review.

Table Shell 4. Information to Report for Impacts on Outcomes at More than One Follow-Up Time Point

| Follow- | Intervention Group | | | | Comparison Group | | | | Estimated Effect | | |
|------------------|---|---|---|--|--|--|---|--|--|---|--|
| Up Time Point | Sample size | Unadjusted Mean | Adjusted Mean | Unadjusted (SD) | Sample size | Unadjusted Mean | Adjusted Mean | Unadjusted (SD) | Impact | p-value | Effect Size |
| 6 mos | 350 | 4.19 | 4.21 | (1.09) | 420 | 4.01 | 3.98 | (1.14) | 0.22 | .0843 | 0.15 |
| 12 mos | 315 | 4.43 | 4.48 | (1.24) | 382 | 4.41 | 4.39 | (1.25) | 0.09 | .3352 | 0.05 |
| 6 mos | 345 | 18.4 | 18.6 | (48.1) | 419 | 47.0 | 47.5 | (74.1) | 28.9 | .0002 | 0.33 |
| 12 mos | 310 | 18.7 | 18.5 | (47.3) | 410 | 46.0 | 46.5 | (73.1) | 28.0 | .0004 | 0.31 |
| 6 mos | 348 | 0.41 | 0.42 | n/a | 416 | 0.50 | 0.51 | n/a | 0.09 | .0032 | 0.22 |
| 12 mos | 327 | 0.43 | 0.46 | n/a | 409 | 0.52 | 0.53 | n/a | 0.07 | .0197 | 0.17 |
| | Up Time Point 6 mos 12 mos 6 mos 12 mos 6 mos 10 mos | Up Time Point Sample size 6 mos 350 12 mos 315 6 mos 345 12 mos 310 6 mos 348 | Follow-Up Time Point Sample size Unadjusted Mean 6 mos 350 4.19 12 mos 315 4.43 6 mos 345 18.4 12 mos 310 18.7 6 mos 348 0.41 | Follow- Up Time Point Sample size Unadjusted Mean Adjusted Mean 6 mos 350 4.19 4.21 12 mos 315 4.43 4.48 6 mos 345 18.4 18.6 12 mos 310 18.7 18.5 6 mos 348 0.41 0.42 | Follow-Up Time Point Sample size Unadjusted Mean Adjusted (SD) 6 mos 350 4.19 4.21 (1.09) 12 mos 315 4.43 4.48 (1.24) 6 mos 345 18.4 18.6 (48.1) 12 mos 310 18.7 18.5 (47.3) 6 mos 348 0.41 0.42 n/a | Follow-Up Time Point Sample size Unadjusted Mean Adjusted Mean Unadjusted (SD) Sample size 6 mos 350 4.19 4.21 (1.09) 420 12 mos 315 4.43 4.48 (1.24) 382 6 mos 345 18.4 18.6 (48.1) 419 12 mos 310 18.7 18.5 (47.3) 410 6 mos 348 0.41 0.42 n/a 416 | Follow-Up Time Point Sample size Unadjusted Mean Unadjusted (SD) Sample size Unadjusted Mean 6 mos 350 4.19 4.21 (1.09) 420 4.01 12 mos 315 4.43 4.48 (1.24) 382 4.41 6 mos 345 18.4 18.6 (48.1) 419 47.0 12 mos 310 18.7 18.5 (47.3) 410 46.0 6 mos 348 0.41 0.42 n/a 416 0.50 | Follow-Up Time Point Sample size Unadjusted Mean Adjusted Mean Unadjusted (SD) Sample size Unadjusted Mean Adjusted Mean 6 mos 350 4.19 4.21 (1.09) 420 4.01 3.98 12 mos 315 4.43 4.48 (1.24) 382 4.41 4.39 6 mos 345 18.4 18.6 (48.1) 419 47.0 47.5 12 mos 310 18.7 18.5 (47.3) 410 46.0 46.5 6 mos 348 0.41 0.42 n/a 416 0.50 0.51 | Follow-Up Time Point Sample size Unadjusted Mean Adjusted Mean Unadjusted (SD) Sample size Unadjusted Mean Adjusted Mean Unadjusted Mean Unadj | Follow-Up Time Point Sample size Unadjusted Mean Adjusted (SD) Sample size Unadjusted Mean Adjusted Mean Unadjusted Mean Mean Unadjusted Mean Mean Unadjusted Mean Unadjusted Mean Mean Unadjusted Mean Mean Unadjusted Mean Unadjusted Mean Mean Unadjusted Mean Mean Mean Mean Unadjusted Mean Mean Mean Mean Mean Mean | Follow-Up Time Point Sample size Unadjusted Mean Unadjusted (SD) Sample size Unadjusted Mean Adjusted Mean Unadjusted Mean |

Table Note. n/a - Not applicable. The Prevention Services Glearinghouse uses the means of binary variables to calculate effect sizes, so it is not necessary to provide the standard devation of binary variables.

1. Sample size of the intervention group analytic sample for this outcome measure. 2. Unadjusted outcome mean, adjusted outcome mean, and unadjusted outcome standard deviation of the intervention group analytic sample.

3. Sample size of the comparison group analytic sample for this outcome measure.

4. Unadjusted outcome mean, adjusted outcome mean, and unadjusted outcome standard deviation of the comparison group analytic sample.

5. Estimated impact of assignment to intervention group on outcome measure.

6. p-value of test of statistical significance of impact.

7. Effect size of estimated impact in standard deviation units.



Reporting when some outcome data are imputed and/or when some baseline data are missing or imputed

For high attrition RCTs and QEDs with missing or imputed baseline data and/or imputed outcome data, the Prevention Services Clearinghouse assesses the potential for bias due to imputed and missing data (see Section 5.9.4 of the *Handbook*). The Prevention Services Clearinghouse uses the WWC v4.0 missing data standards when there are missing data on eligible outcome measures, pre-tests, pre-test alternatives, or race/ethnicity and socioeconomic status (if required to establish baseline equivalence). This appendix describes the information required to compute potential bias when data are imputed or missing under three scenarios. Table A-1 shows these scenarios and the bias assessments required for each scenario. The table shells below illustrate options for reporting the information needed to assess bias under each of the three scenarios shown in Table A-1.

Table A-1. Missing Data Scenarios

| Scenario | Assess bias from imputed outcome data | Assess bias from imputed or missing baseline data |
|---|---------------------------------------|---|
| I. The outcome is imputed for some individuals in the analytic sample and the baseline measure is observed for all individuals in the analytic sample | ✓ | |
| II. The outcome is observed for all individuals in the analytic sample and the baseline measure is imputed <i>or</i> missing for some individuals in the analytic sample | | ✓ |
| III. The outcome is imputed for some individuals in the analytic sample and the baseline measure is imputed <i>or</i> missing for some individuals in the analytic sample | ✓ | ✓ |



I. Outcome is imputed for some individuals and baseline measure is observed for all individuals

In the scenario where an outcome measure has some imputed values but the corresponding baseline measure(s) (i.e., pre-test, pre-test alternative, or race/ ethnicity and SES) are observed for all individuals in the analytic sample, study authors have two options for reporting information needed to assess potential bias in the outcome. These are shown in Tables A-2 and A-3.

- For outcome measures with direct pre-tests or pre-test alternatives, the Prevention Services Clearinghouse relies on the data elements shown in Table A-2.
- For outcome measures for which **baseline equivalence is established on race/ethnicity and socioeconomic status** (see Section 5.7.1 of the *Handbook*), the Prevention Services Clearinghouse relies on the data elements shown in Table A-3.

Table A-2. Scenario I, Option 1: Information to include for each outcome measure for which any observations are imputed.

| | | Intervention Group | | | Correlation between | | |
|--|---|--------------------|-----------------------------|------------------------|---------------------|----------------|---------------------------|
| Sample | Number of observations | Mean of pre-test | SD of pre-test | Number of observations | Mean of pre-test | SD of pre-test | the pre-test and outcome: |
| Entire analytic sample | | | | | | | not applicable |
| Sample for which both the outcome and pre-test are observed | | | not needed | | | not needed | |
| 1. The analytic sample | 2. Measures | 3 . T | his is the complete cases s | sample. | | | |
| is the sample of participants included in an analysis of the impact of the program or service on an outcome. | are observed if they are not missing or imputed. | | | | | | |



- 1. The predicted means and standard deviations in these cells are computed from a regression model with the outcome as the dependent variable and the baseline measures required for baseline equivalence as the independent variables. Either separate regressions for the intervention and comparison groups or a single regression that includes an indicator variable for intervention status are acceptable. The set of baseline measures must include the race/ethnicity and socioeconomic status variables and may include other baseline measures. Use the regression model(s) to predict outcome values for both those units with an observed outcome and those units with a missing outcome and calculate the mean and standard deviation of the predicted outcome values for the entire analytic sample.
- 2. If a single regression is used to compute predicted values, report the R-squared from the model. If separate regressions for intervention and comparison groups are performed, report the average R-squared from the separate regressions.

Table A-3. Scenario I, Option 2: Information to include for each outcome measure for which any observations are imputed.

| | | Interventi | on Gr <mark>oup</mark> | | | Comparis | on Group | | R-squared |
|--|--|--------------------------------|---------------------------------|----------------------|------------------------|--------------------------------|---------------------------------|-------------------------------|--------------------------------|
| Sample | Number of observations | Mean of observed outcome | Mean of predicted outcome value | | Number of observations | Mean of observed outcome | Mean of predicted outcome value | SD of predicted outcome value | from regression model(s) |
| Entire analytic sample | | not needed | | | | not needed | | | not applicable |
| Sample for which both the outcome and baseline measures are observed | | | not needed | not needed | • | Ī | not needed | not needed | |
| Note. When the Prevention S 3. The <i>analytic sample</i> is the sample of participants | ervices Clearinghou | se assesses baselir | | race/ethnicity and S | ES, it assesses pote | ential bias using the i | nformation shown in | Table A-3. | |
| included in an analysis of the impact of the program or service on an outcome. | 4. Measures are if they are not m imputed. | | | | | | | | |



II. Outcome is observed for all individuals and baseline measure is imputed or missing for some individuals

In the scenario where an outcome measure is observed for all individuals in the analytic sample and the corresponding baseline measure(s) (i.e., pre-test, pre-test alternative, or race/ethnicity and SES) are either imputed or missing for some individuals, the Prevention Services Clearinghouse will assess potential bias using different data elements depending on how the missing baseline data are addressed in the study.

Three options are illustrated in Tables A-4, A-5, and A-6.

- For studies in which **the pre-test, pre-test alternative, or race/ethnicity and/or socioeconomic status are missing** (and not imputed), the Prevention Services Clearinghouse relies on the data elements in Table A-4. Table A-4 may also be used when studies use imputed baseline data in impact models but report baseline descriptives with unimputed baseline data.
- The Prevention Services Clearinghouse uses the data elements in Table A-5 for studies that use an acceptable method of imputation for the missing baseline data and report baseline descriptives with imputed baseline data.
- If the imputation model for the pre-test included baseline measures in addition to the outcome, then the smaller set of information shown in Table A-6 may also be used to assess bias from the imputed baseline data.



Table A-4. Scenario II, Option 1: Information to include for each baseline measure for which any observations are imputed or missing.

| | | In | ntervention Grou | ıp | | | С | omparison Grou | ıp | | |
|---|---|---------------------|--------------------|------------------|-------------------|------------------------|---------------------|----------------|-----------------|------------------|--|
| Sample | Number of observations | Mean of pre-test | SD of pre-test | Mean of outcome | SD of outcome | Number of observations | Mean of pre-test | SD of pre-test | Mean of outcome | SD of outcome | Correlation between the pre-test and outcome: |
| Entire analytic | | not needed | not needed | | | | not needed | not needed | | | not applicable |
| Sample for which both the outcome and pre-test are observed | | ı | | | not needed | Ī | 1 | | Ī | not needed | Ţ |
| 1. The analytic sample is the sample of participants included in an analysis of the impact of the program or service on an outcome. | 2. Measures a observed if the are not missin imputed. | re ey | port the samples s | izes, means, and | standard deviatio | ns indicated for the | e complete cases | sample. | | between | the correlation the pre-test and me using only ted data. |



Table A-5. Scenario II, Option 2: Information to include for each baseline measure for which any observations are imputed or missing.

| | | Ir | itervention Grou | ıp | | | | | | | |
|---|---|---------------------|--------------------|------------------|-------------------|------------------------|---------------------|----------------|-----------------|------------------|---|
| Sample | Number of observations | Mean of pre-test | SD of pre-test | Mean of outcome | SD of outcome | Number of observations | Mean of pre-test | SD of pre-test | Mean of outcome | SD of outcome | Correlation between the pre-test and outcome: |
| Entire analytic sample | | | not needed | | | | | not needed | | | not applicable |
| Sample for which both the outcome and pre-test are observed | 1 | Ī | | | not needed | Ī | | Ī | ı | not needed | |
| 1. Report the sample sizes, means, and standard deviations on the analytic sample including imputed values. | 2. Measures are observed if they are not missing o imputed. | | port the samples s | izes, means, and | standard deviatio | ns indicated for the | e complete cases | sample. | | between | the correlation the pre-test and me using only ted data. |

- 1. The predicted means and standard deviations in these cells are computed for the analytic sample from a regression model on the complete cases sample with the pre-test as the dependent variable and the outcome as the independent variable. Either separate regressions for the intervention and comparison groups or a single regression that includes an indicator variable for intervention status are acceptable. The set of independent variables must include the outcome and may include other baseline measures. Use the regression model(s) to predict pre-test values for both those units with an observed outcome and those units with a missing outcome and calculate the mean and standard deviation of the predicted pre-test values for the entire analytic sample.
- 2. If a single regression is used to compute predicted values, report the R-squared from the model. If separate regressions for intervention and comparison groups are performed, report the average R-squared from the separate regressions.

Table A-6. Scenario II, Option 3: Data to include for each baseline measure for which any observations are imputed or missing.

| | | In | tervention Gro | лb | | Comparison Group | | | | | |
|---|---|-------------------|---------------------|--------------------------|-------------------|------------------------|-------------------|------------|--------------------------|------------|------------------------|
| | | Observed pre-test | | Predicted pre-test value | | | Observed pre-test | | Predicted pre-test value | | R-squared from |
| Sample | Number of observations | Mean | SD | Mean | SD | Number of observations | Mean | SD | Mean | SD | regression model(s) |
| Entire analytic sample | | not needed | not needed | | | | not needed | not needed | | | not applicable |
| Sample for which both the outcome and baseline measures are observed | | | | not needed | not needed | | Ī | Ī | not needed | not needed | |
| 3. The analytic sample is the | | 5. Repo | rt the samples size | es, means, and st | andard deviations | of the pre-test for | the complete case | es sample. | | | |
| sample of participants included in an analysis of the impact of the program or service on an outcome. | 4. Measures ar observed if the are not missing imputed. | y | | | | | | | | | |



III. Outcome is imputed for some individuals and baseline measure is imputed or missing for some individuals

In the scenario where an outcome measure is imputed for some individuals *and* the corresponding baseline measure(s) (i.e., pre-test, pre-test alternative, or race/ethnicity and SES) are imputed or missing for some individuals, the Prevention Services Clearinghouse will assess potential bias using different data elements depending on how the missing baseline data are addressed in the study.

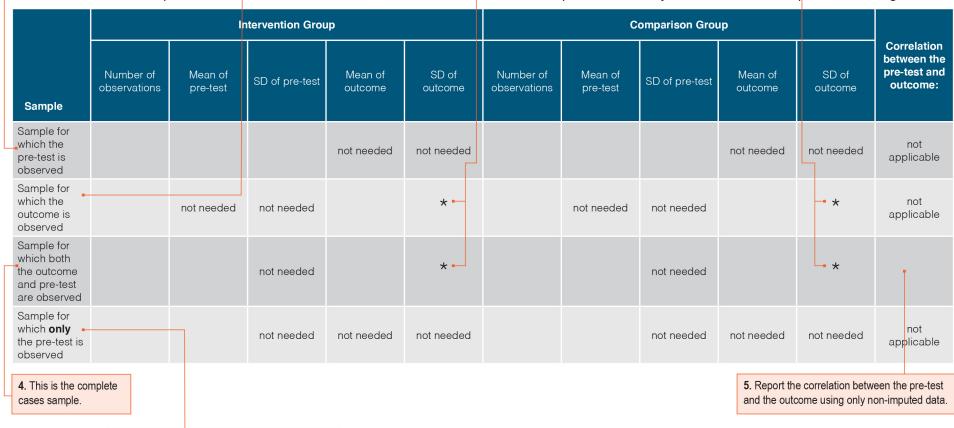
Two options are illustrated in Tables A-7 and A-8.

- For studies in which the pre-test, pre-test alternative, or race/ethnicity and/or socioeconomic status are missing (and not imputed), the Prevention Services Clearinghouse relies on the data elements in Table A-7. Table A-7 may also be used when studies use imputed baseline data in impact models but report baseline descriptives with unimputed baseline data.
- The Prevention Services Clearinghouse uses the data elements in Table A-8 for studies that use an acceptable method of imputation for the missing baseline and missing outcome data and report baseline descriptives with imputed baseline data.



- **1.** The sample for which the pre-test is not missing or imputed.
- The sample for which the outcome is not missing or imputed.
- It is acceptable to report the standard deviation of the outcome for the complete cases sample or the standard deviation of the outcome in the sample for which the outcome is observed.

Table A-7. Scenario III, Option 1: Information to include for each outcome-baseline measure pair for which any observations have imputed or missing values.



6. This is the sample for which the pre-test is observed and the outcome is missing or imputed.



- **1.** The sample for which the pre-test is not missing or imputed.
- 2. The sample for which the outcome is not missing or imputed.
- **3**. It is acceptable to report the standard deviation of the outcome for the complete cases sample or the standard deviation of the outcome in the sample for which the outcome is observed.

Table A-8. Scenario III, Option 2: Information to include for each outcome-baseline measure pair for which any observations have imputed or missing values.

| | | ľ | ntervention Grou | ıp | | | С | omparison Grou | ір | | |
|--|------------------------|---------------------|------------------|-----------------|------------------|------------------------|---------------------|----------------|-----------------|------------------|---|
| Sample | Number of observations | Mean of pre-test | SD of pre-test | Mean of outcome | SD of outcome | Number of observations | Mean of pre-test | SD of pre-test | Mean of outcome | SD of outcome | Correlation between the pre-test and outcome: |
| Sample for which the pre-test is observed | | | | not needed | not needed | | | | not needed | not needed | not applicable |
| Sample for which the outcome is observed | | not needed | not needed | | * | | not needed | not needed | | * | not applicable |
| Sample for which both the outcome and pre-test are observed | | | not needed | | * | | | not needed | | * | |
| Entire analytic sample | | | not needed | not needed | not needed | | | not needed | not needed | not needed | not applicable |

4. This is the complete cases sample.

5. Report the correlation between the pre-test and the outcome using only non-imputed data.

6. Report the sample sizes and means of the pre-test using the analytic sample *including imputed values*.

